

**IN THE UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ALABAMA  
SOUTHERN DIVISION**

<b>HYGIA HEALTH SERVICES, INC.</b>	)	
	)	
<b>Plaintiff,</b>	)	
	)	
<b>v.</b>	)	<b>Case 2:06-cv-04798-IPJ</b>
	)	
<b>UNITED STATES FOOD &amp; DRUG ADMINISTRATION</b>	)	
	)	
	)	
<b>Defendant.</b>	)	
	)	

**PLAINTIFF HYGIA HEALTH SERVICES, INC.’S OPPOSITION  
TO DEFENDANT’S MOTION FOR SUMMARY JUDGMENT**

Hygia Health Services, Inc. (“Hygia”) files this response in opposition to the U.S. Food & Drug Administration’s (“FDA”) motion for summary judgment (doc. 14). FDA’s sweeping application of FOIA’s Exemptions 7(C) and 7(D) to the entire Alliance Medical Corporation Trip Report is not supported by either the law or the facts. FDA’s motion for summary judgment (doc. 14) should therefore be denied, and Hygia’s motion (doc. 9) should be granted.

## **I. FOIA's Exemptions Must be Narrowly Construed**

FDA bears the burden of proving that one of FOIA's exemptions justify its withholding of the Alliance Medical Corporation Trip Report in its entirety. 5 U.S.C. § 552(a)(4)(B); *Nadler v. Dept. of Justice*, 955 F.2d 1479, 1484 (11th Cir. 1992) (“[T]he government agency that seeks to withhold information bears the burden of proving that an exemption applies.”). FDA also bears the burden of proving that the document cannot be segregated for partial release. *See Church of Scientology v. I.R.S.*, 816 F. Supp. 1138, 1162 (W.D. Tex. 1993) (“The burden is on the agency to prove the document cannot be segregated for partial release.”).

In determining whether FDA has met its burden, the Court applies a *de novo* standard of review. 5 U.S.C. § 552(b). As part of this review, all of FOIA's exemptions, including Exemptions 7(C) and 7(D), must be narrowly construed to advance the overall public disclosure purpose of the statute. *L&C Marine Transport Ltd. v. O.S.H.A.*, 740 F.2d 919, 922 (11th Cir. 1984) (“[A]ll FOIA exemptions are to be narrowly construed.”). *See also Church of Scientology International v. Dept. of Justice*, 30 F.3d 224, 228 (1st Cir. 1994) (“[FOIA's policy is] one of broad disclosure, and the government must supply any information requested by an individual unless it determines that a specific exemption, narrowly construed, applies.”).

Further, federal agencies like FDA are not entitled to any deference or presumption of correctness on the issue of whether a FOIA exemption applies, as may be the case in other types of litigation involving federal agencies. *Tax Analysts v. I.R.S.*, 117 F.3d 607, 613 (D.C. Cir. 1997) (“It is true that we will not defer to any agency’s view of FOIA’s meaning.”). It is the Court’s job, not the agency’s, to interpret and apply a FOIA exemption in a given case. *See Reporters Committee for Freedom of the Press v. Dept. of Justice*, 816 F.2d 730, 734 (D.C. Cir. 1987) (“Congress intended that the primary interpretive responsibilities rest on the judiciary, whose institutional interests are not in conflict with [FOIA’s] statutory purpose.”), *rev’d on other grounds*, 489 U.S. 749 (1989). Accordingly, the Court should disregard the conclusory statements in FDA’s evidentiary submissions in this case about whether it thinks certain aspects of Exemptions 7(C) and 7(D) are satisfied. *See, e.g.*, Doc 15, Ex. 3, at ¶¶ 9-11. FDA’s opinions are irrelevant.

## **II. Exemption 7(C) Does Not Apply**

FDA is correct in its general statement of how Exemption 7(C) is applied—it requires a balancing of the personal privacy interest at stake against the public interest in disclosure. *Dept. of Justice v. Reporters*

*Committee for Freedom of the Press*, 489 U.S. 749, 762 (1989).<sup>1</sup> FDA is flat wrong, however, in how that balancing plays out under the facts of this particular case.

**A. There is no cognizable *personal* privacy interest at stake in this case**

The first step in the Exemption 7(C) analysis is to identify the *personal* privacy interest, if any, at stake in the information. *Albuquerque Publishing Co. v. Dept. of Justice*, 726 F. Supp. 851, 855 (D.D.C. 1989) (“Our preliminary inquiry is whether a personal privacy interest is involved.”). *See also* U.S. Department of Justice, *Freedom of Information Act Guide and Privacy Act Overview*, at 567-8 (May 2004) (“Under the balancing test that traditionally has been applied to both Exemption 6 and Exemption 7(C), the agency must first identify and evaluate the privacy interest(s), if any, implicated in the requested records.”) (hereinafter “DOJ FOIA Guide”).<sup>2</sup> In this case, FDA says that the privacy interest in the

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<sup>1</sup> The threshold requirement for Exemption 7 to apply is that the information is “records or information compiled for law enforcement purposes.” 5 U.S.C. § 552(b)(7). Hygia does not dispute that the Alliance Medical Corporation Trip Report was used by FDA for a law enforcement purpose. Hygia does dispute, however, that FDA has proven the remaining requirements of Exemptions 7(C) and 7(D).

<sup>2</sup> The Department of Justice publishes its FOIA Guide on a periodic basis. The most recent edition, from May 2004, is available on-line at [www.usdoj.gov/oip/foi-act.htm](http://www.usdoj.gov/oip/foi-act.htm). The page numbers used in this opposition

Alliance Medical Corporation Trip Report is that of two Alliance Medical Corporation employees in “their names and the information given to FDA.” Doc. 16 at 13. This alleged interest is not a cognizable personal privacy interest under Exemption 7(C).

Businesses like Alliance Medical Corporation do not possess protectible privacy interests under Exemption 7(C). *See Sims v. CIA*, 642 F.2d 562, 572 n.47, 575 (D.C. Cir. 1980) (observing that FOIA’s privacy exemptions are “only applicable to individuals” and were “developed to protect intimate details of personal and family life, not business judgments and relationships”); *Ivanhoe Citrus Ass’n v. Handley*, 612 F. Supp. 1560, 1567 (D.D.C. 1985) (“[N]either corporations nor business associations possess protectible privacy interests”). *See also* DOJ FOIA Guide at 439 (“[N]either corporations nor business associations possess protectible privacy interests [under FOIA].”).

All the evidence in this case demonstrates that the employee who submitted the report to FDA was acting on behalf of Alliance Medical Corporation. FDA’s Deputy Director of Regulatory Affairs, Mr. Larry D. Spears, says the document at issue is an “internal Alliance memo”—not

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correspond to the page numbers in the book version of the DOJ FOIA Guide printed by the U.S. Government Printing Office.

notes or documents of an individual. Doc. 15, Ex.1, at ¶ 9. Mr. Spears attributes the information in the report to Alliance Medical Corporation—saying that the “Trip Report sets forth *Alliance’s* observations and concerns,” (*id.* at ¶ 9) (emphasis added), and contains information “that *the company* had obtained,” (*id.* at ¶ 5) (emphasis added). Mr. Spears also says that the Alliance employee who gave the report to him expressly said “that management clearance would be needed before the information could be provided to FDA.” *Id.* at ¶ 6. All available evidence, therefore, demonstrates that the employee was acting *essentially as the corporation*, and no evidence suggests that the employee was acting on his or her own personal behalf, such that they would face individual repercussions or retaliation.<sup>3</sup> Thus, because there is only a commercial interest involved, and not a personal privacy interest, Exemption 7(C) does not apply.<sup>4</sup>

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<sup>3</sup> FDA’s speculation about possible retaliation that the employee(s) may suffer is unfounded. FDA’s brief says that the employee(s) “could face possible repercussions from Ascent Healthcare Solutions, Inc.,” but it provides no evidentiary citation for this point or even explanation as to why that would happen. Doc. 16 at 13. In fact, the evidence demonstrates that such retaliation would not happen because the Alliance employee was acting *on behalf of* their employer, not criticizing it or giving testimony about its operations. Thus, FDA’s reliance on *L&C Marine Transport Ltd. v. O.S.H.A.*, 740 F.2d 919 (11th Cir. 1984), is misplaced. Doc. 16 at 17 n.7. In that case, the Court was concerned that employee-witnesses would be subject to “problems at their jobs” if the substance of their “comments about the safety of the work place” were disclosed, even with the names redacted. *Id.* No such concern exists here because the internal memo deals with

**B. There is a significant public interest in disclosure**

On the other side of the Exemption 7(C) scale, there is a significant public interest weighing in favor of disclosure of the Alliance Medical Corporation Trip Report. The public interest side of the equation focuses on FOIA's central purpose of opening agency action to the light of public scrutiny and the value of the specific information at issue in furthering that purpose. *Reporters Committee*, 489 U.S. at 772; *King v. Dept. of Justice*, 830 F.2d 210, 234 (D.C. Cir. 1987). In other words, the public interest is the

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Hygia's facility, not Alliance's. Further, the Alliance Medical Corporation Trip Report was provided to FDA voluntarily, and, if there was concern about retaliation or embarrassment or future employment opportunities, the individual who submitted it could have redacted his or her name prior to its submission or submitted it anonymously. Finally, although FDA makes the conclusory claim that confidentiality here is necessary to encourage "voluntary reporting" that "the agency believes is essential to carrying on its law enforcement mission," the evidence in this case does not bear out this belief. Doc. 15, Ex. 3, at ¶ 7. What FDA got in this case was not information essential to its mission, but rather competitively-motivated accusations about matters that turned out to be, in FDA's words, "adequately addressed, or were not relevant concerns to begin with." Doc. 11, Ex. 1, at 4 & Att. 2.

<sup>4</sup> Even in cases where a corporation or other business entity is not involved, individuals acting in a business capacity have a diminished expectation of privacy under Exemption 7(C). See *Oregon Natural Dessert Ass'n v. Dept. of the Interior*, 24 F. Supp. 2d 1088, 1089 (D. Or. 1998) (holding that individual cattle owners have "diminished expectation of privacy" in their names when such information relates to commercial interests).

right of citizens “to be informed about what their government is up to.”  
*Reporters Committee*, 489 U.S. at 773.

In this case, disclosure of the Alliance Medical Corporation Trip Report will shed significant light on what the FDA is up to. FDA is the federal agency entrusted by Congress with the responsibility to, among other things, ensure that medical devices are safe and effective. Doc. 16 at 2. Medical devices are regulated under the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301-397, and the regulations for devices found at 21 C.F.R. Part 800. *Id.* FDA inspects regulated facilities nationwide, and violations of the FDCA can be subject to both civil and criminal penalties. *Id.* at 10.

In the present case, Hygia has offered undisputed evidence that the Alliance Medical Corporation Trip Report was the impetus for FDA’s decision to inspect its facility. Doc. 11, Ex. 1, at ¶¶ 3, 5. FDA has confirmed that fact in its own evidentiary submissions. Doc. 15, Ex.1, at ¶ 10. Thus, given that the Alliance Medical Corporation Trip Report played such an integral role in how FDA wielded its regulatory authority and allocated its enforcement resources, there is a significant public interest in its disclosure. *See City of Chicago v. Dept. of Treasury*, 287 F.3d 628, 637 (holding that there is a “compelling” public interest under Exemption 7(C) in

agency’s “performance of its statutory duties of tracking, investigating and prosecuting illegal [activity]”), *opinion amended in other respects on denial of rehearing*, 297 F.3d 672 (7th Cir. 2002); *Cooper Cameron Corp. v. Dept. of Labor*, 280 F.3d 539, 548 (5th Cir. 2002) (ordering release of witness statements and stating that “there is a cognizable public interest [under Exemption 7(C)] in monitoring agencies’ enforcement of the law in specific instances.”).

The public interest is enhanced in this particular case because FDA was lured into exercising its inspection authority by over-the-top claims of an industry competitor—claims that FDA inspectors later determined were either “adequately addressed, or were not relevant concerns to begin with.” Doc. 11, Ex. 1, at 4 & Att. 2.<sup>5</sup> How FDA could be so easily manipulated and distracted is a matter of public interest, and disclosure of the Alliance Medical Corporation Trip Report will contribute to an understanding of that. *See Washington Post Co. v. Dept of Health and Human Services*, 690 F.2d 252, 264 (D.C. Cir. 1982) (explaining that purpose of FOIA is not to allow agencies “to cover up embarrassing mistakes or irregularities,” but to

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<sup>5</sup> In fact, FDA inspected Hygia’s facility over the course of five days in May 2005, just three months after Alliance Medical Corporation obtained the so-called “disturbing” information about Hygia, and FDA found no objectionable conditions or deviations from the regulations. *See* Supplemental Declaration of Scott Comas, at ¶ 3.

advance “the right of the individual to be able to find out how his government is operating”).

**C. Hygia’s Intended Use of the Alliance Medical Corporation Trip Report is Irrelevant**

FDA spends a considerable amount of its brief speculating on Hygia’s purpose for requesting the Alliance Medical Corporation Trip Report and its intended future use of the document. FDA claims that “the company wants to sue Alliance for its alleged breach of a non-disclosure agreement.” Doc. 16 at 14. Putting aside the fact that this is pure speculation on FDA’s part, whether or not Hygia requested the document for this purpose is completely irrelevant to the FOIA analysis. As FDA itself acknowledges: “The private needs of the companies for documents in connection with litigation . . . *play no part* in whether disclosure is warranted.” Doc. 16 at 16 (quoting *L&C Marine Transp.*, 740 F.2d at 923) (emphasis added). *See also Reporters Committee*, 489 U.S. at 771 (“[T]he identity of the requester *has no bearing* on the merits of his or her FOIA request.”) (emphasis added). In other words, Hygia’s right to documents under FOIA is no greater and no less than any other requester. The cases are legion on this point. *See, e.g., National Archives and Records Administration v. Favish*, 541 U.S. 157, 170 (2004) (“As a general rule, withholding information under FOIA cannot be

predicated on the identity of the requester.”)<sup>6</sup>; *Cooper Cameron*, 280 F.3d at 547-48 (“[T]he specific motives of the party making the FOIA request are irrelevant. . . .Therefore, although we suspect that Cooper seeks the deponents’ statements to impeach testimony in the tort suit, our suspicion counts neither in favor of nor against Cooper’s FOIA request.”) (internal quotations omitted); *Mayock v. Nelson*, 938 F.2d 1006, 1008 (9th Cir. 1991) (“[A] person’s rights under FOIA are neither diminished nor enhanced by ‘litigation-generated’ need for agency documents.”); *Nadler*, 955 F.2d at 1489-90 (“[T]he fact that Nadler’s motive for seeking the information is personal does not enter into our balancing process; rather, we must look for a coincidental public purpose.”). Accordingly, despite FDA’s speculation, Hygia’s intended use of the Alliance Medical Corporation Trip Report is simply irrelevant to the resolution of this case.

Even if Hygia did have the present intention of using the Alliance Medical Corporation Trip Report to sue Alliance Medical Corporation or its successor for breach of the non-disclosure agreement, there is nothing

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<sup>6</sup> In *Favish*, the Supreme Court reaffirmed the general principle that “disclosure does not depend on the identity of the requester,” but also clarified that in the Exemption 7(C) context “the person requesting the information [must] establish a sufficient reason for the disclosure.” 541 U.S. at 172. Hygia has satisfied this obligation by demonstrating that disclosure of the Alliance Medical Corporation Trip Report will contribute significantly to the public’s understanding of FDA’s performance of its statutory duties and enforcement of the law in this specific instance.

untoward or inappropriate about such a use, as FDA tries to imply. Non-disclosure agreements between private companies and the enforcement of such agreements serve important public policy purposes in protecting confidential information, encouraging joint ventures, and fostering the investment of time and money to develop special knowledge. *See, e.g., Eden Hannon & Co. v. Sumitomo Trust & Banking Co.*, 914 F.2d 556, 561, 563 (4th Cir. 1990) (holding that non-disclosure agreement between companies “enables potential joint venturers to share confidential information regarding a possible deal,” that absent such agreements “the incentive to engage in the building of [special] knowledge will be greatly reduced,” and that “public policy seeks to protect the development of trade secrets without ruining competition.”).

#### **D. The Balance Weighs in Favor of Disclosure**

As one court has said in the context of balancing the public interest against personal privacy interests under FOIA, “something [] outweighs nothing every time.” *Horwitz v. Peace Corps*, 428 F.3d 271, 279 (D.C. Cir. 2005). That is certainly the case here—the public interest in knowing the types of information FDA uses to carry out its statutory responsibilities outweighs the non-existent (or at least significantly diminished) privacy

interest of Alliance Medical Corporation and the employees acting on its behalf. Accordingly, Exemption 7(C) does not apply.

### **III. Exemption 7(D) Does Not Apply**

Exemption 7(D) applies to records or information compiled for law enforcement purposes, *but only to the extent* that the production of such law enforcement records or information:

could reasonably be expected to disclose *the identity* of a confidential source, including . . . any private institution which furnished information on a confidential basis, *and, in the case of a record or information compiled by a criminal law enforcement authority in the course of a criminal investigation or by an agency conducting a lawful national security intelligence investigation*, information furnished by a confidential source.

5 U.S.C. § 552(b)(7)(D) (emphasis added). For several reasons, this exemption does not apply to the Alliance Medical Corporation Trip Report.

First, disclosure of the Alliance Medical Corporation Trip Report will not reveal *the identity* of the individual who was FDA's alleged "confidential source." The declaration of Mr. Spears submitted by FDA makes clear that the Alliance Medical Corporation Trip Report is not itself a communication to FDA from the alleged "confidential source," but is instead an "internal Alliance memorandum." Doc. 15, Ex. 1, at ¶ 9. Mr. Spears' declaration establishes that the actual communication identifying the alleged "confidential source" is an e-mail that Mr. Spears received with the subject

line “Hygia Trip Report.” *Id.* at ¶ 8. That e-mail to Mr. Spears is the document that would reveal the identity of the alleged “confidential source,” and that e-mail is not at issue in this case.<sup>7</sup>

Second, even if the names of the Alliance employees in the report are covered under Exemption 7(D) as identifying information, the entire *contents* of the Alliance Medical Trip Report are not protected. Exemption 7(D) makes a pointed distinction between the *identity* of the source and the *information* provided by the source. *See Cooper Cameron*, 280 F.3d at 550 (“It is readily apparent from exemption 7(D)’s language . . . that Congress distinguished between the identity of the source and the information imparted by that source.”). Under the plain language of Exemption 7(D), the *actual information* furnished by the confidential source is only protected where the information was “compiled by a criminal law enforcement authority in the course of a criminal investigation or by an agency

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<sup>7</sup> Mr. Spears says in his declaration that the Alliance Medical Corporation Trip Report “reveals the name of two Alliance employees, including the one who provided me the document.” Doc. 15, Ex. 1, at ¶ 9 (emphasis added). Mr. Spears does not claim that the document itself contains information that would identify which of the two employees sent him the report, only that it includes that employee’s name. Thus, because there is more than one employee name revealed in the document, it is undisputed that disclosure of the document will not reveal who FDA’s source is.

conducting a lawful national security intelligence investigation.” 5 U.S.C. § 552(b)(7)(D). Neither of these conditions is met here.

FDA is not a “criminal law enforcement authority,” as that term is used in FOIA. Although violation of certain laws administered by FDA may be subject to criminal prosecution (doc. 16 at 10), that does not mean FDA is a “criminal law enforcement authority” (like, for example, the Federal Bureau of Investigation). Instead, FDA is properly understood as a “mixed function” agency under Exemption 7, with both regulatory and law enforcement missions. *Pratt v. Webster*, 673 F.2d 408, 417-20 (D.C. Cir. 1982). Further, as a matter of statutory construction, the text of FOIA makes a distinction between an “agency” and a “criminal law enforcement authority.” *See* 5 U.S.C. § 552(f)(1) (definition of “agency”). This distinction is evident in the text of Exemption 7(D) itself. *See* 5 U.S.C. § 552(b)(7)(D). *See also Pratt*, 673 F.2d at 417-18 (“[T]he language of the exemption itself suggests a greater congressional concern with the secrecy of documents held by agencies, such as the FBI, principally committed to criminal law enforcement.”). If a run-of-the-mill regulatory agency like FDA were considered a “criminal law enforcement agency,” then the distinction made by Congress in the text of the statute would have no meaning—all agencies would be “criminal law enforcement agencies” under

such a reading. Apparently recognizing this point, FDA does not even argue in its brief that it qualifies as a “criminal law enforcement authority,” which might have allowed it to legitimately withhold the entire contents of the Alliance Medical Corporation Trip Report under Exemption 7(D).

Finally, there is of course no evidence to suggest that FDA was “conducting a lawful national security intelligence investigation” when it obtained and used the Alliance Medical Corporation Trip Report. There is simply no basis in Exemption 7(D) upon which FDA can withhold the entire contents of the Alliance Medical Corporation Trip Report.

**IV. At a Minimum, the Alliance Medical Corporation Trip Report Must be Disclosed with Individual Identifying Information Redacted.**

FOIA unequivocally states that “[a]ny reasonably segregable portion of a record shall be provided to any person requesting such a record after deletion of the portions which are exempt.” 5 U.S.C. § 552(b). As the Department of Justice has explained, “this important provision was designed to narrow the focus of the application of exemptions from documents to specific segments of information within them.” DOJ FOIA Guide at 792. *See also Schiller v. N.L.R.B.*, 964 F.2d 1205, 1209 (D.C. Cir. 1992) (“The focus in the FOIA is information not documents and an agency cannot justify withholding an entire document simply by showing that it contains

some exempt material.”). The “segregability requirement applies to all documents and all exemptions in the FOIA.” *Center for Auto Safety v. E.P.A.*, 731 F.2d 16, 21 (D.C. Cir. 1984).

Despite this clear statutory mandate, FDA has not even attempted to separate exempt and nonexempt information in the Alliance Medical Corporation Trip Report, although it would be easy to do.<sup>8</sup> Redaction of the individual names of Alliance Medical Corporation employees is a simple way to alleviate FDA’s stated concerns about personal privacy, retaliation, and encouraging voluntary reporting. This is exactly what the Department of Justice instructs federal agencies to do when Exemption 7 is invoked: “[O]f course, agencies should be sure to redact their law enforcement records so that only identifying information is withheld under Exemption 7(C).” DOJ FOIA Guide at 599.

In fact, in Exemption 7 cases, courts routinely hold that the agency must release the document requested, with redaction of only names, addresses, and other individual identifying information. *Department of the*

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<sup>8</sup> FDA has demonstrated in this very case how simple it is to make targeted word-by-word redactions to address specific concerns about disclosure. When FDA finally responded to Hygia’s administrative appeal after this case was filed, it decided to release an additional two words in the five-page “Turtill Memo.” Doc. 11, Ex. 1 at ¶ 12. Given that FDA has demonstrated an ability to make such precise word-by-word redactions, it has no excuse for not doing so with the Alliance Medical Corporation Trip Report.

*Air Force v. Rose*, 425 U.S. 352, 380-81 (1976) (ordering release of case summaries of disciplinary proceedings with personal identifying information deleted); *Aldridge v. I.R.S.*, 2001 WL 196965, at \*3 (N.D. Tex. Feb. 23, 2001) (denying agency's motion for summary judgment and determining that privacy interests of employees recommended for discipline could be protected by redacting only their names); *Hronek v. D.E.A.*, 16 F. Supp. 2d 1260, 1278 (D. Or. 1998) (denying agency's motion for summary judgment, concluding that "[t]he government fails to indicate why the privacy interests at stake could not be protected by simply redacting particular identifying information."). FDA's failure to follow this approach is grounds for denying its motion for summary judgment.

FDA suggests that it cannot release a copy of the Alliance Medical Corporation Trip Report with the individual names redacted because the remainder of the document would threaten revealing the individual source's identity. Doc. 16 at 20. However, FDA offers no facts to back up this assertion; and, in fact, the evidence proves the contrary. As discussed above, even with the two names included, FDA has not established (or even alleged) that one name would be the more likely source over the other. And once the two names are redacted, it would be impossible to determine which Alliance Medical Corporation employee gave FDA the document. Even if

the context of the document suggests that one or both of the two employees were among those present in Hygia's facility in January and February of 2005 (again, a fact that FDA does not even allege), the identity would still be unknowable because there were between fifteen and twenty Alliance Medical Corporation employees in Hygia's facility during that time period.<sup>9</sup> See Supplemental Declaration of Scott Comas, at ¶ 2. And there is absolutely no evidence to suggest that Hygia or any other person could distinguish among this group based on the contents of the Alliance Medical Corporation Trip Report. Thus, FDA's argument that the contents of the report will give away its source is based on nothing more than speculation and conjecture, and that is not sufficient for granting FDA summary judgment. See *Cooper Cameron*, 280 at 543 (holding that agency "affidavits will not suffice if the agency's claims are conclusory, merely reciting statutory standards, or if they are too vague or sweeping").

The only other rationale that FDA offers for not disclosing a redacted version of the Alliance Medical Corporation Trip Report is that FDA has

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<sup>9</sup> As the Supreme Court has explained, redaction is the proper mechanism for accomplishing FOIA's public disclosure requirement, even if it does not eliminate all risks of identifying a protected individual: "To be sure, redaction cannot eliminate all risks of identifiability, as any human approximation risks some degree of imperfection, and the consequences of exposure of identity can admittedly be severe. But redaction is a familiar technique in other contexts and exemptions to disclosure under the Act were intended to be practical workable concepts." *Rose*, 425 U.S. at 381-82.

already “identified the existence of . . . the industry source of [the] complaint [and] there is now no way to de-identify the Trip Report so that it cannot be de-linked with the specific firm that submitted it.” Doc. 15, Ex. 3, at ¶ 11. This is pure non-sense. In other words, because FDA has voluntarily and knowingly identified the company that provided the alleged “confidential” report, FDA says it can now magically protect the entire document.<sup>10</sup> Accepting FDA’s argument would turn on its head Congress’s intent—expressed in the text of Exemption 7(D)—to limit the circumstances under which an agency may withhold *the information* provided by a confidential source. The novelty of this argument by FDA is made evident by the fact that FDA can only support it by citing to a case under a different statute—

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<sup>10</sup> FDA argues that “Hygia seems to believe that because FDA inadvertently made public the fact that it had a document from Alliance, FDA should now make available to Hygia the full contents of the Trip Report.” Doc. 16 at 22. That is not at all what Hygia “believes” or has argued in this case—Hygia seeks the contents of the Alliance Medical Corporation Trip Report because those contents are not covered by any FOIA exemption and must be released after any exempt information is redacted. FDA’s disclosure of identity of the source of the report means that FDA has waived its argument that the source identifying information can be withheld; in contrast, the contents were required to be released even before FDA’s “inadvertent” disclosure. It is FDA, not Hygia, that is seeking to profit from FDA’s “inadvertently disclosure” when it argues that its identification of the source of the report now authorizes it to withhold the entire document. Doc. 15, Ex. 3, at ¶ 11.

the Privacy Act of 1974—with a differently worded exemption. Doc. 16 at 22 (citing *Volz v. Dept. of Justice*, 619 F.2d 49 (10<sup>th</sup> Cir. 1980)).<sup>11</sup>

In fact, FDA’s argument is completely backwards. FDA’s disclosure of the identity of the source of the report as Alliance Medical Corporation means it has waived any argument for withholding the remainder of the document on that basis.<sup>12</sup> *See, e.g., Steinberg v. Dept. of Justice*, 179 F.R.D. 366, 371 (D.D.C. 1998) (Exemption 7 case holding that content of sources’

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<sup>11</sup> The text of the Privacy Act exemption at issue in *Volz* is markedly different from the text of FOIA’s Exemption 7(D), in that it does not make a distinction between the identity of the source and the contents of the information provided, as does Exemption 7(D). *Compare* 5 U.S.C. § 552(b)(7)(D), *with* 5 U.S.C. 552a(k)(5). Thus, FDA is wrong to say that the “logic” of *Volz* “dictates that FDA can withhold the entire content of the Trip Report under FOIA Exemption 7(D).” Doc. 16 at 23.

<sup>12</sup> There is no dispute that FDA made a knowing, authorized, and intentional disclosure of the identity of the company source of the Alliance Medical Corporation Trip Report. The identity was disclosed by an FDA official with authority to do so, and who in fact stated that she had conducted a review of the document for any FOIA-exempt information prior to its release. Doc. 11, Ex. 1, Attach. 2 at 1 (stating that document being released “reflected redactions made by the Agency in accordance with the FOIA.”). The best that FDA can say with respect to waiver is that another agency employee, Mr. Sadler, “believe[s]” that FDA’s New Orleans Office “should have” redacted the reference to Alliance Medical Corporation as its source. Doc. 15, Ex. 3, at ¶ 8. Such beliefs are irrelevant. FDA offers no evidence that the disclosure was inadvertent, a mistake, or unauthorized, and even if it did, waiver would still have occurred. *See* DOJ FOIA Guide at 701-2 (“[A]n agency’s carelessness in permitting access to certain information [and] an agency’s mistaken disclosure of the contents of a document all have resulted in waiver.”).

interviews must be disclosed once agency disclosed their identities—  
“Having chosen to release the names of its sources, the Justice Department cannot plausibly argue that it is still protecting their identities when it withholds the content of their interviews.”)<sup>13</sup> *See also Kimberlin v. Dept. of Justice*, 921 F. Supp. 833, 835-36 (D.D.C. 1996) (granting plaintiff’s motion for summary judgment and ordering government agency to release to FOIA requester information which had previously been released), *aff’d in pertinent part and remanded in other part*, 139 F.3d 944 (D.C. Cir. 1998).

Because FDA has failed to adequately demonstrate that all reasonably segregable, nonexempt information in the Alliance Medical Corporation Trip Report has been disclosed, or provide a coherent reason why this is not possible, its motion for summary judgment must be denied. *See* DOJ FOIA Guide at 795 (“[S]ummary judgment may be denied to an agency if its

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<sup>13</sup> It is important to note that Exemption 7(D) can be waived at FDA’s sole discretion; it is not a mandatory exemption. *See Chrysler Corp. v. Brown*, 441 U.S. 281, 293 (1979) (“We [] hold here that Congress did not design the FOIA exemptions to be mandatory bars to disclosure.”). *See also Bartholdi Cable Co., Inc. v. F.C.C.*, 114 F.3d 274, 282 (D.C. Cir. 1997) (“The fact that information falls within one of the FOIA exemptions does not necessarily mean that the agency cannot disclosure the material. FOIA’s exemptions simply permit, but do not require, an agency to withhold exempted information from the public.”). Accordingly, an agency is not required to seek a source’s permission to waive his or her confidential status under Exemption 7(D). As the Department of Justice itself has explained, an agency that chooses to disclose source-identifying information “has no duty to seek the witness’s permission to waive his confidential status under the Act.” DOJ FOIA Guide at 638-39.

declarations do not adequately demonstrate that all reasonably segregable, nonexempt information has been disclosed.”).

## **V. Conclusion**

Based on the foregoing and its previous submissions (docs. 9, 10, 11), Hygia respectfully requests that the Court deny FDA’s motion for summary judgment, grant Hygia’s motion for summary judgment, and order FDA to disclose the Alliance Medical Corporation Trip Report in its entirety.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 23, 2007, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

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