NO. 06-11774-II

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

DR. AND MRS. ROBERT SHARKEY, on behalf of
RYAN REED SHARKEY, a minor,
Plaintiffs/Appellants,

v.

FOOD AND DRUG ADMINISTRATION,
Defendant/Appellee,

and

MERCK & CO., INC.,
Defendant-Intervenor/Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA

REPLY BRIEF FOR APPELLANTS

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ARGUMENT

The principal issue in this case is whether defendants have met their burden of demonstrating with undisputed evidence that the requested documents may be withheld under FOIA Exemption 4 because disclosure of the records would likely cause substantial competitive harm to Merck or Glaxo. Defendants' speculation concerning the possibility of future competitive harm is too attenuated, unexplained, and illogical to carry their burden. Defendants argue that disclosure of the requested records could allow a series of estimates to be drawn from combinations of unknown variables, setting off a perfect storm that could, some day, cause them competitive harm. As explained below, defendants have failed to provide sufficient evidence and explanation to support their domino theory, and Exemption 4 does not protect information that could cause harm only in combination with additional variables that would remain unknown.

Even if defendants' claims of competitive harm were not too attenuated to carry their burden, the district court erred in granting summary judgment because plaintiffs produced an affidavit from a vaccine expert that disputed the material facts on which defendants' argument depends. Defendants do not dispute that the parties produced conflicting evidence; rather, they argue that the statements of plaintiffs' expert should be ignored because he is scientist and not a salesperson. As explained below, defendants' argument is meritless, and plaintiffs' expert affidavit created fact disputes

sufficient to preclude summary judgment for defendants. In the alternative, pursuant to Fed. R. Civ. P. 56(f), the district court should have allowed discovery to reveal the basis for defendants' conclusory allegations and additional time for plaintiffs to submit evidence to challenge any basis revealed.

I. This Decision Below Must Be Reviewed *De Novo*.

Although FDA and Merck disagree with each other as to the standard of review, both assert that at least part of this case should be reviewed for clear error. Defendants are wrong. Except in limited circumstances not relevant here, this Court reviews summary judgment decisions in FOIA cases *de novo*. *Office of the Capital Collateral Counsel, N. Region of Florida ex rel. Mordenti v. Dep't of Justice,* 331 F.3d 799, 802 (11th Cir. 2003); *Times Pub. Co. v. U.S. Dep't of Commerce,* 236 F.3d 1286, 1288 n.1 (11th Cir. 2001). At least seven other circuits do the same.[1]

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[1] *See Assassination Archives & Research Ctr. v. CIA*, 334 F.3d 55, 57 (D.C. Cir. 2003) ("We review the district court's grant of summary judgment *de novo*. In the FOIA context, *de novo* review requires the court to ascertain whether the agency has sustained its burden of demonstrating that the documents requested are not 'agency records' or are exempt from disclosure under the FOIA.") (internal citations omitted); *Church of Scientology Int'l v. U.S. Dep't of Justice*, 30 F.3d 224, 228 (1st Cir. 1994) ("Our review of the district court's determination that the government was entitled to summary judgment based on its index and affidavits is *de novo*."); *Halpern v. FBI*, 181 F.3d 279, 278-88 (2d Cir. 1999) (rejecting the clear error standard and finding "that a *de novo* standard of review applies on appeal from a district court's grant of summary judgment in FOIA litigation"); *Hanson v. U.S. Agency for Int'l Dev.*, 372 F.3d 286, 290 (4th Cir. 2004) ("The

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Defendants' confusion stems from a line of cases that apply a two-tiered standard of review where the applicability of a FOIA exemption depends on the *content* of the withheld documents. That type of FOIA case presents a unique difficulty for the requesting party, because the requester lacks access to the information on which the exemption claim is based. Therefore, procedures have been established to ensure that the district court has an "adequate factual basis" to determine the applicability of the claimed exemption. *See, e.g., Vaughn v. Rosen*, 484 F.2d 820 (D.C. Cir. 1973). Such procedures can include, for example, the provision of a detailed *Vaughn* index or *in camera* inspection of the withheld documents. In cases involving such circumstances, this Court has stated that it must first determine whether the district court had an adequate factual basis to make the decision, then determine whether the decision was clearly erroneous. *See Miscavige v. IRS*, 2 F.3d 366, 367 (11th Cir. 1993); *Currie v. IRS*, 704 F.2d 523, 528 (11th Cir. 1983); *Chilivis*

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question of whether a district court properly granted the government summary judgment in a FOIA action is one of law which we review de novo."); *Avondale Indus., Inc. v. NLRB*, 90 F.3d 955, 958 (5th Cir.1996) (rejecting clearly erroneous standard and applying *de novo* review to a district court's grant of summary judgment based on the applicability of a FOIA exemption); *Rugiero v. Dep't of Justice*, 257 F.3d 534, 543 (6th Cir. 2001) ("[T]his court reviews the propriety of a district court's grant of summary judgment in a FOIA proceeding de novo."); *Utah v. U.S. Dep't of Interior*, 256 F.3d 967, 969 (10th Cir. 2001) (reviewing *de novo* the district court's grant of summary judgment in a FOIA case).

v. SEC, 673 F.2d 1205, 1210 (11th Cir. 1982); *Stephenson v. IRS*, 629 F.2d 1140, 1144 (5th Cir. 1980).

In this case, the basis for the exemption claimed by defendants is not found *within* the requested documents themselves. The withheld records set forth by lot the net number of hepatitis B vaccine doses distributed in the United States, but those records do not include any information about whether Merck or Glaxo would suffer substantial competitive harm if the numbers were released. The factual assertions on which defendants base their competitive harm claim are found entirely in declarations filed in support of their summary judgment motions and are equally available to plaintiffs. Because this case does not present the unique problem found in the FOIA cases that use the two-tiered standard of review, this case is subject to *de novo* review just like any other appeal of a summary judgment.

FDA acknowledges, as it must, that a grant of summary judgment in a FOIA case is reviewed *de novo*. FDA Br. 8.[2] However, FDA asserts that a district court's findings of fact in FOIA cases decided on summary judgment are reviewed for clear

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[2]Indeed, eight days before it filed its brief in this case, the government filed a brief in another FOIA case in this Court. The "standard of review" section of that brief contains a single sentence and a single citation: "A grant of summary judgment in a case under FOIA is subject to de novo review. *Office of Capital Collateral Counsel, N. Region of Florida ex rel. Mordenti v. Dep't of Justice*, 331 F.3d 799, 802 (11th Cir. 2003)." Brief for Appellants, *Sun-Sentinel Co. v. U.S. Dep't of Homeland Security*, No. 06-13306-EE (11th Cir. filed July 17, 2006).

error. *Id.* (citing *Miscavige* and *O'Kane v. U.S. Customs Serv.*, 169 F.3d 1308, 1309 (11th Cir. 1999)). *Miscavige* does not support FDA's assertion.

In *Miscavige*, the FOIA exemptions claimed by the government were based on information within the requested documents, and the issue was whether affidavits alone sufficed to sustain the government's burden of demonstrating that the claimed exemptions applied. 2 F.3d at 367. Recognizing that it was dealing with the "peculiarly difficult" type of FOIA case where the "exemptions turn on protected information contained in the [withheld] records," the Court recited *Stephenson*'s two-tiered standard of review. *Id.* ("[W]e must decide whether the district court had an adequate factual basis to render a decision that is not clearly erroneous.") (citing *Stephenson*, 629 F.2d at 1144). The Court then held that, "in certain cases, affidavits can be sufficient for summary judgment purposes in an FOIA case if they provide as accurate a basis for decision as would sanitized indexing, random or representative sampling, *in camera* review, or oral testimony." *Id.* at 368. This case does not implicate the two-tiered standard of review used in *Miscavige*, because the claimed exemption does not turn on the withheld information itself, and the adequacy of the government's description of the withheld documents is not at issue.[3]

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[3]Nor does *O'Kane* support the FDA's contention that clear error is the standard of review for findings of fact on which the district court rests a grant of
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Merck goes further than FDA and argues broadly that "[d]ecisions of the district courts determining the applicability of a FOIA exemption are reviewed by this Court for clear error." Merck Br. 13. Merck relies primarily on *Brown v. U.S. Dep't of Justice*, 169 Fed. Appx. 537, 539 (11th Cir. 2006), an unpublished decision lacking precedential value. *See* 11th Cir. R. 36-2.[4]

Moreover, although *Brown* recites the clear error language from *Miscavige*, it was an appeal from a dismissal for failure to state a claim and was reviewed *de novo*. 169 Fed. Appx. at 539. The plaintiff in *Brown* invoked FOIA to challenge the agency's failure to produce certain records in a timely fashion, but the Court held that the FOIA claim was moot because the documents had been produced. *Id.* at 540. All but one of the other cases on which Merck relies are part of the *Stephenson* line of

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summary judgment. Although *O'Kane* recited the *Miscavige* standard, *see* 169 F.3d at 1309, that standard played no role in the decision because the FOIA exemption at issue in *O'Kane* did not turn on the withheld information itself—the home addresses of customs law violators—but on the private-public interest balancing test of FOIA Exemption 6.

[4]To the extent the Court considers unpublished decisions as persuasive authority, it should look to *Hardison v. Sec'y of Veterans Affairs*, 159 Fed. Appx. 93, 94, 2005 WL 3370799, *1 (11th Cir. 2005). In *Hardison*, decided seven weeks before *Brown*, this Court stated that "[w]e review a district court's grant of summary judgment in a FOIA case *de novo*." *Id.* (citing *Capital Collateral Counsel,* 331 F.3d at 802).

cases and involve situations where the claimed exemption depended on the contents of the withheld documents. Merck Br. 13-14 (citing *Miscavige*, *Linsteadt v. IRS*, 729 F.2d 998 (5th Cir. 1984), *Currie, Chivilis,* and *Stephenson*). The other case, *Miami Herald Pub. Co. v. U.S. Small Bus. Admin.*, 670 F.2d 610, 614-15 (5th Cir. Unit B 1982), was an appeal following a bench trial and not an appeal from summary judgment. In *Miami Herald*, the Court applied the clearly erroneous standard to the district court's finding of fact that the testimony presented at trial "did not satisfy the [government]'s burden to show a likelihood of substantial competitive injury," and affirmed *de novo* the district court's legal conclusion that FOIA Exemption 4 was inapplicable to the information sought. *Id.*; *see Moye, O'Brien, O'Rourke, Hogan, & Pickert v. Nat'l R.R. Passenger Corp.*, 376 F.3d 1270, 1274 (11th Cir. 2004) (reviewing for clear error the district court's findings of fact following a bench trial and reviewing *de novo* district court's legal conclusions regarding applicability of a FOIA exemption).

Because the exemption claim at issue in this case is not based on information within the requested records, and because this case was decided on summary judgment instead of after trial, the cases cited by Merck and FDA are inapposite, and this case should be reviewed *de novo*. Thus, the issue is not whether the district court clearly erred, but whether defendants have met their burden of showing that

Exemption 4 permits the requested records to be withheld. *Compare* FDA's and Merck's statement of the issues, FDA Br. 1; Merck Br. 2, *with* plaintiffs' statement of the issues, Pl. Opening Br. 1.

II. Defendants Have Failed to Show That Substantial Competitive Injury Will Result from Disclosure of the Requested Information.

A. Defendants do not dispute that Merck and Glaxo already know or can easily calculate their respective shares of the domestic hepatitis B vaccine market, and defendants have failed to support their assertion that disclosure of such information could harm Merck or Glaxo with respect to foreign competition.

Both FDA and Merck argue that, in general, disclosure of sales volume and market share information can cause competitive injury. FDA cites several cases—none binding on this Court—in support of its claim that sales information is "traditionally protected from disclosure" in a "variety of contexts," as if such information is *per se* exempt from disclosure. FDA Br. 16. It is not. Rather, defendants must explain in detail *how* disclosure of the specific information at issue in this case would cause substantial competitive injury to Merck or Glaxo. *See Public Citizen Health Research Group v. FDA,* 704 F.2d 1280, 1291 (D.C. Cir. 1983) ("Conclusory and generalized allegations of substantial competitive harm, of course, are unacceptable and cannot support an agency's decision to withhold requested documents.").

None of the cases cited by FDA holds that sales information is categorically exempt from disclosure under FOIA, and several of the cases are not on point. For example, *Public Citizen* did not involve sales information; rather, the FOIA request at issue sought "clinical test information" and "reports of complications and adverse reactions." 704 F.2d at 1283. "The theory underlying the withholding of most of the information was that the manufacturers would sustain substantial competitive injury because their competitors would be receiving free of charge, the benefits of their costly research and testing." *Id.* at 1284 (internal quotes and citation omitted). Similarly, FDA cites *Allen v. Howmedica Leibinger*, 190 F.R.D. 518 (W.D. Tenn. 1999), which is not even a FOIA case. *Allen* involved a motion to compel compliance with a subpoena duces tecum served on a nonparty. *Id.* at 519. The issue in *Inter Ocean Free Zone, Inc. v. U.S. Customs Serv.*, 982 F. Supp. 867 (S.D. Fla. 1997), was whether the entity that submitted the withheld information was out of business and thus could not suffer competitive harm. *Id.* at 872. And in *Lion Raisins Inc. v. USDA*, 354 F.3d 1072, 1080 (9th Cir. 2004), the court did not find that the requested information was exempt from disclosure simply because it contained sales information, but because the government submitted declarations containing "detailed and specific descriptions of . . . the ways in which each category of information could be turned to [the requester's] competitive advantage."

Merck claims that "[p]laintiffs implicitly acknowledge that learning a competitor's sales volume and market share information likely would cause substantial competitive injury." Merck Br. 22. Plaintiffs have acknowledged no such thing. To the contrary, plaintiffs explained that no competitive harm could possibly arise from revelation of Merck's and Glaxo's domestic market share and sales volume information because that information is already available to Merck and Glaxo—the only two companies allowed to compete for sales in the domestic market. *See Public Citizen,* 704 F.2d at 1291 n.30 ("We emphasize that the important point for competitive harm in the FOIA context is that it be limited to harm flowing from the affirmative use of proprietary information *by competitors*.") (internal quotes and citation omitted) (emphasis in original).

Merck concedes that with knowledge of the total net number of doses distributed in the United States, both Merck and Glaxo can calculate one another's sales figures and market share. *Id.* at 23. Forced to acknowledge this fact, Merck now questions, but does not dispute, the accuracy of the government report that reveals the total net number of doses. *Id.* at 9 & 23. Indeed, FDA's declarant swore that the study "provides the combined net number of doses distributed for hepatitis B vaccines licensed in the United States during the 1991-2001 period." Doc. 39-2 at 11 n.4. Most tellingly, not one of defendants' declarants asserts that the two

manufacturers lack knowledge of the total net number of doses of hepatitis B vaccine distributed annually in the United States, and Merck acknowledges that demand for the hepatitis B vaccine is steady. Merck Br. 8.

Merck also argues that disclosure of the requested information would provide information about Merck's and Glaxo's United States market share and sales volume to "domestic competitors aside from the two that already have licenses." Merck Br. 23. Of course, there are no such domestic competitors. Only Merck and Glaxo are licensed to distribute the vaccine in the United States. Merck does not even attempt to confront plaintiffs' argument that speculation about potential future competition is inapposite because Exemption 4 applies only where the entity that claims it will suffer harm is in *actual* competition. *See* Pl. Opening Br. 17.

FDA confronts the argument only indirectly, citing *Judicial Watch, Inc. v. FDA*, 449 F.3d 141, 148-49 (D.C. Cir. 2006), for the proposition that release of information from a sole manufacturer can cause economic harm to the submitter because a potential entrant in the market could use the requested data. FDA Br. 21. But *Judicial Watch* involved a request for information far broader than the lot-specific information sought here. There, the request sought "all documents related to the [FDA]'s approval of the drug mifepristone," *id.* at 144, including the voluminous contents of the Investigational New Drug application (IND) and New

Drug Application (NDA), *id.* at 148. Because the IND and NDA contain every piece of information needed to bring a drug to market, a competitor could use the data from a sole manufacturer's NDA "in its own NDA without incurring the time, labor, risk, and expense involved in developing them independently." *Id.* at 149 (internal quotes and citation omitted). Even so, the court in *Judicial Watch* held that "Exemption 4 does not categorically exempt all information in INDs and NDAs," *id.*, and, without reaching the merits, remanded the case for further explanation of the basis for the Exemption 4 claim. *Id.* at 150. In this case, FDA has not explained how knowledge of Merck's and Glaxo's respective shares of the domestic hepatitis B vaccine market could provide "valuable insight" to a new entrant and cause harm to Merck or Glaxo. *See* FDA Br. 21.

Although FDA claims that plaintiffs "ignore potential foreign competition in the hepatitis B vaccine market," *id.*, plaintiffs in their opening brief noted that their request seeks only information regarding the net doses per lot distributed in the United States, and that defendants had failed to explain how release of the requested information could cause harm to Merck or Glaxo abroad. Pl. Opening Br. 17. Merck now concedes that such harm could result, if at all, only to the extent that knowing domestic market share assists a foreign competitor to discover Merck's or Glaxo's manufacturing *capacity*. Merck Br. 24. As explained in plaintiffs' opening brief (at

18-20) and below, disclosure of the specific information requested cannot reveal production capacity.

B. Defendants' assertions that competitive harm could result from disclosure of total lot size, production capacity, and process parameters are irrelevant because such information cannot be revealed by disclosure of the requested records.

Merck claims that "[p]laintiffs do not dispute, and thus seemingly concede," that disclosure of Merck's or Glaxo's total lot size or respective production capacities would cause substantial competitive harm. Merck Br. 24. Plaintiffs have conceded nothing of the sort. Rather, plaintiffs have shown that the specific information they requested *cannot* reveal that information. *See* Pl. Opening Br. 18-20. Because each manufacturer's production capacity cannot be revealed by disclosure of the records sought, Merck's argument that production capacity information is categorically entitled to Exemption 4 protection is inapposite.[5]

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[5]Merck cites five cases in support of its claim that knowledge of a manufacturer's production capacity in all cases would likely cause substantial competitive harm. Merck Br. 24-26. Of the five cases Merck cites, only a single unpublished decision found that production capacity was entitled to Exemption 4 protection and only because detailed declarations "convincingly demonstrate[d]" that the requested materials "would permit other []manufacturers to preempt [the submitter]'s plans by duplicating the arrangements it has produced without incurring associated costs." *Lederle Labs. v. Dep't of Health and Human Servs.*, No. 88-0249, slip op. at 17-18 (D.D.C. July 14, 1988) (attached at Merck Br. Tab A). The other four cases do not involve production capacity, and one of the cases does not even involve Exemption 4. *See Stewart-Warner Corp. v. U.S. Customs*

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Defendants' primary argument is that "[d]isclosure of the requested information, in combination with other data, is likely to cause substantial competitive harm to Merck and Glaxo." Merck Br. 26; *see also* FDA Br. 23-26. Merck recognizes plaintiffs' position that "too many unknown variables render disclosure of the requested data harmless," but offers no direct response to plaintiffs' argument that the net number of doses by lot cannot reveal the total number of doses that comprise the lot, the maximum number of doses that could have been produced in the lot, or the speed with which the lot was made. Instead, Merck cites a handful of cases where courts have protected information based on a precise explanation of how the requested data could cause harm in combination with other readily available information. Merck Br. 27.

Merck misses the point. Plaintiffs do not argue that information that is harmless on its own can *never* be withheld even if there is a detailed showing of how

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Serv., 1981 U.S. Dist. LEXIS 18394, at *13 (D.D.C. June 6, 1981) (finding that requested documents contain unit prices and quantities imported, costs of freight, insurance, and duties, and names and addresses of sellers and purchasers); *Public Citizen Health Research Group v. NIH*, 209 F. Supp. 2d 37, 39 (D.D.C. 2002) (requesting royalty rates); *Morrison-Knudsen Co., Inc. v. Dep't of the Army*, 595 F. Supp. 352, 353 (D.D.C. 1984) (seeking historical cost data withheld under FOIA Exemption 5 based on a claim of privilege); and *Public Citizen Health Research Group v. FDA*, 185 F.3d 898, 900 (D.C. Cir. 1999) (seeking documents relating to drug applications that had been abandoned for health and safety reasons).

disclosure would cause harm in combination with other readily available data. Rather, plaintiffs argue that defendants have failed to make such a showing with respect to the data at issue here.

Indeed, Exemption 4 protection has often been denied despite a claim that the information could cause harm in combination with other variables where, as here, there was no showing that the other variables were public information or could be deduced. *See GC Micro Corp. v. Defense Logistics Agency*, 33 F.3d 1109, 1115 (9th Cir. 1994) (holding that requested information is not protected under Exemption 4 where "[t]he data is made up of too many fluctuating variables for competitors to gain any advantage from the disclosure"); *New York Times Co. v. Dep't of Labor*, 340 F. Supp. 2d 394, 402 (S.D.N.Y. 2004) (ordering disclosure where requested information "cannot easily be 'reverse engineered'" to reveal confidential commercial information); *Ctr. for Pub. Integrity v. Dep't of Energy*, 191 F. Supp. 2d 187, 194-95 (D.D.C. 2002) (rejecting Exemption 4 claim as "not supported by logic or the evidence" where agency sought to withhold a total bid amount on the theory that it would allow competitors to discern the submitter's multiple factor valuation methodology); *Brownstein Zeidman and Schomer v. Dep't of the Air Force*, 781 F. Supp. 31, 33 (D.D.C. 1991) (holding that "Exemption 4 does not apply where the damage that the [submitter] will suffer as a result of release of confidential

information is only speculative," and requiring release of unit prices because of lack of explanation as to how a competitor would obtain other variables needed to make use of the information); *Racal-Milgo Gov't Sys., Inc. v. Small Business Admin.*, 559 F. Supp. 4, 6 (D.D.C. 1981) (rejecting government's claim that "disclosure of the prices for computer equipment would allow a competitor to calculate the supplier's manufacturing costs," because such calculations would require knowledge of additional information); *see also Pacific Architects & Eng'rs Inc. v. U.S. Dep't of State*, 906 F.2d 1345, 1347 (9th Cir. 1990) (upholding determination, in reverse FOIA case, that Exemption 4 did not prevent disclosure of "aggregate figures . . . made up of a number of fluctuating variables" where disclosure would not reveal "the various component parts that make up" the requested data); *Acumenics Research & Tech. v. U.S. Dep't of Justice*, 843 F.2d 800, 808 (4th Cir. 1988) (agreeing, in reverse FOIA case, "with the district court's conclusion that there are too many unascertainable variables" comprising the requested data "for a competitor to derive accurately" information that could harm the submitter); *Martin Marietta Corp. v. Dalton*, 974 F. Supp. 37, 40 (D.D.C. 1997) (upholding, in reverse-FOIA case, agency determination that submitter had "failed to demonstrate with sufficient specificity precisely how it will suffer substantial harm" from release of its cost and pricing information and proprietary management strategies).

The fallacy of defendants' argument that the requested information, though harmless on its own, could cause harm in combination with other facts that will remain secret, is revealed by FDA's awkward attempt to describe the potential for future harm by layering estimate on top of estimate. FDA argues that

> [E]ven if the actual gross number of doses per lot is not revealed . . . [the requested information] would give a competitor a fair *estimate* of the gross number of doses distributed per lot. A competitor could then use this *estimate* to determine *estimates* of both manufacturing capacity and inventory for both Glaxo and Merck. For example, competitors could multiply the *estimated* number of doses per lot distributed by the number of lots released per year to *estimate* the number of doses manufactured per year, which provides information regarding a manufacturer's lower limits of its maximum production capacity. In turn, the lower limits of a manufacturer's maximum production capacity provide an *estimate* of that manufacturer's inventory. Knowing an *estimate* of a manufacturer's inventory could help competitors determine the manufacturer's ability to compete in certain markets and to respond to increased demands for the product. . . . Competitors with a knowledge of vaccine manufacturing could use an *estimate* of the lot yield to determine other process parameters outlined in the vaccine formula, such as incubation times.

FDA Br. 23-24 (emphasis added) (internal citations omitted). FDA's attempt to describe how Merck and Glaxo might suffer from the release of the requested information shows that defendants' Exemption 4 claim is based on a series of leaps far too attenuated and speculative to justify withholding the requested records. Moreover, as explained below, defendants' claim is not supported by logic or the

evidence. *See Ctr. for Pub. Integrity*, 191 F. Supp. 2d at 194-95; *Brownstein Zeidman*, 781 F.Supp. at 33.

First, the requested information cannot reveal the number of doses *manufactured* in any given lot because the requested data will not include the number of doses from the lot that, for instance, were distributed but returned unused, held as inventory, or distributed abroad. Second, even knowledge of total lot size cannot reveal manufacturing *capacity* in the absence of evidence that the largest lot size actually made equals the largest lot that could have been made, and there is no such evidence. Doc. No. 45, Ex. B, ¶ 20. Indeed, Merck admits that demand for the vaccine is steady; thus, there is no reason to believe that Merck and Glaxo manufacture as much vaccine in each lot as they are able, given that they can predict what the demand for their product is likely to be. Merck Br. 8. Put otherwise, the two manufacturers simply produce enough vaccine to meet the publicly-known demand for their product, which may or may not be equivalent to the manufacturers' capacity. Third, there is no such thing as "a manufacturer's lower limits of its maximum production capacity." FDA Br. 23 (citing Doc. No. 52, Ex. A, ¶ 7). This oxymoron is nonsensical, and thus provides no evidence that a method exists by which a competitor can estimate a manufacturer's inventory.

Similarly, the claim that release of the requested information could reveal incubation times is completely unexplained. The only potential competitive harm that defendants allege could flow from revelation of incubation times is that competitors could, with the addition of other variables, estimate the time needed to produce a lot and thus determine Merck's or Glaxo's ability to respond to an unexpected upsurge in demand (notwithstanding Merck's admission that demand is steady). That conclusion rests on the unsupported assumption that production speed alone, rather than both production speed and inventory on hand, determine a manufacturer's ability to fill orders. Moreover, the harm that Merck claims it would suffer if its inability to meet demand was revealed is even more bizarre. Merck asserts that "[i]f a competitor knew that Merck did not have the capability to fill a large tender order, it could price its product to exploit that knowledge, thereby enhancing its overall market performance, confident that Merck could not submit a competitive bid." Merck Br. 10. Merck cannot suffer competitive harm by losing an opportunity that it lacked the ability to seize in the first place.

In sum, defendants assert that release of the requested information, in combination with multiple layers of unknown and unspecified variables, could set off a domino effect that might—at some point in the future—result in competitive harm.

This speculative chain of events is insufficient to justify withholding the documents at issue.

III. The District Court Erred in Granting Summary Judgment for Defendants Because Material Facts Are in Dispute and Abused Its Discretion by Denying Plaintiffs Discovery.

As explained above, plaintiffs are entitled to summary judgment because defendants have failed to meet their burden to demonstrate that the requested records are exempt from disclosure. But even if defendants' claims of competitive harm were not too attenuated to establish that Exemption 4 applies, the district court erred in granting summary judgment for defendants because facts are in dispute. The standard is clear and well-known: Summary judgment is appropriate only if "there is no genuine issue as to any material fact and [] the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). "[T]hese general standards under Rule 56 apply with equal force in the FOIA context." *Washington Post Co. v. U.S. Dep't of Health and Human Servs*., 865 F.2d 320, 325 (D.C. Cir. 1989). Thus, summary judgment should be granted in a FOIA case only if there is "no contradictory evidence in the record." *Public Citizen Health Research Group v. FDA*, 953 F.Supp. 400, 402 (D.D.C. 1996) (quotation marks and citation omitted). "Where there is a conflict in the affidavits as to what adverse consequences will flow from the revelation of the facts contained in the documents sought to be disclosed, then it appears that there is

indeed a conflict regarding very material facts . . . ." *Sears, Roebuck & Co. v. Gen'l Servs. Admin.*, 553 F.2d 1378, 1382 (D.C. Cir. 1977) (finding summary judgment inappropriate where affidavits differed on whether competitive harm would ensue); *see also Niagara Mohawk Power Corp. v. U.S. Dep't of Energy*, 169 F.3d 16, 18 (D.C. Cir. 1999) (same where there were issues of material fact over whether companies faced competition); *Greenberg v. FDA*, 803 F.2d 1213, 1218 (D.C. Cir. 1986) (same where there were issues of material fact over whether disclosure would result in substantial harm); *Worthington Compressors, Inc. v. Costle*, 662 F.2d 45, 54 (D.C. Cir. 1981) (remanding "to resolve the factual issues relevant to consideration of 'substantial competitive harm'").

Assuming that defendants' assertions, if undisputed, would be sufficient to meet their burden, the conflict here, over whether substantial competitive harm would likely ensue from disclosure of the requested records, "calls for some type of adversary procedure." *Sears*, 553 F.2d at 1382 (remanding case for "discovery by interrogatories, oral depositions, requests for admissions, or an open hearing in court"); *see also Public Citizen*, 953 F. Supp. at 403 (finding summary judgment an "inappropriate vehicle" and requiring a bench trial where affiants disagreed whether release of the records would work a substantial competitive harm). In their opening brief, plaintiffs showed that each of the four assertions on which the magistrate judge

based her conclusion that release of the requested information would cause competitive harm was directly contradicted in the affidavit of Donald H. Marks, M.D., Ph.D. In particular, Dr. Marks provided evidence disputing whether release of the withheld information could provide insight into manufacturers' production capacities, incubation times, and marketing capabilities, whether it would allow a competitor to better estimate manufacturing capabilities and production specifics, and whether it would result in a significant competitive disadvantage for the manufacturers. *See* Pl. Opening Br. 22-25.

Defendants do not contest that Dr. Marks's affidavit set forth contradictory evidence. Instead, they seek to discredit Dr. Marks himself, claiming that he is not qualified to offer his opinion because he is a physician and scientist rather than a salesperson. Merck Br. 32. Dr. Marks, however, has over fifteen years of experience in the vaccine industry. Doc. No. 45, Ex. B, ¶¶ 1-7. He holds a medical degree, a doctorate in microbiology, and has extensive experience in the research, development, and production of vaccines that, like the hepatitis B vaccine, are recombinant or genetically engineered. Moreover, Dr. Marks has obtained regulatory approval for vaccines, holds three patents relating to viral vector vaccines, and worked with a group starting a vaccine company, now known as Vaxin, with which he is still affiliated. *Id*. Given his wide-ranging experience in the vaccine field, Dr. Marks is

qualified to testify on whether release of the net number of doses per lot of the hepatitis B vaccine would cause Merck and Glaxo substantial competitive harm.

Defendants' assertions of competitive harm rest on claims that the requested data would provide insight to those with "significant training and experience" in the science of vaccine manufacturing. Doc. No. 53-3 ¶ 7; *see also* Doc. No. 39-4 ¶ 5 (claiming release of information would allow competitors to deduce process parameters and give insight into incubation times); Doc. No. 52, Ex. B ¶ 7 (claiming release of the information would allow competitors to learn manufacturing capabilities and production specifics). As someone who has himself produced vaccines, Dr. Marks is particularly well-qualified to testify on whether release of the net number of doses per lot would shed any light on the manufacturing process. In contrast, defendants' declarants have experience in sales and marketing, not in the science of vaccine production. *See, e.g.*, Doc. 52, Ex. B, ¶ 2 (explaining that declarant has worked "in a variety of sales and marketing positions" and "in commercial and investment banking"). To determine whether disclosure of the net number of doses by lot of vaccine would provide insight into vaccine production methods, the question of whether to credit a scientist and physician with extensive

experience in the manufacture of vaccines, or a salesperson whose job is to market his employer's product, is unquestionably one for a trier of fact.[6]

Defendants also claim that Dr. Marks's affidavit was too speculative. Plaintiffs showed in their opening brief, however, that Dr. Marks's affidavit contains more detail and is less conclusory than defendants' own declarations. Pl. Opening Br. 25. For example, quoting one-half of one sentence of Dr. Marks's affidavit, defendants assert that the argument that "too many variables exist to make the requested data useful to a competitor [] was never even mentioned by Dr. Marks, except in a conclusory manner."[7] Merck Br. 32. In fact, Dr. Marks goes on to give specific examples of other variables that make it impossible to determine the maximum or optimum amount of volume per dose per lot of vaccine manufactured simply by receiving information on net number of doses by lot. Doc. No. 45, Ex. B, ¶ 19. In contrast, defendants' declaration on this point states only that, "if released, the information would likely reveal the maximum or optimum amount of volume per dose

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[6]Merck also attempts to discredit Dr. Marks by labeling him a "professional witness," which is more than a little ironic given that Merck's declarants are, literally, on Merck's payroll. *See* Doc. No. 52, Ex. A, ¶ 2 (employed by Merck since 1988); Doc. No. 52, Ex. B, ¶ 2 (employed by Merck for the last 18 years).

[7]Defendants' own declarant agrees that "[i]n the context of vaccine manufacturing, production capacity is a complex equation consisting of many variables." Doc. No. 53-3, ¶ 6.

per lot of the vaccine that each manufacturer produced during the last ten to twenty years," without giving *any* explanation of *how* release of the requested records would reveal such information. Doc. No. 39-2 ¶ 28.

Even assuming defendants have met their burden, because there are genuine issues of material fact, this Court should reverse and remand this case for further proceedings. In addition, the Court should instruct the district court to allow plaintiffs to take discovery. Plaintiffs have never been allowed to take any discovery in this case, and summary judgment should not be granted without affording such opportunity. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S. Ct. 2548, 2552 (1986). In claiming that discovery is not necessary, defendants cite cases in which discovery was denied because there was no conflicting factual information. *See Carney v. U.S. Dep't of Justice*, 19 F.3d 807, 813 (2d Cir. 1994) (where plaintiff had no "factual support," the district court "did not abuse its discretion in denying him discovery"); *Public Citizen Health Research Group v. FDA*, 997 F. Supp. 56, 73 (D.D.C. 1998) (denying discovery where "no factual dispute remains"), *aff'd in part, rev'd in part,* 185 F.3d 898 (D.C. Cir. 1999). These decisions are inapposite because plaintiffs have shown here that there are real fact disputes.

Defendants' assertion that government declarations are accorded a presumption of good faith is similarly misplaced. That government officials are presumed not to

have submitted declarations in bad faith does not mean that the district court must automatically accept all factual conclusions in agency declarations as true, even in the face of conflicting evidence. Judicial review of FOIA cases is *de novo* with no deference to the agency, *see* 5 U.S.C. 552(a)(4)(B), and even the cases relied on by defendants recognize that, despite the presumption that government officials have not submitted declarations in bad faith, discovery can be justified when plaintiffs have presented evidence showing that the exemption relied on by the government does not apply. *See Carney*, 19 F.3d at 812. Here, as explained in plaintiffs' opening brief, plaintiffs presented more than enough evidence to show that summary judgment in favor of the defendants was inappropriate and that they needed discovery to more fully develop the evidentiary record. *See Washington Post*, 865 F.2d at 326 (in Exemption 4 case, noting that "the ultimate 'facts' in dispute are most successfully approached when all relevant evidentiary underpinnings are fully developed").

CONCLUSION

The Court should reverse the decision of the district court and order FDA to disclose the requested information. In the alternative, the Court should remand the case and instruct the district court to allow plaintiffs to take discovery.

Respectfully submitted,

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August 7, 2006

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Reply Brief for Appellants complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B). The brief is composed in a 14-point proportional typeface, Times New Roman. As calculated by my word processing software (WordPerfect), the Brief contains 6,458 words, excluding the parts exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

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CERTIFICATE OF SERVICE

I hereby certify that on August 7, 2006, I filed the foregoing Reply Brief for Appellants by mailing it to the Clerk of the U.S. Court of Appeals for the Eleventh Circuit by First-Class Mail. Also on that date, I served a copy of this brief by mailing it to:

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