UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CAMPAIGN FOR RESPONSIBLE TRANSPLANTATION, Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant,	Civ. No. 00-2849 (RMU/AK)
CIRCE BIOMEDICAL, INC., et al., Defendant-Intervenors.	

PLAINTIFF'S REPLY IN SUPPORT OF ITS EXPEDITED MOTION TO ENFORCE THIS COURT'S SEPTEMBER 24, 2004 ORDER

Introduction

The opposition of the Food and Drug Administration ("FDA") to plaintiff's expedited motion to enforce this Court's September 24, 2004 Order raises many more concerns than it allays. Thus, plaintiff brought this case – over four and a half years ago – because the FDA had failed even to process plaintiff's request under the Freedom of Information Act ("FOIA"). Thus, all plaintiff ever wanted was the FDA to disclose all of the requested records concerning xenotransplantation that were not exempt from disclosure under the FOIA. Now, many years later, even though the FDA long ago insisted to this Court that the IND G records were "representative" of records in all the other 18 IND files, and that all such records were "essentially uniform" in kind, the FDA still has not disclosed to plaintiff all of the non-exempt

records from the other 18 IND files that are similar to those hundreds of pages of documents from the IND G file that have already been disclosed – as a direct result of this lawsuit.[1]

Instead, the FDA has now made the startling revelation that, although it promised this Court – in 2001 – that the other IND records were "essentially uniform" in kind to all of the IND G files, see Defendant's Memorandum In Opposition To Plaintiff's Motion Requesting A Vaughn Index (June 12, 2001) ("Def. Vaughn Opp.") at 2, for some reason, the agency cannot go through the records for the other 18 INDs and pick out the ones that – because they are similar to IND G files – must also be disclosed to CRT. See also id. at 10 (assuring the Court that a sample Vaughn index "would be truly representative" of all of the documents at issue in this case). Rather, the agency now explains that it has to let each of the sponsors of the 18 INDs make these decisions, and this is why it is taking the agency so long to comply with this Court's September 24, 2004 Order that the FDA must "now disclose" all of the other non-exempt records. See Memorandum Opinion (Sept. 24, 2004) ("Mem. Op.") ("Because IND G was supposed to be representative of all of the INDs, the FDA must now disclose all FDA generated records that pertain to the other 18 INDs that are similar in kind to the IND G records that the FDA has already released") (emphasis added); see also Defendant's Opposition at 6-8 (explaining that agency's delay is the result of its "system" of providing the sponsors' an opportunity to designate which records must be withheld from plaintiff).

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[1]On Friday, April 15, 2005, the government finally delivered a first set of documents to plaintiff, with a cover letter stating that the records cover five INDs. Plaintiff has not yet had a chance to review these documents. However, because, according to the FDA's own submission, these documents do not represent all of the non-exempt records that must be disclosed to plaintiff, see FDA Opp. at 19-20, and because it is also clear that the FDA allowed the sponsors of these products to decide what records are "non-exempt," see *infra* at 7-8, the disclosure of these records does not even begin to resolve plaintiff's motion to enforce this Court's Order.

Plaintiff has several problems with this approach.

1. If The Files Are All "Essentially Uniform" In Kind, The FDA Should Be Able To Easily Ascertain Which Records From The Other 18 IND Files Are Non-Exempt And Hence "Must" Be Promptly Disclosed To The Plaintiff Pursuant To This Court's Order .

First, the FDA cannot have it both ways. It cannot, on the one hand, almost four years ago have insisted to this Court that the reason the agency should not have been required to produce a complete Vaughn index for all of the records at issue – which CRT requested precisely because it knew that this exercise would most likely require the agency to release of hundreds of pages of records for which a FOIA exemption did not apply – yet now, on the other hand, insist that no, each file is unique, and hence, the FDA must let each of the sponsors make the determination of which records can be released and which must remain "confidential." See e.g., FDA Opp. at 16 (explaining that each manufacturer is "in a better position to know whether information has some commercial or financial value"). Indeed, these belated new representations by the FDA border on exposing a Rule 11 violation regarding the agency's previous insistence – upon which this Court heavily relied – that all of the records in each file were "essentially uniform" in kind. See CRT v. FDA, 180 F. Supp.2d 29, 34-35 (D.D.C. 2001) ("CRT I").

In fact, when the agency opposed providing a complete Vaughn index, and instead urged the Court to accept a "representative" index for only one IND, plaintiff was extremely skeptical that this approach would work in this case. Thus, in its opposition, plaintiff explained that "an index of agency records which pertain to only one IND could not possibly be "representative" of all responsive records, but would only represent records that are contained in a single IND file."

Plaintiff's Reply Memorandum In Support Of Its Motion Requesting A Vaughn Index (June 29, 2001) ("Pl. Vaughn Reply") at 2. CRT was concerned that allowing the agency to proceed this way could delay CRT's access to all of the non-exempt records, since forcing the agency to prepare a complete Vaughn index for all of the records would mean that the agency would finally have to process CRT's request, which had been languishing at the agency for almost a year and a half, and that once the agency fully processed the request, CRT would be able to obtain hundreds of non-exempt records concerning each of these extremely controversial experimental products.

Indeed, this is the quintessential purpose of a Vaughn index – it forces the agency to process the request, and decide what is non-exempt and hence must be disclosed to the requester, and what is exempt, and then to explain in detail why the exemption applies so that the requester will have an opportunity to decide whether to pursue the disclosure of any of those additional records. See, e.g., Vaughn v. Rosen, 484 F.2d 820, 826 (D.C. Cir. 1973) (explaining that the Vaughn procedure is necessary because "there are no inherent incentives that would affirmatively spur government agencies to disclose information"). Thus, in opposing the government's insistence that this case could be resolved on the basis of a "representative" Vaughn index, CRT explained that this would forestall the agency from releasing all of the non-exempt records, since it meant that the agency would only be reviewing the IND G file, but none of the other files at issue. See Pl. Vaughn Reply at 3 ("the fact that plaintiff's request may still cover numerous records simply does not excuse the agency from complying with its mandatory statutory duty under the FOIA to make these records available unless they qualify for withholding under one of the exemptions to the statute") (emphasis added).

In any event, having made the representation – over four years ago – that the IND records are all "essentially uniform," the agency cannot now retract that representation by now insisting that the sponsors must review each of the IND files to determine which of their records can be released to plaintiff. Rather, if in fact, as the agency previously represented to this Court, the records in each of the IND files are "essentially uniform," then the FDA should be able to go through each of the remaining 18 IND files, pull out the records that are essentially the same as those from the IND G file that were already released, and promptly provide all such records to CRT – without any input whatsoever from the sponsors of these products.[2]

Indeed, it has been plaintiff's position for years that the FDA should have gone through this process and long ago disclosed all such non-exempt records, consistent with its obligations under the FOIA. See, e.g., Plaintiffs' Opposition To Defendants' Cross-Motion For Summary Judgment (July 9, 2003) at 2-3 ("The Court Should Order The Disclosure Of The Records Pertaining To The Other 18 Investigational New Drug Applications That Are Similar In Kind To The 'IND G' Records That The Government Has Already Disclosed"); Reply Memorandum In Support Of Plaintiff's Cross-Motion For Summary Judgment (August 28, 2003) at 1, note 1.

However, now that this Court has ordered the agency to disclose "all FDA generated records that pertain to the other 18 INDs that are similar in kind to the IND G records that the FDA has already released," and to do this "now," because the time for such disclosure "has

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[2]Moreover, according to the agency's own declaration, the sponsors were already consulted regarding which of the IND G files could be disclosed to plaintiff, and which information in the "representative" sample should be withheld. See Declaration of Beth Brockner Ryan at 5, ¶12 (explaining that the agency "directed its resources, in regard to this litigation, to . . . coordinating the redaction of information privileged under FOIA Exemption 4 with intervenor-defendants") (emphasis added).

arrived," id., the agency should not be permitted to continue to delay the disclosure of these records, and certainly not on the grounds that it needs to let each of the sponsors make these decisions.[3]

2. Letting The Sponsors Decide What Can Be Released Severely Prejudices CRT's Right Of Access Under The FOIA.

The FDA's startling revelation that, instead of the agency deciding which of the records in the other 18 IND Files are similar in kind to the records that were disclosed to plaintiff from the IND G file, it is allowing each of the sponsors to decide what can be released to plaintiff, is extremely worrisome for another – even more troubling – reason: it will likely result in CRT receiving far fewer records than it is entitled to under FOIA. In this regard, it is important for the Court to understand that the FDA is not talking about first segregating out from each of the 18 INDs all of the records that are similar to the IND G files that were released and then letting the sponsors have input as to whether any of the remaining records are exempt from disclosure. On the contrary, it is absolutely clear both from the government's opposition, and from the cover letters that it has sent each of the sponsors, that the FDA is sending all of the responsive records from each of the 18 INDs to the respective sponsors to allow them to designate what, in their opinion, should be withheld from plaintiff because it is "confidential."

Thus, the FDA's brief explains that its "system" for processing the remainder of CRT's March 9, 2000 request, is to provide each sponsor "with an opportunity to review the records for each IND," because the sponsors are in "a better position to know whether the information has

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[3]For this reason, plaintiffs' five-year old request for all the other non-exempt IND records should be treated as a "Fast Track" request by the agency, not a "Complex Track" request, as is apparently the case. See Declaration of Beth Brockner Ryan, ¶¶ 27-33, submitted in support of defendant's opposition.

some commercial or financial value to them." FDA Opposition at 7, 16; see also, e.g., FDA Letter to Jeremy T. Monthy (January 18, 2005) (attached to FDA Opp.) ("We have enclosed these documents to provide you with an opportunity to identify information in those records that you believe is exempt from disclosure under FOIA Exemption 4, 21 C.F.R. §§ 20.61 and 20.63, or other applicable statutes or regulations") (emphasis added).

Moreover, the FDA repeatedly explains that the reason it has taken this approach is to avoid "ancillary" reverse FOIA actions by the sponsors. See FDA Opp. at 16-17. However, since the only way that the FDA can completely assuage this concern is to defer to the sponsors' exemption claims, this raises serious questions about whether the agency can possibly be complying with its statutory duty to release to CRT all non-exempt information. Indeed, the agency's preoccupation with avoiding "ancillary" litigation is a bit strange, in light of the fact that its approach here – to allow each of the sponsors to decide which of their documents are to be withheld and which can be disclosed – puts plaintiff in the position of potentially having to litigate over 18 more IND files.

In fact, while apparently some of the sponsors have "consented" to the disclosure of many of the records at issue, see FDA Opp. at 12, others have informed the agency that they will oppose the release of much of the information, including, presumably many records that the FDA previously represented as "essentially uniform" to the IND G records that have already been released. See, e.g., Letter to G. Matthew Warren, FDA Associate Chief Counsel, from Jacek Rozga, President, arbios Systems (attached to FDA Opp.) ("we are certain that we will request the FDA to withhold most, if not all, the materials from release to the plaintiffs in connection with the CRT v. FDA [case]") (emphasis added); E-mail message to Matthew Warren from

Jeremy Monthy (March 16, 2005) (attached to FDA Opp.) "our client(s) [are] firmly opposed to unauthorized disclosure of documents") (emphasis added); Letter to G. Matthew Warren from Jeremy Monthy (April 7, 2005) ("[t]he designations attached in no way operate as an express or implied waiver of GenVec's rights to assert the applicability of FOIA exclusions for documents and information contained in the other two INDs recently forwarded by FDA for exclusion review") (emphasis added); see also FDA Opp. at 17, n.7 (explaining that "[t]he drug industry takes very seriously the release of confidential commercial information and trade secrets . . . and is willing to pursue judicial relief if it disagrees with the agency's release of material it believes warrants protection") (emphasis added)..

Furthermore, unlike the FDA, which has a mandatory duty under FOIA to err on the side of public disclosure, see e.g., Department of the Air Force v. Rose, 425 U.S. 352, 361 (1976) (agencies must "narrowly construe" FOIA exemptions), the sponsors have no such obligation, and, if anything, will clearly err on the side of keeping as much of this information "confidential" as possible. Indeed, the FDA itself concedes that the intervenors in this case have already "argued that everything in FDA's files was exempt from disclosure . . .." FDA Opp. at 16.

Therefore, in addition to slowing down the process for releasing the remaining non-exempt material to plaintiff, the FDA's "system" for fulfilling the Court's Order to "now disclose" these records, is simply unlawful. Again, based on its own previous representation to the Court that all of these records were "essentially uniform," the FDA should be able to identify all of the non-exempt records from the remaining 18 IND files – without the help of the sponsors – and to disclose them to CRT in a relatively short period of time.

3. Neither This Court Nor The Plaintiff Ever Agreed To Allow The FDA To Let The Sponsors Decide Which Of The Remaining Records Could Be Disclosed.

The government attempts to justify the approach it has taken here – which, again, has not only delayed the release of non-exempt records that plaintiff requested over five years ago, but also allows the IND sponsors to decide what needs to be disclosed – on the grounds that both the Court and plaintiff knew of, and therefore approved, the government's plans. See, e.g., FDA Opp. at 3 ("the Court acknowledged in its Opinion . . . FDA was to process the remaining responsive INDs consistent with the Court's subsequent rulings regarding IND-G") (citing the fact that the Court granted the sponsors' unopposed motions to intervene); id. at 14 ("[a]s this court has recognized in this case, sponsors of INDs have an interest in protecting confidential commercial information and trade secrets submitted in connection with their INDs"); id. at 4 (the FDA did not "read the Order or Opinion to require a process different from the one described in defendant's opposition to plaintiff's motion for summary judgment") (emphasis added). However, nothing could be further from the truth.

This Court did not decide – and defendant certainly has not cited any such ruling – that the FDA could wait until the "representative" exemption claims were fully adjudicated and then forward to the other 18 sponsors all of the responsive records from their IND files so that they could decide what, if anything, needs to be released to CRT because it is essentially the same as the IND G records that have already been disclosed. On the contrary, this Court simply ruled that the FDA could use a "representative" Vaughn index in this case, because the FDA assured the Court that this would be the most expeditious way to resolve which records had to be disclosed and which were exempt. See, e.g., Def. Vaughn Opp. 10 ("the Court can extrapolate from the

representative sample to the larger group of withheld materials" . . . "a sample Vaughn index would be truly representative of the documents that a comprehensive index would list") (emphasis added); id. at 11 ("Plaintiff could rely on the sample Vaughn index with a high degree of confidence that it is representative of the greater universe of FDA-generated documents responsive to its request") (emphasis added). Thus, the Court, like the plaintiff, had every reason to believe that, certainly by the time the "representative" exemption claims were finally decided, the FDA would make all of the remaining non-exempt records promptly available to CRT. See Mem. Op. at 22 (the "time has arrived" . . . "the FDA must now disclose all FDA generated records that pertain to the other INDS that are similar in kind to the IND G records that the FDA has already released") (emphasis added).

Remarkably, in making its argument that the plaintiff fully understood that the FDA would take its current approach – and hence necessarily acquiesced in that approach – the government cites only its own briefs on this subject. See, e.g. FDA Opp. at 3 (citing its own February 5, 2004 opposition to plaintiff's motion for summary judgment); id. at 20 (citing the "unambiguous statements FDA made regarding the time it would take to produce the documents, as well as relevant statutes and its own regulations"). However, the government fails to acknowledge that every single time it alluded to its position on this point, the plaintiff vigorously opposed that approach, and instead argued that the FDA could not continue to withhold from CRT any of the records from the other 18 IND files that are similar in kind to the non-exempt records from the IND G file that had already been released. See, Plaintiffs' Opposition To Defendants' Cross-Motion For Summary Judgment (July 9, 2003) at 2 - 3 ("The Court Should Order The Disclosure Of The Records Pertaining To The Other 18 Investigational New Drug

Applications That Are Similar In Kind To The 'IND G' Records That The Government Has Already Disclosed"); Reply Memorandum In Support Of Plaintiff's Cross-Motion For Summary Judgment (August 28, 2003) at 1, note 1 ("there are still as many as dozens of INDs that contain responsive records – for which the records in IND G were "representative," according to FDA – yet, "the FDA still has not disclosed any records from the other responsive INDs that are similar to the IND G records that FDA has disclosed to CRT during this litigation, such as clinical hold information") (emphasis added).[4]

This Court simply did not rule on this issue – one way or the other – until it resolved the parties' cross-motions for summary judgment. However, at that point, the Court certainly did not rule, as the government appears to suggest, that the government could take its time in disclosing all of those non-exempt records, or that it could farm all of the records out to the various sponsors to let them make these decisions. See Def. Mem. at 4 ("The Court did not set a deadline for production, nor did FDA read the Order or Opinion to require a process different from the one described in defendant's opposition to plaintiff's motion for summary judgment"). On the contrary, because the FDA had represented that all of the IND files were "essentially uniform" in kind, 180 F. Supp.2d at 34, this Court ruled that the FDA "must now disclose all FDA generated records that pertain to the other 18 INDs that are similar in kind -to the IND G records that the FDA has already released." Mem. Op. at 22 (emphasis added).

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[4]Nor does the fact that CRT entered into a "Memorandum of Understanding" ("MOU") with the defendants in 2002 have any relevance to the present dispute. FDA Opp. at 18. As the FDA itself admits, id., that MOU did not concern the non-exempt records at issue here. In addition, that MOU says absolutely nothing about the timing of the release of documents, and, as explained above, the FDA has not provided any justification whatsoever as to why it – without the assistance of the sponsors – cannot easily identify all of the non-exempt records that are in the other 18 IND files, so that such records can finally be released to CRT.

Indeed, in light of the actual ruling of the Court, and the fact that both parties had articulated their views on this subject in their briefs, see *supra*, it appears that plaintiff – not the defendant – prevailed on this particular point. Accordingly, plaintiff requests the Court to enforce its Order and to make it clear that the FDA – not the sponsors – must promptly identify all of the other non-exempt records that are similar in kind to the IND G records that have already been released, and order the FDA to produce all such records within ten days of the Court's Order. Plaintiff also requests that the Court award CRT its attorneys' fees and costs associated with having to file and pursue its motion to enforce. A revised proposed order is attached for this purpose.[5]

Conclusion

For the foregoing reasons, plaintiff respectfully requests that the Court grant plaintiff's Motion to Enforce.

[5]Nor may the sponsors now assert that they must have an opportunity to review all of the IND records that are similar in kind to the IND G files that have already been release, for purposes of asserting exemption claims. These sponsors did not oppose the "representative" IND approach that was used by the FDA, and they have all had ample time to assert and demonstrate that, although certain records in their IND files are "essentially uniform" to the IND G files that have already been released to plaintiff, they are nonetheless unique for some reason and must be withheld under Exemption 4 or some other basis. They have failed to do so. Accordingly, any claims that such records – i.e., those that are similar in kind to the IND G files that have already been released – are nevertheless exempt from disclosure, have been waived. See Maydak v. Department of Justice, 218 F.3d 760, 764 (DC Cir. 2000) (the government "must assert all exemptions at the same time, in the original district court proceedings . . . the delay caused by permitting the government to raise FOIA exemption claims one at a time interferes both with the statutory goals of 'efficient, *prompt*, and full disclosure of information" (emphasis in original).

Respectfully submitted,

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