

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued May 11, 1999 Decided August 6, 1999

No. 98-5161

Public Citizen Health Research Group,  
Appellee

v.

Food & Drug Administration,  
Appellant in 98-5161

Schering Corporation,  
Appellant in 98-5162

Consolidated with  
98-5162

Appeals from the United States District Court  
for the District of Columbia  
(No. 94cv00018)

Marina Utgoff Braswell, Assistant U.S. Attorney, argued  
the cause for appellant Food & Drug Administration. With

her on the briefs were Wilma A. Lewis, U.S. Attorney, and R. Craig Lawrence, Assistant U.S. Attorney.

Bruce N. Kuhlik argued the cause and filed the briefs for appellant Schering Corporation.

Amanda Frost argued the cause for appellee. With her on the brief was Brian Wolfman. Lucinda A. Sikes entered an appearance.

Marjorie E. Powell was on the brief for amicus curiae Pharmaceutical Research and Manufacturers of America.

Before: Ginsburg, Henderson, and Garland, Circuit Judges.

Opinion for the Court filed by Circuit Judge Ginsburg.

Opinion concurring in the result filed by Circuit Judge Garland.

Ginsburg, Circuit Judge: Pursuant to the Freedom of Information Act, the Public Citizen Health Research Group asked the Food and Drug Administration for documents relating to drug applications that had been abandoned for health or safety reasons. The FDA denied this request and Public Citizen sued the agency in district court, where Schering Corporation, which had submitted five investigational new drug applications (INDs) of the sort requested by Public Citizen, intervened as a defendant. The FDA and Schering claimed that certain of the documents in those five INDs contained confidential commercial information and therefore could be withheld under Exemption 4 of the FOIA, 5 U.S.C. s 552(b)(4). Public Citizen argued that the documents could not be withheld under that exemption and that in any event disclosure was required under 21 U.S.C. s 355(1), which it asserted sets a standard for nondisclosure higher than that in Exemption 4 of the FOIA.

The district court ordered the release of all the disputed documents on the ground that, although some could be withheld under Exemption 4, the FDA had not met the higher

standard of s 355(1). We affirm the judgment of the district court in part, albeit on a different ground, reverse it in part, and remand the case for further proceedings consistent with this opinion.

#### I. Background

Before marketing a new drug in the United States a manufacturer must obtain the approval of the FDA contingent upon clinical (i.e., human) tests showing that the drug is safe and effective. See 21 U.S.C. s 355(a), (d). Before a company may begin clinical testing, however, it must first submit an IND describing the drug, the results of laboratory and pre-clinical (i.e., animal) testing, and the proposed clinical testing. See id. s 355(i). An applicant may begin the proposed clinical testing 30 days after submitting its IND; the FDA, however, may place the testing on hold at any time. See 21 C.F.R. ss 312.40(b), 312.42. During clinical testing the company must update its IND with safety reports, annual reports on the progress of the testing, any amendments to the testing protocols, and other information. See id. ss 312.30-312.33. After clinical testing, the company must file a new drug application (NDA), which must include information about the results of both pre-clinical and clinical testing; information previously submitted in the IND may be incorporated by reference into the NDA. See 21 U.S.C. s 355(b); 21 C.F.R. s 314.50.

This case began when Public Citizen filed a FOIA request with the FDA for "[a]ll documents concerning pre-clinical and clinical studies for all prescription drugs which had a discontinuance of the clinical trials because of death or serious injury of patients or because of safety concerns from preclinical studies ... between January 1, 1990 and [July 12, 1993]." When the agency denied the request Public Citizen filed suit in the district court seeking release of the documents.

The FDA moved to dismiss, arguing that although a search of its database identified 230 INDs for which the agency had received safety reports and which were either withdrawn, terminated, or placed on hold by the FDA, it could not

without an unduly burdensome manual search of each file determine which of these were discontinued "because of" health or safety concerns. The district court denied the motion to dismiss, and the agency then determined that 14 of the 230 INDs were responsive to the FOIA request; of those, only portions of the five filed by Schering are at issue in this appeal.

On cross-motions for summary judgment, the district court first held that the disputed documents in the five INDs could be withheld under Exemption 4, because they contain "commercial or financial information obtained from a person [that is] privileged or confidential." 5 U.S.C. s 552(b)(4). Schering's affidavits demonstrated to the court that disclosure would "cause substantial harm to [its] competitive position." National Parks & Conservation Ass'n v. Morton ("National Parks I"), 498 F.2d 765, 770 (D.C. Cir. 1974). The district court then held that under 21 U.S.C. s 355(l)(1) the FDA must nonetheless disclose the same documents absent "extraordinary circumstances." Finding no such circumstances here, the court granted summary judgment for Public Citizen and ordered the agency to release the disputed documents. Both the FDA and Schering appealed to this court.

## II. Analysis

The FDA and Schering argue that the agency may under s 355(l) withhold any data pertaining to the safety and effectiveness of an abandoned drug that it may withhold under Exemption 4 of the FOIA--in other words, that the standards in the two statutes are the same. Public Citizen contends that s 355(l) imposes a more stringent standard for nondisclosure than that in Exemption 4. We need not resolve this dispute over the relationship between the two statutes, however, because we hold that s 355(l) does not apply to INDs. Viewing the documents solely through the lens of Exemption 4, we conclude that the FDA has justified withholding at least some information in four of the five INDs.

### A. Section 355(l)

Section 355(l) requires the FDA, upon request, to disclose "[s]afety and effectiveness data and information which has

been submitted in an application under subsection (b) [of s 355] for a drug" that subsequently was abandoned by its sponsor, "unless extraordinary circumstances are shown." 21 U.S.C. s 355(1)(1). No one disputes that an "application under subsection (b)" is an NDA. Schering argues that s 355(1), therefore, simply does not apply to information in an IND, which is submitted under subsection (i), not subsection (b). That is indeed the plain meaning of the provision, and we cannot understand how "submitted in an application under subsection (b)" could include anything other than information submitted in an NDA. Public Citizen's arguments to the contrary are not convincing.

First, Public Citizen contends that the agency applies s 355(1) to the disclosure of material submitted in an IND and that we should accord "substantial weight" to the FDA's view of its regulatory structure. As Schering notes, however, the FDA has never promulgated a regulation--nor are we apprised of any FDA decision or other document--so interpreting s 355(1). More important, it is apparent that the Congress has spoken to "the precise question at issue" here, *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837, 842-43 & n.9 (1984): s 355(1) by its terms applies only to "safety and effectiveness data and information" submitted in an NDA. Therefore, even if the agency had interpreted the phrase "subsection (b)" in s 355 to include information submitted in an IND, we could not defer to that interpretation.

Second, Public Citizen argues that to read s 355(1) as applying only to NDAs is erroneous because "the IND and NDA are not two distinct stages" in the drug approval process. In support of this view, Public Citizen points out that the FDA stores information related to the approval of a drug in its IND file even after an NDA is submitted. The fact remains, however, that NDAs and INDs are the subject of separate subsections of s 355 and the Congress referred only to one of them in s 355(1). We cannot help but conclude, therefore, that the statute treats the submission of an NDA as a discrete event in the drug approval process, regardless how the FDA maintains its files.

Third, Public Citizen contends that a plain meaning approach to s 355(1) leads to an illogical result: data and information submitted in an IND which later, rather than being resubmitted in an NDA, are incorporated by reference into the NDA would not be "submitted in an application under subsection (b)," that is, an NDA. The FDA and Schering offer a more sensible view, however: to incorporate IND materials by reference into an NDA is indeed to submit those materials as part of the NDA. By the same token, once those materials are incorporated by reference into an NDA, their disclosure is subject to the standard in s 355(1) even if the FDA keeps them in an IND file.

Finally, Public Citizen argues that "[i]t makes no sense to assume Congress enacted a statute mandating disclosure of safety and effectiveness data only when the sponsor had filed an NDA ..., but not when the sponsor had abandoned the drug earlier in the process." In this regard Public Citizen points out that the FDA accords the same treatment to such data regardless whether they were submitted in an NDA or an IND. Specifically, the FDA by regulation (21 C.F.R. s 312.130(b)) provides that disclosure of information in an IND "will be handled in accordance with" the regulation governing disclosure of information in an NDA (21 C.F.R. s 314.430(f)).

Nonetheless, when the Congress enacted s 355(1) it did not mandate disclosure of information in an IND. Moreover, Schering offers a perfectly sensible explanation why the Congress did not do so. The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, of which s 355(1) was a part, established an abbreviated process through which a company could obtain approval to market the generic equivalent of a drug that the FDA had previously approved on the basis of an NDA. See *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063-65 (D.C. Cir. 1998) (describing abbreviated new drug application process). The statute, Schering continues, does "not deal with INDs at all, and Congress had no reason in this legislative context to extend [s 355(1)] to them." Even if, as Public Citizen contends, it would be more wise not to treat informa-

tion submitted in an IND differently from information submitted in an NDA, a matter about which we express no opinion, the Congress may, of course, approach matters one step at a time. See *FCC v. Beach Communications, Inc.*, 508 U.S. 307, 316 (1993)

In view of the above analysis, we hold that s 355(1) does not apply to data and information submitted solely in an IND; such information may be withheld if the agency carries its burden under Exemption 4 of the FOIA. Schering did not file an NDA for four of the five INDs at issue in this case (which four we consider in Part II.B.1), but concedes that it filed two NDAs relating to the drug at issue in IND No. 18113. We need not determine the import of Schering's concession, however, for we conclude (in Part II.B.2) that documents in that IND cannot be withheld under the allegedly more lenient standard in Exemption 4.

#### B. Exemption 4

Exemption 4 of the FOIA permits an agency to withhold "commercial or financial information [that was] obtained from a person [and is] privileged or confidential." 5 U.S.C. s 552(b)(4). Information that a person is required to submit to the Government is considered confidential only if its disclosure 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." *National Parks I*, 498 F.2d at 770. In the present case the FDA and Schering invoke only the latter standard. Meanwhile, Public Citizen claims disclosure would prevent other drug companies "from repeating Schering's mistakes, thereby avoiding risk to human health," and relies upon dicta in several district court opinions in arguing that under Exemption 4 the court should gauge whether the competitive harm done to the sponsor of an IND by the public disclosure of confidential information "is outweighed by the strong public interest in safeguarding the health of human trial participants."\* See Public Citizen

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\* Our concurring colleague is of the opinion that Public Citizen has failed to create a genuine issue of material fact as to whether

Health Research Group v. FDA, 964 F. Supp. 413, 415 (D.D.C. 1997); see also Teich v. FDA, 751 F. Supp. 243, 253 (D.D.C. 1990); AT&T Info. Sys., Inc. v. General Servs. Admin., 627 F.Supp. 1396, 1403 (D.D.C. 1986).

We reject Public Citizen's proposal because a consequentialist approach to the public interest in disclosure is inconsistent with the "[b]alanc[e of] private and public interests" the

disclosure is necessary to safeguard participants in clinical trials, and therefore that it has not done enough to prevent summary judgment from being entered against it, even if its view of the law were correct. See Concur. at 2 & n.1. The record, however, makes clear that Public Citizen has more than met its burden of raising a dispute over this fact. The affidavit it submitted to the district court states:

Defendants' arguments of substantial competitive harm are disturbing from a public health standpoint because the data we seek involve experimental drugs that were determined to pose such serious health or safety risks that clinical testing of the drug was stopped. ...[B]ecause the safety and effectiveness data for this experimental drug is being withheld, we cannot determine whether the FDA adequately protected human subjects in these clinical trials. Defendants will not be competitively harmed from the release of [this information] because tests that reveal the hazards of a drug are simply not the type of studies that competitors would want to copy. On the other hand, the public will benefit significantly from their release. Indeed, if these studies are kept secret, other drug companies may unknowingly conduct similarly hazardous studies, potentially placing many patients needlessly at risk.

Similarly, Public Citizen's affiant states: "disclosure ... serves the public interest in two independent ways. First, it allows the public to scrutinize FDA's decisions concerning human testing of investigational drugs.... Second, disclosure of safety and effectiveness data decreases the likelihood that other drug companies will replicate potentially hazardous human testing."

That the FDA claims it has another, more direct, way to prevent exposure of human beings to this risk, see Op. at 11, merely joins the dispute on the factual question; it does not resolve it. See Niagara Mohawk Power Corp. v. DOE, 169 F.3d 16, 18-19 (D.C. Cir. 1999).

Congress struck in Exemption 4. Critical Mass Energy Project v. NRC, 975 F.2d 871, 872 (D.C. Cir. 1992) (in banc); see also FBI v. Abramson, 456 U.S. 615, 621 (1982) (although FOIA implements policy of broad disclosure, the Congress also realized "that legitimate governmental and private interests could be harmed by release of certain types of information and provided nine specific exemptions under which disclosure could be refused"); see also National Parks I, 498 F.2d at 770 (legislative history of FOIA "firmly supports the inference that [Exemption 4] is intended for the benefit of persons who supply information"). That balance is accurately reflected in the test of confidentiality set forth in National Parks I, which was "known to and acquiesced in by Congress" when it enacted 5 U.S.C. s 552b(c)(4), an exemption to the Government in the Sunshine Act that is identical to

Exemption 4 of the FOIA. CNA Fin. Corp. v. Donovan, 830 F.2d 1132, 1153 n.146 (D.C. Cir. 1987) (describing legislative history of s 552b(c)(4)).

In other words, the Congress has already determined the relevant public interest: if through disclosure "the public would learn something directly about the workings of the Government," then the information should be disclosed unless it comes within a specific exemption. National Ass'n of Retired Fed. Employees v. Horner, 879 F.2d 873, 879 (D.C. Cir. 1989) (emphasis in original). Indeed, Public Citizen's main reason for seeking this information is to "review whether the FDA is adequately safeguarding the health of people who participate in drug trials"; the information sought, in other words, would reveal "what the[ ] government is up to." DOJ v. Reporters Comm. for Freedom of Press, 489 U.S. 749, 773 (1989). It is not open to Public Citizen, however, to bolster the case for disclosure by claiming an additional public benefit in that, if the information is disclosed, then other drug companies will not conduct risky clinical trials of the drugs that Schering has abandoned. That is not related to "what the[ ] government is up to" and the Court has clearly stated that "whether disclosure of a ... document ... is warranted must turn on the nature of the requested document and its relationship to the basic purpose of the Freedom of Informa-

tion Act to open agency action to the light of public scrutiny ... rather than on the particular purpose for which the document is being requested." *Id.* at 772. In other words, the public interest side of the balance is not a function of the identity of the requester, see *id.* at 771, or of any potential negative consequences disclosure may have for the public, *Washington Post Co. v. HHS*, 865 F.2d 320, 327-28 (D.C. Cir. 1989), nor likewise of any collateral benefits of disclosure.

In litigation seeking the release of information under the FOIA, "the agency has the burden of showing that requested information comes within a FOIA exemption." *Niagara Mohawk Power Corp. v. DOE*, 169 F.3d 16, 18 (D.C. Cir. 1999). Even when the requester files a motion for summary judgment, the Government "ultimately [has] the onus of proving that the [documents] are exempt from disclosure." *National Ass'n of Gov't Employees v. Campbell*, 593 F.2d 1023, 1027 (D.C. Cir. 1978). The burden upon the requester is merely "to establish the absence of material factual issues before a summary disposition of the case could permissibly occur." *Id.* Accordingly, in order to obtain a summary judgment Public Citizen need not demonstrate that Schering would suffer no competitive harm from the release of this information; rather, its task is to show that there is no dispute about an issue of fact material to the FDA's burden of demonstrating that Schering would suffer substantial competitive harm from the disclosure of its INDs. See *National Parks I*, 498 F.2d at 770.

1. IND Nos. 35757, 34465, 31911, and 30647

For the reasons stated in the opinion of the district court, 997 F. Supp. at 63-64, we agree with the FDA and Schering that under Exemption 4 the agency may withhold information in the four INDs listed above. Release of that information would cause substantial harm to Schering's competitive position.

With respect to the first three INDs, Public Citizen contends that releasing health and safety information would only "save Schering's competitors the time Schering spent developing and testing a dangerous drug, and thus save human

trial participants from being exposed to a dangerous drug." According to Public Citizen, that "cannot be considered the type of 'competitive harm' justifying withholding of the documents under Exemption 4."

Having already rejected Public Citizen's argument that any collateral benefit from the disclosure of information--that is, any benefit beyond learning "what the[ ] government is up to"--must be weighed against the competitive harm that would result from disclosure, we do not consider Public Citizen's assertion that disclosure would in fact prevent the exposure of human beings to a health risk. In any event, as both the FDA and Schering point out, were a competitor to submit an IND involving a risk known to the FDA because of its experiences with Schering's INDs, the agency could and presumably would refuse to permit that company to begin clinical testing.

We turn therefore to Schering's evidence of competitive harm from disclosure of these three INDs, all of which relate to the same antifungal drug. According to the affidavit of its Dr. George H. Miller, the Company "has just commenced clinical testing on a successor [drug] which was designed based on information learned during development of [the drugs described in those INDs]." Further, Dr. Miller states that "Schering's basic research revealed that the particular type of fungal infection for which this product was designed was not one that was relatively well-controlled by existing products." He also states that "[t]he development and marketing of new antifungal products is ... being actively engaged in by a number of other drug companies," which could make use of the information in the INDs in order to eliminate much of the time and effort that would otherwise be required to bring to market a product competitive with the product for which Schering filed its most recent IND. This is clearly the type of competitive harm envisioned in Exemption 4, as our case law makes clear. See, e.g., National Parks & Conservation Ass'n v. Kleppe ("National Parks II"), 547 F.2d 673, 684 (D.C. Cir. 1976) ("Disclosure would provide competitors with valuable insights into the operational strengths and weaknesses of a [company], while [its competitors] could continue

in the customary manner of 'playing their cards close to their chest' "); cf. *Webb v. HHS*, 696 F.2d 101, 103 (D.C. Cir. 1982) ("If a manufacturer's competitor could obtain all the data in the manufacturer's NDA, it could utilize them in its own NDA without incurring the time, labor, risk, and expense involved in developing them independently").

The fourth IND listed above concerned a drug "designed to suppress allergic inflammations and subsequent symptoms of asthma." Public Citizen concedes that Schering is now testing compounds related to the abandoned drug. Nonetheless, Public Citizen complains that the Company does not "explain with any specificity how the pre-clinical and clinical studies on the old compound would lead its competitors to the new compounds that Schering has subsequently identified."

In the affidavit Schering filed to support withholding the documents in this IND, Dr. Francis Cuss recounts that the Company initially believed the drug was a "leukotrine inhibitor," but that its "scientists observed certain unanticipated effects during toxicity and clinical testing .... suggest[ing] that the drug may have achieved its anti-inflammatory effects through a [different] mechanism." Therefore, states the affiant, the "toxicity and clinical data together could direct a competitor of Schering .... to pursue the the same avenues of research and development" that Schering has pursued since abandoning this IND. We think this explanation sufficiently specific to support Schering's argument that disclosure of information in this IND would cause it substantial competitive harm.

Accordingly, we reverse that portion of the district court's order requiring the agency to release the documents in these four INDs. See *Critical Mass*, 975 F.2d at 880.

2. IND No. 18113

We turn now to the documents in the fifth IND, which involved "one of four isomers making up a prescription medicine currently marketed by Schering and indicated for use in controlling blood pressure in cases of severe hypertension." We find that Schering's affidavit professing the extent of

competitive injury it would suffer from disclosure of the information in this IND is not sufficient to support its motion for summary judgment; indeed, it fails to raise a dispute as to any material issue of fact. Summary judgment for Public Citizen is therefore indicated.

The affidavit of Schering's Dr. Ronald J. Garutti contains only conclusory assertions that disclosure would cause substantial competitive harm. For example, the affiant states that disclosure "would reveal substantial basic research" as well as "disease models ... that have been developed by Schering at a great expense," and that "[t]oxicology data ... have significant value beyond the compound under investigation .... [and would be applicable] to any drug product any of whose metabolites were identical or similar to those of IND 18113 .... [and] other drugs [of] a similar chemical type." Dr. Garutti attests that the clinical protocols also "have applicability beyond the specific drug being tested" and that disclosure "would have substantial commercial value to any company attempting to develop cardiovascular therapies generally." The arguments in Schering's brief are even more general: disclosure would reveal its "assessment of regulatory requirements and its experience with FDA in this area, as well as [its] judgment as to what requirements will be necessary in order to establish the drug's safety and effectiveness."

Although a party opposing a motion for summary judgment is entitled to every favorable inference that may fairly be drawn from its affidavits, see *Greenberg v. FDA*, 803 F.2d 1213, 1216 (D.C. Cir. 1986), such "[c]onclusory and generalized allegations of substantial competitive harm ... cannot support an agency's decision to withhold requested documents." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1291 (D.C. Cir. 1983). Accordingly, we hold that the agency may not withhold the disputed documents in IND No. 18113 under Exemption 4. We therefore affirm that portion of the district court's order requiring the agency to release them to Public Citizen, albeit for a different reason.

### C. Segregability

In view of our holding that the agency may, under Exemption 4, withhold information in four of the INDs, we turn to

Public Citizen's alternative request that we remand the case for the district court to determine whether any non-exempt portions of the documents that the agency may withhold can be segregated and disclosed. Public Citizen contends that the district court did not have occasion to make this determination because it required disclosure of all the records. Schering responds that the district court did not do so because Public Citizen never asked for, and therefore waived, such relief, and that segregation would in any event be "unreasonable" in this case.

From the record we see that Public Citizen did raise this issue before the district court in its Reply in Support of its Cross-Motion for Summary Judgment. In any event, on remand it would be incumbent upon the district court on its own initiative to address the issue of segregability. See *Trans-Pacific Policing Agreement v. United States Customs Serv.*, 177 F.3d 1022, 1028 (D.C. Cir. 1999). One should normally presume that a request for information under the FOIA is a request for all or any, not for all or none, of the information described. Cf. *National Mining Ass'n v. Babbitt*, 172 F.3d 906, 910 (D.C. Cir. 1999) (factual presumption is reasonable when "the circumstances giving rise to the presumption ... make it more likely than not that the presumed fact exists").

In view of the district court's disposition of this case, of course, it had no need to address the issue of segregability the first time around and we do not fault it for passing over the issue then. We have now held, however, that information in four of the five INDs at issue may be withheld. Because "[t]he 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," we remand this case for the district court to determine whether the documents the agency has withheld contain information that can be segregated and disclosed. *Schiller v. NLRB*, 964 F.2d 1205, 1209-10 (D.C. Cir. 1992). In so doing, we express no opinion upon Schering's claim that segregation is impracticable in this case.

### III. Summary and Conclusion

For the foregoing reasons, we hold first that s 355(1) applies only to information submitted in an NDA. In addition we hold that the FDA has not met its burden under Exemption 4 with respect to, and therefore must disclose, the information contained in IND No. 18113; and that the agency has met its burden under Exemption 4 with respect to, and therefore need not disclose, confidential information contained in IND Nos. 35757, 34465, 31911, and 30647. As to the latter four INDs, we remand the case for the district court to determine in the first instance whether there is any non-confidential information that can be segregated and disclosed.

So ordered.

Garland, Circuit Judge, concurring in the result: Today the court exercises appropriate discretion in declining to decide whether section 355(1) and FOIA Exemption 4 are congruent, because it is unnecessary to do so to resolve the dispute before us. I believe the court errs, however, in not exercising similar restraint with respect to an issue regarding the meaning of Exemption 4 itself.

My colleagues hold that in determining whether a document comes within Exemption 4, the court may not "gauge whether the competitive harm" disclosure would cause to the company that submitted the document "is outweighed by the public interest in safeguarding" human health. Op. at 7-8. This means that even if disclosure were the only way to prevent the loss of human life, that would count for nothing as against a showing by the company that disclosure would cause substantial harm to its competitive position. See *id.* at 11 ("[W]e do not consider Public Citizen's assertion that disclosure would in fact prevent the exposure of human beings to a health risk."). This is an important issue, and the kind that should be decided only after full briefing and argument. See, e.g., *Carducci v. Regan*, 714 F.2d 171, 177 (D.C. Cir. 1983).

But we have not had that here. As the argument heading of Public Citizen's brief makes clear, its core Exemption 4 argument was that the requested records "Do Not Constitute Confidential Commercial Information." Public Citizen Br. at 31. In a single clause in a single sentence of that brief, Public Citizen also said: "Any disadvantage to Schering is minimal, and is outweighed by the strong public interest in safeguarding the health of human trial participants." *Id.* at 34 (emphasis added). Schering replied in kind. In a single clause in a single sentence of its reply brief (and without citation), Schering said: "This enterprise [pharmaceutical research] has well-served the public health through the discovery and development of new medicines and should not, in effect, be reorganized to suit Public Citizen's views through an unprecedented and strained reading of exemption 4." Schering Reply Br. at 6 (emphasis added). The italicized phrases are the full extent of the argument we have heard on

this issue. The FDA did not mention the point at all; the parties did not discuss it at oral argument; and the district judge did not refer to it in his opinion.

Nor is this an issue we must decide in order to dispose of this case. Even if a balancing of the public safety interest in disclosure were an element of Exemption 4, and even if Public Citizen had intended to raise the point, the conclusory assertion the court cites is insufficient to prevent the entry of summary judgment in favor of the FDA. As we have said many times before, "[i]t is well settled that [c]onclusory allegations unsupported by factual data will not create a triable issue of fact." *Exxon Corp. v. FTC*, 663 F.2d 120, 126-27 (D.C. Cir. 1980) (internal quotation omitted); see *Alyeska Pipeline Serv. Co. v. EPA*, 856 F.2d 309, 313-14 (D.C. Cir. 1988); *Gardels v. CIA*, 689 F.2d 1100, 1106 (D.C. Cir. 1982); *Military Audit Project v. Casey*, 656 F.2d 724, 749 (D.C. Cir. 1981).<sup>1</sup>

Nor is this a case where the legal conclusion the court has reached is indisputable. To the contrary, although no party cited the relevant precedent on this point, we have twice held that Exemption 4 requires a balancing of the interest in nondisclosure "against the public interest in disclosure." See *Washington Post Co. v. HHS*, 690 F.2d 252, 269 (D.C. Cir.

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<sup>1</sup> The court notes that in addition to the single conclusory statement in its brief, Public Citizen also mentioned the point in an affidavit filed in district court. Op. at 8 n.\*. But as my colleagues' recitation of statements from the affidavit makes clear, that mention is confined to a total of three sentences in that 12-page document. See JA 312 (opining that "the public will benefit significantly from their release" and that "if these studies are kept secret, other drug companies may unknowingly conduct similarly hazardous studies, potentially placing many patients needlessly at risk") (emphasis added); id. at 309 (alleging that disclosure "decreases the likelihood that other drug companies will replicate potentially hazardous human testing"). As the cases cited in the text above indicate, these conclusory statements of affiant opinion are insufficient to defeat a motion for summary judgment. See also 10B Wright, Miller & Kane, *Federal Practice & Procedure* s 2738, at 346-56 (3d ed. 1998).

1982) (Washington Post I); *Washington Post Co. v. HHS*, 865 F.2d 320, 326-27 (D.C. Cir. 1989) (Washington Post II). *Washington Post I* involved an analysis of Exemption 4 under the "impairment" prong of the National Parks test for confidential information.<sup>2</sup> We held that "[t]his inquiry necessarily involves a rough balancing of the extent of impairment and the importance of the information against the public interest in disclosure." *Washington Post I*, 690 F.2d at 269. Rather than decide "the details of the balancing process," we remanded the case to the district court. *Id.* When the case later returned to us, we concluded that the interest the government asserted in nondisclosure--impairment of its information-gathering ability--had not been appropriately resolved. We therefore remanded the case again, instructing that "if the district court ultimately finds that disclosure will impair the government's information-gathering, it will once again be required to conduct the 'rough balancing of the extent of impairment and the importance of the information against the public interest in disclosure.'" *Washington Post II*, 865 F.2d at 326-27 (quoting *Washington Post I*, 690 F.2d at 269). And we made clear that "the only inquiry properly before the district court was the question whether disclosure of the financial information ... would be likely to impair the government's ability to gather this information in the future, and if so whether this risk outweighed the public's interest in disclosure." *Id.* at 324-25 (emphasis added).<sup>3</sup>

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<sup>2</sup> Under the test employed in *National Parks & Conservation Ass'n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974), "commercial or financial matter is 'confidential' for purposes of the exemption if disclosure of the information is likely to have either of the following effects: (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." Nothing in the reasoning of *Washington Post I* suggests that the public interest balancing it requires for prong (1) is not also required for prong (2).

<sup>3</sup> See also *Martin v. Lauer*, 686 F.2d 24, 33 (D.C. Cir.1982) ("A decision whether to release FOIA-exempt material ... requires a considered balancing of the public's interest in disclosure of particu-

None of the cases cited by the court holds that the public safety interest in disclosure should not be weighed in applying FOIA Exemption 4. Certainly Reporters Committee does not. See *United States Dep't of Justice v. Reporters Comm. for Freedom of the Press*, 489 U.S. 749, 773 (1989). In that case there was no question but that a balancing test was required with respect to Exemption 7(C), *id.* at 776; the question was what interests could be weighed in the balance. The Supreme Court held that FOIA does not protect an interest in "disclosure of information about private citizens that is accumulated in various governmental files but that reveals little or nothing about an agency's own conduct." *Id.* at 773. But as my colleagues recognize, the Court also held that an interest in "[o]fficial information that sheds light on an agency's performance of its statutory duties falls squarely within that statutory purpose" and may be weighed in the balance. *Id.*

Unlike the information sought in *Reporters Committee*, the information Public Citizen seeks may reveal much about "an agency's performance of its statutory duties." All of the records sought pertain to clinical trials that could not have proceeded without FDA authorization, and that "were discon-

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lar material and the interests in nondisclosure acknowledged by the statutory exemptions."). The Ninth Circuit has followed our approach, see *GC Micro Corp. v. Defense Logistics Agency*, 33 F.3d 1109, 1115 (9th Cir. 1994) ("We agree with the D.C. Circuit that, in making our determination [of competitive harm under Exemption 4], we must balance the strong public interest in favor of disclosure against the right of private businesses to protect sensitive information."), as has our own district court, see *Public Citizen Health Research Group v. FDA*, 964 F. Supp. 413, 415 (D.D.C. 1997) (citing *Teich v. FDA*, 751 F. Supp. 243, 253 (D.D.C. 1990); *AT&T Info. Sys., Inc. v. General Servs. Admin.*, 627 F. Supp. 1396, 1403 (D.D.C. 1986)). See also 1 James T. O'Reilly, *Federal Information Disclosure* s 14.12, at 14-44 (2d ed. 1990) ("In some cases the public need for the information is factored by the court into its equation of substantial competitive harm.... For example, public health and safety factors may warrant more attention to the substantial harm equation....").

tinued ... because of death or serious injury of patients." FDA Br. at 2 (describing Public Citizen's FOIA request). Disclosure assertedly will reveal "whether the FDA is adequately analyzing data submitted in INDs before allowing human testing to begin and whether safety problems uncovered in clinical trials result in prompt cessation of those trials." Public Citizen Br. at 5. That would certainly permit the public to "learn something directly about the workings of the Government." Op. at 9 (quoting National Ass'n of Retired Fed. Employees v. Horner, 879 F.2d 873, 879 (D.C. Cir. 1989)). Yet, in evaluating the government's Exemption 4 claims, the court makes no effort to determine how important to the public interest learning such information would be,<sup>4</sup> or to weigh it against the injury Schering would suffer from disclosure. Instead, the court ends its analysis upon finding "that disclosure of information in this IND would cause [Schering] substantial competitive harm." Id. at 12.

I cannot dispute my colleagues' conclusion that the briefs' brief mention of this issue gives us the discretion to decide it. But that is "not to say that affirmative exercise of the discretion [is] wise." Fraternal Order of Police v. United States, 173 F.3d 898, 903 (D.C. Cir. 1999), reconsidering Fraternal Order of Police v. United States, 152 F.3d 998 (D.C. Cir. 1998). Deciding an issue in the absence of any substantive briefing may later make us wish that we had

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<sup>4</sup> One, but only one, of the elements of the public interest asserted by Public Citizen is that disclosure would "save human trial participants from being exposed to a dangerous drug" by keeping other drug companies from replicating Schering's "hazardous human testing." Op. at 10-11, 8 n.\* (quoting Public Citizen). As noted above, on the current record this is only a conclusory allegation. But if in fact the FDA has not already protected human trial participants directly by barring authorization for such replicated studies, disclosure of Schering's studies will reveal that fact (to the drug companies, trial participants, their physicians, and other knowledgeable members of the public). By thus revealing the FDA's failure to "perform[ ] its statutory duties," Reporters Committee, 489 U.S. at 773, disclosure may enable the public to protect itself.

waited. See *id.* ("In retrospect, it may well have been imprudent to address the merits on so thin an argumentative record."). For that reason, I would "decline to resolve this issue on the basis of briefing which consisted of [not even] three sentences in the ... brief and no discussion of the ... relevant case law." *Railway Labor Executives' Ass'n v. United States R.R. Retirement Bd.*, 749 F.2d 856, 859 n.6 (D.C. Cir. 1984) (citing *Carducci*, 714 F.2d at 717); see *Washington Legal Clinic for the Homeless v. Barry*, 107 F.3d 32, 39 (D.C. Cir. 1997).