IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

No. 1118

PETER H. FORSHAM, Et Al.,
Plaintiffs-Petitioners,

v.

JOSEPH A. CALIFANO, JR., Et Al.,
Defendants-Respondents.

On Writ of Certiorari to the United States Court of Appeals For the District of Columbia Circuit

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BRIEF OF THE AMERICAN COUNCIL ON EDUCATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, ET AL. AS AMICI CURIAE IN SUPPORT OF DEFENDANTS-RESPONDENTS

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INTRODUCTION AND LIST OF AMICI CURIAE

The amici curiae in this case include the American Council on Education, which is a nonprofit corporation organized under the laws of, and located in, the District of Columbia. Founded in 1918, the Council is a

membership organization of 1355 nonprofit institutions of higher education and 180 educational associations. The Council is the major coordinating body in post-secondary education.

The Association of American Medical Colleges is a voluntary, nonprofit, non-governmental corporation established under the laws of the State of Illinois, having its principal place of business in the District of Columbia. Its corporate purpose is the advancement of medical education. Its institutional membership includes all one hundred twenty four accredited and operating nonprofit medical schools and medical colleges in the United States. Its membership also includes over 400 teaching hospitals in which undergraduate and graduate medical education is conducted, and 63 academic and professional societies, the members of which are actively engaged in medical education and the conduct of biomedical research.

Also included as an amicus curia is the National Association of State Universities and Land Grant Colleges.

We respectfully refer the Court to the Statement of Jurisdiction, Citation of Opinions Below, Statement of the Case and the Statutes Involved presented in the brief of Plaintiffs-Petitioners.

CONSENT OF PARTIES

This amici curiae brief is being filed with the consent of all parties to this proceeding. Letters of consent of all parties have been filed with the Clerk of Court.

QUESTION PRESENTED

Are raw research data in the possession of a grantee of Federal research funds, including all records of basic research information and notes developed in the course of a research project but not included in required research reports, Federal agency records requiring disclosure to the public under the Freedom of Information Act?

INTEREST OF AMICI CURIAE

The amici curiae are associations of colleges, universities, and university officials with a substantial interest in Federally sponsored research. In 1978, America's universities performed 54% of all basic research under taken pursuant to Federal grants. Staats, *Federal Research Grants,* "Science", Vol. 205, July 6, 1979, p. 18. A total of 58% of all research supported by the National Institutes of Health ("NIH") in fiscal year 1978 was performed by institutions of higher education. "Basic Data Relating to the National Institutes of Health", U.S. Department of Health, Education & Welfare, 1979, p. 3 (hereinafter referred to as "Basic Data Relating to the NIH"). In the performance of basic and applied research, the research investigators who conduct such research for institutions of higher education maintain records of various types of all research data and of observations with respect to such data throughout the research project. Such records are voluminous. Reports and other forms of publication which result from the research project do not encompass all of the records of information, data and observations. Such information, data and observations are referred to as raw data as opposed to the data which are reported and published after being interpreted and

analyzed. The amici curiae believe that a decision by this Court in favor of Petitioners resulting in the disclosure of such raw data would have a serious and adverse impact on the capacity of colleges and universities to undertake research supported by the Federal Government.

ARGUMENT

1. The Federal Research Grant Is A Method of Supporting Research Involving Autonomy of Grantees

Research activity by the Federal Government has grown enormously in the past 30 years. In the area of health research, involving mainly basic biomedical research and clinical medical research, Federal expenditures have grown from about $74 million in fiscal year ("FY") 1950 to about $4 billion in FY 1978. "Basic Data Relating to the NIH", U.S. Department of Health, Education & Welfare, 1974, p. 5; "Basic Data Relating to the NIH", *supra,* 1979, p. 5. Research expenditures in the military and space fields are higher than in the health area though the growth rate has not accelerated as it has in the area of health research. "Special Analyses, Budget of the United States Government, Fiscal Year 1980", p. 295. Most research activity in the health field has been conducted through the provision of financial assistance to institutions of higher learning by Federal grants. "Basic Data Relating to the NIH", *supra,* 1979, pp. 5, 26.

The use of Federal grants to support research is the only way a major national undertaking in basic and applied science related to the health of Americans is possible for it enables the Government to utilize the abilities of the many scientists not in the employ of the Federal Government.

In the opinion of the Circuit Court of Appeals in this case, the importance of autonomy for the non-Federal research institutions and investigators and the value of the grant form of asistance in fostering such autonomy are emphasized. The Court's majority makes the following observations:

> "In a grant program the federal government gets the advantage of services rendered by someone who is doing his own thing, his own autonomous thing. It is not the same as a government operation in disguise.
>
> "Through its grant to university groups, the government obtains the efforts of creative persons who flourish in an academic atmosphere. Such arrangements provide a measure of detachment and independence from the mission of the government agency. The researchers may feel the tug of government purse strings, but they also feel answerable to the standards of their academic colleagues. . . .
>
> "The central question is whether the government is really involved in the core of the program. At least in a case such as the one before us, where there was no claim of significant government control of day-by-day operation, or detailed involvement in the planning or execution of the program, the overall concept of autonomy of grantees persists, even though there are federal objectives, rights of federal audit and perhaps some overarching federal requirements."

Forsham v. *Califano,* 587 F.2d 1128 (Circuit Court of Appeals, D.C. Circuit, 1978).

The grant device is one in which the grantee, a non-Federal institution, is helped "in an undertaking of his own, which the government aids because of a gen-

eral approval of the undertaking". Mason, *Current Trends in Federal Grant Law—Fiscal Year 1976,* 35 "Fed. Bar Journal", pp. 163, 166. "The grant is dominated by the grantees goal and his autonomy." Mason, *supra,* p. 167. The role of the Government in such an arrangement "can be likened to that of an interested and concerned donor . . ." Willcox, 22 Admin. L. Rev. 125 (1970). As the Circuit Court of Appeals for the Second Circuit reasoned in *Washba* v. *N.Y.U.,* 492 F.2d 96 (Court of Appeals for the Second Circuit, 1974), at page 102:

> "This kind of arrangement whereby federal funds are used to prime the pump of research efforts in private scientific institutions which the government could not perform as well has social values too obvious to require elaboration. Only rarely are professors of Dr. Ochoa's eminence willing to enter government in peacetime. It is equally clear that scientists of his reputation on staffs of private institutions with a wealth of choices before them are not likely to be willing to undertake projects under public grants if they are deprived of the freedom of management which they consider necessary and would have in grants not federally financed."

In a recent article in "Science", the Comptroller General of the United States echoed these same sentiments about the need for the autonomy of researchers and grantee institutions. Staats, *Federal Research Grants,* "Science", Vol. 205, July 6, 1979, p. 18. In describing the individual grant supported researcher, he states that:

> "He is his own director, his own boss. He has a heightened sense of self-reliance and autonomy, and this serves as crucial motivation for his work

> . . . . Such autonomy has come to be viewed by many scientists, and non-scientists, as necessary to scientific excellence." Staats, *supra,* p. 19.

This article indicates the important role that Federal research grant support has played in fostering such autonomy and excellence. The purpose of grant support is characterized as follows:

> "I would like to emphasize the basic intention of a research grant is to support, not to procure in the sense that one procures hardware. It inherently involves a long-term view, in that it supports and encourages effort which is characterized by its perennial and unspecific potential for social benefits, not by its ability to generate specific products or services." *Ibid.*

The autonomy of research grantees is also demonstrated by the affidavit in this case of Dr. G. Donald Whedon, Director of the National Institute of Arthritis, Metabolism and Digestive Diseases ("NIAMDD") which financed the research involved in this case by grants. The pertinent parts of that affidavit are set forth in *Forsham* v. *Califano,* 587 F.2d 1128 (Circuit Court of Appeals D.C. Circuit, 1978), at p. 1131:

> "The UGDP raw data (e.g. patient charts and forms) are the property of the individual investigators and the Coordinating Center and are not owned by NIAMDD . . . . Management of the day to day operations of grant supported activities is the responsibility of the grantee."

In this connection, see 45 C.F.R. §§ 74.80, 74.82.

In 1977 and 1978 the House and Senate passed the Federal Grant and Cooperative Agreement Act of 1977 which became law on February 3, 1978. 41 U.S.C. §§ 501

to 509. The intent of that legislation was to establish for Federal agencies statutory definitions and standards related to the use of grant, contract and cooperative agreements as methods of providing Federal funds to carry out Federal objectives. 41 U.S.C. § 501, Senate Report No. 95-449 (Government Affairs Committee), September 22, 1977, p. 2. 41 U.S.C. § 504 provides that a grant agreement shall be used whenever (1) the purpose is to transfer money or other Federal property or services to recipients in order to accomplish a public purpose of support or stimulation authorized by statute rather than the acquisition of property or services and (2) no substantial involvement is anticipated between the Federal agency and the recipient. While this provision was enacted in 1978, the legislative history indicates an intent to characterize "existing relationships" between the Federal Government and recipients. Senate Report No. 95-449, *supra,* p. 10. The Senate Report, *supra,* at page 31, makes it clear that the definition of a grant used was intended to embody concepts which had been used in the Federal Government since 1958:

> "Second, the committee examined the House and Senate committee reports accompanying the bill which became Public Law 85-934, the Grants Act. (S. Rept. No. 2044, July 30, 1958 and H. Rept. 2640, August 15, 1958). Both reports relied upon an explanation of the legislation submitted by the Director of the National Science Foundation in expressing legislative intent. The following advantage of the grant over the contract is cited:
>
> > "Where the Government desires to engage the services of an educational or nonprofit organization for the conduct of a specific piece of research directed toward a specific problem, the use of the contract form is obviously in order. On the other hand, where it is the desire of the Government to stipulate and support fundamental research in a given field, with the perimeters of inquiry limited only to the curiosity and creativity of the scientific investigator, the use of the grant form has several marked advantages.
>
> "The committee feels that the legislative intent of the Grants Act was to provide authority for grants in instances wherein the basic relationship established was one of Federal assistance. This intent is compatible with the provisions of S. 1437."

The characterization of the grant agreement in 41 U.S.C. § 504 is certainly consistent with the grant relationship described by Willcox writing in 1970, and by Department of Health, Education & Welfare regulations and grants policy statements effective during the time of the transactions involved in this case. 42 C.F.R. § 52.10; 45 C.F.R. §§ 74.80, 74.82; "Public Health Service Grants Policy Statement", Department of Health, Education & Welfare, October 1974, pp. 33, 56, 57. See the succeeding section of this brief regarding a specific discussion of these regulations and policies.

The Federal Grant and Cooperative Agreement Act of 1977 adds additional weight to the proposition that the grant is intended to optimize grantee autonomy in carrying out research activity and is not intended to procure records of raw data collected in the course of research.

A holding in this case that the raw data involved in the UGDP research projects, and not in the possession of the Government, is subject to disclosure to the public would jeopardize the autonomy of all research grant-

ees and serve to make the major instrument of health research—the grant—much less effective. For reasons stated more fully hereafter, individual investigators and educational institutions would find participation in research undertakings far less attractive if records of basic research data were held to be agency records and subject to public disclosure.

2. HEW Regulations and Policies Reflect No Requirement That Grantees Make Basic or Raw Data Available to the Public

The basic premise of a Federal research grant then is that it is support for activities of the grantee that are consistent with a Federal research policy and that assure maximum autonomy to the grantee and investigators in undertaking that activity. Staats, *Federal Research Grants,* "Science," Vol. 205, July 6, 1979, pp. 18, 19; Mason, *Current Trends in Federal Grant Law —Fiscal Year 1976,* 35 Fed. Bar Journal," (1976), pp. 163, 166; *Washba* v. *N.Y.U.,* 492 F.2d 96 (Court of Appeals for the Second Circuit, 1974); 41 U.S.C. § 504. The Department of Health, Education & Welfare regulations and policy statements on grants are fully consistent with this premise and do not in any way require that the basic research data which underlies research publications and reports supported by Federal grants be treated as agency records. The regulations regarding research grants financed by the Department of Health, Education & Welfare do not require that basic research data be supplied to the Department. 42 C.F.R. § 52.10 establishes that the research grant is to assist in meeting the costs of conducting identifiable research activity, not to procure research data. Progress reports are required during and at the termination of research projects. 42 C.F.R. § 52(a) 12; 45 C.F.R. §§ 74.80, 74.82.

Interim and termination reports are essentially intended to produce a "summary statement of progress toward the achievement of the originally stated aims, a list of the results considered significant, and a list of publications resulting from the project . . . .". "Public Health Service Grants Policy Statement", U.S. Department of Health, Education & Welfare, October 1, 1974, p. 33; "Public Health Service Grants Policy Statement", U.S. Department of Health, Education & Welfare, October 1, 1976, p. 42. Obviously, the reports are not intended to produce the basic research data accumulated during the project; even the results that have to be described are limited to those the scientist deems significant.

Plaintiffs-Petitioners argue that 45 C.F.R. § 74.24 gives the Government rights to the basic research data of research projects supported by grants and the dissent in the Circuit Court of Appeals in this case relies on that section of the regulations also. 45 C.F.R. § 74.24 provides in pertinent part that the Department of Health, Education & Welfare shall have the right of access to any books, or other records pertinent to the grant "in order to make audit, examination, excerpts, and transcripts". The limitation on access related to the purpose for which the information is gathered is explained in the "Public Health Service Grants Policy Statement", *supra,* October 1, 1974, p. 60; "Public Health Service Grants Policy Statement", *supra,* October 1, 1976, p. 77, as follows:

> "An audit is made to:
>
> "1. Verify financial transactions and to determine whether grant funds were used in accordance with applicable laws, regulations, and procedures.

"2. Provide the Government and the management of the grantee institution with objective appraisals of financial, accounting system, and administrative controls.

"3. Determine reliability of financial records and reports."

Clearly, the intention of the regulations is to permit access only to records dealing with the financial and administrative aspects of the grant, not to the scientific data and findings of the research program itself. This point is reinforced by the sections in the "Public Health Service Grants Policy Statement" which explain to grantees what records must be released to the public. "Public Health Service Grants Policy Statement", *supra,* October 1, 1974, pp. 56, 57; "Public Health Service Grants Policy Statement", *supra,* October 1, 1976, p. 77. Those sections list for guidance as discloseable documents only the notice of grant award, the application if an award was made, interim and terminal progress reports, expenditure reports and reports of audits or surveys of grantee performance. Records of basic research data are clearly noticeable by their absence. Even interim reports are available "only with the grantee's approval". "Public Health Service Grants Policy Statement", *supra,* October 1, 1974, p. 57. Grantees should be entitled to rely on these policy statements as establising the limits of the Government to the property of the project and while they may waive those limitations to allow basic data to be analyzed, they may also insist on freedom from disclosure. (Even if it were accepted that 45 C.F.R. § 74.24 provides a right of access to all records for all purposes, program as well as administrative, a right of access does not necessarily make a document the record of that

agency. It is still the record of the grantees at least until that right is exercised and control of the documents taken by the Government).

Unlike the regulations and policies dealing with grants, those dealing with contracts clearly vest in the Government the right to "use, duplicate or disclose all writings, recordings, charts, forms, data files and computer programs and any other records which are to be delivered under a contract". 41 C.F.R. § 3-16.950-315 (14) (the contract form for cost reimbursement contracts with educational institutions). The Department of Health, Education & Welfare could clearly make such data a deliverable product under a contract. Without an explicit provision to this effect in a grant award document or in grant regulations, a grant award would not give the Government such rights since grants are not intended to procure "deliverables" and are intended to assure the autonomy of the grantee and its investigators with respect to the management of the project. Where the Government intends to obtain basic research records as well as research effort and summary progress reports, a contract device must be used which specifies the basic research records as deliverables. Only in that way does the Government obtain a contractual right to treat such material as agency records.

3. Adverse Impact on Science of Requiring Disclosure

What impact would a decision in favor of the plaintiffs-petitioners have on the scientific research conducted with Federal funds in colleges and universities?

First, we must consider the meaning of the term "raw data". In the case before the Court, the raw data being

requested by the plaintiffs-petitioners are in the form of patient records, computer tapes and programs. However, if, in the future, raw data gathered with Federal funds were to be considered agency records under the Freedom of Information Act ("FOIA"), much of the data subsumed under that category would be recorded in the form of laboratory notebooks since there is no reasonable basis to distinguish under the FOIA that raw data from the raw data in this case. In the discussion that follows, we interpret the term raw data to include such laboratory notebooks. However, it should be observed that such raw data can come in many other forms, including field notebooks, strip charts, photographs, etc. Essentially, raw data includes all records of information, both basic and interpretive, related to the research project.

Laboratory notebooks are the basic records of the scientific activity of most investigators. In them are inscribed descriptions of experimental designs, figures from measurements they have made, questions that have occurred to them as the research proceeds, observations and other information and data. More than simple documents in which to record numbers, a scientist's notebooks are not unlike the sketchbooks of artists or composers, or an attorney's case files; they are the basic documents of their professional thinking that often encompass many of the scientist's creative reflections on research data. Personal in a way that the documents associated with an action taken by a Federal agency never can be, they are the intellectual diaries of scientists.

Normally, public or scientific interest in the data of a particular piece of research arises following the publication of the scientist's findings in a scientific journal

or the presentation of the findings before a professional meeting. Let us assume that the Government would not honor any requests for raw data under the Freedom of Information Act until after scientific investigators had made their findings public. At that stage, what impact would the release of their laboratory notebooks have?

At least three major problems are posed. First, laboratory notebooks commonly contain data that are not part of the published findings and that raise issues beyond the scope of the study that generated them. They include data the significance of which the scientist plans to explore at a later date when further research can be conducted to test or verify some hypotheses that the data suggest. If the notebooks were to be made available to anyone on request, this data would be released for others to interpret and use and would provide a serious disincentive to scientific exploration.

A second problem would be the misinterpretation that could result.

Research is a creative process, some of whose components are: the formulation of an hypothesis; the design of an experiment to test the hypothesis; the execution of the experiment, usually involving the collection of raw data; the comparison of the observed results with those predicted by the hypothesis; and, depending on whether or not the observed and predicted results were compatible, the making of a decision to seek further confirmation of the hypothesis or to revise it. This case focuses on only one element in this creative process—the collection of data—as though it were separable from the other essential and inter-connected parts. The public availability of raw

data, totally isolated from the context of the hypothesis under test and the experimental design, would more often than not lead to confusion, misunderstanding, or erroneous conclusions.

The third problem is that information in notebooks about the procedures used and circumstances under which the data were gathered is often skimpy. The scientist trusts his memory to fill the gaps. The requestor, lacking such knowledge, could be seriously misled by the insufficient notice of the information obtained. Also, the early data will usually not be derived from adequately controlled observations and will be very hard to interpret usefully. This too could result in egregious misinterpretation and error.

The problem of inadequate information could be solved by scientists deciding to keep their laboratory notebooks differently in the future. However, this solution would not solve the other problems mentioned. Scientific investigators can seldom forecast which of the data recorded in their notebook might turn out to be central or peripheral to their major conclusions. Inevitably, notebooks would sometimes contain clues of new scientific lodes to mine that are not germain to the Federally supported project and that they would rather not share with others.

There is also an issue regarding the scientist's professional privileges and credibility. These issues arise even more starkly if scientific investigators are required to release their notebooks before they have published findings. In the case before the Court, the request for the raw data was made after the results had been made public. Yet the interpretation of the FOIA being put forward by the plaintiffs does not restrict

the timing of the request. Nor does the FOIA itself do so. Therefore, unless the Court were to provide specific guidance on this issue, the result would stand that a request for raw data would have to be honored at any time after the raw data has come into existence. Thus, an issue arises as to premature release of research findings.

To consider the implications of the premature release of findings for the scientific community, we must understand the importance of the publication process through which most scientists make their findings public. The publication of the findings is an enormously significant benchmark for every scientist. Again there is a parallel with the legal system for advancing knowledge. A judge's words from the bench and his views as expressed in private conversation convey the direction of his legal thinking but the substance of his official position can only be conveyed in the language of his final opinion. The opinion is written and polished with that intent.

The same is true for scientists when they publish their findings. Scientific investigators and their peers view the process as essential for validation. Resolution of questions, criticisms and challenges articulated by peer referees during the process of securing the approval of the editorial board of the journal to publish a manuscript give weight and status to the final publication. The process has been described in this way in a major research journal: "The publication of scientific findings . . . involves refereed journals and thereby helps to ensure that those ideas which are published will not be applied before there has been adequate investigation and testing." T. Morgan, J. Keyes and J.

Sherman, *Confidentiality of Research Grant Protocols,* "Clinical Research", Vol. XXIV, No. 1, p. 10, 1976.

To allow a scientist's comments, findings and tentative interpretations, all of which are contained in his laboratory notebooks, to be released before the researcher feels ready to publish them formally is to rob him of the opportunity to live up to his own professional standards and to deprive him of his essential function of careful interpretation. Releasing the data and findings in this way destroys the traditional process of scientific discovery and seriously compromises and undermines the quality of the scientist's work.

Equally important, it diminishes the opportunity of the scientist to establish a sound professional reputation for himself and to advance his career. Imagining the worst possible circumstances, the scientist may find the contents of his laboratory notebooks about to be published under the authorship of another scientist. To thwart this plagiarism, the original observer may be forced into premature publication to establish priority for discovery, though compelled to do a less than professional job.

The preceeding discussion has considered the effects that premature release of data and interpretations would have on the scientist and his reputation. Most important, however, is the fact that the premature release of data and findings serves the best interests of neither science nor the general public. This is for at least two reasons. First are the effects that the release can have on the scientists who conducted the research. In the most extreme case, they can be demoralized; in the best of worlds, discouraged and frustrated. Unable to set and meet their own professional standards,

stripped of their ability to make a reputation for themselves in their chosen field and of their ability to control their original idea, the investigators would be only human if they lost their strong desire to make further original contributions to research. Thus, the potential harm to the overall advancement of science is real.

Second, the premature release of data and findings confuses, distorts and often pollutes the scientific record. If raw data is released, inaccuracies and misinterpretations are sure to increase in number, with the likely result that science will advance more slowly than before and the emergence of truth will be delayed and error will thrive.

There is also the additional problem that premature release of data collected in clinical trials intended to establish the efficacy or safety of medical treatment may endanger the public. Early data in such trials may not accurately reflect the outcome of a major clinical trial because it will not reflect a large enough pool of information to be valid. The same can be said of large epidemiologic studies intended to establish the relationship between factors such as the environment, the use of food or drugs, age, or other circumstances, and disease. For a thorough discussion of this issue see Volume 44, *Federal Register,* No. 149, Wednesday, August 1, 1979 at page 45252, et seq. which contains a full notice of a meeting of the HEW Ethics Advisory Board involving consideration of proposals by the NIH and the Center for Disease Control of statutory amendments to protect such information from disclosure where it is information actually held by a Government agency.

4. Extent of Federally-Sponsored Research and the Impractical Aspects of a Decision in Support of Plaintiffs-Petitioners

In fiscal year ("FY") 1978, the Federal Government actually spent $26 billion on research and development ("R&D") activity. "Special Analyses, Budget of the United States Government, Fiscal Year 1980", p. 295. The estimated obligations for fiscal year 1979 are $29 billion. *Ibid.* In the current year, fiscal year 1979, about $13 billion of the $29 billion is accounted for by Defense Department R&D, $4.6 billion by Department of Energy R&D, and $3.7 billion by Department of Health, Education & Welfare R&D, principally the National Institutes of Health. *Ibid.* $3 billion alone will be obligated by the National Institutes of Health for basic and applied biomedical research and related activity in FY 1979.

In FY 1978, health research generally was supported at a level of about $4 billion with $2.7 billion of that amount financed by the National Institutes of Health. "Basic Data Relating to the NIH", U.S. Department of Health, Education & Welfare, 1979, p. 3. Other agencies funding health research are the Veterans Administration, the Department of Defense, and the Alcoholism, Drug Abuse & Mental Health Administration of the Department of Health, Education & Welfare. *Ibid.* About 50%, or $2 billion, of all health research and 58% of all National Institutes of Health research is carried out by higher educational institutions. *Id.*, at p. 3. Only 27% of all health research and 19% of National Institutes of Health research is actually performed by the Federal Government itself. *Ibid.* Clearly, the grant method of supporting research is the favored method by National Institutes of Health as well as other R&D agencies since most of the support is in the form of grants.

Of the total $2.7 billion National Institutes of Health funds expended for health research in fiscal year 1978, about $2.1 billion was for research grants and contracts with the remainder for construction, research training and intramural research. "Basic Data Relating to the NIH", *supra,* p. 24. That $2.1 billion produced 16,621 research grants and 2,026 contracts in fiscal year 1978. "Basic Data Relating to the NIH", *supra,* p. 24. The total number of research grants increased from 12,382 in fiscal year 1970 and 14,311 in fiscal year 1974 while research contracts have been about 2,000 in number since 1974. "Basic Data Relating to the NIH", *supra,* p. 24. A total of 374 higher educational institutions and 400 other non-profit institutions and their research staffs received awards in fiscal year 1978.

The extensive impact of a holding that raw research data in the possession of Federal grant recipients must be disclosed to the public is evident from these facts. Some 16,000 NIH research grants alone, each having a number of investigators, would be subject to this requirement. Obviously, research grantees of, for example, the Defense Department, the Department of Energy and the National Science Foundation could be subject to the same requirements involving time-consuming, inconvenient and possibly harmful disclosures.

Plaintiffs-Petitioners argue at page 25 of their brief that a judgment in their favor would have only limited impact on the vast array of Government sponsored research. They argue, in essence, that a decision in this case can be limited to its facts. However, there is little basis in the Freedom of Information Act, its legislative

history, or cases decided under it for the principles of limitation suggested by the plaintiffs-petitioners or by the facts which they allege to be unique. Plaintiffs-Petitioners contend that the research involved in this case is unique and non-replicable because the project was entirely funded by NIH, had substantial NIH involvement throughout, including a right of access to records authorized by NIH regulations, and involved Government reliance in a regulatory proceeding on the basic data involved. In his dissenting opinion in *Forsham* v. *Califano,* 587 F.2d 1128 (Circuit Court of Appeals for the D.C. Circuit, 1978) at p. 1142, Judge Bazelon adopts the position that where "federal funding of the data, federal access to the data and federal reliance on the data in an administrative proceeding" are all present as factors, the materials are agency records.

The first principle of limitation, that Federal funding is involved, does not distinguish this case from any of the 16,000 NIH research grants in existence in 1978. Even the extent of Federal funding offers little assistance here. First, no grant supported activity may by law be paid for entirely by grant funds. See Section 207 of H.R. 4389, the FY 1980 Appropriation Bill for the Department of Health, Education and Welfare, for an example of the traditional appropriations legislation requirement that grantees share in the cost of the supported undertaking. A similar provision has been a part of every annual Labor-HEW appropriation bill commencing with FY 1966. Thus, in addition to the equities of the grantee represented by the experience and creativity of the investigator and the research environment and support systems of the institution, the law creates additional equities in the grantee by assuring

that it bears some identifiable portion of the cost of the projects.

Since government funding will always be present in grant supported activity and will always be less than 100%, the petitioner's theory would require the Court to fashion some ratio of federal funds to grantee funds which would trigger the disclosure requirement. There being no statutory or legislative history to guide it, the Court would be required to choose between some precise but totally arbitrary threshold, such as 85% federal funds, and a less precise, conceptual threshold, such as a substantial or preponderant Federal contribution. The former would insert a new factor in the policies and considerations governing the extent of federal participation, essentially irrelevant to the mission of the agency and the significance of the research. The latter would leave both the government and the academic community in a sea of uncertainty. Greater precision would become a prerequisite of FOIA determinations and could only be achieved after exhausting and fruitless litigation.

With regard to a "substantial Federal involvement" principle of limitation, the record is similarly bereft of any guideposts suitable for constructing a threshold for disclosure. The question of what is substantial would thus be the subject of additional litigation until such a standard could be evolved. This is all the more unnecessary and regretable in view of the statutory mandate that the contract be used as the instrument of support for activity substantially involving the government in its planning and execution. See 41 U.S.C. §§ 503 and 504. Furthermore, the contract mechanism has the additional advantage of facilitating the specification of the government's interest in the data, as re-

search contracts may, and often do, define the raw data as a product to be delivered. In such cases, what constitutes the agency record is ascertainable with a reasonable degree of certainty.

Furthermore, the alleged "right of access to grantee records" serves no useful function as a principle of limitation. While we in no way concur in the expansive reading of 45 C.F.R. § 74.24 advanced by the plaintiffs-petitioners, (see section 2 of this brief), the provision for audit access is equally applicable to all grant supported activity. Consequently, the petitioner's reading of this provision would serve no basis for limiting the scope of disclosure should they prevail in this case. On the contrary, all grantees would be equally susceptible to the demands for data disclosure.

Finally, it is claimed that in this case the Food & Drug Administration ("FDA") relied on the raw data in a regulatory proceeding and that therefore it became an agency record. To the extent that research data is involved in regulatory proceedings, parties with standing to participate in such proceedings have rights beyond those raised in this case under the Freedom of Information Act. See *Forsham* v. *Califano,* 587 F.2d 1128 (Circuit Court of Appeals for the D.C. Circuit, 1978), p. 1134. As Judge Leventhal noted, however, such regulatory proceedings and rights are not involved in this proceeding. As plaintiffs-petitioners note in their brief at page 51, their standing to participate in the FDA regulatory proceeding was limited. They should not be able to challenge that limitation in this proceeding which is what their claim attempts to do. Nonetheless, it seems clear from their brief at page 51 that they were able to raise the question of whether

this raw data was relied upon improperly or improperly omitted in the FDA proceeding.

Amici curiae suggest that the limited holding urged by plaintiffs-petitioners is not limiting for the reasons stated above. A holding for plaintiffs-petitioners will result in a principle of law that all raw data and records of research in projects supported primarily with Federal funds through the use of a grant agreement are agency records and subject to disclosure to any member of the public under the Freedom of Information Act. This is a Freedom of Information Act proceeding brought by members of the public, not a proceeding dealing with the adequacy or inadequacy of the record in a regulatory proceeding. None of the factors such as Federal funding, or unexercised rights of access under ordinary grant rules or other indicia of involvement of the Government distinguish this case for purposes of Freedom of Information Act law from any NIH research grant which produces raw data and records.

CONCLUSION

The extension of the concept of agency records under the Freedom of Information Act to raw data and basic scientific records of grantees of Federal research funds and the research investigators utilized by such grantees represents an unwarranted expansion of that Act which is inconsistent with Federal grant law and with the recognized Federal policy of stimulating investigator excellence through the autonomy a research grant permits. Such a decision would likely decrease the motivation of individual scientists supported by Federal grants and could well result in misleading and harmful release of incomplete or premature research data. We do not believe that Congress ever intended such a result nor that plaintiffs-petitioners desire it, but we see a holding for plaintiffs-petitioners having such consequences unless the decision is limited to facts unique to this case alone. However, as argued previously in this brief, we do not believe that there are facts relevant to this proceeding which distinguish this case from other NIH financed research which involves grant agreements.

Respectfully submitted,

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