UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

INFORMED CONSENT ACTION NETWORK, Plaintiff, -v- UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant.	20 Civ. 689 (AJN)

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFF'S CROSS-MOTION FOR SUMMARY JUDGMENT

AUDREY STRAUSS
Acting United States Attorney for the
Southern District of New York
86 Chambers Street, 3rd Floor
New York, New York 10007
Tel.: (212) 637-2677
E-mail: samuel.dolinger@usdoj.gov

SAMUEL DOLINGER
Assistant United States Attorney
– Of Counsel –

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Defendant FDA,[1] by its attorney, Audrey Strauss, Acting United States Attorney for the Southern District of New York, respectfully submits this reply memorandum of law in further support of its motion for summary judgment under Rule 56 of the Federal Rules of Civil Procedure, and in opposition to Plaintiff's cross-motion for summary judgment.

PRELIMINARY STATEMENT

Plaintiff ICAN's brief in opposition, Dkt. No. 18 ("ICAN Br."), presents no argument that persuasively opposes FDA's motion for summary judgment or supports the entry of judgment in ICAN's favor. ICAN spends much of its brief block-quoting its own correspondence enunciating its "concerns" with the safety of vaccines, *see* ICAN Br. at 7-11—but such assertions are simply irrelevant to this FOIA action. The issue before the Court is whether ICAN's request for reports of clinical trials of Engerix-B, a hepatitis-B vaccine, with "a safety review period longer than seven days following administration of this vaccine" reasonably describes the records ICAN is seeking.

For the reasons set forth in FDA's opening brief, Dkt. No. 15 ("Gov't Br."), ICAN's request fails to reasonably describe the records sought. ICAN's briefing in opposition does not correct these fundamental flaws: it refuses to clarify the irreducibly vague terminology ICAN used in its original FOIA request. Further, the request impermissibly attempts to use FOIA to requisition government employees to conduct a research project on the requester's behalf. ICAN also fails to provide a reasonable rationale for its refusal to accept the full set of pre-approval clinical trial records related to the Engerix-B vaccine, which would have permitted ICAN to conduct its own analysis of the "safety review period" in the trials.

[1] Capitalized terms and abbreviations herein have the same meaning assigned to them in FDA's opening brief, Dkt. No. 15.

Last, ICAN's request for discovery is inappropriate and should be denied. Discovery is generally disallowed in FOIA actions except on a showing of agency bad faith. FDA's declarations—which are entitled to a presumption of good faith—adequately explain and justify its response to the FOIA request, in light of ICAN's refusal to define key terms and its rejection of FDA's reasonable alternative offer to provide a broader set of Engerix-B records. ICAN makes only a conclusory argument for discovery, and fails to demonstrate bad faith or any other valid reason to authorize discovery here. Furthermore, ICAN is attempting to access some of the same records through discovery that are subject to the FOIA request, which would amount to an impermissible end-run around FOIA's statutory requirements.

For all these reasons, the Court should grant FDA's motion for summary judgment, deny ICAN's cross-motion, and deny ICAN's request to conduct discovery in this FOIA action.

ARGUMENT

I. ICAN's FOIA Request Fails to Reasonably Describe the Subset of Engerix-B Vaccine Records It Seeks

ICAN does not contest that a request must "reasonably describe[]" the records sought under 5 U.S.C. § 552(a)(3)(A), and a request that fails to do so is a nullity that does not require a search for records or satisfy the requirement that a requester must exhaust administrative remedies. *See Truitt v. Dep't of State*, 897 F.2d 540, 544 (D.C. Cir. 1990); *Sussman v. DOJ*, No. 03 Civ. 3618 (DRH) (ETB), 2006 WL 2850608, at *9 (E.D.N.Y. Sept. 30, 2006); *Manfredonia v. SEC*, No. 08 Civ. 1678 (SLT) (LB), 2009 WL 4505510, at *5 (E.D.N.Y. Dec. 3, 2009); *see* Gov't Br. at 5-7. Because ICAN's request does not meet this requirement under FOIA, as further set forth below, judgment should be entered in the government's favor.

A. ICAN's Request Does Not Permit the Agency to Determine Precisely What Records Have Been Requested

ICAN's opposition fails to demonstrate how its request leads to an ascertainable set of records. FOIA requires only that an agency respond to appropriate requests for records that enable it to "determine precisely what records are being requested." *Yeager v. DEA*, 678 F.2d 315, 326 (D.C. Cir. 1982) (quotation marks and alterations omitted). Here, ICAN's FOIA request used the undefined term "safety review period," coupled with the time period of "longer than seven days," which ICAN has repeatedly refused to clarify, both at the administrative stage and during this litigation. *See* Dkt. No. 16 ("Burk Decl.") ¶¶ 9-18, 22-28. In its brief, ICAN makes the conclusory statement that its request is "crystal clear," and then simply recites the language of its own request, *see* ICAN Br. at 3, 18, without any meaningful attempt to dispel the ambiguity. An agency need not respond to a request that—like this one—is "insufficiently specific to enable a search under the parameters of FOIA." *Williams v. DOJ*, No. 16 Civ. 512, 2016 WL 3027543, at *5 (D. Md. May 27, 2016).

ICAN fails to clarify whether its request for trials with "a safety review period longer than seven days following administration" would encompass, for instance, trials where there was follow-up with study participants shortly after each of multiple administrations of the vaccine, spaced weeks or months apart. *See* Burk Decl. ¶ 20. Despite the fact that FDA specifically identified this ambiguity in its opening brief and declaration, *see id.*, Gov't Br. at 8-9, ICAN did nothing to reduce the "guesswork" that would be required to respond to its request, *see Yagman v. Pompeo*, 868 F.3d 1075, 1081 (9th Cir. 2017); *see also Nat'l Sec. Counselors v. CIA*, 960 F. Supp. 2d 101, 158 (D.D.C. 2013) (request failed to reasonably describe the records sought where it "left a significant amount of ambiguity about precisely what records were being requested" (quotation marks and brackets omitted)).

The fact that the phrase "safety review period" has been used, in context, in a few FDA documents regarding drug trials that ICAN has selectively presented here, ICAN Br. at 15-16, does not give it a generally ascertainable meaning that FDA can reasonably apply to ICAN's FOIA request. A review of files from a separate set of pre-approval clinical vaccine trials, relating to a different hepatitis-B vaccine called Recombivax HB (previously produced to ICAN in response to a separate FOIA request) is instructive, as set forth in FDA's supplemental declaration, annexed hereto. *See* Supplemental Declaration of Suzann Burk ("Suppl. Burk Decl.") ¶¶ 18-25. Among the Recombivax clinical trials, FDA "identified no records" that "use the terminology 'safety review period.'" *Id.* ¶ 18.

As FDA states, the "reporting of safety information in clinical trial records can be complex and nonstandardized." Suppl. Burk Decl. ¶ 19. Excerpts of the Recombivax clinical trial records, annexed to FDA's declaration, are instructive in showing the difficulties in making these assessments. For instance, one of the Recombivax clinical trials measured adverse events for five days after the administration of doses of the vaccine given at 0, 1, and 6 months. *Id.* ¶ 20 & Ex. 1. However, the study appears to have continued to follow patients through doses administered 1 and 6 months later. *See id.* Ex. 1. Moreover, the trial report stated that "there have been no serious or alarming reactions attributable to the vaccine," and further stated "that the trial was still 'in progress,' more than a year after commencement." *Id.* ¶ 21 (brackets omitted) & Ex. 1. The report did "not state whether the period for reporting adverse events or other safety information had been completed at that time." *Id.* Further, "it is unclear . . . whether the reporting of complaints, known as adverse events, would comprise a 'safety review,' as additional factors not listed could be taken into account to determine a vaccine's overall safety, and adverse events can often be unrelated to a vaccine." *Id.* ¶ 22.

Another Recombivax clinical trial—summarized in the records produced by FDA—stated that "at eight months into the study, patients showed 'no serious or alarming adverse events attributable to the vaccine' and that 'vaccination and follow-up continue in progress.'" Suppl. Burk Decl. ¶ 24 (brackets omitted) & Ex. 2. However, the "summary does not state the time period reviewed to make this determination" that there were no serious adverse events, nor "whether these patients only reported adverse events for a specific number of days following a dose administration," or if "the period for reporting adverse events or other safety information had been completed at that time." *Id.* ¶ 24.

In light of comparable obstacles to interpreting ICAN's request for Engerix-B records, FDA's actions in response here were reasonable. At the administrative phase, FDA exchanged communications with ICAN's representatives in an attempt to clarify the unclear portion of the request or to find an alternate resolution. *See* Burk Decl. ¶¶ 22-27. In response, ICAN refused to engage: it simply repeated that it was looking for clinical trials with a "safety review period" of "longer than seven days." *Id.* ¶¶ 24-27 & Ex. B-2 to B-4. Courts have taken requesters' refusals to meaningfully confer into account in concluding that FOIA requests failed to reasonably describe the records sought. *See Robert v. CIA*, No. 02 Civ. 6788 (JS) (AKT), 2018 WL 1598611, at *6 (E.D.N.Y. Mar. 31, 2018) (noting that requester "did not meaningfully narrow or clarify his request," and agreeing with agency that the request did not reasonably describe the records sought), *aff'd*, 779 F. App'x 58 (2d Cir. 2019) (summary order); *see also Dale v. IRS*, 238 F. Supp. 2d 99, 105 (D.D.C. 2002) (noting court's reluctance to "reward" a requester for its "failure to engage in meaningful and reasonable discussions with the [agency] in an attempt to resolve issues concerning the scope and specificity of [the relevant FOIA] request").

B. ICAN Cannot Use Government Resources to Conduct Research Projects

ICAN provides no support for its position that it is entitled to have FDA employees conduct a research project on its behalf, using vague parameters of its choosing.

ICAN first argues that the FDA's statutory duties include determining whether vaccines are safe and effective. ICAN Br. at 1. Contrary to ICAN's arguments, however, the safety of vaccines is not at issue in this litigation; rather, the issue is whether ICAN's FOIA request sufficiently specified what records it was seeking—and it failed to do so, as explained above.

FOIA does not permit requests that would allow a requester to dragoon agency staff into performing an indeterminate, subjective, or scientific inquiry to locate the records at issue. For this reason, courts have previously rejected FOIA requests that would require an agency to sift through a larger body of records and analyze them using ambiguous terms provided by the requester. *See Nat'l Sec. Counselors*, 960 F. Supp. 2d at 158 (concluding that agency properly declined to respond to request that "superimpose[d] a layer of subjective analysis onto the agency's response effort which the FOIA does not require").

ICAN makes the facile argument that FOIA requires agency employees to review documents in the course of conducting a search. ICAN Br. at 3, 13. But as FDA made clear, the issue is not whether it must "review . . . agency records for the purpose of locating those records which are responsive to a request," 5 U.S.C. § 552(a)(3)(D), which FDA does with respect to FOIA requests including this one, *see* Burk Decl. ¶¶ 7-10, 12-15. In fact, ICAN concedes that FDA did so here. *See* ICAN Br. at 14, 18. Rather, the problem with ICAN's request is that it uses indeterminate terms that fail to make clear what records are within its scope, which precluded FDA from identifying which records among the Engerix-B clinical trials were in fact responsive to the request after it performed its initial search and review to locate potentially responsive records. *See supra* Part I.A; Gov't Br. at 8-10.

Among other issues, ICAN's request would require clinical *interpretation* of the records, not just a manual review. *See* Burk Decl. ¶¶ 16-21. As FDA has explained, even if an "FDA clinical or medical regulatory reviewer" might be able to make certain clinical determinations upon review of vaccine trial records, an FDA "disclosure reviewer processing FOIA requests" cannot do so, *id.* ¶ 21—nor does FOIA require it. *See Hall & Assocs. v. EPA*, No. 16-5315, 2018 WL 1896493, at *2 (D.C. Cir. Apr. 9, 2018) (unpublished) (FOIA request did not "reasonably describe the documents sought" where it "would have required [the agency] to undertake research, analysis, and formulation of opinions—actions not required by FOIA").

ICAN appears to recognize this distinction, quoting a source stating that a "*multidisciplinary FDA reviewer team*" must review BLAs to ensure they contain "the efficacy and safety information necessary to make a risk/benefit assessment and to recommend or oppose the approval of a vaccine." ICAN Br. at 14-15 (emphasis added; quotation marks omitted). Obviously, however, FOIA does not saddle an agency's substantive experts with the burden of conducting a bespoke expert analysis at public expense for the benefit of a FOIA requester. *See* Burk Decl. ¶¶ 16-21; Suppl. Burk Decl. ¶¶ 17, 25; *see also Hall & Assocs. v. EPA*, 83 F. Supp. 3d 92, 102 (D.D.C. 2015) (an agency is not required to "conduct research in response to a FOIA request"), *aff'd*, No. 16-5315, 2018 WL 1896493 (D.C. Cir. Apr. 9, 2018) (unpublished); *Nat'l Sec. Counselors*, 960 F. Supp. 2d at 158 (concluding that "sifting and analysis is not a burden that the FOIA imposes on federal agencies"); *Dale*, 238 F. Supp. 2d at 105 (FOIA does not require an agency to engage in a "fishing expedition" at "taxpayer expense").

Last, ICAN makes the irrelevant assertion that its request is less extensive in scope than certain requests that courts have rejected on undue burden grounds. ICAN Br. at 17. But this is a straw-man argument: FDA has not asserted that ICAN's request is burdensome due to

excessive scope. Rather, the critical flaw in ICAN's request is the indefinite nature of the request and the fact that it asks FDA to provide a clinical judgment. Indeed, in making this argument, ICAN ignores the fact that FDA offered to produce a *larger* number of Engerix-B clinical trial records, but ICAN refused to accept those records, as further described below.

C. ICAN Presents No Valid Rationale for Its Refusal of FDA's Offer to Provide a Broader Set of Engerix-B Records

ICAN cannot convincingly explain why it refused FDA's reasonable offer to provide *all* of the pre-approval clinical trials for Engerix-B, so that ICAN could conduct its own analysis of the "safety review period" as it deemed appropriate. *See* Burk Decl. ¶¶ 25-27 & Ex. B-3 to B-4. ICAN claims that it did not want the full set of documents, ICAN Br. at 2, but it does not contest that the full set of clinical trial records would necessarily contain the documents ICAN requested through FOIA, *see* ICAN Br. at 16; *see also* Burk Decl. ¶ 26.

ICAN protests that FDA's proposal would have provided *too much* information. ICAN Br. at 20. But ICAN's purported rationale for its refusal to accept the full set of clinical trial records is both inconsistent with its own arguments and contradicted by its conduct respecting other FOIA requests. The set of records FDA offered here hardly amounts to a "production dump." *Id.* The full set of potentially responsive clinical trial records was estimated to consist of approximately 3,000 hard-copy pages, Burk Decl. ¶ 12—hardly an insurmountable task for ICAN to review. ICAN also fails to respond to case law indicating that a broader response to a FOIA request can be appropriate where the nature of the plaintiff's requested search necessitates it. *See Pinson v. DOJ*, 80 F. Supp. 3d 211, 216 (D.D.C. 2015) (citing *Greenberg v. U.S. Dep't of Treasury*, 10 F. Supp. 2d 3, 13 (D.D.C. 1998)).

The notion that it would be burdensome for ICAN to conduct its own review of the clinical trial records is belied by its own papers, where it refers to the "limited universe of

potentially responsive documents" in this case and says that only a "simple review" is required. ICAN Br. at 4, 22; *see id.* at 16 (ICAN's claim that a responsiveness review would require only a "simpl[e] glance at the duration that safety was reviewed"). ICAN says that all that is necessary would be to look at summaries of the clinical trials' methodology, and that it can "easily determine the safety review period in the clinical trials" for other vaccines "within minutes." ICAN Br. at 21. Such assertions, however, cannot be squared with the fact that FDA offered ICAN the opportunity to conduct this purportedly "simple" analysis of the Engerix-B clinical trial records for itself, but ICAN declined. *See* Burk Decl. ¶¶ 25-27.

Moreover, ICAN is a serial FOIA requester and frequent FOIA litigant, regularly seeking vaccine information from federal health agencies, including FDA. The notion that it is trying to avoid what it terms a "document dump," ICAN Br. at 2, is belied by its prior requests and litigation conduct. Indeed, for a number of other vaccines, ICAN has previously requested precisely what FDA offered here: the full set of pre-approval clinical vaccine trials. As set forth in FDA's supplemental declaration, ICAN "has requested and received thousands of pages of clinical trial records in response to numerous other FOIA requests." Suppl. Burk Decl. ¶ 6. Since August 2018, ICAN has requested the full set of pre-approval clinical trials for nine different vaccines—which have resulted in the production of more than 18,000 pages of records. *See id.* ¶¶ 6-7. Two additional FOIA requests by ICAN for pre-approval clinical trial records for vaccines are currently pending with FDA. *Id.* ¶ 7.[2]

[2] ICAN is also a frequent FOIA litigant, having filed eight additional FOIA actions in this district since 2018. *See ICAN v. CDC*, 20 Civ. 6177 (JGK); *ICAN v. FDA*, 20 Civ. 5554 (JPO); *ICAN v. CDC*, 20 Civ. 1453 (ALC) (OTW); *Inst. for Autism Science & ICAN v. CDC*, 19 Civ. 11947 (LJL); *ICAN v. FDA*, 19 Civ. 10235 (JGK); *ICAN v. FDA*, 18 Civ. 11237 (VEC); *ICAN v. HHS*, 18 Civ. 3215 (JMF); *ICAN v. NIH*, 18 Civ. 2000 (PAC).

Among other vaccine-related records, ICAN previously requested and received the full set of pre-approval clinical trial records for another hepatitis-B vaccine known as Recombivax HB, as noted *supra* in Part I.A. The history of ICAN's requests with respect to Recombivax HB is worth noting here. ICAN first requested the full set of pre-approval clinical trial reports for Recombivax HB in August 2018. Suppl. Burk Decl. ¶ 8. FDA produced these records by November 2019—a total of more than 1,200 pages. *Id.* ¶¶ 7, 10-11. But despite having made this outstanding request for *all* pre-approval clinical trials for Recombivax HB, ICAN made a second request in June 2019, seeking the pre-approval Recombivax HB trials "that had a safety review period longer than seven days following administration of this vaccine," *id.* ¶¶ 12-13—the same language in dispute here with respect to the Engerix-B clinical trials. As with the Engerix-B request, FDA informed ICAN that its request using these terms did not reasonably describe the records sought. *Id.* ¶ 14.

FDA made a similar proposal to modify ICAN's second Recombivax request to seek the full set of pre-licensure clinical trial reports, and further noted that the responsive records would be included in ICAN's pending first request for Recombivax records. *Id.* ¶ 15. ICAN declined this proposal. *Id.* FDA later confirmed to ICAN in January 2020 that all records responsive to ICAN's second Recombivax request had already been produced in response to ICAN's first Recombivax request, which sought the full set of pre-approval clinical trials for the vaccine. *Id.* ¶¶ 15-16. There is no apparent explanation why ICAN requested a subset of Recombivax HB clinical trial records—the same subset it is demanding as to Engerix-B—when it had already requested the full set of pre-approval clinical trials for this vaccine.

In its brief, ICAN presents the unfounded speculation that FDA's response to its response is "political, rather than [due to] an inability to locate the responsive records," and theorizes that

"there may be no such clinical trials relied upon to license Engerix-B which reviewed safety for more than one week after administration." ICAN Br. at 2. But a requester cannot "design[]" its FOIA request "as a trap," where the agency must "either . . . produce[] or create[] documents disproving [the requester's] accusations, or the [requester] would assume based on the lack of response that [the agency] could not disprove them." *Hall & Assocs.*, 83 F. Supp. 3d at 102. Such a request does "not adequately describ[e] the records sought, and [the agency] thus ha[s] no obligation to process" the request. *Id.* Finally, ICAN's baseless conjectures and its protests that FDA is using a "loophole[]" to "deny . . . access," ICAN Br. at 19 (quotation marks omitted), only underscore the curiousness of ICAN's refusal to accept the full set of Engerix-B pre-approval clinical trial records, as offered by FDA more than a year ago, *see* Burk Decl. ¶¶ 24-27.

* * *

For the foregoing reasons, ICAN's FOIA request fails to reasonably describe the records sought, and ICAN unreasonably refused FDA's alternative offer to produce all pre-approval clinical trials for Engerix-B. Accordingly, FDA's motion for summary judgment should be granted, and ICAN's cross-motion should be denied.

II. Plaintiff's Request for Discovery Is Meritless and Should Be Denied[3]

"[D]iscovery is not favored in lawsuits under the FOIA." *Main St. Legal Servs., Inc. v. Nat'l Sec. Council*, 962 F. Supp. 2d 472, 478 n.4 (E.D.N.Y. 2013) (quotation marks

[3] ICAN has served a discovery request (attached as Exhibit A to its brief, Dkt. No. 18) on the government by e-mail. The government agreed to accept service by e-mail but objects to the request for discovery in this FOIA matter, as set forth herein. The government does not believe that any further responses or objections under Fed. R. Civ. P. 26 and 34 are required at this time, because prior Court authorization is necessary to conduct discovery in FOIA matters. ICAN has advised that it "does not believe the government should be able to object both now in its papers and again, if necessary, after the Court's decision," and also believes that "the Court's June 3, 2020 Endorsement permits the discovery." The government intends to seek a conference

omitted)), *aff'd*, 811 F.3d 542 (2d Cir. 2016); *accord, e.g.*, *Estate of Ghais Abduljaami v. U.S. Dep't of State*, No. 14 Civ. 7902 (RLE), 2016 WL 94140, at *2 (S.D.N.Y. Jan. 7, 2016); *Ferguson v. U.S. Dep't of Educ.*, No. 09 Civ. 10057 (FM), 2011 WL 4089880, at *14 (S.D.N.Y. Sept. 13, 2011). Indeed, "discovery of any type is generally not allowed in FOIA proceedings." *Pinson v. DOJ*, 55 F. Supp. 3d 80, 82 (D.D.C. 2014).[4]

An agency's declarations are "accorded a presumption of good faith." *Grand Cent. P'ship, Inc. v. Cuomo*, 166 F.3d 473, 489 (2d Cir. 1999) (quotation marks omitted). Once an agency has demonstrated the propriety of its response through its declarations, as FDA has here, a FOIA plaintiff may obtain discovery only if it can show "bad faith on the part of the agency sufficient to impugn the agency's affidavits," or "provide some tangible evidence that . . . summary judgment [in favor of the agency] is otherwise inappropriate." *Carney v. DOJ*, 19 F.3d 807, 812 (2d Cir. 1994); *see Baker & Hostetler LLP v. U.S. Dep't of Commerce*, 473 F. 3d 312, 318 (D.C. Cir. 2006) ("Discovery in FOIA is rare and should be denied where an agency's declarations are reasonably detailed, submitted in good faith and the court is satisfied that no factual dispute remains." (quoting *Schrecker v. DOJ*, 217 F. Supp. 2d 29, 35 (D.D.C. 2002))).

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pursuant to Rule 2.C of Your Honor's individual practices and Local Civil Rule 37.2 regarding these improper discovery demands.

[4] *See, e.g.*, *Shapiro v. DOJ*, No. 12 Civ. 313, 2020 WL 3615511, at *5 (D.D.C. July 2, 2020) (request for discovery is an "uphill challenge" because "the law is well settled that discovery is generally disfavored in mine-run FOIA cases" (quotation marks omitted)); *Freedom Watch v. Bureau of Land Mgmt.*, 220 F. Supp. 3d 65, 68 (D.D.C. 2016) (discovery is "both rare and disfavored" in FOIA actions); *Justice v. IRS*, 798 F. Supp. 2d 43, 47 (D.D.C. 2011) ("In FOIA actions . . . discovery is disfavored."), *aff'd*, 485 F. App'x 439 (D.C. Cir. 2012) (unpublished); *Harrison v. Fed. Bureau of Prisons*, 681 F. Supp. 2d 76, 80 (D.D.C. 2010) (same); *Thomas v. HHS*, 587 F. Supp. 2d 114, 115 n.2 (D.D.C. 2008) (discovery is "an extraordinary procedure" in a FOIA case); *Wolf v. CIA*, 569 F. Supp. 2d 1, 9 (D.D.C. 2008); *Wheeler v. CIA*, 271 F. Supp. 2d 132, 139 (D.D.C. 2003) ("Discovery is generally unavailable in FOIA actions.").

Even in cases where courts conclude that an agency's affidavits are "deficient" at summary judgment, "courts generally do not grant discovery but instead direct the agency to supplement its affidavits." *Beltranena v. Clinton*, 770 F. Supp. 2d 175, 187 (D.D.C. 2011) (quotation marks omitted); *accord Freedom Watch v. Bureau of Land Mgmt.*, 220 F. Supp. 3d 65, 70 (D.D.C. 2016) ("Even if . . . the Court concluded that [agency] declarations were insufficient, discovery would not be the remedy of first resort"; instead the court could "request that the agency supplement its supporting declarations" (quotation marks omitted)).

Motions for discovery are rarely granted in FOIA cases for good reason: because "discovery requests in these cases threaten to turn FOIA on its head, awarding plaintiff in discovery the very remedy" that it seeks through its suit. *Freedom Watch*, 220 F. Supp. 3d at 68 (alterations and quotation marks omitted). Courts thus "must not grant FOIA plaintiffs discovery that would be tantamount to granting the final relief sought." *Tax Analysts v. IRS*, 410 F.3d 715, 722 (D.C. Cir. 2005) (quotation marks omitted).

Plaintiff fails to establish any ground for bad faith, and makes no effort to provide "tangible evidence" that summary judgment is inappropriate. Rather, ICAN makes only the conclusory and unsupported statement that it "has a reasonable basis to believe that the FDA's argument regarding the words 'safety review period' was asserted in bad faith." ICAN Br. at 23. But ICAN's meager attempt to claim bad faith amounts to nothing more than disagreement with FDA's reasonable efforts to seek clarification regarding the scope of ICAN's nebulous request.

In effect, ICAN "essentially asks the Court to presume bad faith" by FDA, but this is precisely "the opposite of what the law instructs." *Conti v. DHS*, No. 12 Civ. 5827 (AT), 2014 WL 1274517, at *14 (S.D.N.Y. Mar. 24, 2014); *cf. Trudeau v. FTC*, 384 F. Supp. 2d 281, 295 (D.D.C. 2005) ("The bad faith of government actors is notoriously easy to allege and difficult to

disprove, and [a plaintiff] cannot avail himself of the discovery process in the hopes of stumbling upon such evidence where he can point to no indication that it exists to begin with."), *aff'd*, 456 F.3d 178 (D.C. Cir. 2006). Rather, "[i]t is well established that the Government is entitled to a presumption of good faith" in its response to FOIA requests. *Adamowicz v. IRS*, 672 F. Supp. 2d 454, 464 (S.D.N.Y. 2009), *aff'd*, 402 F. App'x 648 (2d Cir. 2010) (summary order).

ICAN's "mere assertion of bad faith is not sufficient to overcome a motion for summary judgment." *Baker & Hostetler*, 473 F.3d at 318 (quoting *Assassination Archives & Research Ctr. v. CIA*, 177 F. Supp. 2d 1, 8 (D.D.C. 2001)) (quotation marks omitted). What is more, here FDA demonstrated its good faith by attempting to negotiate with ICAN to provide all of the information ICAN sought, and indeed, a *broader* set of information that would necessarily include all of the requested records. *See supra* Part I.C; Burk Decl. ¶¶ 24-27.

ICAN's proposed discovery requests would also violate the basic principle that a FOIA requester cannot receive the records it seeks under FOIA through discovery. *Tax Analysts*, 410 F.3d at 722; *Freedom Watch*, 220 F. Supp. 3d at 68. Here, among other things, ICAN seeks the Court's authorization to request "Documents reflecting the study procedures (a.k.a., clinical protocol or study design) and any summary for each clinical trial involving babies or children that the FDA relied upon to license Engerix-B." ICAN Br. Ex. A. Evidently, permitting such a request through discovery would grant ICAN access to some, if not all, of the very records that it did not properly request under FOIA—a clearly unacceptable outcome. *See Tax Analysts*, 410 F.3d at 722; *Elgabrowny v. CIA*, No. 17 Civ. 66 (TSC), 2019 WL 1440345, at *16 (D.D.C. Mar. 31, 2019) (denying "discovery request . . . tantamount to a request for the same records sought in [plaintiff's] FOIA Requests").

ICAN's other proposed discovery requests are also flawed. One seeks "[a]ll emails" concerning its own FOIA request, and another seeks "[a]ll emails and electronic documents that contain the phrase 'safety review period,'" ICAN Br. Ex. A, without any attempt to make a logical showing that these requests are germane to the issues in dispute here—much less that this matter requires the extraordinary step of permitting discovery in a FOIA action. As stated above, the fact that the phrase "safety review period" may exist generically in agency documents does not mean that it has an ascertainable meaning in ICAN's FOIA request.

In sum, "mere suspicion of bad faith on the part of the government"—all that ICAN presents here—"cannot be used as a dragnet to authorize . . . discovery that is irrelevant to the remaining issues in a case." *In re Clinton*, --- F.3d ---, No. 20-5056, 2020 WL 5104233, at *5 (D.C. Cir. Aug. 31, 2020). Accordingly, ICAN's request for discovery should be denied.

CONCLUSION

For the foregoing reasons, and for the reasons set out in Defendant's opening brief, the Court should grant FDA's motion for summary judgment under Rule 56 of the Federal Rules of Civil Procedure, and deny Plaintiff's cross-motion and request for discovery.

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New York, New York

Respectfully submitted,

AUDREY STRAUSS
Acting United States Attorney for the
Southern District of New York

By: /s/ Samuel Dolinger
SAMUEL DOLINGER
Assistant United States Attorney
86 Chambers Street, 3rd Floor
New York, New York 10007
Tel.: (212) 637-2677
E-mail: samuel.dolinger@usdoj.gov