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Forsham Vs. Harris

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Appeal No. : 445 U.S. 169

Appellant : Forsham

Respondent : Harris

Judgement :

Forsham v. Harris - 445 U.S. 169 (1980)
U.S. Supreme Court Forsham v. Harris, 445 U.S. 169 (1980)

Forsham v. Harris

No. 78-1118

Argued October 31, 1979

Decided March 3, 1980

445 U.S. 169

CERTIORARI TO THE UNITED STATES COURT OF APPEALS

FOR THE DISTRICT OF COLUMBIA CIRCUIT

SYLLABUS

Under federal grants awarded by the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD) (a federal agency), the University Group Diabetes Program (UGDP), a group of private physicians and scientists, conducted a long-term study of the effectiveness of certain diabetes treatment regimens. Pertinent federal regulations authorized some supervision of UGDP and gave NIAMDD the right of access to, or permanent custody of, the raw data generated by UGDP. However, the day-to-day administration of grant-supported activities was in UGDP's hands, and NIAMDD did not exercise its right to review or obtain custody of the raw data, which remained at all times in UGDP's possession and under its ownership. The UGDP's reports on the results of its study, indicating that the use of certain drugs in diabetes treatment increased the risk of heart disease, ultimately resulted in proceedings by the Secretary of Health, Education, and Welfare (HEW) and the Food and Drug Administration (FDA) to restrict the labeling and use of the drugs. After both UGDP and HEW denied petitioners' request for access to the UGDP raw data underlying its published reports, petitioners filed suit in Federal District Court to require HEW to make the raw data available under the Freedom of Information Act (FOIA), which empowers federal courts to order an "agency" to produce "agency records improperly withheld" from an individual requesting access. The District Court granted summary judgment for respondents, holding that HEW properly denied the request on the ground that the data did not constitute "agency records" under the FOIA. The Court of Appeals affirmed.

Held: HEW need not produce the requested data because they are not "agency records" within the meaning of the FOIA. Data generated by a privately controlled organization which has received federal grants (grantee), but which data has not at any time been obtained by the agency, are not "agency records" accessible under the FOIA. Pp 445 U. S. 177 -187.

(a) There is no merit to petitioners' claim that the data were at least records of UGDP, and that the federal funding and supervision of UGDP alone provide the close connection necessary to render its

records "agency records" as that term is used in the FOIA. While "agency record" is not defined in the Act, Congress excluded private grantees from FOIA disclosure obligations by excluding them from the Act's definition of "agency," an action consistent with its prevalent practice of preserving the autonomy of federal grantees and their records. Since Congress found that federal funding and supervision (short of Government control) did not justify direct access to the grantee's records, it cannot be concluded that those identical activities were intended to permit indirect access through an expansive definition of "agency records." Pp. 445 U. S. 178 -182.

(b) Nor may a broad definition of "agency records" be invoked so as to include all documents created by a private grantee to which the Government has access and which the Government has used. Such a broad definition is not supported by either the language, structure, or legislative history of the FOIA. Instead, Congress contemplated that an agency must first either create or obtain a record as a prerequisite to its becoming an "agency record" within the meaning of the FOIA. This conclusion is also supported by other Acts in which Congress has associated creation or acquisition with the concept of a governmental record. Although, in this case, HEW has a right of access to the data, and a right if it so chooses to obtain permanent custody of the UGDP records, in this context, the FOIA applies to records which have been, in fact, obtained, and not to records which merely *could have been* obtained. Without first establishing that the agency has created or obtained the document, the agency's reliance on or use of the document is similarly irrelevant. Pp. 445 U. S. 182 -186.

190 U.S.App.D.C. 231, 587 F.2d 1128, affirmed.

REHNQUIST, J., delivered the opinion of the Court, in which BURGER, C.J., and STEWART, WHITE, BLACKMUN, POWELL, and STEVENS, JJ., joined. BRENNAN, J., filed a dissenting opinion, in which MARSHALL, J., joined, *post,* p. 445 U. S. 187 .

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MR. JUSTICE REHNQUIST delivered the opinion of the Court.

The Freedom of Information Act, 5 U.S.C. 552, empowers federal courts to order an "agency" to produce "agency records improperly withheld" from an individual requesting access. 552(a)(4)(B). We hold here that written data generated, owned, and possessed by a privately controlled organization receiving federal study grants are not "agency records" within the meaning of the Act when copies of those data have not been obtained by a federal agency subject to the FOIA. Federal participation in the generation of the data by means of a grant from the Department of Health, Education, and Welfare (HEW) does not make the private organization a federal "agency" within the terms of the Act. Nor does this federal funding, in combination with a federal right of access, render the data "agency records" of HEW, which is a federal "agency" under the terms of the Act.

I

In 1959, a group of private physicians and scientists specializing in the treatment of diabetes formed the University Group Diabetes Program (UGDP). The UGDP conducted a long-term study of the effectiveness of five diabetes treatment regimens. Two of these treatment regimens involved diet control in combination with the administration of either tolbutamide, or phenformin hydrochloride, both "oral hypoglycemic" drugs. The UGDP's participating physicians were located at 12 clinics nationwide, and the study was coordinated at the Coordinating Center of the University of Maryland.

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The study generated more than 55 million records documenting the treatment of over 1,000 diabetic patients who were monitored for a 5- to 8-year period. In 1970, the UGDP presented the initial results of its study indicating that the treatment of adult-onset diabetics with tolbutamide increased the risk of death from cardiovascular disease over that present when diabetes was treated by the other

methods studied. The UGDP later expanded these findings to report a similarly increased incidence of heart disease when patients were treated with phenformin hydrochloride. These findings have, in turn, generated substantial professional debate.

The Committee on the Care of the Diabetic (CCD), a national association of physicians involved in the treatment of diabetes mellitus patients, have been among those critical of the UGDP study. CCD requested the UGDP to grant it access to the raw data in order to facilitate its review of the UGDP findings, but UGDP has declined to comply with that request. CCD therefore sought to obtain the information under the Freedom of Information Act. The essential facts are not in dispute, and we hereafter set forth those relevant to our decision.

The UGDP study has been solely funded by federal grants in the neighborhood of $15 million between 1961 and 1978. These grants were awarded UGDP by the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD), a federal agency, [Footnote 1] pursuant to the Public Health Service Act, 42 U.S.C. 241(c). NIAMDD has not only awarded the federal grants to UGDP, but has exercised a certain amount

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of supervision over the funded activity. Federal regulations governing supervision of grantees allow for the review of periodic reports submitted by the grantee and on-site visits, and require agency approval of major program or budgetary changes. 45 CFR 74.80-74.85 (1979); 42 CFR 52.20(b) (1979). It is undisputed, however, both that the day-to-day administration of grant-supported activities is in the hands of a grantee, and that NIAMDD's supervision of UGDP conformed to these regulations. [Footnote 2]

The grantee has also retained control of its records: the patient records and raw data generated by UGDP have at all times remained in the possession of that entity, and neither the NIAMDD grants nor related regulations shift ownership of such data to the Federal Government. NIAMDD does, however, have a right of

access to the data in order to insure compliance with the grant. 45 CFR 74.24(a) (1979). And the Government may obtain permanent custody of the documents upon request. 74.21(c). But NIAMDD has not exercised its right either to review or to obtain permanent custody of the data.

Although no employees of the NIAMDD have reviewed the UGDP records, the Institute did contract in 1972 with another private grantee, the Biometric Society, for an assessment of the validity of the UGDP study. The Biometric Society was given direct access to the UGDP raw data by the terms of its contract with NIAMDD. The contract with the Biometric Society, however, did not require the Society to seek access to the UGDP raw data, nor did it require that any data actually reviewed be transmitted to the NIAMDD. While the Society did review some UGDP data, it did not submit any raw data reviewed by it to the NIAMDD. The Society

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issued a report to the Institute in 1974 concluding that the UGDP results were "mixed," but "moderately strong."

An additional connection between the Federal Government and the UGDP study has occurred through the activities of the Food and Drug Administration. After the FDA was apprised of the UGDP results, the agency issued a statement recommending that physicians use tolbutamide in the treatment of diabetes only in limited circumstances. After the UGDP reported finding a similarly higher incidence of cardiovascular disease with the administration of phenformin, the FDA proposed changes in the labeling of these oral hypoglycemic drugs to warn patients of cardiovascular hazards. FDA Drug Bulletin (June 23, 1971). The FDA deferred further action on this labeling proposal, however, until the Biometric Society completed its review of the UGDP study. [Footnote 3]

After the Biometric study was issued, FDA renewed its proposal to require a label warning that oral hypoglycemics should be used only in cases of adult-onset, stable diabetes that could not be treated adequately by a combination of diet and

insulin. The FDA clearly relied on the UGDP study in renewing this position. 40 Fed.Reg. 28587, 28591 (1975). At the time the proposal was published, the FDA invited public comment. In response to criticism of the UGDP study and the Biometric Society's audit, the FDA conducted its own audit of the UGDP study pursuant to a delegation of NIAMDD's authority to audit grantee records. In conducting this audit, the FDA examined and copied a small sample of the UGDP raw data. This audit report has been made available for public inspection. 43 Fed.Reg. 52733 (1978).

Although this labeling proposal has not yet become final, other FDA regulatory action has been taken. On July 25,

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1977, the Secretary of HEW suspended the New Drug Application for phenformin, one of the oral hypoglycemic medications studied by the UGDP. The decision was premised in part on the findings of the UGDP study. *See* Order of the Secretary of Health, Education, and Welfare, July 25, 1977. After the Secretary's temporary order of suspension was issued, proceedings before the FDA continued. The Administrative Law Judge ordered the FDA to produce all UGDP data in its possession. The FDA then produced those portions of the UGDP raw data which the agency had copied, abstracted, or directly transferred to Government premises during its audit. The ALJ found that the HEW suspension order was supported by the evidence. On November 15, 1978, the Commissioner of Food and Drugs affirmed the ALJ's finding that phenformin was not shown to be safe, and ordered it withdrawn from the market. 44 Fed.Reg. 20967 (1979). This decision was not based substantially on the UGDP study. [Footnote 4]

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Petitioners had long since initiated a series of FOIA requests seeking access to the UGDP raw data. On August 7, 1975, HEW denied their request for the UGDP data on the grounds that no branch of HEW had ever reviewed or seen the raw data; that the FDA's proposed relabeling action relied on the UGDP published

reports and not on an analysis of the underlying data; that the data were the property of the UGDP, a private group; and that the agencies were not required to acquire and produce those data under the FOIA. [Footnote 5] The following month, petitioners filed this FOIA suit in the United States District Court for the District of Columbia to require HEW to make available all of the raw data compiled by UGDP. The District Court granted summary judgment in favor of respondents, holding that HEW properly denied the request on the ground that the patient data did not constitute "agency records" under the FOIA.

The Court of Appeals affirmed on the same rationale. *Forsham v. Califano,* 190 U.S.App.D.C. 231, 587 F.2d 1128 (1978). The court found that, although NIAMDD is a federal agency, its grantees are not federal agencies. The court rejected the petitioners argument that the UGDP's records were nevertheless also the federal agency's records. Although HEW has a right of access to the documents, the court reasoned that this right did not render the documents "agency records," since the FOIA only applies to records which have been "created or obtained . . . in the course of doing its work." [Footnote 6] *Id.* at 239, 587 F.2d at 1136. The dissenting

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judge concluded that the UGDP data were "agency records" under the FOIA, since the Government had been "significantly involved" in the study through its funding, access to the raw data, and reliance on the study in its regulatory actions.

II

As we hold in the companion case of *Kissinger v. Reporters Committee for Freedom of the Press, ante* p. 445 U. S. 136 , it must be established that an "agency" has "improperly withheld agency records" for an individual to obtain access to documents through an FOIA action. We hold here that HEW need not produce the requested data because they are not "agency records" within the meaning of the FOIA. In so holding, we reject three separate but related claims of petitioners: (1) the data they seek are "agency records" because they were at least

"records" of UGDP, and UGDP, in turn, received its funds from a federal agency, and was subject to some supervision by the agency in its use of those funds; (2) the data they seek are "agency records" because HEW, concededly a federal agency, had sufficient authority under its grant agreement to have obtained the data had it chosen to do so; and (3) the data are "agency records" because they formed the basis for the published reports of UGDP, which, in turn, were relied upon by the FDA in the actions described above. [Footnote 7]

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Congress undoubtedly sought to expand public rights of access to Government information when it enacted the Freedom of Information Act, but that expansion was a finite one. Congress limited access to "agency records," 5 U.S.C. 552(a)(4)(B), [Footnote 8] but did not provide any definition of "agency records" in that Act. The use of the word "agency" as a modifier demonstrates that Congress contemplated some relationship between an "agency" and the "record" requested under the FOIA. With due regard for the policies and language of the FOIA, we conclude that data generated by a privately controlled organization which has received grant funds from an agency (hereafter grantee), [Footnote 9] but which data has not at any time been obtained by the agency, are not "agency records" accessible under the FOIA.

A

We first examine petitioners' claim that the data were at least records of UGDP, and that the federal funding and supervision of UGDP alone provides the close connection necessary to render its records "agency records" as that term is used in the Freedom of Information Act. Congress did not define "agency record" under the FOIA, but it did define "agency." The definition of "agency" reveals a great deal about congressional intent as to the availability of records

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from private grantees under the FOIA, and thus, a great deal about the relevance of federal funding and supervision to the definitional scope of "agency records." Congress excluded private grantees from FOIA disclosure obligations by excluding them from the definition of "agency," an action consistent with its prevalent practice of preserving grantee autonomy. It has, for example, disclaimed any federal property rights in grantee records by virtue of its funding. We cannot agree with petitioners, in light of these circumstances, that the very federal funding and supervision which Congress found insufficient to make the grantee an agency subject to the FOIA nevertheless makes its records accessible under the same Act. Under 5 U.S.C. 552(e) an "agency" is defined as

"any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government . . or any independent regulatory agency."

The legislative history indicates unequivocally that private organizations receiving federal financial assistance grants are not within the definition of "agency." In their Report, the conferees stated that they 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.Conf.Rep. No. 93-1380, pp. 14 15 (1974), reprinted in Freedom of Information Act and Amendments of 1974 Source Book 231-232 (Jt. Comm.Print 1975). Through operation of this exclusion, Congress chose not to confer any direct public rights of access to such federally funded project information. [Footnote 10]

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This treatment of federal grantees under the FOIA is consistent with congressional treatment of them in other areas of federal law. Grants of federal funds generally do not create a partnership or joint venture with the recipient, nor do they serve to

convert the acts of the recipient from private acts to governmental acts, absent extensive, detailed, and virtually day-to-day supervision. *United States v. Orleans,* 425 U. S. 807 , 425 U. S. 818 (1976). Measured by these standards, the UGDP is not a federal instrumentality or an FOIA agency. [Footnote 11]

Congress could have provided that the records generated by a federally funded grantee were federal property even though the grantee has not been adopted as a federal entity. But Congress has not done so, reflecting the same regard for the autonomy of the grantee's records as for the grantee itself. Congress expressly requires an agency to use "procurement contracts" when the "principal purpose of the instrument is the acquisition . . . of property or services for the direct benefit or use of the Federal Government. . . ." Federal Grant and Cooperative Agreement Act of 1977, 4, 92 Stat. 4, 41 U.S.C. 503 (1976 ed., Supp. II). In contrast, "grant agreements" must be used when money is given to a recipient

"in order to accomplish a public purpose of support or stimulation authorized by Federal statute, rather than acquisition . . . of property or services. . . ."

5, 41 U.S.C. 504 (1976 ed., Supp. II). As in this case, where a grant was used,

there is no dispute that the documents created are the property of the recipient, and not the Federal Government. *See* 45 CFR 74.133 (1979). The HEW regulations do retain a right to acquire the documents. Those regulations however, clearly demonstrate that, unless and until that right is exercised, the records are only the "records of grantees." 45 CFR 74.24 (1979). [Footnote 12] Therefore, were petitioners to prevail in this action, they would have obtained a right of access to some 55 million documents created, owned, and possessed by a private recipient of federal funds. While this fact itself is not dispositive of the outcome, it is nonetheless an important consideration when viewed in light of these congressional attempts to maintain the autonomy of federal grantees and their records.

The fact that Congress has chosen not to make a federal grantee an "agency" or to vest ownership of the records in the Government does not resolve with mathematical precision the question of whether the granting agency's funding and supervisory activities nevertheless make the grantee's records "agency records." Records of a nonagency certainly could become records of an agency as well. But if Congress found that federal funding and supervision did not justify direct access to the grantee's records, as it clearly did, we fail to see why we should nevertheless conclude that those identical activities were intended to permit indirect access through an expansive definition of "agency records." [Footnote 13] Such a conclusion

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would not implement the intent of Congress; it would defeat it.

These considerations do not finally conclude the inquiry, for conceivably other facts might indicate that the documents could be "agency records" even though generated by a private grantee. The definition of "agency" and congressional policy towards grantee records indicate, however, that Congress did not intend that grant supervision short of Government control serve as a sufficient basis to make the private records "agency records" under the Act, and reveal a congressional determination to keep federal grantees free from the direct obligations imposed by the FOIA. In ascertaining the intended expanse of the term "agency records" then, we must, of course, construe the Act with regard both for the congressional purpose of increasing public access to governmental records and for this equally explicit purpose of retaining grantee autonomy.

B

Petitioners seek to prevail on their second and third theories, even though their first be rejected, by invoking a broad definition of "agency records," so as to include all documents created by a private grantee to which the Government has access, and which the Government has used. We do not believe that this broad definition of "agency records," a term undefined in the FOIA, is supported by either

the language of that Act or its legislative history. We instead agree with the opinions of the courts below that Congress contemplated that an agency must first either create or obtain a record as a prerequisite to its becoming an "agency record" within the meaning of the FOIA. While it would be stretching the ordinary meaning of the words to call the data in question here "agency records," we need not rest our conclusions solely on the "plain language" rule of statutory construction. The use of the term "record" by Congress in two other Acts, and the structure

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and legislative history of the FOIA alike support the same conclusion.

Although Congress has supplied no definition of agency records in the FOIA, it has formulated a definition in other Acts. The Records Disposal Act, in effect at the time Congress enacted the Freedom of Information Act, provides the following threshold requirement for agency records:

"'records' includes all books, papers, maps, photographs, machine readable materials, or other documentary materials, regardless of physical form or characteristics, *made or received* by an agency of the United States Government under Federal law or in connection with the transaction of public business. . . ."

44 U.S.C. 3301. [Footnote 14] (Emphasis added.) The Attorney General's Memorandum on the Public Information Section of the Administrative Procedure Act 23-24 (1967), S. Doc. No. 93-82, pp. 222-223 (1974), concludes that Congress intended this aspect of the Records Act definition to apply to the Freedom of Information Act.

The same standard emerges in the Presidential Records Act of 1978. The term "presidential records" is defined as "documentary materials . . . *created or received* by the President. . . ." 44 U.S.C. 2201(2) (1976 ed., Supp. II). (Emphasis added.) While these definitions are not dispositive

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of the proper interpretation of congressional use of the word in the FOIA, it is not insignificant that Congress has associated creation or acquisition with the concept of a governmental record. The text, structure, and legislative history of the FOIA itself reinforce that significance in this case.

The only direct reference to a definition of records in the legislative history, of which we are aware, occurred during the Senate hearings leading to the enactment of FOIA. A representative of the Interstate Commerce Commission commented that,

"[s]ince the word 'records' . . . is not defined, we assume that it includes all papers which an agency preserves in the performance of its functions."

Administrative Procedure Act: Hearings on S. 1160 *et al.* before the Subcommittee on Administrative Practice and Procedure of the Senate Committee on the Judiciary, 89th Cong., 1st Sess., 244 (1965). [Footnote 15] The legislative history of the FOIA abounds with other references to records acquired by an agency. For example, the legislative Reports clarify that confidential information "submitted . . . to a Government . . . agency," "obtained by the Government," or "given to an agency" otherwise subject to disclosure, was made exempt. S.Rep. No. 813, 89th Cong., 1st Sess., 9 (1965), reprinted in Freedom of Information Act Source Book, S. Doc. No. 93-82, p. 44 (Comm.Print 1974); H.R.Rep. No. 1497, 89th Cong., 2d Sess. (1966), reprinted in Source Book, at 31.

Section 552(b)(4) provides the strongest structural support for this construction. This section exempts trade secrets and commercial or financial information "obtained from a person." This exemption was designed to protect confidential information "submitted" by a borrower to a lending agency or "obtained by the Government" through questionnaires or other inquiries, where such information "would customarily not be released to the public by the person from whom it was

obtained." S.Rep. No. 813, *supra* at 9; H.R.Rep. No. 1497, *supra* at 10. It is significant that Congress did not include a similar exemption for confidential

information contained in records which had never been "obtained from a person." It is obvious that this omission does not reflect a congressional judgment that records remaining in private control are not similarly deserving of this exemption, but rather a judgment that records which have never passed from private to agency control are not agency records which would require any such exemption. This possessory emphasis is buttressed by similar considerations implicit in the use of the word "withholding" in the statutory framework. *See Kissinger v. Reporters Committee for Freedom of the Press, ante* p. 445 U. S. 136 . [Footnote 16]

The same focus emerges in a congressional amendment to the Securities Exchange Act of 1934. That Act had provided its own standards for public access to documents generated by the Act. Congress amended the Act to provide:

"For purposes of [the FOIA] the term 'records' includes all applications, statements, reports, contracts, correspondence, notices, and other documents filed with or otherwise *obtained* by the Commission pursuant to this chapter or otherwise."

(Emphasis added.) 15 U.S.C. 78x.

We think that the weight this construction lends to our conclusion is overborne neither by an agency's potential access to the grantee's information nor by its reliance on that information in carrying out the various duties entrusted to it by Congress. The Freedom of Information Act deals with "agency records," not information in the abstract. Petitioners place great reliance on the fact that HEW has a right of access to the data, and a right if it so chooses to obtain permanent custody of the UGDP records. 45 CFR 74.24,

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74.21 (1979). But in this context, the FOIA applies to records which have been *in fact* obtained, and not to records which merely *could have been* obtained. [Footnote 17] To construe the FOIA to embrace the latter class of documents would be to extend the reach of the Act beyond what we believe Congress

intended. We rejected a similar argument in *NLRB v. Sears, Roebuck & Co.,* 421 U. S. 132 , 421 U. S. 161 -162 (1975), by holding that the FOIA imposes no duty on the agency to create records. By ordering HEW to exercise its right of access, we effectively would be compelling the agency to "create" an agency record, since, prior to that exercise, the record was not a record of the agency. Thus, without first establishing that the agency has created or obtained the document, reliance or use is similarly irrelevant.

We think the foregoing reasons dispose of all petitioners' arguments. We therefore conclude that the data petitioners seek are not "agency records" within the meaning of the FOIA. UGDP is not a "federal agency" as that term is defined in the FOIA, and the data petitioners seek have not been created or obtained by a federal agency. Having failed to establish

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this threshold requirement, petitioners' FOIA claim must fail, and the judgment of the Court of Appeals is accordingly

Affirmed.

[Footnote 1]

The NIAMDD is one of several Institutes of the National Institutes of Health (NIH). It is authorized by statute to conduct and fund research on diabetes and other diseases. 42 U.S.C. 289a, 289c-1. The NIH are a component of the federal Public Health Service, which is itself a part of the Department of Health, Education, and Welfare. *See* Reorg. Plan No. 3 of 1966, 3 CFR 1023 (1966-1970 Comp.), note following 42 U.S.C. 202, and Reorganization Order of April 1, 1968, 33 Fed.Reg. 5426.

[Footnote 2]

Petitioners do contend that the federal supervision of the UGDP study was substantial, and more extensive than that ordinarily exercised. They do not, however, maintain that there was day-to-day supervision. *See infra* at 445 U. S.

180 , and n. 11.

[Footnote 3]

Prior to the FDA's decision to defer action, petitioners in this case sued the FDA to enjoin the proposed labeling, contesting the validity of the UGDP study. The First Circuit remanded the case to the FDA for exhaustion of administrative remedies. *Bradley v. Weinberger,* 483 F.2d 410 (1973).

[Footnote 4]

The order of the Commissioner discounts reliance on the UGDP study. The order states that the ALJ was correct in concluding that, from "an evidentiary standpoint," the "lack of availability of underlying data casts considerable doubt on the reliability of the UGDP conclusions." 44 Fed.Reg. 20969 (1979). The ALJ did permit reference to the UGDP study as a basis for expert opinion. The Commissioner concluded that this use of the study was permissible, since the data underlying expert opinions need not always be admitted to substantiate the opinions. Nearly 400 published articles were included in the record of the phenformin proceeding, and none of the articles was accompanied by the raw data on which it was based. The Commissioner noted that the ALJ referenced the UGDP study in only one paragraph of his eight-page summary.

The Commissioner concluded that the agency was not required to submit the UGDP data, since it had not relied upon that data, but only upon the actual study. 21 CFR 12.85 (1979). Nevertheless, the Commissioner stated that he

"reviewed the testimony of the Bureau of Drug's expert witnesses and [found] that their reliance upon the UGDP study was not substantial, and cannot reasonably be characterized as pivotal to the opinions expressed by those witnesses."

44 Fed.Reg. 20969 (1979).

[Footnote 5]

The denial of this FOIA request preceded the FDA's audit of the UGDP data.

[Footnote 6]

The court opinion also suggested that a document is an "agency record" if the federal agency has a duty to obtain the record. 190 U.S.App.D.C. at 239, and n. 18, 587 F.2d at 1136, and n. 18 (Leventhal, J.). Judge MacKinnon concurred separately to reserve the question of whether or not records which an agency had a duty to obtain were recoverable under the FOIA. We side with Judge MacKinnon on the breadth of the principle necessary to the decision in this case. *Id.* at 242, 587 F.2d at 1139.

[Footnote 7]

Petitioners maintain that the FDA has relied on all the raw data through reliance on the report and through reliance on information obtained pursuant to its audit of a sample of the data. The Court of Appeals found, however, that data reviewed by the FDA have been made available to petitioners. *Id.* at 236, 587 F.2d at 1133. As we indicate *infra,* reliance on a document does not make it an agency record if it has not been created or obtained by a federal agency. Reliance or use may well be relevant, however, to the question of whether a record in the possession of an agency is an "agency record." *See Kissinger, ante* at 445 U. S. 157 .

[Footnote 8]

In 552(a)(3), Congress did not use the term "agency records." That section provides: "[E]ach agency, upon any request for records . . . shall make the records promptly available to any person." Since the enforcement provision of the Act, 552(a)(4)(b), refers only to "agency records," it is certain that the disclosure obligations imposed by 552(a)(3) were only intended to extend to agency records. That limitation is implicit throughout the Act.

[Footnote 9]

We use the term "grantee" or "private grantee" to describe private recipients of federal funds not subjected to sufficient Government control to render them federal agencies. We do not suggest, by use of this term, that an organization receiving

federal grant funds could never be found to be a federal agency. *See infra* at 445 U. S. 180 , and n. 11.

[Footnote 10]

Numerous bills seeking to extend the FOIA to federal grantees have been introduced in each Congress since the 92d, but none has yet been reported out of committee. *See* H.R. 11013, 92d Cong., 1st Sess. (1969); H.R. 1291, 93d Cong. 1st Sess. (1973); H.R. 1205, 94th Cong., 1st Sess. (1975); H.R. 3207, 95th Cong., 1st Sess. (1977); H.R. 1465, 96th Cong., 1st Sess. (1979).

[Footnote 11]

Before characterizing an entity as "federal" for some purpose, this Court has required a threshold showing of substantial federal supervision of the private activities, and not just the exercise of regulatory authority necessary to assure compliance with the goals of the federal grant. *See United States v. Orleans,* 425 U. S. 807 (1976). While the petitioners emphasize the Government's interest in monitoring the UGDP's study, they do not contend that this supervision is sufficient to render UGDP a satellite federal agency. The funding and supervision indicated by the facts of this case are consistent with the usual grantor-grantee relationship, and do not suggest the requisite magnitude of Government control. *Orleans, supra* at 425 U. S. 815 -816.

[Footnote 12]

The particular grant agreement in issue similarly confers on the NIAMDD a limited right of access to "records of the grantee."

[Footnote 13]

Nor could this distinction be explained by a hypothetical congressional preference for placing the burdens of production on the agency, rather than the private grantee. Although, under the petitioners' construction of the Act, the request would have to be made by the agency, the administrative burdens of searching and producing, or providing access would necessarily accrue substantially to the party

in possession, *i.e.,* the private grantee.

[Footnote 14]

The definition of "records" under the Records Disposal Act further requires that records made or received by the agency also be

"preserved or appropriate for preservation by that agency . . . as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of data in them."

Government documents made or received by an agency that are not appropriate for preservation are referred to as "nonrecord materials." 41 CFR 101-11.401-3(d) (1979). It has not been settled whether the FOIA definition of agency records extends to "nonrecord materials." We need not reach that question, since the documents sought by petitioners do not meet the threshold requirement that they be "made or received" by a federal agency.

[Footnote 15]

It is interesting to note that the witness expressed concern that such an "all-expansive meaning" necessitated clear categorical exemptions.

[Footnote 16]

We certainly do not indicate, however, that physical possession, or initial creation, is, by itself, always sufficient. *See Kissinger, ante* at 445 U. S. 157 .

[Footnote 17]

We need not categorize what agency conduct is necessary to support a finding that it has "obtained" documents, since an unexercised right of access clearly does not satisfy this requirement. Government access to documents clearly could not be the central component of the definition of agency records contemplated by Congress, since the Federal Government has access to near astronomical numbers of private documents. A mere sampling of access statutes includes:

Internal Revenue Code of 1954, 7602, 26 U.S.C. 7602 (taxpayers or potential taxpayers); 15 U.S.C. 78q, 78u (persons subject to the Securities Exchange Act of 1934); 29 U.S.C. 657 (each employer subject to the Occupational Safety and Health Act of 1970).

Even if the Court were to accept petitioners' argument that only contractual access should give rise to "agency record" status, a limitation which does not appear readily supportable, the class of documents subject to FOIA disclosure would still be staggering. The record in this case indicates that NIAMDD alone has some 18,000 research grants outstanding.

MR. JUSTICE BRENNAN, with whom MR. JUSTICE MARSHALL joins, dissenting.

I agree with the Court that "[r]ecords of a nonagency certainly could become records of an agency as well." *Ante* at 445 U. S. 181 . But the Court does not explain why such a conversion does not occur in this case. [Footnote 2/1] Because I believe we should articulate standards under which to analyze such cases, and because I believe that, under a proper test, UGDP's data should be treated as "agency records," I dissent.

I

The Court argues at length that UGDP is not an agency. But whether or not UGDP is an "agency" is simply not at issue in this case. Rather, the only question is whether data generated in the course of this UGDP study are "agency records."

The Court concedes, of course, that the statute itself does not define "agency records." [Footnote 2/2] Therefore, our task is to construe

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the statutory language consistently with the purposes of FOIA. [Footnote 2/3] As detailed in the dissenting opinion below, *Forsham v. Califano,* 190 U.S.App.D.C. 231, 244-245, 587 F.2d 1128, 1141-1142 (1978) (Bazelon, J., dissenting), FOIA is a broad enactment meant to open the processes of Government to public

inspection. It reflects a finding that, if left to themselves, agencies would operate in near secrecy. [Footnote 2/4] FOIA was, therefore, enacted to provide access to information to enable "an informed electorate," so "vital to the proper operation of a democracy," to govern itself. S.Rep. No. 813, 89th Cong., 1st Sess., 3 (1965). Nothing whatever in the legislative history suggests that Congress meant to allow agencies to insulate important steps in decisionmaking on the basis of the technical niceties of who "owns" crucial documents.

Where the nexus between the agency and the requested information is close, and where the importance of the information to public understanding of the decisions or the operation

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of the agency is great, I believe the congressional purposes require us to hold that the information sought is an "agency record" within the meaning of FOIA.

Admittedly, this test does not establish a bright line, but the evaluation of a calculus of relevant factors is nothing new to the law. [Footnote 2/5] The first such factor is the importance of the record to an understanding of Government activities. If, for instance, the significance of the record is limited to understanding the workings of the nonagency, the public has no FOIA-protected interest in access. The weight to be given this factor can be tested by examining the role accorded the material in agency writings and the extent to which the agency reached its conclusions in reliance upon the particular source.

Mere materiality of information, standing alone, of course, is not enough. [Footnote 2/6] FOIA does not give the public any unrestricted right to examine all data relied on by an agency. Congress required that the information constitute an "agency record." Thus, another necessary factor is that there be a link between the agency and the record. [Footnote 2/7] Nothing in FOIA or its history suggests, however, that the connection must amount to outright possession or creation. Instead, again drawing from the legislative purposes, I believe the link must be such that the agency has treated the record as if it were

part of the regulatory process, as if it were, in effect, a record which exists to serve the regulatory process. Government by secrecy is no less destructive of democracy if it is carried on within agencies or within private organizations serving agencies. The value of the record to the electorate is not affected by whether the relationship between the agency and the private organization is governed formally by a procurement contract, a "joint venture" agreement, or a grant. [Footnote 2/8] The existence of this factor can be tested by examining, *inter alia,* the degree to which the impetus for the creation of the record came from the agency or was developed independently, the degree to which the creation of the record was funded publicly or privately, the extent of governmental supervision of the creation of the record, and the extent of continuing governmental control over the record.

II

On the facts of this case, I would conclude that UGDP's raw data are records of HEW. Both HEW and the FDA have taken significant actions in complete reliance on the UGDP study. The FDA has directly endorsed the study's conclusions and, in reliance thereon, sought mandatory labeling warnings on the drugs criticized by the UGDP. HEW cited the UGDP study as one of its basic sources when it suspended one of the drugs as an immediate hazard. The suggestion that these administrative actions relied solely on the published reports, and not on the underlying raw data at issue here, is unrealistic. The conclusions can be no stronger or weaker than the data on which they are based. One cannot even begin to evaluate an agency action without access to the raw data on which the conclusions were based, especially in a case, such as this, where the data are nonduplicable. The importance of the raw data in evaluating derivative conclusions was

recognized by the FDA when it employed another independent organization, the Biometric Society, to check UGDP's work. FDA secured access for the Society to

the raw data, and the Society used a sample of the data.

This case is set against the background of an intense, often bitter, [Footnote 2/9] battle being waged in the medical community over the validity of the UGDP study and the correct treatment regimen for diabetes. By endorsing the UGDP study, the Federal Government has aligned itself on one side of the fight, and has all but outlawed the regimen recommended by the other side. Petitioners in this case are medical scientists seeking to resolve questions that have been raised about the scientific and statistical methods underlying an agency's conclusions. This seems to me to be an archetypical instance of the need for public dissemination of the information.

Even so, I doubt that the information could be held to be an "agency record" had the Government not been so deeply involved in its creation. Petitioners have argued that the National Institutes of Health, in effect, did create these records. The agency not only completely funded the project's operation, but initiated the project and took responsibility for developing its research protocol as well. *See Forsham v. Califano,* 190 U.S.App.D.C. at 251, 587 F.2d at 1148 (Bazelon, J., voting for rehearing). They contend further that, beyond the normal level of NIH involvement in its grantees' studies set out by the Court, *ante* at 445 U. S. 173 , the NIH exercised continuing supervision over his study through a "Policy Advisory Board" as a condition of the grant renewals. [Footnote 2/10] *Forsham v. Califano, supra.* Finally, as the Court also

acknowledges, there is no question that the Government has full access to the data under the terms of the grant and under federal regulations. Indeed, if it so chose, the Government could obtain permanent custody of the data merely by requesting it from UGDP. Thus, the data remain with the grantee only at the pleasure of the Government. In my view, the record abundantly establishes that these data were developed with public funds and with Government assistance and, in large part, for governmental purposes. Therefore, I would hold that they are agency records, and I respectfully dissent.

III

I emphasize that the standards I suggest do not mean opening to the public the files of all grantees or of all who submit information to the Government. In many cases, grantees' records should not be treated as agency records. But the Court's approach must inevitably undermine FOIA's great purpose of exposing Government to the people. It is unavoidable that, as the work of federal agencies mushrooms both in quantity and complexity, the agencies must look to outside organizations to assist in governmental tasks. Just as the explosion of federal agencies, which are not directly responsible to the electorate, worked to hide the workings of the Federal Government from voters before enactment of FOIA, S.Rep. No. 813, 89th Cong., 1st Sess., 3 (1965), the understandable tendency of agencies to rely on nongovernmental grantees to perform myriad projects distances the electorate from important information by one more step. If the records of such organizations, when drawn directly into the regulatory process, are immune from public inspection, then government by secrecy must surely return.

[Footnote 2/1]

The Court suggests that, if a federal grant created a partnership or joint venture between the agency and the grantee, the grantee might become an agency, and thus its records might become agency records. *Ante* at 445 U. S. 180 . Likewise, the Court might reach a different result where the agency has chosen to buy data through a procurement contract instead of a grant. *Ibid.* But neither of these is an instance involving records of a nonagency. In the first, the grantee becomes an agency, and in the second, the records do not belong to the nonagency.

[Footnote 2/2]

Therefore, the Court surely overstates the fact in saying that Congress "clearly" found that federal funding and supervision are not relevant to whether direct access to grantee's records is justified, *ante* at 445 U. S. 181 , and the Court does not explain why Congress' silence "reflect[s] the same regard for the

autonomy of the grantee's records as for the grantee itself," *ante* at 445 U. S. 180 . Moreover, nothing whatever is cited in the legislative history to support the Court's claim that the "purpose of retaining grantee autonomy" was "equally explicit" as a purpose of FOIA as was increasing public access to governmental records. *Ante* at 445 U. S. 182 .

[Footnote 2/3]

I find the Court's references to other statutes unenlightening. The Records Disposal Act and Presidential Records Act of 1978 are properly limited to records created or received because the agencies or the Executive cannot physically dispose of what they do not possess. These Acts are aimed at monitoring the physical destruction of agency documents and settling claims of ownership of Presidential documents. The agencies and the Executive cannot destroy or take for private use what they have never possessed.

As for the "structural" argument drawn from 5 U.S.C. 552(b)(4), I cannot imagine that trade secrets or commercial information not submitted to the Government would have been created or used for governmental purposes or with governmental funds. In short, the Government would have no claim of any kind on the information if it had not been submitted .

[Footnote 2/4]

FOIA was enacted because agencies had turned the predecessor statute on its head, transforming a public information statute into a secrecy statute. H.R.Rep. No. 1497, 89th Cong., 2d Sess. (1966), reprinted in Freedom of Information Act Source Book, S. Doc. No. 93-82, pp. 22, 25-27 (Comm.Print 1974).

[Footnote 2/5]

The Court offers no manageable standards of any kind. No guidance is given to the decisionmaker as to how to determine at what point a relationship between an agency and another organization ripens into a "joint venture." And, of course, we are given no key to guide the determination of what nonagency records "become

records of an agency as well." *Ante* at 445 U. S. 181 .

[Footnote 2/6]

The Court, by insisting on analyzing petitioners' contentions separately, never addresses the full, combined force of the arguments. It is only in combination that the various factors alluded to by petitioners tell the full story of governmental reliance on and involvement with the data, and thus the importance to the success of Congress' FOIA scheme of disclosing this information.

[Footnote 2/7]

See Note, The Definition of "Agency Records" Under the Freedom of Information Act, 31 Stan.L.Rev. 1093, 1106-1114 (1979).

[Footnote 2/8]

Certainly the agency cannot control the legal consequences simply by the label it attaches to a relationship.

[Footnote 2/9]

one former UGDP investigator has challenged the scientific honesty of the research coordinator, who is also the current custodian of the raw data.

[Footnote 2/10]

Because the case comes to us on affirmance of the grant of respondents' motion for summary judgment, we must accept petitioners' version of any disputed facts. Thus, for instance, we are not free to de-emphasize the extent of federal supervision of the UGDP study alleged by petitioners.

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