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OPEN Season on Parallel Litigation

Precluding Disclosure under FOIA Requests

By Kimberly D. Baker and Manish Borde

A primer on the extent of discoverability of information relating to drugs and medical devices pursuant to Freedom of Information Act requests.

The Freedom of Information Act (FOIA) affords the public access to virtually any federal government record that FOIA itself does not specifically exempt from disclosure. 5 U.S.C. §552. Though the FOIA has been around for decades, 2007 legislation may prove to have far-reaching effects in the pharmaceutical industry. The Openness Promotes Effectiveness in our National Government Act of 2007 or OPEN Government Act of 2007 amends the FOIA by revising the requirements for federal agency information disclosure. The amendments include a provision providing for the award of costs and attorneys fees to FOIA requestors who are forced to file suit to enforce their requests and are subsequently found to be the prevailing party. A party does not have to receive a judgment in court to be a prevailing party; a party also prevails if an agency eventually agrees to voluntarily hand over the documents. Thus, federal agencies such as the Food & Drug Administration (FDA) may have a strong incentive to acquiesce to the demands of requestors in a timely fashion. Consequently, drug and device manufacturers now have an additional factor to consider when deciding whether to intervene if a citizen, citizen group, or plaintiffs have submitted comprehensive FOIA requests to the FDA. Companies need to be more mindful of this economic incentive that may influence the production of documents that include trade secrets, research and development, and other information generated or secured at great company expense. This article provides a survey of the scope of information that plaintiffs have succeeded in obtaining from the FDA under FOIA requests in recent years and offers some suggestions on effective arguments to preclude disclosure of documents.

A party dissatisfied with the FDA's response to a FOIA request may file suit to secure greater production of documents. When the FDA has declined to produce documents requested in a FOIA request, it has the burden of justifying nondisclosure, and the court must ascertain whether the FDA has met its burden of demonstrating

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that the requested documents are exempt from disclosure under the FOIA. A manufacturer may intervene in the lawsuit and seek protection from disclosure of its documents produced to the FDA. Fed. R. Civ. P. 24. The manufacturer must make legal arguments opposing production based upon the statutory exemptions, bolstered by well-articulated declarations and reports that clearly demonstrate the harm likely to result from document production. Mere "assertions" that harm is likely, without strong backing, will be insufficient to establish exemptions to production in response to a FOIA request. 5 U.S.C. §552(a)(4)(B). The nine exemptions enumerated in the FOIA can be summarized as follows:

1. National security information concerning national defense or foreign policy, provided that it has been properly classified in accordance with the substantive and procedural requirements of an executive order;
2. Records related solely to internal personnel rules and practices of an agency;
3. Information that other federal statutes protect from disclosure;
4. Trade secrets and commercial or financial information that is privileged or confidential;
5. Interagency or intraagency memorandums or letters that would not be available by law to a party in litigation with the agency;
6. All information about individuals in personnel and medical files and similar files when the disclosure of such information would constitute a clearly unwarranted invasion of personal privacy;
7. Records or information compiled for law enforcement purposes;
8. Records of financial institutions; and
9. Geological and geophysical information and data, including maps, concerning wells.

To remain competitive, companies must be particularly attentive to exemption 4. Exemptions 5 and 6 can also serve as useful defenses for companies that are forced to intervene in suits seeking to enforce FOIA requests. As evidenced in the case law, the trend that had developed over the last 20 years was that courts became increasingly wary of disclosing sensitive documents. This prompted recent congressional action:

> Chief among the problems with FOIA is the major delays encountered by FOIA requestors. And, while the number of FOIA requests submitted each year continues to rise, our federal agencies remain unable—or unwilling—to keep up with the demand. Just recently, the Government Accountability Office found that federal agencies had 43 percent more FOIA requests pending and outstanding in 2006, than they had in 2002.

Senator Patrick Leahy, Chairman, Senate Judiciary Committee, Address at the United States Senate: Reintroduction of the Leahy-Cornyn OPEN Government Act (March 13, 2007) (*See* http://leahy.senate.gov/press/200703/031307a.html) (last visited June 11, 2008).

Given such congressional dissatisfaction with federal agencies' responses to FOIA requests, companies need to be very specific in outlining the anticipated harm and providing a financial, economic and scientific basis to support a ruling of nondisclosure. Convincing the courts to make a sustainable record for denial or limitations to a FOIA request will limit the new act and minimize any perception that the threshold for production has been lowered.

Protection under FOIA Exemption 4

The FOIA does not apply to "trade secrets and commercial or financial information (that are) obtained from a person and (are) privileged or confidential." 5 U.S.C. §552(b)(4). Commercial information is confidential if disclosure is likely to (1) impair the government's ability to obtain necessary information in the future; or (2) cause substantial harm to the competitive position of the person who submitted the information. *Public Citizen Health Research Group v. Food & Drug Admin.*, 964 F. Supp. 413, 434 (D.D.C. 1997).

In *Teich v. Food & Drug Admin.*, 751 F. Supp. 243 (D.D.C. 1990), the plaintiff made a FOIA request seeking a series of animal studies and consumer complaints about breast implants manufactured by Dow Corning. The FDA refused to disclose the animal study records, asserting that they were exempt under the FOIA exemption 4. Eventually, the FDA allowed discovery of a complaint summary, and Dow Corning intervened to prevent its disclosure. The court concluded disclosure of the consumer complaint summary would not cause competitive injury to Dow Corning, in part because the complaints would have been submitted pursuant to the Medical Device Reporting System requirements.

The defendants in *Teich* also asserted animal studies prepared by Dow Corning were confidential commercial information and protected from disclosure under exemption 4. They argued that competitors could use Dow Corning's test results as a guide to their own testing and piggyback on the research and time expended by Dow Corning. The court ruled that disclosure of studies demonstrating a product's danger was in the public interest and not confidential. The court also concluded that although studies that did not necessarily reveal a product was dangerous may be useful to competitors, it was unlikely their disclosure alone would aid a competitor in bringing a product to market. In reaching its conclusion, the court made the following observation:

> Moreover, if silicone breast implants are, in fact, a "killer product," it is urgent that this information be made public immediately. This is precisely one of the reasons for which the FOIA was created.

Teich at 249.

The significance of this dictum was undermined by the appellate court in a subsequent opinion:

> It is not open to [plaintiff], 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 [the manufacturer] has abandoned.

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Public Citizen Health Research Group v. Food & Drug Admin., 185 F.3d 898, 904, 337 U.S. App. D.C. 343 (D.C. Cir. 1999).

In the *Public Citizen* case, the plaintiff made a FOIA request to the FDA seeking "all 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 pre-clinical studies…" *Id.* at 901. Public Citizen filed suit when the FDA denied its request. Schering Corporation intervened because it had submitted five investigational new drug applications that were of the sort requested by Public Citizen. Public Citizen argued that disclosure would stop other drug companies from duplicating Schering's mistakes, thereby "…avoiding risk to human health…." *Id.* at 903. After reminding Public Citizen that the purpose of FOIA was to shed light on the actions of government agencies and not for other purposes (such as barring companies from conducting allegedly risky clinical trials), the court found that disclosure of three investigational new drug applications would result in substantial competitive harm since Schering had just started clinical testing on a successor drug that was designed based on information learned during development of the new drugs. Consequently, competitors would be in a position to use information in the documents to reduce the time that would otherwise be required to bring a competitive product to market. Notably, the trial court, whose opinion was heavily relied upon by the appellate court, paid particular attention to the fact that only select Schering employees had access to the information concerning the new drugs and that third parties were privy to such information only after confidentiality agreements had been signed. *Public Citizen Health Research Group v. Food & Drug Admin.*, 997 F. Supp. 56, 63 (D.D.C. 1998).

Posting nonprivileged information on a company website will force potential litigants to take a hard look at the cost/benefits of pursuing a FOIA request.

The court's adverse rulings are also instructive. Schering was unable to demonstrate that documents relating to another investigational new drug application were protected under exemption 4 of the FOIA. The affidavit provided by Schering to support its position stated that disclosure "…would reveal substantial basic research" and "disease models [were]… developed by Schering at a great expense…" *Public Citizen Health Research Group v. Food & Drug Admin.*, 185 F.3d 898, 906, 337 U.S. App. D.C. 343 (D.C. Cir. 1999). The court also found the following declarations to be too general to warrant a finding of substantial competitive harm:

> 'toxicology 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.'… [D]isclosure 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.'

Id.

In *Public Citizen Health Research Group v. Food & Drug Admin.*, 964 F. Supp. 413 (D.D.C. 1997), Public Citizen took up a different cause. In this instance, the citizen's group made a FOIA request seeking the protocol for a 10,000-patient study of the drug Metformin. Metformin was an oral anti-hyperglycemic drug used to aid in the control of non-insulin-dependent diabetes mellitus. Bristol-Myers manufactured the drug and intervened to prevent disclosure. The issue before the court was whether the documents contained confidential commercial information that was exempt from disclosure under exemption 4. The court found unconvincing the defendants' argument that data submitted to the agency as part of its drug approval process would not be submitted as freely if the desired protocol was disclosed. The court acknowledged that 20 manufacturers of oral diabetic therapies existed, but held that the record failed to identify any substantial competitive injury would result if the FOIA information request was honored. The court found Bristol-Myers Squibb's contentions that disclosure of the protocol could lead to patient drop-out, bias in the results, and delays in the study's completion to be too generalized and lacking in specific factual support. Though the court was more receptive to the argument that disclosure of the protocol would allow competitors to take advantage of the study's design for their own uses, it did not perceive how a competitor could gain from a protocol specifically tailored to Metformin. Although the defendants did not suffer a total loss, given that the court ordered production of a copy of the protocol for *in camera* review, the court was not able to adjudicate the matter on summary judgment.

In *Heeney v. Food & Drug Admin.*, No. 99-5629, 2001 WL 371921 (9th Cir. April 12, 2001), Mr. Heeney made a FOIA request seeking files held by the FDA regarding an electrode catheter distributed by Boston Scientific Corporation. Heeney then filed suit to enforce his request. Boston Scientific intervened. The FDA and Boston Scientific submitted detailed affidavits demonstrating that certain information was protected from disclosure under exemption 4 of the FOIA. The 9th Circuit agreed that the following was protected: (1) the identity of a catheter that had been submitted by Boston Scientific to the FDA for approval but that was later withdrawn; and (2) the catheter's product design, testing and manufacturing date, construction materials, manufacturing agreements, and sales and marketing agreements with other companies. Since Boston Scientific withdrew its application because the FDA had determined the catheter was not substantially equivalent to devices already on the market, the court found that releasing the information could "suggest to competitors that Boston Scientific intended to modify the device or market it for new and different uses." *Heeney* at *1. Accordingly, the documents were protected from disclosure by exemption 4.

In *Appleton v. Food & Drug Admin.*, 451 F. Supp. 2d. 129 (D.D.C. 2006), the plaintiff submitted a FOIA request seeking all

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communications between the FDA and the United States Pharmacopeia regarding the drug levothryoxine sodium. He later clarified his request and stated it was "… intended to focus on chemistry information, with biopharmaceutical information requested only insofar as it invoked analytical chemistry methodology not elsewhere disclosed." *Id.* at 135. After becoming dissatisfied with the FDA's response, the plaintiff filed suit. Subsequently, Jones Pharma, Inc., Abbott Laboratories, Alara Pharmaceutical Corporation, and Lloyd Inc. were granted leave to intervene.Some of the requested documents contained information relating to the product's safety and effectiveness, which were obtained through preliminary research and human clinical trials, and also included evidence of side effects and their magnitude, the chemical stability of the drug, the method of drug synthesis, specifications of the finished drug product, and analytical methods used for drug and drug components. The court agreed with the FDA that disclosure of certain documents would reveal trade secrets: "Release of this information would reveal how the drug being discussed in the document is formulated, chemically composed, manufactured, and quality controlled." *Id.* at 141 (internal citations omitted). In *Judicial Watch, Inc. v. Food & Drug Admin.*, 407 F. Supp. 2d 70 (D.D.C. 2005), the court affirmed the FDA's decision to not disclose information submitted voluntarily to support a drug sponsor's new drug application, in part because the information was "…of a kind that would customarily not be released to the public by the person from whom it was obtained…" *Id.* at 75 (citing *Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, 975 F.2d 871, 879 (D.C. Cir. 1992)).

In *Sharkey v. Food & Drug Admin.*, No. 06-11774, 2007 WL 2914212 (11th Cir. Oct. 5, 2007), the Sharkeys' son had suffered an adverse reaction to a hepatitis B vaccine. The parents filed a FOIA request with the FDA seeking "records reflecting the net number of doses in each lot of Rocombivax HB and Engerix-Bhepatitis B vaccine[s] distributed in the United States." *Id.* at *1. The plaintiffs alleged they needed the information to determine whether an adverse reaction was the cause of their son's medical problems. The FDA identified 19 responsive documents from Merck & Co. and GlaxoSmithKline, Inc., filed pursuant to regulations mandating periodic reporting of vaccine distributions. However, the FDA refused to disclose the documents, claiming the records fell within exemption 4 of the FOIA. The Sharkeys subsequently filed suit against the FDA, and Merck intervened. The defendants argued that Merck and GlaxoSmithKline would suffer substantial competitive harm from disclosure. The court agreed, concluding that substantial competitive harm would likely result from disclosure, given that: (1) disclosure of the net number of doses per lot of each manufacturer's hepatitis B vaccine would reveal market share and sales volume; (2) such disclosure would enable competitors to ascertain production capacity and manufacturing specifics; and (3) competitors with knowledge of sales volume would know the optimum volume of doses per lot of vaccine distributed by Merck and GlaxoSmithKline, which is highly sensitive information. The court also noted that Merck took drastic measures to keep this information confidential:

> Both the efforts to keep this information confidential and the highly sensitive information that may be gleaned from it leads us to conclude that public knowledge of [the company's] domestic market shares… will likely result in substantial competitive harm.

Id. at *5.

Protection under Exemptions 5 and 6

Exemption 5 protects inter-agency or intra-agency memorandums or letters that would not be available by law to a party other than an agency in litigation with the agency. 5 U.S.C. §552(b)(5). The courts have interpreted the two exemptions to "exempt those documents, and only those documents, normally privileged in the civil discovery context." *Appleton* at 142 (citing *Nat'l Labor Relations Bd. v. Sears, Roebuck & Co.*, 421 U.S. 132, 149, 95 S. Ct. 1504, 44 L. Ed. 2d 29 (1975); *Martin v. Office of Special Counsel*, 819 F.2d 1181, 1184 (D.C. Cir. 1987)). The courts have extended exemption 5 to cover deliberative-process privilege, attorney work-product, and attorney-client privilege. The deliberative-process privilege protects the decision making processes of regulatory agencies and focuses on advisory opinions, recommendations and deliberations constituting part of the process by which governmental decisions and policies are formulated. The *Appleton* court found all of the following to be protected by the deliberative-process privilege: (1) exchanges of thoughts, ideas, and documents regarding levothryoxine sodium drugs; (2) reasons behind the FDA's position for proposed USP revisions; (3) decisions regarding approval of applications; (4) developing future protocols for levothryoxine sodium studies; (5) responses to citizen petitions; (6) internal discussions and draft guidance documents regarding levothryoxine sodium bioequivalence studies; and (7) potential agency action regarding regulatory or enforcement actions.

Intervening defendants would also be wise to note the courts' liberal interpretation of exemption 6. Exemption 6 of FOIA exempts from disclosure "personnel and medical files and *similar files* the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. §552(b)(6) (emphasis added). "Similar files" is broadly defined to include "government records on an individual which can be identified as applying to that individual." *Appleton* at 144–145 (citing *U.S. Dep't. of State v. Wash. Post. Co.*, 456 U.S. 595, 601–02, 102 S.Ct. 1957, 72 L. Ed. 2d 358 (1982)). Exempt are "…bits of personal information, such as names and addresses, the release of which would 'create[ ] a palpable threat to privacy.'" *Judicial Watch, Inc. v. Food & Drug Admin.*, 449 F.3d 141, 152, 371 U.S. App. D.C. 187 (2006). In *Appleton*, documents containing the following information about employees of intervening defendants were exempt from disclosure: names; biographical information related to employment, education and medical history; and the employees' duties and titles.

In *Judicial Watch, Inc.*, the D.C. Circuit cited exemption 6 in preventing the publication of the names and street addresses of FDA personnel, private individuals and companies who worked on the approval of the abortion drug RU-486. In another attempt to unearth information about RU-486, *Judicial Watch, Inc. v. Food & Drug Admin.*, 407 F. Supp. 2d 70, 76–77 (D.D.C. 2005), the court found that documents described as "pregnancy tests" necessarily

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related to a particular individual and therefore, were protected from disclosure under exemption 6.

Notwithstanding the decisions described above supporting nondisclosure, some information will have to be disclosed. In *Citizens Com'n on Human Rights v. Food & Drug Admin.*, 45 F.3d 1325 (9th Cir. 1995), the plaintiff requested copies of all records, notes, electronic information, or other information concerning Prozac that was in the custody of the FDA. The plaintiff was dissatisfied with the FDA's response and filed suit for unlawful nondisclosure of its records. Eli Lilly & Company manufactures Prozac and intervened. The FDA contended that it notified the plaintiff about the procedure for requesting the complete reports of individual adverse reactions, but that plaintiff never complied. The FDA argued it required specific requests because the pertinent files included 60,000 pages and routinely releasing them would be unduly burdensome. Regardless of whether the plaintiff received notification from the FDA about the specificity of procedural requirements, the court reiterated that the plaintiff was "…clearly entitled to the individual adverse reaction reports." *Id.* at 1329.

Lessons Learned

Even though the OPEN Government Act of 2007 permits recovery of fees for enforcement of FOIA requests, recovery of such fees does not happen instantaneously. Thus, to decrease the incentive for information seekers to make FOIA requests, it may be in a company's best interest to post more nonprivileged information on its website. Posting nonprivileged information on a company website will force potential litigants to take a hard look at the cost/benefits of pursuing a FOIA request when information is available through other means. At the same time, companies can still be selective about what to publish. Moreover, *Appleton* arguably supports the notion that courts consider the extent of information voluntarily submitted by companies in determining the universe of disclosable information.

Great care should be taken in preparing affidavits describing the competitive harm that can arise from disclosure. Affidavits should state with particularity any anticipated harms, as courts are extremely wary of conclusory statements. *Public Citizen Health Research Group v. Food & Drug Admin.*, 185 F.3d 898, 337 U.S. App. D.C. 343 (D.C. Cir. 1999), teaches us that it is worthwhile to undertake measures such as employing economic experts when it is necessary to convey the prospects for competitive injury. Companies must take care to build a sufficiently complete record to enable a court to adjudicate on summary judgment the extent of a potential competitive injury or the existence of confidential commercial information. In light of *Sharkey*, the record should emphasize the steps taken to keep information confidential.