

To be printed at a later date  
UNITED STATES COURT OF APPEALS  
FOR THE DISTRICT OF COLUMBIA CIRCUIT

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No. 86-5017

SIDNEY M. WOLFE, et al.

v.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Appeal from the United States District Court  
for the District of Columbia

(Civil Action No. 85-1033)

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Argued En Banc December 2, 1987

Decided February 5, 1988

James M. Spears, Deputy Assistant Attorney General, with whom, Richard K. Willard, Assistant Attorney General, Joseph E. diGenova, United States Attorney, Robert Kopp, Leonard Schaitmman and Alfred Mollin, Attorneys, Department of Justice, were on the brief for appellant.

William B. Schultz, with whom, Alan B. Morrison was on the brief for appellees.

Before: WALD, Chief Judge, ROBINSON, MIKVA, EDWARDS, RUTH B. GINSBURG, BORK, STARR, SILBERMAN, BUCKLEY, WILLIAMS, D.H. GINSBURG and SENTELLE, Circuit Judges.

Opinion for the court filed by Circuit Judge BORK in which STARR, SILBERMAN, BUCKLEY, WILLIAMS, D.H. GINSBURG and SENTELLE, Circuit Judges, join.

Dissenting opinion filed by Chief Judge WALD with whom ROBINSON, MIKVA, EDWARDS and RUTH B. GINSBURG, Circuit Judges, join.

Dissenting opinion filed by Circuit Judge EDWARDS with whom WALD, Chief Judge, ROBINSON, MIKVA, and RUTH B. GINSBURG, Circuit Judges, join.

Dissenting opinion filed by Circuit Judge RUTH B. GINSBURG with whom WALD, Chief Judge, ROBINSON, MIKVA, and EDWARDS, Circuit Judges, join.

BORK, Circuit Judge: The plaintiffs-appellees, members of the Public Citizen Health Research Group, requested access under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552 et seq. (1982), to records which indicate what actions have been completed by the Food and Drug Administration ("FDA") but which await final decision or approval by the Secretary of Health and Human Services ("HHS") or the Office of Management and Budget ("OMB"). HHS refused plaintiffs' requests, contending that the information sought was exempt under FOIA Exemption 5, which shields from disclosure those documents that would not be routinely available in civil litigation with the agency. See 5 U.S.C. § 552(b)(5) (1982). The government claimed that the information should be exempt under the deliberative process privilege. The district court granted summary judgment for the plaintiffs. A divided panel of this court affirmed the district court. The full court granted review in order to address the proper scope of the deliberative process privilege as it is applied through Exemption 5. We hold that the privilege protects against disclosure of the

information requested and therefore reverse the district court.

I.

Plaintiffs filed the instant FOIA request in order to influence decision-makers more efficiently during predecisional deliberations and in order to locate the cause of what they allege to be unreasonable delay in the issuance of Food and Drug Administration ("FDA") regulations. This case reflects dissatisfaction with the results of the development of formal presidential oversight of executive branch rulemaking. See DeMuth & Ginsburg, White House Review of Agency Rulemaking, 99 Harv. L. Rev. 1075 (1986). Two developments within the last seven years have sparked this particular attack. First, in 1981 the Secretary of HHS withdrew the delegation of power to the FDA to issue regulations that it deemed in the public interest. Instead, such regulations now must first be reviewed and approved by the Secretary. See 21 C.F.R. § 5.11 (1987). Second, on February 17, 1981, the President issued Executive Order No. 12,291 which requires all agencies considering issuance of a rule to submit any draft proposed rule and any draft final rule for review by OMB. See Exec. Order No. 12,291, Section 3(c)(1) & (2), 3 C.F.R. 127 (1981), reprinted in 5 U.S.C. § 601 note (1982).<sup>1/</sup> OMB, insofar as the relevant statutory law permits, reviews the rule for consistency with presidential policies and for net gain as

shown by cost benefit analysis. Thus, before a rule can be proposed or promulgated by FDA it must be reviewed and approved first by the Secretary of HHS and then by OMB.

Members of the public are excluded only from the inter-agency stages of the rulemaking process. After FDA, HHS, and OMB have approved a regulatory proposal, members of the public are guaranteed an opportunity to comment on the proposed rule. The APA requires that the FDA publish a general notice specifying the time and place of the rulemaking proceedings, 5 U.S.C., § 553(b)(1) (1982), and guarantees the public the opportunity to comment on the proposed rule. 5 U.S.C. § 553(c) (1982). There may be an opportunity for oral argument. Id. Thereafter the FDA is required to consider relevant comments presented to it and to incorporate in any rule adopted a concise and general statement of its basis and purpose. Id. The draft final rule is then reviewed by OMB. Plaintiffs, unsatisfied with their statutorily guaranteed input, during the comment period seek the ability to influence the inter-agency stage in the rulemaking process.

In essence, plaintiffs wish to be able to identify, in general, which regulatory actions have been proposed by FDA and to know how long regulatory actions initiated by FDA are spending at each stopping point along the approval route from FDA to HHS to OMB and back to HHS, so that they can identify decision-makers and contest delays in the consideration of FDA



regulations. Plaintiffs began by submitting on July 18, 1984, a written request to HHS for access to records indicating which FDA proposals were then pending for review by HHS or OMB. Joint Appendix ("J.A.") at 8. HHS denied this request by letter dated August 23, 1984, on the ground that the information sought is exempt from disclosure under FOIA Exemption 5. Id. at 9. Plaintiffs renewed their request by letter dated March 7, 1985, to which they received no formal response. Id. at 11. Plaintiffs then filed this action in the district court on April 1, 1985. By letter dated April 16, 1985, plaintiffs submitted to HHS a second request for the same information and in addition sought access to the dates of transmittal of proposed rules from FDA to HHS, from HHS to OMB, and from OMB back to HHS. Id. at 15. On April 19, 1985, HHS denied this second request on the same ground as the denial of the first request. Id. at 16. On April 25, 1985, plaintiffs appealed by letter their April 16 request. Id. at 18. The appeal was formally denied on May 31, 1985. Id. at 19. On June 14, 1985, plaintiffs amended their complaint in this action to include their second request.

While plaintiffs' case was pending in district court, HHS disclosed that it maintains a log (the "Regulations Log") that contains, among other things, all the information sought by plaintiffs. The Regulations Log is used by HHS as an internal tracking device that allows the Secretary to monitor actions

moving through the clearance process. It lists by title regulatory action proposed by FDA, the date on which the proposal was received by HHS, and, if applicable, the date on which HHS sent it on to OMB. The Log also contains information about the offices and persons within HHS to which the matter has been routed, but plaintiffs have not sought access to this information.<sup>2/</sup> Plaintiffs' access to the Regulations Log is limited by their original FOIA request which seeks the dates on which regulatory proposals, identified by subject matter title, were transmitted from one agency to another.<sup>3/</sup>

Although plaintiffs do not seek access to the specific substance of the proposed rules, they already know the general identity of important regulations and other FDA projects under consideration because "these matters are generally known to those with an interest in the FDA." Brief of Appellees at 3. In addition, as plaintiffs point out, the FDA publishes a semi-annual Regulatory Agenda that lists all current and projected rulemaking being considered by the FDA, all existing FDA regulations presently under review, and all actions that have been completed by the FDA within the prior six months. Id. Thus, if the information requested is made public and shows a transmittal from the FDA to HHS, it is known that the FDA has proposed to regulate a particular subject, and if no transmittal is shown, it is known that the FDA has decided not to recommend such regulation or not to recommend it yet. If no

transmittal to OMB is shown, HHS is known to have disapproved the FDA's proposal. If a transmittal is shown but no regulation is put out for notice and comment, OMB is known to have disapproved the regulatory proposal. At oral argument, plaintiffs' counsel conceded that plaintiff was not entitled to information which would reveal that a recommendation to regulate had been made.<sup>4/</sup>

The district court ruled that FOIA Exemption 5 did not apply to this case because the information requested does not fall under the deliberative process privilege. The district judge reasoned that none of the policies underlying the privilege would be significantly implicated by disclosure of the requested material and concluded that the mere fact that "a recommendation has been made by one agency to another" is not information "sufficiently 'deliberative' to trigger the protections of the privilege." Wolfe v. Department of Health & Human Serv., 630 F. Supp. 546, 550 (D.D.C. 1985). Accordingly, the district court granted summary judgment for plaintiffs, denied defendant's cross-motion for summary judgment, and ordered disclosure of the requested information within thirty days. HHS filed a timely appeal, and on January 17, 1986, a panel of this court granted the agency's unopposed motion for a stay of the district court's order pending appeal.

On appeal the government continued to argue that the information requested is protected by the common law

deliberative process privilege.<sup>5/</sup> A majority of the panel affirmed the district court's grant of summary judgment to the plaintiffs. Wolfe v. Department of Health & Human Servs., 815 F.2d 1527, 1529-32 (D.C. Cir. 1987), vacated and r'hg en banc granted, 815 F.2d 1527 (July 2, 1987). The panel majority recognized that the information requested would reveal that a pre-decisional recommendation had been made. Id. at 1531. But since disclosure would reveal pre-decisional recommendations at a broad level of generality they were "insufficiently deliberative" and thus did not fall within the protection of the privilege. Id. The majority rejected the government's argument that the privilege protects not only deliberative materials but the deliberative process itself. Id. at 1532. The dissent argued that Exemption 5 permits the withholding of information when, as in the instant case, disclosure would harm the deliberative process itself. Id. at 1535-37. The full court granted a hearing to determine the scope of the deliberative process privilege. We reverse the judgment of the district court and hold that Exemption 5's deliberative process privilege protects against disclosure of the information requested.

## II.

Exemption 5 allows an agency to withhold from the public "inter-agency or intra-agency memorandums or letters which would not be available to a party other than an agency in

litigation with the agency." 5 U.S.C. § 552(b)(5) (1982). The common law discovery privilege at issue is the executive or deliberative process privilege. Congress adopted Exemption 5 because it recognized that the quality of administrative decision-making would be seriously undermined if agencies were forced to operate in a fishbowl. Mead Data Cent. Inc. v. U.S. Dep't of Air Force, 566 F.2d 242, 256 (D.C. Cir. 1977). As is stated in the legislative history, the purpose of Exemption 5 is to encourage the "frank discussion of legal and policy issues." S. Rep. No. 813, 89th Cong., 1st Sess. 9 (1965); see also H.R. Rep. No. 1497, 89th Cong., 2d Sess. 10 (1966).

In other words, the privilege "rest[s] . . . upon the policy of protecting the 'decisionmaking processes of government agencies.'" NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 150 (1975) (quoting Tennessean Newspapers, Inc. v. FHA, 464 F.2d 657, 660 (6th Cir. 1972)); see also Mead Data Cent., 566 F.2d at 256 ("Exemption five is intended to protect the deliberative process of government and not just deliberative material" (citation omitted)). However, in accordance with the general disclosure policy of FOIA, Exemption 5 is to be construed "as narrowly as consistent with efficient Government operation." S. Rep. No. 813, supra, at 9.

Thus, the Supreme Court has limited the deliberative process privilege to materials which are both predecisional and deliberative. EPA v. Mink, 410 U.S. 73, 88 (1972).

Accordingly, the Supreme Court and this court require disclosure of documents which explain an agency's final decision but protect documents which are pre-decisional. Renegotiation Bd. v. Grumman Aircraft, 421 U.S. 168, 184-85 (1975); Coastal States Gas Corp. v. Department of Energy, 617 F.2d 854 (D.C. Cir. 1980). In the instant case, the materials are unquestionably pre-decisional. This case turns, therefore, on whether or not the information requested is deliberative -- that is "whether it reflects the give-and-take of the consultative process." Coastal States, 617 F.2d at 866; see also Sears, 421 U.S. at 150 (privilege focuses on documents which reflect process by which governmental decisions and policies are formulated).

It is not possible to resolve whether the information is deliberative by characterizing it, as plaintiffs do, as merely involving a factual request for dates and titles. Exemption 5 disputes can often be resolved by the simple test that factual material must be disclosed but advice and recommendations may be withheld. Mead Data Cent., 566 F.2d at 256. Indeed the fact/opinion distinction "offers a quick, clear, and predictable rule of decision," for most cases. But "courts must be careful not to become victims of their own semantics." Id. In some circumstances, even material that could be characterized as "factual" would so expose the deliberative process that it must be covered by the privilege. Id. We know

of no case in which a court has used the fact/opinion distinction to support disclosure of facts about the inner workings of the deliberative process itself.

The Supreme Court recognized this when it approved the fact/opinion distinction. In EPA v. Mink the Court required disclosure of "purely factual material contained in deliberative memoranda" which was "severable from its context" Mink, 410 U.S. at 88; Dudman Communications v. Department of Air Force, 815 F.2d 1565, 1568 (D.C. Cir. 1987); see also Ryan v. Dep't of Justice, 617 F.2d 781, 791 (D.C. Cir. 1980) (requiring disclosure of facts only if they "do not reveal the deliberative process and are not intertwined with the policy-making process"); accord Montrose Chem. Corp. v. Train, 491 F.2d 63, 68 (D.C. Cir. 1974) (disclosure of factual summaries made in preparing final agency opinion "would be the same as probing the decision-making process itself."). These cases illustrate that this court cannot mechanically apply the fact/opinion test. Instead, we must examine the information requested in light of the policies and goals that underlie the deliberative process privilege.

Moreover, in Grumman, the Supreme Court specifically noted that the context in which the documents were used itself "serve[d] to define the document." Grumman, 421 U.S. at 170. Thus the first step in determining whether disclosure would harm the deliberative process is to examine the context in which the materials are used.

Once the information requested is examined within the context of the FDA's predecisional approval process, it becomes clear that it must be protected. The information would disclose that proposals have been made, and that these preliminary recommendations have been accepted or rejected, at various levels of review.

The fact of forwarding is, in each instance, the functional equivalent of an intra-agency or inter-agency memorandum that states, "We recommend that a regulation on this [named] subject matter be promulgated." The fact of a failure to forward from the FDA to HHS, or from HHS to OMB is the equivalent of a memorandum from HHS to FDA that states, "We disapprove of your recommendation that a particular regulation on this [named] subject matter be promulgated."<sup>6/</sup>

In addition, the information sought would reveal the timing of the deliberative process and it would indicate the agency in which the deliberative process is at the moment going forward. Thus the information sought will generally disclose the recommended outcome of the consultative process at each stage of that process, as well as the source of any decision not to regulate.<sup>7/</sup>

That the information requested does not fully reveal the reasoning of the recommendation but merely memorializes it no more strips it of protection than would a court's sheet memorializing a panel's tentative decision by stating "Reverse;



I will write."<sup>8/</sup> See Mead Data Cent., 566 F.2d at 257 ("To exempt documents in which staff recommended certain action . . . but require disclosure of documents which only 'report' what those recommendations . . . are" is "to exalt form over substance.").

It would be impossible for courts to administer a rule of law to the effect that some but not all information about the decisional process may be disclosed without violating Exemption 5. Courts would become enmeshed in a continual process of estimating or, more accurately, guessing about the adverse effects on the decisional process of a great variety of combinations of pieces of information. That would inevitably lead courts on some occasions to undercut legitimate Exemption 5 protections. Indeed, such a procedure would not result in a rule at all. Agencies would have to pass on requests wholly impressionistically, subject to the impressionistic second-guessing of the courts. That is hardly a satisfactory or efficient way of implementing FOIA.

This court has previously noted that the deliberative process privilege embodied in Exemption 5 serves a number of purposes among which are the protection of subordinates' willingness to provide decision-makers with frank opinions and recommendations and the prevention of the premature disclosure of proposed policies before they have been finally formulated or adopted. Coastal States, 617 F.2d at 866.

Disclosure of the information requested in this case would certainly reveal policies prematurely. The FDA's very decision to regulate in a particular area often embodies a sensitive and important policy judgment, sometimes more sensitive and important than the later decisions concerning the precise extent and nature of the regulation. Decisions to allow AIDS patients to use experimental drugs, or to regulate health claims on food products come to mind as examples. The general views of the decision-maker on whether to regulate at all are often crucially important pieces of information about pre-decisional recommendations.

When, as in the instant case, subordinates are reporting to superiors, disclosure could chill discussion at a time when agency opinions are fluid and tentative. See Coastal States, 617 F.2d at 866 (exemption serves to ensure that subordinates "will feel free to provide the decisionmaker with their uninhibited recommendations without fear of later being subject to public ridicule and criticism"); accord Ryan, 617 F.2d at 789.

Moreover, disclosure would force officials to punch a public time clock. Requests for information at regular intervals would allow plaintiffs, or any other interested group, to attribute delay to FDA, HHS, or OMB. Given plaintiffs' intimate knowledge of these agencies it is likely that plaintiffs would quickly learn to identify and publicize

the office or even the person they deem responsible. It strains credulity to believe that such attention would not lead to hasty and precipitous decision-making. Decisional delay is not a fact but an opinion; what plaintiffs or others may identify as delay may be caused by unexpected scientific complications or the difficulties of weighing competing values.

Exemption 5 is manifestly not meant to isolate agency decision-makers from public opinion or to silence public voices. But the statutory framework of the APA allows agencies a space within which they may deliberate. See Sunstein Factions and Self-Interest, and the APA: Four Lessons Since 1946, 72 Va. L. Rev. 271, 282 (1986). As plaintiffs explicitly admitted in their pleadings, they seek access to the information, in part to issue themselves an invitation to agency deliberations. It is just such a fishbowl that Congress sought to avoid when it enacted Exemption 5. The purposes of Exemption 5 can be adequately served only by permitting HHS to withhold these pre-decisional recommendations.

We reverse the judgment of the district court and remand the case with instructions to enter summary judgment for HHS.

FOOTNOTES

1/ For the purposes of this opinion, we will treat as identical OMB's review of draft proposed rules and draft final rules.

2/ We need not determine the exact contents of the Regulations Log in order to decide this case. It is immaterial whether the Regulations Log contains records of communications (other than the information requested) from FDA to HHS, from HHS to OMB, or from OMB to HHS. The term Regulations Log is a convenient shorthand label for the place at HHS where the information requested by the plaintiffs is stored. Plaintiffs did not request the Regulations Log, and indeed did not know of the existence of such a log until the proceedings before the district court.

3/ The information requested is, in some respects, tantamount to a Vaughn index. *Vaughn v. Rosen*, 484 F.2d 820 (D.C. Cir. 1973), cert. denied, 415 U.S. 977 (1974). But, on the narrow facts before us, even a Vaughn index would reveal the very information concerning the agency's deliberative process which the plaintiffs seek. Where the index itself would reveal significant aspects of the deliberative process, this court has not hesitated to limit consideration of the Vaughn index to in camera inspection. See *Hayden v. U.S.A.*, 608 F.2d 1381, 1384-85 (D.C. Cir. 1979) (review of Vaughn index in camera appropriate where "the itemization and justification are themselves sensitive."), cert. denied, 446 U.S. 937 (1980). We anticipate, however, that where an index does not reveal the deliberative process it should be used. Only in rare circumstances, such as the one before us, where a Vaughn index itself reveals the preliminary results of agency decisionmaking, may it be dispensed with under Exemption 5. We perceive no "inherent conflict," Chief Judge Wald dissenting op. at 9, with our "traditional requirement of a Vaughn index," id., because normally a Vaughn index does not reveal whether a recommendation to regulate has been accepted or rejected.

4/ Counsel had argued that the information requested did not reveal that a recommendation had been made. That argument is inconsistent with many of the Stipulations of Material Fact made before the district court. Stipulation 15 states that "[d]isclosure of the fact that an HHS proposed regulation has been transmitted to OMB will also disclose the fact that HHS has recommended issuance of that proposed regulation." Joint

Appendix ("J.A.") at 70. Stipulation 11 covers communication from FDA to HHS and states that in "virtually every" instance when FDA sends its views on regulation to HHS "FDA will initially recommend taking regulatory action. . . ." Id. at 69. Such a communication between FDA and HHS is also referred to as a "recommendation" in stipulations 13 and 14. Id. at 69-70.

Plaintiffs' counsel argued that Stipulation 15 is limited by Stipulation 16 which states that HHS communicates with OMB on a wide range of subjects. Thus, disclosure would not be tantamount to an intra-agency memorandum. See J.A. at 70. We think this argument inadequate to support the conclusion sought to be drawn.

Plaintiffs did not request all communications between FDA and HHS and between HHS and OMB. Plaintiffs' counsel asks us to ignore the limited scope of plaintiffs' original request and read Stipulation 16 as evidence that disclosure of the Regulations Log will not disclose pre-decisional recommendations by FDA and HHS. Insofar as the Regulations Log contains information on subjects other than proposed regulations, that information is outside the scope of plaintiff's FOIA request and plaintiffs are not entitled to it for that reason. Insofar as the Log shows recommendations to regulate particular subjects, counsel appears to concede that plaintiffs are not entitled to that.

The exchange at oral argument was as follows:

JUDGE MIKVA: Let me get this straight -- you're conceding that you're not entitled to the information that they -- that HHS had recommended -- had approved [a] regulation.

COUNSEL: Well, maybe, as we did not ask for it -- yes.

JUDGE MIKVA: You didn't ask for it?

COUNSEL: Yes, I'm not entitled to in this case.

JUDGE MIKVA: As far as this case is concerned.

A few moments later Judge Silberman returned to the issue.

JUDGE SILBERMAN: Counsel, can I go back to one point that I thought one of the judges questioned you on, I think it was Judge Mikva. Suppose there was a flat letter of recommendation from FDA

to HHS or then over to OMB. We recommend that this regulation be issued for the following reasons. You concede that that would not be disclosable in the face of an Exemption 5 defense.

COUNSEL                    We -- Under this case we concede that we did not ask for that.

JUDGE SILBERMAN:        No, no, no. I'm not asking whether you asked for that. Did you concede as a matter of law that that's not disclosable in the event that an Exemption 5 defense is raised.

COUNSEL:                    What it is -- is that we recommend issuing a final rule for [subject matter]. I agree that that appears to be deliberative under Exemption 5.

JUDGE SILBERMAN:        Then it would seem to me what is left of the case under your theory is only the factual issue on which Judge Bork and you had some measure of disagreement as to what the significance of the stipulation is.

It thus appears that counsel said that plaintiffs did not seek information that a regulation had been proposed and so were not entitled to it. That seems odd since we understood that to be precisely what plaintiffs wanted. Be that as it may, in the body of this opinion we give our reasons for agreeing that plaintiffs may not obtain that information.

In any event, the argument that the information requested is not the equivalent of a recommendation, comes far too late to be credible. The district court judge and all members of the divided panel assumed that releasing the requested information would result in disclosing that a recommendation had been made.

The district court judge described the consequences of disclosure thus,

disclosure of the fact that an HHS proposed regulation has been transmitted to OMB will also disclose the fact that HHS has recommended issuance of that proposed regulation. Likewise, disclosure of the fact that a FDA proposal has been transmitted to HHS will also likely disclose the fact that FDA has recommended issuance of the proposed regulation.



Wolfe v. Department of Health & Human Servs., 630 F. Supp. 546, 548 (D.D.C. Cir. 1985). Later the district court noted that "plaintiffs go so far as to acknowledge that disclosure would enable them to infer that FDA made a recommendation to proceed with issuance of a proposed regulation. . . ." Id. at 549.

The panel majority also noted that the information would "usually reveal whether and when FDA proposes rulemaking and whether and when such proposals are approved by HHS and OMB." Wolfe v. Department of Health & Human Serv., 815 F.2d 1527 at 1529 (D.C. Cir. 1987), vacated and r'hg en banc granted, 815 F.2d 1527 (July 2, 1987). The dissent was even more explicit. Id. at 1534-35.

If all of these judges, at both the trial and appellate level, were laboring under a crucial factual misapprehension, we are certain that counsel would have informed the court of that long ago.

5/ For the first time on appeal, the government raised the argument that a constitutionally based executive privilege protects communications between HHS and OMB. The majority rejected this argument. See Wolfe, 815 F.2d at 1532-33. The dissent, although not reaching the issue of constitutional privilege, argued that the question deserved serious consideration. Id. at 1538-40. Before the full court, the government abandoned the argument. Thus, the constitutional privilege issue is no longer before this court.

6/ We doubt the relevance of Judge Ruth B. Ginsburg's reference to the BNA publication, Report by Legislation and Regulations Division of Internal Revenue Service's Office of Chief Counsel on Status of Regulations Projects. First, the case before us involves FDA and HHS; it does not involve IRS. The path and nature of regulatory revision and approval between IRS, Treasury and OMB may be quite different from the FDA, HHS, OMB process. See Regulatory Program of the United States Government 633 (April 1, 1987 - March 31, 1988) (exempting some IRS rules from OMB review). The fact that the IRS does not find disclosure harmful to its deliberative process does not demonstrate that HHS is wrong in resisting such disclosure as to its processes. Second, judges are bound by the facts and the record before them. We do not have a commission to search the publications of the Bureau of National Affairs or other materials to find extra-record facts, much less to use the extra-record facts as the basis for speculation of what might be true in this case.

7/ Chief Judge Wald's dissenting opinion misreads these facts, characterizing the information sought as "procedural." Chief Judge Wald dissenting op. at 9, n.5. But the very point of this case is that the information sought will disclose "substantive agency views." Id.

8/ The district court rejected any analogy to judicial decision-making since judges are not subject to the FOIA Wolfe 630 F. Supp. at 551 n.1. That is a proposition not in dispute and utterly irrelevant. Courts are not subject to the FOIA for the same reasons that Exemption 5 takes agency deliberative processes out of the FOIA. That is why courts have long looked by analogy to the needs of their own decision-making processes to assess claims of privilege based on the needs of executive decision-making. See, e.g., United States v. Nixon, 418 U.S. 683, 708 (1974) (President's expectation of "confidentiality in his conversations and correspondence" is "like the claim of confidentiality of judicial deliberations"); Carl Zeiss Stiftung v. V.E.B. Carl Zeiss, Jena, 40 F.R.D. 318, 326 (D.D.C. 1966) aff'd, sub nom. V.E.B. Carl Zeiss, Jena v. Clark, 384 F.2d 970 (D.C. Cir), cert. denied, 389 U.S. 952 (1967); see also United States v. Morgan, 313 U.S. 409, 422 (1941) (mental processes of administrator, like those of judge, may not be examined).



Sidney M. Wolfe, et al. v. Department of Health  
and Human Services, No. 86-5017

WALD, Chief Judge, with whom Circuit Judges  
ROBINSON, MIKVA, EDWARDS, and RUTH B. GINSBURG join,  
Dissenting: While I find this case a close one, I  
nonetheless agree with my dissenting colleagues and write  
separately only to underscore my view that the majority  
has erred in interpreting the facts to which it has  
applied Exemption 5 law, and that, even so, its opinion  
must be given a narrow reading, if it is not to work a  
major disruption in circuit law under FOIA.

I.

The majority opinion states that disclosure of the  
fact of communications between HHS and OMB as to a  
proposed rule is tantamount to a memo stating, "We  
recommend that a regulation on this named subject matter  
be promulgated." Maj. op. at 11. As Judge Ginsburg's  
dissent indicates, this analogy vastly overstates how  
definitive a message is actually communicated by the mere  
knowledge of the fact of such a transmittal or  
nontransmittal.

The majority opinion envisions an FDA-HHS-OMB  
relationship in which decisionmakers act in lock-step,  
giving unadorned "yes" or "no" answers to transmittals  
from below. While information that there has been a  
transmittal from FDA to HHS about a possible subject of  
regulation may indeed suggest that the FDA proposes at

that point in time to do something about a particular subject, that is all it tells. See Stipulation 11, J.A. at 69. It sheds no light on what happens later in the process; the FDA may modify or even rescind any of its tentative decisions throughout the process of HHS and OMB review "up until the time when a notice of proposed rulemaking is sent to the Federal Register for publication." Stipulation 12, J.A. at 69. Thus, the majority erroneously asserts that if no transmittal from HHS to OMB is shown, it can be surmised that HHS has disapproved of the FDA proposal. Maj. op. at 5-6. Obviously, this is not true; it might be that although HHS approved the regulation, the FDA itself thought better of it and withdrew it. HHS also may have returned the regulation to the FDA for modifications or may have simply not yet taken any action at all. Even actual transmittal from HHS to OMB shows only that some--perhaps drastically altered--version of the original FDA proposal has received HHS approval.

The same argument may be made against the majority's too-facile conclusion that if it becomes known that a transmittal has been made from HHS to OMB, but no regulation is subsequently put out for notice and comment, it is reasonable to conclude that OMB has disapproved of the regulatory proposal. Maj. op. at 6. OMB may have rejected the regulation or simply returned it for

clarification or refinement. See J.A. at 52 (Affadavit of HHS Executive Secretary David A. Rust) (information "might also show, or purport to show, that an action is being delayed by OMB when, in fact, OMB, as part of its review, requested further information from HHS about the matter"). Or OMB may have been on the brink of finally approving the proposal when the FDA itself rescinded its initial decision to act.

In sum, the information requested by the plaintiff--i.e. the date and destination of transmittals to other agencies about rules that the FDA has already revealed are under consideration--discloses neither "the recommended outcome" at each stage nor "the source of any decision not to regulate." Maj. op. at 11. The majority assumes a rigidified, and therefore predictable deliberation process that the record and the realities of government decisionmaking do not support.

## II.

But even if information regarding the date of a proposal's interagency transmittal did provide a clear signal that a particular agency had given a "thumbs up" or "thumbs down" sign on it, this alone would still not inevitably justify invocation of the deliberative process privilege.

Unlike the case posited by the majority, in which a judge writes a memorandum "Reverse, I will write," a

mere "yes" or "no" answer to a proposed regulation, about whose content nothing is initially known other than the subject matter title,<sup>1</sup> will rarely disclose anything about the substance of any agency's recommendation or reasoning. In a judicial appeal, the decision which will be reversed or upheld is a matter of public record and therefore the simple memorandum "Reverse" discloses the reviewing judge's substantive recommendation and a specific line of reasoning that she rejects.<sup>2</sup> But, in the case before us, a "yes" or "no" recommendation is informative only to the degree that the initial recommendation itself is known. In many cases, because of the generality of the proposals

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<sup>1</sup>Although the Regulatory Agenda discloses regulations under FDA consideration, nothing guarantees that when a proposal is actually made by the agency it is in conformity with those initial published summaries of the issue.

<sup>2</sup>A recent Ninth Circuit case suggests a more apt analogy. In *Standley v. Dep't. of Justice*, No. 85-2317 (9th Cir. Dec. 30, 1987) (LEXIS, Genfed library, U.S.App. file), the court rejected the claim that information identifying persons who received information about a grand jury investigation from a United States Attorney were "records of the grand jury" exempt from disclosure under the Privacy Act as records of "the courts of the United States." 5 U.S.C. § 551(1)(B). Since the information sought was not "material presented to the grand jury during its . . . investigation . . . disclosure of such a list would not breach grand jury secrecy nor expose a court record." Similarly, disclosing the fact and date of inter-agency communications would reveal neither the substance of what goes on within any agency nor any of the agencies' tentative conclusions. A truly substantive "memorandum or letter," like an actual court record, should be privileged, but a mere listing of who received such privileged information and at what time should not.

published in the FDA's Regulatory Agenda or undisclosed FDA policy shifts in the interim, the "yes" or "no" will tell the reader only that something is going forward. The degree to which anything about ongoing deliberations will be revealed will depend, in each situation, on the sum of what was known originally about the FDA's intent and what, in the context of that proposal's history, the transmittal may show additionally.

In my view, to be exempted "inter-agency . . . memoranda or letters" must disclose something meaningful about the substance of an agency's preliminary reasoning or tentative conclusions. 5 U.S.C. § 552(b)(5).<sup>3</sup> In this case, that will depend on how much information a regulation's title discloses. Thus, while a transmittal under the general heading "AIDS" would not alone disclose enough substance, a regulation entitled "Federal Funding for AIDS Education in Public Schools" might. Again, however, exemption should follow only if the transmittal itself reveals the substance of the agency's recommendation. Here, I conclude, this has not been shown.

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<sup>3</sup>Strictly construed, Exemption 5 would seem not to apply at all to a log that merely indicates receipt or transmittal of proposals. It exempts only "memoranda or letters," undoubtedly for the express purpose of limiting its privilege to documents which divulge agency reasoning and conclusions.

The burden of demonstrating that disclosure would be likely to have adverse effects on agency decisionmaking falls on the government. I believe that it is inappropriate, in the context of FOIA's overriding policy in favor of disclosure, for today's majority to shield a whole category of information based on the mere speculation that, under some circumstances, some of it might be legitimately exempt; the information sought should be examined on a case-by-case basis.

III.

The majority opinion intimates that Exemption 5 protects the "deliberative process itself." Maj. op. at 5 n.2, 7, 9-10. In making this claim, it may be confusing two analytically distinct meanings of "deliberative process." I agree that the reasoning and tentative conclusions of agency decisionmakers are privileged, although, for the reasons set out above and in the panel opinion, I disagree that the specific information requested in this case effectively reveals either agency deliberations or their fruits.

But the majority seems to go further in suggesting that the mere existence of formal FDA-HHS-OMB communications in any particular instance is itself

protected under the deliberative process privilege. That betokens a dangerous departure from past Exemption 5 law and certainly does not construe the exception as "narrowly as consistent with efficient Government operation." S. Rep. No. 813, 89th Cong., 1st Sess. 9 (1965).

The majority's footnote 3 demonstrates the danger in the amorphous claim that Exemption 5 protects the "deliberative process itself." There, the court suggests that the information requested in this case "is, in some respects tantamount to a Vaughn index." The court claims that a Vaughn index could not be required in this case, because it would "reveal the very information concerning the agency's deliberative process which the plaintiffs seek." But a Vaughn index by its very nature is designed only to identify the existence of certain documents for which privilege is claimed. There is no Exemption 5 precedent suggesting that the mere existence of communications between agencies reveals so much about agency reasoning that it may not be mentioned in a Vaughn index justifying its withholding.

The majority opinion's reliance on Hayden v. USA, 608 F.2d 1381, 1384-85 (D.C. Cir. 1979) highlights the danger of its disturbingly broad assertions in this respect. In Hayden, we found that public itemization and detailed justification for withholding information

regarding the National Security Agency's "signals intelligence operations" would compromise legitimate secrecy interests, and therefore it was appropriate for the district court to accept in camera affidavits rather than public Vaughn indices in order to determine whether the information requested was exempt under the national security exemption. See 5 U.S.C. § 552(b)(1). The existence of valid national security interests in Hayden, however, does not advance the majority opinion's apparent suggestion that FDA, HHS and OMB have some analogous secrecy interest in the timing of communications among themselves. The court in Hayden itself explained that:

In most other types of cases, a public Vaughn itemization does not compromise secrecy, because the contents of the requested documents are not thereby disclosed, and it is only substantive content which is allegedly exempt from disclosure.

Id. at 1385 (emphasis in original).<sup>4</sup>

The subject matter of deliberations on proposed rulemakings before the FDA, HHS and OMB are not secret, nor is the process by which these deliberations occur; Exemption 5 protects only the substantive content of the decisionmaking process. Premature disclosure of the

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<sup>4</sup>Of course, if a strong showing can be made that disclosure of the existence of certain documents would affect national security, then the information requested may be found exempt under Exemption 1. Hayden v. USA, 608 F.2d at 1385.



agencies' tentative rationales and preliminary conclusions (and factual materials to the extent that they inevitably reflect these predecisional views)<sup>5</sup> is the only ground for invoking Exemption 5.

The majority's conclusion that hereafter Exemption 5 will bar disclosure of the mere existence of communications between agencies prior to a formal rulemaking proposal, regardless of whether the fact that those communications exist tells us anything or not about their content, creates an inherent conflict with our traditional requirement of a Vaughn index, as a prerequisite to exemption. The resolution of that potential conflict in our circuit law is not at all clear at this point.

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<sup>5</sup>The majority cites no case in which a court has held that Exemption 5 allows the procedural workings of the interagency deliberative process to be kept secret. See Maj. op. at 9-10. All of the cases cited by the majority for its proposition that Exemption 5 protects "the deliberative process itself," involve the different situation in which factual agency memoranda implicitly disclose agency reasoning and conclusions. See Maj. op. at 10. Those cases are inapposite because the indirect disclosure of substantive agency views can be expected "to discourage candid discussion" and "thereby undermine the agency's ability to perform its function," *Dudman Communications v. Department of Air Force*, 815 F.2d 1565, 1568 (D.C. Cir. 1987), whereas the procedural fact of interagency transmittal cannot. See supra Parts I & II.

IV.

The information requested in this case is not deliberative material because it discloses nothing about the substance of agency recommendations or rationales. It does not even show a clear "yes" or "no" agency response to anything in many situations. Finally, there is no independent basis under Exemption 5 for protecting facts about the "deliberative process itself" unless such information discloses an agency's substantive views in a way that may chill candid deliberations. The majority opinion overstates the amount of information disclosed, exaggerates its likely effect on agency deliberations and confuses the appropriate scope of Exemption 5's deliberative memorandum exception as well.

I dissent.

EDWARDS, Circuit Judge, dissenting, with whom WALD, Chief Judge, and ROBINSON, MIKVA and RUTH B. GINSBURG, Circuit Judges, join: I adhere to the views expressed by the majority in the original panel opinion. See Wolfe v. Department of Health & Human Servs., 815 F.2d 1527, 1528-34 (D.C. Cir. 1987), vacated and r'hg en banc granted, 815 F.2d 1527 (July 2, 1987). I would therefore affirm the District Court's judgment in favor of the plaintiffs.

No. 86-5017, Sidney M. Wolfe, M.D. v. HHS

GINSBURG, Ruth B., Circuit Judge, with whom WALD, Chief Judge, and Circuit Judges ROBINSON, MIKVA, and EDWARDS join, dissenting: Like Judge Edwards, I would adhere to the disposition of the original panel; further, I note some respects in which the current court opinion slips from my grasp. First, the current majority opinion reports that "the FDA publishes a semi-annual Regulatory Agenda that lists all current and projected rulemaking being considered by the FDA." Court's opinion at 5. Given that revealing publication, it is not evident to me that "the information requested in this case would certainly reveal policies prematurely." See court's opinion at 13.

Second, the current majority opinion appears to envision an FDA-HHS-OMB world in which decisionmakers always say "Yes" or "No," "Approve or Disapprove," never "Modify," "Amend," "Explain."\* Might it not be the case, for example, that "[i]f

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\* Would it not be extraordinary for administrative units always to relate to each other in so fixed and definite a fashion? Compare, e.g., the report published periodically by the Bureau of National Affairs, Inc. (BNA) on "the current plans of the Internal Revenue Service and the Treasury Department (Office of Tax Policy) for the development and the publication of regulations." This BNA commercial publication, is titled Report by Legislation and Regulations Division of Internal Revenue Service's Office of Chief Counsel on Status of Regulations Projects; available to any interested person by subscription or at a law library, the publication describes the subject matter of the regulatory projects tracked, identifies by name the particular decisionmakers responsible for the most current action, and notes the reason for the transmittal of each of the listed items. Relevant to the instant case, a common explanation for a transmittal is "returned for revision."

no transmittal to OMB is shown," see court's opinion at 5-6, HHS may not have "disapproved the FDA's proposal," id. at 6, it may instead have returned the regulation to the FDA for refinement or alteration, if indeed HHS has moved at all.

"Reverse; I will write," see court's opinion at 11-12, seems to me a very different matter from the one here at issue. As it moves along administrative tracks, a proposed regulation may change shape significantly. Nothing in the FOIA request we face seeks the substance of a regulatory proposal at the first or any other administrative stage. But a lower court decision or agency adjudication has a known content; the matter is set out in a public document, displaying the tribunal's reasons. "Reverse; I will write," thus conveys concrete information to the reader, for she knows just what the district court or agency ruled and why.

In sum, I doubt that today's decision construes Exemption 5 "as narrowly as consistent with efficient Government operation," court's opinion at 8, quoting S. Rep. No. 813, 89th Cong., 1st Sess. 9 (1965); rather, the decision appears to me to stray from the legislature's will.