Biology, Medicine, and the Bill of Rights

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BIOLOGY, MEDICINE, AND THE BILL OF RIGHTS

SPECIAL REPORT

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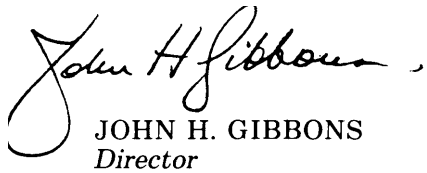
Foreword

Rapid progress in biological sciences–so dramatic that we now speak of "The New Biology"–has brought in its wake many social, legal, and ethical issues. In research laboratories, medical practice, public health programs, genetic counseling, law enforcement, insurance, the patenting process, agriculture, and many other fields, legal controversies and public policy debates have arisen. Some of these issues, many of which have been probed in recent OTA reports, also entail challenges to traditional interpretations of constitutional principles and precedents.

This special report considers the implications of new developments in biological sciences for the freedoms and protections embedded in our Bill of Rights. It is one of a series of publications coming from OTA's Constitutional Bicentennial Project, begun in 1987 at the request of the House Committee on the Judiciary and its Subcommittee on Courts, Civil Liberties, and the Administration of Justice. Earlier publications include a background paper, *Science, Technology, and the Constitution* (September 1987), and two special reports: *Science, Technology, and the First Amendment* (January 1988), and *Criminal Justice, New Technology, and the Constitution* (May 1988).



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Chapter 1

Biology and the Constitution

> Our laws and institutions must move forward with the progress of the human mind.
> —Thomas Jefferson

A few decades ago, genes and inheritance were still mysteries to science. The discovery of DNA, of how genetic characteristics are passed on between generations, and how genetic information is expressed and modified as a person matures, opened the door to understanding and manipulating these fundamental biological processes. Today, in many instances, we can modify genes and genetic inheritance to suit our own ends. Some deadly genetic diseases have been traced to their root causes—making it possible that in the future we will find a way to cure or avoid them. Genetic engineering holds out the hope for permanent cures for simple genetic disease, and is already providing better pharmaceuticals, crops, and industrial products. Other new biological technologies amplify the potential of genetic engineering, and still other biomedical technologies-computerized sensors, artificial prostheses, tissue implants-promise powerful new capabilities.

The application of new biological advances is not new. People have throughout history used all means at their disposal to improve health, extend their life span, increase the quality and yield of food, have or avoid having children, and enhance their physical and mental capabilities. For thousands of years we have bred cattle and beans, used contraception and fertility enhancers, developed medicines, brewed drugs, and followed social customs thought to produce healthy children. These basic human desires have helped define individual rights within a society. Social custom, law, and government authority have regulated technologies in order to help individuals achieve these goals within the framework of their society. The U.S. Constitution was designed to guarantee individual rights and to bound the powers of government, while ensuring a place for societal interests. It guides the application of technologies in those murky areas between individual rights and societal interests, between individual privacy and freedom and the needs of government to carry out its duties and ensure the social welfare. New biotechnologies, because of their unprecedented power to extend human intervention, raise correspondingly unprecedented challenges to the Constitution and to the laws built on that constitutional foundation.

THE CONSTITUTIONAL CONCEPT OF MANKIND

The Constitution of the United States embodies an 18th century view of the nature of Man: a rational being, possessed of free will and amoral sense, endowed by his Creator with inalienable rights and inescapable responsibilities, accountable to the State and to his fellow men through the implicit contract to which he consents by continuing to live within a democratic republic.[1] His biological inheritance, his mental competence, and indeed to a large extent his present physical and mental health were beyond his own power to control, or that of the State. And though Man had a natural right to Life, Liberty, and Property, in the real world all of those—like health, happiness, and the ability to beget children and raise them to adulthood—could be seen to depend on chance, fate, or the incomprehensible Will of God. They could be accepted, but seldom explained by science or controlled by human choice.

The common view of the human condition is different, now; in some ways it is less clear,

*Use of the terms “Man” or “mankind” here reflects the 18th century assumption that it was in males that civic authority and moral responsibility were lodged.

less satisfying, less firmly grounded in philosophy and ethics. We may indeed cling to the ethical and spiritual truth in the constitutional assumptions about responsibility. Yet at the same time we often analyze human behavior in terms of environment or genes, infantile experiences or biochemical imbalances, socioeco nomic deficits or neurocortical connections; and we oscillate between education and coercion, rehabilitation and conditioning, treatment and punishment. In some ways, we have diminished the scope of accountability embodied in the 18th century political philosophy, but perhaps we have more than compensated for this; we have enhanced the 18th century concept of the fundamental equality of "all Men" by giving explicit recognition and practical effect to the principle that this includes women, and men and women of all races and all economic classes.

WHY THE "NEW BIOLOGY" RAISES CONSTITUTIONAL ISSUES

There are in summary several reasons why advances in biological knowledge and capability to intervene in human biology have implications for constitutional rights:

1. The capability for biological interventions, especially with regard to reproduction, bodily health, mental functions, and death, gives people new choices, and forces them to make decisions about things that were previously beyond our control. The question arises as to whether the State should or constitutionally can regulate such decisions in the public interest.
2. Biology-based technology, alone and in combination with other kinds of science and technology, increases the power of the State to enforce its laws and policies (e.g., by screening for drug use, or by using DNA typing for identification). These uses may intrude on the constitutionally guaranteed sphere of individual privacy.
3. The power to identify biological risks (e.g., exposure to infectious disease or genetic vulnerability to chemicals in the environment) often outstrips the capability to remove or reduce those risks. This raises a demand for social control measures that sometimes impinge on constitutional freedoms. Some of these are traditional public health techniques falling under States' "police power" but now often at odds with increased public expectations of, and judicial affirmation of, the scope of constitutional liberties.
4. The increasing possibility of effective intervention to prolong life, remove physical and mental handicaps, and enhance physical and mental performance reinforces the growing assertion of a "right to health care. " Such assertions may be based on the contribution of Federal funding to the development of new medical capabilities, but are also often claimed as a constitutional right although no such right has been judicially recognized.
5. Biological knowledge is likely to impinge on formal or informal religious beliefs or at least on traditional formulations of religious doctrine. Because the evolution of English common law, classical political philosophy, constitutional government, and the doctrines of several European Christian churches are historically intertwined, the constitutional separation of Church and State requires repeated attempts to distinguish between religious values and common cultural values.

There are strong indications that biological research will provide increasing evidence for a genetic and biochemical basis for variations in human abilities and performance and for much human behavior, including some behaviors that we now regard as voluntary, and therefore punishable. New pharmaceuticals, psychosurgery, or other treatments will become available to moderate mental functions and modify behavior. Genetic engineering of human germ

cells or somatic cells could remove inherited mental traits.

Biology is allowing major human interventions at the boundary between life and death. By resting the definition of death on brain functions, we have raised the question of how much quality or competence in brain functioning is necessary for recognition of constitutional rights. By making it possible to artificially maintain bodily functions we have vested in some people, with or without their willingness, awesome responsibilities for making decisions about life and death for other people who can no longer decide for themselves. At the beginning of life, advancing technological capabilities have changed, and may further change, the point at which a new life is viable outside the womb—indeed, gestation from test tube to "birth" may someday be possible in artificial wombs, reflecting again the question of when constitutional rights begin.

Advances in biological sciences and technologies are creating choices, in situations where in the past people had no choice. Or, less positively, they force people to make decisions about situations that in the past were beyond human control. Increasingly (though not yet always) people can choose whether or not to reproduce, and in the future, they maybe able routinely to choose the gender of the child they wish to have, to select some of its genetic characteristics, to choose to use an embryo from other biological parents, or to donate their own embryos to others.

New biological knowledge and technologies give people powers to make critical decisions about the life and death of themselves, other people, and future generations. When technology allows people to make such choices or decisions, the question arises as to whether the State should regulate, or even absolutely control, those decisions. Constitutionally, this question becomes: would State intervention impinge on some individual liberty that is guaranteed by the Bill of Rights? and if so, is the individual's interest in exercising that right far outweighed by the contrary interest of the State, which is considered to be the public interest?

The balancing of the State interest with individual rights is forever going on, and where the balance is struck often involves two kinds of social change. One frequent factor is new technological capability that gives us new control of natural processes or new power to manipulate our physical and biological environment. The second is the rising expectation of self-determination and privacy.

Some traditional public health techniques, well established in law and in constitutional decisions as permissible under State police powers, are almost certain to be challenged anew because of today's broader interpretation of individual rights of privacy and autonomy. This is occurring, for example, in the context of the AIDS epidemic with regard to techniques of mandatory reporting, contact tracing, mandatory testing, and partial or full quarantine. As the risks of environmental and workplace contaminants are increasingly revealed, the State could decide to use genetic screening technology (now at an early and unsatisfactory state of development, but likely to be made much more effective in the future) to write regulations forbidding some groups of people from assuming occupational or environmental risks to which they are especially vulnerable.

Many kinds of medical and genetic interventions raise complementary questions. First, when can the State, in the exercise of its police power, legitimately mandate preventive or therapeutic treatment, as it has long mandated vaccination, in the public interest? Second, should the Courts (or Congress) at some point in the future rule that there is a constitutional basis for a "right to health" or at least to health care? If, for example, interventions became possible (as a result perhaps of research at the National Institutes of Health) that would significantly control or slow aging and extend normal lifetimes, say by 25 years-would we leave it to market mechanisms to determine who received this "priceless" boon?

Decisions about kidney dialysis and organ transplants have so far obscured and delayed rather than answered this question, which is already being raised by some public interest groups not only as a public policy issue but as a constitutional challenge. They argue that Americans have an "equal protection" right to the results of medical research supported by taxpayers.

Recent decisions about the teaching of evolution or of "creation science" in public schools have not removed the possibility of further efforts to restrict either the teaching or the application of new biological knowledge on religious or quasi-religious grounds. There are strong indications that a major area of constitutional debate in the future will deal with conflicts between biological research objectives and procedures, on the one hand, and religious or ethical values on the other. The present debates over animal rights, research using fetal tissue, patenting of human cell lines and derived biological, the safety of bioengineering laboratories, and release of engineered organisms in the environment, have some common grounds. Is there a constitutional right to do research? Should there be areas of "forbidden knowledge?" What values should be reflected in Federal research funding allocation and Federal guidelines?

This introduction to the report on "biology and the Constitution" contains many questions, and few answers. Indeed, this is true of the rest of the report. In looking into the future, much can be anticipated but little can be said with certainty. When we consider the triple uncertainties of rapidly advancing knowledge, steadily rising expectations of civil liberty and self-determination, and conflicting value systems that are themselves caught in turbulence and challenge, there are indeed few certain answers to the troublesome questions raised here.

Chapter 2

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Chapter 2

Personal Rights and Technological Might

Technology is a powerful force for change. Law, especially constitutional law, is a powerful reinforcer of stability and continuity. The tension between these two has much to do with how well a society's political system can adapt to economic and social forces that affect the distribution of power and wealth.

Between 1787 and 1987, the United States evolved from a small agrarian nation, relatively poor and powerless in the international system, to a modern industrial world leader. The Constitution has provided the political and legal framework for technological change, and it has accommodated both a growth in the role of government and enhanced expectations of individual rights.

In the face of technological, social, and economic change, both Congress and the Supreme Court have repeatedly reexamined the meaning, the intent, and the scope of constitutional provisions. Both, for example, struggled to decide whether the right of people "to be secure in their persons, houses, papers, and effects" does or does not include the right to be secure in one's electric communications (from wiretapping), or protection against having the content of one's blood, breath, or genetic code 'seized' without a warrant.

In constitutional government, the powers of the State are limited and the rights of individuals are acknowledged and protected. The most essential individual rights or civil liberties are, in modern constitutions, nearly always specified in a Bill of Rights.[1] The full meaning of these rights and the strength with which they will be protected become clear only gradually, as statutory laws are written and judicial precedents are set. In the United States, their scope has been worked out by the courts and by the political process, often with reference to English common law. Even the simple and elegant prose of the United States Constitution has required continuing examination, explanation, and interpretation as social institutions, economic forces, and technological conditions have changed.

[1] Ralph C. Chandler, Richard A. Enslen, and Peter G. Renstrom, *The Constitutional Law Dictionary* (Santa Barbara, CA: ABC-CLIO, 1985), vol. 1, Individual Rights, pp. 10-11. Great Britain had no single written "Constitution," but traditional rights of individuals based on centuries of common law were put into statutory form in the Bill of Rights Act of 1689.

TECHNOLOGY AND GOVERNMENT POWER

A constitution empowers a government by giving legitimate authority to its actions as the instrument and agent of the people. At the same time, a constitution, and particularly its bill of rights, is designed to limit the power of government. Its effectiveness depends on the determination of citizens that government shall abide by these limits.

The role that technology plays in the balance between individual rights and governmental power to act in the public interest is seldom explicitly discussed. But technical capability at least partly determines the effectiveness of both government's actions and the legal restraints on those actions. It also increases the individual's power to act in ways that may offend the conscience of the community, or to create and use technology that may adversely affect the welfare of others. Can or should civil liberties, as defined in 1791, restrain governments in regulating such choices?

Opinions on these questions differ dramatically among citizens, among legal experts, among constitutional scholars, among judges, and among courts. Hence, the questions addressed in the several reports and papers coming from OTA's study of "Science, Technology, and the Constitution" are: what new and

emerging technological capabilities may stimulate constitutional challenges in the foreseeable future? How may Congress and the Court be asked to reconsider the scope of fundamental rights? This report considers these questions in relation to several areas in which basic scientific knowledge and related technological capability are making rapid advances: bioengineering, public health and medicine.[2] Before turning to this analysis, further discussion of the basic concepts within the Bill of Rights will be useful.

[2] Two earlier special reports explored similar questions with regard to new technologies for communication and news reporting (*Science, Technology, and the First Amendment,* February 1988) and new technologies for law enforcement (*Criminal Justice, New Technology, and the Constitution,* March 1988). See also *Science, Technology, and the Constitution–Background Paper,* September 1987, for an overview of OTA'S Constitutional Bicentennial Project.

BY POPULAR DEMAND: THE BILL OF RIGHTS, 1787-91

In 1787, many State constitutions included a Bill of Rights, but no Bill of Rights was written into the national Constitution. Several proposals to add one were voted down in the closing days of the Philadelphia Convention with relatively little discussion. Most of the delegates thought that a national Bill of Rights was unnecessary because the new government was to have only limited, delegated powers. An explicit prohibition against the establishment of religion, for example, might imply that the national government would otherwise have the power to regulate the practice of religion. During the critical debate on ratification, a Bill of Rights might thus increase rather than decrease the already widespread fears of the power of a new central government.[3]

The lack of one however, drew more public criticism than any other aspect of the Constitution. The Constitution was finally adopted only with the understanding that the first business of the Congress would be to correct this defect.

Twelve amendments to the Constitution were therefore proposed by the First Congress on September 25, 1789. Ten were ratified by the States and added to the Constitution on December 15, 1791.[4] Since then, the meaning and scope of these rights has been asserted or has been challenged in hundreds of Court cases. Sometimes the questions raised are directly related to new technological capabilities. Often they are indirectly related, because they reflect profound economic, social, and political changes associated with technological change.

It is not only the Supreme Court that interprets constitutional protections, although it does so most formally and definitively. Both Federal and State courts at all levels repeatedly ponder the rights of citizens, the powers of governments, and the nature of due process. Congress and 50 State legislatures declare their understanding of the Constitution in framing legislation. And Americans are generally willing to assert, either in celebration or complaint, their own understanding of their rights. That is one reason we have been called a litigious society.

Federalism—Dual Citizenship and Constitutional Rights

Even when Americans can quote from the Bill of Rights or describe its content, they are

[3] James MacGregor Burns, *The American Experiment: 'he Vineyard of Liberty (New* York, NY: Alfred A. Knopf, 1982), pp. 53-55. Also Chapter 3, "The Experiment Begins, " pp. 86-90. See also, Catherine Drinker Bowan, *Miracle at Philadelphia* (Boston, MA: Little, Brown, 1966). Also Edward S. Corwin and J.W. Peltason, *Understanding the Constitution,* 4th ed. (New York, NY: Holt, Rinehart& Winston, 1967), p. 104. The Constitution already included prohibitions of bills of attainder, and ex post facto laws, and guarantees of the writ of habeas corpus and of trial by jury in Federal criminal cases.

[4] Th, two that were proposed but not ratified prescribed the ratio of Representatives to population and prohibited any increase in Congressmen's pay during a term. They were probably perceived as not properly included in a list of the rights of individuals. Corwin and Peltason, op. cit., footnote 3, p. 104.

often somewhat vague about just whose actions they are protected from. Americans of 1989, unlike those of 1789, usually do not clearly distinguish their rights and duties as citizens of Virginia, New York, or Massachusetts from their rights and duties as American citizens. The consciousness of dual citizenship has faded.

The Bill of Rights itself restricted only the Federal Government, as Chief Justice John Marshall ruled in 1833.[5] In 1868 the addition of the Fourteenth Amendment changed that: it said that all persons born in (or naturalized by) the United States are citizens;[6] and it then continued:

> No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States. . . .

This was intended to guarantee the rights of those who had been slaves, and their descendants; it extended the constraints imposed on the Federal Government to State governments as well, on behalf of all citizens.[7]

Yet only in the last three decades has the Bill of Rights come to be effectively applied to restrain State governments.[8] In 1873, in the Slaughterhouse Cases,[9] the Supreme Court used tortured reasoning to declare that most key civil and political rights were part of State citizenship, rather than U.S. citizenship. The "privileges and immunities of citizens of the United States, " the Court said, were limited to a few rights such as travel between the States and voting for Federal officials. This declaration has never been explicitly overturned.

But the Fourteenth Amendment went onto say:

> . . . nor shall any State deprive any person of life, liberty, or property, without due *process of law,* nor deny to any person within its jurisdiction the *equal protection of the laws.* (Emphasis added.)

It was these two provisions that the Supreme Court eventually used to extend to the States the limitations placed on the Federal Government by the first Ten Amendments. The Due Process Clause was used until the late 1930s to strike down State laws aimed at improving the lot of workers through economic regulation; the property rights of "corporate persons" were protected through the doctrine of substantive due process. But in a series of cases after the Second World War, the Court has declared that the Fourteenth Amendment "incorporates' most of the protections and rights listed in the Bill of Rights. In effect, it has said that "due process" includes the fundamental concepts of justice and liberty spelled out in the first eight Amendments and further strengthened with the Ninth Amendment declaration that their enumeration does not "... deny or disparage others retained by the people." In the discussion that follows, therefore, note is often made that a particular right has been incorporated by the Supreme Court into the Due Process Clause of the Fourteenth Amendment, and therefore is binding on the States.

The Constitution limits only government actions, not the actions of private persons. Only if discriminatory actions by private institutions are somehow sanctioned by Federal, State or local government (e.g., by licenses, tax exemptions or other benefits that give a private institution a semi- or quasi-public char-

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[5] *Barron* v. *Baltimore,* 7 Peters 243 (1833).

[6] This reversed the conclusion of the Dred Scott Case, before the Civil War, that Negroes even if free were not "intended to be included, under the word 'citizen' in the Constitution, and can therefore claim none of the rights and privileges which that instrument provides for and secures to citizens. . . ." Citizenship was henceforth based on place of birth, not by parentage or race. By statutory law, Congress has also conferred citizenship on those born outside of the United States to U.S. citizens.

[7] The States, of course, had their own Bills of Rights, but Federal courts cannot enforce those protections if the State courts do not.

[8] Three amendments were added immediately after the Civil War, the Thirteenth, Fourteenth, and Fifteenth Amendments. The Thirteenth prohibited forever the institution of slavery; the Fifteenth assured slaves and their descendants of the right to vote. The Eleventh Amendment, which had been added in 1798, provided that individuals cannot sue a State (without its consent) in Federal Courts, thus amending (or clarifying) a provision in Article III, Section 2, which extends the Federal judicial power to "cases and controversies between a state and citizens of another state. " The Twelfth Amendment, in 1804, changed the manner of election of the President by the electoral college; requiring that they cast separate ballots for President and Vice President.

[9] The Slaughterhouse Cases, 16 Wallace 36 (1873). *Twining* v. ZVew *Jersey,* 211 U.S. 78 (1908).

acter), can they be said to violate the Bill of Rights.

The other great principle in the Fourteenth Amendment, "Equal Protection of the Laws," is discussed later. Here we will return to a discussion of the Bill of Rights of 1791.

Fundamental Rights

Freedom of Religion

The First Amendment embodies four freedoms deemed most critical for the preservation of republican government: namely, the freedoms of conscience, expression, assembly, and petition. It begins:

> Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof. . . .

Many of the ratifying generation, or their forebears, had come to this country to be free to worship as they chose. Jefferson and Madison regarded "freedom of conscience" or "the basic inalienable right to religious liberty" as a cornerstone of all other rights and liberties, and the prohibition against state interference with it as a basic tenet of republicanism.[10]

The Establishment Clause applies to State actions, under the Due Process Clause of the Fourteenth Amendment. Scientific research and teaching have stimulated many challenges to the scope of this principle. State laws concerning the teaching of the principles of evolution, which are considered by some churches to be in conflict with their religious doctrines, have several times been struck down, most recently in 1987.[11]

Technology has figured in other challenges. The Court has for example let stand State mandatory vaccination laws in spite of the objections of some religious sects. The Court has also ruled that States may provide transportation for children to church schools, in the interest of promoting the health, safety, and education of children rather than their religious indoctrination.

Freedom of Speech and Press

The First Amendment also forbids Congress to make laws

> . . . abridging the freedom of speech, or of the press. . . .

Freedom of speech and press were in 1791 considered the most powerful popular constraint on government. Because free speech is not truly effective without the means of broader communication, a free press is included within this fundamental right–the only technology specifically protected in the Bill of Rights. *2 The right of free speech was seldom the subject of Supreme Court interpretation until after the First World War, when there began a series of cases involving political and social protest or communication.[13] Congress has by law established, and the Court has permitted, a three-tier system of regulation distinguishing between press, broadcast media, and common carrier systems. But these distinctions are becoming hard to maintain, as discussed in an OTA special report, *Science, Technology, and the First Amendment* (January 1988), as electronic technologies supplement the printed press in the dissemination of news, information, and opinion.

The constitutional status of science, and of scientific communications, is ambiguous. Along with artistic expression, scientific communications probably fall somewhere between po-

[10] Neal Riemer, *James Madison: Creating the American Constitution* (Washington, DC: Congressional Quarterly, Inc., 1986), pp. 14-15, pp. 136-40.

[11] *Edwards v. Aquillard et al.*, 107 Sup. Ct. 2573 (1987).

[12] The Court has established that symbolic expression as well as speech is protected; for example, wearing an armband (in public school) to protest government actions in Vietnam. *Tinker v. Des Moines School District, 393* U.S. 509, 89 S. Ct. 733, 21 L. Ed. 2d 731 (1969).

[13] *Schenck v. United States, 249* U.S. 47 (1919), established a "clear and present danger" test to determine when the government could regulate political expression in the interest of national security. *Gitlow v. New York,* 268 U.S. 652, 45 S. Ct. 625, 69 L. Ed. 1139 (1925) modified this doctrine to allow suppression of speech that might lead to "substantive evil" or unlawful ends. *Dennis v. United States,* 341 U.S. 494 (1951), allowed conspiracy convictions by distinguishing between advocacy of illegal acts and advocacy of doctrines. *Yates v. United States, 354* U.S. 208 (1957), weakened this slightly by requiring that specific illegal acts be shown; membership in an organization advocating them cannot be made a crime.

litical and commercial speech in terms of the protection it is afforded. *Science, Technology, and the First Amendment also* examines the restrictions placed on scientific communications in the name of both national security and technological export controls, and probes the question of whether the cumulative effects of these restrictions are eroding freedoms of speech and press. The present report carries this discussion further, to examine the restrictions placed on science in the interest of religion, ethics, and public safety.

The Rights of Assembly and Petition

As another fundamental protection of political freedom, the First Amendment forbids Congress to abridge:

> . . . the right of the people peaceably to assemble and to petition the government for a redress of grievances.

The Fourteenth Amendment extended this prohibition to the States. State and local governments can to some extent regulate public meetings and assemblies to prevent disorder and violence; but these necessary police functions are carefully and suspiciously examined by the courts.

The Prohibition on Unreasonable Searches and Seizures

The Fourth Amendment, like the First, has repeatedly been brought into question by changing technology. It reads:

> The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath and affirmation, and particularly describing the place to be searched, and the persons or things to be seized.

British authorities in the American colonies issued general "writs of assistance" that allowed searches at will or on slight suspicion, especially for contraband smuggled in violation of Parliamentary duties. The Fourth Amendment prohibited searches without a magistrate's warrant.[14] This constraint applies to the States under the Fourteenth Amendment.

The Supreme Court has in the last 70 years ruled that wiretapping and more recent electronic surveillance devices are "searches," and more recently, has had to decide whether evidence may be seized from bank, medical, and insurance records in computerized databases.[15] So far, the Court has allowed authorities to "seize" a suspect's breath (for analysis for alcohol), or one's urine, semen, blood, or other fluids and tissues for evidence, but these questions are probably not fully resolved.

The Rights of Those Accused and Convicted of Crimes

The rights of people suspected or accused of crime are protected in several places in the body of the Constitution and in the Fifth, Sixth, and Eighth Amendments. These civil liberties constrain or limit how the State may deprive a person of life, liberty, and property in enforcing its laws.[16] The affect of technological changes on interpretation of these Constitutional rights is considered in detail in the OTA Special Report, *Criminal Justice, New Technology, and the Constitution*, April, 1988. For example, the use of biology-based techniques for identifying offenders, such as DNA (genetic) pattern recognition, will probably be challenged constitutionally.

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[14] During an arrest, a warrantless search is permissible if the authority has "probable cause" to believe a crime has been committed.

[15] Chandler et al., op. cit., footnote 1, p. 168, citing *Zurcher v. Stanford Daily* (436 U.S. 547: 1978).

[16] *Palko v. Connecticut*, 302 U.S. 319, 58 S. Ct. 149, 82 L. Ed. 288 (1937), established "selective incorporation" in determining which Bill of Rights provisions related to rights of the accused should be applied to State actions. This was a case involving double jeopardy; the guideline or "rationalizing principle" enunciated by Justice Cardozo, was whether a particular protection is "of the very essence of a scheme of ordered liberty, " such that its bypassing would violate "a principle of justice so rooted in the tradition and conscience of our people as to be ranked as fundamental. This case held that the prohibition of double jeopardy was not so fundamental, but this was overturned later; now only the grand jury provision of the Fifth Amendment and the Excessive Fines and Bails prohibition of the Eighth Amendment have not been "selectively incorporated' as limitations on the States.

Due Process

Both the Fifth Amendment and the Fourteenth Amendment provide that a person may not:

> . . . be deprived of life, liberty, or property, without due process of law. . . .

The Court has developed two complementary definitions of "due process": procedural due process and substantive due process. Procedural due process means that laws, regulations, and government procedures must not be arbitrary, vague, or inconsistent, and the protections set out in the Bill of Rights should be carefully applied. "Substantive due process" suggests that some areas are beyond the reach of government authority, and some laws are unconstitutional because of their intent. This concept has been used to wall off from government interference certain private activities, primarily marriage, procreation, child rearing, and educational choice, held to be beyond the appropriate reach of legislation.[17]

Limitations on Eminent Domain

The Fifth Amendment also says that:

> . . . private property may not be taken for public use, without just compensation . . .

This power of "eminent domain" is an inherent power of all governments. It means that the rights conferred by private ownership of property must, in some cases, give way to the good of society as a whole. Thus, when it is necessary to build a highway in a given location and a landowner refuses to sell land to the government for that purpose, the land may be taken for public use, but the owner must be justly compensated. What constitutes "taking" of property has often been challenged, and some of these challenges have been stimulated by technology. For example, the Court has held that airport noise that renders adjacent land unusable for normal purposes may be a "taking" for which government must compensate.[18]

Retained or Inherent Rights, and Reserved Powers

The Ninth Amendment says that:

> The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.

One of the strongest objections raised to a Bill of Rights during the Constitutional Convention and the ratifying process was that the Federal government was not in general expected to act on individual citizens. The Federal government was to have delegated, limited powers, plus those other inherent governmental powers necessary to exercise those authorized functions effectively. The philosophy expressed in the Ninth Amendment is that the "Bill of Rights did not *confer* rights but merely *protected* those already granted by the natural law."[19]

Until 1965 no law had been struck down on the basis of violation of unenumerated rights. In that year, a Connecticut law forbidding the use of birth control was ruled unconstitutional because it violated an unenumerated right of marital privacy, which is "within the penumbra of specific guarantees of the Bill of Rights" and one of those fundamental rights assumed to be "retained by the people" because it has not been delegated to the nation or a state.[20]

The Tenth Amendment further provides along the same lines that:

> The powers not delegated to the United States by the Constitution nor prohibited by it to the States, are reserved to the States respectively, or the people.

It has been generally understood that this amendment did not alter the distribution of power between two levels of government, but merely restated the philosophy of government expressed throughout the Constitution, under which the States retained many sovereign powers not delegated nor clearly necessary to the Federal government. Until the mid-1930s the Supreme Court often used the doctrine of

[17] Corwin and Peltason, op. cit., footnote 3, pp. 124-125.

[18] *Griggs v. Allegany County*, 369 U.S. 841 (1962). Rent-control laws however do not constitute a taking, nor do other legislative actions that may diminish the value of property by regulating how it is used.

[19] Corwin and Peltason, op. cit., footnote 3, p. 132.

[20] Chandler et al., *The Constitutional Law Dictionary*, vol. 1, pp. 369-371.

"Dual Federalism" to prevent Congress from using its powers of taxation or interstate commerce regulation to accomplish other ends, such as making exploitation of child labor unprofitable for interstate businesses. The Tenth Amendment, in this way, reinforced the effectiveness of the Fifth Amendment requirement of "substantive due process" as interpreted by the Court.

After 1937, the Court returned to the view of John Marshall that this Amendment is a truism,[21] which does not by itself limit the national government in exercising powers that it would otherwise be understood to have. Both the Ninth and Tenth Amendments, however, contributed to the development of the constitutional doctrine of "a right to privacy, " in that they emphasize the principle that the people, in forming a government, retained some powers beyond the reach of government.

The Right of Privacy

The Bill of Rights as a whole is understood to indicate a sphere of personal autonomy where government should not intrude, even though this sphere is not exhaustively marked out or specified by any formal listing of rights. This sphere of individual autonomy has come to be called the "right of privacy, " although the word "privacy" is not used in the Constitution.

In one of his classic dissents, in 1928, Judge Brandeis said that the Fourth and Fifth Amendments together recognized "a right to be let alone, and defined this as "the most comprehensive of rights and the right most valued by civilized men. "[22] In a 1958 civil liberties case Justice Harlan spoke of the "vital relationship between freedom to associate and privacy in one's associations. " In a 1969 pornography case Justice Marshall said that regulation of obscenity cannot extend into "the privacy of one's own home, " and that the government has no business to tell a man "sitting alone in his own house, what books he may read or what films he may watch. "

The right to privacy was finally made explicit and definitive in *Griswold v. Connecticut,*[23] in 1965, as the Court struck down a law forbidding contraception. Since then it has been expanded to include other aspects of *marriage,* reproduction, and health.

Equal Protection of the Laws

No discussion of the Bill of Rights can ignore the Equal Protection Clause of the Fourteenth Amendment, which was intended to buttress the rights of former slaves. Yet for nearly ninety years it was not applied as intended. The Court held in 1896 that a legal distinction between the races did not destroy their equal protection or legal equality, as long as they were given "separate but equal" treatment.[24]

This doctrine was finally modified in 1950, and it was definitively struck down in 1954 when public school segregation was ruled unconstitutional.[25] In a further series of cases in the late 1950s and 1960s, the court established that it will look with great suspicion ("strict scrutiny' at any different or special treatment of a class of citizens in applying laws for the purpose of allocating a benefit or imposing a restriction, especially where such classification is based on race. Later Equal Protection cases have extended the scope to classifications other than those based on race. This transfers the burden of proof to the State and demands more than a showing of reasonableness; the State must demonstrate that it has a compelling interest and a critical need to give special treatment to some class of citizens.

In effect, the Court looks at the intent of any classification. If the intent can be shown to be related to a legitimate legislative objective, and not to social discrimination, classifications may be allowed to stand. For example, classifications related to age have been allowed,

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"Quoted in Corwin and Peltason, op. cit., footnote 3, p. 132.

[22] *Olmstead v. United States* (277 U.S. 438: 1928).

[23] 381 U.S. 479

[24] *Plessy v. Ferguson*, 163 U.S. 537 (1896).

[25] *Sweatt v. Painter*, 339 U.S. 629 (1950) struck down one State law requiring separation of races in State law schools; *Brown v. Board of Education, 374* U.S. 483 (1954) definitively ended the doctrine that "separate" could be "equal" in public education and by extension in other public accommodations and services. For discussion of related cases and decisions see Chandler et al., op. cit., foonote 1, pp. 308ff.

to give special services or protections to those under 18 or over 65. Classifications by gender or by indigency are not necessarily suspect, but some classifications based on gender have recently been disallowed.

Special treatment related to fundamental rights, such as the right to vote, the right to cross state lines, or even the right to have certain medical procedures, are subjected to what the Court calls "strict scrutiny. This is especially true when the classification itself is "inherently suspect. "

The Forgotten Amendments

Several of the first Ten Amendments have been of relatively little importance in our constitutional history.

> A well regulated Militia, being necessary to the security of a free State . . . ,

The Second Amendment guarantees the "right of the people to keep and bear arms. " Although it is often loosely cited in debate over gun control laws, there have been few if any judicial interpretations of this clause. According to most scholars, the Amendment was primarily intended to prevent Congress from disarming the State militia, a touchy subject less than a decade after the end of a revolutionary war and at a time when antifederalists feared the creation of a possibly despotic central government.[26] If this Amendment was intended, as some have assumed, to assure the possibility of revolution against despotism, then the modern technology of weaponry has almost surely negated that protection.

The Third Amendment provides that

> No soldier shall, in time of peace, be quartered in any house, without the consent of the Owner, nor in time of war, but in a manner to be prescribed by law.

This provision too was never the subject of judicial challenge.[27] By the time of the Civil War, if not before, it had been rendered obsolete by the advancing technology of warfare and the logistics of modern armies.

[26] *Corwin and Peltason*, op. cit., footnote 3, p. 115.
[27] Ibid.

MOLECULAR BIOLOGY AND NEW TECHNOLOGY

Molecular biology is in this decade an extraordinarily productive field of scientific research and application. The traditional disciplines of biology, chemistry, and physics here converge to support wave after wave of advances in scientific knowledge. New knowledge quickly leads to innovative scientific instrumentation, which in turn produces further advances in knowledge and is also translated rapidly into practical applications, improved testing and measuring techniques, and commercializable technology. In this area, strong social needs indicate that "market pull" as well as "knowledge push" will continue to encourage innovation and commercialization. These social needs are related to both genetic and infectious diseases (especially the new epidemic of AIDS); mental illness and mental retardation; and the mental and physical problems associated with aging.

From advances in the basic science, or sciences, of molecular biology are pouring two mighty streams of further development. One of these is bioengineering, with techniques for use in manufacturing processing, agriculture, and environmental management. The second line of development flowing from molecular biology is concerned directly with the human body, brain, behavior, and genetic inheritance. Much is being learned about the materials and processes of human genetics and about the biochemical basis of body and brain functions. Techniques are being developed for their further analysis, testing, measurement, manipulation, correction, or enhancement.

Some new or proposed techniques are already highly controversial. Such applications are in various stages of study or achievement-some already in limited use, some in laboratory

trials, some only promised or even hypothetical. For example, debate has arisen over mandatory testing for disease exposure and for use of drugs, genetic screening for special susceptibility to environmental risks, human germ cell or somatic cell gene therapy, interspecies gene transfers, brain transplants, fetal surgery, and several kinds of technologies for assisted reproduction, including in vitro fertilization, the freezing of embryos, etc.

Part of the promise of these new biology-based technical capabilities comes from their combination with other especially fruitful areas of scientific research and technological development. Computers and related information technologies have not only made many of the breakthroughs in biology possible, but also make it possible to use this knowledge in ways commensurate with its enormous complexity and data richness. More recent rapid developments in materials sciences and molecular engineering may loosen many constraints associated with the differences in nature between organic and inorganic materials. The cognitive, behavioral, and social sciences offer nearly endless ways to check, extend, and apply knowledge gained through biological and chemical research on human beings.

These combined techniques and technologies are related not only to medicine or public health; they have possible applications in many other fields in which significant issues maybe raised, some of them with obvious constitutional applications. In law enforcement and corrections, the use of biological techniques such as drug or hormone therapy as alternatives to prison could point to a new paradigm of criminal justice—treatment for disorders rather than punishment for crime. In education, prediction of performance could affect (perhaps in one of several directions) the design of or the equal access to educational opportunities and resources. In many other areas, a person may come to be thought of less as autonomous and accountable, and more as manipulatable or predictable.

The opportunities promised by these emerging technologies are immense: more efficient and effective delivery of human services, enhanced human performance, better health and prolongation of useful life, even eradication of tragic physical or mental defects and diseases.

At the same time, many of these biology-based technological capabilities seem to be particularly likely to raise political and ethical issues, which often ultimately become constitutional issues, or are so construed by those seeking their resolution. They may offer alternative explanations of causality in behavior, performance, motivation, or attitude—i.e., biochemical or genetic determinants or influences rather than choice or will. They provide new means of influencing, controlling, or modifying behavior, emotions, or judgment. They may challenge religious definitions and principles. And they may allow individual choices to purposefully change the genetic inheritance of future generation.

These technologies and techniques, in short, enlarge the capabilities of both individuals and the State to make and implement decisions that increase tension between the general welfare and individual rights. The State has always claimed an interest in protection of human life, in reproduction, in decisions made for those who cannot decide for themselves, and in the welfare of future generations. These are also the areas in which people most readily assert their right to privacy, family integrity, and individual autonomy.

This conflict is what creates and defines constitutional issues—the testing of the terms of the social contract. But until recently, only some of the events in these critical areas were within the power of either the person or the State to decide or even to influence; and this has minimized the conflict or tended to limit its effects to the most dependent and powerless members of society. As technology changes this condition and increases the possibility of constitutional clashes, concerned citizens, Congress, and the courts will be called on to reexamine the nature and scope of constitutional principles.

Chapter 3

The New Biology

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Chapter 3
The New Biology

Of all the areas of science and technology where rapid advances are now occurring, probably none will have more direct and profound implications for individual rights and responsibilities than molecular biology. This has come to be called "the new biology. " This field of research is producing dramatic new knowledge derived from the increasing ability to map and manipulate the genetic materials in the cells of microorganisms, higher plants and animals, and people; and from far-ranging explorations into biochemical factors in physiological and mental functions.

From the new biology flow two major streams of applications. One deals with genetic engineering in industry, agriculture, and management of the natural environment. The second consists of tools and techniques for analysis, prediction, correction, control, and enhancement of the human body, brain, and behavior.

The first has already raised several direct constitutional issues related to the right to patent new "engineered" life forms, and the right of scientists to carry out experiments that some people perceive as imposing significant risks to human safety or to the environment. It is likely to raise other constitutional questions in the future. The second, knowledge of human biology, affects assumptions about what constitutes human nature, what people are capable of, and thus what they can be held responsible for. New technologies based on this knowledge will also increasingly present people with the necessity for new decisions about life and death, reproduction and inheritance, culpability and punishment.

In order to probe some of these potential challenges in later chapters, it is helpful to review briefly the basic premises and promises of the new biology. Those readers who are already well informed about this area may wish to skip this chapter, which provides a summary in nontechnical language. For those who know little about the new biology, it will be worth some effort to read carefully the following section, as a primer for the discussion of potential constitutional issues that follows in later chapters on genetics, public health, and medical interventions.

MOLECULAR BIOLOGY: WHAT'S IT ALL ABOUT?[1]

In molecular biology the traditional disciplines of biology, chemistry, and physics converge and overlap in the study of the detailed structure and functions of biological macromolecules. These are very large complex molecules made up of several subgroups of atoms. Cells, the basic building blocks of all living organisms, are generally made up of such macromolecules.

Until very recently, biochemistry dealt mostly not with macromolecules, but with small molecules such as vitamins, hormones, and amino acids. This research had many practical applications in nutrition, medicine, and agriculture, and was relatively quickly commercialized in the form of specific products. Macromolecules, in contrast, are made in and retained within living cells and carry out the basic cellular functions. During the first two decades of molecular biology-roughly, the 1950s and '60s– research on macromolecules yielded few practical applications that could give rise to commercializable technologies.

This changed dramatically in 1974 with the development of recombinant DNA techniques. DNA is the basic material in genes. During

[1]Much of the material in this chapter, not otherwise attributed, was prepared for the Office of Technology Assessment by Dr. Bernard Davis, Professor Emeritus of Bacterial Physiology, Harvard University, in the form of a contractor report "The New Biology," May 1987.

conception the DNA in egg and sperm combine and so transmit traits from one generation to the next, from parents to offspring. Along with this continuity, DNA allows for variability, since the traits from two lines of inheritance-two parents-are combined and mixed. An ability to analyze, map, and manipulate DNA opened up both deeper insights into living processes and immense prospects for practical applications. A review of some key steps in the short history of molecular biology, especially the recombinant methodology, shows vividly how much unforeseen knowledge we have gained. It also shows that the advance of science and technology depends only in part on orderly, step-wise research; occasional unanticipated breakthroughs open up new territories that in turn rapidly spawn new information and understanding.

Start With Bacteria . . .

The study of bacteria played a key role in the emergence of molecular genetics. The very small size of these single-celled organisms—about one thousandth the volume of an average human cell—had always been a major obstacle to dissecting their internal structures. There was no science of bacterial genetics until the 1940s—no one had observed either the transfer of genes between organisms or mutations in bacteria. But in 1944 (when pneumonia was a leading cause of death), research on pneumococcus showed that the material of genes is DNA and that it can be transferred between bacterial cells.[2]

Bacteria offer several advantages for the study of molecular genetics: their relative simplicity, rapid multiplication (as many as three generations per hour), and the ease of selecting even very rare mutants from populations of billions of cells. Moreover, the relatively simple viruses that infect bacteria (which are called bacteriophages) have even greater advantages for many studies. Analysis of their life cycle has laid the foundation for understanding the viruses of animals and plants, and gave us the ability to rapidly identify and characterize the AIDS virus, as will be described in chapter 5.

An important consequence of microbial genetics has been the recognition of the remarkable unity of biology at a molecular level. The living world is enormously diverse. Millions of species have adapted to their environment through astoundingly varied structures, functions, and behaviors. But at a molecular level all organisms-man as well as microbe-make their nucleic acids and proteins from precisely the same building blocks, and these acids and proteins function in essentially the same way. The inherited differences between organisms—between, for example, a person and an earthworm-appear to be determined by differences in the sequence of the basic building blocks comprising the genes.

Such basic unity in the midst of diversity gives us, with the development of bioengineering, the ability to make useful products such as insulin by inserting human genes into bacteria. The bacterial cellular mechanism can then produce insulin, illustrating the fundamental similarity in basic proteins and genetic structures. This close biochemical relationship between two extremes of biological complexity-the human and the bacteria—is evident throughout the living world and provides strong evidence for its evolutionary continuity.

James Watson and Francis Crick, in 1953, demonstrated the structure of DNA. Within DNA the basic building blocks are chemical bases, of which there are only four kinds: adenine, thymine, guanine, and cytosine, known as A, T, G, and C. In order for genes to be passed on from one generation to another, DNA must replenish itself. The fact that DNA within the cell is double-stranded, and that complementary bases are paired-A always with T, and G with C—gave scientists an immediate clue to how replication occurs. Thesequence of each strand-the order in which its

[2]The discovery was made by Oswald Avery. Until then it was generally assumed that chromosomal proteins carry genetic information and DNA played some secondary role. The importance of the discovery was not widely recognized at the time. Avery never received a Nobel Prize. Lubert Stryer, *Biochemistry,* 2nd ed. (San Francisco, CA: W.H. Freeman & Co, 1981), p, 562; or G.J.V. Nossal, *Reshaping Life: Key Issues in Genetic Engineering* (Cambridge University Press, 1985).

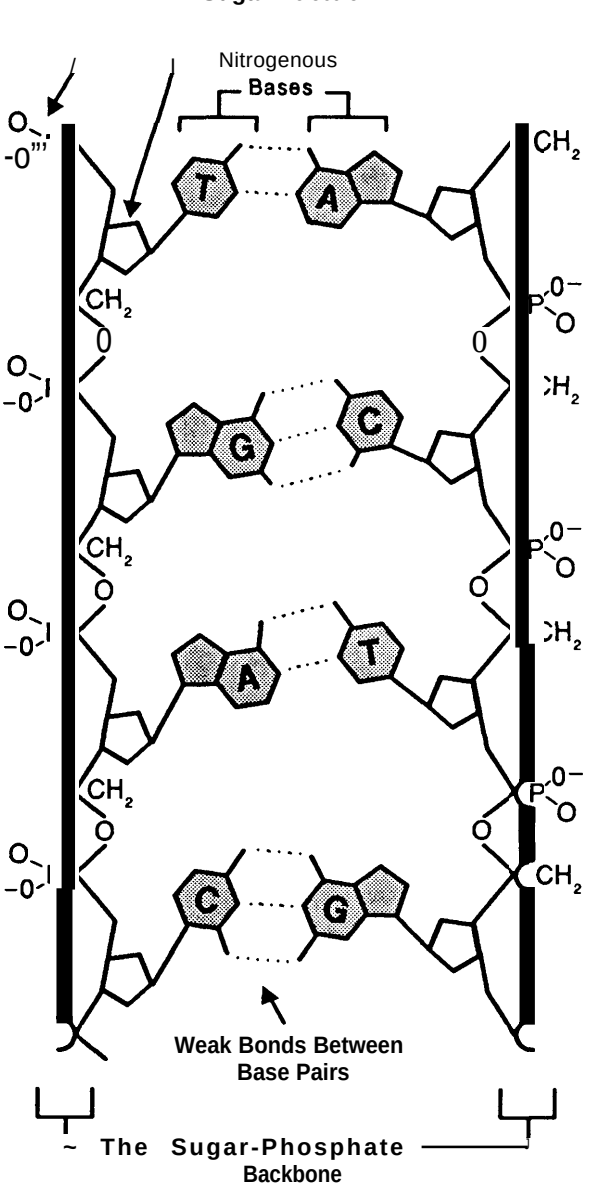
building blocks are arranged-serves as a template for the synthesis of its complementary strand, and hence for the formation of two double-stranded molecules from one. (See figures 3-1, 3-2). Moreover, mutations could now be explained as errors in the pairing of bases during replication.

The research that has grown from the explanation of DNA by Watson and Crick has provided an enormous amount of detailed information about the chemical and biological properties of DNA. Each gene is a sequence of bases within a chain; within bacteria the length of that chain is about a thousand times the diameter of a cell. To accommodate this length within the cell, the DNA chain is tightly folded. The genetic information itself is linear, coded much like sequential sentences in a printed book or electronic signals on a magnetic tape.

There are many kinds of errors, or "misprints. " Mutation eventually turned out to be much more complicated than was originally thought. Sometimes chromosomes (or strings of genes) become rearranged, or one base is substituted for another, or bases are duplicated or deleted when they should not be. Some sequences seem to be particularly transposable; they are often transferred to another site in DNA.

Some of these transposable elements also can be incorporated into viruses that can carry them to other cells, to other individuals, or even –although rarely-to individuals belonging to other species. This also contributes to the increase of genetic variety. Some scientists even suggest that the role of viruses in causing disease may be only a byproduct of a more fundamental evolutionary role in expanding genetic variety. As an analogy, there are only a few bacteria that cause disease, compared to those that play essential roles in the cycle of

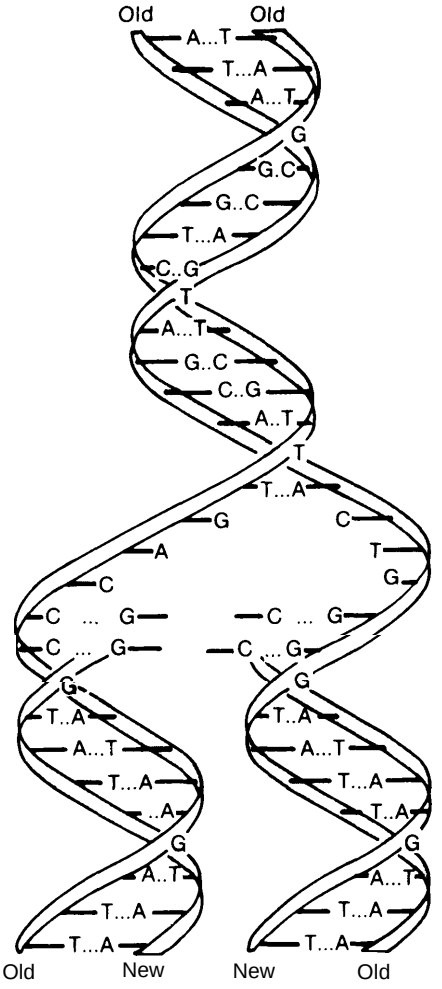
Figure 3-1 .–The Structure of DNA



The four nitrogenous bases, adenine (A), guanine (G), cytosine (C), and thymine (T), form the four letters in the alphabet of the genetic code. The pairing of the four bases is A with T and G with C. The sequence of the bases along the sugar-phosphate backbone encodes the genetic information.

SOURCE: Office of Technology Assessment, 1988.

Figure 3-2.—Replication of DNA



When DNA replicates, the original strands unwind and serve as templates for the building of new complementary strands. The daughter molecules are exact copies of the parent, with each having one of the parent strands.

SOURCE Off Ice of Technology Assessment

matter between the organic and the inorganic world.

From another perspective, however, mutations are rare exceptions. DNA is transmitted from generation to generation with extraordinary accuracy. This accuracy depends not only on the inherent chemical stability of DNA, but on repair mechanisms that recognize and correct most errors in replication and most of the genetic damage caused by radiation, chemicals, or other environmental factors.

The information contained in genes directs the formation of the other molecules that comprise the core of the working machinery of cells –RNA and proteins. In this process a DNA sequence, by "un-pairing" its bases, gives rise to a complementary RNA sequence, and this "messenger" RNA is then translated into proteins. Each successive set of three bases in messenger RNA calls forth a specific amino acid. Amino acids are linked together to forma proteins. This translation of RNA to produce proteins occurs with a remarkably low error rate.

Several different regulatory mechanisms that affect the expression of specific genes have been recognized. Such regulatory mechanisms allow even the simple bacterium to adjust the formation of its components to various environmental circumstances. Appropriate human cells "turn on" antibody genes when the body is invaded by a disease organism. The regulatory elements or mechanisms are key factors in the bioengineering synthesis of useful proteins through the use of recombinant bacteria, as described below.

The more complex regulatory processes in the cells of higher organisms, which are of great importance for medicine and pharmacology, are as yet much less well understood. For example, it is not yet understood why certain processes (e.g., loss of a limb) are effectively irreversible in higher animals, but not in plants.

Recombining DNA: How and Why?

A number of additional discoveries in the fields of bacteriology and molecular genetics led to the development of recombinant DNA methodology, which is popularly called bioengineering. Before this development, the problem of isolating the different genes in a chromosome seemed unsolvable, because they are sequences in a giant chain and physical methods for breaking that chain simply yield random fragments. The breakthrough came with the discovery in cells of "restriction en-

zymes, which destroy unwanted DNA by cutting or cleaving it at a specific sequence. Restriction enzymes can be used in the laboratory to cleave DNA purposefully into a set of fragments with known ends that can be relinked or recombined with other fragments that have complementary ends, by using other enzymes.

By using restriction enzymes and ligation (linkage) enzymes, scientists can now splice a DNA fragment into an appropriate unit and multiply it indefinitely (i.e., "clone" it) by inserting it into an appropriate cell that then multiplies. After years of effort, a simple procedure has been developed to genetically modify the bacterium *Escherichia coli* or *E. coli.* Bacteria contain a single, very long circular chromosome that contains most of the genetic information necessary to function. The chromosome of *E. coli,* a common bacterium living in the human gastrointestinal tract, is some 4 million nucleotide base pairs in length. But like most bacteria, *E. Coli* contain other "accessory" genetic elements that carry genes involved in reproduction and resistance to drugs. These small circular units of DNA are called plasmids and can be transferred from one bacterium to another.

The entire "library" of genes of a mammal, containing around 3 billion base or building block pairs, can be stored in the bacteria in a single test tube. Such a mixture of perhaps 10 billion bacteria will contain thousands of different recombined genes, but the "library" can be separated into "books," or smaller pieces of DNA containing several genes, and each "book" or piece can be inserted indifferent bacteria. Ingenious techniques have been developed for efficiently selecting those cells that have incorporated a particular gene.

What Goes On in a Cell?

Molecular biology has two major branches: molecular genetics and macromolecular structures. The first branch was described above; it aims at determining how genetic information is transferred from DNA to RNA and finally to production of proteins. The second or structural branch of molecular biology aims at determining how these proteins, in turn, carry out biological functions through specific interactions; for example, how insulin controls the storage and processing of sugar. This branch too is contributing to both streams of future technological development, that leading to commercial applications for industry and agriculture, and that focusing on the human body and brain.

As they study biochemical reactions, scientists are attempting to develop enzymes to affect not only naturally occurring compounds but also synthesized or novel organic compounds. Genetic variation in the microbial world is so rapid that microbiologists can now accelerate natural evolution by selecting mutant bacteria with enzymes having the capacity to attack a specific organic molecule.

Researchers are learning that a small number of genes can generate large numbers of unique proteins. For example, antibodies are specialized proteins that attack and destroy foreign substances, or antigens, thus protecting the body from disease organisms. This process requires very specific physical binding of the antibody to the antigen. Specificity results from the unique amino acid sequences of antibodies that are encoded by genes. Although it is known that the body can generate in excess of a million different types of antibodies, there are just a few hundred antibody genes. Recently it was discovered that this enormous number of antibodies can be generated by mixing, matching, and splicing a small number of genes together. It is now known that natural gene rearrangements of this kind are responsible for the generation of many kinds of proteins.

Short synthetic protein chains are already under trial as vaccines. The analysis of the interactions of drugs with their receptors in living cells is also having a revolutionary effect on pharmacology.

[3]An *enzyme* is a complex protein that catalyzes a specific biochemical reaction within the body; that is, causes the reaction to occur without the catalyst enzyme itself being used, changed, or destroyed.

The proteins in cell membranes, including the receptors for hormones and drugs, were long a mystery to biochemists. They seemed part of an insoluble debris. But new laboratory techniques, including the use of certain detergents to make them soluable, have made them accessible to study. Biochemists are now able to make artificial membranes that reproduce some natural biological functions. It is not yet clear how far this approach can go toward reconstructing cells from their components, or toward "tissue engineering" formedical purposes.

In the future, there maybe nearly unlimited possibilities for designing synthetic protein chains for specific purposes. Enzymes produced to order by engineered organisms will be used in the chemical industry, perhaps replacing chemical reagents that are more risky to workers or to the environment.

Enzymes and Proteins: Regulating Life

In the memory of a computer, information is stored in an intricate pattern of switches, each of which may be "off" or "on," represented by O or 1, so that information is put into a code, like 01001001110. Genetic information is stored in a different way, in the linear sequences of four different chemical bases within a giant molecule. Thus it uses a 4-letter code rather than the 2-letter code of 0/1.

For day-to-day conduct of cellular business, cell functions are regulated by still another means of transmitting biological information —special proteins that sense the presence or concentration of some molecule and react to it. This key discovery came about through research that had a more limited aim: to explain how bacterial cells stop making a certain amino acid when it is supplied to them in the medium in which they are grown. In this feedback response, the initial enzyme that begins the process of creating an amino acid is directly inhibited by the end-product of that process, i.e., by the presence of amino acid. This spares material and energy for other purposes when more amino acid is not needed. Enzymes thus act as valves controlling the flow through a pathway from raw material to end-product, each enzyme specific to a particular starting material.

The mechanism by which this occurs involves the ability of many proteins to shift between two stable alternative shapes or conformations; this is called allostery. The same simple principle has provided a general explanation for an enormous variety of biological phenomena, from the expression of a gene, to the actions of drugs on the body, to the secret of mechanochemical coupling resulting in movement in biological systems. It has been useful in explaining how muscle fibers work, the migration of cells in embryonic development, and the mechanisms by which some cells, called phagocytes, engulf and digest foreign bacteria, allowing the body to resist infection.

The understanding of this and other regulatory mechanisms is certain to contribute to the understanding and control of disease, to the development of drugs, and to the manufacture of desired proteins by genetic engineering.

Mapping the Human Genome

Soon scientists will have mapped the complete DNA genetic sequence of the common bacterium *E. coli*, with its 3 million base pairs. Some scientists argue that we should now mount a major national effort to do the same for the human genome (i.e., complete set of chromosomes), which is about 1,000 times larger.

There are two alternatives for further work, ‘‘mapping, and "sequencing" the genome. The difference is important because of current policy debates about which way to proceed. At present, small regions of the genome concerned with specific functions are being sequenced. These regions are identified in two ways: the sequence of a known protein is used to locate the corresponding gene, or the abnormal form of a gene associated with a disease is located through genetic comparisons and then is used

to identify the normal version. To continue along this path would involve studying key sites on the human genome; physically, in terms of the succession of restriction enzyme cleavage sites, and genetically, in terms of the genes as they are identified. Detailed sequencing of the various regions, base by base, would be done gradually, with priorities set by interest and importance rather than by location—i.e., the work would "skip around" with gaps being filled in slowly (See figure 3-3.).

This program is in fact being carried out now, in many laboratories, and the information is being collected and correlated. It has revealed unexpected parallels between sequences in genes with very different functions. This indicates that as organisms became more complex and as they therefore increased the number of their genes, new genes evolved from older ones in branching patterns, much like the branching pattern of the evolution of species through modification of earlier organs.

The alternative approach is mapping or complete systematic step-by-step description of the entire human DNA sequence, containing possibly 100,000 genes and over 3 billion bases. Only a few hundred genes have so far been described, less than 1 percent of the total. Current techniques can produce rough sequencing of about 20,000 bases a day, and are rapidly improving. One approach would be to map the structure of DNA in sections some 40,000 bases long. Sections of DNA of that length can be cloned into special vectors called "cosmids," in such a way that these partial maps would overlap. Mapping of the complete genome would be the largest single biological project ever undertaken.[4] A major governmental initiative toward this end has been proposed, involving the establishment of a few major research centers to carry out the work with centralized coordination. It is highly controversial.

[4] "Sequencing the Human Genome," *Issues in* Science *and Technology*, Spring 1987. See "Prologue," p. 25. This seminar in print includes: Walter Gilbert, "Genome Sequencing: Creating a New Biology for the Twenty-First Century, pp. 26-35: Leroy Hood and Lloyd Smith, "Genome Sequencing: How To Proceed, pp. 36-46; and commentaries by David Baltimore and Francisco Ayala, pp. 48-56.

The advantages of comprehensively mapping the human genome are that it would make it much easier and faster to link a newly identified gene with a disease or human function. Currently, a gene must be located through a painstaking search for genetic markers before it can be isolated and its bases sequenced for further study of its functions. Mapping the full genome would mean that when biologists want to study a specific protein within the body, analysis of a bit of its amino acid would make it possible to go to the genome database and locate the specific gene that guides the production of that protein. Advocates say this would dramatically accelerate achievement of the goal of fully understanding human inheritance and its limits. Possibly diseases that depend on the interaction of several genes, or that have alternative genetic causes, could be understood. There would also be spin-off benefits for many other areas of biological research, including ecology, immunology, and cancer control.

Mapping the entire genome would be a large and ambitious undertaking, probably taking 10 to 20 years, and with a cost estimated by some experts to be at least $3 billion. Critics fear it could divert research funds from other research that they think is more urgent. Some sections of the human genome, it is thought, will be much more difficult to clone and map than others, and some scientists suspect that the technology is not yet up to the task.

Some biologists argue that 90 percent of the effort of such a project would be wasted because it is now believed that only about 10 percent of DNA codes for proteins and the rest is "irrelevant" or "junk." Advocates respond that we do not really know what genetic material is irrelevant to our needs, and that the effort to filter out the junk would in any case be more time-consuming than systematic mapping.

Allowing the U.S. Department of Energy (DOE) to take the lead in mapping the human genome has been considered as one possibility, on the grounds that this would be a natural extension of DOE research in molecular bi-

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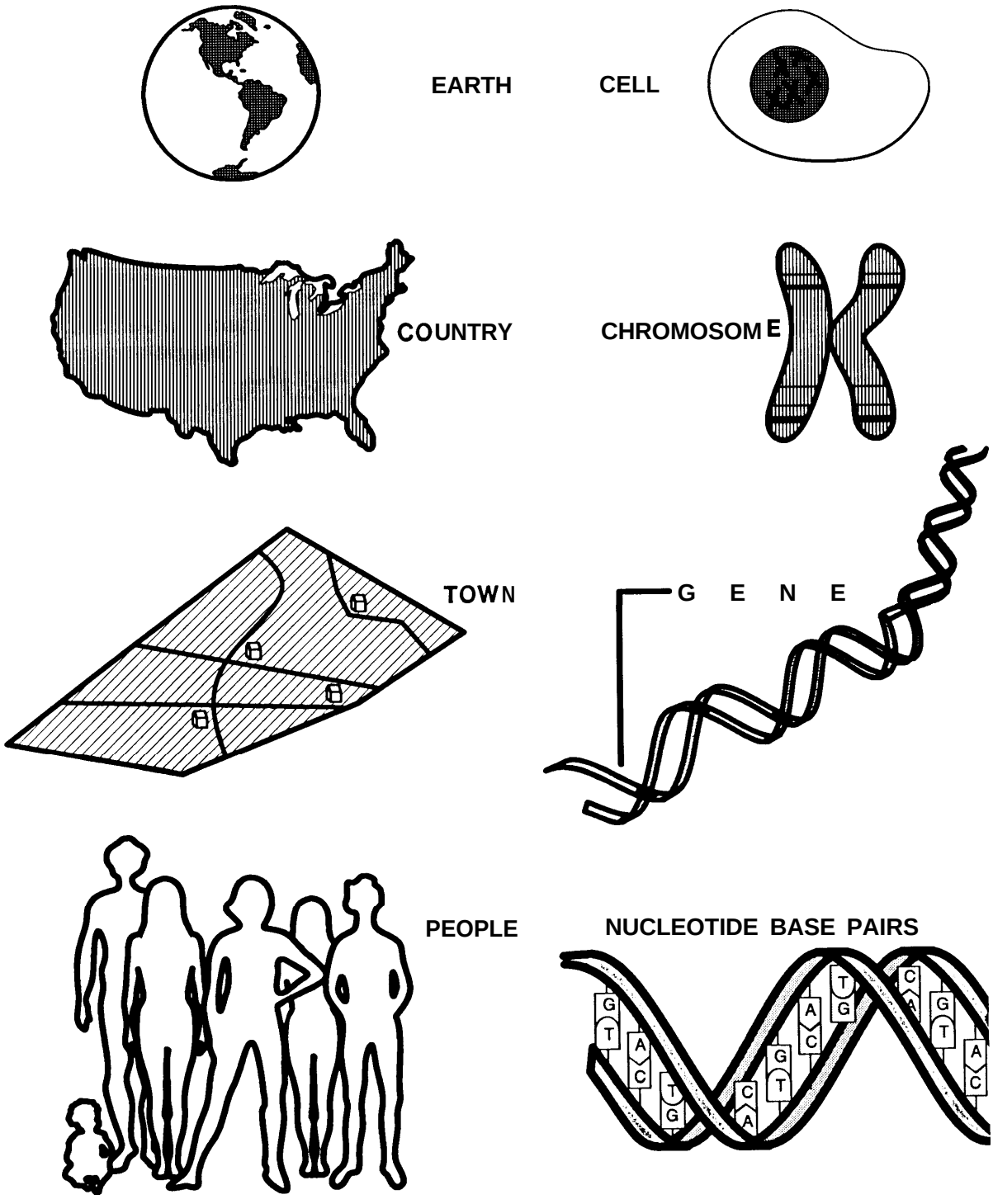
Figure 3.3.—Comparative Scale of Mapping



The number of base pairs of DNA in human cells is roughly comparable to the number of people on Earth. The scale of genetic mapping efforts can be compared to population maps, with chromosomes (50 to 250 million base pairs) analogous to nations, and genes (thousands to millions of base pairs) to towns.

ology (focusing on mutations that result from radiation or energy production) and would take advantage of DOE-funded scientific instruments and staff at national laboratories. Alternatively, the project could be led by a new, directed effort of the National Institutes of Health (NIH). An NIH-led effort would build on a much larger base of biomedical research. These and other strategies for carrying forward genome mapping efforts has been widely debated inside and outside of government in the last 2 years. Most likely is a set of projects funded through two or more Federal agencies, with formal or informal means of coordinated planning.

The situation in mid-1988 is that there is no single human genome project but instead many projects, in NIH, DOE, and other government laboratories and in universities and private sector laboratories. They aim at establishing and enhancing databases about DNA sequences, markers, and gene structure and expression; creating chromosomal maps; and developing new instruments, analytical techniques, and other scientific resources for biomedical research. No agency or organization, and no national government, has made a commitment to massive sequencing projects, or to a unitary, single focus program of research like that of the Apollo Project, the Manhattan Project, or other celebrated government research initiatives. Recent reports by the National Academy of Sciences[5] and the congressional Office of Technology Assessment[6] concluded that any such initiative would be inappropriate. They suggest, rather, that the Federal Government should, through funding and oversight, encourage and coordinate the continuing enhancement of databases and resources in many cooperating units and centers of research.

[5]National Research Council, *Mapping and Sequencing the Human Genome* (Washington, DC: National Academy Press, 1988).

[6]U.S. Congress, Office of Technology Assessment, *Mapping Our Genes– The Genome Projects: How Big, How Fast?* OTA-BA-373 (Washington, DC: U.S. Government Printing Office, April 1988).

The Evolutionary Record

The new field of molecular evolution provides more direct evidence for evolutionary continuity than even the fossil record. For example, man and chimpanzee, species which separated only around 10 million years ago—a short time in evolutionary history, have about 99 percent of their DNA sequences in common. This similarity indicates that man and chimp have a relatively recent common ancestor, compared to the much smaller genetic overlap between man and other species. DNA changes over time, due to mutations that are not eliminated, and the more similarity there is in the DNA of two species, the shorter the time in which they have been developing separately and thus diverging. There are decreasing degrees of homology, or genetic similarity, between man and increasingly distant organisms down to the lowest of the vertebrates. By contrast, bacteria have been diverging from each other not for thousands of years but for several billion years, and they show sequence homology only between very close species; that is, different bacteria may have very little overlap in DNA sequences. Some of the gaps in the evolutionary record are likely to soon be clarified and closed by such molecular comparisons, and some current misunderstandings and misinterpretations may be identified and swept away.

Evolution has implications not only for describing the origin and development of our species but also for increasing our appreciation of its rich genetic diversity, and for the still richer genetic diversity in our environment at large. This diversity could be needlessly reduced by careless or misguided agricultural and environmental management practices.[7] With respect to humans, a deeper understanding of the value of the wide variety in nearly all human traits enormously enriches life and literature, and when combined with understanding of the basic unity of life, as revealed by molecular biology, can further complement the already strong moral, political, cultural and re-

[7]U.S. Congress, Office of Technology Assessment, *Technologies To Maintain Biological Diversity*, OTA-F-330 (Washington, DC: U.S. Government Printing Office, March 1987).

ligious grounds for treating all races and all individuals with equal consideration and respect.

Tools of the Trade: Innovations in Conducting Biological Sciences

Progress in science depends on technical as well as conceptual advances. As biochemistry expanded its scope it has become increasingly dependent on elaborate (and expensive) instruments.[8] Also of major importance has been the use of computers. Automation and computers greatly facilitate the accumulation of data. While the investigator sleeps, his instruments continue to collect successive samples in a fractionator, to measure radioactivity, to determine or synthesize base sequences in genes. Indeed the rate of production of data is overwhelming the ability to publish it; a case in point is DNA sequence information.

The focus of biochemistry on larger molecules, and the simultaneous focus of cell biology on ever finer structures, has had another fundamental benefit. It has done away with the troublesome range where cell features were too small to be studied by microscopy but too large to be defined chemically. The field of cell biology increasingly overlaps that of molecular biology, and any line between biology and organic chemistry is becoming artificial.

An even more fundamental breakthrough has been the development of monoclinal antibodies. An animal produces antibodies in response to the presence within its body of a disease organism. In the ordinary antibody response, an "antigen" or stimulus (such as a protein on the surface of a virus) stimulates the formation of a protein molecule (antibody). The antibody is shaped to fit the antigen like a lock fits a key. The antibody covers the antigen so that it cannot latch on to another body cell. This prevents the virus from invading the cell and replicating itself.

The difficulty is that a normal antibody response leads to the formation of hundreds of different antibodies, differing with respect to the small region on the protein surface that each is attracted to and binds. The distribution of antibodies elicited by a given antigen varies somewhat from person to person, and even in the same person at different times. This made it hard for scientists to study the formation of antibodies.

There is a kind of cancer that attacks antibody-producing cells, called multiple myeloma. The cancer makes the "sick" cell reproduce itself uncontrollably. The new or daughter cells are clones of (i.e., identical with) the original cell. Scientists learned how to fuse an antibody-producing cell with a myeloma cell to get a cell that is called a hybridoma, which both produces one species of antibody and replicates itself over and over. These identical antibodies are called monoclinal antibodies, and are a powerful tool for analyzing the process of antibody formation. (See figure 3-4.) Their specificity allows them to be used, for example, to carry fluorescent markers or poisons to cancer cells. Monoclinal antibodies can be accurate and thorough biochemical scouts, spies, and assassins in the service of medicine. They have nearly unlimited potential for diagnosis, therapy, and analysis, and a growing industry has sprung up to produce them.

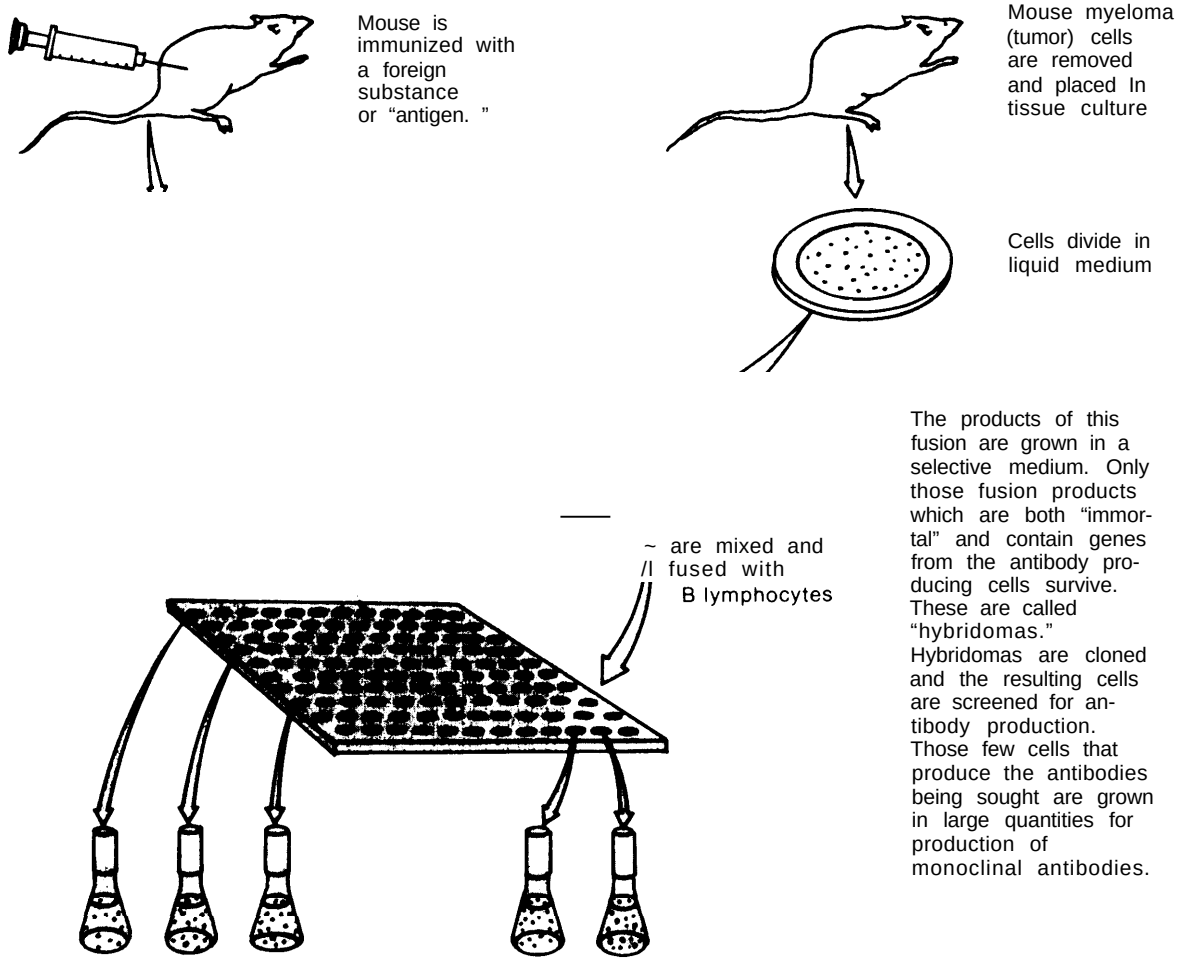
The Changing Environment for Biological R&D

The development of recombinant DNA and monoclinal antibody techniques have had a significant impact on the relationship between biomedical sciences and industry. Until recently most research in biology has not had much potential for commercial applications. But now a substantial number of the leading researchers have become involved in commercial enterprises.

It is clearly desirable that scientists doing basic research also encourage the development of applications that will benefit society through better health, improved agriculture, or increased economic productivity. In the United States, such benefits are perhaps most likely to be realized when the initial discovery is developed and marketed by an industry.

[8] For example, high-speed centrifuges, chromatography columns, flourescence cell sorters, electrophoresis apparatuses.

Figure 3-4.—Preparation of Monoclinal Antibodies



SOURCE Off Ice of Technology Assessment, adapted from Y. Baskin, "In Search of the Magic Bullet, " *Technology Review*, pp. 19-23

But there may also be problems associated with this changing relationship. Scientists who are also university faculty members may be tempted to spend too much time on commercial activities, and too little time on teaching. Students may be attracted to those areas promising the most immediate commercial payoff while other lines of basic scientific research get too little attention. There may be an adverse impact on the openness of scientific communication and sharing of knowledge. Concern about priority in discovery-for either winning prizes or patenting-could encourage scientists to postpone publication of preliminary or intermediate results, as could industrial secrecy.

FROM SCIENCE TO TECHNOLOGIES: THE USES OF NEW BIOLOGY

Bioengineering in Industry and Agriculture

People have throughout history domesticated various microbes by empirical selection of genetic variants with improved properties –for example, in making bread, wine, cheese, and antibiotics. Now, directed manipulation of genes through bioengineering can further improve strains. Also new strains of selected properties can be designed without waiting to select from variants that nature offers. The use of enzymes may increasingly replace traditional methods of organic chemistry in manufacturing processing, especially if biological processing proves to be more environmentally benign than older methods. Engineering of microbes could also increase both the efficiency and versatility of the conversion of biomass into energy and other useful products, or solve the problem of economically producing single-cell protein for food.

A successful early application of the new biology has been the use of recombinant bacteria to produce mammalian proteins. One of the first was the human growth hormone, used to treat children who otherwise would not grow to normal stature. Another early product was bovine hormone to increase milk production in cows. A third was human insulin for the relatively rare diabetic people who are allergic to insulin derived from other animals. A more *re*-cent product is tissue plasminogen activator, to dissolve the blood clots that may cause coronary thrombosis or strokes. These products from engineered microorganisms have the added advantage that they do not risk contamination with lethal human viruses as can occur with hormones extracted from human tissues and glands. The variety of products under development is growing rapidly.

Manipulation of DNA will supplement, rather than supplant, traditional methods of strain improvement in domesticated plants and animals. But bioengineering is different from conventional techniques in that it can produce changes in more stable portions of the genome not ordinarily changed by selective breeding. With animals, the extent of possible alterations through genetic engineering may be limited because the traits one would wish to alter often involve a large number of undefined genes, rather than being determined by a single gene. With plants, somewhat more extensive changes may be likely. Promising possibilities include enhanced resistance to pests, drought, or temperature extremes, and changes in nutritive value and flavor. Currently, there is extensive research on the possibility y of incorporating in various plants the set of genes responsible for nitrogen fixation, thus removing the need for expensive nitrogen fertilizer. However, since these genes are found naturally only in bacteria, it is not yet certain that they will function or will remain sufficiently stable within a plant.

Technical problems have been encountered both in achieving strong expression of inserted genes even in bacteria, and in preventing destruction of the resulting proteins before they are harvested. Since genes can also be cloned in cultured mammalian cells and in yeast cells (which are more similar to mammalian cells than are bacteria), future production of mammalian proteins may well be shifted to these organisms. Moreover, though the knowledge of molecular genetics of higher plants is so far not well developed, it is conceivable that cloning into these organisms will eventually prove economical; some optimists suggest that a single field of corn could meet the world's need for insulin.

Some scientists hope that eventually it may be possible to preserve the DNA of rare species that are threatened with extinction. It has been suggested that inserting preserved DNA into the egg of an existing closely related species could allow us to reconstitute an extinct species, or that related DNA might be modified for that purpose. These applications are speculative at present, but not beyond the realm of possibility.

One constitutional issue, that of patenting of engineered organisms, has been addressed

by the Supreme Court, which allowed the patenting of a genetically altered bacterium.[9] The Patent Office, citing the Supreme Court decision, extended patent protection to other bioengineered plants and animals. In April 1988, Harvard University was granted a patent on a genetically altered mouse, the first patent to be issued for higher life forms.

Soon thereafter at a meeting sponsored by several national church groups, a panel of ethicists and theologians called this "a matter of deep philosophical and spiritual concern" because it portrays animals 'as human creations . . . rather than as God's creation or subject of nature. . . .'" O The patenting of animals, and of human cells and tissues, raises issues that are now being debated in Congress. Two bills before the 100th Congress as it nears adjournment call for a moratorium on granting animal patents. Court cases challenging the government's decision to allow experimental release of engineered organisms for field trials also have some implicit constitutional implications and will be discussed in chapter 4.

The Biology of People

The new biology is having a profound effect on the sciences and practice of human genetics, medicine, and public health. As it does, many complex public policy issues are being raised, and many of them have constitutional aspects and implications that will be explored in later chapters.

While genetic counseling has been done for along time, it was practiced mainly on the basis of knowledge of the health and life experience of parents and grandparents and statistical analysis of health records of the offspring of people with similar heredity. Several radically new techniques are now being developed: genetic screening for hereditary diseases associated with known genetic defects, prenatal diagnosis of disease or defects through testing of fetal tissue or cells, and human cell therapy. These will be discussed in chapter 4.

Diagnostic Tools and Vaccines

Molecular and cell biology have revolutionized both basic and applied immunology. Monoclinal antibodies and fluorescent dyes or tags have provided particularly valuable tools. Growing knowledge of the complex immune response will surely make it possible to enhance protective responses and to prevent damaging allergic responses. Autoimmunity, the abnormal formation of antibodies or immune cells that attack normal body constituents, is recognized as a factor in some chronic diseases and is strongly suspected in others; these include pernicious anemia, juvenile diabetes, multiple sclerosis, arthritis, and ulcerative colitis. Antibodies and other visible agents are widely used with microscopy to reveal the distribution of cell components. Their chemical coupling to powerful toxins or drugs promises to provide a means of targeting these agents to specific cells.

Advances in immunology have also made possible simple and sensitive diagnostic tests for infectious agents, which are also much faster than cultures and other traditional methods. One example is differentiation between streptococcal throat infection (which requires antibiotic treatment) and viral infection (for which there is no specific treatment). Simple home tests have been developed for many diseases.

Vaccines, which stimulate protective antibody formation, were formerly prepared by modification of either viruses, intact bacterial cells, or toxins. With better understanding of the immune response and improved methods for purifying or synthesizing macromolecules, it is possible to use specific components of the pathogenic organisms, or synthesized protein sequences, to make much more effective and non-toxic vaccines. This should be particularly effective against viruses, which offer fewer

[9] *Diamond v. Chakrabarty*, *477* U.S. 303 (1980).

'('United States Patent No. 4,736,866, Apr. 13, 1988. The meeting of ethicists and theologians was sponsored by the National Council of Churches, the Humane Society, the Presbyterian Church, the New Creation Institute, "and other groups, " as described by David E. Anderson, ''Halt Urged on Patents of Engineered Animals, " *The Washington Post*, Apr. 30, 1988, p. B8. Quotations are taken from that article.

unique features for selective attack than do bacteria.

The methods of molecular biology are also being applied to studies of protozoal parasites. Some experts believe that prospects are bright for vaccines for parasitic diseases, such as malaria or trypanosomiasis, that are major causes of death in the Third World. Others are less optimistic, although tending to agree that such vaccines will ultimately be developed. The problem is that some microbes—including some viruses and bacteria as well as protozoa –have a capability of making reversible genetic changes that permit them to replace a surface antigen with various alternative antigens that cannot be neutralized by the same antibodies.

Targeting Cancer

Animal cells, unlike bacteria, undergo differentiation and organ formation, and these processes involve intricate interactions with neighboring cells. Accordingly, the regulation of cell growth has been much more difficult to study in animals than in bacteria. It is the regulation of cell growth that is disrupted in cancer.

Recombinant DNA methodology has already dispelled some of the mystery of cancer, by tracing the origin of some cancers to alterations in the amount or structure of various genes called oncogenes. These gene changes explain why viral infection, radiation, or mutagenic chemicals as well as spontaneous mutations might all cause cancer. Moreover, researchers are exploring the effects of these genes on regulatory mechanisms and on the cell surface.

Molecular genetics has led to drugs that interfere with DNA replication and thus in a limited way with cell growth, and potentially with cancer. Growing understanding of the biochemistry and immunology of cancer offers promise of greater future advances in prevention or cure and unlike many other advances in medicine, they may decrease rather than increase the costs of controlling cancer.

Human Body and Brain Enhancement

Gene therapy is aimed at curing well-defined hereditary diseases. But bioengineering might also theoretically be aimed at enhancing desired traits or creating new traits or new physical or mental capabilities. This possibility has often been raised in speculation and in fiction, with some scenarios going as far as the creation of superior and inferior classes of people.

In fact, the technical possibilities for significant enhancement through genetic engineering appear limited. Genetic manipulation in humans is likely to be restricted for a long time at least to addition or replacement of a single gene, and there are only a few known single genes with significant effects generally agreed to be desirable. If one assumes that the traits society might be tempted to enhance would be intelligence (or more precisely, some aspect of intelligence), memory, strength, size, athletic ability or some other specialized talent, each involves a large and as yet undefined number of genes. Anyone attempting to manipulate such traits would be facing a formidable task.

For many years, however, neurobiologists have been studying conduction of electrical impulses along nerve fibers and the chemical transmission of impulses from one cell to many others. Specific functions in the brain have been identified and localized in specific regions. It has been known for some time that some hormones, distributed throughout the body, influence both physiology and behavior.[11]

Now science is identifying a variety of neuropeptides, hormones that are released within the brain and modulate functions such as blood pressure and digestion. It is increasingly likely that neuropeptides will prove to be involved in controlling mood or emotions, although none have yet been shown specifically to do so under physiological conditions. It is even possible that a biochemical explanation may be

[11]U.S. Congress, Office of Technology Assessment, *Impacts of Neuroscience—Background Paper, OTA-BP-BA-24* (Springfield, VA: National Technical Information Service, March 1984).

found for violent, aggressive, or antisocial behaviors. Such knowledge could be expected to lead to medications or treatment for a range of conditions, such as emotional disorders; it could also lead to less beneficial forms of behavior control or mind control. According to Dr. James L. McGaw, director of the Center for the Neurobiology of Learning and Memory at the University of California, Irvine, "The basic science of neuropeptides and neurotransmitters . . . is exploding at the present time. Dr. Herbert Weingartener, Chief of Cognitive Studies at the National Institute of Mental Health, added, "We're sitting on a revolution that rivals quantum physics in the 1920s."[12]

A second line of research is also leading to new theories and new knowledge about the genetic basis of mental and behavioral traits—the study of identical twins, including pairs that were separated at birth by adoption. A series of studies at the University of Michigan has been widely reported; this research entails both biological and social science research and may provide clues for further genetic research.

The molecular basis of memory is being worked out in simple animals. In higher animals analysis of the paths and mechanisms of communication between different regions within the brain is providing new insights into the ability of the brain to integrate information, much like a computer but with complex branching rather than more linear connections.[13] There could be ways to enhance the functioning of these pathways and possibly the storage of information; already clinical tests of such chemical aids are underway.

Individuals appear to differ widely in the speed of the search-and-find processes in their brains that produce complex responses to an input of information. The molecular genetics of development suggests that one source of differences in this aspect of "general intelligence"[14] might be differences among individuals in certain proteins of their synapses; whether these proteins can ever be 'enhanced" is highly controversial at present.

Advances in neurobiology will almost certainly have major impacts on the understanding and treatment of various mental illnesses. A better understanding of the role of biological factors and the role of social factors could eliminate unwarranted blame for mental illness that has been attributed to the family environment or to other aspects of society. Recent indications that genetic factors may play a decisive role in some kinds of manic-depressive illness have focused attention on biological factors in other mental illnesses.

The brain, with its hundred billion or more cells and a thousandfold greater number of connections, seems likely to provide a virtually endless challenge for molecular scientists. Many people, however, may find that their discoveries, or even their hypotheses and research, are unsettling and disturbing. They bring into question familiar assumptions about human nature, responsibility and freedom, and basic equality among people.

The Control of Aging

The branch of biology with the most recalcitrant gaps between empirical description and molecular analysis is developmental biology, or the study of how cells and organisms mature and age. Scientists still lack adequate knowledge of the mechanisms by which cells in a developing embryo differentiate, move, and relate to neighboring cells in an orderly way to yield a coherent set of organs. They do understand or are beginning to understand some of the key features: how genes are selec-

[12]Both are quoted in Michael Schrage, "Soon Drugs May Make Us Smarter, " *Washington Post,* Feb. 3, 1985, p. Cl.

[13]For a good journalistic account of this line of research, see George Johnson, "Memory: Learning How It Works, New *York Times Magazine,* Aug. 9, 1987, pp. 16-34ff.

[14]The definition and the use of the term "intelligence' is frought with difficulties, both technical/scientific and political. It is probably best, from both standpoints, to think of multiple kinds of "intelligences' or mental capabilities, with people *differ*ing in performance across the range both individually, as compared with other individuals, and among and between groups or populations. Quite distinct from questions of definition or measurement of intelligence or intelligences, is the mystery of various forms of dyslexia, or defects in specific aspects of handling language.

tively turned on or off, how concentration gradients of chemicals released by cells influence neighboring cells, and how cells find and adhere to each other. They are still far from understanding in detail how nerve fibers extending from specific cells in the brain connect with other specific cells in other brain regions. It is generally anticipated, however, that advances along these lines will now proceed rapidly and the results will be translated into major medical advances in the years ahead.

Despite the progress in cell biology, the basic mechanism of aging in higher organisms is not understood—even in terms of whether the key changes occur in genes, intracellular structures, membranes, blood vessels, the immune system, or all of these. The general increase in life span is a product of improvements in prevention and treatment of infectious and other diseases, as well as in nutrition and sanitation, rather than a product of specific interference with the aging process. If life were sufficiently prolonged, or aging and natural death sufficiently delayed, then the birth rate might need to be lowered to avoid problems of overpopulation. A lowering of the birth rate might come about either by a general consensus of individuals, by public policy intervention, or by some natural adaptation. Such interference does not seem to be in sight now, but if it comes about it could radically alter the normal process of generations with major social consequences.

Chapter 4

Human Genetics and the Constitution

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Chapter 4

Human Genetics and the Constitution

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.

Chapter 5

Public Health Techniques and Technologies

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Chapter 5
Public Health Techniques and Technologies

The public health is a significant part of "the general Welfare, " which the Constitution was intended to better secure. Enormous strides have been made in the medical sciences in the last two decades, in large part as a result of development of the "new biology." Medical capabilities increasingly present us, as individuals and as a society, with options far beyond our traditional understanding of rights and duties, choice and necessity, consent and obligation. This chapter deals with the use of medical science and associated technologies in government programs to protect the health of Americans. The next chapter discusses some specific medical interventions as they apply to individuals.

In public health, it is not so much new technologies and techniques that promise to raise future constitutional issues, but rather the use of old (and historically accepted) techniques and technologies that appear newly controversial in the context of modern expectations of privacy and civil liberties and modem attitudes about risk and exposure. Another factor is new scientific capability to identify risks and exposure pertaining to people who are not yet ill, or pertaining to licit behaviors such as smoking or overeating.

In some areas public expectations outstrip the ability to solve urgent problems. A high expectation of good health and an unrealistic optimism about medical capabilities may contribute to the growing problem of liability or malpractice suits against physicians and hospitals. Not all medical interventions are successful. All of the effort thrown into the study of cancer, with enormously promising results, cannot yet assure anyone that he or she will be cured.

In public health, we are faced with a terrible epidemic at a time when people had become almost complacent about the ability of vaccines and antibiotics to deal with infectious disease. The capability to identify risks, predict the spread of disease, screen for exposure, and test for infectiousness is much greater than in historical epidemics; yet in the case of AIDS we cannot cure the disease, nor prevent it once exposure has occurred. The social frustration that this incurs may challenge us to define the limits of individual rights and the scope of our mutual obligations to society.

In dealing with such health provisions as mandatory vaccination, quarantine, housing inspections, school health, and mandatory seat belts, one is nearly always operating under State laws, based on State police power. Police power is the inherent power of governments to exercise within their jurisdictions reasonable control over persons and property in the interest of the general security, health, safety, morals, and welfare.

In public health, the Federal Government has only necessary and implied powers derived from its powers to tax and spend for the general welfare, to regulate interstate commerce, and to provide for the national defense. The States retain primary responsibility for public health policies and programs through their inherent police power. But both State and Federal Government are subject to the Bill of Rights limitations on governmental power.

AMERICAN PUBLIC HEALTH LAW, 1787-1887[1]

In the colonial period, epidemics could devastate a community. Smallpox and yellow fever sometimes sickened from 30 to 50 percent of a town's population within a short time, and might kill 10 percent. Even measles could be a major disaster; Cotton Mather in 1713 lost his wife, three of his children, and a servant to measles. The effects of such infection on the Indians, who had no resistance from past exposure, were often even more cataclysmic.

Public health programs in the 17th and 18th centuries consisted of emergency measures to meet these crises. When epidemics threatened, towns often declared quarantines, posting guards at the docks and on roads leading into town. Sick people were cared for in their homes or the pest house. Town funds were provided for medical care and to feed and shelter orphans or the children of sick parents. No one questioned the right of the authorities to take whatever measures were necessary.

After the Civil War there was somewhat more disposition to question the scope and limits of police power. In 1894, the terms of States' public health authority were laid out one by one in a Supreme Court decision:[2]

- The police power is very broad, and the State legislature has wide discretion to determine when and how it is used.
- Public interests must require such interference by the State; there must be a serious threat.
- The means used by the State must be "reasonably necessary" and not "unduly oppressive."
- The State must not impose "unusual and unnecessary" or "arbitrary" restrictions on persons or occupations.
- The courts will examine or supervise the legislature's exercise of police power to ensure that these conditions are met.

Until well into the twentieth century judicial decisions about public health law and practices seldom emphasized individual rights as such. They turned on questions of how the State exercised its authority, whether or not the Court perceived that the State was dealing with a serious problem, how great an intrusion the State action would be, and how strictly the authorizing statute was read. Courts generally permitted public health authorities great leeway in infringing on the freedom of an individual.

[1] Dr John Duffy, Professor Emeritus of Medical History, University of Maryland, assisted in the preparation of this section of the chapter.

[2] *Lawton v. Steele*, 152 u.S. 133, 136-7 (1893).

THE POLICE POWER IN THE TWENTIETH CENTURY

Due Process and Police Power

The tension between the State's police power and the constitutional right to due process is central to discussions of modern public health practice. One of the most cited Supreme Court cases on public health and police power is a 1905 case, *Jacobson v. Massachusetts.*[3] It involved the constitutionality of a State statute that provided a fine of $5 for any adult refusing to be vaccinated when a city board of health had decided vaccination was "necessary for the public health." The Cambridge board of health did so when a smallpox epidemic threatened in 1902. Jacobson, refusing to be vaccinated on the grounds that it was dangerous and ineffective, was tried and fined $5. He appealed first to the Massachusetts Supreme Judicial Court and then to the U.S. Supreme Court, arguing that the vaccination law violated his Fourteenth Amendment rights to due process and equal protection of laws (the latter because

[3] 197 Us. 11.

under the law physicians could declare some children "unfit subjects for vaccination").

The Supreme Court confirmed that the State legislature can enact "reasonable regulations" to protect public health and safety, and may vest this authority in local bodies like boards of health. The Court said that constitutional rights must be preserved, but it found that the Fourteenth Amendment right to "liberty" does not mean absolute freedom, and the State may restrain personal and property rights in order to secure the "general comfort, health, and prosperity of the State. " Under the "principle of self-defense, of paramount necessity, a community has the right to protect itself against an epidemic of disease. " Further, the Supreme Court would be "usurping the functions of another branch of government" if it judged the method chosen by the legislature to be unreasonable, arbitrary, or unnecessary. Vaccination was a well recognized, generally accepted means of preventing smallpox; the legislature accepted it as such, and the courts had no superior knowledge. Judicial review of a general welfare enactment, according to the Court, should be very narrow, and such a statute would be invalid only when it is ". . . beyond all question, a plain, palpable invasion of rights secured by the fundamental law. . . ."

This case is a starting point for the discussion of future cases of constitutional limitations on police power because it confirms that the legislature need not be "right" in its public health decisions; its acts need only have some "real or substantial relation" to the preservation of the public's health-not the "best" way but a "reasonable" way. Courts are not to be the arbiters of scientific disputes.

Underlying the Court opinion was the concept of a social contract between individual and community and between State and Federal Governments. The Court said:

> We are unwilling to hold it to be an element in the liberty secured by the Constitution . . . that one person . . . residing in any community and enjoying the benefits of local government, should have the power thus to dominate the majority when supported in their action by the authority of the State.

And it also said:

> The safety and health of the people of Massachusetts are, in the first instance, for that Commonwealth to guard and protect. They are matters that do not ordinarily concern the Federal government.

Jacobson dealt with a real, identifiable, and familiar public health problem. But in the same 1905 term, the Supreme Court dealt with the constitutionality of a State statute concerned with occupational health and safety, in the case of *Lochner v. New York*.[4] The statute prohibited bakery and confectionery employees from working more than 60 hours in 1 week. The Court framed the issue in this way:

> Is this a fair, reasonable, and appropriate exercise of the police power of the State, or is it an unreasonable, unnecessary, and arbitrary interference with the right of the individual to his personal liberty or to enter into those contracts in relation to labor which may seem to him appropriate or necessary for the support of himself and his family?

This decision came less than 2 months after *deciding Jacobson*. The Court again recognized that it may not merely substitute its judgment for that of the legislature and strike down a law. Nevertheless the Court did not view limitation of the work day as a health or welfare issue, but as State regulation of economic relationships between two competent adults. It denied that this law was within the police power of the State, because bakers are no less able "to assert their rights and to care for themselves than members of other occupations. . . ." The "welfare, safety, and morals of the general public (were) not protected by the law" since there was no evidence that clean and wholesome bread is related to the number of hours the baker works.[5] This case was contrasted by the Court with an earlier one upholding a law limiting the working day of underground miners and shelterers, because

[4] 198 U.S. 45 (1905).

[5] The New York court in upholding the statute had concluded that there was sufficient evidence to demonstrate that the occupation of baker or confectioner was unhealthy and tended to result in diseases of the respiratory organs.

working underground was "clearly unhealthy."[6]

These two cases, within a few months of each other, demonstrate the significance of the standards which courts use in evaluating the legislature's exercise of the police power. Had the Court actually applied the Jacobson standard of minimal rationality and the presumption of constitutionality, Lochner would have been decided differently. But the vaccination law was indisputably a health law, aimed at reducing contagious disease; while in the *Lochner* case the law was not perceived as enforcing a well-recognized medical procedure. *Lochner* signaled the beginning of an era in which the Court struck down as economic regulations many statutes framed around public health goals.[7]

Ultimately, however, the Jacobson standard prevailed. In 1934 the Supreme Court returned to the more restrictive standard of judicial review, saying that the Due Process Clause only requires that "the law not be unreasonable, arbitrary, or capricious and that the means selected shall have a real and substantial relation to the object sought to be attained."[8]

A modern court in a police power case still will not generally evaluate arguments as to the scientific soundness of the exercise of police power. For example, the Court ruled in 1955 on the constitutionality of State laws regulating the fitting and sale of eyeglasses.[9] Opticians were prohibited from placing an old lens in a new frame or from reproducing a broken lens without a prescription. A trial court struck down this law, holding that the requirements were not 'reasonably and rationally related to the health and welfare of the people. " But the Supreme Court reversed, on the grounds that the legislature might have concluded that eye examinations were so important "for the detection of latent ailments" as to justify their requirement on all possible occasions. Said the Court:

> The day is gone when this Court uses the Due Process Clause of the Fourteenth Amendment to strike down State laws, regulatory of business and industrial conditions, because they may be unwise, improvident, or out of harmony with a particular school of thought.

In summary, the courts will generally be inclined to accept as constitutional public health actions that appear to be reasonably related to preservation of the health of the population without attempting to determine independently the scientific validity and efficacy of the measures taken. Nevertheless, this remains an area where the scope of individual rights and presumed limitations on state power appear to be constantly subject to challenge.

Privacy and State Police Power

The evolution of the concept of privacy as a constitutional right was traced in the first chapter. The case of *Buck v. Bell*, the 1926 case upholding the right of the State to sterilize inmates of State mental institutions, was described in chapter 3 and illustrates both the deference to State interests and the lack of acknowledgment for privacy rights that were the rule until recent decades. Fifteen years after that case, the Court struck down a State statute providing for compulsory sterilization of

[6] *Holden v. Hardy*, 169 U.S. 366 (1898); the Court found 'hat *given* the dangers of working underground, the deprivation of fresh air and sunlight, and being frequently subjected to foul air, the law was a proper exercise of police power, designed to protect the health of miners. It also recognized that the State could reasonably conclude that workers needed protection because the owners and workers do not have equal bargaining power.

[7] In *Adkins v. Children's Hospital*, 261 U.S. 525 (1923), 'he Court struck down a law which established a minimum wage for women and children, the explicit purpose of which was to protect them from "conditions detrimental to their health and morals, resulting from wages which are inadequate to maintain decent standards of living. " The Court claimed the law was arbitrary, that the "relationship between earning and morals is not capable of standardization, ' and that the law did not take into account the fact that different people need different amounts of money to maintain a minimum acceptable standard of living.

[8] *Nebbia v. New York*, 291 U.S. 505 (1934). The Court upheld a New York statute establishing a board to determine the maximum and minimum prices retailers could charge for milk. Three years later the Court upheld a minimum wage law for women. The judicial policy of examining the substance of the law under the umbrella of the Constitution's Due Process Clause, and "second guessing" the legislature as to its efficacy, is called "substantive due process. " It is to be distinguished from "procedural due process," in which the Court asks whether a law affects people in an arbitrary, discriminatory, or irrational manner. In recent years, the Court has returned to the doctrine of substantive due process in emphasizing fundamental individual rights.

[9] *Williamson v. Lee Optical* (70., 348 U.S. 483 (1955).

"habitual criminals, " using the Equal Protection Clause of the Fourteenth Amendment, but also affirming that marriage and procreation were fundamental rights.[10]

The right of privacy has repeatedly been used by the Courts since 1965 to protect the individual's right to make decisions about marital, reproductive, and family matters. State supreme courts have extended this right to cover individuals refusing life-sustaining medical care,[11] refusal to take anti-psychotic medication,[12] and obtaining acupuncture treatments." But the Supreme Court specifically refused to extend this right to cover consensual sodomy .14 It is thus uncertain how this right might be applied in future issues related to public health techniques and technologies.

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

[11] *In re Karen Quinlan, 355* A.2d 647 (N. J., 1976); *Superintendent of Belchertown v. Saikewicz, 373* Mass/ 728 (1977).

[12] *Rogers v. Okin,* 821 F.2d 22 (Neb., 1987).

[13] *Andrews v. Ballard,* 498 F. Supp. (S.D. Texas, 1980).

[14] *Bowers v. Hardwick,* 106 S.Ct. 2841 (1986). Although the challenge was brought by a homosexual male, the challenged statute was written to apply to heterosexual or homosexual behavior, by married or single persons.

MODERN PUBLIC HEALTH TECHNIQUES AND TECHNOLOGIES

In the extended discussion that follows, frequent reference will be made to the current epidemic of acquired immunodeficiency syndrome (AIDS). Many of the traditional public health techniques are being used in this epidemic, but in a social, political, and legal framework that has radically changed in recent decades. New scientific knowledge and capabilities are also providing new approaches—although not as many or as rapidly as society had hoped—and these by definition may raise new constitutional issues.

AIDS is not like most of the severe epidemics associated with the origins of public health programs in the United States. It appeared suddenly, but it is not episodic as were yellow fever, Asiatic cholera, or influenza. It can have a very long incubation, it has a very low infectivity, and it cannot spread by casual contact. There do not appear to be any factors calling for engineering or environmental remedies, which have been major factors in control of past epidemics.

Yet AIDS does represent the working of some traditional Public Health techniques and technologies that need to be examined further for their constitutional implications; and more pertinently, AIDS also demonstrates the public health applications of some new developments in biology.

The problems raised by the AIDS epidemic are not intrinsically new. Larger numbers of people die every year from other single causes, including the effects of smoking.[15] But the problems raised by AIDS are so severe and acute as to revive old and neglected issues of public health and civil liberties, to emphasize structural problems in the capability to respond to civil emergencies, and to stress weak points in our social fabric. The problems throw into sharp relief the potential conflict between constitutional principles of individual rights and protection of the general welfare. The resolution of AIDS problems, if done humanely and with full attention to both fundamental freedoms and the protection of the general welfare, may stand us in good stead in the future in other contexts.

Prevention: Inoculation and Vaccination

The major medical innovation during the colonial period was smallpox inoculation, introduced in Boston in 1721, but already an old practice. 16 In the colonies it was denounced

[15] Smoking was officially blamed for 350,000 deaths in 1985, 100 times the number of AIDS deaths in the same year, as pointed out by William Pollin, "Drug Abuse, U. S. A., " *Issues in Science and Technology,* Winter 1987, p. 24.

'Gin inoculation, matter from pustules in an active smallpox case was inserted under the skin of a healthy person who thereby,

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by some physicians as too dangerous, and by many ministers as an attempt to evade God's punishment for immorality. But because of its obvious value, inoculation was an accepted practice by the time of the Revolution.

The success of inoculation in reducing the toll from smallpox prepared the way for vaccination, introduced by Jenner in 1798.[17] Vaccination won immediate acceptance, and the incidence of smallpox fell sharply during the next 30 years. By the 1830s, a generation that had never known a smallpox epidemic saw little reason to be vaccinated, and there was a steady rise in smallpox until about the 1870s. After the Civil War, health officials began urging compulsory vaccination of school children and mass vaccination of adults during outbreaks. In spite of a strong anti-vaccination movement, joined by a few doctors alarmed by infections arising from vaccination withinfected needles, the movement succeeded in most States.[18]

When there is strong public awareness of the possibility of epidemics, most people can compare the risk of taking the vaccine against the clear and present risk of the disease, and can thus appreciate the value of vaccination. As immunization programs succeed and the acute disease threat disappears, the benefit to the individual is less well perceived. The benefit accrues to the community at large. Any risks or undesirable side-effects of a vaccine which become known are therefore apt to stimulate resistance.

Of all infectious human diseases for which a vaccine has been developed, only smallpox has been eradicated; the rest are merely held at bay. In Britain and in Japan, whooping cough reemerged as an epidemic disease when the use of pertussis vaccine diminished during the 1970s because of public alarm about rare side-effects.

Nevertheless, vaccination remains a primary tool of public health. Because it was one of the earliest tools for protecting public health, its use is well established in law and judicial precedents. At present, there is no vaccine against AIDS, although several are being tested. Should a vaccine be developed, there would almost certainly not be a mandatory program of vaccination for the general population, since the risk of AIDS is concentrated in certain age groups and even more narrowly in specific behavior-defined populations.

Mandatory vaccination laws for more general infectious diseases would however almost certainly be sustained. The presumption on the part of the courts would continue to be that vaccine programs are a "reasonable" public health strategy.

Although physicians have generally welcomed vaccines, local medical societies have often opposed free vaccination for lower income groups by public health departments, unless there is a life-threatening epidemic or the threat of one.[19] A possible constitutional issue is the assertion of the right to a vaccine when one is available for a disease perceived as highly threatening. But as discussed in the following chapter, courts have so far consistently maintained that there is no constitutional right to medical treatment and government has no constitutional obligation to make it available.

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usually, acquired immunity. The immunity came from antibodies produced in response to this small scale invasion of disease organisms, but the response was not understood at the time.

[17] Vaccination is the use of dead or attenuated viruses from cows inoculated with cowpox to produce immunity to smallpox in humans.

[18] Such waves of popular opposition have been associated with other public health innovations, such as fluoridation of water supplies; they are sometimes attacked as hazardous or even as plots by internal or external enemies to poison the citzenry.

[19] Despite the great attention to vaccines as a result of AIDS, the U.S. capability to develop vaccines for new or newly epidemic diseases is in general weak. Almost all vaccines have a sole manufacturer or a very few possible manufacturers. There is no governmental capability for vaccine production. Vaccines are relatively unprofitable and product liability is a strong disincentive to potential developers. The United States is the only country in the industrialized world where vaccine manufacture is unprotected from litigation regardless of compliance with manufacturing regulations, according to Dr. June Osborn, Dean of the School of Public Health, University of Michigan.

Reporting Morbidity Data

The first necessity in controlling epidemics is to recognize them early. Thus it is mandatory for physicians to report certain infectious diseases. Historically, there has been little connection between the diseases which cause the greatest morbidity and mortality and those which arouse the greatest public fear or attention. The two diseases that most worried the public in the 19th century were yellow fever and Asiatic cholera—deadly, erratic and unfamiliar. To Americans these epidemics seemed to be malignant forces that struck mysteriously and vanished almost as strangely. Such diseases always awaken more public fear and stronger public actions than diseases that may exact a far higher toll but do so consistently rather than episodically, and hence become familiar conditions of life. The disorders that were steadily and consistently responsible for the most sickness were malaria and respiratory infections. They were regarded as inevitable, much as we tend to regard high death rates from automobile accidents.

The chief killer disease of the 19th century was tuberculosis. Yet in the early 19th century it was regarded as a romantic disease, as pictured in *La Boheme* or Camille. Later in the century it was considered a natural disorder about which little could be done. Most insurance policies did not insure against death from tuberculosis; hence the family received no burial money and the doctor might not get paid. Therefore tuberculosis deaths were often recorded under other headings. When health departments at the end of the century began ordering physicians to report cases of tuberculosis, the medical profession rose up in arms. The New York City Health Department, making tuberculosis a reportable disease in 1897, found itself opposed by the New York Academy of Medicine, the County Medical Society, and most medical journals. The medical societies went to the State legislature in an attempt to limit the powers of the board of health.

Venereal disease has always been underreported by physicians. In 1882 the American Public Health Association rejected a resolution to make venereal disease reportable on the grounds that it would bring disapprobation on the association. In 1892 the New York Academy of Medicine dismissed a similar resolution on the same grounds. A New Orleans physician writing in a medical journal in 1920 called proposals to require reporting of venereal disease "socialist tommy-rot" that would "undermine the morals of the American people. "

Since then, a wide array of mandatory reporting statutes, such as for venereal disease, have been considered necessary and permissible. Laws requiring mandatory reporting by physicians or health care facilities of the names and other information about people who have been infected receive great impetus from advances in the ability to acquire, store, and disseminate such information using computers.[20] In this decade, however, mandatory reporting laws have again become highly controversial in regard to abortion, drug use, and AIDS.

The Supreme Court has addressed the issue of mandated release of medical information to the State by the physician on several recent occasions. One example concerns New York State's Controlled Substances Act of 1972, which requires reporting by physicians of prescriptions for certain drugs." Public disclosure of the identity of the patients is prohibited and punishable by one year imprisonment and a $2000 fine. In spite of this, the Federal District Court found the law to be unconstitutional, as intruding too broadly into the doctor-patient relationship, part of the "zone of privacy" accorded constitutional protection. But the Supreme Court reversed, finding the requirement was a reasonable exercise of police powers, and that there was no violation of privacy interests.[22]

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[20] Material in this section is drawn largely from "Constitutional Implications of Scientific and Technological Advances in Public Health, " prepared for OTA by Dr. Leonard H. Glantz, Professor of Health Law, Boston University Schools of Medicine and Public Health.

[21] Information about the physician, the drug and dosage, and the name, address, and age of the patient is sent to the computer of the State Department of Public Health. Only 17 departmental employees have access to the information.

[22] *Whalen v. Roe*, 429 U.S. 595 (1977).

It had been argued without avail that the constitutional right of privacy encompasses two distinct interests; the individual interest in avoiding disclosure of personal information, and the freedom to make certain kinds of important decisions without State interference; and that both interests were violated by the law. Knowing that the State would receive this information would make doctors reluctant to prescribe, and patients reluctant to use, certain medication.

Justice Brennan, in his concurring opinion, specifically recognized that new technology may require the Court to address this issue again:

> The central storage and easy accessibility of computerized data vastly increase the potential for abuse of that information, and I am not prepared to say that future developments will not demonstrate the necessity of some curb on such technology.

Another case in 1976 involved the reporting requirement of a State abortion law,

> . . . the purpose of which shall be the preservation of maternal health and life by adding to the sum of medical knowledge through the compilation of relevant maternal health and life data. .. .23

The statute stated that the information must be confidential, must be used only for statistical purposes, but must be available for inspection by local, State, or national health officers. The Court also upheld the constitutionality of this provision, finding that it is useful in protecting the health of female citizens, and may be a resource for future medical decisions. Given these realistic goals, the guarantee of confidentiality, and the fact that the reporting has no legally significant impact on the abortion decision or on the physician-patient relationship, the Court found no constitutional violation, but it did suggest that the law approaches "impermissible limits." This decision was especially significant because of the close scrutiny that the Court gives all legislation regulating abortion.

[23] *Planned Parenthood of Missouri v. Dan forth, 428* U.S. 52, *70 (1976).*

Ten years later the Supreme Court invalidated a Pennsylvania abortion reporting requirement which called for very detailed reporting,[24] available for public inspection and copying (in a form that would not bear the identification of the person filing the report). The Court struck this down on the grounds that: 1) many of the details were unrelated to health interests, 2) the records could be inspected by anyone, which indicated to the Court that the legislature had some purpose in mind other than protecting the public's health; 3) even though the woman's name was not listed there were enough data that identification became "likely," and may have been the "obvious purpose of these extreme reporting requirements." The Court said that the law would have a chilling effect on the exercise of a constitutional right.

Given the fact that public disclosure about having AIDS or being an AIDS carrier could have a devastating effect on an individual, it is reasonable to surmise that the Court may give as much scrutiny to State AIDS reporting requirements, if challenged, as to an abortion reporting requirement. The State would have the burden of proving the public health need and showing adequate privacy safeguards. In such circumstances the interests of the State in learning the extent and distribution of the disease would have to be balanced against the individual's concern for privacy. However, the balance could be struck differently in the case of AIDS than in the abortion example, because of the risk to the population at large.

Screening and Testing Techniques[25]

Mandatory testing or screening of large populations or specific categories of people has

[24] *Thornburgh v. American College of Obstetricians 106 S.* Ct. 2169 (1986). Reporting requirements included the identification of the referring and primary physicians and the name of the facility or agency; the woman's political subdivision, age, residence, race, marital status, number of previous pregnancies; the basis for determination that the fetus was not viable; the method of payment; and other information. The report was to be signed by the attending physician.

[25] Material in this section was prepared for OTA by: Dr. Sheila Jasanoff, Cornell University Program in Science, Technology, and Society; Dr. June Osborn, Dean of the School of

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been done or has been considered for purposes of detecting hereditary disease (primarily in the case of newborn infants, where early treatment is effective), for control of infectious disease, and for detecting drug abuse.

The constitutionality of data collection will depend on a variety of factors, including the purpose for which information is obtained. Thus questions of obtaining information cannot be wholly separated from questions of use, which might be, for example, to document the spread of the disease. Courts have not been reluctant to sustain a requirement that public school students undergo an annual physical examination[26] or that couples seeking marriage licenses submit to tests for venereal disease.[27] Nevertheless, some features of the testing process, whether for hereditary disease, infectious disease, or law enforcement, may raise constitutional problems regardless of the uses to which the State puts the information being collected.

Screening for Hereditary Disease

Mass screening has been undertaken in this country in the past primarily for the purpose of identifying individuals at special risk of producing genetically damaged offspring. Such programs were initiated during the 1970s for Tay-Sachs disease and sickle cell anemia. Both programs focused on ethnic minorities with which those diseases are uniquely associated. The former aroused less concern because it was carried out largely without legislative requirements.[28] By contrast, laws mandating screening for sickle cell disease (associated with people of African descent) were passed in many States in the early 1970s. In 1972 Congress enacted the National Sickle Cell Anemia Control Act, which allocated $115 million over 3 years for a program of screening, counseling and education.[29]

Following initial support from the Black community, these sickle cell initiatives later came under fire. Black leaders questioned the propriety of the legislative focus on sickle cell anemia when there are so many other important causes of illness among Blacks.[30] Some critics said that sickle cell screening increased the potential for stigmatizing a particular minority group and could reinforce latent feelings of racism. A few saw the overt tie-in between screening and marriage-licensing laws in several States as particularly sinister. In the words of one Black activist, such a connection represented "the entering wedge for governmental involvement in genetic criteria for procreation. "[31]

Similar concerns are reported to have troubled some leaders of the gay community in the early days of the AIDS epidemic; fearing that association of gays with an epidemic disease would intensify discrimination against them, some leaders resisted early efforts at public education about the ways in which the disease was transmitted.[32] Such concerns suggest that whenever mandatory screening programs are limited to identifiable minorities, there may be perceptions of conflicts between the State's interest in public health and the constitutional goal of equal protection. If testing is limited to discrete subgroups, then the burden on the State to justify it should be especially high.

Mandatory screening for heritable traits or biological susceptibilities thus raises issues of due process, unreasonable search and seizure, and privacy. The legitimacy of such programs

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Public Health, University of Michigan; and Dr. Leonard Glantz, *Professor* of Health Law, Boston University Schools of Medicine and Public Health.

[26] *Streichv. Board of Education, 34* S.D. 169 (1914).

[27] *Peterson v. Widule, 157* Wis. 641 (1914).

[28] Madeleine J. Goodman and Lenn E. Goodman, "The Overselling of Genetic Anxiety, " *Hastings Center Report,* October 1982, pp. 20-21.

[29] Aubrey Milunsky and George J. Annas, *Genetics and the Law* (New York, NY: Plenum Press, 1976), p. 174.

[30] Lawrence E. Gary, "The Sickle Ceil Controversy, " in Adela S. Baer (cd.), *Heredity and Society,* 2nd ed. (New York, NY: Macmillan), pp. 363-364. Sickle cell anemia is almost exclusively found in those of Black African ancestry. About 10 to 13 percent of American Blacks carry the trait (which is recessive); about 3 percent have the disease,

[31] Ibid., p. 366.

[32] Randy Shilts, *And the Band Played On: Politics, People, and the AIDS Epidemic (New* York, NY: St. Martin's Press, 1987), pp. 52-103.

will turn to a large extent on the nature of the State's interest in acquiring information.

Mandatory Drug Testing

Drug testing programs have been adopted by numerous State and Federal agencies, and have given rise to a number of court cases. In regard to the constitutionality of various forms or programs of drug testing, very little is certain and challenges are likely to continue, at least until the Supreme Court decides two cases scheduled to come before it in the 1988-89 term. One of these cases involves Federal workers, and one involves railroad employees.

In the future, the "new biology" is likely to lead to development of many drugs that are related to, and closely resemble, naturally occurring bodily substances such as opiates in the brain. Some of these new drugs maybe subject to abuse; that is, may have socially undesirable effects. It maybe particularly hard to test for such drugs; and to distinguish them from the naturally occurring substances that people may have in widely varying quantities. Their detection might require tests that are even more intrusive than urine analysis, which many people find highly objectionable. Thus drug testing issues are unlikely to be resolved completely and for all time.

In considering the constitutional implications of drug testing it is necessary to distinguish carefully between what can be done by government with regard to the public or some categories of the public; what can be done by government with regard to its employees; and what can be done by non-government employers with regard to their employees.

In terms of government drug testing in the interest of general law enforcement—testing members of the general public to detect violations of the laws limiting use of controlled substances-the constitutional question is whether or when drug testing by government officials is "an unreasonable search and seizure, " under the Fourth Amendment. At least one judge has argued that one "cannot retain a privacy interest in a waste product . . . "[33] but the weight of authority runs counter to this. Courts have held that one does have an interest in avoiding the mandatory testing of urine or blood and also in the information contained in bodily fluids,[34] although that individual interest may be inferior to a State interest. One court has said,

> Drug testing is a form of surveillance, albeit a technological one. Nonetheless, it reports on a person's activities just as surely as if someone had been present and watching. It is George Orwell's "Big Brother" society come to life.[35]

But the Constitution has been found in general not to prohibit such bodily intrusions as compelled vaccination, blood tests or urinalysis where the government provides sufficient justification and evidence of procedural regularity. For example, in *Schmerber v. California* in 1966,[36] the Supreme Court upheld the performance in a hospital of a blood test for alcohol content performed on an automobile crash victim, without a warrant. It has long been established that a State interest in health and safety may justify testing programs that intrude to some degree on individual liberty and privacy. The use of roadblocks and alcohol tests to deter drunk driving has been ruled constitutional.[37] Courts have traditionally considered that here the gravity of the public interest outweighs the intrusion into personal liberty, particularly in view of the effectiveness of the testing program.

And in *Shoemaker v. Handle* (1986)[38] breathalyzer and urinalysis tests of race horse jockeys were deemed constitutional in view of the procedural safeguards built into the process and the fact that testing occurred in the context of a closely regulated industry.

The ordinary individual as citizen (rather than employee) enjoys a significantly higher expectation of privacy. Courts are certain to be cautious in assessing the legitimacy of gen-

[33] Judge Nebeker, concurring, *Turner v. Fraternal Order of Police, 500* A.2nd.1000 (D.C.App.1985).

[34] *McDonell* v. *Hunter*, 612 F. Supp. 1122 (D. Iowa 1985); *Capua v. City of Plainfield*, 1 IER Cases 625 (U.S. Dist. Ct., N.J. 1986).

[35] *Capua v. City of Plainfield*, at 626.

[36] 384 U.S. 757 (1966).

[37] *State v. Superior Court in and for County of Pima*, 691 P.2d 1073 (Ariz. 1984).

[38] 795 F,2d 1136 (3 Cir. 1986).

eralized screening programs. In order to overcome these barriers, the government would have to present an extremely strong showing of need.

When government *as employer* proposes to test its employees for drug use, it must still observe constitutional safeguards. Here one must distinguish between drug testing when there is probable cause for suspicion, completely random testing, and mass testing of all employees.

Recent cases have struck down the mass testing of both Federal and municipal employees for drug abuse on the ground that the circumstances did not justify dispensing with the Fourth Amendment's requirement that searches and seizures should be based on individualized suspicion. The most recent Federal precedent is a permanent injunction granted by a U.S. District Court judge in July 1988 to prevent random urine testing of employees of the U.S. Department of Justice. The judge said that be cause there was no evidence of a drug problem in the Department there was no justification for infringing on the constitutional rights of "trusted and apparently law-abiding employees. "3[9] In a case involving municipal workers, another court noted that the city's testing program for fire fighters was overly broad in that it would collect information that bore no relation to the government's interest in preventing illegal drug abuse.[40]

Courts have also stressed the need for appropriate procedures to protect the employees' legitimate expectation of privacy against such administrative searches. One court has even held that a public employee who at the time he is hired signs a consent to be tested cannot be held to that consent because "advance consent to future unreasonable searches is not a reasonable condition of employment. "[41]

On the other hand, there is much disagreement among courts on these points. In June 1988, the Third Circuit U.S. Court of Appeals upheld a program subjecting municipal police officers to random urinalysis done in the course of an annual physical examination, yet a month earlier the Sixth Circuit U.S. Court of Appeals struck down a program of compulsory drug testing of firefighters and police officers, saying the intrusion on their privacy was not justified.[42]

The courts have banned only "random" drug testing programs. The courts agree that if a public employer has "reasonable cause" or "reasonable suspicion" that a person's job performance *is* presently impaired by the use of drugs, a drug test maybe required. Thus when public employees were discovered smoking marijuana on the job, it was held that the employer could require testing.[43] Certain public employees such as police have been held to have a lesser expectation of privacy due to their "paramilitary nature"; and a search may be conducted without a warrant, or "probable cause" if there is some objective basis for the search.[44]

The U.S. Supreme Court has held that "facilitative searches" such as those conducted by fire marshals and building inspectors can be done without the need for "probable cause" or 'reasonable suspicion, if they comply with a reasonable administrative plan and are based on neutral criteria. Thus some experts believe that random drug testing will be upheld if governments use a plan that does not discriminate and if there is legislation authorizing such testing, with appropriate safeguards.[45]

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[39] Ruth Marcus, "Drug Tests Blocked for Justice Workers, " *Washington Post,* July 30, 1988, p. Al.

[40] *Capua* v. *City of Plainfield*, ITER Cases 625 (U.S. Dist. Ct., N. J., 1986).

[41] *McDonell* v. *Hunter,* 612 F. Supp. 1 122, (D. Iowa 1985).

[42] *Policeman's Benevolent Association of New Jersey v. Washington Township,* CA 3, No. 87-5793, June 21, 1988; *Lovvorn v. Chattanooga,* CA 6, No. 86-6281, May 23, 1988.

[43] *Allen v. City of Marietta, 601* F. Supp. 482 (M = N.D. GA. 1985).

[44] *Turner*, p. 10008. The Fourth Amendment and the Due Process Clause are flexibly applied. The strictness which which both are applied is related to the reasonable expectations of the person claiming protection and the nature of the interest at stake. Thus one court held that jockeys may be subjected to random drug testing because of the long history of testing in that occupation and because of the pervasive way the racing industry is regulated. *(Shoemaker v. Handel, 795* F.2nd 1136 (3rd Cir. 1986).

[45] See, for example, a letter to the Editor of the New *York Times,* June 18, 1987, from John F. Banzhaf, 3rd, Professor of Law and Legal Activism, The George Washington University.

Another issue was raised in a recent case before the U.S. Court of Appeals for the District of Columbia, involving the testing of school bus drivers and attendants as part of an annual required physical examination. The Court said that such tests were permissible, but also said that the test must detect current impairment, not merely past use, in order to justify occupational restriction.[46]

The use of illicit drugs in the workplace has prompted private sector employers to begin or to consider urine screening programs. They may be motivated by concern for safety in the workplace, safety in facilities and transportation systems used by the public, the productivity of workers, or the general health and welfare of workers. The question is often raised as to whether employers have a right to know or to restrict what is done in the employee's off-the-job time, so long as it has not been shown to affect their performance.

Debate about drug testing is complicated by the multiplicity of drugs at issue, the complication of cross-reacting innocent compounds that can trigger false-positive test results, the practical problem of ascertaining whose urine is being tested, and questions about the frequency of testing. The cost of testing is fairly high, especially if confirmatory testing is used, as it should be. How frequently testing should be done is another question that can be decided only arbitrarily.

Questions about scientific validity play a significant part in decisions concerning the permissibility of mass screening programs. The more accurate and reliable the test, and the lower the degree of unavoidable error, the more likely it is to pass judicial scrutiny. The false positive rates associated with some widely used drug screening tests, for example, are unacceptably high to many experts. For example, the radio-immunoassay screening of blood may yield a false positive rate of as much as 43 percent for cocaine, while the enzyme multiplied immunoassay technique of urinalysis may have a false positive rate as high as 10 percent." Because of the potential for stigmatization and legal misuse, such error rates are likely to make judges wary about declaring mass testing programs to be lawful.

Use of drugs is clearly a health hazard. Health professionals treat addicts as sick people, and the Supreme Court has held that drug addiction is a disease or "status" for which people cannot be punished, as opposed to an act or behavior (e.g., possessing or selling drugs) for which they could be punished.[48] Advocates of mandatory drug testing use public health language ("an epidemic of drug abuse"). They also cite the danger to others, for example, coworkers in factories or passengers on trains and airplanes, to justify strong public health measures. However, mandatory drug testing is aimed at detecting only illegal drugs, although the use of some legal drugs, such as tranquilizers, might also result in some impairment of performance. In fact, drug testing does not determine whether one is presently *impaired* but detects past use of a drug. Effects of the drug may not have overlapped the workday at all. Because of these factors, courts have looked closely at random drug testing—i.e., testing where there is no probable cause to suspect illegal behavior on the part of a given person—and for the most part have struck down such provisions.

People not trained in law often forget that the Constitution provides limitations on government only; that constitutional provisions do not protect them against actions by private citizens; and that only when Congress has passed laws embodying those constitutional principles do they have an effect in the private sector.

Thus it surprises some citizens to learn that public employees may, because the government is their employer, have some constitutional rights in the workplace that private company employees do not enjoy. Private sector employees must depend on State or Federal

[46] *Jones v. McKenzie, 85-01624, Nov. 17, 1987.*

[47] Morris J. Panner and Nicholas A. Christakis, "The Limits of Science in On-theJob Drug Screening," *Hastings Center Report,* December 1986, p. 8.

[48] *Robinson v. California,* 380 U.S. 660 (1962).

privacy statutes or individual contractual bargaining agreements with employers; they have no constitutional rights to their job or to privacy as a condition of employment.

Diagnostic Testing for Infectious Disease

Diagnostic testing to determine who has a disease is usually looked on as beneficial for the patient, who can then begin treatment, and for the community, since steps can be taken to reduce the transmission of a disease. The exception comes when there is no curative treatment to be given, when available control measures may infringe on the patient's freedom, and when the testing creates an information file that is viewed as a threat of further infringement or discriminatory actions in the future.

Within less than 3 years of the first reported description of the clinical disease AIDS in 1981, three laboratories had independently isolated and identified the virus, HIV, that is the causative agent of AIDS.[49] This gave immediate hope of developing a test to identify infected individuals. Laboratory work then established the usefulness of a particular cell line to grow the virus to high concentrations in tissue culture and allow it to be purified and concentrated. That in turn facilitated the production of the large quantities of virus needed to serve as diagnostic antigen,[50] suitable for recognition of human antibody responses to HIV.

All viruses contain a number of different proteins or antigens that can stimulate the immune response. Antibodies to HIV usually appear during the first 4 to 8 weeks after infection and nearly always within 3 months, and usually persist indefinitely. There are several variations of the screening test for HIV.

The development of diagnostic AIDS tests was accomplished within a few months by several U.S. firms. Most of the tests are variations of what is called an ELISA test. The initials stand for enzyme-linked immunosorbent assay. The virtue of the test lies in its easy readability, using techniques and equipment thoroughly familiar to blood banks and clinical laboratories. Other variations such as indirect immunofluorescence or radioimmuno-precipitation have been developed, but their principles are similar. All blood and plasma donations to U.S. blood banks have since 1985 been routinely screened for AIDS. Testing of individuals can be done by private physicians or in special or general clinics and laboratories. Protection of the confidentiality and integrity of this data, most of which is probably computerized, has raised many concerns.

Media coverage of the race to develop an antibody test was extensive. Nevertheless public confusion over the terms sensitivity and specificity led to a widespread false impression that the tests were not reliable. This residual public unease is confounded with very different problems of the uncertainty of clinical diagnosis and prognosis.[51]

Any biological phenomenon has "outliers"-i.e., variations extend across a broad range, with some unusual examples that are far from the mean or average. When a disease detection test is developed, it can be made highly *sensitive*, in order to pick up even the outliers

[49] Some critics maintain that this could have been accomplished as much as 2 years earlier had there been appropriate funding and attention when the existence of the epidemic was first discovered. For a critical account of the process, see Randy Shilts, *And the Band Played On (New* York: St. Martin's Press, 1987). There was competition between research scientists to discover the infectious agent, and acrimonious dispute over the allocation of credit for the discovery. Three groups of scientists used their own terminology in naming the virus. This contributed to serious confusions in discussion even within the scientific community. The terminologic dispute created problems for persons concerned with the critical task of educating the public about the new virus and its risks. For that reason an international committee of virologist was assembled and proposed a uniform nomenclature. The virus was named *human immunodeficiency virus* or HIV. As new relatives of that virus are uncovered by further research, they are referred to as HIV-2, HIV-3, etc. J. Coffin, A. Haase, J.A. Levy, et al., "Human Immunodeficiency Viruses," *Science 232: 697, 1986.*

[50] An *antigen* is a protein or carbohydrate substance-a toxin, enzyme, or the jacket of a virus-that when introduced into the human body stimulates that body to produce *antibodies*, or substances whose function is to combine with the antigen and neutralize, agglutinate, or precipitate it, rendering it harmless. This is the primary means by which the body protects itself from disease.

[51] *Diagnosis* is identifyin, a disease from its signs or symptoms. *Prognosis* is predicting the course of the disease, the likelihood of recovery, or the duration of survival in a specific case.

or unusual cases, but then it will also pick up some false signals. If the goal is accuracy, or specificity-i.e., no false positives—then the outlier cases or signals must be ignored or allowed to escape. The majority of cases, falling near the mean, will be clearly recognized, but there will be some false negatives.

When the antibody test for HIV was developed, it was purposely designed to provide maximum protection of the blood bank supply, and therefore was made especially sensitive. Here, it was clearly best to err on the side of being too careful, at the cost of a substantial number of false positives. Unfortunately, some press reporters interpreted this as a sign of a poor test, when it fact it was a necessary accompaniment of appropriate caution.

The false positives made it necessary to have a confirmatory test, or supplemental procedure, to be sure that a positive reaction in the ELISA test was in fact an indication of infection with HIV. The first supplemental test was called the "Western Blot, " and identified antibodies to specific proteins of HIV, thus giving a detailed picture of the immune response reflected in the patient's blood serum. This has been replaced in some laboratories by other supplemental tests, but they operate on the same general principle. At present, the state of the art allows both sensitivity and specificity of greater than 99 percent for the ELISA test, which already compares favorably with any clinical laboratory test in medical use, and supplemental tests permit very reliable identification of infected individuals when done properly. Recently, questions have been raised about the accuracy of the Western Blot. Many commercial laboratories are apparently unfamiliar with and possibly unskilled in using it, and there is no standard for its interpretation.

Some experts hope for a generically different supplementary diagnostic test: one that would allow recognition of the antigen rather than the antibody in test material. The hope is that it might be possible chemically to identify virus proteins in blood and tissue samples with a greater sensitivity than that of antibody detection.[52] This would be of great merit chiefly because in the interval early in infection, the antibody has not had time to develop, and a person tested during that time may be falsely reassured, and may inadvertently infect other people as a result. However, the benefit of an antigen test maybe counterbalanced by a large number of false negatives, since HIV can exist solely as integrated DNA in host cells, without any antigen expression. Thus failure to detect viral antigen would not necessarily mean the absence of infection.

Present AIDS tests are moderately expensive and time-consuming, and require trained laboratory personnel. Confidential testing is offered by many physicians and clinics, but there may be long waits, and there is much variability in the adequacy of the counseling that is offered. There have been no "home test kits," or tests that give fast results, but a home test kit is expected to be on the market within a few months. If fast, inexpensive, and highly accurate tests are developed, some of the purely technical restraints on mass screening will fade. However, medical and public health experts, persons with AIDS, and care-givers stress the importance of linking testing to supportive counseling. This is important both for the good of the infected, and to maximize the likelihood that these people will take care to avoid infecting others. The possibility of "on-the-spot" or home testing is likely to further erode that link to counseling. In the meanwhile, the question is whether large scale mandatory testing programs should be undertaken now.

In early 1988 researchers at CDC announced a technique called PCR (for polymerase chain reaction) or DNA amplification, which identifies proviral sequences of HIV-I in the DNA of blood cells of people who are infected. This method may make it possible to obtain test results within 3 days. CDC currently speaks cautiously of the "potential utility of the PCR

[52] It is already possible in specialized laboratories to grow HIV itself from white blood cells of persons with HIV antibody, with a success of over 60 percent on a single try, but this is unwieldy and expensive. Also, antigen is usually not recoverable from Ab-positive persons.

technique in complemention or replacing virus isolation as a routine means of determining the presence of HIV-I. "[53]

Debate over the desirability of systematically screening large populations—e.g., prisoners, Federal employees, marriage license applicants, hospital patients—seems to be growing. In March, 1988, the U.S. District Court for the District of Nebraska refused to allow a multicounty mental retardation agency to require some of its employees to submit to testing for HIV infection, on the grounds that this violated employees' Fourth Amendment (search and seizure) rights." The agency had acted on the grounds that employees might transmit AIDS to clients who bit or scratched them.

In part the impetus for mandatory testing may come from the fact that there is little else to be done, and mandatory screening seems more activist than reliance on voluntary testing. In some limited populations, mandatory testing would provide the opportunity for some control; for example, screening of prisoners allows authorities to isolate those who are infected or to take strong measures to prevent other prisoners being subjected to risk through sexual activity .55

Testing of marriage license applicants could allow an uninfected partner to be warned and possibly reduce the number of infants born infected with AIDS, but heterosexual couples other than IV drug users are not a high risk group at present. Some States routinely require testing for syphilis in connection with a marriage license application.[56] Louisiana and Illinois both passed laws requiring AIDS testing for applicants for a marriage license; Texas passed a similar statute that will go into effect only when the state incident rate reaches 0.83 (when the law was passed, the rate was 0.01). But in July 1988, Louisiana repealed the premarital test law after only 6 months, and in Illinois there is also a strong movement for repeal. Of 75,000 people tested under the Illinois law, only 10 tested positive (the prediction had been for 80 to 100 positives) and the cumulative costs for testing were reported to exceed $6 million (paid for by the applicants for a marriage license, at costs of $30 to $200 per couple)."

Mandatory testing for health-care professionals themselves has been proposed, but there has been little public or professional discussion of the pros and cons of this measure.

Many people, including many public health and medical experts, conclude that any benefits from mandatory screening programs are more than counterbalanced by the separating of testing from counseling and the likelihood of driving persons at risk "underground." The National Academy of Sciences/Institute of Medicine reached that conclusion, as did a preliminary consultation at the World Health Organization in March 1986.

The issue of how to balance these costs against the benefits of testing programs has not yet been fully resolved. The conclusion that mandatory screening is unwarranted is greatly affected by the lack of treatment, the clear need for counseling in the event of a positive test, and the uncertainty that confidentiality can

[53] Chin-Yih Ou et al., "DNA Application for Direct Detection of HIV- I in DNA of Peripheral Blook Mononuclear Cells," *Science,* Jan. 15, 1988, pp. 295-297.

[54] *Glover v. Eastern Nebraska Community Office of Retardation*, DC Neb, No. CV. 87-0-830, Mar. 29, 1988.

[55] According to Professor Wayne Welch of The George Washington University's Intergovernmental Health Project staff, there is already mandatory testing for members of the Armed Services, the Foreign Service, and the Job Corps, and for Federal prison inmates. Prisoners are being screened in seven states. Utah has passed a law prohibiting a person diagnosed as having AIDS from marrying. Florida requires pregnant women with "high risk characteristics" to be tested.

Nevada, where prostitution is legal, requires that prostitutes be screened for AIDS. *Government Executive,* July-August 1987, p. 13.

[56] This is becoming a serious problem in prisons, and the rights of prisoners in this regard are a matter of debate and uncertainty. A Massachusetts trial judge said in September that a prisoner could not be forced to take an AIDS test merely because he had scratched and injured a guard. On the same day, a Federal judge in Minnesota upheld the conviction of an infected prisoner for assault with a dangerous weapon after he bit two judges, noting that the human mouth and teeth do not ordinarily constitute a deadly or dangerous weapon. Associated Press, "AIDS Decisions Diverge in Cases Against Prisoners," *The National Law Journal.* Sept. 28, 1987, p. 4.

[57] Sandra G. Boodman, "Premarital Testing Annoying Many in Illinois," *The Washington Post,* July 30, 1988, p. Al.

be maintained. Screening at least spares those who are unknowingly infectious from the additional grief of finding too late that they have passed on the infection, perhaps to spouses or offspring. If a cure or effective treatment were possible, past precedents argue that the State interest in saving lives and preventing the spread of the threat would almost certainly override concern about individual privacy rights.

Voluntary testing, as compared to mandatory testing, is likely to involve those who are: 1) already well informed about AIDS, 2) socially responsible about the risks of infecting others, 3) comparatively well off financially, and 4) relatively sophisticated about medical procedures. Two high risk groups are probably least likely to ask for testing: IV drug users and prostitutes, who are already at risk both of incurring other life-threatening diseases and of arrest for illegal activities; who are likely to have little access to health services and little money; and who are hardest to reach with public education.

The cost of screenings also a significant factor. The screening of a unit of blood by the ELISA test costs at least $2 and more commonly approaches $5. When a positive ELISA test occurs, repeat and supplemental testing are required, adding at least another $50 to the cost. These figures do not include the need for skilled counselors and for procedures to assure confidentiality of test results. Thus the economic and social costs of mass screening for AIDS, both for those who have been exposed and for the public at large, are significant.

Contact Tracing

Still another traditional Public Health technique, contact tracing, has also again become controversial because of the AIDS epidemic. Public health management of sexually transmitted diseases has along history. Mandatory contact tracing-i. e., tracking down and warning people who have had sexual relations with an infected partner-is a technique that has usually been closely associated with reporting and testing strategies. Contact tracing in the case of AIDS has become attractive to some Federal officials and State legislatures because that strategy is perceived to have been useful in the control of syphilis and gonorrhea. Such action also seems indicated by fairness to people who have unknowingly been put at direct risk, and may consequently unknowingly put others at risk.

To the surprise of many observers, the American Medical Association (AMA) in June 1988 recommended that its members warn sexual partners of patients with AIDS and of AIDS carriers. This is an exception to the strong tradition of physician-patient confidentiality, on which the AMA has always insisted.[58]

There are however two problems with mandatory contact tracing as a strategy for AIDS control. First, some experts question the assumption that it was effective in the past. Syphilis came under control primarily because of the discovery of penicillin rather than because of contact tracing; and gonorrhea is at present out of control in spite of contact tracing.

Second, in those epidemics the impetus for contact tracing was the knowledge that treatment could be offered to the contact. The patient had a strong ethical reason for reporting, and the contact a highly practical reason for welcoming, the news. Both benefits tended to compensate for the sacrifice of privacy. With AIDS there is no therapeutic help to be offered. The only benefit to contacts would be that of counseling if their tests prove positive. But 2 or 3 months are usually required for antibodies to appear, so there may be an interval of uncertainty, distress, and disruption of relationships even if the tests are ultimately negative. For public health officials and physicians, sustained infectiousness of the patient over many months makes it difficult to be sure of complete contact identification, especially since many sexual partners may be involved. The need for reiterative testing becomes a ma-

[58] Isabel Wilkerson, "A.M.A. Urges Breach of Privacy To Warn Potential AIDS Victims," *New York Times*, July 1,1988, p. Al.

jor difficulty. Techniques for assuring the confidentiality of data are available but may be demanding and expensive, and may still not be trusted by those supplying the information.

These problems must however again be weighed against the great benefit of warning those who have been exposed, so that in turn he or she will not unknowingly expose others. Some public health officials are swinging toward support of contact tracing. New York health officials for example recently asked physicians to warn sex partners of AIDS patients of the risk.[59] The City Health Commissioner said, however, that there is no way to force patients to disclose the names of contacts, and that under current rules governing professional behavior in New York, physicians and hospitals that breach patient confidentiality would be subject to civil penalties, such as lawsuits. Current New York laws do allow health officials to notify people who have been in intimate contact with patients with venereal disease or tuberculosis, and some states have already authorized contact tracing for AIDS cases. California and Texas allow but do not require physicians or surgeons to disclose positive test results to a patient's spouse, and provide confidentiality safeguards for patients who voluntary consent and list names for contact tracing. Illinois provides immunity from civil liability for those willing to provide names for contact tracing.

Some people urge that people who know they are infected should be legally required to warn sex partners. An army sergeant in San Antonio was recently sentenced to 5 months in stockade and a dishonorable discharge for ignoring orders from officers and having sex without telling his partners he was infected with AIDS, or taking protective measures.[60] In June 1988, a military trial was beginning of an Army private accused of having sexual relations with male and female soldiers without warning them that he was infected.

On June 24,1988, the Presidential Commission on the Human Immunodeficiency Virus Epidemic recommended that State health officials be required to contact and notify sex partners of persons infected with AIDS.

Social Controls: Full or Partial Quarantine

The strategies of final resort for control of most epidemics are: 1) infrastructure or environmental reform, when there is believed to bean environmental factor such as an animal vector, and 2) failing all else, social control measures including quarantine or isolation.

There are no known environmental factors in the AIDS epidemic, in the sense of sanitation factors, industrial contaminants, or animal vectors for the disease agent. One factor in the urban environment proved to be important: the "bathhouses" in some large cities that were a primary focus of promiscuous homosexual behavior that facilitated the transmission of the disease. Action by public health authorities to close these commercial establishments in San Francisco and New York was delayed by the protest and political and legal resistance of proprietors and clients, on the grounds of civil liberties, but once the fact of an infectious disease and a mode of transmission had been established, there was little doubt that the closure fell within the long established scope of State police power.

Three further social control measures, beyond those already discussed, have been suggested or proposed in the context of the AIDS epidemic: full quarantine, excluding children with AIDS from public schools, and prohibiting persons with AIDS (or carrying the infection) from engaging in certain occupations. These potential control measures have very significant constitutional implications.

Quarantine would impose a harsh burden on those infected with AIDS, particularly those who as yet suffer no symptoms of the disease, because the quarantine would be life-long. In

[59] Ronald Sullivan, "Warn AIDS Patients' partners, Health Official Urges," *The New York Times*, Oct. 15, 1987, p. B1.

[60] He was found guilty of disobeying officers, of adultery, and of sodomy, but not guilty of aggravated assault and reckless endangerment. "Soldier Guilty of Concealing AIDS Infection from Partners," *The Washington Post*, Dec. 3, 1987, p. A20.

spite of this, newspaper polls have shown many Americans (one poll said 51 percent) favor quarantines, and legislatures in 5 States are said to be considering, or to have considered, such legislation. Florida health authorities have quarantined one prostitute to her home, wearing an electronic anklet.[61] Social attitudes and judicial decisions regarding quarantines may have changed significantly in the last few decades, but this conclusion is somewhat hypothetical, as the use of traditional quarantines has become relatively rare and unfamiliar.

In the early national period, quarantines were often imposed. The major infectious disease problem was yellow fever. The disease reappeared in 1793 after a long absence, and a devastating epidemic struck along the entire coast from Boston to New Orleans. Philadelphia, New York, and other cities established temporary health boards with broad authority, and began quarantines. They isolated yellow fever victims and began massive programs to cleanup the foul streets and privies. As the epidemic increased in intensity, temporary hospitals were established, and funds were provided to care for the sick and those left orphaned.

The disease was spread by water transport and generally struck hardest in the low-lying crowded dock areas occupied by the poor. The rich fled. Philadelphia and New York City in 1797 began a policy of evacuating entire sections of the city. New York, for example, provided temporary housing out in the country, in Greenwich Village. The city authorities assumed full responsibility in this way for epidemics of yellow fever for another century, through the final large outbreak in 1905 in New Orleans, when Federal, State, and local officials joined together to cut short the epidemic.

Courts have since often struggled with the issue of quarantine as an ultimate social control measure, and have generally dealt with it according to: 1) the nature of the disease and 2) the length of time for which a person is infectious and would need to be isolated. Until recent decades, courts gave great weight to the inherent power of government to protect the general welfare by whatever means were considered to be appropriate, by the public and their legislators even if not by experts.

For example, a 1909 case involved the quarantine in South Carolina of an elderly woman, who had contracted leprosy many years earlier as a missionary in Brazil.[62] Subsequently she mingled freely in the society of a small town for years, even teaching Sunday School, until the city board of health decided that she should be isolated. She had infected no one, medical authorities testified that she was only slightly if at all contagious, and the woman frantically offered to remain isolated in her own home. Nevertheless, the court permitted her involuntary removal to and confinement in a cottage built for her outside the city limits. The court held that even though the disease was only "slightly contagious' the board of health was justified because of the "distressing nature of the malady."

By contrast, public health officials in San Francisco and elsewhere made no move to quarantine persons with AIDS who continued to frequent commercial bathhouses for reasons of anonymous sexual activity, in spite of the repeated warnings of their physicians that they were likely to be transmitting the infectious disease.[63] In the intervening half century, attitudes toward individual rights had changed significantly.

Even at the turn of the century when quarantine was more often applied than now, courts did intervene in quarantine programs where the exercise of police power was extreme and arbitrary. In 1900 San Franciso's board of health quarantined a 12 block district inhabited by 10,000 to 15,000 people, because bubonic plague was thought to exist in the area. This was challenged on the grounds that it was differentially enforced against Chinese but not non-Chinese (most of the residents in the area

[61] Deborah Jones Merritt, "Communicable Disease and Constitutional Law: Controlling A IDS," *New York University Law Review*, vol. 61, No. 5, 1986, p. 775. The *Los Angeles Times* poll cited by Merritt was published Dec. 19, 1985, p. 1.

[62] *Kirk v. Wyman*, 65 S.E. 387 (S.C. 1909).

[63] Shilts, op. cit., footnote [49]

were Chinese); there was insufficient evidence of bubonic plague;[64] and in many blocks there was no evidence of any illness at all. A Federal judge terminated the quarantine on the grounds that it was "unreasonable, unjust, and oppressive. "[65]

In 1922, the Supreme Court of Illinois upheld the isolation of a boarding house operator who was not ill but was a carrier of typhoid bacillus.[66] She could, the court said, be quarantined for as long as she presented a danger to the public, ever though this would likely be for the rest of her life. The court noted several requirements: the person must be known to be ill or infectious ("mere suspicion" was not sufficient); State authorities must have reasonable ground to believe that public health would be endangered; the action must cease when the necessity for it ceases; and the emergency or necessity must exist, not merely be anticipated. However, public authorities need not wait until the disease has already been transmitted to take action. "One of the important elements in the administration of health and quarantine regulations is a full measure of common sense. "

Some courts were less concerned about the principles governing exercise of police power. The Supreme Court of Ohio, also in 1922, allowed city health commissions to make examinations of all persons suspected of having venereal disease, and "all known prostitutes" were considered to be, per se, reasonably suspected. Another regulation allowed the quarantine of one who had or was reasonably suspected of having venereal disease when in the opinion of the health commissioner such quarantine was necessary to protect the public health. A woman was arrested as a prostitute; charges were dismissed but she was then involuntarily institutionalized by the commissioner of health for 2 months' treatment. In refusing a writ of habeas corpus, the State Supreme Court said:

> There is perhaps no provision of the Federal Constitution that is more overworked than the Fourteenth Amendment . . . It has been so many times decided that the Fourteenth Amendment does not limit the states in the proper exercise of the police power that the citation of authority seems needless.[67]

A generation later, in 1944, there was a similar case in which two women arrested for having 'unlawfully solicited for prostitution" were held without bail until examined for venereal disease, pursuant to a State statute. The Supreme Court of Illinois upheld their detention on the sole grounds of the *charge* of prostitution, saying that:

> It has been almost universally held in this country that constitutional guarantees must yield to the enforcement of the statutes and ordinances designed to promote the public health. .. .68

The court also cited with approval another authority, that "whenever a police regulation is reasonably demonstrated to be a promoter of public health, all constitutionally guaranteed rights must give way. . . ."

Even in recent years, courts have upheld statutes that permitted involuntary testing of women arrested for prostitution.[69] Public health measures may be less likely to be limited by courts under constitutional principles when they are aimed at venereal disease, or when applied to prostitutes who are by definition engaged in criminal activity, than in more general cases of infectious disease.

But most of these statutes and court decisions occurred during wartime; Dr. Allan M. Brandt, in his book No *Magic Bullet,*[70] dis-

[64] There had been 11 deaths in which some symptoms of bubonic plague appeared on autopsy, but no case in which a living person was diagnosed as having the disease and no evidence of any transmission of disease by the deceased,

[65] *Jew Ho* v. *Williamson,* 103 F. 10 (N.D. Cal 1900).

[66] *People Ex Rel. Barmore* v. *Robertson,* 134 N.E. 815 *(111.1922).* The court said that it would not evaluate the wisdom of the State legislature and board of health, and would not interfere with a particular action so long as it did not appear to be, on its face, "arbitrary, oppressive, and unreasonable. "

[67] *Ex Parte Company* 139 N.E. 204 (Ohio 1922).

[68] *People ex rel. Baker* v. *Strautz,* *54* N.E. *2nd* 41 (1944).

[69] For example, *People v. Superior Court* (Hartway) 562 P.2d 1315 *(Cal.* 1977).

[70] Allan M. Brandt, *No Magic Bullet* (Oxford: Oxford University Press, 1985).

cussed the impact of wartime preparedness initiatives on the creation and enforcement of laws aimed at reducing the prevalence of venereal disease. In the past, quarantines for venereal disease have been limited in duration since those who were infected could be rendered non-infectious by medical treatment.

The courts have upheld quarantines for many other infectious diseases including scarlet fever[71] and tuberculosis;[72] and have upheld lifelong quarantines for typhoid. But quarantine has come to be used less and less as vaccines or cures were developed for many infectious diseases.

On the one hand, the pattern of court decisions about quarantine shows an ever broadening tolerance for the exercise of police powers. This tolerance has expanded from quarantine based on demonstrated necessity to quarantine based on suspicion of disease, to quarantine based not on disease symptoms but on accusation of sexual activities. On the other hand, some constitutional authorities believe that courts would now be very reluctant to uphold the broad use of long quarantines, because concern for individual rights has increased. Deborah Jones Merritt, for example, suggests that:

> Recent developments in constitutional law suggest that courts would no longer uphold such broad quarantine orders. Although the courts might still approve the isolation of individuals who either knowingly engage in activities threatening a high-risk of infection to others or lack the mental competence to avoid those activities, judges would be unlikely to sustain the quarantine of individuals who are willing to modify their activities to avoid such risks.[73]

Not all authorities concur in that judgment, on the grounds that courts have in general given wide discretion to governments in exercising their police power when the public perceives a serious risk. In particular, some people warn, any evidence that AIDS has been transmitted through non-sexual, non-drug related contact in even a very few cases would be likely to increase both political demands for and judicial acceptability of quarantine. This occurrence seems highly unlikely.

The constitutional acceptability of some lesser forms of social control is also still unclear. For example, continued admission of children with AIDS to public school has brought about conflict in many communities. The Centers for Disease Control (CDC) in August 1985 reassured parents about the "apparent nonexistent risk of transmission" of the virus to other school children and recommended that schools decide how to handle children with AIDS on a case-by-case basis.[74] Some school districts have adopted CDC's guidelines, some have refused to admit AIDS children, some have segregated them within schools.[75] Both parents and school boards have resorted to the courts. State and Federal legislators have introduced bills to ban AIDS sufferers from schools. These struggles are so far unresolved except on a case-by-case local basis.

In the first decades of this century courts allowed school boards almost unlimited authority to exclude students with communicable diseases." Not only children who were ill, but those who had been exposed to infectious diseases at home or elsewhere could be excluded. In recent decades, while declining to recognize education as a fundamental right," the Court has nevertheless scrutinized any law or policy that excludes children from public schools.

The State was not allowed to exclude undocumented alien children, on the grounds that this would relegate the children to a permanent 'subclass, " that the children were not re-

[71] *Stone v. Racjowski*, 86 A 606 (1913).
[72] *Moore v. Draper*, 57 So.2d 618 (1952 'la")"
[73] Merritt, op. cit., footnote 61, p. 778.

[74] CDC discounted most means of "casual transmission," but recognized parents' fears that body fluids may be exchanged among children by biting, scratching, uncontrolled urination, casual injuries, etc. 'Education and Foster Care of Children Infected with Human T-Lymphotropic Virus Type III/Lymph-adenopathy-Associated Virus, " 34 *Morbidity & Mortality Weekly Rept. 517. 519 (1985).*
[75] Merritt, op. cit., footnote 61, pp. 756 ff.
[76] Ibid. The remainder of this section draws heavily on Merritt, op. cit., unless otherwise referenced.
[77] *Papasan v. Allain*, 106 S. Ct. 2932, 2943-45 (1986); *Plyler V. Doe*, 457 U.S. 202, 223 (1982).

sponsible for their alien status, and that the cost of educating these children was insubstantial in the light of the costs of lack of education for the children, the State, and the Nation. These reasons could apply to children with AIDS, except that they are unfortunately unlikely to live to constitute a permanent subclass. The likelihood of transmission through schoolroom contact is generally regarded by experts, although perhaps not by all members of the public, as extremely small or nonexistent. A New York trial judge recently followed this reasoning in ruling that automatic exclusion of all AIDS patients from public schools would violate the Equal Protection Clause.[78]

In 1979 the New York City Board of Education began to exclude from regular classrooms mentally retarded children who were also carriers of the hepatitis B virus. Hepatitis B is communicable in a similar fashion to AIDS—through the use of contaminated needles, blood-to-blood contact, and sexual contact (usually homosexual contact). While the virus has been isolated in saliva, there is no evidence that it has been transmitted through this route." The New York City policy was challenged on the grounds that it violated the Rehabilitation Act of 1973, the Education of the Handicapped Act, the New York Education Law, and the Due Process and Equal Protection Clauses of the Fourteenth Amendment.[80]

The Board of Health argued that it was making traditional use of the police power to protect the health, safety, and welfare of its citizens and that its actions were "rationally related" to this purpose. The Court nevertheless struck down the Board's policy. It cited the Fourteenth Amendment, although it relied primarily on antidiscrimination laws.[81] A California court ordered a school district to readmit a child with AIDS to kindergarten on the grounds that AIDS is a handicap under Section 504 of the Rehabilitation Act.[82]

In a similar case a New York court invalidated a school board policy excluding children with AIDS. Again recognizing that public education is not a fundamental right, the court said that when a State does provide it, it must be available to all on equal terms. The courts will give any denial of schooling close scrutiny because of the significant negative impact this could have on children.[83]

The Public Health Service (PHS) has officially urged that AIDS sufferers or carriers not be excluded from work, saying that "No known risk of transmission . . . exists" for workers in offices, schools, factories, construction sites, food service jobs, health service delivery, etc.[84] The Public Health Service recommended only routine disinfection of equipment contaminated by anybody fluids, regardless of known infection.

Some school districts decide on a case-by-case basis whether public school teachers and associated workers with AIDS may continue to work. Several cities have barred persons with AIDS or AIDS-Related Complex from working as food servers or as teachers. Judicial precedents could support these restrictions. Under the rational basis test, as long as the courts perceive that there is even remote risk of infection,[85] they would be obliged to uphold such regulations. The Supreme Court held, in 1978, that New York City could con-

[78] *District* 27, 130 Misc. 2d 398, 502 N. Y.S.2d 325; cited by Merritt, op. cit., footnote 61, p. 762.

[79] According to Dr. Leonard Glantz, Prof. of Health Law, Schools of Medicine and Public Health, Boston University, some authorities think that there is a greater likelihood that hepatitis B could endanger others in a classroom or household than that AIDS could do so. The material on school admission in this section relies heavily on analysis by Dr. Glantz as well as Dr. Merritt.

[80] *New York State Association for Retarded Children v. Carey, 612* F. 2d. 644 (2nd Cir. 1979).

"The court said that since the policy excluded only mentally retarded children and made no effort to find or exclude other children who were carriers, the Board evidently recognized that carriers presented only a "remote possibility" of infecting others.

[82] *Thomas v. Atascadero Unified School District*, No. 886-609 AHS(BY) (C. D.) Calif. Nov. 17, 1986.

[83] *District 27 Community School Board v. Board of Education, 502* N. Y. S.2nd. 325,337 (Sup.1986).

'recommendations for Preventing Transmission of Infection with Human T- Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus in the Workplace, 34 *Morbidity & Mortality Rept. 681,682 (1985),* hereafter cited as *PHS* Workplace Recommendations.

[55] The Public Health Service holds that there is some possibility of such transmission, for example, by direct transfer of blood through the injury of one person and an open lesion on another person's skin, but says that this kind of transmission is highly unlikely.

stitutionally bar all methadone users from working for its transit authority even though the bar was "broader than necessary to exclude those methadone users who were not actually qualified to work. "[86] Thus if the courts found sufficient grounds to exclude some AIDS victims from health care, personal service, or food handling occupations, they would be likely to uphold broad rules barring AIDS victims rather than insist on individualized determinations of the threat posed by a particular employee. But those "sufficient grounds" do not appear to exist, and the Supreme Court has said that the protection given to the handicapped by recent legislation extends to people with infectious disease.

None of these judgments are at all conclusive; they represent possibilities rather than predictions of how courts would decide in future situations. Constitutional lawyers and scholars differ strongly on these points. Clearly, scientific knowledge about risks and exposures, in this case, has not been sufficient to prevent or resolve challenges to public policy on the basis of constitutional principles; it may only have complicated those challenges.

In June 1988, the President's Commission on AIDS and the National Academy of Sciences both recommended tough new Federal laws to prohibit discrimination against the 28,000 Americans with AIDS and the more than 1 million other Americans estimated to be infected. The Presidential commission, with a divided vote, recommended that the Federal law against discrimination against the handicapped be extended to apply to private sector employees.

Treatment

Health care in the United States is primarily provided through the private sector, but the public health system is an important developer of new drugs and other health care regimes and techniques. In addition, Medicare and Medicaid do provide payment for health care for many Americans. As discussed in the next chapter, there is a growing concern about the availability of adequate medical care for Americans who may not be able to pay for increasingly expensive care, or who do not have access to health insurance: "A(n). . . issue confronting society and its political elements is the question of whether health is a universal human right."[87]

Neither Congress nor the Supreme Court has in any way recognized such a "human right" as a constitutional right. But the AIDS epidemic may fuel pressure for new health care delivery mechanisms or programs because of the high costs of treatment, because those with AIDS are young and more likely than the average worker not to have health insurance, because they may lose their jobs when their illness becomes known, and because health insurance providers try to avoid enrolling those in high-risk categories.

The projected costs of health care for AIDS patients in the next few years are enormous. While AIDS is uniformly lethal, it entails many weeks or months of progressive debilitation, including necrologic deterioration. Since this is a disease of young adults whose health insurance is usually dependent on their employment status, early termination of employment has abroad impact. Home care, day care, long-term care in skilled nursing facilities, and hospice care can improve the quality of remaining life for many patients, while reducing costs. The range of lifetime health care cost estimates per case range from $29,000 to $157,000, reflecting in part the variation in availability of such options.

Health care will become still more costly and difficult as drug addicts become an increasingly large proportion of the patients. Many of the innovations in patient care so far have relied heavily on the volunteerism characteristic of some gay communities, which has no parallel in some of the other high risk groups.

[86] *New York City Transit Authority v. Beazer*, 440 U.S. *568 (1979),* as cited by Merritt, op. cit., footnote 61, p. 771.

[87] J.C. Snyder, "Public Health in the U. S.A., " in John Walton, Paul B. Beeson, Ronald Bodley Scott (eds.), *The Oxford Companion to Medicine,* vol. ii, p. 172.

The appearance of the first anti-HIV drug, AZT, raised some thorny issues likely to recur with other candidate treatments. The handful of drugs that have been developed for treatment of virus infections of any sort are usually very toxic. Antiviral drugs present very different problems from those of antibiotics for bacterial infections. Most bacteria are distinctive, self-contained organisms, subject to attack through their specialized mechanisms of multiplication. Viruses act as "fifth columns," taking over the host cell so completely that it is difficult to kill the virus without seriously damaging the host.

AZT, for example, has a serious suppressive effect on the patient's bone marrow, usually necessitating regular blood transfusions. It has other toxic properties, often so severe that treatment must be stopped. Its cost is nearly $10,000 yearly per patient. This is not a promising solution even in the affluent United States, where over a quarter of a million cases of AIDS are anticipated by 1991; it certainly will not work for developing countries. But so desperate are AIDS patients that even at that cost, the demand for AZT exceeds the supply.

The urgent need for some treatment prompted creation of an unusual mechanism for early licensing of AZT and an even more unusual system to try to get more equitable distribution of the drug. The intense pressures that prompted these actions will worsen tenfold in the next 5 years if there are no other effective treatments. A large number of unauthorized treatments, ranging from health food diets to drugs authorized for other medical purposes, are being widely used by those with AIDS who can afford their often high costs. Many people are highly critical of government agencies for what they view as foot-dragging in testing these "treatments."

Yet other people are concerned that the rapidity of licensure of AZT seems to herald more rapid deployment of new drugs in general—not just for AIDS—and they fear that the slow but cautious approach which has assured drug safety in the past maybe replaced with a faster but more hazardous approach. Few hazards, however, appear prohibitive compared to a disease that is probably 100 percent fatal.

In the meantime, in response to the growing demand from the AIDS community, the FDA announced in July 1988 that it would allow Americans to import unapproved drugs from abroad in small quantities for personal use in treating or preventing AIDS.[88]

Blood Banking

Blood supply and transfusion was a primitive process until World War II. Blood groups were recognized only in the 1930s. Until the need for close matching of blood types was recognized it was not uncommon for hemorrhage to be dealt with by direct arm-to-arm transfer of untested blood.

Blood transfer for medical purposes increased dramatically with expansion of surgical capabilities and other therapeutic interventions. It prolonged the lives of cancer patients and many others who needed transfusions for maintenance. By 1983, an average of 13 million voluntary blood donations were made per year. Most donations were divided into two or three components (i.e., red cells, plasma, platelets). There were over 3 million recipients per year, many receiving multiple infusions.[89]

The transmission of the disease hepatitis as a complication of blood transfusion was recognized in the early 1940s. By misadventure the newly developed live-virus vaccine for yellow fever was stabilized using human serum that was infected with hepatitis viruses. Over 50,000 cases of hepatitis resulted. Blood screening for the disease agent then began.

[88] Philip M. Boffrey, "F.D.A. Will Allow Patients To Import AIDS Medicines," *New York Times*, July 25, 1988. One example of such a drug is dextran sulfate, which the Federal Government is now beginning to test in human trials, but which is already in use in some countries.

[89] J.R. Allen, "Scientific and Public Health Rationales for Screening Donated Blood and Plasma for Antibody to LAV/HTLV-III," Chapter 15 in *AIDS: The Safety of Blood and Blood Products*, J.C. Petricciani et al. (eds.), The World Health Organization. New York: John Wiley and Sons Ltd. Also J.C. Petricciani, "Licensed Tests for Antibody to Human T-Lymphotropic Virus Type III, *Arm.intern.ilfed. 102: 726-729, 1985.*

The identification of hepatitis B virus and development of a means of screening had been expected to eliminate most of the hepatitis contamination. But as it turned out, only a small proportion of the transfusion-associated hepatitis was eliminated. Clearly at least one other virus was involved. The remaining blood transmitted hepatitis was subsequently referred to as "non-A, non-B hepatitis. "[90] Later immunologic evidence strongly suggests that there are at least two other hepatitis viruses.

The risk of hepatitis is still significant; blood-transfusion hepatitis continues to threaten 7 to 10 percent of those getting transfusions. Additional "surrogate" screening tests have recently been added in an effort to prevent these infections, and they add several dollars to the cost of each unit of blood.

Besides blood donation there is a large "industry" of plasmapheresis growing from extensive demand for gamma globulin and from the recent capability to fractionate blood plasma and prepare concentrated materials (e.g., clotting factors to substitute for genetically lacking proteins in hemophiliacs). The pooling and concentrating of donated plasma has allowed the life expectancy of severe hemophilia A patients to rise from about 14 years in the early 1960s to 42 years in the early 1980s. Unfortunately the same technical feat made them early victims of the spread of AIDS.[91]

This was the second great disaster to hit bloodbanking. By 1982 it was suspected that AIDS was infectious, and that the unknown agent might be transmitted through blood exchange, and several cases of AIDS in hemophiliacs had been reported.[92] In March 1983, the FDA after consultation with the major blood banking organizations, the National Institutes of Health, and the National Gay Task Force, recommended that persons "at increased risk of AIDS" (specifically homosexual males) be asked to refrain from donating blood; that there be expanded medical screening of donors to detect early symptoms of AIDS, and that this screening include examination for lymph node enlargement and weighing to detect early weight loss.

Critics have since charged that this action was delayed by resistance from both blood banks and gay organizations.[93] The Centers for Disease Control officially reported only in January 1984 that there were cases of AIDS associated with transfusions, and later in 1984 some blood banks began using surrogate tests. Many lots of blood thought to be infected were withdrawn and destroyed. In April 1984, the AIDS virus was identified, and a specific AIDS blood screening test became available in mid-1985. Screening for AIDS now adds about $5 per unit to the cost of blood transfusions.

By the end of 1987, according to the Centers for Disease Control, 1,608 cases of AIDS acquired through blood transfusion had been reported in the United States. Of all persons with hemophilia A (12,400 persons), approximately 70 percent maybe infected with AIDS; of those with hemophilia B (3,100), about 35 percent may be infected.[94] The number of cases of transfusion-related AIDS will thus increase for some time even if the risk of infection through blood transfusions has ended.

Public anxiety about the safety of the blood supply has led to the demand that "directed donations" be allowed, in which one chooses one's own blood donors from personal friends and relatives. The costs of such a program, i.e., subdividing blood units and allowing special storage, is potentially very high. It also creates a "two-class" blood system, and so has been opposed by many professionals in transfusion medicine.

Autologous donation is the process by which one donates one's own blood for anticipated future use. In planned, elective surgery this

[90] Hepatitis A is caused by still another virus which is physiochemically similar to polio virus and is rarely a factor in blood transfusions.

[91] J. F. Desforges, "AIDS and Preventive Treatment in Hemophilia.," New *Eng. J. Med. 308: 94-95, 1983.*

"U.S. Congress, Office of Technology Assessment, *Blood Policy & Technology*, *OTA-H-260* (Washington, DC: U.S. Government Printing Office, January 1985), p. 13.

[93] Shilts, op. cit., footnote 32, Parts IV and V.

[94] U.S. Public Health Service, Centers for Disease Control, *Morbidity and Mortality Weekly Report,* vol. 36, Supplement No. S-6, Dec. 18, 1987, table 14, p. 40.

can be a wise precaution. It is not generally useful for emergencies.

Blood supply system professionals generally insisted that would-be donors must be informed that tests will be done on the blood and a donor who tests positive will be informed of the results; and most have strongly supported the position of many other health professionals that counseling must be offered in conjunction with blood testing for HIV antibodies. An elaborate process has been set up for obtaining donor consent, notification of results, and follow up counseling. The burden on blood banks is very large. Strong pleas have been made for persons whose behavior puts them at risk of AIDS not to donate. But in communities without alternative testing sites, access to the AIDS test through blood banks means that some people will donate in order to find out if they are infected.

The American Red Cross in 1986 instituted a look-back procedure, in which infected donors who are identified through a current donation have their prior donations traced. Stored samples are tested; recipients of prior positive donations are contacted and told of their possible contamination.

Public Education and Statistical Forecasting

Epidemics are usually attacked through preventive education, prevention by vaccine, drug treatments, and sometimes social control measures such as quarantines. Only the first has yet shown real promise for the AIDS epidemic in the next decade. Education is now the major public health strategy, other than research and the screening of blood and organ donors. This means a combination of strategies to inform the general public about the disease in a way that will be effective yet minimize diffuse fear, that will alert adolescents to the lethal hazard implicit in certain behaviors, and that will urge people to avoid behaviors that put them at high risk. The NAS/IOM panel proposed that for every dollar invested in research an equal sum should be invested in education for prevention.

There are however strong political constraints on this strategy because some people perceive any information about avoidance strategies (other than abstinence or heterosexual monogamous marriage) as equivalent to condoning homosexuality or promiscuity. The Public Health Service and Centers for Disease Control had planned to mail an AIDS information brochure to every U.S. household in October 1987. But because of political resistance from those who feared it would offend some religious groups, the President's Commission on AIDS delayed the mailing until late spring 1988.[95]

There is some evidence that public education about AIDS has brought about behavior change within the group so far at highest risk, homosexual males. Most observers report, although there is probably no real quantitative data, that extreme promiscuity has strongly declined and the use of condoms has risen. Most experts believe however that other high risk behavior, i.e., intravenous drug use, is much less likely to change, since its practitioners are already accepting very high legal and health risks.

Public education is also regarded as the best strategy for dealing with some newly identified behavioral or environmental risks, and for some that have been recognized for several decades, such as smoking. There will soon be increasing non-genetic predictive power concerning the likelihood of a variety of pathologic states such as coronary artery disease and adult-onset diabetes. Medical science is leading toward a refined definition of desirable "health behaviors" to reduce the likelihood of or severity of such outcomes, so much so that some have been codified in a fully sanctioned set of Federal objectives.[96] Increasingly, public health programs emphasize lifestyle change and preventive health measures.

The first strongly documented scientific warnings that smoking was deleterious to

[95] William Booth, "The Odyssey of a Brochure on AIDS," Science, vol. 237, Sept. 18, 1987, p. 1410.

[96] Public Health Service, U.S. Department of Health and Human Services, *The 1990 Health Objectives for the Nation: A Mid-Course Review* (Washington, DC: Public Health Service, 1986).

health came from epidemiologic studies in the 1950s, when epidemiologic methods were not well accepted except when dealing with infectious diseases. The data are now well-established; smoking contributes directly and materially to over 350,000 deaths a year in the United States, and "passive smoking" (indirect inhalation of tobacco fumes from others' smoking) has been found to be physiologically real and pathologically significant.[97]

This raises a social/ethical, and ultimately perhaps a constitutional issue, "how much personal liberty can be tolerated in self-damaging behavior?" Society has debated this issue before in terms of motorcycle helmets, seat belts, and alcohol; and will increasingly face it in terms of other lifestyle, nutrition, or environmental factors. Increasingly accurate predictive power concerning adverse health behavior brings us closer to the zone in which society claims an interest in the individual's assumption of risk. Complicating this is the question raised earlier with regard to occupational genetic screening: should some people, who are genetically sensitive to some environmental factors, be legally prevented from entering occupations, jobs, workplaces, or general locations that are accessible to less susceptible people?

Public education and social pressure—even without laws and regulations seeking to control behavior-is considered excessively intrusive by some people, when it pertains to eating habits, weight control, recreational pursuits and other matters that they regard as highly personal. Some social observers see the possibility of a backlash against such pressures, such as occurred against "Blue Laws" and obscenity and pornography laws, raising new demands for protection of personal privacy and choice.

On the other hand, to the extent that forecasting carries a useful personal message, issues of cost, access, and equity arise. Affluent people may have full benefit of forewarning and preventive care, and others may not, even when much of the predictive capability results from knowledge and technology developed with public funding. It is in fact only recently that government-funded health programs countenanced reimbursement for any prevention or health maintenance costs.[98]

Public health professionals increasingly argue for a national goal of comprehensive health care for all[99] based on the statement in the Preamble to the Constitution of the World Health Organization, which the United States formally endorsed, that

> The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic, or social condition. .. .100

The fundamental public health issue of the next generation may be the question of whether this goal can implicitly be found in the constitutional language of a right to life, liberty, and property.

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[97] U.S. Department of Health and Human Services, The *Health Consequences of Smoking: Cancer,* A Report of the Surgeon General, 1982 (PHS 82-50179); *The Health Consequences of Smoking: Cardiovascular Disease,* A Report of the Surgeon General, 1983 (PHS 84-50204); *The Health Consequences of Smoking: Chronic Obstructive Lung Disease,* A Report of the Surgeon General, 1984 (PHS 84-50205).

[98] C.J. Schramm, "Can We Solve the Hospital-Cost Problem in Our Democracy." New *Eng. J. Med. 311: 729-732, 1984.*

[99] Snyder, op. cit., footnote 87, p. 1170.

[100] Preamble t. the Constitution, *World Health Organization Basic Documents* (Geneva, Switzerland, 1963), p. 1.

Chapter 6

Medical Interventions: The Beginning and End of Life

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Chapter 6

Medical Interventions: The Beginning and End of Life[1]

Rapid progress has been made in medical technologies in recent decades and seems certain to continue, with scientific breakthroughs in many fields. Emerging or impending advances in medical capability are often foreseeable, sometimes years before they occur. They can be anticipated when:

- there are no theoretical or logical barriers to their achievement,
- the scientific and technical barriers are identifiable and understood,
- there are alternative research strategies for attacking the problems, and
- society puts a high priority on achieving the goal and therefore provides incentives for persistent effort.

Some medical goals are less definitely achievable, yet continue to be strongly pursued because their contribution to length of life, quality of life, or reduction of suffering is potentially great. Other great achievements in health care occur when there is a sudden discovery such as penicillin, a breakthrough such as organ transplants, or a new vaccine; such discoveries often give rise to a long procession of innovations and inventions.

Some of the trends and developments noted in this chapter are already underway. The timing and achievability of others are debated by experts. Nearly all are, however, considered likely to become available within 5 to 20 years. This is, indeed, a conservative view. It neglects many other achievements that may be equally or more likely, or even closer at hand. It is intended only to indicate the fertile, rapidly developing possibilities of medical science and technology and their potential power to intervene in matters of life and death.

While not all of these developments will impinge on constitutional principles many of them involve issues that may face America in the 21st century. This chapter looks at some of the most important impending developments, and the possible constitutional implications of their use.

[1] In preparing this chapter, OTA drew on interviews and focus group sessions conducted at the annual meeting of the American Association for the Advancement of Science (AAAS), Chicago, January 1987; results of a mailed questionnaire to section officers of the AAAS in December 1986, and an OTA workshop on Biology, Medicine, and Public Health, May 1987. In addition, Jonathan Peck, Institute for Alternative Futures, and Irene Jillson, Policy Research Incorporated, as OTA contractors, contributed to the development of this chapter.

ADVANCES IN MEDICAL TECHNOLOGIES

Rapid advancement in information sciences, materials sciences, and molecular biology mean that new technologies will be developed over the next 5 to 20 years in the areas of medical communications and record-keeping, imaging of body structures, surgical techniques, prosthetics, organ and tissue implants and transplants, pharmaceuticals and family planning assists.

Computers and Communications

Knowledge about health care has proliferated because of better monitoring of bodily systems and the environment. Computers have greatly improved the collection, measurement and analysis of statistics on disease occurrence, outcomes of treatment, and research results. This knowledge has changed the direction of research and development.

Reporting surgical results was common practice as far back as the 16th century,[2] but until recent decades other treatment outcome measures were largely limited to indicators of patient satisfaction, postoperative infection rates and numbers of malpractice suits. Computers have encouraged expansion of data about results of therapy, and thus assessment of the effectiveness of treatments.[3] New disease trends now may become evident much quicker, an important factor in public health programs.

Computers enhance the efficiency of laboratory research by saving labor costs in processing, storing and analyzing diagnostic tests results. Expert systems are used to help in diagnosis and in designing therapies. Computers analyze and model bodily systems and processes such as skin blood flow, to determine the best locus for amputations.[4] With computers, scientists simulate the immune system and thus search for the basic principles governing complex systems. This in turn can lead to future medical breakthroughs.

Outside the laboratory, computers can by integrating medical and financial data, allow cost-benefit analysis of various treatment possibilities to develop models for more efficient allocation of health care resources. Computers are also an essential component in nearly all new medical instruments. Older sensors could aid the physician in perceiving conditions within the body, but today's enhanced medical sensors can also measure, correlate, analyze and store information. Computers are also used to design instruments, analyze equipment failure, and repair equipment.[5] In scanners such as the CAT (computer-aided tomography), the computer provides valuable information, but in two dimensional form which is easily interpreted by radiologists but less appropriate for surgeons. Computer graphics, however, can create three dimensional images that are more easily usable for appreciating special relationships and rectilinear measurements.[6]

Telecommunications technologies may in the future facilitate the delivery of health care to rural and remote areas difficult to service with health professionals. Information, imaging, and patient monitoring systems can integrate remote areas with regional hospitals.[7]

Beyond these new or developing uses of computers, there may be new kinds of computers for medical use. Bio-computers made of proteins and other molecules may someday be developed. These minute, fast machines would be invaluable in medical research and medical care. The technical bases for such biocomputers already exist or are being developed by molecular biologists, physicists, and computer scientists.[8]

Imaging Technologies

Imaging technologies can analyze bodily tissue and body chemistry, monitor bodily functions and diagnose disease. Computerized axial tomography (CAT) scanners and position emission technology (PET) have already produced more knowledge of normal and pathological functions than could have been imagined a few years ago. PET can scan the brain without invasive surgery, reveal biochemical reactions taking place, show the response of

[1] Richard Cales and Donald Trunkey, "Preventable Trauma Deaths," *JAMAU*, vol. 254, No. 8, Aug. 23-30,2985, p. 1062.

[3] Clement Bezold, "Health Trends and Scenarios," in Jack A. Meyer and Marion Ein Lewin (eds.), *Changing the Future of Health Care* (Washington, DC: American Enterprise Institute for Public Policy Research, 1987), p. 84.

[4] Veterans' Administration, *Rehabilitation R&D Progress Reports* (Washington, DC: Veterans Administration Medical Center, 1986), p. 11.

[5] Murray Eden, "Smart Instruments, Microprocessors, and Personal Computers," *International Journal of Technology Assessment in Health Care,* vol. 3, 1987, pp. 327-330.

[6] Michael W. Vannler and Jeffrey L. Marsh, "3D Imaging Aids Skull Surgeons," *Computer Graphics World,* vol. 8, December 1985, pp. 49-50, 52-55.

[7] Chris Higgins, Earl Dunn, and David Conrath, "Telemedicine: An Historical Perspective," *Telecommunications Policy*, vol. 9, December 1984, pp. 307-313. In the early 1900s heart tracings were successfully sent via telegraph lines by Einthoven, the developer of the electrocardiogram, for analysis at a far-off laboratory site. Various combinations of television and telephone systems have successfully provided service to Indian reservations, jails, and remote areas of Alaska. Their use has generally been constrained because of high costs rather than technical inadequacy.

[8] Michael Conrad, "The Lure of Molecular Computing," *IEEE Spectrum,* October 1986, pp. 55-60.

a tumor to drug treatment, evaluate changes due to stroke, and observe the lesions causing Parkinson's disease, Alzheimer's disease, and perhaps schizophrenia. Magnetic resonance imaging (M RI) reveals not only bodily structures but even chemical processes within individual cells. It can measure blood-flow rates from specific locations in the brain (to predict possible strokes), and drugs such as antidepressants could be labeled with MRI-sensitive compounds and traced within the brain.[9] In the future, this capability will supplement, and could even replace in some situations, more subjective modes of diagnosis of mental illness. This could introduce into the constitutional debate new arguments regarding responsibility for behavior.

The increased knowledge about health raises the long range possibility of conflicts over response to that knowledge. For example, imaging equipment shows clearly the arterial plaque build-up often responsible for heart attacks, much of which, scientists believe, might be avoided by appropriate diet. This has led to development of plaque-dissolving drugs for cleaning out arteries and ridding kidneys of stones. But not all problems revealed by new medical technologies can be resolved by still more new technologies. In that case, social controls are sometimes proposed. Some people argue, for example, that those who eat irresponsibly (thus filling their arteries with plaque) are costing society too much in terms of heath care and thus should perhaps be discouraged from doing so, perhaps by higher health insurance premiums.

Surgery, Prothesis, and Trauma Repair

Trends in surgical practice point to continued development of less invasive and destructive surgery. This is illustrated by balloon angioplasty, the use of stereotaxic headpieces in brain surgery, the *use* of lasers rather than scalpels in many areas of surgery, and microsurgery. Surgical instruments made with fiberoptics permit looking directly into internal structures of the body; combining lasers and fiberoptic allows more sophisticated repair and less destructive removal of diseased tissues, and more sophisticated neurological procedures. New microsurgery techniques together with immunological advances may eventually allow the restitching of severed nerves or spinal cords.[10]

These procedures and instruments make surgery safer, less traumatic and less fearsome to the patient, and more effective. More surgery can now be done on an outpatient basis. The added safety may mean that more surgery will be done in the future, and more radical procedures will be attempted. This may well aggravate current debate about when physicians should and should not intervene to prolong life, and about who has the right to refuse such interventions for themselves or for others. The development of fetal surgery to correct abnormalities before birth is, for example, already raising constitutional issues.

Some scientists suggest the possibility of limb regeneration and of synthesis of organic tissues.[11] In the meantime, models created from computer scans aid in the design and production of prosthetics. Research engineers hope someday to develop cybernetic devices—building on advances in robotics, artificial intelligence and sensing systems—that will permit paraplegics to walk, blind people to see, and deaf people to hear. This could include electronically assisted and controlled artificial

[9] Lawrence Galton, *Med Tech (New York, Ny: Harper & Row, 1985),* pp. *286-303.*

[10] **Angioplasty** is surgical reconstruction of the blood vessels, in which a balloon catheter is inserted into a blood vessel and inflated to flatten plaque against the wall of the blood vessel. The **stereotaxic** headpiece is a metal framework surrounding the patient's head to allow precise, minimal invasion of the brain for biopsy, removal of tumors, and so on. Laser surgery, using a cutting and cauterizing ray rather than a blade, minimizes bleeding and swelling, allows spot-welding of detached retinas, and reduces incidental injuries to healthy tissue. Microsurgeons use high-powered microscopes, extremely thin needles, and miniaturized instruments to reattach nerves and veins, reconstruct the middle ear, reroute arteries, and perform other extremely delicate repairs, even in some cases on fetuses in the womb. Henry C. Adler et al., *Meditrends* (Chicago, IL: The Hospital Research & Educational Trust, 1986), p. 26.

[11] **Replacement skin** from human cadavers has been successfully transplanted to a burn victim with the aid of the anti-rejection drug, cyclosporine. See "Harvesting New Skin," *Science* 86, vol. 7, April 1986, p. 9.

limbs or limb supports, arms and hands that move in response to neural impulses, hand-held human-like voice synthesizers, and TV cameras implanted in eyes. Computerized electromyographic (EMG) feedback is being studied for the purpose of restoring function in persons with long-term spinal cord injury .12

A new class of materials, bio-ceramics, shows great promise in prostheses. Bone will grow into and unite with one class of ceramics for firm fixation of teeth and artificial joints to the surrounding tissues, an innovation that promises new opportunities for patient rehabilitation.[13]

Further medical technologies being developed for the care of traumas include:

- Artificial blood for use in treatment of chronic blood disorders and emergency treatment for traumas, particularly desirable to prevent transmission of diseases such as AIDS and hepatitis, is currently at the stage of basic research, although many problems are still unsolved.
- Dry curing of burns to eliminate serious infection is undergoing human experimentation.
- Artificial skin and drugs to control rejection are being perfected.
- Phototherapy or light treatment for a variety of health problems including psoriasis, sleeping disorders and apneas, radiation-related diseases, etc., is now at the basic research stage.
- A diapulse device for promoting healing of damaged nerves and spinal injuries is at the stage of animal experimentation.
- Treatment of damaged spinal cord nerves through bombardment of cells with electrically charged silver ions is being studied by scientists.

Transplants and Implants

The transplantation of hearts and kidneys is no longer considered experimental, although still risky and severely limited by the scarcity of donors. Transplants of livers are still experimental. The use of artificial organs, such as the artificial heart, is also highly experimental and at present beset with serious and seemingly intractable problems. Yet a number of trends are working together to increase the feasibility of organ replacement with either real or artificial organs:

- gradual improvement in surgical techniques and in preservation of organs and tissues;
- developments in pharmacology, and especially in immunosuppressive, anti-rejection therapy;
- rapid advances in materials technology, including submolecular and surface engineering;
- development of sensors that can send feedback to control movement of muscles;
- development of miniature nuclear power packs; and
- computerized registry and matching of potential organ donors and recipients.

Implantation of either human organs or artificial organs may become more practical by the end of the century. Cryogenic techniques could be developed for preserving organs for later use; or organ incubators with computerized chemical baths and solutions may allow organs to be preserved for months.[14] pancreatic cells have been frozen, thawed, and grafted onto the kidneys of diabetic rats where they produced insulin; scientists will attempt to develop this technique for use in humans.[15]

Transplants of neural-type tissue from a Parkinson's patient's adrenal medulla to his brain have been performed in Sweden and Mexico, and brain tissue transplants using fetal brain tissue to assist patients with Parkinson's

[12] Veterans' Administration, *Rehabilitation R&D Progress Reports* (Washington, DC: Veterans' Adrninistration Medical Center, 1986), p. 11, p. 66.

[13] John W. Boretos, "Bioceramics," *Chemtech*, *vol.* 17, April 1987, p. 224.

[14] Arthur C. Clarke, *July* 20, 2019, (New York, NY: MacMillan Publishing Co., 1986), p. 238.

[15] Shawna Vogel, "Cold Storage," *Discover,* February 1988, pp. 52-54.

disease have been done in Mexico and elsewhere." As discussed in chapter 4, this procedure has been discouraged in the United States because of some ethical concerns. Further development of these medical procedures and techniques outside of the United States is likely to stimulatec hallenges to Federal and State regulation or prohibition.

Implants of microchips and biochips may in the future allow better monitoring of bodily functions, regulate drug delivery devices, enhance defective sight or hearing, and provide neural control of damaged limbs. Some scientists hope that eventually "biological machines" could be implanted to repair human tissue and organs.

Advances in biological and non-biological materials and in microelectronics hold the promise of significant advances in related technologies, such as the following:

- programmable implantable medication systems including infusion pumps, for use in treatment of such problems as diabetes and cardiovascular disease; some are now in clinical trials;
- implanted electrodes and brain peptide releasers, for treatment of depression, propensity to aggression, and other emotional disorders;
- implanted electronic hearing aids;
- cerebella pacemakers for control of epilepsy, chronic pain, schizophrenia, and violent behavior;
- automatic defibrillator for assisting damaged hearts; and
- artificial visual implants or assists and image enhancers for the visually impaired.

Pharmaceuticals

Breakthroughs in pharmaceutical products and delivery systems promise radically different medical treatments for many illnesses. Drugs are being developed that act closer to the disease site and are specific to the damaging side effects of older untargeted treatments. Entirely new types of therapeutic agents are being developed, some both more potent and more natural to the body than conventional pharmaceuticals.[17] Some possibilities are:

- Immunomodulators-These maintain proper functioning of the immune system, without the problems associated with current cell-killing drugs. New treatments would involve the use of natural substances such as interferon, to modif y specific functions in the body. These immunomodulators will be used, first, as therapy for immune deficiency diseases and to suppress the immune system for grafting and transplanting organs, then to enhance the natural killer cells to attack new cancers and other diseases.
- Neurotransmitters-Scientists are becoming more familiar with the activities of these materials and new and more effective treatments should follow for Parkinson's disease, Alzheimer's disease, amyotrophic lateral sclerosis (ALS), Huntington's disease and mental diseases caused by neurotransmitter deficiencies. Some pharmaceuticals to enhance or prolong memory are already being tested.
- Neurotrophic hormones–It is hoped that neurotrophic hormones may stimulate growth in dying nerve cells that produce the transmitters. Research to identify neurotrophic hormones will probably be followed by large-scale synthesis and treatment. Drugs capable of penetrating the blood-brain barrier could treat loss of function in the neocortex due to severe head injury.
- Mood-altering drugs—These drugs have been found to exist naturally in the body as a class of compounds made up of endorphins and enkephalins. Many functions have been attributed to these materials including acting as a pain-blocking analgesia, tranquilizer, and antidepressant. Opiate blockers can be used to modify such behaviors as overeating and aberrant sex

[16]"Brain Graft Revives Sufferer From Parkinson's Disease," New *Scientist,* Jan. 14, 1988, p. 28.

[17]William Check, "New Drugs and Drug Delivery Systems in the Year 2000," *American Pharmacy*, vol. NS24, No. 9, September 1984.

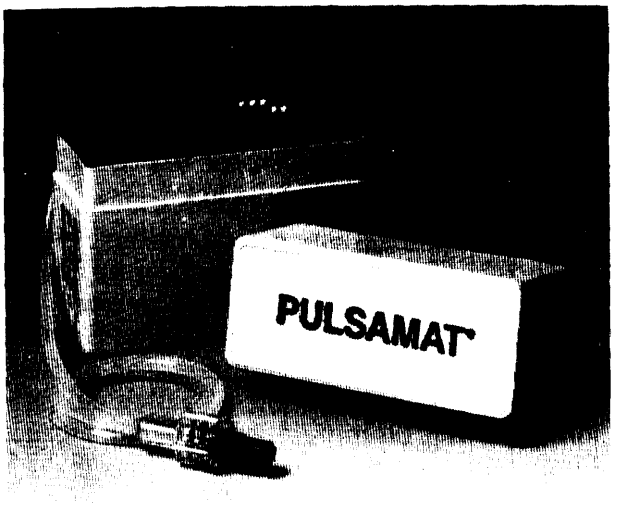
drives. These substances, being natural to the body, may not be addictive and may eliminate the side effects of current "mood elevator" and other drugs.

- Monoclinal antibodies-These products of genetic engineering have opened up a wealth of new therapeutic possibilities, such as cancer chemotherapy in which the cell-killing drugs would attack only the cancer-causing cells in the body. Toxic chemicals attached to the antibodies would then seek out cancerous cells before being activated. Monoclinal antibodies may also be used to kill donor cells that cause lethal conditions in bone marrow transplantations. They can be made to react with infectious bacteria against which antibiotics have not been successful. They can be designed to behave as enzymes, catalyzing chemical reactions and opening up the possibility of unlimited diversity in specific-acting enzymes. *8
- Prostaglandins-A natural substance in the body, synthesized prostaglandins can be used as anticlotting agents useful in heart bypass surgery, prevention of heart attacks through clot prevention, and treatment of asthma, ulcers and inflammation.
- Vaccines—Synthetic vaccines that confer multiple protection could be used for influenzas. Viruses that cause cold sores, genital herpes, chicken pox, etc., could be attacked with new vaccines.

New delivery systems may have nearly as momentous effects on medical care as new pharmaceuticals themselves do. Especially important will be the controlled release of drugs at dosages and times that are needed. New materials used for coating will release drugs at a constant rate through degradation, permeable membranes and electric charges. Magnetic systems can be used for pulse-released drugs such as immunosuppressants for transplant patients and implanted pumps will deliver precise dosages for treatment of cancer and for delivery of insulin. (See figure 6-l.) Dosages

[18]See ch. 3 for a more detailed description.

Figure 6.1 .—Portable Infusion Pump



Infusion pump is worn continuously and delivers gonadotropin releasing hormone intermittently either subcutaneously or intravenously.

SOURCE" Ferring Laboratories, Inc., Suffern, NY, 1988.

can be altered with time and, as equipment becomes smaller and simpler, can be used by patients to provide their own chemotherapy at home. Another form of delivery system will be sprays.

Reproduction Technologies

For those wishing to have children, the possibilities of technological help have recently been greatly increased. These new assists are not always successful, and many carry significant risks and high costs. They include fertility drugs; artificial insemination using the semen of the husband, a selected partner, or an unknown donor; and in-vitro fertilization using either both parents' germ cells or donated eggs and/or semen, with implantation in the uterus of either the biological mother or a surrogate mother. Sperm freezing techniques permit an increase in the number of donors and theoretically make possible the selection of specific genetic characteristics for the babies. Frozen embryos have increased the ease and success rate of in-vitro fertilization and implantation, but raised ethical issues regarding the use of "excess" or left-over embryos.

For those wishing to curtail production of a family, technologies will also provide choices: injectable contraceptives, a contraceptive vaccine, intrauterine devices for preventing embryo implantation; and non-surgical sterilization.

These "technologies at the beginning of life" promise to raise a number of serious constitutional issues, which are discussed in later sections of this chapter.

Science fiction abounds with stories about chimeras and clones. Chimeras are animals with the genes—and characteristics-of two or more species; in Greek mythology the chimera was a beast that had the head of a lion, the body of a goat and the tail of a serpent. Clones are animals genetically identical to a parent, i.e., reproduced asexually, or to a sibling (when an early stage embryo is divided and reimplanted). These have until recently been considered in the class of fairy tales. But large animals such as valuable cattle are now produced in multiple identical copies by removing a fertilized egg after two cell divisions, dividing it and allowing each fragment to begin cell reproduction again, and implanting each new embryo in the womb of a less valuable brood cow. Chimeras have been developed by placing foreign genes in animals as complex as mice. A series of experiments have produced healthy chimeric mice by implanting in the uterus of a mouse, differentiated cells found in tumors. The interesting issue here is that what were thought to be undifferentiated cells in a tumor, actually contained a variety of tissues-tooth, bone, gland, etc.—from which could be grown an entire animal.[19]

It now appears unlikely that human clones or chimeras will be developed, although the barriers are in the long-run apt to be ethical and political rather than technical. The evolution of this capability could nevertheless result in production of body tissues, or new body parts, and at least in theory could allow unisex pregnancy and childbearing, even by males.

[19] KarlIllmenseeand Leroy C. Stevens, "Teratomas and Chimeras, " *Scientific American*, vol. 240, April 1979, pp. 120-132.

TRENDS SHAPING THE FUTURE OF MEDICAL TECHNOLOGY

Important trends that are emerging in regard to new and future medical technologies *are:*

1. an explosive increase in knowledge about the biology of disease, the environment, bodily functions and new treatments;
2. earlier diagnosis and treatment, increasingly moving beyond control of symptoms to interventions that will prevent symptoms;
3. an ever larger attention to the costs of health care in choices of treatment and in development of new technologies; resulting in an important role for technology assessment;
4. growing capability to maintain basic bodily functions technologically, when neurological control is degraded or almost entirely absent;
5. a proliferation of techniques to assist, control, or avoid reproduction; and
6. growing ability to evaluate, diagnose, and give medical or surgical treatment to the fetus in the womb.

Some of these themes, and particularly the last three listed above, promise to raise complex ethical, political, legal, and constitutional issues.

Earlier and More Effective Diagnosis, Intervention, and Prevention

Intervention in the disease process can vary from consumer education on diet and lifestyles, to genetic engineering and drug therapy. The shift from controlling symptoms to more positive intervention is the result of a circular interaction between new scientific knowledge,

new instruments, and treatment-enabling technologies that in turn produce further knowledge. Earlier diagnosis and prevention of disease are of particular importance in approaches to chronic illnesses, which constitute the major illness burden in industrialized nations. They will, however, also affect acute illnesses in which genetic, behavioral and environmental factors can be identified.

Prevention of disease itself carries a potential for clashes between the general welfare and the assertion of individual rights, as illustrated by AIDS containment and crusades against tobacco use. As knowledge of disease-causing behavior, aversion to risk, and the incentive to control health care costs all grow, some people are arguing that freedom to indulge in unhealthy behavior should be curtailed. This issue was introduced in chapter 5 as raised by public health programs.

Self-Care

New technologies, while causing some of this rapid increase in costs, also enable more people to take care of themselves when ill, thus potentially reducing health care costs. Home-based computers linked with diagnostic-treatment centers or implanted microchips for sensing body conditions and for release of drugs, could for example make possible self-administered chemotherapy treatment of cancer. Intravenous physical and respiratory therapy and monitoring of chronic disease could take place in the home.

A strong trend toward self-diagnosis, self-care, and home-care techniques has been evident for some time. Pregnancy test kits, kits for testing or measuring urine sugar content, and consumer instruments for monitoring blood pressure have already become familiar. Further home diagnostic tests are being developed. Implantable time-released medication is already in use for some conditions. Some experts anticipate the development of "hospitals on the wrist," i.e., wearable devices that monitor certain body functions and make chemotherapeutic and electromagnetic adjustments as necessary. Potentially, this might include administering mood-altering or behavior-controlling medication.

Public policy problems with the trend toward self care include the cost, which is not currently reimbursed by medical insurance providers, the question of the reliability of tests and the expertise needed for their use, and concern about the provision of home care for those who are unable to care for themselves adequately. These problems do not appear to imply any constitutional issues.

The Growing Importance of Health Care Costs

The cost of medical care is an important ingredient in a discussion of health care technologies and their constitutional implications. Health care in 1985 accounted for 11.2 percent of gross national product, up from 5.9 percent in 1965. Health cost increases far outstrip inflation and although they have lessened, they still outpace price increases of other goods and services. This growth is expected to continue, reaching 15 percent of GNP by the turn of the century.'" In 1985 and 1986 the growth in the number of surgical procedures performed, which had flattened since 1981, resumed.

The health care system is being reshaped as joint ventures proliferate between hospitals, physicians and other investors; the role of market forces becomes more important in technology choices; and consumers and payers of health care demand more say in the process.[21] As costs become a major factor in health care, medical decisions are no longer the sole prerogative of physicians.

While some technologies such as expert systems and diagnostic testing kits can potentially decrease health care costs, others such as imaging machines and transplants are likely to remain very expensive. Technology has been called both the culprit in raising medical costs,

[20] Daniel R. Waldo et al., "National Health Expenditures, 1985," *Health* Care *Financing Review,* Fall 1986, vol. 8, No. 1, pp. 1-21. Also see "National Health Expenditures, 1986-2000," *Health Care Financing Review,* vol. 8, No. 4. Figures for 1987 obtained by telephone from Daniel Waldo, February 1988.

[21] *Meditrends*, footnote 10, p. vii.

and the benefactor that is improving health and life expectancy .22 Even when new, less costly technologies are developed, the rate of use often increases, offsetting potential savings. And increased knowledge regarding health hazards in the environment is likely to increase the demand for health care, including research and product development. How the change in hospitals from an altruistically oriented local industry to a for-profit national chain industry affects health care costs is not yet clear, but this could become an important issue in the future.

While this report cannot explore in depth the issue of medical costs, governmental policy toward medical advances that provides some with great benefits, at high cost to others than the beneficiaries, is part of the general constitutional discussion on equality of access and of the alleged right to treatment.[23]

[22] Louis P. Garrison, Jr., and Gail R. Wilansky, "Cost Containment and Incentives for Technology," *Health Affairs*, vol. 5, Summer 1986, pp. 46-58.

[23] For a discussion of the economies of the distributional issues and the criterion of social welfare, see John H. Doggeeris, "Medical Insurance, Technological Change, and Welfare, *Economic Inquiry*, vol. XXII, January 1984, pp. 56-67.

EXTREME MEDICAL INTERVENTIONS AND THE EXPANDING LIMITS OF PERSONAL CHOICE[24]

Some of the major "medical miracles" recently unveiled or now on the horizon so fundamentally challenge our assumptions about human limitations that they may change our view of the proper relationship between the State and the individual, or of personal liberty and responsibility.

Taking the heart from a person whose circulation and respiration could be maintained only with a mechanical ventilator, and transplanting the heart into another person, directly challenged laws that conventionally determined death as the time when one's heart stopped beating. A strict application of this legal definition would make a human heart transplant a double homicide, in spite of the fact that its purpose is to save life. This technological innovation helped to force us to reach a new definition of death—the death of the brain.

A person who is dead ceases to have constitutional rights. Thus before the redefinition of death, a person on a mechanical ventilator, even if "brain dead," was a person and retained all of the rights of a person under the Constitution; after the redefinition, the person in identical circumstances was a corpse with no rights, and could be used as a source of donor organs with or without his or her intent prior to death. This redefining of death was brought about primarily by three technologies: the electroencephalogram, which permitted physicians to confirm the absence of brain activity or functioning; mechanical ventilation, which maintained circulation until vital organs could be "harvested"; and immunosuppression drugs, which help control rejection and made organ transplantation workable.[25]

The law permitted physicians to develop this new definition of death on their own, because the law has always been that a person is dead when the doctor pronounces him or her dead, provided that the doctor make this pronouncement on the basis of "good and accepted med-

[24] Much of the material in this section is based on contractor reports: "Constitutional Issues in Extreme Medical Measures at the Beginning and End of Life," prepared for OTA by George J. Anus, J. D., M. P. H., Utley Professor of Health Law, Boston University Schools of Medicine and Public Health, and "Constitutional Implications of Scientific and Technological Advances in Public Health, prepared for OTA by Dr. Leonard H. Glantz, Professor of Health Law, Boston University Schools of Medicine and Public Health, April 1987.

[25] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Defining Death (Washington*, DC: U.S. Government Printing Office, 1981). G.J. Anus, "Defining Death: There Ought To Be A Law, *Hastings Center Report*, vol. 13, No. 1, 1983, pp. 20-21.

ical standards. "[26] Some people have objected to having this standard developed by the medical profession because they object to giving physicians the first opportunity at defining the implications of new medical technology for basic rights.

The adoption of brain death as an acceptable criteria for human death raises further questions: Is brain functioning a necessary or appropriate criteria for life, or for personhood, or for rights? Do those who are born without functioning brains, e.g., anencephalic neonates,[27] have any rights?[28] What about those who are permanently comatose? If science can develop a test that confirms the irreversible loss of all higher brain functions, (neocortical), could brain death be expanded to include this category as well?[29]

Most medical technologies will not so radically alter the rights of individuals in this "all or none" fashion. But many of them have potentially profound impacts on the definition or application of critical constitutional rights because they affect life, death, procreation and privacy. For example, evolving technical capabilities to assist and support reproduction give rise to questions about the individual rights of the mother and the interest of the State in the welfare of the potential or developing fetus.

The development of the judicial concept of privacy was described in chapter 2. To recapitulate, the Supreme Court has concluded that the rights specifically protected in the Bill of Rights and buttressed by the Fourteenth Amendment delineate a penumbra of privacy, or a sphere of autonomy and confidentiality, on which government should intrude only when impelled by an important and pressing interest of State.

The concept of constitutional privacy has been applied most directly to individual decisions about reproduction. The old deference to the State interest was indicated in chapter 4 and again in chapter 5 by reference to the case of Buck v. Bell, in 1926,[30] which upheld the constitutionality of a State's involuntary sterilization statute. Justice Holmes said: "The principle that sustains compulsory vaccination is broad enough to sustain cutting the Fallopian tubes. . . ." But in a very similar case in 1942, the Court specifically affirmed that marriage and procreation were fundamental rights, essential "to the very existence and survival of the race. "

Griswold v. Connecticut,[31] in 1965, was however the real landmark case in this area. A State statute made it illegal for "any person" to "use any drug, medicinal article or instrument for the purpose of preventing conception. . . ." The statute also made it a crime to "assist, abet, or counsel" any person in committing this illegal act. A Planned Parenthood counselor and a physician gave advice on birth control to a married couple and prescribed a contraceptive device for the wife; they were then arrested and convicted.

The Supreme Court, in overturning the State statute, said, "We do not sit as a super-legislature to determine the wisdom, need, and propriety of laws. . . ." But it also said that taken as a whole, the Bill of Rights creates penumbral rights of "privacy and repose, " in other words, a sphere of personal choice in which government has no business.

The Court was recognizing that modern science and technology-in this case, biological science and contraceptive technology-create new choices for people in their personal lives, and that government would at times attempt to regulate or negate those choices by controlling (or banning) the use of the technology, especially if this seemed essential for the general welfare. The Court said:

> The present case, then, concerns a relationship lying within the zone of privacy created

[26] G.J. Anus, L.H. Glantz, B.K. and Katz, *The Rights of Doctors, Nurses, and Allied Health Professionals (New* York, NY: Avon Publishing Co., 1981).

[27] A newborn infant with an incomplete and non-functioning brain.

[28] A. M. Capron, "Anencephalic Doners: Separate the Dead From the Dying, *Hastings Center Report,* vol. 17, No. 1, 1987, pp. 5-9.

[29] R. Veatch, *Death, Dying and the Biological Revolution (New* Haven, CT: Yale University Press, 1976).

[30] *Buck v. Bell*, 274 U.S. 200 (1926).

[31] 381 U.S. *479 (1965).*

> by several fundamental Constitutional guarantees. . . .Would we allow the police to search the sacred precincts of marital bedrooms for telltale signs of the use of contraceptives? The very idea is repulsive to the notions of privacy surrounding the marriage relationships.

Three Justices concurred that the right of marital privacy is a "fundamental and basic" personal right but gave as the source of that right the Ninth Amendment.[32] Seven years later the Court extended the right of "reproductive privacy" to unmarried persons.[33] The Court said in that case:

> If the right of privacy means anything, it is the right of the individual, married or single, to be free from unwanted governmental intrusion into matters so fundamentally affecting the person as the decision whether to bear or beget a child.

The decision specifically rejected arguments that the State was attempting to regulate potentially harmful articles, because as between married and unmarried people "the evil, as perceived by the State, would be identical. " This indicated that the Court will closely scrutinize State interference into areas of life which are considered "private."

The Court has been strongly influenced in cases involving contraception and abortion by advances in medical technology. Improvements in medical technology have allowed individuals safer and more effective control over reproduction, and at the same time have tended to undercut the State interest so far as that interest was traditionally based on the safety of the mother.

This was made clear by the abortion decisions, *Roe v. Wade* and *Doe v. Bolton*[34] both in 1973. The first involved a statute making it illegal for a physician to perform an abortion even if a woman's life was endangered by pregnancy. The Court recognized that the right of privacy is "broad enough to encompass a woman's decision whether or not to terminate her pregnancy." This right, while not absolute, is "fundamental" and may be infringed only if there is a compelling State interest.

The State claimed two such interests: preserving the life of unborn children and protecting maternal health. The Court rejected the latter interest because with new medical technology, abortion during at least the first trimester carries less risk to the mother than childbirth. After the first trimester, the Court said, the State could "regulate the abortion procedure to the extent that the regulation reasonably related to the preservation and protection of maternal health, " but could not prohibit abortion. At the point of fetal viability (when the "fetus could live outside the mother's womb, albeit with artificial aid") the State could prohibit abortion because its interest in the potential life becomes compelling. Even then, the State could not prohibit abortion when it was necessary to preserve the life or health of the mother.

The second of the two 1973 abortion cases concerned State requirements that all abortions take place in hospitals accredited by the Joint Commission on Accreditation of Hospitals. The Court could have chosen to apply a "minimum rationality" criteria and accepted the State's authority to regulate in the interest of public health. Instead it recognized persuasive data about the technology, indicating that facilities other than hospitals could safely perform abortions. It found that the State was attempting to regulate abortions during the first trimester of pregnancy contrary to the earlier Roe decision.

Since 1973 the Court has heard a number of cases involving restrictive abortion statutes,

[32] In Justice White's concurring opinion it is noted that the State claimed to ban the use of contraceptives in order to discourage all forms of illicit sexual relations, premarital and extramarital. Because he could find no rational relationship between the use of contraceptives by married couples and the legitimate policy of discouraging illicit sexual activity, Justice White found that the law violated the Fourteenth Amendment right to liberty.

[33] *Eisenstadt v. Baird*, 405 U.S. 438 (1972). The statute at issue authorized prescription of contraceptives for married persons, made it illegal to prescribe or sell contraceptives to unmarried persons, but permitted both married and unmarried persons to obtain contraceptives if the purpose was to prevent disease rather than to prevent pregnancy.

[34] *Roe v. Wade*, 410 U.S. 113 (1973) and *Doe* v. *Bolton*, 410 U.S. 179 (1973).

scrutinizing them closely for potential infringement on the right of privacy. Some of these decisions involved points related to the safety of advanced technology .35 A recent case indicated that the Court will look closely not only the legislature's rationale for legislation but also at the motive in passing it.[36]

These decisions illustrate the relationship between new technological capabilities and pressure for reexamination of constitutional provisions. New abortion methods—safer to the mother and less costly than old methods—increased the demand for abortion and at the same time undercut one rationale for the State's interest in prohibiting it, i.e., the safety of the mother, by making early abortion statistically safer than childbirth. (Continuing political support for prohibition of abortion indicates that this rationale was not the only, or perhaps even a primary, reason for the State's position.) With medical technology now moving back the point of fetal viability, it may again encourage or at least support reexamination of the Court's position, for example, by eventually challenging the assumption that the second-trimester fetus could not survive. Indeed, "artificial wombs" could someday make it possible for all or most of gestation to take place outside of a mother's body. On the other hand, and probably sooner, progress in medical technology could make second- and third-trimester abortions as safe or safer for the mother as either natural childbirth or cesareans. In the long run, therefore, any definition of the interest of the State that is grounded on an assessment of technological capability will be subject to challenge and reinterpretation.

The full scope of activities that the Court will consider to fall under the rubric of the fundamental right to privacy is not yet clear. The Court has applied it to the distribution of contraceptives,[37] to the possession of obscene materials in one's own home,[38] and to prohibitions on interracial marriages.[39] State Supreme Courts have extended this right further: as a basis for individuals to refuse life sustaining medical care, or for their families to refuse it on their behalf,[40] to refuse antipsychotic medications,[41] and to obtain acupuncture treatments without State interference.[42]

On the other hand, the Supreme Court has refused to strike down a law that outlawed consensual sodomy,[43] saying that where no fundamental privacy right was implicated (implying that the right does not cover all forms of sexual activity per se) the State needs only show 'a rational basis for the law. " The "presumed belief of a majority of the electorate in Georgia that homosexual sodomy is immoral and unacceptable" provided that rational basis. Dissenters on the Court said that the issue is the right "to conduct intimate relationships in the intimacy of his or her own home. "[44] It appears that the scope of the constitutional right to privacy as regards the body and its reproductive functions is still being defined by the Court.

Another marital privacy issue is suggested by the recent action of a judge of the Arizona Superior Court in sentencing a woman to life-

[35] *Planned Parenthood of Missouri v. Dan forth, 428 U.S.* 52: A State prohibition of the use of saline amniocentesis for abortion after the first semester, based on the argument that alternative methods such as prostaglandin instillation were safer, was struck down because saline amniocentesis was an acceptable procedure, the alternatives were less readily available, and more hazardous techniques such as hysterectomy were allowed. Thus the prohibition was "an unreasonable or arbitrary regulation designed to inhibit . . ." abortion. *Akron v. Akron Center for Reproductive Health, 462* U.S. 416,433 (1983): a statute requiring hospitalization for all abortions after the first trimester was struck down as merely an attempt to place "a significant obstacle" in the path of those seeking abortions; the Court recognized continuing improvement in safety of second trimester abortions.

[36] *Thornburgh* v. *American* College *of Obstetricians and Gynecologists*, 106 S. Ct. 2169 (1986). See L. Glantz, "Abortion and the Supreme Court: Why Legislative Motive Matters, " *Am. J. Pub. Health,* vol. 76, 1986, p. 1452.

[37] *Carey v. Population Services International, 431* U.S. 678 (1976).

[38] *Stanley v. Georgia, 394* U.S. 557, 564 (1969).

[39] *Loving* v. *Virginia*, 338 U.S. 1, 12 (1967).

[40] In the case of Karen Quinlan, for example, 355 A. 2d 647 (N.J. 1976); also *Superintendent of Belchertown v. Saikewicz, 373* Mass. 728 (1977).

[41] *Rogers* v. *Okin*, 390 Mass., 489).

[42] *Andrews* v. *Ballard*, 498 F. SUpp. S.D. Texas (1980).

[43] *Bowers* v. *Hardwick*, 106 S. Ct. 2841 (1986). The law was so written that it applies to married and single persons, and to both heterosexual and homosexual behavior. The challenge was brought by a homosexual male.

[44] *Blackmun*, dissenting, 2848, 2853.

time probation and ordering her to maintain birth control throughout her childbearing years. At about the same time a judge in Indiana, sentencing a woman for the death of her child, suggested that he would significantly reduce the sentence if she agreed to surgical sterilization. There were immediate indications that both of these sentences would be appealed on the grounds that they violate the constitutional right to privacy .45

[45] Mother Who Deserted Her Infants Is Ordered To Stay On Birth Control, " *New* York Times, May 26, 1988. "Is Sterialization the Answer: A Controversial Punishment for Abusive Mothers, " *Newsweek*, Aug. 8, 1988, p. 59.

MEDICAL INTERVENTIONS AT THE BEGINNING OF LIFE

Modifications in the mode of human reproduction have long been the stuff of science fiction. For example, in George Orwell's 1984,[46] artificial insemination by donor was mandatory, and in Aldous Huxley's Brave New *World*,[47] reproduction was the exclusive domain of the State, and embryos were produced and monitored in artificial uteruses in government-run "hatcheries. Much more recently, Margaret Atwood in *Handmaid's Tale*[48] pictured a nation in which most women are sterile, but a lower caste of "handmaids" bear children for the ruling class as surrogate mothers, "two-legged wombs. . . ambulatory chalices. "

The Supreme Court has yet to consider whether there are constitutional issues involved in human reproduction via the new "noncoital" reproductive technologies that permit reproduction without sexual intercourse.

The Supreme Court has protected the right to use birth control outside of marriage. It has not expressly recognized a right to bear children outside of marriage, and in the *Bowers* case, the decision included a dictum to the effect that State laws against sexual activity outside of marriage were not precluded. Therefore it is uncertain whether there is a constitutional right to procreate, by either coital or non-coital means (i.e., through artificial insemination and/or in vitro fertilization), or whether such right, if it exists, extends to homosexual as well as heterosexual couples or individuals.[49]

Some experts, drawing analogies from court challenges associated with sterilization, contraception, and abortion, suggest that the concept of a "right to privacy" in procreation would be involved if government attempted to regulate or prohibit such technologies as in vitro fertilization (IVF) or the use of frozen embryos for implantation.[50] (See figure 6-2.)

Constitutional interpretation in this area has come to depend heavily on prevailing scientific views and on up-to-date assessments of technological capability and safety. The sterilization cases discussed above reflect the values of the eugenics movement of the first t wo decades of this century; after that period court decisions reflect new knowledge about genetics and newly available medical alternatives.

In Vitro Fertilization (IVF) and Surrogacy

IVF was developed to assist married couples who were unable to have children because the wives' fallopian tubes were blocked or diseased. The IVF method bypassed diseased fallopian tubes, removing ova from the ovaries through a surgical procedure, combining the

[46] George Orwell, *1984 (New* York, NY: Harcourt, Brace, 1949).

[47] Aldous Huxley, *Bravae New World (New* York, NY: Harper & Brothers, 1946).

[48] Margaret Atwood, *Handmaid Tale* (Boston, MA: Houghton-Mifflin, 1986).

[49] U.S. Congress, Office of Technology Assessment, *Infertility: Medical and Social Choices* (Washington, DC: U.S. Government Printing Office, May 1988), pp. 219-220.

[50] More radical or unlikely possibilities such as cross-species fertilization, extracorporeal gestation (embryos brought to term in artificial wombs), or cloning might become highly controversial at the R&D stage, raising the issue of the "right to experiment" or "forbidden knowledge, as discussed in chapter 4.

Figure 6-2.-Multicellular Embryo



Human embryo developing in vitro before transfer to female reproductive tract or cryopreservation.

SOURCE: Reprinted with permission. A A. Acosta and J.E Garcia, "Extracorporeal Fertilization and Embryo Transfer," *Infertility: Diagnosis and* Management, J Alman (cd.) (New York, NY: Springer Verlag, 19S4).

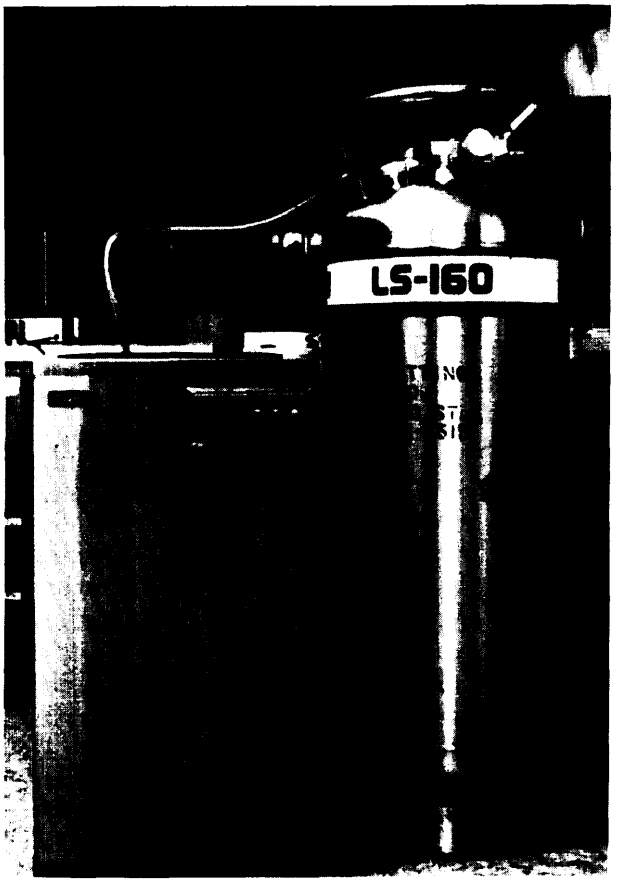
ova with the husband's sperm in a petri dish or test tube, and after fertilization and a number of cell divisions, transferring the embryo to the wife's uterus for implantation.[51] About 3,000 births have resulted from IVF in the United States in the past decade. IVF, at least as confined to married couples using their own gametes (ova and sperm) appears to raise only one possible constitutional issue: could a government prohibit the use of IVF?

This would presumably be based on the claim of potential harm to the embryo. If such legislation were based on an argument that IVF is "unnatural" and *therefore* "immoral" it might be challenged as a violation of the separation of church and State. Based on the precedent of *Roe v. Wade,* the embryo is not considered "viable" until it is implanted in a uterus and thus, at the petri dish stage, it would have no rights that would outweigh the right of the gamete donors to decide whether to use it or not for procreation. If complete extracorporeal gestation outside of the womb becomes a possibility, then it is possible that the Court would be challenged to reconsider this assumption, but to do so would invite a reexamination of some forms of birth control technology, which work by preventing implantation of fertilized ova in the womb. This would, however, imply that rights predate the individual, or that the egg and sperm have rights.

Another objection to IVF, however, is that usually more than one embryo is created in the process. Decisions must then be made about the use of "left-over" embryos—i.e., ones created but not needed after transplantation of one of the embryos is successful. Could the State prohibit or regulate secondary use, in which the embryo is frozen and donated to a sterile couple? (See figure 6-3.) If the alternative to secondary use is destruction or open-ended storage of the embryo, it is difficult to see what interest the State would assert. Could the State require the donation of excess embryos to some embryo bank to avoid destruction? Gamete donors might claim a property right to choose whether or not the frozen embryo is donated or might object to the State allowing their genetic offspring to be raised by others. Should the State forbid experimentation on the "spare" embryos? Could the gamete-producing couple object? In fact, nearly always more than one embryo is implanted in the womb of the potential mother, since the failure rate is high (as is, very likely, the failure rate for "natural" implantation), and "excess" embryos are sacrificed either naturally, by the body, or deliberately by medical intervention. The difficulty is that the more nearly scientific artifice approaches "natural" processes, the more it takes on some of nature's own profligacy with potential life. These intertwined issues are likely to be brought forward

[51] G.J. Anus and S. Elias, "In Vitro Fertilization and Embryo Transfer: Medicolegal Aspects of a New Technique To Create a Family," *Family Law Quarterly,* vol. 17, 1983, pp. 199-223.

Figure 6-3.—Cryopreservation of Human Embryos in Liquid Nitrogen Storage Chamber



SOURCE Martin M Qulgley Cleveland Cltnlc, Cleveland OH

in the near future and may or may not be argued as constitutional issues.

The capability of preserving the viability of an embryo through freezing also makes it easier to transfer it to a surrogate mother for gestation, rather than to the wife or egg donor. In this case IVF would be used to allow a couple to avoid pregnancy altogether and yet have a child with the genes of both.

The line of judicial precedents already described supports a married couple, or a woman, or (probably) a heterosexual couple being protected from State interference in the decision to beget, conceive, or bear a child. In addition fetuses can be protected only after their viability and then only in ways that do not harm the mother.

Use of a surrogate mother, however, introduces a third, unrelated party into the process of procreation. The State has a strong interest in protecting this person from exploitation. "Surrogacy" is in fact an imprecise term; arrangements might involve several different combinations of genetic parents who provide the ova and sperm, a host mother who carries the fetus through gestation, and adoptive parents who may or may not include one or more genetic parents-three, four, or five different persons might be involved. New questions arise as to the terms of the contract between biological parents, host mother, and adoptive parents; the State would be called on to enforce these terms. For example, one question might be the right of the surrogate (host) mother to alienate or give up (by contract) her right to abort; would enforcement of such a contract amount to violation of the Thirteenth Amendment prohibition on involuntary servitude?

While a general ban on reproductive surrogacy might be constitutionally challenged as interfering with a right to procreate without State regulation (barring a compelling State interest), a State prohibition on *commercial* surrogacy, or the buying or selling of embryos, may be permitted as regulation of commerce; the selling of children is for example generally prohibited.

In June 1988, the governors of both Michigan and Florida were reported to have before them for signature legislation making it a felony to arrange a surrogate mother contract for payment. According to news reports bills to regulate or prohibit surrogacy have been introduced in at least 18 States.[52]

State-mandated record-keeping is common, and genetic record-keeping would probably be permissible either to document the safety of procedures such as IVF or to protect the future interests of children in learning about their genetic heritage. The major limitation on record-keeping in medical practice is assurance

[52]Andrew H. Malcolm, "Steps To Control Surrogate Births Stir Debate Anew," New *York Times,* June 26, 1988, p. 1.

that confidentiality can be maintained.[53] The Court has permitted record-keeping and mandatory reporting of abortions and complications, but only under very close scrutiny to ascertain that the records are for protection of maternal health and are kept confidential. The Court has also approved laws requiring pathological examination of fetal tissue. Requiring physicians to keep permanent records of sperm donors, ova donors, surrogate mothers, etc., and the collection of this data by the State would presumably not raise any constitutional issue provided it were released only to those involved, and to the child.[54]

Finally, there may be issues regarding the financing of new reproductive technologies. There have been two significant Supreme Court decisions on the question of State funding of abortions under the Medicaid program. In 1977, the Court concluded[55] that laws providing public funding for childbirth, but not for abortion, were not a denial of equal protection because poverty is not a "suspect" classification, like race or religion[56] and because by failing to fund abortions the State "places no obstacles in the pregnant woman's path to an abortion. " In other words, the State did not cause the poverty that alone prevents the woman from obtaining an abortion.

In 1980 the Court examined the constitutionality of the "Hyde Amendment, " which restricted Federal funding of abortions.[57] The Court used the same reasoning as in the earlier case, i.e., the government is not required by the Constitution to fund any medical care, no matter how vital such care may be; funding is a matter for Congress or the State legislatures to decide. As discussed elsewhere, some people argue for a different interpretation of the Constitution, asserting a general "right to health care," but unless and until such a right is recognized, the refusal to fund infertility treatments while other medical interventions are funded would not raise constitutional issues.

Fetal Surgery

With the capability of antenatal (before birth) examination, diagnosis, and treatment of the fetus has come the possibility of viewing the fetus as "the doctor's second patient. The ability to intervene to treat the fetus is at present very limited; in most cases, the only treatment possible now when a disease or defect can be diagnosed antenatally is termination of the pregnancy. But about 50 cases of hydrocephalis[58] have been treated in the womb by surgical decompression, with results that are "not encouraging. "[59] There have been fewer cases of surgery for urinary tract obstruction, but with somewhat better results. Other potential uses for fetal surgery may include diaphragmatic hernia, spina bifida, gastroschisis, and allogenic bone transplants. These procedures are now experimental, and cannot be performed without the woman's informed consent, which she is under no obligation to give.

But in the future it is likely to be possible to treat the fetus for many conditions. The procedures are likely to be perfected and to become "standard medical procedures. " They will, however, remain highly invasive. They will demand the cooperation of the pregnant woman, will involve doing things to or through

[53] The Supreme Court has concluded that all prescriptions for controlled substances can be entered into a central state computer, provided there are strict access procedures to limit disclosure to those who need to know, for law enforcement purposes. *Whalen v. Roe,* 429 U.S. 589 (1977).

[54] J.A. Robertson, "Embryos, Families, and Procreative Liberty: The Legal Structure of the New Reproduction, " So. Cal. *Law* Rev.. vol. 59, 1986, pp. 939-1041.

[55] *Maher* v. *Roe*, 432 U.S. 438 (1977).

[56] As discussed in ch. 2, any laws that distinguish between people on the grounds of race or religion are given particularly close scrutiny by the Court, and the burden is on the government to show that such classification is necessary and appropriate and not intended to be discriminatory.

[57] *Harris* v. *McRae*, 448 U.S. 297 (1980). The Hyde Amendment is named after its congressional sponsor; the regulation under consideration by the Court forbade the use of Federal funds for abortion except where the life of the mother is endangered, or when the mother was the victim of rape or incest that was properly reported to a law enforcement or public health agency.

[58] An abnormal increase in the volume of fluid within the cranial cavity, resulting in pressure that causes atrophy of the brain.

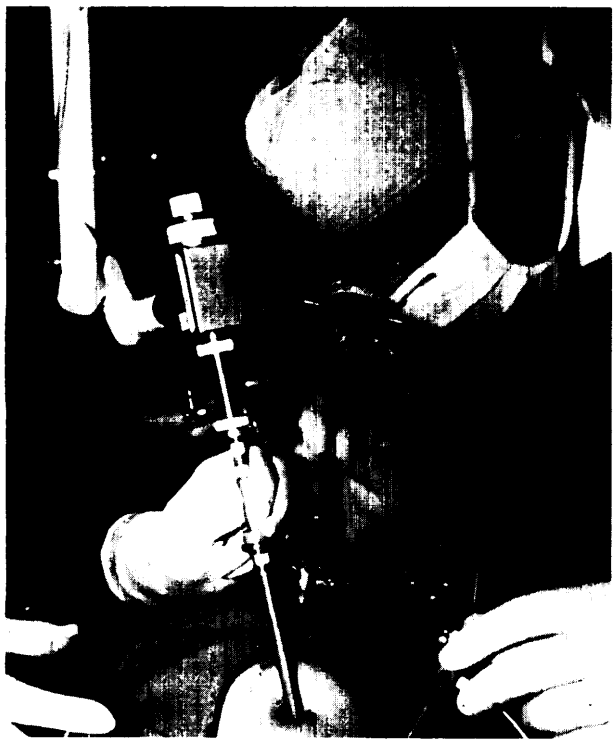
[59] S. Elias and G.J. Anus, *Reproductive Genetics and the Law* (Chicago, IL: Year Book Medical Publishers, 1987).

her body, and in some cases may cause her pain or put her life or health at risk. (See figure 6-4.) Legislators or the courts will then be asked to deal with the competing rights of the mother and the fetus.

There have been approximately two dozen court-ordered "forced cesarean sections" in the past 5 years.[60] Only one of these cases, the first, reached an appellate court level. A woman, due to deliver her child in about 4 days, had notified the hospital where she would be attended that she would not allow surgery because it was her religious belief that what happened to the child was the Lord's will. The hospital sought a court order authorizing physicians to perform a cesarean section and give any necessary blood transfusions. At an emergency hearing, conducted in the hospital, the examining physician testified that she had

[60]V.E B. Kolfrt, J. Gallagher, and M.T. Parsons, "Court-Ordered Obstetrical Interventions, " New *England Journal of Medicine,* vol. 316, May 7, 1987, pp. 1192-1196.

Figure 6-4.— Laparoscope in Use for Laser Surgery



SOURCE Martin M Quigley, Cleveland Clinic, Cleveland, OH

complete placenta previa, an abnormal condition of the placenta, with a 99 percent certainty that her child could not survive vaginal delivery and a 50 percent chance that she herself would not survive. The court decided that the unborn child merited legal protection and authorized the administration of "all medical procedures deemed necessary by the attending physician to preserve the life of the defendant unborn child. " A public agency petitioned the same court for temporary custody of the allegedly deprived child. The court granted this petition on the basis that the State

> has an interest in the life of this unborn, living human being (and) the intrusion involved . . . is outweighed by the duty of the state to protect a living, unborn human being from meeting his or her death before being given the opportunity to live.

The State Supreme Court immediately heard and denied the petition of the parents to stay the order,[61] with a two sentence conclusory opinion citing *Roe v. Wade.*

In spite of these legal decisions and orders, however, the woman uneventfully delivered a healthy baby—without surgical intervention.

In a second, lower court case, a hospital administration requested that a juvenile court find an unborn baby a "dependent and neglected child" and order a cesarean to safeguard its life. A cesarean section had been recommended on the grounds of an indication by a fetal heart monitor of possible fetal hypoxia. The patient was an unmarried woman who had previously born twins, and who was described as obese, angry, and uncooperative. She refused a cesarean out of fear of surgery. Her mother and sister and the father of the unborn child had tried unsuccessfully to change her mind. The court ordered the surgery, and it was performed, resulting in a healthy child and no maternal complications in spite of the fact that more than nine hours had elapsed since the tracings of an external fetal heart monitor indicated fetal distress and 6 hours after this

[61]*Jefferson v. Griffen Spalding Co. Hospital, 247* Ga. 86, S.E, 2nd 457 (1981).

was confirmed with internal tracings. The physician commented that the case "underscores the limitations of continuous fetal heart monitoring as a means of predicting neonatal outcome. "[62]

All of the forced cesarean section cases relied on two earlier cases, Roe v. *Wade* and Ra*leigh Fitkin-Paul Morgan Memorial Hospital v. Anderson,* in 1964.[63] The latter involved an 8-month pregnant woman whom physicians be lieved was likely to hemorrhage severely. If that happened, she and her unborn child would need blood transfusions, but as a Jehovah's Witness, she would refuse them. The trial court upheld her refusal and the hospital appealed to the New Jersey Supreme Court. Although the woman had already left the hospital, against medical advice, the State Supreme Court determined that the unborn child was entitled to the law's protection and that blood transfusions could be forcibly administered to the woman "if necessary to save her life or the life of her child, as the physician in charge at the time may determine. "

This precedent is thought to be of limited value. No transfusions were actually done as a result of the decision. It was a one-page opinion with little analysis or discussion. In any case the extent of bodily invasion or risk involved in a blood transfusion is less than that involved in major abdominal surgery such as a cesarean section. Eight years later, the same State Supreme Court decided the case of Karen Ann Quinlan, which extended the right to privacy to refusal of medical treatment,[64] allowing Quinlan's respirator to be removed.

Roe v. Wade, as already discussed, said that the State has a compelling interest in the life of viable fetuses, but it also said that it does not have such an interest if the "the life or health of the mother" is endangered by carrying the child to term. These two cases do not appear to favor the life or health of a fetus over that of the pregnant woman.

A somewhat analogous situation occurs when a court authorizes a' 'search and seizure' of a substance inside the body of a criminal suspect. In a famous case[65] the Supreme Court ruled that blood tests to determine alcohol intake were reasonable, because of the strong interest of the community in determining guilt or innocence, the inability of determining intoxication by other means, and the very minor bodily invasion involved in drawing blood. In an earlier case, the administering of an emetic to induce vomiting in order to extract narcotics capsules that a suspect had swallowed, was held to violate the subject's interest in human dignity.[66] Much more recently the Supreme Court said it was an "unreasonable search and seizure" to order surgery to remove a bullet from an accused robber, because the state would be "taking control of. . . (his) body" and violating his "personal privacy and bodily integrity. "[67]

A forced cesarean section is a more intrusive and dangerous surgical procedure than bullet removal, and may be considered more demeaning to the subject's bodily integrity, personal privacy, and human dignity. On the other hand, the potential State interest in the life of a child ready to be born is high. Other factors that courts may consider are whether a medical procedure is considered unusual and risky, or routine and safe. Many legal experts believe that surgery involving general anesthetic or physical invasion of the mother's body is now unlikely to be permitted.

Some ethicists argue that once a woman has implicitly given up the right to an abortion by carrying a fetus to near-term, she has an affirmative obligation to consent to any medical or surgical intervention that may help the fetus. Opponents argue that this is more a moral construct than an enforceable legal obligation. First, there is no point in pregnancy in which a woman formally or publicly waives the right to an abortion, although the State is allowed to limit the exercise of that right at some point.

[62] W A. Bowers and B. Salgestad, "Fetal v. *Maternal Rights, " Am. J. Obstet. Gynecol,* vol. 58, 1981, p. 209.
[63] 210 A. 2nd 537 (N.J. 1964).
[64] *Matter of Quinlan,* 355 A. 2nd 647 (N.J. 1976).
[65] *Schmerber* v. *California,* 384 U.S. 757 (1966).
[66] *Rochin* v. *California, 342* U.S. 165 (1952).
[67] *Winston* v. *Lee,* 470 *Us. (1985).*

Secondly, the "waiver" argument would mean that a woman has full right to elect abortion, but if she elects childbirth she is required to surrender basic rights to bodily integrity and privacy. This is, arguably, an unconstitutional penalty on the exercise of the right to bear a child,[68] and would be contrary to the State's presumed interest in encouraging marital procreation. It should be noted that at some time in the future the State might not be presumed to have an interest in encouraging procreation. In the 1970s and even today some people have argued that the State should actively discourage population growth.

To some extent, the interpretation of a woman's constitutional right to refuse medical treatment during pregnancy may in the future be technologically driven: is there a treatment that is effective in preventing or curing a serious illness or defect, is it safe for the mother, can it be delivered nonintrusively? Affirmative answers may encourage courts in the future to give greater weight to the constitutional rights of a fetus as compared to those of the mother.

Fetal Abuse

Less invasive interventions may also require balancing the interests of a woman with that of her unborn child. In some ways, however, supervision of diet, smoking, or drinking–that is, of otherwise legal activities-although physically less invasive, could be perceived as requiring more massive infringement on privacy or liberty than one-time surgery. Could a State constitutionally define a new crime, "fetal abuse, analogous to "child abuse, " and use it to force a pregnant woman to refrain from taking certain actions harmful to a fetus? Or could the State force her to take actions thought to be good for the fetus?

Pamela Monson Stewart, because of placenta previa, was advised by her physician to stay off her feet, avoid intercourse, refrain from taking drugs, and seek immediate medical attention should she begin to hemorrhage. According to police she ignored this advice, having intercourse with her husband and taking amphetamines after she noticed some bleeding, and not going to the hospital until many hours later. Her son was born with massive brain damage and died six weeks later. Criminal charges were filed under the State's child support statute, which includes "unborn children. "[69]

The case was dismissed in early 1987 when the trial judge determined that this statute did not apply to her conduct. This may not indicate how similar cases might be decided. The prosecution, for example, argued that "disobeying instructions" or "failure to follow through on medical advice" should be grounds for criminal action. This seems foreign to the usual meaning of "medical advice" and would surely change the nature of the doctor-patient relationship.

The "fetal protection" policy enunciated by the prosecution appears to assume that like mother and child, mother and fetus are two separate individuals with separate rights. But unlike a child, the fetus is absolutely dependent on the mother's body and cannot be treated without invading the mother. Treating them separately before birth can only be done by favoring one over the other where rights conflict; and this appears to many people to treat the mother like an inert incubator or culture medium, or like the servant of the fetus.

Another problem is more technical. Child support laws requiring provision of food, housing, medical attention, etc., do not require parents to provide "optimal" or 'desirable" quality of these goods. They do not forbid taking risks with children (e.g., having them ride in automobiles, or ski), or even causing pain to children (e.g., punishment). Thus fetal abuse laws would in effect be more stringent than child abuse laws.

[68] D.E. Johnsen, "The Creation of Fetal Rights: Conflicts With Women's Constitutional Rights to Liberty, Privacy and Equal Protection, " Yale *L. J.*. vol. 95, 1986, p. 599.

[69] Cal. Penal Code, Sec. 270 [West, 1986]: If a parent of a minor child willfully omits, without lawful excuse, to furnish necessary clothing, food, shelter, or medical attendance, or other remedial case for his or her child, he or she is guilty of a misdemeanor . . .

MEDICAL INTERVENTIONS AT THE END OF LIFE

Various types of life-extending devices such as kidney dialysis machines, heart-lung machines, and finally the Jarvis heart, are encouraging people to think of their organs as potentially replaceable parts, and of death from aging and deterioration as at least postponable. If life can be extended, should we have the liberty to use or to refuse those extenders? Could it ever come to be assumed that we have a right to them, or that all have an equal right to them?

As already noted, there is no constitutional right to health, or to medical or health care, in the United States.[70] The President's Commission for the Study of Ethical Problems in Medicine[71] recognized this, but concluded that:

> Society has amoral obligation to ensure that everyone has access to adequate care without being subject to excessive burdens.

The Commission based this obligation on the criticality of health to the individual's opportunity to pursue a life plan, the necessity of medical care to "relieve pain and suffering and restore functioning, and prevent death, " and the fact that most illnesses and injuries are beyond the control of the individual. The Commission concluded that the societal obligation does not extend to "everything needed" but clearly means that everyone should have access to some level of care.

It is therefore argued by many people that the courts may, at sometime in the future, conclude that access to a basic minimum of decent health care is fundamental to the exercise of personal liberty. They point out that while the Court has ruled that government need not fund any medical procedures, this was a 5-4 decision.[72] A few lower court cases have required Medicaid financing of organ transplants.

At present, many advanced medical technologies are extremely costly. They raise serious questions about the equity with which the Federal government does make funding allocations to medical care, and whether this raises questions about due process and equal protection.

Use of Artificial Hearts

The human trials of artificial hearts in the mid-1980s have constituted the most public human experiments in history. The impacts and issues associated with an artificial heart were debated long before that. The National Heart and Lung Institution convened a multidisciplinary panel to review these issues in the early 1970s.[73] The Panel noted that many of the issues surrounding the artificial heart "may lie in the realm of the symbolic and the irrational, " given the role the human heart has always played, in speech, myth, poetry, and religion. But 12 years later, when NIH's most recent panel on the artificial heart reported in May 1985, the artificial heart tends to be seen by doctors and by the public as not much different from the other mechanical assist systems with which one has become familiar. The potential social issues are viewed primarily in terms of cost-effectiveness.

The 1985 panel concluded that were the heart fully successful, as much as $4.25 billion annually might be necessary to provide one for every candidate whose life could be extended by the device.[74] This is more than is spent on any other medical procedure, over twice as much as is spent on kidney dialysis and transplantation, and half the annual budget of the National Institutes of Medicine. Nevertheless, the argument can certainly be made that the

[70] Of all major industrialized nations, only the United States and the Union of South Africa do not provide some form of health care insurance to all citizens.

"President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Securing Access to Health Care, vol.* 1 (Washington, DC: U.S. Government Printing Office, 1983), pp. 22.

[72] *Harris* v. *McRae*, 1980.

[73] Artificial Heart Assessment Panel of the National Heart and Lung Institute, *The Totally Implantable Artificial Heart,* DHEW Pub. No. (NIH) 74-191, Washington, DC, 1973.

[74] Using a series of assumptions, the panel arrived at a cost per heart of approximately $150,000, and a range of 17,000 to 35,000 candidates.

United States could afford that cost, if high enough priority were given to the goal.

As with other high-cost medical procedures, the question of constitutional importance is the following: how should artificial heart implants (on a post-experimental basis) be allocated and funded, or how could access be rationed or limited to certain groups or individuals?

There are basically three options: universal coverage, rationing, and no funding. This question was presented when kidney dialysis was developed in the 1960s.[75] At first, patient selection for dialysis was made by committee; the committee's deliberations were described as reflecting "the prejudices and mindless cliches" of the white middle class.[76] To avoid having to make explicit, arbitrary "social worth" judgments, Congress in 1972 provided Federal funding for all kidney dialysis and transplantation. This approach has not been followed for heart and liver transplantation, perhaps because the kidney program has cost much more than originally anticipated.

There are four basic approaches to "rationing' artificial organs (and by extension, other extremely costly medical interventions): 1) the market, 2) committee selection, 3) lottery, and *(4)* the customary approach.

The market approach would let anyone pay for an artificial heart out of their own funds or private insurance. This approach seems to put a dollar value on life; it does not put a high value on fairness and equality. It is also open to the objection that artificial heart technology was largely developed with public funds, and that hospitals and medical schools that use and teach implant procedures are heavily subsidized with public funds. It is, nevertheless, currently constitutionally acceptable since there is no obligation on the part of government to provide any medical care or fund any medical program.

If the government does however decide to fund some artificial heart implants, but not all, some rationing or allocation method will be necessary. The Court has in the past been reluctant to interfere with government rationing schemes. For example, a maximum family allocation under a State Aid to Families with Dependent Children (AFDC) program was upheld against the challenge that it discriminated against members of large families.[77] But the Court struck down a food stamp requirement that all members of a household be related. Even though the Federal Government argued that this requirement was necessary to prevent fraud, the Court was unable to find a rational relationship between the regulation and the purpose of the food stamp program.[78]

This suggests that a rationing scheme is constitutional if based on a valid government interest, if it is for a legitimate government purpose, if it is reasonably related to that purpose, and if it is not invidiously discriminatory. When the necessities of life are involved, as with food stamps, the Court may be more inclined to examine critically the relationship between the statutory purpose and the rationing scheme. An artificial heart cannot well be considered an optional "luxury" for one who needs it; thus one would expect any rationing scheme the government adopts to be carefully scrutinized.

Infant Care Review Committees are a recent example of committee selection procedures; they review decisions to treat or not treat handicapped newborns. Such committees were formed to avoid the necessity of explicitly setting out criteria for selection decisions. But in the long run only two results are possible:[79] if a pattern develops in committee choices, then it can be articulated and those decision rules can be codified and used directly; if no pattern develops, the committee is vulnerable to the charge of arbitrariness. In the end, the committee approach may too closely

[75] R.A. Rettig, "The Policy Debate on Patient Care Financing for Victims of End Stage Renal Disease, " Law *and Contemporary Problems* 40:196 *(1976).*

[76] David Sanders and Jesse Dukeminier, "Medical Advance and Legal Lag: Hemodialysis and Kidney Transplantation, " *UCLA Law Rev.,* vol. 15, 1968, p. 357.

[77] *Dandrige v. Williams, 397* U.S. 471 (1970).

[78] *Department of Agriculture v. Moreno, 413* U.S. 528 (1973).

[79] G. Calabresi and P. Bobbitt, *Tragic Choices (New* York, NY: Norton, 1978).

involve the State in valuing some individuals over others. This approach also tends to undermine the concept of equality and the value of human life.

It is not clear whether such procedures might be successfully challenged by an unselected candidate on the grounds of lack of due process. If the Court views committee deliberations as like "adjudicatory hearings at which a decision is made based on the "facts' of the candidate's medical condition, family support structure, past history, likely compliance with medical directions, then it might be decided that the candidate had certain constitutional rights to be involved in the deliberations (perhaps to have advice of counsel, to call witnesses, etc.) since his or her life is at stake. If the committee is making judicial-like decisions, the Court may also require candidate participation. If the Court views the deliberations as more like a legislative committee—setting policies and reviewing applications to see if they must be excluded on non-discretionary grounds-that may meet the conditions of due process.

Another allocation strategy is to put all candidates into a pool from which they are selected at random up to the limits of funding for artificial hearts.[80] This approach takes "equalizing" as the ultimate goal but has little else to recommend it because it makes no allowance for the potential for survival, quality of life, or other relevant characteristics of the candidates. There are, however, no obvious constitutional problems with this strategy.

The traditional approach of having individual physicians select patients on the basis of clinical suitability sloughs off public responsibility to private persons and (usually) prevents decisions from becoming openly controversial or politicized. "Clinical suitability" or "medical criteria" often include factors that are not strictly speaking medical, such as degree of family support for aftercare; medical criteria also usually take in mental illness, IQ, criminal records, employment, alcoholism, etc. There is little accountability in this approach, but it has not yet been challenged constitutionally.

Prolongation of Bodily Functions

As already noted, the mechanical ventilator, together with the EEG, required a new definition of death—whole brain death. (See figure 6-5.) This redefinition allowed withdrawal of artificial "life support at the time when brain death is already confirmed, since there is "no legal duty to administer medical treatment after death."[81] But society was presented with anew problem: when is it acceptable to remove life support systems from one who is not totally brain dead, if removal of the system will likely result in death? In other words, if one is "alive" only by virtue of the machine, is that life? Or an artificial substitute **for life?**

These questions were raised compellingly in the case of Karen Ann Quinlan. Following an episode not completely understood but assumed to be associated with drug intake, she stopped breathing for at least 15 minutes, after which she was resuscitated in an emergency room. Quinlan retained some brain activity but never regained consciousness. Her breathing was done by a mechanical ventilator (figure 6-6), and she was diagnosed as being in a persistent vegetative state, a permanent coma in which one has sleep-wake cycles but is unaware, so far as can be ascertained, of one's environment or one's existence.

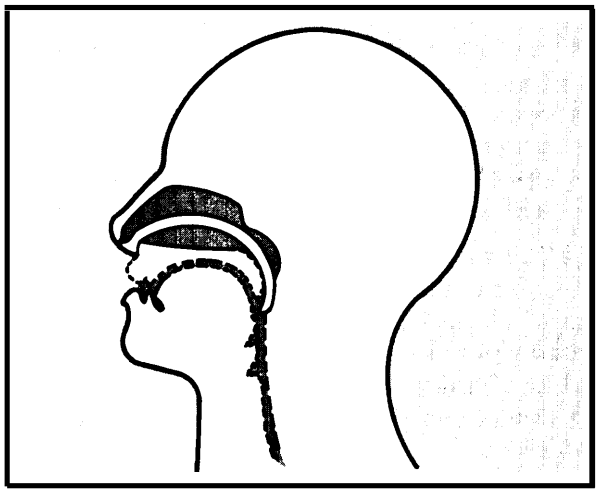
Convinced that their daughter's case was hopeless, her parents asked that the ventilator be removed and she be allowed to die. Sympathetic but fearing criminal prosecution for homicide, physicians insisted that the parents obtain a court order. This was refused by a lower court after hearing some physicians testify that removal of the ventilator (stopping of treatment) was unethical. The State Supreme Court in a unanimous decision[82] au-

[80] George J. Anus, "Allocation of Artificial Hearts in the Year 2002, *Minerva v. National Health Agency,"* *Am. J. Law and Med.,* vol. 3, 1977, pp. 59-76.

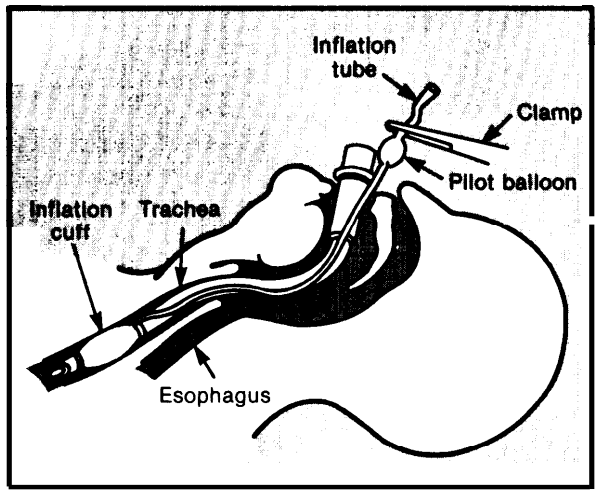
[81] *In re Spring*, 405 N.E.2d 115 (Mass. 1980).

[82] *Matter of Quinlan*, 355 A. 2d 647 (NJ 1976).

Figure 6-5.—Examples of Airway Devices Used in Advanced Cardiac Life Support



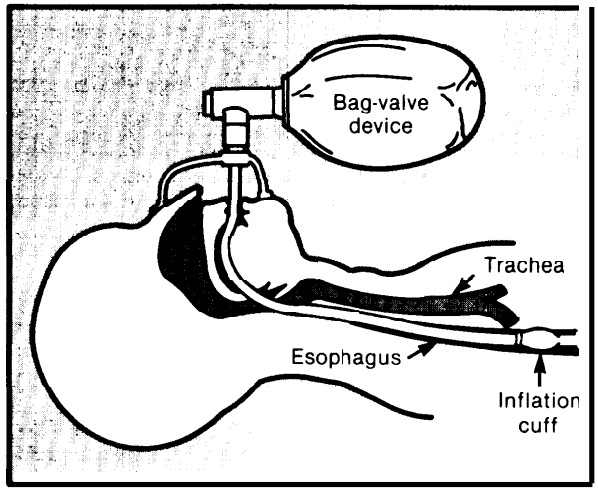
A nasopharyngeal airway may be inserted through the nose to the back of the throat to keep a path for air open.



An endotracheal tube with an inflatable cuff may be inserted through the nose or mouth (as pictured here) into the trachea. It is the most effective means of securing the airway of an unconscious patient.



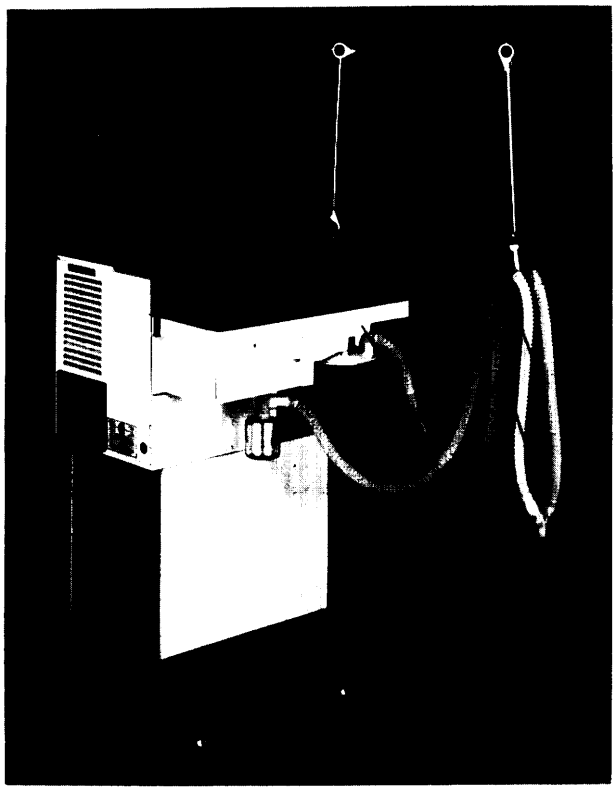
An oropharyngeal airway may be inserted through the mouth to keep a path for air open.



An esophageal obdurator airway consists of a cuffed tube that is inserted through the mouth into the esophagus. Airholes in the portion that is in the throat allow passage of air into the trachea. A sealed mask prevent: air leakage from the patient's mouth and nose. When the cuff in the esophagus is inflated, air is prevented from entering the stomach, stomach contents are prevented from entering the trachea and an open airway exists that can be used with a bag-valve device (shown) or a mechanical ventilator.

SOURCE' C K Cassel, M Silverstein, J. LaPuma, et al , "Cardiopulmonary Resuscitation in the Elderly, " prepared for the Office of Technology Assessment, U S Congress, Washington, DC, November 1985

Figure 6-6.— Positive Pressure Ventilator



The Bennett 7200a is a microprocessor-controlled volume ventilator typical of the positive pressure ventilators used in hospitals today.

SOURCE: Puritan-Bennett Corp.

thorized the removal, on the basis of Quinlan's constitutional right to privacy, saying

> . . . Presumably this right is broad enough to encompass a patient's decision to decline medical treatment under certain circumstances, in much the same way as it is broad enough to encompass a woman's decision to terminate pregnancy under certain conditions.

Only 5 years earlier the same court had ruled that there was "no constitutional right to die. "[83] In the Quinlan case, the Court examined in detail the question of whether the State had any "compelling interests" in maintaining Quinlan's life, given her (in fact, her guardians') choice to refuse medical treatment. The court examined four possible interests:

- the preservation and sanctity of human life,
- prevention of suicide,
- protection of third parties, and
- upholding the ethical integrity of the medical profession.

The Court said the ethics of the profession were consistent with removal at the patient's request. There were no third parties to be protected since Quinlan had no spouse or children and her family requested removal. The ensuing death could not be homicide because it would come "from existing natural causes" in the absence of artificial interventions. For the same reason, there could be no charges of assisted suicide.

This case has become the touchstone for all post-1976 court cases examining the "right to privacy" in relation to refusing medical interventions. Some courts have based decisions to permit treatment withdrawal on common law battery principles but most also followed the Quinlan case in enunciating a constitutional right to refuse treatment. Another State court argued that honoring the right to privacy is itself honoring the sanctity of life:

> The constitutional right to privacy, as we conceive it, is an expression of the sanctity of individual free choice and self-determination as fundamental constituents of life. The value of life as so perceived is lessened not by a decision to refuse treatment, but by the failure to allow a competent human being the right of choice.[84]

Since these cases courts have ruled that the constitutional right to privacy extends to refusing any medical intervention, including artificial feeding. However, other questions could arise with such devices as the (implanted) artificial heart. If it is seen as an assist machine like a mechanical ventilator then the person will have a right to have the machine "unplugged." There is little doubt that this would

[83] *JFK Memorial Hospital* v. *Heston*, 279 A2d 670 (NJ 1971). The young woman in this case was unable to express her wishes but was "apparently salvable to long life and vibrant health."

[84] *Superintendent of Belchertown* v. *Saikewicz*, 370 N.E. 2d 417 (1977).

be the case with the current version of the artificial heart, which requires a pneumatically powered device roughly the size of a dishwasher. A fully-implantable heart with a ten year power supply could be perceived differently, perhaps more like the results of a mitral valve replacement or a cardiac bypass operation.

The Right To Die

As described above, the right to refuse or terminate the use of life support systems now seems well-established, even when it is virtually certain that death will rapidly result. Should a "right to die" also be recognized for those who are not machine-dependent? who are perhaps medicine-dependent? in intractable pain? or merely tired of dying, or even tired of living?

Some would argue that just as one has a constitutional right of privacy in making decisions about marriage and reproduction, one should be able to exercise a right of privacy in deciding against further survival. There is, after all, no other decision so intensely personal; and it is the only situation when one in fact exercises the choice that theoretically underlies all civil rights and duties—that of consenting or declining to participate in organized society. Further, it can be argued, the State has no compelling interest in prolonging life which is already unproductive and burdensome to the individual and the public, or in delaying a death which is welcome, inevitable, and already imminent.

On the other side of the argument, death is always inevitable, and a few people at any stage of life find life unpromising and unproductive and death welcome. In other words, to accept voluntary euthanasia, some argue, is to open the door to recognition of a general right to suicide. Further, medical diagnosis may be incorrect; when medical treatment is refused or discontinued, the patient sometimes survives against expectations. Suicide on the other hand is irrevocable. Some people oppose voluntary euthanasia because it would almost surely require direct involvement of the State through some sort of prior judicial sanctioning. However, this has also often been the case with termination of treatment. Moreover the State is already directly involved in killing through the criminal death penalty. Finally, physicians might be required to assist or advise involuntary death, which could erode the ethical position of the profession or the public trust in it.

These are strong arguments on both sides. In the long run, constitutional decisions as to whether the scope of individual privacy and autonomy extends to an affirmative right to die will probably depend on both the value placed on self-determination within the society, and the progress made by medical technology in preserving not only life, but a high quality of life; that is, physical and mental health. The greater the degree of control over life or death that can be offered by science and technology, the more certain it is that difficult choices will be presented, and the more likely it is that constitutional questions will be raised by those choices.

Appendix

Appendix

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Other OTA Assessments in Progress as of September 1988

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Technology, Innovation, and U.S. Trade
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Agricultural Approaches To Reduce Agrichemical Contamination of Groundwater in the United States
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Managing Low-Level Radioactive Waste
Climate Change: Ozone Depletion and the Greenhouse Effect
Potential for Mineral Resources Development in Antarctica and the Convention of the Regulation of Antarctic Mineral Resource Activities
Infrastructure Technologies: Rebuilding the Foundations

NOTE: For brief descriptions of these studies in progress, see OTA's booklet on "Assessment Activities"- available from OTA's Publications Office, 224-8996.

Related OTA Publications

- Bicentennial Project:
  –*Science, Technology, and the Constitution–Background Paper. BP-CIT-43,* September 1987, 32 p. GPO #052-O03-O1086-l; $1.50.
  –*Science, Technology, and the First Amendment–Special Report. CIT-369,* January 1988, 80 p. GPO #052-O03-O1090-9; $3.50.
  –*Criminal Justice, New Technologies, and the Constitution–Special Report. CIT-366,* May 1988, 64 p. GPO #052-O03-Ol105-l; $2.75.
- *Federal Response to AIDS:*
  –*Cost-Effectiveness of Educational Programs to Prevent AIDS–Background Paper. TM-H-24,* February 1985.
  –*Do Insects Transmit AIDS?–Staff Paper.* September 1987, 48 p. NTIS #PB 88-143 177/AS.
  –*Review of the Public Health Services' Response to AIDS–Technical Memorandum. TM-H-24,* February 1985, 168 p. GPO #052-O03-O0984-6; $5.50. NTIS #PB 85-246 668/AS.
- *Mood Policy & Technology. H-260,* January 1985, 64 p. GPO #052-O03-O0977-3; $7.50. NTIS #PB 85-234 8701AS.
- *Impacts of Neuroscience–Background Paper. BP-BA-24,* March 1984,36 p. NTIS # 84-196 716/AS.
- *Infertility: Medical and Social Choices. BA-358,* May 1988, 412 p. GPO #052-O03-O1091-7; $16.00.
- New *Developments in Biotechnology:*
  –*Field-Testing Engineered Organisms: Genetic and Ecological Issues. BA-350,* May 1988, 160 p. GPO #052-O03-Ol104-2; $7.50.
  –*Ownership of Human Tissues and Cells-Special Report. BA-337,* March 1987, 176 p. GPO #052-O03-O1060-7; $7.50. NTIS #PB 87-207 536/AS.
  –*Public Perception of Biotechnology-Background Paper. BP-BA-45,* May 1987, 136 p. NTIS #PB 87-207 544/AS.
- *Life-Sustaining Technologies and the Elderly. BA-306,* July 1987, 472 p. GPO #052-O03-O1074-7; $19.00. NTIS #PB 87-222 527/AS.
- *Losing a Million Minds: Confronting the Tragedy of Alzheimer's Disease and Other Dementias. BA-323,* April 1987, 548 p. GPO #052-O03-O1059-3; $24.00. NTIS #PB 87-183 752/AS.
- *The Role of Genetic Testing in the Prevention of Occupational Disease. BA-194,* April 1983, 244 p. NTIS #PB 83-233734.
- *Technology Dependent Children: Hospital v. Home Care–Technical Memorandum. TM-H-38,* May 1987, 116 p. NTIS #PB 87-194551.
- *Technologies for Detecting Heritable Mutations in Human Beings. H-298,* September 1986, 156 p. GPO #052 -O03-O1037-2; $8.00. NTIS #PB 87-140 158/AS.