



**association of american  
medical colleges**

November 19, 1976

*Recd  
12/28/76  
MHL*

MEMORANDUM

TO: Mary H. Littlemeyer  
FROM: Mignon Sample *MS*  
SUBJECT: 1976 CAS Annual Meeting

According to the attendance sheets for the November 12, 1976 CAS Business Meeting, 55 individuals attended representing 44 of 59 societies.

The following societies were not represented at the meeting:

American Association for the Study of Liver Diseases  
American Society for Clinical Investigation, Inc.  
Central Society for Clinical Research  
Southern Society for Clinical Investigation  
Society of Critical Care Medicine  
Association of Professors of Medicine  
Association of University Professors of Ophthalmology  
Association of Pathology Chairmen, Inc.  
American Pediatric Society  
Association for Medical School Pharmacology  
Association of Academic Psychiatrists  
Association of Teachers of Preventive Medicine  
American Society of Therapeutic Radiologists  
Society of Surgical Chairmen  
Society of University Surgeons



# association of american medical colleges

## ASSOCIATION OF AMERICAN MEDICAL COLLEGES PROGRAMS AND ACTIVITIES\* 1976 OVERVIEW

The Association of American Medical Colleges (AAMC), working with its members, engaged in a wide range of activities during 1976. These were in the areas of biomedical research, faculty, education, federal liaison, health care, students, institutional development, teaching hospitals, and communications. Foremost among these programs are the following:

### *Biomedical Research*

1. AAMC participated in studies commissioned by the President's Biomedical Research Panel. After the Panel Report was published AAMC constituted a special Task Force to evaluate the Report. AAMC endorsed the general conclusions of the Report which emphasized the necessity for continued support of a sizeable, high quality, and broad biomedical and behavioral research effort.

2. AAMC continued to be active in discussions of the ethics of biomedical research and the protection of human subjects. As a result, the public has become aware of the effects on biomedical research of the Freedom of Information Act and the Federal Advisory Committee Act.

3. AAMC gathered information about the effects of cutbacks in research training funds and mobilized support to seek adequate funding levels.

4. AAMC took leadership in coordinating a number of studies of research manpower.

### *Faculty*

1. AAMC's faculty development program to help faculty members enhance their effectiveness as teachers was fully implemented during the year. Plans were completed for a pilot test that will provide the first available overview of how medical teaching is conducted, what faculty members perceive as instructional problems, and whether there are areas in which they would like assistance to improve their instructional effectiveness. These findings will guide the AAMC in the development of services that will be offered to medical school faculty.

*\*This summary has been especially prepared for the Council of Academic Societies. For additional detail, see the AAMC Annual Report, 1976, distributed at the AAMC Annual Meeting, San Francisco, California, November, 1976.*

2. AAMC will offer a voluntary, confidential self-assessment program to all faculty members during 1977.

3. AAMC presented at the 1976 Annual Meeting a "Workshop on Workshops," the first of a series intended to support the work of individuals in the medical schools who are responsible for offering workshops on instruction for faculty members.

4. AAMC began a study of factors associated with the choice of careers in biomedical research, a part of which will be a study to identify possible means by which the quality of research and teaching may be measured.

5. AAMC provided to the schools in an organized and systematic manner data from the Faculty Roster Project, initiated in 1965 and now containing information on almost 45,000 individuals.

6. AAMC utilized its Faculty Roster Data for studies on faculty mobility, faculty attrition, faculty participation in federal programs, and career performance within academic medicine.

7. AAMC published a report, Descriptive Study of Salaried Medical School Faculty, covering information on faculty appointment characteristics, educational characteristics, and employment history with various breakdowns by sex, minority group, and country of medical training.

8. AAMC released the 1975-76 Medical School Faculty Salary Survey which, for the first time, included data reported separately for the 16 Canadian medical schools.

#### *Education*

1. AAMC's Group on Medical Education (GME) continued its efforts to enhance information and resource sharing through regional and national efforts.

2. AAMC expanded its GME-sponsored Conference on Research in Medical Education to include poster session and enlarged symposium formats.

3. An AAMC Ad Hoc Committee on Continuing Medical Education has identified the need to initiate research and development programs for this important academic function.

4. AAMC continued its Collaborative Program for Developing a National Resource for Educating Health Professionals.

5. AAMC collaborated with the Lister Hill National Center for Biomedical Communications in the design of research and development programs for the Learning Resource Center.

6. AAMC developed self-instructional educational materials for use of medical students who have an interest in international perspectives of health and health care.

7. AAMC continued its Study of Three-Year Curricula in U.S. medical schools.

8. AAMC provided the annually revised Biochemistry Special Achievement Test to 21 medical schools for use in a variety of purposes and scored the test for these schools after a total of 29 administrations.

9. AAMC completed the development of the New Medical College Admission Test (New MCAT) which will be first administered to students in the spring of 1977 and prepared a test manual to serve as a comprehensive guide to assist students preparing to take the test.

10. AAMC completed its follow-up survey of approximately 2,500 physicians who participated in the AAMC Longitudinal Study of Medical Students of the Class of 1960.

#### *Federal Liaison*

During 1976 AAMC presented testimony on the following:

1. Appropriations for the DHEW, Fiscal 1977 budget.
2. Appropriations for the Veterans Administration, Fiscal 1977 budget.
3. Clinical Laboratory Improvement Act of 1976.
4. Salary Levels for Senior Staff at the NIH.
5. National Health Insurance.
6. Medicare-Medicaid Administrative and Reimbursement Reform Act.
7. Medicare Hospital Reimbursement.
8. Health Problems of the Elderly.
9. District of Columbia Medical and Dental Manpower Act of 1970.
10. Pennsylvania House Bill 1976 (re "Fifth Pathway").

#### *Health Care*

1. AAMC completed a program centered upon the development of optimum curriculum for undergraduate and graduate physician training in the HMO model in six affiliated HMO programs.

2. AAMC resurveyed the medical schools to identify their education and training of physicians and nonphysicians as primary care providers.
3. AAMC developed a series of national workshops to assist academic medical centers and their affiliated teaching hospitals in the improvement of ambulatory care services and related educational programs.
4. AAMC sponsored several regional meetings on quality assurance methodologies and peer review procedures at the undergraduate level.
5. AAMC published a group of papers resulting from an AAMC Symposium on Teaching Quality Assurance during the year.

#### *Students*

1. AAMC published a descriptive study of medical school applicants for the 1974 entering class and expanded its analysis of data for the 40,888 applicants filing 366,040 applications to the 1975 entering class.
2. AAMC processed 288,266 applications for admission in 1975 to 83 medical schools through AMCAS (American Medical College Application Service).
3. AAMC sponsored an Early Decision Plan, in which 58 institutions participated, through which 1,046 students were admitted for 1977-78 without filing an application to any other school.
4. AAMC authorized a Task Force on Student Financing to examine existing and potential mechanisms for providing financial assistance to medical students.
5. AAMC filed an amicus curiae brief in the case of Bakke v. Regents of the University of California, which supported the position that special admission programs for minority students do not violate constitutional equal protection safeguards.
6. AAMC established a Task Force on Minority Student Opportunities in Medicine to make recommendations on ways in which to improve opportunities for minorities seeking a career in medicine.
7. AAMC offered the Simulated Minority Admissions Exercise, developed in 1974, to regional groups of admissions officers, advisers, and medical school admissions committees.
8. AAMC prepared and distributed the Minority Applicant Registry (Med-MAR) to all U.S. medical schools to assist them in identifying minority candidates seeking admission.
9. AAMC, in cooperation with the National Board of Medical Examiners and the Bureau of Health Manpower, offered a special opportunity for Vietnamese refugee medical students to receive AAMC sponsorship to take NBME Part I in June.

10. AAMC continued COTRANS (Coordinated Transfer Application System) for U.S. citizens studying medicine abroad.

11. AAMC extended the analysis of its survey of student financing and prepared reports on medical student indebtedness and career plans; relationship of medical student finances to personal characteristics; and relationship of medical student finances to institutional characteristics.

12. AAMC published a definitive review of the literature on the medical school admissions process for the 20-year period 1955-1976.

13. AAMC published a descriptive analysis of U.S. citizens studying medicine abroad and using COTRANS during 1975.

14. AAMC initiated a comprehensive study of career choice of 1976 graduates based on information available from both the National Intern and Resident Matching Program (NIRMP) and the AAMC.

#### *Institutional Development*

1. AAMC continued sponsorship of its Management Advancement Program in which over 100 deans have now participated. A total of 99 department chairmen have attended follow-up seminars.

2. AAMC initiated the Management Education Network Project in the spring of 1976. This will expand the target audience of the Management Advancement Program and make possible documentation of academic medical center institutional problem-solving.

3. AAMC undertook a project focused on the relations between the medical school and a principal teaching hospital.

4. AAMC began to investigate in detail the affiliation arrangements between a sample of six selected medical schools and the network of teaching hospitals with which they are affiliated.

5. AAMC established a Visiting Professor Emeritus Program developed to fill temporary faculty positions in the medical schools with available emeriti professors.

6. AAMC devoted major efforts to the program which assists the establishment of close relationships between social security institutions in Latin American countries and their medical schools.

7. AAMC participated in a conference to formulate minimal standards for the development of new medical schools in Latin American countries.

8. AAMC assisted the new Executive Director of the Pan American Federation of Associations of Medical Schools in the development of background materials for several projects, including a proposal for the initiation of a Panamerican Institute for the Training of Teachers of Health Associated Professions in Caracas, Venezuela.

*Teaching Hospitals*

AAMC expended considerable effort toward analyzing and responding to legislation, regulations, and special studies dealing with health care industry controls having a special impact on teaching hospitals.

1. AAMC presented its views on the portion of the Institute of Medicine (IOM) study of Medicare and Medicaid reimbursement practices that would threaten the ability of teaching hospitals and physicians to fulfill patient care and medical education responsibilities as well as those recommendations directed to the issues of specialty and geographic distribution of physicians and foreign medical graduates.

2. AAMC actively discussed general concepts and tentative provisions of the Medicare-Medicaid Administrative and Reimbursement Reform Act, introduced by Senator Talmadge, with staff of Senate committees during the development of the legislation.

3. AAMC's appeal of its suit on the implementation of routine service cost limitations under Section 223 is pending before the U.S. Court of Appeals for the District of Columbia Circuit. In the absence of court-ordered relief or legislation replacing the cost limitations of Section 223, the Association is actively monitoring the impact of this section on teaching hospitals.

4. AAMC filed numerous comments with Executive Branch agencies on proposed regulations and activities including limitations on in-patient costs under Medicare and Medicaid. Standards for personnel in clinical laboratories, requirements for State Health Coordinating Councils, procedures for Certificate of Need review, Medicare's draft proposal on recognizing self-insurance contributions as reimbursable costs, and the draft uniform accounting system being prepared by the Bureau of Health Insurance.

5. AAMC initiated a Corresponding Membership category for teaching hospitals ineligible for membership in the Council of Teaching Hospitals (COTH) and that have a documented affiliation agreement with a school of medicine and obtain a letter of support from the dean of the affiliated medical school.

6. AAMC published and distributed to COTH member hospitals four regular and recurring surveys: Educational Programs and Services Survey, House Staff Policy Survey, Income and Expense Survey for University-Owned Hospitals, and Executive Salary Survey.

7. AAMC published and distributed to COTH members two special surveys: Survey of the Impact of Section 223, and Survey of Professional Liability Insurance in University-Owned Hospitals.

*Communications*

AAMC communicates its views, studies, and reports to its constituents, interested federal representatives, and the general public through a variety of publications, news releases, news conferences, personal news media interviews, and memoranda.

1. The major communications vehicle for keeping AAMC constituents informed is the President's Weekly Activities Report, issued 43 times a year. It reports on AAMC activities and federal actions that have a direct effect on medical education, biomedical research, and health care.

2. AAMC's major scholarly publication, the Journal of Medical Education, published 1,042 pages of editorial material in fiscal 1976.

3. AAMC publishes several other specialized newsletters: AAMC Education News, which appears five times each year and is circulated free-of-charge to all medical school full-time faculty members whose names are registered with the AAMC Faculty Roster; The Advisor; COTH Report; CAS Brief; Student Affairs Reporter; and the OSR Bulletin Board.

4. AAMC distributed numerous other AAMC publications such as directories, reports, papers, studies, proceedings, and archival listings.

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*CAHS Business Meeting  
Handout*

TENTATIVE AGENDA

AAMC OFFICERS' RETREAT

December 15-17, 1976

- I. AAMC Organizational Concerns
  - a. Regionalization and Fractionalization of the Association's Membership
  - b. Representation of Vice Presidents in the AAMC
  - c. Housestaff Representation in the AAMC
  
- II. Graduate Medical Education
  - a. AAMC Conference on Graduate Medical Education
  - b. Housestaff Collective Bargaining Rights
  
- III. Federal Concerns
  - a. Implementation of the Health Manpower Bill
  - b. Preparing for Health Manpower Renewal
  - c. National Health Insurance
  - d. Legislative Outlook in the Coming Year
  - e. Getting Good People Into Federal Agencies
  - f. Update on FTC Activities
  
- IV. Miscellaneous Topics
  - a. Process of Developing CCME Policy
  - b. Staffing of the CCME & Liaison Committees
  - c. 1977 Annual Meeting

For Information and Review: Presentation of AAMC  
Activities by Department  
and Division

## V. CONFLICTING INTERESTS FOR AND AGAINST DISCLOSURE

In order to determine whether the disclosure of research protocols, hypotheses and designs in grant applications should be available to the public under the FOIA and whether the NIH peer review system should operate in public view, it is necessary to understand the conflicting interests which are involved. Like most public questions, there is no simple resolution to this problem, as there are good reasons both for and against public disclosure of the materials involved here.

### A. Interests in Nondisclosure

The interests to be served by preserving the confidentiality of research protocols and hypotheses have been stated in the report of the President's Biomedical Research Panel, in an article on the subject published in Clinical Research which is intended to state the position of the Association of American Medical Colleges,<sup>123/</sup> and by representatives of HEW and the AAMC at various legislative hearings.<sup>124/</sup> These parties have also presented more specific, practical arguments against requiring disclosure of the formerly confidential materials contained in grant applications.

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<sup>123/</sup> Morgan, Keyes & Sherman, Confidentiality of Research Grant Protocols, 24 Clinical Research 5 (1976) (hereinafter cited as "Morgan Article").

<sup>124/</sup> See testimony of Majorie Lynch, Undersecretary of HEW, and accompanying HEW exhibits, Metcalf Hearings, at 175-240; testimony of Dr. Ronald W. Lamont-Havers, Acting Director of NIH; and testimony of John Sherman, V.P., AAMC, and accompanying statement of AAMC, in Hearing Before Subcomm. on Health of the Senate Labor and Public Welfare Comm., 94th Cong., 1st Sess. ("Kennedy Hearings"), at 47-53, 119-20, 134-35 (Mar. 17, 1975).

The considerations put forth by these parties are (1) research protocols are analogous to trade secrets, and scientists have something akin to a proprietary right in them which should be protected; (2) disclosure requirements will inhibit the submission of fully detailed research proposals, thus impairing the ability of HEW to evaluate grant applications; (3) disclosure of the research protocols may inhibit some scientists from even attempting to gain HEW grants, thus completely foreclosing valuable and necessary health research; (4) premature disclosure of research designs may destroy valuable patent, copyright or trade secret rights of scientists, thus unfairly destroying their actual property rights and also destroying the economic incentives for better health care; and (5) premature disclosure of research designs may lead to pressure from the public on their physicians to use untried treatments.

Each of these considerations is discussed more fully below.

1. Trade Secret Analogy

The President's Biomedical Research Panel, the AAMC and HEW representatives have each argued strenuously that the research designs of a scientist applying for a grant application are his "stock in trade," and thus by virtue of this analogy equivalent to the trade secrets of a commercial business.<sup>125/</sup>

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<sup>125/</sup> President's Panel Report at 11; Morgan Article at 7; AAMC statement in Kennedy Hearings at 134-35; Lamont-Havers testimony in Kennedy Hearings at 49-50; Statement of Advisory Comm. to Director, NIH, in Metcalf Hearings at 202-03.

This argument is based upon the principle that a scientist's research conceptions are the key to his advancement, and consequently it is unfair to deprive him of the power to control the timing of their release. The research scientist needs to prevent premature release of his ideas in order to insure that they are not copied either purposely or inadvertently by competing research scientists, and also to insure that his reputation is not darkened by the premature release of what turn out to be unwarranted or unfounded hypotheses.

Proponents of this argument point out that scientists have an incentive to publish their work as soon as it is ready for release, which should act as a check on any abuse of confidential treatment of their research designs.<sup>126/</sup>

Proponents of this argument are aware of the counterargument that research designs should not be entitled to proprietary treatment when they are in fact being purchased by the government with public monies. The AAMC contests the proposition that funding of research constitutes a purchase of the intellectual property of the scientist, stating that instead it "represents a public investment in an investigator's work with the hope and expectation that his work will bear fruit for the betterment of mankind and, in the case of biomedical research, for the ultimate prevention, alleviation, or cure of disease."<sup>127/</sup> Proponents of the trade

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<sup>126/</sup> E.g., President's Panel Report at 22; Morgan Article at 10.

<sup>127/</sup> Morgan Article at 10.



**AGENDA**  
**FOR**  
**COUNCIL OF ACADEMIC**  
**SOCIETIES**

**BUSINESS MEETING**

**Friday, November 12, 1976**

**8:30 a.m. - 12:30 p.m.**

**San Francisco Hilton Hotel  
Anza Room  
San Francisco, California**

● **ASSOCIATION OF AMERICAN MEDICAL COLLEGES**

*One Dupont Circle*

*Washington, D. C. 20036*

AAMC ANNUAL MEETING

November 11-15, 1976

San Francisco Hilton  
San Francisco, CA

1977 MEETING DATES

CAS Administrative Board Meetings

January 11-13, 1977

March 29-30, 1977

June 22-23, 1977

September 14-15, 1977

Washington, D.C.

Public Affairs Workshop

December 12-14, 1977

West Palm Beach, Florida

AAMC Annual Meeting

November 5-10, 1977

Washington, D.C.

AGENDA  
 COUNCIL OF ACADEMIC SOCIETIES  
 BUSINESS MEETING

Friday, November 12, 1976  
 8:30 am - 12:30 pm  
 Anza Room - San Francisco Hilton Hotel  
 San Francisco, California

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VII. NEW BUSINESS

12:30 p.m.

Announcement of Election Results

Adjourn



MINUTES  
COUNCIL OF ACADEMIC SOCIETIES  
BUSINESS MEETING

November 3, 1975

Washington Hilton Hotel  
Washington, D.C.

I. Call to Order

The meeting was called to order at 9 a.m. Dr. Jack W. Cole, Chairman, presided. Sixty-five individuals, representing 43 of the 56 member societies, were present. Societies not represented were:

American Academy of Neurology  
American Association for the Study of Liver Diseases  
American Neurological Association  
American Society for Clinical Investigation, Inc.  
American Society of Therapeutic Radiologists  
American Urological Association  
Association of American Physicians  
Biophysical Society  
Central Society for Clinical Research  
Society of Critical Care Medicine  
Society of Surgical Chairmen  
Society of University Otolaryngologists  
Southern Society for Clinical Investigation

II. Approval of Minutes

The minutes of the meeting held November 12, 1974 were approved as circulated with one amendment: Dr. Leslie T. Webster reported that the Association of Medical School Pharmacology was represented. With this amendment, 46 of the 57 societies then members were represented at the 1974 meeting.

III. Chairman's Report - Jack W. Cole

Dr. Cole commended Dr. Swanson and his staff for their able and dedicated efforts over the past year. Also, Dr. Cole thanked Dr. Rolla Hill, CAS Chairman-Elect, for serving as Chairman-Designate on the occasions when Dr. Cole was unable to attend due to serving his sabbatical year in England.

Dr. Cole reflected on the heterogeneity of the Council of Academic Societies which currently consists of 56 organizations, expected to increase to 61 assuming favorable action by the Assembly of the Association. To bring together the diverse interests of these organizations, which it is estimated represent some 100,000 individuals, into a forceful and influential body has been the challenge of this Council.

Dr. Cole added that he thought there was a tendency among these ranks for individuals to retreat to their laboratories or respective settings but that their abilities to do these jobs in the years ahead would depend upon the way in which the members can influence and modify the important forces that are beginning to intrude upon individual and collective activities such as the problem of continuing medical education, recertification, relicensure, health manpower, PSRO, HMOs, human investigations, and national health insurance. Dr. Cole stressed the importance of the official representatives reporting to the groups that they represent.

Continuing the established procedure, the CAS Administrative Board has met quarterly preceding the meetings of the AAMC Executive Council. In April the CAS Administrative Board agreed to hold its quarterly business meeting the evening prior to the regularly scheduled meetings. The following morning is devoted to considering prospective issues for which Board members develop discussion papers.

During the course of the year, two of the Board members, Drs. D. Kay Clawson and David Challoner, resigned when they became ineligible for further service by virtue of taking positions as deans. Their seats remained unfilled until the regularly scheduled meeting of the full Council on November 3.

The CAS Administrative Board took action during the past year in over 40 different areas and forwarded their actions to the AAMC Executive Council.

Members of the Council of Academic Societies had an opportunity to meet with five of the seven members of the President's Biomedical Research Panel during a two-day CAS Spring Meeting. Representatives of the 39 academic societies attending the meeting told the Panel that the major problem facing the biomedical research community is the problem of instability in program funding and program direction. The Panel was also told that as a result of diminished support for research and training grants there exists a real threat to the future of biomedical research because of the lack of support for young, innovative investigators. The problem of the ratio of support for investigator-initiated research versus targeted research was discussed also.

#### IV. President's Report - John A. D. Cooper

Dr. John A. D. Cooper, AAMC President, was present with the Council and gave an overview of the general political climate which prevails in Washington with regard to health manpower and other legislation of major interest to the Council of Academic Societies. Dr. Cooper alluded to the increase of external forces on the academic institutions both from the legislation and from regulations being published. In one year, he said, the Federal Register (where the regulations are published) has increased in size by 10,000 pages (a 30-percent increase). More and more legislation is intervening into the missions and curricula of the institution with short-range

solutions to problems whose consequences are long-range. In place of general support, special project grants which compel the student to pursue special goals are in the new order. The problems of reduced funding, common to both education and research, he concluded, derive from the anti-intellectual, populist movement that now pervades the national mood, what could be characterized as a "Jacksonian" period.

An informal discussion followed Dr. Cooper's remarks. He was asked first to comment on the housestaff unionization process. Dr. Cooper explained that the AAMC had joined with various institutions appearing before the National Labor Relations Board in filing an Amicus Curiae Brief stating that the major function of individuals in a residency program is one of education rather than service and that they, therefore, should not come under the jurisdiction of the NLRB. Dr. Cooper reminded the group that some housestaff unions had previously been formed but that they were organized under state labor laws rather than under the national Taft-Hartley Act. The case to determine whether housestaff would fall under this jurisdiction has not yet been decided. In the meantime some 100 representatives attending the meeting in Washington of the Physicians National Housestaff Association voted to become a labor union and to establish union locals in all of the institutions. The membership will be kept informed on this issue as developments proceed.

One member asked about the faculty representation in the Institute of Medicine. It was generally thought to be well represented.

In his closing comments Dr. Cooper emphasized the increasingly important role of the Council of Academic Societies in the activities and the policy development of the Association.

V. Report of the Director, Department of Academic Affairs - August G. Swanson

Dr. Swanson highlighted a number of AAMC activities in the Department of Academic Affairs that normally might not come to the constituents' attention.

The Division of Faculty Development, headed by Dr. Hilliard Jason, has obtained foundation support (\$500,000 from Kellogg and Commonwealth) and is fully staffed. The purpose of that division is to provide faculty members resources to examine how successful they are in carrying out their educational mission. The division sponsored a workshop for the Anatomy Chairmen's Association.

The Division of Educational Resources, now headed by Dr. Emanuel Suter, is in its third year. The development of AVLINE under this program was described in the Agenda. There will be a continued identification for inclusion in AVLINE of multimedia educational materials which are particularly recommended by faculty. The current thrust is in the area of computer-based medical education.

The AAMC Longitudinal Study of the Class of 1960 has been reactivated. A questionnaire, now being developed, will go to 2,500 physicians who graduated from the 28 study schools. Through this questionnaire, correlations between the career development of these physicians since graduation will be made with information obtained during their medical school years. A special study of 500 of these physicians who are on medical school faculties will be undertaken. Dr. Tom Morgan, Director of the Division of Biomedical Research, is doing a corollary study in an attempt to define the characteristics of the institutions that produce the faculty and the characteristics of the faculty the institutions produce.

This year 15,259 medical students were admitted to medical school. The management of that mass of applicant activity was eased considerably by the development of AMCAS which this year handled applications from over 42,000 students.

An AAMC study of how medical students finance their medical education will be reported in December. These data will be useful as the matter of tuition increases gains greater focus.

The AAMC has been involved in discussions of the problems and prospects of remote site education. The AAMC Group on Medical Education is sponsoring a special debate on this as a part of its regular annual meeting.

Through his role as Chairman of the Board of the National Intern and Resident Matching Plan (NIRMP), John Cooper has been actively exerting considerable positive influence in the NIRMP. Specifically, he has attracted John Graettinger, who is a former Dean of Student Affairs and now Dean for Rush University Faculty Affairs, as Executive Director of the NIRMP to succeed John Nunemaker who resigned this year. The understanding of the problems of both the students and the program directors that Dr. Graettinger brings to NIRMP is expected to improve the operation of the NIRMP.

Speaking for himself and for Dr. Morgan, Dr. Swanson invited the constituents to visit with them at the headquarters. Any way in which communications can be improved between the constituents and the staff, they are anxious to pursue.

Following his remarks, Dr. Swanson answered several questions from the representatives. To the question of what had been done since last year with regard to the problem of cheating in connection with the NIRMP, Dr. Swanson indicated two things. First, a monitoring system in the medical schools was established through the efforts of the Organization of Student Representatives (OSR). With regard to a second possibility, that the NIRMP be enforced through the mechanism of the Liaison Committee on Graduate Medical Education (LCGME), this was considered by the LCGME as not germane to its role and function.

When a question was posed about the availability to the constituents of Dr. Jason's program, Dr. Sam Clark volunteered that the experience of the Anatomy Chairmen with the Faculty Development workshop had been very favorable.

VI. Action Items

A. Membership Applications

In accordance with the established procedures election to membership in AAMC of Academic Society Members is upon recommendation by the Council of Academic Societies to the Executive Council and by majority vote in the Assembly. It was the recommendation of the CAS Administrative Board that the following applications for membership be approved by the full Council:

American College of Obstetricians & Gynecologists  
American Society of Hematology  
American Society of Plastic & Reconstructive Surgeons  
Association of Medical School Departments of Biochemistry  
Society for Gynecologic Investigation (reinstatement)

ACTION: The above applications for membership were unanimously approved.

NOTE: On November 4, 1975 by action of the AAMC Assembly, these five societies were elected to AAMC Membership, increasing to 61 the number of organizations in the CAS.

B. Election of Members to the 1975-76 CAS Administrative Board

ACTION: The council elected by ballot the following to serve on the CAS Administrative Board effective 1975-76:

Chairman-Elect

A. Jay Bollet, M.D., Official Representative, Association of American Physicians (Chairman, Department of Medicine, SUNY Downstate)

For Administrative Board, from the Clinical Sciences

one-year term

Philip R. Dodge, M.D., President, Association of Medical School Pediatric Department Chairmen, Inc. (Chairman, Department of Pediatrics, Washington University, St. Louis)

three-year term

Daniel Freedman, M.D., Official Representative, American Association of Chairmen of Departments of Psychiatry (Chairman, Department of Psychiatry, University of Chicago)

For Administrative Board, from the Basic Sciences

one-year term

Donald West King, Jr., M.D., Past-President, American Association of Pathologists and Bacteriologists (Chairman, Department of Pathology, Columbia P&S)

three-year term

Carmine D. Clemente, Ph.D., President, American Association of Anatomists (Chairman, Department of Anatomy, UCLA)

Leslie T. Webster, M.D., Official Representative, Association for Medical School Pharmacology (Chairman, Department of Pharmacology, Northwestern)

A roster of the 1975-76 CAS Administrative Board is attached to these minutes.

C. Election of 1975-76 Nominating Committee

ACTION: In Accordance with the CAS Rules and Regulations (Section V. Paragraph 1), the Nominating Committee is comprised of seven members of the Council. The Chairman of the Administrative Board serves as the nonvoting Chairman of the Nominating Committee. The Committee consists of six individuals (three basic science and three clinical science) who are chosen from among the representatives present at the Annual Fall Meeting of the Council by a majority vote. It was determined during the year just past that the CAS Administrative Board would be ineligible for nomination to these six seats.

Nominations were made from the floor, and a written ballot was conducted. The following were chosen to comprise the Nominating Committee, which will be chaired by Dr. Rolla Hill.

For Nominating Committee, from the Clinical Sciences

John E. Steinhaus, M.D., Ph.D., Official Representative Society of Academic Anesthesia Chairmen, Inc. (Chairman, Department of Anesthesiology, Emory University)

Floyd W. Denny, M.D., Official Representative, American Pediatric Society (Chairman, Department of Pediatrics, University of North Carolina)

David R. Hawkins, M.D., Official Representative, American Association of Chairmen of Departments of Psychiatry (Chairman, Department of Psychiatry, University of Virginia)

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For Nominating Committee, from the Basic Sciences

James B. Preston, M.D., Official Representative, Association of Chairmen of Departments of Physiology  
(Chairman, Department of Physiology, SUNY Upstate)

Frank E. Young, M.D., Ph.D., Official Representative, Association of Medical School Microbiology Chairmen  
(Chairman, Department of Microbiology, The University of Rochester)

Ronald W. Estabrook, Ph.D., Official Representative, American Society of Biological Chemists (Chairman, Department of Biochemistry, The University of Texas, Dallas)

III. Discussion Items

The format to the meeting this year was designed to permit and promote greater participation by those present in an active dialogue with various resource individuals on hand, from both the CAS Administrative Board and from AAMC Staff. Approximately one-half day was devoted to these discussion items. A major portion of the program, beginning the discussion was centered on Health Manpower. Renewal of the Comprehensive Health Manpower Training Act which expired June 30, 1974 is still a subject of debate in the 94th Congress. In July, 1975 the House passed a bill (HR 5546). The Senate Health Subcommittee is planning to hold hearings during the next 2 to 3 months. The debate over the renewal of this Act is around 3 major public policy concerns.

Aggregate supply of physicians. Even though the number of entering students has increased from 8,759 in 1965 to nearly 15,000 in 1975 schools may be required to increase their class size in order to qualify for basic support through capitation.

Specialty Distribution. A provision in HR 5546 which would have provided the Coordinating Council on Medical Education an opportunity to designate the number of individuals to be trained annually in each specialty was removed by amendment. The only support for primary care training is for family practice residencies and undergraduate programs.

Geographic Distribution. HR 5546 provides that medical schools not choosing to increase class size must provide education in remote sites to a specified proportion of their students. The Senate Subcommittee is still considering a mandatory requirement for federal service as a condition for admission to medical school. Increased support for the voluntary National Health Service Corps is contained in HR 5546 and likely to be in a Senate bill.

Of great concern to the AAMC and the CAS is the propensity for both Houses of Congress to dictate numerous requirements for the schools to qualify for essential capitation support. The freedom and flexibility of the academic medical centers and their capability to fulfill their responsibilities will be seriously curtailed if this movement persists and grows.

Dr. Morgan led a subsequent discussion on the President's Biomedical Research Panel and Biomedical Research Training. The President's Biomedical Research Panel was created by Congress in mid-1974 and appointed February 1, 1975. At the spring meeting, as Dr. Cole reported, the CAS formulated opinions and presented testimony to members of the Panel. Members emphasized their concern for the instability of research funding, the need for support of research training programs and basic biomedical and behavioral research, and the need for increased participation of the research community in the planning of future biomedical and behavioral research initiatives. Responding in part to this dialogue, the President's Panel set up a number of study groups of scientists whose responsibility is to examine the state of the art of 12 clusters of research endeavor and to advise the Panel what steps should be taken to conduct research more effectively in each area.

The Association took a leadership role with the staff of the President's Panel to assess the stability of research funding and the trends occurring in the pattern of federal involvement in the research effort. As a result, a study of the impact of federal research funding on the academic medical center has now been undertaken by a consortium of the AAMC, the American Council on Education, and the Rand Corporation under contract with the Panel. Efforts to date have been the construction of a data base which will depict the dimensions and trends in funding of academic medical centers in the past decade. Construction of the computerized data base for addressing questions about the impact of research funding on academic medical centers is now near completion. It will be completed by January, 1976. By law the report of the President's Panel must be submitted by April.

Confidentiality of Research Grant Protocols was another discussion led by Dr. Morgan. The peer review system employed by NIH for awarding grants and contracts is widely recognized as outstanding. This award process has been conducted under rules in which the applications are submitted and reviewed in confidence. This system is now buffeted by a series of post-Watergate waves seeking to insure openness in governmental operation. The Freedom of Information Act (FOIA) of 1967 has been employed by public interest groups seeking to safeguard the rights of children to support their requests for access to grant applications. In a landmark court decision, Judge Gesell agreed that research applications should be made public.

As a result of the Gesell decision, more than 700 requests for applications have now been received by NIH. However, the issue is not simply one of revealing funded grant applications to those who request them but also involves the peer review process, the intellectual property rights of scientists, the protection of human subjects of research, the protection of the public from premature exploitation and the patent rights of individuals.



The struggle to resolve these conflicting ideals is far from concluded. Public interest groups continue to seek not only funded grants but all applications and access to study section proceedings as well. In Congress, supporters of complete access threaten additional legislation to compel disclosure of pink sheets and to open all grant review meetings. The AAMC has drafted an explanatory paper dealing with this problem which will be published in Clinical Research in late 1975. Copies of this paper are also available on request.

In an attempt to improve communications with the members, a quarterly CAS Brief has been published. The first issue went out this fall, and from a dozen of the academic societies the response has been very positive. A number are reproducing it in whole or in part for distribution to their full membership, while about half are disseminating it among their executive committees or boards. The staff, Drs. Morgan or Swanson, solicit reactions from the other societies.

CAS Administrative Board Member, Dr. Robert Berne, called to the member's attention the desire of the Board to receive from the members nominations for both the AAMC Borden and Flexner Awards. Calls for nominations will be forthcoming from the President's office this spring.

During a discussion of biomedical research manpower training concerns were expressed that Ph.D. programs in the biomedical sciences are quite variable in their breadth of emphasis and quality. The following action was approved by the Council by a majority voice vote.

ACTION: That the Council of Academic Societies explore the development of methods for the appropriate external review of institutional Ph.D. programs in biomedical sciences.

Among other discussion items covered in the agenda were:

Coordinating Council on Medical Education and Its Subcommittees-- The major policy decisions made or in the process of development in the Coordinating Council on Medical Education and its three liaison committees were presented to the Council. The mode of operation of the Liaison Committee on Graduate Medical Education during the first year of officially acting on the decisions of the residency review committees was particularly brought out in the discussion.

Continuing Medical Education--The issues and problems posed by a growth in relicensure and recertification requirements based on participation by physicians in continuing medical education was discussed. The Council was informed that the AAMC Executive Council has appointed a task force to study the issues surrounding continuing medical education and recommend positions and programs to the Association.

AAMC Response to the GAP Committee Report to the NBME--The AAMC response to the GAP Committee report to the NBME was revised by the Council. The response, which was presented to the Assembly for ratification on the following day, was found to be in substantial agreement with the sense of the Council discussion at the last annual meeting.

Input into Retreat Agenda--During the second week in December, the Chairman and Chairman-Elect of the Councils and the Chairman and Chairman-Elect of the Assembly, will meet with selected AAMC staff to discuss AAMC activities and plan the Association's programs for the coming year. The CAS Membership was invited to suggest topics for consideration in the Retreat.

VIII. Information Items

Information items included in the agenda were on the following topics:

- Commission for the Protection of Human Subjects
- AAMC Data Systems
- AAMC/NLM Educational Materials Project
- Medical College Admissions Assessment Program
- Study of Three-Year Curricula
- National Citizens Advisory Committee for the Support of Medical Education
- CAS Membership Changes
- Annual Meeting Program Outlines

IX. Next Meeting

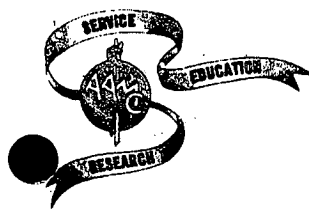
The Spring Meeting of the Council of Academic Societies will be held in Philadelphia, Pennsylvania. The meeting will be at the Bellevue-Stratford Hotel on March 16, 1976 and will immediately precede the National Board of Medical Examiners Annual Invitational Conference. The NBME this year will focus on "An International View of Qualifications for Medical Practice." The Conference on the 17th and 18th will include speakers from around the world. CAS representatives will be welcome to attend the Invitational Conference.

X. Adjournment

ACTION: The meeting was adjourned at 5:00 p.m.

Attachment (1)

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ASSOCIATION OF AMERICAN MEDICAL COLLEGES  
SUITE 200, ONE DUPONT CIRCLE, N.W., WASHINGTON, D.C. 20036

COUNCIL OF ACADEMIC SOCIETIES  
ADMINISTRATIVE BOARD  
1975 - 1976

CHAIRMAN

Rolla B. Hill, Jr., M.D. (76)\*  
SUNY Upstate Medical Center  
*American Association of  
Pathologists & Bacteriologists*

CHAIRMAN-ELECT

A. Jay Bollet, M.D. (76)  
SUNY Downstate Medical Center  
*Association of American  
Physicians*

IMMEDIATE PAST-CHAIRMAN

Jack W. Cole, M.D. (76)  
Yale University School of  
Medicine  
*American Surgical Association*

MEMBERS

Robert M. Berne, M.D. (77)  
University of Virginia  
School of Medicine  
*American Physiological Society*

F. Marion Bishop, Ph.D. (77)  
University of Alabama at  
Huntsville  
*Society of Teachers of Family  
Medicine*

Carmine D. Clemente, Ph.D. (78)  
UCLA School of Medicine  
*American Association of  
Anatomists*

Philip R. Dodge, M.D. (76)  
Washington University School  
of Medicine  
*Association of Medical School  
Pediatric Department Chairmen*

Daniel X. Freedman, M.D. (78)  
University of Chicago  
Pritzker School of Medicine  
*American Association of  
Chairmen of Depts. of Psychiatry*

Donald W. King, M.D. (76)  
Columbia University College  
of Physicians & Surgeons  
*American Association of  
Pathologists & Bacteriologists*

Thomas K. Oliver, Jr., M.D. (77)  
University of Pittsburgh  
School of Medicine  
*Association of Medical School  
Pediatric Department Chairmen*

\*\*Robert G. Petersdorf, M.D. (76)  
University of Washington  
School of Medicine  
*Association of American  
Physicians*

Leslie T. Webster, M.D. (78)  
Case Western Reserve University  
School of Medicine  
*Association for Medical School  
Pharmacology*

REPRESENTATIVES TO THE AAMC  
EXECUTIVE COUNCIL

Rolla B. Hill, Jr., M.D. (77)  
A. Jay Bollet, M.D. (78)  
Jack W. Cole, M.D. (76)  
Robert G. Petersdorf, M.D. (76)

\*Expiration of Term

\*\*Ex Officio

MEMBERSHIP APPLICATION  
COUNCIL OF ACADEMIC SOCIETIES  
ASSOCIATION OF AMERICAN MEDICAL COLLEGES

MAIL TO: AAMC, Suite 200, One Dupont Circle, N.W., Washington, D.C. 20036  
Attn: Ms. Mignon Sample

NAME OF SOCIETY: The American Society for Clinical Nutrition

MAILING ADDRESS: 9650 Rockville Pike, Bethesda, Maryland 20014

PURPOSE: To encourage undergraduate and graduate education and research in human nutrition in health and disease, to provide an opportunity for investigators to present and discuss their research in human nutrition, and to provide a journal or journals for publication of meritorious work in experimental and clinical nutrition. It is a further major aim of the Society to promote the proper application of the findings of nutrition research to the practice of medicine and related health professions.

MEMBERSHIP CRITERIA: Nominees for active membership must become members of the American Institute of Nutrition; nominations to the two societies may be considered simultaneously. Any person who has conducted and published meritorious original investigations in clinical nutrition shall be eligible for active membership in the society.

NUMBER OF MEMBERS: July 1, 1976: 380, of which 22 are emeritus (retired).

NUMBER OF FACULTY MEMBERS:

DATE ORGANIZED: Founded May 1, 1960

SUPPORTING DOCUMENTS REQUIRED: (Indicate in blank date of each document)

Revised 1972 1. Constitution & Bylaws

May 1, 1976 2. Program & Minutes of Annual Meeting

(CONTINUED NEXT PAGE)

QUESTIONNAIRE FOR TAX STATUS

1. Has your society applied for a tax exemption ruling from the Internal Revenue Service?

X  YES   NO

2. If answer to (1) is YES, under what section of the Internal Revenue Code was the exemption ruling requested?

501(c) (3)

3. If request for exemption has been made, what is its current status?

- X  a. Approved by IRS  
  b. Denied by IRS  
  c. Pending IRS determination

4. If your request has been approved or denied, please forward a copy of Internal Revenue letter informing you of their action.

Ann Knight   
(Completed by - please sign)  
Executive Assistant, ASCN  
June 11, 1976  
   
(Date)

MEMBERSHIP APPLICATION  
COUNCIL OF ACADEMIC SOCIETIES  
ASSOCIATION OF AMERICAN MEDICAL COLLEGES

MAIL TO: AAMC, Suite 200, One Dupont Circle, N.W., Washington, D.C. 20036  
Attn: Ms. Mignon Sample

NAME OF SOCIETY: American Society of Clinical Pathologists

MAILING ADDRESS: 2100 West Harrison Street  
Chicago, Illinois 60612

PURPOSE: Continuing medical education for all laboratory personnel.

MEMBERSHIP CRITERIA: Qualified physicians practicing Pathology who are certified by the American Board of Pathology, or are Board eligible; (2) those holding academic doctorates in fields related to the practice of Pathology, or (3) certified laboratory personnel currently registered with the Board of Registry of the American Society of Clinical Pathologists.

NUMBER OF MEMBERS: 19,560

NUMBER OF FACULTY MEMBERS: approx. 1,000 volunteer members

DATE ORGANIZED: 1922

SUPPORTING DOCUMENTS REQUIRED: (Indicate in blank date of each document)

taken from yearbook  
published 11/75

1. Constitution & Bylaws

10/10/74

2. Program & Minutes of Annual Meeting

(CONTINUED NEXT PAGE)

QUESTIONNAIRE FOR TAX STATUS

1. Has your society applied for a tax exemption ruling from the Internal Revenue Service?

   X    YES                    NO

2. If answer to (1) is YES, under what section of the Internal Revenue Code was the exemption ruling requested?

                  501 (C) 3                  

3. If request for exemption has been made, what is its current status?

- X    a. Approved by IRS
- b. Denied by IRS
- c. Pending IRS determination

4. If your request has been approved or denied, please forward a copy of Internal Revenue letter informing you of their action.

    
*Mark Bostick President*

(Completed by - please sign)

    
September 1, 1976

(Date)



# association of american medical colleges

## BALLOT

### COUNCIL OF ACADEMIC SOCIETIES

1976-77

### ADMINISTRATIVE BOARD POSITIONS

#### CHAIRMAN-ELECT

Vote For One:

**BERNE, Robert M., M.D.**  
*American Physiological Society*

**BERNE, ROBERT MATTHEW**, physiologist, educator; b. Yonkers, N.Y., Apr. 22, 1918; s. Nelson and Julia (Stahl) B.; A.B., U. N.C., 1939; M.D., Harvard, 1943; D.Sc., Med. Coll. Ohio, 1973; m. Beth Goldberg, Aug. 18, 1944; children: Julie, Amy, Gordon, Michael. Intern Mt. Sinai Hosp., N.Y.C., 1943-44; resident, 1946-48; research fellow Western Res. U. Sch. Medicine, Cleve., 1948-49; instr. physiology, 1949-50; sr. instr., 1950-52; asst. prof., 1952-55; asso. prof., 1955-61; prof., 1961-66; prof., chmn. dept. physiology U. Va. Sch. Medicine, Charlottesville, 1966-. Mem. evaluation com. on post doctoral fellowships in life scis. Nat. Acad. Scis., 1963-65; mem. physiology ing. com. NIH, 1964-65; mem. heart and vascular disease panel, nat. research and devel. demonstration rev. com., 1973-74; mem. tng. com. Nat. Heart Inst., 1966-70; mem. cardio-pulmonary tng. program VA, 1968-71; mem. physiology test Com. Nat. Bd. Med. Examiners, 1969-70; mem. panel on heart and blood vessel diseases, task force Nat. Heart and Lung Inst., 1972; mem. heart and lung program project com., 1975; adminstrv. bd., council acad. soes. Assn. Am. Med. Colls., 1975; Nathanson Meml. lectr. U. So. Cal., 1973; Trustee Cleve. Area Heart Soc., 1962-65; pres. sci. council, 1964-65; steering com. Circulation Group Physiol. Soc., 1969-71. Served with M.C., AUS, 1944-46. Recipient Carl J. Wiggers award, 1975. Mem. Am. Physiol. Soc. (mem. council 1970-72; mem. finance com. 1966-70, 75-; pres. 1972-73), Am. Soc. for Clin. Investigation, Am. Heart Assn. (com. on med. edn. 1963-66; vice chmn. com. on council basic sci.), A.A.A.S., Cardiac Muscle Club, Assn. Chmn. Depts. Physiology (pres. 1970), Microcirculatory Soc. (mem. council 1971-72; liaison com. 1973), Landis award com. (1975), Phi Beta Kappa, Sigma Xi. Author: (with Matthew N. Levy) Cardiovascular Physiology, 1967, 2d edit., 1972; Editor: Circulation Research, 1970-75; Sect. editor Am. Jour. Physiology, Jour. Applied Physiology, 1964-65; mem. editorial bd. Circulation Research, 1961-67, 68-. Jour. Molecular and Cellular Cardiology, 1969-. Proc. Soc. Exptl. Biology and Medicine, 1962-64; mem. editorial com. Annual Rev. of Physiology, 1976-. Home: 1851 Wayside Pl. Charlottesville VA 22903

#### (CAS Administrative Board, 1974-77)

**CLEMENTE, Carmine D., Ph.D.**  
*American Association of Anatomists*

**CLEMENTE, CARMINE DOMENIC**, educator; b. Penns Grove, N.J., Apr. 29, 1928; s. Erranno and Caroline (Friozzi) C.; A.B., U. Pa., 1948, M.S., 1950, Ph.D., 1952; postdoctoral fellow U. London, 1953-54; m. Juliette Vance, Sept. 19, 1968. Asst. instr. anatomy U. Pa., 1950-52; faculty U. Cal. at Los Angeles, 1952-. prof., 1963-. chmn. dept. anatomy, 1963-73. Hon. research asso. Univ. Coll., U. London, 1953-54; cons. Sepulveda VA Hosp., NIH. Mem. med. adv. panel Bank Am.-Giannini Found.; chmn. sci. adv. com. Nat. Paraplegia Found. Recipient award for merit in sci. Nat. Paraplegia Found., 1973. Mem. Pavlovian Soc. N.Am. (Ann. award 1968, pres. 1972), Brain Research Inst., Am. Physiol. Soc., Am. Assn. Anatomists (v.p. 1970-72), Am. Acad. Neurology, Am. Acad. Cerebral Palsy, Am. Neurol. Assn., Assn. Am. Med. Colls., Council Acad. Soes. (adminstrv. bd. 1973-.), Assn. Anatomy Chairmen (pres. 1972), Biol. Stain Commn., Internat. Brain Research Orgn., Med. Research Assn. Cal., N.Y. Acad. Sci., Nat. Acad. Sci. (mem. com. neuropathology, BEAR com.), Sigma Xi, Democrat. Author: Aggression and Defense: Neurol. Mechanisms and Social Patterns, 1967; Physiological Correlates of Dreaming, 1967; Sleep and the Maturing Nervous System, 1972. Editor: Gray's Anatomy, 1973. Editor, Exptl. Neurology; asso. editor Anatomical Record, Conditional Reflex, Brain Research, Am. Jour. Anatomy, Contrb. articles to sci. journals. Home: 11737 Bellagio Rd. Los Angeles CA 90049

#### (CAS Administrative Board, 1973-78)



CAS Administrative Board Ballot  
Page Two

ADMINISTRATIVE BOARD, BASIC SCIENCES

Vote For One: (One to be elected to complete the unexpired term  
of Board Member selected as Chairman-Elect)

HANAHAN, Donald J., Ph.D.  
*Association of Medical School  
Departments of Biochemistry*

HANAHAN, DONALD J.(AMES), b. Springfield, Ill, May 13, 19; m. 47; c. 5.  
BIOCHEMISTRY. B.S. Illinois, 41, Ph.D. 44. Res. assoc. Manhattan Proj.  
Chicago, 44; E.I. du Pont de Nemours & Co, 45; physiol. div. California, 45-  
48; instr. chem. Washington (Seattle), 48-49, asst. prof. 49-50, BIOCHEM,  
50-53, assoc. prof. 53-59, prof. 59-67; MEM. FACULTY BIOCHEM, COL.  
MED, UNIV. ARIZ. 67- Guggenheim fel, 55; Nat. Insts. Health spec. fel,  
65-66. Am. Soc. Biol. Chem; Am. Chem. Soc. Simple and complex lipids;  
lipolytic action, membrane structure; coagulation. Address: Dept. of Bio-  
chemistry, University of Arizona College of Medicine, Tucson, AZ 85724.

SWAN, Roy C., M.D.  
*Association of Anatomy Chairmen*

SWAN, ROY C(RAIG), JR, b. N.Y.C, June 7, 20; m. 49; c. 3. ANATOMY.  
A.B. Cornell, 41, M.D. 47. Intern med, N.Y. Hosp, 47-48, asst. res. 48-49,  
res. endocrinol. & metab, 49-50; Life Ins. Med. Res. Fund fel, Harvard  
Med. Sch, 50-52; instr. physiol, MED. COL, CORNELL UNIV, 52-53, asst.  
prof, 53-55, assoc. prof, 55-59, prof. ANAT, 59-70, JOSEPH C. HINSEY  
PROF, 70-, CHMN. DEPT, 59- Markle scholar, 54-59. Asst, Peter Bent  
Brigham Hosp, 50-52; res. assoc, Cambridge, 55-56; mem. Health Res.  
Coun, City New York. Consult, U.S. Pub. Health Serv, 60-65; Off. Sci. &  
Tech, 63-64. U.S.N.R, 43-46, Lt. Am. Physiol. Soc, Am. Soc. Clin. Invest;  
Am. Ann. Anat. Ion transport; muscle function and structure; fine struc-  
ture of excitable cells. Address: Dept. of Anatomy, Cornell University  
Medical College, 1300 York Ave, New York, NY 10021.

CAS Administrative Board Ballot  
Page Three

ADMINISTRATIVE BOARD, CLINICAL SCIENCES

Vote For Three:

BRAUNWALD, Eugene, M.D.  
*Association of Professors  
of Medicine*

BRAUNWALD, E(UGENE), b. Vienna, Austria, Aug. 15, 29; nat; m. 52; c. 3. INTERNAL MEDICINE, CARDIOLOGY. A.B. N.Y. Univ, 49, Schepp Found. scholar, 49-52, M.D. 52. Intern. Mt. Sinai Hosp, N.Y. 52-53, fel, med, 53-54; col. physicians & surgeons, Columbia Univ, 54-55; clin. assoc. physiol, Nat. Heart Inst, 55-56, resident med, 56-57; Johns Hopkins Hosp, 57-58, chief cardiol. sect, Nat. Heart Inst, 58-60; cardiol. br, 60-66, clin. dir, 66-68; PROF. & CHMN. DEPT. MED. SCH. MED, UNIV. CALIF, SAN DIEGO, 68- Clin. prof, med. sch, Georgetown Univ, 65-68. Hall Award; Jacobs Award; Schlassie Award. U.S.P.H.S. 54-63, Med. Dir. Am. Soc. Clin. Invest; Am. Col. Physicians; Am. Physiol. Soc; Am. Fedn. Clin. Res.(pres, 69-70); Asn. Am. Physicians; Am. Soc. Pharmacol. & Exp. Therapeut; Harvey Soc. Cardiovascular hemodynamics and diagnostic techniques; clinical cardiology; internal medicine. Address: Dept. of Medicine, University Hospital of San Diego County, 225 W. Dickinson St, San Diego, Calif. 92103.

EGGERS, George W.N., Jr., M.D.  
*Association of University  
Anesthetists*

EGGERS, GEORGE WILLIAM NORDHOLTZ, JR, b. Galveston, Tex, Feb. 22, 29; m. 55; c. 2. MEDICINE, ANESTHESIOLOGY. B.A. Rice Inst, 49; M.D. Texas, 53. Instr. ANESTHESIOLOG, med. br, Texas, 56-59, asst. prof, 59-61; assoc. prof, SCH. MED, UNIV. MO-COLUMBIA, 61-67, PROF, 67-, CHMN. DEPT, 70- Grants, Med. Res. Found. Tex. & Galveston Heart Asn, 59-60, Tex. Heart Asn, 60-61, Nat. Insts. Health, 61-68; vis. res. prof, med. sch, Northwest. Univ, 68. Dipl. Am. Bd. Anesthesiol, 59. AAAS; fel. Am. Col. Anesthesiol; Am. Med. Asn; Am. Soc. Anesthesiol; Asn. Am. Med. Colls; Int. Anesthesia Res. Soc. Human pharmacology and physiology; cardiovascular dynamics; pulmonary circulation. Address: University of Missouri Medical Center, Columbia, MO 65201.

GLENN, James F., M.D.  
*Society of University  
Urologists*

GLENN, JAMES FRANCIS, b. Lexington, Ky, May 10, 28; m. 48; c. 4. UROLOGY. B.A. Rochester, 50; Kentucky; M.D. Duke, 53. Intern gen. surg; Peter Bent Brigham Hosp, Boston, Mass, 52-54; resident urol. surg, med. ctr, Duke, 56-59, asst. urol, sch. med, 56-58, Instr, 58-59; asst. prof, Yale, 59-61; assoc. prof, Bowman Gray Sch. Med, 61-63; PROF. UROL. & CHIEF UROL. SURG, MED. CTR, DUKE UNIV, 63- Asst. surgeon, Grace-New Haven Hosp, 59-61; attend. urol, N.C. Baptist Hosp, 61-63; consult, Vet. Admin. Hosp, Durham, 63-; Watts Hosp, 64-; Lincoln Hosp, 65- Med. C. Res, 53-55, Capt. Am. Col. Surg; Am. Urol. Asn; Soc. Pediat. Urol; Int. Soc. Urol; Am. Asn. Genito-Urinary Surg; Soc. Univ. Urol. (pres). Adrenal surgery; pediatric urology; genitourinary malignancies. Address: Dept. of Urology, Duke University Medical Center, Durham, NC 27706.

Continued . . .

CAS ADMINISTRATIVE BOARD BALLOT  
Page Four

CLINICAL SCIENCES (Continued)

HAWKINS, David R., M.D.  
*American Association of  
Chairmen of Departments  
of Psychiatry*

HAWKINS, DAVID R(OLLO), b. Springfield, Mass, Sept. 22, 23; m. 46; c. 4. PSYCHIATRY. B.S. Amherst Col, 45; M.D. Univ. Rochester, 46. Intern & asst. res. path, Strong Mem. Hosp, Univ. Rochester, 46-47, intern internal med, 47-48, Commonwealth Fund fel, 50-52; instr. PSYCHIAT, sch. med, Univ. N.C, 52-53, asst. prof, 53-57, assoc. prof, 57-62, prof, 62-67; PROF. & CHMN. DEPT, SCH. MED, UNIV. VA, 67- Nat. Insts. Health & Commonwealth Fund spec. res. fcls, Inst. psychiat, Univ. London, 63-64. Assoc. attend. physician, N.C. Mem. Hosp, 52-62, attend. physician, 62- Consult, Watts Hosp, Durham, N.C, 52-67; Vet. Admin. Hosp, Fayetteville, 56-67; Salem, Va, 68-; East. State Hosp, Williamsburg, 69-; psychiatrist-in-chief, Univ. Va, 67- Mem. ment. health small grant comt, Nat. Inst. Ment. Health, 59-62; nursing res. study sect, Nat. Insts. Health, 65-67; Va. Gov. Comn. on Mental, Indigent & Geriat. Patients, 68- Chief med. & prof. servs, U.S. Army Hosp, Regensburg, Ger, Med.C, 48-50. Capt. AAAS; Am. Med. Asn; Am. Psychosom. Soc; Am. Psychiat. Asn; Asn. Am. Med. Col; Acad. Psychoanal; Am. Psychoanal. Asn; Am. Col. Psychiat; Soc. Neurosci; Group Anal. Soc; Group Advan. Psychiat. Application of understanding of human behavior to the general practice of medicine and techniques of its teaching to medical students and house officers; elucidation of the psychophysiological interrelationships of emotions; psychopharmacology; understanding of the process of psychotherapy; psychophysiology of sleep. Address: Box 203, Dept. of Psychiatry, University of Virginia School of Medicine, Charlottesville, VA 22901.

JACOBSON, Harold G., M.D.  
*Society of Chairmen of  
Academic Radiology  
Departments*

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## ELECTION OF CAS ADMINISTRATIVE BOARD

### CAS Rules and Regulations, Section III. Administrative Board

The Council of Academic Societies shall be governed by an Administrative Board which shall be composed of a Chairman, Chairman-Elect, immediate Past-Chairman, and nine other members. Three of said nine members shall be elected by written ballot at each annual meeting of the Council of Academic Societies, and each such member shall serve for a term of three years or until his successor is elected and installed. Members elected to serve on the Executive Council of the Association shall continue to hold membership on the Administrative Board until their terms on the Executive Council expire.

The Administrative Board shall meet at least twice each year at the time and place of the meetings of the Council of Academic Societies. The Administrative Board may meet at any other time and place upon call of the Chairman, provided ten (10) days written notice thereof has been given.

The Administrative Board shall recommend to the Nominating Committee of the Association, nominees for positions on the Executive Council of the Association. The Chairman-Elect shall be one (1) nominee, and the remainder shall be chosen from members of the Administrative Board, chosen so as to present a balanced representation between societies primarily concerned with preclinical disciplines and societies primarily concerned with clinical disciplines.

Individuals elected as members of the Executive Council of the Association of American Medical Colleges representing the Council of Academic Societies may hold their membership in the Council of Academic Societies, ex officio, even though they may be succeeded by new representatives from their constituent organizations.

## ELECTION OF CAS NOMINATING COMMITTEE

### CAS Rules and Regulations, Section V. Committees

The Nominating Committee shall be comprised of seven members of the Council. The Chairman of the Administrative Board shall be the non-voting Chairman of the Nominating Committee. The Nominating Committee will consist of six individuals (3 basic science and 3 clinical science) who shall be chosen from among the representatives present at the Annual Business Meeting of the Council by a majority vote of the representatives present at that meeting. The Officers of the Council and its representatives to the Executive Council of the Association of American Medical Colleges are eligible to serve on the Nominating Committee with the exception of the Chairman-Elect. No society may be represented on the Nominating Committee by more than one person. The Nominating Committee shall meet to select a slate of officers prior to June 1st of the year of the election. In the event of a tie vote, the Chairman of the Nominating Committee shall break the tie with a vote.

The Nominating Committee shall nominate not more than two individuals for each office. The Committee will also recommend to the AAMC Nominating Committee candidates for Council of Academic Societies vacancies on the Executive Council as well as Council of Academic Societies recommendation for Association of American Medical Colleges Chairman-Elect.

DESIGNATION OF PUBLIC AFFAIRS REPRESENTATIVE TO CAS

As the number of federal regulations increase and as biomedical funding patterns change, one of the areas which increasingly concerns members and officers of constituent societies is that of public affairs. With this growing concern it seemed natural to establish better communications in the public affairs area between AAMC staff and societies. The CAS Administrative Board, with representatives of more than 35 societies concurring, recommended that each society appoint a public affairs representative who will serve as liaison between the officers and members of each society and AAMC. Each representative should be willing to serve for a five-year term to provide continuity which is often lacking due to the annual turnover of elected officers. Each representative will be asked to organize communications within their society so that, among other purposes, effective input can be coordinated on topics of importance to each society.

An important objective of this plan is to increase the input of societies into the legislative process. To achieve this objective each representative has been invited to a public affairs workshop to be held December 12-14 in Palm Beach, Florida. Leading Congressional health staffers together with Assistant Secretary for Health, Dr. Theodore Cooper, will serve as faculty in a practical course in public affairs. The response to this plan has been very favorable and, with an outstanding faculty scheduled for the workshop, the plan seems to have considerable promise for the future.

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## HEALTH MANPOWER ACT

The Health Professions Educational Assistance Act of 1976 was signed into law by the President on October 12, 1976. Three years of debate through two sessions of Congress principally centered around the requirements schools of medicine would have to meet in order to qualify for federal capitation support. The desire by some members of Congress to stipulate rigid federal requirements which would preempt institutional prerogatives for student selection and curriculum development was demonstrated by provisions in early versions of the Act to require all students to agree in advance of admission to medical school to participate in the National Health Service Corps, and to require schools to develop remote site educational settings. These do not appear in the final Act.

The recognition by the Congress that specialty distribution is closely linked to graduate medical education opportunities was demonstrated by proposals to establish a national system for the allocation of graduate medical education positions amongst the specialties and institutions. This approach was eliminated in the final Act, but specific percentages of first-year graduate medical education positions must be in the primary care specialties (internal medicine, pediatrics, and family practice) in hospitals directly operated by or affiliated with medical schools. In 1978, 35% must be in primary care; 40% are required in 1979; and 50% in 1980. Defining first-year positions and developing a data base to determine whether the requirements are being met in the national aggregate and by institutions, will require careful attention to the development of regulations. A requirement that percentages be adjusted to eliminate those positions which are filled by students who, in their second year, leave a primary care specialty for training in a non-primary care specialty, will be difficult to implement. It should be anticipated that institutions and program directors will have to develop data collecting and reporting systems which will be needed to determine whether the graduate medical education requirements of the Act are fulfilled.

The appearance in the final Act of a requirement not discussed prior to the Conference Committee meeting, which provides a special opportunity for U.S. citizens in foreign medical schools to be admitted to U.S. schools, demonstrates the persistent and increasingly organized efforts of this class of students to be given access to a professional career in medicine through special pleading. Schools will be required to reserve a number of positions for this class of student, so that all of those who have had two years in a foreign school and have passed NBME, Part I can be admitted if they so desire. This requirement clearly infringes on institutional prerogatives by preempting any judgment of academic preparedness, save for the Part I examination. This requirement will become operative for the 1978-1979 academic year. It applies only to students enrolled in foreign schools on or before September 12, 1976. The Conference report clearly states that there is no intention that those who enter foreign schools after this date will, in the future, be given special attention.

A detailed analysis, including the authorization levels, of the entire Manpower bill has been distributed. The AAMC staff will maintain close liaison with the institutions, other organizations, and those responsible for implementation of the Act in the Executive Branch.

## CLINICAL LABORATORY IMPROVEMENT ACT OF 1976

This Act died as time ran out on the last day of the 94th Congress but will be re-introduced in January, 1977. It has very important implications for clinical biomedical research. The bill would have required DHEW to license and set quality standards for clinical laboratories including standards for training of employees. Through efforts of CAS members and AAMC staff the original House language requiring licenses for individual physicians and for clinical research laboratories was modified. Physicians who perform their own laboratory work and research laboratories could be exempted from the bill's provisions upon application.

During the course of hearings on this bill CAS/AAMC gave testimony which emphasized the importance of the relationship of clinical laboratories to biomedical research. It pointed out to the Committee that biomedical research depends heavily on clinical research laboratories as well as basic science research laboratories. In research laboratories, as opposed to laboratories involved only in routine procedures, the personnel may have been trained not as clinical technicians or technologists but rather for research. Therefore, they may not be professionally trained in clinical laboratory techniques, the training that would be required for employees of clinical laboratories by the bill. Our testimony also stressed that clinical laboratories involved mainly in research not only devise new procedures and tests for use in clinical laboratories, but that they set high standards of quality, competence and accuracy for the routine clinical laboratories. On this basis, the House Health Subcommittee was persuaded that those clinical laboratories that are entirely devoted to biomedical research should be provided with an exemption from the provisions of this bill.

A middle ground exists between those clinical laboratories involved mainly but not exclusively in research and those involved solely in routine clinical testing, and the Committee recognized the difficulty of creating regulations for those laboratories which provide clinical services while at the same time being involved with clinical research. The final version of the bill did resolve this problem satisfactorily but would have required licensing of such "mixed" clinical laboratories.

While the Congress was deliberating the Department of Health, Education and Welfare, acting under existing authority, held hearings on an even more onerous set of regulations which would require all clinical research laboratories to be licensed, to be directed by board-certified specialists and to employ only graduates of clinical laboratory programs. Clearly there is a need for much education by academic societies in both the Congress and the Executive branches to achieve a satisfactory solution to this problem.



## OTHER LEGISLATIVE ACTION

On the day of adjournment, Congress passed the Arthritis, Diabetes, and Digestive Disease Amendments of 1976 and the Emergency Medical Services Amendments of 1976. At the time of this writing the President had still not acted on either bill.

The Arthritis, Diabetes, and Digestive Disease legislation establishes a National Arthritis Advisory Board, a National Diabetes Advisory Board, and a National Commission on Digestive Diseases. The two Boards are designed to review and evaluate implementation of the Arthritis Plan and the Diabetes Plan, respectively, and are to expire in 1980. The National Commission is to evaluate the current knowledge and available resources to combat digestive diseases and formulate a long-range plan. This bill also authorizes extension of programs for arthritis demonstration projects, arthritis centers, the arthritis data system, and the diabetes research and training centers.

This "disease-a-year" legislation is a direct descendant of the Cancer and Heart, Lung and Blood authorities. The mood of Congress, as epitomized by recent statements of Senators Kennedy and Eagleton, is increasingly hostile to new categorical programs which they view as making the job of NIH more difficult.

In other legislative action of significance to the Council of Academic Societies - Emergency Medical Services (EMS) legislation was passed which revises and extends the planning grant and training programs in the original law. The key issue for medical schools related to the institutional settings in which training of emergency medical physicians would be permitted to take place. Under this bill, as passed, it is possible for the first time for this training to take place in hospitals not affiliated with medical schools. The AAMC had opposed this provision and worked to have language included in the final report accompanying the bill which would direct the Bureau of Health Manpower to give priority to funding those EMS physician training programs that are in hospitals affiliated with medical schools. Unfortunately, our language was not adopted.

Attached as a rider to the EMS legislation was a one-year extension of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In addition to the Commission's important deliberations on safeguards for human subjects of research, the Commission must also make recommendations soon to the Congress regarding the confidentiality of research protocols and the closure of NIH peer-review sessions (see next item). The interest and activities of the Council of Academic Societies in both these areas goes back several years and CAS/AAMC activities now seem to be productive.

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The so-called "Government in the Sunshine Act" is legislation which makes significant revisions in the Freedom of Information Act (FOI). A number of changes have been made in information which is exempted from FOI provisions and which may thus be kept confidential. In a surprise move during the House debate, Representative John Moss (D-Calif.) amended the FOI bill to apply the same exemptions to the Federal Advisory Committee Act (FACA). This amendment was part of the bill signed into law by President Ford on September 13, 1976. Its importance is that it changes the basis on which NIH now closes from the public study sections and other peer-review meetings. The particular problems of NIH and the possible damage which might be done to the NIH peer-review process was communicated to House-Senate conferees by AAMC staff and CAS members. As a consequence of these efforts conferees noted the special problem of NIH and pointed out ways in which the new exemptions could be used to continue closure of peer-review sessions until definitive legislation can be drafted. Senators Lee Metcalf (D-Mont.) and Charles Percy (R-Ill.) have indicated a willingness to address the NIH problem in the next session of Congress. Meanwhile, it is expected that NIH will continue to close peer-review sessions under the new law.

## BIOMEDICAL RESEARCH AND RESPONSIBILITY FOR TECHNOLOGY TRANSFER

In its Report the President's Biomedical Research Panel addressed only briefly the subject of the transfer of research-proven ideas to patient care and the cure of disease (so-called "technology transfer"). However, "technology transfer" was a recurrent theme of witnesses appearing before the Panel and is very likely also to become the dominant theme of both forthcoming Congressional hearings and discussions in the Executive Branch. The following is an excerpt from the AAMC Assembly memorandum on the President's Panel Report. It is presented at this time to stimulate further discussion on this timely subject.

"The Panel found that there have been, in the past, no avoidable delays in transferring research findings or technology to health care. However, there is concern on the part of the scientific as well as the lay community that no system exists to guarantee that research technology will be promptly and appropriately transferred into clinical practice in the future. This concern stems in part from the fact that, in the past, transfer was relatively simple. In contrast, diseases and the medical management of them have become steadily more complex while, in the future, financial and personnel resources for research, evaluation and development probably will become more limited. For this and other reasons, there appears to be a need to formalize the technology transfer mechanism for the future. The following discussion examines some of the considerations which we believe important in such a formalization process.

One consideration is the impact of research on health care costs. There seems little doubt but that the products of research have contributed to a demand for more and better health care. Superimposed on increased health care costs due to labor, fuel and other factors, advances in health technology brought about by research have also contributed to cost escalation. There is a danger that in an unthinking campaign to control costs the value of basic research and its applicability to the cure of human disease will be challenged and the specious argument advanced that because research leads to technological innovation which in turn leads to increased costs, some or all research should be stopped. Research must continue and costs controls, if needed, should be applied at the point of the decision to use new technology.

A second consideration is the mission of NIH/ADAMHA and the responsibility of the scientific community for making available the fruits of its research to the public which supports that research. The AAMC agrees with Senator Kennedy that the research community has a responsibility to define "basic research and protect it, while using its best judgment to guide the rest of our vast investment into areas most likely to meet the public's most urgent needs".<sup>1</sup> The President's Biomedical Research Panel believes the mission of NIH/ADAMHA is steps 1 through 4 of the following continuum of activities:

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<sup>1</sup>Speech by Senator Edward M. Kennedy at Tufts Medical Alumni Dinner, April 23, 1976.

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1. *discovery, through research, of new knowledge and the relating of new knowledge to the existing base;*
2. *translation of new knowledge, through applied research, into new technology and strategy for movement of discovery into health care;*
3. *validation of new technology through clinical trials;*
4. *(a) determination of the safety and efficacy of new technology (b) for widespread dissemination through demonstration projects;*
5. *education of the professional community in the proper use of the new technology and of the lay community on the nature of these developments; and*
6. *skillful and balanced application of the new developments to the population".<sup>2</sup>*

The AAMC agrees with the President's Panel that the mission of NIH is primarily research but that the research mission encompasses the above items 1 through 4(a) only. NIH activities should include the initial "determination of the safety and efficacy of new technology (4a)" but the further adjudication of claims of safety and efficacy is not properly an NIH function. The "widespread dissemination (of new technology) through demonstration projects" (4b) is a health service, not a biomedical research, agency function. To add such service requirements to a research agency would be an error because widespread demonstration projects and health care delivery impose almost insatiable demands on the energies and resources of the agency. The experience of the National Institute of Mental Health is instructive in this regard. As the Overview Cluster pointed out: "It is unfortunate that the ADAMHA has already become committed to large-scale service programs, and it is clear that the research programs have suffered because of this".<sup>3</sup>

Biomedical technology transfer increasingly arouses concern and attracts attention among those interested in health research. The AAMC holds that this transfer is so multi-faceted and necessary that responsibility for it

<sup>2</sup>Report of the President's Biomedical Research Panel, Page 7.

<sup>3</sup>Report of the President's Biomedical Research Panel, Appendix A, Page 21.

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should be shared by the biomedical research community, by private agencies, by public agencies (including but not limited to the NIH) and by industry. The transfer of research advances to clinical care is the area which is the most complex, poorly understood, and demands most resources. The uncoordinated nature of current activities in this area would appear to require new approaches, but the number and complexity of activities and the interrelationships between research, testing, demonstration and practice are such that no single government agency should be expected to assume the entire burden of whatever the Federal role is finally determined to be. Primary responsibility for technology transfer should not be assigned to the NIH simply because NIH has performed its research mission so well. A more rational responsibility for NIH would be to act as a broker in the initiation and promotion of technology transfer. In this capacity, NIH would exercise its judgment, where it had the necessary expertise and capacity, in the selection of research-proven areas for further clinical testing and application by other agencies. NIH would take leadership in seeing that such projects are undertaken but would not itself be required to test, to disseminate or to educate where such activities would compromise its ability to perform its basic mission. NIH would participate in the planning and evaluation of appropriate demonstration projects, sharing this responsibility with other public agencies, the biomedical research community and professional groups. "Widespread dissemination through demonstration projects (4b)", determination of cost effectiveness, professional and lay education and widespread application of new technology are functions which can better be accomplished by the private sector, including industry, or by other federal agencies specially competent in education, control programs or regulation.

As specific examples, it would be an appropriate function of the National Center for Health Services Research to determine the cost effectiveness of new technology, of the Food and Drug Administration to answer questions of safety and efficacy of drugs and devices, of the National Center for Disease Control to conduct educational and control programs, etc. None of these agencies has sufficient resources at present for these tasks, but then neither does NIH. Each of these agencies does have a specific function in the areas mentioned whereas for NIH a new function would have to be created, possibly at the expense of existing programs. Only in the areas of the development and application of low-profit technology can an argument be made for NIH's greater involvement with transfer and application. In this case, NIH has a responsibility to identify such opportunities and to stimulate their development. The need for all the functions listed above is questionable. However, the best means to meet such a need is by no means clear and should be the subject of further study. While these and other complex questions are being addressed and answered, the research mission of NIH

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must continue to receive full public support or a valuable national resource may be lost.

AAMC Recommendation:

The transfer of research proven technology to health care should be the mission of a number of federal and private agencies working together with industry. The research mission of NIH should not be compromised by adding the requirement that it serve as the primary agency for technology transfer."

## CLINICAL RESEARCH TRAINING

In the past several months AAMC staff have become increasingly concerned about the problem of support for research training in clinical areas. Our appreciation of this problem has been heightened by the conclusions of the President's Biomedical Research Panel and the recent Senate Health Subcommittee hearings on the programs of the National Institutes of Health and the Alcohol, Drug Abuse and Mental Health Administration. In the following statement we will describe the problem and its background to stimulate discussion and reaction by the academic community. Suggestions are also needed as to the best way to document the present and future changes which may be occurring in clinical research training.

The support of research training by the Federal government has been under continued attack for several years for a variety of reasons. There have been consistent attempts on the part of the Administration to stop all research training and although these were not entirely successful, training programs have not regained their former vigor. Congressional support for research training has also waned. Paradoxically, during the same period of time increasing demands are being made by the Congress and others for an increase in certain clinical research activities which can be roughly grouped under the heading "technology transfer"<sup>1</sup>. For example, the Senate Health Subcommittee has suggested that a larger percentage of the Federal research budget should be used for applied rather than basic research, for clinical trials and for the testing and demonstration of the safety and efficacy of drugs and devices. The Congress has also called for increases in the numbers and expertise of the scientists in the Food and Drug Administration and for increased monitoring of drugs and devices. To respond to these demands would require that the numbers of scientists qualified in clinical research be increased while support for research training becomes increasingly uncertain.

The academic community has come to the defense of both basic and clinical research training. In mounting the defense, the community has placed much emphasis upon the basis science predoctoral programs while serious changes in the clinical research training of physicians have elicited relatively little attention. Now, however, a variety of forms of evidence - most of it anecdotal - suggests that fewer and fewer physicians are being attracted to careers in academic research. The purpose of this paper is to examine some of the factors which may be responsible for the declining attractiveness of clinical research, the data available to substantiate such a decline and possible actions which may be taken to assure a continued supply of well-trained clinical researchers.

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<sup>1</sup>By this term is meant all those activities by which research-proven ideas in the basic sciences are advanced through clinical testing and applied to the care of patients and the cure of disease.

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Comparison of Ph.D. and M.D. Research Training

The research training of physicians differs markedly from that of Ph.D.'s in the biomedical sciences (see Table 1). Ph.D.'s undergo rigorous predoctoral training in research in a basic science discipline. After the award of the Ph.D. degree they continue their research in academe or in industry. During their predoctoral training, they demonstrate competence both in research and in teaching, work actively on research projects, and prepare for the role which they will play following the award of the doctoral degree. It can be fairly said that most basic science Ph.D.'s aspire to faculty positions which are the logical, successful outcome of their predoctoral training.

In contrast to the relative certainties of the pre- and postdoctoral training of basic researchers, the clinical research training of M.D.'s occurs at a later age and is marked by numerous uncertainties. The predoctoral M.D. trainee (with the exception of the relatively rare combined degree M.D.-Ph.D. candidate) receives little or no exposure to research during the predoctoral period. After graduation with the M.D. degree new physicians pursue several years of clinical training without research exposure. Late in their training career and almost always at the postdoctoral level physicians attracted to research may finally receive training in research. In most cases, these physicians have satisfied the requirements for board eligibility in their specialty (e.g., internal medicine, pediatrics, etc.). At this point, they have several options: 1) They may enter practice; 2) They may continue training in a clinical subspecialty as clinical fellows, or 3) They may receive training as research fellows. Until recently, this training has been almost always supported by categorical training grants but clinical research training usually lacks the scientific rigor and discipline of basic science training. There is also an important fourth option: Some fellows combine a year of clinical fellowship and a year or more of research fellowship. In doing this they may receive support from two or more sources and often mix the clinical and research responsibilities. This leads to a blurring of not only their support and duties, but also their titles. As a result, the definition of what is a research fellow is blurred and it is often difficult even to count the total numbers of research trainees in clinical departments.

Ph.D.'s during their predoctoral training have proven their research and, usually, their teaching ability. In contrast, physicians, when first exposed to research through a postdoctoral fellowship, are faced with several uncertainties. First, they do not know whether they can succeed in research, whether they will be acceptable teachers or whether they can become faculty members at the conclusions of their research training experience. Second, they are faced with a variety of financial disincentives and finally they must, in the present climate, go against considerable social pressure urging them to enter the clinical practice of medicine.



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Table 1. Comparison of Ph.D. and M.D. Training

Begin graduate training (1-2 years course work and research	21	Begin medical school (2 years basic science courses
1-3 years research and teaching)		2 years clinical courses)
Ph.D. awarded	25	M.D. awarded
Active research/teaching on postdoctoral fellowship, on faculty, or in industry	26	Internship
	27	Residency
	28	Residency
	29	Fellowship (research)
	30	Fellowship
	31	Active research/teaching on faculty

### Financial Disincentives to Clinical Research Training

What are the financial disincentives to clinical research training? The first is the differential between the earnings of the academic research physicians and physicians in clinical practice. Each year the discrepancy between these two groups grows larger. At present the differential between a physician beginning a research fellowship and one beginning active practice may be as much as \$30,000 per year. After several years of research training, the young physician may enter the faculty while cohort physicians have progressed to established practice with even greater financial awards. A second financial disincentive is the payback provision for research training. Resident physicians have established their clinical ability but must "gamble" in research. By accepting Federal support for their research training, young physicians incur a payback liability which will be imposed even if they fail at research and clearly have no future in it. This liability can only be satisfied if the physicians repay the funds or continue to work in research for which they may have clearly demonstrated their lack of ability! A third form of financial disincentive is the uncertainty of support. In recent years a repeated pattern of fiscal uncertainty has emerged which is due in part to legislative delays or attempts to cut back the traditional forms of research training support. Traditionally, the academic year begins on July 1; most resident physicians begin to make plans the preceding October. Fiscal uncertainty has made it impossible to guarantee in the Fall that support for the coming July will be available. Residents know that programs have started and have been terminated, that funds have been impounded and released, and that research training program directors are unable to promise that grant support will really be available. Finally, there is the increasing uncertainty that faculty positions and research grants may not be available at the end of the research training period. Compared with the certainty that a career as a practitioner is waiting, the insecurity that attends faculty appointment is a major disincentive indeed.

There is a corollary to such uncertainties that cannot be overlooked. As the future of training grants became clouded in recent years, training grant program directors have turned to hospitals, private foundations, and other sources for funds to support their programs and trainees. In providing such support hospitals often do not allow trainees to receive research training because the hospitals are required to document to third party insurers that clinical service has been rendered in exchange for the funds for such services. Thus, subspecialty residencies or clinical fellowships have been established which compete actively for trainees with the uncertain research training grant programs. In some circumstances, no funds are available at all and the research training programs disappear, patients laboriously gathered over the years disperse and the faculty turn to other activities. The net effect is a loss of the capacity to provide clinical research training to succeeding generations of physicians.

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Effects of Changing Social Goals on Research Training

A word should be said about the effect of increased emphasis on training of primary care physicians on clinical research training programs. From the time of entry into medical school students are subjected to a variety of social pressures intended to increase the numbers of physicians caring for the sick and pursuing primary care activities in general. These laudable social goals are reducing even further the already small numbers of individuals who might be interested in academic careers in research and teaching. Even in the most research-oriented institutions only 10 to 12% of medical students have chosen research careers (1, 2). The evidence is that the numbers of students electing such faculty careers is decreasing sharply and that faculty careers in general are viewed with increasing disfavor by students and house officers.

Changes in the "life-style" attitudes of young people are also having an effect. Ten years ago trainees would go wherever the research opportunity presented itself. Now they seem to hold much more important where and how they live. This is leading to a geographic maldistribution in clinical research as real as the one in clinical practice.

There is another form of social change which may be having a more subtle effect on clinical research. There can be little doubt that new federal regulations are making the conduct of research more difficult. Changes in the freedom of information laws threaten to make all researchers' ideas public property. The conduct of clinical research has become much more difficult with the imposition of needed but complex rules for informed consent of subjects, new drug and device testing requirements and access of patients to records. For example, all of these requirements may make clinical research trials difficult or even impossible to conduct. While none would deny the desirability of the objectives of these laws and regulations, it seems that they are increasingly constraining clinical research.

Changes in Numbers of Clinical Research Trainees

What evidence supports possible changes in the numbers of clinical research trainees? Ten years ago, physicians (as compared to Ph.D.'s) were the principal investigators on 60% of individual research grants awarded by the National Institutes of Health. In the past several years, the numbers of M.D.'s receiving research grants has declined so that now 70% of principal investigators on individual research grants are Ph.D.'s. Although it is impossible that these M.D.'s are now being supported on program projects, center grants or clinical trial contracts, the data to clarify this situation are not at hand. The number of applications for research training grants and fellowships from M.D.'s has declined, but there is little or no

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data to indicate to what extent the Federal support of clinical research training has been transferred to the private sector - either private foundation or hospital funds. Anecdotal evidence from department chairmen and training grant program directors indicates that as new clinical fellowships are established, those trainees who in past years would have participated in research training are not allowed or encouraged to do so.

Thus, it appears that the number of new physicians receiving clinical research training may be declining but that the data needed to give dimension to the decline is not at hand. No systematic study of the numbers of clinical research trainees or their sources of support has been conducted although a number of individual specialty groups have looked at parts of the problem. The most promising possibility to define the problem is the National Survey of Internal Medicine Manpower now being conducted by the Federated Council of Internal Medicine (3). AAMC encourages this study, similar efforts by concerned pediatric societies, continuing studies by the National Academy of Sciences' Commission on Human Resources and efforts of the Institute of Medicine. Further data is also needed to define the total clinical research effort expenditure and the career patterns of clinical researchers.

Areas for Public Policy Emphasis

Although data is urgently needed to define this problem some suggestions for changes in public policy with respect to clinical research training may be put forward:

- 1) Clinical research training should be emphasized. The numbers of clinical training positions should be increased as recommended by the National Academy of Sciences.
- 2) Training grants in clinical disciplines should be encouraged. Long-term, stable support should be provided to programs which have demonstrated an ability to train clinical researchers who remain on faculty and are productive in research. A mix of direct fellowships and training grants should be mandated.
- 3) Specific programs should be emphasized which will increase the scientific capability of clinical researchers. These programs should a) provide M.D.-Ph.D. training (as at present) or broad basic training in clinically related areas; b) provide research exposure earlier in the graduate medical education program so as to emphasize the desirability of clinical research careers; c) provide flexible research grant support to those just

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beginning research careers; and d) provide for the training of clinical scholars by a variety of mechanisms.

- 4) Payback provisions should be eliminated. The counter-productive effects of such requirements should be recognized. A program of incentives to encourage research careers should be instituted and stable support provided to those programs which have proven records in producing research faculty.
- 5) A data base should be established. Because clinical research training is complex, special efforts should be made to obtain a consistent and continuous data base to assure that the correct supply of manpower is available for national needs.

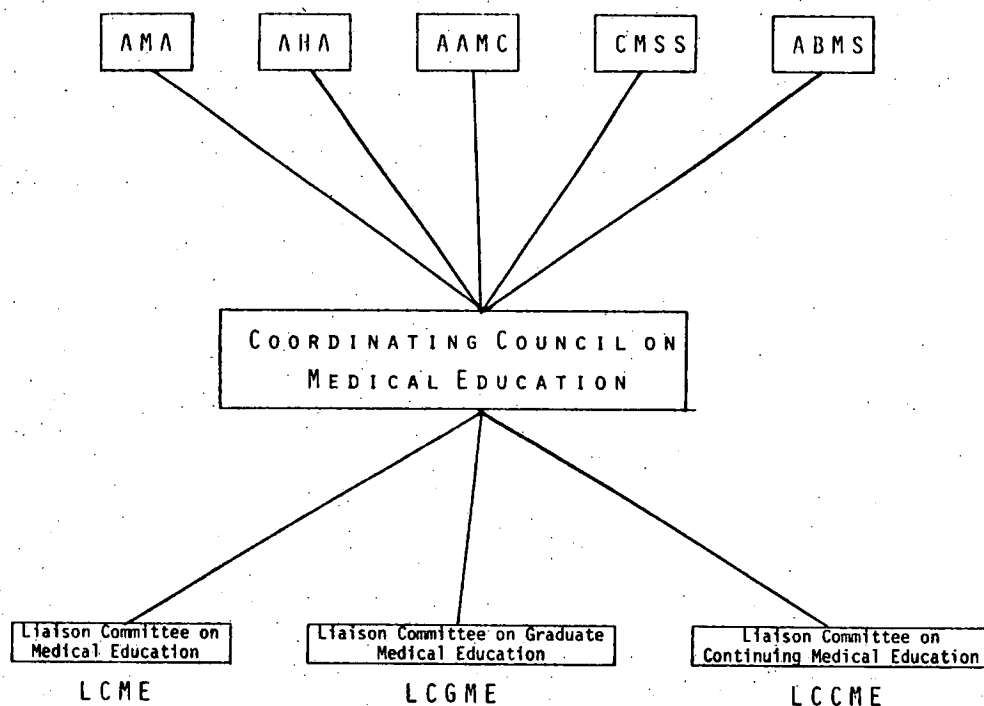
These should be the elements of a positive public policy to support and encourage clinical research training.

REFERENCES

1. Report of the President's Biomedical Research Panel, Appendix C: p. 13 (1976). DHEW Publication Number (OS) 76-503.
2. Ibid. Supplement 2: p. 4-101 (1976). DHEW Publication Number (OS) 76-507.
3. Members of the Federated Council of Internal Medicine are the American College of Physicians, American Board of Internal Medicine, Association of Professors of Medicine and the American Society of Internal Medicine.

## COORDINATING COUNCIL ON MEDICAL EDUCATION AND ITS SUBCOMMITTEES

The Coordinating Council on Medical Education (CCME) was established by its five parent organizations in 1972. These are the Association of American Medical Colleges, the American Medical Association, the American Hospital Association, the American Board of Medical Specialties, and the Council of Medical Specialty Societies. The purpose of the Council is to provide a forum for discussion of policy questions relevant to all phases of the continuum of medical education and to establish policies to be reviewed and ratified by the parent organizations. The CCME is particularly the body which reviews, approves and forwards to parent organizations, policies relating to the accreditation of medical education. Three liaison committees have been established under the umbrella of the CCME. These are the Liaison Committee on Medical Education (LCME), which has been responsible for accreditation of institutions offering medical education leading to the M.D. degree in the U.S. and Canada since 1942; the Liaison Committee on Graduate Medical Education (LCGME), which is responsible for the accreditation of programs in graduate medical education; and the Liaison Committee on Continuing Medical Education (LCCME), which will be responsible for the accreditation of continuing medical education. Diagrammatically, the Coordinating Council on Medical Education and its liaison committees are represented below. Members of the Council and liaison committees are shown on pages eleven and twelve of this report.



- AMA - American Medical Association
- AHA - American Hospital Association
- AAMC - Association of American Medical Colleges
- CMSS - Council of Medical Specialty Societies
- ABMS - American Board of Medical Specialties

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During this year concerns have been raised regarding whether the Coordinating Council on Medical Education and the liaison committees can fulfill their responsibilities effectively if the sponsoring parent organizations of the CCME continue to have the right to veto policies developed by the CCME or the liaison committees. At present, any one of the five sponsoring organizations can veto a policy recommendation sent forward by the Coordinating Council. This year, for example, the AAMC vetoed a recommendation in the FMG report that acknowledged the so-called "Fifth Pathway" into graduate medical education. This Pathway, which was established by the Council on Medical Education of the AMA in 1972, permits U.S. citizens who have studied medicine abroad, but have not yet received a degree, to enter graduate medical programs if they spend a year in a clinical clerkship program sponsored by a U.S. medical school. The AMA vetoed the Coordinating Council's proposal to change the procedure for recognizing new specialties (see below).

Another concern is whether the Coordinating Council on Medical Education and the liaison committees can function effectively with the staff support for these agencies being provided by employees of one of the sponsoring professional organizations. The AMA exclusively provides staffing for all activities except for the Liaison Committee on Medical Education, which is staffed on alternate years by the AAMC. A foundation has offered limited assistance to develop a separate staff for the Coordinating Council. A subcommittee of the CCME is considering this possibility. It is expected that there will be extensive discussions of these issues during the coming year.

The major issues and policy developments which concerned the CCME and liaison committees this year follow.

COORDINATING COUNCIL ON MEDICAL EDUCATION

Foreign Medical Graduates

A document entitled "The Role of Foreign Medical Graduates in the U.S." was approved by all five sponsoring professional organizations and is now being promulgated. The recommendations set forth are directed toward assuring that the foreign exchange visitor program is returned to its original intent to provide educational opportunities for foreign students who are selected by their countries to achieve special knowledge and skills which are needed by those countries. It is recommended that exchange visitor graduate medical education programs only be authorized when sponsored by U.S. medical schools together with their teaching hospitals, and that these institutions only provide opportunities to students who are sponsored by an agency in the sending country.

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The report also recommends that FMGs be required to show that they have equivalent educational attainment to graduates of U.S. medical schools. The FMG report has other detailed recommendations particularly directed towards the Department of Labor and the State Department. Copies of the report will be available at the CAS Business Meeting.

Recognition of New Specialties

A subcommittee of the Coordinating Council on Medical Education, with representation from the Liaison Committee on Graduate Medical Education and the Liaison Committee for Specialty Boards, was established in 1975 to review the present procedure for recognizing new specialties and to propose an alternative procedure if deemed appropriate.

At the present time, the Liaison Committee for Specialty Boards (LCSB) is the body which reviews proposals for establishing a new clinical specialty and makes recommendations to the two sponsoring bodies of the LCSB, which are the AMA and the American Board of Medical Specialties (ABMS). The LCSB's recommendations become final when approved by both the AMA and the ABMS.

The committee recommended to the Coordinating Council that the LCSB, as currently composed, should continue as the primary review body for proposals for new specialties, and that the CCME have the final approval authority. The CCME approved the committee recommendation and forwarded it to the sponsoring professional organizations for final action.

The CAS Administrative Board and the Executive Council of the AAMC approved the new procedure at their June meeting.

The AMA announced at the September, 1976 CCME meeting that it would not approve the new procedure, and offered a substitute in which the ABMS has initial review, the LCSB a secondary review, and the AMA final approval.

The Executive Council, at its September meeting, approved the following position statement, which has been sent to the CCME and its sponsoring organizations.

*The establishment and official recognition of new specialties requires that educational programs for the training of physicians be provided and that resources be devoted to develop and maintain these programs, and medical schools and teaching hospitals are expected to establish departments in the newly recognized specialty. The constituent institutional members of the AAMC provide the facilities, faculty*



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Page Four

*and resources for most of graduate medical education in the United States. Therefore, the AAMC is deeply concerned about policy decisions leading to the establishment of new specialties.*

*Furthermore, establishing and recognizing new specialties must also concern the hospitals, which will be required to provide supportive services and facilities, and the established specialties, which must be concerned with the effective provision of medical services without undue fragmentation.*

*Therefore, the decision to recognize a new specialty must involve those organizations which represent academic medical centers, hospitals, and specialty societies, as well as the organized practicing profession and the specialty boards.*

*For these reasons, the AAMC maintains that the Coordinating Council on Medical Education must make the final decision to recognize the establishment of a new specialty. Because the Coordinating Council on Medical Education is responsible for policies relating to the accreditation of programs in graduate medical education, it should not authorize the Liaison Committee on Graduate Medical Education to accredit graduate medical education programs for specialties which the Coordinating Council has not officially recognized.*

*The authority to establish a certifying board for a specialty that has been recognized by the CCME and for which requirements for accredited training programs have been established by the LCGME should be granted by the American Board of Medical Specialties.*

Meanwhile, the LCSB has agreed to review a proposal to establish a new specialty of emergency medicine. The AAMC was invited to appear before the LCSB in October to state a position on the emergency medicine proposal. In lieu of appearing, the following letter was submitted:

*Glen R. Leymaster, M.D.  
Secretary, Liaison Committee for Specialty Boards*

*The Association of American Medical Colleges has not considered nor developed a position on the substantive question of whether emergency medicine should be recognized as a specialty. However, it is requested that this letter be placed before the Liaison Committee for Specialty Boards for consideration at the October 27 meeting.*

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Page Five

*The AAMC has a substantial interest in whether a new specialty of any genre evolves, for the appearance of any new specialty has significant implications for undergraduate and graduate medical education. Also, a new specialty will impact on the provision of medical services in the academic medical centers as well as in the non-academic sector.*

*One consequence of recognizing a new specialty is that there will be a press for organizational recognition of the specialty within academic institutions. Establishing a new department or a new division requires additional resources. In an era of scarce resources, the benefits to be provided to students and patients must be carefully weighed against the expenditures required.*

*Graduate medical education programs for a new specialty will have to be developed. The dollars to establish such programs will have to be budgeted by academic medical centers. Even though short-term funding may be available to start up programs in a new specialty, ultimately, provision must be made for sustained, long-term dollar support. This cost will have to be justified to governing boards and to reimbursement agencies. Further, training programs for a new specialty may also be very dependent upon other specialties for the provision of educational services to students. Often the faculties of other specialties are hardpressed to fulfill their current obligations and the addition of a new training program, which depends upon them will require additional resources for these units as well.*

*Finally, with the cost of medical services rapidly increasing, the purpose of establishing a new specialty must be examined from the perspective of whether its recognition will substantially improve the quality of services without increasing cost. If costs will increase, then the increase must be justified on the basis of a pressing need to improve the quality of services in the specialty's proposed area of practice in order to protect the public.*

*These issues are so fundamental that those who advocate the establishment of a new specialty should be required to assess the national impact of its establishment in quantitative terms. This written assessment should then be submitted for comment to both the public and private agencies which will be involved in developing the specialized personnel and paying for the medical services they will provide.*

*John A.D. Cooper, M.D.  
President, AAMC*

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The eventual outcome of this issue is at present uncertain. The decision to recognize a new specialty has broad impact on the academic medical centers and the health care system in general. The AAMC position is to continue to work toward having a body such as the CCME have final approval authority.

Comprehensive Qualifying Examination

A subcommittee of the Coordinating Council, charged to make recommendations on the need for a Comprehensive Qualifying Examination (CQE) at the interface between undergraduate and graduate medical education, came forth with the following recommendations.

The Committee recommends that:

- 1) *The CCME adopt the following statement as policy:  
"There is a need for a comprehensive qualifying assessment procedure to be required of all physicians about to assume patient care responsibilities under supervision as residents (or fellows) in an approved program of graduate medical education."*
- 2) *The CCME recommend to the LCGME that the General Essentials for Approved Programs of Graduate Medical Education be revised to require that when a comprehensive qualifying assessment procedure becomes available in a form satisfactory to the LCGME, all physicians shall pass the procedure before assuming patient care responsibilities under supervision as residents (or fellows) in an approved program of graduate medical education.*
- 3) *The CCME recommend to the LCGME that it identify and encourage the appropriate agency(ies) to develop and administer a satisfactory comprehensive qualifying assessment procedure.*

At the September meeting the CCME voted to table consideration of these recommendations until such time as a model CQE is available for inspection. The National Board of Medical Examiners is moving ahead with the development of new testing methodologies with the intent of developing a prototype examination.

The AAMC's position is that passing a Comprehensive Qualifying Exam should be a necessary, but not necessarily sufficient, requirement for entering accredited programs in graduate medical education. The Coordinating Council on Medical Education has charged the LCGME to determine a minimally acceptable standard of professional competence requisite for assuming responsibility for patient care under

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supervision for both FMGs and U.S. FMGs. As yet, the LCGME has not moved towards responding to this charge.

At present, the introduction of a Comprehensive Qualifying Exam is not certain. The question will doubtlessly be re-opened when the National Board of Medical Examiners' prototype exam is available.

LIAISON COMMITTEE ON GRADUATE MEDICAL EDUCATION

Subspecialty Training Programs

The LCGME was requested by several residency review committees and specialty boards to make provisions for identifying subspecialty training programs in the various specialties which provide recognition of special competence in subspecialties.

The desire was to have subspecialty training programs listed in the Directory of Approved Residencies (the Green Book) and to develop procedures to accredit subspecialty training programs.

The LCGME has approved the following recommendations brought forth by a subcommittee.

Subspecialty training programs will be listed in conjunction with primary programs in the Directory if they fulfill the following requirements:

- 1) *There is a provision by the relevant primary board for certification of special competence in the subspecialty;*
- 2) *The program meets the requirements for certification of special competence set forth by the relevant board;*
- 3) *The program is an integral part of an accredited graduate medical education program in the primary specialty (e.g. internal medicine, pediatrics, etc.);*
- 4) *There is an individual identified as director of the subspecialty program;*
- 5) *The individuals who enter the program are required to complete training for the primary specialty.*

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The listing will not imply accreditation. The subcommittee recommended that accreditation of subspecialty training programs by the LCGME not be undertaken until there is a thorough study of current review and approval procedures for accrediting all programs in graduate medical education. The object of such a study will be to improve the current procedure and integrate subspecialty accreditation into the LCGME's responsibilities.

Structure and Function of Residency Review Committees

A manual has been prepared by the LCGME to provide common policies for the structure and function of residency review committees. The manual, which became effective as of July 1, 1976, is a first step toward improving review and approval procedures. Previously, the residency review committees for the 23 specialties for which programs are accredited by the LCGME carried out their functions under individually developed procedural processes. The new manual, which will be modified as experience demonstrates the need, sets forth standardized policies relating to the review process. The manual does not invade the responsibilities of the residency review committees in the area of setting standards and developing criteria for judging whether programs have met these standards.

LIAISON COMMITTEE ON MEDICAL EDUCATION

Institutional Self-Study

The Liaison Committee on Medical Education introduced a self-study program into the procedures for institutional accreditation for medical schools. In advance of the accreditation site visit, faculties are now asked to analyze their programs for undergraduate medical education and identify their strengths and weaknesses.

Guidelines

A set of guidelines explaining and expanding upon the fundamental accreditation standards set forth in "Structure and Functions of a Medical School" is in preparation. A draft, presented to the AAMC Administrative Boards in the spring, has had extensive comment from members of the CAS and other Councils. It is expected that another draft will be brought forward by the LCME early in 1977.

LIAISON COMMITTEE ON CONTINUING MEDICAL EDUCATION

In November 1974 the parent professional organizations of the CCME agreed to establish the Liaison Committee on Continuing Medical Education. The membership of this Liaison Committee was to consist, in addition to the five parents of the CCME, of representatives from the AHME and the FSMB. The complete membership of the Committee thus is as follows:

American Board of Medical Specialties	3
American Hospital Association	3
American Medical Association	4
Association for Hospital Medical Education	1
Association of American Medical Colleges	3
Council of Medical Specialty Societies	3
Federation of State Medical Boards	1
Public	1
Federal	1

The LCCME met for the first time in November 1975 and has since held four more meetings. Taking the state of the art of continuing medical education into consideration, the scope and function of the Committee were more broadly defined than those of the LCME or the LCGME. The LCCME thus, in addition to accreditation, should examine present day practices of continuing medical education and recommend new principles and policies in the field as it deems them necessary. To discharge these assignments, the Committee has chosen to organize as subcommittees charged with specific areas such as bylaws, goals and priorities, procedures and and finances.

Thus far the LCCME has written its bylaws which are now awaiting approval by the CCME parent organizations. It has established a modus operandi based on the principle by which all accreditation decisions will rest with the LCCME while surveys will be conducted in either of two fashions: organizations and institutions offering national programs will be surveyed by a national review committee while regional and local organizations and institutions will be surveyed by regional or state review committees. In the beginning the composition of the regional review committees is most likely to retain their present composition while within the next two years these regional or state committees will have to reflect in their membership the composition of the LCCME. It is anticipated that the LCCME will take over the accreditation function from the Council on Medical Education of the AMA during the 1977 calendar year.

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So far the deliberations of the LCCME have been conducted in a constructive fashion. Many issues, however, have remained untouched particularly those of staffing of the Committee, the nature of the credit to be given to the physician for CME, the development of an information system on continuing education and a better understanding of the entire process of relating continuing medical education to physician performance.

The AAMC has been able to participate fully and aggressively in this first formative year of the LCCME. The recently appointed Ad Hoc Committee on Continuing Medical Education of the Association under the chairmanship of William D. Mayer, M.D. will assist the AAMC representatives to retain a degree of initiative so important for the LCCME. The second year of operation of the LCCME will probably show whether or not it will be able to provide leadership beyond an accreditation function and thus will become a national focus for continuing medical education. National leadership will be most important for continuing medical education because of its lack of institutional focus, of clearly defined educational objectives, and of evaluative procedures. For continuing medical education to become a significant contribution to quality medical care, a concerted effort of the medical profession, the medical schools and the hospitals is essential.

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ROSTER OF MEMBERS

Coordinating Council on Medical Education

*American Board of Medical Specialties:*

John C. Beck,  
Thomas B. Ferguson,  
Charles A. Hunter, Jr.  
\*Glen R. Leymaster

*American Hospital Association:*

Donald J. Caseley  
H. Robert Cathcart  
David D. Thompson  
\*E. Martin Egelston  
\*Raymond Nordquist

*American Medical Association:*

Merrill O. Hines  
Tom E. Nesbitt  
Bernard J. Pisani  
\*C.H. William Ruhe, Secretary

*Association of American Medical Colleges:*

William G. Anlyan  
John A.D. Cooper  
Ronald W. Estabrook  
\*George R. DeMuth

*Council of Medical Specialty Societies:*

C. Rollins Hanlon, Chairman  
B. Leslie Huffman  
M.T. Jenkins  
\*L. Jack Carow  
\*Richard S. Wilbur

*Federal Government Representative:*

Harold Margulies

*Public Member:*

Lucius P. Gregg, Jr.

*Ex-Officio, Without Vote:*

James A. Pittman  
Thomas D. Kinney  
William D. Holden  
\*Thomas D. Dublin

LIAISON COMMITTEE ON MEDICAL EDUCATION

*American Medical Association:*

Warren L. Bostick  
Louis W. Burgher  
Patrick J.V. Corcoran  
William F. Kellow  
Joseph M. White, Vice-Chairman  
Chris J.D. Zarafonetic  
\*Richard L. Egan  
\*C.H. William Ruhe

*Association of American Medical Colleges:*

Steven C. Beering  
Ralph J. Cazort  
Ronald Estabrook  
John P. Kempf  
Thomas D. Kinney, Chairman  
C. John Tupper  
\*John A.D. Cooper  
\*James R. Schofield

*Public Members:*

Harriett S. Inskeep  
Arturo G. Ortega

*Federal Government Member:*

John H. Mather

\*Staff Member

\*Staff Member, ex-officio, without vote



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LIAISON COMMITTEE ON GRADUATE  
MEDICAL EDUCATION

*American Board of Medical Specialties:*

James A. Clifton  
Gordon W. Douglas  
William K. Hamilton  
\*Glen Leymaster  
Victor C. Vaughan, III

*American Hospital Association:*

\*\*E. Martin Egleston  
Bruce W. Everist  
\*Raymond O. Nordquist  
Eugene L. Staples

*American Medical Association:*

Richard G. Connar  
Richard V. Ebert  
\*Leonard D. Fenninger  
Russell S. Fisher, Vice-Chairman  
Gordon H. Smith

*Association of American Medical Colleges:*

Jack W. Cole  
Robert M. Heyssel  
James A. Pittman, Chairman  
\*\*August G. Swanson

*Council on Medical Specialty Societies:*

Robert G. Fisher  
\*Richard S. Wilbur  
Truman G. Schnabel, Jr.  
\*L. Jack Carow

*Public Member:*

O. Meredith Wilson

*Federal Government Representative:*

Robert F. Knouss

*House Staff Representative:*

Ralph M. Stanifer

LIAISON COMMITTEE ON CONTINUING  
MEDICAL EDUCATION

*American Board of Medical Specialties:*

Saul J. Farber, Chairman pro tem  
George F. Reed  
Jerald R. Schenken  
\*Glen R. Leymaster

*American Hospital Association:*

Donald W. Cordes  
Harry C.F. Gifford  
Robert F. Scates  
\*E. Martin Egleston  
\*Raymond Nordquist

*American Medical Association:*

John H. Killough  
John W. Moses  
Donald W. Petit  
Charles N. Verheyden  
\*Rutledge W. Howard, Secretary  
\*C.H. William Ruhe

*Association for Hospital Medical  
Education:*

Gail I. Bank  
\*Clement Brown

*Association of American Medical Colleges:*

Richard M. Bergland  
William D. Mayer  
Jacob R. Suker  
\*\*Emanuel Suter

*Council of Medical Specialty Societies:*

John Connolly  
James L. Grobe  
Charles V. Heck  
\*Jack Carow  
\*Richard Wilbur

*Federation of State Medical Boards:*

Howard L. Horns

*Federal Representative:*

Federick V. Featherstone

*Public Representative:*

Margaret E. Mahoney

\*Staff Member, ex-officio, without vote

\*\*Voting Staff Member

## CAS REPRESENTATION IN THE GROUP ON MEDICAL EDUCATION

The Group on Medical Education (GME) was established in 1972 to provide a forum for the exchange of information and development of ideas about medical education. At present, membership is restricted to individuals designated by medical school deans. The Executive Council has approved a recommendation of the Governance and Structure Committee that both the CAS and the Council of Teaching Hospitals be provided the opportunity to designate individuals for membership in the GME.

The Group on Medical Education is composed of several sections. Individuals with particular interests or responsibilities are designated for these sections. The sections are:

- 1) Research - Individuals with particular interests or responsibilities in research into the education of physicians at all levels along the continuum.
- 2) Undergraduate Medical Education - Individuals with particular interests or responsibilities in curriculum development and academic administration in the medical schools.
- 3) Graduate Medical Education - Individuals with particular interests or responsibilities in the development of clinical graduate programs and their administrative management.
- 4) Continuing Medical Education - Individuals with particular interests or responsibilities in the development of continuing medical education opportunities for physicians.
- 5) Biomedical Communications - Individuals with particular interests and responsibilities in the development and provision of educational materials utilizing audiovisual and/or computer technologies.

The Group on Medical Education has an extensive program at the Annual Meeting, including the Conference on Research in Medical Education. Regional meetings of the GME are held each spring.

Some member societies of the CAS may have specific interests in one or more sections of the GME. In the near future, information regarding how individuals may be designated to participate in the Group on Medical Education will be sent to society officers.

## THE NEW MEDICAL COLLEGE ADMISSION TEST

The New Medical College Admission Test (MCAT) will be introduced in the spring of 1977. Applicants seeking to enter medical school in 1978 will be the first to have their scores on the New MCAT considered as one of the selection factors.

The New MCAT is a totally new exam based upon specifications which were derived through surveying faculties of undergraduate colleges, medical schools, medical students, and physicians. The specifications delimit the level of knowledge in biology, chemistry, and physics, and the analytical skills needed to study medicine. The new exam will provide separate scores for biology, chemistry, and physics; science problem-solving; analytical reading skills; and quantitative analytical skills.

The number of questions or test items has been increased and the exam will now require a full day of testing in contrast with the half-day required for the old MCAT. In the sciences, there will be 145 items as compared to 86 in the old MCAT. The problem-solving section consists of 72 additional items dealing with problem-solving in all three sections. The sections on analytical skills provide for 73 items for analytical reading skills and 73 items for quantitative analytical skills.

Nineteen medical schools are participating in experimental testing of the new instruments. Volunteer students at several levels in medical school, and house officers, are taking the examination to provide concurrent validity data. There will be an extensive program to acquaint admissions officers and committees with the characteristics of the New MCAT and its application to student selection during the winter and spring of 1977. A manual for students, which provides detailed information about the exam and a sample set of test items, has been prepared and is now available. A technical manual for the use of psychometric researchers is in preparation.

The New MCAT is the first major product of the Medical College Admissions Assessment Program (MCAAP) which was initiated in 1973. Another major dimension of MCAAP is to develop more systematic ways to assess the personal qualities of applicants to medical schools. A proposal to develop criteria for assessing personal qualities in the seven areas listed below has been prepared and funds to implement the program are being sought from foundations.

- Area I Compassion
- Area II Coping Capabilities
- Area III Decision-Making
- Area IV Interprofessional Relations
- Area V Realistic Self-Appraisal
- Area VI Sensitivity in Interpersonal Relations
- Area VII Staying Power--Physical and Motivational

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## CORRESPONDING MEMBERSHIP AND SUBSCRIBERS

### Corresponding Membership

At the 1975 Annual Meeting, the Assembly approved a Corresponding Membership category. The criteria, as set forth in the By-laws of the AAMC, are Corresponding Members "shall be hospitals involved in medical education in the United States or Canada which do not meet the criteria established by the Executive Council for any other class of membership. Corresponding Members will be recommended to the Executive Council by the Council of Teaching Hospitals." The Executive Council voted to require the following additional criteria.

- 1) Corresponding Members shall have a documented institutional affiliation with a school of medicine for the purpose of participating in medical education.
- 2) Corresponding Members shall have the written endorsement of the dean of the affiliated school of medicine as part of its application for membership.

### Subscribers

The Executive Council approved a non-membership service to be made available to institutions, organizations, or individuals who did not qualify for any AAMC voting membership category. The criteria for Subscribers and the benefits of the subscription are as follows.

- 1) These subscriptions shall be open to any institution, organization, or individual demonstrating a commitment to medical education and not eligible for any class of voting membership.
- 2) Any institution which is part of a member medical school (or individual affiliated therewith) must have the approval of the dean of that medical school.
- 3) All Subscribers shall be approved by the Executive Council prior to attaining Subscriber status.
- 4) Benefits of this subscription shall be:
  - a. Journal of Medical Education
  - b. President's Weekly Activities Report
  - c. COTH Report
  - d. Student Affairs Report
  - e. Directory of American Medical Education
  - f. Assembly Memoranda (other than questionnaires and confidential "members only" communications)
  - g. Other memoranda or communications of general interest to these institutions and individuals.
- 5) Satellite campuses of multi-campus medical schools who wish to receive these services shall be required to become Subscribers.

Subscription Rate - \$500.00 per year

## INPUT INTO RETREAT AGENDA

During the second week in December, the Chairman and Chairman-Elect of the Councils and the Chairman and Chairman-Elect of the Assembly, will meet with selected AAMC staff to discuss AAMC activities and plan the Association's programs for the coming year. Areas of concern which members of the Council of Academic Societies believe should be called to the attention of the Association officers should be brought up during the discussion of the Retreat Agenda. The Annual Report of the Association, which has been distributed to you, provides information regarding Association activities during the past year.

CAS MEMBERSHIP CHANGES

The following societies have withdrawn from the CAS:

<u>NAME</u>	<u>EFFECTIVE DATE</u>
American Society of Hematology	December 23, 1976
Biophysical Society	May 7, 1976

COUNCIL OF ACADEMIC SOCIETIES PROGRAM

FRIDAY, NOVEMBER 12

Ballroom 5

"THE ROLE OF MEDICAL EDUCATION IN REDUCING MEDICAL COSTS  
AND THE DEMAND FOR MEDICAL SERVICES"

Moderator/Chairman:

Rolla B. Hill, Jr., M.D.  
Chairman, Department of Pathology  
SUNY Upstate Medical Center

2:00 p.m.

Duncan Neuhauser, Ph.D.  
Assistant Professor of Health Services Administration  
Harvard University School of Public Health

Sherman M. Mellinkoff, M.D.  
Dean  
University of California, Los Angeles, School of Medicine

5:00 p.m.

Adjourn

A PRESENTATION OF DATA

ILLUMINATING TRENDS IN NATIONAL INSTITUTES OF HEALTH  
SUPPORT OF BIOMEDICAL RESEARCH  
IN THE LAST DECADE

By: Solomon Eskenazi  
Chief, Statistics & Analysis Branch  
Division of Research Grants, NIH

On: Friday, November 12, 1976  
5:30 pm - 7:00 pm

At: San Francisco Hilton  
Ballroom 3



*CHS Business Meeting  
Handout*

PHYSICIAN MANPOWER AND DISTRIBUTION

The Role of  
The Foreign Medical Graduate

A Report of the

COORDINATING COUNCIL ON MEDICAL EDUCATION

June, 1976

PHYSICIAN MANPOWER AND DISTRIBUTION

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The Foreign Medical Graduate

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*The Health Resources Administration of the  
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## PHYSICIAN MANPOWER AND DISTRIBUTION

### The Role of the Foreign Medical Graduate

A Report of the  
Coordinating Council on Medical Education

June, 1976

Since World War II, large numbers of physicians have migrated throughout the world, increasingly from nations which are developing economically to those whose economics are stronger. Particularly during the past decade the rate of increase in foreign medical graduates (FMG's) in the United States has been three times greater than the increase in the total number of physicians in the United States. Foreign medical graduates now comprise almost 22 percent of all physicians in the United States. (Table 1)

About one-third of all hospital interns and residents are FMG's. In the five-year period 1970-74 approximately two in five of the medical school graduates added to the licensure registries for physicians in the separate states were alumni of other than U.S. schools. (Table 2)

In 1974, FMG's made up 50 percent or more of physicians licensed for the first time in 14 states or other jurisdictions and in 5, FMG's comprised 75 percent or more of the new licentiates that year. (Table 3)

These developments have taken place concurrently with the marked expansion in the number of U.S. medical schools and even more marked expansion of U.S. medical student enrollment in those training institutions. In 1973, for the first time, U.S. medical graduates exceeded 10,000 and in 1975, 114 domestic medical schools awarded medical degrees to 12,714 graduates. (Table 4) It is anticipated that by 1980 the annual output of U.S. medical schools will approximate 15,000, a goal widely endorsed as providing a better balance between the total number of physicians and the total U.S. population in the years ahead. Yet, as the Coordinating Council has cautioned in a previous report on the primary care physician<sup>1</sup> such balance can be achieved only through planned and sustained national effort. Concerted effort must continually be directed to the number of physicians produced by our medical educational system, to their distribution geographically as well as by specialty and to the effect that these considerations have on the amount and quality of medical care available to the U.S. population.\*

Some observers have viewed the utilization of large numbers of FMG's in our health care system as a readily available, though temporary, means of relieving excessive burdens, financial as well as other, on the domestic medical educational system. The future flow of FMG's to the U.S. may prove less predictable than it has been in the past. Accordingly, appropriate national concern must also be directed toward domestic and foreign factors that influence international migration of physicians to the U.S. Furthermore, the graduate educational needs of FMG's are of major magnitude and

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\* Subsequent reports on Physician Manpower and Distribution are in preparation. The present report deals only with the specific problems related to foreign medical graduates.

may differ considerably from those of graduates of U.S. medical schools.

This report would not be complete without an expression of gratitude and appreciation to the thousands of FMG's who have been completely assimilated into the U.S. health care system and who have rendered valuable service to the American people. Particular recognition is due those who have become faculty members of U.S. medical schools and have assisted in the education of USMG's.<sup>2</sup> Many good things have occurred, and will continue to occur, as the result of the mix of products of educational systems in foreign countries with the products of our own educational system. This is valuable and should be encouraged under the proper conditions. However, many problems have arisen which need to be addressed.

Critical issues affecting the entrance of FMG's into the U.S., their graduate medical training, their distribution and utilization include:

1. Coherent national policies determining the role FMG's can or should play in the U.S. health care system have not been formulated. The lack of national, regional, or state plans is in part due to the widely dispersed and often unrelated authorities that share responsibilities in this area. There is a pressing need for the early reconciliation and coordination of the disparate and conflicting policies and programs of various Federal agencies, national professional and related organizations and the 55 separate state and territorial licensure authorities.
2. Curriculum content and standards of education in different medical schools around the world vary considerably. Thus, FMG's coming to the U.S. comprise a highly heterogeneous group and demonstrate an equally wide range of professional competence. The growing number of FMG's in the United States and their performance on ECFMG state licensure and specialty certifying examinations have highlighted questions about the equivalency of their educational preparation with that available to U.S. medical school graduates. Questions have also been raised concerning their performance in the delivery of health care.<sup>2</sup> This assessment applies particularly to those FMG's who received their basic medical education in languages other than English or in cultures dissimilar to that of the United States.
3. Whether the FMG enters the U.S. health care system as an exchange visitor, an immigrant, or as a returning U.S. national who has studied medicine abroad, his point of entry is almost invariably at the graduate level of medical education, the hospital internship or residency. Graduate educational positions in the U.S. have far exceeded the number of U.S. and Canadian graduates enrolled in residencies. (Table 5) Many of the programs to which FMG's gain appointment emphasize service activities with minimal attention to an educational program designed to meet their special educational needs.
4. In order to meet the demand for physician service in some hospitals and in institutions providing long-term, chronic care, particularly state institutions, a large--but inexact--number of FMG's have been

employed under limited or temporary medical licensure arrangements. Some of these FMG's have failed to obtain ECFMG certification or to meet state licensure requirements for unrestricted medical practice.<sup>3</sup> Estimates place the number of such unqualified FMG's as high as 10,000. Many are serving as institutional staff physicians presumably under professional supervision or in a variety of paramedical capacities yet their prospects are severely limited in obtaining the credentials of a physician fully qualified to practice independently.

5. Serious doubts have been raised, particularly in a period of major transition in graduate medical education in the United States, as to the appropriateness of the present ECFMG examination both as a test of the readiness of FMG's to benefit from this graduate educational experience and as an adequate safeguard of the health and welfare of patients. In effect different standards now exist for USMG's and FMG's for admission to graduate medical education.

In its report, issued in 1967, the National Advisory Commission on Health Manpower urged that "at a minimum, foreign trained physicians who will have responsibility for patient care should pass tests equivalent to those for graduates of U.S. medical schools."<sup>4</sup> More recently the Committee on Goals and Priorities of the National Board of Medical Examiners has recommended that a new system of examination, applicable to both domestic and foreign medical graduates be instituted to evaluate performance capabilities requisite for providing patient care in a supervised setting.<sup>5</sup> This recommendation predicates the revision of the existing ECFMG examination as well as the provision of improved evaluation instruments to assess better the English language capability and potential ability of FMG's to adjust to the U.S. medical education and health care delivery systems and to the cultural environment within which they will practice.

6. Despite significant growth in the enrollment capacity of U.S. medical schools, large numbers of applicants cannot be accommodated. (Table 6) Increasing numbers of U.S. citizens are attending foreign medical schools. Serious questions have been raised about the quality of medical education in those institutions most willing to accept U.S. students and the appropriateness of that educational experience as a preparation for health care needs in the United States. These U.S. nationals studying medicine abroad present many of the same problems encountered by other FMG's entering the mainstream of American medical practice. Policies regarding U.S. nationals studying medicine abroad are in need of careful review and reappraisal.

7. For more than 20 years, the United States, as a component of its programs of foreign aid, has encouraged FMG's to come to the U.S. to obtain a type of graduate medical education not available to them in their home country. Presumably such training would prepare these physicians to practice at a higher level of proficiency upon returning to their home country. As currently operating, the exchange visitor program for physicians is no longer serving its declared purpose and may be counterproductive to the improvement of health services both in the countries represented by the exchange visitor physicians and in the U.S.

8. The Immigration and Naturalization Act Amendments of 1965 (P.L. 89-236) and 1970 (P.L. 91-225) have had major impact on the migration of FMG's to the United States. The termination of the National quota system previously in effect opened avenues of entry to the U.S. for physicians trained in countries where, even in the face of major unmet health needs, the available physician supply exceeds effective economic demand. Secondly, preferential immigration status has been assigned to medicine and to some related health professions thought to be in short supply in the U.S. Thus, physicians from these developing countries are encouraged to emigrate to the U.S. without regard to the appropriateness of their professional education for medical licensure requirements. Based on current data, physicians migrating to the U.S. each year represent about one-quarter of the annual output of all of the medical schools of the world outside of the U.S., the People's Republic of China, the U.S.S.R., and the socialist countries of Eastern Europe.<sup>6</sup>

#### RECOMMENDATIONS

The issues summarized above demonstrate the extent and complexity of the problems associated with the entrance into the U.S. health care system of large numbers of FMG's. In 1967, a Panel on Foreign Medical Graduates submitted to the National Advisory Commission on Health Manpower detailed recommendations to resolve the problems then identified with FMG's.<sup>4</sup> In the main, these recommendations have not been implemented. Concurrently changes in immigration laws and regulations as well as other forces have increased the flow of FMG's to the U.S. and the problems have become more deep-seated and complex. Simplistic solutions to one phase or another of the problems have already proved inadequate. Moreover, in our pluralistic health care system unilateral action by one organization or agency, even at the Federal level, will fall short of its desired objectives and may, in fact, create additional problems.

To date there has not been concerted and sustained nationwide effort to develop sound and coherent policies affecting the entrance of FMG's into the U.S., their education and training in appropriate institutions and their effective utilization in the U.S. health care system. There is an urgent need for unified and continuing national, state and local action programs in which all concerned agencies play an appropriate role in implementing agreed-upon policies.

#### I. General Recommendations

The Coordinating Council on Medical Education recommends that the following statements be adopted as basic tenets of a proposed Statement of National Policies on the Role of the Foreign Medical Graduate in the U.S. Health Care System:

1. That the U.S. medical educational system (including graduate as well as undergraduate education) provide a sufficient number of well-trained physicians to meet the health needs of the nation;

2. That the U.S. medical educational system offer assistance to other countries, particularly the developing countries of the world, in improving their systems of medical education and their levels of medical practice and public health;
3. That the resolution of problems arising from the current massive international migration of physicians be achieved in a manner consistent with the Universal Declaration of Human Rights adopted by the U.N. General Assembly in 1948, assuring for every individual the right to leave any country, including his own, and to return to his country;
4. That in resolving these migration problems the U.S. should avoid the use of selective discrimination, based on occupation or nationality, against foreign medical graduates seeking either temporary or permanent admission to the U.S.;
5. That the resolution of medical care problems arising from shortages or uneven distribution of physicians in the U.S. should not depend on recruitment of foreign medical graduates from abroad or on the assignment of preferential immigration status to members of selected health professions;
6. That all foreign medical graduates seeking opportunities for graduate medical education must demonstrate that they have met a standard of professional proficiency equivalent to that required of U.S. medical graduates eligible for the same type or level of graduate education so that there may be assurance of their capacity not only to benefit from the educational experience but to provide effective care under supervision;
7. That a physician, FMG or USMG, whether engaged in the independent or institutional practice of medicine, must possess an unrestricted license to practice his profession in the governmental jurisdiction in which his practice is located unless the physician is formally enrolled in a medical educational program approved for such training;
8. That a required component of an accredited graduate medical educational program for FMG's consist of a formal orientation and educational experience incorporating appropriate curriculum content and of sufficient duration to insure the proper orientation of FMG's to the U.S. systems of medical education and health care as well as the acquisition of an adequate understanding of the basic medical sciences, the English language, and U.S. culture, including the moral and ethical bases of medical practice.

9. That such acculturative experiences be conducted under the sponsorship of appropriate educational agencies and where feasible and appropriate on an areawide or regional basis;
10. That, in exercising its appropriate responsibility for national policies in graduate medical education, the Coordinating Council on Medical Education formulate national policies with respect to medical educational programs for FMG's; that the Liaison Committee on Graduate Medical Education be assigned responsibility for the accreditation of all graduate medical educational programs in which FMG's are enrolled, including fellowships and other special programs; and that a comprehensive national program be designed to improve the professional and related skills of all FMG's coming to the U.S. for graduate medical education.
11. That the funds necessary to establish and maintain for a five-year period the national programs encompassed in the above recommendations be secured through foundations, Federal grants and voluntary contributions of concerned national, state and local organizations;
12. That the Coordinating Council on Medical Education invite the Federal Interdepartmental Subcommittee on International Exchanges-- Working Group on Foreign Medical Graduates\* to establish an ongoing liaison with the Coordinating Council and with other professional and related organizations concerned with international medical exchange.

## II. Specific Recommendations

There are significant differences between the problems (and appropriate measures to resolve these problems) presented by physicians born and educated in foreign countries who come to obtain additional education in the United States with the intent of returning to their homeland when they have achieved their educational goal and those who enter with the interest of settling and practicing medicine on a career basis in the United States. The former are temporary visitor physicians usually gaining admission to this country under regulations established by the U.S. Information and Educational Exchange Act of 1948, as amended. Recommendations regarding those visitors are set forth in Section II-A below; recommendations regarding foreign national physicians seeking permanent residence in the U.S. are set forth in Section II-B; and

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\* Established in November, 1974 at the request of Assistant Secretary of State for Educational and Cultural Affairs Mr. John Richardson, Jr., and includes representatives of the Departments of State; Health, Education, and Welfare; Justice (Immigration and Naturalization Service); Labor; and the Veterans Administration.



recommendations pertaining to U.S. nationals who have studied medicine abroad are set forth in II-C. Recommendations on an inextricably related set of issues, namely U.S. assistance to international medical education and particularly assistance to medical education in developing countries, the source of all but a small fraction of the FMG's now migrating to the U.S., are encompassed in Section II-D.

A. Recommendations on Temporary Visitor Physicians

Since 1962 over 60,000 foreign medical graduates have been admitted to the United States as exchange visitors in programs authorized by the Mutual Educational and Cultural Exchange Act of 1961 (The Fulbright-Hayes Act).\*\* The purposes of that Act are: "The improvement and strengthening of the international relations of the United States by promoting better mutual understanding among the peoples of the world through educational and cultural exchanges."

In conformity with the intent of the authorizing legislation, the CCME recommended:

1. That admission of foreign medical graduates to the United States as exchange visitors be limited to the defined purposes and the limited period of time authorized by Department of State regulations governing designated exchange visitor programs; improved safeguards should be established to prevent the employment of exchange visitor programs as alternate pathways for FMG's to immigrate to the United States;
2. That FMG's coming to the U.S. as exchange visitor physicians be assured high quality graduate medical education especially designed to improve their medical knowledge and skills for teaching and practice in their own country;
3. That the U.S. Government, in consultation with the Coordinating Council on Medical Education, should aid in the development of appropriate agreements with the governments of other countries wherein the medical educational system of the U.S. agrees to provide specific educational opportunities in graduate medical education. Within the framework of these governmental agreements,

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\*\* As defined by Federal Regulations an exchange visitor is a foreign national who has entered the United States temporarily on a J-1 visa for an educational or cultural experience and as a participant in a program designated by the Secretary of State as an Exchange Visitor Program. An exchange visitor may be paid and may accept a stipend for meaningful contributions or valuable services rendered to the institutional or agency sponsor of the designated program. The State Department has designated AMA approved internships and residencies sponsored by hospitals and related institutions not a part of educational institutions as P-II Exchange Visitor Programs.

individual educational institutions in this country should make appropriate agreements with recognized educational agencies and institutions in other countries. Candidates selected for such educational experience in the U.S. would be required before entering into such training to meet standards of professional preparation established by the U.S. educational institutions and accrediting agencies, would be committed to return to their home country on the completion of the agreed upon educational program and would be assured of previously specified academic, governmental or other professional appointments on their return to their home country;

4. That commencing one year following the adoption of this report the sponsorship of FMG's coming to the U.S. for graduate medical education as exchange visitor physicians be limited only to accredited U.S. medical schools, together with their participating affiliated hospitals, or to other accredited schools of the health professions;
5. That such medical schools or schools of the health professions specifically approved by the LCGME to sponsor exchange visitor physicians for graduate medical education should:
  - a) Have the capability to develop programs tailored to meet the needs of each accepted exchange visitor physician;
  - b) Have developed the necessary attitudes and resources needed to achieve mutual cultural understanding between these exchange visitor physicians and those with whom they will be associated in the institution.
  - c) Have clearly demonstrated that all interinstitutional arrangements made for the development of especially tailored programs are specifically entered into for the benefit of the exchange visitor;
6. That the issuance of an exchange visitor visa be contingent upon each FMG applicant submitting to the U.S. sponsoring educational institution acceptable evidence that he meets its standards of educational attainment, has demonstrated the potential to adapt to the cultural milieu in which he will be studying in the U.S. as well as an effective mastery of the English language and, if his educational experience is to include training at the residency level, that he has met in a manner acceptable to the LCGME a minimally acceptable standard of professional competence for assuming responsibility for patient care under supervision;
7. That the duration of graduate medical education in the U.S. of all exchange visitor physicians be specified in advance of entering into such training, be limited, in general, to two years or less

and be subject to extension only on the request initiated by the governmental and institutional or agency sponsors in their country of origin assuring them of employment on completion of the extended training period;

8. That the Directory of Approved Residencies identify the graduate medical education programs approved by the LCGME available to FMG's seeking educational opportunities as exchange visitors, and that the ECFMG be prepared to provide information to FMG's concerning the types of training offered (specialty or other), the number of training positions approved and the number of training positions filled. In addition ECFMG should provide current statistical data on the operational aspects of educational exchange programs, and periodic evaluation of whether these programs are achieving their assigned purposes and whether exchange visitor physicians are fulfilling the commitments made when they accepted a temporary visa to enter the U.S. for graduate medical education;
9. That, as an integral part of this country's international education and cultural exchange activities, Federal funds be authorized and appropriated on an annual basis to support this national coordinated graduate medical education program for exchange visitor physicians. Binational cost-sharing agreements should be encouraged and the participation and support of international agencies, such as WHO, should also be invited;
10. That the Congress be asked to review and reconsider those amendments to the Immigration and Naturalization Act enacted in 1970 (P.L. 91-225) that permit FMG's and other exchange visitors to convert a temporary visa granted for educational and cultural exchange purposes to permanent immigrant status; and
11. That the granting of H-1 temporary visas\* to FMG's be restricted to foreign nationals of "distinguished merit and ability" who have been invited by universities and other appropriate institutions and agencies to teach and conduct research. In addition, there should be continued monitoring of all H temporary visas issued to physicians and the regular reporting of the activity of the holders of such visas to concerned public and private agencies.

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\*\* The 1970 amendments to the Immigration and Naturalization Act (P.L. 91-225) redefine the H category of temporary visitors as follows: "(H) An alien having a residence in a foreign country which he has no intention of abandoning (1) who is of distinguished merit and ability and who is coming temporarily to the United States to perform services of an exceptional nature requiring such merit and ability; or (2) who is coming temporarily to the United States to perform temporary services or labor, if unemployed persons capable of performing such services or labor cannot be found in this country; or (3) who is coming temporarily to the United States as a trainee; and the alien spouse and minor children of any such alien specified in this paragraph if accompanying him or following to join him."

B. Recommendations on Foreign National Physicians Seeking Permanent Residence

Since 1962 over 47,600 FMG's, graduates of no less than 400 different foreign medical schools and representing over 100 nationalities, have been admitted to the United States as immigrants. The problems they face in qualifying for a license to practice medicine in one or another of the 55 licensing jurisdictions in the U.S. are primarily reflections of the wide variations that exist among countries in standards of medical education and of medical practice in those countries. The possession of a medical degree or even a license to practice medicine obtained in one country does not and should not qualify a physician automatically to practice in another; to disregard these considerations in the administration of our immigration policies will deleteriously affect existing standards of medical education and medical practice in the U.S.

The CCME recommends:

1. That physicians seeking admission to the United States as permanent residents be neither discriminated against in obtaining immigration visas nor assigned special occupational preference for such visas based solely on their possession of a medical degree; physicians (and other health personnel so designated--nurses, pharmacists, physical therapists and dieticians) should not be singled out for blanket (Schedule A) certification by the Labor Department for the issuance of preference of non-preference immigration visas;
2. That in order to qualify for the Labor Department certification required prior to the issuance of a Third or Sixth Preference or a Non-Preference immigration visa,\* an applicant physician should be required to demonstrate to the Department of Labor that he possess an unrestricted license to practice medicine in a State or other licensing jurisdiction of the United States or has reasonable prospect of qualifying for such licensure; i.e., he has been accepted for graduate medical education in a program approved by the Liaison Committee on Graduate Medical Education;
3. That, in granting labor certification to an alien physician applying for an immigration visa, the Department of Labor should

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\* The 1965 Amendments to the Immigration and Naturalization Act (P.L. 89-236) assigned preferential status to immigrants with close kin living in the United States or with professional and technical skills in short supply in this country. Third Preference applies to "qualified immigrants who are members of the professions, or who because of their exceptional ability in the sciences or the arts will substantially benefit prospectively the national economy, cultural interests or welfare of the United States." Sixth Preference applies to "qualified immigrants who are capable of performing specified skilled or unskilled labor, not of a temporary or seasonal nature, for which a shortage of employable and willing persons exists in the United States."

not base its determination on the premise that there is an insufficient supply of physicians in the United States as a whole; consideration should be given to the wide range of physician-population ratios that exist in different geographic areas of the United States and to the specialty distribution of physicians already in the area in which the alien physician proposes to locate;

4. That physician shortage areas in the U.S. designated by the Labor Department for immigration purposes should coincide with physician shortage areas designated by the Department of Health, Education, and Welfare for the assignment of National Health Services Corps personnel, for service repayment of Physician Shortage Area Scholarships and of Health Professions Educational Loans or for other purposes; such shortage area determinations should also be subject to review by and concurrence of state or regional health planning authorities including appropriate medical societies;
5. That state legislatures and medical licensure boards adopt eligibility requirements and qualifying procedures for licensure that are uniform for all states and apply equally to U.S. and foreign medical graduates;
6. That eligibility requirements for medical licensure in every State, applicable to both FMG's and USMG's, include two or more years of supervised graduate medical education at the residency level in a program approved for such training by the Liaison Committee on Graduate Medical Education;
7. That eligibility requirements for graduate medical education at the residency level include the provision that all physicians, FMG's as well as USMG's, entering such training meet in a manner to be determined by the LCGME, a minimally acceptable standard of professional competence requisite for assuming responsibility for patient care under supervision;
8. That, in addition, FMG's who have received their undergraduate medical education in a medical school not accredited by the Liaison Committee on Medical Education and who are seeking appointment to an approved residency program be required to demonstrate through appropriate testing procedures acceptable to the LCGME that they meet standards of educational attainment equivalent to those expected of graduates of accredited medical schools and that they have achieved an effective mastery of the English language;

9. That the responsibility for coordination of educational programs for exchange visitor physicians referred to in Section A above be assigned by the Coordinating Council on Medical Education for:
  - a) the administration of improved screening procedures, preferably as a prerequisite for the issuance of immigration visas to FMG's seeking to immigrate to the U.S. and seeking appointments in approved residency programs, and
  - b) the planning of a comprehensive national program designed to improve the professional and related skills of all immigrant physicians seeking to engage in the practice of medicine in the United States;
10. That the Directory of Approved Residencies list the graduate medical education programs approved by the LCGME available to immigrant physicians seeking residency level training, the types of training offered (specialty or other), the number of positions offered and the number of positions filled (including the respective number of FMG's and USMG's in training in the same program). ECFMG, in addition to providing current statistical data on the operational aspects of these programs, should evaluate periodically whether these programs are fulfilling their assigned purposes and whether immigrant physicians are being effectively integrated within the U.S. health care system; and,
11. That exceptions to these policies and procedures for immigrant physicians seeking to practice their profession in the U.S. be permitted only under unusual circumstances, e.g., when a distinguished medical educator or research scholar seeks to take up permanent residence in the U.S.

C. Recommendations on U.S. Nationals Studying Medicine Abroad

Between 4,000 and 6,000 American citizens are believed to be currently enrolled in medical schools located outside of the U.S., almost 1,800 of them in a single medical school in Mexico. Such an aggregated estimate of U.S. nationals studying medicine abroad is equivalent to the total enrollment of ten to fifteen average-sized medical schools in this country. Only the 16 Canadian schools, providing educational opportunities for approximately 100 U.S. medical students, are subject to accreditation procedures identical with those required of all U.S. medical schools.

U.S. students contemplating medical education abroad have not had access to reliable information about entrance into U.S. graduate medical education or requirements of the various licensing jurisdictions for full and unrestricted licensure on their return to the United States. The number of U.S. applicants to medical schools will far exceed for some years to come those who can be accepted in U.S. medical schools despite the significant and continuing expansion of enrollments in existing U.S. schools and the establishment

of a number of new schools in the past 10 years.

In 1968, two of the major national medical associations most directly concerned with medical education in the U.S. jointly endorsed the position "that all medical schools should now accept as a goal the expansion of their collected enrollments to a level that permits all qualified applicants to be admitted. As a nation we should address the task of realizing this policy goal with a sense of great urgency." This aim has not been achieved and does not appear to be feasible today. An alternate and sounder approach is now in order, namely "a broadly based effort...to study the long term future requirement for physicians in the United States, with enrollment levels to be adjusted accordingly."<sup>8</sup>

The CCME recommends:

1. That continuing efforts be made to establish and maintain the United States as self-sufficient in meeting its future health manpower needs;
2. That current selection procedures assuring every American interested in and qualified for entry to the study of medicine an equal opportunity to compete for admission to an accredited U.S. medical school be continued; unsuccessful candidates should be encouraged through counseling to consider entering an alternative career rather than to enroll in a medical school abroad where the quality of medical education may fail to meet U.S. standards and may be inappropriate to U.S. health care needs; those who counsel students in high schools and colleges should be better informed about medical education and practice in giving guidance to students who indicate an interest in medicine;
3. That U.S. medical schools continue and expand their use of the Coordinated Transfer Application System (COTRANS) established by the Association of American Medical Colleges in 1970 to facilitate and accelerate the reintroduction into the mainstream of American medical education larger numbers of qualified U.S. nationals enrolled in foreign medical schools;
4. That, pending the achievement of the objective set forth in recommendation C-1 above, funds should be sought from a variety of sources to assist U.S. medical schools in underwriting the special costs of educational programs for U.S. nationals who are studying in or have graduated from foreign medical schools; and
5. That eligibility requirements for U.S. nationals who have obtained their medical degrees in a medical school not accredited by the Liaison Committee on Medical Education and who seek to enter graduate medical education or to qualify for medical licensure in the U.S. be identical with those required of other graduates of unaccredited medical schools.

D. Recommendations on U.S. Assistance to Medical Education in Developing Countries

The "pull factors" drawing these FMG's to the U.S. have been reasonably well defined. The "push factors" impelling larger and larger numbers of recent medical graduates in developing countries to seek additional training or career opportunities elsewhere than in their homeland are beginning to attract the attention they deserve. Basic responsibility for the resolution of the economic, cultural, professional, and other problems underlying these international migrations must rest within the countries in which these physicians originate. Nonetheless, the United States, when requested, can, with great benefit to its own interest, materially assist lesser developed countries in finding solutions to their most pressing medical educational problems.

The National Council for International Health (NCIH)\* has provided a means of coordinating discussion and informational exchange among organizations and individuals interested in the international field. NCIH should be encouraged to continue these efforts and to serve as a focal point for informational and monitoring purposes for international medicine educational programs in the developing countries.

The CCME recommends:

1. That an educational exchange program be established as an integral component of U.S. foreign policy to assist, on request, developing countries in strengthening their own medical and other health professions schools; the objective of this program should be to encourage those countries to establish and maintain educational institutions meeting their own educational standards and which prepare indigenous health manpower specifically to utilize locally available resources in meeting local needs;
2. That the U.S. encourage and support training programs for teachers in developing countries to improve and enhance faculty competence in schools of medicine and of related health professions and occupations and, on request, assist in the development of the educational resources in those countries including audiovisual materials and library facilities. Where appropriate, these international educational activities should be conducted on a multi-national regional basis.
3. That the U.S. participate in and support the current efforts of the World Health Organization and associated United Nations agencies to study in detail the worldwide problems resulting from the international migration of physicians and nurses;

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\* NCIH was established in 1971 by 10 national sponsoring organizations, with ex-officio membership from 4 governmental agencies. One of its purposes is "to provide a means by which the problems of international health can be approached jointly by the various agencies and disciplines concerned with it; to achieve definition of common problems; and to seek rational and practical solutions to problems so defined."



4. That cooperative educational programs be developed as a demonstration of the potentials of medical educational exchange for mutual benefit in which medical schools in developing countries share with U.S. medical schools in the training of both American and foreign medical graduates;
5. That the U.S. encourage both directly and through WHO and other U.N. agencies programs of education in preventive medicine, public health and comprehensive health care in developing countries to meet the mass needs of rural and urban populations now receiving little or no health care;
6. That provisions be made for students and graduates of both domestic and foreign medical schools to participate in programs experimenting with new ways of meeting community needs in the U.S. and in developing countries and to provide these students and physicians an educational experience demonstrating approaches which may assist them in developing similar or related activities in their respective countries.

### III. Implementation of Recommendations

The 45 recommendations offered above parallel and in some instances coincide with the recommendations made in 1967 by the Panel on Foreign Medical Graduates and endorsed by the National Advisory Commission on Health Manpower. Many of the highly pertinent recommendations made at that time have not yet been implemented. In the interim the full effect of the 1965 and 1970 amendments to the Immigration and Naturalization Act has greatly encouraged FMG's to migrate to the United States. This migration has been particularly from less economically advanced countries where standards of medical education and medical practice are not equivalent with our own and cultural backgrounds are quite different from those of the U.S. These amendments have also resulted in a marked increase in the number of foreign national physicians remaining permanently in the U.S. Moreover, in this same period, larger and larger numbers of U.S. nationals have enrolled in medical schools abroad. The majority of these U.S. nationals fail to complete the required course of instruction; even those who obtain a foreign medical degree encounter serious difficulties in qualifying for medical licensure in the U.S.

In setting forth its recommendations, the National Advisory Commission expressed the hope that they be implemented through the voluntary acceptance of appropriate responsibility, by government, universities, the health professions and other organizations and agencies. Until now there has been no organizational framework on a nationwide scale for such coordinated voluntary action related to key educational components of the issues and problems involving FMG's.

It is the conclusion of the Coordinating Council on Medical Education that the CCME and its associated Liaison Committees are an appropriate mechanism

to implement the recommendations on foreign medical graduates set forth in this report. Accordingly, to accelerate such implementation, the CCME recommends:

1. That the five parent bodies of the CCME approve the adoption of this report as a policy statement of the Coordinating Council on Medical Education;
2. That all national professional and related organizations and concerned Federal and state agencies adopt the recommendations set forth in this report as the framework for sound national policies affecting the graduate medical education and professional function of foreign medical graduates in the U.S. health care system;
3. That the CCME and its associated Liaison Committees in cooperation with all concerned Federal, state and private agencies promote and assist in the early implementation of each of the recommendations set forth in this report; and
4. That CCME assume responsibility for the preparation of reports of progress achieved in the implementation of the recommendations set forth in this policy statement and that an initial progress report be issued not later than two years following adoption of this policy statement.

Adopted by the CCME and approved by  
its following parent organizations as  
of June, 1976

American Board of Medical Specialties  
American Hospital Association  
American Medical Association  
Association of American Medical Colleges  
Council of Medical Specialty Societies

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8. Schofield, J.R., The Stork, Admission to Medical Schools, Going to a Foreign School and Other Hazards, (Editorial), Journal of Medical Education 48:693-695, July, 1973.

TABLE 1

## U.S. Physician (M.D.) Supply

1963-1974

	1963	1974	Increase	
			Number	Percent
Total Physicians	275,140	379,748	104,608	38.0
U.S. Medical Graduates	238,571	296,833	58,262	24.4
Foreign Medical Graduates	36,569	82,915	46,346	126.7
Canadian	5,644	6,411	767	13.6
Other	30,925	76,504	45,579	147.4
Percent FMG's	13.3	21.8		
Physicians/10,000 Population				
Total	14.5	17.9		
U.S.M.G.'s	12.6	14.0		
FMG's	1.9	3.9		
Total U.S. Population (in thousands)	189,242	211,381	22,139	11.7

Source: Physician Distribution and Medical Licensure in the United States, 1974, and Special Tabulations, Center for Health Services Research and Development, American Medical Association, Chicago.

Population Estimates and Projections. Current Population Reports Series P-25, Nos. 538, 615. U.S. Department of Commerce.

TABLE 2

Licentiates Representing Additions  
to the Medical Profession in the U.S.  
1950 - 1974

	<u>Total</u>	<u>USMG's</u> <u>Number</u>	<u>FMG's</u>	
			<u>Number</u>	<u>Percent</u>
1950	6,002	5,694	308	5.1
1951	6,273	5,704	450	7.2
1952	6,885	6,316	569	8.3
1953	7,276	6,591	685	9.4
1954	7,917	7,145	772	9.8
1955	7,737	6,830	907	11.7
1956	7,463	6,611	852	11.4
1957	7,455	6,441	1,014	13.6
1958	7,809	6,643	1,166	14.9
1959	8,269	6,643	1,626	19.7
1960	8,030	6,611	1,419	17.7
1961	8,023	6,443	1,580	19.7
1962	8,005	6,648	1,357	17.0
1963	8,283	6,832	1,451	17.5
1964	7,911	6,605	1,306	16.5
1965	9,147	7,619	1,528	16.7
1966	8,851	7,217	1,634	18.5
1967	9,427	7,346	2,081	22.1
1968	9,766	7,581	2,185	22.4
1969	9,978	7,671	2,307	23.1
1970	11,032	8,016	3,016	27.3
1971	12,257	7,943	4,314	35.2
1972	14,476	7,815	6,661	46.0
1973	16,689	9,270	7,419	44.5
1974	16,706	10,093	6,613	39.6
<b>TOTAL</b>	<b>231,667</b>	<b>178,328</b>	<b>53,220</b>	<b>23.0</b>
<b>Averages:</b>				
1950-54	6,871	6,290	557	8.1
1955-59	7,747	6,634	1,113	14.4
1960-64	8,050	6,628	1,423	17.7
1965-69	9,434	7,487	1,947	20.6
1970-74	14,232	8,627	5,605	39.4
1950-74	9,267	7,133	2,129	23.0

Source: Medical Licensure 1973, Statistical Review, Journal of the American Medical Association, 229:445-456, July 22, 1974.

Physician Distribution and Medical Licensure in the U.S., 1974.  
Chicago: Center for Health Services Research and Development,  
American Medical Association, 1975.

TABLE 3

M.D. Licentiates, Additions to  
the Medical Profession  
1974

States (or Territories) with 50 Percent or more Initial Licenses Granted to FMG's

<u>STATE</u>	<u>USMG's</u>	<u>FMG's</u>	<u>TOTAL</u>	<u>PERCENT FMG's</u>
Guam	2	6	8	75.0
Virgin Islands	1	1	2	50.0
Maine	118	122	140	87.1
North Dakota	8	51	59	86.4
Delaware	3	18	21	85.7
Puerto Rico	61	120	181	66.3
Michigan	348	597	945	63.2
New Jersey	93	121	214	56.5
Illinois	350	690	1,040	66.3
District of Columbia	61	364	425	85.6
Virginia	173	433	606	71.5
Florida	241	503	744	67.6
New York	1,176	1,325	2,501	53.0
West Virginia	40	70	110	63.6
TOTAL - Above 14 States	2,573	4,415	6,988	63.2
TOTAL - ALL STATES	10,093	6,613	16,706	39.6

Source: Physician Distribution and Medical Licensure in the U.S., 1974. Chicago: Center for Health Services Research and Development, American Medical Association, 1975.

TABLE 4

STUDENTS AND GRADUATES IN MEDICAL AND BASIC SCIENCE SCHOOLS

<u>YEAR</u>	<u>NUMBER OF SCHOOLS</u>	<u>1ST YEAR ENROLLMENT</u>	<u>TOTAL ENROLLMENT</u>	<u>GRADUATES</u>
1930-31	76	6,456	21,982	4,735
1940-41	77	5,837	21,379	5,275
1950-51	79	7,177	26,186	6,135
1960-61	86	8,298	30,288	6,994
1970-71	103	11,348	40,487	8,974
1971-72	108	12,361	43,650	9,551
1972-73	112	13,726	47,546	10,391
1973-74	114	14,185	50,886	11,613
1974-75	114	14,963	54,074	12,714
1975-76	114	15,295	55,818	N.A.

Source: Information published annually, Medical Education in the United States, The Journal of the American Medical Association. 1975-76 data were derived from Datagram, Medical Student Enrollment, 1971-72 through 1975-76. Journal of Medical Education 50:144-146, February 1976.

TABLE 5

AMA Approved Internships and Residencies  
1950-51 to 1970-71  
and 1973-74

	<u>Total Positions Offered</u>	<u>Total Positions Filled</u>	<u>Positions Filled by U.S. &amp; Can. Graduates</u>	<u>Positions Filled by FMG's*</u>	<u>Positions Vacant</u>
<u>Internships</u>					
1950-51	9,370	7,030	6,308	722	2,340
1955-56	11,616	9,603	7,744	1,859	2,013
1960-61	12,547	9,115	7,362	1,753	3,432
1965-66	12,954	9,670	7,309	2,361	3,284
1970-71	15,354	11,552	8,213	3,339	3,802
1973-74	12,165	11,031	7,606	3,425	1,134
<u>Residencies</u>					
1950-51	19,364	14,495	13,145	1,350	4,869
1955-56	26,516	21,425	17,251	4,174	5,091
1960-61	32,786	28,447	20,265	8,182	4,339
1965-66	38,979	31,898	22,765	9,133	7,074
1970-71	46,584	39,463	26,495	12,968	7,121
1973-74	54,137	49,078	34,159	14,923	4,819
<u>Both</u>					
1950-51	28,734	21,525	19,453	2,072	7,209
1955-56	38,132	31,028	24,995	6,033	7,104
1960-61	45,333	37,562	27,627	9,935	7,771
1965-66	51,933	41,568	30,074	11,494	10,358
1970-71	61,938	51,015	34,708	16,307	10,923
1973-74	66,302	60,109	41,765	18,348	5,953

\*Exclusive of graduates of Canadian medical schools

Source: Medical Education in the United States January 1973-74  
Table 24, Journal of the American Medical Association 231  
Supplement, January 1975.



TABLE 6

Applicants, Acceptances, New Entrants  
and First Year Enrollment, U.S. Medical  
Schools, 1963-64 to 1974-75

<u>First-Year Class</u>	<u>Number of Applicants</u>	<u>Number of Applications</u>	<u>Applications Per Individual</u>	<u>Accepted Applicants</u>	<u>New Entrants</u>	<u>First-Year Enrollment*</u>	<u>Percent of Total Applicants Accepted</u>
1963-64	17,668	70,063	4.0	9,063	8,565	8,842	51.3
1964-65	19,168	84,571	4.4	9,043	8,587	8,836	47.2
1965-66	18,703	87,111	4.7	9,012	8,554	8,760	48.2
1966-67	18,250	87,627	4.8	9,123	8,775	8,991	50.0
1967-68	18,724	93,332	5.0	9,702	9,314	9,473	51.8
1968-69	21,118	112,195	5.3	10,092	9,740	9,863	47.9
1969-70	24,465	133,822	5.5	10,547	10,269	10,422	43.1
1970-71	24,987	148,797	6.0	11,500	11,169	11,348	46.0
1971-72	29,172	210,943	7.2	12,335	12,088	12,361	42.3
1972-73	36,135	267,306	7.4	13,757	13,352	13,677	38.1
1973-74	40,506	328,275	8.1	14,335	13,771	14,159	35.4
1974-75	42,624	362,376	8.5	15,066	N.A.	14,763	35.3

\* Includes previously enrolled students.

Source: Dubè, W.F., Applicants for the 1972-73 Medical School Entering Class, Datagram, Journal of Medical Education 48:1161-1163, December 1973; Applicants for the 1973-74, Medical School Entering Class, Datagram, Journal of Medical Education 48:1070-1072, November 1974, and Applicants for the 1974-75 First-year Medical School Class, Datagram, Journal of Medical Education 50:1134-1136, December 1975.

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*Orbbie -  
Here's the paper I  
told you about. The  
AAMC proposal is the  
current one pp. 57-60.  
-Jennifer*

LEGAL ANALYSIS OF  
PUBLIC DISCLOSURE REQUIREMENTS  
RELEVANT TO APPLICATIONS  
FOR BIOMEDICAL RESEARCH GRANTS

BY

JAMES H. WALLACE, JR.  
THOMAS C. ARTHUR

Prepared Under  
Contract No. PD-171701-6  
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### SUMMARY OF MEMORANDUM

Disclosure of the contents of grant applications made to HEW by research scientists is governed by the Freedom of Information Act ("FOIA"). As currently interpreted, the FOIA requests disclosure by HEW of the contents of grant applications, unless such contents contain "trade secret" or other confidential "commercial" materials. The courts have rejected the argument that a research scientist's ideas, even if they have no business value, are so analogous to trade secrets that they should be exempt from disclosure under FOIA Exemption 4, which covers trade secrets and other business confidential materials.

Whether the "peer review" meetings which evaluate grant applications need be opened to the public is governed by the Federal Advisory Committee Act ("FACA"). Under an amendment to the FACA contained in the recent Sunshine Act, the FACA now clearly requires that these meetings be open to the public, except for those portions of a meeting which would result in the disclosure of the same type of commercial trade secret information covered by FOIA Exemption 4.

This principle of disclosure of the contents of research grant applications could conceivably endanger the proprietary patent and trade secret rights of a researcher. Even where the FOIA does not require the disclosure of ideas which may be patentable, it is not always possible to detect a patentable idea at the time a research grant application might be made public. Premature disclosure, however, of a research idea which would otherwise be patentable, may infringe upon the researcher's future right ever to get a patent.

There are meritorious interests both for and against disclosure of the contents of research applications. The meritorious interests against disclosure are (1) the researcher's interest in controlling to some degree the timing of the release of his own ideas, which are his "stock in trade," and (2) his interest in preserving patent or trade secret rights by preventing premature disclosure of his application.

Meritorious interests for disclosure of the contents of research grant applications are (1) general first amendment and FOIA interests in public disclosure of information used in government decision-making, i.e., the "public's right to know," (2) the necessity for public information so that the press and public interest groups can protect the rights of human subjects, and (3) the interest in free exchange of scientific ideas.

Several proposals have been made to solve these conflicting interests. None of these proposals gives full protection to all of the interests involved, and it is doubtful that any such proposal could be created. The authors of this report make their own proposal, which they hope more adequately protects the competing interests than the prior proposals that they have examined.



## INTRODUCTION

This memorandum has been prepared for the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to assist it in performing its duties under Public Law 94-278. That statute requires the Commission to report by December 31, 1976 to the Committee on Interstate and Foreign Commerce of the House of Representatives and the Committee on Labor and Public Welfare of the Senate on the implications of disclosure of research protocols, hypotheses and designs received by the Department of Health, Education and Welfare in connection with applications for grants or contracts under the Public Health Service Act.<sup>1/</sup>

### A. The Commission and Its Duties

The Commission was established by Title II of Public Law 93-348 ("Natural Research Service Award Act of 1974"). It is composed of eleven members appointed by the Secretary of HEW from individuals distinguished in the fields of medicine, law, ethics, theology, the biological, physical, behavioral and social sciences, philosophy, humanities, health administration, government and public affairs. In appointing members of the Commission, the Secretary of HEW is required to consider recommendations from the National Academy of Sciences and other appropriate entities.<sup>2/</sup>

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<sup>1/</sup> Act of April 22, 1976, Pub. L. No. 94-278, § 301(a)(1), 90 Stat. 406. Portions of this memorandum contain materials previously copyrighted by James H. Wallace, Jr., 1975 and 1976, and are reproduced herein solely for the Commission's use in connection with the purpose of this Memorandum.

<sup>2/</sup> Act of July 12, 1974, Pub. L. No. 93-348, § 201(b)(1), 88 Stat. 342 (codified at 42 U.S.C. § 2891-1 n. (Supp. V, 1975)).

The Commission's original charter was to conduct research regarding the basic ethical principles which should underlie biomedical and behavioral research involving human subjects. From that study, the Commission was to develop guidelines which should be followed in such research to assure that it be conducted in accordance with these principles, and to make recommendations to the Secretary of HEW for such administrative regulations as would be appropriate to apply these ethical precepts to biomedical and behavioral research conducted or supported by the United States.<sup>3/</sup> Pursuant to the statutory mandate, the Commission has recommended such regulations to the Secretary of HEW, and the Secretary has promulgated those regulations.<sup>4/</sup>

In Public Law 94-278 Congress gave the Commission the additional task of conducting

" . . . an investigation and study of the implication of the disclosure to the public of information contained in research protocols, research hypotheses, and research designs obtained by the Secretary of Health, Education and Welfare . . . in connection with an application or proposal . . . to the Secretary for a grant, fellowship, or contract under the Public Health Service Act."<sup>5/</sup>

Congress also requested the President's Biomedical Research Panel to conduct a similar investigation, but required the panel to make

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<sup>3/</sup> Pub. L. No. 93-348, § 202(a).

<sup>4/</sup> 45 C.F.R. Part 46 (1975); 40 Fed. Reg. 11854 (Mar. 13, 1975), 40 Fed. Reg. 33428 (Aug. 8, 1975).

<sup>5/</sup> Pub. L. No. 94-278, § 301(a)(1).

its report to Congress no later than June 30, 1976.<sup>6/</sup> The panel's report has been made public.<sup>7/</sup>

In particular, Congress requested the Panel and the Commission to consider the following:

- (1) The number of requests made to the Secretary of HEW for disclosure of information contained in such research protocols, hypotheses and designs, and the interests represented by the persons making such requests;
- (2) The purposes for which such information was used; and
- (3) The effect of the disclosure of such information on -
  - (a) Proprietary interests in the research protocols from which such information was disclosed and on patent rights;
  - (b) The ability of HEW's peer review systems to insure high quality federally funded research; and
  - (c) The protection of the public against research which represents an unreasonable risk to human subjects and the adequacy of informed consent procedures.<sup>8/</sup>

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<sup>6/</sup> Pub. L. No. 94-278, §§ 301(a)(1) & (2)(A).

<sup>7/</sup> President's Biomedical Research Panel, Disclosure of Research Information, DHEW Pub.No. (OS) 76-513 (June 30, 1976). This publication will be cited in this memorandum as "President's Panel Report."

<sup>8/</sup> Pub. L. No. 94-278, § 301(a)(1).

B. The Scope of This Memorandum

This memorandum has been requested by the Commission for its use in preparing the report required by Congress. This memorandum will, after summarizing HEW's funding process for biomedical research, first summarize the pertinent statutory provisions which now govern the disclosure of research protocols, hypotheses, and designs contained in grant applications made to HEW. The memorandum will also consider the current statutes which govern the publicity which must be given to the "peer review" process which is used by HEW to evaluate grant applications. In connection with this description of the current legal framework, the memorandum will analyze the impact of these statutes upon the ability of the federal government to protect proprietary interests -- copyright, trade secrets and patent rights -- of individual scientists and institutions applying for federal research grants.

The memorandum will then attempt to establish a conceptual framework against which the present legal framework can be evaluated. This conceptual framework will attempt to describe the conflicting interests affected by current disclosure requirements, which interests the Commission must weigh in deciding whether to recommend to the Congress any alteration of present disclosure requirements. This section of the memorandum will also describe and evaluate the specific arguments which have been put forth for and against disclosure.

After setting up this conceptual framework, the memorandum will describe and evaluate in terms of the conflicting interests here identified the more prominent of the proposed alternatives

to the present disclosure requirements which have been made by, among others, the American Association of Medical Colleges and the report of the President's Biomedical Research Panel.

In addition, we set forth our own recommendations for balancing the legitimate interests in disclosure of research information, including the protection of human subjects, against the interests of research institutions and the public in protection of their materials from premature disclosure.

## I. HEW GRANT APPLICATION PROCESS

A brief description of the contents of applications for medical research grants from HEW and of HEW's process for evaluating and approving such grant applications is necessary for an understanding of the matters to be discussed in this report.<sup>9/</sup>

The Department of Health, Education and Welfare makes available under the Public Health Service Act<sup>10/</sup> grants for biomedical and behavioral research under the auspices of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration relating to the causes, diagnosis, prevention and treatment of the diseases or health problems to which the activities of the Institutes and Administration are directed. These grants are available for research conducted at the NIH and the ADAMHA, at non-federal public institutions and at non-profit private institutions. Profit-making organizations are not eligible for these grants.<sup>11/</sup>

HEW regulations<sup>12/</sup> require that grant applications set forth the nature, duration, purpose and plan of any proposed research project. In addition, they require the name and qualifications of the principal investigator and the qualifications of his principal staff members, the total facilities and resources which will

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<sup>9/</sup> This process is described in detail in Washington Research Project, Inc. v. HEW, 504 F.2d 238, 241-43 (D.C. Cir. 1974), cert. denied, 421 U.S. 963 (1975). The text of this decision is attached as Appendix A.

<sup>10/</sup> 42 U.S.C. § 2897-1 (Supp. V, 1975).

<sup>11/</sup> 42 U.S.C. § 2897-1(a)(1) (Supp. V, 1975).

<sup>12/</sup> 42 C.F.R. Part 52 (1975).

be available in the project, and a justification of the amount of grant funds requested.<sup>13/</sup>

In practice, grant applications commonly describe the basic idea or ideas to be investigated, the proposed methodology for conducting such investigation and a description of the proposed experimental program which will be used to verify the hypotheses under investigation. Where grant applications are successful, the researcher from time to time submits progress reports detailing the data being developed, and may also apply for a renewal of the grant to support either a continuation of the project or further research based upon the ideas developed in the first project.

Per HEW regulations, grant applications are either approved, deferred because of lack of funds or a need for further evaluation, or disapproved in whole or in part by the Secretary of HEW or his delegate.<sup>14/</sup> This decision is based upon the evaluation of each research proposal by an appropriate National Advisory Council which is appointed to advise him.<sup>15/</sup> The majority of the members of these councils are not civil servants, but instead are persons drawn from the fields of science and medicine to advise HEW as to disposition of research grants. These councils make their recommendations primarily based upon summaries of the grant applications made by so-called "initial review groups" (IRGs), which consist of from ten to twenty outside consultants drawn from the particular specialized disciplines

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<sup>13/</sup> 42 C.F.R. § 52.12 (1975).

<sup>14/</sup> 42 C.F.R. § 52.13(b) (1975).

<sup>15/</sup> 42 C.F.R. § 52.13(a) (1975).

within the broad field of biomedicine in which grant applications are made. Only one employee of the IRG, the Executive Secretary, <sup>16/</sup> is an HEW employee. The others are outside consultants.

The process by which the IRGs evaluate the grant applications is as follows. Each grant application is initially assigned to one member of the IRG as a "primary assignee," and to one or more other members with secondary responsibilities. These assignees undertake to evaluate the application and gather such additional information as may be necessary, including visits by IRG members to the facility at which the applicant proposes to conduct the research. Thereafter, these outside consultants prepare a report of their observations. When the outside consultants have completed their work, the assignees then write an evaluation of each application, which is circulated to the whole IRG, together with the application, and any site visit reports, prior to its next meeting. (IRGs meet three times yearly.) At the meeting, the application is discussed at length and a recommendation voted upon. If approval is recommended, the proposal is also given a relative priority rating, since the cost of all proposals deemed worthy of funding may exceed the funds available. In that event, the priority rating <sup>17/</sup> is used to allocate the scarce monetary resources.

Following the IRG meeting, the Executive Secretary prepares a summary of the IRG's observations and deliberations, which draws upon their site visit reports, if any. This report (or "pink sheet")

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<sup>16/</sup> Washington Research Project, Inc. v. HEW, supra, 504 F.2d at 242-43.

<sup>17/</sup> Id. at 242.



describes the proposal and recounts the considerations that led the IRG to recommend approval or disapproval. It contains, among other things, an opinion of the professional qualifications of the sponsor and evaluation of his competence and facilities. It also contains the IRG's evaluation of the risk to human subjects, if any. If there is a minority of two or more, the minority's view is also summarized, although these views are not attributed by name to individual IRG members.<sup>18/</sup>

These Summary Statements and accompanying applications are then submitted to the National Advisory Councils for their evaluation. The appropriate National Advisory Council may approve, disapprove, defer consideration of, or require additional IRG consideration of any application. While on occasion it does reject an IRG's recommendation, ordinarily it gives primary attention to policy direction and emphasis, generally acting on applications in subject matter groups. Applicants are notified of the outcome, but only 90% of those receiving approval are actually funded, due to limitations on funds.<sup>19/</sup>

Thus the materials generated by HEW's research grant application process are:

- (1) the grant applications filed by researchers seeking federal funding of their proposed research;
- (2) the reports of initial on-site visits made by selected IRG members.

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<sup>18/</sup> Id. at 242-43.

<sup>19/</sup> Id. at 243.

- (3) the evaluations of the proposed research prepared by assigned IRG members for discussion by the entire group;
- (4) the Summary Statements ("pink sheets") containing the IRG recommendations prepared by the Executive Secretary.

For purposes of this legal analysis, these documents will be referred to as grant applications (category 1 above), IRG working papers (categories 2 and 3), and Summary Statements (category 4).

We will now examine the extent to which current law mandates their disclosure to the public.

II. SUMMARY OF KEY STATUTES RELATING  
TO GOVERNMENT DISCLOSURE

The principal laws governing the disclosure of information by government agencies are the Freedom of Information Act ("FOIA"),<sup>20/</sup> the Privacy Act,<sup>21/</sup> the Federal Advisory Committee Act ("FACA")<sup>22/</sup> and the Sunshine Act.<sup>23/</sup> This section of the memorandum briefly summarizes each of these statutes and analyzes their interrelationship and impact on HEW grant documentation.

A. The Freedom of Information Act

1. Disclosure Requirements of the FOIA

The Freedom of Information Act mandates disclosure of much of the federal bureaucracy's vast collection of documents. Per the statutory scheme, there are three levels of disclosure of agency records.

First, the Act requires publication in the Federal Register of the agency's organization, rules of procedure and substantive rules of general applicability.<sup>24/</sup>

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20/ 5 U.S.C. § 552 (1970), as amended, (Supp. V, 1975). The entire FOIA, as amended, is attached as Appendix B.

21/ Act of Dec. 31, 1974, Pub. L. No. 93-579, 88 Stat. 1897 (codified at 5 U.S.C. § 552a (Supp. V, 1975)). The Privacy Act is attached as Appendix C.

22/ Act of Oct. 6, 1972, Pub. L. No. 92-463, 86 Stat. 770 (codified at 5 U.S.C. Appendix I (Supp. V, 1975)). The FACA is attached as Appendix D.

23/ Act of Sept. 13, 1976, Pub. L. No. 94-409, 90 Stat. 1241 (codified at 5 U.S.C. § 552b). The Sunshine Act is attached as Appendix E.

24/ 5 U.S.C. § 552(a)(2)(1970), as amended, (Supp. V, 1975).

Second, the agency must make available for public inspection all final opinions, policy statements and interpretations, and staff manuals not published in the Federal Register.<sup>25/</sup>

Third, the FOIA provides that all other documents in the agency's possession shall, unless specifically exempted, be promptly made available upon request.<sup>26/</sup>

## 2. The FOIA's Nine Exemptions

Carved out of the Act's broad disclosure mandates are nine statutory exemptions:

1. National Security materials classified per executive order to be kept secret in the interest of "national defense or foreign policy."<sup>27/</sup>
2. Internal Personnel Rules of the agency.<sup>28/</sup>
3. Specific Statutory Exemptions.<sup>29/</sup> By this provision the Act incorporates about 100

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<sup>25/</sup> 5 U.S.C. § 552(a)(3)(1970), as amended, (Supp. V, 1975).

<sup>26/</sup> 5 U.S.C. § 552(a)(3)(1970), as amended, (Supp. V, 1975).

<sup>27/</sup> 5 U.S.C. § 552(b)(1)(1970), as amended, (Supp. V, 1975). See generally "Top Secret" -- the National Security Exemption to the Freedom of Information Act As Viewed in the Public Interest, Address by James H. Wallace, Jr., before Federal Bar Association Seminar on "Openness in Government: A New Era," San Francisco, California (May 10, 1976).

<sup>28/</sup> 5 U.S.C. § 552(b)(2)(1970). See, e.g., Department of Air Force v. Rose, 48 L.Ed.2d 11 (April 21, 1976).

<sup>29/</sup> 5 U.S.C. § 552(b)(3)(1970).

exemptions scattered throughout various statutes.<sup>30/</sup>

4. "[T]rade secrets and commercial or financial information obtained from a person and privileged or confidential."<sup>31/</sup>
5. "[I]nter-agency or intra-agency memorandums or letters."<sup>32/</sup> This exemption applies only to such documents as would not be available to a party in litigation with the agency.<sup>33/</sup>
6. Invasion of Personal Privacy. This section covers such items as personnel and medical files.<sup>34/</sup>
7. "[I]nvestigatory files" are exempted under a complex set of conditions.<sup>35/</sup>
8. "[F]inancial Institutions'" data in the possession of agencies charged with regulating them.<sup>36/</sup>
9. "Geological and geophysical" data concerning wells.<sup>37/</sup>

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<sup>30/</sup> A collection of these is contained in House Comm. on Government Operations, 86th Cong., 2d Sess., Federal Statutes on the Availability of Information (Comm. Print 1960). See H.R. Rep. No. 1497, 89th Cong., 2d Sess 10 (1966); Attorney General's Memorandum on the Public Information Section of the Administrative Procedure Act 31-32 (1967). This exemption was recently amended in the Sunshine Act, Pub. L. No. 94-409 (Sept. 13, 1976). This amendment may limit the number of statutes included under Exemption 3, but the effect of the amendment has not been decided by any court decisions.

<sup>31/</sup> 5 U.S.C. § 552(b) (4) (1970). See generally Wallace, Proper Disclosure and Indecent Exposure: Protection of Trade Secrets and Confidential Commercial Information Supplied to the Government, 34 Fed. Bar J. 295 (1975).

<sup>32/</sup> 5 U.S.C. § 552(b) (5) (1970).

<sup>33/</sup> See, e.g., NLRB v. Sears, Roebuck & Co., 421 U.S. 132 (1975).

<sup>34/</sup> 5 U.S.C. § 552(b) (6) (1970).

<sup>35/</sup> 5 U.S.C. § 552(b) (7) (1970), as amended, (Supp. V, 1975).

<sup>36/</sup> 5 U.S.C. § 552(b) (8) (1970).

<sup>37/</sup> 5 U.S.C. § 552(b) (9) (1970).

The FOIA is less than a model of legal draftmanship, resulting in extensive litigation as to the precise scope of the exemptions. The exemptions pertinent to HEW applications for grants and contracts are reviewed in depth in Part III.A of this memorandum.

B. The Privacy Act

The Privacy Act was passed (1) "to provide that individuals be granted access to records concerning them which are maintained by Federal Agencies," and (2) "to safeguard individual privacy from the misuse of Federal records."<sup>38/</sup>

The access aspect of the Privacy Act is directed primarily toward a person's right to inspect dossiers, personnel files and other data about himself, e.g., CIA and FBI files. There is the possibility that this aspect of the Privacy Act could be invoked by an individual seeking NIH grant documentation to the extent that such documents might be construed as a "system of records" and contain information on that specific individual.<sup>39/</sup>

The prevention of misuse objective of the Privacy Act is specifically implemented by § 2(b) of the Act, 5 U.S.C. § 552a(b): "No agency shall disclose any record . . . to any person . . . ." But this broad prohibition is weakened by several exceptions, including subparagraph (2) which specifically allows production

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<sup>38/</sup> 5 U.S.C. § 552a (Supp. V, 1975).

<sup>39/</sup> 5 U.S.C. §§ 552a(a)(4) & (d)(1) (Supp. V, 1975).

under the FOIA. Thus, privacy rights are protected by the standards of Exemption 6 (privacy) to the FOIA.<sup>40/</sup> The effect of the Privacy Act, then, is to make Exemption 6 of the FOIA mandatory rather than merely a permissive exemption, otherwise waivable by the agency.

C. The "Sunshine Act"

The "Government in the Sunshine Act"<sup>41/</sup> was passed in the most recent term of Congress, and signed by President Ford on September 13, 1976. The Sunshine Act declares the policy of the United States "that the public is entitled to the fullest practicable information regarding the decisionmaking processes of the Federal Government."<sup>42/</sup> In line with that policy, the Act's purpose is "to provide the public with such information while protecting the rights of individuals and the ability of the Government to carry out its responsibilities."<sup>43/</sup>

In order to achieve this purpose, the Act provides that meetings of federal agencies which are "headed by a collegial body composed of two or more individual members" shall be open to the public, unless there is a probability that an open meeting will result in the disclosure of the information specified

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<sup>40/</sup> 5 U.S.C. § 552(b)(6)(1970).

<sup>41/</sup> Pub. L. No. 94-409.

<sup>42/</sup> Pub. L. No. 94-409, § 2.

<sup>43/</sup> Pub. L. No. 94-409, § 2.

in one of ten exemptions.<sup>44/</sup> These exemptions, which are mostly drawn from the FOIA's exemptions, are intended to prevent the disclosure of the following:

1. National Security materials classified per executive order to be kept secret in the interest of "national defense or foreign policy."<sup>45/</sup>
2. Internal Personnel rules and practices of an agency.<sup>46/</sup>
3. Specific Statutory Exemptions. As with the FOIA, by this provision the Sunshine Act incorporates a variety of exemptions scattered throughout various statutes.<sup>47/</sup>
4. Trade Secrets and other commercial and financial information.<sup>48/</sup>
5. Criminal Accusations, or any discussion of the formal censure of any person.<sup>49/</sup>
6. Invasion of Personal Privacy, i.e., "information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy."<sup>50/</sup>
7. Investigations, subject to the same complex set of conditions in FOIA Exemption 7.<sup>51/</sup>

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<sup>44/</sup> 5 U.S.C.A. §§ 552b(a)(1) & (2), 552b(c)(1976 Supp.). The Act does not apply to the agencies' staff meetings. 5 U.S.C.A. § 552b(a)(2)(1976 Supp.).

<sup>45/</sup> 5 U.S.C.A. § 552b(c)(1)(1976 Supp.).

<sup>46/</sup> 5 U.S.C.A. § 552b(c)(2)(1976 Supp.).

<sup>47/</sup> 5 U.S.C.A. § 552b(c)(3)(1976 Supp.).

<sup>48/</sup> 5 U.S.C.A. § 552b(c)(4)(1976 Supp.).

<sup>49/</sup> 5 U.S.C.A. § 552b(c)(5)(1976 Supp.).

<sup>50/</sup> 5 U.S.C.A. § 552b(c)(6)(1976 Supp.).

<sup>51/</sup> 5 U.S.C.A. § 552b(c)(7)(1976 Supp.).



8. Financial Institutions' data obtained by the agencies responsible for their regulation.<sup>52/</sup>
9. Premature Disclosure. Meetings may be closed where (A) in the case of an agency regulating securities, commodities or currencies, open meetings would be likely to lead to undue financial speculation or endanger the stability of any financial institution; or (B) in the case of any agency, be likely to significantly frustrate implementation of a proposed agency action.<sup>53/</sup>
10. Agency Litigation. Meetings regarding an agency's participation in court, arbitration, or administrative litigation.<sup>54/</sup>

The Sunshine Act exemptions are precisely the same as those to the FOIA, except that the Sunshine Act contains no equivalent to FOIA Exemptions 5 (intra- and inter-agency memoranda) and 9 (geological and geophysical data concerning wells). Conversely, there is no FOIA counterpart to Sunshine Act Exemptions 5, 9 and 10.

As the Sunshine Act has just been passed, there have as yet been no judicial interpretations of it, nor does any federal agency have any experience with it.

D. Federal Advisory Committee Act

The Federal Advisory Committee Act<sup>55/</sup> applies to advisory committees, boards, commissions, councils and similar groups which

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<sup>52/</sup> 5 U.S.C.A. § 552b(c) (8) (1976 Supp.).

<sup>53/</sup> 5 U.S.C.A. § 552b(c) (9) (1976 Supp.).

<sup>54/</sup> 5 U.S.C.A. § 552b(c) (10) (1976 Supp.).

<sup>55/</sup> 5 U.S.C. Appendix I (Supp. V, 1975).

have been established to advise officers and agencies of the executive branch of the Federal Government. One of the purposes of the FACA is the same as the basic purpose of the Sunshine Act: to require that the activities of these advisory committees, and the advice that they give to the government, be conducted in the open, unless covered by narrow exemptions.

Before the passage of the Sunshine Act, the FACA required each meeting of an advisory committee to be open unless the subject matter of the meeting would be the same as in one of the nine FOIA exemptions.<sup>56/</sup> With the passage of the Sunshine Act, which contained exemptions specifically crafted for the purpose of determining whether meetings should be opened or closed, Congress amended the FACA to substitute the ten Sunshine Act exemptions for the nine FOIA exemptions as the only excuses for closing parts of an advisory committee meeting.<sup>57/</sup>

The significance of this change is that it removes FOIA Exemption 5 as a reason for closing Federal Advisory Committee meetings. The breadth of FOIA Exemption 5, an exemption for internal memoranda containing advice to agency decision-makers, was so great as possibly to negate the purpose of the Act and was the source of several lawsuits. The recent Sunshine Act amendments to the FACA make it clear this possible blanket exception to the FACA's general open meeting requirements is no longer applicable.

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<sup>56/</sup> 5 U.S.C. Appendix I, § 10 (Supp., V, 1975).

<sup>57/</sup> Pub. L. No. 94-409, § 5(c).

III. APPLICABILITY OF CURRENT STATUTORY  
REQUIREMENTS TO DISCLOSURE OF  
RESEARCH DESIGNS AND OPEN  
"PEER REVIEW" MEETINGS

A. Disclosure of Research Designs

The principal bases for possible nondisclosure of research designs are to be found in FOIA Exemptions 4 (trade secrets), 5 (inter- and intra-agency memoranda) and 6 (privacy).

1. FOIA Exemption 4: "[T]rade secrets and commercial or financial information obtained from a person and privileged or confidential."

Congress has recognized that allowing the public to monitor governmental decision-making does not necessarily require that the government facilitate competitive snooping. Thus, in order to balance the competing interests of full government disclosure, on the one hand, and the need to protect valuable secrets, on the other hand, the Freedom of Information Act provides Exemption 4, which expressly excludes from the Act's mandatory production requirements "trade secrets and commercial or financial information obtained from a person and privileged or confidential."<sup>58/</sup> Other statutory safeguards are also available.<sup>59/</sup>

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<sup>58/</sup> 5 U.S.C. § 552(b)(4) (1970).

<sup>59/</sup> See, e.g., 18 U.S.C. § 1905 (1970). Per the 1966 House Report, there are "nearly 100 statutes or parts of statutes which restrict public access to specific Government records." H.R. Rep. No. 1497, 89th Cong., 2d Sess. 10 (1966). See also Administrator, FAA v. Robertson, 422 U.S. 255, 265 (1975).

a. The Ambiguities of Exemption 4

But Exemption 4 of the Act is pregnant with ambiguities. In the first place, it is not at all clear whether the Exemption embraces two or three categories of information. One interpretation is that it covers (1) "trade secrets," (2) "commercial or financial information," and (3) "privileged or confidential" matters obtained from a person outside the government. The interpretation that "confidential" matters not otherwise within the first two categories are exempt was adopted by several early rulings.<sup>60/</sup>

A possibly narrower interpretation is that "privileged or confidential" modifies "commercial or financial" information. Under this view, the exemption is limited to (1) "trade secrets" and (2) "commercial or financial" information which is also "privileged or confidential."<sup>61/</sup>

In any event, regardless of which of these interpretations is followed, there is the further problem as to what "confidential" means. Some courts have indicated that "commercial or financial"

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60/ GSA v. Benson, 415 F.2d 878, 881 (9th Cir. 1969); Barceloneta Shoe Corp. v. Compton, 271 F. Supp. 591, 594 (D.P.R. 1967); Consumers Union of United States v. VA, 301 F. Supp. 796, 802-04 (S.D.N.Y. 1969), appeal dismissed as moot, 436 F.2d 1363 (2d Cir. 1971). See Davis, The Information Act: A Preliminary Analysis, 34 U. Chi. L. Rev. 761, 787-88 (1967); Katz, The Games Bureaucrats Play: Hide and Seek Under the Freedom of Information Act, 48 Tex. L. Rev. 1261 (1970); Note, 88 Harv. L. Rev. 470, 472 n.13 (1974).

61/ E.g., Brockway v. Department of Air Force, 518 F.2d 1184 (8th Cir. 1975); Getman v. NLRB, 450 F.2d 670, 673 (D.C. Cir.), stay denied, 404 U.S. 1204 (1971) (Black, acting circuit judge); Grumman Aircraft Eng'r Corp. v. Renegotiation Bd., 425 F.2d 578 (D.C. Cir. 1970); Consumers Union of United States v. VA, 301 F. Supp. 796, 802 (S.D.N.Y. 1969), appeal dismissed as moot, 436 F.2d 1363 (2d Cir. 1971); cf. Bristol-Myers Co. v. FTC, 424 F.2d 935, 938-39 (D.C. Cir.), cert. denied, 400 U.S. 824 (1970).

information is "confidential" and thus within the Exemption merely if the supplier of information "wishes" to keep it confidential or if there is an express or implied promise to hold it confidential.<sup>62/</sup> Other courts have taken the view that something is "confidential" if it is "customarily" held in confidence.<sup>63/</sup>

However, in National Parks & Conservation Ass'n v. Morton,<sup>64/</sup> the District of Columbia Circuit drastically narrowed the meaning of "confidential" and thus the scope of the Exemption itself by establishing a two-pronged confidentiality test. Under Morton, it must be shown that disclosure would either "impair the ability of the Government to obtain this information in the future" or cause "substantial harm to the competitive positions of the parties from whom it has been obtained."<sup>65/</sup>

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<sup>62/</sup> GSA v. Benson, 415 F.2d 878, 881 (9th Cir. 1969) (dicta); Barceloneta Shoe Corp. v. Compton, 271 F. Supp. 591, 594 (D.P.R. 1967); H.R. Rep. No. 1497, 89th Cong., 2d Sess. 10 (1966) ("Moreover, where the Government has obligated itself in good faith not to disclose documents or information which it receives, it should be able to honor such obligations"); S. Rep. No. 813, 89th Cong., 1st Sess. 3 (1965).

<sup>63/</sup> Sterling Drug Inc. v. FTC, 450 F.2d 698, 709 (D.C. Cir. 1971); Grumman Aircraft Eng'r Corp. v. Renegotiation Bd., 425 F.2d 578, 580-81 (D.C. Cir. 1970); see also S. Rep. No. 813, 89th Cong., 1st Sess. 9 (1965).

<sup>64/</sup> 498 F.2d 765 (D.C. Cir. 1974).

<sup>65/</sup> National Parks & Conservation Ass'n v. Morton, 498 F.2d 765, 770-71 (D.C. Cir. 1974), noted in 88 Harv. L. Rev. 470 (1974). The competitive harm requirement appears to be a stricter standard than is normally applied in trade secret cases. See generally Doerfer, The Limits on Trade Secret Law Imposed by Federal Patent and Anti-trust Supremacy, 80 Harv. L. Rev. 1432, 1435-39 (1967); R. Milgrim, Trade Secrets, § 6.02, at 6-6 (1967). Moreover, some confidential protections are of a constitutional nature. See, e.g., United States v. Nixon, 418 U.S. 683, 703-16 (1974) (qualified Presidential immunity); Gravel v. United States, 408 U.S. 606 (1972) (Congressional immunity); NAACP v. Alabama, 357 U.S. 449 (1958) (membership list protected by Fourteenth Amendment).

Over and above the Morton test, the Congressional intent to construe FOIA exemptions narrowly has been implemented in other respects. For example, Exemption 4 has been held not to apply to confidential information unless it was obtained "from a person" outside the government.<sup>66/</sup> Moreover, the burden of proving that a document is within the exemption usually rests with the government or the party seeking to protect his proprietary information.<sup>67/</sup> Courts are now insisting on a "detailed justification" in support of asserted applicability of Exemption 4, by requiring "specific factual or evidentiary material" regarding:

- "(a.) the extent to which data of the sort in dispute is customarily disclosed to the public . . . .
- "(b.) the extent to which disclosure of this information will impair the government's ability to obtain necessary information of this type in the future . . . .
- "(c.) the extent to which disclosure of the information will cause substantial harm

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<sup>66/</sup> Soucie v. David, 448 F.2d 1067, 1078 (D.C. Cir. 1971) (U.S. Office of Science and Technology held not a person outside of government; thus report on SST must be produced, but material supplied by others contained in report may be deleted); Grumman Aircraft Eng'r Corp. v. Renegotiation Bd., 425 F.2d 578, 582 (D.C. Cir. 1970); GSA v. Benson, 415 F.2d 878, 881 (9th Cir. 1969); Consumers Union of United States v. VA, 301 F. Supp. 796, 802-03 (S.D.N.Y. 1969), appeal dismissed as moot, 436 F.2d 1363 (2d Cir. 1971).

<sup>67/</sup> National Cable Television Ass'n v. FCC, 479 F.2d 183, 193 (D.C. Cir. 1973); Getman v. NLRB, 450 F.2d 670, 677 (D.C. Cir.), stay denied, 404 U.S. 1204 (1971) (Black, acting circuit judge); Bristol-Myers Co. v. FTC, 424 F.2d 935, 938 (D.C. Cir.), cert. denied, 400 U.S. 824 (1970) ("[T]he statutory scheme, however, does not permit a bare claim of confidentiality to immunize agency files from scrutiny."). Thus, in camera inspection is required); M.A. Schapiro & Co. v. SEC, 339 F. Supp. 467, 470-71 (D.D.C. 1972).

to the competitive position of the person from whom the information is obtained, . . . and

"(d.) the extent to which any harms of the type mentioned in (b.) and (c.) could be reduced or eliminated by nondisclosure of the identity of the person submitting the information in dispute."<sup>68/</sup>

b. Examples of Matters Covered by Exemption 4

Because so many litigated FOIA Exemption 4 cases are determined on procedural or technical grounds, very few cases have addressed themselves to the types of proprietary data which are covered by the Exemption.<sup>69/</sup> But there are a few helpful decisions.

In McCoy v. Weinberger,<sup>70/</sup> Exemption 4 was held to forbid production of documents showing income, balance sheets, profit

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<sup>68/</sup> Pacific Architects & Eng'rs v. Renegotiation Bd., 505 F.2d 383, 385 (D.C. Cir. 1974). See also Gifford-Hill & Co. v. FTC, Civil No. 75-1033, at 12-14 (D.D.C., January 13, 1976).

<sup>69/</sup> Of course, the presence of Exemption 4 material in a document does not necessarily preclude production. If the sensitive material can easily be stricken, the remainder of the document, not otherwise exempt, should be produced. E.g., National Cable Television Ass'n v. FCC, 479 F.2d 183, 193 (D.C. Cir. 1973); Grumman Aircraft Eng'r Corp. v. Renegotiation Bd., 425 F.2d 578, 582 (D.C. Cir. 1970); Bristol-Myers Co. v. FTC, 424 F.2d 935, 938-39 (D.C. Cir.), cert. denied, 400 U.S. 824 (1970). Cf. EPA v. Mink, 410 U.S. 73 (1973). But cf. Sears v. Gottschalk, 357 F. Supp. 1327, 1329 (E.D. Va. 1973), aff'd, 502 F.2d 122 (4th Cir. 1974), cert. denied, 422 U.S. 1056 (1975) (where large number of documents containing proprietary information, government is not required to delete sensitive parts and produce documents). See also amended 5 U.S.C. § 552(b), Supp V (1975) ("Any reasonably segregable portion of a record shall be provided . . ."); Freedom of Information Act Amendments, Pub. L. No. 93-502, § 552(b), 88 Stat. 1561 (Nov. 21, 1974), amending 5 U.S.C. § 552 (1970).

<sup>70/</sup> 386 F. Supp. 504 (W.D. Ky. 1974).

and loss statements, statistics of occupancy and costs. In National Parks & Conservation Ass'n v. Morton,<sup>71/</sup> contractors' records in the possession of the government disclosing sales statistics, inventory levels, and salaries were held exempt from disclosure. Exemption 4 was held to justify withholding abandoned patent applications in Sears v. Gottschalk.<sup>72/</sup>

On the other hand, the courts have held that Exemption 4 does not apply in a number of situations. Getman v. NLRB<sup>73/</sup> rules that Exemption 4 did not prevent production of names and addresses of employees eligible to vote in labor elections. In Getman, there was no showing of any competitive impact resulting from the disclosure. Ditlow v. Volpe<sup>74/</sup> rejected the claim that material submitted to the National Highway Traffic Safety Administration by General Motors relating to pending Corvair litigation was covered by Exemption 4. Per the court, there must be a showing that the item is "independently confidential," a burden which the NHTSA failed to sustain.<sup>75/</sup>

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<sup>71/</sup> 498 F.2d 765 (D.C. Cir. 1974).

<sup>72/</sup> 357 F. Supp. 1327 (E.D. Va. 1973), aff'd, 502 F.2d 122 (4th Cir. 1974), cert. denied, 422 U.S. 1056 (1975).

<sup>73/</sup> 450 F.2d 670, 673 (D.C. Cir.), stay denied, 404 U.S. 1204 (1971) (Black, acting circuit judge).

<sup>74/</sup> 362 F. Supp. 1321 (D.D.C. 1973), rev'd on other grounds, 494 F.2d 1073 (D.C. Cir.), cert. denied, 419 U.S. 974 (1974).

<sup>75/</sup> Id. at 1326.



c. Interrelationship between Exemption 4 and Other Statutory Protections

A determination that Exemption 4 (or any other exemption) applies does not end the required legal analysis to ascertain whether the proprietary materials will be protected. Other questions involve whether the FOIA itself precludes production of the document if the government wants to produce it, whether the court's general equity powers can be invoked to protect documents not within the specific FOIA exemptions, and whether other civil and criminal federal statutes relating to improper disclosure of confidential matters broaden or supplement Exemption 4.<sup>76/</sup>

Although there is some early authority for the proposition that courts can invoke their equitable powers to prevent disclosure of materials not specifically exempted by the Act,<sup>77/</sup> most courts have rejected this approach.<sup>78/</sup>

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76/ Exemption 3, 5 U.S.C. § 552(b)(3) (1970), covers matters that are "specifically exempted from disclosure by statute." Per the 1966 House Report, there are "nearly 100 statutes or parts of statutes which restrict public access to specific Government records." H.R. Rep. No. 1497, 89th Cong., 2d Sess. 10 (1966).

77/ Consumers Union of United States v. VA, 301 F. Supp. 796, 806-08 (S.D.N.Y. 1969), appeal dismissed as moot, 436 F.2d 1363 (2d Cir. 1971) (Government's need for confidentiality outweighed requesting party's need for data).

78/ E.g., Getman v. NLRB, 450 F.2d 670, 677-80 (D.C. Cir.), stay denied, 404 U.S. 1204 (1971) (Black, acting circuit judge). But cf. Rose v. Department of Air Force, 495 F.2d 261, 269-70 (2d Cir. 1974), aff'd on other grounds, 48 L.Ed.2d 11 (April 21, 1976) (court can weigh equities in refusing production under Exemption 6 relating to personal privacy).

The FOIA's Exemption 3 precludes production of documents "specifically exempted from disclosure by statute."<sup>79/</sup> In Administrator, FAA v. Robertson,<sup>80/</sup> the Supreme Court rejected arguments that Exemption 3 embraces only those statutes which specify documents "precisely" or "by describing the category in which they fall." Instead the Court recognized the applicability of Exemption 3 to nearly 100 nondisclosure statutes.<sup>81/</sup>

One of these nondisclosure statutes, Section 1905 of the Criminal Code,<sup>82/</sup> prohibits unauthorized disclosure by government officials of various information, including "trade secrets." Although arguments that Exemption 4 is broadened by Section 1905 have been rejected,<sup>83/</sup> Section 1905 can prevent discretionary disclosure of proprietary information which falls within Exemption 4.<sup>84/</sup> The United States Court of Appeals for the District of Columbia in its

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<sup>79/</sup> 5 U.S.C. § 552(b) (3) (1970) (emphasis added).

<sup>80/</sup> 422 U.S. 255 (1975).

<sup>81/</sup> Id. at 265.

<sup>82/</sup> 18 U.S.C. § 1905 (1970). Exemption 3 was recently amended to read as follows:

"(3) specifically exempted from disclosure by statute . . . , provided that such statute (A) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (B) establishes particular criteria for withholding or refers to particular types of matters to be withheld." Pub. L. No. 94-409, § 5(b).

<sup>83/</sup> E.g., Grumman Aircraft Eng'r Corp. v. Renegotiation Bd., 425 F.2d 578, 580 n.5 (1970).

<sup>84/</sup> Charles River Park "A", Inc. v. HUD, 519 F.2d 935, 941-43 (D.C. Cir. 1975).

amended Charles River Park "A", Inc. v. HUD<sup>85/</sup> opinion indicates that the government's violation of statutory safeguards against disclosure may be reviewed at the request of the aggrieved party under the Administrative Procedure Act.<sup>86/</sup> Thus, even if Exemption 4 itself does not prevent disclosure, the broad prohibitions of Section 1905 and other federal statutes as implemented by private parties' use of the APA may, as a practical matter, provide the same result.

d. Application of Exemption 4 to  
Contents of Application for HEW  
Grants

The "commercial" qualification in Exemption 4 was relied upon by defendants to protect them against disclosure of information in research grant applications submitted to the National Institute of Mental Health in Washington Research Project, Inc. v. HEW, supra.<sup>87/</sup> However, the circuit court of appeals rejected Exemption 4 protection of research protocols submitted to HEW by applicants affiliated with colleges, universities, and other admittedly non-commercial organizations on this ground,<sup>88/</sup> because they were not in the traditional categories of "trade secret" or "commercial information" usually kept confidential.<sup>89/</sup> The court

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<sup>85/</sup> 519 F.2d 935, 941 n.6 (D.C. Cir. 1975).

<sup>86/</sup> 5 U.S.C. §§ 551, et seq. (1970).

<sup>87/</sup> 504 F.2d at 238.

<sup>88/</sup> Id. at 244-45 n.6.

<sup>89/</sup> Id. at 244.

did not hold that an individual researcher or nonprofit institution could not have such trade secrets or commercial information which would be protected by Exemption 4.<sup>90/</sup> Instead, it merely stated that it was not faced with this issue, as there was no claim in the case that any of the protocols in question had any trade secret or commercial value.<sup>91/</sup>

The court declined to expand the scope of Exemption 4 by analogizing the information in the protocols to trade secrets. The court rejected plaintiff's argument that Exemption 4 should be expanded because "ideas are a researcher's 'stock in trade'" and their "misappropriation" might deprive a researcher of "career advancement and attendant material rewards in which the academic and scientific market deals."<sup>92/</sup>

Noting that the FOIA exemptions were to be construed narrowly,<sup>93/</sup> the court stated that the researchers' interest in nondisclosure was "surely more the interest of an employee than of an enterprise," and that it was "far from persuaded that Congress intended in Exemption 4 to apply terms drawn from the business context to the employment market."<sup>94/</sup> The court refused to

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<sup>90/</sup> For example, a non-profit institution could well be engaged in a commercial venture, such as patent licensing, to deploy its costs.

<sup>91/</sup> 504 F.2d at 244-45 n.6.

<sup>92/</sup> Id. at 244.

<sup>93/</sup> Id. at 245.

<sup>94/</sup> Id. (footnote omitted).

adopt an "analog[y] that lead[s] so far away from the plain meaning of Exemption 4."<sup>95/</sup>

Thus, the law today is that research protocols contained in grant applications to HEW must be made public under the FOIA, unless it can be shown that they contain traditional forms of trade secret or other valuable commercial information such as, for example, patentable ideas.

2. Exemption 5: "[I]nter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency."

The inter- and intra-agency exemption would obviously have no impact on the applications for research grants, since these are submitted to HEW from outside the federal government. However, the followup site reports, working papers and Summary Statements ("pink sheets") are created by IRGs, comprised of outside consultants appointed by HEW. The Washington Research Project, Inc. case held that the IRGs operate as "advisory committees" performing "staff functions through the medium of outside consultancy."<sup>96/</sup> It further found that the IRGs, having no autonomous decision-making authority, are not separate "agencies" within the meaning of the FOIA and that therefore the site reports, working papers, and "pink sheets" gener-

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<sup>95/</sup> Id.

<sup>96/</sup> Id. at 246.

ated by them are HEW intra-agency memoranda not disclosable under Exemption 5.<sup>97/</sup>

Of course, there may be circumstances under which all or parts of memoranda are producible despite their intra- or inter-agency character if "[a]ny reasonably segregable portion" is not otherwise exempt.<sup>98/</sup> In the case of Exemption 5, factual materials which could be separated from a memorandum otherwise exempt as a staff policy recommendation would be disclosable.

3. Exemption 6: "[P]ersonnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy."

Conceivably, research grant documentation could contain data within the scope of this exemption. For example, a research application could disclose prior research on identified human subjects. In such event, this exemption might preclude disclosure of the entire document. However, in the case of personnel records, the Supreme Court has endorsed the principle of production of the documents with names deleted.<sup>99/</sup>

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<sup>97/</sup> Id. at 248. See also Soucie v. David, 448 F.2d 1067, 1076 (D.C. Cir. 1971) (documents generated for an agency by outside consultant are agency documents for FOIA purposes).

<sup>98/</sup> 5 U.S.C. § 552(b) (1970). See EPA v. Mink, 410 U.S. 73, 89 (1974) (non-exempt portions of documents must be produced if segregable); cf. Montrose Chem. Corp. v. Train, 491 F.2d 63 (D.C. Cir. 1974) (documents exempt when disclosure of non-exempt facts would reveal decision-making process).

<sup>99/</sup> Department of Air Force v. Rose, 48 L.Ed.2d 11, 32 (April 21, 1976).

B. Disclosure of "Peer" Review Process

The disclosure problem with respect to the "peer review" evaluation process utilized by HEW has two aspects: (1) whether disclosure of the materials used by IRGs in making their evaluations and the Summary Statements containing those evaluations may be disclosed by HEW to the public under the FOIA, and (2) whether the deliberations of the IRGs may be made in private, confidential sessions, or whether these meetings, or at least transcripts of the meetings, need be made public under either the Federal Advisory Committee Act or the "Government in the Sunshine Act."

The FOIA issues were determined in the Washington Research Project case <sup>100/</sup> which, as stated above, also dealt with the status of the grant applications. Unlike its decision with respect to the grant applications, however, the court did not hold that either the working papers or the Summary Statements of IRGs need be made public under the FOIA. Instead, the court held these materials nondisclosable under FOIA exemption 5, <sup>101/</sup> which covers intra-agency memoranda prepared for use in agency decisionmaking. While HEW must make public its grant decisions, IRG recommendations need not be disclosed. <sup>102/</sup>

Whether IRG meetings need be opened to the public is determined by the Federal Advisory Committee Act, which governs the

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<sup>100/</sup> Washington Research Project, Inc. v. HEW, 504 F.2d 238 (D.C. Cir. 1970), cert. denied, 421 U.S. 963 (1975).

<sup>101/</sup> 5 U.S.C. § 552(b)(5) (1970).

<sup>102/</sup> 504 F.2d at 245-52. See Part III.A, supra.

meetings of advice-giving groups, such as IRGs composed mostly of private citizens.<sup>103/</sup>

As noted above,<sup>104/</sup> The FACA until recently permitted advisory committee meetings to be closed if any of the subjects contained in the nine FOIA exemptions were to be covered in the meeting. Citing FOIA Exemptions 4 (Trade Secrets and Other Confidential Information), 5 (Intra-agency Memoranda) and 6 (Privacy Information), NIH determined that the meetings of IRGs should be closed to the public. NIH's principal rationale was FOIA Exemption 5, claiming that the "peer review" process should be sheltered from public scrutiny in order that the IRG meetings could be frank and open, and so that IRG members would not be subject to harassment for the views stated in those meetings.<sup>105/</sup>

Congress in the Sunshine Act amended the FACA to require that advisory committee meetings be open to the public unless one of the Sunshine Act exemptions, rather than FOIA exemptions,

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<sup>103/</sup> Meetings of government agencies are covered by the Sunshine Act. The IRGs were determined not to be government agencies in the Washington Research Project case, supra, 504 F.2d at 245-48.

<sup>104/</sup> See Part II.D, supra.

<sup>105/</sup> See HEW Statement for the Record in Hearings Before the Subcomm. on Reports, Accounting and Management of the Senate Government Operations Comm. on S.2947 and S.3013 ("Metcalf Hearings"), 94th Cong., 2d Sess., at 238-39 (1976). Whether FOIA exemption 5 was an adequate justification for closing IRG and other advisory committee meetings was a hotly contested legal issue. See testimony of Reuben B. Robertson, III, Metcalf Hearings, at 141-43, and compare Washington Research Project, Inc. v. HEW, supra, 504 F.2d at 249 n.15 (dictum) with Wolfe v. Weinberger, 403 F. Supp. 238 (D.D.C. 1975). Insofar as future meetings are concerned, this legal dispute is now moot, as Congress has amended the FACA explicitly to remove FOIA Exemption 5 as a justification for closing advisory committee meetings. See Part II.D, supra.



applied.<sup>106/</sup> As a result, the main prop used by NIH for pre-serving the secrecy of IRG meetings, FOIA Exemption 5, has now been removed. In its place, NIH must rely upon "Sunshine Act" Exemptions 4, 6 and 9(B). Sunshine Act Exemptions 4 and 6 are identical to FOIA Exemptions 4 and 6, and provide little justifi-cation for secret IRG meetings except in unusual cases.

NIH is considering whether Exemption 9(B)<sup>107/</sup> might justify the continuation of closed meetings by IRGs. However, it is difficult to see how a good faith reading of the Act would permit continued closed meetings under this exemption. First, the exemp-tion is concerned with the timing of disclosure of the contents of the meeting, rather than, as is currently the practice, any kind of permanent exemption. Second, the proposed agency action being considered by an IRG, the ultimate award of a research grant, would not, in the usual situation, be likely to be frus-trated by an open IRG meeting.

Accordingly, it appears that the new amendments to the Federal Advisory Committee Act made in the recent Sunshine Act require that future IRG meetings be open to the public, except in unusual circumstances. A concomitant result will be that FOIA Exemption 5 might prove of little value in protecting the contents of the Summary Statements which result from the IRG

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<sup>106/</sup> See Part II.D, supra.

<sup>107/</sup> "Sunshine Act" Exemption 9(B) provides that meetings need not be opened to the public if a public meeting would "disclose information the premature disclosure of which would . . . be likely to significantly frustrate implementation of a proposed agency action . . . ." 5 U.S.C.A. § 552b(c)(9)(B)(1976 Supp.).

meetings, as well as the working papers used in those meetings. While these documents themselves will still be exempt from disclosure under FOIA, the exemption will not mean much if their contents are disclosed in the give and take of an open meeting under FACA.

Congress was aware of the effect of the recent Sunshine Act Amendment upon the peer review system of NIH. In the Conference Report on the Sunshine Act, <sup>108/</sup> the conferees stated that they were

". . . concerned about the possible effect of this amendment upon the peer review and clinical trial preliminary data review systems of the National Institutes of Health. The conferees thus wish to state as clearly as possible that personal data, such as individual medical information, is especially sensitive and should be given appropriate protection to prevent clearly unwarranted invasions of individual privacy. While the conferees are sympathetic to the concerns expressed by NIH regarding its committees' funding recommendations and analysis of preliminary data, the conferees are equally sympathetic to concerns expressed by citizens' groups that important fiscal and health-related information not be unnecessarily withheld from the public.

With these competing interests in mind, the conferees have secured assurances that the appropriate House and Senate committees will review the unique problems of NIH under the new standards."<sup>109/</sup>

Thus, it appears that Congress does intend that IRG meetings be open to the public, but with the understanding that the particular status of IRG meetings should be reviewed by Congress with the

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<sup>108/</sup> H. Rep. No. 94-1441, 94th Cong., 2d Sess. 26 (Aug. 26, 1976).

<sup>109/</sup> Id. at 26-27 (emphasis added).

prospect of future legislation in mind which may once again insulate the peer review process from public scrutiny.

IV. IMPACT OF PRESENT DISCLOSURE REQUIREMENTS  
UPON COPYRIGHT, TRADE SECRET AND PATENT  
RIGHTS OF GRANT APPLICANTS

The protection of intellectual property is derived in part from Article I, Section 8 of the Constitution: "The Congress shall have Power . . . [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." Congress has implemented this constitutional grant by passage of the Patent Code<sup>110/</sup> and the Copyright Act.<sup>111/</sup> In addition, the Supreme Court has recognized that state laws may be used to protect trade secrets.<sup>112/</sup>

Research design papers may contain a broad range of intellectual property protectable as copyrighted material, trade secrets or patentable inventions. In this section, we examine the extent to which disclosure by HEW may affect intellectual property rights.

A. Copyrights

The copyright statute gives the author of an original writing the exclusive right to prevent others from copying his work for a limited number of years.<sup>113/</sup> The protection is obtained by simply publishing the work together with a "copyright notice,"<sup>114/</sup> e.g., "Copyright 1976 by John Doe." Subsequently, registration is filed

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<sup>110/</sup> 35 U.S.C. § 1 et seq. (1970).

<sup>111/</sup> 17 U.S.C. § 1 et seq. (1970).

<sup>112/</sup> Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974).

<sup>113/</sup> 17 U.S.C. §§ 1, 24 (1970).

<sup>114/</sup> 17 U.S.C. § 10 (1970).

with the Copyright Office. <sup>115/</sup> A condition for obtaining a copy-right is that the work has not been previously published. <sup>116/</sup> Thus, to the extent the writing is released by HEW without copyright notice prior to the researcher's publication, the copyright may be entirely destroyed.

After January 1, 1978, a comprehensive revision of federal copyright law will become effective. For a work that is in existence, but has not been published and has not otherwise entered the public domain before that date, federal copyright protection will automatically extend to the work by operation of law (i.e., it need not be obtained by publication with notice). This copyright in the work may be preserved despite publication of the work without notice of the copyright if a claim of copyright is registered within five years of its publication.

Despite the preservation of copyright protection in the event of publication without notice, however, even after January 1, 1978, it will remain prudent for the author to attempt to insure that any release of the material bears a copyright notice, as suggested above. The new statutory provisions will not be tested in court until 1978 or later. Until then, it is not possible to predict what problems may arise which would endanger the copyright of an author relying upon the new procedures.

One possible solution to the problem would be for the author to include the following disclaimer in his submission to HEW:

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<sup>115/</sup> 17 U.S.C. §§ 11, 13 (1970).

<sup>116/</sup> 17 U.S.C. § 8 (1970).

"The author does not hereby authorize any publication or public release or distribution of this work by HEW. In the event that HEW does publish or publicly release or distribute the work, any so such published, released or distributed copies of the work bear the legend 'Copyright [author's name] [the year of publication],' in such fashion as to provide sufficient notice of copyright by the author in the work, under the applicable provisions of title 17 of the U.S. Code."

Another possible approach to this problem would be for HEW to agree to notify the researcher prior to release so that he may independently publish the material prior to HEW release or advise HEW to release the material with an appropriate copyright notice.

B. Trade Secrets

Trade secret protection is afforded to a wide variety of material -- both patentable and unpatentable -- e.g., secret formulae, customer lists, scientific protocols, sales data and the like.<sup>117/</sup> To the extent such materials are contained in HEW grant applications and disclosed to the public, the legal protection is destroyed.

To accommodate the researcher's trade secret rights, HEW could rely on Exemption 4 to prevent disclosure of the trade secret portions of the grant application -- if the researcher

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<sup>117/</sup> R. Milgrim, Trade Secrets ¶¶ 2.01-2.09 (1975). See, e.g., Kewanee Oil Co. v. Bicron Corp., supra note 112.

is operating for profit, or could license his idea to a commercial firm. See discussion of Washington Research Project, Inc. v. HEW, supra. Or, in the alternative, HEW could warn grant applicants that trade secrets will not be protected, and therefore either should not be included in the applications or should be protected under the copyright or patent statutes prior to submission.

C. Patent Rights

The U.S. Patent Code provides that the inventor or discoverer of a new, useful and non-obvious process, machine, manufacture or composition of matter or any new and useful improvement thereof may obtain a patent.<sup>118/</sup> With such a patent, the inventor may exclude others from producing his invention.<sup>119/</sup> But one of the conditions of United States patentability is that the invention not have been described in a publication, or in public use or on sale more than one year before the patent application.<sup>120/</sup> At the time of the grant application, the inventor may not be aware of the value of his invention or may believe further work is needed. Thus, to the extent that HEW discloses the invention more than one year before the filing of the patent application, legal complications arise which may forever preclude the obtaining of a United States patent.<sup>121/</sup>

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<sup>118/</sup> 35 U.S.C. §§ 101-03 (1970).

<sup>119/</sup> 35 U.S.C. §§ 281-84 (1970).

<sup>120/</sup> 35 U.S.C. § 102(b) (1970).

<sup>121/</sup> Id. See, e.g., In re Yarn Processing Patent Validity Litigation, 498 F.2d 271, 277-78 (5th Cir.), cert. denied, 419 U.S. 1057 (1974) (discussion of complexities involved in "experimental" exception to one-year rule).

Moreover, disclosure may cause even more severe problems respecting foreign patent rights, since many countries do not provide 122/ a grace period as is found in the United States statute.

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122/ E.g., the Republic of France has no comparable provision. See G. Hamelink, Manual Applications for Patents, Designs and Trade Marks Throughout the World -- France (Supp. No. 31, April 1975).



secret analogy argue that, in any event, the Government does not purchase outright research designs that are not publicly funded.

## 2. Inhibition of Detailed Grant Applications

The President's Biomedical Research Panel has expressed its concern that

"If researchers could expect that their own research ideas would be subject to disclosure that might result in imitation, or jeopardy to their intellectual property rights, it is possible that they would provide less informative applications and proposals for review."<sup>128/</sup>

In other words, the Panel fears that HEW's evaluation process for determining the recipients of research grants will be impaired because research scientists, fearing the evils of disclosure, will no longer provide adequate detail in their grant applications.

But the Panel's report admits that there has yet been no evidence of any decline in the specificity or quality of grant applications submitted to HEW since the Washington Research Project case forced disclosure of the contents of grant applications.<sup>129/</sup> The report also admits that according to a survey recently taken by the Panel, many FOIA requests for funded grant applications come from parties who desire to learn how to prepare a "winning application."<sup>130/</sup> It stands to reason that if scientists continue to desire the grants, they will file grant applications which give them the

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<sup>128/</sup> President's Panel Report at 20. This concern has also been expressed by the AAMC. See Morgan Article at 8.

<sup>129/</sup> President's Panel Report at 20.

<sup>130/</sup> Id. at 5-6.

best chance of succeeding. Obviously, an application which gives few details will have little chance of obtaining this funding. In balance, then, it seems likely that the scientist's reluctance to disclose details of his proposed research will be outweighed by his need to obtain funding.

### 3. Inhibition of Grant Applications

HEW has even argued that the evils of disclosing the contents of grant applications will discourage some scientists from submitting applications at all.<sup>131/</sup> This contention, however, is made in the face of the fact that the federal government is by far the principal source of support for the nation's health research and development. More than three-fifths of the expenditures for health, research and funding are from federal sources.<sup>132/</sup> As a practical matter, as long as HEW maintains its dominant position as a source of research funds, scientists will have little choice but to continue to apply to HEW for grants. It hardly seems realistic to believe that scientists will suppress their ideas rather than undergo the danger of premature disclosure in the HEW grant application process.

### 4. Patent and Other Proprietary Rights

Both the AAMC and the President's Panel emphasize the fact that premature disclosure of the contents of grant applications

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<sup>131/</sup> Testimony of Undersecretary of HEW Marjorie Lynch, Metcalf Hearings at 176.

<sup>132/</sup> President's Panel Report at 12.

may impinge upon a scientist's patentable ideas. The panel report especially emphasizes the importance of the patent system in encouraging private sources of money to develop and provide to the public new drugs and medical devices which arise out of biomedical research.<sup>133/</sup>

Both the Panel and AAMC recognize that the Washington Research Project case does not require explicitly that patentable rights in grant applications be revealed.<sup>134/</sup> HEW has taken the position that patentable ideas in these applications are covered by FOIA Exemption 4, since patentable ideas, even those held by a non-profit organization, are within the scope of commercial information protected by the exemption. AAMC points out, however, that the requirement that HEW screen each grant application for the presence of patentable rights imposes a large burden upon that agency.<sup>135/</sup> The President's Panel in addition notes that current judicial interpretations of FOIA Exemption 4 make the continued protection of patent rights "very unpredictable."<sup>136/</sup> Both groups emphasize the necessity for clarifying the scope of protection given to patent and trade secret rights actually involved in grant applications.

The danger to patent and trade secret rights is not as great when the researcher recognizes that his research idea may have commercial use. In such a case, HEW will not disclose them, since

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<sup>133/</sup> Morgan Article at 9-10; President's Panel Report at 8-17.

<sup>134/</sup> President's Panel Report at 10-11; Morgan Article at 9.

<sup>135/</sup> Morgan Article at 9.

<sup>136/</sup> President's Panel Report at 10.

even under Washington Research these ideas are covered by Exemption 4. In addition, if a researcher has ideas with commercial potential, he can opt for private financing from, e.g., a drug company for his research, and thereby avoid the necessity of preliminary disclosure.

To be sure, a researcher may prefer to develop his commercial ideas with public money, and thus be able to negotiate with private parties only after the utility of his idea has been proven. While this is obviously in the researcher's interest, as it would give him more bargaining power, it is not necessarily in the interest of the public.

The real danger to proprietary rights comes in the case where a patentable idea is developed in the course of a project which was originally intended to be basic research. There is an obvious unfairness in jeopardizing the patent rights of a scientist whose application may have been disclosed before anyone was aware that ideas of potential commercial value were involved.

#### 5. Dangers to the Public from Premature Disclosure

The final argument put forward is that premature disclosure of the ideas in grant applications may be harmful to the public, because the public may pressure physicians to use untested "miracle" treatments suggested by grant applications.

There are three fundamental flaws in this contention. First, there is the unacceptable suggestion that the public should be protected from information because they are incapable of dealing with it. This idea is completely antithetical to the concepts that lie

behind the First Amendment, the FOIA, the Sunshine Act and the  
FACA.<sup>137/</sup> Second, this contention implies that physicians allow  
their treatments to be prescribed by their patients, which is simply  
not true. State and federal laws governing the use of new drugs  
and medical treatments, as well as the code of ethics to which  
physicians subscribe, should be an adequate protection against  
this problem. Third, in most instances, there is a lag between  
the development of new treatments and their use by ordinary physi-  
cians. Thus, the more normal case is the problem of getting doc-  
tors to try the latest methods. This lag between the development  
of new ideas and their implementation indicates that the danger  
from premature use of untried treatments is, in most cases, remote.

6. Additional Specific Arguments Against  
Disclosure

In addition to these broad contentions, several practical  
arguments have also been advanced. The President's Panel has  
taken a survey of FOIA requests for the contents of grant appli-  
cations, the availability of which demonstrates to the panel the  
dangers of imitation and outright plagiarism of winning ideas.<sup>138/</sup>  
The Panel concludes from its survey that since only a handful of  
requesters sought to obtain information to protect human subjects,

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<sup>137/</sup> See, e.g., Consumers Union of United States v. VA, 301 F.  
Supp. 796, 806-08 (S.D.N.Y. 1969), appeal dismissed as moot, 436  
F.2d 1363 (2d Cir. 1971) (when only possible harm resulting from  
disclosure is public being misled, data not exempt from disclo-  
sure).

<sup>138/</sup> President's Panel Report at 5-7, 21.

protection of human subjects is not really a consideration here.<sup>139/</sup> There are at least two basic fallacies in this reasoning, however. First, while the Panel's survey showed that only three groups interested in protecting human subjects had made FOIA requests, we have been informed these three requesters accounted for a significant portion of total requests. Nor does the Panel take into account the fact that there does not need to be a large number of groups involved in this activity for its purpose to be accomplished, as only one active group is sufficient to uncover abuses and publicize them. In addition, the threat of public disclosure alone has an inhibiting effect upon experiments which are harmful to human subjects.

Second, the fact that many FOIA applications seek to discover the elements of winning grant applications does not necessarily indicate that plagiarism is afoot. This finding could as easily show that research scientists are trying to discover the standards imposed by IRGs so as to find how better to prepare grant applications. The Panel's survey could also demonstrate that research scientists are seeking to avoid unnecessary duplicative research by learning which areas have already been explored. A similar objective is sought by graduate students consulting a listing of dissertations in progress at the outset of their research.

Both groups also argue that protection of human subjects can be achieved without disclosure of grant applications. They point

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<sup>139/</sup> Id. at 6, 26.

to the review boards which have been established by HEW to protect human subject involved in clinical research projects. They contend that this institutional review process will be sufficient to the task, and that there is no need for this process to be conducted in public so the press and other interested members can monitor and hold accountable before the fact these review groups.<sup>140/</sup> But this argument flies in the face of the FOIA.

B. Interests in Disclosure

Proponents of disclosure of research protocols point to (1) the need for public disclosure to protect adequately human subjects of research projects; (2) the need to hold accountable HEW policy makers whose decisions have an effect on society's economic and physical well-being, i.e., "the public's right to know" information which is key to government decisions; (3) the fact that the public is paying for the research involved, so that any proprietary rights are being "purchased" by the government; and (4) the interest in free exchange to scientific ideas to stimulate further research. These contentions are discussed in detail below.

1. Protection of Human Subjects

The necessity for protecting human subjects of biomedical research is the interest which has been most actively considered by those who wish to compel disclosure of research protocols. The contention of these parties is that public scrutiny of these

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<sup>140/</sup> President's Panel Report at 24-26; Morgan Article at 9.

protocols is necessary to insure that incidents such as the notorious Alabama syphilis experiment are not repeated. These persons reject the idea that the scientists involved, with their given bias in favor of research, can be relied upon to protect this interest when their decisions are not available for public scrutiny. These persons also reject the idea that even the best review panel system, such as the one now set up by HEW, can be fully relied upon to protect this interest when the press and public have no access to their information.

In support of this contention, it should be noted that the activities of, for example, the CIA have long been monitored by select committees whose job is to insure that the CIA did not abuse its powers. Yet, as these congressional "watchdog" committees developed, they became infected with an institutional bias in favor of the agencies they were commissioned to oversee and were thus unable to check the abuses which have been subsequently discovered. Moreover, only with public disclosure of the CIA abuses has the public been able to make known its desire that its government curb these activities.<sup>141/</sup>

This is not to imply that the NIH has anything like a record of abuses such as has been discovered at the CIA. It is merely to make the point that the availability of information to the press and the public, and the threat of such availability, is a necessary

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<sup>141/</sup> For a general survey of CIA abuses which have finally come to light, see generally the "Church Committee" Report on the CIA, Final Report of the Select Comm. to Study Governmental Operations with Respect to Intelligence Activities, S. Rep. No. 94-755, 94th Cong., 2d Sess. (1976).



check on government decision-makers, and the only sure check against government abuse, even with the best thought out secret review processes.

Further, despite the contentions of the President's Panel based on its fallacious survey results, it is clear that the press and public interest groups interested in the protection of human subjects have used the FOIA to monitor research protocols involving those subjects. The inescapable conclusion is that some degree of disclosure about the intentions of researchers with human subjects is a desirable objective which should be considered in any attempt to resolve the conflicting interests here.

## 2. "Public's Right to Know"

This contention is akin to the first contention above, but has a broader scope. Simply stated, this is the interest of the public in knowing the contents of the competing proposals which are being considered by HEW for funding with public money. It is the interest which is represented basically in the First Amendment, the FOIA, the FACA, and the Sunshine Act, i.e., that the democratic process is best served by the availability of information relevant to government decision-making.

These are powerful ideas which lie at the very heart of this nation's system of government. To be sure, exceptions are made to this principle of openness, such as the nine FOIA exceptions -- but the guiding principle is that such exceptions are to be narrowly construed, and any proposal to add new exceptions bears a heavy burden of persuasion.

### 3. Government "Purchase" of Research Ideas

This is a further argument in support of the contention in number 2 above, that the public especially has a right to know contents of research designs which are funded by HEW, since the public's money is being used to further that research. Despite the contentions of the AAMC that the government is not "purchasing" these ideas, there could be no gainsaying the fact that the expenditure of the public's money does give the public some right, whether proprietary or not, to the benefits and contents of this research. In addition, some would contend that disclosure of even unfunded applications is not an unreasonable requirement for being considered for federal funding. In view of the government's near "monopoly power" over the research market, one can question the desirability of justifying federal "strings" on these funds with a glib "who pays the piper calls the tune" attitude. Instead, it could be argued that where scientists have no alternative but to submit to government regulations, those regulations should undergo extra scrutiny to insure that the government does not abuse its position by requiring scientists to submit to regulations which are not in fact in the interests of the public and the scientific community, or fair to the scientists themselves.

Thus, the government "purchase" idea, while superficially attractive, adds little to the discussion. The true question is not what the government's money permits it to require of recipients in the way of disclosure, but rather what the government should require. The question of disclosure should be considered in the

light of the public interest involved here, rather than any concept of the government as a commercial concern purchasing ideas.

#### 4. Free Exchange of Scientific Ideas

This is the concept that the freest flow of scientific ideas, unimpeded by undue secrecy, will in the long run promote the growth of knowledge. The intellectual "cross-fertilization" that comes from disclosure of research designs and ideas has historically been key to the growth of scientific knowledge, as scientists build upon other scientists' ideas.

Particularly significant has been the fact that sometimes a scientist will come up with an idea, but is unable to develop it fully. In such instances, other scientists have taken these ideas and brought them to fruition. Obviously, this could not happen without the free exchange of scientific ideas.

On the other hand, it should be remembered that opponents of free disclosure are not maintaining that the ideas should be permanently kept from open ventilation. Instead, they point to the fact that an academic researcher has a very real incentive to publish his work as soon as possible. They argue with some cogency that the amount of delay which would be involved in permitting the researcher to perfect the idea for publication is not a significant inhibition on the exchange of scientific ideas.

While this is true, there still remains the problem of unsuccessful research ideas which do not get published. With these ideas permanently secret, the possibility that another researcher could take another's idea and make it work is diminished, thus hampering the progress of medical research.

C. Openness of "Peer Review" Meetings

The above conflicting interests are also presented in the question whether the "peer review" meetings conducted by HEW should be open to the public, as now required by the FACA.

In addition to those contentions, HEW, the AAMC and the President's Panel all argue that closed IRG meetings are necessary for the "preservation of candor," the "free exchange of views," and to "avoid unnecessary interference" with agency decisionmaking.<sup>142/</sup>

These questions are based upon the fact that IRG meetings often discuss the qualifications of the researcher, as well as the merit of his research idea. The thought is that the scientists in the IRGs would be reluctant to discuss fellow scientists frankly if the meetings were held in public, or transcripts of the meetings were available for review.<sup>143/</sup> The AAMC contends that the result will be that the "grant review process could become very bland."<sup>144/</sup>

It is also contended that the result of open meetings will be that decisions may actually be made by small cliques meeting prior to the public meeting which ends up merely ratifying the results of these rump sessions.<sup>145/</sup>

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<sup>142/</sup> Testimony of HEW Undersecretary Majorie Lynch, in Metcalf Hearings at 176-77. See also Morgan Article at 8; President's Panel Report at 1.

<sup>143/</sup> Testimony of Dr. Donald S. Fredrickson, Director of NIH, in Metcalf Hearings at 236-37.

<sup>144/</sup> AAMC statement at 3, in Metcalf Hearings at 251.

<sup>145/</sup> Id. at 2, Metcalf Hearings at 250.

The other side of this argument is that the concepts of the First Amendment, the FOIA, the FACA and the Sunshine Act all require that government decision-making be made in public, both because public scrutiny is a check against abuse of power, and because the public cannot make informed decisions when kept in the dark.

On a more practical level, the opposing contention is that peer review meetings are not so very different from any other meeting which has to evaluate competing applications for federal largesse. Many collegial bodies such as city councils have always met in open meetings, and the record simply does not support the contention that the evaluation processes in these meetings are "bland."

Finally, there is an element of a "public is too stupid to judge" attitude in some of the arguments for secret meetings. It is a fair question whether these important decisions should be made only by members of the "guild" of professional scientists.

VI. EVALUATION OF PROPOSED ALTERNATIVES

As shown above, there is no simple answer to the problems presented by disclosure of grant applications and openness of peer review meetings. Forceful arguments can be made on both sides of each issue, and intelligent results can only be reached after consideration of the valid contentions on both sides and an attempt to resolve the conflicting interests in a way which most adequately protects the competing interests. This section of the memorandum will examine several alternatives which have been proposed to deal with this problem, and attempt to evaluate the strengths and weaknesses of each in view of the interests, contentions and arguments set forth in the preceding sections.

A. Proposals of the AAMC

The AAMC has recommended that NIH restructure its research grant application form to separate the investigator's research ideas from other parts of the application which describe proposed experiments involving human subjects. AAMC proposes legislation providing that the "basic idea" of the researcher would then be kept confidential while the rest of the application, including the matters describing tests on human subjects, be made public. In addition, the AAMC proposes that the remaining part of the grant application be made public after an unspecified "reasonable" period of time.<sup>146/</sup>

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<sup>146/</sup> Morgan Article at 11.

AAMC would also support legislation amending the FACA to provide that the NIH "peer review" process be conducted in closed meetings.<sup>147/</sup>

The AAMC proposal with respect to the grant applications is basically an attempt to resolve the conflicting interests of protecting human subjects and the several interests cited in favor of protecting confidentiality for at least a reasonable period. The AAMC proposal does not provide for the protection of the interests in public decision-making with respect to any other subject than protection of human subjects, other than the provision that the grant application contents would be made public after a "reasonable" period of time. Thus, public scrutiny of the proposal for spending the public's money could come only after the fact of funding, and could only serve as a check on future allocations.

Another built-in weakness of the AAMC proposal is the likelihood that the proposed separation of parts of the grant application may be easier in theory than in practice. It is not demonstrated that a method for segregating disclosable from non-disclosable information can be devised.

The proposal also fails to specify the time period before full disclosure would be made. It is not demonstrated that there is any uniform time period which would actually allow the researcher to bring his idea to fruition and publish it. This of course is a problem with any legislative solution to a problem, as hard lines

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<sup>147/</sup> Id.

have to be drawn which cannot possibly meet every case. The alternative is to purposely leave the time period open, to be decided on a case-by-case basis by HEW. This solution is likewise unsatisfactory in that it defines only what is reasonable in the select number of cases receiving judicial consideration.

The greatest weakness of the AAMC proposal, however, is the fact that the AAMC has not really established that there is any need to delay full disclosure. Instead of hard facts to support its contentions that researchers' ideas will be stolen or copied, that research grant applications will be inhibited, that patent rights will be lost and that the public will be harmed by having more knowledge than is good for it, the AAMC merely presents its unsupported predictions of what will happen.

The AAMC's proposal to close IRG meetings to the public makes no attempt to balance the conflicting interests presented by the issue of open versus closed IRG meetings. The AAMC proposal would protect against any dangers of inhibiting the IRG discussions by opening the meeting, but gives no consideration of the interests in open decision-making. HEW does announce which research proposals have been funded. The bases, however, of these HEW funding decisions will go unknown if the IRG meetings and accompanying papers remain confidential.

Significantly, AAMC did not propose any sort of "timing" proposal which would make the transcripts of IRG meetings public after a specified interval of time. To be sure, it is not clear whether there is any reasonable time period which would serve to



protect both the interests in favor of non-disclosure and the interests of public scrutiny of the IRG process.

Finally, the AAMC's proposal to close the IRG meetings is based only on speculation that the peer review process would become inhibited. This may be true, but as yet there is no factual evidence of it.

B. Proposals of the President's Panel

The President's Biomedical Research Panel has also proposed that the IRG meetings remain closed. As its solution is the same as AAMC's with regard to this issue, the discussion above is also applicable here.

The President's Panel has also proposed that legislation be passed providing that unfunded grant applications and proposals shall remain confidential permanently, while funded proposals would be made public when the grant funds have been received by the grantee institution. In the case of applications which contain clinical protocols there would then be a period of at least 30 days for public review of these protocols before the research could be commenced.

The President's Panel has further recommended that the Public Health Service Act be amended to "provide adequate protection for intellectual property rights" of investigators submitting applications in support of research, although the Panel does not explain what further practical protection would be afforded other than in its funded/unfunded proposal.

The main difficulty with the funded/unfunded proposal is that it is by no means clear that any of the interests which would be harmed by disclosure before the funding decision are any less harmed after the funding decision. Thus, the same danger of copying and of premature disclosure would still seem to be present. This would be particularly true since the funded applications would presumably be the ones most likely to involve proprietary rights, and also the most likely to stimulate imitation or to create pressure for use of the treatments described therein. The basis of the idea seems to come from the government purchase of property concept, which, as mentioned above, is hardly an adequate basis of distinction.

The idea's chief merit is that unfunded applications presumably do not present the dangers to human subjects or the question of waste of public money which need to be protected by disclosure. On the other hand, under this proposal outside investigators could not evaluate whether the funded applications were truly the most deserving, since this judgment would have to be made in the absence of the rejected grant applications.

With respect to the suggestion that further legislation be passed to protect intellectual property rights in these ideas, it should be noted that while the federal patent laws could possibly be modified for this purpose, any adverse effects of disclosure on foreign patent rights cannot be cured by any federal statute.

C. HEW Proposals

NIH has proposed that the contents of funded grant applications be made public twelve months after the funding decision has been made, except where human subjects are involved. Where the funded grant involves experiments with human subjects, the grant application would be made public immediately after funding. Un-<sup>148/</sup>funded grants would presumably never be disclosed.

This HEW proposal overcomes the basic weakness of the President's Panel's funded/unfunded distinction as it would protect the funded grant applications -- those with the most merit -- for one year after funding. HEW has apparently made the judgment that twelve months is a sufficient time to permit a researcher to prepare his idea for publication, to prevent an undue risk of imitation, and to protect the public against too much knowledge. It is not clear how HEW arrived at the twelve-month figure, especially in light of the fact that most of its research grants are for periods much longer than twelve months, some as long as seven years.

HEW has also apparently decided that where human subjects are concerned, the balance of interests tips toward immediate disclosure after funding, despite the problems involved in the immediate disclosure of the successful ideas. If non-disclosure is justified, it would seem to be also justified with respect to these ideas, provided that details of the arrangements for testing human subjects could be disclosed separately, as AAMC has proposed.

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<sup>148/</sup> Statement of the Advisory Committee to the Director, NIH, Metcalf Hearings at 202-03.

HEW has also proposed that the peer review process be conducted in secret meetings, and, like AAMC and the President's Panel, has not suggested any accommodation of the competing interests with respect to these meetings.

D. Our Proposal

It should be evident from the discussion of other proposals that it is not easy to construct a solution to the problems here. No solution can completely protect each of the conflicting interests involved, and it is with no little diffidence that we proposed a solution.

We propose that legislation be passed amending the Public Health Service Act to provide the following:

1. As AAMC has suggested, HEW shall by regulation revise its grant application format so that the researcher's basic innovative idea, i.e., what is novel in his application, will be kept separate from the rest of the application.

2. All parts of the revised grant application other than the "basic idea" will be available to the public under the FOIA, as is currently the practice.

3. The "basic idea" parts of each grant application, whether that application is funded or unfunded, shall be protected from disclosure under the FOIA for a period of twelve months following the funding decision with respect to that application.

4. After this twelve-month period, the "basic idea" section of the grant application would be disclosable under the FOIA, unless it contains proprietary rights which would otherwise be exempt

under Exemption 4. Before making this portion of the grant application public, HEW would be required to check back with the researcher to see if his subsequent research has indicated that a patentable idea has been developed. If there is a good faith claim that such an idea may be involved, the statute would provide that the "basic idea" part of the application remain confidential until the filing of the patent application.

We recognize several unavoidable weaknesses in this proposal. First, we realize that, as in HEW's proposal, our suggested waiting period of twelve months is arbitrarily selected. A more appropriate time period could possibly be selected.

Second, we recognize that it may be a difficult task to design a grant application that separates out the "basic idea" from the rest of the application.

Finally, we realize that this proposal does not protect every meritorious interest which we have identified. Our proposal is obviously tailored to protect research scientists' interests in non-disclosure of their "stock in trade" and proprietary ideas. In order to attempt to protect the conflicting interests in disclosure, we have limited this protection to a relatively short period of time, and we have tried to ensure that only the minimum of information is exempt from disclosure for even this limited period.

We are hopeful the division of the grant application into disclosable and non-disclosable portions will result in the information with respect to experiments in human subjects being disclosed immediately, thus taking into account the interest in

protecting human subjects. We recognize that this proposal will sacrifice to some degree the other two important interests in disclosure: the first amendment and exchange of scientific ideas interests. We justified this limited infringement upon those two interests by our belief that, unlike the interests in protecting human subjects, the delay in disclosure of information will not prejudice them greatly.

Thus, while the information necessary for full public review of the funding process will only be available after the fact of funding, it is unlikely that pre-funding public review of this process would actually affect many, if any, funding decisions. Individual funding decisions are unlikely to be issues. The overall performance of the HEW system, however, may well be a public issue, and the availability of all the data relevant to such decisions within one year after most decisions should permit the press and other investigators to monitor the overall process.

Similarly, we recognize that the one-year non-disclosure period acts as a slight inhibition upon the free exchange of scientific ideas. However, the scientific process does not take place overnight, and we do not believe that this one-year delay will significantly impede the exchange of scientific ideas.<sup>149/</sup>

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<sup>149/</sup> We have considered but rejected the idea of an Amendment to Exemption 4 because (1) an amendment of Exemption 4 might well exempt from disclosure materials other than the ones which we are concerned about, (2) we doubt if Congress would look favorably upon any tinkering with Exemption 4, and (3) coverage of the materials here by Exemption 4 would result in permanent non-disclosure, thus short-changing all the interests in disclosure of these materials.

This proposed legislation would modify the disclosure requirements of the FOIA, since FOIA Exemption 3 covers materials which are otherwise exempt under a separate statute. With respect to the question of whether IRG meetings should be open to the public, we are not convinced at this time that there is adequate evidence that they should be closed. However, under Sunshine Act Exemption 3, such meetings can be closed if an open meeting might reveal materials which are exempt from disclosure under another statute such as the one proposed here. Thus, we recognize that our proposed statute might permit some portion of IRG meetings to be closed. We would address this problem by including in our proposed statute a provision which states explicitly that such meetings would only be closed when necessary to protect the "basic idea" portions of the research grant application. This statute would further propose that a transcript of the closed portion of the meeting be made, such transcripts to be made available to the public at the same time the "basic idea" section of the research grant application discussed at that meeting is made available to the public.

VII. CONCLUSION

Resolution of the competing interests in disclosure and non-disclosure of the materials in research grant applications made to HEW is not an easy task. Serious students of this problem have put forward several proposals. None of these is a perfect solution to the problem. We have tried to evaluate the strengths and weaknesses of each proposal as objectively as possible, and submit a proposal of our own which we believe more adequately protects the meritorious interests on both sides of the question, as we see them, than the other proposals.

James H. Wallace, Jr.

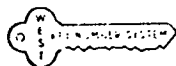
Thomas C. Arthur



himself. It is enough that thereafter he fails to utilize with reasonable care the ability which he then has to avert the plaintiff's harm." Restatement (Second) of Torts § 479 (1965). Thus the proximate cause is the failure to avoid the accident in circumstances where the defendant, and not the plaintiff, can reasonably do so.<sup>3</sup>

[4] Applying the principle of last clear chance to the facts of this case, viewing the evidence as we have indicated in the light most favorable to appellant, we cannot say that the jury could not have reasonably found for the plaintiff. Certainly the evidence was sufficient to put the defendant to his proof or risk a jury verdict against him.

Reversed.



WASHINGTON RESEARCH  
PROJECT, INC.

v.

DEPARTMENT OF HEALTH, EDUCA-  
TION AND WELFARE et al.,

Appellants.

No. 71-1027.

United States Court of Appeals,  
District of Columbia Circuit.

Argued May 24, 1974.

Decided Sept. 12, 1974.

Rehearing Denied Nov. 18, 1974.

Action was brought under Freedom of Information Act to compel disclosure of certain information pertaining to 11 specifically identified research projects that had been approved and funded by

3. Moreover, should the jury here find that appellee violated § 51 of the Traffic and Motor Vehicle Regulations, that "in itself evidence of proximate cause where the injury is generally of the kind intended to be avoided by the law or regulation involved. If that evidence is not rebutted or offset, proximate

the National Institute of Mental Health. The United States District Court for the District of Columbia, Gerhard A. Gesell, J., 366 F.Supp. 929, ordered disclosure of all of the requested information, except that certain deletions could be made in respect of statements of opinion as to qualifications and competency of applicants, and ordered the agency to amend its application instructions and regulations to conform with the decision, and appeal was taken. The Court of Appeals, McGowan, Circuit Judge, held that exemption provision of Act for trade secrets and commercial or financial information is not necessarily coextensive with existence of competition in any form, that a noncommercial scientist's research design is not a trade secret, that the initial grant applications, together with any continuation, renewal or supplemental applications incident thereto, either approved or pending, were not exempt from disclosure, that site visit reports and summary statements prepared by outside consultants engaged by the NIMH to initially evaluate an application were exempt from disclosure as intra-agency memoranda not subject to discovery in litigation and that it was an inappropriate exercise of equity jurisdiction to order that HEW conform its regulations to the district court's mandate.

Affirmed in part and reversed in part and remanded.

1. Records  $\approx$  11

Freedom of Information Act requires disclosure, on request, of the final opinion and identifiable records of each agency of the government, unless in the case of the latter, they come within one of the nine specific exemptions. 5 U.S.C.A. § 552.

cause is established as a matter of law. Where other evidence provides an offset, proximate cause becomes an issue for the jury." *Rowman v. Robbing & Co., supra* note 1, 115 U.S.App.D.C. at 392, 149 F.2d at 954.

**2. Records** ⇨14

In a proceeding under the Freedom of Information Act the burden of proof is on the agency opposing disclosure. 5 U.S.C.A. § 552.

**3. Records** ⇨14

Exemptions from disclosure requirements of the Freedom of Information Act are to be narrowly construed. 5 U.S.C.A. § 552.

**4. Records** ⇨14

Reach of the exemption from disclosure requirement of Freedom of Information Act for "trade secrets and commercial or financial information" is not necessarily coextensive with existence of competition in any form. 5 U.S.C.A. § 552.

See publication Words and Phrases for other judicial constructions and definitions.

**5. Records** ⇨14

Burden of showing the trade or commercial character of research design information submitted in grant applications and described in summary statements, site visit reports, and progress reports was on the National Institute of Mental Health, which sought to avoid disclosure of requested information on ground that it fell within provision of Freedom of Information Act exempting trade secrets and commercial or financial information. 5 U.S.C.A. § 552.

**6. Records** ⇨14

A noncommercial scientist's research design is not a "trade secret or commercial or financial information" within meaning of exemption provisions of Freedom of Information Act. 5 U.S.C.A. § 552.

**7. Records** ⇨14

In view of mandate of Freedom of Information Act to construe the exemptions narrowly the court cannot extend the exemptions by analogies that lead far afield of the plain meaning of the statutory language. 5 U.S.C.A. § 552.

**8. Records** ⇨14

Research design information contained in applications to National Institute of Mental Health for projects involving research into comparative effects of various psychotropic drugs on behavior of children with certain learning disabilities, as well as description of such designs in summary statements, site visit reports and progress reports, did not fall within exemption of Freedom of Information Act for "trade secrets and commercial or financial information" regardless of whether such information was contained in initial applications or continuation, supplemental or renewal applications or progress reports pertaining thereto. 5 U.S.C.A. § 552.

**9. Records** ⇨14

Initial review groups, which initially pass on research grant applications made to National Institute of Mental Health and which make influential recommendations but do not have legal authority to make decisions, do not constitute an "agency" within meaning of Administrative Procedure Act or Freedom of Information Act. 5 U.S.C.A. §§ 551(1), 552; Public Health Service Act, § 217(a, c), 42 U.S.C.A. § 218(a, c).

See publication Words and Phrases for other judicial constructions and definitions.

**10. Records** ⇨14

For purpose of applying the Freedom of Information Act the employing of consultants to improve the quality of the work that is done cannot elevate the consultants to the status of the agency for which they work unless they become the functional equivalent of the agency, making decisions for it. 5 U.S.C.A. § 552.

**11. Records** ⇨14

Important consideration in determining whether outside consultants or agency staff are themselves an "agency" within meaning of the Freedom of Information Act, is whether such staff or consultants have any authority in the law to make decisions; fact that the au-

thority to which the staff or consultants make a recommendation is greatly influenced thereby does not make the recommending body an agency. 5 U.S.C.A. § 552.

#### 12. Records $\text{C}\Rightarrow\text{14}$

In applying the Freedom of Information Act a court may not involve itself in determining the care with which the decisional officers of the governmental agencies supervise their staff in order to determine whether in fact the staff is the stand-in for the officer or agency; whether its recommendations are the agency's decisions and whether it ought not therefore in law to be held accountable as the agency. 5 U.S.C.A. § 552.

#### 13. Records $\text{C}\Rightarrow\text{14}$

A staff recommendation may achieve the dignity of an agency's final decision, for purpose of applying Freedom of Information Act, when the agency adopts it as its own; at that point disclosure can be required. 5 U.S.C.A. § 552.

#### 14. Records $\text{C}\Rightarrow\text{14}$

As a general rule, exemption provision of Freedom of Information Act for inter or intra-agency memoranda that would not be available by law to a party other than agency in litigation with the agency does not shield from disclosure purely factual, investigative matters, as opposed to materials reflecting deliberative or policy-making processes; however, even purely factual matter may be exempt if it is inextricable without compromise of the deliberative process and, so too, may be a summary of factual material that is part of the deliberative process, even though the facts themselves are elsewhere on the public record. 5 U.S.C.A. § 552.

#### 15. Records $\text{C}\Rightarrow\text{14}$

Project résumés, which were part of summary statements prepared by outside consultants engaged by National Institute of Mental Health to initially evaluate grant applications and which gave only most general indications of subject

matter of the project, constitute factual matters and, thus, were not exempt from discovery under Freedom of Information Act as intra-agency memoranda not subject to discovery in litigation. 5 U.S.C.A. § 552; Public Health Service Act, §§ 217, 222(a, b), 301(d, i), 42 U.S.C.A. §§ 218, 217a(a, b), 241(d, i).

#### 16. Records $\text{C}\Rightarrow\text{14}$

Exemption from disclosure requirements of Freedom of Information Act for interagency or intra-agency memoranda or letters which would not be available by law to party other than an agency in litigation with the agency is directed to policy of protecting the deliberative process of the agency. 5 U.S.C.A. § 552.

#### 17. Records $\text{C}\Rightarrow\text{14}$

Those portions of outside consultant's summary statements consisting of description of proposed research project, its aims and methodology as well as factual matter contained in summary of site visit report were exempt from disclosure under Freedom of Information Act, notwithstanding that they were abstracts of other information, since such matters, even if factual, constitute an integral part of the deliberative process of the National Institute of Mental Health; such information fell within exemption of Act for interagency memoranda that would not be subject to discovery in litigation. 5 U.S.C.A. § 552.

#### 18. Records $\text{C}\Rightarrow\text{14}$

Budget references, which were contained in site visit report prepared by outside consultants engaged by National Institute of Mental Health to review applications for research grants and which related amount requested to site visitors' analysis of amount needed and suggested a possibly economizing step to be considered by entire consulting group, was part of the deliberative process and exempt from compelled disclosure under Freedom of Information Act for intra-agency memoranda not subject to discovery in litigation. 5 U.S.C.A. § 552.

19. Records ⇨14

References in summary statements and site-visit reports, which were prepared by outside consultants engaged by National Institute of Mental Health to initially pass on applications for research grants, concerning professional qualifications or competency of a particular researcher were exempt from discovery under Freedom of Information Act as intra-agency memoranda not available by discovery in litigation. 5 U.S.C.A. § 552.

20. Courts ⇨265

It was an inappropriate exercise of equity jurisdiction to order Department of Health, Education, and Welfare to amend the application instructions and regulations governing federally funded research grants to conform with decision in suit under Freedom of Information Act where there was no warrant for anticipating that HEW would not proceed in good faith to incorporate the substance of decision into its rules and practices; in any event, considerations of interbranch comity compelled withholding of coercive orders that were not demonstrably necessary. 5 U.S.C.A. § 552.

David M. Cohen, Atty., Dept. of Justice, with whom Irving Jaffe, Acting Asst. Atty. Gen., Earl J. Silbert, U. S. Atty., and Leonard Schaitman, Atty., Dept. of Justice, were on the brief, for appellants. John A. Terry and Michael J. Ryan, Asst. U. S. Attys., also entered appearances for appellants.

Michael B. Trister, Washington, D. C., for appellee.

Bruce R. Hopkins and Robert O. Tyler, Washington, D. C., filed a brief on behalf of the Association of American Medical Colleges as amicus curiae urging reversal.

Before MCGOWAN and ROBB, Circuit Judges; and WEIGEL,\* District Judge for the Northern District of California.

MCGOWAN, Circuit Judge:

Appellee brought this action in the District Court to compel disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, of certain information pertaining to eleven specifically identified research projects that had been approved and funded by the National Institute of Mental Health (NIMH), a unit of the Public Health Service of the Department of Health, Education, and Welfare (HEW). The eleven projects all involve research into the comparative effects of various psychotropic drugs on the behavior of children with certain learning disabilities. After *in camera* inspection of sample documents, the District Court ordered disclosure of all of the information sought, except that it contemplated that certain deletions might conceivably be made in respect of statements of opinion about the qualifications and competence of applicants for grants. The court further ordered the agency to amend its application instructions and regulations to conform with its decision. 366 F. Supp. 929. For the reasons hereinafter appearing, we affirm in part and reverse in part.

I

The information in dispute is contained in three types of documents: ---

1. *The Grant Application.*

The initial grant application, among other things, identifies the research applicant, any research organization with which he may be affiliated, his qualifications and experience, the budget estimates, and the research protocol or design. Subsequent to the approval of the initial grant application, there may be filed continuation applications, renewal applications, and supplemental applications. Projects are approved for a specific "project period" that may extend over several years, 42 C.F.R. § 52.2(b), but a continuation application must be

\* Sitting by designation pursuant to Title 28 U.S. Code Section 292(d).

filed each year to report progress to date and justify support for the coming year. *Id.* § 52.14(d). Renewal applications are required for periods beyond the originally scheduled project period, while supplemental applications are required for additional grants awarded because the amount previously awarded proves inadequate to carry out the project properly. *Id.*<sup>1</sup>

2. *The Site Visit Report.*

Outside consultants, engaged by HEW to review the grant application, frequently visit the location at which the research is proposed to be done, and thereafter prepare a report on their observations.

3. *The Summary Statement ("pink sheet").*

When the outside consultants have completed their work, an NIMH staff member assigned to them prepares a summary of their observations and deliberations and reports their recommendations. This statement will draw upon the site visit reports, if any.

The process by which applications are processed by NIMH and HEW, an understanding of which is necessary to appraise the significance of each type of document for FOIA purposes, is set out in considerable detail in the opinion of the District Court. Accordingly, we begin with only a brief recapitulation of how the process works.

Research of the type sponsored by NIMH is often of a highly sophisticated and specialized nature. In order to assure competent evaluation of each proposal, a system of so-called "peer review" has been established, using the expertise of nongovernmental consultants functioning in panels organized around particular specialized disciplines within the broader field of biomedicine. These

panels, called "initial review groups" (IRGs), consist of from ten to twenty members, only one of whom, the Executive Secretary, is an NIMH employee.

Applications for NIMH research support are referred by the Executive Secretary to one member of the IRG as "primary assignee," and one or more other members with secondary responsibility. These assignees undertake to evaluate the application and gather such additional information as may be necessary to that task. This may involve a "site visit" to the facility at which the applicant proposes to conduct his research. A site visit may be made, for example, in order to observe an experimental technique to be used in the proposed research.

An evaluation of each application, and a site visit report where applicable, are written by the assignee group and circulated to the whole IRG, together with the application, prior to its next meeting. (IRGs meet three times a year.) The application is discussed at length and a recommendation voted. If approval is recommended, it is also given a relative priority rating, since the cost of all proposals deemed worthy of funding may exceed the funds available.

Following the IRG meeting, the Executive Secretary prepares a Summary Statement for each application acted upon. The Summary Statement describes the proposal and recounts the substantive considerations that led the IRG to recommend approval or disapproval. It contains an opinion of the professional qualifications of the sponsor and an evaluation of his competence and facilities. The IRG's evaluation of the risk to human subjects, if any, is included, as is also a reference to the site visit report, if there is one. If there is a minority of two or more, the minority's view is also summarized, without attribution by name. The Executive Secretary may add a "Note" in order to

1. We consider that continuation, renewal, and supplemental applications are all incident to the initial applications; and we see no rea-

son to distinguish between them for purposes of their availability for disclosure under FOIA.

clarify any matter not resolved by the IRG, call attention to factors other than scientific merit, including policy considerations, or incorporate information obtained subsequent to the IRG meeting at which the application was considered.

Each application and the corresponding pink sheet is submitted to the National Advisory Mental Health Council (NAMHC),<sup>2</sup> which was established to "advise, consult with, and make recommendations to" the Secretary on Public Health Service activities in the field of mental health, 42 U.S.C. § 218(c). The NAMHC is composed of three officials—the Assistant Secretary for Health, the chief medical officer of the Veterans Administration, and a medical officer designated by the Secretary of Defense—and twelve private citizens appointed by the Secretary on the basis of their qualifications in science, medicine, and/or public affairs. 42 U.S.C. § 218(a).

The NAMHC may approve, disapprove, defer consideration of, or require additional IRG consideration of, any application. On occasion it does reject an

IRG's recommendation of approval or disapproval,<sup>3</sup> but ordinarily, instead of passing upon the scientific merits of each application, it gives primary attention to policy direction and emphasis, generally acting on applications in subject matter groups. Applicants are notified of the outcome, but only about 90% of those receiving approval are actually funded by NIMH, to which the Secretary has delegated this function, due to limitations on funds. There is some ambiguity as to whether funding is determined solely on the basis of the ratings given by the IRGs and NAMHC, but the ratings may be presumed to be very influential in the funding decision.<sup>4</sup>

Each month NIMH makes public a list of all research grants awarded during the preceding month, including a general description of the project and its budget, and releases final progress reports received, except that release may be delayed up to six months pending publication by the researcher in a scholarly journal. The research design, proposed methods, and specific aims of a project are not made public, nor are the names

2. The District Court stated that "the Council members do not receive individual grant applications. Their decision is based solely on the review group Summary Statements," 366 F.Supp. at 934. The NIMH Handbook for Initial Review Staff states, however, that the NAMHC "reviews each application and its accompanying Summary Statement." P. 38. This publication was in the record before the District Court as Plaintiff's Exhibit No. 1. The only contradictory indication seems to be a statement in the deposition of Dr. R. S. Lipman, Chief of the Clinical Studies Section, Psychopharmacology Research Branch, NIMH. Dr. Lipman was Acting Executive Secretary at the time of his deposition, and was familiar with the operation of the IRGs but not with that of the NAMHC. When asked whether the latter group acted solely with the Summary Statements before it, he replied (p. 102):

A. I believe, and I am really talking off the top of my head, I believe they have all of the pink sheets and then they can have made available to them any particular grant [application] that they have a particular question about.

The best evidence of what the practice is would appear to be the official publication

on which both parties have relied extensively and the accuracy of which neither has questioned in any particular.

3. Instances are related in House Comm. on Government Operations, The Administration of Research Grants in the Public Health Service, H.Rep.No.800, 90th Cong., 1st Sess. 62 (1967).

4. The District Court stated that "[g]eneral priorities for funding are determined by the Director of NIMH, with the advice of the [NAMHC]," and no further elaboration is possible on the basis of this record. See Def.Exh. No. 2, U. S. Government Information Policies and Practices—Public Access to Information from Executive Branch Advisory Groups, Hearings Before a Subcomm. of the House Comm. on Government Operations, 92d Cong. 2d Sess., pt. 9, at 3619 (1972) (Statement of Dr. John F. Sherman, Deputy Dir., NIMH). The finding that "[w]ithin these general priorities [approval] is in the order of numerical priority set by the [IRG]" is very likely correct, however, since often nobody other than the IRG will examine the scientific merit of a particular application.

or proposals of any applicants whose applications are disapproved.

## II

[1-3] The Freedom of Information Act requires disclosure, upon request, of the final opinions and identifiable records of each agency of the government, unless, in the case of the latter, they come within one of the nine specific exemptions in the Act. The burden of proof is on the agency opposing disclosure, and the exemptions therefrom are to be narrowly construed. The government relies upon three separate exemptions to justify nondisclosure of the various types of information here sought, as follows:

1. Exemption 4, for trade secrets and commercial or financial information received in confidence, is invoked to cover the research designs submitted in applications and described in the Summary Statements, site visit reports, and progress reports.
  2. Exemption 5, for inter-agency or intra-agency memoranda that would not be subject to discovery in litigation, is said to cover the Summary Statements and site visit reports in their entirety, except insofar as purely factual information is involved.<sup>5</sup>
  3. Exemption 6, which applies to personnel, medical, and "similar" files the disclosure of which would be a clearly unwarranted invasion of personal privacy, is raised with respect to statements of opinion in the Summary Statements and site
5. The purely factual information in these documents had been released by NIMH voluntarily.
  6. Public Health Service regulations provide that "[a]ny corporation, institution, agency or other such person, other than an individual, that is organized or operated for profit" is ineligible to receive a grant award. 42 C.F.R. § 52.116(a)(2). Only an individual grantee engaged in profit-oriented research, or a non-profit organization that engages in profit-making ventures based on biomedical research, could conceivably be shown to have

visit reports as to the professional qualifications and competence of applicants who received grants.

### A. Exemption 4.

[4] The essence of the argument that the research designs submitted in the expectation of confidentiality are trade secrets or commercial information is that "ideas are a researcher's 'stock-in-trade.'" Their misappropriation, which, it is claimed, would be facilitated by premature disclosure, deprives him of the career advancement and attendant material rewards in which the academic and scientific market deals, in much the same way that misappropriation of trade information in the commercial world deprives one of a competitive advantage. Indeed, the government has been at some pains to argue that biomedical researchers are really a mean-spirited lot who pursue self-interest as ruthlessly as the Barbary pirates did in their own chosen field. Whether this is the sad truth, or whether, as appellee suggests, "secrecy is antithetical to the philosophical values of science," is not, however, an issue in this case; the reach of the exemption for "trade secrets or commercial or financial information" is not necessarily coextensive with the existence of competition in any form.

[5-8] It is clear enough that a non-commercial scientist's research design is not literally a trade secret or item of commercial information, for it defies common sense to pretend that the scientist is engaged in trade or commerce.<sup>6</sup>

a commercial or trade interest in his research design. For the eleven grantees whose protocols are sought in this case, however, their institutional affiliations with colleges and universities (7), research institutes (2), hospitals and state agencies (1 each), make this possibility extremely remote. In addition it is established by an undenied allegation in the complaint that "[o]ne of the grants is concerned with the production or marketing of the drugs being tested." \*9, JA 5. This does not absolutely preclude the possibility of commercial ac-

This is not to say that the scientist may not have a preference for or an interest in nondisclosure of his research design, but only that it is not a trade or commercial interest. To the extent that his interest is founded on professional recognition and reward, it is surely more the interest of an employee than of an enterprise,<sup>7</sup> and we are far from persuaded that Congress intended in Exemption 4 to apply terms drawn from the business context to the employment market.<sup>8</sup> We cannot, consistently with the Act's recognized mandate to construe exemptions narrowly, see *Vaughn v. Rosen*, 157 U.S.App.D.C. 340, 484 F.2d 829, 823 (1973), cert. denied 415 U.S. 977, 94 S.Ct. 1564, 39 L.Ed.2d 873 (1974); *Getman v. NLRB*, 146 U.S.App.D.C. 209, 450 F.2d 670, 672, stay denied, 404 U.S. 1204, 92 S.Ct. 7, 30 L.Ed.2d 8 (1971), extend them by analogies that lead so far away from the plain meaning of Exemption 4. Consequently, we hold that research designs submitted in grant applications are not exempt from disclosure under the Act. This holding extends to all types of applications—initial, continuation, supplemental, and renewal—and to progress reports made by grantees as part of the last three kinds of applications.

**B. Exemption 5.**

The applicability of Exemption 5 to the site visit reports made by members

of the IRG, and to the Summary Statement written by the Executive Secretary to report on the IRG's recommendation to the NAMHC, turns on whether the IRG is an "agency" under the Administrative Procedure Act, of which the FOIA is a part. If the IRG is indeed an agency, then appellee's position that the Summary Statements and accompanying site visit reports constitute its final opinions, which must be made available, 5 U.S.C. § 552(a)(2)(A), is not without force. If, on the other hand, the IRG is not an agency but merely a unit within another agency, then these documents are identifiable records in the hands of that agency and it is our task to determine whether they are exempt from disclosure as intra-agency memoranda.

1. The IRG as an agency *vel non*.

The APA defines the term "agency" to mean "each authority of the Government of the United States, whether or not it is within or subject to review by another agency," with certain specific exceptions not applicable in this case. 5 U.S.C. § 551(1). The generality of this definition has required the commentators that have dealt with it to attempt an elaboration along more functional lines than the phrase "each authority" conveys,<sup>9</sup> but recent cases have made it clear that any general definition can be of only limited utility to a court con-

7. See note 6, *supra*.

8. See Restatement of Torts § 757, Comment b (1939): "Definition of trade secret. A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it." (Emphasis added.)

9. See Final Report of the Attorney General's Comm. on Administrative Procedure, S.Doc.

No. 8, 77th Cong., 1st Sess. 7 (1941) ("the power to determine, either by rule or by decision, private rights and obligations"); 1 K. Davis, *Administrative Law Treatise* § 1.01, at 1 (1958) ("a governmental authority, other than a court and other than a legislative body, which affects the rights of private parties through either adjudication or rule-making"); Freedman, *Administrative Procedure and the Control of Foreign Direct Investment*, 119 U.Pa.L.Rev. 1, 9-10 (1970): "Where a center of gravity lies, where substantial powers to act with respect to individuals are vested, there is an administrative agency for purposes of the APA."

[But] a definition stated thus broadly is not self-applying. It is an abstract proposition that does not neatly decide concrete cases."



fronted with one of the myriad organizational arrangements for getting the business of the government done. See *Grumman Aircraft Engineering Corp. v. Renegotiation Board*, 157 U.S.App.D.C. 121, 482 F.2d 710 (1973) (Regional Boards) (hereinafter *Grumman II*), cert. granted, 417 U.S. 907, 94 S.Ct. 2602, 41 L.Ed.2d 211 (1974); *Soucic v. David*, 145 U.S.App.D.C. 144, 448 F.2d 1067 (1970) (Office of Science and Technology); *International Paper Co. v. FPC*, 438 F.2d 1349 (2d Cir. 1971) (Staff of FPC); *Larche v. Hannah*, 177 F.Supp. 816 (W.D.La.1959) (Civil Rights Commission), rev'd on other grounds, 363 U.S. 420, 80 S.Ct. 1502, 4 L.Ed.2d 1307 (1960). The unavoidable fact is that each new arrangement must be examined anew and in its own context.

Congress has authorized the Secretary of HEW to make only such mental health and medical research grants "as are recommended" by the various National Advisory Councils, in this case the NAMHC, 42 U.S.C. § 241(d), (i), that it established, 42 U.S.C. § 218.<sup>10</sup> It also, however, authorized the Secretary to "appoint such advisory committees (in addition to those authorized to be established under other provisions of law) . . . as he deems desirable for the purpose of advising him in connection with any of his functions," 42 U.S.C. § 217a(a), and to compensate nongovernmental members thereof. *Id.* at § 217a(b).<sup>11</sup>

The authority to establish advisory committees by administrative action was first exercised in the period after World War II, when the vast expansion of supported biomedical research made it "impractical to encompass in a council mem-

bership the expertise in all the numerous disciplines, fields, specialties, and areas represented in biomedical research proposals. . . . To overcome these deficiencies, initial review groups were established to assist the councils." S. Rep. No. 381, 93d Cong., 1st Sess. 38 (1973). In 1968, when NIMH was established as a distinct part of HEW, this system was carried over with the creation of the NAMHC, and the Institute's decision to create the IRGs. Hearings, *supra* note 4, at 3620-21. The NIMH dual review process remains, however, "less formal" than that of the NIH: "IRGs are established or phased out as required by the size and nature of the grant review workload. . . ." S.Rep. No. 381, *supra*, at 38. Ad hoc IRGs are formed to advise on particular applications "not within the competence" of any then-standing group. NIH Handbook, *supra* note 2, at 9.

[9] Under the prior decisions of this court, we think the IRGs are advisory committees, performing staff functions through the medium of outside consultancy, and are not agencies. The considerations raised in *Soucic v. David*, *supra*, and *Grumman II*, *supra*, point unmistakably to this conclusion, which comports with our present impression of how this question should be handled. *Soucic* involved the status of the Office of Science and Technology, which, in addition to advising and assisting the President in coordinating federal policy for science and technology, was also authorized, as we emphasized, independently to evaluate federal programs.<sup>12</sup> It was created by an executive reorganization plan submitted to Congress and "ex-

10. This system originated with the National Cancer Institute Act, which created, in addition to the Institute, the National Cancer Advisory Council. Ch. 565, § 3, 50 Stat. 599 (1937).

11. *As added*, Pub.L. No. 87-828, 76 Stat. 1073; see Public Health Service Act § 301, ch. 373, § 301, 58 Stat. 691 (1944).

12. "If the OST's sole function were to advise and assist the President, that might be tak-

en as an indication that the OST is part of the President's staff and not a separate agency. In addition to that function, however, OST inherited from the National Science Foundation the function of evaluating federal programs. . . . By virtue of its independent function of evaluating federal programs, the OST must be regarded as an agency subject to the APA and the Freedom of Information Act." 448 F.2d at 1075.

explicitly considered" by the House. *Id.* at 1074. Congress approved the plan with the understanding that it was "delegating [to OST] some of its own broad power of inquiry in order to improve the information on federal scientific programs available to the legislature." *Id.* at 1075. It "clearly contemplated," as did the Executive, "that the OST would function as a distinct entity and not merely as part of the President's staff."<sup>13</sup> Finally, we noted that since the OST had published FOIA regulations, it had apparently considered itself, prior to the litigation, to be an agency subject to the APA—a consideration of some weight. *Udall v. Tallman*, 380 U.S. 1, 16, 85 S.Ct. 792, 13 L.Ed.2d 619 (1965). All of these factors taken together led to the determination that OST exercised "substantial independent authority," and to the conclusion that it was an agency subject to the Freedom of Information Act.

Some of the same factors considered in *Soucie* were present in *Grumman II*, which dealt with the status of the Regional Boards established by the Renegotiation Board. The Regional Boards' exercise of formal decision making power delegated from the National Board was found to be "within Congress' [sic] contemplation when it established the Renegotiation Board apparatus." Indeed, the statutory authorization there at issue was expressly that of delegating functions "to any agency of the Government, including any such agency established by the Board." 50 U.S.C. App. § 1217(d) (emphases added). Further, the National Board had promulgated FOIA regulations for disclosure of some Regional Board documents, again indicating its own view, prior to litigation, that they were agencies subject to the FOIA. Furthermore, the Regional Boards fell squarely within the analytic definition supplied by Professor Freed-

man, whose consideration of this question is the fullest and most discerning, namely, they were the body in which "substantial 'powers to act' with respect to individuals [were] vested." Freedman, *supra* note 9, at 9. They had their own staffs to investigate and negotiate with contractors, and their "recommendation is communicated openly to the contractor prior to any assumption of jurisdiction by the National Board." 482 F.2d at 715. They were, in short, the agency with which an affected member of the public dealt, and from whose decision appeal might lie, depending upon the amount in controversy.

The contrast between the agencies involved in *Soucie* and *Grumman II*, on the one hand, and the IRGs, on the other, could not be greater. Unlike the OST, the IRGs do confine themselves to making recommendations; authority to make grants is vested in the Secretary, and authority to recommend doing so lies with the NAMHC. The IRGs act as consultants to the NAMHC; their members are strictly forbidden from communicating their group's recommendations to applicants. NIMH Handbook, *supra* note 2, at 30. Applicable regulations and administrative rules within NIMH and HEW have consistently reflected the view that the IRGs are not subject to the FOIA, *see id.*; 45 C.F.R. §§ 5.72(b), 5.73(a); and the authority under which they are appointed gives no hint of a congressional expectation that NAMHC's delegation of the initial review function would somehow make either more or less information available to the legislature or the public.

[10] Clearly, the work now done by IRGs could again be done by the NAMHC if it sat continuously instead of meeting three times a year for about two days each time. Employing consultants to improve the quality of the work that is done cannot elevate the consult-

13. The executive branch represented the proposed OST as being organizationally analogous to the Bureau of the Budget, the Council of Economic Advisors, the National Security Council and the Office of Emergen-

cy Planning. 418 F.2d at 1075 & n. 22. Congress contemplated that OST would be sufficiently distinct from the President's staff to be beyond the reach of executive privilege and thus responsible to Congress.

ants to the status of the agency for which they work unless they become the functional equivalent of the agency, making its decisions for it. There is no doubt in this instance that the usually perfunctory review the NAMHC gives to a particular application—as opposed to the group of which it is a part—makes the IRG's recommendations an often crucial element in the approval process. But, just as the APA makes the fact that a government authority's decisions are subject to review irrelevant in determining whether that authority is an agency, at least in this case the degree of scrutiny its decisions are given on review is equally beside the point.

[11,12] The important consideration is whether it has any authority in law to make decisions. The IRGs have not; their favor is not necessary because the law empowers the Secretary to make grant awards if (and only if) the NAMHC so recommends. The fact that the NAMHC may be greatly influenced by the IRG's expert view does not make the IRG an agency. See *International Paper Co. v. FPC*, 438 F.2d 1349, 1359 (2d Cir. 1971). In *Soucic* this court did not consider whether the President generally accepted the advice of OST. In that case and in *Grumman II* we looked to the functions that OST and the Regional Boards respectively were empowered by law to perform. The alternative would inevitably involve the courts in determining the care with which the decisional officers of government agencies supervise their staffs, in order to determine whether in fact the staff is not the stand-in for the officer or agency—its recommendations his decisions—and whether it ought not therefore in law to

be held accountable as the agency. This we cannot do. *Morgan v. United States*, 304 U.S. 1, 18, 58 S.Ct. 999, 82 L.Ed. 1129 (1938); *United States v. Morgan*, 313 U.S. 409, 422, 61 S.Ct. 999, 85 L.Ed. 1429 (1941).

[13] That is not to say that a staff recommendation may never achieve the dignity of an agency's final decision; it may do so when the agency adopts it as its own, and at that point its disclosure can be required. *American Mail Line, Ltd. v. Gulick*, 133 U.S.App.D.C. 382, 411 F.2d 696 (1969), is a case in point. There the question was "whether an administrative agency [the Maritime Subsidy Board] may take affirmative action against a private party by means of a decision in which it states that the only basis for such action is a certain specified [staff] memorandum and then refuse to disclose the memorandum to the party affected by the action." While the question was answered in the negative, the reason was that the agency had made the memorandum the express and only basis for its decision and not that it had made the staff into the "agency." In the present case, however, leaving aside the problem of whether even the denial of a grant award is "affirmative action" against an applicant, the reasoning of the IRG is not the "only basis" for the Secretary's decision. The Executive Secretary's Note and the NAMHC's policy choices, and in some instances the latter's particularized scrutiny, intervene.<sup>14</sup> Cf. *Sterling Drug, Inc. v. FTC*, 146 U.S.App.D.C. 237, 450 F.2d 698, 706 (1971). We hold, therefore, that the IRG is not itself an agency under the APA nor, consequently, subject to the strictures of the FOIA.<sup>15</sup>

14. The result may be that there is no "final opinion" of the agency—NIMH—accompanying its decision on whether to make a grant award. Whether this comports with existing notions of administrative fairness is not an issue in this case, nor do we see how it could be an issue for the courts in the absence of a legislative provision for judicial review of the decision.

15. The rather sparse legislative history of Section 2 of the APA is collected in Freed-

man, *supra* note 9, at 6-12, and analyzed with reference to the meaning of "agency." That history tends to confirm our view that IRGs are not agencies. Staff of Senate Comm. on the Judiciary, Report on the Admin.Proc.Act, 79th Cong., 1st Sess. 13 (Comm.Print 1915): "'Authority' means any officer or board, whether within another agency or not, which by law has authority to take final and binding action with or without appeal to some superior administrative au-

## 2. Application of Exemption 5.

[14] Having decided that the IRG is not an agency, nor its Summary Statements and site visit reports the final decisions of an agency, it becomes necessary to determine just how much of the disputed information in these intra-agency documents is exempt from disclosure. Exemption 5 applies only to matters "which would not be available by law to a party other than an agency in litigation with the agency." While there are often problems in determining the precise scope of the exemption without the benefit of actual litigation the nature of which informs the breadth of discovery, see *Environmental Protection Agency v. Mink*, 410 U.S. 73, 86, 93 S.Ct. 827, 35 L.Ed.2d 119 (1973), its application in this case is relatively uncomplicated. As a general proposition Exemption 5 does not shield from disclosure "purely factual, investigative matters," as opposed to "materials reflecting deliberative or policy-making processes." *Id.* at 89, 93 S.Ct. at 837. Even purely factual matter may be exempt, however, if it is inextricable without compromise of the deliberative process, *id.* at 91, 93 S.Ct. 827, and so too may be "a summary of factual material

thority." See H.Rep.No. 1980, 79th Cong., 2d Sess. 19 (1946). See also Attorney General's Manual on the Administrative Procedure Act 9 (1947).

Whether the IRG is subject to the disclosure requirements of the Federal Advisory Committee Act, 5 U.S.C. App. I, § 10, is not a question before this court. We note, however, that that Act makes the FOIA standards applicable to advisory committees' reports and other papers only insofar as the head of the agency to which the committee reports fails to determine in writing that the reports or documents contain information within an exemption to the FOIA. *Id.* § 10(d). Whether such a determination has been made respecting IRG reports is not disclosed by the record in this case. But see Summary Statement, Dept. of HEW (Notice of determination to close certain meetings under authority of Executive Order 11671 of June 5, 1972), in U. S. Government Information Policies and Practices, *supra* note 4, at 3628, which made the same determination under the pre-Committee Act regime established by executive order. Simi-

[that] is part of the deliberative process," even though the facts themselves are elsewhere on the public record. *Montrose Chemical Corp. v. Train*, 160 U.S.App.D.C. 270, 491 F.2d 63 (1974).

[15] In order to apply these propositions to the facts at bar, the contents of the Summary Statements and site visit reports need further elaboration at this point. We take as our texts appellee's Exhibit 1, the NIMH Handbook, *supra* note 2, at 33-36, documents as illustrated by the sample submitted to the court. The Summary Statements begin with (1) a concise resume, "no more than six or seven sentences," of the proposed project, its review by the IRG, and the reasons for the IRG's recommendation, including the contrary reasons offered by a minority.<sup>16</sup> There follows (2) a "brief description of the proposal," its "aims, methodology, and, for renewal, supplemental and revised proposals, the background or history." The next and "most critical" section is the IRG's critique (3) which discusses "the strengths and weaknesses of various aspects of the proposal in detail."<sup>17</sup> The "background and competence" of the applicant and his associates (4) are dis-

larly, the court is not now called upon to decide whether failure to make such a determination subjects the affected information to disclosure at the instance of "any person" as under the FOIA.

16. From the Summary Statement submitted for *in camera* inspection it appears that exemption is claimed for the resume of the IRG's review and reasons, but not for the resume of the project itself, which gives only the most general indication of its subject matter and cannot be regarded as anything but purely factual and nonexempt.

17. The critique is specifically directed to the following issues:

Are the aims logical? Is the approach valid and adequate? Are the procedures feasible? Is the research likely to produce new data and concepts or confirm existing hypotheses? What is the significance and pertinence of the proposed work with regard to the state of the field and importance of the aims? For continuation and supplemental requests, comment on past progress.

cussed, as are (5) "any special aspects of the facilities and equipment and the extent of departmental and interdepartmental cooperation" at the applicant's institution. The proposed project budget is then analyzed with reference to its adequacy, justification, and projected duration (6). Supplemental requests are related to previously approved amounts.<sup>18</sup> To all of this may be appended (7) the Executive Secretary's Note, described *supra* at p. 242, (8) the minority report of two or more dissenting members, and (9) a summary of any site visit report.

The site visit report itself contains, in addition to purely identifying material, such as application number, date, and persons seen, (10) evaluations of the proposal, the investigator, and his staff, (11) sections on the facilities and other support available at the institution and (12) the budget, and (13) "other comments." Because of the substantial overlap necessary between the site visit report and Summary Statements, site visitors are advised to follow the format for the latter document "since the site visit report, if accepted by the [IRG], can serve as a basis for the Summary Statement." NIMH Handbook, at 46.

[16] From this mere recitation it is clear that most of the matters called for in the site visit report and Summary Statement for each application are evaluative, and call into play the policy of protecting the deliberative process, at which Exemption 5 is directed. See *EPA v. Mink, supra*; *Soucie v. David, supra*. Indeed, the only matters that are even arguably subject to compelled disclosure are the Summary Statements' (2) description of the proposal, its aims and methodology, and any factual matter contained in (9) the summary of the site visit report. In the site visit report itself, only (11) the statement of facili-

ties, and (12) the budget, merit comment.

[17] Of these four items, the two (2 and 9) in the Summary Statement are abstracts of other information—either the site visit report or portions of the underlying application. As such we think them covered by the reasoning of *Montrose Chemical, supra*. That case involved application of Exemption 5 to summaries, made by agency staff attorneys, of evidence developed at a public hearing. The summaries were prepared for and submitted to the Administrator of the Environmental Protection Agency "to assist [him] in his study of the record" on the basis of which he was obliged to make a decision. This court held the summaries exempt as an integral part of the deliberative process. Sensitive to the necessity of attaching varying degrees of significance to different facts in the course of epitomizing the record, we said:

Even if they cited portions of the evidence verbatim, the assistants were making an evaluation of the relative significance of the facts recited in the record; separating the pertinent from the impertinent is a judgmental process, sometimes of the highest order; no one can make a selection of evidence without exercising some kind of judgment, unless he is simply making a random selection. 491 F.2d at 68.

No significant difference distinguishes the present case from *Montrose Chemical*. The research design and description of methodology in the application submitted for *in camera* inspection covers fifteen, single-spaced typewritten pages; their description in the Summary Statement is one page in length.<sup>19</sup> In the *Montrose Chemical* paradigm, the judgmental element arises through the necessity to select and emphasize certain

18. When the IRG is an ad hoc committee, the names and institutional affiliations of each reviewer are listed. Five additional criteria are to be addressed in the case of foreign applications.

19. The site visit report, which is two and one-half pages in length, is not summarized but rather incorporated by reference. Were it summarized the principle discussed in the text would apply equally to that summary.

facts at the expense of others. In the instant case, where the whole proposal must be described at least in general, various aspects of it are described in greater detail than others. In virtually every sentence the author must operate at a level of specificity that reflects his personal perspective on the material being summarized.

An example may be taken from the Summary Statement before us without compromising any information for which exemption is claimed. In the course of describing a proposal for evaluating the relative efficacy of a number of drugs in the treatment of hyperkinetic children, the following statement appears: "The assessment battery consists of a number of rating scales, and various cognitive and performance measures." Significantly, however, while the various performance and cognitive tests are then enumerated, the rating scales are neither identified nor described, but are said only to have proved sensitive in prior, unspecified studies. This difference of treatment may well reflect no more than the greater ease with which named tests can be referenced than rating scales described. It may, on the other hand, reflect the view that certain well-known tests have a definite reputation for reliability, and that rating scales are only so much surplusage. A different group of reviewers with a different set of views might well have elaborated on the rating scales' utility and never specified the cognitive and performance tests proposed. What the effect of such a choice might be on the proposal's prospects we need not

guess. The point is simply that choices are and must be made by someone or some group with a unique perspective, and decisions may be based on them. Accordingly, the two items under discussion must also be held exempt from disclosure.<sup>20</sup>

[18, 19] The NIMH Handbook alone does not indicate whether the two items in the site visit report—(11) the facilities and (12) budget references—are meant to be narrative or analytic. The representative site visit report submitted to the District Court, which is of controlling significance,<sup>21</sup> suggests the latter, however, at least with respect to budgetary considerations. The short section on the budget relates the amount requested to the site visitors' analysis of the amount needed, and suggests for IRG consideration a possible economizing step. As such, it is clearly a part of the deliberative process and exempt from compelled disclosure. But this particular report makes no reference to the matter of facilities, neither describing nor rendering an opinion on the adequacy of the facilities available to the grant applicant.<sup>22</sup> The entire document, however, other than the opening paragraphs which describe the proposal and for which no claim of exemption is made, is an expression of the visitors' opinions and not a recitation of facts. This suggests that facilities references, if any, in the site visit reports for other of the applications sought by appellee would be of the same nature. In light of the parties' agreement, *supra* note 21, however, we need not choose between reliance on this speculation, with its po-

20. As in *Montrose Chemical*, the court does not confront a situation in which the underlying information, a summary of which is determined to be exempt, is itself secreted from public inspection, and in which we said "a different result might be reached." The proposals summarized in item (2) are available by virtue of our holding in Part II.A, *supra*. The site visit reports summarized in item (9), insofar as purely factual, were not even claimed to be exempt, although, as appellant points out, they have very little factual content.

21. The parties "agreed that the determinations made by the Court based on this example would control the disposition as to other similar material covered by plaintiff's request and presently withheld." 366 F.Supp. at 932.

22. The proposal in question did not require the use of technical medical equipment, which undoubtedly made the question of facilities irrelevant to the IRG's evaluation of the application.

tential effect of relieving the agency of its statutory burden of proof, and *in camera* inspection of all the site visit reports in suit. Finding no matter of the type sought in the controlling document, there is no relief respecting item (12) to which appellee can lay claim.<sup>23</sup>

### III

[20] Appellant challenges the District Court's jurisdiction to order the agency to amend its regulations to conform with the court's opinion. The FOIA, it is contended, "grants jurisdiction to the district courts only to review agency denials of requests for specific documents and to enjoin withholding of those documents" from the person who made the request. That is of course true insofar as it goes, but is not responsive to whether the court may not draw on powers apart from, and unbridged by, the FOIA in order to give complete relief where it is due. "With the express vesting of equitable jurisdiction in the District Court by § 552(a), there is little to suggest, despite the Act's primary purpose, that Congress sought to limit the inherent powers of an equity court." *Renegotiation Board v. Bannerkraft Clothing Co.*, 415 U.S. 1, 94 S.Ct. 1028, 39 L.Ed.2d 123 (1974) (dictum).

One can imagine circumstances, such as where an agency simply refuses to conform its actions to the known requirements of the Act in order to deter requests for information by repetitive litigation, that would tempt a court to

use any or all of "the usual weapons in the arsenal of equity." *Bannerkraft Clothing Co. v. Renegotiation Board*, 466 F.2d 345, 354 (1972), rev'd on other grounds, 415 U.S. 1, 94 S.Ct. 1028, 39 L.Ed.2d 123 (1974). In the case at bar, however, it is unnecessary to decide whether the District Court would be so empowered.

Appellee initiated the process culminating in this action by a letter requesting access to documents relating to eleven specifically identified research grants. When the request had been denied in part and administrative appeal exhausted, appellee filed a complaint the prayer of which requested that the court declare the plaintiff's right to disclosure of the disputed records and order their disclosure, and "[t]hat this Court declare invalid under the Freedom of Information Act the regulations issued by [HEW] which exempt from public disclosure all research protocols and all proposed grant applications." JA6. In its opinion the District Court merely suggested that "[a]t a minimum, the defendants should promptly modify existing regulations and grant application instructions to bring them into conformity with the decision of this Court," but its order elevated this suggestion into an injunctive obligation presumably enforceable in the same manner as any injunction, namely, by contempt.

The FOIA requires each agency to make information, not exempt by the terms of the Act, available "in accordance with published rules." From this

23. The District Court rejected appellant's argument that Exemption G, which applies to certain files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, is an alternative ground for non-disclosure of any references, in the Summary Statements and site visit reports, to the professional qualifications or competence of a particular researcher. Our holding that the non-factual information in these documents falls within Exemption 5 extends to these expressions of opinion, and we therefore need not reach the merits of this argument.

Neither do we need to deal with the District Court's intimation that under certain

circumstances HEW may delete from the site visit report or the Summary Statement an expression of opinion adverse to the qualifications or competence of particular individuals involved in the research project under consideration. The District Court, of course, found that these documents constituted the opinions of an agency and were disclosable as such; and it then referred to a provision of FOIA which says that an agency may make such deletions in an opinion. 5 U.S.C. § 552(a)(3). We, of course, have reached a different conclusion on this latter score, and under our approach the deletion authority contained in the statute is not applicable.

may readily be inferred an obligation to publish rules that accurately reflect the agency's substantive obligations under the Act, and rules that fail to do so are of no force when "any person" seeks access to information not exempt from disclosure under the Act. Premitting the very real question of whether a single request for documents creates a continuing case or controversy<sup>24</sup> sufficient to support an order to amend regulations of only speculative future effect on an FOIA plaintiff, there is no warrant in the record of this case for anticipating that HEW would not proceed in good faith to incorporate the substance of a final court decision into its rules and practices.

The District Court was sensitive to the public interest that the FOIA, "to the extent practical, be self-operative to insure prompt disclosure." It was equally aware of the necessity "that grant applicants be placed on notice that information submitted pursuant to an application for NIMH grant funds" is subject to public disclosure. We, of course, share the court's concern, but are without sufficient reason to doubt that appellant does also. Considerations of inter-branch comity impel us to withhold coercive orders that are not demonstrably necessary. Cf. *Nixon v. Sirica*, 159 U.S.App.D.C. 58, 487 F.2d 700, 712 (1973).

What we have held hereinabove is that the eleven initial grant applications involved in this case (all of which had been approved by HEW), together with any continuation, renewal, or supplemental applications incident thereto (either approved or pending), are not exempt from disclosure under the Freedom of Information Act. Contrarily, we have held that site visit reports and Summary Statements are exempt under Exemption 5. The impact of this latter holding is limited in this case by the fact that

24. The District Court itself prefaced its consideration of this prospective relief with the

HEW has voluntarily disclosed the purely factual matter contained therein, in an apparent recognition that such matters do not come within the purposes of the exemption. Lastly, we have found, in the circumstances of this record, an inappropriate exercise of equity jurisdiction in the District Court's injunctive command that HEW conform its regulations to the court's mandate.

The judgment of the District Court is, accordingly, affirmed in part and reversed in part; and the case is remanded for the entry of a decree consistent herewith.

It is so ordered.



UNITED STATES of America  
v.  
Clarence I. WEST, Jr., Appellant.  
No. 73-1665.  
United States Court of Appeals,  
District of Columbia Circuit.  
Argued April 10, 1974.  
Decided Sept. 11, 1974.

Defendant was convicted in the United States District Court for the District of Columbia, William B. Bryant, J., of possession of stolen mail, and he appealed. The Court of Appeals, Solomon, District Judge, held that Government had burden of justifying 13-month delay between defendant's arrest and trial, and that delay which was not caused by defendant violated his right to a speedy trial and required dismissal of indictment.

Reversed and remanded.

Bazelon, Chief Judge, filed a concurring opinion.

words, "Apart from resolution of the instant controversy . . ."



## APPENDIX B

## 11. STATUTE AND OTHER TEXTUAL MATERIAL

### 11.1 FREEDOM OF INFORMATION ACT, AS AMENDED IN 1974 BY PUBLIC LAW 93-502

(Editor's Note: Headings Added)

§ 552. Public information; agency rules, opinions, orders, records, and proceedings

(a) Each agency shall make available to the public information as follows:

#### AFFIRMATIVE RESPONSIBILITY OF AGENCIES

(1) Each agency shall separately state and currently publish in the Federal Register for the guidance of the public—

(A) descriptions of its central and field organization and the established places at which, the employees (and in the case of a uniformed service, the members) from whom, and the methods whereby, the public may obtain information, make submittals or requests, or obtain decisions;

(B) statements of the general course and method by which its functions are channeled and determined, including the nature and requirements of all formal and informal procedures available;

(C) rules of procedure, descriptions of forms available or the places at which forms may be obtained, and instructions as to the scope and contents of all papers, reports, or examinations;

(D) substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency; and

(E) each amendment, revision, or repeal of the foregoing.

Except to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published. For the purpose of this paragraph, matter reasonably available to the class of persons affected thereby is deemed published in the Federal Register when incorporated by reference therein with the approval of the Director of the Federal Register.

#### SECRET LAW AND INDEXES

(2) Each agency, in accordance with published rules, shall make available for public inspection and copying—

(A) final opinions, including concurring and dissenting opinions, as well as orders, made in the adjudication of cases;

(B) those statements of policy and interpretations which have been adopted by the agency and are not published in the Federal Register; and

(C) administrative staff manuals and instructions to staff that affect a member of the public;

unless the materials are promptly published and copies offered for sale. To the extent required to prevent a clearly unwarranted invasion of personal privacy, an agency may delete identifying details when it makes available or publishes an opinion, statement of policy, interpretation, or staff manual or instruction. However, in each case the justification for the deletion shall be explained fully in writing. Each agency shall also maintain and make available for public inspection and copying current indexes providing identifying information for the public as to any matter issued, adopted, or promulgated after July 4, 1967, and required by this paragraph to be made available or published. Each agency shall promptly publish, quarterly or more frequently, and distribute (by sale or otherwise) copies of each index or supplements thereto unless it determines by order published in the Federal Register that the publication would be unnecessary and impracticable, in which case the agency shall nonetheless provide copies of such index on request at a cost not to exceed the direct cost of duplication. A final order, opinion, statement of policy, interpretation, or staff manual or instruction that affects a member of the public may be relied on, used, or cited as precedent by an agency against a party other than an agency only if—

(i) it has been indexed and either made available or published as provided by this paragraph; or

(ii) the party has actual and timely notice of the terms thereof.

#### RIGHT TO REQUEST

(3) Except with respect to the records made available under paragraphs (1) and (2) of this subsection, each agency, upon any request for records which (A) reasonably describes such records and (B) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, shall make the records promptly available to any person.

#### ADMINISTRATIVE PROCEDURES

(4) (A) In order to carry out the provisions of this section, each agency shall promulgate regulations, pursuant to notice and receipt of public comment, specifying a uniform schedule of fees applicable to all constituent units of such agency. Such fees shall be limited to reasonable standard charges for document search and duplication and provide for recovery of only the direct costs of such search and duplication. Documents shall be furnished without charge or at a reduced charge where the agency determines that waiver or reduction of the fee is in the public interest because furnishing the information can be considered as primarily benefiting the general public.

#### District Court Jurisdiction

(B) On complaint, the district court of the United States in the district in which the complainant resides, or has his principal place of business, or in which the agency records are situated, or in the District of Columbia, has jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant. In such a case the court shall determine the matter *de novo*, and may examine the contents of such agency records in camera to determine whether such records or any part thereof shall be withheld under any of the exemptions set forth in subsection (b) of this section, and the burden is on the agency to sustain its action.

#### Answers

(C) Notwithstanding any other provision of law, the defendant shall serve an answer or otherwise plead to any complaint made under this subsection within thirty days after service upon the defendant of the pleading in which such complaint is made, unless the court otherwise directs for good cause shown.

### Expedite Treatment

(D) Except as to cases the court considers of greater importance, proceedings before the district court, as authorized by this subsection, and appeals therefrom, take precedence on the docket over all cases and shall be assigned for hearing and trial or for argument at the earliest practicable date and expedited in every way.

### Attorney's Fees

(E) The court may assess against the United States reasonable attorney fees and other litigation costs reasonably incurred in any case under this section in which the complainant has substantially prevailed.

### Administrative Sanctions

(F) Whenever the court orders the production of any agency records improperly withheld from the complainant and assesses against the United States reasonable attorney fees and other litigation costs, and the court additionally issues a written finding that the circumstances surrounding the withholding raise questions whether agency personnel acted arbitrarily or capriciously with respect to the withholding, the Civil Service Commission shall promptly initiate a proceeding to determine whether disciplinary action is warranted against the officer or employee who was primarily responsible for the withholding. The Commission, after investigation and consideration of the evidence submitted, shall submit its findings and recommendations to the administrative authority of the agency concerned and shall send copies of the findings and recommendations to the officer or employee or his representative. The administrative authority shall take the corrective action that the Commission recommends.

### Contempt

(G) In the event of noncompliance with the order of the court, the district court may punish for contempt the responsible employee, and in the case of a uniformed service, the responsible member.

## VOTES OF PUBLIC PROCEEDINGS

(5) Each agency having more than one member shall maintain and make available for public inspection a record of the final votes of each member in every agency proceeding.

## TIME LIMITS

(6) (A) Each agency, upon any request for records made under paragraph (1), (2), or (3) of this subsection, shall—

### Initial Response

(i) determine within ten days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of any such request whether to comply with such request and shall immediately notify the person making such request of such determination and the reasons therefor, and of the right of such person to appeal to the head of the agency any adverse determination; and

### Response to Appeals

(ii) make a determination with respect to any appeal within twenty days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of such appeal. If on appeal the denial of the request for records is in whole or in part upheld, the agency shall notify the person making such request of the provisions for judicial review of that determination under paragraph (4) of this subsection.

## Extensions

(B) In unusual circumstances as specified in this subparagraph, the time limits prescribed in either clause (i) or clause (ii) of subparagraph (A) may be extended by written notice to the person making such request setting forth the reasons for such extension and the date on which a determination is expected to be dispatched. No such notice shall specify a date that would result in an extension for more than ten working days. As used in this subparagraph, "unusual circumstances" means, but only to the extent reasonably necessary to the proper processing of the particular request—

(i) the need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request;

(ii) the need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or

(iii) the need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or more components of the agency having substantial subject-matter interest therein.

## Remedies for Failure to Respond

(C) Any person making a request to any agency for records under paragraph (1), (2), or (3) of this subsection shall be deemed to have exhausted his administrative remedies with respect to such request if the agency fails to comply with the applicable time limit provisions of this paragraph. If the Government can show exceptional circumstances exist and that the agency is exercising due diligence in responding to the request, the court may retain jurisdiction and allow the agency additional time to complete its review of the records. Upon any determination by an agency to comply with a request for records, the records shall be made promptly available to such persons making such requests. Any notification of denial of any request for records under this subsection shall set forth the names and titles or positions of each person responsible for the denial of such request.

## Exemptions

(b) This section does not apply to matters that are—

## CLASSIFIED INFORMATION

(1) (A) specifically authorized under criteria established by an executive order to be kept secret in the interest of national defense or foreign policy and (B) are in fact properly classified pursuant to such Executive order;

## INTERNAL RULES AND PRACTICES

(2) related solely to the internal personnel rules and practices of an agency;

## OTHER STATUTES

(3) specifically exempted from disclosure by statute;

## TRADE SECRETS AND COMMERCIAL OR FINANCIAL INFORMATION

(4) trade secrets and commercial or financial information obtained from a person and privileged or confidential;

## INTERNAL DOCUMENTS

(5) inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency;

## PERSONAL PRIVACY

(6) personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

## INVESTIGATORY FILES

(7) investigatory records compiled for law enforcement purposes, but only to the extent that the production of such records would (A) interfere with enforcement proceedings, (B) deprive a person of a right to a fair trial or an impartial adjudication, (C) constitute an unwarranted invasion of personal privacy, (D) disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source, (E) disclose investigative techniques and procedures, or (F) endanger the life or physical safety of law enforcement personnel;

## BANKING INFORMATION

(8) contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; or

## WELL INFORMATION

(9) geological and geophysical information and data, including maps, concerning wells.

Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under this subsection.

## Rights of Congress

(c) This section does not authorize withholding of information or limit the availability of records to the public, except as specifically stated in this section. This section is not authority to withhold information from Congress.

## Reports to Congress

(d) On or before March 1 of each calendar year, each agency shall submit a report covering the preceding calendar year to the Speaker of the House of Representatives and President of the Senate for referral to the appropriate committees of the Congress. The report shall include—

- (1) the number of determinations made by such agency not to comply with requests for records made to such agency under subsection (a) and the reasons for each such determination;
- (2) the number of appeals made by persons under subsection (a) (4), the result of such appeals, and the reason for the action upon each appeal that results in a denial of information;
- (3) the names and titles or positions of each person responsible for the denial of records requested under this section, and the number of instances of participation for each;
- (4) the results of each proceeding conducted pursuant to subsection (a) (4) (F), including a report of the disciplinary action taken against the

officer or employee who was primarily responsible for improperly withholding records or an explanation of why disciplinary action was not taken;

- (5) a copy of every rule made by such agency regarding this section;
- (6) a copy of the fee schedule and the total amount of fees collected by the agency for making records available under this section; and
- (7) such other information as indicates efforts to administer fully this section.

The Attorney General shall submit an annual report on or before March 1 of each calendar year which shall include for the prior calendar year a listing of the number of cases arising under this section, the exemption involved in each case, the disposition of such case, and the cost, fees, and penalties assessed under subsections (a) (4) (E), (F), and (G). Such report shall also include a description of the efforts undertaken by the Department of Justice to encourage agency compliance with this section.

## Definition of Agency

(e) For purposes of this section, the term "agency" as defined in section 551(1) of this title includes any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency.

As amended by Section 5(b), Pub. L. No. 94-409 (Sept. 13, 1976):

(b) Section 552(b) (3) of title 5, United States Code, is amended to read as follows:

"(3) specifically exempted from disclosure by statute (other than section 552b of this title), provided that such statute (A) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (B) establishes particular criteria for withholding or refers to particular types of matters to be withheld:"

## 31. STATUTE AND TEXTUAL MATERIALS

### 31.1 PRIVACY ACT OF 1974. PUBLIC LAW 93-579

An act to amend title 5, United States Code, by adding a section 552a to safeguard individual privacy from the misuse of Federal records, to provide that individuals be granted access to records concerning them which are maintained by Federal agencies, to establish a Privacy Protection Study Commission, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Privacy Act of 1974".

#### Congressional Findings

Sec. 2.(a) The Congress finds that—

(1) the privacy of an individual is directly affected by the collection, maintenance, use, and dissemination of personal information by Federal agencies;

(2) the increasing use of computers and sophisticated information technology, while essential to the efficient operations of the Government, has greatly magnified the harm to individual privacy that can occur from any collection, maintenance, use, or dissemination of personal information;

(3) the opportunities for an individual to secure employment, insurance, and credit, and his right to due process, and other legal protections are endangered by the misuse of certain information systems;

(4) the right to privacy is a personal and fundamental right protected by the Constitution of the United States; and

(5) in order to protect the privacy of individuals identified in information systems maintained by Federal agencies, it is necessary and proper for the Congress to regulate the collection, maintenance, use, and dissemination of information by such agencies.

#### STATEMENT OF PURPOSE

(b) The purpose of this Act is to provide certain safeguards for an individual against an invasion of personal privacy by requiring Federal agencies, except as otherwise provided by law, to—

(1) permit an individual to determine what records pertaining to him are collected, maintained, used, or disseminated by such agencies;

(2) permit an individual to prevent records pertaining to him obtained

by such agencies for a particular purpose from being used or made available for another purpose without his consent;

(3) permit an individual to gain access to information pertaining to him in Federal agency records, to have a copy made of all or any portion thereof, and to correct or amend such records;

(4) collect, maintain, use, or disseminate any record of identifiable personal information in a manner that assures that such action is for a necessary and lawful purpose, that the information is current and accurate for its intended use, and that adequate safeguards are provided to prevent misuse of such information;

(5) permit exemptions from the requirements with respect to records provided in this Act only in those cases where there is an important public policy need for such exemption as has been determined by specific statutory authority; and

(6) be subject to civil suit for any damages which occur as a result of willful or intentional action which violates any individual's rights under this Act.

Sec. 3. Title 5, United States Code, is amended by adding after section 552 the following new section:

#### § 552a. Records Maintained on Individuals

##### "(a) DEFINITIONS"

For purposes of this section—

"(1) the term 'agency' means agency as defined in section 552(e) of this title;

"(2) the term 'individual' means a citizen of the United States or an alien lawfully admitted for permanent residence;

"(3) the term 'maintain' includes maintain, collect, use, or disseminate;

"(4) the term 'record' means any item, collection, or grouping of information about an individual that is maintained by an agency, including, but not limited to, his education, financial transactions, medical history, and criminal or employment history and that contains his name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a finger or voice print or a photograph;

"(5) the term 'system of records' means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual;

"(6) the term 'statistical record' means a record in a system of records maintained for statistical research or reporting purposes only and not used in whole or in part in making any determination about an identifiable individual, except as provided by section 8 of title 13; and

"(7) the term 'routine use' means, with respect to the disclosure of a record, the use of such record for a purpose which is compatible with the purpose for which it was collected.

##### (b) CONDITIONS OF DISCLOSURE

"No agency shall disclose any record which is contained in a system of records by any means of communication to any person, or to another agency, except pursuant to a written request by, or with the prior written consent of, the individual to whom the record pertains, unless disclosure of the record would be—

"(1) to those officers and employees of the agency which maintains the record who have a need for the record in the performance of their duties;

"(2) required under section 552 of this title;

"(3) for a routine use as defined in subsection (a) (7) of this section and described under subsection (e) (4) (D) of this section;

"(4) to the Bureau of the Census for purposes of planning or carrying

### 31.1 Access Reference File

out a census or survey or related activity pursuant to the provisions of title 13;

"(5) to a recipient who has provided the agency with advance adequate written assurance that the record will be used solely as a statistical research or reporting record, and the record is to be transferred in a form that is not individually identifiable;

"(6) to the National Archives of the United States as a record which has sufficient historical or other value to warrant its continued preservation by the United States Government, or for evaluation by the Administrator of General Services or his designee to determine whether the record has such value;

"(7) to another agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency which maintains the record specifying the particular portion desired and the law enforcement activity for which the record is sought;

"(8) to a person pursuant to a showing of compelling circumstances affecting the health or safety of an individual if upon such disclosure notification is transmitted to the last known address of such individual;

"(9) to either House of Congress, or, to the extent of matter within its jurisdiction, any committee or subcommittee thereof, any joint committee of Congress or subcommittee of any such joint committee;

"(10) to the Comptroller General, or any of his authorized representatives, in the course of the performance of the duties of the General Accounting Office; or

"(11) pursuant to the order of a court of competent jurisdiction.

#### (c) ACCOUNTING OF CERTAIN DISCLOSURES

"Each agency, with respect to each system of records under its control, shall—

"(1) except for disclosures made under subsections (b)(1) or (b) (2) of this section, keep an accurate accounting of—

"(A) the date, nature, and purpose of each disclosure of a record to any person or to another agency made under subsection (b) of this section; and

"(B) the name and address of the person or agency to whom the disclosure is made;

"(2) retain the accounting made under paragraph (1) of this subsection for at least five years or the life of the record, whichever is longer, after the disclosure for which the accounting is made;

"(3) except for disclosures made under subsection (b) (7) of this section, make the accounting made under paragraph (1) of this subsection available to the individual named in the record at his request; and

"(4) inform any person or other agency about any correction or notation of dispute made by the agency in accordance with subsection (d) of this section of any record that has been disclosed to the person or agency if an accounting of the disclosure was made.

#### (d) ACCESS TO RECORDS

"Each agency that maintains a system of records shall—

##### Personal Review

"(1) upon request by any individual to gain access to his record or to any information pertaining to him which is contained in the system, permit him and upon his request, a person of his own choosing to accompany him, to review the record and have a copy made of all or any portion thereof in a form comprehensible to him, except that the agency may require the individual to furnish a written statement authorizing discussion of that individual's record in the accompanying person's presence;

##### Amendment Request

"(2) permit the individual to request amendment of a record pertaining to him and—

"(A) not later than 10 days (excluding Saturdays, Sundays, and legal

public holidays) after the date of receipt of such request, acknowledge in writing such receipt; and "(B) promptly, either—

"(i) make any correction of any portion thereof which the individual believes is not accurate, relevant, timely, or complete; or "(ii) inform the individual of its refusal to amend the record in accordance with his request, the reason for the refusal, the procedures established by the agency for the individual to request a review of that refusal by the head of the agency or an officer designated by the head of the agency, and the name and business address of that official;

##### Review

"(3) permit the individual who disagrees with the refusal of the agency to amend his record to request a review of such refusal, and not later than 30 days (excluding Saturdays, Sundays, and legal public holidays) from the date on which the individual requests such review, complete such review and make a final determination unless, for good cause shown, the head of the agency extends such 30-day period; and if, after his review, the reviewing official also refuses to amend the record in accordance with the request, permit the individual to file with the agency a concise statement setting forth the reasons for his disagreement with the refusal of the agency, and notify the individual of the provisions for judicial review of the reviewing official's determination under subsection (g) (1) (A) of this section;

##### Notation of Dispute

"(4) in any disclosure, containing information about which the individual has filed a statement of disagreement, occurring after the filing of the statement under paragraph (3) of this subsection, clearly note any portion of the record which is disputed and provide copies of the statement and, if the agency deems it appropriate, copies of a concise statement of the reasons of the agency for not making the amendments requested, to persons or other agencies to whom the disputed record has been disclosed; and

"(5) nothing in this section shall allow an individual access to any information compiled in reasonable anticipation of a civil action or proceeding.

#### (e) AGENCY REQUIREMENTS

"Each agency that maintains a system of records shall—

"(1) maintain in its records only such information about an individual as is relevant and necessary to accomplish a purpose of the agency required to be accomplished by statute or by executive order of the President;

"(2) collect information to the greatest extent practicable directly from the subject individual when the information may result in adverse determinations about an individual's rights, benefits, and privileges under Federal programs;

"(3) inform each individual whom it asks to supply information, on the form which it uses to collect the information or on a separate form that can be retained by the individual—

"(A) the authority (whether granted by statute, or by executive order of the President) which authorizes the solicitation of the information and whether disclosure of such information is mandatory or voluntary;

"(B) the principal purpose or purposes for which the information is intended to be used;

"(C) the routine uses which may be made of the information, as published pursuant to paragraph (4) (D) of this subsection; and

"(D) the effects on him, if any, of not providing all or any part of the requested information;

##### Publication in Federal Register

"(4) subject to the provisions of paragraph (1) of this subsection, publish in the Federal Register at least annually a notice of the existence and character of the system of records, which notice shall include—

"(A) the name and location of the system;

"(B) the categories of individuals on whom records are maintained in

the system;

"(C) the categories of records maintained in the system;

"(D) each routine use of the records contained in the system, including the categories of users and the purpose of such use;

"(E) the policies and practices of the agency regarding storage, retrievability, access controls, retention, and disposal of the records;

"(F) the title and business address of the agency official who is responsible for the system of records;

"(G) the agency procedures whereby an individual can be notified at his request if the system of records contains a record pertaining to him;

"(H) the agency procedures whereby an individual can be notified at his request how he can gain access to any record pertaining to him contained in the system of records, and how he can contest its content; and

"(I) the categories of sources of records in the system;

"(5) maintain all records which are used by the agency in making any determination about any individual with such accuracy, relevance, timeliness, and completeness as is reasonable necessary to assure fairness to the individual in the determination;

"(6) prior to disseminating any record about an individual to any person other than an agency, unless the dissemination is made pursuant to subsection (b) (2) of this section, make reasonable efforts to assure that such records are accurate, complete, timely, and relevant for agency purposes;

"(7) maintain no record describing how any individual exercises rights guaranteed by the First Amendment unless expressly authorized by statute or by the individual about whom the record is maintained or unless pertinent to and within the scope of an authorized law enforcement activity;

"(8) make reasonable efforts to serve notice on an individual when any record on such individual is made available to any person under compulsory legal process when such process becomes a matter of public record;

### Rules of Conduct

"(9) establish rules of conduct for persons involved in the design, development, operation, or maintenance of any system of records, or in maintaining any record, and instruct each such person with respect to such rules and the requirements of this section, including any other rules and procedures adopted pursuant to this section and the penalties for noncompliance.

### Confidentiality of Records

"(10) establish appropriate administrative, technical, and physical safeguards to insure the security and confidentiality of records and to protect against any anticipated threats or hazards to their security or integrity which could result in substantial harm, embarrassment, inconvenience, or unfairness to any individual on whom information is maintained; and

### Publication in Federal Register

"(11) at least 30 days prior to publication of information under paragraph (4) (D) of this subsection, publish in the Federal Register notice of any new use or intended use of the information in the system, and provide an opportunity for interested persons to submit written data, views, or arguments to the agency.

### (f) AGENCY RULES

"In order to carry out the provisions of this section, each agency that maintains a system of records shall promulgate rules, in accordance with the requirements (including general notice) of section 553 of this title, which shall—

"(1) establish procedures whereby an individual can be notified in response to his request if any system of records named by the individual contains a record pertaining to him;

"(2) define reasonable times, places, and requirements for identifying an individual who requests his record or information pertaining to him before the agency shall make the record or information available to the individual;

"(3) establish procedures for the disclosure to an individual upon his request of his record or information pertaining to him, including special procedure, if deemed necessary, for the disclosure to an individual of medical records, including psychological records, pertaining to him;

"(4) establish procedures for reviewing a request from an individual concerning the amendment of any record or information pertaining to the individual; for making a determination on the request, for an appeal within the agency of an initial adverse agency determination, and for whatever additional means may be necessary for each individual to be able to exercise fully his rights under this section; and

### Fees

"(5) establish fees to be charged, if any, to any individual for making copies of his record, excluding the cost of any search for and review of the record.

The Office of the Federal Register shall annually compile and publish the rules promulgated under this subsection and agency notices published under subsection (e) (4) of this section in a form available to the public at low cost.

### (g) (1) CIVIL REMEDIES

"Whenever any agency

"(A) makes a determination under subsection (d) (3) of this section not to amend an individual's record in accordance with his request, or fails to make such review in conformity with that subsection;

"(B) refuses to comply with an individual request under subsection (d) (1) of this section;

"(C) fails to maintain any record concerning any individual with such accuracy, relevance, timeliness, and completeness as is necessary to assure fairness in any determination relating to the qualifications, character, rights, or opportunities of, or benefits to the individual that may be made on the basis of such record, and consequently a determination is made which is adverse to the individual; or

"(D) fails to comply with any other provision of this section, or any rule promulgated thereunder, in such a way as to have an adverse effect on an individual, the individual may bring a civil action against the agency, and the district courts of the United States shall have jurisdiction in the matters under the provisions of this subsection.

"(2) (A) In any suit brought under the provisions of subsection (g) (1) (A) of this section, the court may order the agency to amend the individual's record in accordance with his request or in such other way as the court may direct. In such a case the court shall determine the matter *de novo*.

"(B) The court may assess against the United States reasonable attorney fees and other litigation costs reasonably incurred in any case under this paragraph in which the complainant has substantially prevailed.

"(3) (A) In any suit brought under the provisions of subsection (g) (1) (B) of this section, the court may enjoin the agency from withholding the records and order the production to the complainant of any agency records improperly withheld from him. In such a case the court shall determine the matter *de novo*, and may examine the contents of any agency records *in camera* to determine whether the records or any portion thereof may be withheld under any of the exemptions set forth in subsection (k) of this section, and the burden is on the agency to sustain its action

### Damages

"(4) In any suit brought under the provisions of subsection (g) (1) (C) or (D) of this section in which the court determines that the agency acted in a manner which was intentional or willful, the United States shall be liable to the individual in an amount equal to the sum of—

"(A) actual damages sustained by the individual as a result of the refusal or failure, but in no case shall a person entitled to recovery receive less than the sum of \$1,000; and

"(B) the costs of the action together with reasonable attorney fees as determined by the court.

"(5) An action to enforce any liability created under this section may

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### 31.1 Access Reference File

be brought in the district court of the United States in the district in which the complainant resides, or has his principal place of business, or in which the agency records are situated, or in the District of Columbia, without regard to the amount in controversy, within two years from the date on which the cause of action arises, except that where an agency has materially and willfully misrepresented any information required under this section to be disclosed to an individual and the information so misrepresented is material to establishment of the liability of the agency to the individual under this section, the action may be brought at any time within two years after discovery by the individual of the misrepresentation. Nothing in this section shall be construed to authorize any civil action by reason of any injury sustained as the result of a disclosure of a record prior to the effective date of this section.

#### (h) RIGHTS OF LEGAL GUARDIANS

"For the purposes of this section, the parent of any minor, or the legal guardian of any individual who has been declared to be incompetent due to physical or mental incapacity or age by a court of competent jurisdiction, may act on behalf of the individual.

#### (i) (1) CRIMINAL PENALTIES

"Any officer or employee of an agency, who by virtue of his employment or official position, has possession of, or access to, agency records which contain individually identifiable information the disclosure of which is prohibited by this section or by rules or regulations established thereunder, and who knowing that disclosure of the specific material is so prohibited, willfully discloses the material in any manner to any person or agency not entitled to receive it, shall be guilty of a misdemeanor and fined not more than \$5,000.

"(2) Any officer or employee of any agency who willfully maintains a system of records without meeting the notice requirements of subsection (e) (4) of this section shall be guilty of a misdemeanor and fined not more than \$5,000.

"(3) Any person who knowingly and willfully requests or obtains any record concerning an individual from an agency under false pretenses shall be guilty of a misdemeanor and fined not more than \$5,000.

#### (j) GENERAL EXEMPTIONS

"The head of any agency may promulgate rules, in accordance with the requirements (including general notice) of sections 553 (b) (1), (2), and (3), (c), and (e) of this title, to exempt any system of records within the agency from any part of this section except subsections (b), (c) (1) and (2), (e) (4) (A) through (F), (e) (6), (7), (8), (10), and (11), and (i) if the system of records is—

"(1) maintained by the Central Intelligence Agency; or

(2) maintained by an agency or component thereof which performs as its principal function any activity pertaining to the enforcement of criminal laws, including police efforts to prevent, control, or reduce crime or to apprehend criminals, and the activities of prosecutors, courts, correctional, probation, pardon, or parole authorities, and which consists of (A) information compiled for the purpose of identifying individual criminal offenders and alleged offenders and consisting only of identifying data and notations of arrests, the nature and disposition of criminal charges, sentencing, confinement, release, and parole and probation status; (B) information compiled for the purpose of a criminal investigation, including reports of informants and investigators, and associated with an identifiable individual; or

(C) reports identifiable to an individual compiled at any stage of the process of enforcement of the criminal laws from arrest or indictment through release from supervision.

At the time rules are adopted under this subsection, the agency shall include in the statement required under section 553 (c) of this title, the reasons why the system of records is to be exempted from a provision of this section.

#### (k) SPECIFIC EXEMPTIONS

"The head of any agency may promulgate rules, in accordance with the requirements (including general notice) of sections 553 (b) (1), (2), and (3), (c), and (e) of this title, to exempt any system of records within the agency from subsections (c) (3), (d), (e) (1), (e) (4) (G)-(H); and (i) and (f) of this section if the system of records is—

"(1) subject to the provisions of section 552 (b) (1) of this title;

"(2) investigatory material compiled for law enforcement purposes, other than material within the scope of subsection (j) (2) of this section: *Provided, however,* That if any individual is denied any right, privilege, or benefit that he would otherwise be entitled by Federal law, or for which he would otherwise be eligible, as a result of the maintenance of such material, such material shall be provided to such individual, except to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to the effective date of this section, under an implied promise that the identity of the source would be held in confidence;

"(3) maintained in connection with providing protective services to the President of the United States or other individuals pursuant to section 3056 of title 18;

"(4) required by statute to be maintained and used solely as statistical records;

"(5) investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information, but only to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to the effective date of this section, under an implied promise that the identity of the source would be held in confidence;

"(6) testing or examination material used solely to determine individual qualifications for appointment or promotion in the Federal service the disclosure of which would compromise the objectivity or fairness of the testing or examination process; or

"(7) evaluation material used to determine potential for promotion in the armed services, but only to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to the effective date of this section, under an implied promise that the identity of the source would be held in confidence.

At the time rules are adopted under this subsection, the agency shall include in the statement required under section 553 (c) of this title, the reasons why the system of records is to be exempted from a provision of this section.

#### (l) (1) ARCHIVAL RECORDS

"Each agency record which is accepted by the Administrator of General Services for storage, processing, and servicing in accordance with section 3103 of title 44 shall, for the purposes of this section, be considered to be maintained by the agency which deposited the record and shall be subject to the provisions of this section. The Administrator of General Services shall not disclose the record except to the agency which maintains the record, or under rules established by that agency which are not inconsistent with the provisions of this section.

"(2) Each agency record pertaining to an identifiable individual which was transferred to the National Archives of the United States as a record which has sufficient historical or other value to warrant its continued preservation by the United States Government, prior to the effective date of this section, shall, for the purposes of this section, be considered to be maintained by the National Archives and shall not be subject to the provisions of this section, except that a statement generally describing such records (made after the requirements relating to records subject to subsections (e) (4) (A) through (G) of this section) shall be published in the



Federal Register.

"(3) Each agency record pertaining to an identifiable individual which is transferred to the National Archives of the United States as a record which has sufficient historical or other value to warrant its continued preservation by the United States Government, on or after the effective date of this section, shall, for the purposes of this section, be considered to be maintained by the National Archives and shall be exempt from the requirements of this section except subsections (e) (4) (A) through (G) and (e) (9) of this section.

#### (m) GOVERNMENT CONTRACTORS

"When an agency provides by a contract for the operation by or on behalf of the agency of a system of records to accomplish an agency function, the agency shall, consistent with its authority, cause the requirements of this section to be applied to such system. For purposes of subsection (i) of this section any such contractor and any employee of such contractor, if such contract is agreed to on or after the effective date of this section, shall be considered to be an employee of an agency.

#### (n) MAILING LISTS

"An individual's name and address may not be sold or rented by an agency unless such action is specifically authorized by law. This provision shall not be construed to require the withholding of names and addresses otherwise permitted to be made public.

#### (o) REPORT ON NEW SYSTEMS

"Each agency shall provide adequate advance notice to Congress and the Office of Management and Budget of any proposal to establish or alter any system of records in order to permit an evaluation of the probable or potential effect of such proposal on the privacy and other personal or property rights of individuals or the disclosure of information relating to such individuals, and its effect on the preservation of the constitutional principles of federalism and separation of powers.

#### (p) ANNUAL REPORT

"The President shall submit to the Speaker of the House and the President of the Senate, by June 30 of each calendar year, a consolidated report, separately listing for each Federal agency the number of records contained in any system of records which were exempted from the application of this section under the provisions of subsection (j) and (k) of this section during the preceding calendar year, and the reasons for the exemptions, and such other information as indicates efforts to administer fully this section.

#### (q) EFFECT OF OTHER LAWS

"No agency shall rely on any exemption contained in section 552 of this title to withhold from an individual any record which is otherwise accessible to such individual under the provisions of this section."

### Other Amendments

Sec. 4. The chapter analysis of chapter 5 of title 5, United States Code, is amended by inserting: "552a. Records about individuals." immediately below: "552. Public information; agency rules, opinions, orders, and proceedings."

## Privacy Protection Study Commission

Sec. 5. (a) (1) There is established a Privacy Protection Study Commission (hereinafter referred to as the "Commission") which shall be composed of seven members as follows:

(A) three appointed by the President of the United States,

(B) two appointed by the President of the Senate, and

(C) two appointed by the Speaker of the House of Representatives.

Members of the Commission shall be chosen from among persons who, by reason of their knowledge and expertise in any of the following areas—civil rights and liberties, law, social sciences, computer technology, business, records management, and State and local government—are well qualified for service on the Commission.

(2) The members of the Commission shall elect a Chairman from among themselves.

#### Vacancies

(3) Any vacancy in the membership of the Commission, as long as there are four members in office, shall not impair the power of the Commission but shall be filled in the same manner in which the original appointment was made.

(4) A quorum of the Commission shall consist of a majority of the members, except that the Commission may establish a lower number as a quorum for the purpose of taking testimony. The Commission is authorized to establish such committees and delegate such authority to them as may be necessary to carry out its functions. Each member of the Commission, including the Chairman, shall have equal responsibility and authority in all decisions and actions of the Commission, shall have full access to all information necessary to the performance of their functions, and shall have one vote. Action of the Commission shall be determined by a majority vote of the members present. The Chairman (or a member designated by the Chairman to be acting Chairman) shall be the official spokesman of the Commission in its relations with the Congress, Government agencies, other persons, and the public, and, on behalf of the Commission, shall see to the faithful execution of the administrative policies and decisions of the Commission, and shall report thereon to the Commission from time to time or as the Commission may direct.

#### Budget requests

(5) (A) Whenever the Commission submits any budget estimate or request to the President or the Office of Management and Budget, it shall concurrently transmit a copy of that request to Congress.

#### Legislative Recommendations

(3) Whenever the Commission submits any legislative recommendations, or testimony, or comments on legislation to the President or Office of Management and Budget, it shall concurrently transmit a copy thereof to the Congress. No officer or agency of the United States shall have any authority to require the Commission to submit its legislative recommendations, or testimony, or comments on legislation, to any officer or agency of the United States for approval, comments, or review, prior to the submission of such recommendations, testimony, or comments to the Congress.

(8) The Commission shall—

(1) make a study of the data banks, automated data processing programs, and information systems of governmental, regional, and private organizations, in order to determine the standards and procedures in force for the protection of personal information; and

(2) recommend to the President and the Congress the extent, if any, to which the requirements and principles of section 552a of title 5, United States Code, should be applied to the information practices of those organizations by legislation, administrative action, or voluntary adoption of such requirements and principles, and report on such other legislative recommendations as it may determine to be necessary to protect the privacy of individuals while meeting the legitimate needs of government

and society for information.

(c) (1) In the course of conducting the study required under subsection (b) (1) of this section, and in its reports thereon, the Commission may research, examine, and analyze—

(A) interstate transfer of information about individuals that is undertaken through manual files or by computer or other electronic or telecommunications means;

(B) data banks and information programs and systems the operation of which significantly or substantially affect the enjoyment of the privacy and other personal and property rights of individuals;

(C) the use of social security numbers, license plate numbers, universal identifiers, and other symbols to identify individuals in data banks and to gain access to, integrate, or centralize information systems and files; and

(D) the matching and analysis of statistical data, such as Federal census data, with other sources of personal data, such as automobile registries and telephone directories, in order to reconstruct individual responses to statistical questionnaires for commercial or other purposes, in a way which results in a violation of the implied or explicitly recognized confidentiality of such information.

### Commission May Study

(2) (A) The Commission may include in its examination personal information activities in the following areas: medical; insurance; education; employment and personnel; credit, banking and financial institutions; credit bureaus; the commercial reporting industry; cable television and other telecommunications media; travel, hotel and entertainment reservation; and electronic check processing.

(B) The Commission shall include in its examination a study of—

(i) whether a person engaged in interstate commerce who maintains a mailing list should be required to remove an individual's name and address from such list upon request of that individual;

(ii) whether the Internal Revenue Service should be prohibited from transferring individually identifiable data to other agencies and to agencies of State governments;

(iii) whether the Federal Government should be liable for general damages incurred by an individual as the result of a willful or intentional violation of the provisions of sections 552a (g) (1) (C) or (D) of title 5, United States Code; and

(iv) whether and how the standards for security and confidentiality of records required under section 552a (e) (10) of such title should be applied when a record is disclosed to a person other than an agency.

### Religious Organizations, Exception

(C) The Commission may study such other personal information activities necessary to carry out the congressional policy embodied in this Act, except that the Commission shall not investigate information systems maintained by religious organizations.

### Guidelines for Study

(3) In conducting such study, the Commission shall—

(A) determine what laws, Executive orders, regulations, directives, and judicial decisions govern the activities under study and the extent to which they are consistent with the rights of privacy, due process of law, and other guarantees in the Constitution;

(B) determine to what extent governmental and private information systems affect Federal-State relations or the principle of separation of powers;

(C) examine the standards and criteria governing programs, policies, and practices relating to the collection, soliciting, processing, use, access, integration, dissemination, and transmission of personal information; and

(D) to the maximum extent practicable, collect and utilize findings, reports, studies, hearing transcripts, and recommendations of governmental, legislative and private bodies, institutions, organizations, and individuals which pertain to the problems under study by the Commission.

(d) In addition to its other functions the Commission may—

(1) request assistance of the heads of appropriate departments, agencies, and instrumentalities of the Federal Government, of State and local governments, and other persons in carrying out its functions under this Act;

(2) upon request, assist Federal agencies in complying with the requirements of section 552a of title 5, United States Code;

(3) determine what specific categories of information, the collection of which would violate an individual's right of privacy, should be prohibited by statute from collection by Federal agencies; and

(4) upon request, prepare model legislation for use by State and local governments in establishing procedures for handling, maintaining, and disseminating personal information at the State and local level and provide such technical assistance to State and local governments as they may require in the preparation and implementation of such legislation.

(e) (1) The Commission may, in carrying out its functions under this section, conduct such inspections, sit and act at such times and places, hold such hearings, take such testimony, require by subpoena the attendance of such witnesses and the production of such books, records, papers, correspondence, and documents, administer such oaths, have such printing and binding done, and make such expenditures as the Commission deems advisable. A subpoena shall be issued only upon an affirmative vote of a majority of all members of the Commission. Subpoenas shall be issued under the signature of the Chairman or any member of the Commission designated by the Chairman and shall be served by any person designated by the Chairman or any such member. Any member of the Commission may administer oaths or affirmations to witnesses appearing before the Commission.

### Reports, Transmittal to Commission

(2) (A) Each department, agency, and instrumentality of the executive branch of the Government is authorized to furnish to the Commission, upon request made by the Chairman, such information, data, reports and such other assistance as the Commission deems necessary to carry out its functions under this section. Whenever the head of any such department, agency, or instrumentality submits a report pursuant to section 552c (a) of title 5, United States Code, a copy of such report shall be transmitted to the Commission.

(B) In carrying out its functions and exercising its powers under this section, the Commission may accept from any such department, agency, independent instrumentality, or other person any individually identifiable data if such data is necessary to carry out such powers and functions. In any case in which the Commission accepts any such information, it shall assure that the information is used only for the purpose for which it is provided, and upon completion of that purpose such information shall be destroyed or returned to such department, agency, independent instrumentality, or person from which it is obtained, as appropriate.

(3) The Commission shall have the power to—

(A) appoint and fix the compensation of an executive director, and such additional staff personnel as may be necessary, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, but at rates not in excess of the maximum rate for GS-18 of the General Schedule under section 5332 of such title; and

(B) procure temporary and intermittent services to the same extent as is authorized by section 3109 of title 5, United States Code.

The Commission may delegate any of its functions to such personnel of the Commission as the Commission may designate and may authorize such successive redelegations of such functions as it may deem desirable.

### Rules and Regulations

(4) The Commission is authorized—

(A) to adopt, amend, and repeal rules and regulations governing the manner of its operations, organization, and personnel;

(B) to enter into contracts or other arrangements or modifications thereof, with any government, and department, agency, or independent

instrumentality of the United States, or with any person, firm, association, or corporation, and such contracts or other arrangements, or modifications thereof, may be entered into without legal consideration, without performance or other bonds, and without regard to section 3709 of the Revised Statutes, as amended (41 U.S.C.5);

(C) to make advance, progress, and other payments which the Commission deems necessary under this Act without regard to the provisions of section 3648 of the Revised Statutes, as amended (31 U.S.C. 529); and

(D) to take such other action as may be necessary to carry out its functions under this section.

## COMPENSATION

(f) (1) Each [the] member of the Commission who is an officer or employee of the United States shall serve without additional compensation, but shall continue to receive the salary of his regular position when engaged in the performance of the duties vested in the Commission.

(2) A member of the Commission other than one to whom paragraph (1) applies shall receive per diem at the maximum daily rate for GS-18 of the General Schedule when engaged in the actual performance of the duties vested in the Commission.

(3) All members if the Commission shall be reimbursed for travel, subsistence, and other necessary expenses incurred by them in the performance of the duties vested in the Commission

## REPORT TO PRESIDENT AND CONGRESS

(g) The Commission shall, from time to time, and in an annual report, report to the President and the Congress on its activities in carrying out the provisions of this section. The Commission shall make a final report to the President and to the Congress on its findings pursuant to the study required to be made under subsection (b) (1) of this section not later than two years from the date on which all of the members of the Commission are appointed. The Commission shall cease to exist thirty days after the date on which its final report is submitted to the President and the Congress.

## PENALTIES

(h) (1) Any member, officer, or employee of the Commission, who by virtue of his employment or official position, has possession of, or access to, agency records which contain individually identifiable information the disclosure of which is prohibited by this section, and who knowing that disclosure of the specific material is so prohibited, willfully discloses the material in any manner to any person or agency not entitled to receive it, shall be guilty of a misdemeanor and fined not more than \$5,000.

(2) Any person who knowingly and willfully requests or obtains any record concerning an individual from the Commission under false pretenses shall be guilty of a misdemeanor and fined not more than \$5,000.

Sec. 6. The Office of Management and Budget shall—

(1) develop guidelines and regulations for the use of agencies in implementing the provisions of section 552a of title 5, United States Code, as added by section 3 of this Act; and

(2) provide continuing assistance to and oversight of the implementation of the provisions of such section by agencies.

Sec. 7. (a) (1) It shall be unlawful for any Federal, State or local government agency to deny to any individual any right, benefit, or privilege provided by law because of such individual's refusal to disclose his social security account number.

(2) the provisions of paragraph (1) of this subsection shall not apply with respect to—

(A) any disclosure which is required by Federal statute, or

(B) the disclosure of a social security number to any Federal, State, or local agency maintaining a system of records in existence and operating before January 1, 1975, if such disclosure was required under statute or regulation adopted prior to such date to verify the identity of an individual.

(b) Any Federal, State, or local government agency which requests an

individual to disclose his social security account number shall inform that individual whether that disclosure is mandatory or voluntary, by what statutory or other authority such number is solicited, and what uses will be made of it.

## Effective Date

Sec. 8. The provisions of this Act shall be effective on and after the date of enactment, except that the amendments made by sections 3 and 4 shall become effective 270 days following the day on which this Act is enacted.

## Appropriation

Sec. 9. There is authorized to be appropriated to carry out the provisions of section 5 of this Act for fiscal years 1975, 1976, and 1977 the sum of \$1,500,000, except that not more than \$750,000 may be expended during any such fiscal year.

Approved December 31, 1974.

## LEGISLATIVE HISTORY:

HOUSE REPORT No. 93-1416 accompanying H.R. 16373 (Comm. on Government Operations).

SENATE REPORT No. 93-1183 (Comm. on Government Operations).

CONGRESSIONAL RECORD, Vol. 120 (1974): Nov. 21, considered and passed Senate. Dec. 11, considered and passed House, amended, in lieu of H.R. 16373. Dec. 17, Senate concurred in House amendment with amendments. Dec. 18, House concurred in Senate amendments.

WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 11, No. 1: Jan. 1, Presidential statement.

## 21. STATUTE AND OTHER TEXTUAL MATERIAL

### 21.1 FEDERAL ADVISORY COMMITTEE ACT OF 1972. PUBLIC LAW 92-463

An act to authorize the establishment of a system governing the creation and operation of advisory committees in the executive branch of the Federal Government, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Federal Advisory Committee Act".

#### Findings and Purposes

Sec. 2. (a) The Congress finds that there are numerous committees, boards, commissions, councils, and similar groups which have been established to advise officers and agencies in the executive branch of the Federal Government and that they are frequently a useful and beneficial means of furnishing expert advice, ideas, and diverse opinions to the Federal Government.

(b) The Congress further finds and declares that—

(1) the need for many existing advisory committees has not been adequately reviewed;

(2) new advisory committees should be established only when they are determined to be essential and their number should be kept to the minimum necessary;

(3) advisory committees should be terminated when they are no longer carrying out the purposes for which they were established;

(4) standards and uniform procedures should govern the establishment, operation, administration, and duration of advisory committees;

(5) the Congress and the public should be kept informed with respect to the number, purpose, membership, activities, and cost of advisory committees; and

(6) the function of advisory committees should be advisory only, and that all matters under their consideration should be determined, in accordance with law, by the official, agency, or officer involved.

#### Definitions

Sec. 3. For the purpose of this Act—

(1) The term "Director" means the Director of the Office of Management and Budget.

(2) The term "advisory committee" means any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof (hereafter in this paragraph referred to as "committee"), which is—

(A) established by statute or reorganization plan, or

(B) established or utilized by the President, or

(C) established or utilized by one or more agencies,

in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government, except that such term excludes (i) the Advisory Commission on Intergovernmental Relations, (ii) the Commission on Government Procurement, and (iii) any committee which is composed wholly of full-time officers or employees of the Federal Government.

(3) The term "agency" has the same meaning as in section 551(1) of title 5, United States Code.

(4) The term "Presidential advisory committee" means an advisory committee which advises the President.

#### Applicability

Sec. 4. (a) The provisions of this Act or of any rule, order, or regulation promulgated under this Act shall apply to each advisory committee except to the extent that any Act of Congress establishing any such advisory committee specifically provides otherwise.

#### Restrictions

(b) Nothing in this Act shall be construed to apply to any advisory committee established or utilized by—

(1) the Central Intelligence Agency; or

(2) the Federal Reserve System.

(c) Nothing in this Act shall be construed to apply to any local civic group whose primary function is that of rendering a public service with respect to a Federal program, or any State or local committee, council, board, commission, or similar group established to advise or make recommendations to State or local officials or agencies.

#### Responsibilities of Congressional Committees.

#### Review

Sec. 5. (a) In the exercise of its legislative review function, each standing committee of the Senate and the House of Representatives shall make a continuing review of the activities of each advisory committee under its jurisdiction to determine whether such advisory committee should be abolished or merged with any other advisory committee, whether the responsibilities of such advisory committee should be revised, and whether such advisory committee performs a necessary function not already being performed. Each such standing committee shall take appropriate action to obtain the enactment of legislation necessary to carry out the purpose of this subsection.

#### Guidelines

(b) In considering legislation establishing, or authorizing the establishment of any advisory committee, each standing committee of the Senate and of the House of Representatives shall determine, and report such determination to the Senate or to the House of Representatives, as the case may be, whether the functions of the proposed advisory committee are being or could be performed by one or more agencies or by an advisory committee already in existence, or by enlarging the mandate of an existing advisory committee. Any such legislation shall—

(1) contain a clearly defined purpose for the advisory committee;

(2) require the membership of the advisory committee to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee;

## 21.1 Access Reference File

(3) contain appropriate provisions to assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's independent judgment;

(4) contain provisions dealing with authorization of appropriations, the date for submission of reports (if any), the duration of the advisory committee, and the publication of reports and other materials, to the extent that the standing committee determines the provisions of section 10 of this Act to be inadequate; and

(5) contain provisions which will assure that the advisory committee will have adequate staff (either supplied by an agency or employed by it), will be provided adequate quarters, and will have funds available to meet its other necessary expenses.

(c) To the extent they are applicable, the guidelines set out in subsection (b) of this section shall be followed by the President, agency heads, or other Federal officials in creating an advisory committee.

### Responsibilities of the President

Sec. 6. (a) The President may delegate responsibility for evaluating and taking action, where appropriate, with respect to all public recommendations made to him by Presidential advisory committees.

#### Report to Congress

(b) Within one year after a Presidential advisory committee has submitted a public report to the President, the President or his delegate shall make a report to the Congress stating either his proposals for action or his reasons for inaction, with respect to the recommendations contained in the public report.

#### Annual Report to Congress

(c) The President shall, not later than March 31 of each calendar year (after the year in which this Act is enacted), make an annual report to the Congress on the activities, status, and changes in the composition of advisory committees in existence during the preceding calendar year. The report shall contain the name of every advisory committee, the date of and authority for its creation, its termination date or the date it is to make a report, its functions, a reference to the reports it has submitted, a statement of whether it is an ad hoc or continuing body, the dates of its meetings, the names and occupations of its current members, and the total estimated annual cost to the United States to fund, service, supply, and maintain such committee. Such report shall include a list of those advisory committees abolished by the President, and in the case of advisory committees established by statute, a list of those advisory committees which the President recommends be abolished together with his reasons therefor.

#### Exclusion

The President shall exclude from this report any information which, in his judgment, should be withheld for reasons of national security, and he shall include in such report a statement that such information is excluded.

### Responsibilities of the Director, Office of Management and Budget

#### Committee Management Secretariat

#### Establishment

Sec. 7. (a) The Director shall establish and maintain within the Office of Management and Budget a Committee Management Secretariat, which shall be responsible for all matters relating to advisory committees.

#### Review

(b) The Director shall, immediately after the enactment of this Act, institute a comprehensive review of the activities and responsibilities of each advisory committee to determine—

(1) whether such committee is carrying out its purpose;

(2) whether, consistent with the provisions of applicable statutes, the responsibilities assigned to it should be revised;

(3) whether it should be merged with other advisory committees; or

(4) whether it should be abolished.

#### Recommendations to President and Congress.

The Director may from time to time request such information as he deems necessary to carry out his functions under this subsection. Upon the completion of the Director's review he shall make recommendations to the President and to either the agency head or the Congress with respect to action he believes should be taken. Thereafter, the Director shall carry out a similar review annually. Agency heads shall cooperate with the Director in making the reviews required by this subsection.

#### Performance Guidelines

(2) The Director shall prescribe administrative guidelines and management controls applicable to advisory committees, and, to the maximum extent feasible, provide advice, assistance, and guidance to advisory committees to improve their performance. In carrying out his functions under this subsection, the Director shall consider the recommendations of each agency head with respect to means of improving the performance of advisory committees whose duties are related to such agency.

#### Uniform Pay Guidelines

(d)(1) The Director, after study and consultation with the Civil Service Commission, shall establish guidelines with respect to uniform fair rates of pay for comparable services of members, staffs, and consultants of advisory committees in a manner which gives appropriate recognition to the responsibilities and qualifications required and other relevant factors. Such regulations shall provide that—

(A) no member of any advisory committee or of the staff of any advisory committee shall receive compensation at a rate in excess of the rate specified for GS-18 of the General Schedule under section 5332 of title 5, United States Code; and

#### Travel Expenses

(B) such members, while engaged in the performance of their duties away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons employed intermittently in the Government service.

(2) Nothing in this subsection shall prevent—

(A) an individual who (without regard to his service with an advisory committee) is a full-time employee of the United States, or

(B) an individual who immediately before his service with an advisory committee was such an employee,

from receiving compensation at the rate at which he otherwise would be compensated (or was compensated) as a full-time employee of the United States.

#### Expense Recommendations

(e) The Director shall include in budget recommendations a summary of the amounts he deems necessary for the expenses of advisory committees, including the expenses for publication of reports where appropriate.

**Responsibilities of Agency Heads**

Sec. 8. (a) Each agency head shall establish uniform administrative guidelines and management controls for advisory committees established by that agency, which shall be consistent with directives of the Director under section 7 and section 10. Each agency shall maintain systematic information on the nature, functions, and operations of each advisory committee within its jurisdiction.

**Advisory Committee Management Control Officer, Designation**

(b) The head of each agency which has an advisory committee shall designate an Advisory Committee Management Officer who shall—

- (1) exercise control and supervision over the establishment, procedures, and accomplishments of advisory committees established by that agency;
- (2) assemble and maintain the reports, records, and other papers of any such committee during its existence; and
- (3) carry out, on behalf of that agency, the provisions of section 552 of title 5, United States Code, with respect to such reports, records, and other papers.

**Establishment and Purpose of Advisory Committees**

Sec. 9. (a) No advisory committee shall be established unless such establishment is—

- (1) specifically authorized by statute or by the President; or

**Publication in *Federal Register***

(2) determined as a matter of formal record, by the head of the agency involved after consultation with the Director, with timely notice published in the *Federal Register*, to be in the public interest in connection with the performance of duties imposed on that agency by law.

(b) Unless otherwise specifically provided by statute or Presidential directive, advisory committees shall be utilized solely for advisory functions. Determinations of action to be taken and policy to be expressed with respect to matters upon which an advisory committee reports or makes recommendations shall be made solely by the President or an officer of the Federal Government.

**Charter, Filing**

(c) No advisory committee shall meet or take any action until an advisory committee charter has been filed with (1) the Director, in the case of Presidential advisory committees, or (2) with the head of the agency to whom any advisory committee reports and with the standing committees of the Senate and of the House of Representatives having legislative jurisdiction of such agency.

**Contents**

Such charter shall contain the following information:

- (A) the committee's official designation;
- (B) the committee's objectives and the scope of its activity;
- (C) the period of time necessary for the committee to carry out its purposes;
- (D) the agency or official to whom the committee reports;
- (E) the agency responsible for providing the necessary support for the committee;

(F) a description of the duties for which the committee is responsible, and, if such duties are not solely advisory, a specification of the authority for such functions;

(G) the estimated annual operating costs in dollars and man years for such committee;

(H) the estimated number and frequency of committee meetings;

(I) the committee's termination date, if less than two years from the date of the committee's establishment; and

(J) the date the charter is filed.

A copy of any such charter shall also be furnished to the Library of Congress.

**Advisory Committee Procedures**

**Meetings**

Sec. 10. (a)(1) Each advisory committee meeting shall be open to the public.

**Notice**

**Publication in *Federal Register***

**Regulations**

(2) Except when the President determines otherwise for reasons of national security, timely notice of each such meeting shall be published in the *Federal Register*, and the Director shall prescribe regulations to provide for other types of public notice to insure that all interested persons are notified of such meeting prior thereto.

(3) Interested persons shall be permitted to attend, appear before, or file statements with any advisory committee, subject to such reasonable rules or regulations as the Director may prescribe.

(b) Subject to section 552 of title 5, United States Code, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist.

**Minutes**

**Certification**

(c) Detailed minutes of each meeting of each advisory committee shall be kept and shall contain a record of the persons present, a complete and accurate description of matters discussed and conclusions reached, and copies of all reports received, issued, or approved by the advisory committee. The accuracy of all minutes shall be certified to by the chairman of the advisory committee.

**Annual Report**

(d) Subsections (c)(1) and (c)(3) of this section shall not apply to any advisory committee meeting which the President, or the head of the agency to which the advisory committee reports, determines is concerned with matters listed in section 552(b) of title 5, United States Code. Any such determination shall be in writing and shall contain the reasons for such determination. If such a determination is made, the advisory committee shall issue a report at least annually setting forth a summary of its activities and such related matters as would be informative to the public consistent with the policy of section 552(b) of title 5, United States Code.

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### Federal Officer or Employee, Attendance

(e) There shall be designated an officer or employee of the Federal Government to chair or attend each meeting of each advisory committee. The officer or employee so designated is authorized, whenever he determines it to be in the public interest, to adjourn any such meeting. No advisory committee shall conduct any meeting in the absence of that officer or employee.

(f) Advisory committees shall not hold any meetings except at the call of, or with the advance approval of, a designated officer or employee of the Federal Government, and in the case of advisory committees (other than Presidential advisory committees), with an agenda approved by such officer or employee.

### Availability of Transcripts

Sec. 11. (a) Except where prohibited by contractual agreements entered into prior to the effective date of this Act, agencies and advisory committees shall make available to any person, at actual cost of duplication, copies of transcripts of agency proceedings or advisory committee meetings.

### "Agency Proceeding"

As used in this section "agency proceeding" means any proceeding as defined in section 551(12) of title 5, United States Code.

## Fiscal and Administrative Provisions

### Recordkeeping

Sec. 12. (a) Each agency shall keep records as will fully disclose the disposition of any funds which may be at the disposal of its advisory committees and the nature and extent of their activities. The General Services Administration, or such other agency as the President may designate, shall maintain financial records with respect to Presidential advisory committees.

### Audit

The Comptroller General of the United States, or any of his authorized representatives, shall have access, for the purpose of audit and examination, to any such records.

### Agency Support Services

(b) Each agency shall be responsible for providing support services for each advisory committee established by or reporting to it unless the establishing authority provides otherwise. Where any such advisory committee reports to more than one agency, only one agency shall be responsible for support services at any one time. In the case of Presidential advisory committees, such services may be provided by the General Services Administration.

## Responsibilities of Library of Congress

### Reports and Background Papers

#### Depository

Sec. 13. Subject to section 552 of title 5, United States Code, the Director shall provide for the filing with the Library of Congress of at least

eight copies of each report made by every advisory committee and, where appropriate, background papers prepared by consultants. The Librarian of Congress shall establish a depository for such reports and papers where they shall be available to public inspection and use.

## Termination of Advisory Committees

Sec. 14. (a) (1) Each advisory committee which is in existence on the effective date of this Act shall terminate not later than the expiration of the two-year period following such effective date unless—

(A) in the case of an advisory committee established by the President or an officer of the Federal Government, such advisory committee is renewed by the President or that officer by appropriate action prior to the expiration of such two-year period; or

(B) in the case of an advisory committee established by an Act of Congress, its duration is otherwise provided for by law.

(2) Each advisory committee established after such effective date shall terminate not later than the expiration of the two-year period beginning on the date of its establishment unless—

(A) in the case of an advisory committee established by the President or an officer of the Federal Government such advisory committee is renewed by the President or such officer by appropriate action prior to the end of such period; or

(B) in the case of an advisory committee established by an Act of Congress, its duration is otherwise provided for by law.

### Renewal

(b)(1) Upon the renewal of any advisory committee, such advisory committee shall file a charter in accordance with section 9(c).

(2) Any advisory committee established by an Act of Congress shall file a charter in accordance with such section upon the expiration of each successive two-year period following the date of enactment of the Act establishing such advisory committee.

(3) No advisory committee required under this subsection to file a charter shall take any action (other than preparation and filing of such charter) prior to the date on which such charter is filed.

### Continuation

(c) Any advisory committee which is renewed by the President or any officer of the Federal Government may be continued only for successive two-year periods by appropriate action taken by the President or such officer prior to the date on which such advisory committee would otherwise terminate.

### Effective Date

Sec. 15. Except as provided in section 7(b), this Act shall become effective upon the expiration of ninety days following the date of enactment.

Approved October 6, 1972.

### LEGISLATIVE HISTORY:

HOUSE REPORTS: No. 92-1017 (Comm. on Government Operations) and No. 92-1403 (Comm. of Conference).

SENATE REPORT No. 92-1098 accompanying S. 3529 (Comm. on Government Operations).

CONGRESSIONAL RECORD, Vol. 118 (1972):

May 9, considered and passed House. Sept. 12, considered and passed Senate, amended, in lieu of S. 3529. Sept. 19, Senate agreed to conference report. Sept. 20, House agreed to conference report.

As amended by Section 5(c), Pub. L. No. 94-409 (Sept. 13, 1976):

(c) Subsection (d) of section 10 of the Federal Advisory Committee Act is amended by striking out the first sentence and inserting in lieu thereof the following: "Subsections (a) (1) and (a) (3) of this section shall not apply to any portion of an advisory committee meeting where the President, or the head of the agency to which the advisory committee reports, determines that such portion of such meeting may be closed to the public in accordance with subsection (c) of section 552b of title 5, United States Code." 5 USC app. I.





Public Law 94-409  
94th Congress, S. 5  
September 13, 1976

## An Act

To provide that meetings of Government agencies shall be open to the public, and for other purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,* That this Act may be cited as the "Government in the Sunshine Act".

### DECLARATION OF POLICY

SEC. 2. It is hereby declared to be the policy of the United States that the public is entitled to the fullest practicable information regarding the decisionmaking processes of the Federal Government. It is the purpose of this Act to provide the public with such information while protecting the rights of individuals and the ability of the Government to carry out its responsibilities.

### OPEN MEETINGS

SEC. 3. (a) Title 5, United States Code, is amended by adding after section 552a the following new section:

#### "§ 552b. Open meetings

"(a) For purposes of this section—

"(1) the term 'agency' means any agency, as defined in section 552(e) of this title, headed by a collegial body composed of two or more individual members, a majority of whom are appointed to such position by the President with the advice and consent of the Senate, and any subdivision thereof authorized to act on behalf of the agency;

"(2) the term 'meeting' means the deliberations of at least the number of individual agency members required to take action on behalf of the agency where such deliberations determine or result in the joint conduct or disposition of official agency business, but does not include deliberations required or permitted by subsection (d) or (e); and

"(3) the term 'member' means an individual who belongs to a collegial body heading an agency.

(b) Members shall not jointly conduct or dispose of agency business other than in accordance with this section. Except as provided in subsection (c), every portion of every meeting of an agency shall be open to public observation.

"(c) Except in a case where the agency finds that the public interest requires otherwise, the second sentence of subsection (b) shall not apply to any portion of an agency meeting, and the requirements of subsections (d) and (e) shall not apply to any information pertaining to such meeting otherwise required by this section to be disclosed to the public, where the agency properly determines that such portion or portions of its meeting or the disclosure of such information is likely to—

"(1) disclose matters that are (A) specifically authorized under criteria established by an Executive order to be kept secret in the

Government  
in the  
Sunshine Act.  
5 USC 552b  
note.  
5 USC 552b  
note.

5 USC 552b.  
Definitions.

5 USC 552.

5 USC 552.

interests of national defense or foreign policy and (B) in fact properly classified pursuant to such Executive order:

"(2) relate solely to the internal personnel rules and practices of an agency;

"(3) disclose matters specifically exempted from disclosure by statute (other than section 552 of this title), provided that such statute (A) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (B) establishes particular criteria for withholding or refers to particular types of matters to be withheld;

"(4) disclose trade secrets and commercial or financial information obtained from a person and privileged or confidential;

"(5) involve accusing any person of a crime, or formally censuring any person;

"(6) disclose information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy;

"(7) disclose investigatory records compiled for law enforcement purposes, or information which if written would be contained in such records, but only to the extent that the production of such records or information would (A) interfere with enforcement proceedings, (B) deprive a person of a right to a fair trial or an impartial adjudication, (C) constitute an unwarranted invasion of personal privacy, (D) disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source, (E) disclose investigative techniques and procedures, or (F) endanger the life or physical safety of law enforcement personnel;

"(8) disclose information contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions;

"(9) disclose information the premature disclosure of which would—

"(A) in the case of an agency which regulates currencies, securities, commodities, or financial institutions, be likely to (i) lead to significant financial speculation in currencies, securities, or commodities, or (ii) significantly endanger the stability of any financial institution; or

"(B) in the case of any agency, be likely to significantly frustrate implementation of a proposed agency action.

except that subparagraph (B) shall not apply in any instance where the agency has already disclosed to the public the content or nature of its proposed action, or where the agency is required by law to make such disclosure on its own initiative prior to taking final agency action on such proposal; or

"(10) specifically concern the agency's issuance of a subpoena, or the agency's participation in a civil action or proceeding, an action in a foreign court or international tribunal, or an arbitration, or the initiation, conduct, or disposition by the agency of a particular case of formal agency adjudication pursuant to the procedures in section 554 of this title or otherwise involving a determination on the record after opportunity for a hearing.

5 USC 554.

"(d)(1) Action under subsection (c) shall be taken only when a majority of the entire membership of the agency (as defined in subsection (a) (1)) votes to take such action. A separate vote of the agency members shall be taken with respect to each agency meeting a portion or portions of which are proposed to be closed to the public pursuant to subsection (c), or with respect to any information which is proposed to be withheld under subsection (c). A single vote may be taken with respect to a series of meetings, a portion or portions of which are proposed to be closed to the public, or with respect to any information concerning such series of meetings, so long as each meeting in such series involves the same particular matters and is scheduled to be held no more than thirty days after the initial meeting in such series. The vote of each agency member participating in such vote shall be recorded and no proxies shall be allowed.

Recorded voting.

"(2) Whenever any person whose interests may be directly affected by a portion of a meeting requests that the agency close such portion to the public for any of the reasons referred to in paragraph (5), (6), or (7) of subsection (c), the agency, upon request of any one of its members, shall vote by recorded vote whether to close such meeting.

"(3) Within one day of any vote taken pursuant to paragraph (1) or (2), the agency shall make publicly available a written copy of such vote reflecting the vote of each member on the question. If a portion of a meeting is to be closed to the public, the agency shall, within one day of the vote taken pursuant to paragraph (1) or (2) of this subsection, make publicly available a full written explanation of its action closing the portion together with a list of all persons expected to attend the meeting and their affiliation.

Copies, availability.

"(4) Any agency, a majority of whose meetings may properly be closed to the public pursuant to paragraph (4), (8), (9)(A), or (10) of subsection (c), or any combination thereof, may provide by regulation for the closing of such meetings or portions thereof in the event that a majority of the members of the agency votes by recorded vote at the beginning of such meeting, or portion thereof, to close the exempt portion or portions of the meeting, and a copy of such vote, reflecting the vote of each member on the question, is made available to the public. The provisions of paragraphs (1), (2), and (3) of this subsection and subsection (c) shall not apply to any portion of a meeting to which such regulations apply: *Provided*, That the agency shall, except to the extent that such information is exempt from disclosure under the provisions of subsection (c), provide the public with public announcement of the time, place, and subject matter of the meeting and of each portion thereof at the earliest practicable time.

Meeting closure, regulation.

"(e)(1) In the case of each meeting, the agency shall make public announcement, at least one week before the meeting, of the time, place, and subject matter of the meeting, whether it is to be open or closed to the public, and the name and phone number of the official designated by the agency to respond to requests for information about the meeting. Such announcement shall be made unless a majority of the members of the agency determines by a recorded vote that agency business requires that such meeting be called at an earlier date, in which case the agency shall make public announcement of the time, place, and subject matter of such meeting, and whether open or closed to the public, at the earliest practicable time.

Public announcement.

Scheduling, public announcement.

"(2) The time or place of a meeting may be changed following the public announcement required by paragraph (1) only if the agency publicly announces such change at the earliest practicable time. The

Scheduling changes, public announcement.

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subject matter of a meeting, or the determination of the agency to open or close a meeting, or portion of a meeting, to the public, may be changed following the public announcement required by this subsection only if (A) a majority of the entire membership of the agency determines by a recorded vote that agency business so requires and that no earlier announcement of the change was possible, and (B) the agency publicly announces such change and the vote of each member upon such change at the earliest practicable time.

Scheduling notice, publication in Federal Register.

“(3) Immediately following each public announcement required by this subsection, notice of the time, place, and subject matter of a meeting, whether the meeting is open or closed, any change in one of the preceding, and the name and phone number of the official designated by the agency to respond to requests for information about the meeting, shall also be submitted for publication in the Federal Register.

Closed meetings, certification.

“(f)(1) For every meeting closed pursuant to paragraphs (1) through (10) of subsection (c), the General Counsel or chief legal officer of the agency shall publicly certify that, in his or her opinion, the meeting may be closed to the public and shall state each relevant exemptive provision. A copy of such certification, together with a statement from the presiding officer of the meeting setting forth the time and place of the meeting, and the persons present, shall be retained by the agency. The agency shall maintain a complete transcript or electronic recording adequate to record fully the proceedings of each meeting, or portion of a meeting, closed to the public, except that in the case of a meeting, or portion of a meeting, closed to the public pursuant to paragraph (8), (9) (A), or (10) of subsection (c), the agency shall maintain either such a transcript or recording, or a set of minutes. Such minutes shall fully and clearly describe all matters discussed and shall provide a full and accurate summary of any actions taken, and the reasons therefor, including a description of each of the views expressed on any item and the record of any rollcall vote (reflecting the vote of each member on the question). All documents considered in connection with any action shall be identified in such minutes.

Transcripts, recordings or minutes.

Public availability.

“(2) The agency shall make promptly available to the public, in a place easily accessible to the public, the transcript, electronic recording, or minutes (as required by paragraph (1)) of the discussion of any item on the agenda, or of any item of the testimony of any witness received at the meeting, except for such item or items of such discussion or testimony as the agency determines to contain information which may be withheld under subsection (c). Copies of such transcript, or minutes, or a transcription of such recording disclosing the identity of each speaker, shall be furnished to any person at the actual cost of duplication or transcription. The agency shall maintain a complete verbatim copy of the transcript, a complete copy of the minutes, or a complete electronic recording of each meeting, or portion of a meeting, closed to the public, for a period of at least two years after such meeting, or until one year after the conclusion of any agency proceeding with respect to which the meeting or portion was held, whichever occurs later.

Retention.

Regulations. Notice, publication in Federal Register.

“(g) Each agency subject to the requirements of this section shall, within 180 days after the date of enactment of this section, following consultation with the Office of the Chairman of the Administrative Conference of the United States and published notice in the Federal Register of at least thirty days and opportunity for written comment by any person, promulgate regulations to implement the requirements

of subsections (b) through (f) of this section. Any person may bring a proceeding in the United States District Court for the District of Columbia to require an agency to promulgate such regulations if such agency has not promulgated such regulations within the time period specified herein. Subject to any limitations of time provided by law, any person may bring a proceeding in the United States Court of Appeals for the District of Columbia to set aside agency regulations issued pursuant to this subsection that are not in accord with the requirements of subsections (b) through (f) of this section and to require the promulgation of regulations that are in accord with such subsections.

Judicial proceeding.

“(h) (1) The district courts of the United States shall have jurisdiction to enforce the requirements of subsections (b) through (f) of this section by declaratory judgment, injunctive relief, or other relief as may be appropriate. Such actions may be brought by any person against an agency prior to, or within sixty days after, the meeting out of which the violation of this section arises, except that if public announcement of such meeting is not initially provided by the agency in accordance with the requirements of this section, such action may be instituted pursuant to this section at any time prior to sixty days after any public announcement of such meeting. Such actions may be brought in the district court of the United States for the district in which the agency meeting is held or in which the agency in question has its headquarters, or in the District Court for the District of Columbia. In such actions a defendant shall serve his answer within thirty days after the service of the complaint. The burden is on the defendant to sustain his action. In deciding such cases the court may examine in camera any portion of the transcript, electronic recording, or minutes of a meeting closed to the public, and may take such additional evidence as it deems necessary. The court, having due regard for orderly administration and the public interest, as well as the interests of the parties, may grant such equitable relief as it deems appropriate, including granting an injunction against future violations of this section or ordering the agency to make available to the public such portion of the transcript, recording, or minutes of a meeting as is not authorized to be withheld under subsection (e) of this section.

Jurisdiction.

Civil actions.

Relief.

“(2) Any Federal court otherwise authorized by law to review agency action may, at the application of any person properly participating in the proceeding pursuant to other applicable law, inquire into violations by the agency of the requirements of this section and afford such relief as it deems appropriate. Nothing in this section authorizes any Federal court having jurisdiction solely on the basis of paragraph (1) to set aside, enjoin, or invalidate any agency action (other than an action to close a meeting or to withhold information under this section) taken or discussed at any agency meeting out of which the violation of this section arose.

Inquiry.

“(i) The court may assess against any party reasonable attorney fees and other litigation costs reasonably incurred by any other party who substantially prevails in any action brought in accordance with the provisions of subsection (g) or (h) of this section, except that costs may be assessed against the plaintiff only where the court finds that the suit was initiated by the plaintiff primarily for frivolous or dilatory purposes. In the case of assessment of costs against an agency, the costs may be assessed by the court against the United States.

Litigation costs, assessment.

“(j) Each agency subject to the requirements of this section shall annually report to Congress regarding its compliance with such requirements, including a tabulation of the total number of agency

Report to Congress.

meetings open to the public, the total number of meetings closed to the public, the reasons for closing such meetings, and a description of any litigation brought against the agency under this section, including any costs assessed against the agency in such litigation (whether or not paid by the agency).

5 USC 552.

"(k) Nothing herein expands or limits the present rights of any person under section 552 of this title, except that the exemptions set forth in subsection (c) of this section shall govern in the case of any request made pursuant to section 552 to copy or inspect the transcripts, recordings, or minutes described in subsection (f) of this section. The requirements of chapter 33 of title 44, United States Code, shall not apply to the transcripts, recordings, and minutes described in subsection (f) of this section.

44 USC 3301.

"(l) This section does not constitute authority to withhold any information from Congress, and does not authorize the closing of any agency meeting or portion thereof required by any other provision of law to be open.

5 USC 552a.  
5 USC prec.  
500.

"(m) Nothing in this section authorizes any agency to withhold from any individual any record, including transcripts, recordings, or minutes required by this section, which is otherwise accessible to such individual under section 552a of this title."

(b) The chapter analysis of chapter 5 of title 5, United States Code, is amended by inserting:

"552b. Open meetings."

immediately below:

"552a. Records about individuals."

EX PARTE COMMUNICATIONS

SEC. 4. (a) Section 557 of title 5, United States Code, is amended by adding at the end thereof the following new subsection:

"(d) (1) In any agency proceeding which is subject to subsection (a) of this section, except to the extent required for the disposition of ex parte matters as authorized by law—

"(A) no interested person outside the agency shall make or knowingly cause to be made to any member of the body comprising the agency, administrative law judge, or other employee who is or may reasonably be expected to be involved in the decisional process of the proceeding, an ex parte communication relevant to the merits of the proceeding;

"(B) no member of the body comprising the agency, administrative law judge, or other employee who is or may reasonably be expected to be involved in the decisional process of the proceeding, shall make or knowingly cause to be made to any interested person outside the agency an ex parte communication relevant to the merits of the proceeding;

"(C) a member of the body comprising the agency, administrative law judge, or other employee who is or may reasonably be expected to be involved in the decisional process of such proceeding who receives, or who makes or knowingly causes to be made, a communication prohibited by this subsection shall place on the public record of the proceeding:

"(i) all such written communications;

"(ii) memoranda stating the substance of all such oral communications; and

"(iii) all written responses, and memoranda stating the substance of all oral responses, to the materials described in clauses (i) and (ii) of this subparagraph;

"(D) upon receipt of a communication knowingly made or knowingly caused to be made by a party in violation of this subsection, the agency, administrative law judge, or other employee presiding at the hearing may, to the extent consistent with the interests of justice and the policy of the underlying statutes, require the party to show cause why his claim or interest in the proceeding should not be dismissed, denied, disregarded, or otherwise adversely affected on account of such violation; and

"(E) the prohibitions of this subsection shall apply beginning at such time as the agency may designate, but in no case shall they begin to apply later than the time at which a proceeding is noticed for hearing unless the person responsible for the communication has knowledge that it will be noticed, in which case the prohibitions shall apply beginning at the time of his acquisition of such knowledge. Applicability.

"(2) This subsection does not constitute authority to withhold information from Congress."

(b) Section 551 of title 5, United States Code, is amended—

(1) by striking out "and" at the end of paragraph (12);

(2) by striking out the "act," at the end of paragraph (13) and inserting in lieu thereof "act; and"; and

(3) by adding at the end thereof the following new paragraph:

"(14) 'ex parte communication' means an oral or written communication not on the public record with respect to which reasonable prior notice to all parties is not given, but it shall not include requests for status reports on any matter or proceeding covered by this subchapter."

"Ex parte communication."

(c) Section 556(d) of title 5, United States Code, is amended by inserting between the third and fourth sentences thereof the following new sentence: "The agency may, to the extent consistent with the interests of justice and the policy of the underlying statutes administered by the agency, consider a violation of section 557(d) of this title sufficient grounds for a decision adverse to a party who has knowingly committed such violation or knowingly caused such violation to occur."

5 USC 557.

#### CONFORMING AMENDMENTS

SEC. 5. (a) Section 410(b)(1) of title 39, United States Code, is amended by inserting after "Section 552 (public information)," the words "section 552a (records about individuals), section 552b (open meetings)."

(b) Section 552(b)(3) of title 5, United States Code, is amended to read as follows:

"(3) specifically exempted from disclosure by statute (other than section 552b of this title), provided that such statute (A) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (B) establishes particular criteria for withholding or refers to particular types of matters to be withheld:"

(c) Subsection (d) of section 10 of the Federal Advisory Committee Act is amended by striking out the first sentence and inserting in lieu thereof the following: "Subsections (a)(1) and (a)(3) of this section shall not apply to any portion of an advisory committee meeting where

5 USC app. 1.

the President, or the head of the agency to which the advisory committee reports, determines that such portion of such meeting may be closed to the public in accordance with subsection (c) of section 552b of title 5, United States Code."

## EFFECTIVE DATE

5 USC 552b  
note.

Sec. 6. (a) Except as provided in subsection (b) of this section, the provisions of this Act shall take effect 180 days after the date of its enactment.

(b) Subsection (g) of section 552b of title 5, United States Code, as added by section 3(a) of this Act, shall take effect upon enactment.

Approved September 13, 1976.

LEGISLATIVE HISTORY:

HOUSE REPORTS: No. 94-880, Pt. 1 and No. 94-880, Pt. 2, accompanying H.R. 11656 (Comm. on Government Operations) and No. 94-1441 (Comm. of Conference).

SENATE REPORTS: No. 94-354 (Comm. on Government Operations), No. 94-381 (Comm. on Rules and Administration) and No. 94-1175 (Comm. of Conference).

## CONGRESSIONAL RECORD:

Vol. 121 (1975): Nov. 5, 6, considered and passed Senate.

Vol. 122 (1976): July 28, considered and passed House, amended, in lieu of H.R. 11656.

Aug. 31, House and Senate agreed to conference report.

## WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS:

Vol. 12, No. 38 (1976): Sept. 13, Presidential statement.