

**Test Report  
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**Part IV**

**Department of  
Health and Human  
Services**

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**Public Health Service**

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**Protection of Human Subjects; Reports  
of the President's Commission for the  
Study of Ethical Problems in Medicine  
and Biomedical and Behavioral Research;  
Notice of Availability and Request for  
Public Comment**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Public Health Service

#### Protection of Human Subjects; Reports of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research

**AGENCY:** Office of the Assistant Secretary for Health, HHS.

**ACTION:** Notice of availability of reports and request for public comment.

**SUMMARY:** This notice summarizes the reports of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, provides information on how these reports may be obtained, and requests public comment on the reports. The following summaries are intended to highlight conclusions and recommendations and do not provide in themselves complete information. It is strongly suggested that interested persons obtain complete copies of reports in order to fully understand the context in which various conclusions and recommendations were made.

**DATE:** The comment period will close November 25, 1983.

**ADDRESS:** Please send comments or requests for additional information to: Carol Young, Office for Protection from Research Risks, National Institutes of Health, 9000 Rockville Pike, Building 31, Room 4B09, Bethesda, Maryland 20205. Please specify to which report each comment pertains. All comments received will be available for inspection weekdays (Federal holidays excepted) between the hours of 9:00 a.m. and 4:30 p.m. at this address.

**SUPPLEMENTARY INFORMATION:** On November 9, 1978, the Public Health Service Act (Pub. L. 95-622) was amended to establish the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. The Commission was charged with responsibility to study and report on the ethical and legal implications of a number of issues in medicine and research, as well as such other matters relating to medicine or biomedical or behavioral research as directed by the President, requested by the head of a Federal agency, or undertaken by the Commission on its own initiative. The Commission published ten reports before it terminated on March 31, 1983. Each report is briefly summarized

below. Information on obtaining the reports is provided at the end of this notice. Public comment on any of the reports is welcome and should be sent to the address provided above.

#### Defining Death—A Report on the Medical, Legal and Ethical Issues in the Determination of Death (July 1981)

The legislation for the Commission directed it to study "the ethical and legal implications of the matter of defining death, including the advisability of developing a uniform definition of death." In summary, the central conclusions arrived at by the Commission in this report are:

1. That recent developments in medical treatment necessitate a restatement of the standards traditionally recognized for determining that death has occurred.
2. That such a restatement ought preferably to be a matter of statutory law.
3. That such a statute ought to remain a matter for state law, with federal action at this time being limited to areas under current federal jurisdiction.
4. That the statutory law ought to be uniform among the several states.
5. That 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. That death is a unitary phenomenon which 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. That 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 recommends the adoption of the following statute in all jurisdictions in the United States:

#### *Uniform Determination of Death Act*

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.

#### Protecting Human Subjects—First Biennial Report on the Adequacy and Uniformity of Federal Rules and Policies, and their Implementation, for the Protection of Human Subjects in Biomedical and Behavioral Research (December 1981)

The Commission was mandated to report on the adequacy and uniformity of the rules, policies, guidelines, and regulations of all Federal agencies regarding the protection of human subjects of research that such agencies conduct or support. The recommendations of this report affect 19 Federal agencies, and therefore this report was published in full in the **Federal Register** on March 29, 1982 (47 FR 13272). In summary, this report recommended the following:

- (1) All Federal agencies should adopt the regulations of the Department of Health and Human Services (HHS) (45 CFR Part 46).
- (2) The Secretary, HHS, should establish an office to coordinate and monitor government-wide implementation of the regulations.
- (3) Each Federal agency should apply one set of rules consistently to all its subunits and funding mechanisms.
- (4) Principal investigators should be required to submit annual data on the number of subjects in their research and the number and nature of adverse effects.
- (5) The National Commission's recommendations on research involving children and the mentally disabled should be acted upon promptly.

(6) "Private" research organizations receiving direct Federal appropriations should be required to follow regulations for the protection of human subjects.

(7) Institutions should be free to use offices other than IRBs to respond to reports of misconduct and should have procedures for prompt reporting of their findings to the funding agency.

(8) IRBs should be required only to report to appropriate officials of their institution (rather than to the funding agency) when they learn of possible misconduct and to respond to the findings of those officials.

(9) There should be government-wide procedures for debarring grantees and contractors found guilty of serious misconduct, as well as a consolidated list of formal debarments and suspensions that is actively shared with government agencies, professional societies, and licensing boards. Any formal finding by one agency, following such procedures, should be conveyed to other Federal agencies, along with the determination on which it was based.

**Compensating for Research Injuries—  
The Ethical and Legal Implications of  
Programs to Redress Injured Research  
Subjects (June 1982)**

This study was not within the Commission's specific mandate, but was taken up at the request of former Department of Health and Human Services Secretary Patricia Harris and at the urging of the former HEW Ethics Advisory Board. After studying the issue of whether to recommend compensation for subjects injured in research the Commission concluded that present data does not provide an adequate basis to decide how the ethical obligation towards subjects should be met. Therefore, the Commission recommended that the Secretary of Health and Human Services conduct a small-scale experiment in which several institutions would receive Federal support over three to five years for the administrative and insurance costs of providing compensation on a nonfault basis to injured research subjects. The Commission also recommended that the features of the compensation plan be varied at different institutions (i.e., the level of benefits provided; means of determining causation; whether nonphysical injuries would be covered). The Commission contends that information derived from such variations, as well as from the experience of comparable institutions without research compensation programs, should permit HHS to determine not only the need for a full-scale program, if any, but also the format and auspices that appear best suited to achieve the desired result.

This report was published in full in the **Federal Register** on November 23, 1982 (47 FR 52880).

**Making Health Care Decisions—A  
Report on the Ethical and Legal  
Implications of Informed Consent in the  
Patient-Practitioner Relationship  
(October 1982)**

*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. Special attention is given to the values underlying informed consent, and to innovative approaches in patient-professional communication and decisionmaking that appear to be practically as well as theoretically sound. The report examines legal rules along with professional attitudes and behavior as they are shaped by education and training, for their potential to provide patients with an

effective basis to participate in decisionmaking. 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 in this report 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 individual's. 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 professionals own deeply held moral beliefs or would draw on a limit 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.

**Splicing Life—A Report on the Social  
and Ethical Issues of Genetic  
Engineering with Human Beings  
(November 1982)**

This study, which was not within the Commission's specific legislative mandate, was prompted by a letter to the President in July 1980, from Jewish, Catholic, and Protestant associations. At the urging of the President's Science Advisor, the Commission addressed some of the major ethical and social

implications of development and prospects in the human applications of molecular genetics. First, *Splicing Life* attempts to clarify concerns about genetic engineering and to provide technical background intended to increase public understanding of the capabilities and potential of the technique. Next, the report evaluates the issues of concern and analyzes the need for an oversight mechanism.

In summary, the Commission found that:

(1) Although public concern about gene splicing arose in the context of laboratory research with microorganisms, it seemed to reflect a deeper anxiety that work in this field might remake human beings, like Dr. Frankenstein's monster. These concerns seem to the Commission to be exaggerated. It is true that the genetic engineering techniques are not only a powerful new tool for manipulating nature—including means of curing human illness—but also a challenge to some deeply held feelings about the meaning of being human and of family lineage. But as a product of human investigation and ingenuity, the new knowledge is a celebration of human creativity, and the new powers are a reminder of human obligations to act responsibly.

(2) Genetic engineering techniques are advancing very rapidly. Two breakthroughs in animal experiments during 1981 and 1982, for example, bring human applications of gene splicing closer: in one, genetic defects have been corrected in fruit flies; in another, artificially inserted genes have functioned in succeeding generations of mammals.

(3) Genetic engineering techniques are already demonstrating their great potential value for human well-being. The aid that these new developments may provide in the relief of human suffering is an ethical reason for encouraging them.

—Although the initial benefits to human health involve pharmaceutical applications of the techniques, direct diagnostic and therapeutic uses are being tested and some are already in use.

—Use of the new techniques in genetic screening will magnify the ethical considerations already seen in that field because they will greatly enlarge the demand for, and even the objectives of, prenatal diagnosis.

(4) Many human uses of genetic engineering resemble accepted forms of diagnosis and treatment employing other techniques. The novelty of gene splicing ought not to erect any automatic

impediment to its use but rather should provoke thoughtful analysis.

—Especially close scrutiny is appropriate for any procedures that would alter the genes passed on to patients' offspring.

—Interventions aimed at enhancing "normal" people, as opposed to remedying recognized genetic defects, are problematic; there is a danger of drifting toward attempts to "perfect" human beings once the door of "enhancement" is opened.

(5) Questions about the propriety of gene splicing are sometimes phrased as objections to people "playing God." The Commission is not persuaded that the scientific procedures in question are inherently inappropriate for human use. It does believe, nevertheless, that objections of this sort, which are strongly felt by many people, deserve serious attention and that they serve as a valuable reminder that great powers imply great responsibility. If beneficial rather than catastrophic consequences are to flow from the use of "God-like" Powers, an unusual degree of care will be needed with novel applications.

(6) The generally very reassuring results of laboratory safety measures have led to a relaxation of the rules governing gene splicing research that were established when there was widespread concern about the Potential risks of the research. Today those regulating gene splicing research operate from the assumption that most such research is safe, when conducted according to normal scientific standards; those opposing that position face the task of proving otherwise.

(7) The Recombinant DNA Advisory Committee (RAC) at the National Institutes of Health has developed guidelines for laboratory research involving genetic engineering. The time has now come to broaden the area under scrutiny to include issues raised by the intended uses of the technique rather than solely the unintended exposure from laboratory experiments. It would also be desirable for this "next generation" RAC to be independent of Federal funding bodies such as NIH, which is the major Federal sponsor of gene splicing research, to avoid any real or perceived conflict of interest.

(8) The process of scrutiny should involve a range of participants with different backgrounds—not only the Congress and Executive Branch agencies but also scientific and academic associations, industrial and commercial groups, ethicists, lawyers, religious and educational leaders, and members of the general public. Several formats deserve consideration, including

initial reliance on voluntary bodies of mixed public-private membership. Alternatively, the task could be assigned to this Commission's successor, as one among a variety of issues in medicine and research before such a body, or to a commission concerned solely with gene splicing. Whatever format is chosen, the group should be broadly based and not dominated by geneticists or other scientists, although it should be able to turn to experts for advice.

(9) The need for an appropriate oversight body is based upon the profound nature of the implications of gene splicing as applied to human beings, not upon any immediate threat of harm.

#### **Screening and Counseling for Genetic Conditions—A Report on the Ethical, Social and Legal Implications of Genetic Screening, Counseling, and Education Programs (February 1983)**

In this report, the Commission discusses basic facts about past genetic screening and counseling efforts and sets forth a number of conclusions and recommendations on how education, screening, and counseling programs could take account of important ethical and legal concerns. The Commission found that advances in medical genetics have greatly enhanced health and well-being, and that 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 fall into five categories and can be summarized as follows:

#### *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 interest, 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 prescreening 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 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.

#### **Deciding to Forego Life-Sustaining Treatment—Ethical, Medical, and Legal Issues in Treatment Decisions (March 1983)**

This subject was not part of the Commission's specific legislative mandate but was added as a natural outgrowth of earlier studies on informed consent, the definition of death, and access to health care. 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 decision-making 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.

#### **Securing Access to Health Care—The Ethical Implications of Differences in the Availability of Health Services (March 1983)**

This report responds to the mandate that the President's Commission report on the ethical implications of "differences in the availability of health services" among various groups in the United States. The Commission does not propose any new policy initiatives, for its mandate lies in ethics not in health policy development. But it has tried to provide a framework within which debates about health policy might take place, and on the basis of which policymakers can ascertain whether some proposals do a better job than others of securing health care on an equitable basis.

The Commission concludes that:

(1) Society has an ethical obligation to ensure equitable access to health care for all.

(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,

(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, rest with the Federal government.

(5) The cost of achieving equitable access to health care ought to be shared fairly, and not be 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.

**Implementing Human Research Regulations—The Adequacy and Uniformity of Federal Rules and of their Implementation (March 1983)**

The President's Commission was directed by Congress to report every two years on the adequacy and uniformity of the federal rules and policies for the protection of human subjects in biomedical and behavioral research, as well as the adequacy and uniformity of their implementation. In this, the second "Biennial Report," the Commission makes six recommendations which can be summarized as follows:

*Improving the Adequacy of Regulations*

(1) Congressional committees with oversight responsibilities for biomedical and behavioral research should monitor the progress of the administrative agencies in responding to the recommendations of the Commission's 1981 and 1982 reports on *Protecting Human Subjects*.

(2) An Ethics Advisory Board should be reestablished within the Department of HHS either through Congressional action, as part of the authorization of the NIH and ADAMHA research programs, or by the HHS Secretary.

(3) Federal agencies should clarify the meaning of certain procedural requirements of present regulations, particularly what is meant by "IRB review."

*Improving the Implementation of the Regulations*

(4) A uniform system for implementing all Federal rules to protect human subjects should be established under a single office, and should include both assurances of regulatory compliance provided in advance by research institutions and periodic site visits to the institutions. Federal agencies that do not already do so should, as soon as practicable, identify the IRB's responsible for the initial and continuing review of research for which they have regulatory responsibility.

(5) The prospective review of institutional assurances of compliance with applicable regulations should consider the amount and types of research that each IRB anticipates reviewing and should determine that requirements regarding IRB composition are met, that sound procedures have been established for the IRB's review of research, and that the institution understands its responsibilities for protecting human subjects.

(6) A broad educational and monitoring program covering the protection of human subjects and designed to reach investigators, IRB members, and research administrators should be conducted. Among the various activities included in the program should be site visits of research institutions using experienced IRB members and staff as site visitors.

**Summing Up—Final Report on Studies of the Ethical and Legal Problems in Medicine and Biomedical and Behavioral Research (March 1983)**

This report provides an overview of the Commission's work since its inception in January, 1980, to its expiration in March, 1983. All of the Commission's reports are summarized in this volume, and the current status of the reports' recommendations is reviewed. In addition, this final report places the individual Commission studies into a larger context of recurring themes. A summary of the Commission's work and conclusions on its congressionally mandated study of privacy and confidentiality in medicine, which were not presented in a separate report, is also included in this volume.

Copies of the Commission's reports, as well as accompanying appendices, are available through the Government Printing Office. To receive copies, specify the title of the document and the stock number, and send a check in the appropriate amount payable to the Superintendent of Documents,

Government Printing Office, Washington, D.C. 20402 (Telephone 202-783-3238).

Document	Stock No.	Cost per copy
Compensating for Research Injuries		
Volume One: Report.....	040-000-00455-6	\$5.50
Volume Two: Appendices....	040-000-00456-4	8.50
Deciding to Forego Life-Sustaining:		
Treatment.....	040-000-00470-0	8.00
Defining Death.....	040-000-00451-3	6.50
Implementing Human Research Regulations (1983 Biennial Report).....	040-000-00471-8	5.50
Making Health Care Decisions:		
Volume One: Report.....	040-000-00459-9	6.00
Volume Two: Appendices....	040-000-00468-8	8.00
Volume Three: Appendices....	040-000-00469-6	6.50
Protecting Human Subjects (1981 Biennial Report).....	040-000-00452-1	6.50
Screening and Counseling for Genetic Conditions.....	040-000-00461-1	5.00
Securing Access to Health Care:		
Volume One: Report.....	040-000-00472-6	6.00
Volume Two: Appendices....	040-000-00473-4	7.00
Volume Three: Appendices....	040-000-00474-2	7.50
Splicing Life.....	040-000-00464-5	5.00
Summing Up (Final Report).....	040-000-00475-1	5.50

Dated: July 21, 1983.  
**Edward N. Brandt, Jr.**  
*Assistant Secretary for Health.*  
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