Summing Up

The Ethical and Legal Problems in Medicine and Biomedical and Behavioral Research

President's Commission for the Study of
Ethical Problems in Medicine and
Biomedical and Behavioral Research

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Final Report on Studies of the Ethical and Legal Problems in Medicine and Biomedical and Behavioral Research

March 1983

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research

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March 31, 1983

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

I am pleased to transmit the Final Report of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. As you know, the Commission's statutory authority expires today. This volume provides an overview of the Commission's work since our inception in January 1980. During the past three years, we have published eleven volumes--nine reports, the proceedings of a workshop on whistle-blowing in research, and a guidebook for the local committees that review research with human beings.

The basic American values of liberty, fairness, compassion, and respect for human dignity have recurred in many settings throughout our work. In light of these values, we have addressed many of the most troubling issues facing Americans in the last quarter of this century, such as: When, if ever, should life-sustaining treatment be foregone? Who should bear the costs of injuries to human subjects in research? Should society ensure that everyone gets health care and, if so, how much? Ought physicians to tell their patients the truth, even if it is very dismal? What should be done about attempts to remake human genes?

In this Report, Summing Up our work, we review each of our projects and the current status of the recommendations we have made. I am happy to say that our studies have provoked a great deal of interest, and we hope that even after our closing these reports will go on stimulating thoughtful discussion of the important issues of bioethics not only in Washington but also among people across the country. Some of our conclusions are broadly applicable to health professionals and patients, while others involve governmental action. We trust that recommendations of the latter sort will continue to receive prompt and careful attention from yourself and others in the Administration.

We are truly grateful for the opportunity to have served on this Commission and hope that we contributed to public understanding and the development of sound policy on these vital issues.

Respectfully,

Morris B. Abram
Chairman

Copies to: Honorable George Bush
Honorable Thomas P. O'Neill, Jr.

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Scope of Activities

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Who will live and who will die? Who decides, and on what grounds? Are there certain characteristics—hen "defining" life or setting the boundaries of permissible genetic experimentation—that are essential for "humanness"? In distributing risks and benefits, when should choices be left to the consciences of individuals and when should they be constrained collectively—by expert or lay groups, legislators, administrators, or judges?

The awesome powers of medicine, which are continually expanded by developments in the life sciences, have sparked growing public interest in a number of what are now termed "bioethical" issues. To the traditional matters of personal conscience for physicians and other health care professionals have been added the increasingly difficult questions that face courts, legislators, sponsors and regulators of research, and patients and their families as biomedical and behavioral scientists and practitioners explore new ways to conquer illness, to sustain organ functions artificially, to probe and even manipulate the genetic basis of life itself.

Although public awareness of bioethics has been galvanized by the dramatic achievements that emerge from hospitals and research laboratories—and occasionally by reports of research abuses—the concerns are not just momentary ones, nor are they necessarily best addressed in the context of particular revelations or discoveries, however startling. For these reasons, the U.S. Congress in November 1978 authorized the creation of a presidential commission with continuing responsibility to study and report on the ethical and legal implications of a number of issues in medicine and research,

and gave the Commission the power to extend that list as it or the President saw fit[1] It was intended that the Commission would have approximately four years from its statute until its legislative "sunset." Delays in appointing and funding the Commission meant that it has had to complete all its assigned studies—and several additional ones—in little more than three years. The mandate of the Commission expanded on the work of earlier Federal bodies that had primarily death with ethical issues in research with human beings.[2] This mandate reflects the Congressional conclusion that, just as medical and scientific activities merit public support, the wide range of bioethical issues raised by these activities deserve to be considered in a public forum.

Commissions are established for a number of reasons. Sometimes the intent is "merely to allow deferral of action on a problem that confronts a legislative or governmental agency."[3] Although this may have played a part in the creation of the President's Commission's predecessor, the National Commission for the Protection of Human Subjects, in 1974—and especially in the National Commission's mandate to study such highly charged subjects as fetal research and psychosurgery[4]—similar controversy did not surround the instructions given the President's Commission. Nor was the Commission empaneled to offer advice on a highly technical matter or on subjects involving primarily the operation or policies of the Federal government.

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[1]Title III of Public Law 95-622, enacted on Nov. 9. 1978, and codified at 42 U.S.C. Ch.6A. authorized the creation of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research with a "sunset" date of Dec. 31, 1982, subsequently amended to March 31, 1983 by Public Law 97-377 (Dec. 20, 1982).

[2] Title III of the National Research Act of 1974, P.L. 93-348, created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. That body, which was appointed by the Secretary of Health, Education, and Welfare. studied primarily issues in human research; between 1975 and 1978 it issued a series of reports that became the basis for a revision of the HHS regulations governing the protection of research subjects. One of the Commission's recommendations that was adopted by the Department was the creation of an Ethics Advisory Board to review proposals for research on particularly vulnerable subjects. An EAB was appointed by Secretary Califano in 1978; it was dissolved by Secretary Harris in 1980 after the establishment of the President's Commission, although HHS regulations continue to provide for the existence of such a board. *See. e.g.,* 45 CFR 46.204.

[3]Michael S. Yesley, *The Use of an Advisory Commission,* 51 S. CAL. L. REV. 1451, 1452 (1978). This seems to have been the effect of the Ethics Advisory Board of the Department of Health, Education, and Welfare in its 1978-79 study of research involving human-in *vitro* fertilization.

[4]National Research Act, Pub. L. No. 93-348, § 202, 88 Stat. 342 (1974).

Instead, the Commission was charged with studying problems whose value components are at least as important as their technical aspects. In effect, the Commission was instructed to bring ethical analysis of the implications of medical practice and research out of the classrooms, the hospital wards, and the scholarly journals and into a public forum in Washington. If not unique in the annals of government panels, the President's Commission was at least highly unusual. In fulfilling its mandate, the Commission has chosen to speak to many different audiences, depending upon the topic—not only the President and Congress, to whom it reports directly, but also the American people, as individuals and as members of professional associations, law reform bodies, groups of state and local officials, and religious and civic organizations.

The topics scrutinized by the President's Commission over the past three years have carried it to the heartlands as well as the frontiers of biomedical practice and investigation. The enormously challenging issues addressed by the Commission are not arcane. Rather, they are questions that increasingly confront all Americans, individually as participants in health care and collectively as citizens in a democracy in which many bodies, from local hospitals to Federal agencies, must grapple with issues of life and death. The intention of the Commission in all its reports has been

- To help clarify the issues and highlight the facts that appear to be most relevant for informed decisionmaking;
- to suggest improvements in public policy at various levels, not exclusively Federal, and through various means, not—it turned out—primarily legislative; and
- to offer guidance for people involved in making decisions, though not to dictate particular choices on moral grounds.

Since mid-1981 the Commission has published most of its findings and conclusions in a series of nine reports.[5] The

[5]These reports are described more fully in Chapters Two and Three *infra.* In each case, the Commission's report was in a single volume; for some subjects, supporting materials and documents are included in the same publication, while for others one or more appendix volumes were published. In addition, the Commission submitted Annual Reports for fiscal years 1980, 1981, and 1982 to the President and Congress in December of each year, as required by Public Law 95-622.

The Commission also published a guidebook (in a looseleaf binder) for participants in the process by which studies with human subjects are reviewed at research institutions and the proceedings of a Sept. 1981 workshop on whistle blowing in biomedical research, which was held at the National Academy of Sciences under joint sponsorship. These projects are summarized in Chapter Three *infra.*

purposes of this final report are to summarize the Commission's work, to place the individual studies into a larger context, and to look to the future, in terms both of the issues studied by the Commission on which responses are pending and of the need for further attention to the impact of bioethics on matters of importance to the public. This volume also contains a summary of the Commission's work and conclusions on its Congressionally mandated study of privacy and confidentiality in medicine, which have not been previously presented in a separate report.

Membership

On July 18, 1979, President Carter announced his intention to name 11 Commissioners, and on September 29, 1979, the Senate gave its advice and consent to the appointment of Morris B. Abram as Chairman. The enabling legislation mandated that:

(1) three of the members shall be appointed from individuals who are distinguished in biomedical or behavioral research;

(2) three of the members shall be appointed from individuals who are distinguished in the practice of medicine or otherwise distinguished in the provision of health care; and

(3) five of the members shall be appointed from individuals who are distinguished in one or more of the fields of ethics, theology, law, the natural sciences (other than a biomedical or behavioral science), the social sciences, the humanities, health administration, government, and public affairs.[6]

The Commission officially began its work on January 14, 1980, when the original members were sworn in at the White House by Judge David L. Bazelon. The three Commissioners representing biomedical or behavioral research were Mathilde Krim, an associate member of the Sloan-Kettering Institute for Cancer Research and coordinator of its International Laboratories for the Molecular Biology of Interferon Systems; Arno G. Motulsky, a professor of medicine and genetics and Director of the Center for Inherited Diseases at the University of Washington; and Frederick C. Redlich, a professor of psychiatry at UCLA Medical School and former Yale Medical School Dean.

The three Commissioners distinguished in the practice of medicine were Mario Garcia-Palmieri, a professor and Head of the Department of Medicine at the University of Puerto Rico and former Secretary of Health for the Commonwealth; Donald N. Medearis, Chief of the Children's Service at Massachusetts

[6] 42 U.S.C. § 300v(a)(1).

General Hospital and Charles Wilder Professor of Pediatrics at Harvard University; and Charles J. Walker, a physician in private practice in Nashville, Tennessee, and a member of the Board of Trustees at Fisk University.

The five Commissioners from the fields other than medical research and practice were Morris B. Abram (Chairman), a New York City attorney, formerly President of Brandeis University and U.S. Representative to the United Nations Commission on Human Rights; Renee C. Fox, a leading medical sociologist and Annenberg Professor of the Social Sciences at the University of Pennsylvania; Albert R. Jonsen, Chairman of the Bioethics Group for the five University of California schools of medicine and member of the former National Commission for the Protection of Human Subjects; Patricia A. King, an associate professor of law at Georgetown University and also a member of the former National Commission for the Protection of Human Subjects; and Anne A. Scitovsky, Chief of the Health Economics Division of the Palo Alto Medical Research Foundation.[7] (For further biographical information on all the Commissioners, see Appendix A.)

In February 1980 Dr. Redlich resigned as a member of the Commission because, in addition to his position at UCLA, he was Acting Director of the Veterans Administration Hospital in Brentwood, California, and the authorizing legislation precluded the appointment of full-time employees of the Federal government to the Commission. Frances K. Graham, Hilldale Professor of Psychology and Pediatrics at the University of Wisconsin and former President of the Society for Research in Child Development, was sworn in to replace Dr. Redlich on May 16, 1980. Commissioner King resigned in May 1980 to accept a position with the Department of Justice. Carolyn A.

[7] In addition, P.L. 95-622 directed the heads of six Federal agencies to provide the Commission with liaison officers. Liaison has been provided as follows: Department of Health and Human ServicesCharles R. McCarthy, Ph.D., Director. Office for Protection from Research Risks, Office of the Director, NIH, assisted by Richard Riseberg, HHS, Office of General Counsel, and Stuart Nightingale. M.D.. Associate Commissioner for Health Affairs, FDA; Department of Defense-Captain Peter A. Flynn. MC. USN, Special Assistant for Professional Activities, Office of the Assistant Secretary of Defense (Health Affairs); Central Intelligence Agency-Bernard M. Malloy, M.D.. Chief of the Psychiatric Division, Office of Medical Services, assisted by Dennis Foreman. Office of General Counsel; Office of Science and Technology Policy-Gilbert S. Ommen. M.D., Ph.D., Associate Director for Human Resources and Social and Economic Services. OSTP, Executive Office of the President, succeeded by John Ball, M.D., J.D., succeeded by Denis Prager, Ph.D.; Veterans Administration-Dorothy C. Rasinski. M.D., J.D.. Associate Director, Medical Legal Affairs; National Science Foundation-Richard T. Louttit, Ph.D., Division Director for Behavioral and Neural Sciences.

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Williams, a faculty member in epidemiology and nursing at the University of North Carolina at Chapel Hill, was sworn in as her successor on September 16, 1980.

Four new Commissioners were announced by President Reagan on January 25, 1982, to replace Commissioners Graham, Medearis, and Fox, whose two-year terms had ended, and Commisssioner Krim, who resigned in October 1981 due to conflicting commitments (Appendix B). The new Commissioners were George R. Dunlop, a professor of surgery at the University of Massachusetts Medical School and former President of the American College of Surgeons; Daher B. Ram, a physician in private practice in St. Clair Shores, Michigan, and former President of the Michigan Association of Osteopathic Physicians and Surgeons; Seymour Siegel, a professor of ethics and theology at the Jewish Theological Seminary of America and professor of humanities in medicine at the Medical College of Pennsylvania; and Lynda Hare Smith, a Colorado Springs housewife and advisor to the Chancellor of the University of Colorado Health Science Center. Drs. Dunlop and Rahi and Rabbi Siegel were sworn in at the Commission's meeting on February 1982, and Mrs. Smith joined the Commission the following month.

President Reagan nominated four additional Commissioners on July 12, 1982, to succeed Commissioners Garda-Palmieri, Jonsen, Scitovsky, and Williams, whose terms of office were ending that month. The new Commissioners, sworn in at the Commission's meeting on August 12,1982, were H. Thomas Ballantine, Jr., a clinical professor of neurological surgery at Harvard Medical School and Senior Neurosurgeon at Massachusetts General Hospital; Bruce Kelton Jacobson, Director of the Family Practice Residency Program at John Peter Smith Hospital in Fort Worth, Texas, and an associate professor of family practice and community medicine at Southwestern Medical School; John J. Moran, Director of the Moran Foundation in Houston, Texas, and former owner of a company that makes diagnostic reagents and instruments for the professional medical community; and Kay Toma, a physician in private practice in Bell, California, and President of the Bell Medical Center.

Staff and Funding

The Commission's work was directed by Alexander Morgan Capron, who was on leave from the University of Pennsylvania, where he was a professor of law and of human genetics; at the conclusion of the Commission's work, Mr. Capron joined the faculty of Georgetown University as a professor of law, ethics, and public policy. The Deputy Director was Barbara Mishkin, former Assistant Director of the National Commission for the Protection of Human Subjects and Staff

Director of the HEW Ethics Advisory Board. Mrs. Mishkin's primary responsibility was for the Commission's work in the area of biomedical and behavioral research.

Joanne Lynn, a former director of clinical services in the Division of Geriatric Medicine at George Washington University, served as Assistant Director for Medical Studies. Dr. Lynn directed the Commission's study on decisionmaking about lifesustaining treatment; she also participated in the study of informed consent and in the medical aspects of other projects. The position of Assistant Director of Legal Studies was filled first by Alan Weisbard, formerly a practicing attorney in the field of administrative law, and then by Alan Meisel, a professor of law, psychiatry, and sociology at the University of Pittsburgh. Mr. Weisbard worked primarily on informed consent, as well on the studies of compensation for research injuries and decisions about life-sustaining treatment. When Mr. Weisbard left to join the faculty of Cardozo School of Law, Professor Meisel took over direction of the legal studies on informed consent and decisions to forego life-sustaining treatment.

The position of Staff Ethicist, which entailed collaboration on all the studies related to health care, was filled in succession by three professors of moral philosophy: Daniel Wikler, of the University of Wisconsin; Dan Brock, chairman of the department at Brown University; and Allen Buchanan, of the University of Minnesota and the University of Arizona.

Renie Schapiro, a former staff fellow in the Office of the Commissioner at the Food and Drug Administration, provided expertise in the area of public health. Ms. Schapiro worked primarily in the areas of genetic screening and counseling, genetic engineering, and decisionmaking about the care of seriously ill newborns; she also provided assistance in epidemiology for the study on defining death.

The Commission's work on access to health care was directed by Susan Morgan, who was formerly Director of the Division of Health Resources and Services Analysis in the Department of Health and Human Services. She was assisted by the staff economist, Mary Ann Baily, formerly an assistant professor of economics at Yale University, and by Kathryn Kelly, whose training is in public health and social welfare.

Marian Osterweis, on leave from the Departments of Community and Family Medicine and of Sociology at Georgetown University, served as the Commission's staff sociologist. Professor Osterweis worked primarily on the studies of informed consent and decisions to forego life-sustaining treatment; she also assisted the empirical studies regarding compensation for research injuries.

In addition to the full-time professional staff, Bradford Gray, a senior staff member at the Institute of Medicine and

former staff sociologist for the National Commission for the Protection of.Human Subjects, served as a special consultant to the President's Commission. Dr Gray directed a pilot study on the value of site visits to Institutional Review Boards.

The Commission's Public Information Officer was Andrew Burness, formerly an assistant for health and education policy to Representative Richardson Preyer of North Carolina. The Commission's permanent staff positions also included an administrative officer, a staff assistant responsible for meeting management, and a secretary. In addition, the Commission's temporary positions included two research assistants, two secretaries, a staff aide, two editors, and a philosophy graduate student who served as a part-time consultant to assist the Deputy Director on the research-related reports.

The Commission laundered an internship program for the summer of 1980 in order to introduce students in philosophy, medicine, law, and related fields to the practical implications of bioethics. To broaden the basis of this program to include term-time appointments, as well as to relieve the strain on the Commission's budget created by the program, the Commonwealth Fund created a fellowship program that provided $25,000 for the period from May 1981 to September 1982. Under this program, which was administered by the Institute of Society, Ethics and the Life Sciences (The Hastings Center), applicants were sought through direct contact with numerous graduate and professional schools and through an announcement in the *Hastings Center Report.* Approximately 60 students applied each year. Overall 14 graduate students assisted the professional staff during the course of the Commission's work. They included law students, medical students, and graduate students in health policy, genetic counseling, psychology, and philosophy. Each summer, the Commission also had the voluntary services of an undergraduate intern.

Although authorized at $20 million ($5 million per year for four years), the Commission expended less than $4 million over its lifetime. The Commission's funding for the nine months of fiscal year 1980 took the form, with the consent of Congress, of reprogrammed funds from the Department of Health and Human Services (then HEW) in the amount of $697,500. (The amount originally provided was $1,200,000; $502,500 was returned to HHS because, in the Commission's judgment, the full amount could not be expended wisely in fiscal year 1980, especially since the projects that the Commission undertook during its first months did not involve large empirical surveys.) For fiscal year 1981, 1981, President Carter requested an appropriation of $2,054,000, and the Commission actually operated with a budget authority of $1,545,000 under the series of continuing resolutions that funded agencies in the health area of the Federal budget. For fiscal year 1982, President

Reagan initially requested an appropriation of $2,200,000 for the 15 months through December 31, 1982. The Senate Appropriations committee approved $2,000,000 and the House voted $1,500,000; the latter amount, decreased by the government-wide 4% reduction under the September 1981 Continuing Resolution, provided initial funding of $1,440,000. This was increased to $1,749,000 by the July 1982 Urgent Supplemental Appropriations Act; these funds supported the Commission for the 18 months through its closing on March 31, 1983, under the terms of the December 1982 Continuing Resolution.

Procedures

Commission Meetings. The Commission held 28 meetings between January 1980 and March 1983. Typically, two-day meetings were held once a month. All meetings were open to the public, and attendance ranged from 25 to 200 persons. Twenty-four meetings were held in or near Washington, D.C.[8] In order to gather information and to make the Commission more accessible nationally, four meetings were held in other parts of the country: in Boston, Atlanta, Miami, and Los Angeles. Notice of each meeting and of the topics to be discussed was published in the *Federal Register* and announced in the minutes that were distributed to approximately 1500 individuals and organizations on the Commission's mailing list.

Information Gathering. Prior to each meeting, the Commissioners were provided with briefing books that contained extensive background materials taken from the existing literature as well as new studies prepared by staff, contractors, and consultants to the Commission. The Commission contracted for scholarly studies in all areas of its mandate. These included large empirical studies, small pilot projects, and analytical research papers. Studies conducted under contract are published in the appendices of the relevant reports.

The Commission heard testimony from more than 300 scheduled witnesses including philosophers, physicians, biologists, lawyers, clergy, political and social scientists, university and hospital administrators, members of the insurance industry, representatives of the Federal government, representatives of interest groups (such as the Association of American Medical Colleges, the American Psychological Association, and the American Council on Education), and members of the public, including health care consumers. In each area of inquiry, special care was taken to solicit the views of

[8] The Commission is especially grateful to the U.S. Water Resources Council and to the Medical Society of the District of Columbia for allowing their meeting rooms to be used by the Commission for public hearings on numerous occasions.

individuals with firsthand experience in the area under study and to obtain a balanced range of viewpoints. And at each meeting, time was set aside for comments from the floor by members of the general public.

In addition to testimony at Commission meetings, advice was sought from several panels convened by the Commission staff. For example, nurses drawn from practice, academia, and government addressed the topics in the Commission's mandate, particularly the areas of informed consent and decisions to forego life-sustaining treatment; a group of philosophers considered the issue of distributive justice in the availability of health care; neurologists, neurosurgeons, anesthesiologists, pediatricians, and other medical experts prepared clinical guidelines for the determination of death; and biologists, physicians, lawyers, philosophers, and social scientists assisted in identifying the ethical, social, and legal issues in the use of gene splicing in human beings. Other panels were convened to discuss access to health care, protection of human subjects, compensation of injured research subjects, the definition of death, and informed consent. (For a complete list of witnesses and panel members, see Appendix C.)

Dissemination of Information. In order to keep the public informed of its activities, the Commission developed an extensive information program. Each meeting of the Commission was covered by both local and national print and broadcast media. Commission representatives appeared on national network news and public information programs, on cable and public broadcasting programs, and on television programs in cities where the Commission met. Radio coverage was also local, national, and international in scope. The Commission also learned more about public opinion when talk show hosts invited its representatives to appear on programs originating in virtually every part of the country. The Commission's work received particular attention in journals addressed to specialists in the fields covered by Commission studies. Commission representatives also met with academic, civic, and public interest groups, both in and outside of Washington. The staff testified before Congress on fraud in research, implementation of regulations for the protection of human subjects, genetic screening; and genetic engineering.

As a follow-up to each meeting, detailed minutes were distributed to a mailing list of approximately 1500 individuals and organizations, including members of the lay public, Congressional and Federal agency staff, scientific and professional organizations, public interest groups, the media, and university professors and researchers. An informational brochure about the Commission was also circulated. Additionally, all materials provided to the Commissioners were available to the public upon request. In order to provide a permanent

record of its activities that will be readily accessible to scholars, the Commission provided complete sets of meeting notebooks to the libraries of the Institute of Society, Ethics and the Life Sciences in Hastings-on-Hudson, New York, and the Kennedy Institute of Bioethics at Georgetown University, in Washington, D.C.

In addition to being sent to people on the Commission's mailing list, copies of the nine Commission reports are placed in the Federal regional depository libraries by the Superintendent of Documents. The format for the reports are designed by Peter Masters, Director of General Service Administration's Graphic Communications and Design Staff. The graphic design and illustrations were executed by Sharon Waltersdorff, of GSA, and by Linda Berns and Lee Schuyler of Berns & Kay, in conjunction with the Commission's staff.

Studies on Health Care

2

The Commission prepared five reports on topics related to the provision of health care: *Defining Death* (July 1981); *Making Health Care Decisions* (October 1982); *Screening and Counseling for Genetic Conditions* (February 1983); *Securing Access to Health Care* (March 1983); and *Deciding to Forego Life-Sustaining Treatment* (March 1983). The first four topics were assigned to the Commission by the Congress; the fifth was added early in the Commission's tenure when it arose during the study on the "definition" of death and because it applied several areas of the Commission's work to a set of ethical problems of great importance and immediacy. In addition. as part of its statutory mandate, the Commission studied the ethical aspects of privacy and confidentiality in the health field; for several reasons, it chose not to issue a separate report on that subject but to present its conclusions in this final report.

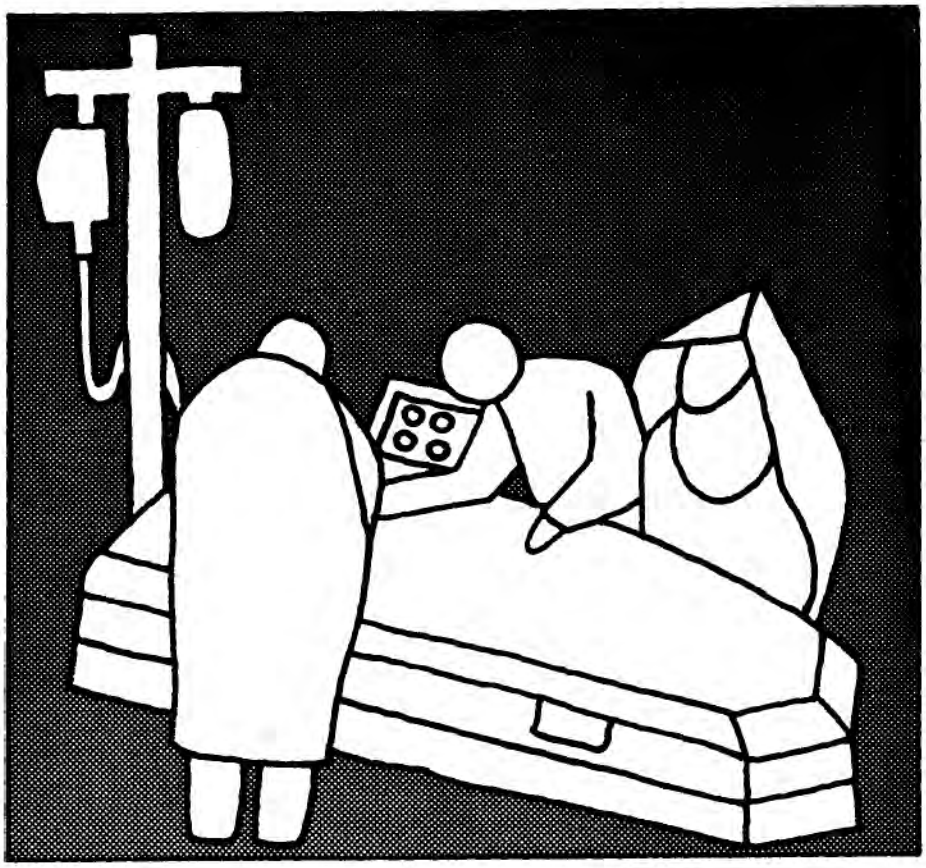
The Definition of Death

> Death is the one great certainty. The subject of powerful social and religious rituals and moving literature, it is contemplated by philosophers, probed by biologists, and combatted by physicians. Death, taboo in some cultures, preoccupies others... The question addressed here is not inherently difficult or complicated. Simply, it is whether the law ought to recognize new means for establishing that the death of a human being has occurred.
>
> *Defining Death,* p. 3

The Issues. The first issue posed in the Commission's mandate is whether the law ought to recognize new means for establishing that human death has occurred. Although straight-

forward, this question has seemed troublesome for several reasons.

In a small number of cases, ventilators and associated medical technologies can maintain heartbeat and respiration in dead bodies-those having sustained total and irreversible cessation of all brain functions. Thus, the beating heart has sometimes lost the importance customarily accorded it in differentiating the living from the dead.



Moreover, confusion arises because the same technology that keeps heart and lungs functioning-and that thus masks the meaning of these functions in some dead people-can also sustain life in others who have been less severely injured. Inexact medical and legal descriptions of these two categories of cases have blurred of the important distinction between patients who are *dead* and those who are *dying,* though perhaps beyond any reasonable probability of recovery. The latter situation is more problematic in medical, ethical, and legal terms and became the subject of a separate Commission report, rather than being addressed as an aspect of *Defining Death.*

The Commission's Study. The Commission's study of the "ethical and legal implications of the matter of defining death," as it was stated in the Congressional mandate, was also the first it completed. The study began with hearings in May and

June 1980 on the medical, ethical, religious, legal, and public policy aspects of the subject through written and oral presentations. The Commission also sponsored empirical investigations on the various outcomes of respirator support for patients in coma of both traumatic and nontraumatic origin, in order to have a rough idea of how frequently the determination of death by traditional measures of heartbeat and respiration is rendered difficult by artificial means of support. It was this empirical study that highlighted for the Commissioners the importance of addressing the ethical implications of decisions to cease treatment, since most "hard cases" faced by clinicians involved patients who were failing to recover, not those who had ceased to have any brain functions.

The Commission's Report. The Commission concluded that the necessary changes in the law, as well as the desirable goal of "uniformity" contemplated by its mandate, could best be achieved through statutory revision of the law. In its report the Commission noted that:

(1) Recent developments in medical treatment necessitate a restatement of the standards traditionally recognized for determining that death has occurred.

(2) Such a restatement ought preferably to be a matter of statutory law.

(3) Such a statute ought to remain a matter for state law, with Federal action at this time being limited to areas under exclusive Federal jurisdiction.

(4) The statutory law ought to be uniform among the several states.

(5) The "definition" contained in the statute ought to address general physiological standards rather than medical criteria and tests, which will change with advances in biomedical knowledge and refinements in technique.

(6) Death is a unitary phenomenon that can be accurately demonstrated either on the traditional grounds of irreversible cessation of heart and lung functions or on the basis of irreversible loss of all functions of the entire brain.

(7) Any statutory "definition" should be kept separate and distinct from provisions governing the donation of cadaver organs and from any legal rules on decisions to terminate life-sustaining treatment.

To embody these conclusions in statutory form, the Commission worked with the major professional bodies in medicine, law, and legislative reform to develop a new proposed statute. The American Bar Association, the American Medical Association, and the National Conference of Commissioners on Uniform State Laws joined the Commission in endorsing the Uniform Determination of Death Act, to replace their previous, separate proposals:

An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards.

The Commission recommended the adoption of this statute in all jurisdictions in the United States. The proposal recognizes that the traditional means to determine death will continue to be applied in the overwhelming majority of cases. In those instances in which artificial means of support require direct evaluation of the functions of the brain, the statute would recognize the use of accepted medical procedures.

As an aid to the implementation of the proposed statute, the Commission also published *Guidelines for the Determination of Death* as an appendix to its report. These were developed by a group of over 50 medical and scientific consultants representing a wide range of medical specialities. The Guidelines represent a distillation of current practice in regard to the determination of death, and are designed to be advisory. The purpose of the guidelines is to ensure that, to the greatest extent possible, a determination that death has occurred will:

(1) eliminate errors in classifying a living individual as dead,

(2) allow as few errors as possible in classifying a dead body as alive,

(3) allow a determination to be made without unreasonable delay,

(4) be adaptable to a variety of clinical situations, and

(5) be explicit and accessible to verification.

Response to the Report. More than 6000 copies of the report were distributed by the Commission. Copies went to all members of Congress, appropriate offices in the Executive branch, state legislators and administrators in health-related positions, members of health professional and law reform organizations, members of the public on the Commission's mailing list, and medical and law school libraries. *Defining Death* quickly became a standard reference point in the public policy debate on this topic and has been widely cited in the scholarly literature.

The *Guidelines for the Determination of Death* were published in their entirety (with an accompanying editorial that praised them as a "landmark") in the November 13, 1981, issue of the *Journal of the American Medical Association;* they have subsequently been reprinted in a number of specialty journals and textbooks.

Since the Commission concluded that the matter of "defining" death should continue to be the province of state legislatures, with the Federal government reserving responsibility only for those areas of exclusive Federal jurisdiction, the focus of follow-up activities has been in the states rather than in the national legislature. In addition to supplying the report to all members of state health and judiciary subcommittees, the Commission staff testified before state committees when requested and supplied information to help coordinate state legislative activities. To date, the Uniform Determination of Death Act recommended by the Commission has been enacted in a dozen jurisdictions and is pending in as many more; Congress, however, has yet to respond to the recommendation for a statute to be applied in areas under Federal jurisdiction.

The Commissioners and staff have frequently been called upon as a resource on this issue, to clarify existing laws and to improve public understanding as certain cases received media attention (such as the Korean boxer Kim Duk Koo, who was declared dead on the basis of brain criteria and subsequently became an organ donor). Commission representatives were also able to discuss this issue in a number of national forums.

Informed Consent

> The complexities of modern life make it difficult for individuals to be masters of their own fate. Perhaps in no sphere of everyday activity is this more acute than in health care... .Traditionally, many cultures, including this one, have responded by according healers a unique deference and authority in their relationships with patients. Yet this authority is not, and has not been, absolute.…American courts, supported by legal and ethical commentary, have articulated a legal doctrine of "informed consent" that requires health care practitioners not simply to seek the consent of their patients, but also, through a process of disclosure and discussion between practitioners and patients, to make such consents "informed."
>
> *Making Health Care Decisions,* pp. 15-16

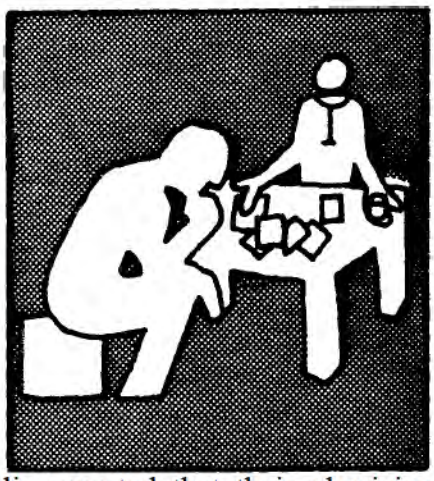
The Issues. The Commission's statutory mandate calls for a study of "the ethical and legal implications of the requirements for informed consent to participation in research projects and to otherwise undergo medical procedures." In view of the considerable attention accorded to informed consent requirements in the research setting by the National Commission for the Protection of Human Subjects, as well as this Commission's continuing attention to that subject in its separate Biennial Reports, the Commission decided to focus the "informed consent" project on medical treatment rather than upon research. In addition, the Commission—though

recognizing that "informed consent" is a doctrine developed by the law—decided that it could make a larger contribution on the subject if it did not limit its study solely to the legal aspects of informed consent. Instead, the broader issue of relationships between patients and health care providers in the delivery of health care was considered. This included an examination of the role of informed consent in promoting both communication between patients and health care professionals and "better" or "more autonomous" decisions by patients, as well as in improving therapeutic outcomes by increasing patient trust and decreasing provider anxiety over legal liability.

The Commission's Study. A large number of witnesses were heard on the subject of enhancing patient participation in health care decisions; additional presentations and discussions focused on the issues raised by patients' incapacity to participate in decisionmaking and on the role of families as surrogates. The Commission also received testimony from leaders in medicine, nursing, the humanities, and the social sciences on the need for better education of health care professionals about informed consent and on possible means of achieving it.

In order to learn more about informed consent as it occurs in practice, the Commission contracted for three empirical studies. Two studies involved observation and recording of interactions between health care professionals and patients in hospital settings as well as interviews with the people involved. The third was a national survey by Louis Harris and Associates of the views of physicians and members of the public regarding attitudes toward, experience with, and knowledge of informed consent, disclosure of information, and decisional authority in medical care. The results of all three studies are summarized in the report; a fuller description of the studies and the data obtained may be found in the first of two appendix volumes that accompany the report.

In the national survey—the first ever to compare simultaneously the attitudes on informed consent of patients and providers—telephone interviews were conducted with representative samples of 800 physicians and 1250 adults in the general public. The results showed that the public and physicians agree that patients have a right to all available information regarding their conditions and treatments and that the public universally desires such information. Moreover, the desire for information is universal and not specific to any age-group, sex, race, or social class. For example, 86% of the physicians believed most patients want a candid assessment of their diagnosis and prognosis, and 94% of the public reported they wanted to be told everything about their condition and treatment, even if it was unfavorable. However, when faced with a sick patient—such as one with a fully confirmed diagnosis of advanced lung cancer—physicians reported being



unwilling to be candid. Only 13% said they would "give a straight statistical prognosis for his class of disease."

Further, the proportion of physicians who reported discussing certain matters with their patients was generally greater than the proportion of patients who reported that their physicians do so. For example, while 98% of the physicians said they usually discuss diagnosis and prognosis with their patients, only 78% of the public reported that their physicians usually explained this to them. Likewise, 84% of the physicians claimed that they usually discuss the pros and cons of the recommended treatment, compared with 68% of the public who said their physician usually explains this to them.

The two observational studies examined the interaction of patients and health care professionals in various hospital settings. The results of both studies reveal that the actual practice of informed consent is not as close to the ideal as the results of the Harris survey suggest. In one study, which involved treatment refusals that the investigators subsequently discussed with the patients, refusals were generally triggered by the provision of too little (rather than too much) information. The second study examined whether the nature of the physician/patient interaction varied in several settings. Thus, the investigators compared the consent process for inpatients and outpatients, medical and surgical patients, and patients with acute versus chronic illness. With the exception of patients with chronic illness, the study showed that physician/patient communication in practice bore little relation to "informed consent" as envisioned by law.

The Commission's Report. *Making Health Care Decisions* traces the history of informed consent in the law and in medical practice and briefly sketches recent changes in the nature of health care and in society's expectations for the patient-professional relationship. As a group on bioethics, the Commission gave special attention to the values underlying informed consent.

The Commission discussed the customarily accepted ethical and legal obligations of health care professionals against a backdrop of what is known about actual practice, including the findings of its own empirical studies. The report also explored several means to bring goals and realities closer together. Attention was directed to innovative approaches in patient-

professional communication and decisionmaking that appear to be practically as well as theoretically sound. Legal rules, along with professional attitudes and behavior as they are shaped by education and training, were examined for their potential to provide patients with an effective basis to participate in decisionmaking. Finally, since certain people are unable to make some or all decisions on their own behalf, the Commission set forth principles and procedures for health care decisions that others must make for patients who lack decisionmaking capacity.

The Commission's findings and conclusions on this subject can be summarized as follows:

(1) Although the informed consent doctrine has substantial foundations in law, it is essentially an ethical imperative.

(2) Ethically valid consent is a process of shared decisionmaking based upon mutual respect and participation, not a ritual to be equated with reciting the contents of a form that details the risks of particular treatments.

(3) The literature about informed consent often portrays it as a highly rational process, suitable primarily for intelligent, highly articulate, self-aware individuals. The Commission found, however, a universal desire for information, choice, and respectful communication about decisions--for all patients, in all health care settings.

(4) Informed consent is based upon the principle that competent individuals are entitled to make health care decisions based upon their own personal values and in furtherance of their own personal goals. However, patient choice is not absolute:

- Patients are not entitled to insist that health care practitioners furnish them services when to do so would breach the bounds of acceptable practice or violate a professional's own deeply held moral beliefs or would draw on a limited resource to which the patient has no binding claim.
- In order to promote self-determination and patient well-being, individuals should be presumed to have decisionmaking capacity; only in a small minority of cases should incapacity disqualify a patient from making a decision regarding health care.
- Alternative arrangements should be made for decisionmaking on behalf of individuals who lack substantial capacity to make their own decisions; incapacity should be viewed, however, as specific to each particular decision.
- Persons lacking decisional capacity should be consulted about their own preferences, to the extent feasible, out of respect for them as individuals.

(5) Health care providers should not ordinarily withhold unpleasant information simply because it is unpleasant.

(6) Achieving the goal of shared decisionmaking based upon mutual respect is ultimately the responsibility of individual health care professionals. However, health care institutions such as hospitals also have important roles to play in fostering the process.

(7) Patients should have access to the information they need to help them understand their conditions and make treatment decisions.

(8) Improvements in the relationship between health care professionals and patients must come not primarily from the law but from changes in the teaching, examination, and training of health care professionals.

(9) Family members are often of great assistance to patients in helping them to understand information about their condition and in making decisions about treatment. Their involvement should be encouraged to the extent compatible with respect for the privacy and autonomy of individual patients.

(10) In order to promote a greater commitment of time to the process of shared decisionmaking, reimbursement schedules for all medical and surgical interventions should take account of the time necessarily spent in discussion with patients.

(11) To protect the interests of patients who lack decisionmaking capacity:

- Decisions made by others should, when possible, replicate those the patients would make if they were capable; when that is not feasible, the decisions of surrogates should protect the patients' best interests.
- Health care institutions should consider using mechanisms such as "ethics committees" for review and consultation regarding decisionmaking for those who lack the capacity to decide.
- State courts and legislatures should consider making provision for advance directives through which people may designate others to make health care decisions on their behalf and/or give instructions about their care should they become incapacitated.

Response to the Report. The Commission's report on informed consent, which was widely distributed to medical and nursing schools, as well as to scholars and teachers in related fields, struck a responsive chord, coming at a time when educators seem worried about the future direction of education and training of health care professionals. Particularly in medical education, concerns have been voiced increasingly about the large amounts of time students must devote to

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absorbing a complex and overwhelming volume of scientific details. Some educators told the Commission that this current emphasis dehumanizes prospective physicians, resulting in practitioners who may lack sensitivity or who may overemphasize the importance of technological solutions to human problems.

Such concerns are now the subject of a study by a panel of the Association of American Medical Colleges (AAMC). In a first-year progress report of this three-year study, the panel identified many issues that parallel those in the Commission's study. The AAMC plans to continue to assess ways in which undergraduate institutions and medical schools might improve the essential knowledge and personal communication skills of future physicians.

The Commission learned that *Making Health Care Decisions* has already been found useful as teaching material in medical and nursing school classes. The Commission also provided copies to groups such as the National Council on Patient Information and other private and public organizations that are working to break down barriers of communication between health care providers and their patients.

The extensive data generated by the studies contracted by the Commission were welcomed by scholars in the field as a rich resource for further study. The Commission's survey of physicians and the public—which revealed some startling conclusions and contradicted common assumptions about patients' desire for information—also received widespread attention in the public press, confirming that this subject is of much more than academic concern.

Genetic Screening and Counseling

> The rapid advances now occurring in genetic screening techniques and the increased resources devoted to genetic counseling give Americans new opportunities to understand their biological heritage and to make their health care and reproductive plans accordingly.
>
> *Screening and Counseling for Genetic Conditions,* p. 1

The Issues. The Commission's mandate regarding genetic screening directed the Commission to undertake studies of the ethical and legal implications "of voluntary testing, counseling, and information and education programs with respect to genetic diseases and conditions, taking into account the essential equality of all human beings, born and unborn."

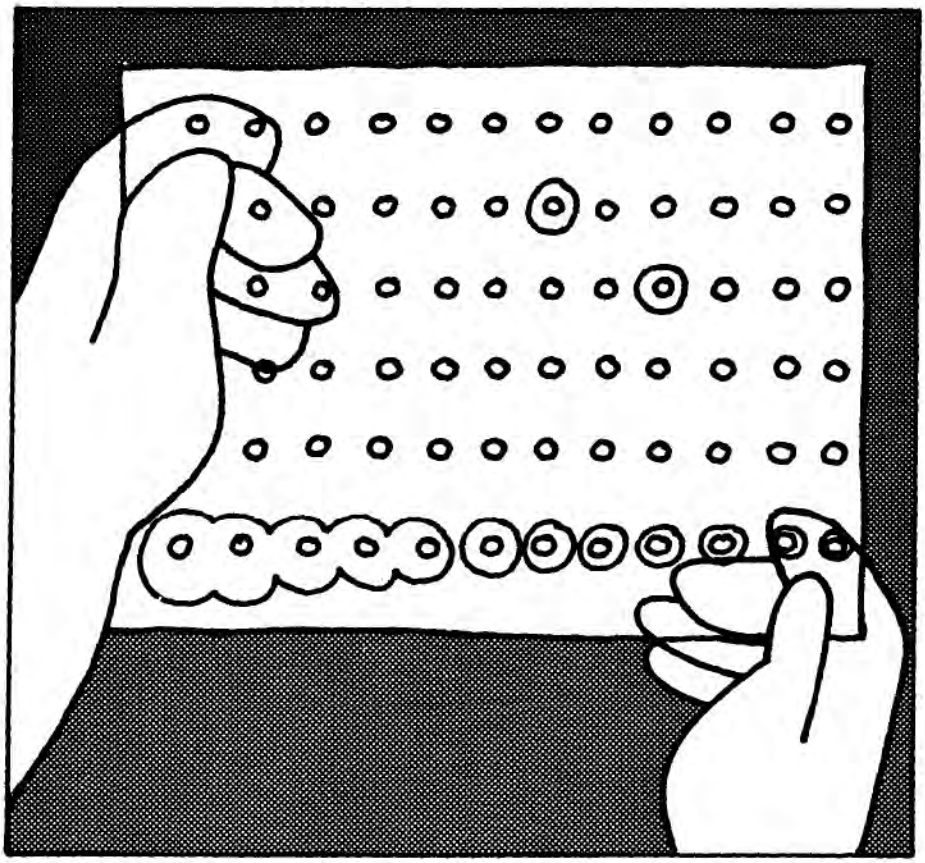
Genetic screening may be undertaken either to permit medical intervention or to provide information about reproductive choices. Genetic screening of the first type-that is, to uncover a person's need for medical care-is similar to other types of screening (such as routine blood pressure or tuberculin

tests) in that the goal is to determine whether remedial or preventive health care is needed. Genetic screening to provide information for reproductive decisions, on the other hand, differs from other routine tests in that the information produced is often relevant to medical decisions by individuals other that the person screened. The information provided—and the decisions based on it—have significance not only for people's own health, but also for the health of their children. Genetic counseling is an individualized process in which a specialist in medical genetics confers with an individual, a couple, or sometimes a group seeking additional information or assistance. It helps people with a potential or manifest genetic problem understand and, as far as possible, adjust to genetic information; when necessary, it aids them in making decisions about what course to follow.

The Commission's Study. At the Commission's first hearing on genetic screening, in May 1981, witnesses described screening for several serious inheritable conditions, including Tay-Sachs disease, sickle-cell anemia, phenylketonuria (PKU), and neural tube defects. The Commission also heard about recent research suggesting that prenatal or carrier screening tests for cystic fibrosis (CF), the most common lethal genetic disease in the United States, may available in the not-too-distant future. The Commission decided to examine past experience with screening programs and to explore the ethical aspects of genetic screening as a means of anticipating issues that will be raised by large-scale screening for CF.

To ensure that the Commission would make a useful contribution in illuminating the ethical principles that should underlie the formulation of public policy on genetic screening, Commission staff reviewed with governmental and nongovernmental experts related work they have undertaken or plan to conduct on the ethical and legal aspects of genetic screening. In the spring of 1982, a second hearing was held, focused on genetic counseling issues, at which time a panel of experts commented on a staff draft of the report. The panel consisted of a genetic counselor, the director of Federal genetic activities, a philosopher, and two pediatrician/geneticists. This project was also coordinated with the Commission's work on informed consent and access to health care.

The Commission's Report. In *Screening and Counseling for Genetic Conditions,* the Commission discussed the basic facts about past genetic screening and counseling efforts and then set forth a number of conclusions and recommendations on how education, screening, and counseling programs could take account of important ethical and legal concerns. In the report's final chapter, these points were applied to cystic fibrosis screening as a hypothetical test case; the issues that would be



of concern there could also be expected to arise regarding tests developed for other genetic conditions.

On the whole, the Commission found that advances in medical genetics have greatly enhanced health and well-being. Some programs could have less beneficial consequences if they are not limited in certain ways, but most are not matters for concern or controversy. The Commission's major conclusions fell into five categories.

Confidentiality

(1) Genetic information should not be given to unrelated third parties, such as insurers or employers, without the explicit and informed consent of the person screened or a surrogate for that person.

(2) Private and governmental agencies that use data banks for genetics-related information should require that stored information be coded whenever that is compatible with the purpose of the data bank.

(3) Genetic information should be released to relatives (or their physicians) without the patient's consent if and only if the following four conditions are met: (a) reasonable efforts to elicit voluntary consent to disclosure have failed; (b) there is a high probability both that harm will occur if the information is withheld and that the disclosed information will actually be used to avert harm; (c) the harm that identifiable individuals

would suffer if the information is not disclosed would be serious; and (d) appropriate precautions are taken to ensure that only the genetic information needed for diagnosis and/or treatment of the disease in question is disclosed.

(4) Law reform bodies, working closely with professionals in medical genetics and organizations interested in adoption policies, should urge changes in adoption laws so that information about serious genetic risks can be conveyed to adoptees or their biological families. Genetic counselors should mediate the process by which adoptive records are unsealed and newly discovered health risks are communicated to affected parties.

Autonomy

(5) Mandatory genetic screening programs are only justified when voluntary testing proves inadequate to prevent serious harm to the defenseless, such as children, that could be avoided were screening performed.

(6) Professionals should generally promote and protect patient choices to undergo genetic screening and counseling, although the use of amniocentesis for sex selection should be discouraged.

Knowledge

(7) Decisions regarding the release of incidental findings (such as nonpaternity) or sensitive findings (such as diagnosis of an XY-female) should begin with a presumption in favor of disclosure, while still protecting a client's other interests, as determined on an individual basis. In the case of nonpaternity, accurate information about the risk of the mother and putative father bearing an affected child should be provided even when full disclosure is not made.

(8) Efforts to develop genetics curricula for elementary, secondary, and college settings and to work with educators to incorporate appropriate materials into the classroom are commendable.

(9) Professional educators, working with specialty societies and program planners, should identify effective methods to educate professionals about new screening tests. Programs to train health professionals, pastoral counselors, and others in the technical, social, and ethical aspects of genetic screening deserve support.

Well-Being

(10) Screening programs should not be undertaken unless accurate results will be produced routinely and a full range of pre screening and follow-up services are available.

(11) A genetic history and, when appropriate, genetic screening should be required of men donating sperm for artificial insemination; professional medical associations should take the lead in identifying what genetic information

should be obtained and in establishing criteria for excluding a potential donor.

- Records of sperm donors are necessary, but should be maintained in a way that preserves confidentiality to the greatest extent possible.
- Women undergoing artificial insemination should be given genetic information about the donor as part of the informed consent process.

Equity

(12) Access to screening may take account of the incidence of genetic disease in various racial or ethnic groups within the population without violating principles of equity, justice, and fairness.

(13) Policies on the availability of a genetic service should be subjected to review by a broadly based process that is responsive to the full range of relevant considerations.

- The time has come for such a review of the common medical practice of limiting amniocentesis for "advanced maternal age" to women 35 years or older.

(14) Determination of issues such as which groups are at high enough risk for screening or at what point the predictive value of a test is sufficiently high requires ethical as well as technical analyses.

(15) Cost-benefit analysis can make a useful contribution to allocational decisionmaking; difficult ethical issues, however, must still be confronted.

Response to the Report. The release of the Commission's study at the end of February 1983 was front-page news in the *New York Times* and other papers across the country. The Commission's Chairman and Director discussed the Commission's findings and conclusions on national television and radio programs. There was considerable public interest in the report; in addition to those on the regular mailing list, the report was distributed by the Commission to over 1500 other people, and supplies were quickly exhausted.

Differences in the Availability of Health Care

Health care can relieve pain and suffering, restore functioning, and prevent death; it can enhance good health and improve an individual's opportunity to pursue a life plan; and it can provide valuable information about a person's overall health. Beyond its practical importance, the involvement of health care with the most significant and awesome events of life—birth, illness, and death—adds a symbolic aspect to health care: it is special because it signifies not only mutual empathy and caring but the mysterious aspects of curing and healing. Furthermore, while people have some

> ability—through choice of life-style and through preventive measures—to influence their health status, many health problems are beyond their control and are therefore undeserved... .Finally, the incidence and severity of ill health is distributed very unevenly among people....Together, these considerations lend weight to the belief that health care is different from most other goods and services. In a society concerned not only with fairness and equality of opportunity but also with the redemptive powers of science, there is a felt obligation to ensure that some level of health services is available to all.
>
> *Securing Access to Health Care,* pp. 11-12

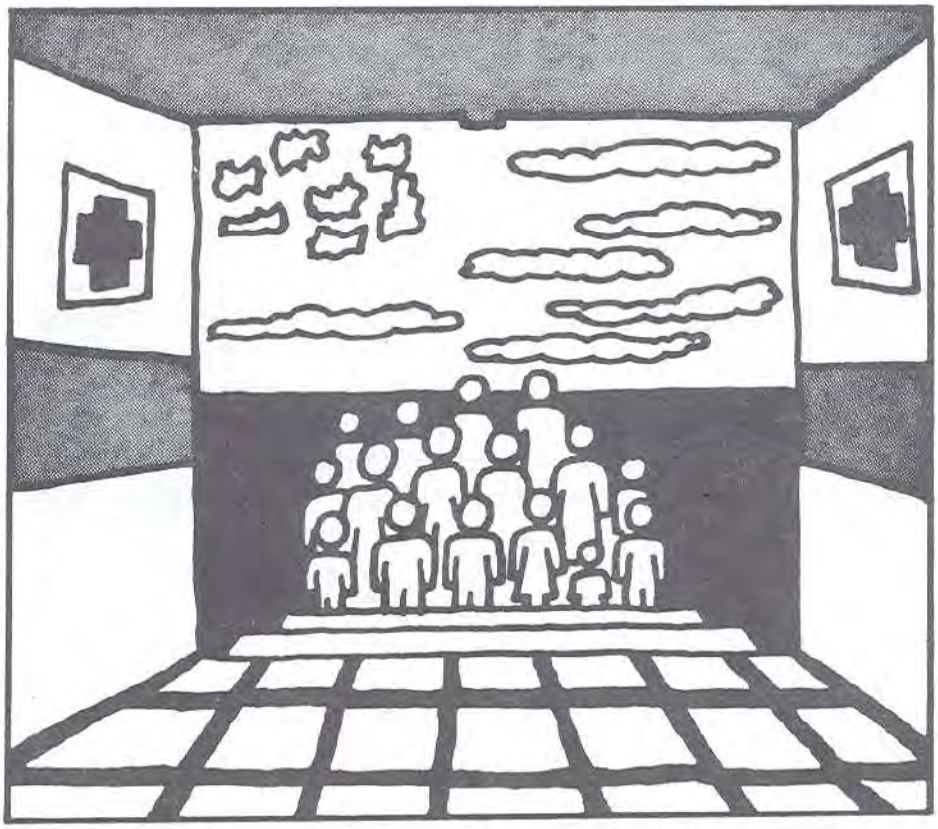
The Issues. In 1980, the nation spent an estimated $247 billion on health care—an average of more than $1000 for every citizen. Yet despite this enormous investment, all Americans do not share equally in the benefits of the health care system. Testimony presented to the Commission indicates that certain groups—the poor, minorities, the uninsured, and residents of inner-city and rural areas—are more likely to receive inadequate health services. Although most would agree that society has an ethical obligation to secure some level of care for those in need, past governmental programs and pronouncements by public officials do not reveal a consensus as to the level and nature of this commitment.

Government financing programs, like Medicare and Medicaid, as well as programs that provide care directly to veterans and the military and through local public hospitals, have greatly improved access to health care. These efforts, coupled with the expanded availability of private health insurance, have resulted in almost 90% of Americans having some form of health insurance coverage in normal economic times. Yet the patchwork of government programs and the uneven availability of private health insurance through the workplace has resulted in the exclusion of millions of people. In mid-1982, the Surgeon General observed that with rising unemployment, the percent of the population without health insurance coverage would rise rapidly, a prognosis confirmed by more-recent studies by the Congressional Budget Office. Many such people lack effective access to health care, and many more who have some form of insurance are unprotected from the severe financial burdens of sickness.

The Commission's Study. In pursuing its mandate to study the ethical implications of differences in the availability of health services, the Commission elected to step back from the current health policy debate in order to examine possible justifications for the conclusion that health care should, as a matter of national policy, be available to all. Which patterns of access should be considered equitable? And how can the

burdens encountered in striving to eliminate the inequities in access be fairly distributed?

At one meeting, the Commissioners explored in detail a number of philosophical issues in health care. In addition to reports by members of a panel of philosophers, who had been studying the subject for the Commission, witnesses from medicine and law joined in discussing the right to health care, the concept of adequate care, health care needs and deserts, and providers' and patients' freedom of choice. Another meeting dealt with ethical issues in the allocation of health care resources. The discussion focused on how decisions that limit available care are made within different delivery settings (hospitals and health maintenance organizations) and about various types of services (end-stage renal disease, adult and neonatal intensive care, and hypertension screening and treatment), as well as the role of third-party payors in this process. The hearing concluded with testimony about the implications that malpractice and regulatory law have for efforts to improve equity of access to health care.



The final hearing on this subject was held in Atlanta, where testimony was presented by members of the public who had found it difficult to secure or pay for health services, from physicians and a hospital administrator about problems in delivering health care to the poor, and from several health officials and the heads of voluntary organizations about access

patterns and policies in their states. The Commission also received the report of a study on insurance coverage and the use of health services, and it heard testimony on innovative solutions to the maldistribution of health care providers. Finally, while in Atlanta, the Commissioners visited a Federally supported primary care center that serves a largely low-income, urban neighborhood.

The Commission's hearings and site visit added personal and immediate experiences to the wealth of data provided by analyses undertaken for the Commission and by published studies, including several national surveys on health status and the use of health services related to demographic characteristics such as race, income, and place of residence. Over the course of a number of subsequent meetings, at one of which a number of experts provided comments on a draft of the report, the Commissioners refined successive versions of the report, before adopting it (by a vote of ten to one) in December 1982. (The report was released at the end of March 1983, after the present report was in press.)

The Commission's Report. In *Securing Access to Health Care,* the Commission did not propose any new policy initiatives. Rather, it tried to provide a framework within which debates about health policy might take place, in the hope it would aid policymakers in considering whether some proposals do a better job than others of securing health care on an equitable basis. The Commission summarized its conclusions as follows:

(1) The Commission concludes that society has an ethical obligation to ensure equitable access to health care for all. This obligation rests on the special importance of health care, which derives from its role in relieving suffering, preventing premature death, restoring functioning, increasing opportunity, providing information about an individual's condition, and giving evidence of mutual empathy and compassion. Furthermore, although lifestyle and the environment can affect health status, differences in the need for health care are for the most part undeserved and not within an individual's control.

(2) The societal obligation is balanced by individual obligations. Individuals ought to pay a fair share of the cost of their own health care and take reasonable steps to provide for such care when they can do so without excessive burdens. Nevertheless, the origins of health needs are too complex, and their manifestation too acute and severe, to permit care to be regularly denied on the grounds that individuals are solely responsible for their own health.

(3) Equitable access to health care requires that all citizens be able to secure an adequate level of care without excessive burdens. Discussions of a right to health care have frequently been premised on offering patients access to all

beneficial care, to all care that others are receiving, or to all that they need--or want. By creating impossible demands on society's resources for health care, such formulations have risked negating the entire notion of a moral obligation to secure care for those who lack it. In their place, the Commission proposes a standard of "an adequate level of care," which should be thought of as a floor below which no one ought to fall, not a ceiling above which no one may rise.

Equitable access also means that the burdens borne by individuals in obtaining adequate care (the financial impact of the cost of care, travel to the health care provider, and so forth) ought not to be excessive or to fall disproportionately on particular individuals.

(4) When equity occurs through the operation of private forces, there is no need for government involvement, but the ultimate responsibility for ensuring that society's obligation is met, through a combination of public and private sector arrangements, rests with the Federal government. Private health care providers and insurers, charitable bodies, and local and state governments all have roles to play in the health care system in the United States. Yet the Federal government has the ultimate responsibility for seeing that health care is available to all when the market, private charity, and government efforts at the state and local level are insufficient in achieving equity.

(5) The cost of achieving equitable access to health care ought to be shared fairly. The cost of securing health care for those unable to pay ought to be spread equitably at the national level and not allowed to fall more heavily on the shoulders of particular practitioners, institutions, or residents of different localities.

(6) Efforts to contain rising health care costs are important but should not focus on limiting the attainment of equitable access for the least well served portion of the public. The achievement of equitable access is an obligation of sufficient moral urgency to warrant devoting the necessary resources to it. If the nation concludes that too much is being spent on health care, it is appropriate to eliminate expenditures that are wasteful or that do not produce benefits comparable to those that would flow from alternate uses of these funds. But measures designed to contain health care costs that exacerbate existing inequities or impede the achievement of equity are unacceptable from a moral standpoint.

Life-Sustaining Treatment

> Death comes to everyone. To a few, it comes suddenly and completely unexpectedly, but to most, it follows an opportunity for leave-taking and for directing to some extent the mode and timing of death. Virtually all people

> who die in this country will have been under treatment by health care professionals who have, especially in the last four decades, developed powerful means to forestall death…Physicians realize, of course, that the mission of vanquishing death is finally futile, but often they and their patients are quite determined to do all that is possible to postpone the event. Sometimes this objective so dominates care that patients undergo therapies whose effects do not actually advance their own goals and values. Specifically, the drive to sustain life can conflict with another fundamental (and arguably more venerable) objective of medicine-the relief of suffering....The attempt to postpone death should at times yield to other, more important goals of patients.
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> *Deciding to Forego Life-Sustaining Treatment,* pp. 15-16

The Issues. In responding to its legislative mandate to study the "definition" of death, the Commission was struck by the depth of public concern about life-sustaining treatment of patients who are dying or permanently unconscious. The general public and the news media-as well as health care professionals-were very interested in the Commission's responses to a number of specific policy problems such as care for patients in Karen Quinlan's situation, "living will" legislation, hospice care, and "do not resuscitate" orders. Feeling a responsibility to address these issues, the Commission decided to undertake a separate study of the ethical and legal implications of decisions to forego (that is, either to halt or not to initiate) life-sustaining treatment.

Today, for almost any life-threatening condition, some intervention is capable of delaying the moment of death. The frequency of dramatic breakthroughs in medical care--insulin, antibiotics, resuscitation, chemotherapy, dialysis, and transplantation, to name but a few--has made it possible to retard and even to reverse many conditions that were until recently regarded as fatal. Matters that were once the province of fate have now become a matter of human choice, a development that has profound ethical and legal implications.

Moreover, medical technology often renders patients less able to communicate or to direct the course of treatment. Even for mentally competent patients, others must usually assist or acquiesce in any decision to forego life-sustaining treatment. Conflicting values between physicians and patients, between patients and their families, or among family members are not uncommon. When joined with the confusion that surrounds issues of rights and liabilities, it is hardly surprising that judges have been called upon more often than previously to serve as the final bioethical arbiters in decisions to forego life-support measures. Consequently, it appeared to the Commission that

attempting to clarify the rights, duties, and liabilities of all concerned could be most valuable--drawing on the thinking of health professionals as well as ethical and legal commentators and concluding with appropriate guidance for hospitals, legislatures, and courts.

The Commission's Study. The Commission's study was undertaken not merely because of the report on defining death but also because of the relationship of this subject to the other studies that were being prepared. Deciding about life-sustaining therapy is one instance—and a particularly important one—of applying the principles of decisionmaking in medicine, which was the subject of *Making Health Care Decisions.* Such decisions are also constrained by considerations of justice and equity in the allocation of often scarce and expensive resources, a subject discussed in *Securing Access to Health Care.* The report on decisions about life-sustaining treatment thus represented an effort to apply the conclusions of two Commission reports to a particular area of current concern, while also responding to some of the tensions highlighted in *Defining Death.*

The five hearings on this report and those on the four allied reports overlapped to some extent; for example, the February 1982 hearing on "competence" in health care decisionmaking was relevant to both this study and the one on informed consent, as were hearings on resuscitation orders and the care of permanently unconscious patients. The Commissioners also heard testimony on the special problems arising in neonatal intensive care units and the medical, ethical, and legal aspects of life-sustaining treatment. Altogether, this study appeared on the Commission's agenda on more occasions than any other, a reflection of the difficulty of the issues raised and of the scope of the Commission's inquiry.

The Commission's Report. Building on a central conclusion of the report on informed consent—that decisions about health care must ultimately rest with competent patients—the Commission examined the situations in which a patient's choice to forego life-sustaining therapy may be limited on moral or legal grounds. In addition to providing clarification of the issues, the report suggested appropriate procedures for decisions regarding both competent and incompetent patients and scrutinized the role of various public and private bodies in shaping and regulating the process. *Deciding to Forego Life-Sustaining Treatment* did not judge any particular future case nor did it seek to provide a guidebook of morally correct choices for patients and health care providers who are facing such a decision. Rather, the Commission tried to illuminate the strengths and weaknesses of various considerations and various instruments of public policy. Clarifying the relevant

considerations and prohibitions may help decisionmakers even while it forces them to confront painful realities more directly.

The first half of the Report examined the considerations common to all decisionmaking about life-sustaining therapy. The social context of the report was highlighted by attention to the historical, cultural, and psychological dimensions of the subject. Although shared decisionmaking between provider and patient is the objective, the Commission pointed out that, particularly for seriously ill patients, constraints on choice arise when patients are inadequate decisionmakers; other constraints are imposed by the community's need to ensure that life is protected and that wrongful death is deterred and punished. The report scrutinized the distinctions that have commonly been made between acceptable and unacceptable foregoing of treatment and suggested how such distinctions, though often not in themselves of ethical importance, can still be useful in sound decisionmaking. The report paid particular attention to limitations on patients' choices that result from the actions of family members and care-giving professionals, from society's pursuit of equitable allocation of resources, and from the policies and practices of health care institutions (hospitals, nursing homes, and hospices), which are typically the settings where these many forces come together.

The report then considered several groups of patients whose situations raise special public policy concerns. The Commission first suggested certain concepts and procedures relevant to decisionmaking for incompetent patients generally, including advance directives (such as "living wills"), intra-institutional review (such as ethics committees), and court proceedings. It then turned to two groups of incompetent patients—those who have permanently lost all consciousness and seriously ill newborns. Finally, the report considered when and why "orders not to resuscitate" may be written for hospitalized patients whose hearts stop beating, and recommended institutional policies on such orders.

The Commission's conclusions in *Deciding to Forego Life-Sustaining Treatment* are numerous and deal with complex issues of law, medicine, ethics, and social policy in a manner

that cannot be paraphrased or summarized without introducing the possibility of significant distortion, misinterpretation, or over-simplification. In general, the conclusions describe the appropriate roles and responsibilities of individuals, institutions, and framers of public policy (including the courts) in three important areas--assisting patients and their families in making difficult decisions, resolving different views among interested parties, and setting limits on the choices that may be accepted under certain circumstances.

Throughout the report the Commission emphasized the importance of:

- respecting the choices of individuals competent to decide to forego even life-sustaining treatment;
- providing mechanisms and guidelines for decision making on behalf of patients unable to do so on their own;
- maintaining a presumption in favor of sustaining life;
- improving the medical options available to dying patients;
- providing respectful, responsive, and supportive care to patients for whom no further medical therapies are available or elected; and
- encouraging health care institutions to take responsibility for ensuring that adequate procedures for decisionmaking are available for all patients.

The Commission also concluded that the choices of patients, their families, and health care providers may legitimately be limited in certain ways on grounds of public policy, professional judgment, and considerations of resources scarcity.

Response to the Report. This study generated the greatest public response of any the Commission produced. Even before the report was issued, over 1000 individuals requested draft copies, based upon media attention during the Commission's consideration of the topic. The report received prominent and respectful coverage in the new and editorial columns of papers across the country and in journals for specialized audiences, and the Commission's Chairman and senior staff appeared on national television and radio to discuss the report. Portions of the report have already been incorporated in medical and nursing school curricula and have been studied by those responsible for framing the policies of hospitals, nursing homes, and other health care institutions.

Privacy and Confidentiality

The Issues. The Commission was mandated by its enabling legislation to undertake a study of "the ethical and legal implications of current procedures and mechanisms designed

(i) to safeguard the privacy of human subjects of behavioral and biomedical research, (ii) to ensure the confidentiality of individually identifiable patient records, and (iii) to ensure appropriate access of patients to information contained in such records."

Previous Commissions and legislative bodies had already considered many of the problems posed by the dissemination of medical information, and a medical records privacy act was pending in Congress during the first year of the Commission's work. When, in late 1980, the 96th Congress failed to pass that act the Commissioners turned their attention to this subject.

The Commission's Study. The Commissioners received a briefing on privacy at their first meeting in January 1980, at which an overview of principal issues was presented. A comprehensive hearing on the subject was held in March 1981, during which the Commission explored the relevant ethical issues and discussed several ways of fulfilling its mandate.

The Commission heard testimony from the former general counsel to the Privacy Protection Study Commission, who described that group's work from 1974 to 1977; the counsel to the Royal Commission of Inquiry into the Confidentiality of Medical Records in Ontario, which issued its final report in 1980; and the counsel to the National Commission on the Confidentiality of Medical Records, a private group that was active in the late 1970s and that served as a focal point for consumer complaints. In addition, a special assistant to the Director of the National Institutes of Health described privacy issues associated with the use of medical records in research. Finally, the former counsel to the Minority for the U.S. Senate's Committee on Governmental Affairs discussed efforts in the 96th Congress to pass legislation protecting the confidentiality of medical records.

After considering the testimony of these expert witnesses, the Commissioners decided the issues of privacy and confidentiality could be best addressed by considering them as follows:

- issues relating to the privacy of research records and to the use of patient records in research would be incorporated into the biennial reports on the protection of human research subjects;
- issues relating to the access to medical records by patients and third parties (such as insurance companies and employers) would be incorporated into the report on informed consent; and
- matters regarding records relating to genetic information would be included under the study of genetic screening and counseling.

In addition, the Commissioners requested an analysis of the major philosophical issues that had been identified,

although they specified that such a study should not delay other Commission studies, as it was apparent that the others were more likely to make significant new contributions to public policy on bioethical issues.

In March 1982, the Commissioners reviewed the consultants' report on the philosophical aspects of privacy and confidentiality of medical records, accompanied by a statutory appendix summarizing current U.S. laws on the subject. The wide-ranging paper considered the subject from the diverse perspectives of law, philosophy, economics, politics, and public opinion.

Before examining the special nature of privacy and confidentiality in relationship to health care, the consultants defined the terms:

> Privacy is a concept that applies to *individuals* with respect to others; confidentiality is a concept that applies only to *relationships* between or among persons and institutions. Privacy concerns control over access and disclosure in the first instance; confidentiality concerns only redisclosure of information previously disclosed. Privacy is normally controlled by the individual; confidentiality by the person for/to whom the individual's privacy is relinquished.

They found that although not absolute, these values are fundamental and morally important in that acceptance of and respect for them underlies the formation of the doctor-patient relationship. They also identified other values—such as knowledge, truth, or safety—that may come in conflict with privacy and confidentiality.

In health care settings, patients often must relinquish control over not only their bodies but also their sensations, thoughts, and even feelings. Within the confines of the physician-patient relationship, privacy is given up—either as part of a patient's ritual response to the relationship or at a physician's explicit (and sometimes quite insistent) urging. The justification for this relinquishing of control—that is, the ethical value on which it rests—is the promotion of well-being for the patient. The process of shared decisionmaking about health care that the Commission advocated in its report on informed consent depends on full and open communication between professional and patient. Therefore, the patient must drop the barriers of privacy and share verbal and physical information with the practitioner if the patient is to derive maximum benefit from the treatment.

To encourage this process, patients are assured that the information they disclose will not be repeated to others. Confidentiality in health care is intended to protect patients against harm to reputation or personal relationships, threats against employment, or exploitation by public agencies or

private interests. The protection of confidentiality thus reflects respect for persons, the same value that underlies patient autonomy and self-determination.

It is apparent that however valuable privacy and confidentiality may be in health care, there are competing values that may sometimes outweigh them. While emphasizing the connection between consent and confidentiality in *Making Health Care Decisions,* the Commission also recognized that there are circumstances when other goals should predominate. Likewise, in *Screening and Counseling for Genetic Conditions,* the Commission concluded that under certain, limited circumstances a genetic counselor may be justified in overriding a patient's desire for confidentiality in order to protect identifiable relatives from severe and otherwise unavoidable harm.

There are many points of tension—and many issues in contention—in the law and ethics of medical privacy today. Detailed empirical exploration beyond that which the Commission could undertake in light of its other studies would be indispensable in clarifying and possibly resolving these issues. For example, research scientists are concerned that present legal rules exalt privacy at the expense of important scientific findings that could benefit large numbers of people. But would an exception for a epidemiologist from the National Institutes of Health also apply to a union representative who want to examine workers' medical records to gather grounds for filing a complaint against—and possibly closing—the factory where they work?

Although the construction of a set of statutory or administrative rules and procedures that rested on a firm ethical principle is too large a task to be undertaken here, the Commission found several basic points of agreement. In large part, the Commission hopes its identification of these points here will serve to encourage health care providers to give greater attention to this subject.

(1) Respect for patients' legitimate expectations of privacy is an important part of ethical health care practices, as well as the foundation on which a relationship of mutual trust and benefit can be built between patient and professional.

(2) Health care institutions and providers are urged to educate the public about their expectations and practices on private medical matters.

- In particular, patients need to be better informed about the scope of confidentiality and to be given the opportunity to give waivers for specific information rather than blanket waivers,
- Specific warnings should be made if disclosures of patient information are anticipated without prior consent.

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(3) Instances of unconsented disclosures are to be regarded as exceptions to the general norm of confidentiality and require special justification, such as an important public purpose.

(4) When information is provided based upon a general consent by a patient (for example, permission for a hospital to send records to a third-party payor), no more information should be disclosed than is necessary for the functions to be performed by the third party.

- Efforts should be made to permit patients to review for accuracy any records to be disclosed.
- Third-party recipients of confidential information are encouraged to find economical methods of notifying patients whose records they are requesting or when they plan to pass along individually identifiable information to other persons or organizations.