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Access to Grantee Records under the Freedom of Information Act: An Analysis of *Forsham v. Harris*

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NOTES

Access to Grantee Records Under the Freedom of Information Act: An Analysis of *Forsham v. Harris*

A group of private physicians and scientists specializing in the treatment of diabetes organized the University Group Diabetes Program (UGDP)¹ to conduct a long-term clinical study² of the effectiveness of certain diabetes treatment regimens.³ Two of the regimens involved treatment of diabetes with phenformin⁴ and tolbutamide,⁵ which belong to a class of drugs known as oral hypoglycemics.⁶ The National Institute of Arthritis, Metabolism and Digestive Diseases,⁷ pursuant to statutory grant-in-aid authority of the Public Health Services Act,⁸ funded the program entirely. Although the Institute had a right of access to the data accumulated by UGDP and could have obtained permanent custody of the documents upon request, it did not exercise either of these rights. As a result of the clinical investigations, UGDP published several reports implicating both phenformin and tolbutamide in increased cardiovascular mortality.⁹ Relying on these re-

1. The program was conducted at 12 university medical centers. The processing and analysis of data was performed at the UGDP Coordinating Center, University of Maryland, under the direction of Dr. Christian Klimt. See Kolata, *Controversy Over Study of Diabetes Drugs Continues For Nearly a Decade*, 203 SCIENCE 986 (1979).

2. The study focused on the treatment of adult-onset diabetes mellitus. Diabetes mellitus is a metabolic disease in which carbohydrate utilization is reduced due to a deficiency in insulin production. The disease is characterized, in part, by elevated blood glucose levels. Adult-onset diabetes mellitus is generally a mild form of diabetes that develops gradually in obese individuals over the age of 35. STEDMAN'S MEDICAL DICTIONARY 385 (4th unabridged ed. 1976).

3. Over 1000 patients were recruited for the UGDP study. Each patient was placed on a standard diabetic diet and was assigned randomly to one of four treatment categories: (1) fixed dose of tolbutamide; (2) fixed dose of insulin; (3) variable dose of insulin; or (4) placebo tablets. In 1963 a fifth patient group, treated with fixed doses of phenformin, was added. 40 Fed. Reg. 28,587 (1975).

4. Phenformin, a biguanide, is a synthetic organic compound that lowers elevated blood glucose levels in diabetics. The drug's precise mode of action is unknown. PHYSICIANS' DESK REFERENCE 880 (32d ed. 1978).

5. Tolbutamide is a member of a class of organic compounds known as the sulfonylureas. It functions to lower blood glucose levels in diabetic patients by stimulating the synthesis and release of endogenous insulin. *Id.* at 1716.

6. Oral hypoglycemics may be divided into two classes on the basis of chemical structure, the biguanides and the sulfonylureas. Although the drugs of each class operate through different modes of action, both classes reduce blood sugar levels in diabetic patients.

7. The National Institute of Arthritis, Metabolism and Digestive Diseases is one of several institutes of the National Institutes of Health and is authorized by statute to conduct and fund research on diabetes. 42 U.S.C. §§ 289a, 289c-1 (1976). The Institute is a component of the Public Health Service, which is a component of the Department of Health, Education, and Welfare. The Institute, the Public Health Service, and HEW are federal agencies within the meaning of the FOIA.

8. 42 U.S.C. § 241(a)(3) (Supp. II 1978).

9. Klimt, Knatterud, Meinert & Prout, *A Study of the Effects of Hypoglycemic Agents*

ports, the Food and Drug Administration (FDA) proposed labeling changes for the oral hypoglycemics.¹⁰ Although the proposal has yet to become effective,¹¹ the FDA subsequently reported that phenformin was not safe¹² and ordered it withdrawn from the market.¹³ Contending that the results of the UGDP study were unreliable,¹⁴ the Committee on the Care of the Diabetic, an unincorporated association of physicians who treat diabetes, petitioned the Department of Health, Education, and Welfare (HEW) and the FDA to gain access to the raw patient data pursuant to the disclosure mandates of the Freedom of Information Act (FOIA).¹⁵ After repeated denials of their requests for what they alleged were agency

on Vascular Complications in Patients with Adult-Onset Diabetes, 19 *DIABETES* 747 (Supp. 2, 1970); Knatterud, Klimt, Osborne, Meinert, Martin & Hawkins, *A Study of the Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes*, 24 *DIABETES* 65 (Supp. 1, 1975); Knatterud, Meinert, Klimt, Osborne & Martin, *Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes*, 217 *J.A.M.A.* 777 (1971).

10. 40 Fed. Reg. 28,587 (1975). The Commissioner of the FDA specifically cited the results of the UGDP study as the basis of the proposal. *Id.* at 28,593. The FDA regulates the content of drug labeling pursuant to 21 U.S.C. §§ 352, 355, 371(a) (1976).

11. The FDA originally proposed a labeling change in 1971. In response to heavy criticism of UGDP by the medical community, the National Institute of Arthritis, Metabolism and Digestive Diseases contracted with Biometric Society, a private professional society of biostatisticians, to review the UGDP. Brief for the Federal Respondents at 6 n.7. The society published its report in 1975, concluding that the evidence of phenformin's dangers was moderately strong, but conceding that they had some reservation concerning the conclusion that oral hypoglycemics were toxic. *Report of the Committee for the Assessment of Biometric Aspects of Controlled Trials of Hypoglycemic Agents*, 231 *J.A.M.A.* 583 (1975). The FDA subsequently conducted its own audit of the UGDP data and determined that while some errors were noted, the basic conclusions of the study were sound. 43 Fed. Reg. 52,732, 52,733 (1978). Because of the continuing controversy surrounding the reliability of the study, the FDA extended the period for comment on the labeling proposal to September 14, 1979. 44 Fed. Reg. 42,714 (1979).

12. 44 Fed. Reg. 20,967 & 20,977 (1979). The primary concern of the FDA was the association between the use of phenformin and the development of lactic acidosis, an often fatal condition in which abnormal amounts of lactic acid accumulate in the blood. Reports of this association began appearing soon after the approval of phenformin's New Drug Application in 1959 and resulted in labeling changes in 1964, 1970, 1974, 1976, and 1977. *Id.* at 20,967. UGDP did not study this condition. See note 9 *supra* and accompanying text. The FDA received the UGDP reports as evidence of the dangers of phenformin, but they were not the substantial basis of the FDA Commissioner's final order. 44 Fed. Reg. 20,967, 20,969 (1979).

13. 43 Fed. Reg. 54,995 (1978). The FDA may withdraw approval of a New Drug Application if new clinical evidence, unavailable at the time of the application's approval, indicates that the drug is "not shown to be safe for use under the conditions of use upon the basis of which the application was approved." 21 U.S.C. § 355(e)(2) (1976).

14. Criticisms of the study have been pervasive and have focused largely on the design, methodology, and execution of the program and on the personal integrity of one of the principal investigators. See Kolata, *supra* note 1.

15. 5 U.S.C. § 552 (1976). The Committee on the Care of the Diabetic had petitioned the FDA to rescind the proposed labeling change in 1971 pending independent evaluation of the UGDP reports. Appendix at 18, *Forsham v. Harris*, 100 S. Ct. 978, 63 L. Ed. 2d 293 (1980). The Committee subsequently filed suit in the United States District Court for the District of Massachusetts, seeking injunctive relief to prevent the FDA from implementing the proposed labeling change and also seeking access to the UGDP raw data. The grant of a preliminary injunction was vacated by the First Circuit Court of Appeals and the case was remanded to the FDA for exhaustion of administrative remedies. *Bradley v. Weinberger*, 483 F.2d 410 (1st Cir. 1973).

records,¹⁶ the Committee sued under the FOIA¹⁷ to require HEW to make available all raw patient data. Granting summary judgment for the defendant, the district court found that the raw data were not agency records because HEW had neither custody nor control of the records.¹⁸ The court of appeals affirmed on the same rationale, noting that the FOIA applies only to already existing records that have been created or obtained by an agency in the course of its business.¹⁹ The United States Supreme Court granted certiorari. *Held, affirmed*: Written data generated, owned, and possessed by a private organization receiving federal study grants are not agency records within the meaning of the Freedom of Information Act when copies of the data have not been obtained by a federal agency subject to the Act. *Forsham v. Harris*, 100 S. Ct. 978, 63 L. Ed. 2d 293 (1980).

I. DEFINITION OF AGENCY AND AGENCY RECORDS UNDER THE FREEDOM OF INFORMATION ACT

The Freedom of Information Act, enacted in 1966 as an amendment to the information section of the Administrative Procedure Act of 1946 (APA),²⁰ provides the public with broad access to information concerning the workings of the federal government.²¹ The Act requires governmental agencies to make records available upon request of any person for any reason²² unless the requested records fall within one of nine exempted categories.²³ If access to records is wrongfully denied, an aggrieved party may seek judicial review to enjoin the withholding and to order disclosure.²⁴

Before an FOIA request for disclosure is granted, the requesting party

16. Brief for Plaintiff-Petitioners at 3.

17. 5 U.S.C. § 552(a)(4)(B) (1976).

18. *Forsham v. Mathews*, No. 75-1608 (D.D.C. Feb. 1, 1976), *reprinted in* Appendix at 180-81. The district court observed that none of the federal defendants had ever possessed the UGDP data and that the data were "the property of the individual investigators and UGDP study coordinating enter [*sic*] and remain[ed] in the possession, custody and control of the UGDP study coordinating center." *Id.* The court failed to note that both the Biometric Society and the FDA had obtained portions of the raw patient data for evaluation and audit by relying on the Institute's right of access. *Forsham v. Harris*, 100 S. Ct. 978, 981, 63 L. Ed. 2d 293, 300-01 (1980).

19. *Forsham v. Califano*, 587 F.2d 1128, 1136 (D.C. Cir. 1978).

20. Ch. 324, § 3, 60 Stat. 238 (current version at 5 U.S.C. § 552 (1976)).

21. Before the amendment, the public information section of the APA provided that "matters of official record . . . be made available to persons properly and directly concerned except information held confidential for good cause found." *Id.* § 3(c). The "properly and directly concerned" test was used by various agencies as authority for withholding information and it was this abuse that prompted Congress to amend the APA. *See* H.R. REP. NO. 1497, 89th Cong., 2d Sess. (1966), *reprinted in* SENATE COMMITTEE ON THE JUDICIARY, FREEDOM OF INFORMATION ACT SOURCEBOOK: LEGISLATIVE MATERIALS, CASES, ARTICLES, S. DOC. NO. 82, 93d Cong., 2d Sess. 22 (1974) [hereinafter cited as [1974] FOIA SOURCEBOOK].

22. 5 U.S.C. § 552(a)(3) (1976).

23. *Id.* § 552(b). Most litigation concerning FOIA requests has centered on the question of which agency records are exempt under this section. The controversy surrounding the UGDP study focused on whether the data were agency records. Accordingly, the exemptions were irrelevant to the controversy.

24. *Id.* § 552(a)(4)(B).

must establish that the entity petitioned is an agency and that the records sought are agency records.²⁵ Despite the clear intent of Congress to mandate the fullest possible disclosure of agency business,²⁶ the statutory language and the legislative history of the Act provide little guidance in determining the scope of FOIA obligations.²⁷ As enacted in 1966, the FOIA did not include a definition of agency, but instead relied on the definition provided in the Administrative Procedure Act.²⁸ The APA's definition, however, proved troublesome for FOIA purposes because the general statutory guide was of limited usefulness to courts confronted with the task of evaluating the complex organization of the federal bureaucracy.²⁹ In 1974 the FOIA was amended in an attempt to extend its coverage to those entities "which perform governmental functions and control information of interest to the public."³⁰ In addition to those administrative units designated in section 551 of the Administrative Procedure Act,³¹ the new definition of agency included "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."³²

Despite the 1974 amendments, confusion remained as to whether entities from the private sector involved in governmental work were agencies within the scope of the FOIA.³³ Receipt of federal funds alone does not

25. *Id.* § 552(a)(3).

26. Much of the legislative history of FOIA is reprinted in [1974] FOIA SOURCEBOOK, *supra* note 21. The history of the 1974 amendments may be found in SENATE COMMITTEE ON THE JUDICIARY, FREEDOM OF INFORMATION ACT AND AMENDMENTS OF 1974 (P.L. 93-502), 94th Cong., 1st Sess. (1975) [hereinafter cited as [1975] FOIA SOURCEBOOK]. See generally Clark, *Holding Government Accountable: The Amended Freedom of Information Act*, 84 YALE L.J. 741 (1975); Davis, *The Information Act: A Preliminary Analysis*, 34 U. CHI. L. REV. 761 (1967); Note, *The Freedom of Information Act: A Seven-Year Assessment*, 74 COLUM. L. REV. 895 (1974).

27. For a discussion of the definitions of records, agency, and agency records under FOIA, see Note, *The Definition of "Agency Records" Under the Freedom of Information Act*, 31 STAN. L. REV. 1093 (1979).

28. 5 U.S.C. § 551(1) (1976). This section defines agency as "each authority of the Government of the United States, whether or not it is within or subject to review by another agency." *Id.* Specifically exempted from this definition were Congress and federal courts. *Id.* §§ 551(1)(A)-(B). Whether Congress intended to include the Office of the President under the obligations of the APA is unclear. See *Soucie v. David*, 448 F.2d 1067 (D.C. Cir. 1971).

29. *Washington Research Project, Inc. v. Department of HEW*, 504 F.2d 238, 245-46 (D.C. Cir. 1974), *cert. denied*, 421 U.S. 963 (1975).

30. H.R. REP. NO. 876, 93d Cong., 2d Sess. (1974), reprinted in [1975] FOIA SOURCEBOOK, *supra* note 26, at 121, 128.

31. 5 U.S.C. § 551(1) (1976).

32. *Id.* § 552(e).

33. Private individuals and institutions performing government work fall into several categories. One group, represented by private grantees such as UGDP, receive federal funds because of "general . . . [government] approval of the undertaking." Mason, *Current Trends in Federal Grant Law—Fiscal Year 1976*, 35 FED. B.J. 163, 166 (1976). The work performed by such grantees is not viewed as work done for the benefit of the federal government, but rather for the furtherance of social goals. *Id.* at 167. In other instances individuals from the private sector may be called upon to function in an advisory capacity to agencies. The work performed is the work of the agency, although the individuals themselves are not considered

convert a private group into an agency.³⁴ The courts confronting this problem have adopted a functional analysis, conferring agency status for FOIA purposes when the group in question is subject to federal supervision.³⁵ Under this test, however, the supervision must be substantial.³⁶ In *United States v. Orleans*³⁷ the United States Supreme Court held that a local community action agency funded by the Office of Economic Opportunity was not a federal agency within the meaning of the Federal Tort Claims Act.³⁸ The Court found that the controlling issue was not whether the community group received federal funds or whether it was obligated to comply with federal regulations effectuating the philosophy of the grant program, but whether the group was supervised in its daily activities by the federal government.³⁹

Without supervision, a private group also may be deemed an agency when it functions with "substantial independent authority in the exercise of specific functions."⁴⁰ In such cases the controlling issues are whether the group is functioning under legal authority delegated from Congress⁴¹ and whether it is involved in a final decision-making process.⁴² In con-

to be employees of the federal government. See *Washington Research Project, Inc. v. Department of HEW*, 504 F.2d 238 (D.C. Cir. 1974), *cert. denied*, 421 U.S. 963 (1975); *Wu v. National Endowment for Humanities*, 460 F.2d 1030 (5th Cir. 1972), *cert. denied*, 410 U.S. 926 (1973); *Wolfe v. Weinberger*, 403 F. Supp. 238 (D.D.C. 1975). Individuals from the private sector also may supply property and services for the benefit and use of the government under procurement contracts. The property supplied becomes the property of the contracting agency. See 41 U.S.C. § 503 (Supp. II 1978).

34. *United States v. Orleans*, 425 U.S. 807 (1976); *Spark v. Catholic Univ.*, 510 F.2d 1277 (D.C. Cir. 1975); *Wahba v. New York Univ.*, 492 F.2d 96 (2d Cir.), *cert. denied*, 419 U.S. 874 (1974).

35. *Rocap v. Indiek*, 539 F.2d 174 (D.C. Cir. 1976). In *Rocap* the court held that the Federal Home Loan Mortgage Corporation was a federal agency within the statutory guidelines of the FOIA. For examples of government-supported institutions or programs held not to be agencies, see *Ciba-Geigy Corp. v. Mathews*, 428 F. Supp. 523 (S.D.N.Y. 1977) (UGDP); *Lombardo v. Handler*, 397 F. Supp. 792 (D.D.C. 1975), *aff'd*, 546 F.2d 1043 (D.C. Cir. 1976), *cert. denied*, 431 U.S. 932 (1977) (National Academy of Sciences). Congressional conferees, clarifying the reach of FOIA's definition of agency, have indicated that Congress did not intend "to include corporations which receive appropriated funds but are neither chartered by the Federal Government nor controlled by it, such as the Corporation for Public Broadcasting." H.R. CONF. REP. NO. 1380, 93d Cong., 2d Sess. 13-14 (1974), *reprinted in* [1975] FOIA SOURCEBOOK, *supra* note 26, at 219, 231-32. The Corporation for Public Broadcasting is funded under authority of 47 U.S.C. §§ 390-398 (Supp. II 1978).

36. *Rocap v. Indiek*, 539 F.2d 174 (D.C. Cir. 1976).

37. 425 U.S. 807 (1976).

38. 28 U.S.C. §§ 1346(b), 2671 (1976).

39. 425 U.S. at 815.

40. *Soucie v. David*, 448 F.2d 1067, 1073 (D.C. Cir. 1971).

41. *Soucie v. David*, 448 F.2d 1067 (D.C. Cir. 1971); *Public Citizen Health Research Group v. Department of HEW*, 449 F. Supp. 937 (D.D.C. 1978). For federal entities held not to be agencies due to their lack of independent legal authority, see *Lombardo v. Handler*, 397 F. Supp. 792 (D.D.C. 1975), *aff'd*, 546 F.2d 1043 (D.C. Cir. 1976), *cert. denied*, 431 U.S. 932 (1977); *Gates v. Schlesinger*, 366 F. Supp. 797 (D.D.C. 1973).

42. *Soucie v. David*, 448 F.2d 1067 (D.C. Cir. 1971); *Public Citizen Health Research Group v. Department of HEW*, 449 F. Supp. 937 (D.D.C. 1978). The *Soucie* controversy, involving the agency status of the Office of Science and Technology, was decided prior to the 1974 amendments when the APA definition of agency determined the success of FOIA requests. 5 U.S.C. § 551(1) (1976). An analysis of the legislative history behind § 551(1) indicated that "Congress, in using the term 'agency,' intended the APA to apply to authorities of

trast, entities functioning merely to advise or to recommend, but not to implement a final action, have not been designated agencies.⁴³

No statutory or congressional guidance has been provided to determine what constitutes an agency record. The FOIA does not define agency records⁴⁴ and the legislative history is silent on the matter.⁴⁵ Two troublesome questions arising from this deficiency have confronted the courts: first, whether agencies may be compelled to create records for FOIA requests;⁴⁶ and secondly, under what circumstances records generated by a private organization funded by a federal agency may be considered agency records.⁴⁷

The courts have designated records as agency records when they are owned by an agency or subject to agency control.⁴⁸ Under this property/control theory, mere reliance by an agency upon records⁴⁹ or possession of records,⁵⁰ without ownership, is not sufficient to show that the

government which are the center of gravity for the exercise of substantial power against individuals." Freedman, *Administrative Procedure and the Control of Foreign Direct Investment*, 119 U. PA. L. REV. 1, 10 (1970). Use of this criterion is apparent in decisions construing the definition of agency under § 552(e) of the FOIA, 5 U.S.C. § 552(e) (1976). *Ciba-Geigy Corp. v. Mathews*, 428 F. Supp. 523 (S.D.N.Y. 1977); *Wolfe v. Weinberger*, 403 F. Supp. 238 (D.D.C. 1975).

43. *Washington Research Project, Inc. v. Department of HEW*, 504 F.2d 238 (D.C. Cir. 1974), *cert. denied*, 421 U.S. 963 (1975); *Wu v. National Endowment for Humanities*, 460 F.2d 1030 (5th Cir. 1972), *cert. denied*, 410 U.S. 926 (1973); *Wolfe v. Weinberger*, 403 F. Supp. 238 (D.D.C. 1975).

44. While the Act does not define agency record, it characterizes the type of documents that are exempt from disclosure obligations as matters, information, memorandums, letters, files, and reports. 5 U.S.C. § 552(b) (1976). These references, admittedly vague, indicate that writings memorializing agency activity are contemplated as the proper subjects of FOIA requests. *See Nichols v. United States*, 325 F. Supp. 130 (D. Kan. 1971), *aff'd*, 460 F.2d 671 (10th Cir.), *cert. denied*, 409 U.S. 966 (1972). In *Nichols* the court found that the written autopsy report of President Kennedy was an agency record, but that bullets, cartridges, and the late President's shirt were not records within the scope of FOIA obligations. 325 F. Supp. at 134-36.

45. *See* H.R. CONF. REP. NO. 1380, 93d Cong., 2d Sess. (1974), *reprinted in* [1975] FOIA SOURCEBOOK, *supra* note 26, at 219; H.R. REP. NO. 1497, 89th Cong., 2d Sess. (1966), *reprinted in* [1974] FOIA SOURCEBOOK, *supra* note 21, at 22; S. REP. NO. 813, 89th Cong., 1st Sess. (1965), *reprinted in* [1974] FOIA SOURCEBOOK, *supra* note 21, at 36. *See also* Comment, *What Is a Record? Two Approaches to the Freedom of Information Act's Threshold Requirement*, 1978 B.Y.U.L. REV. 408.

46. *See* note 51 *infra* and accompanying text.

47. *Ciba-Geigy Corp. v. Mathews*, 428 F. Supp. 523 (S.D.N.Y. 1977).

48. *Goland v. CIA*, 607 F.2d 339 (D.C. Cir. 1978), *cert. denied*, 100 S. Ct. 1312, 63 L. Ed. 2d 759 (1980); *SDC Dev. Corp. v. Mathews*, 542 F.2d 1116 (9th Cir. 1976); *Public Citizen Health Research Group v. Department of HEW*, 477 F. Supp. 595 (D.D.C. 1979); *Ciba-Geigy Corp. v. Mathews*, 428 F. Supp. 523 (S.D.N.Y. 1977); *Nichols v. United States*, 325 F. Supp. 130 (D. Kan. 1971), *aff'd*, 460 F.2d 671 (10th Cir.), *cert. denied*, 409 U.S. 966 (1972). In *Goland* the court held that congressional documents on loan to the CIA were not agency records under the FOIA because the records in question had not passed from the control of Congress. 607 F.2d at 346-47. Congressional documents are exempt from disclosure under 5 U.S.C. § 551(1)(A) (1976). When an agency creates a record and retains control over it, the record is within the scope of the FOIA. *Public Citizen Health Research Group v. Department of HEW*, 477 F. Supp. 595 (D.D.C. 1979). Litigation may arise concerning whether the record is exempt from disclosure under 5 U.S.C. § 552(b) (1976). 477 F. Supp. at 599-605.

49. *Ciba-Geigy Corp. v. Mathews*, 428 F. Supp. 523 (S.D.N.Y. 1977).

50. *Goland v. CIA*, 607 F.2d 339 (D.C. Cir. 1978), *cert. denied*, 100 S. Ct. 1312, 63 L.

materials sought are accessible under the FOIA. Furthermore, the courts have decided that an agency may not be ordered to create records in response to an FOIA request⁵¹ or to produce records that are not in its physical possession.⁵² Rather, the judicial requirement for control demands not only a clear title to the property in question but also a present possessory interest in that property.⁵³ The decisions, however, do not make clear whether the cumulative effect of federal involvement in the creation of records by private organizations through federal funding and supervision, federal access to records, and federal reliance upon records is sufficient to bring the records held by the private grantees within the scope of FOIA obligations.

II. FORSHAM V. HARRIS

In *Forsham v. Harris* the United States Supreme Court, in an opinion by Justice Rehnquist,⁵⁴ held that data generated under a federally funded research grant to private recipients are not agency records accessible under the FOIA unless they have been obtained by the funding agency.⁵⁵ The decision was premised on the finding that UGDP was not an agency as defined in the FOIA.⁵⁶ Rejecting an expansive definition of agency records that would impose obligations of disclosure upon private grantees independent of their agency status,⁵⁷ the Court stated that if private grantees are not agencies, their records are not agency records.⁵⁸

The Court initially observed that private grantees are not only excluded from the FOIA definition of agency⁵⁹ but that the legislative history of the 1974 FOIA amendments indicates that Congress intended to exclude such groups.⁶⁰ The Court also stated that the exclusion of private grantees from

Ed. 2d 759 (1980); *SDC Dev. Corp. v. Mathews*, 542 F.2d 1116 (9th Cir. 1976). The *SDC Dev. Corp.* holding indicates that not all documents owned by an agency are subject to the FOIA. Rather, the type of document, in relation to the underlying purposes of the FOIA, is the controlling issue. Refusing to find reference materials owned by the National Library of Medicine agency records, the court in *SDC Dev. Corp.* stated that the "type of documents Congress was seeking to include . . . were primarily those which dealt with the structure, operation, and decision-making procedure of the various governmental agencies." *Id.* at 1119.

51. *Renegotiation Bd. v. Grumman Aircraft Eng'r Corp.*, 421 U.S. 168 (1975); *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132 (1975). In *Grumman* and *Sears* the Court held that an agency is not required to create a record in response to an FOIA request. In *Forsham* the records in question were already in existence.

52. *Nichols v. United States*, 325 F. Supp. 130 (D. Kan. 1971), *aff'd*, 460 F.2d 671 (10th Cir.), *cert. denied*, 409 U.S. 966 (1972).

53. 325 F. Supp. at 137.

54. The decision was divided seven to two, with Justices Brennan and Marshall dissenting.

55. 100 S. Ct. at 983, 63 L. Ed. 2d at 302-03.

56. *Forsham v. Mathews*, No. 75-1608 (D.D.C. Feb. 1, 1976), *reprinted in* Appendix at 180-81.

57. 100 S. Ct. at 985, 63 L. Ed. 2d at 305.

58. *Id.* at 983, 63 L. Ed. 2d at 302.

59. *Id.* at 984, 63 L. Ed. 2d at 303.

60. *Id.* The Court noted that the Corporation for Public Broadcasting was not intended by Congress to be included in the FOIA definition of agency. H.R. CONF. REP. NO. 1380, 93d Cong., 2d Sess. 14-15 (1974), *reprinted in* [1975] FOIA SOURCEBOOK, *supra* note 26, at

agency status is consistent with a congressional and judicial tendency to preserve private grantee autonomy.⁶¹ Refusing to apply the FOIA to the UGDP data, the Court adopted the opinion of the appellate court that the interest in disclosure must be balanced with the interest in respecting the privacy and property rights of private grant recipients.⁶² Citing *United States v. Orleans*,⁶³ the Court found that a federal grant does not create a joint venture or partnership with a private grantee and that the work of the grant recipient does not become the work of the government unless the grantee's activities are subject to extensive, detailed, and daily federal supervision.⁶⁴ Finding the requisite degree of federal supervision absent in the UGDP program, the Court concluded that UGDP could not be considered an agency of the federal government.⁶⁵ Rather, the Court found that the government involvement in the UGDP program was consistent with the typical grantor-grantee relationship and necessary only to ensure compliance with the policy goals of the grant.⁶⁶ To support its conclusion, the

219, 231-32. This concern for the status of the Corporation, however, did not specifically extend to other recipients of federal funds. 120 CONG. REC. 6803 (1974). During congressional hearings, Representative Young proposed that disclosure be required of records of grant recipients but this suggestion elicited no comment from his colleagues. *Id.* at 6809. Under these circumstances, the Court's interpretation of the conference report concerning the Corporation for Public Broadcasting may be expansive. The Court also noted that several bills designed to extend the FOIA to federal grantees have been introduced in the House but that none has been reported from committee. 100 S. Ct. at 984 n.10, 63 L. Ed. 2d at 303 n.10. See also H.R. 1465, 96th Cong., 1st Sess. (1979); H.R. 3207, 95th Cong., 1st Sess. (1977); H.R. 1205, 94th Cong., 1st Sess. (1975); H.R. 1291, 93d Cong., 1st Sess. (1973); H.R. 11,013, 92d Cong., 1st Sess. (1969). Of course, congressional failure to enact legislation cannot be equated with a statement of intent. The cumulative effect of these observations, however, does tend to support the Court's conclusion.

61. 100 S. Ct. at 984, 63 L. Ed. 2d at 303-04.

62. *Forsham v. Califano*, 587 F.2d 1128 (D.C. Cir. 1978). The concern for balancing the interest in disclosure with the interest in preserving private grantee autonomy is more apparent in the lower court decision in which Judge Leventhal noted that "Congress struck a balance in fashioning the FOIA, which precludes the boundless pursuit of one policy goal, even a dominant policy, to the exclusion of all countervailing considerations." *Id.* at 1137. See *Environmental Protection Agency v. Mink*, 410 U.S. 73 (1973). Congress also recognized that the FOIA should not be applied indiscriminately to deprive individuals and institutions of their privacy. See S. REP. NO. 813, 89th Cong., 1st Sess. (1965), reprinted in [1974] FOIA SOURCEBOOK, *supra* note 21, at 36. See also *Lombardo v. Handler*, 397 F. Supp. 792 (D.D.C. 1975), *aff'd*, 546 F.2d 1043 (D.C. Cir. 1976), *cert. denied*, 431 U.S. 932 (1977), in which the circuit court, holding that the National Academy of Sciences is not a federal agency, stated that the "strength of the F.O.I.A. is the concept of public accountability for the operation of federal agencies. It was not intended to be applied directly to private entities which merely contract with the government to conduct studies." 397 F. Supp. at 802.

63. 425 U.S. 807 (1976). In *Orleans* a child was injured in an automobile accident while on an outing sponsored by a local community action agency funded entirely by the Office of Economic Opportunity. The child and his father sued the United States under the Federal Tort Claims Act, alleging that employees of the action agency were federal employees by virtue of the Office of Economic Opportunity's financial support of the agency's programs. The Court held that the action agency was not an agency within the meaning of the Act and that its employees were not instrumentalities of the federal government. *Id.* at 819.

64. 100 S. Ct. at 984, 63 L. Ed. 2d at 304.

65. *Id.* The Court conceded that grantees may be considered agencies under some circumstances. *Id.* at 983 n.9, 63 L. Ed. 2d at 303 n.9. The circumstances, however, refer to the *Orleans* requirement for day-to-day supervision. *Id.* at 984 n.11, 63 L. Ed. 2d at 304 n.11.

66. *Id.* at 984 n.11, 63 L. Ed. 2d at 304 n.11. The Court did not respond specifically to petitioner's contention that the National Institute's involvement in the UGDP was signifi-

Court noted that the Federal Grant and Cooperative Agreement Act of 1977⁶⁷ provides that a procurement contract⁶⁸ must be used when the purpose of the funding is to acquire property and services for federal use and benefit, whereas grant⁶⁹ and cooperative⁷⁰ agreements, such as those to UGDP, must be used when money is given to "accomplish a public purpose of support or stimulation."⁷¹ Accordingly, the products of grants are not the property of the federal government, and instead, title to records vests in the individual researcher.⁷²

Regardless of the degree of federal supervision and funding of the UGDP, the petitioners contended⁷³ that the UGDP raw data were agency records because of HEW's right of access to the records⁷⁴ and the FDA's reliance on the results of the UGDP study in administrative actions.⁷⁵ Rejecting this argument, the Court observed that the FOIA applies only to records presently in the custody of an agency.⁷⁶ Therefore, only records which "have been *in fact* obtained, and not [those] which . . . *could have been obtained*" are agency records and thus the proper subjects of FOIA requests.⁷⁷ The Court found this interpretation to be consistent with the language of the FOIA⁷⁸ as well as with the congressional definition of gov-

cantly greater than that of the typical grant program. Brief for Plaintiff-Petitioners at 28-36. The involvement described by petitioner, however, falls short of the standards enunciated in *Orleans*. See *United States v. Orleans*, 425 U.S. 807, 815 (1976).

67. 41 U.S.C. §§ 501-509 (Supp. II 1978). Although the Act was passed in 1978, after the funding of the UGDP, legislative history indicates that Congress intended to "formalize existing relationships." S. REP. NO. 449, 95th Cong., 1st Sess. 9-10 (1977).

68. 41 U.S.C. § 503 (Supp. II 1978).

69. *Id.* § 504.

70. *Id.* § 505.

71. *Id.* § 504(1).

72. *Id.* §§ 504-505. The Court also found support in the HEW regulations governing grants. 100 S. Ct. at 985, 63 L. Ed. 2d at 304. The Court referred to 45 C.F.R. § 74.133 (1979), which provides that "title to real property, equipment, and supplies acquired under a grant . . . shall vest, upon acquisition, in the grantee." Upon examination of this language, the Court's interpretation that title to records and data are included in this provision is difficult to accept. Section 74.24 of these regulations provides, however, that "HEW . . . shall have the right of access to . . . records of the grantee which are pertinent to the HEW grant, in order to make audit, examination, excerpts, and transcripts." *Id.* § 74.24(a). Implicit in this regulation is a recognition that the records are the property of the grantee.

73. Brief for Plaintiff-Petitioners at 37-50.

74. In addition to § 74.24, § 74.21 of the HEW regulations requires grantees to retain grant-related records for a period of three years and authorizes the granting party to gain custody of records possessing long retention value or of records that are "continuously needed for joint use." 45 C.F.R. § 74.21(c) (1979). The regulation, however, appears to refer to financial and equipment records, and its applicability to data is uncertain. See Brief of the American Council on Education, Association of American Medical Colleges, et al. as Amici Curiae in Support of Defendant-Respondents at 11-12.

75. See note 10 *supra* and accompanying text and note 13 *supra*.

76. 100 S. Ct. at 987, 63 L. Ed. 2d at 307.

77. *Id.* (emphasis in original).

78. *Id.*, 63 L. Ed. 2d at 306. The Court noted that § 552(b)(4) of the FOIA, 5 U.S.C. § 552(b)(4) (1976), applicable to exemptions for trade secrets and confidential information, refers to information possessed by an agency that has been "obtained from a person," and that no similar exemption applies to confidential information in records that have not been obtained by an agency. Relying on this plain language, the Court interpreted this omission as indicating that Congress intended the FOIA to apply only to records actually in the possession of an agency. 100 S. Ct. at 987, 63 L. Ed. 2d at 307. In addition, the Court inter-

ernment records in other legislation.⁷⁹ Additionally, the Court noted that to order HEW to exercise its right of access would be tantamount to compelling HEW to create records,⁸⁰ an argument previously rejected by the Court in *NLRB v. Sears, Roebuck & Co.*⁸¹ Finally, the Court found that the FDA's reliance on the published reports of UGDP in initiating regulatory action, in the absence of federal ownership of the underlying data, was irrelevant.⁸²

Justice Brennan, joined by Justice Marshall, dissented, submitting that the critical question in *Forsham* was whether the data generated by the UGDP study were agency records, and not whether UGDP was an agency.⁸³ Justice Brennan found nothing in the legislative history of the FOIA to compel the conclusion that a common law theory of property and custody should define agency records,⁸⁴ and he dismissed the majority opinion as one based on the "technical niceties of who 'owns' crucial documents."⁸⁵ Maintaining that the congressional intent behind the FOIA was to promote the fullest possible disclosure,⁸⁶ Justice Brennan proposed that when the existence of a close link between a record and an agency is demonstrated, and when the record contains information essential to the understanding of that agency's activities, the record should be accessible under the FOIA.⁸⁷ According to Justice Brennan, the necessary link between the records of a private grantee and a federal agency would be established when the agency incorporates the records into a regulatory process.⁸⁸ Justice Brennan found such a link in *Forsham* because of HEW's role in conceiving, funding, and supervising the UGDP study.⁸⁹

preted the remedy provided for wrongful withholding as being indicative of a requirement that records sought under an FOIA request actually be in the custody of an agency. *Id.*

79. 100 S. Ct. at 986, 63 L. Ed. 2d at 305-06. See Presidential Records Act of 1978, § 2(a), 44 U.S.C. § 2201(2) (Supp. II 1978) ("created or received by the President"); Records Disposal Act, § 4(c)(2), 44 U.S.C. § 3301 (1976) ("made or received" by an agency); Securities Exchange Act of 1934, 15 U.S.C. § 78x (1976) ("documents filed with or otherwise obtained").

80. 100 S. Ct. at 987, 63 L. Ed. 2d at 307-08.

81. 421 U.S. 132 (1975).

82. 100 S. Ct. at 987-88, 63 L. Ed. 2d at 308. The requirement for actual possession of records becomes more apparent upon examination of the decision in the companion case of *Kissinger v. Reporters Comm. for Freedom of the Press*, 100 S. Ct. 960, 63 L. Ed. 2d 267 (1980), in which the Court held that the FOIA does not compel agencies to retrieve records wrongfully taken from their possession.

83. 100 S. Ct. at 988, 63 L. Ed. 2d at 308.

84. *Id.* at 988-89, 63 L. Ed. 2d at 309.

85. *Id.* at 989, 63 L. Ed. 2d at 309.

86. *Id.* at 988, 63 L. Ed. 2d at 309.

87. *Id.* at 989, 63 L. Ed. 2d at 309.

88. *Id.*, 63 L. Ed. 2d at 310.

89. *Id.* Under Justice Brennan's test, a link must be established between an agency and the records in question and that agency must have used the data in a regulatory or administrative action. Justice Brennan apparently does not view the National Institute of Arthritis, Metabolism and Digestive Diseases and the FDA as separate agencies. Although both administrative units are components of HEW, no contention was made in this controversy that the units had a joint involvement in the UGDP study. The court of appeals viewed the FDA and the Institute as separate agencies and noted that the question of reliance would be appropriate only to possible litigation against the FDA concerning its regulatory actions based on the UGDP results. *Forsham v. Califano*, 587 F.2d 1128, 1134 (D.C. Cir. 1978).

He further determined that this involvement was substantial enough to indicate that HEW, in fact, had created the data for a governmental purpose.⁹⁰ The actions of the FDA and HEW concerning oral hypoglycemics could be evaluated only by examining the raw data because the FDA's reliance on the published reports of the UGDP was tantamount to an endorsement of the accuracy of the entire study.⁹¹ Therefore, Justice Brennan concluded that the data were clearly agency records⁹² and were retained by UGDP only because HEW had elected not to exercise its right of access.⁹³

Justice Brennan's suggestion that the Court's technical requirement for actual ownership considerably narrows the scope of the FOIA contrary to congressional intent to provide for openness in government affairs⁹⁴ may be unfair in view of federal policies designed to preserve the autonomy of private grantees.⁹⁵ Government officials and legal scholars have recognized that receipt of federal funds by private grantees should not be viewed as converting the work product of grantees into federal projects.⁹⁶ Typically, a research grant is awarded to promote a general social policy, and is rooted in the belief that self-reliance and autonomy of the researcher is "necessary to scientific excellence."⁹⁷ Under these circumstances, the government plays the role of an "interested and concerned donor."⁹⁸ The *Forsham* Court, in light of these countervailing considerations, refused to extend FOIA obligations to individuals who traditionally have not been regarded as associated with the federal government.⁹⁹

90. 100 S. Ct. at 990, 63 L. Ed. 2d at 311. Justice Brennan does not compare the agency involvement in the UGDP study with the day-to-day supervision standard required under the *Orleans* decision. *United States v. Orleans*, 425 U.S. 807, 815 (1976). Because *Forsham* involved the additional factor of agency reliance on the work product of a grantee, Justice Brennan may have viewed the *Orleans* test as irrelevant to the controversy.

91. 100 S. Ct. at 989-90, 63 L. Ed. 2d at 310. Unlike the majority, Brennan found the reliance issue central to the resolution of the controversy. He states that the UGDP study was one of HEW's "basic sources" when it suspended phenformin as an imminent hazard. *Id.* at 990, 63 L. Ed. 2d at 310. The facts of the case indicate, however, that the suspension of phenformin was not based on the UGDP warning of cardiovascular complications but on the association between use of phenformin and the development of lactic acidosis. See note 12 *supra*. In fact the agency reliance has been limited to proposed regulatory action that has yet to become effective because of claims that the UGDP reports are unreliable. See notes 11 & 14 *supra*. Accordingly, the reliance that Brennan found to be determinative should not be held as sufficient to compel disclosure of the raw data.

92. 100 S. Ct. at 990, 63 L. Ed. 2d at 311.

93. *Id.*

94. *Id.* at 991, 63 L. Ed. 2d at 311.

95. See note 62 *supra* and accompanying text.

96. See Mason, *supra* note 33; Staats, *Federal Research Grants*, 205 SCIENCE 18 (1979).

97. Staats, *supra* note 96, at 19.

98. Willcox, *The Function and Nature of Grants*, National Institute on Federal Urban Grants: Policies and Procedures, 22 ADMIN. L. REV. 125, 130 (1969).

99. The Court noted that "Congress found that federal funding and supervision did not justify direct access" to grantee records and declined to find that "those identical activities were intended to permit indirect access through an expansive definition of 'agency records.'" 100 S. Ct. at 985, 63 L. Ed. 2d at 305.