APPEAL NO. 05-5256

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA

JUDICIAL WATCH, INC.,

Plaintiff-Appellant,

v.

FOOD & DRUG ADMINISTRATION, *et al.*,

Defendants-Appellees.

BRIEF OF THE APPELLANT

ON APPEAL FROM THE U.S. DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Paul J. Orfanedes
Meredith L. Di Liberto
JUDICIAL WATCH, INC.
Suite 500
501 School Street, S.W.
Washington, D.C. 20024
(202) 646-5172

Counsel for Plaintiff-Appellant

CORPORATE DISCLOSURE STATEMENT

Appellant, Judicial Watch, Inc., is a section 501(c)(3) educational foundation that advocates transparency, integrity, and accountability in government, politics and the law. Judicial Watch, Inc. has no parent corporation, and no publically held corporation owns 10% or more of Judicial Watch, Inc.

CERTIFICATE AS TO PARTIES, RULINGS AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), Appellant Judicial Watch, Inc. hereby submits its Certificate as to Parties, Rulings, and Related Cases:

A. Parties and Amici The Parties appearing in the lower court and in this appeal are Plaintiff-Appellant Judicial Watch, Inc., Defendant-Appellee Food and & Drug Administration, and Interveners-Appellees Population Council, Inc. and Danco Laboratories, LLC. There were no *amici curiae* in the lower court.

B. Rulings Under Review The ruling under review in this appeal is the April 27, 2005 Memorandum Opinion and Order of the Honorable Richard J. Leon, reproduced at pages 198-210 of the Joint Appendix and reported at 2005 U.S. Dist. LEXIS 8060 (D.D.C. April 27, 2005).

C. Related Cases This case has not previously been before this or any other Court. Counsel for Appellant Judicial Watch, Inc. is not aware of any related cases within the meaning of Circuit Rule 28(a)(1)(C).

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page**

Cases **Page**

Cases **Page**

Statutes, Rules and Other Authorities

Statutes, Rules and Other Authorities **Page**

* Authorities upon which Appellant chiefly rely are marked with asterisks.

STATEMENT OF JURISDICTION

This case arises under the Freedom of Information Act ("FOIA"). Jurisdiction in the District Court was based upon 28 U.S.C. § 1346(a)(2) and 5 U.S.C. § 552(a)(4)(B). This Court has jurisdiction over this appeal pursuant to 28 U.S.C. § 1291 because a final judgment disposing of all parties' claims was entered by the District Court. This appeal is timely as the District Court entered its final judgment on April 27, 2005 and Appellant Judicial Watch, Inc. ("Judicial Watch") filed its notice of appeal on June 15, 2005.

STATEMENT OF THE ISSUES PRESENTED

I. Whether, in accordance with District of Columbia Circuit precedent, Defendant-Appellee Food & Drug Administration ("FDA") submitted an adequately detailed *Vaughn* Index.

II. Whether, pursuant to 5 U.S.C. § 552(b)(4), (5) and (6), the FDA properly withheld information under FOIA Exemptions 4, 5 and 6.

STATEMENT OF THE CASE

I. Introduction.

This case highlights agency abuse of FOIA, plain and simple. Despite the fact that the subject matter of the FOIA that gave rise to this case is based on a health and safety issue – the very type of issue the American public relies on the

FDA to treat with careful deliberation and not party politics or party-line loyalty – the FDA has acted in blatant disregard for the law. Instead of attempting to rapidly dispel any indication of agency preferences or neglect in its approval of the abortion drug RU-486, the FDA has retreated to a position of disregard for its FOIA obligations and reliance on unsubstantiated and inflammatory opinions. In this brief, Judicial Watch clearly demonstrates that the FDA failed to satisfy its FOIA obligations and that the District Court erred in granted Appellees' summary judgment.

II. Factual Background.

In October 2000, Judicial Watch served the FDA with a FOIA requesting all documents regarding the drug mifepristone (a.k.a. "RU-486") and the FDA's approval of mifepristone. JA at 12-29. After Judicial Watch was forced to sue the FDA to protect its FOIA rights, both Population Council, Inc. ("Population Council") and Danco Laboratories, LLC ("Danco") intervened to protect their interests in RU-486.[1]

The FDA granted approval for RU-486 on September 28, 2000. Since its

---

[1] Population Council sponsored the application for approval of RU-486 and owns the trademark for "Mifeprex" – the official trade name for mifepristone. Danco, the for-profit distributor of mifepristone, was started and licensed by Population Council with the intention of marketing the new drug.

approval, the safety of RU-486 has come under fire requiring Danco to revise its warning labeling – the so-called black box labeling. In November 2004, the FDA announced new safety changes to Danco's labeling of RU-486 after it received reports of serious bacterial infection, bleeding, rupturing ectopic pregnancies, and death. After waiting eight months, Danco announced it was issuing important new safety information regarding RU-486. In a "dear doctor" letter, Danco advised doctors about the new safety information included on the boxed warning and warning section of the drug, but added three times that reports of serious bacterial infection, bleeding, rupturing ectopic pregnancies, and death had no causal relationship to RU-486.[2]

The subject of RU-486 has also come under intense scrutiny by members of Congress and the Centers of Disease Control ("CDC"). Just this year, the CDC launched an investigation into five confirmed deaths of women who took RU-486 and the Congressional Subcommittee on Criminal Justice, Drug Policy, and Human Resources began an investigation into the overall safety of RU-486.

---

[2] Danco made this claim in spite of the fact that it was named in a wrongful death lawsuit in Alameda County, California in late December 2004 and the coroner in that case concluded that Holly Patterson's use of RU-486 caused the infection that subsequently killed her.

III. Procedural Background.

On December 12, 2000, Judicial Watch filed suit against the FDA for failure to adequately respond to its October 13, 2000 FOIA request. The District Court granted the FDA's motion for a stay and ordered the FDA to produce all responsive documents to Judicial Watch by October 15, 2001.

On October 15, 2001, the FDA served Judicial Watch with a CD-ROM containing approximately 9,300 pages of records. On April 23, 2002, the District Court granted Intervenors-Appellees Population Council and Danco's unopposed motion to intervene.

On June 14, 2002, motions for summary judgment were filed by the FDA, Population Council and Danco. Subsequently, on or about June 18, 2002, the FDA filed a three-volume, 1,500 page *Vaughn* Index. The Index contained over 6,000 withholdings, with over 4,000 documents withheld in their entirety.

Judicial Watch opposed the motions for summary judgment filed on October 11, 2002, and later filed a surreply to correct certain incorrect assertions and misstatments made by the FDA, Population Council and Danco in their reply briefs. (Docket No. 64).

On April 27, 2005, the District Court granted summary judgment in favor of the FDA, Population Council and Danco. On June 15, 2005, Judicial Watch

appealed. On September 12, 2005, the FDA, Population Council and Danco filed motions for summary affirmance with this Court. On December 9, 2005, this Court denied the motions for summary affirmance holding "the merits of parties' positions are not so clear as to warrant summary action." 2005 U.S. App. LEXIS 27101, *1 (D.C. Cir., December 9, 2005).

SUMMARY OF THE ARGUMENT

For over five years, the FDA has blatantly refused to satisfy its obligations under FOIA and has put its own bureaucratic interests ahead of the health and safety of American women. Population Council and Danco have similarly put their own political, as well as financial interests, before the health and safety of American women. In so doing, not only have the Appellees turned FOIA law on its head, they have endangered the lives of thousands of women.

The FDA's refusal to satisfy its FOIA obligations is most clearly evidenced in its submission of an inadequate *Vaughn* Index. The FDA's Index contains thousands of documents without full descriptions, without dates and without any basis for the claims of exemption. The FDA's *Vaughn* Index is contrary to D.C. Circuit precedent because it does not meet even the most basic elements of an adequate Index.

The inadequacy of the Index prevented Judicial Watch from having the

opportunity to properly challenge the FDA's withholdings. Despite the inadequate *Vaughn* Index, it is clear that the FDA improperly withheld information pursuant to FOIA Exemptions 4, 5 and 6. Making mostly general and/or facial challenges, Judicial Watch demonstrated that the FDA's application of Exemption 4 was vague and misapplied, many of the necessary elements of Exemption 5 were missing, and Exemption 6 was misapplied and unbalanced.

ARGUMENT

The overall purpose of FOIA is to provide a vehicle for private citizens and citizen groups to access government records. *Vaughn v. Rosen*, 484 F.2d 820, 823 (D.C. Cir. 1973). While FOIA contains a discrete list of exemptions, disclosure is the pervading goal. Indeed, even the exemptions are construed narrowly. *See id.* And because FOIA "distorts the traditional adversary nature of our legal system's form of dispute resolution," government agencies are required to satisfy several requirements in an effort to better level the playing field. *Id.* at 827. Included in this category of agency requirements is the agency's FOIA obligation to submit an adequately detailed *Vaughn* Index. *Id.* at 826-28. The *Vaughn* Index, while not requiring a particular form, must at a minimum:

> [P]rovide a relatively detailed justification, specifically identifying the reasons why a particular exemption is relevant and correlating those claims with the particular part of the withheld document to

which they apply.

Mead Data Control v. Dep't of Air Force, 566 F.2d 242, 251(D.C. Cir. 1977).

Another agency FOIA obligation is the proper application of the nine FOIA exemptions in withholding responsive information. Keeping in mind the general policy of openness and disclosure, it is the agency's obligation to properly apply the exemptions to the responsive documents and disclose as much as possible. *See Vaughn*, 484 F.2d at 823.

In this case, the FDA[3] failed to submit an adequately detailed *Vaughn* Index and failed to properly apply FOIA exemptions 4, 5 and 6. As a result, the FDA failed to satisfy its FOIA obligations and summary judgment should not have been granted in its favor.

I. The FDA Failed to Submit An Adequately Detailed *Vaughn* Index In Accordance With D.C. Circuit Precedent.

The crux of Judicial Watch's argument is that the FDA failed to submit an adequately detailed *Vaughn* Index and, as such, Judicial Watch was put in a position of being unable to properly challenge – as is its FOIA right – individual

---

[3] Submitting an adequate *Vaughn* Index was the obligation of the FDA. Neither Population Council nor Danco had any control over the compilation of the Index; therefore, this section focuses mainly on the FDA. Additionally, while Population Council and Danco lobbied to withhold certain information, it was ultimately the FDA's decision whether to release or withhold the information.

withholdings.

The *Vaughn* Index is essential to the proper application of the FOIA statute. Because the "party with the greatest interest in obtaining disclosure is at a loss to argue with desirable legal precision for the revelation of the concealed information," the Index is intended to assist the requestor in being able to challenge the withholdings. *Vaughn*, 484 F.2d at 823. In short, the Index submitted by the agency "in justification for its exemption claims must therefore strive to correct, however imperfectly, the asymmetrical distribution of knowledge that characterizes FOIA litigation." *King v. Dep't of Justice*, 830 F.2d 210, 218 (D.C. Cir. 1987).

The purpose of the *Vaughn* Index is:

> [T]o permit adequate adversary testing of the agency's claimed right of exemption, and enable the District Court to make a rational decision whether the withheld material must be produced without actually viewing the documents themselves, as well as to produce a record that will render the District Court's decision capable of meaningful review on appeal.

King, 830 F.2d at 218-19.

While it is true that the adequacy of the Index varies factually on a case-by-case basis, the D.C. Circuit has provided criteria to assist in the adequacy determination. For example, the Index must provide a "relatively detailed justification, specifically identifying the reasons why a particular exemption is

relevant," and correlate "those claims with the particular part of the withheld document." *Mead Data Central*, 566 F.2d at 251. In describing the withheld documents, the agency must "describe *each* document or portion thereof withheld, and for *each* withholding it must discuss the consequences of disclosing the sought-after information." *King*, 830 F.2d at 223-24 (emphasis in original). The descriptions cannot be "conclusory, merely reciting statutory standards," or be "too vague or sweeping," and "categorical description of redacted material coupled with categorical indication of anticipated consequences of disclosure is clearly inadequate." *King*, 830 F.2d at 219, 224.

The FDA's *Vaughn* Index falls short of the adequacy criteria set forth by the D.C. Circuit. The FDA fails to provide a relatively detailed justification for the withholdings, or to specifically identify the reasons why a particular exemption is relevant. Additionally, the FDA makes no attempt to identify which portion of the withheld document applies to each exemption, providing instead a list of exemptions and an assumption that each exemption applies equally to the entire document. *See e.g. Vaughn*, 484 F.2d at 827-28 ("While it is not impossible, it seems highly unlikely that a particular element of information sought would be exempt under both exemptions. Even if isolated portions of the document are exempt under more than one exemption, it is preposterous to contend that all of

the information is equally exempt under all of the alleged exemptions.")

A. Standard of Review.

Grants of summary judgment are reviewed *de novo*. *Carter v. George Washington Univ.*, 387 F.3d 872, 878 (D.C. Cir. 2004). Pursuant to Rule 56(c) of the Federal Rules of Civil Procedure, summary judgment is appropriate only if the pleadings, depositions, answers to interrogatories, admissions, and affidavits filed ... show that, first, 'there is no genuine issue as to any material fact' and second, 'the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); *see Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). In making this determination, the evidence is viewed in the light most favorable to the non-moving party. *See Holcomb v. Powell*, 2006 U.S. App. LEXIS 520, * 8 (D.C. Cir., Jan. 10, 2006). In the FOIA context, the determination includes whether the agency has fulfilled its FOIA obligations. *See Summers v. Dep't of Justice*, 140 F.3d 1077, 1080 (D.C. Cir. 1998).

B. The FDA Submitted An Inadequately Detailed *Vaughn* Index.

The District Court did not specifically address the issue of the adequacy of the FDA's *Vaughn* Index. Rather, the Court chose to skim over the argument and briefly mention it within the discussion of the individual exemptions. *See Judicial Watch, Inc. v. FDA*, 2005 U.S. Dist. LEXIS 8060, *8,

10-12, 14, n.5, 7 (D.D.C. April 27, 2005). In fact, the District Court describes the case as merely regarding the adequacy of the FDA's search and the justification for withholding information pursuant to FOIA exemptions.[4] *Id.* at *2. Respectfully, this demonstrates the problem with the District Court's opinion as it glosses over the central issue – the adequacy of the FDA's *Vaughn* Index. The importance of an adequately detailed Index cannot be overstated. Without such an Index, the requester, and indeed the Court itself, simply cannot properly review or challenge the agency's withholdings. Diminishing the central role an adequately detailed *Vaughn* Index plays transfers the burden onto the requester which, in the words of this Court, is a "clear contravention of the statutory mandate." *Vaughn*, 484 F.2d at 828.

In both its motion for summary judgment and its motion for summary affirmance, the FDA claims its *Vaughn* Index included a "full description of each document," the date of the document, the parties (if known), the claim of relevant exemptions, "along with an explanation of the basis for the claim." *See* Memorandum of Points and Authorities in Support of Defendant's Motion For Summary Judgment ("FDA's Memo") at 7 (Docket No. 39); *see also* Federal

---

[4] Judicial Watch did not appeal the issue of the adequacy of the FDA's search or the use of FOIA Exemption 3.

Appellee's Motion For Summary Affirmance ("FDA's Affirmance") at 9. This very fulsome description of the FDA's *Vaughn* Index simply is not true.

1. Lack of Full Descriptions.

Many of the thousands of documents in the FDA's *Vaughn* Index do not contain a "full description." In its opposition brief, Judicial Watch carefully listed some of the more troubling examples. *See* Plaintiff's Opposition to Defendant's Motion For Summary Judgment ("Plaintiff's Opposition") at 10-12, n.10. Some of these examples have been reproduced in the Joint Appendix ("JA"). For example Documents 1787 and 1788 are both described as "table - main lab temp." JA at 139. This is the only description given for these documents and can hardly be considered a "full description."

Another example is Document 3078 which is described simply as "outstanding issues." JA at 161. In addition to lacking any real description, Document 3078 contains no date, and no author or recipient. Equally unclear is Document 3222 which is described as "fax re: listing w/attach." JA at 164. Document 3222 is 13 pages of completely unknown information. Document 3331 is also a mystery, described as "references 89/11450gn." JA at 166. The FDA's code-like description leaves Judicial Watch totally in the dark.

The FDA also withheld several documents described simply as a "fax

transmission sheet," or a "fax cover page." *See* Documents 6033, 6035 and 6036, JA at 183-184. These scant descriptions in no way satisfy the FDA's obligation to submit an adequately detailed *Vaughn* Index or the FDA's claim that it included a "full description" of each withheld document.

In *Campaign For Responsible Transplantation v. FDA*, 219 F.Supp. 2d 106, 116 (D.D.C. 2002), the District Court held that "without a proper *Vaughn* index, a requester cannot argue effectively for disclosure and this court cannot rule effectively." As a result, the District Court ordered the FDA to submit properly detailed indices. *Id.* The District Court took issue with the FDA's descriptions of the documents, or lack thereof. The Court stated:

> [M]any of the descriptions only provide a vague hint at the possible contents of the documents. This type of description does not give the court or the requester the necessary functional description of the documents at issue.

Id. at 112.

The inadequate descriptions in *Campaign* and in this case are eerily similar. For example, the District Court was troubled by descriptions such as: "Internal Memo RE: Xeno;" "IND G: Undated Internal Memo re: Testing;" "IND G: 10/7/99 Memorandum to File;" "IND G: Letter, sent approx. on 10/24/94;" "IND G: 2/23/99, Internal E-mail, RE: response to E-mail;" "IND G: 7/16/98, Internal E-mail;" "IND G: Undated typed noted from response re: various issues;" and

"General: undated, Review, RE: Master File." *Campaign*, 219 F. Supp. 2d at 114, n. 9. In this case, we have similarly troubling descriptions such as: "memo re: phone issue" (Document 3221, JA at 164); "draft internal q & a" (Document 662, JA at 118); "report re: additional information" (Document 2573, JA at 153); "general letters" (Document 4816, JA at 177); "email re: sending of new e-mail" (Document 1007, JA at 130); "fda form w/attach" (Document 2377, JA at 150); "handwritten notes" (Document 1839, JA at 141); and "fda form: handwritten" (Document 2676, JA at 155).

In short, the FDA has failed to submit a *Vaughn* Index containing fully described documents. Without a full description, neither Judicial Watch nor this Court can properly evaluate or challenge the individual documents.

2. Missing Dates.

The FDA claims that the withheld documents listed in the *Vaughn* Index contain the dates of the documents. Viewing only the documents reproduced in the Joint Appendix reveals that 106 of the listed documents do not contain dates. This constitutes approximately one-third of the documents reproduced in the Joint Appendix. The FDA's claim is untenable.

3. Explanation of Basis For Claim.

The FDA's final claim is that the *Vaughn* Index contains "an

explanation of the basis for the claim" of exemption. The **only** explanation given by the FDA in the "reason for withholding" boxes is a recitation of the terms contained in the general legal standards for the relevant FOIA exemption. As seen in *Campaign*, mere recitation of key words from the legal standards governing the applicable FOIA exemption is not an adequate explanation of the basis for the claim. *Campaign*, 219 F. Supp. 2d at 114. For example, every document purporting to be withheld pursuant to FOIA Exemption 6 states as the basis for withholding: "personal privacy." Additionally, every document purporting to be withheld pursuant to FOIA Exemption 5 states as the basis for withholding: "deliberative process," or the very rare: "attorney-client privilege." These "brief legal standards do not provide the required 'clear explanation.'" *Id.* (*quoting Judicial Watch, Inc. v. Export-Import Bank*, 108 F. Supp. 2d 19, 34 (D.D.C. 2000)).

The FDA failed to provide the Court and Judicial Watch with full descriptions of the withheld documents, dates for all of the withheld documents, and a basis for the claims of exemptions for the withheld documents. Without these three elements, the FDA's *Vaughn* Index cannot be considered adequately detailed. The District Court erred in granting Appellees' motions for summary judgment.

II. The FDA Improperly Withheld Responsive Information Under FOIA Exemptions 4, 5 and 6.

The overall inadequacy of the FDA's *Vaughn* Index wreaks havoc on Judicial Watch's ability to challenge individual withholdings. However, despite the inadequacy, the information contained in Appellees' pleadings and declarations, in addition to the *Vaughn* entries, permits some general and facial challenges.

A. Exemption 4.

Exemption 4 of FOIA exempts "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). To sustain an Exemption 4 withholding, each of these elements must be demonstrated. The FDA failed to demonstrate the Exemption 4 elements in three ways. First, the overall descriptions of many of the documents is too vague to permit Judicial Watch the opportunity to properly challenge them. Second, the FDA misapplied Exemption 4 by including information which is not, in the ordinary meaning of the words, trade secrets or confidential commercial or financial information. Third, it is unclear whether the documents withheld by the FDA pursuant to Exemption 4 were confidential.

1. Vague Entries.

The FDA's application of Exemption 4 is perhaps the best example of

why the inadequately detailed *Vaughn* Index is the overriding root of the problem in this case. Many of the documents withheld pursuant to Exemption 4 are so poorly described that it is impossible for the Court to review them and impossible for Judicial Watch to challenge them. Judicial Watch argued this point earlier in its opposition to Appellees' motions for summary judgment. *See* Plaintiff's Opposition at 20-23 (Docket No. 53). In its opposition brief, Judicial Watch specifically addressed ten examples of vague Exemption 4 descriptions and listed more than 200 examples in a footnote. *Id.*, n.14-16. In its reply brief, the FDA addressed only **two** of these specific examples. *See* FDA's Reply at 28-31 (Docket No. 58). Subsequently in its summary affirmance motion, the FDA claimed that it "addressed the specific Vaughn index entries asserting Exemption 4 that Appellant suggested were too vague and demonstrated that they were in fact sufficient." *See* FDA's Summary Affirmance at 12. This is simply not true. Judicial Watch specified more than 210 examples of vague Exemption 4 descriptions; the FDA only addressed 2 of the 210 examples. Even if there were no other examples, and Judicial Watch does not concede this, there are still more than 200 unexplained withholdings.

Many of the vague descriptions pointed out by Judicial Watch in its opposition brief have been reproduced in the Joint Appendix. For example,

Documents 526 and 527 are described simply as "study summary data," and Document 528 is described as "combined study data." JA at 113. The FDA has withheld these three documents because they allegedly contain confidential commercial information and raw data. However, there is no explanation as to what constitutes a "study summary data." It is the FDA's FOIA obligation to fully describe each document in a manner that would allow Judicial Watch to challenge and the Court to review.

Other examples of vague Exemption 4 documents are the group of documents identified only by unexplained coding. For example: Document 3021 described as "study 88/739/cn;" Document 3022 described as "study s/87/486/15;" Document 3023 described as "study f/85/486/40;" and Document 3024 described as "study 86/200/tx." JA at 159. These four rather large documents have no further description. There is also no indication as to whom the information is from and to whom the information was transmitted. The FDA included no glossary of terms or index of codes with its *Vaughn* Index. In fact, the FDA makes no attempt to explain this group of documents.

The District Court barely addressed this issue. In a footnote the Court states that it finds the information in the *Vaughn* Index and the declaration to be "sufficiently detailed to justify the withholdings." *Judicial Watch v. FDA*, 2005

U.S. Dist. LEXIS at *9, n.5. The District Court does not explain its rational,, nor does it address the fact that the FDA failed to account for the more than 200 specific documents identified as vague. *Id.*

The FDA's failure to address the larger problem of the inadequacy of the *Vaughn* Index by inaccurately claiming it explained the entries at issue is demonstrative of the FDA's overall failure to satisfy its FOIA obligations.

2. Misapplication of Exemption 4.

Exemption 4 can only be used to protect information that is a trade secret or confidential commercial information. In *Center For Auto Safety v. NHTSA*, 244 F.3d 144, 151 (D.C. Cir. 2001), the court defined "trade secret" as "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." The terms "commercial" or "financial" information are not as clearly defined, but the courts seem to agree that the terms should be given their ordinary meanings. This Court holds that records are commercial "so long as the submitter has a commercial interest in them." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1290 (D.C. Cir. 1983) (internal quotation omitted).

In a misapplication of the law, the FDA used Exemption 4 to withhold the

names and addresses of contract manufacturers. *See* Memorandum of Points and Authorities In Support of Defendant's Motion For Summary Judgment ("FDA's Motion") at 24-25; *see also* Statement of Points and Authorities in Support of Motion of Population Council, Inc. and Danco Laboratories, LLC For Summary Judgment ("Intervenors' Motion) at 20-21. It claims that because of an alleged threat of violence, the names and addresses of the contract manufacturers are protected as confidential commercial information. *Id.* This novel use of Exemption 4 simply has no legal authority. Rather, for authority the FDA's pleadings point to the declaration of Andrea C. Masciale, who in turn points to the opinions of (former) FDA Commissioner Jane Henney and (former) Acting Principle Deputy Commissioner Bernard Schewtz. JA at 43. Both Henney and Schewtz admit that their opinions were based on discussions with Department of Justice ("DOJ") attorneys who served on the National Task Force on Violence Against Reproductive Health Care Providers. JA at 70-74. This convoluted path not only poses serious questions of bias, it also lacks any legal authority. Regardless of any single DOJ attorney's personal politics or bias, or indeed any FDA commissioner's personal politics or bias, no single person can alter the statutory application of FOIA. The courts apply Congressional intent to FOIA litigation, not agency preference.

Additionally, the name of the contract manufacturer, the Chinese pharmaceutical company in Shangai, Hua Lian Pharmaceutical Company, appears both in the *Vaughn* Index and in the Documents released on the FDA's own website. *See* Documents 1719, 1977, JA at 135, 148. Hua Lian's identity as the manufacturer of mifespristol has also been the subject of several articles in national publications. *See* Plaintiff's Opposition, Exhibit 3. Therefore, as a practical matter, the need for secrecy does not exist. *Judicial Watch v. FDA*, 2005 U.S. Dist. LEXIS at *9.

The District Court held that the names and addresses of the contract manufacturers could be withheld under Exemption 4 based on the statements of Henney and Schewtz. In addition to side-stepping the obvious potential for bias, the Court saddles Judicial Watch with disproving the existence of abortion-related violence. This flip-flopping of the FOIA burdens is contrary to the law governing FOIA and the overall intent of FOIA. Ironically, Judicial Watch made a discovery request to the District Court which was never addressed by the Court.

3. **Failure to Demonstrate Actual Competition.**

In *Critical Mass Energy Project v. Nuclear Regulatory Commission,("Critical Mass I")*, 830 F.2d 278, 281-82 (D.C. Cir. 1987), *vacated by Critical Mass Energy Project v. Nuclear Regulatory Commission, ("Critical*

Mass II"), 975 F.2d 871 (D.C. Cir. 1992), the Court held that in order for a commercial document to be considered confidential, it must be shown that "disclosure of the information is likely...either...(1) to impair the Government's ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained." *Critical Mass I* at 282. The agency withholding the information was required to bear the burden of persuading "the reviewing court that 'the impairment is significant enough to justify withholding the information.'" *Id.* at 286 (quoting *Washington Post Co. v. Dep't of Health and Human Services,* 690 F.2d 252, 268, n.51, (D.D.C. 1982)).[5] Therefore, the FDA must demonstrate that the information is either likely to impair the FDA's ability to obtain necessary information in the future or that release of the information is likely to cause substantial competitive harm to Danco and Population Council. In their various pleadings, Appellees' claim the latter – that release of the information is likely to cause substantial competitive harm to Danco and Population Council.

In *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C. Cir.

---

[5] Several years after *Critical Mass I*, the court vacated its original holding and made an exception for cases in which the commercial or financial information was given voluntarily to the agency. However, since the information in this case was mandatory for approval, the exception does not apply. *Critical Mass* II at 878-79.

1979), the court stated that in order to demonstrate the required element of substantial competitive harm, the agency needed to show "actual competition and the likelihood of substantial competitive injury." Despite Appellees' repeated contestations to the contrary, neither the FDA nor Population Council or Danco has yet to make a showing of actual competition. Appellees have made repeated recitations of the legal standards governing Exemption 4, but none of the Appellees have demonstrated **actual** competition. Appellees also repeatedly allege what "could" happen or what "would likely" happen, but no one has made a showing of actual competition.[6]

B. Exemption 5.

Exemption 5 of FOIA concerns records that are: "inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency ...." 5 U.S.C. § 552(b)(5). This provision exempts from disclosure those records normally privileged in the civil discovery context. While this statutory language has been interpreted

---

[6] The closest allegation of actual competition was made by Population Council and Danco in their motion for summary judgment where they claim that "at least one would-be marketer of mifepristone is seeking a manufacturer to compete with Danco." *Statement of Points and Authorities in Support of Motion of Population Council, Inc. and Dano Laboratories, LL For Summary Judgment* at 3. (Docket No. 40).

broadly to incorporate "all civil discovery rules into FOIA [Exemption 5]" (*Martin v. Office of Special Counsel*, 819 F.2d 1181, 1185 (D.C. Cir. 1987)), each discovery rule or privilege asserted by an agency in any particular case must be construed narrowly to effect FOIA's overall purpose of liberal disclosure. As the Supreme Court has noted:

> Since virtually any document not privileged may be discovered by the appropriate litigant, if it is relevant to his litigation, and since the [FOIA] Act clearly intended to give any member of the public as much right to disclosure as one with a special interest therein, it is reasonable to construe Exemption 5 to exempt those documents, and only those documents, normally privileged in the civil discovery context.

NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 148-49 (1975) (citations omitted); *see also Mapother v. Dep't of Justice*, 3 F.3d 1533, 1537 (D.C. Cir. 1993) ("[Exemption 5], like all FOIA exemptions, must 'be construed as narrowly as consistent with efficient government operation.'"). The Supreme Court has recognized three primary privileges/protections covered by this exemption: (1) the deliberative process privilege; (2) the attorney-client privilege; and (3) the attorney work-product doctrine. *Id.* The privileges at issue in this appeal are the deliberative process privilege and the attorney-client privilege.

1. <u>Deliberative Process Privilege</u>.

The deliberative process privilege protects from disclosure "any

documents that reveal an agency's deliberative process in reaching policy decisions." *Judicial Watch, Inc. v. U.S. Postal Service*, 297 F.Supp. 2d 252, 258 (D.D.C. 2004), *see NLRB*, 421 U.S. at 150. In order to invoke the deliberative process privilege properly, an agency must demonstrate that a record is both predecisional and deliberative. *Vaughn v. Rosen*, 523 F.2d 1136, 1144 (D.C. Cir. 1975). Documents are predecisional when they are prepared prior to the adoption of agency policy. *Id.* Additionally, the agency "must also either 'pinpoint an agency decision or policy to which the document contributed,' or identify a decisionmaking process to which a document contributed." *Judicial Watch, Inc.*, 297 F. Supp.2d at 259. (internal citations omitted). Documents are deliberative when they "reflect the give-and-take of the consultative process." *Coastal States Gas Corp. v. Dep't of Energy*, 617 F.2d 854, 866 (D.C. Cir. 1980). The agency bears the burden of demonstrating that the record satisfies both requirements. *Id.*

While it is impossible for Judicial Watch to fully challenge each document withheld pursuant to FOIA Exemption 5 because of the lack of adequate detail, there are several general and/or facial challenges to be made. First, many of the documents withheld by the FDA pursuant to the deliberative process privilege fail to satisfy the "pre-decisional" requirement outright. As mentioned above, many of

the documents listed in the FDA's *Vaughn* Index do not contain a date.[7] Without a date, the FDA cannot argue that the documents are predecisional. Additionally, the FDA's *Vaughn* Index lists many documents withheld pursuant to FOIA Exemption 5 that contain dates **after** the date of approval. The FDA granted formal approval of RU-486 on September 28, 2000; therefore, documents dated after September 28, 2000 cannot be considered predecisional.[8] *See Petroleum Info. Corp. v. U.S. Dept' of Interior*, 976 F.2d 1429, 1434 (D.C. Cir. 1992). Each of the documents listed in the FDA's *Vaughn* Index that is either missing a date, or contains a post-decisional date, should be released immediately because they cannot satisfy the predecisional requirement.

Second, many of the documents withheld pursuant to the deliberative process privilege fail to reflect the deliberative nature of the information withheld. The necessary "give-and-take of the consultative process" is near to impossible to

---

[7] The documents reproduced in the Joint Appendix and withheld pursuant to FOIA Exemption 5 that do not contain dates are: Document Nos: 656, 1645, 1646, 1647, 3078, 3213-3215, 4840, 5952-5953 and 6003. JA at 116, 134, 161, 163, 178 and 180-181.

[8] The documents reproduced in the Joint Appendix and withheld pursuant to FOIA Exemption 5 that contain post-decisional dates are: Document Nos: 921-924, 929-932, 934, 936, 948, 985-988, 993, 995, 997-1008, 3126-3128, 3216, 4593, 4595, 4768, 4770 and 6016-6019. JA at 122-30, 162-163, 174, 176 and 182.

ascertain from the FDA's descriptions. One method used by courts to assist in the determination of whether information is deliberative is an assessment of the identities of the parties involved. Documents from a subordinate to a superior official is more likely part of the "give-and-take of the consultative process," than information flowing from a superior to a subordinate, which is more likely to be directional. *Coastal States*, 617 F.2d at 868.

Many of the documents make it impossible to ascertain not only the identities of the parties, but also their relationship to one another. For example, the large majority of *Vaughn* pages reproduced in the Joint Appendix and withheld pursuant to the deliberative process privilege fall into three problem categories. First, the documents described as being from "fda employee(s)" to "fda employee(s)."[9] From this scant description, it is impossible to determine whether this is the type of relationship that the deliberative process privilege was designed to protect - the type that encourages the give-and-take of the consultative process. The second category is the documents which are described as being from an "fda

---

[9] The *Vaughn* documents reproduced in the Joint Appendix described as such are: Document Nos: 419, 659, 662, 705, 845, 847, 921-924, 929-932, 934, 936, 945-948, 985-988, 993-1008, 1217-1220, 1262-1264, 1321-1324, 1645-1648, 1977, 2673, 2845, 3125, 3127, 3216, 3221, 3222, 4818, 5954, 5955 and 6016-6019. JA at 112, 117-118, 120-134, 148, 155-156, 163-164, 177, 180 and 182.

employee" and leave the "to" box blank.[10] Obviously not knowing who one of the parties is prevents the Court from determining whether the relationship was the type protected by the deliberative process privilege. The last category of documents fail to list any party at all.[11]

Lastly, as a part of the deliberative process privilege, it is the agency's obligation to demonstrate the individualized harm associated with the release of each document. The FDA failed to articulate the necessary element of harm required under Exemption 5. In *Mead Data Central, Inc.*, the D.C. Circuit reversed the lower court's decision allowing the Department of the Army to withhold documents under Exemption 5. In regard to the documents withheld under the deliberative process privilege, the D.C. Circuit held that:

> [A]n agency cannot meet its statutory burden of justification by conclusory allegations of possible harm. It must show by specific and detailed proof that disclosure would defeat, rather than further, the purposes of the FOIA.

---

[10] The *Vaughn* documents reproduced in the Joint Appendix described as such are: Document Nos: 3065-3068, 3079, 3126, 3223, 6003 and 6039. JA at 160-162, 164, 181 and 184.

[11] The *Vaughn* documents reproduced in the Joint Appendix described as such are: Document Nos: 846, 3078, 3213, 4311, 4313, 4593, 4595, 4768, 4770, 4840, 4841, 5952 and 5953. JA at 121, 161, 163, 171, 174, 176, 178 and 180. Documents 846 and 3212 were withheld in their entirety pursuant only to the deliberative process privilege. The lack of identifiable parties is especially pertinent here.

Mead Data Central, 566 F.2d at 258. And in *Judicial Watch, Inc. v. U.S. Postal Service*, this Court followed *Mead* by denying the USPS' Exemption 5 withholdings. This Court found that:

> USPS does not identify the specific harm in disclosing any of these documents, reiterating only that each 'reflects the predecisional thoughts, judgments, and recommendations' of USPS employees. Though even a conclusory allegation of harm would be insufficient, USPS fails to allege any harm at all.

Judicial Watch, 297 F Supp.2d at 265; *see also Senate of Puerto Rico ex rel. Judiciary Comm. v. Dep't of Justice*, 823 F.2d 574, 585 (D.C. Cir. 1987).

The FDA's *Vaughn* Index is completely devoid of any discussion of harm. The first declaration of Andrea C. Masciale very briefly mentions harm. In the declaration, Ms. Masciale states:

> These documents contain predecisional opinions, discussions, and/or recommendations of FDA personnel, and disclosure of the withheld documents would discourage the frank exchange of opinions and recommendations among such individuals. Disclosure, therefore, would be harmful to the deliberative processes within FDA.

Declaration of Andrea C. Masciale, JA at 45, ¶ 39.

This is exactly the type of conclusory allegation of potential harm that this Court rejected in *Mead.* Ms. Masciale's supplemental declaration does not clarify the individualized harm; in fact, the deliberative process privilege is never mentioned at all. The FDA's failure to identify the individualized harm associated

with the responsive documents withheld pursuant to the deliberative process privilege in accordance with the law of this jurisdiction is fatal to their claim.[12]

The District Court's holding regarding Exemption 5 is puzzling. First, the Court takes issue with Judicial Watch's argument that the *Vaughn* Index as a whole is insufficiently detailed. *Judicial Watch v. FDA*, 2005 U.S. Dist. LEXIS at *12. Despite acknowledging that "some of the descriptions in the Vaughn index provide limited details," the Court holds that Judicial Watch "provides no evidence, or information that would cause the Court to question Ms. Masciale's declaration, given under oath." *Id.* Respectfully, the District Court again confuses the burdens of proof in this case. In accordance with clear D.C. Circuit precedent, the FDA was required to demonstrate that the documents withheld pursuant to Exemption 5 were both predecisional and deliberative. As Judicial Watch has indeed demonstrated, the FDA failed to satisfy that burden. The fact that Ms. Masciale's statement is sworn does not remedy the missing or post-decisional dates, the unclear nature of the deliberative process, or the missing descriptions of

---

[12] There are several other arguments to be made regarding the deliberative process privilege including, but not limited to, whether the information withheld was of a factual nature or one expressing an opinion and whether the opinion became the final policy of the FDA. Judicial Watch is not in a position to make these arguments in relation to individual documents because of the overall lack of description in the *Vaughn* Index.

individualized harm.

2. Attorney-Client Privilege.

"It is settled law that the party claiming the privilege bears the burden of proving that the communications are protected." *In re Lindsey*, 148 F.3d 1100, 1106 (D.C. Cir. 1998), *cert. denied*, 525 U.S. 996 (1998). "A blanket assertion of the privilege will not suffice. Rather, 'the proponent must conclusively prove each element of the privilege.'" *In re Lindsey*, 148 F.3d at 1106, *quoting Securities and Exchange Commission v. Gulf & Western Indus.*, 518 F. Supp. 675, 682 (D.D.C. 1981). The attorney-client privilege applies only if:

> (1) the asserted holder of the privilege is or sought to become a client; (2) the person to whom the communication was made (a) is a member of the bar of a court or his subordinate and (b) in connection with this communication is acting as a lawyer; (3) the communication relates to a fact of which the attorney was informed (a) by his client (b) without the presence of strangers (c) for the purpose of securing primarily either (i) an opinion on law or (ii) legal services or (iii) assistance in some legal proceeding, and not (d) for the purpose of committing a crime or tort; and (4) the privilege has been (a) claimed and (b) not waived by the client.

In re Sealed Case, 737 F.2d 94, 99 (D.C. Cir. 1984). Business and personal advice are not covered by the privilege, even when given by an attorney. *Gulf & Western Indus., Inc.*, 518 F. Supp. at 681. In addition, the substance of communications from attorney to client are shielded **only if** they rest on confidential information

obtained from the client. *Mead*, 566 F.2d at 254. Any voluntary disclosures by a client to a third party breaches the confidentiality of the attorney-client relationship and therefore waives the privilege, not only as to the specific communication disclosed, but often as to all other communications relating to the same subject matter. *In re Sealed Case*, 676 F.2d at 809.

As with the shortcomings its deliberative process privilege withholdings, the FDA has failed to demonstrate all of the necessary elements of the attorney-client privilege. Judicial Watch made this argument in its opposition to the Appellees' motions for summary judgment. *See* Plaintiff's Opposition at 28-30 (Docket No. 53). The FDA's reply admitted to some "clerical errors," but maintained that these errors were "isolated and not representative of the index." *See* Defendant's Reply at 31-33 (Docket No. 58).[13] The FDA then attempted to remedy the errors by re-describing six of the erroneous entries. *See id.* First, it is clear that the overriding inadequacy of the *Vaughn* Index is **not** isolated to a few clerical errors. Second, the FDA's attempt to remedy the errors by re-describing the entries fails.[14]

---

[13] These errors were not confined solely to the invocation of the attorney-client privilege, but are best highlighted by these examples.

[14] Additionally, the FDA's reference to another declaration violated the "one document" rule. Judicial Watch was left to cross-reference the *Vaughn* Index

In its opposition, Judicial Watch referenced three documents as examples of inadequately described attorney-client documents. Specifically, Judicial Watch demonstrated that Documents 110, 660, and 787 were all withheld pursuant to attorney-client privilege, but contained no evidence of attorney involvement. *See* Plaintiff's Opposition at 29-30; *see also* JA at 117. The FDA attempted to remedy these three examples by stating that Document 110 should have been described as being from a Department of Justice attorney, and Documents 660 and 787 should not have claimed Exemption 5 at all. *See* Defendant's Reply at 32-33. The FDA fails to acknowledge that these errors are not isolated and that re-describing three documents does not account for the fact that many other documents claiming attorney-client privilege protection are also inadequate.

For example, in the documents reproduced in the Joint Appendix , there are nine documents withheld pursuant to attorney-client privilege that contain absolutely no reference to an attorney.[15] And while nine may not seem like a large

---

itself, the memorandum of law, the reply brief and two declarations from Ms. Masciale. *See Founding Church of Scientology v. Bell*, 603 F.2d 945, 949 (D.C. Cir. 1979). Adding Population Council and Danco to the mix further required Plaintiff to add its memorandum and reply briefs and declaration to the cross-referencing.

[15] The *Vaughn* documents withheld pursuant to attorney-client privilege reproduced in the Joint Appendix are Document Nos: 921, 932, 934, 993, 995, 1219, 1220, 1321 and 3214. JA at 123-124, 127, 131, 133 and 163.

number, it is important to note that there are only nine documents in the Joint Appendix that claim attorney-client privilege. In other words, **every** document reproduced in the Joint Appendix that claims attorney-client privilege fails to properly allege any attorney involvement at all. The District Court missed this point as well. In a cursory footnote, the Court states that because the FDA addressed the three documents identified by Judicial Watch and Judicial Watch did not further address the issue in its surreply, the issue must be resolved. *Judicial Watch v. FDA*, 2005 U.S. Dist. LEXIS at *13, n.6. Judicial Watch's argument that the FDA's assertion of attorney-client privilege was inadequate, was a general argument regarding the privilege as a whole. Judicial Watch pointed to a few examples to illustrate the inadequacy. *See* Plaintiff's Opposition at 28-30. The issue was not revisited in the surreply because Judicial Watch was presenting only incorrect assertions and misstatements by the Appellees. Judicial Watch's general argument regarding the FDA's use of the attorney-client privilege was not resolved in the FDA's reply.

It is impossible to discern from the description given by the FDA if there is an attorney involved in the communication; if the person is seeking legal advice; if the person seeking advice is a client of the attorney; or if there was anyone else present who would have destroyed the privilege or if the privilege was waived.

The FDA provides none of this information, but simply claims the privilege exists. This claim clearly fails to carry FDA's burden of proving that the communications are protected by the attorney-client privilege.

C. Exemption 6.

Exemption 6 protects from disclosure "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6). "[S]imilar files" are defined to include any "Government records on an individual which can be identified as applying to that individual." *United States Department of State v. Washington Post Co.*, 456 U.S. 595, 601 (1982). These are the only types of records to which Exemption 6 applies and it is the agency's burden to demonstrate that the exemption is applicable to the information being redacted and or withheld.

If Exemption 6 is applicable, the focus of the inquiry turns to whether disclosure of the records at issue would constitute a clearly unwarranted invasion of personal privacy. This requires a balancing of the public's right to disclosure against the individual's right to privacy. *See Fund for Constitutional Gov't v. National Archives and Records Serv.* 656 F.2d 856, 862 (D.C. Cir. 1981). As a preliminary matter in the balancing test, it must be ascertained whether a protectible privacy interest exists that would be threatened by disclosure. The

threat to the privacy interest from disclosure must be concrete rather than speculative. *See Department of the Air Force v. Rose*, 425 U.S. 352, 380 n.19 (1976). If no privacy interest is found, further analysis is unnecessary and the information at issue must be disclosed. *See Ripskis v. Hud*, 746 F.2d 1, 3 (D.C. Cir. 1984); *Holland v. CIA*, No. 91-1233, slip. op. at 32 (D.D.C. Aug. 31, 1992) (information must be disclosed when no significant privacy interest, even if the public interest is *de minimis*).

However, if the preliminary inquiry determines that a privacy interest exists, then the public interest in disclosure is weighed against the privacy interest in nondisclosure. *See Ripskis*, 746 F.2d at 3. Whether the public interest would be served by disclosure "turn[s] on the nature of the requested document and its relationship to" the public interest, which the Supreme Court defined for FOIA purposes as "shed[ding] light on an agency's performance of its statutory duties." *Department of Justice, et al., v. Reporters Committee for Freedom of the Press*, 489 U.S. 749 at 772, 773 (1989). If no public interest exists, or if the privacy interest outweighs the public interest, the information should be protected. *See National Ass'n of Retired Fed. Employees v. Horner*, 879 F.2d 873, 879 (D.C. Cir. 1989). However, where the public interest in disclosure outweighs any privacy interest, the information must be released.

1. Personnel, Medical And Similar Files.

The FDA withheld the names of various agency personnel and government employees, the names of various HHS employees, Danco's street address and the names and addresses associated with the development and approval of mifepristone pursuant to Exemption 6. *See* Masciale Decl. at ¶¶ 43, 47-49 (JA at 46, 48-49). None of this information, however, constitutes personnel, medical or similar files. With the exception of redacting actual patient names, which Judicial Watch concedes is a proper application of Exemption 6, none of the information withheld by the FDA appears to be from medical or personnel files.[16] It is also not a similar file for the purposes of Exemption 6. In *United States Department of State v. Washington Post Co.*, the U.S. Supreme Court defined the term "similar file" and explained its application:

> '[T]he exemption [was] intended to cover detailed Government records **on an individual** which can be identified as **applying to that individual**.' When disclosure of information which applies to a particular individual is sought from Government records, courts must determine whether release of the information would constitute a clearly unwarranted invasion of that person's privacy.

---

[16] The overall inadequacy of the *Vaughn* Index prevents Judicial Watch from knowing for certain if much of the withheld information has been taken from medical or personnel files. Unlike Documents 1741 - 1744, which even with the scant description of "exhibit - pregnancy test," can be presumed to have redacted patients' names, Documents such as 1324 described as "e-mail re: special government employee consult," cannot be so presumed. *See* JA at 133, 137.

Washington Post, 456 U.S. at 602 (quoting H.R. Rep. No. 1497) (emphasis added).

The FDA has not demonstrated that the information withheld under Exemption 6 consists of records **on an individual** which can be identified as applying to that individual. The names of agency personnel, government employees and private individuals in association with the development and approval of mifepristone, as well as the street address of Danco and the private individuals in association with the development and approval of mifepristone, is not information taken from records about the agency personnel, government employees, private individuals or Danco. More likely, these names and addresses appear within the records and files of something else. All of these individuals are people associated with the approval of mifepristone, not the subject of the files. And while certain agency personnel, government employees and private individuals may wish not to be associated with a topic as contentious as mifepristone, association with a trade or project is not an Exemption 6 function.

In *Board of Trade of the City of Chicago v. Commodity Futures Trading Commission*, 627 F.2d 392, 399-400 (D.C. Cir. 1980), the court held that the "withheld information associates these individuals with business of the Board, and not with any aspect of their personal lives. The interest in non-disclosure thus

asserted is not in continued privacy of personal matters, but in anonymity of criticism on purely commercial matters." Like *Board of Trade*, the information the FDA, Population Council and Dano seek to withhold is information in relation to an individual's association with the mifepristone approval. It is not the type of personal information the courts exempt under Exemption 6. Withholding the names of agency personnel, government employees and private individual in files that do not pertain personally to them is improper under the *Washington Post* holding.

The District Court did not address *Board of Trade* or the holding in *Washington Post* cited above. Instead the Court simply stated that the FDA provided "sufficient information." *Judicial Watch v. FDA*, 2005 U.S. Dist. LEXIS at *14.

2. Public Interest Outweighs Personal Privacy.

Even if the Court finds that the information withheld by the FDA is a "similar file," Exemption 6 is tempered by the fact that even information decidedly personal can be released if the public interest sufficiently outweighs the individual's privacy. *See Department of Justice v. Reporters Committee*, 489 U.S. 749 (1989). The balancing inquiry is two-fold. First, "to establish that the release of information contained in government files would result in a clearly unwarranted

invasion of privacy, the court first asks whether disclosure 'would compromise a substantial, as opposed to a *de minimis*, privacy interest.'" *National Ass'n of Home Builders v. Norton*, 309 F.3d 26, 33 (D.C. Cir. 2002) (citation omitted). Second, if the privacy interest is determined to be substantial, the court must then:

> [W]eigh that interest 'against the public interest in the release of the records in order to determine whether, on balance, disclosure would work a clearly unwarranted invasion of personal privacy.' ... The public interest to be weighed against the privacy interest in this balancing test is 'the extent to which disclosure would serve the 'core purposes of FOIA' by contributing significantly to public understanding of the operations or activities of the government.'

Id. (internal citations omitted).

First, there is a question as to whether the information Appellees seek to withhold would comprise a substantial privacy interest. As mentioned earlier in reference to the FDA's misapplication of Exemption 4, the allegation giving rise to need for privacy is the risk of threats and violence to those associated with the development, marketing, and distribution of RU-486. *See* Masciale Decl. at ¶¶ 43-49 (JA at 46-49). *See supra* II.A.2. As Judicial Watch demonstrated, the potential that these allegations of threat and harm are based more on bias than fact is too great to give them the kind of weight Appellees' desire. The allegations are not based on any substantiated facts. In fact neither former FDA Commissioner Jane Henney nor formerActing Principle Deputy Commissioner Bernard Schewtz point

to any specific facts of threats or harm. This type of inflammatory and unsubstantiated opinion has no place in FOIA litigation.

However, even if the Court determines that the privacy interest is substantial, the public interest in this case clearly outweighs those privacy interests. This information concerns a drug that in 2000 had the potential to be deadly, and since 2000, has proven to be deadly. It is absurd to suggest, as Appellees appear to, that information about a potentially deadly drug does not qualify as public interest. Public health and well-being is historically a proper reason to make public information that overlaps into areas of personal privacy. Despite these concerns, the District Court never balanced the public interest, or even made mention of the public interest. *Judicial Watch v. FDA*, 2005 U.S. Dist. LEXIS at *13-15.

Since the approval of RU-486, there have been five (confirmed) deaths and many other non-fatal, but medically dangerous cases. These cases have caused the warnings to be revised, wrongful death lawsuits to be filed, and both the CDC and a Congressional subcommittee to launch independent investigations. It is absolutely essential to the public's understanding of how and under what circumstances RU-486 was approved to have access to records demonstrating who was involved. It has been alleged by various sources that the FDA was under

pressure from the Clinton White House and that Danco was permitted to by-pass several FDA statutory requirements in order to gain approval. This goes to the very heart of the operations of government. Should the investigations that have been launched uncover either negligence or malfeasance in the approval process, the American public has a right to know who in their government is responsible for the deaths and physical ailments caused by the approval of RU-486.

CONCLUSION

For the foregoing reasons, this Court should reverse and remand the District Court's April 27, 2005 memorandum opinion for further proceedings.

Respectfully submitted,

JUDICIAL WATCH, INC.

Paul J. Orfanedes
Meredith L. Di Liberto
Suite 500
501 School Street, S.W.
Washington, D.C. 20024
(202) 646-5172

Attorneys for Plaintiff-Appellant

CERTIFICATE OF COMPLIANCE PURSUANT TO
FED. R. APP. P. 32(a)(7)(C) AND CIRCUIT RULE 32(a)(2)

I certify that pursuant to Fed. R. App. P. 32(a)(7)(C) and the District of Columbia Circuit Rule 32(a)(2) that the attached Brief of the Appellant is proportionally spaced, as a typeface of 14 points or more and contains 10,665 words.

Meredith L. Di Liberto

CERTIFICATE OF SERVICE

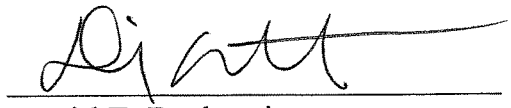
I hereby certify that on January 25, 2006, two true and correct copies of the foregoing BRIEF OF THE APPELLANT was served by first-class mail, postage prepaid, on the following:

Attorney for Defendant-Appellee FDA:

Fred E. Haynes
Assistant United States Attorney
555 4th Street, Room E-4110
Washington, D.C. 20530

Attorneys for the Intervenor-Appellees:

Nancy L. Buc
Kate C. Beardsley
Carmen M. Shepard
Buc & Beardsley
919 Eighteenth Street, N.W., Suite 600
Washington, D.C. 20006



David F. Rothstein