

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

In the Matter of)
)
CAROLINA POWER & LIGHT COMPANY)
and NORTH CAROLINA EASTERN) Docket No. 50-400 OL
MUNICIPAL POWER AGENCY)
)
(Shearon Harris Nuclear Power)
Plant))

AFFIDAVIT OF DR. THOMAS S. ELLEMAN

County of Wake)
) ss.
State of North Carolina)

Thomas S. Elleman, being duly sworn according to law, deposes and says as follows:

1. My name is Thomas S. Elleman and my business address is P.O. Box 1551, Raleigh, North Carolina 27602. I am employed by Carolina Power & Light Company ("CP&L") as Vice President and head of the Corporate Nuclear Safety & Research Department. My statement of professional qualifications and experience is set forth in "Applicants' Joint Testimony of E.E. Utley, M.A. McDuffie, Dr. Thomas S. Elleman and Harold R. Banks on Joint Intervenors' Contention I (management Capability)" dated August 9, 1984 following Tr. 2452. This statement of professional qualifications and experience remains current to this date.

2. This affidavit is made in support of Applicants' application for withholding privileged or confidential commercial information pursuant to 10 C.F.R. § 2.790(b)(1). The document in question is the "Final Report SHNPP QA/QC-Construction Inspector Review Panel," dated August 30, 1984 ("Review Panel Report"), which was submitted to the Board by Applicants' counsel by cover of a letter dated May 20, 1985.

3. In August 1983, CP&L established a QA/QC-Construction Inspector Review Panel ("Review Panel"). The purpose the Review Panel was to determine if there were QA/QC or Construction Inspector concerns related to the quality of construction at the Harris site, to ensure any concerns were identified and evaluated by the appropriate corporate department, to convey the results and recommendations to the inspectors and CP&L management, and to monitor implementation of recommendations until closed-out to Panel satisfaction.

4. As Vice-President for Corporate Nuclear Safety and Research, I was designated as Chairman of the Review Panel. Members of the Panel included representatives from the CP&L Corporate Quality Assurance Department, the Nuclear Engineering and Licensing Department, a representative from Employee Relations, representatives of the Daniel Construction Company and a representative from the Harris Corporate Nuclear Safety Unit. The Review Panel was advised by an outside consultant from the Duke Power Company.

5. Interviews were scheduled with all QA/QC and Construction Inspectors at the Shearon Harris site to determine if the inspectors had technical concerns related to the quality of construction and future operational safety of the Harris plant. Interviews were actually conducted with 298 of the 367 inspectors. Review Panel members assured each inspector that the information would be held confidential. Sixty-nine inspectors either signed waivers indicating that they had no technical concerns or simply elected not to attend the scheduled interview. The Review Panel solicited and obtained written responses to the concerns identified by the inspectors from the appropriate Harris organizations and conducted a review to ensure adequate timely resolution of all such concerns.

6. The Review Panel Report summarizes the results of the investigation, describes each of the inspector concerns and the resolution of those concerns, and evaluates for management the implications of the information obtained during the Review Panel's efforts.

7. The Review Panel Report was distributed only to a small number of senior executives in the management of CP&L and to the members of the Review Panel. The Review Panel Report was not submitted to the NRC nor was it ever intended to be submitted to the NRC as part of the application for the Harris Operating License. The Review Panel Report has been maintained confidential to the Company by the members of the Review Panel and the senior executives who received a copy.

8. The Review Panel efforts were not mandated by the NRC either in the context of the Operating Licensing Proceeding or an enforcement action. The Review Panel was not established in response to an identified problem, but rather as a precautionary measure to determine the effectiveness of the QA/QC and Construction inspection program, to determine whether the inspectors had concerns and, overall, to assess how the inspection program was being implemented at the Harris Plant construction site. The Review Panel Report provides critical, self-appraisal of the inspection program to CP&L management for possible further actions in improving the inspection program at the Harris Plant site.

9. It is entirely appropriate that the results of such a critical, self-appraisal be held confidential within the Company. If such reports were subject to public disclosure, given the litigious nature of opponents of public utilities -- especially those with nuclear construction projects -- it would significantly reduce the incentive of utility management to embark on such a critical, self-appraisal. Even if management were to determine that the benefits of such critical, self-appraisals outweigh the risk of disclosure of the information, any report produced as the result of such reviews would likely be considerably less candid in its criticism of existing practices and, therefore, less useful to management.

10. While the purpose of the Review Panel was to enhance the safety at the Harris Plant, the ability of CP&L to complete

the construction of the Harris Plant and to operate the Plant safely is certainly vital to the commercial success of the Company.

Thomas S. Elleman
Thomas S. Elleman

Subscribed and sworn to before me
this 8 day of July, 1985

Theresa D. Austin
Notary Public

My Commission Expires on _____
My Commission Expires 2-12-90

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE WASHINGTON POST COMPANY,

Plaintiff,

v.

UNITED STATES DEPARTMENT
OF JUSTICE,

Defendant,

and

ELI LILLY AND CO.,

Intervenor-Defendant.

Civil Action No. 84-3581

FILED

APR 8 1985

CLERK, U.S. DISTRICT COURT,
DISTRICT OF COLUMBIA

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF
DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Preliminary Statement

This is an action under the Freedom of Information Act ("FOIA"), 5 U.S.C. §552 (1982), as amended by Pub. L. No. 98-620, 98 Stat. 3335 (1984), in which plaintiff seeks access to a record maintained by the Civil Division of the United States Department of Justice--a report of a Special Committee of the Board of Directors of Eli Lilly and Company regarding the drug Oraflex. The declaration of James M. Kovakas, Attorney in Charge of the FOI and Privacy Acts Office of the Civil Division (hereinafter "Kovakas Declaration"), filed herewith, recounts the chronology of the administrative handling of plaintiff's FOIA request and explains the bases for the withholding of the requested record pursuant to applicable exemptions of the FOIA. The Court is also respectfully referred to the affidavit of Mr. C. Harvey Bradley,

Jr., General Counsel of Eli Lilly and Company (hereinafter "Bradley Affidavit"), filed in support of the Motion For Summary Judgment of intervenor-defendant Eli Lilly and Company, which sets forth certain details regarding the Special Committee's report.

On the basis of the declaration and affidavit and the entire record herein, and for the reasons set forth below, defendant United States Department of Justice respectfully submits that there exists no genuine issue of material fact and that defendant is entitled to judgment as a matter of law.

Factual Background

The document sought by plaintiffs in this case is a report generated by a Special Committee of the Board of Directors of Eli Lilly and Company regarding the development and marketing by Lilly of the anti-arthritic drug benoxaprofen, more commonly known as Oraflex. Kovakas Declaration, para. 10.¹ After receiving reports of side effects and deaths associated with Oraflex, Lilly withdrew it from the market in August 1982. Id.

¹ The correspondence exchanged in the course of the handling of plaintiff's FOIA request for the report is set forth in detail in the Kovakas Declaration and in defendant's Statement Of Material Facts As To Which There Is No Genuine Issue, Pursuant To Local Rule 1-9(i), filed herewith.

See also Bradley Affidavit, para. 2. Subsequently, in the face of criticisms of Lilly's development and marketing of the drug and allegations that the company may have violated Food and Drug Administration ("FDA") regulations, the Board of Directors of Lilly approved a resolution in December 1982 that established the Special Committee (hereinafter "committee"), consisting of the board's outside members, to investigate these various charges. Kovakas Declaration, para. 10; Bradley Affidavit, paras. 3-6.

The committee's report, completed on October 11, 1983, sets forth in detail the results of the committee's investigation into the foregoing matters, its analysis of all aspects of Lilly's handling of the drug, and its recommendations in this regard. Kovakas Declaration, para. 10; Bradley Affidavit, paras. 4 and 8. The report--which extends over 118 pages plus eleven appendices totaling 196 pages, was and continues to be treated by Lilly as a highly confidential, internal study setting forth in detail the committee's candid analysis, conclusions and recommendations regarding the marketing of Oraflex. Kovakas Declaration, para. 10; Bradley Affidavit, paras. 8-9.²

² It is not possible to give any more detailed description of the report on the public record because of the prohibition of Rule 6(e) of the Federal Rules of Criminal Procedure. See infra pp. 5-12. Compare Murphy v. FBI, 490 F. Supp. 1138, 1141 & nn.3-4 (D.D.C. 1980), vacated as moot, No. 80-1612 (D.C. Cir. 1980).

The Department of Justice obtained a copy of the report on October 20, 1983, in the course of an investigation by the Civil Division's Office of Consumer Litigation into whether Lilly may have violated federal criminal laws by failing to report to the FDA certain adverse reactions associated with Oraflex. Kovakas Declaration, para. 11; Bradley Affidavit, para. 10. The report was requested by the Department of Justice and was provided voluntarily by Lilly with the express, written understanding that the Department of Justice would treat the document as confidential and that it would be disclosed only to persons employed by the Justice Department who needed access to it in the course of the Department's investigation. Kovakas Declaration, para. 11; Bradley Affidavit, para. 10 and Attachment 1.

In March 1984, a federal grand jury empaneled in the Southern District of Indiana continued the investigation into the possible violations of federal law by Lilly. Kovakas Declaration, para. 11. The report was examined by the grand jury and used by it in examining witnesses and subsequently was specifically subpoenaed, along with other relevant documents, by the grand jury in September 1984. Id.; Bradley Affidavit, para. 11. The grand jury is still convened at this time. Kovakas Declaration, para. 11.

Procedural Background

Plaintiff filed its Complaint on November 26, 1984; defendant filed its Answer on December 26, 1984. Lilly moved to

intervene as a defendant on December 28, 1984, and its motion was granted by Order of this Court dated January 15, 1985. A status hearing was held on February 15, 1985, to establish a briefing schedule. By its Order of February 19, 1985, this Court directed defendants to file their motions for summary judgment by April 8, 1985, with plaintiff's opposition thereto to be filed by May 8, 1985, and any reply briefs to be filed by May 24, 1985.

Argument

NO INFORMATION HAS BEEN IMPROPERLY
WITHHELD FROM PLAINTIFF

Defendant has withheld the requested report on the basis of three FOIA exemptions: Exemption 3, because it is material prohibited from disclosure by Rule 6(e) of the Federal Rules of Criminal Procedure; Exemption 4, because it is privileged commercial information obtained by the government from an outside party; and Exemption 7(B), because it is an investigatory record the release of which would deprive a person of a right to a fair trial. As will be demonstrated below, the invocation of each exemption is entirely justified under the law.

I. Pursuant To 5 U.S.C. §552(b)(3), Defendant Has
Properly Withheld Information Which Is Specifically
Prohibited From Disclosure By Statute

Title 5, United States Code, Section 552(b)(3), exempts from mandatory disclosure matters that are "specifically exempted from disclosure by statute . . . provided that such statute (A) requires that the matters be withheld from the public in such a

manner as to leave no discretion on the issue, or (B) establishes particular criteria for withholding or refers to particular types of matters to be withheld." 5 U.S.C. §552(b)(3). In the instant case, defendant has invoked Exemption 3, in conjunction with Rule 6(e) of the Federal Rules of Criminal Procedure, to protect the special committee's report which was subpoenaed and examined by a federal grand jury and was used by the grand jury in examining witnesses before it. Kovakas Declaration, paras. 5, 11, 12 and 13; Bradley Affidavit, para. 11.

Rule 6(e) states, in pertinent part:

A grand juror, an interpreter, a stenographer, an operator of a recording device, a typist who transcribes recorded testimony, an attorney for the government, or any person to whom disclosure is made under paragraph (3)(A)(ii) of this subdivision [government personnel assisting the attorney for the government] shall not disclose matters occurring before the grand jury

Fed. R. Crim. P. 6(e)(2) (emphasis added). As this Court has previously recognized, it is well settled that "Rule 6(e) is a withholding statute for the purposes of Exemption 3." Iglesias v. CIA, 525 F. Supp. 547, 555 (D.D.C. 1981); see also, e.g., Fund for Constitutional Government v. National Archives & Records Service, 656 F.2d 856, 867-68 (D.C. Cir. 1981); Ferri v. United States Department of Justice, 573 F. Supp. 852, 856 (W.D. Pa. 1983). As such, Rule 6(e), in conjunction with Exemption 3, has been held to prohibit the disclosure of materials that would reveal the strategy or direction of a grand jury investigation,

the nature of the evidence produced before a grand jury, or any other detail of a grand jury's deliberations. See Fund for Constitutional Government v. National Archives & Records Service, 656 F.2d at 869. Disclosure of the report at issue here would indisputably reveal "the strategy or direction of the [grand jury] investigation," Fund for Constitutional Government v. National Archives & Records Service, 656 F.2d at 869, and is properly barred through Exemption 3 of the FOIA.³

The kinds of materials that have been consistently found to be within the prohibitive scope of Rule 6(e) as "matters occurring before the grand jury"--because they would reveal the strategy or direction of a grand jury's investigation--include documents subpoenaed as exhibits and even potential documentary exhibits. See, e.g., Fund for Constitutional Government v. National Archives & Records Service, 656 F.2d at 869; Fiumara v. Higgins, 572 F. Supp. 1093, 1104-05 (D.N.H. 1983) (protecting

³ While it is the case that the grand jury is still convened in connection with its investigation of Lilly, see Kovakas Declaration at para. 11, defendant notes that the requirements of Rule 6(e) would remain applicable even if the grand jury had concluded its activities. See Douglas Oil Co. v. Petrol Stops Northwest, 441 U.S. 211, 222 (1979). Indeed, "the chronological remoteness of grand jury proceedings bears no relevance to [a] FOIA inquiry. The general rule admits to no exception for old grand jury proceedings and whatever relevance that factor might have for a party seeking disclosure under Rule 6(e) (3) (C) (i) simply has no applicability [under the FOIA]." Fund for Constitutional Gov't v. Nat'l Archives & Records Service, 656 F.2d at 869 n.32.

documents subpoenaed by the grand jury but not presented to it); Iglesias v. CIA, 525 F. Supp. at 556 (protecting documents "subpoenaed and/or presented to the grand jury"); cf. In re Grand Jury Matter, 697 F.2d 511, 512-13 (3d Cir. 1983) (auditors' analyses of target's books and records, prepared to assist grand jury, protected from disclosure by Rule 6(e) even though results of analyses, and not analyses themselves, were presented to grand jury). In the instant case, as the report was both subpoenaed by and presented to the grand jury, and was even specifically used in examining witnesses, its release would surely reveal specific matters considered by, of interest to and occurring before the grand jury.

To be sure, courts have recognized that in certain circumstances documents sought for their "intrinsic value" may not necessarily reveal "matters occurring before the grand jury." See United States v. Interstate Dress Carriers, Inc., 280 F.2d 52, 54 (2d Cir. 1960); see also In re Grand Jury Investigation, 630 F.2d 996, 1000-01 (3d Cir. 1980); SEC v. Dresser Industries, Inc., 628 F.2d 1368, 1383 (D.C. Cir. 1980); United States v. Stanford, 589 F.2d 285, 291 (7th Cir. 1978). Such cases, however, have involved circumstances clearly not present in the instant case.

The Court of Appeals for the Second Circuit considered in United States v. Interstate Dress Carriers, Inc., 280 F.2d at 52, the question of whether Rule 6(e) prohibited the Interstate

Commerce Commission, authorized by statute to examine the financial records of persons subject to its regulation, from obtaining such financial records being held by the Department of Justice pursuant to a federal grand jury subpoena. When the subject of the ICC's investigation opposed the Justice Department's application to the court for leave to permit the ICC to examine and copy the subpoenaed records, the Second Circuit held that

[I]t is not the purpose of the Rule to foreclose from all future revelation to proper authorities the same information or documents which were presented to the grand jury. Thus, when testimony or data is sought for its own sake--for its intrinsic value in the furtherance of a lawful investigation--rather than to learn what took place before the grand jury, it is not a valid defense to disclosure that the same information was revealed to a grand jury or that the same documents had been, or were presently being, examined by a grand jury.

Id. at 54. That reasoning has been adopted by other courts faced with similar circumstances, i.e., a person's resistance to disclosure of records generated by that person when such records, previously provided to a grand jury, were sought to be obtained by a government entity with an independent need to examine the records. See, e.g., In re Special March 1981 Grand Jury, No. 84-1187, slip op. at 4-7 (7th Cir. Jan. 23, 1985) (Illinois Department of Public Aid not prohibited from obtaining subpoenaed business records required by federal and state law to be maintained by party resisting disclosure) (copy attached hereto

as "Attachment A"); In re Grand Jury Investigation, 630 F.2d at 1001 (once state Commission of Investigation "demonstrated a legitimate purpose flowing from its investigatory authority for subpoenaing the [company's] records," disclosure should not have been denied simply because records had been reviewed by grand jury in unrelated matter); SEC v. Dresser Industries, Inc., 628 F.2d at 1382-83 (Securities and Exchange Commission not prohibited from subpoenaing directly from Dresser Industries, without mention of grand jury, documents created for independent corporate purpose and which had previously been subpoenaed by grand jury); In re Grand Jury Investigation of Ven-Fuel, 441 F. Supp. 1299, 1303-04 (M.D. Fla. 1977) (congressional subcommittee not prohibited from obtaining subpoenaed documents needed by subcommittee for its authorized inquiry). Cf. Iglesias v. CIA, 525 F. Supp. at 556 (holding materials presented to grand jury protected by Rule 6(e) from disclosure under FOIA and pointing out that "plaintiffs are not 'proper authorities' seeking the information in the furtherance of a lawful investigation").

In such cases, that the records had been "created for an independent corporate purpose," SEC v. Dresser Industries, Inc., 628 F.2d at 1383, and were being sought for their "intrinsic value," United States v. Interstate Dress Carriers, Inc., 280 F.2d at 54, were hardly dispositive of those courts' conclusions that Rule 6(e) did not prohibit their release. Rather, the critical factor in those cases was the context in which the

records were sought to be disclosed. As the Court of Appeals for this Circuit explained in Fund for Constitutional Government v. National Archives & Records Service, 656 F.2d at 870, a case in which the appellant was seeking access under the FOIA to records generated by the Watergate Special Prosecution Force:

This is not an instance where documentary information coincidentally before the grand jury would be revealed in such a manner that its revelation would not elucidate the inner workings of the grand jury. See SEC v. Dresser Industries, Inc., 202 U.S.App.D.C. at 360, 628 F.2d at 1383; United States v. Stanford, 589 F.2d 285, 291 (7th Cir. 1978), cert. denied, 440 U.S. 983, 99 S.Ct. 1794, 60 L.Ed.2d 244 (1979); United States v. Interstate Dress Carriers, 280 F.2d 52, 54 (2d Cir. 1960). In this case, appellant seeks information from an entity whose possession of that information is directly linked to its role relating to the grand jury investigations. The relevant inquiry is not whether the party seeking the information has an interest other than in its role in a grand jury investigation but whether revelation in the particular context would in fact reveal what was before the grand jury. See Murphy v. FBI, 490 F. Supp. 1138, 1141 (D.D.C. 198[0]), vacated as moot, No. 80-518 (D.D.C. Jan. 8, 1981).

(emphasis added). See also In re Special February 1975 Grand Jury, 662 F.2d 1232, 1243-44 (7th Cir. 1981) (subpoenaed documents created for purposes other than grand jury investigation cannot automatically be considered outside protection of Rule 6(e): "The policies favoring grand jury secrecy in most instances must still be given due weight."), aff'd sub nom. United States v. Baggot, 103 S. Ct. 3164 (1983); In re Grand Jury Investigation, 630 F.2d at 1001 (court should

evaluate whether subpoenaed business records would reveal secrecy of grand jury proceedings); Iglesias v. CIA, 525 F. Supp. at 556 (rejecting FOIA plaintiff's argument that Interstate Dress Carriers rationale justified disclosure of documents "sought for [their] intrinsic value and not to learn of what transpired before the grand jury").⁴

In the instant case, release of the document sought by plaintiff would certainly reveal matters that were of interest to--and which were specifically considered by--the federal grand jury in the Southern District of Indiana, thereby disclosing "matters occurring before the grand jury." The report is therefore prohibited from disclosure by Fed. R. Crim. P. 6(e) and is properly withheld pursuant to FOIA Exemption 3.

II. Pursuant To 5 U.S.C. §552(b)(4), Defendant Has
Properly Withheld Privileged Commercial Information

Title 5, United States Code, Section 552(b)(4), exempts from mandatory release "trade secrets and commercial or financial

⁴ Defendant notes that the report in the instant case is not a document generated for recordkeeping or accounting purposes, but rather is a detailed evaluation and analysis of some of the same issues obviously before the grand jury. Compare Murphy v. FBI, 490 F. Supp. at 1141 (release of videotape recordings of plaintiff's activities that were examined by grand jury "would reveal the nature, scope, and direction of the grand jury investigation"), with In re Special March 1981 Grand Jury, slip op. at 6-7 (medical or financial records consisting of prescription receipts or ledger sheets "are not narratives, but records of transactions; they contain no defamatory or embarrassing material").

information obtained from a person and privileged or confidential." 5 U.S.C. §552(b)(4). Accordingly, Exemption 4 protects from disclosure information which is (a) commercial or financial and (b) obtained from a person and (c) privileged or confidential. See, e.g., Gulf & Western Industries, Inc. v. United States, 615 F.2d 527, 529 (D.C. Cir. 1979); Consumers Union of United States, Inc. v. VA, 301 F. Supp 796, 802 (S.D.N.Y. 1969), appeal dismissed as moot, 436 F.2d 1363 (2d Cir. 1971). The report at issue in this case clearly satisfies all three requisites of Exemption 4. See Kovakas Declaration, para. 14.

First, the report is certainly "commercial" in character. For purposes of Exemption 4, "commercial" has been interpreted as meaning "pertaining or relating to or dealing with commerce." American Airlines, Inc. v. National Mediation Board, 588 F.2d 863, 870 (2d Cir. 1978) (Exemption 4 protects from disclosure the number of authorization cards submitted in confidence by union to Board). See also Miller, Anderson, Nash, Yerke & Wiener v. Department of Energy, 499 F. Supp. 767, 770 (D. Or. 1980) (legal memorandum prepared by commercial entity's lawyer qualifies as commercial information because it "concerns a transaction integrally related to commerce"); Brockway v. Department of the Air Force, 370 F. Supp. 738, 740 (W.D. Iowa 1974) (report generated by commercial enterprise regarding findings and opinions as to causes of accident qualifies under exemption

because such reports "must generally be considered commercial information"), rev'd on other grounds, 518 F.2d 1184 (8th Cir. 1975). Indeed, the Court of Appeals for this Circuit recently rejected the argument that the commercial information provision of Exemption 4 be confined to "records that actually reveal basic commercial operations" and instead found that manufacturers' documentation of health and safety considerations of their product was commercial because the manufacturers had "a commercial interest" in the information. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1290 (D.C. Cir. 1983) (citing Washington Research Project, Inc. v. HEW, 504 F.2d 238, 244 n.6 (D.C. Cir. 1974) (recognizing that "an individual . . . engaged in profit-oriented research . . . could conceivably be shown to have a commercial or trade interest in his research design"))).

The report at issue was generated by a major pharmaceutical manufacturer and deals exclusively with the production and marketing of a particular drug by that commercial entity. See Kovakas Declaration, para. 14; Bradley Affidavit, para. 3. As such, it unquestionably concerns matters and transactions in which Lilly has "a commercial interest," see Public Citizen Health Research Group v. FDA, 704 F.2d at 1290, and therefore qualifies as "commercial information" within the meaning of Exemption 4. See also Brockway v. Department of the Air Force, 370 F. Supp. at 740 (private defense contractor "is

unquestionably a commercial enterprise and the reports it generates must generally be considered commercial information").

Second, the requirement that the report have been "obtained from a person" is also readily met in this case. The term "person" has been held to refer to a wide range of entities, including, of course, corporations. See, e.g., Comstock International v. Export-Import Bank of the United States, 464 F. Supp. 804, 806 (D.D.C. 1979). The report was obtained by the Department of Justice directly from Lilly. Kovakas Declaration, para. 11; Bradley Affidavit, para. 10.

Finally, the report qualifies as "privileged" commercial information protected from disclosure under Exemption 4.

Although most of the cases construing this exemption have focused on the "confidential" rather than the "privileged" aspect of the exemption, it is clear that the two are not to be considered synonymous. See Washington Post Co. v. HHS, 690 F.2d 252, 267 n.50 (D.C. Cir. 1982).⁵ "Thus, information which is not confidential under the test in National Parks & Conservation

⁵ See also Miller, Anderson, Nash, Yerke & Wiener v. Dep't of Energy, 499 F. Supp. at 771-72 (document found to be confidential for purposes of Exemption 4 found to be additionally protected under that exemption by virtue of attorney-client privilege); Indian Law Resource Center v. Dep't of the Interior, 477 F. Supp. 144, 148-49 (D.D.C. 1979) (confidential information protected under Exemption 4 also held to be Exemption 4 privileged information on basis of attorney work-product privilege).

Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974), may nevertheless be privileged and exempt from disclosure under the FOIA." Washington Post Co. v. HHS, Civil No. 80-1681, slip op. at 7 (D.D.C. Feb. 8, 1985) (copy attached hereto as "Attachment B"). In the latter case, this Court considered the applicability of Exemption 4 to listings of financial interests submitted to the Department of Health and Human Services by members of advisory boards and committees of the National Cancer Institute. See slip op. at 1. This Court found that such information-- information which previously had been held by the Court of Appeals for this Circuit to be privileged from civil discovery under Fed. R. Civ. P. 26(b)(1), see Association for Women in Science v. Califano, 566 F.2d 339, 346 (D.C. Cir. 1977)--was protected from disclosure under FOIA Exemption 4 as "privileged" financial information by virtue of the "confidential report" privilege. See id. at 5.

In reaching its conclusion, this Court in Washington Post Co. v. HHS relied upon the Supreme Court's recent decision in United States v. Weber Aircraft Corp., 104 S. Ct. 1488 (1984). The Court in Weber Aircraft held that FOIA Exemption 5, 5 U.S.C. §552(b)(5),⁶ exempts documents normally privileged in the civil

⁶ Exemption 5 protects from disclosure "inter-agency or intra-agency memorandums or letters which would not be available (footnote cont'd)

discovery context, regardless of whether the claimed privilege is one that was explicitly mentioned in the legislative history of Exemption 5. 104 S. Ct. at 1492-93.⁷ In so holding, the Court observed:

[R]espondents' contention that they can obtain through the FOIA material that is normally privileged would create an anomaly in that the FOIA could be used to supplement civil discovery. We have consistently rejected such a construction of the FOIA. We do not think that Congress could have intended that the weighty policies underlying discovery privileges could be so easily circumvented.

Id. at 1494 (citations omitted). Following this reasoning, this Court in Washington Post Co. v. HHS held that the confidential report privilege, which "is based on the governmental interest in protecting the flow of information concerning the subject of the report in question" and which had been held to protect from civil discovery the same information sought in the FOIA action, was incorporated into FOIA Exemption 4 and it thus protected from disclosure the requested financial information. Washington Post Co. v. HHS, slip op. at 8.

(footnote cont'd)

by law to a party other than an agency in litigation with the agency."

⁷ Of course, Congress expressly incorporated evidentiary privileges into Exemption 4 as well as into Exemption 5. See Washington Post Co. v. HHS, 690 F.2d at 258.

In the instant action, the report of the special committee has specifically been held privileged from civil discovery under the "self-evaluative" privilege by three state courts in civil suits brought against Lilly in connection with the drug Oraflex. See Kovakas Declaration, para. 14. Invocation of the self-evaluative privilege in this case thus not only comports with "the plain language" of Exemption 4, see 104 S. Ct. at 1492, and with the legislative intent to protect commercial information provided to the government in confidence, but any other result would be in direct conflict with the Supreme Court's frequently and emphatically stated policy that the FOIA not be allowed to circumvent the protection extended to information in civil discovery. Id. at 1494; see also Baldrige v. Shapiro, 455 U.S. 345, 360 (1982); NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 143 n.10 (1975).⁸

⁸ Indeed, FOIA exemption protection is essential in this case to ensure that the discovery circumvention proscribed by the Supreme Court does not occur. Although the plaintiff in this case is not in litigation with Lilly, the release of the report to one FOIA requester would mean that those parties who are in fact in litigation with Lilly, and who have been denied discovery of the document thus far, would also be able to obtain the report under the FOIA. See, e.g., State of North Dakota ex rel. Olson v. Andrus, 581 F.2d 177, 180-182 (8th Cir. 1978) (holding that release of documents in civil litigation precludes government from asserting that documents are exempt from disclosure under FOIA).

The self-evaluative privilege (also known as the self-critical analysis privilege) has been described as "avoid[ing] discouraging an organization from undertaking a critical self-evaluation of its practices and procedures when there are strong policy reasons for ensuring that such an evaluation takes place." In re Application of the New York Times Co., Civil No. M8-85, slip op. at 3 (S.D.N.Y. Oct. 9, 1984) (copy attached hereto as "Attachment C"). See generally Note, The Privilege of Self-Critical Analysis, 96 Harv. L. Rev. 1083 (1983). The privilege is generally acknowledged, see, e.g., FTC v. TRW, Inc., 628 F.2d 207, 210 (D.C. Cir. 1980), to have been formulated first by this Court fifteen years ago in the case of Bredice v. Doctor's Hospital, 50 F.R.D. 249 (D.D.C. 1970), aff'd mem., 479 F.2d 920 (D.C. Cir. 1973). Bredice was a medical malpractice suit in which the plaintiff sought to discover the minutes and reports of the hospital staff committee dealing with the death in question. See 50 F.R.D. at 249. In denying the requested discovery, this Court held that such internal reports were entitled to a qualified privilege. See id. at 251. This Court noted that the "[c]andid and conscientious evaluation of clinical practices is a sine qua non of adequate hospital care," id. at 250, and that the purpose of the staff meetings was "the improvement, through self-analysis, of the efficiency of medical procedures and techniques." Id. In light of its finding that confidentiality was essential to such a procedure, this Court

held that there was "an overwhelming public interest in having those staff meetings held on a confidential basis so that the flow of ideas and advice can continue unimpeded." Id. at 251.

The principles enunciated in Bredice were thereafter considered and applied by both federal and state courts in a variety of factual situations. See, e.g., Keyes v. Lenoir Rhyne College, 552 F.2d 579, 581 (4th Cir. 1977) (discovery denied of confidential faculty evaluation records); Gillman v. United States, 53 F.R.D. 316, 318 (S.D.N.Y. 1971) (hospital board of inquiry's findings as to discipline and future procedures held entitled to qualified privilege); Banks v. Lockheed-Georgia Co., 53 F.R.D. 283, 285 (N.D. Ga. 1971) (company's affirmative action plan held not discoverable as its release would "discourage frank self-criticism and evaluation"); Oviatt v. Archbishop Bergan Mercy Hospital, 191 Neb. 224, 227, 214 N.W.2d 490, 492 (1974) (proceedings and records of medical staff committee held privileged). Although even a few years after the decision in Bredice the privilege was described as one that "at the most remains largely undefined and has not generally been recognized," Lloyd v. Cessna Aircraft Co., 74 F.R.D. 518, 522 (E.D. Tenn. 1977),⁹ in fact the privilege in the intervening years has been

⁹ See also FTC v. TRW, Inc., 628 F.2d at 210 (quoting Lloyd v. Cessna Aircraft Co., supra) (dicta).

recognized in a growing number of cases, including the three separate civil suits in which the privilege recently has been applied to the very document at issue in this case.¹⁰

The self-evaluative privilege has been addressed most often in two categories of cases: those concerning affirmative action plans evaluating a company's compliance with employment anti-discrimination laws and those concerning other kinds of internal, voluntary reports regarding evaluations of and recommendations for practices and procedures, typically in the health field. The former line of cases descend from Banks v. Lockheed-Georgia Co., 53 F.R.D. 283, and have recognized that "a qualified privilege of 'self-examination' exists to permit free discussion looking toward compliance with law." Rosario v. New York Times Co., 84 F.R.D. 626, 631 (S.D.N.Y. 1979). See also, e.g., Mazzella v. RCA Global Communications, Inc., Civil No. 83-3716, slip op. at 8 (S.D.N.Y. Mar. 28, 1984) (privilege recognized for self-evaluative portions of affirmative action plans) (copy attached hereto as "Attachment D"); Roberts v. National Detroit Corp., 87 F.R.D. 30, 32-33 (E.D. Mich. 1980) (privilege applied for affirmative action plans and reports of

¹⁰ See infra pp. 25-26. It is not entirely clear from the many cases construing the self-evaluative privilege to what extent the privilege covers factual materials. The Court need not reach that issue in this case, however, inasmuch as the entire report is prohibited from disclosure under Fed. R. Crim. P. 6(e).

investigation "to the extent that they include 'self-critical analysis'"); O'Connor v. Chrysler Corp., 86 F.R.D. 211, 218 (D. Mass. 1980) (privilege held to protect self-evaluative statements in affirmative action plan); McClain v. Mack Trucks, Inc., 85 F.R.D. 53, 58 (E.D. Pa. 1979) (privilege for entire affirmative action plan); Webb v. Westinghouse Electric Corp., 81 F.R.D. 431, 434 (E.D. Pa. 1978) (recognizing privilege for subjective evaluative materials).¹¹

As in many of the cases dealing with affirmative action plans, the courts that have recognized the privilege with regard to other types of internal reports have emphasized the public's interest in confidentiality in order to promote candid and critical evaluation with a view towards self-improvement, particularly in the area of public health and safety. See, e.g., Davidson v. Light, 79 F.R.D. 137, 139 (D. Colo. 1978) (privilege recognized in Bredice held "grounded on a perceived strong public interest in promoting health care improvements"); Dade County

¹¹ But see Emerson Electric Co. v. Schlesinger, 609 F.2d 898, 907 (8th Cir. 1979) (privilege recognized, but found not applicable to affirmative action plans submitted to government for purpose of complying with federal law and not prepared solely for internal use, "unlike the situation in Bredice"); Reynolds Metals Co. v. Rumsfeld, 564 F.2d 663, 667 (4th Cir. 1977) (same); compare Witten v. A.H. Smith & Co., 100 F.R.D. 446, 452 (D. Md. 1984) (privilege not recognized for affirmative action plans as they are mandatory), with Resnick v. American Dental Association, 95 F.R.D. 372, 375 (N.D. Ill. 1982) (study on employment practices not privileged because not mandatory).

Medical Association v. Hlis, 372 So.2d 117, 119-120 (Fla.App. 1979) (holding records of medical association's ethics committee privileged because "improving the quality of medical practice in our community through self-regulation . . . should be encouraged"). Recently, for example, a New Jersey Superior Court addressed the application of the self-evaluation privilege to the report of a company's internal investigation of an accident, an investigation conducted to determine whether certain procedures should be changed to avoid future injuries. Wylie v. Mills, 195 N.J. Super. 332, 478 A.2d 1273 (1984). The court identified the following factors to be considered in determining whether the privilege should prevent disclosure of material in discovery: (1) the information must be "criticisms or evaluations or the product of an evaluation or critique conducted by the party opposing the production request"; (2) the "public need for confidentiality" of this analysis must be such that "the unfettered internal availability of such information should be encouraged as a matter of public policy"; (3) the analysis or evaluation "must be of the character which would result in the termination of such self-evaluative inquiries or critical input in future situations if this information is subject to disclosure." 195 N.J. Super. at 339, 478 F.2d at 1277. The court went on to state:

In short, confidentiality and the "public need for confidentiality" are the sine qua non of effective internal self-critical analysis

since such confidentiality will encourage open and frank criticism. Such criticism is essential in recognizing the cause of past problems and the elimination of future problems. If the public policy of safety improvements in practice and procedure is to be encouraged, the "public need for disclosure" for the individual must give way. This is especially so if such improvements are to continue and develop.

Valuable criticism can neither be sought nor obtained nor generated in the shadow of potential or even possible public disclosure. It is not realistic to expect candid expressions of opinion or suggestions as to future policy or procedures in an air of apprehension that such statements may well be used against one's colleague or employer in a subsequent litigated matter.

The purpose of an investigation intended to seek criticism, opinion or suggestion and form the basis of criticism of then existing policy or procedure is self-improvement. The value of the investigation is questionable if the input is not reliable.

Id. at 339-40, 478 A.2d at 1277 (emphasis added). The court found that the evaluative portions of the report of investigation at issue should be withheld, concluding that "[u]nless confidential safety investigations are encouraged, safety improvements in the workplace and in general will be stifled." Id. at 340, 478 A.2d at 1277.

The instant case presents almost identical considerations and likewise mandates the same protection accorded in Wylie. The special committee's report was the result of a purely internal investigation designed to determine, inter alia, whether the company's policies and procedures were inadequate with respect to

the development and marketing of the drug Oraflex and what changes, if any, should be undertaken to correct such inadequacies with regard to the development and marketing of future drugs. See Kovakas Declaration, para. 14; Bradley Affidavit, paras. 3 and 8. Such an investigation and analysis, with its obvious implications for the public marketing and safety of future pharmaceutical products, presents a clear case in which the public interest in confidentiality--in order to promote self-improvement and thus the safety of the public--is of utmost importance. As was stated by one of the courts ruling recently on a claim of privilege for this very document:

Eli Lilly and Company is a major supplier of prescription medicines. The public interest in health and medical safety will be served by protecting the efforts of this pharmaceutical manufacturer to perform internal self-critical assessments of its performance and that of its employees. The Report at issue is a self-critical investigation and assessment of the conduct of Lilly. It was designed to determine among other things, whether Lilly has claims against any person and whether it was in the best interest of Lilly and its shareholders to prosecute such claims by litigation or otherwise. The Report addresses the Special Committee's opinions, conclusions and recommendations on those subjects. To allow this self-evaluation to be used by litigation adversaries would have an undue chilling effect on a corporation's ability to evaluate its performance and the actions of its employees where such evaluation is in the public interest.

McCracken v. Eli Lilly & Co., Civil No. 34,463 (Johnson County Cir. Ct., Indiana, Order filed March 19, 1984) (emphasis added) (copy attached hereto as "Attachment E"). See also Parrish v.

Eli Lilly & Co., Civil No. 82-237944CZ (Wayne County Cir. Ct., Michigan, Order of Dec. 14, 1984) (oral order issued from bench denying discovery of report) (copy of transcript attached hereto as "Attachment F"); Wheeler v. Eli Lilly & Co., Civil No. A215848 (8th Jud. D. Ct., Clark County, Nevada, Order filed March 19, 1984) (denying discovery of report without opinion) (copy attached hereto as "Attachment G").

The recognition under FOIA Exemption 4 of the self-evaluative privilege as it applies to the instant report comports clearly with the intent of the exemption, by protecting information provided in confidence to the government that "would customarily not be released to the public by the person from whom it was obtained." S. Rep. No. 813, 89th Cong., 1st Sess. 9 (1965). In addition, protection under Exemption 4 is consonant with the same policies articulated by the Supreme Court in United States v. Weber Aircraft Corp., in connection with the underlying basis for the privilege that it held was incorporated in FOIA Exemption 5. In Weber Aircraft the privilege at issue was one that had been held to be applicable to confidential statements made to air crash safety investigators in Machin v. Zuckert, 316 F.2d 336 (D.C. Cir.), cert. denied, 375 U.S. 896 (1963). The Supreme Court in Weber Aircraft observed:

[R]ecognition of the Machin privilege would not be inconsistent with the fundamental goals of the FOIA since it does not necessarily reduce the amount of information available to the public. The privilege is recognized because the

Government would not be able to obtain the information but for its assurance of confidentiality. Thus, much if not all of the information covered by the Machin privilege would not find its way into the public realm even if we refused to recognize the privilege, since under those circumstances the information would not be obtained by the Government in the first place.

104 S. Ct. at 1495 n.23.

Indeed, the concern for confidentiality in order to promote the free flow of information comes into play in more than one way in the instant situation. The self-evaluation process would be severely hampered if those persons from whom the evaluators sought information, as well as the evaluators themselves, were faced with the prospect of having their candid work exposed in detail to the public. Kovakas Declaration, para. 14. See Wylie v. Mills, 195 N.J. Super. at 340, 478 A.2d at 1277 ("It is not realistic to expect candid expressions of opinion or suggestions as to future policy or procedures in an air of apprehension that such statements may well be used against one's colleague or employer in a subsequent litigated matter."). Secondly, the results of any self-evaluative process--particularly where it is a voluntary one, as here--will not readily be provided to the government if the self-evaluator expects that information it would not otherwise be required to release to the public will become disclosable once in the hands of the government. See Kovakas Declaration, para. 14; Bradley Affidavit, para. 10 ("Lilly would not have submitted the Report without a promise of

confidentiality."). Cf. Washington Post Co. v. HHS, slip op. at 8 (protecting information pursuant to the confidential report privilege, which "is based on the governmental interest in protecting the flow of information concerning the subject of the report in question"). As the Supreme Court cautioned in Weber Aircraft, the absence of privilege or FOIA protection would ultimately lead to the information "not be[ing] obtained by the Government in the first place." 104 S. Ct. 1495 n.23.

For all of the foregoing reasons, defendant respectfully submits that the report at issue is properly withheld from release pursuant to Exemption 4 as privileged commercial information.

III. Pursuant To 5 U.S.C. §552(b)(7)(B), Defendant Has Properly Withheld Information The Release Of Which Would Deprive A Person Of A Fair Trial

Title 5, United States Code, Section 552(b)(7)(B), exempts from mandatory disclosure investigatory records compiled for law enforcement purposes, the release of which would "deprive a person of a right to a fair trial or an impartial adjudication." 5 U.S.C. §552(b)(7)(B). The report at issue in this case clearly meets the threshold requirement, "investigatory records compiled for law enforcement purposes," 5 U.S.C. §552(b)(7), as it and other records were compiled by the Civil Division's Office of Consumer Litigation in the course of its investigation into whether Lilly may have violated certain federal laws. Kovakas

Declaration, para. 15. See Pratt v. Webster, 673 F.2d 408, 421 (D.C. Cir. 1982).

Exemption 7(B) has been the subject of virtually no judicial interpretation and no specific explanation of the exemption is contained in its legislative history. See A.G.'s 1974 FOI Amdts. Mem. at 8 (reprinted in Freedom of Information Act and Amendments of 1974 (P.L. 93-502), Source Book (1975), at 507). It would, however, "normally be thought to apply to judicial proceedings, both civil and criminal, in Federal and State courts." Id. The Attorney General's memorandum also explains:

Clause (B) would typically be applicable when requested material would cause prejudicial publicity in advance of a criminal trial, or a civil case tried to a jury. The provision is obviously aimed at more than just inflammation of jurors, however, since juries do not sit in administrative proceedings. In some circumstances, the release of damaging and unevaluated information may threaten to distort administrative judgment in pending cases, or release may confer an unfair advantage upon one party to an adversary proceeding.

Id. at 9.

Lilly is currently the defendant in a number of civil suits that have been brought against it in connection with Oraflex. See Bradley Affidavit, para. 5; Kovakas Declaration, para. 15. The release of the report at issue, "a self-evaluative document which deals critically with business practices and policies as well as actual performance, could easily adversely prejudice the Company in its attempt to defend itself." Kovakas Declaration,

para. 15. Indeed, although the report has been sought specifically by several tort plaintiffs through civil discovery, the courts faced with such discovery requests have without exception found that the report should not be produced. See id. at para. 14. The release of the report in the instant case would, therefore, not only directly frustrate the orders of those courts¹² but would generate publicity that could prejudice the company's defense in those and other suits.¹³ It is absolutely clear that plaintiff in this case is interested in the report precisely because of its publicity value--it seeks the report "for purposes of a news story on a subject . . . that is a matter of general interest to the American public." See id. at Exhibit A and attachments thereto.¹⁴ Lilly's candid evaluations and

¹² As noted supra note 8, release of the report to plaintiff under the FOIA would mandate its release to other requesters.

¹³ Counsel for defendant has recently been advised that the Wheeler case in Nevada (see Attachment G hereto) has been settled. The other cases in which the report has been held privileged are still pending, as are a number of other suits.

¹⁴ Compare Playboy Enterprises, Inc. v. United States Dep't of Justice, 516 F. Supp. 233, 246 (D.D.C. 1981) (amount of publicity speculative, especially where prosecution was permanently enjoined), aff'd in part, rev'd in part, 677 F.2d 931 (D.C. Cir. 1982).

findings as to its handling of Oraflex, regardless of whether or not its ultimate conclusions are favorable to the company, should not be brought to the attention of the juries that are supposed to assess those very issues on the basis of the evidence presented to them, rather than on the basis of information that the courts have found should not be produced.

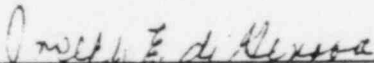
Moreover, there is the possibility of prejudice in yet another context. Inasmuch as the grand jury investigation in the Southern District of Indiana is continuing, there exists the possibility that indictments may be issued by that grand jury. Kovakas Declaration, para. 15. In such a case, release of the report, with its attendant publicity, could be prejudicial to the rights of any persons who are indicted and face trial in this connection.

For the foregoing reasons, defendant respectfully submits that the report at issue is properly withheld from release pursuant to Exemption 7(B) as its release would deprive persons of a right to a fair trial.

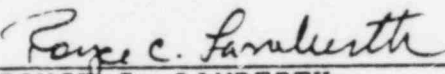
Conclusion

The report sought by plaintiff must be withheld in accordance with the mandate of Rule 6(e) of the Federal Rules of Criminal Procedure and in order to protect the important interests embodied in FOIA Exemptions 4 and 7(B). For all of the foregoing reasons, and based on the entire record herein, defendant submits that its Motion For Summary Judgment should be granted.

Respectfully submitted,

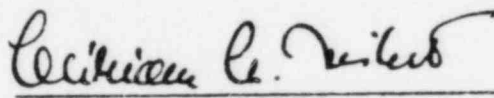


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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

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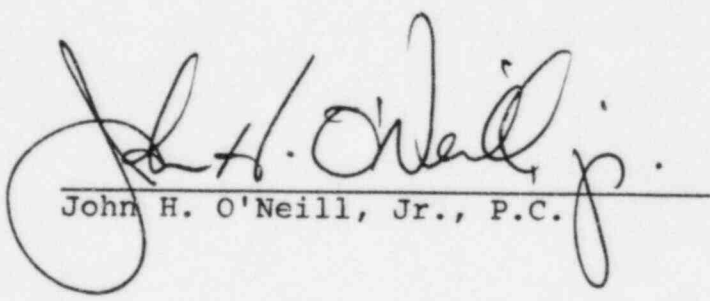
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In the Matter of)
)
CAROLINA POWER & LIGHT COMPANY)
and NORTH CAROLINA EASTERN)
MUNICIPAL POWER AGENCY)
)
(Shearon Harris Nuclear Power)
Plant))

Docket No. 50-400000 OFFICE OF SECRETARY
DOCKETING & SERVICE
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CERTIFICATE OF SERVICE

This is to certify that copies of the foregoing "Applicants' Response to Intervenor Wells Eddleman's Petition for Production of Certain Documents by Making Them Part of a Public Record or, in the Alternative, Pursuant to the Freedom of Information Act" were served by deposit in the United States mail, first class, postage prepaid, this 9th day of July, 1985, to all those on the attached Service List.


John H. O'Neill, Jr., P.C.

Dated: July 9, 1985

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

In the Matter of)	
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