CONFIDENTIALITY OF MEDICAL RECORDS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON FINANCE

UNITED STATES SENATE

NINETY-FIFTH CONGRESS

FIRST SESSION

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CONFIDENTIALITY OF MEDICAL RECORDS

THURSDAY, SEPTEMBER 15, 1977

U.S. SENATE,
SUBCOMMITTEE ON HEALTH
OF THE COMMITTEE ON FINANCE,
Washington, D.C.

The subcommittee met, pursuant to notice, at 8 a.m. in room 2221, Dirksen Senate Office Building, Hon. Herman E. Talmadge (chairman of the subcommittee) presiding.

Present: Senators Talmadge, Dole, and Laxalt.

Senator TALMADGE. The hearing will come to order.

[The committee press release announcing this hearing and the statement of Senator Dole follow:]

FINANCE COMMITTEE ANNOUNCED HEARINGS ON "CONFIDENTIALITY OF RECORDS" PROVISIONS IN THE MEDICARE ANTI-FRAUD BILL

Senator Herman E. Talmadge (D., Ga.), Chairman of the Subcommittee on Health of the Senate Finance Committee, announced today that the Subcommittee will hold a hearing on Thursday, September 15, 1977 at 8:00 A.M. in Room 2221 Dirksen Senate Office Building, to receive testimony from witnesses who will testify concerning the "confidentiality of medical records" provisions contained in H.R. 3, the Medicare and Medicaid Anti-Fraud and Abuse Amendments.

The hearing will focus primarily on differences in the approach toward medical records confidentiality as reflected in the section of H.R. 3 approved by the Committee on Ways and Means and that section on confidentiality approved by the Committee on Interstate and Foreign Commerce.

Senator Talmadge noted that, following testimony on this issue, the Committee would be able to decide on an appropriate confidentiality provision and then order the Anti-Fraud bill reported to the Senate.

Written Statements.—Those individuals or organizations who desire to present their views to the Subcommittee should submit a written statement for inclusion in the record of the hearings. These written statements should be submitted to Michael Stern, Staff Director, Committee on Finance, Room 2227, Dirksen Senate Office Building not later than September 16, 1977.

STATEMENT OF SENATOR BOB DOLE

Thank you, Mr. Chairman. I join you today in welcoming those scheduled to testify before this subcommittee. I look forward to hearing their comments and suggestions on the important matter of access to medical records. But before we begin I would like to make one or two brief comments.

In addressing any issue of privacy a number of factors must be taken into consideration. The interests of the individual, the record keeping of an institution, and the needs of society in general.

It has been estimated that Americans made one billion, 56 million visits to physicians during 1975. The visits took place in private offices, clinics, and in hospitals. The magnitude of these numbers alone are staggering. The number of records involved even more overwhelming. These records, and the records of

individuals from years past, hold much information. Some of this information is vital to research efforts designed to advance health care in this country and in the world. All of the information is of a highly private nature.

The privacy protection commission report contains the following quote from Alan F. Westin:

The outward flow of medical data . . . has enormous impact on peoples lives. It affects decisions on whether they are hired or fired; whether they can secure business licenses and life insurance; whether they are permitted to drive cars; whether they are placed under police surveillance or labelled a security risk; or even whether they can get nominated for and elected to a political office.

Where do we draw the line? How do we insure the continued growth of vital medical research yet protect all our citizens regardless of whether their care is paid for by the Government or private funds, from unwarrented disclosure of information.

I look to each of you testifying today, to provide us with information that will assist us in making a responsible decision. We must say to the public, your privacy is as vital to us as any other protection offered to you as citizens. Thank you again, Mr. Chairman.

Senator TALMADGE. The purpose of the hearing this morning is to receive testimony with respect to different provisions dealing with confidentiality of medical records, and approved by the Committee on Ways and Means and the section approved by the Interstate and Foreign Commerce Committee.

This difference of opinion on the confidentiality of medical records was the only difference between the two committees in their work on H.R. 3, the House counterpart of my medicare and medicaid antifraud and antiabuse amendment.

The Finance Committee has essentially completed its work on the antifraud and antiabuse bill. The testimony we hear this morning should enable us to deal with the remaining issues before the committee, whether to include the confidentiality language approved by the Commerce Committee or that approved by Ways and Means.

Further, Mr. Satterfield of Virginia has another approach which he anticipates offering on the House floor. In that regard, Senator Byrd has requested various material on the Satterfield amendment be made a part of the record of this hearing, and without objection, that will be done.

[The material to be furnished follows:]

BRIEF EXPLANATION OF THE SATTERFIELD AMENDMENT ON CONFIDENTIALITY OF MEDICAL RECORDS

This amendment would not allow federal officers, employees, or agents to inspect or require the disclosure of individually identifiable medical records, unless . . .

(A) the inspection was authorized by the patient; or,

(B) the inspection is made upon the request or with the permission of a state health official who has the authority to perform such inspections himself (Note: Center for Disease Control officials do not at present investigate epidemics without the request or agreement of state health officials, so it is unlikely that any further state authorizing legislation would be needed):

(C) such inspection is made necessary by a medical emergency presenting an immediate threat to human life.

The prohibition established by the amendment would not apply to:

(1) inspection of medical records pertaining to care paid for or provided by the United States when such inspection is by medical personnel for the purpose of providing care

(2) inspection by PSRO's and other qualified personnel for the purpose of performing Medicaid and Medicare utilization review

(3) inspection for the purpose of verifying or auditing payments for medical care

(4) inspection for the purpose of investigating or prosecuting Medicare or Medicaid fraud and abuse

(5) inspection of medical records to the extent such inspection is authorized under Title 10 (relating to the Armed Forces) or Title 38 (relating to VA benefits) of the U.S. Code.

This amendment deals only with the problem of access to identifiable private medical records by federal employees. It does not attempt to modify present laws prohibiting unwarranted disclosure of information contained in medical records in the possession of the government or its officers and employees. It is designed to require, except in a few specific cases, an objective decision by an independent state health official that an unconsented inspection of a private medical record is necessary to protect the public health, and that such protection outweighs the individual patient's right to privacy. This amendment is also designed to insure that state laws protecting the confidentiality of medical records are not contravened by federal employees.

Amendment Offered by Mr. Satterfield to the Substitute Recommended by the Committee on Interstate and Foreign Commerce to the Second Amendment Recommended by the Committee on Ways and Means to H.R. 3, As Reported.

Page 70, strike out line 6 and all that follows through line 19 on page 71 and insert in lieu thereof the following:

(1) (1) (A) Part A of title XI of such Act (as amended by section 3(a) of this Act) is amended by adding after section 1124 the following new section:

"Inspection of Individually Identifiable Medical Records

"SEC. 1125. (a) (1) Except as provided in paragraphs (2) and (3), no officer, employee, or agent of the United States, or of any Professional Standards Review Organization, or any person acting or purporting to act on behalf of such Organization, may inspect or require the disclosure of, for any reason whatever, any individually identifiable medical record, unless—

"(A) the individual (or his legally authorized representative) has authorized such inspection or disclosure in accordance with subsection (b); or

"(B) such inspection or disclosure is made upon the request (or, in the case of medical research, with the permission)—

"(i) of an official who is authorized under the laws of the State in which the record is located to inspect or require the disclosure of the record, and

"(ii) which states the specific purpose for the inspection or disclosure, the time period during which the inspection or disclosure may occur, and the date on which the authorization for the inspection or disclosure expires; or

"(C) such inspection or disclosure is made by medical personnel to the extent necessary to meet a medical emergency which presents an immediate threat to human life.

"(2) The prohibition of paragraph (1) shall not apply to the inspection or disclosure of an individually identifiable medical record relating to medical care which is or was paid for or provided by (in whole or in part) an agency of the United States, to the extent such inspection or disclosure is (A) by medical personnel for the purpose of providing such medical care; (B) by a Professional Standards Review Organization, or any person acting on behalf of such an Organization, or other qualified personnel for the purpose of peforming utilization review under part B of this title or otherwise with respect to such medical care, (C) for the purpose of verifying or auditing payment for such medical care, or (D) for the purpose of investigating or prosecuting fraud and abuse in the provision of, or payment for, such medical care.

"(3) The prohibition of paragraph (1) shall not apply to the inspection or disclosure of an individually identifiable medical record to the extent to which such inspection or disclosure is authorized under title 10 (relating to the armed forces) or title 38 (relating to veterans' benefits) of the United States Code.

"(b) An individual (or his legally authorized representative) authorizes an inspection, or disclosure of an individually identifiable medical record or records for purposes of subsection (a) only if, in a signed and dated statement, he—

"(1) authorizes the inspection, or disclosure for a specified period of time;

"(2) identifies the medical record or records authorized to be inspected or disclosed;

"(3) specifies the purposes for which the record or records may be inspected or disclosed; and

"(4) specifies the agencies which may inspect the record or records or to which the record or records may be disclosed.

"(c) Any person who knowingly violates subsection (a) shall be fined not more than $10,000 or imprisoned for not more than five years, or both.

"(d) In addition to any other remedmy contained in this Act or otherwise available, injunctive relief shall be available to any person aggrieved by a violation or threatened violation of this section.

"(e) The provisions of subsection (a) supersede any other law or regulation of the United States which grants, or appears to grant, power or authority to any person to violate subsection (a), except those statutes which are enacted after the date of enactment of this section and which specifically refer to this section. The provisions of subsection (a) shall not be construed to permit any officer, employee, or agent of the United States to contravene any State law which otherwise limits such individual's access to individually identifiable medical records.

"(f) For the purposes of this section, the term 'individually identifiable medical record' means data or information that (1) relates to the medical, dental, or mental condition or treatment of an individual, (2) is in a form which either identifies the individual by name or permits identification of the individual through means (whether direct or indirect) available to the public, (3) is not in the public domain, and (4) was provided by an individual with the reasonable expectation that it would remain confidential.".

(B) The amendment made by subparagraph (A) shall apply to inspections and requiring the disclosure of individually identifiable medical records on and after the first day of the fourth calendar month beginning after the date of enactment of this Act.

Separate Views of Representative David E. Satterfield III

The necessity for confidentiality in the relationship between doctor and patient has been appreciated for as long as medicine has been practiced. The duty of the physician to preserve the confidentiality of information obtained from his patients is explicitly recognized in the Hippocratic Oath and the American Medical Association's Principles of Ethics.

Fortunately, as a result of this recognition, the confidentiality of medical records has rarely been abused, and most patients assume that their privacy will be protected by the medical profession. Nevertheless, concern has been increasing that the ethics of the medical profession are no longer sufficient guaranty of the confidentiality of medical records. I see two basic reasons for this increased concern. First, the Health Care System of the United States is changing rapidly. The role of the Federal Government in paying for, providing and reviewing health care has increased enormously and all signs are that it will continue to increase. A growing percentage of health care is being provided by institutions—hospitals, HMO's, clinics—rather than by physicians practicing alone, and that care is more and more likely to be paid for by a third party. Consequently, when the individual patient provides sensitive information to a physician he may be placing that information within the control of an enormous, interlocking, health care bureaucracy. Secondly, the application of computer technology in the field of health care is steadily increasing. This development is described by Professor Alan F. Westin in a study prepared for the U.S. Department of Commerce[1]:

Spokesmen from medicine and the computer industry expect the use of computers in doctor's offices and small clinics to move slowly but steadily upward in the next five years. They cite the increased exposure to computers that physicians receive as they treat their patients in hospitals; courses in medical schools about administrative and clinical uses of computers; the current trend toward greater group rather than solo practice, creating more practice units for which computers could be cost-effective; and the funding of various projects (such as CAPO) by federal health agencies to develop tested applications and encourage greater EDP use in doctors offices. Possibly the most important factor is the rapid price decline that is taking place in computing services, as small-system

[1] Westin, Alan F., Computers, Health Records, and Citizens Rights, Nat. Bur. Stand. (U.S. Monograph 157 (December 1976)).

computers and minicomputers move into monthly costs for business data processing that many physicians are finding attractive." (at page 95)

As in doctor's offices, computer use in hospitals is changing the nature of the patient's file. In many hospitals in the precomputer era, record-keeping was hit-or-miss, and though lots of paper accumulated in the record, these documents were often in disarray, without any indexing or current summary. Now, while the character of personal information that is being collected for automatic patient records is not different from what was recorded before, the automated personal data are being more systematically collected, more fully recorded and more centralized in permanent files. Patients processed through automatic history-taking are systematically asked to disclose the full range of physical, social, family, emotional and other personal data, and the resulting detailed patient profiles become a regular feature of the file, updated steadily as the patient remains with that care provider.

From a health care standpoint, this is one of the most desirable features of automation—patient records are full, up-to-date, easily understood and are linked together from various departments and previous episodes. From a civil liberties standpoint, however, this trend means that all the medical and paramedical personnel in a facility who have access to the computerized files now have more detailed personal data and more comprehensive social histories than in the typical manual system, except for psychiatric facilities.

> In addition, computerization of patient data is facilitating (and is sometimes directly intended to facilitate) the sending of some automated patient data to organizations outside the primary care sector—to service payers and those charged with quality care assurance, and to the Zone 3 users such as public health agencies, welfare and rehabilitation programs, licensing authorities, judicial authorities, employment-insurance evaluators and so forth. (at pages 99–100)

In response to concern over these developments, the House Ways and Means Committee adopted an amendment to H.R. 3 which would limit the access of federal officers, employees, and agents to individually identifiable medical records without the consent of the patient. Unfortunately, this amendment would be overly broad and indiscriminate in its effects. It fails to make exceptions for those situations in which the health of the general public must override the right to privacy of the individual. For example, as Professor Westin points out:

> While securing informed, voluntary consent should cover most situations in which medical research and program evaluations need to be conducted, through the use of identified data from health systems, there will be situations in which this is not feasible.

I share the belief that statutory protection for the privacy of medical records is needed, especially with respect to access by federal employees to the records of individual patients whose medical care is not financed in whole or in part by the Federal Government. To legislate merely to limit the disclosure of medical information about a citizen obtained by federal employees without the knowledge or consent of the patient is grossly inadequate. This belief has been strengthened by the recently released Department of HEW audit agency report, which revealed a shocking lack of security for computerized records of the Social Security Administration containing highly confidential personal information on millions of Americans. Particularly disturbing was the revelation that many federal employees have access to this personal information even though their jobs do not require such access.

I can think of no more deserving of protection than the right to confidentiality of one's medical file. I do recognize, however, that there are occasions and circumstances when the public interest transcends the individual right, for example in cases of communicable disease. Even so, the accessability of a citizen's medical record in such circumstances should be clearly and carefully circumscribed. I can think of no better way to insure this protection of the public interest than to permit federal health officials to aid and assist the chief medical officer of the individual states when specifically requested to do so, and then only to the extent permitted by state law governing the authority of the chief medical authority in such state.

Accordingly, I shall offer an amendment which, except in the case of a medical emergency presenting an immediate threat to the life of an individual patient,

would require federal officials, employees, or agents, before inspecting or requiring the disclosure of individually identifiable medical records, to obtain the written consent of the patient. It would further permit such inspection and disclosure when the federal health official or officials are requested to do so in writing, by an official authorized by state law to inspect or require the disclosure of medical records, with the further provision that the purpose and scope of authority to be exercised as well as the period of time such authority is delegated be also set forth in writing.

This basic safeguard would impose only a reasonable, minimal inconvenience on researchers and other federal health officials, an imposition which in my view is more than warranted by the added protection for individual privacy which it affords.

The amendment would not apply to alter the present rules governing access to medical records in the possession of the Armed Services or the Veterans' Administration. Nor would it apply to inspection of medical records in the course of (1) the delivery of medical care which is paid for or provided by the Federal Government, (2) review by PSROs of medical care paid for or provided by the Federal Government, and (3) auditing for, investigating, or prosecuting fraud and abuse in the provision of, or payment for, medical care which the Federal Government provides.

In drafting this amendment, I have taken great pains to insure that Federal assistance to State and local authorities in the control of communicable disease, the investigation of epidemics, and in epidemiologic research would not be unduly hampered.

It has been suggested that Congress should postpone action in this area until the final report of the Privacy Commission is received and the Department of HEW has had an opportunity to study the report and submit suggestions for legislation. This, of course, would virtually insure that no legislation governing the right of privacy in question will be enacted during the session of Congress. I do not feel such a delay is justified. A provision such as I propose is a careful first step and is fully consistent with the Draft Medical Records Policy Recommendations of the Privacy Commission. Adoption of it would in no way preclude future legislation on this point. Again, Professor Westin's observations are pertinent:

> Predictably, there are divergent views among observers as to the nature and extensiveness of threats to privacy in various new health care programs, and in the growth of automated data systems. But there is widespread agreement that dealing wisely and effectively with the privacy "issued" is a vital matter, not only to the public's confidence in new health care institutions in the coming decade but also to the protection of fundamental citizen rights.
>
> The time is ripe, therefore, for focusing expert and public attention on these issues before changes in health care financing and review are enacted, before the new wave of computer applications and information systems unfold, and before arrangements to incorporate national patient identifiers and file-linking arrangements in the health field are put into place."

For the foregoing reasons, I urge my colleagues to support my amendment on the floor of the House when H.R. 3 is considered.

DAVID E. SATTERFIELD III.

ADDITIONAL VIEWS BY MR. ROGERS

During the course of the Subcommittee consideration of H.R. 3, a significant amount of time and attention was devoted to the issue of the confidentiality of individually identifiable medical records. Much of the discussion centered around two alternative approaches:

(1) The approach adopted by the Ways and Means Committee, which bans all access to and inspection or disclosure of individually identifiable medical records by Federal employees, officers, agents, and PSRO's without specific, detailed, time-limited consent of the individual concerned, whether the care is paid for by public or private sources, with the following exceptions: (a) a PSRO may have access to the medical records of persons whose care was

paid for by Medicare, Medicaid, or the maternal and child health program for the purpose of performing utilization review, or (b) the care is paid for by medicare, medicaid or the maternal and child health program, and inspection of the record is for purposes of auditing for, investigating or prosecuting fraud and abuse.

(2) The approach adopted by the Committee on Interstate and Foreign Commerce (a) which banned access or disclosure to Federal employees of individually identifiable medical records in the possession of the PSRO where the care was not paid for by Medicare, Medicaid or the maternal and child health program, without the specific consent of the patient, and (b) which required the Secretary of HEW to submit proposed legislation within three months of the issuance of the Privacy Protection Study Commission report, which embodies the recommendations of that group pertaining to the privacy of patients' medical records, the circumstances under which they may be examined, and the safeguards which should be established with respect to examination and disclosure.

The subcommittee received little evidence of abuse by Federal employees of their access to individually identifiable records. They did receive assurance that unwarranted disclosure is subject under current law to up to 1 year imprisonment and a fine of up to $1,000, or both, and loss of employment. While we felt a great deal of concern that the privacy of patient records should be protected, the subcommittee members also believe that certain vital activities to protect the health and safety of the population should not be unnecessarily impaired. Further, we were convinced by statements of members and staff of the Privacy Commission that translating the Commission's recommendations into law would require careful and time-consuming deliberations and painstaking attention to detail since the nuances of language are extremely important and can have far-reaching implications in this area. After weighing all aspects of the issue, the subcommittee determined that it was the prudent and appropriate course to wait until the Privacy Commission's final report was issued, to allow the administration to formulate suggested legislation, to hold public hearings on the legislation and other legislative approaches that might be suggested by Members, and then report a bill to the House which we can recommend with assurance.

During the full committee consideration of H.R. 3, my colleague, the Honorable David Satterfield, proposed an amendment concerning confidentiality of medical records which, while patterned on the approach followed by the Way and Means Committee, provided additional exceptions to the ban on Federal access to records without specific individual consent. These exceptions included (a) the inspection or disclosure is made on the specific request on an official authorized under State law to inspect or require the disclosure of records, and whose request states the specific purpose of the disclosure, who may inspect the record, over what time period, etc.: (b) the inspection or disclosure is made to meet a medical emergency presenting an immediate threat to human life; (c) the care is paid for in whole or part by the Federal government and access to the record is for the purpose of providing care, is by a PSRO or others to carry out utilization review, or is to investigate fraud or abuse, or (d) the access is authorized by legislation relating to the armed forces or veterans benefits. While the amendment proposed by Congressman Satterfield removes some of the objections to the more stringent amendment adopted by the Ways and Means Committee, it by no means addresses sufficiently the problems heard in testimony before the subcommittee.

First, although the proposed amendment sets up an exception for instances of medical emergency, access to medical records is often needed to determine whether or not there is in fact an emergency. The records themselves disclose the facts upon which action by the Center for Disease Control, for example, is predicated. Such access would be precluded by this amendment. Because of this, the restrictions contained in the amendment would undermine the investigations of epidemics, the search for causes and prevention of disease, and the monitoring of the quality of research on new drugs.

Investigation of an epidemic might appear to be manageable with the Satterfield provision for access upon the request of a State official. But this is not the case. The Center for Disease Control in fact does not now investigate epidemics or perform hospital or medical record review without the State's request or agreement. But if State legislative authority of the specificity required in this amend-

ment becomes the basis for future cooperation, immediate and complicated legal problems will certainly surface. There are substantial variations in legislative authority, state by state, for such request for assistance. HEW has estimated that in one quarter of the States, the authorities—particularly relating to chronic, occupational, and environmentally related disease—are vague or nonexistent. Doubts and confusion about the authority of State officials to authorize Federal access under this amendment would complicate the currently smooth, productive, effective Federal-state cooperation in disease control. Prompt investigation of epidemics would almost certainly be impeded.

Research into the origins and course of disease would be also halted. Access to records for long-range research purposes is not appropriate keyed to the authority of State officials, whose authority to inspect or require disclosure of records is typically not explicit. Neither does "medical emergency" exception offer much basis for investigating the course of an illness like cancer in a large population over a period of time.

It is a cruel distinction to permit disclosure when the danger is immediate, but to deny to future generations the possibility of elucidating the origins of the disease and developing measures for prevention or cure.

In assuring the quality of research used in support of new drug applications, it is sometimes necessary to inspect the records of patients to whom the drugs were administered. This is essential to establishing that drugs are safe for public use. Requiring prior consent would prevent this, because it is impossible to know the identity of the patient before examining the record.

The work of the National Institute for Occupational Safety and Health (NIOSH) could also be adversely affected. The Institute's research has been vital to establishing standards protecting many thousands of American workers from such cancer-causing agents as asbestos, vinyl chloride, coke oven emissions, and 14 chemical carcinogens.

Many occupational diseases, particularly occupationally-induced cancer, take many years to develop. To establish cause and effect relationships between exposure and disease, NIOSH may need access to all plant medical records for certain employees going back as many as 20 or 30 years. Frequently those employees are no longer at the plant and may not be readily available to give permission for examination of their records.

There could also be a problem if the workers were still employed at the plant. If individual consent were required for examination of those records, an employer would be in a position to discourage his employees from permitting access to employment-related medical records, thus preventing a thorough assessment of the health risks at this plant.

An additional concern is that the proposed amendment sets up a double standard, one for Veterans, employees of the Defense Department and those whose care is financed by the United States, and another for the balance of the residents of this country. David F. Linowes, Chairman of the Privacy Commission, has stated that this differs from the Commission approach which seeks to establish uniform standards for all medical record information. Differentation of the rights to privacy on the basis of who pays for the care is not a precedent which should be accepted lightly. If such a differentiation is to be made, surely it should be limited to inspection of records, not disclosure of them.

This is only an initial set of concerns with the approach suggested by my colleague. I have no doubt that further study of the amendment and its review by persons engaged in public health, cancer research, and similar activities would uncover more problems. It seems apparent that legislation in this complex area should build on the Privacy Commission Study and should not be adopted in haste. It should be carefully reviewed in a full set of legislative hearings with the benefit of the advice and consultation of the public. That, in my view, is the only responsible course for the Congress to follow.

PAUL G. ROGERS.

MEMORANDUM

Subject: Rogers criticisms of the Satterfield Amendment.
Date: August 22, 1977.

(1) It is asserted that the exception for cases of medical emergency is inadequate because "access to medical records is often needed to determine whether

or not there is in fact an emergency." This criticism is based upon a misunderstanding of the purpose of the medical emergency exception, which is to allow Federal medical personnel rapid access to medical records in cases (which, from a practical standpoint, are unlikely) in which the brief delay necessary to secure the approval of a state health official might endanger human life. The discovery of "medical emergencies" in the course of Federally sponsored research would not require such an exemption, because the approval of a state health official would have been secured *prior* to the commencement of the research.

(2) With regard to the requirement that Federal employees obtain the request of a state health official prior to inspecting medical records, it is admitted that "The Center for Disease Control in fact does not now investigate epidemics or perform hospital or medical record review without the State's request or agreement." However, it is contended that "if State legislative authority of the specificity required in this amendment becomes the basis for future cooperation, immediate and complicated legal problems will certainly surface." This statement also reflects a misunderstanding of the Satterfield Amendment. The amendment would require no new state legislation. All that it would require is that the requesting state official have the authority to inspect or require the disclosure of the medical records to be inspected by Federal employees. In other words, the state official could allow inspection in cases in which he personally has authority to inspect or require disclosure. It is believed that requiring Federal employees to justify the inspection of individually identifiable medical records to a state official when the consent of the patient has not been obtained will provide at least a rudimentary safeguard against unwarranted invasions of privacy.

(3) The statement is made that "Access to records for long-range purpose [sic] is not appropriate keyed [sic] to the authority of state officials, whose authority to inspect or require disclosure of records is typically not explicit." Why is it not appropriate, in cases where the privacy of state citizens is invaded without their consent? Furthermore, what difference does it make whether or not the authority of the state official is explicit or implicit?

(4) The statement that the work of NIOSH would be adversely affected is simply an unsupported assertion. In those cases in which NIOSH cannot obtain the consent of a worker to inspect his medical records, it does not seem unduly burdensome to require the consent of a state official before allowing inspection.

(5) It is quite true that "the proposed amendment sets up a double standard, one for Veterans, employees of the Defense Department, and those whose care is financed by the United States, and another for the balance of the residents of this country." However, it is difficult to see how a distinction could be avoided between the necessary access by Federal employees to records of medical care provided or paid for by the Federal government and access to purely private medical records. It must be remembered that the Satterfield Amendment is concerned only with the unconsented inspection or *requiring* the disclosure of medical records in the possession of third parties by Federal employees, not with the disclosure of medical records once they are in the possession of the government. The Amendment does not grant any new authority to Federal employees, nor would it preclude the development of uniform rules governing disclosure.

(6) It is also true that "legislation in this complex area should build on the Privacy Commission Study and should not be adopted in haste." It is for this very reason that the Satterfield Amendment narrowly focuses on a single aspect of the confidentiality of medical records issue. It does not clash with a single one of the recommendations of the Privacy Protection Study Commission[1] or with the spirit behind those recommendations. Indeed, the strongest criticism of the Satterfield Amendment is that it does not go far enough in limiting access to medical records. This Amendment is merely a modest step in the direction of protecting the privacy of medical records. The possibility of more comprehensive legislation in this area in the future does not justify present inaction.

Senator TALMADGE. Previously, the staff had recommended and the committee had tentatively approved adoption of the Commerce Com-

[1] The Commission recommended that the confidentiality of medical records be protected by regulations of the Department of HEW and State Statutes. The Satterfield Amendment would simply supplement this protection. Personnal Privacy in an Information Society: *The Report of the Privacy Protection Study Commission* 307. See generally Chapter 7, "Recommendations (9), (10), and (11), at 304–13.

mittee provision—the so-called Rogers amendment. Senator Laxalt requested the committee give further consideration to the alternative proposal, the so-called Crane amendment approved by the Committee on Ways and Means.

I expect that with the record of the hearing this morning, the committee will be able to resolve this question and order the medicare and medicaid antifraud and abuse bill reported to the Senate.

Before proceeding with our witnesses, I would like to read the text of a letter that I just received from the Criminal Division of the Department of Justice. The letter is signed by Mr. Civiletti, Assistant Attorney General and head of the Civil Division.

As you recall, Attorney General Bell testified favorably before your Subcommittee with respect to H.R. 3, the Medicare and Medicaid Anti-Fraud and Anti-Abuse amendment. I recently learned that your Subcommittee is seriously considering an amendment to provide for certain descriptions on disclosure of individually identifiable medical records: Section 1123 known as the Crane amendment.

I am greatly concerned about any such provision which does not specifically and broadly exempt Federal criminal audits and investigations, particularly Grand Jury investigations.

Preindictment litigation is increasingly being used as a vehicle to forestall significant white collar crime investigations. The proposed amendment limits disclosure of any medical record of a patient while attempting to exempt audit investigations prosecutions of fraud and abuse. However, the exemption, as drafted, only applies to medical records relating to medical care, thereby leaving open the argument that the patient's financial records are still covered by the disclosure restrictions.

The exemption only applies to medical care which is, or was paid in whole or in part, under Title V, XVIII or XIV of the Social Security Act, leaving other such records still covered by the disclosure restrictions. Our experience in Medicare/Medicaid prosecutions is that records not relating to Medicare/Medicaid transactions are often needed to prove Medicare/Medicaid reimbursement procedures for costs which were falsified.

In summary, I would urge your careful consideration on any such disclosure provisions. It indeed would be ironic if H.R. 3, even to a limited degree, had a debilitating effect on our increased enforcement efforts in Medicare and Medicaid fraud.

I understand that the Department of HEW has several witnesses here this morning, but if Congressman Edwards is here, we will take him first.

Is Congressman Edwards of Oklahoma in the audience?

Apparently he has not arrived, and we will proceed with the HEW witnesses, and if you gentlemen will step forward and identify yourselves, we will proceed.

Is Senator Laxalt here?

Do you have a statement, Senator Laxalt?

Senator LAXALT. No; I do not.

Senator TALMADGE. Mr. Spaeth, are you the spokesman for the group?

Mr. SPAETH. Yes, sir.

Senator TALMADGE. Identify yourself and all of those who are accompanying you for the record, will you please?

STATEMENT OF C. GRANT SPAETH, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION (HEALTH), DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, ACCOMPANIED BY ROBERT DERZON, ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION; DR. MICHAEL GREGG, DEPUTY DIRECTOR, BUREAU OF EPIDEMIOLOGY, CENTER FOR DISEASE CONTROL; DR. ROBERT GORDON, SPECIAL ASSISTANT TO THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH; DR. JOHN FINKLEA, DIRECTOR, NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH, CENTER FOR DISEASE CONTROL; AND DR. JOHN JENNINGS, ASSOCIATE COMMISSIONER FOR MEDICAL AFFAIRS, FOOD AND DRUG ADMINISTRATION

Mr. SPAETH. I am Grant Spaeth, Deputy Assistant Secretary for Health Legislation.

To my left is Mr. Robert Derzon, Administrator, Health Care Financing Administration; to my right, Dr. Michael Gregg, Deputy Director, Bureau of Epidemiology, Center for Disease Control. Dr. Robert Gordon will arrive any moment, Mr. Chairman.

Also at the table are Dr. John Finklea, Director, National Institute for Occupational Safety and Health of the Center for Disease Control, and Dr. John Jennings, Associate Commissioner for Medical Affairs, Food and Drug Administration.

Mr. Chairman, it is a privilege to appear before this distinguished committee on a matter we consider is of extraordinary importance to you and to the Department of HEW.

Rather than read the rather lengthy statement, I will summarize it and turn over the microphone to my colleagues for a brief discussion of the impact of the proposed amendments on various agencies and bureaus within the Department.

Mr. Chairman, I will state our position, as succintly as possible, as follows. The Congress, in 1975, in the face of an increasingly computerized and regulated society, asked the question whether or not the privacy of individuals was at risk. To that end, it formed a Privacy Commission, and I have in my hand the outcome of a 2-year study by that Commission, a work product of a distinguished group with a large staff and which is to say the least, a major work.

This was received by us 2 months ago. We have since promised to respond to this report and make our legislative recommendations by mid-October. That gives us 90 days to analyze it, both the specifics as well as basic approach to the problem, and to get the required clearances.

We have the assurance from the White House, which is making a similar analysis of the entire report, that the subject of medical records is a clear priority item and that we have every support from the White House that our deadline will be met.

In short, we want to have the opportunity to respond in this manner. Thereafter, we would expect that there would probably be intense debate which would take place in the Congress, and as a consequence of all of this process, we think that we have the best opportunity for informed and sensible balance between the interests of individual privacy and national health interest.

That is our position. We desire to approach the problem in that thorough, thoughtful way and in consultation with this body.

Mr. Chairman, I would like to express, first of all, my concern about having to respond, in my judgment, prematurely to the amendments that face you. But as we do that, I simply cannot emphasize too strongly our objection to what is being described as the Crane amendment. My formal statement attempts to explain the specific consequences, as will my colleagues from HEW. In four or five sentences, let me summarize that.

The Crane amendment would restrict access to patient records so severely that it would seriously hamper this Department in assisting States in preventing and controlling disease, most specifically epidemics as they break out.

It would interfere with our ability to study the origins of disease, particularly those resulting from environmental hazards or occupational exposure to cancer-causing agents, which take many years to act.

It would impede, seriously, efforts to assure efficacy and safety. It would undermine the efforts of our health financing programs to assure that those programs are paying for medically necessary services and for covered services which are reasonably priced, as required by current congressional mandates, many formed by this committee.

Finally, it would hamper the assessment of the quality of care for beneficiaries, prevention of fraud and abuse, and accounting for the appropriate use of Federal funds.

Mr. Chairman, I would now like to call on my colleagues for statements of 3 or 4 minutes in duration, each addressing the issue as outlined.

Senator TALMADGE. That would be fine, Mr. Spaeth.

Mr. SPAETH. Thank you.

I would like to first call on Dr. Michael Gregg for the Center for Disease Control. Dr. Gregg?

Senator TALMADGE. Are you stationed in Atlanta?

Dr. GREGG. That is right. The Center for Disease Control—CDC—has as one of its primary duties the controlling of the spread of disease in the United States. This is accomplished by investigating epidemics that are reported to us by State and local health departments.

Between 1,000 and 1,200 epidemic investigations are performed each year by CDC medical epidemiologists, virtually all of which require access to medical records of some sort.

As with medical emergencies, time is of the essence in epidemic investigations. Any legislation, such as the Ways and Means amendment, that would deny or profoundly delay access to medical records for those fields of investigation would essentially prevent CDC from determining the cause of these epidemics and implementing control measures.

Let me give you a simple example of what it would lead to.

Last year, on August 2, we received a request for epidemic assistance for the Pennsylvania State Health Department because of the report of 30 cases of pneumonia and 11 deaths among American Legionnaires who had recently attended a convention in Philadelphia.

Within 4 hours, we had sent four medical epidemiologists to Pennsylvania, to join one who is already there, to start the investigation, and within 24 hours we had a total of 15 medical epidemiologists in Pennsylvania.

What did they do? Because the disease apparently was acquired in Philadelphia, the highest priority of investigation was centered in Philadelphia. The major problem was to determine whether the disease has spread beyond the confines of those who attended the Legionnaire's convention and see if there was existing disease in the rest of Philadelphia.

The epidemiologists went to the five largest hospitals that provided care to greater Philadelphia and asked those hospitals to pull every medical record that had signs and symptoms compatible with Legionnaire's disease. This resulted in a review of literally hundreds of medical records and charts to determine if there had been cases of Legionnaire's disease recurring before the recognized epidemic, but particularly important, whether the disease was spreading throughout rest of Philadelphia.

If written approval or obliteration of patient identifiers had been required before we started reviewing these records, it would have taken days, if not weeks, to determine that the Legionnaire's disease was not a threat to the rest of Philadelphia and indeed was confined primarily to those who had attended the convention.

Even now, in Columbus, Ohio, the same medical chart reviews are being done in a variety of hospitals to determine the extent of Legionnaire's disease in that city and hopefully determine how it is spread so that we can ultimately prevent it.

I think that that is the best example that I can give of how this legislation could profoundly affect our operations at CDC.

Mr. SPAETH. Thank you, Doctor.

Mr. Robert Derzon, to my left, Administrator of the Health Care Financing Administration.

Mr. DERZON. I will try to keep my comments mercifully brief, but this is a critical issue to the ordinary day-to-day operation of the health care financing activities of the Federal Government.

There is no insurance plan or insurance company in the health insurance business anywhere in the world that we can find that inhibits the flow of information between provider of service and the payer of health services. Indeed, every claim form, every bill form, has identifying information as to the name and unit number and beneficiary's number. It tells what kinds of services were rendered. It usually tells the patient's diagnosis. It tells all of those things which are necessary for us to determine whether or not that claim should be paid and whether or not beneficiaries are entitled to those benefits.

So we regret the Crane amendment, because, as far as we can see, the ordinary day-to-day operations of our program would so badly

be hampered that there is no way to assure you that we would be able to provide and pay for only those services that are required to be paid for under the laws.

The magnitude of this problem, to give you a rough idea, is about 100 million claims a year alone in medicare. I should point out to this committee that as far as our historians can tell us in HEW, there has not been a single instance, a single legal claim against the Department or whatever, of an incident where a carrier, an intermediary, or a person involved in the financing of patient care, released information of a confidential nature.

We are not saying that that could not happen, but we do not know of any. That is why, in effect, for the benefit of patients, not for the hindrance of patients, there are no barriers, as a general rule, between payers and providers.

I might add also on this particular point, that we receive each year hundreds of thousands of inquiries about the status of patients' accounts, bills, very often from the Congress. We would have, under ordinary circumstances, no way of knowing whether a patient had given consent for us to inquire into the activities of the carrier, or to inquire into a particular bill item of a particular constitutent or patient. We would have to first find out whether there was a release of medical information.

Another facet of the program, I will just touch on, one of Congress expectations, is that we monitor our carriers, our intermediaries, the States and the medicaid program and so forth, and we try in earnest to do that. In fact, the bill, H.R. 3 in the Senate version, is going to substantially strengthen our ability to do that.

We do that by looking at claim forms, trying to find out what contractors and providers are doing. We look at billing information and we look at medical records. One of the reasons that we look at medical records is to make sure that our program beneficiaries are not being treated differently than nonprogram beneficiaries. It is a fundamental philosophy of the medicare and medicaid programs that we do not want people taking advantage of people on public programs, and we do not want our beneficiaries to be at a disadvantage.

And so, in order to determine whether patients are being charged the same, whether patients are being treated the same, whether the hospital utilization is the same, we not only look at the experience of our own patients, but we also look at the experience of our nonpublic patients, namely, the private patients.

I might also add that we have many patients who are both private and public patients at different times, in different courses of their illness. Many patients become public patients after they were private patients. It is impossible to distinguish.

We do not know how we could handle this under the proposed provisions of this bill, how we could handle that particular set of problems. The PSRO is involved in the monitoring of utilization of care and as a general principle, the PSRO looks at all patients as a base and not simply Federal patients, federally supported patients.

Let me just touch on one last point which is discussed amply in our written testimony, and that is in the fraud and abuse area. Most fraud and abuse comes about in the routine monitoring of routine auditing. It does not come about just because somebody complains.

Under the Crane amendment provisions, we do not see how we can do the ordinary job of monitoring and auditing that you have come to expect of the medicare and medicaid agencies.

That concludes my comments.

Mr. SPAETH. Dr. Robert Gordon.

Dr. GORDON. I have come to speak for the National Institutes of Health, and we, too, feel that the language as proposed by Mr. Crane and related amendments that might strictly limit Federal access to medical records would be a serious blow to our being able to investigate the causes of major chronic diseases responsible for most of the mortality and morbidity in the United States.

I think an example is better than generalized statements. I would like to draw your attention to cancer which, of course, is one of our principal research thrusts. There is growing reason to believe that a large fraction or perhaps the majority of cancers are caused by environmental agents. The other well-accepted principle in the causation of cancer is that the time interval between the operation of the cause and the manifestation of the chronic disease is long, probably decades in the majority of cases. It would be unthinkable to do human experiments to investigate a hypothetical cause of cancer. We cannot apply an agent to people to see if it causes cancer later.

The only ethically permissible approach to this is to identify people who, in the course of medical treatment, occupation, or whatever their exposure would have been, have encountered something that we believe might be the cause of cancer. They must have encountered it many years ago, decades ago, for the effect to be manifested at the present time.

Therefore, the design of a study which would investigate a cause of cancer involves looking through old records created long before these privacy considerations came to mind, long before medicare and medicaid programs existed and, in many cases, of course, the possibility of obtaining the individual's consent has long been lost. The individual may, in fact, have died, or emigrated, or otherwise become unavailable.

In any event, in our search through old records we usually identify a number of people who have been exposed to a hypothetical cancer-causing agent, and one can identify a number who are otherwise similar but have not been so exposed. If those people can then be traced through time using existing records, finding them at the present time if they are still alive and evaluating their health status or cause of death, if they have died, from death records, it is then possible to develop at least strong inferences that a certain agent is under suspicion as a cause of cancer.

This leads rather directly, in many cases, to the possibility of prevention, which I think we all recognize is a better approach to disease than an attempt to cure it.

Under the Crane amendment, or similar restrictive language, it would be impossible for NIH investigators, and possibly, contractors, to search through old hospital records to identify the cohorts of people who would be useful for examining these hypotheses.

We could conceivably undertake similar studies by identifying other people exposed at the present time and obtaining their current consent. That means we have to wait decades for the outcome. That means it

would literally set back cancer research by 20 to 30 years if restrictive language such as Mr. Crane has proposed is enacted.

You might ask whether the same work could be done with medical records from which personal identifiers have been deleted. I think the answer to this is clearly no, because the medical history of any individual over a 20- to 30-year period is never contained in only one record. Just think of your own past history. How many doctors and how many hospitals have you seen?

In order to assemble a case history, it is necessary to assemble all the records pertaining to an individual, and the only way you can be sure that you have one individual traced through time is to bring those records together with personal identifiers evident. After this record linkage has occurred, it is possible to delete identifiers, and this is usually done in the analysis of records of this type. It is always done before the results are published, so that we feel that it is perfectly possible, by following the provisions and recommendations of the Privacy Protection Study Commission, to set up a system whereby investigators will have access to records and the personal identifying information will be held in strict confidence. After the study is completed and the results which are of public benefit are brought forth, the results can be published with no reference to individuals and with no privacy violated.

Thank you.

Mr. SPAETH. Mr. Chairman, Dr. John Finklea, Director, National Institute of Occupational Safety and Health.

Dr. FINKLEA. To identify, evaluate, control health and safety hazards in the workplace, our Institute will continue to require access to personally identifiable employment and medical records. Several personally identifiable records must be matched to relate the job and workplace exposures to health risks.

Let me take as an example one of over 100 investigations we conduct each year. A worker at an older chemical plant making a number of different products and utilizing many other different chemicals in the process, provided us with a list of his coworkers who were said to have died from cancer. There was even a street in that town called "Widow's Alley."

Our Institute needed to find out what chemicals were used at the plant, who had been exposed in past years, and whether or not there was a significant excess of cancer, based on scientific methods, and what exposures may have contributed to this excess.

The company, in this case, had a policy of destroying employment records that were several years old, but retaining medical records for many years after an employee had left work. The company and the hospital records also contained information that was necessary to construct a listing for worker followup and to specify the cell types of cancer that had occurred.

The worker had reported a cluster of eye cancers. These are very unusual cancers, and it was necessary to check these out from hospital records. Without this kind of information, we cannot do the research necessary to identify, evaluate and control health risks in this or many other plants.

Now companies such as this are in a position to discourage employees to permit access to medical records held by that company. Such a com-

pany would also be in a position to discourage his physician employees from reporting occupational health problems to responsible governmental officials.

Unless the access to this information is guaranteed, those companies which are not socially responsible will be tempted to keep health and safety problems hidden, and if they are kept hidden, we cannot control them to protect the health of the worker.

My colleague, Dr. Kerr, will discuss some of the specific impacts on the Coal Mine Health and Safety Act later on; I will not go into those at this time.

Mr. SPAETH. Finally, Mr. Chairman, Dr. John Jennings from the Food and Drug Administration.

Dr. JENNINGS. The assurance of the safety and effectiveness of drugs, medical devices, other medical equipment and sources of radiation are a prime concern of the Food and Drug Administration. In this regard, we share the concerns of NIH and CDC because we, too, utilize frequently the kinds of studies, especially of safety, that start with examination of medical records.

Examples of this would be review of safety of interuterine devices and hormones used during pregnancy, but in addition, we have a regulatory function that sometimes requires review of medical records. The research that we monitor is not funded directly by the Federal Government but by the drug and medical device industries primarily, and occasionally the data submitted to us is, for one reason or another, inaccurate or invalid, usually because of carelessness, occasionally incompetence, and rarely by design.

In such instances, it is necessary to go back and ascertain that the subjects of the clinical investigations actually participated in the fashion that has been reported to us. In such cases it is necessary to start with review of records and occasionally even to contact the individual subject.

In addition, we occasionally must examine these records in order to identify the subjects of such studies for their own protection when information turns up that the drug that was administered in the course of the investigation has unexpected hazards that were not known at the time of the institution of the study.

Thank you.

Senator TALMADGE. Gentlemen, I thank all of you for the lucidity and brevity of your remarks.

I understand that the Crane amendment would affect the ability of the Social Security Administration to process in a timely fashion applications for social security disability benefits. Do you gentlemen have any information on that?

Mr. SPAETH. We certainly do, Mr. Chairman. We have been advised by the Social Security Administration that that would be the precise consequence; the procedures would be lengthened, the delays in payments would be increased, the problems of program integrity exacerbated.

No question about the attitude of the Administration on that program.

Senator TALMADGE. At present, do we investigate and prosecute the illegal prescribing or dispensing of narcotics and other drugs?

Mr. SPAETH. The Administration does.

Senator TALMADGE. Does this involve going through prescription records, and are prescriptions considered medical records under the House amendment?

Mr. SPAETH. The answer is that they are considered medical records. Those very records are the object of our scrutiny in such investigation.

Senator TALMADGE. Would Federal enforcement of the narcotics laws be therefore seriously impaired under the Crane and Satterfield amendments?

Mr. SPAETH. Mr. Chairman, I would prefer for the Department of Justice to speak. I have been advised that that would be the case.

Senator TALMADGE. I read a letter in my opening statement from the Assistant Attorney General. To what extent would the investigation and the prosecution of crime or violence under Federal law, such as murder, rape, kidnapping be handicapped under these amendments?

Mr. SPAETH. I would like to defer to the Department of Justice in answer to that question likewise, Mr. Chairman.

Senator TALMADGE. Can medical examinations, including psychiatric examinations with respect to killers and rapists be used by the FBI and prosecutors without the specific consent of the accused?

Mr. SPAETH. That would appear to be the case, Mr. Chairman.

Senator TALMADGE. Are Federal judges considered officers, employees or agents of the U.S. Government?

Mr. SPAETH. I believe that would be the interpretation of the amendment.

Senator TALMADGE. If so, would the Federal courts be precluded from subpenaing or otherwise ordering the production of medical or psychiatric records without the specific consent of the patient or patients involved?

Mr. SPAETH. I, again, would have to defer to the Department of Justice on that.

Senator TALMADGE. Was the amendment considered by the Interstate and Foreign Commerce Committee during the course of its work on the confidentiality of records?

Mr. SPAETH. Was the Satterfield amendment considered?

Senator TALMADGE. Yes.

Mr. SPAETH. Yes; it was, Mr. Chairman.

Senator TALMADGE. And rejected?

Mr. SPAETH. It was rejected.

Senator TALMADGE. How do the Crane and Satterfield amendments deal with the question of examining medical records of patients who have died where a review of those records is necessary for medical research?

Mr. SPAETH. Forgive me, Mr. Chairman, would you be good enough to restate the question?

Senator TALMADGE. Do the Crane and Satterfield amendments deal with the question of examining medical records of patients who have died where a review of those records is necessary for medical research?

Mr. SPAETH. Dr. Gordon, can you answer that? He covered it very thoroughly in his remarks.

Dr. GORDON. If I understand the language correctly, sir, this would require obtaining the consent of the next of kin and in the case of an individual who had died many years before, tracing the next of kin may be extraordinarily difficult. To study a death certificate does not require consent since that is a public record.

Senator TALMADGE. That concludes my interrogation.

Senator Laxalt?

Senator LAXALT. Gentlemen, is it not true in relation to social security that on the application you quickly obtain consent from the person making the application?

Mr. SPAETH. Mr. Laxalt, if you refer to the two amendments that you are considering, it is a very restrictive amendment. Consent is described as explicit. First of all, it must describe the particular record to which you are consenting.

Senator LAXALT. You can cure the problem very quickly by securing the consent of the patient, can you not?

Mr. SPAETH. No. As I interpret the Crane amendment, the consent is time-limited.

Senator LAXALT. Any time a given patient can simply give his or her consent, then the problem is solved, is it not?

Mr. SPAETH. That is existing law. That law would be changed by language which would drastically limit the reach, extent, and duration of the effectiveness of the consent because it has four separate requirements. That is the problem, Mr. Laxalt, as we perceive it.

Senator LAXALT. That is curable later by securing another consent?

Mr. SPAETH. You go back to the person when the consent expires.

Senator LAXALT. That, I do not think, is the intent of the Crane amendment, certainly not as one of the supporters of this amendment, to thwart epidemic investigation, to thwart the pursuit of criminals. In the matter of the questions asked in relation to criminal disclosure, there is a matter of the fifth amendment, is there not?

Mr. SPAETH. Yes, sir.

Senator LAXALT. If a person does not want to divulge, or make available, incriminating information, all they have to do is stand on the fifth and the Crane amendment aside, there is total protection in that situation, is there not?

Mr. SPAETH. That would be my perception as a lawyer; I am here on behalf of HEW, but that would be my sense of what the status of the law is, yes, Senator Laxalt.

Senator LAXALT. The gentlemen here know what my position is. I think I can essentially state Mr. Crane's position.

We simply think we should protect with all available means the right of private patients not to have their medical records divulged to anybody, in particular a government official. I believe strongly in that principle.

It is my information that many people are willing to consent to disclosure. Many insurance companies require consent. That apparently is a part of their procedure.

All the public patients are not touched at all by this amendment, but there would be in the ordinary case ample information for you gentlemen to be able to conduct the necessary research that we need. Am I wrong in that?

Mr. SPAETH. It is our opinion, not that there is anything wrong in your approach. I think there is going to be no question that we will respond most favorably to the Privacy Commission's report, which, I would say, in concept agree with the opening part of your statement.

It is our interpretation, legally, and our desire to limit access to patient records to only those parties or on those occasions where it is truly in the national interest and that are important. That is not translated into the language of either the Crane amendment or the Satterfield amendment.

I want to make it absolutely clear, Senator, that we do not like the position in which we appear to be encouraging invasions into the privacy of individuals. Quite the opposite.

What is about to emerge in the next 30 days—because we will be back to the Congress in 30 days—is a rather intense debate, because there are those who feel that some in the Department wish to reach too far. I can guarantee, having talked to the Secretary at length, that he is going to reflect those opening remarks of yours.

What I am fearful of is that we do not have the kind of legal craftsmanship taking the balancing of those interests. They are not reflected in these two amendments. That is really our concern at this moment.

Senator LAXALT. Does not Satterfield, though, strike a very reasonable compromise in this situation between your position and the Crane position?

Mr. SPAETH. I have no doubt that the Satterfield amendment was drafted with that in mind, to eliminate some of the excesses of the Crane amendment which we have disclosed.

Senator LAXALT. I gather that is even not acceptable?

Mr. SPAETH. The best way to characterize it is that in our interpretation there are ambiguities. Nonetheless, a reasonable interpretation is what the Health Care Financing Administration has expressed concern about and this would continue to be of concern because the language of that provision is identical.

I think that everything that Dr. Gordon has told you would not qualify as a life-threatening type of occasion, or an acute emergency. I do think that the Center for Disease Control and the Legionnaire's disease situation would be met quite well. I am a little less clear about NIOSH and its investigations. I do not know how immediate they are, or how those investigations would be defined, and frankly, I am uncertain as to the impact of Satterfield on the Food and Drug Administration's verification of the validity of its testing.

So yes, as you accurately describe it, we remain most apprehensive, nonetheless.

Senator LAXALT. Just summarizing how I feel about this, I think that the right that the person has to obtain confidentiality of his or her medical records should be given away only under the most compelling public consideration. Whether Satterfield reaches that, I do not know. I just do not know.

I think that is something that we have to guard very carefully. The Privacy Commission Report is fine, but it presupposes the fact that the information is already available, then you take it from there.

What we question is whether or not that information should be made available to any governmental agency in the first instance. That is our problem.

I think that is all I have for now, Mr. Chairman.

Senator TALMADGE. Senator Dole?

Senator DOLE. Very quickly, because I know we have a time problem this morning, what happens if we do not do anything?

Mr. SPAETH. The existing law, or the state of the law, is as follows. Every State in the Union has laws of some sort or another governing the conduct of not only doctors but of hospitals, nursing homes, and the like. So those laws are in place.

There are some privacy provisions in the United States Code. There are a plethora of regulations which we have adopted controlling the conduct of every agency that is represented at this table. Needless to say, in the view of the Department, there are regulations which are responsive to Senator Laxalt's concerns, not in law, but regulations adopted by the Department.

We feel that the system is working. We are not denying that it may need revision because the risks are there, there is no question about that.

Senator DOLE. How long would it be--how soon will the new recommendations come forth? About 60 days?

Mr. SPAETH. Actually, October 13 was the commitment the Secretary made to Chairman Paul Rogers. This was 90 days after we received the report. We have the task force in place, headed by Mr. Fanning who is with us. I am told we will meet that deadline; we certainly will not miss it by much. We will have a response to that part of the Privacy Report and legislative recommendations. That is 90 days from its receipt, October 13 of this year.

Senator DOLE. It will probably be next year before Congress acts. I am wondering, are there protections in place between now and, say, next April if we do nothing?

Mr. SPAETH. The protections that I have just described——

Senator DOLE. The unwarranted disclosure? There is a law against unwarranted disclosure. Has anybody ever been prosecuted under that law?

Mr. SPAETH. This is Mr. Fanning, from the Office of the Assistant Secretary for Health.

Mr. FANNING. Not that I know of. The Social Security Act has strict provisions prohibiting, under a criminal penalty, any disclosure of information received by the Secretary, or by anyone, in the course of administering that act. I do not know of any prosecution. I am not sure I would, if there were. I have not heard of any violations.

PSRO's, which also collect information under the Social Security Act, have their own confidentiality provisions, which also make it a crime to disclose information.

There are additional statutes which make it a crime to disclose information received by the Federal Government. The National Center for Health Statistics has one, and there are others very similar to the Census statute.

Senator DOLE. Then I guess, is there some way that the Satterfield amendment can be modified that would satisfy some of the concerns expressed this morning by the very knowledgeable panel that we have?

Mr. SPAETH. Senator Dole, we are certainly in touch with Mr. Satterfield. I met with him and his staff people just a few days ago. I could not say decisively that we could not, in the space of a few days, put together some accommodations but we have resisted for the reasons I outlined. I think it requires more thorough clear study and analysis, and I would urge and hope that you could wait for us. I am worried about the ultimate product of that kind of rushed activity.

The Satterfield amendment does introduce a different concept. What it says, if a State has a law which authorizes the State officials to look at records for the types of inquiries that we have discussed today, then they will give the okay for the Federal Government to do so. It is really a completely different approach, and I am not sure we can reconcile that. It is an interesting approach; it puts the responsibility on the States.

However, we find that the variety of State laws is amazing, considering confidentiality, privacy, consent. So we are not rejecting it; we have our doubts.

Senator TALMADGE. Will the Senator from Kansas yield at this point?

Senator DOLE. Yes.

Senator TALMADGE. Exactly when will you have your formal recommendation ready for this and other committees?

Mr. SPAETH. October 13, Mr. Chairman.

Senator DOLE. There was a well-known case about 2 weeks ago. A Mr. McDonnell who went to a hospital in Boston and his family did not want the cause of his illness disclosed. Kenny McDonnell, who is a well-known name. I assume it was not disclosed. They still have that right, whatever is done. Is that right?

Mr. SPAETH. That is right.

Senator DOLE. Does anybody have a right to go in in that case and look at his records, even though the family did not consent, and obviously he did not consent?

Mr. SPAETH. I defer to the experts here, Senator, but there could be such a case, I am sure. First of all, the hospital itself is under some obligations to step forward if the disease was of a type that might put the rest of the population at risk. You well know that hospitals report regularly to the State people who have epilepsy, for example, or certain kinds of diseases.

The hospital under certain important risk situations could step forward. It could be obligated, or I imagine we could require—there could be such a circumstance.

Senator DOLE. As the Chairman just indicated, insurance might be a factor, too. There might be a need to know on that basis or for that reason.

I think the thing that concerns most Americans is the fact that people are sorting through records and picking out little tidbits about people that is none of their business. There are some legitimate concerns. I think you understand the concerns that the American public have voiced. I guess that is why we are trying to find some balance.

Mr. SPAETH. I think that states it absolutely correctly so far as the Department is concerned.

Senator DOLE. We are supposed to meet tomorrow on some of this—in other words if we do nothing, if we have no agreement at all, there is some protection in the law.

Mr. SPAETH. In my opinion, it needs improvement, and that is what we are working on.

Senator DOLE. If we did not do anything—it would probably be next year before we acted on the recommendations you will make on October 13.

Mr. SPAETH. That is correct.

Senator DOLE. If the Crane amendment were adopted, is it really going to stop everything for that short period of time? Just bring it to a halt?

Mr. SPAETH. It is effective immediately, and presumably if it was passed in October, it is in place immediately. The consequences, and there may be differences in the various agencies, is that it would stop the activities which we have described this morning. I can say that with considerable confidence.

Senator DOLE. Is that pretty well agreed to across the board?

Mr. SPAETH. Yes.

Senator DOLE. I think, as Senator Laxalt has pointed out, we would not want to be responsible for some epidemics because of some legislation. Maybe you can help us find some exceptions that would prevent that from happening.

Mr. SPAETH. We are wide open as far as accommodation. Our position, I hope, is clear.

Senator TALMADGE. Senator Laxalt?

Senator LAXALT. Mr. Spaeth, what, again, is the present situation? If someone in a PSRO or otherwise in Washington wanted to have access to my private medical record without my consent, could you secure that?

Mr. SPAETH. No; we could not, Senator, except in a medical audit procedure.

Senator LAXALT. At the present time?

Mr. SPAETH. That is correct.

If you filed a claim with an insurance company you would sign a consent to permit your records to be examined by it or others at the discretion of the insurance company.

Increasingly in this country, insurance companies are turning those records over to the PSRO's for analysis.

Senator LAXALT. In the absence of that, you cannot reach that record?

Mr. SPAETH. That is correct, not on an individual determination.

Senator LAXALT. What is the effect of this current legislation, then, on that situation?

Mr. SPAETH. In order to examine your record, you have not consented, you have filed your insurance claim, the insurance company wants the PSRO to look at it. The PSRO would have to come back to you and request that you sign a new fresh consent in accordance with the Crane and Satterfield requirements, for how long the PSRO might examine it, for what purpose, which records—in other words,

you specify whether it is the hospital or doctor, you itemize them, and then and only then could the PSRO examine your records as a private patient.

Senator DOLE. It is your understanding, then, that the effect of the Crane amendment would be to reach only those insurance-related cases where there has been previous consent given? It would have to be reaffirmed?

Mr. SPAETH. That is the thrust. The PSRO cannot disclose any information; that is in the Rogers bill.

Senator LAXALT. I recognize that, but getting back to a disclosure, in the first instance, the PSRO, that would be available currently?

Mr. SPAETH. Could you restate that?

Senator LAXALT. In the present position—first of all, let us take the noninsurance situation. Could you reach my record? Could the PSRO reach my record without my consent?

Mr. SPAETH. No, it could not, if you are a private patient.

Senator LAXALT. If I am an insurance case and I previously have given consent to my insurance company, can they then reach my record at the present time?

Mr. SPAETH. If the insurance company decides to make use of the PSRO.

Senator LAXALT. What if the insurance company does not consent?

Mr. SPAETH. If the insurance company does not retain the PSRO, the PSRO does not have access.

Senator LAXALT. It would not have the power and capacity to do that?

Mr. SPAETH. That is correct.

Mr. DERZON. It is my understanding of the PSRO law, that the PSRO does not routinely look at a private record, but when PSRO's have delegated to the hospital the right of medical audit, the medical audit requirements, then the PSRO delegated body, in effect, looks at all records, looks at the public patients, the privately-financed, those that are both status.

Senator LAXALT. It was my understanding the PSRO could get my record.

Mr. DERZON. In a medical audit procedure, that is correct, but no on individual determinations except in those cases where the PSRO has contracted with a private group and that is usually through an insurance carrier or something else. They would be private patients, with the consent given to the private carrier.

Senator TALMADGE. Thank you very much, gentlemen. We appreciate your contributions to our deliberations.

[The prepared statement of Mr. Spaeth follows. Oral testimony continues on p. 33.]

STATEMENT BY C. GRANT SPAETH, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION (HEALTH)

Mr. Chairman and members of the committee:

We appreciate the opportunity to appear before this distinguished Committee to discuss the issue of confidentiality of medical records. We have been asked to comment on various proposals which are before this Committee as amendments to S. 143, the "Medicare-Medicaid Anti-Fraud and Abuse Amendments," and which are also under consideration in the House of Representatives as amendments to H.R. 3. The Administration has expressed its support for most of the provisions of these bills. However, we have grave concerns about proposed

amendments which would sharply restrict the access of Federal officials to individually identifiable medical records. I will briefly summarize the issues involved here and then turn over the floor to my distinguished panel of experts for further comments and to answer questions specifically related to their agencies.

WAYS AND MEANS AMENDMENT TO H.R. 3

The provision in H.R. 3 as reported by the Ways and Means Committee (the Crane amendment) bans all access to and inspection or disclosure of individually identifiable medical records by Federal employees, officers, agents, and PSRO's without specific, detailed, time-limited consent of the individual concern, whether the care is paid for by public or private sources, with the following exceptions: (a) a PSRO may have access to the medical records of persons whose care was paid for by Medicare, Medicaid, or the Maternal and Child Health program, and (b) inspection of records is permitted for purposes of auditing for, investigating or prosecuting fraud and abuse. There are criminal penalties for violation, and this statute would override any existing statute that authorizes access.

EFFECTS OF WAYS AND MEANS AMENDMENT ON DEPARTMENT'S PROGRAM

Mr. Chairman, I cannot emphasize strongly enough our objection to section 5(1)(1) of the House bill, H.R. 3, as reported by the Ways and Means Committee. The so-called Crane amendment would have immediate and far-reaching consequences. We will attempt to clarify these consequences with the belief that the Congress would not choose to impose this type of restriction on our activities. In summary: It would restrict access to patient records so severely that it would seriously hamper this Department's ability to assist States in preventing and controlling disease. It would interfere with our ability to study the origins of disease, particularly those resulting from environmental hazards or occupational exposure to cancer-causing agents which take many years to act.

It would impede efforts to assure drug efficacy and safety. It would seriously undermine the efforts of our health care financing programs to assure that Federal programs are paying for medically necessary services and for covered sevices which are reasonably priced, as required by current congressional mandates, many formed by this Senate Committee. Further, it would hamper the assessment of the quality of care for beneficiaries, prevention of fraud and abuse, and accounting for the appropriate use of Federal funds.

We want to make it very clear at the outset that the choice to use or collect individually identifiable records—whether the Department or its contractors does so—is not made casually. The medical and other personnel who deal with such records are all acutely aware, as an element of their professional ethic, that information about people has to be treated with great care. Most of the situations in which records are used with identifiers are ones in which the job cannot be done any other way.

There are many careful controls on establishing systems of records. Under the Privacy Act, for example, there must be public notice, formal notification to OMB and the Congress, and a careful delineation of the purpose of the record system. These requirements assure careful thought before embarking on the collection of individually identifiable information. The review process for grant and contract applications addresses the issues of the necessity of record systems. Other control devices, such as: agency regulations, OMB clearance under the Federal Reports Act, and Institutional Review Boards for the protection of human subjects, also serve as protections against casual or unnecessary establishment of new data files by contractors and grantees.

Thus, in outlining the various situations in which Federal officials or contractors need access to individually identifiable records, we want to emphasize that in all these instances we obtain the least possible identifiable information, consistent with the public health and other purposes for which access or collection is necessary. I should note that our conservative approach to the collection of information is taken whether we get the individual's consent or not.

DISEASE PREVENTION AND CONTROL

The primary mission of the Center for Disease Control (CDC) is to prevent and to control diseases of public health importance in the United States. Working

with the support and approval of State health departments, CDC has developed extensive networks for collection of clinical, laboratory, and epidemiological data that serve to direct these control efforts.

Epidemic investigations.—Between 1,000 and 1,200 epidemic investigations are performed each year by CDC medical epidemiologists located either in State health departments or in Atlanta. Ranging in nature and scope from clusters of 3 to 4 cases of childhood leukemia to toxemia from environmental exposures in single communities to literally hundreds of cases of hospital-acquired infections or thousands of cases of mosquito-borne encephalitis covering large areas of the country, these epidemic investigations universally require access to medical records of one variety or another for clinical, laboratories, and epidemiologic information as well as for case confirmation and followup. Moreover, in many instances nonaffected persons must also be found to make appropriate comparisons so that risk factors can be identified and control measures instituted.

Any legislation such as the Ways and Means Amendment that would seriously hamper or profoundly delay access to medical records for epidemic field investigations essentially would prevent CDC from determining the cause of epidemics and implementing measures for prevention and control. As with any medical emergency, time is of the essence in epidemic investigations. A requirement for prior written approval or for elimination of patient/case names for medical record review would effectively prevent any meaningful data gathering and efforts to control the speed of disease and resulting deaths. The burdensome task of removing or otherwise obliterating names from medical records and particularly hospital charts not only would make followup investigations of family or contact studies impossible, but would add a logistic burden to chart reviews that in most instances would prevent effective and timely control and prevention of disease. Patients' names appear on medical records many times on a single page of hospital charts; hospital charts are often 50 to 100 or more pages long; and the impracticability of duplicating and removing names from hundreds to thousands of pages of hospital records prior to review is staggering and would effectively stop meaningful investigation and identification of causes of diseases and ultimate prevention and control. Moreover, the necessary painstaking cross checking and confirmation of extensive laboratory results without patient name confirmation would lead to chaotic data retrieval and inevitable error.

Consider the effect on our investigation of Legionnaires' disease if we had been required to obtain written approval or arrange for elimination of patients' names from medical records before we could review them. During this investigation hundreds of records from five city hospitals were reviewed to determine if the disease had spread beyond the hotel to the rest of the city. Obliterating patient identities could have seriously impeded the investigation and delayed unacceptably from a human care viewpoint the conclusion that no spread had occurred. If public health measures had been determined a necessity to stop the disease, delay would have been irresponsible to those at risk of being affected.

There are many examples of important investigations which required immediate access to medical records:

1. Venezuelan equine encephalitis—Texas: daily hospital chart reviews of hundreds of patients for over a month in 38 Texas cities were conducted by CDC and Texas medical epidemiologists to detect suspect cases and to prevent possible spread from South Texas to the rest of the State and beyond.

2. Blood poisoning (bacteremia) associated with intravenous fluids—nationwide: A nationwide epidemic of 425 cases and 40 deaths from bacteremia was traced to contaminated intravenous equipment. Rapid review of thousands of hospital records—a major logistical undertaking—was absolutely essential, and lead to incrimination and recall of the contaminated product, stopping the epidemic.

3. Meningococcal meningitis—Washington and Oregon: 12 cases of meningococcal meningitis occurred in a skid row population. To identify the populations in which the disease was occurring and to design control measures, patients were identified from laboratory records, traced back to hospital records and then interviewed. This permitted the "skid row" focus to be identified, and immunizations to control the outbreak.

St. Louis encephalitis—Illinois: This outbreak required daily searching of over 2,000 hospital records for possible causes of encephalitis. The logistics of removing names from hospital records, laboratory records, and diagnostic results would have prevented identification of suspect cases of encephalitis, their con-

firmation, and place of address, and stymied direction of mosquito spraying and encephalitis control efforts to affected areas.

Denying access to personally identified (name and address) medical records would prohibit performance of other important public health interventions and epidemiological investigations carried out by CDC with State and local health department support.

Vaccine-preventable childhood diseases.—CDC employees could not review student medical records to determine each child's immunization status or contact histories thus preventing assessment of vaccines, outbreak control, and determination of program target areas. They could also no longer review medical records of suspected cases of congenital rubella syndrome and subacute sclerosing panencephalitis, inhibiting epidemiologic studies of the relationship of these complications to immunization.

Venereal disease prevention.—Epidemiologists and field workers working for CDC in State and local health departments must rapidly review medical histories and laboratory data for adequate case identification of venereal diseases. Interviewing infected patients, determining followup treatment, and identifying all contacts for treatment are the cornerstones of venereal disease control. Unnecessary delay in medical records review necessitated by written permission or removal of patient names would seriously hamper or prevent adequate case detection, followup, and appropriate treatment of contacts.

To prevent dissemination of the new, penicillin-resistant gonorrhea in the U.S., Federal, State, and military health authorities have intensified gonorrhea screening efforts to uncover penicillin-resistant cases. The only mechanism for controlling these new strains is intensive contact tracing and targeted screening around penicillin-resistant cases—impossible without immediate access to medical records of such cases.

Laboratory reports.—Public health responses to contagious disease outbreaks often depend on access to names and addresses of persons with a positive laboratory test—e.g., encephalitis, typhoid, plague, etc. In addition, infectious diseases frequently can be identified, located, and diagnosed early and disease transmission interrupted, by reviewing laboratory results. In these circumstances, intervention is impossible without rapid access to laboratory records (e.g., infectious syphilis, hepatitis, and food-borne diseases). Laboratory findings of a positive prenatal test for syphilis or positive gonorrhea culture in a pregnant woman may be critical indications for followup, to prevent congenital syphilis, still births, or gonococcal ophthalmia.

Epidemiologic research.—Following discovery of angiosarcoma of the liver associated with vinyl chloride (VC) CDC began a casefinding effort to identify all cases of this rare tumor for the years 1964–1974. A mailing to pathologists and State epidemiologists sought case information, and pathological specimens were requested for review. On each confirmed case, consent was obtained from next-of-kin for review of patient's medical record and completion of a questionnaire on history of VC exposure. None of this would have been possible without first getting the patient's name and access to records.

Occupational health.—Another part of CDC, the National Institute for Occupational Safety and Health (NIOSH) is responsible for developing criteria documents upon which Federal occupational safety and health standards are based. As a direct result of the Institute's research, Federal standards have been established protecting many thousands of American workers from such cancer-causing agents as asbestos, vinyl chloride, coke oven emissions, and 14 specific chemical carcinogens. The more than 70 criteria documents NIOSH has developed have been widely distributed and many companies and workers use them voluntarily to control hazards even before they have the force of law. Since the NIOSH recommendations can have a substantial impact on the industries and workers involved, it is imperative that they be based upon the best available scientific evidence. The proposed amendments restricting Federal employee access to medical records would make it difficult, and in some cases impossible, for NIOSH to gather essential information.

Most NIOSH studies require personal identifiers initially because of the need to correlate a number of different records on the same individual. The Institute examines work histories, medical histories, and exposure information to determine whether workers exposed to certain substances exhibit common disease patterns. It is often only after this preliminary research is conducted that NIOSH determines which workers appear to be at risk of contracting occupational

disease. Names of those workers are needed to locate them, determine their current health status, and, if appropriate, obtain their consent to examine them. If the worker is deceased, the name is needed to locate his death certificate and determine cause of death. In some cases pathology tissues are also obtained to determine more precisely the cause of death. Such research would be delayed or even prevented if it were necessary to obtain prior consent from the individual worker or his next of kin.

NIOSH is in a different position from most Federal researchers because they frequently need to examine medical records maintained by plant management, as opposed to those held by the individual's physician. If individual consent were required before these records were released, an employer would be in a position to discourage his employees from permitting access to the employment-related medical records, thus preventing a thorough assessment of the health risks at the plant.

NIOSH would also have difficulty in responding to emergency situations where workers suddenly develop clinical symptoms that may be due to workplace exposures if they did not have immediate access to medical records. Such situations generally involve delicate labor-management relationships in which careful medical and industrial hygiene evaluations must be made quickly. Delay in obtaining records could prevent the cause from being determined soon enough to prevent additional workers from becoming sick.

BIOMEDICAL RESEARCH

Many valuable avenues of biomedical investigation require access to identifiable medical records, and we believe such access for health research purposes is vital. Much research into the etiology and course of illness, and the effect of various modes of prevention and treatment depends on the examination of the medical and other records of large numbers of people made years and even decades ago. For certain diseases such as cancer which are not always manifest at any one time in the population, but which over time take a heavy toll, epidemiological studies, using records made many years before, provide an important approach to understanding their prevalence, geographical distribution, and ultimately their cause and prevention. If consent of the patients whose records are being used were to be required, such studies would, in effect, be barred. The Department conducts such studies; the Department's contractors, which might be seen by some as falling within the term "agent," conduct a large portion of the nation's research. In addition, the difficulty, expense and, in some cases, the impossibility of locating such persons to obtain their consent would render this kind of epidemiological research totally unfeasible. One would have to have access to the record to identify the patient to begin with, an action which would be prohibited by the proposed provision.

Also, a study of only the records of individuals who can be found to give consent may not give an accurate picture of the pattern of the condition being investigated. It might, for example, result in a conclusive that the long-range mortality is lower than it really is—because it would find only the people who are still alive.

Another important research approach, the "historical prospective study," would also be precluded were researchers' access to medical records to be restricted. In such studies past medical records are used to identify a population group which was exposed to some factor suspected of causing disease, and a comparison group not so exposed, but otherwise similar, is chosen. Both groups are then compared through the past to the present (again, often using "old" records). Differences in the disease experience of the groups indicate whether the suspected factor may actually be associated with the disease. The records involved include medical, employment, school, and other types. The use of discrete personal identifiers is essential so that the several records from different sources, all applying to the one individual, can be properly linked. Once linking is accomplished, personal identifiers are deleted and. an analysis of the data can be made. The final outcome of the study is a conclusion regarding the groups of people as a whole and no individual is identified.

Studies of this type are particularly useful in research on cancer, where the time interval from exposure to outcome is long. However, the same applies to many other chronic diseases which now constitute the main causes of morbidity and mortality in the United States.

The following is a brief list of some of the kinds of studies which would be severely compromised or rendered impossible were Federal researchers' access to medical records to be restricted:

Exploration of the relationship between fibrocystic disease and breast cancer.

Determination of incidence, prevalence, and costs of neurological diseases.

Development and clinical testing of vaccines for such diseases as penumococcal pneumonia and cerebrospinal meningitis.

Studies of the relationship between saccharin and cancer.

Determination of population groups or persons at high risk of cancer.

Elucidating the relationship between X-irradiation of the head and face of children and the development of cancer of the thyroid in such persons as young adults; subsequent efforts to notify individuals who had received such irradiation so that they might obtain medical care for early diagnosis and treatment.

In all of the types of disclosures of records we have discussed, careful steps are taken to assure that the records are not seen by anyone but the persons directly connected with the activity. They are never used to affect the individual, except to the extent that the individual would be contacted, for the sake of his own health, or to seek further information.

DRUG SAFETY AND EFFICACY

The Food and Drug Administration's (FDA) current authority in which investigational new drugs and devices are processed or held includes the authority to examine research data that would be subject to reporting and inspection. They specifically authorize access by FDA investigators to the case histories and to records of disposition of the drug or device maintained by the clinical investigator conducting the study. Such inspections may under certain circumstances extend to records containing the names of human subjects or patients participating in the study.

FDA's access to individual medical records has always been exercised in a cautious and carefully circumscribed manner designed to protect the physician-patient relationship and the subject's right to privacy. The current regulations state that "the names of subjects need not be divulged unless the records of the particular subjects require a more detailed study of the cases or unless there is a reason to believe that the records do not represent actual studies or do not represent actual results obtained." FDA seeks access to individual medical records for two important purposes: (1) to verify that the investigator has obtained and documented the consent of each test subject; and (2) to assure that the clinical data derived from the study can be validated and thus present a reliable basis for scientific judgments as to the quality of the research and the safety and effectiveness of the drug or device under the study. Access to and use of the records is not for the purpose of inquiring into the medical history or experience of particular subjects.

Further, FDA has adopted stringent internal procedures for conducting these inspections. The names of the subjects are copied only if there is reason to believe that the records contain false or misleading information concerning the studies performed or the results obtained. In such cases, it may become necessary to determine whether the subject in fact exists and actually participated in the investigation. In all such instances, the clinical investigator is kept fully informed as to the information being reviewed and copies by FDA.

It is also necessary for FDA to consult medical histories to discover and study adverse reactions or contraindications for approved drug and device products. Such reviews assist in protecting future patients from a hazardous drug or device as well as protecting individual to whom the record pertains. Such reviews have proven invaluable in situations such as the case with the Dalkon Shields, a defectively designed IUD, where it was of utmost importance to discover those women who had the device inserted, as the device had caused the deaths of a number of women as well as precipitating other serious injuries.

Apart from the general criminal code (28 USCA 1905) and the Privacy Act (5 USCA 552a(a)), FDA has promulgated detailed regulations which safeguard personal medical or other confidential information acquired in the execution of the Agency's enforcement responsibilities (21 CFR, Parts 20 and 21). Without this carefully controlled access to individual medical records, the Agency could not carry out its enforement program or its public health and safety functions in a responsible or adequate manner.

HEALTH CARE FINANCING

Many aspects of the health financing programs would be adversely affected by the proposal. For example, in making their determinations that services are covered by the Medicare program and are medically necessary, intermediaries and carriers are not exempt from the specific consent requirements of the proposal. Considerable administrative difficulties will be encountered in processing the many millions of claims reviewed annually by Medicare contractors. We believe that it is questionable whether the consent statement can actually be secured in a routine matter.

When the claims form is signed by the patient, usually at the same time as admission to a hospital or skilled nursing facility, neither the patient nor the provider will know the specific period of time which the claim will cover, or the particular patient records which the intermediary will need to support payment of benefits. Adoption of the specific provisions in the proposed amendment could cause delays in claims payment and considerable proliferation of paperwork because of the need to obtain new statements as time periods expire and new medical records are created. These delays would be compounded under the Medicaid program where recipients go on and off the eligibility rolls frequently.

Without access to medical records, we cannot effectively carry out compliance reviews in the Medicaid program to determine whether States are meeting the requirements of both law and Federal regulations. In two areas, where the Congress has established penalties for non-compliance, our ability to determine whether penalties should be assessed would be seriously jeopardized. Section 1903(g) of the Social Security Act requires the Department to reduce Federal Medicaid payments by one-third in any quarter for States which do not make satisfactory showings that they have an effective program of utilization control in operation. Federal employees must validate these State showings by carrying out on-site surveys on a sample basis. Validation cannot be reasonably carried out without review of medical records to document that States are meeting the requirements. Section 403(g) requires the Federal Government to reduce Federal AFDC payments by 1 percent in any quarter in which a State does not inform all eligible individuals of the availability of Early and Periodic Screening, Diagnosis and Treatment services; provide for screening services as requested; and arrange for corrective treatment as required. The Department's Child Health Assessment Proposal currently being considered by the Congress would also require the assessment of penalties for non-compliance. Federal employees must conduct reviews of State EPSDT programs to determine compliance with this provision and our regulations. Review of medical information is an absolute necessity. The Department is only too aware of criticisms received by the Congress in the past in connection with delayed implementation of the EPSDT program and allegations about inappropriate utilization of services and errors in eligibility determinations. To severely limit Federal access to program records would seriously impede our progress in these areas.

The need for access to medical records goes beyond specific compliance issues. Federal employees conduct thorough management assessments of State Medicaid operations to determine whether States have adequate systems in place to control costs, prevent fraud and abuse, assure quality of care, and verify eligibility and the appropriateness of expenditures. Inherent in these assessments are reviews of the claims payment system which are the underpinning of the program. Reviews of specific claims, medical information, and case files are essential to determine whether controls are working and whether there are particular problems in the system that the States must deal with.

In essence, reasonable access to medical records is essential to program monitoring and compliance, since our purpose of our review is to determine whether appropriate care is being delivered by qualified providers to Medicaid recipients at reasonable cost.

Another important point concerns the need to assure that the Government only pays for care that is lawfully covered under these programs. Although your Committee has done much good work in exposing fraud and abuse in the Medicare and Medicaid programs, the amendment could severely hamper our joint efforts in this regard. Although the amendment exempts fraud and abuse investigations from its restriction, it only does so with regard to Medicare and Medicaid-funded patients. However, where fraud is suspected, we need to be able to look at the pattern of care provided in order to know whether a physician or provider has one standard of care for Medicare and Medicaid patients and another for privately funded patients.

Furthermore, about 40 percent of fraud and abuse investigations are initiated as a direct result of routine claims processing and the restrictions which the amendment would place on that area of program operations would undermine our capabilities to detect the existence of fraudulent or abusive practices. We are concerned that the ambigious language of this amendment (which "supersedes other regulations") may in effect nullify the authorities which the Congress has given the Inspector General in this particular instance. It might also negate section 9 of H.R. 3 which grants new authority for Federal access to medical records.

In Oregon, a State law prohibits access to medical records without the patient's consent—the verification process is impossible in a practice sense; about half the patients were unreachable, dead, or uncooperative. Review in Florida has been indefinitely delayed because of provider refusal to cooperate and success in court-ordered delays which made review impractical. In a recent criminal case, evidence that the physician treated and billed his private pay patients in a manner directly contrary to what he testified was his medical judgment in caring for his Medicare and Medicaid patients was critical in a felony conviction.

Medicaid and Medicare both rely heavily upon auditing in order to determine their formulas for reimbursing hospitals and skilled nursing facilities. The programs would be unable to obtain much of their needed data under this amendment and would give those people being audited additional ways of delaying the audit.

The amendment would also severely curtail activities of PSROs. PSRO access to the medical records of nonfederally funded patients is necessary to carry out Medical Care Evaluation (MCE) studies, which have proven to be one of the most successful methods for assessing and improving the quality of health care. These studies assessing the quality of care provided are designed to evaluate an entire patient population such as all patients with a given diagnosis in a particular institution. To carry out MCE studies it is not necessary to acquire the specific identity of the patients under study, but it is important that PSROs be able to access the records of the private pay patients appropriate to the study. States with special coverage programs, such as payment for medical indigents, may request PSRO review of these patients. Restrictions on access to medical records for these purposes may result in less satisfactory assessment of the quality of health care provided to Federal patients and may put States in the position of maintaining expensive and burdensome review systems for a small percentage of the State population supported solely with State funds.

Also, many PSROs have contracted with private health insurers to conduct review of the health care services reimbursed by that organization. Currently, 54 percent of the conditionally designated PSROs are involved in conducting some form of private review. If PSROs are required to acquire patient consent from private pay patients but not from Federal-funded patients, the possibility of a uniform system of review across a particular institution or group of patients would be seriously undermined. Furthermore, this approach provides different standards of consent for Federally-funded patients than for private pay patients which may be interpreted as a penalty against Federally-funded patients.

Finally, as you know, we have worked with the Congress to resolve the Medicare and Medicaid problems of constituents. In many cases, this requires obtaining medical information. Because of this bill's requirement that specific consent be obtained, we would have to get special authorization from each constituent before we could proceed to resolve his problem. We believe that this would be contrary to our mutual desire to serve people in need.

Similar proposed legislation

Mr. Chairman, during markup of H.R. 3 by the Interstate and Foreign Commerce Committee, an amendment was introduced by Congressman Satterfield which was a well-meaning attempt to meet the objections raised against the Ways and Means provision.

The Satterfield amendment, rejected by Interstate and Foreign Commerce, is similar to the Ways and Means provision, but includes additional exemptions to the ban on Federal access to records without specific individual consent. These exceptions include: (a) the inspection or disclosure is made on the specific request of an official authorized under State law to inspect or require the disclosure of records, and whose request states the specific purpose of the disclosure, who may inspect the record and over what time period; (b) inspection or disclosure is made to meet a medical emergency presenting an immediate threat to human life; (c) the care is paid for by the Federal government and access to the record is for the purpose of providing care, is by a PSRO or others to carry out utilization review, or is to investigate fraud or abuse, or (d) access is authorized by legislation relating to the armed forces or veterans benefits.

On the surface, it might appear that this would not only provide adequate assurances of confidentiality of medical records, but would allow Federal employees or their agents adequate and immediate access to medical records when needed. Unfortunately, this is not entirely the case, and we therefore oppose this approach for many of the same reasons we object to the Ways and Means amendment. The medical emergency exemption would obviously not apply to studies of chronic disease particularly where there is a long latency period between exposure to a harmful substance—e.g., in the workplace—and onset of an illness.

Investigation of an epidemic might appear to be taken care of by the exception for access upon request of a State official. However, while there appears to be appropriate legislative authority in states that permit such investigations to be carried out, in noninfectious disease categories, the legislative authority in states either is nonexistent or is sufficiently obscure as to prevent any effective use by medical investigators. If Federal investigators or their agents must depend upon established state statute for noncommunicable disease epidemiologic studies, the vast majority of investigations similar to the vinyl chloride-angiosarcoma investigation of the long term effects of contraceptive measures could not be done and our citizens will be the poorer because of it.

Furthermore, reliance upon invitations from State officials acting under authority of State laws would be a giant step backward for worker health. The Occupational Safety and Health Act of 1970 gave Federal employees authority to investigate workplaces and workplace records precisely because State laws in this area were inadequate. Although some States provide general authority to investigate occupational diseases and injuries, very few, if any, provide specific authority to inspect medical records to determine the cause of occupational disease. Thus, the Satterfield amendment offers little improvement over the Crane amendment as far as this is concerned.

Privacy Commission recommendations

Mr. Chairman, we have attempted to address some of the ways the Ways and Means amendment and similar legislation would affect our programs and hinder our ability to protect the public health. At this point we do not know what all of the consequences might be. This is an extremely complex issue, as you have recognized by holding these hearings today.

Our opposition to the legislation we are discussing should in no way be construed as a lack of concern for the importance of protecting the privacy of an individual's medical record, or the need to reassess our current methods of providing this assurance. Rather, we resist resolving this complex problem through piecemeal legislation. We believe that the cause of privacy is best served by approaching the issue in a comprehensive way, rather than by focusing on one portion of the problem (although it is an important part) and not taking into account other values.

The Department is currently at work on recommendations for a comprehensive, systematic approach to the confidentiality of medical records. We are studying the recommendations of the Privacy Protection Study Commission, and the bills already introduced by Congressmen Koch and Goldwater to implement the recommendations, as well as other bills to provide protection to medical records.

The Commission, mandated by the Congress, has just completed its two-year study of just these kinds of issues.

The Commission heard testimony from many parts of the private sector, as well as from Federal agencies (based on the agencies' experience with the Privacy Act). Its recommendations are strict with respect to the care with which records must be treated, but they acknowledge that in certain instances

disclosures without the patient's consent, in situations where the patient will not be directly affected, are warranted. In these instances careful safeguards are proposed, to prevent inappropriate use of records. We believe all interests in the privacy area will be well served by considering the Commission's recommendations, particularly the treatment of implementation of the Privacy Act in medical and medical research settings. And we agree that there is a need to develop legislation which protects the privacy of individuals while also permitting us to proceed with our responsibilities to improve the health of the American people.

This is consistent with the approach taken by the House Commerce Committee. That version of H.R. 3 requires the Department to submit recommendations, including draft legislation, to the Congress within 90 days of the issuance of the report by the Privacy Protection Study Commission.

We expect to submit our recommendations to Congress within that time frame—that is, by mid-October.

Summary

In conclusion, Mr. Chairman, the Department fully recognizes the need for legislation which would protect the privacy of idnividuals and at the same time permit us to proceed with our responsibilities to safeguard the public health. We strongly oppose a hurried, piecemeal appoach to accomplishing this objective, and urge that the Interstate and Foreign Commerce Committee provision of H.R. 3 be favorably considered.

Senator TALMADGE. Congressman Edwards, I don't believe has arrived.

We will insert Congressman Crane's statement in the record.

[The prepared statement of Congressman Crane follows:]

TESTIMONY OF CONGRESSMAN CRANE

Mr. CHAIRMAN: I certainly appreciate the opportunity to present testimony this morning on S. 143 and, in particular, on the question of medical records confidentiality. As you know, the House Ways and Means Committee and the House Interstate and Foreign Commerce Committee have each addressed this issue relative to H.R. 3, the House counterpart to the legislation before you today.

When the Privacy Act was passed in 1974, Congress took the first step in addressing itself to questions involving access to, correction of and disclosure of personal records held by various agencies of the federal government. However, it did not come to grips with what I believe is an even more fundamental question—what personal records of a confidential nature should the government be able to acquire in the first place?

The current conflict over medical records confidentiality spotlights this distinction. Looking carefully at the amendment offered by Congressman Rogers, Chairman of the Health Subcommittee of the House Interstate and Foreign Commerce Committee, it becomes apparent that its thrust is to guard against inappropriate disclosure once the records are on hand. By contrast, the Ways and Means Committee version, which I co-sponsored along with my colleague from California, Mr. Stark, prohibits any agent or agency of the federal government from acquiring, to say nothing of inspecting, any patient medical records unless (1) the patient gives his consent or (2) the purpose is to determine reimbursement by, or possibly fraud and abuse in, the Medicare or Medicaid program. If the world was perfect and all federal bureaucrats could be expected to be deterred from illegally or improperly disclosing sensitive personal records by the sanctions in the Rogers language, one could argue it might be sufficient. But, the world is not perfect (as the Ellsberg break-in, the leaking of President Nixon's tax records to Jack Anderson and the Pentagon papers case illustrate), and with little that can be done to remedy the damage caused by unauthorized release of sensitive medical information, it seems to me that prohibiting dis-

closure of private patient records after acquisition has already been allowed smacks of shutting the barn door after the horse has gotten loose in the paddock.

There are any number of instances where the federal government has gotten its hands on records with unfortunate results for patient confidentiality but perhaps the most illustrative is one that occurred in New York state just a short while ago. There, the Health Department began a federally funded ($308,000 from NIH) study on some 27,000 women who had previously had abortions. Instead of being asked if they wanted the records pertaining to their abortions used for this study, the agency simply conducted the study without informing them and, worse yet, did it in such a way that 28 of the names became public. Furthermore, the study when completed must be made available, under federal law, to anyone who requests it, so the privacy of those identified will continue to be compromised.

Not only does this incident point up the dangers inherent in allowing government to have any more medical records than are absolutely necessary—especially if the patients haven't gotten any type of federal financial assistance for the care they have received—but it demonstrates the risks involved in letting the government do all kinds of medical record research without getting patient consent. Now, I am not crusading against medical research but I think that, in most instances, doing the research and getting consent for it are not mutually incompatible. It may be a little more inconvenient for the bureaucrats to get consent, but that is a small price to pay for protecting one of the most basic and important privacies a person can have—the assurance that the only people who know one's physical condition are those of one's own choosing.

As a matter of fact, and history, the idea of patient medical record confidentiality has long been established. It is part of the Hippocratic Oath all doctors take, it is part of the American Medical Association's Principles of Ethics and violation of the so-called doctor-patient privilege has not been looked upon with favor by the courts. Conceptually, the doctor-patient privilege, recognizing as it does the principle of confidentiality, is no different from the lawyer-client relationship which, in order to protect the client's rights, sometimes makes it difficult for the government to get all the records it wants without seeking either permission or a search warrant. If, then we recognize that inconveniencing the government in that instance is a necessary price to pay for the right to due process, why not also accept the idea that making it a little more difficult (not impossible) for the government to get individually identifiable medical records is just as necessary to protect the right to privacy.

I am fully aware, of course, that there have been a number of objections raised to the approach I have suggested. However, I think some of them—such as allowing for the Center for Disease Control to assist in fighting epidemics—can be met by the inclusion of language recommended by Congressman Satterfield, who led the fight for the Crane-Stark language in the Interstate and Foreign Commerce Committee, while any that may be left over, or that subsequently pop up, can be dealt with in future legislation. In that context, it should be noted that both House Committee versions of the confidentiality amendment include language calling on HEW to make recommendations, including proposed legislation and draft consent forms, for maintaining patient record confidentially. Moreover, by acting now, we avoid what is otherwise likely to be at least a six-month wait for legislation in this area and we do so in a manner that gives the patient rather than the government the benefit of the doubt. Inasmuch as our republican form of government was designed to serve the people rather than the people serve the government, this is only appropriate.

Finally, I think it must be remembered that with the rapid development of computer technology and the continuing growth of federal programming (with its attendant bureaucracy), the threat to our right to privacy, not just in the medical area but in all areas, is likely to increase unless corrective action is taken. The Privacy Act of 1974 was a step in the right direction but, especially in such a sensitive area as medical records, it was not enough. For real protection to be provided, acquisition as well as disclosure of records should be circumscribed and, with all due respect, I think the Crane-Stark language will do just that.

Mr. Chairman, I urge its adoption.

Senator TALMADGE. The next witness is Maj. Gen. Benjamin R. Baker, Deputy Assistant Secretary of Defense for Health Resources

and Programs, Office of the Assistant Secretary of Defense for Health Affairs, Department of Defense; accompanied by Lt. Col. Bruce Chase, Medical Corps, U.S. Army.

We are very happy to have you. You may insert your full statement in the record and summarize it, if you desire.

STATEMENT OF MAJ. GEN. BENJAMIN R. BAKER, DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR HEALTH RESOURCES AND PROGRAMS, OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS, DEPARTMENT OF DEFENSE, ACCOMPANIED BY LT. COL. BRUCE CHASE, MEDICAL CORPS, U.S. ARMY

General BAKER. Thank you, Mr. Chairman.

We appreciate the opportunity to comment on these matters with respect to confidentiality. If H.R. 3 as reported by the Committee on Ways and Means and Interstate and Foreign Commerce is enacted into law, if the section known as the Crane amendment is enacted into law, we believe it would seriously damage medical care and support of our military forces.

We are sensitive to the need for privacy and feel that it must be protected, but at the same time we want to provide high quality medical care and support to those forces.

We do believe the Ways and Means bill could damage military medicine in that circumstances, as described, might arise. There are a considerable number of people in medicine other than attending physicians who must have access at least to parts of individually identifiable medical records—consultant nurses, therapists, clerical personnel, et cetera.

Without access to records, they cannot consult their files, their doctors' orders, or write laboratory results, et cetera.

It is our understanding that this kind of access would be restricted by the Crane amendment. At best, it would make medical care slower and less efficient and, under some circumstances, might be life threatening.

For example, the Ways and Means bill does not provide a mechanism for us to get information through civilian doctors who may be providing emergency care to our beneficiaries. If the military dependent is taken unconscious to a civilian hospital with epilepsy or diabetes or whatever relevant problem, we need to be able to release information about that patient.

The Ways and Means bill, we think, would also hurt our training programs on which we depend for replacement personnel. We sponsor a significant number of military health professionals, scholarship students, in civilian schools. We see an administrative nightmare to get authorization for each student to have access to each medical record. We estimate that that would cost us something on the order of 10 million individualized forms a year, for example.

You have heard testimony from the HEW people about epidemics and occupational diseases. We second that speech and we believe at best that research would cost more and take longer and be less accurate under the circumstances described.

There are also some administrative aspects of military medicine that we think need to be considered. For example, researching aviation accidents also requires reviewing medical records of pilots to evaluate medical hazard and may include post mortem review and review of the dependents' records.

We need access to such records to determine fitness for special duties and overseas assignments, to determine disability, to answer congressional and White House mail, to correct military records and administer occupational health and safety programs. Even if we could always obtain such authorization, the time, cost and manpower would be significant.

In other cases, society as a whole would suffer if people withheld information essential to decisions of fitness for duty, disability and other situations for manipulations for individual gain. The good of society also requires that we disclose medical information related to communicable disease, child abuse, law enforcement and other purposes.

We believe the Ways and Means bill is so restrictive that it would keep us from making a thorough review of the quality of medical care in our hospitals and would have difficulty complying with such accreditation bodies as the Joint Commission on the Accreditation of Hospitals.

In summary, we do believe that individual privacy must be protected, but it must be done in a balanced way, or it would be detrimental to both individual and society.

In our view, it would be very detrimental to the Department of Defense's programs and to the Nation.

We believe the Privacy Act already provides a good protection and that any further legislation should be based on the careful review of the recommendations of the Privacy Protection Study Commission.

We believe the Interstate and Foreign Commerce version of H.R. 3 would allow us to continue to meet military requirements without unwarranted risks to individual privacy while the Department of Health, Education, and Welfare takes action on the Commission report.

Thank you.

Senator TALMADGE. Thank you very much, General Baker. I notice in your prepared statement you stated that in the event of any air crashes in the Air Force you always look at the medical records of the crew involved. Is that same procedure of reviewing medical records of crew members also followed in investigating civilian crashes of aircraft?

General BAKER. It is my understanding that it is, sir.

Senator TALMADGE. Senator Laxalt?

Senator LAXALT. Your testimony, I gather, General, is directed to military personnel?

General BAKER. And their families. The difference in our story, I think, mainly relates to military personnel, sir.

Senator LAXALT. I do not recall when you are sworn in to be a member of the Armed Forces, do we waive our right to the privacy of medical records?

General BAKER. No, not in that oath. There are, in the operation of military processes, some abridgement of individual privacy related to national security, sir.

Senator LAXALT. In an ordinary case, if I were a GI, could you search my record without my consent?

General BAKER. Yes, sir.

Senator LAXALT. So there is a practical matter of waiver when you enter into the Armed Forces?

General BAKER. There is a generalized waiver, as I understand it, but title X does not have specific provisions, I believe, sir.

Senator LAXALT. Your principal concern, I gather, as a practical matter, you are going to reach those who are part of the Armed Forces anyway, for whatever reason, would be to reach the families, then?

General BAKER. Yes, sir.

Senator LAXALT. As I understand your testimony you refer to balance. Unless there were some compelling public consideration, you would not for a moment advocate that a person, even in the Armed Forces, could not protect these records if they were dependents of an Armed Forces member?

General BAKER. I would not, sir.

Senator LAXALT. I think that is all I have, Mr. Chairman.

Senator TALMADGE. Senator Dole?

Senator DOLE. I have no questions.

Senator TALMADGE. Thank you very much, General Baker. I only have one further comment I wish to make.

You state in your testimony:

> We currently sponsor 5,000 health professional scholarship students in scholarship students in civilian schools. It would be an administrative nightmare to obtain authorization for each of these students to have access to the medical record of each of them.

You indicated this would require paperwork, and 10 million pieces of paper.

General BAKER. That is our Pentagon math, yes, sir.

Senator TALMADGE. Thank you.

Senator LAXALT. You are not contending we should invade the right of privacy purely for administrative convenience, are you? Even if it required 20 million pieces of paper?

General BAKER. No, sir, it is not my contention that the administrative nightmare is a reason for rejection, no, sir.

Senator LAXALT. All right.

Senator TALMADGE. Thank you very much, General Baker and Colonel Chase.

[The prepared statement of Major General Baker follows:]

STATEMENT OF MAJOR GENERAL BENJAMIN R. BAKER, DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR HEALTH RESOURCES AND PROGRAMS, OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS

Mr. Chairman, I am Major General Benjamin R. Baker, U.S. Air Force Medical Corps, Deputy Assistant Secretary of Defense for Health Resources and Programs, Office of the Assistant Secretary of Defense for Health Affairs. Accompanying me is Lieutenant Colonel Bruce Chase, Medical Corps, U.S. Army, of my staff.

We appreciate the opportunity to comment on confidentiality of medical records as related to H.R. 3 and S. 143. In reviewing H.R. 3 as reported by the committees on Ways and Means and Interstate and Foreign Commerce, we find that the Ways and Means version could have a disastrous effect on medical care and support of U.S. Military Forces. One of our consultants stated succinctly

that "passage of certain sections of this bill would set many of our efforts back to 1947." We in the department of defense are sensitive to the need for privacy and feel that adequate means must be available to protect privacy. At the same time it is our duty to insure that we provide high quality medical care and support to the military forces. However, we do not believe these goals to be incompatible. Without question the Ways and Means version could seriously degrade military medicine. It would even prohibit the attending physician from unhindered access to the records of the patients for whom he is responsible. There are many members of the health care team who must have access to at least portions of individually identifiable medical records. These include consulting physicians. Nursing personnel, many types of therapists, (such as occupational and physical therapists), laboratory technicians, clerical personnel, dietitians, and others. Without access to records, they cannot execute the doctor's order, enter progress notes, post laboratory results, or prepare records for living. Such access would be restricted by the Ways and Means version of H.R. 3. At best there would be an inconvenient delay, while in other situations a delay would be life-threatening. For example there is no provision for release of information to civilian health care providers in emergencies involving military health care beneficiaries at civilian facilities. There is not even a provision by Ways and Means for third party authorization for patients who are too young or too ill to sign for themselves.

The Ways and Means bill would also be very harmful to our training programs on which we depend for replacement personnel.

We currently sponsor 5,000 professional scholarship students in civilian schools. It would be an administrative nightmare to obtain authorization for each of these students to have access to medical records for each of their patients.

As with other federal health agencies, our ability to deal effectively with epidemic and occupational diseases would be greatly impaired and combat readiness could be affected.

We are concerned about the impact on research and clinical investigation by which the practice of medicine is improved. Restricted access to records would preclude altogether valid research and clinical investigation of the retrospective type and would severely restrict other types. It would be difficult or impossible to completely evaluate different forms of prevention and treatment of disease, to develop new methods of prevention and treatment, or to improve physical standards for military duty. At best, research would cost more, take longer, and be less accurate.

Another concern is the impact on administrative aspects of military medicine. For example, researching the causes of aviation accidents often requires reviewing medical records of aircrews to identify aeromedical hazards. Access to records is required to determine fitness for special duties, for overseas assignments, for determination of disability, for congressional and White House inquiries, for correction of military records, and for Administration of Occupational Health and Safety programs. Even if authorization could be obtained in all cases, the cost in time and manpower would be excessive. In other cases, society as a whole could suffer if individuals withheld information necessary to make sound decisions regarding fitness for duty, retirement disability, and other situations subject to manipulation for individual gain.

The Ways and Means bill would preclude a thorough and effective review of the quality of medical care in our hospitals and correction of deficiencies which might be found only through such review. We would even be prevented from compliance with the requirements of the Joint Commission on Accreditation of Hospitals if access to records were restricted as proposed by Ways and Means.

We do believe that individuals must be protected, but we believe this must be done appropriately or it will be detrimental to both individuals and to society. We believe the Privacy Act already provides good protection and that any further legislation should be based on a study by HEW of the recommendations of the Privacy Protection Study Commission as is proposed by the Committee on Interstate and Foreign Commerce.

Senator TALMADGE. The next witness is Dr. Robert B. Hunter, chairman of the Board of Trustees, American Medical Association.

Dr. Hunter, if you desire, you may insert your full statement in the record and summarize it, sir.

STATEMENT OF ROBERT B. HUNTER, M.D., CHAIRMAN, BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION; ACCOMPANIED BY HARRY N. PETERSON, DIRECTOR, DEPARTMENT OF LEGISLATION, AMERICAN MEDICAL ASSOCIATION

Dr. HUNTER. I am accompanied by Mr. Harry N. Peterson, director of the American Medical Association's Department of Legislation.

Mr. Chairman, members of the committee, we are pleased to be present today to discuss the American Medical Association's views regarding provisions of H.R. 3 relating to the confidentiality of medical records.

The provisions on this subject have been adopted in one format by the House Committee on Ways and Means and in a different version by the House Interstate and Foreign Commerce Committee. The announcement of today's hearings requested that testimony focus on the differences between these two versions.

We believe that today's hearings are particularly important since the provisions under consideration were added in committees of the House without an opportunity for public comment on these issues.

We commend the chairman and members of the subcommittee for calling today's hearings. However, we are disappointed that the hearings will not encompass other important provisions which have been added during committee markup sessions.

For example, the proposal concerning State-PSRO relationships—memorandums of understanding—raises a number of questions about the future efficacy of local peer review. These questions, too, should be considered publicly so that the views of all interested parties can be heard.

Mr. Chairman, concerning the subject of today's hearings, the sensitive subject of confidentiality of medical records, particularly in relation to the availability of that information to the Federal Government, is of major importance to the American Medical Association.

The AMA believes that this hearing can be the initial step in exploring the myriad issues surrounding the confidentiality of medical records. These issues are complex and subtle, and are deserving of careful study by the Congress and the public before comprehensive legislative responses are enacted.

We need to attain a proper balance between individual rights and the public welfare in any legislation that is enacted.

The rapid growth of governmental involvement in health care has created a massive system of medical records unknown in this country as little as 15 years ago. The sheer volume of data magnifies the problems of keeping such infomation confidential, and computerization of these records compounds those difficulties.

The problem is further exacerbated by demands for information collected by other programs in the health care field, leading to a proliferation of uses of data which had been originally collected for limited purposes.

Personal medical records are among the most sensitive data collected in our society. Proper controls over the transmission and use of this information are essential. Inappropriate distribution of individual medical records adversely affects the indivdual's constitutonally

protected right of privacy and can have a devastating effect on the patient-physician relationship.

The relationship of patient and physician is a highly personal one and its success depends largely on the willingness of the patient to discuss freely with his physician all subjects relating to individual health no matter how personal or sensitive. Such communication can only occur in an atmosphere of trust, privacy, and confidentiality.

This exchange is essential to the provision of quality health care. Should either party feel that this information, discussed privately, will become a matter of public record, the foundation of the patient-physician relationship would be irreparably harmed. We believe that it is vitally important to maintain medical privacy.

Before the subcommittee are two divergent legislative approaches relating to the confidentiality of medical records.

One reported by the House Ways and Means Committee prohibits officers, employees, or agents of the Federal Government or of PSRO's from acquiring, inspecting, or requiring the disclosure of individually identifiable medical records of any patient without the patient's written consent.

The prohibitions would not apply to the inspection, acquisition or disclosure of individually identifiable medical records of any patient without the patient's written consent. The prohibitions would not apply to the inspection, acquisition, or disclosure of individually identifiable medical records of patients whose care is paid for in whole or in part under title V, XVIII, or XIX of the Social Security Act, if such inspection, acquisition, or disclosure is by a PSRO for the purpose of PSRO utilization review of services furnished to such beneficiaries, or is for the purpose of auditing, investigating, or prosecuting fraud in these programs.

The other amendment, reported by the House Interstate and Foreign Commerce Committee, provides that no officer, employee or agent of a professional standards review organization may disclose to any officer, employee, or agent of the Federal Government, and no officer, employee, or agent of the Federal Government may inspect or have access to any part of any individually identifiable medical record which is in the possession of a PSRO, and which relates to medical care not provided directly by the Federal Government or reimbursed either in whole or in part under a Federal program or under a program receiving Federal financial assistance, without the written consent of the patient.

Both amendments call for the Secretary of Health, Education, and Welfare to prepare and submit legislative recommendations for appropriate procedures to maintain the confidentiality of all individually identifiable medical records to the appropriate congressional committees, not later than 3 months from the date when the Privacy Protection Study Commission submits its final report. This deadline should be extended, since the report was filed in July.

Also, both amendments specify requirements for a written consent form.

The intent of these proposals, the protection of the confidentiality of an individual's medical records, is good. However, we believe that neither alternative fully addresses all the complex issues raised by the

potential use of medical records for a variety of purposes unrelated to that for which the information was collected in the first place.

In our view, either amendment should be considered an interim measure for application pending an opportunity to develop a more comprehensive response to these issues.

While both the Interstate and Foreign Commerce Committee and Ways and Means Committee versions of the amendment are directed at the issue of confidentiality, we believe that the Ways and Means Committee amendment is overly restrictive. It would prohibit the inspection and acquisition, as well as the requirement of disclosure, of individually identifiable medical records by any Federal entity (except by a PSRO or other entities for the specified reasons) without written consent.

In so doing, many valid and important uses of medical data by Federal entities other than PSRO would be prohibited. For example, the collection of identifiable medical information for epidemiological studies, which has been a valuable and lifesaving tool for the medical profession to use in combatting communicable and infectious diseases, would be extremely difficult, if not impossible.

Any legislation affecting the use of medical records must allow for legitimate medical research. In our opinion, the amendment approved by the Ways and Means Committee would hamper appropriate medical research.

Abuses of the confidentiality of medical information do not take place because of the mere fact that such information is collected. Such abuse takes place when private medical information is wrongfully usde, or transmitted to unauthorized persons for improper use.

We believe that the prohibition affecting only the distribution of medical record information as contained in the Commerce Committee version of the amendment, while more limited in its application, strikes a better balance between an individual's right of privacy and the need to protect public health and safety.

Mr. Chairman, the American Medical Association has had a long-standing concern as to unauthorized use of individual medical records. We have testified before congressional committees and the Privacy Protection Study Commission and have developed model State legislation on this subject.

We note that this committee has adopted one confidentiality provision designed to protect PSRO records from discovery in civil proceedings. We are gratified because this is similar to a PSRO amendment which the AMA has proposed in this and previous Congresses.

As to the overall subject of confidentiality of medical records, we are convinced that careful deliberations are necessary with regard to development of long-range legislative solutions in this area. We believe that adoption of the Interstate and Foreign Commerce Committee amendment would provide the better interim and partial solution to an extremely complex problem.

We understand that HEW is currently undertaking development of additional proposals for the Congress taking into consideration the recent report by the Privacy Commission. The enactment of any further legislative solutions should come only after appropriate hearings allowing widespread input from interested persons including

professional associations such as the AMA. We stand ready to cooperate with HEW and this committee in any such endeavors.

Mr. Chairman, if the committee has any questions, I will be pleased to answer them now.

Senator TALMADGE. Thank you very much, Doctor, for an excellent statement. I think it speaks for itself, and I concur fully with what you have stated.

Senator Laxalt?

Senator LAXALT. Doctor, has the membership of AMA addressed itself to the particular problem of the Crane amendment, or are you just speaking generally of the position of AMA in matters past?

Dr. HUNTER. I am speaking of the response of the organization to a specific piece of legislation. The membership has not specifically considered the Crane amendment, no, sir.

Senator LAXALT. I see.

I gather that you feel if the Crane amendment is passed that it should be on an interim basis pending further investigation of this entire problem?

Dr. HUNTER. I would agree with that entirely. I think that this is a very complex matter and I heard the suggestions of members of the subcommittee that perhaps we could proceed without any such legislation being passed. This might be a more desirable solution to the problem than to pick an unsatisfactory piece of legislation as an interim solution.

Senator LAXALT. It has been indicated here that PSRO's can reach the medical records without consent. Is that not of concern to your doctors?

Dr. HUNTER. Yes.

Senator LAXALT. In the interim, there is no protection, according to the testimony today.

Dr. HUNTER. In the proposed legislation, the PSRO's would still have the opportunity to review the medical records of those persons covered under the medicare proposals.

Senator TALMADGE. If the Senator would yield on that point.

Senator LAXALT. Yes.

Senator TALMADGE. Is it not a fact that PSRO's are restricted to doctors on the staff of that particular hospital?

Dr. HUNTER. The PSRO's? No, sir. A PSRO may be areawide, it may be statewide, and it has the investigative authority to enter any hospital where medicare patients are taken care of.

Senator TALMADGE. Is there not a specific criminal penalty if PSRO are unauthorized to release that data?

Dr. HUNTER. Yes, sir.

Senator TALMADGE. Thank you.

Senator Laxalt?

Senator LAXALT. That is all I have.

Mr. PETERSON. I would like to add one comment, if I may, Mr. Chairman, in response to Senator Laxalt's question whether the Crane amendment should be considered an interim measure.

The statement said that either amendment should be considered as interim, but I want to clarify that the recommendation was with respect to the Interstate and Foreign Commerce Committee amendment.

That would be a better interim measure for consideration if the Congress is going to act.

Senator LAXALT. If, at this point, as we are going to consider it tomorrow, we have an option of preserving the confidentiality of those records entirely in this interim measure, or permitting the existing situation with substantial access to private records without consent of the PSRO.

Which option do you prefer?

Dr. HUNTER. I think, rather than the restrictive amendment, that, as you heard, would quickly grind things to a halt, that we would be more in favor of the so-called Rogers amendment, the Interstate and Foreign Commerce amendment.

Senator LAXALT. This is a point that is lost on me. It grinds things to a halt. How? For the purposes described. They can secure information with consent of all the public patients involved. They have all the insurance company consents, which apparently can be translated into consents without too much difficulty.

How do things grind to a halt? I do not follow that.

Dr. HUNTER. Within the present system, of course, no information can be released without an individual patient's consent. It is sometimes obtained as a matter of routine upon admission to a hospital.

In other instances, it is an outside authority foisted upon the patient because the PSRO Act allows review of medical records and, as you heard, in the case of a delegated hospital, the same specifics apply to all the patients within that hospital.

I think the case in point is that identifiers of individual patient records are not necessarily available to Federal agencies, only cumulative data or cumulative statistics.

Senator LAXALT. That is precisely what we are trying to protect here; precisely.

Dr. HUNTER. As you heard me say, we must indeed strike a balance between the individual right of privacy and that which constitutes public welfare. You asked about an individual's hospitalization and asked whether or not his records should be made available to the public.

If he had a communicable disease, such as cholera, which is a current concern, his records should indeed be available for public consideration or a public agency, or a health agency.

Senator LAXALT. If he has a mental difficulty unrelated to any epidemic, certainly not.

Dr. HUNTER. Absolutely. If his hospitalization has been paid for by an insurance company, they are entitled to a diagnosis to decide whether or not benefits are applicable.

Senator LAXALT. That is all I have. Thank you very much.

Senator TALMADGE. Senator Dole?

Senator DOLE. I have no questions. I think you clearly and objectively stated the problem we have with either amendment. There is a third option of doing nothing in this interim. It could be 6 months, or it could be longer, depending on how long it takes the Congress to act on the recommendations sent to us on October 13, and I agree with the statement you make that there must be this balance.

How do we find the balance? Is there some way that we can fine tune existing laws and regulations to preserve that until we get into the big overhaul of the problems of the recommendations?

Dr. HUNTER. We have created a model State law that has been sent on to the individual States and territories for their consideration. We feel that this is a better place to solve the problem because of the variability from one State to another.

Of course, if Federal agencies are involved, Federal law prevails over an individual State, in many instances.

Senator DOLE. What about the so-called Satterfield amendment? Do you find that objectionable, or is that somewhere between the Crane amendment and the Rogers amendment?

Dr. HUNTER. It is between the two, and it is a very sincere effort on Congressman Satterfield's part to correct some of the difficulties that have been pointed out.

Senator DOLE. Do you think that that might be a proper course to follow, or is that still too restrictive? Other witnesses have indicated that it is still too restrictive.

Dr. HUNTER. I would tend to agree with that conclusion, although, as I say, it is a very sincere effort to correct the dilemma.

Really, the ultimate solution calls for a digest of some 75 pages out of 650 pages in the Privacy Protection Study Commission report dealing with medical records; and not only digestion, but considered thought of the many ramifications of a very complex issue.

I do not think that a hurried acceptance against a potential problem rather than current violations—and that is what we really are considering, that the potentials implied rather than today's malfeasance, if you will—that 6 months is going to make much difference.

Senator DOLE. Thank you.

Senator TALMADGE. Dr. Hunter, as soon as HEW makes its recommendations on October 13, will you make available the views of the American Medical Association on their recommendations to this committee?

Dr. HUNTER. We would be very happy to do so, sir.

Senator TALMADGE. We would appreciate it very much. Thank you for your contribution.

The next witness is Dr. Loren Kerr, director, department of occupational health, United Mine Workers of America.

Doctor, we are delighted to have you. You may insert your statement into the record in full and summarize it.

STATEMENT OF DR. LOREN KERR, DIRECTOR, DEPARTMENT OF OCCUPATIONAL HEALTH, UNITED MINE WORKERS OF AMERICA

Dr. KERR. You have copies of the full statement. I just wanted to briefly summarize it, if I may Mr. Chairman.

The reason for our appearance here today is because I thought it might be helpful to share with you the experiences that we have had during the last 7 years with the Federal Coal Mine Health and Safety Act of 1969 as amended.

As you know, this bill was designed to eliminate the daily toll of coal mine accidents and stop the far greater losses from death and disability due to the dust diseases.

The Congress for the first time recognized that an occupational disease should be eliminated in a major industry. Black lung, like all job-related illnesses, is preventable and can be eliminated in one generation. Congress did provide the method of dust control but also said that this was inadequate. The controls had to be combined with a chest X-ray program of the working coal miners, which is the only known method for evaluating the adequacy of the dust suppression program.

In addition to the advantages of the X-ray program, it provides additional information concerning lung cancer which is occurring among the men. There is also a new exposure to asbestos in some of the strip mines. Moreover the X-rays provide the capability to diagnose previously unknown conditions, such as pulmonary tuberculosis, cardiac enlargement and histoplasmosis.

The chest X-rays provide the only film that enables miners to exercise their option to request a transfer to a less dusty area of the mine.

The standards for these X-rays are very strict. They are held under the strictest confidentiality in Morgantown, maintained by NIOSH. The films, and the related reports, cannot be released to any representative of the coal miners, coal mineowners, or to the union.

There is no reason for any of us handling that information, but it is essential for assessing the adequacy of the dust program and protecting the health of the men.

I can assure you that those films are kept under lock and key and there is strict confidentiality of this information. The results are made public but only in a manner that no specific miner can be identified.

We feel that the Crane-Satterfield amendments would completely emasculate the portion of Public Law 91-173 that is concerned with the X-ray program. There would no longer be any means of protecting the health of the miners and the prevention of black lung would be hopeless.

There is a further problem involved with the question of the transfer. When the X-rays show evidence of any amount of dust disease, the miners have the option to transfer to a less dusty area. Should the miners exercise these rights, then MESA assumes responsibility for transferring him.

NIOSH has done an excellent job of controlling the accuracy of these films, and we also feel that they have protected the miners in every instance.

Two studies that have recently been released, one a mortality study the other a hearing study, nearly indicate that the related records have been kept confidential. I request that these studies be inserted into the hearing record.

Senator TALMADGE. That will be done.[1]

Dr. KERR. There are other problems that would be encountered with these two amendments. The black lung program, for example, which has involved literally hundreds of thousands of applications, was administered at first by the Social Security Administration and now by the Department of Labor. I have given you a brief summary of the figures in my more complete statement.

[1] The two studies referred to were made a part of the official committee file.

These amendments would also have a serious effect on OSHA, because their responsibility—their main responsibility—is setting standards for toxic substances in the workplace. We feel that these levels would not be able to be established without access to medical records. Development of these criteria do require identification of the workers by the union and employer records, examination of plant industrial hygiene and medical records to estimate employee exposure and a determination of the workers with symptoms of the occupational disease.

I cannot stress too strongly at this point that it is extremely difficult to diagnose occupational diseases in their incipiency. It is next to impossible to identify workers at highest risk in the absence of medical records and the actual examination of all exposed workers.

These investigations are essential if we are going to reduce the toll that we are encountering in all of the industry today with nearly 300,000 deaths due to occupational diseases every year.

As a medical care administrator, I also feel that that the amendments would have a very serious effect on medical care programs. These proposals would make it next to impossible to do good research, including that which is so sorely needed, studies designed to contain the rapidly escalating costs of medical care.

I question, if this legislation were to go into effect, whether it would be possible to ferret out some of the major problems, such as ghost surgery and split fees. Also, the question of communicable disease control. These records would make it extremely difficult to do the case and contact investigations essential to control and prevent tuberculosis and venereal disease.

I ask this committee to reject the amendments under consideration. Nobody believes more strongly than I of the need for the privacy of medical records. However, as proposed, these amendments would eliminate adequate control of communicable diseases, terminate research by medical care providers, and eliminate all prevention and control of occupational diseases, thereby doubly increasing the threat of the environment to the entire Nation.

Senator TALMADGE. Thank you.

Senator Laxalt?

Senator LAXALT. Doctor, you have been here during the course of the hearings?

Dr. KERR. Yes, sir.

Senator LAXALT. We, in support of this amendment, do not want to thwart meaningful research of the type you describe. Would it not be a rather simple matter in the workers who are involved in your particular search, to educate them and get their free and voluntary consent?

Dr. KERR. I doubt it. For instance, the miner has to designate the physician to receive the X-ray information. Many of the miners do not have personal physicians, so we even have a problem in that connection of getting information back to the right doctor.

Senator LAXALT. This amendment would not preclude that type of activity, Doctor.

Dr. KERR. I know it would not, but I use this as an example to indicate that we have a problem here on getting even that kind of infor-

mation. I am not sure how I could answer you on how we could get that information from the miners.

Senator LAXALT. In the union relationships, do they sign consents or waivers in exchange for union coverage?

Dr. KERR. Heavens no.

Senator LAXALT. That is not done, is it, as ordinarily it would be in the case of an insurance company?

Dr. KERR. No; because the UMWA medical care is self-insured.

Senator LAXALT. That does not require that kind of consent?

Dr. KERR. Not to my knowledge. I was with the program for 21 years before I came to the union.

Senator LAXALT. You would certainly know.

Dr. KERR. I think so.

Senator LAXALT. That is all.

Senator TALMADGE. Senator Dole?

Senator DOLE. I have no questions.

Senator TALMADGE. Doctor, I compliment you on an excellent statement. Thank you very much.

Dr. KERR. Thank you, sir.

[The prepared statement of Dr. Kerr follows:]

STATEMENT BY LORIN E. KERR, M.D., M.S.P.H.

My name is Doctor Lorin E. Kerr and I am the Director of the Department of Occupational Health, United Mine Workers of America. I want to thank you for the opportunity to appear before you today. It is my understanding that you are considering the privacy amendments offered in the House to the Medicare-Medicaid Antifraud and Abuse Amendments (H.R. 3 and S. 143). The seven year experience of the United Mine Workers of America with the historic Federal Coal Mine Health and Safety Act of 1969 (Public Law 91-173) may be of help to you in your deliberations on these amendments.

Public Law 91-173 is designed to eliminate the daily toll of coal mine accidents and stop the far greater losses from death and disability due to dust diseases. This federal act is the first breakthrough in the Union's long battle to control and eventually eliminate the black lung menace from the coal mining industry. For the first time, Congress recognized an occupational disease and provided federal funds to pay some remuneration to the victims of this disease. The health sections of Public Law 91-173 attack coal workers pneumoconiosis from three directions: detection, prevention and control. Each approach goes beyond anything Congress has ever done regarding an occupational disease in a major industry.

At last the miners and their Union have secured the enactment of federal legislation essential for wiping out the man-made plague. They are highly intolerant of any attempts to delay or subvert enforcement and compliance.

Black lung like all job-related illnesses, is preventable and can be eliminated in one generation. The technology is not new; the use of ventilation and water has been well known for several decades.

In accordance with Public Law 91-173 the current level of coal mine dust must be at 2 mg. of respirable dust per cubic meter of air. The vast majority of nearly 3,200 operating sections are reported to be in compliance with the 2 mg. standard and slightly more than 50 percent are reported to be operating at 1 mg.

During the 1969 hearings on the federal coal mine act Congress became aware that a dust suppression campaign must be constantly evaluated. Dust measurement by itself is inadequate. The only known method is periodic chest X-rays of the miners. The development of new cases of coal workers' pneumoconiosis or progression of the disease provides convincing evidence of non-compliance with dust standards or the need to revise downwards the existing standard at 2 mg.

Closely associated is the previously unknown but recently reported elevation of the standardized mortality rate for lung and stomach cancer among coal miners.

There is also a new exposure to asbestos in some strip mines. Moreover, the X-rays are of considerable assistance in the diagnosis of previously unknown conditions such as pulmonary tuberculosis, cardiac enlargement and histoplasmosis. Finally, these chest films provide those miners with X-rays characteristic of coal workers' pneumoconiosis with the only legal evidence that enables them to request a transfer to a less dusty area of the mine.

The first two rounds of chest X-rays of the working miners have been completed and the initiation of the third round is only a few months away.

The qualifications of the physicians taking the X-rays and the confidentiality of the films are essential for the success of the program. The regulations specifying the criteria for evaluating the physicians and their equipment are strengthened for the third round.

When the X-ray is made the only identification permissable on the film is the miner's social security number. At that time the miner designates the name of the physician to whom the medical interpretation of the film can be sent. That physician is immediately notified of any non-pneumoconiotic condition observed in the film. A short occupational history taken at the same time is forwarded with the X-ray to the NIOSH Appalachian Laboratory for Occupational Safety and Health in Morgantown, West Virginia. The film is read again but this time by one of several experts specifically trained to read X-rays for pneumoconiosis. The final results are sent to MESA which notifies the miners of the results. About 85 percent are normal and the remaining 15 percent show some X-ray evidence of coal workers' pneumoconiosis. The X-rays are retained in Morgantown where they are filed under rigidly enforced security measures.

The regulations specifying the conduct of the chest X-ray program carefully delineate every procedures necessary to assure the confidentiality of the films and the reports. The X-rays are filed by social security number and the master file tying the name of the miner to the correct film is kept unde tight security. The individual films and related reports cannot be released to any representative of coal mine owners or a union. The information they need for the prevention and control of black lung is provided in a statistical form in which it is impossible to identify any individual miner.

The security and confidentiality of this information can only be assured when the program is conducted by a federal agency which in this instance is NIOSH. Moreover, NIOSH has the capability to perform the task at hand which involves making X-rays of nearly 200,000 miners in a period of 12 to 18 months. It is difficult to have each miner designate a physician because many have no physician. To expect each miner to provide written consent for a federal employee to have access to the X-rays, related reports and occupational history is ludicrous. There is barely enough time to complete the required X-ray examinations.

Both the Crane/Stark and Satterfield amendments would completely emasculate Public Law 91-173. There would no longer be any means of protecting the health of the miners and the prevention of black lung would be hopeless.

This is further emphasized by the transfer option. Public Law 91-173 currently provides that when the working miner X-ray shows evidence of coal workers' pneumoconiosis the miner shall have the option to request transfer to a less dusty area of the mine. Today, that means an area where the dust level is 1 mg. The notification from MESA informs the miner of the transfer rights. Should the miner choose to exercise these rights, MESA is so notified by the miner and MESA notifies the mine operator that the transfer must be effected within 45 days. The miner is the only one who receives the medical report on the X-ray. Nearly 6,000 miners have received notice of these transfer rights.

The enormity of the task (X-ray examination of 200,000 miners) and the sensitivity of the medical information involved precludes the possibility of protecting the miner's health and rights were we to be afflicted with Crane/Stark or Satterfield amendments.

Additional evidence of the punitive effects of these amendments is provided by the recently published NIOSH Research Report entitled "Mortality Among Coal Miners Covered by the UMWA Health and Retirement Funds." This long overdue study is essential for determining the health hazards in the coal mining industry. The excess mortality from the non-malignant respiratory diseases was no surprise. It, confirmed, however with substantial evidence the overwhelming significance of pneumoconiosis as a cause of death. The moderate elevation of deaths from lung cancer and the excess from stomach cancer have been unknown heretofore. The amendments you are considering would make all such studies impossible.

The amendments would also make impossible such studies of living workers as the NIOSH Research Report entitled, "Survey of Hearing Loss in the Coal Mining Industry." To assist in evaluating the seriousness of our contention I have copies of both these NIOSH Research Reports which I request be inserted in the record of this hearing.

There are numerous other health hazards which NIOSH has evaluated upon our request. In each instance an examination of personally identifiable medical records was essential for the identification and elimination of the hazard. Examples include exposure to such conditions as noise, heat stress, resin bolting, creosote treated lumber, and most recently perchlorethylene—a known carcinogen.

The Federal black lung benefits program specified in title IV of Public Law 91-173 would have been inoperable had the amendments under consideration been in effect. When the SSA ceased operation of the program on June 30, 1973 nearly 600,000 applications had been filed in four and one-half years. Of this number, about 225,000 totally disabled miners and 140,000 widows were approved for Federal black lung benefits. Since July 1, 1973 when the Department of Labor began administration of the benefits program nearly 109,000 black lung claims have been received of which more than 54,000 have been disallowed and nearly 51,000 are pending. About 4,500 claims have been approved. While the coal mine owners have unsuccessfully used the black lung benefits section of the Federal coal mine act on two different occasions to test the constitutionality of the law before the U.S. Supreme Court the amendments before this Committee would accomplish what the operators were seeking—dissolution of the Federal Coal Mine Health and Safety Act of 1969 as amended.

Equally important is the deadening impact of these amendments on the Occupational Safety and Health Act of 1970. The amendments would effectively eliminate one of the basic authorities established by the Act namely the ability of OSHA to set standards for toxic substances in the workplace. In addition, NIOSH would be unable to establish its legally required criteria documents.

The development of these criteria requires identification of the workers from union or employer records; examination of plant industrial hygiene and medical records to estimate employee exopsure; and a determination of workers with symptoms of occupational diseases. I must stress at this point that it is exceedingly difficult to diagnose occupational diseases in their incipiency. It is next to impossible to identify workers at highest risk in the absence of medical records and the actual examination of all exposed workers.

Investigation of occupational diseases that usually take many years to develop requires examination of retirees and those no longer at the work site being investigated. The names of these individuals are necessary when a determination of current health status and further medical examinations are indiacted. NIOSH in conducting such studies must have ready access to employer medical records to compare past and present medical information. This type of investigation would be delayed or even prevented were it necessary to obtain prior consent from the worker or next of kin.

Employers would also be in a position to discourage workers consenting to NIOSH access to medical records. This would compound the jeopardy already confronting the workers.

The amendments would also make it difficult for NIOSH to respond promptly in emergency situations. The delay forced by lack of immediate access to company medical records would needlessly increase the number of exposed and ill workers.

As a former medical care administrator for most of my professional career, I must add that the burden placed upon medical care providers appears far greater than the facts merit. In fact there is good reason to believe that research—including sorely needed studies designed to contain the rapidly escalating costs of medical care—would come to a roaring halt.

My initial professional employment in county health departments in Ohio and Michigan makes me equally fearful of the deadening impact of these amendments on the prevention and control of communicable diseases by official health agencies. The nation is currently confronted with an alarmingly low percentage of children protected against communicable diseases, a disturbing increase in reported cases of tuberculosis and an increase of unknown magnitude of the veneral diseases. Prevention and control of all these diseases require more than immunization. Tuberculosis and the venereal diseases in particular require

case finding and follow-up on sources and contacts. Access to medical records has been a long accepted control measure used by knowledgeable public health workers. Official health agencies must not be deprived of these essential tools.

I strongly urge this Committee to reject all such proposals presented by the amendments under consideration. No one believes more strongly than I about the need for privacy of medical records. However, as proposed these amendments would eliminate adequate control of communicable diseases, terminate research by medical care providers and eliminate all prevention and control of occupational diseases, thereby doubly increasing the threat of the environment to the entire nation.

Senator TALMADGE. The next witness is Dr. Leon Gordis, on behalf of the Society for Epidemiologic Research and the Association of American Medical Colleges.

Dr. Gordis, you may insert your full statement in the record and summarize it, sir.

STATEMENT OF DR. LEON GORDIS, ON BEHALF OF THE SOCIETY FOR EPIDEMIOLOGIC RESEARCH AND THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES

Dr. GORDIS. Thank you, Mr. Chairman. I would like to briefly summarize the written statement that I have submitted to the committee.

I would like to begin by saying that it is a privilege for me to appear before this committee to discuss the pending amendments regarding the use of medical records.

In the brief time allotted to me this morning, I should like to demonstrate to you how profoundly destructive such amendments would be to health-related research in the United States and consequently, how their adoption would be a major blow to the maintenance and improvement of the health of American citizens.

First, I would like to say a few words about my own professional background to demonstrate to the committee my qualifications for testifying this morning. I am a professor of epidemiology and chairman of the Department of Epidemiology at the Johns Hopkins University School of Hygiene and Public Health. I am also an associate professor of pediatrics at the Johns Hopkins School of Medicine.

I am a board-certified pediatrician and a member of a number of professional societies including the American Pediatric Society, the Society for Pediatric Research, the American Epidemiologic Society and the Society for Epidemiologic Research. I have been actively engaged in epidemiologic and pediatric research for more than a decade. In addition, for the past 14 years, I have served as a member of the Institutional Committee on Human Volunteers of the Johns Hopkins University School of Hygiene and Public Health, which is charged by the Department of Health, Education, and Welfare with protecting the rights of subjects of research studies, including confidentiality of their records.

This morning, I am testifying in a dual capacity. First, as a member and representative of the Society for Epidemiologic Research. This society is the official organization of those engaged in epidemiologic research in this country and has over 700 members. I serve as chairman of its standing committee on protection of privacy in epidemiologic research.

In addition to representing the Society for Epidemiologic Research, I am also here as spokesman for the Association of American Medical Colleges—AAMC. Established in 1876 to work for reforms in medical colleges, the AAMC has broadened its activities over the years so that today it represents the whole complex of individuals, organizations, and institutions charged with the undergraduate and graduate education of physicians in the United States. It is the national voice for all of the 120 operational U.S. medical schools, more than 400 teaching hospitals and over 60 learned academic societies, whose members are engaged in medical education, biomedical research and the delivery of health care.

Now, in the few moments I have this morning, I would like to cover a few topics, if I may. First, I would like to talk about the scope of epidemiologic research even beyond what Dr. Gordon alluded to this morning.

Second, I would like to point out how essential medical records are and why requirements for patient consent would make much research impossible.

I would also like to refer to the system that is currently in effect for the protection and confidentiality of medical records and to suggest some recommendations. I would like to emphasize that both of the organizations that I represent this morning, the Society for Epidemiologic Research and the Association of American Medical Colleges, are fully committed to protecting the confidentiality of all the personal medical data obtained in the course of research activities.

Our strong opposition to the amendment, therefore, reflects only our conviction that it will destroy medical and epidemiologic research in this country and thus severely damage the health of the American public. We do believe, however, that privacy protection is crucial. It can best be accomplished through the regulations enforced by HEW and through new legislation based on the recommendations made by the Privacy Protection Study Commission in its report to the Congress.

I would like to briefly discuss what epidemiology does. Epidemiology is defined as the study of the distribution of disease and the dynamics of disease in the human population, and the purpose of epidemiology is to identify specific agents or factors related to people and their environment that may either cause disease or may identify people who have a high risk for developing a disease.

By finding these causes and eliminating the exposure for these causes, we can hopefully prevent disease in the population. By finding people who are at high risk, we can direct them to medical care and detect their disease at an earlier stage.

The public health programs which are made possible through epidemiologic research include all of the infectious diseases, cancer, stroke, cardiovascular disease, and many other acute and chronic diseases that affect the American people. Legionnaires disease, which you heard about this morning, required an epidemiologic approach. The investigation of the deleterious effects of the swine flu vaccine last year also required an epidemiologic approach.

Certainly the issue which is of paramount interest to this committee is the cost benefit involved in medical care. In examining cost benefit

of a type of health care, one must first demonstrate that it has a benefit, and such a demonstration requires epidemiologic methods.

Now, in order to carry out these studies, as was said earlier this morning, individually identifiable information from medical records is essential. It is necessary so that we can find individuals who have a specific disease and obtain followup information. It is also necessary in order to link records from hospitals, death certificates, and areas of employment in order to investigate specific diseases.

Without the individual identifying information, much of the research could not be carried out.

On pages 6 through 8 of my prepared testimony, I have listed, for your information, a large number of studies which are prototypes of the kinds of investigations which we believe could not be carried out if the restrictive effects of an amendment such as that proposed by Representative Crane are in effect.

I will not read them now, but I would like to comment in detail on one or two of them.

I would like to stress that the epidemiologic investigations, whether they deal with environmental agents, newly developed medications, the natural history of disease, or the effectiveness of medical care, are of great potential benefit to society, the conduct of such studies requires that with proper safeguards, individually identifiable data from medical and other records be made accessible for purposes of legitimate medical and epidemiologic research without requiring individual patient consent.

Why would requiring consent make this research impossible? It would make it impossible for the following reasons. Many of these studies are conducted years after the information is obtained. Many of the patients who are studied may have been hospitalized 10 to 20 years before.

At the time they were hospitalized, the state of knowledge at that time might not even have permitted these studies to be conceived, so patient consent could not possibly have been obtained.

Often, reviewing the medical record is only the first step in finding out which patients have the disease. This is necessary in order to trace patients and obtain further information.

Therefore, we believe that the requirement to obtain consent for using a medical record prior to reviewing the record would be profoundly damaging to the maintenance and improvement of the health of all Americans.

I think that this issue, Mr. Chairman, can be made clear with a few specific examples, instead of talking about generalities. I would like to mention a few studies that were carried over. The first has to do with DES and cancer of the vagina.

Let me mention that diethylstilbestrol is extremely important, because for many years it was added to animal feed for livestock in the United States. A few years ago, investigators in Boston carried out an epidemiologic study and demonstrated that when a mother had taken diethylstilbestrol during pregnancy to prevent a miscarriage, her female children were at risk of a rare cancer of the vagina which developed many years later when they reached adolescence.

This study could not have been carried out without the use of medical records. I would like to point out, first, that the cancer did not appear in the patient taking the medication. Second, the cancer appeared 15 to 20 years after the initial exposure. Third, the only way the girls and young women with this cancer were identified was by going to the medical records.

It was necessary to go to the medical records in order to identify the patient population of these studies. This was a very important study. This study is the first demonstration in human beings that a cancer-producing agent can cross the placenta during pregnancy and produce cancer in the offspring.

We suspect that there are probably more agents of this type, but without epidemiologic investigations using medical records, we would be unlikely to identify these other agents.

On another topic, I would like to refer to occupational cancer. In recent years, there has been increasing recognition that Americans employed in industries are often subjected to high concentrations of toxic substances. For example, workers exposed to vinyl chloride are at risk of cancer of the liver. The study that confirmed this also required medical records. I will not go into detail for reasons of time.

I have described on pages 14 and 15 of my statement studies regarding preventable forms of blindness in premature infants. These studies were only possible through the use of medical records. Other similar studies concern the benefits of anticoagulant drugs for coronary patients and other studies that time will not permit me to review.

The current public health problems that we have in this country—coronary disease, cancer, other forms of cardiovascular disease, and infectious diseases, such as hepatitis and venereal disease, and the evaluation of the benefits and possible harmful effects of new drugs and new vaccines—all require epidemiologic studies and the use of medical records. This use of records is particularly crucial.

Any legislation that would limit the use of these records and would require patient consent would seriously compromise medical and epidemiologic research in this country and make most of these studies impossible. It would seriously damage the health of many Americans and certain groups in particular, such as American workers. Women and children would be left at high risk of exposure to toxic, cancer causing and malformation causing agents without any means of protection.

The question was raised earlier about existing safeguards in regard to PSRO's. I would just like to comment on these safeguards in regard to research.

At the present time, the Department of Health, Education, and Welfare has an elaborate system codified under the Privacy Act which requires every institution receiving Federal funds to have a committee on the protection of human subjects. These committees minimize the invasion of privacy as much as possible. They require the investigator to demonstrate before any funds are released for his project that the people who are participating in the study are well protected and that the privacy and confidentiality of the medical records is also protected.

As Dr. Gordon said earlier, that data has never been released in individual form, only in the aggregate. As I said earlier in my testimony, it is essential that during the time the study is being conducted that individually identifiable data be obtained for linking of records and for identification of patients.

There is an elaborate and quite effective system in operation now. We believe that this can be built on in conjunction with the Privacy Commission recommendations, in terms of enhancing the welfare of the American public.

So, in conclusion, I would like to say that we believe the interests of privacy and confidentiality are complex and cannot be addressed by a single, simple amendment such as that proposed without doing irreperable harm. For the past 2 years, the Privacy Protection Study Commission established by the Congress has been addressing these important issues.

In July of this year, the Commission submitted its final report. In addition to a thorough discussion of these issues, the report embodies a series of recommendations for legislative action.

We therefore respectfully and strongly urge the members of this committee not to destroy American medical and epidemiological research by adopting any amendment under consideration, but rather to use the recommendations of the Privacy Protection Study Commission as a basis for drawing up new legislative proposals.

We also recommend that this be done only after a thorough discussion of the impact of these proposals on health-related research of the United States and their implications for the long-term health of American citizens. In this way, we will be able to assure the American public that it will continue to reap the benefits derived from the most outstanding medical and epidemiological research of any country in the world.

Thank you.

Senator TALMADGE. Senator Laxalt?

Senator LAXALT. Thank you for an excellent statement. I do not think I have any questions.

Senator TALMADGE. I also want to compliment you, doctor, for a very comprehensive, detailed, excellent statement. In my judgment, the argument you make is absolutely irrefutable.

Dr. GORDIS. Thank you very much.

[The prepared statement of Dr. Gordis follows:]

STATEMENT OF LEON GORDIS, M.D., DR. P.H., ON BEHALF OF THE SOCIETY FOR EPIDEMIOLOGIC RESEARCH AND THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES

1. INTRODUCTION

It is an honor and privilege for me to appear before this Committee in connection with its consideration of an amendment which would prohibit the use of medical records for medical and epidemiologic research without the patient's consent. In the brief time allotted to me this morning, I should like to demonstrate to you how profoundly destructive such an amendment would be to health-related research in the United States and consequently, how its passage would be a major blow to the maintenance and improvement of the health of American citizens.

First, I would like to say a few words about my own professional background to help explain to the Committee my qualifications for testifying this morning. I am a Professor of Epidemiology and Chairman of the Department of Epidemi-

ology at The Johns Hopkins University School of Hygiene and Public Health. I am also an Associate Professor of Pediatrics in The Johns Hopkins School of Medicine. I hold a Medical Degree and Masters and Doctorate Degrees in Public Health. I am a board certified pediatrician and a member of a number of professional societies including the American Pediatric Society, the Society for Pediatric Research, the American Epidemiologic Society and the Society for Epidemiologic Research. I have been actively engaged in epidemiologic and pediatric research for more than a decade. In addition, for the past four years, I have been a member of the Committee on Human Volunteers of The Johns Hopkins University School of Hygiene and Public Health. In accordance with the guidelines of the Department of Health, Education and Welfare which are currently in force, this committee is charged with protecting the rights of human research subjects and guaranteeing the confidentiality of all personal and medical data obtained in the course of any research investigation.

This morning I am testifying in a dual capacity. First as a member and representative of the Society for Epidemiologic Research. This society is the official organization of those engaged in epidemiologic research in this country and has over 750 members. I serve as Chairman of its standing committee on Protection of Privacy in Epidemiologic Research.

In addition to representing The Society for Epidemiologic Research this morning, I am also here as spokesman for the Association of American Medical Colleges (AAMC) formed in 1876 to work for reform in medical colleges. It has broadened its activity over the years so that today it represents the whole complex of individuals, organizations and institutions charged with the undergraduate and graduate education of physicians. It serves as a national voice for all of the 119 operational U.S. medical schools and their students, more than 400 of the major teaching hospitals, and 60 learned academic societies whose members are engaged in medical education, biomedical research and the delivery of health care. Through its members, the concerns of the Association range far beyond medical education itself and include the total health and well-being of the American people.

In the time allotted me this morning I should like to do several things: First, I should like to describe very briefly the scope of epidemiologic research and its importance for the health and well-being of the American people. Second, I should like to demonstrate how essential the use of medical records has been in the past in a number of landmark epidemiologic studies which have made invaluable contributions to the health of our population. Third, I should like to indicate some of the important health problems we now face which desperately need knowledge gained from epidemiologic research if they are to be prevented and controlled, and how such a restrictive amendment as this Committee is considering would make them virtually impossible. Fourth, I will briefly discuss why the requirement proposed by this amendment that patient consent be obtained prior to using a medical record, would make most epidemiologic and medical research in this country impossible. Finally, I should like to describe to you briefly the safeguards which are currently in effect for protecting the rights of human research subjects and the confidentiality of their personal information, including that in medical records, during the course of a research project.

I should like to emphasize that the members of the Society for Epidemiologic Research and the Association of American Medical Colleges are fully committed to protecting the confidentiality of the medical and personal data they obtain in the course their research activities and share a deep concern for the protection of all people who participate in medical and epidemiologic research. Our strong opposition to this amendment, therefore, reflects only our conviction that it will destroy medical and epidemiologic research in this country and will thus severely damage the health of the American population. We do believe however, that privacy protection is crucial, and that it can best be accomplished through the regulations presently enforced by the Department of Health, Education and Welfare, and through new legislation based on the recommendations made by the Privacy Protection Study Commission in its report to the Congress entitled, "Personal Privacy in an Information Society" which was submitted this summer after two years of careful study of this complex area by the Commission.

2. EPIDEMIOLOGY AND THE NATION'S HEALTH—THE NEED FOR USING MEDICAL RECORDS

Epidemiology may be defined as the study of the distribution and dynamics of disease in human populations. Its purpose is to identify specific agents or

factors related to people and their environments which may be the cause of disease or which may identify people who are at high risk for developing a disease. In so doing, epidemiology provides the basis for public health programs directed at prevention and control of diseases. Prevention can be effected by reducing or eliminating people's exposure to a specific factor, once its importance in producing disease has been demonstrated. Identification of people at high risk for disease is important so that they can receive close medical supervision and undergo screening tests where appropriate so that if they do develop disease, the illness can be identified at a very early stage when it can be successfully treated.

The public health programs made possible by knowledge gained from epidemiologic investigations include those directed at prevention and control of infectious diseases, and of cancer, stroke, heart and other cardiovascular diseases, and many other acute and chronic conditions which affect the American people. Investigation of so-called "Legionnaire's Disease", for example, required an epidemiologic approach. Epidemiologic methods are also essential for evaluating the efficacy of new preventive and therapeutic measures as well as their possible harmful side effects. For example, the possible harmful effects of swine flu immunization last year required epidemiologic investigation. Epidemiologic methods are also needed for determining the effectiveness of new organizational patterns of delivering health care. In addition, those of us who are concerned with the question of cost-benefit in health care recognize that the issue cannot be reasonably discussed by focusing only on cost. For in examining cost-benefit of a type of health care, one must first demonstrate that it has a benefit and such a demonstration requires epidemiologic methods.

In this context, I should like to direct this Committee's attention to the invaluable contribution of medical and vital records to various types of health-related research. These records are used in epidemiologic investigations, in longitudinal studies of the natural history of disease, and in studies which are designed to evaluate the quality and effectiveness of health care delivered to the community. I should like to stress that individually identifiable information in medical records is essential for conducting epidemiologic studies. It is necessary so that the records can be used as the basis for identifying individuals with a certain disease and individuals without the disease—some of whom may have had their disease many years prior to the time of the study—so that these individuals can be followed up through interviews, questionnaires or other methods. Individually identifiable information is also necessary in order to link records from different sources which pertain to a given individual. Thus, for example, in investigating whether a new form of treatment improves survivorship, it is necessary to link hospital records with death certificates for each individual receiving the new treatment and for each individual not receiving the new treatment so that the death rates in both groups can be compared.

3. SOME MAJOR HEALTH STUDIES WHICH HAVE REQUIRED USE OF MEDICAL RECORDS

Epidemiologic inquiry depends on the availability of the medical and vital records of large numbers of people, both for the data that they contain as well as to ascertain and identify individuals for subsequent interview and study. The major contributions of epidemiology to our understanding of disease have been based on studies using data from such sources, studies sometimes conducted many years after the information was recorded. These contributions can be demonstrated by a few selected examples of past investigations which have elucidated the causes of human diseases and facilitated their prevention. Many would have been virtually impossible to carry out had the amendment under consideration been in effect. Among these studies are:

1. Cancer

Studies which demonstrated:

(*a*) the relationship of cigarette smoking to lung cancer as well as to coronary heart disease, bladder cancer and other conditions.

(*b*) that the daughters of women who receive the hormone diethylstilbestrol (DES) during pregnancy have an increased risk of developing cancer of the vagina many years later.

(*c*) an increased cancer risk associated with occupational exposure to substances such as asbestos, vinyl chloride and arsenic.

(*d*) the increased risk of several types of cancer after exposure to radiation.

(*c*) that women taking estrogens for menopausal symptoms are at increased risk of endometrial or uterine cancer.

(*f*) the effectiveness of breast cancer screening in reducing mortality from breast cancer.

2. Cardiovascular Diseases

Studies which demonstrated:

(*a*) that high blood fats, high blood pressure and smoking shorten life expectancy, particularly through early death from coronary heart disease.

(*b*) that women taking oral contraceptives are at increased risk of developing thromboembolism or stroke.

(*c*) the benefit of early detection and treatment of hypertension.

(*d*) that administration of anticoagulants to patients with myocardial infarctions is associated with lower post-infarction mortality rates.

3 Infectious Diseases

Studies which:

(*a*) led to the development of vaccines for poliomyelitis, measles and other infectious diseases.

(*b*) showed that cases of polio which developed subsequent to polio immunization in 1955 resulted from a vaccine lot having been contaminated with live virus.

4. Health of Children

Studies which demonstrated:

(*a*) that the administration of high concentrations of oxygen to premature infants results in blindness.

(*b*) that maternal rubella (German measles) infection during pregnancy produces congenital malformations in the infant.

(*c*) that the use of thalidomide during pregnancy results in severe congenital malformations of the arms and legs of infants.

(*d*) that maternal radiation exposure during pregnancy is associated with an increased risk of childhood cancer and congenital malformations.

(*e*) that Rh disease (erythroblastosis fetalis) in newborns can be prevented.

(*f*) that inner-city comprehensive care programs for children and youth are effective in reducing rates of rheumatic fever.

These are but a handful of the important studies which have produced direct benefits for human health by identifying the causes of disease, facilitating the development of preventive methods, and evaluating new ways of providing medical care and organizing health care delivery. It would be tragic indeed if the potential benefits to society of such research were to be lost as a result of a proposal which in essence would make such studies impossible.

Society has a vital stake in these types of studies. Society as well as the affected individuals must bear the costs of disease. Consequently, society must ensure that a reasonable approach will prevail, in which the dignity and privacy of patients will be protected while the advancement of knowledge of disease through epidemiologic investigation will be facilitated. The social contract which facilitates the existence of communities as social groups requires that each individual yield some of his individual rights, including confidentiality and freedom of action, for the benefits of society as a whole. Compliance with traffic regulations and with income tax laws are but two examples. Each society must decide when a limited compromising of individual rights is justified by the potential benefits for the community as a whole. Epidemiologic investigations of the etiology of a disease—whether dealing with environmental agents, newly developed medications, the natural history of a disease, or the effectiveness of preventive and therapeutic intervention—are of great potential benefit to society and its members. The conduct of such studies, however, requires that with proper safeguards, individually identifiable data from medical and other records be made accessible for purposes of legitimate medical and epidemiologic research without requiring patient consent.

4. HOW EPIDEMIOLOGIC INVESTIGATIONS ARE CARRIED OUT USING MEDICAL AND OTHER RECORDS

In order to carry out epidemiologic research it is often necessary to identify individuals with specific diseases or disabilities, or individuals who share some common environmental exposure. Medical records are essential for identifying

populations with specific diseases and for obtaining detailed historical, clinical and laboratory information about the patients. Individually identifiable information is essential in these studies, because access to these records is only a first step in ascertaining and identifying these patients so that they can be subsequently contacted and, with their informed consent, interviewed and studied. Identification of specific individuals during the time the research is conducted is also essential to link records on a given person from different sources, such as physician records, hospital records, employment records, and birth and death certificates. Furthermore, since groups of patients with a particular disease must be compared with groups who are non-diseased or who do not have the particular disease under study, in order that meaningful inferences about the causes of the disease can be derived, identifying information about nondiseased and non-patient subjects must also be available. This approach is fundamental to epidemiologic studies of the etiologic and risk factors of disease, to studies of the natural history and prognosis of disease, to the evaluation of new approaches to prevention, early detection and treatment, and to the evaluation of new methods for delivering health services.

5. WHY REQUIRING PATIENT CONSENT WOULD MAKE MOST STUDIES IMPOSSIBLE

It is important to point out that such research would be virtually impossible to carry out were patient consent required in order for the investigator to have access to medical records as has been proposed in the amendment under discussion. Since the studies described above were frequently conducted many years after the information was recorded, the state of knowledge at that time may not even have permitted the study to be conceived, so that patients' consents could not possibly have been obtained. In addition, reviewing medical records is often only the first step in ascertaining and identifying patients with a given disease so that they may be subsequently traced, contacted and with their permission, studied further. Any requirement that consent be obtained before any medical record is reviewed would be extremely destructive to medical and epidemiologic research and consequently would be profoundly damaging to the maintenance and improvement of the health of all Americans.

Some Specific Examples

a. *DES and Vaginal Cancer.*—In order to convey some idea of just how destructive this amendment would be, I should like to cite a few major findings from epidemiologic studies which will demonstrate to you the serious threat to the health of the American people which is posed by this amendment. First, I should like to refer to the studies dealing with diethylstilbestrol or DES as it is known. These studies of the effects of DES in human being are particularly important since for many years DES was added to livestock feeds in the United States. A few years ago, investigators in Boston demonstrated through an epidemiologic study, that when mothers took DES during pregnancy to prevent a miscarriage, female offspring of these pregnancies were at increased risk of developing a rare type of cancer of the vagina when they reached adolescence.

This study could only be carried out through the use of medical records. Three particular features are noteworthy here: First, the cancer did not appear in the person taking the medication but only in her female offspring exposed to DES during intrauterine life. Second, the cancer appeared some 15 to 20 years after the exposure to DES so that it was necessary to go back many years to identify the drugs taken in pregnancy. Third, in this study, the girls and young women with this cancer were first identified from their medical records, and only then could their mothers be contacted and followed-up. Consequently, if use of medical records were prohibited, or if such use were permitted only with the consent of the patient, these studies which demonstrated the cancer producing effect of DES in women many years after exposure, would have been impossible to carry out.

This study is perhaps the first demonstration in man of transplacental carcinogenesis, i.e., that cancer-causing agents taken by the mother can cross the placenta and produce cancer in the offspring. There may be other such agents—presently unknown—which mothers should avoid during pregnancy because of the hazard to their children. In order to identify these agents, thorough epidemiologic investigations using medical records are needed to protect the health of American women and their children. This is an issue which could not be explored, however, if the restrictions of the amendment under consideration were to be implemented.

b. *Occupational Cancers.*—I should like to turn next to another important damaging effect this amendment would have in terms of the health of the American worker. In recent years, there has been increasing recognition that Americans employed in industries are often subjected to high concentrations of potentially toxic substances. Thus, for example, workers exposed to vinyl chloride have been shown to be at high risk of liver cancer. This finding, which has now been confirmed in a number of studies, could only be made by reviewing the medical records of large groups of employees in specific industries and linking the employees' records at the factory site with hospital records and death certificates if they exist. Without access to these records it would be impossible to have identified vinyl chloride as a cause of cancer in occupationally exposed human beings. I should also point out in this connection, that had the restriction of this amendment been in effect—namely, that patient consent must be obtained before a record is made available—these studies could also not have been carried out because many patients had either died by the time the study was done or else had moved and could not be traced.

It is clear that we have only begun to scratch the surface in terms of the toxic and cancer producing potential of substances to which American workers are exposed in the course of their daily labors. A restrictive amendment such as that under discussion would preclude the possibility of identifying new damaging substances and documenting their harmful effects and would be a major setback to the protection of the health of the American worker.

c. *Preventable Blindness in Premature Infants.*—I should like to turn briefly to a tragic medical story which unfolded during the 1950's. At that time premature infants who were of small birthweight, were found to have an increased risk of blindness called retrolental fibroplasia. Surprisingly, the risk of blindness was highest in the best medical centers in our country while in the less sophisticated and less well-equipped medical centers, the risk seemed lower. Initially there was no clue as to what might be causing this blindness and numerous investigations in many areas were carried out. However, epidemiologic investigations subsequently demonstrated that the cause of this blindness was high oxygen concentrations administered to the premature newborns. These high concentrations were often only provided in the best medical centers, since at that time, the highest possible oxygen concentration was considered the optimal medical care for these infants. Since that time, restriction of the oxygen concentration to a lower level when administered to premature infants has virtually wiped out this form of blindness in prematures. Again, these studies which demonstrated that high oxygen concentrations were the cause of blindness in children and that reducing these concentrations could prevent such blindness, would have been totally impossible to carry out were access to medical records restricted as proposed in the present amendment.

d. *Benefits of Anticoagulant Drugs for Patients with Heart Attacks.*—For many years, there has been a difference of opinion among physicians with regard to the possible benefits of anticoagulants in the treatment of patients who have heart attacks. Several years ago, we carried out a study in which we reviewed the records of a large number of patients with heart attacks who had been hospitalized some years previously. We ascertained which patients had received anticoagulants and which patients had not and then followed the course of these patients to see which ones had died during their hospitalizations.

We were able to show that the death rate was much lower in patients who had received anticoagulants during their hospitalization than in those who had not. This important observation has now been confirmed in another study carried out in our department. We believe that in the coming years, the findings will have major implications for the care of heart attack victims. Yet this study and the one which followed, could not have been carried out without the use of medical records, and would have been impossible had the consent of the patient been required for using these records.

e. *Harmful Effects of the Pill (Oral Contraceptives).*—Although the "pill" has been demonstrated to be a highly effective and convenient form of birth control which has been adopted by many American women as their form of contraception, a large number epidemiologic studies have now demonstrated that women taking the pill for long periods of time are at increased risk for blood clots, strokes, heart attacks, high blood pressure, liver tumors, gallbladder disease, congenital malformations in their offspring and other conditions. These

highly significant findings were in large measure the result of large-scale studies which used hospital and medical records—studies which again would have been impossible to carry out if patient consent had been required. The pill studies are examples of studies of the adverse effects of many drugs which are critical for protecting the health and well-being of the American public and which will be precluded by any amendment similar to that proposed here.

f. *Improved Survival in Childhood Leukemia.*—One of the greatest accomplishments of American medicine during the past decade or two has been the breakthrough in the treatment of acute leukemia in children. While children with leukemia at one time died within a few months after diagnosis, with the new advances in therapy, they now live many years—and are often free of any evidence of their disease. The demonstration that new forms of therapy have resulted in an improved outcome such as this for the patient requires the use of medical records and also would not be possible if the proposed amendment were to be implemented.

6. MEETING CURRENT CHALLENGES TO THE HEALTH OF THE AMERICAN PUBLIC—THE NEED FOR RESEARCH USING MEDICAL RECORDS

Among the major public health problems today in the United States are those of cancer, cardiovascular disease and other chronic conditions, as well as infectious diseases such as hepatitis, venereal diseases and influenza, and the evaluation of benefits and possible risks of new vaccines. Much of cancer today is probably environmentally determined. In a recent interview, Dr. Arthur C. Upton, newly appointed director of the National Cancer Institute, responded to a question about research needs in the cancer field, saying, "We need a lot more good epidemiology. It can tell us not only about environmental factors but also about genetic influences and we really do need to know about both." Dr. Upton's comments apply just as well to cardiovascular diseases, including coronary diseases, high blood pressure and stroke, neurological diseases including epilepsy, diabetes, arthritis, digestive diseases and virtually all other chronic conditions in this country. In addition, the effects on human health of new drugs and other chemicals in the environment which require close attention if the health of the American public is to be protected, can only be identified through epidemiologic and other investigations, most of which depend on the availability of medical records.

Any legislation which would limit the availability of these records and would require patient consent, would seriously compromise medical and epidemiologic research in this country and would make most of these studies impossible. The result would be serious damage to the health of many Americans, and certain groups in particular, such as American workers, women and children would be left at high risk of exposure to toxic, cancer-causing or malformation-causing agents, without any form of protection. Thus, the maintenance and improvement of the health of Americans and their protection from environmental hazards, requires the facilitation of epidemiologic research and the continued availability of medical records. At the same time, confidentiality and privacy must be protected—not through a destructive amendment such as that under discussion today, but rather through the means discussed in the next section.

7. EXISTING SAFEGUARDS PROTECTING CONFIDENTIALITY

On May 3rd of this year, I testified before the National Commission for the Protection of Human Subjects regarding the safeguards currently in force for protecting confidentiality. Today, time does not permit a detailed discussion such as that I presented in May. Suffice to say, that as studies are conducted, epidemiologists and all medical researchers have a major professional and personal responsibility to minimize invasion of privacy as much as possible, and to protect vigorously the confidentiality of the data in their possession. The provisions of the National Research Act (P.L. 93-348) and its implementing regulations on Protection of Human Subjects, codify an elaborate system of safeguards, currently in operation within the scientific community, to prevent violations of the rights of patients for purposes of research. This system is complete with institutional review committees which are responsible for protecting the rights of human subjects and to which each investigator must justify the rationale for subjecting any human research subject to any risk—including invasion of

privacy, and must demonstrate the measures he is taking to ensure the confidentiality of all personal and medical data in his possession.

In any study, Institutional Review Committees serve to ensure that *unnecessary* invasion of privacy will not take place and that adequate safeguards will be provided for the confidential handling of data and that the use of individual identifying information together with the data will be kept to an absolute minimum consistent with carrying out the study properly. Investigators must assure the Institutional Review Committee that the research data that they collect will be kept under lock and key, and they must inform the committee who will have access to the data, how individually identifiable information will be effectively separated from other data and at what point in the research, and whether or not the data will be retained at the close of the study, and if so, why. Each committee thoroughly reviews interview instruments and questionnaires, the consent statement and any accompanying material which must be sufficiently informative to enable the subjects to decide on their participation freely and rationally. If the subjects are patients, they are regularly assured that their care will not be jeopardized in any way by their failure to participate and further, all subjects are assured that they are free to withdraw from a study at any time. Many of these provisions are spelled out in the current regulations of the Department of Health, Education and Welfare.

It is thus apparent that epidemiologists and other medical investigators are keenly sensitive to the challenge of ensuring confidentiality and protecting human subjects, and as presented briefly in this section, already have an elaborate and effective system which protects the subjects and the confidentiality of their personal and medical data, and at the same time facilitates the conduct of medical and epidemiologic research so that the cause of improving the health of Americans will be advanced as rapidly as possible. However, the amendment being considered would stop this advance almost completely and would force the American population to continue to bear the heavy burden of diseases which in all likelihood could be prevented by future medical and epidemiologic research.

8. SUMMARY AND RECOMMENDATIONS

The issue of privacy and confidentiality is an important one which must be addressed by society. Epidemiologic and medical investigators whose goal is the improvement of human health and the prevention and control of disease, are keenly aware of this issue and operate under safeguards designed to protect human subjects participating in research and to ensure the confidentiality of the information they provide—be it through questionnaires, interviews or their medical records.

Continued epidemiologic and medical research are essential to improve the health of the American public and to protect all Americans, and in particular certain subgroups such as industrial and other workers, who are at high risk from old and new environmental hazards. Identifying the causes of disease in order to develop prevention programs, and evaluating the effectiveness of new preventive and therapeutic measures as well as new ways of organizing and delivering health and medical care, all require an epidemiologic approach which must utilize medical and hospital records. Access to these records must be unhampered, and a restriction such as that proposed that these records not be accessible without the consent of the patient, would make most of this research completely impossible and thus would seriously damage the cause of improving the health of the American people.

The issues of privacy and confidentiality are complex and cannot be addressed by a simple amendment such as that proposed without doing irreparable harm. For the past two years the Privacy Protection Study Commission, established by the Congress, has been addressing these important issues. In July of this year, the Commission submitted its final report entitled "Personal Privacy in an Information Society". In addition to a thorough discussion of these issues, the report embodies a series of recommendations for legislative action. We therefore respectfully but strongly urge the members of this Committee not to destroy American medical and epidemiologic research by adopting the amendment under consideration, but rather to use the recommendations of the Privacy Protection Study Commission, which was established by the Congress, as the basis for drawing up new legislative proposals. We further recommend that this be done only after a thorough discussion of the impact

of these proposals on health-related research in the United States and of their implications for the long-term health of American citizens. In this way, we will be able to assure the American public that it will continue to reap the benefits derived from the most outstanding medical and epidemiologic research program of any country in the world.

Senator TALMADGE. This concludes our hearings this morning on the confidentiality of medical records.

I would ask all personnel to please clear the hearing room as rapidly as possible because the full committee will meet at 10 a.m. on the energy hearings.

Thank you very much.

[Thereupon, at 9:45 a.m. the subcommittee recessed, to reconvene at the call of the Chair.]

[By direction of the chairman the following communications were made a part of the record:]

HARVARD SCHOOL OF PUBLIC HEALTH,
Boston, Mass., September 15, 1977.

Hon. HERMAN E. TALMADGE,
Chairman, Subcommittee on Health, Senate Finance Committee,
Dirksen Senate Office Building, Washington, D.C.

DEAR MR. CHAIRMAN: I write, not only as a Dean of a School of Public Health, but also a physician who has long been engaged in biomedical research, particularly in the field of cancer. As you develop your Subcommittee's report on S. 143, I urge you to reject any provision similar to the Crane Amendment to the House Ways and Means Committee version of H.R. 3. The Crane Amendment would ban access to medical records by biomedical investigators without patient permission. Such access is basic to the epidemiological search for causes and ways to prevent cancer, heart disease and other major diseases that develop slowly and must be the subject of retrospective studies of individuals' health records over time.

As has been pointed out in the excellent guidelines prepared by the Privacy Protection Study Commission, it would be impossible to determine whether cancer is induced in workers exposed to particular chemicals over a period of years without recourse to the medical records of the workers involved. Yet deaths, changes in a place of employment and residence and other factors would decrease the number of permissions obtainable below the volume required for statistically valid findings.

The recent discovery that treatment of pregnant women with DES can result in uterine cancer in their daughters required the study of medical records of the mothers concerned. Enactment of the Crane Amendment or a similar ban, would halt the current review of records describing DES treatment during pegnancy as a means of identifying possible victims of uterine cancer among young women who may be unaware of their condition. Obviously, until record of DES treatment is found in medical histories, there is no way of knowing what women's permission might have been sought in advance. Many other examples could be cited.

Protecting the privacy of medical records beyond the needs for biomedical research is imperative. The Privacy Protection Study Commission has proposed important safeguards. Meanwhile, at a time when over 80% of cancer is believed casually related to environmental factors, it is imperative that such factors be identified. Society's best hope for success in this effort rests in epidemiology for which medical records constitute an indispensable source of information. The necessary information cannot be obtained if patient permission is required in every case.

For these reasons, I appeal to you and your fellow Subcommittee members to adopt confidentiality provisions in line with the House Commerce Committee version of H.R. 3, rather than those of the Ways and Means Committee.

With best wishes,

Sincerely yours,

HOWARD H. HIATT, M.D., *Dean.*

AMERICAN HOSPITAL ASSOCIATION,
Washington, D.C., September 16, 1977.

Hon. HERMAN E. TALMADGE,
Chairman, Subcommittee on Health, Senate Finance Committee,
Washington, D.C.

DEAR MR. CHAIRMAN: The American Hospital Association, representing 6,500 hospitals in the United States, appreciates this opportunity extended to it by the Senate Finance Committee to comment on provisions to be included in S. 148 governing access to and confidentiality of patient medical records.

We are concerned that appropriate safeguards be established in the Professional Standards Review Organizations' program to preserve and protect the confidential nature of information contained in medical records and health data which are identifiable with individual patients. It is our judgment that the provisions adopted in H.R. 3 by the House Ways and Means Committee are too restrictive and, on the other hand, that provisions adopted in the House Interstate and Foreign Commerce version of this bill do not go far enough. This is an extremely complex and important issue.

We have noted that the House Ways and Means Committee, as well as the House Interstate and Foreign Commerce Committee, adopted provisions in their versions of H.R. 3 that would require the Secretary of Health, Education and Welfare to report back to Congress within three months of the issuance of the report by the Privacy Protection Study Commission. Such a report by the Department of HEW would be required to include legislative recommendations to maintain the confidentiality of all individually identifiable medical records and data and to establish appropriate safeguards and protections against unwarranted or unauthorized disclosure of identifiable patient information. As you are aware, the report of the Privacy Protection Study Commission was issued on June 12 of this year. It is our understanding that the Department is presently developing the recommendations.

We strongly urge that the committee defer action on this issue at this time. However, on receipt of the Department's report, we would hope that the committee would schedule public hearings on the kinds of strictures which would be placed upon the disclosure of identifiable medical information in both the PSRO program and other federal programs that are health related and rely upon direct access to identifiable patient information.

Thank you again for this opportunity to express our view on this important issue.

Sincerely,

LEO J. GEHRIG, M.D.,
Senior Vice President.

ASSOCIATION OF AMERICAN MEDICAL COLLEGES,
September 14, 1977.

Hon. RUSSELL B. LONG,
Chairman, Committee on Finance, U.S. Senate,
Washington, D.C.

DEAR MR. CHAIRMAN: I am writing to express the concerns of the Association of American Medical Colleges regarding the provisions relating to the disclosure of individually identifiable medical records currently under consideration by the Committee on Finance during the mark-up of S. 143, the Medicare-Medicaid Antifraud and Abuse Amendments.

The Association, established in 1876 to work for reform in medical colleges, has broadened its activities over the years, so that today it represents the whole complex of individuals, organizations, and institutions charged with the undergraduate and graduate education of physicians. It serves as a national voice for all of the 116 operational U.S. medical schools and their students, more than 400 of the major teaching hospitals, and over 60 learned academic societies whose members are engaged in medical education, biomedical research, and the delivery of health care. It is because of the Association's particular interest in biomedical research and technology transfer that we are concerned that the final language adopted by the Congress in this legislation both protect the privacy of individuals and permit the continuation of important biomedical research and technology transfer.

During its deliberations on S. 143, the Committee on Finance will have before it two different provisions relating to the disclosure of individually identifiable medical records adopted by the House Committee on Ways and Means and the House Committee on Interstate and Foreign Commerce during their mark-ups of H.R. 3, the companion legislation to S. 143. The language adopted by the Committee on Ways and Means states: "No officer, employee or agent of the United States, or any office, agency, or department thereof, or any Professional Standards Review Organization or any person acting or purporting to act on behalf of such Organization, may inspect, acquire, or require the disclosure of, for any reason whatever, any individually identifiable medical record of a patient, unless the patient has authorized such inspection, acquisition, or disclosure." The Ways and Means Committee language further states that a PSRO may have access to the medical records of persons whose care was paid for by Medicare and Medicaid for the purpose of performing utilization review or for purposes of auditing for, investigating, or prosecuting fraud and abuse.

It is our belief that the provision adopted by the Committee on Ways and Means would essentially eliminate the possibility of conducting important research studies in epidemiology and preventive medicine on a large body of Federal medical records, as well as prohibit the use of Federal repositories of medical records which are of priceless research value. For instance, the vast archive of health records of the veterans of military service that has yielded so many important statistical correlations between environmental effects such as electromagnetic radiation and diseases such as cancer would effectively be made unavailable for research purposes. Also interdicted would be large scale epidemiological studies that involve the examination of the clinical records of literally thousands of patients. These studies identify and tabulate specific data elements in each patient's chart, aggregate them and finally present them as mass statistics. In view of the patent impossibility of obtaining informed consent from these thousands of individuals, current addresses or other whereabouts of whom are usually unknown and often unknowable, such studies simply could not be undertaken if the Ways and Means Committee language becomes law. Thus, we urge you to oppose the incorporation of this language into S. 143.

The Association would not want the Congress to interpret our opposition to the Ways and Means Committee language as opposition to the privacy rights of individuals. We genuinely support those rights and believe that it is possible to conduct studies of the character cited without in any way revealing information that could be associated with any identifiable individual. The approach suggested by the President's Privacy Protection Study Commission regarding medical records accomplishes both objectives and overall is more consonant with the long-range goals for biomedical research established by the Congress than is the language adopted by the Committee on Ways and Means. The recommendations of the Privacy Commission have been developed after wide consultation with and support from individuals in the scientific community; they take into consideration the rights of patients and the principles of informed consent, and at the same time recognize the important contributions of the research programs based on medical records to the health of the people of this country.

The language adopted by the House Committee on Interstate and Foreign Commerce appears to the AAMC to be a more reasonable approach to preserving patients rights while not impeding research. This language deals solely with the records in the possession of a PSRO, prohibiting access or disclosure of those records to Federal employees unless the care was paid for by Medicare or Medicaid, without the specific consent of the patient. Thus, the large library of Federal medical records would still be available for epidemiology research.

The AAMC also endorses the specification in the version of the bill adopted by the Committee on Interstate and Foreign Commerce which requires the Secretary, DHEW, to submit to the Congress a legislative proposal based upon the recommendations of the Privacy Protection Study Commission. (The Committee on Ways and Means subsequently adopted this Secretarial requirement as well.) This DHEW proposal would be the vehicle to definitely resolve the difficult problem of protecting privacy and simultaneously protecting health through biostatistical research. The Association believes that the inclusion of S. 143 of the Interstate and Foreign Commerce Committee language will provide the best possibility that both patient privacy and biomedical research advances will be fostered without conflict.

If you have any additional questions regarding this issue, please feel free to contact me. The AAMC appreciates your consideration of our position.

Sincerely,

JOHN A. D. COOPER, M.D.

AMERICAN PSYCHIATRIC ASSOCIATION,
Washington, D.C., September 15, 1977.

Hon. RUSSELL B. LONG,
Chairman, Finance Committee,
U.S. Senate, Washington, D.C.

DEAR SENATOR LONG: The Committee on Confidentiality of the American Psychiatric Association is pleased to learn of your activity in protecting our country from abuse and fraud in the Medicare and Medicaid programs. We are practitioners of psychiatry and concerned citizens who have had a long-time commitment to the efficient delivery of mental health care to the American public. Out of our professional interest in privacy and confidentiality we are appreciative of the knowledge and technical skill demonstrated in the drafting of H.R. 3. The bill strikes an admirable balance between provisions for the investigation and prevention of fraud and abuse and the protection of individual constitutional privacy rights.

We support the provisions of Section 5(h) concerning the processing of data by Professional Standards Review Organizations without patient identifiers. Further, we applaud the protection of patient records in the possession of PSRO's from subpoena or other discovery proceedings in civil actions. We suggest, however, that you consider extending such protection to records in the possession of third parties other than PSRO's.

Additionally, we favor the provisions of mandating informed consent. The balance drawn between access by the GAO to patient records and the limitations and strictures placed on GAO employees with respect to access and disclosures is also commendable. The sincerity of H.R. 3 is evident in providing realistic penalties for unauthorized access and disclosure.

Section 6 establishing subpoena power in the Comptroller General provides appropriate procedural safeguards. We note the provision that the Comptroller General must determine evidence of fraud or abuse in a record before a GAO employee may disclose the record to another federal or state agency. Subsection (d) protects personal medical records in the possession of GAO from subpoena or discovery in civil actions. We recommend this protection be extended to records in the possession of other agencies or persons.

We note the concern in the Reports of the House Committee on Ways and Means and the House Committee on Interstate and Foreign Commerce that the confidentiality provisions of H.R. 3 may restrict scientific research and epidemiological activities. As physicians we recognize the importance of protecting the public health. We respectfully point out that the confidentiality provisions in H.R. 3 apply only to the fraud-and-abuse controls. The confidentiality aspects enabling research should be dealt with in separate legislation.

We recommend the inclusion of Title XX programs also be covered by the provisions of H.R. 3. Sixty to seventy percent of these Title XX programs are medical in character. In addition, privacy rights should not be determined solely by the source of payments for medical care.

We look forward to the legislative implementation of the Privacy Protection Study Commission's recommendations on the protection of the privacy of medical records and would be pleased to provide technical input at the appropriate time.

Thank you for the opportunity to comment on this very important and innovative legislation.

Very truly yours,

JEROME S. BEIGLER, M.D.,
Chairperson, APA Committee on Confidentiality.

NATIONAL ASSOCIATION OF CHAIN DRUG STORES, INC.,
Arlington, Va., September 13, 1977.

Hon. HERMAN E. TALMADGE,
Chairman, Subcommittee on Health, Senate Committee on Finance, Dirksen Senate Office Building, Washington, D.C.

DEAR SENATOR TALMADGE: The National Association of Chain Drug Stores, Inc., (NACDS) has noted with great interest that your subcommittee will be holding hearings on the subject of confidentiality of medical records as it applies to H.R. 3, the Medicare-Medicaid Anti-Fraud and Abuse Amendments.

In this regard, NACDS wishes to go on record to register our total support for those provisions contained in this important Medicare-Medicaid Reform legislation which would ensure the confidentiality of medical records.

Of utmost concern to our membership is that the Department of Health, Education, and Welfare (HEW) and state Medicaid agencies are attempting to gain access to the prescription drug files of private patients. In brief, we believe that this sort of activity is an unwarranted intrusion into the practice of pharmacy and a blatant invasion into the privacy of patients who are having their prescriptions filled in our stores.

Thus, NACDS on behalf of our entire membership, which consists of more than 200 corporations that are operating in excess of 10,000 drug stores and 1,500 leased pharmacy departments throughout the United States, strongly recommends that all provisions providing for the protection of medical records of private patients from governmental access should be incorporated in this legislation when the Senate takes final action.

We appreciate the opportunity to present these views and it is our hope that your Subcommittee will give our comments full consideration.

Sincerely,

TY KELLEY,
Vice President, Government Affairs.

LOMA LINDA, CALIF.,
September 12, 1977.

LEON GORDIS,
Director, Johns Hopkins University School of Hygiene and Public Health, Baltimore, Md.

I'm concerned about the portion of Senate bill number 143 regarding the access to medical records which is to be considered by the Senate Finance Committee on Tuesday, September 13. Medical records contain a wealth of information which is invaluable to researchers and physicians seeking better understanding of the cause and prevention of major chronic diseases prevalent in the U.S. Passage of this amendment would be a very serious setback to maintaining quality medical care as well as research.

I fully concur, with the concept of controlling access to private medical records, but the wording of this bill is too broad. I would urge you to either vote against this bill or attempt to reword it so that access to medical records for the type of essential activities mentioned above would not be precluded. It is my understanding that the Privacy Protection Study Commission has looked into this matter in some detail. They have recently published their full report and I would hope that a decision on the mechanism of access to medical records would be delayed until their full report has been duly considered.

Respectfully yours,

ROLAND L. PHILLIPS, MD. DR., P.H.,
Chairman, Department of Epidemiology,
School of Public Health, Loma Linda University.

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