UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

INFORMED CONSENT ACTION NETWORK,

Plaintiff,

-against-

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendant.

1:20-cv-00689-AJN

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

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Plaintiff Informed Consent Action Network ("**ICAN**" or "**Plaintiff**"), by and through its attorneys, respectfully submits this memorandum of law in support of its cross-motion for summary judgment and in opposition to the motion for summary judgment by defendant the United States Food and Drug Administration ("**FDA**" or "**Defendant**") .

PRELIMINARY STATEMENT

Plaintiff commenced this action, pursuant to the Freedom of Information Act ("**FOIA**"), to compel Defendant to respond to its FOIA request seeking the pre-licensure clinical trials that reviewed safety for longer than seven days that the FDA relied upon to approve Engerix-B for babies and children. The FDA objected to this request claiming that the request did not reasonably describe the clinical trials Plaintiff was seeking because the FDA does not know how to identify the clinical trials it relied upon to license Engerix-B that reviewed safety for more than seven days after injection.

This objection is incredible. The FDA's raison d'être, core function, and statutory mandate with regard to vaccines, such as Engerix-B, *is* to review clinical trials conducted by their manufacturers to determine if they are safe and effective. Reviewing clinical trials is *how* the FDA fulfills its statutory mandate to only license "safe and effective" products. In fact, the very first sentence of the FDA's webpage entitled "Vaccines" states that "Vaccines, as with all products regulated by the FDA, undergo a *rigorous review of laboratory and clinical data* to ensure the safety, efficacy, purity and potency of these products."[1] It is, as the FDA explains, "What We Do."[2]

[1] https://www.fda.gov/vaccines-blood-biologics/vaccines (last visited August 11, 2020).

[2] *Id.*

Here, the FDA would have this Court believe that it is incapable of determining what "a safety review period of longer than seven days" means and, therefore, is incapable of producing records responsive to Plaintiff's request. Instead of responding to Plaintiff's simple request, the FDA demanded that Plaintiff modify its request to request all clinical trials, spanning 3,000 pages, relied upon by the FDA to license Engerix-B. The FDA would then, as it explains, perform a "line-by-line, word-by-word disclosure review" to identify needed exemptions and electronically apply needed redactions to the 3,000 pages – a time-consuming and expensive process.

Plaintiff is not interested in a document dump or in waiting for what will likely be an extended period for this broader production. It is only interested in the clinical trials for babies and children that reviewed safety for longer than one week after administration, and Plaintiff is entitled by FOIA to receive a response to this straightforward, targeted, and specific request. Nevertheless, the FDA's refusal to answer this simple request may be political, rather than an inability to locate the responsive records. The FDA may not want to respond to this request because there may be no such clinical trials relied upon to license Engerix-B which reviewed safety for more than one week after administration. Meaning, the FDA's response to the FOIA request may be "no responsive records." This may also not be the case and there may be responsive clinical trial records.

Either way, the FDA has deployed arguments that on their very face strain credibility and do not withstand even the slightest scrutiny. Its initial argument is that the term "safety review period" is not a defined term. First, the FDA surely understands what is being requested. The phrase "safety review period" is used by scientists, including those who work for the FDA, in peer-reviewed publications to mean the period that safety was reviewed in a clinical trial. Second, even if this was not a standard term used in the industry, by even grade school grammar standards, the

phrase "safety review period longer than seven days following administration of this vaccine" is not overly challenging to understand. It means: clinical trials in which safety was reviewed for more than seven days after administering this product. FOIA merely requires that the documents requested be "reasonably described" and it is abundantly clear that Plaintiff's request satisfies this standard by describing the clinical trial reports being requested.

Quizzically, and in contradiction to its first argument, the FDA then admits it *does* understand precisely what is being asked and could even identify responsive clinical trials if it reviews the clinical trial reports. Yet the FDA then bizarrely argues that since this "can only be done by reading" the clinical trial reports, the FDA is not required to respond under FOIA. However, that is precisely what FOIA requires. It requires the FDA to manually review agency records for the purpose of locating responsive documents. *See* 5 U.S.C. § 552(3)(D) ("'Search' means to *review, manually*… agency records *for the purpose of locating those records which are responsive to a request.*") (emphasis added). The FDA even admits in its declaration on this motion that the FDA officer "must search for and collect potentially responsive records from various file locations … [and] after she collects potentially responsive records, *she conducts an initial review to verify that the records are, in fact, responsive to the request*." Indeed, a requester would be hard-pressed to make a request that required no reading or review of documents.

The FDA's final excuse for not reviewing the documents is that "a safety review period longer than seven days following administration of this vaccine" is "indefinite" because it does not "sufficiently specify what the start date of a seven-day 'safety review period' would be." This argument is truly dumbfounding. The start of the seven days is crystal clear in the request. It is "seven days *following the administration of the vaccine*."

"The burden is on the agency to justify that it has performed an adequate search in response to a proper FOIA request." *Am. Oversight v. EPA*, 386 F.Supp.3d 1, 6 (D.D.C. 2019); *see also* 5 U.S.C. § 552(a)(4)(B). "Every reasonable effort shall be made by the Food and Drug Administration to assist in the identification and location of the records sought." 21 C.F.R. § 20.40(b)(2). Plaintiff is only asking the FDA to uphold its duty to have an FDA employee familiar with clinical trials review the already identified universe of potentially responsive documents to determine which clinical trials are, indeed, responsive. Plaintiff is not asking the FDA to create a new document that does not exist; nor is the FDA being asked to "create documents or opinions in response to" Plaintiff's request. To argue that this reasonable effort should not include a review of an identified, limited universe of potentially responsive documents is nonsensical. Thus, the FDA has not made a reasonable effort to comply.

Indeed, the FDA has not submitted any explanation of any efforts made to identify the clinical trial reports within the 3,000 pages that were quickly and easily located. The FDA provides no explanation as to whether an FDA reviewer attempted to locate the period safety was reviewed in each trial, how long it might take to conduct this simple review, or whether any summary or analyses of the clinical trials exists which may contain this information. The FDA has not evidenced *any* effort to assist in the identification and location of the clinical trials sought from within the larger universe of documents and therefore is a far cry from meeting its duty to make "every reasonable effort."

For these reasons, as explained below, the Court should deny the FDA's motion for summary judgment and grant Plaintiff's cross-motion for summary judgment.

BACKGROUND

Engerix-B is a vaccine for Hepatitis B. The Centers for Disease Control and Prevention ("**CDC**") Recommended Child and Adolescent Immunization Schedule, as of 1991,[3] recommends universal vaccination of all infants with a Hepatitis B vaccine at birth, 1-month of age, and 6-months of age.[4] There are only two Hepatitis B vaccines licensed for administration to newborns – Engerix-B and Recombivax HB.[5]

Plaintiff is a not-for-profit 501(c)(3) organization that advocates for informed consent and disseminates information necessary for same with regard to all medical interventions. In 2017, a supporter of ICAN notified Plaintiff's President, Del Bigtree, that the clinical trial relied upon by the FDA to license each of the two Hepatitis B vaccines on the market only reviewed safety for a few days after injection. Mr. Bigtree found this claim incredible as it sounded nothing short of a conspiracy theory.

Indeed, the importance of capturing all potential health issues for a material duration during a clinical trial is reflected in the trials of, for example, the drugs Enbrel[6], Lipitor[7], and Xenical,[8] which had safety review periods of 6.6 years, 4.8 years, and 2 years respectively, with a placebo

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[3] *See* https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm (last visited August 11, 2020); *see also* https://www.cdc.gov/mmwr/preview/mmwrhtml/00038256.htm (last visited August 11, 2020).

[4] *See* https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-hepb (last visited August 11, 2020).

[5] *See* https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states (last visited August 11, 2020).

[6] *See* https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/103795s5503lbl.pdf (last visited August 11, 2020).

[7] *See* https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020702s056lbl.pdf (last visited August 11, 2020).

[8] *See* https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020766s026lbl.pdf (last visited August 11, 2020).

control group. As another example, the weight loss drug Belviq, indicated only for adult use, was safety tested in a placebo-controlled trial for two years before being licensed by the FDA in 2012.[9]

The FDA states that the clinical trial relied upon for licensure is typically "1 to 4 years"[10] and that the duration of a clinical trial should "reflect the product and target condition."[11] The time frame for the safety review should be longer for minors, and in particular for babies and toddlers, since "the administration of some drugs during vulnerable periods of growth and development may have implications for the attainment of adequate growth and development among children."[12] Notably, autoimmune, neurological, and developmental disorders will often not be diagnosed until after babies are at least a few years old.[13] Indeed, a 2019 review of 306 pediatric studies, authored by researchers at the FDA and Duke University, explained that,

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[9] *See* https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022529lbl.pdf (last visited August 11, 2020). In February 2020 the drug was voluntarily removed from the US market at the request of the FDA due to emerging data showing that people who had taken the drug as part of a large clinical trial had an increased occurrence of cancer five years later. https://www.fda.gov/drugs/drug-safety-and-availability/fda-requests-withdrawal-weight-loss-drug-belviq-belviq-xr-lorcaserin-market (last visited August 11, 2020); *see also* https://www.health.harvard.edu/blog/weight-loss-drug-belviq-recalled-2020040919439 (last visited August 11, 2020).

[10] https://www.fda.gov/patients/drug-development-process/step-3-clinical-research (last visited August 11, 2020).

[11] https://www.fda.gov/media/102332/download (last visited August 11, 2020).

[12] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6526087/U (last visited August 11, 2020).

[13] For example, according to the CDC, even for a common neurological disorder such as ADHD, "5 years of age was the average age of diagnosis for children reported as having severe ADHD." https://www.cdc.gov/ncbddd/adhd/features/key-findings-adhd72013.html (last visited August 11, 2020). As another example, learning disabilities, a group of common developmental issues, are often "identified once a child is in school." https://www.nichd.nih.gov/health/topics/learning/conditioninfo/diagnosed (last visited August 11, 2020). Even for asthma, a very common autoimmune condition, whose symptoms are obvious, diagnosis can be difficult for children under 5 years of age because lung function tests aren't accurate before 5 years of age and "[s]ometimes a diagnosis can't be made until later, after months or even years of observing symptoms." https://www.mayoclinic.org/diseases-conditions/childhood-asthma/diagnosis-treatment/drc-20351513 (last visited August 11, 2020).

compared to licensing a drug for adults, "data on drug efficacy and safety in children may require an additional 6 years."[14]

Hence, the claim that Engerix-B and Recombivax HB were licensed by the FDA based on only a few days of safety data after each injection sounded like science fiction. ICAN therefore began to assess this claim by first reviewing the package inserts for these products. Upon review, they appeared to indicate that safety was only reviewed for a few days after the injection of each product into babies in their clinical trials. Hence, on October 12, 2017, ICAN sent a letter to the FDA's parent department, HHS, which states in relevant part:

> All drugs licensed by the FDA undergo long-term double-blind pre-licensure clinical trials during which the rate of adverse reactions in the group receiving the drug under review is compared to the rate of adverse reactions in a group receiving an inert placebo, such as a sugar pill or saline injection. … And even with these long-term studies, drugs are still often recalled. …
>
> [Nonetheless], of the two Hepatitis B vaccines licensed by the FDA for injection into one-day-old babies, [based on its package inserts it appears] Merck's was licensed after trials that solicited adverse reactions for *only five days* after vaccination and GlaxoSmithKline's was licensed after trials that solicited adverse reactions for *only four days* after vaccination.[15] …
>
> The 1986 Act expressly requires that you, as the Secretary, "shall make or assure improvements in … the licensing … and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." (42 U.S.C. § 300aa-27(a)(2).) Given this statutory obligation: … **Please list and provide the safety data relied upon when recommending babies receive the Hepatitis B vaccine on the first day of life?**

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[14] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6526087/U (last visited August 11, 2020).

[15] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf (last visited August 11, 2020); https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf (last visited August 11, 2020).

HHS, in a response reviewed and approved by the FDA[16], responded by letter, dated January 18, 2018, to the foregoing question as follows:

> Data relied upon in licensing infant use of hepatitis B vaccines is summarized in the respective package inserts. Furthermore, pediatric data from other countries and in the literature, support the safety of these vaccines in infants. The recommendation for all children to receive these vaccines was made by the Advisory Committee for Immunization Practices. Their reasoning is summarized in a *Morbidity and Mortality Weekly Report* at https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm. Follow-up studies support the safety of infant vaccination with hepatitis B vaccines.

After a careful review of HHS and the FDA's response by ICAN, it responded by letter, dated December 31, 2018, which provided in relevant part as follows:

> In our opening letter, we asked that HHS "Please list and provide the safety data relied upon when recommending babies receive the Hepatitis B vaccine on the first day of life."[17]
>
> *A. Safety Data for Hepatitis B Licensure is Plainly Deficient*
>
> HHS begins its response by stating: "Data relied upon in licensing infant use of hepatitis B vaccine is summarized in the respective package insert."[18] It is troubling that HHS responds to the above request by citing the package inserts when our opening letter explained that these precise package inserts provide that their safety was not monitored for longer than five days after injection.[19] As a result, HHS's response merely affirms the concerns we expressed in our original letter that the Hepatitis B vaccine was inadequately tested for safety prior to licensure.
>
> Recombivax HB's package insert asserts it was deemed safe for children based on a clinical trial in which 147 infants and children

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[16] *See* https://www.icandecide.org/wp-content/uploads/2020/08/Review-Copy.pdf (last visited August 11, 2020).

[17] http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf (last visited August 11, 2020).

[18] http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf (last visited August 11, 2020).

[19] *See* https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf (last visited August 11, 2020); *see also* https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf (last visited August 11, 2020).

(up to 10 years of age) were monitored for five days after vaccination.[20] This trial is useless for assessing the safety of this vaccine for pediatric use (let alone for babies on the first day of life) because the sample size is too small, the safety review period is too short, and there is no placebo control. The safety information in the package insert for Engerix-B is just as inadequate since the clinical trial for this vaccine also had no placebo control and only monitored safety for four days after vaccination.[21]

These package inserts plainly do not support the safety of administering these products to babies. Hence, HHS's assertion that the "Data relied upon in licensing infant use of hepatitis B vaccine is summarized in the respective package insert" is very troubling.

B. Safety of Hepatitis B Recommendation for Babies Plainly Deficient

Aside from the package inserts, HHS's response points to only one other identifiable document to support its claim that the Hepatitis B vaccine is safe for babies – a report from the Advisory Committee on Immunization Practices (**ACIP**) that HHS asserts it relied upon for its "recommendation for all children to receive these vaccines."[22] Sadly, as with the package inserts, this ACIP report does not support the safety of these vaccines for babies or children. A copy of the report is cited in a footnote to this sentence.[23]

The ACIP report cites seven studies to support its recommendation that every baby in this country receive Hepatitis B vaccine injections at 1-day, 1-month, and 6-months of life.[24] Two of the cited studies only included adult[s] … and therefore provide no useful data to evaluate the safety of injecting newborns.[25] The third was a retrospective study that did not use either of the Hepatitis B vaccines licensed for infants in the United States, excluded children that did

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[20] *See* https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdfU (last visited August 11, 2020).

[21] *See* https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm224503.pdf (last visited August 11, 2020).

[22] http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf (last visited August 11, 2020).

[23] *See* https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm (last visited August 11, 2020).

[24] *See* https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm (last visited August 11, 2020).

[25] *See* https://www.ncbi.nlm.nih.gov/pubmed/6810736 (last visited August 11, 2020);

see also https://www.ncbi.nlm.nih.gov/pubmed/6997738 (last visited August 11, 2020).

> not complete the vaccine series and lacked a placebo control.[26] The fourth was a retrospective study of potential neurological events from the Hepatitis B vaccine based on reports submitted to a passive surveillance system … "[in which] underreporting is a well-recognized problem" … [which] involved "virtually all" adults and did not provide any separate results for infants or children.[27]
>
> The three remaining studies … were clinical trials. But none … are useful for understanding the safety of injecting Hepatitis B vaccine into babies.[28] First, none of them had a placebo control.[29] Second, none … assessed safety for longer than seven days after vaccination.[30]
>
> Indeed, one study had 122 infants and monitored safety for only 7 days.[31] Another study had 79 children monitored for 5 days.[32] Remarkably, in this study 18 percent of the children experienced a systemic or serious adverse reaction … but, absent a placebo control, the pharmaceutical company paid researchers were left to decide [if they] were related to the vaccine.[33] The final study had 3,000 infants and children but *only* monitored safety on the day of and the third day after vaccination.[34] …
>
> *C. Urgent Need for Placebo-Controlled Trial of Hepatitis B Vaccine*
>
> The need to assess the safety of each Hepatitis B vaccine in robust clinical trials is manifest. The following is a list of the reported post-marketing adverse reactions added to the package insert for Engerix-B because Merck had a "basis to believe there is a causal relationship between the drug and the occurrence of the adverse event"[35]:

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[26] Chen D-S. Control of hepatitis B in Asia: mass immunization program in Taiwan. In: Hollinger FB, Lemon SM, Margolis HS, eds. Viral hepatitis and liver disease. Baltimore: Williams & Wilkins, 1991:716-9.

[27] https://www.ncbi.nlm.nih.gov/pubmed/2962488 (last visited August 11, 2020).

[28] *See* https://www.ncbi.nlm.nih.gov/pubmed/2952812 (last visited August 11, 2020); *see also* https://www.ncbi.nlm.nih.gov/pubmed/2943814 (last visited August 11, 2020); https://www.ncbi.nlm.nih.gov/pubmed/2528292 (last visited August 11, 2020).

[29] *Id.*

[30] *Id.*

[31] *See* https://www.ncbi.nlm.nih.gov/pubmed/2952812 (last visited August 11, 2020).

[32] *See* https://www.ncbi.nlm.nih.gov/pubmed/2943814 (last visited August 11, 2020).

[33] *Id.*

[34] *See* https://www.ncbi.nlm.nih.gov/pubmed/2528292 (last visited August 11, 2020).

[35] 21 C.F.R. 201.57.

> Abnormal Liver Function Tests; Allergic Reaction; Alopecia; Anaphylactoid Reaction; Anaphylaxis; Angioedema; Apnea; Arthralgia; Arthritis; Asthma-Like Symptoms; Bell's Palsy; Bronchospasm; Conjunctivitis; Dermatologic Reactions; Dyspepsia; Earache; Eczema; Ecchymoses; Encephalitis; Encephalopathy; Erythema Multiforme; Erythema Nodosum; Guillain-Barré Syndrome; Hypersensitivity Syndrome (serum sickness-like with onset days to weeks after vaccination); Hypoesthesia; Keratitis; Lichen Planus; Meningitis; Migraine; Multiple Sclerosis; Myelitis; Neuritis; Neuropathy; Optic Neuritis; Palpitations; Paralysis; Paresis; Paresthesia; Purpura; Seizures; Stevens-Johnson Syndrome; Syncope; Tachycardia; Tinnitus; Transverse Muscular Weakness; Thrombocytopenia; Urticaria; Vasculitis; Vertigo; Visual Disturbances.[36] …
>
> These post-marketing reactions reveal a consistent pattern of autoimmune, neurological and other chronic disorders that would appear or only be diagnosed years after vaccinating a baby. Nevertheless, … HHS responds to these post-marketing reports of chronic life-long injuries by saying that "causation has not been proven," knowing … that causation is highly unlikely to be proven, one way or another, until a placebo-controlled trial of sufficient duration is conducted. …
>
> Please identify and provide a copy of any placebo-controlled trial with a safety review period longer than one week that HHS relied upon when it recommended that every baby in this country receive either Recombivax HB or Engerix-B on the first day of life.

FOIA REQUEST

After HHS did not respond to the foregoing (despite follow-up), on June 21, 2019, ICAN submitted to the FDA the FOIA request at issue in this action which requested the following:

> **A copy of the report for each clinical trial relied upon by the FDA to approve Engerix-B for babies and children in 1989 that had a safety review period longer than seven days following administration of this vaccine.**

[36] *See* https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm224503.pdfU (last visited August 11, 2020).

(Dkt. No. 16-1).

On July 9, 2019, the FDA sent an email which stated that the request did "not reasonably describe the records" Plaintiff was seeking "in a way that the records can be identified and located." (Dkt. No. 16-2). The FDA acknowledged that Plaintiff had "identified the brand name of the vaccine of interest, as well as a date range" but took issue with the fact that Plaintiff had "not provided information related to the clinical trial(s) … in a way that allows us to search our record systems without reading all the records in the application file and trying to identify which clinical studies may have had 'a safety review period longer than 7 days.'" (Dkt. No. 16-2).

In an attempt to clarify, counsel for ICAN responded on July 12, 2019 that ICAN was seeking: (1) pre-licensure clinical trials, (2) relied upon by the FDA, (3) to approve the listed vaccines, (4) for babies and children, and (5) that had a safety review period longer than seven days. (Dkt. No. 16-3).

The FDA subsequently asked if Plaintiff would agree to amend the request to broaden it to read, "The clinical trial reports submitted by the sponsor for the original BLA for Engerix B." (Dkt. No. 16-4). Plaintiff did not agree to broaden its specific request to include thousands of irrelevant pages and so, on August 13, 2019, the FDA sent a final response letter stating it was closing the request. (Dkt. No. 16-6). On November 22, 2019, ICAN appealed the FDA's failure to provide responsive records to the FOIA request, but still received no responsive documents from the FDA. ICAN then filed the instant action on March 16, 2020.

ARGUMENT

The principal question in this matter is whether Plaintiff's request "reasonably describes" the records sought. The answer is "yes," it certainly does. When a request "reasonably describes" such records and is made in accordance with published rules, FOIA requires agencies to search for

and make such records promptly available. 5 U.S.C. § 552(3)(A). The statute defines the term "Search" to mean "*to review, manually* or by automated means, agency records *for the purpose of locating those records which are responsive to a request.*" 5 U.S.C. § 552(3)(D) (emphasis added).

"Once an agency becomes reasonably clear as to the materials desired, FOIA's text and legislative history make plain the agency's obligation to bring them forth … and disclose all reasonably segregable, nonexempt portions of the requested record(s)." *Public Emples. For Envtl. Responsibility v. United States EPA*, 314. F.3d. 68, 74 (D.D.C. 2018).

The FDA's own FOIA regulations state that the FDA's duties to conduct a reasonable search are triggered when a request "reasonably describe[s] the records being sought, in a way that they can be identified and located" and that "*every reasonable effort shall be made* by the Food and Drug Administration to assist in the identification and location of the records sought." 21 C.F.R. § 20.40(b) (emphasis added).

I. Plaintiff's Request Reasonably Describes the Clinical Trials Sought

Here, Plaintiff's request, as originally submitted, spells out precisely what records are being requested. ICAN's email to the FDA, dated July 12, 2019, even enumerated into bite-sized pieces precisely what was being requested:

1. Pre-licensure clinical trials;
2. Relied upon by the FDA;
3. To approve [Engerix-B];
4. For babies and children; and
5. That had a safety review period longer than seven days.

(Dkt. No. 16-3).

"A record is 'reasonably described' if a professional employee of the agency familiar with the subject matter can locate the records with a reasonable amount of effort." *Freedom Watch, Inc. v. CIA*, CV No. 12-0721, 895 F. Supp. 2d 221, 2012 U.S. Dist. (D.D.C. 2012) (internal citations and quotation marks omitted).

The Declaration of Suzann Burk, FDA, (Dkt. No. 16, "**Burk Decl.**"), explains that upon review of Plaintiff's request, the FDA – without need for further information and with a reasonable amount of effort – "determined that the records sought by Plaintiff would likely be included in the 'clinical trial reports' … in the original application file for the vaccine Engerix-B" and that FDA "personnel determined that the original product application file for the 1989 licensure of Engerix-B is located at FDA's office in Silver Spring, Maryland, and contains approximately 3,000 pages of 'clinical trial reports.'" (Burk Decl. ¶¶ 10, 12).

The FDA, once it identified the precise records wherein the requested clinical trial reports could be located, could have quickly and easily identified which of those clinical trial reports involved children or babies and which of those reviewed safety for more than seven days. Instead, the FDA decided to take issue with the portion of the FOIA request that limited the request to clinical trial reports with "a safety review period longer than seven days following administration of this vaccine." The FDA's objections to this portion of the request are disingenuous and without merit.

II. Every Biologics License Application Contains Safety Review Data

The FDA's first argument is that the words "safety review period" is not a defined term or a term used to "categorize clinical trials." However, this argument places form over substance. By statute, every Biologics License Application ("**BLA**") must "provide the multidisciplinary FDA reviewer team … with the efficacy and safety information necessary to make a risk/benefit

assessment and to recommend or oppose the approval of a vaccine."[37] It should go without saying that every BLA must contain safety data from clinical trials. In fact, Ms. Burk states that "[p]roduct application files for vaccines submitted by the manufacturer must contain data … which demonstrate that the manufactured product meets prescribed requirements of safety…" (Burk Decl. ¶ 11). The FDA cannot, therefore, argue that the safety review data is not substantively available. Instead, the FDA must be arguing that it cannot understand the term "safety review period" or that this term is not used in the BLA.

However, there is no requirement that the Plaintiff must request documents with the exact terminology used by the manufacturers or the FDA. FOIA only requires that the documents sought be "reasonably described," which is certainly the case here. The term "safety review period" as used in the FOIA request plainly refers to the period of time safety was reviewed after administering the vaccine.

Indeed, even the FDA and its scientists have used the term "safety review period" to describe the period of time during which safety was reviewed. For example, in the FDA's recent review of the clinical trials for Aptiom, a drug to treat seizures in patients 4 years and older, it explains that "there was a death in an adult patient reported during the *safety review period*." [38] (emphasis added). As another example, eight FDA authors of an article titled *Safety Monitoring of Drugs Receiving Pediatric Marketing Exclusivity* discuss that "[d]uring the pediatric *safety*

[37] https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-product-approval-process (last visited August 11, 2020).

[38] *See* https://www.fda.gov/media/109082/download (last visited August 11, 2020).

review period, 135 AEs [adverse events] were identified and reported."[39] (emphasis added). The clinical trial for Tramadol HCl includes a "5-day *safety review period*" between doses.[40]

As the FDA itself states, the "linchpin inquiry is whether 'the agency is able to determine precisely what records are being requested.'" (D's MOL at 7).[41] Here, Plaintiff identified what it was looking for – certain clinical trial reports for Engerix-B. The FDA had no issue identifying these reports and has no issue with identifying and producing only those involving infants or children. However, it does not want to take the further step of producing from this subset of clinical trial reports only those in which safety was reviewed for more than seven days. The fact that it can easily identify the period during which safety was reviewed in each trial is apparent from the study design of every pre-licensure vaccine clinical trial at www.clinicaltrials.gov – every single one of them lists the precise duration that safety will be reviewed.

The argument that the FDA should not have to review the clinical trials and determine which ones reviewed safety for more than seven days is undercut by agreeing that it will review the clinical trials to identify which ones involved children. (Burk Decl. ¶ 17). When the FDA is reviewing the summary of each clinical trial report for the age range of participants, it can simply glance at the duration that safety was reviewed in each of these trials as well. The FDA nonetheless claims that while a manual review for the age of participants is not beyond the scope of FOIA, the duration that safety was reviewed is beyond the scope of FOIA. The FDA's position is not only contradictory but is also not in accord with FOIA since it requires the FDA to "*review, manually*… agency records *for the purpose of locating those records which are responsive to a*

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[39] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2561901/ (last visited August 11, 2020).

[40] https://clinicaltrials.gov/ct2/show/NCT01947920 (emphasis added) (last visited August 11, 2020).

[41] "D's MOL at __" refers to Defendant's *Memorandum of Law in Support of Defendant's Motion for Summary Judgment*, dated July 10, 2020.

request." *See* 5 U.S.C. § 552(3)(D) (referring to manual searches as part of the very definition of the term "Search") (emphasis added).

In *Public Citizen, Inc. v. Dep't of Educ.*, the plaintiff submitted a FOIA request for records of students whose loans had been improperly denied discharges for a specific reason during a specified time frame. The defendant argued that there were "over 25,000 loan discharge applications [] denied for a variety of reasons" and that "there [was] no way to determine why each individual was denied a loan discharge …without pulling individual files, and manually reviewing each loan discharge application individually." The court rejected defendant's objection and ordered the files reviewed and responsive loan discharge applications produced. The court explained that the objection "that searching these 25,000 paper files would be 'costly and take many hours to complete,'" was not a valid reason to deny the FOIA request and hence, "[w]ithout more specification as to why a search certain to turn up responsive documents would be unduly burdensome, defendants' claim must be rejected." *Public Citizen, Inc. v. Dep't of Educ.*, 292 F. Supp. 2d 1, 3-4, 13 (D.D.C. 2003). *See also Nat'l Day Laborer Org. Network v. United States Immigration and Customs Enforcement*, No. 16-cv-387 (KBF), 2017 U.S. Dist. LEXIS 66429, at *37 (S.D.N.Y. 2017) (summary judgment granted for plaintiff seeking records, which according to the agency "would require manual location, collection, review, and processing of countless paper and physical case files, and of A-files, in an attempt to locate specific case files of A-files containing the data fields plaintiffs seek, and reviewing page-by-page the files to locate the specific data fields" which "would be an extremely burdensome and time consuming task."). Here, Plaintiff's request is far less "burdensome," in that it merely seeks certain clinical trial reports from a clearly identifiable universe of 3,000 pages of such reports.

A requester would be hard-pressed to make a FOIA request which required no reading or review of documents. Even Ms. Burk admits that for every FOIA request, a reviewer must "conduct[] an initial review to verify that the records are, in fact, responsive to the requests…" (Burk Decl. ¶ 8). Reviewing, analyzing, categorizing, and summarizing clinical trials are tasks that the FDA does every single day. The clinical trials relied upon by the FDA to license Engerix-B involving children and which reviewed safety for more than seven days after injecting this product will be easy to identify, especially to FDA personnel.

III. A "Safety Review Period Longer Than 7 Days Following Administration" of Engerix-B is a Definite and Specific Term

The FDA's second excuse for not reviewing the documents is that "a safety review period longer than seven days following administration of this vaccine" is "indefinite" because it does not "sufficiently specify what the start date of a seven-day 'safety review period' would be." (D's MOL at 8). This argument is truly dumbfounding. The start of the seven days is crystal clear in the request. It is "seven days *following the administration of the vaccine*." (D's MOL at 8). Hence, if the safety of Engerix-B was reviewed in the clinical trial involving children for any length of time longer than seven days after it was administered, then that clinical trial would be responsive.

The FDA cites *Dale v. IRS*, stating that "the linchpin inquiry is whether 'the agency is able to determine precisely what records are being requested.'" (D's MOL at 7). What the FDA ignores is the *Dale* court's explanation as to how an agency would make that determination: "[a] description would be sufficient if it enabled a professional employee of the agency *who was familiar with the subject area of the request* to locate the record with a reasonable amount of effort." *Dale v. IRS*, 238 F. Supp. 2d 99, 104 (D.D.C. 2002) (emphasis added). Despite the FDA's contentions, reviewing records for the purpose of locating responsive ones is not a call for

"clairvoyant capabilities." (D's MOL at 11). It is, however, a call for an FDA employee familiar with clinical trials, which FOIA requires.

The other cases cited by the FDA are also inapposite. *Amnesty International* addresses a FOIA request that specifically sought a list referenced in a Washington Post article. After learning such a list did not exist, the plaintiff attempted to recharacterize the request as one for "information responsive to the underlying request." *Amnesty Int'l USA v. CIA*, 728 F.Supp.2d 479, 499 (S.D.N.Y. 2010). The court held that the agency was not tasked with divining the requester's intent or knowing that the plaintiff sought more than was requested. Here, Plaintiff's request is specific like the plaintiff's original request was in *Amnesty International*. The difference here is that if no such documents exist, Plaintiff is not asking the FDA to go the step further of divining a new request. Instead, here, Plaintiff would accept a reply from the FDA that "no responsive documents exist."

Likewise, the FDA cites to *Yagman*, which makes plain that the requirement to "reasonably describe" the requested records does not act as "a loophole through which federal agencies can deny the public access to legitimate information." *Yagman v. Pompeo*, 868 F.3d 1075, 1081 (9th Cir. 2017). The court in that case held that "broad, sweeping requests lacking specificity are not permissible" and that the FOIA request at issue in that case failed because the plaintiff therein "submitted a poorly framed request with limited specifics" and "[d]efendants could not know what records would be responsive." *Id.* The request at issue in the instant action is the opposite of a "broad, sweeping request lacking specificity." It is a specific request, using terminology the FDA is familiar with and has itself used.

Plaintiff agrees with the FDA's contention that "Courts have noted with approval the agency practice of engaging in 'cooperative discussion to *narrow and focus* requests.'" (D's MOL

at 11). The FDA's regulations similarly address "nonspecific and overly burdensome requests" explaining that the FDA "*will make every reasonable effort to comply fully with all requests*" but that in "any situation in which it is determined that *a request for voluminous records would unduly burden* and interfere with the operations of the Food and Drug Administration, the person making the request will be asked *to be more specific and to narrow the request*…" 21 C.F.R. §20.50 (emphasis added). The irony is that the FDA here is seeking to do the opposite by objecting to Plaintiff's specific and narrow request and demanding that Plaintiff agree to broaden this request to result in a large unwanted and unnecessary production dump.

The FDA's position that it may challenge requests as being nonspecific and overly burdensome and yet also challenge requests as being too narrow, creates an untenable situation for any requester. "FOIA's prodisclosure purpose and legislative history reflect an intent to ***avoid creating loopholes for denial of access*** and reinforces the duty of federal agencies to construe a FOIA request liberally." *Public Emples. for Envtl. Responsibility v. EPA*, 314 F. Supp. 3d 68, 74-75 (D.D.C. 2018) (internal quotation marks and citations omitted) (emphasis added).

Finally, the FDA would have this Court believe that only Plaintiff is able "to sort and analyze the responsive records" and to determine "which 'clinical trial reports' had a 'safety review period longer than seven days.'" (D's MOL at 11-12). The FDA is the agency tasked with reviewing clinical trial data as part of its core function in determining safety requirements. This function is handled by professional employees presumably familiar with the subject matter. As Ms. Burk acknowledges, "[p]roduct application files for vaccines submitted by the manufacturer must contain data…which demonstrate that the manufactured product meets prescribed requirements of safety…" (Burk Decl. ¶ 11). Yet it now claims it is unable to do so without

possessing "clairvoyant capabilities," "divining intent," or "engaging in guesswork." (D's MOL at 11-12).

The reality is that the FDA likely need look no further than the summary of each clinical trial, which would include the period safety was reviewed. Each clinical trial specifies in plain English the length of time safety is reviewed, including in the summary of the clinical trial report.

For example, in each of the eight clinical trial reports relied upon by the FDA to license M-M-R-II in 1978, the safety review period is easily located in the "procedure" section, stating in each that safety was "followed clinically for 42 days" or "followed 6 weeks."[42] As another example, the "Summary Basis for Regulatory Action" for Hiberix, another vaccine, plainly states that "solicited adverse events were monitored during Days 0-4 post-vaccination. Serious and non-serious unsolicited adverse events were monitored during Days 0-30 post-vaccination."[43]

If Plaintiff can easily determine the safety review period in the clinical trials for these vaccines within minutes, the FDA can do the same for Engerix-B. To the extent that the FDA actually conducts a review and finds any record for which it is incapable of determining the safety review period, then perhaps it could work with Plaintiff to identify whether or not that record would be responsive. But given these examples where it is easy to determine the safety review period – even for non-FDA employees – FOIA demands that the FDA actually perform a search, and only after having done so, come back to Plaintiff to limit the request if necessary.

Regardless, Plaintiff is only asking the FDA to uphold its duty to have an FDA employee familiar with clinical trials manually review the already identified universe of potentially

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[42] *See* https://www.icandecide.org/wp-content/uploads/2019/11/20190327-FDA-Production-2018-6847IR0039.pdf (last visited August 11, 2020).

[43] https://wayback.archive-it.org/7993/20170723144609/https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm181598.htm (last visited August 11, 2020).

responsive documents to determine which records are, indeed, responsive. Plaintiff is not asking the FDA to create a new document that does not exist (as was the case in *Nat'l Sec. Counselors v. CIA*, cited by the FDA in D's MOL at 9). Nor is the FDA being asked to "create documents or opinions in response to" Plaintiff's request (as was the case in *Knowles v. U.S. Dep't of State*, also cited by the FDA in D's MOL at 9). The task is less burdensome than the search ordered by the *Public Citizen* court discussed above.

IV. The FDA Has Not Met Its Duty of "Every, Reasonable Effort"

"Every reasonable effort shall be made by the Food and Drug Administration to assist in the identification and location of the records sought." 21 C.F.R. § 20.40(b)(2). To argue that this reasonable effort should not include a review of an identified and limited universe of potentially responsive documents would upend the entire function, statutory and regulatory framework, and policy behind FOIA.

What the FDA should have done is what the law requires: perform every reasonable effort to respond to the FOIA request. Indeed, "[t]he burden is on the agency to justify that it has performed an adequate search in response to a proper FOIA request." *Am. Oversight v. EPA*, 386 F.Supp.3d 1, 6 (D.D.C. 2019); *see also* 5 U.S.C. § 552(a)(4)(B). Yet, the FDA has not stated that it has made any effort to identify the responsive clinical trials, if any, from within the 3,000 pages the FDA concedes it located. The FDA does not even explain how many clinical trials there are to review, how many involve babies and children, whether or not any FDA reviewer attempted to locate the period safety was reviewed in each of these trials, and how long it might take to do so; nor has the FDA advised whether any summary of the clinical trials already exists. The FDA's response to the instant request is a far cry from meeting its duty to make "every reasonable effort."

DISCOVERY

Plaintiff has a reasonable basis to believe that the FDA's argument regarding the words "safety review period" was asserted in bad faith. If this term is truly alien to the FDA, it should have little difficulty responding to the following document request which is limited in duration and to electronic records: "All email and electronic documents that contain the phrase 'safety review period.'" Given the FDA's position, this search should result in few, if any, records.

To further test the veracity of its claimed objections and handling of the instant FOIA request, Plaintiff also seeks: "All emails concerning the FOIA Request" and "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." A copy of this document request is attached as Exhibit A.

CONCLUSION

For the foregoing reasons, the Court should deny the FDA's motion for summary judgment, grant Plaintiff's cross-motion for summary judgment, and order the FDA to disclose all responsive records.

Dated: August 14, 2020

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

INFORMED CONSENT ACTION NETWORK, Plaintiff, -against- UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant.	1:20-cv-00689-AJN

PLEASE TAKE NOTICE that, pursuant to the Federal Rules of Civil Procedure Rule 34, Informed Consent Action Network ("**Plaintiff**") by their counsel, requests that the United States Food and Drug Administration ("**Defendant**") produce the following described documents and things in its possession, custody or control (the "**Request**"). Said documents and things are to be produced by email to ebrehm@sirillp.com.

DEFINITIONS and INSTRUCTIONS

1. "**Documents**" shall be given the broadest sense of the term allowable under Fed. R. Civ. Pro. 34. "**Concerning**" shall be interpreted broadly and shall include, but not be limited to, the following meanings: relating to, containing, regarding, recording, discussing, mentioning, noting, pertaining to and/or referring, in whole or in part, to the matters set forth. "**FOIA Request**" shall mean Plaintiff's FOIA request at issue in the above captioned matter.

2. The singular of any noun or pronoun shall embrace, and be read and applied as embracing the plural, except where context clearly makes it inappropriate. "And" as well as "or", shall be construed either as disjunctive or conjunctive so as to bring within the scope of the Request any documents that might otherwise be construed to be outside the scope of the Request. "All" shall also mean "any." If you are aware of any document responsive to this Request, which is not

in your possession, custody, or control, on a separate schedule set forth sufficient information to identify the document and its current location if known. If Documents are stored electronically they shall be produced electronically in such a manner as to preserve all meta data. Any documents withheld because of privilege shall be listed with apporrpiate detail in a privilege log.

3. The first request below shall be limited to existing electronic Documents and to the period from January 1, 2010 to the date of the date of this Request.

REQUESTS

1. All emails and electronic documents that contain the phrase "safety review period."

2. All emails concerning the FOIA Request.

3. 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.

Dated: August 14, 2020

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