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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

JAMES E. GOETZ, an individual; BAUM HEDLUND ARISTEI AND GOLDMAN, PC, a California professional corporation; Plaintiffs, vs. U.S. FOOD AND DRUG ADMINISTRATION Defendant.	Case No. **COMPLAINT**

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COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF

Plaintiff James E. Goetz ("Goetz" or "Plaintiff"), on behalf of himself and all plaintiffs in California JCCP No. 5150 ("JCCP Plaintiffs"), states as follows:

INTRODUCTION

1. This is an action under the Freedom of Information Act ("FOIA") 5 U.S.C. § 552, to compel the production of certain agency documents regarding a U.S. Food and Drug Administration ("FDA" or "Defendant") sponsored study. The subject FDA study, "Effect of Oral Ranitidine on Urinary Excretion of N-Nitrosodimethylamine (NDMA)," was published in the Journal of the American Medical Association on June 28, 2021 ("FDA Study").[1] The FDA Study focused on the once highly popular but recalled antacid medication, Zantac (ranitidine)[2] and carcinogenicity. The year prior to the FDA Study's publication, the FDA recalled all Ranitidine Containing Drugs in April 2020 because they were found to contain unsafe levels of the potent, probable human carcinogen, N-Nitrosodimethylamine ("NDMA").[3]

2. With this Complaint, Plaintiff seeks agency emails and any other communications—internally amongst the authorship team as well as with any third parties—about the FDA Study plus initial drafts of the work from June 2019 to June 2022 (this is the widest timeframe; most requests are for a shorter period of time, January 2020 to June 2022). These documents were initially sought via a FOIA request that was submitted in April 2022 by and through the Judicial Council Coordinated Proceeding ("JCCP")[4] Plaintiffs' counsel ("FOIA Request"). Exh. 1. In other words, the FOIA

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[1] https://jamanetwork.com/journals/jama/fullarticle/2781670

[2] The Complaint and the general, subject literature will interchangeably refer to Zantac and ranitidine. Zantac is simply the brand name of ranitidine which is the actual, active ingredient in the product. Ranitidine is how scientific/medical literature tends to refer to the drug including the FDA Study. In the broadest possible sense, the universe of ranitidine products will be collectively referred to as "Ranitidine Containing Drugs." This includes ranitidine, whether over-the-counter or prescription, in any packaging from any seller, i.e. brand name Zantac or generic, as well drug forms such as tablet/pill, injection, syrup, capsule, etc.

[3] https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market

[4] A California JCCP, short for Judicial Council Coordination Proceedings, is where cases from across multiple counties are coordinated before one court in the interest of judicial efficiency. It is the California equivalent of Federal Multidistrict Litigation ("MDL"). There is also an MDL based

Request concerns a small universe of documents with a clearly defined topic, identified-by-name custodians, and conservative, demarcated timeframe parameters. The FOIA Request is not a demand for "all documents ever" about Zantac going back for decades. The FOIA Request is targeted and tailored. It seeks only documents about the FDA Study and only those documents that the FDA has in its possession, custody, and control—no more, no less.

3. Plaintiff seeks these documents for vital reasons. Most importantly is that the FDA Study—funded with taxpayer dollars—is being used by the Drug Companies,[5] who are the manufacturers of Zantac and defendants in the California litigation, to defend the underlying lawsuits brought by the JCCP Plaintiffs. The JCCP Plaintiffs, who number in the thousands, all allege that Ranitidine Containing Drugs caused their, or a loved one's, cancer. Plaintiff Goetz has the first bellwether case scheduled to go to trial in Alameda County Superior Court on February 13, 2023. Accordingly, Mr. Goetz and the thousands of other JCCP Plaintiffs urgently need to understand the FDA Study which has become an important part of the JCCP litigation.

4. All of these thousands of California cases turn on the scientific questions of whether or not Zantac causes cancer, generally, and whether Zantac caused a particular plaintiff's cancer, specifically. To that end, the Drug Companies aggressively assert that the FDA Study stands for the proposition that Ranitidine Containing Drugs are not carcinogenic—despite the FDA's NDMA-based recall—and therefore they have no liability to any of the JCCP Plaintiffs, including Mr. Goetz. The Drug Companies are leveraging the FDA's color of office and the agency's ostensible imprimatur of regulatory neutrality and expertise. The Drug Companies will undoubtedly do so at trial as well; the FDA Study is central to their defense narrative.

5. Critically, however, the FDA Study has a number of alarming and jarring flaws. For

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in the Southern District of Florida where the plaintiffs there make similar claims. The underlying FOIA Request and this Complaint are not brought on behalf of the MDL plaintiffs, but on behalf of the California JCCP Plaintiffs.

[5] The underlying defendant drug companies in California JCCP No. 5150 who sold Ranitidine Containing Drugs are: GlaxoSmithKline, LLC ("GSK"), Pfizer, Inc. ("Pfizer"), Sanofi-Aventis U.S. LLC, Sanofi-US Services Inc. (collectively, "Sanofi"), Boehringer Ingelheim Pharmaceuticals Inc., and Boehringer Ingelheim USA Corporation (collectively, "BI"). They will be referred to collectively as the "Drug Companies."

example, the FDA Study equates the amount of NDMA in a Zantac pill to common foods such as cured meats (e.g., bacon). While it is true, for example, that bacon tends to contain NDMA, the amount of NDMA in one pill of Zantac would be equal to the consumption of *six pounds of bacon in a single day*.[6] The FDA Study used a study protocol that was seemingly designed to obscure any endogenous formation of NDMA. For example, the FDA Study required participants to ingest unusually high levels of vitamins C & E, which are known to stop NDMA formation. Additionally, the FDA Study focused on urinary excretion of NDMA, even though it is also well known that practically no NDMA is excreted in the urine. And, the results are also suspect. The FDA Study contains data results that are completely incongruous with common benchmarks about normal NDMA excretion. These are just a few of the many issues with the FDA Study. All of these issues must be explored, and that cannot be done without access to the underlying documents. These documents will put the FDA Study in its proper, overall context (e.g., validity of methodology, conclusions, bias, etc.). And, this will be crucial for a trier of fact to evaluate as part of the whole liability and causation picture.

6. Accordingly, and as referenced, the JCCP Plaintiffs, by and through their counsel, submitted the subject FOIA Request in April 2022. The FDA, however, provided a tardy and deficient, non-responsive "response." Exh. 2 at 1. In contravention of FOIA itself and related Code of Federal Regulations ("CFRs"), the FDA did not provide the required response, i.e., a clear reply, saying yes or no to document requests within twenty (20) working days. 5 U.S.C. §§ 552(a)6(A)(i), (a)(6)(C).

7. This is constructive denial. *See Oglesby v. U.S. Dept. of Army*, 920 F.2d 57, 65 (D.C. Cir. 1990); *Natl. Sec. Counselors v. C.I.A.*, 931 F. Supp. 2d 77, 95 (D.D.C. 2013). To be clear, Section 552 does not require actual production of documents within twenty working days, but it does

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[6] For some context, a typical package of bacon at a supermarket, which has multiple servings, contains one pound of bacon. https://www.amazon.com/Fresh-Brand-Hickory-Smoked-Bacon/dp/B07YVMYYTM/ref=sr_1_5_f3_0g_fs?c=ts&keywords=Bacon&qid=1659477847&s=grocery&sr=1-5&ts_id=2256164011. A bulk Costco package of bacon contains four pounds of bacon. https://www.costco.com/kirkland-signature-bacon%2C-hickory-smoked%2C-sliced%2C-1-lb%2C-4-count.product.100411288.html.

require that an agency inform a requester whether or not the FOIA request will be complied with or not. That did not happen here. Indeed, the FDA neither approved or rejected the FOIA Request, either in whole or in part. The FDA merely said that it was processing the JCCP Plaintiffs' FOIA Request and added that "the minimum estimated processing timeframe is 24 months." Plus, the FDA clarified that processing did not mean "approved and eventually producing." Processing meant to evaluate the propriety of the FOIA Request in the first place; what was supposed to be done in twenty working days.

8. This is untenable. It is also against the law. Making matters worse, the FDA noted that even if the FOIA Request was approved two years down the road (again, at a minimum) that it would then take another 12 months to collect the documents and actually produce them, probably more. No explanation was provided for this extremely long production timeframe (after a two-year search and evaluation period no less) to transmit documents. Regardless, this representation by the FDA puts the earliest and most optimistic possible production date of actual documents to the JCCP Plaintiffs in June 2025. This date is not just two years after Mr. Goetz's trial, but it is after every single scheduled bellwether trial in the thousands-of-cancer-cases-at-issue JCCP process.

9. The JCCP Plaintiffs communicated these issues to the FDA, but the FDA was unmoved. The entire FDA Study took less than a year to conduct, yet somehow the FDA contends that reviewing, processing, and producing documents about that study will take a minimum of three years. This stark contrast, in and of itself, should tell the Court everything it needs to know about the earnestness and validity of the FDA's "response" to the JCCP Plaintiffs.

10. Further, this constructive denial occurred despite the fact that the FDA's decision to conduct the study was not required by the FDA, but was voluntarily done. The FDA injected itself into the scientific discussion of Zantac's carcinogenicity using taxpayer money on behalf of the drug companies they are supposed to regulate. We have a right to know why taxpayer money was used this way, but the FDA has eschewed transparency and accountability. This is not how FOIA and good government are supposed work.

11. As a matter of well-settled law, the FDA's response is deficient and in clear violation of its statutory deadlines for responding and producing documents or justifying their withholding.

So, the JCCP Plaintiffs appealed. Exh. 3. Specifically, the JCCP Plaintiffs followed the proper procedures to internally appeal the FDA's decision and timely filed their administrative appeal at the FDA within twenty (20) working days after the FDA's constructive denial. The JCCP Plaintiffs' appeal was almost immediately rejected. Exh. 4. In its dismissal of the JCCP Plaintiffs' appeal, the FDA did however acknowledge the JCCP Plaintiffs' right to bring this lawsuit, stating: "You have the right to judicial review of this action in a United States District Court in accordance with 5 USC § 552(a)(4)(B)." Exh. 4.

12. Accordingly, Mr. Goetz filed the instant action on behalf of himself and all other JCCP Plaintiffs to obtain timely disclosure of the highly relevant FOIA Request documents. Mr. Goetz brings the following declaratory and injunctive relief causes of action: (1) Failure to Make Reasonable Search for Records; (2) Failure to Make Records Available; and, (3) Wrongful Withholding of Records.

PARTIES

13. Plaintiff Goetz is an individual citizen residing in the state of California and is not a citizen of the District of Columbia or any other state.

14. Plaintiff Baum, Hedlund, Aristei, and Goldman, PC ("BHAG") is a professional law corporation incorporated and doing business in the state of California. BHAG has offices in Los Angeles, California, and Greenbrae, California. The issuing attorney, Mr. R. Brent Wisner, Esq. is also the Court-appointed co-liaison counsel for the JCCP Plaintiffs. He primarily works at the BHAG Greenbrae office which is located in the Northern District of California. BHAG issued the FOIA Request on behalf of Mr. Goetz and all JCCP Plaintiffs.

15. Defendant FDA is a component of the Department of Health & Human Services located in Washington, DC. The FDA is an agency of the United States within the meaning of 5 U.S.C. § 552(f)(1). The FOIA Request sought records from the FDA.

JURISDICTION AND VENUE

16. This Court has subject matter jurisdiction over this action and personal jurisdiction over the Defendant pursuant to 5 U.S.C. §§ 552(a)(4)(B) and 552(a)(6)(E)(iii). This Court also has jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 5 U.S.C. §§ 701–06.

17. Venue is proper before this Court pursuant to 5 U.S.C. § 552(a)(4)(B) because Mr. Goetz's case, as well as the entire JCCP, is located in Alameda County (Oakland, CA) which is in the Northern District of California. Moreover, as discussed, the BHAG attorney who actually made the FOIA Request on behalf of Mr. Goetz and all the JCCP Plaintiffs, Mr. Wisner, is also located in the Northern District of California.

FACTUAL BACKGROUND

Brief History of Zantac

18. The Drug Companies marketed and sold Ranitidine Containing Drugs under the brand name "Zantac" or its generic version by either prescription or over the counter ("OTC"). The Drug Companies sold ranitidine in the following forms: injection, syrup, tablets/pills, and capsules.

19. Zantac (ranitidine) was originally discovered and developed by GSK in 1976. Essentially, Zantac works by decreasing the amount of acid produced by cells in the lining of the stomach. Zantac is used to treat a variety of symptoms including heartburn, GERD, peptic ulcers, acid reflux, upset stomach, etc.

20. Zantac was approved by the FDA, pursuant to the New Drug Application ("NDA") process in 1983 (NDA 18-703) and, quickly, became one of GSK's most successful products, being the first prescription drug in history to reach $1 billion in sales, which in the pharmaceutical industry is referred to as a "blockbuster." Zantac was, at one point, the world's highest selling drug.

21. To date, the FDA has approved numerous generic manufacturers for the sale of prescription and OTC Ranitidine Containing Drugs through an Abbreviated New Drug Application ("ANDA") process.

22. Ranitidine Containing Drugs' sales remained robust over decades even as the brand name OTC Zantac sales rights were sold from major pharmaceutical company to major pharmaceutical company.[7] Initially, OTC brand-name Zantac was sold from GSK to Pfizer, and then

[7] The Drug Companies, particularly GSK, however still manufactured much of the drug's API (Active Pharmaceutical Ingredient) for each other as well as for generic manufacturers. This includes the drug in its various forms. In other words, even though GSK sold the rights to sell the

from Pfizer to BI and from BI to Sanofi. Moreover, even though the Drug Companies would sell their rights to market and sell the brand-name OTC Zantac, the Drug Companies still often actually manufactured the API of the drug for various sellers including to each other.

23. Years after its release, Zantac/ranitidine still frequently made top seller lists of pharmaceutical products and Zantac had substantial brand equity and loyalty. Millions had or were taking Ranitidine Containing Drugs (including branded Zantac) when the FDA issued its nationwide recall in April 2020.

The Withdrawal and FDA Recall of Ranitidine Containing Drugs from the Market

24. On September 9, 2019, pharmacy and testing laboratory Valisure LLC and ValisureRX LLC (collectively, "Valisure") filed a Citizen Petition calling for the recall of all Ranitidine Containing Drugs due to exceedingly high levels of NDMA found in ranitidine pills.

25. As briefly discussed earlier, NDMA is a potent carcinogen. Discovered as a biproduct in the manufacturing of rocket fuel in the early half of the 1900s, today, NDMA's only use is to induce tumors in animals as part of laboratory experiments.

26. After Valisure's Citizen Petition, FDA and European regulators started reviewing the safety of ranitidine with specific focus on the presence of NDMA.[8] This triggered a cascade of recalls by the manufacturers and retailers of Ranitidine Containing Drugs.

27. Indeed, starting in September 2019, retailers and then the Drug Companies and generic manufactures all withdrew Zantac and any other Ranitidine Containing Drugs from the market.

28. On January 2, 2020, research laboratory, Emery Pharma, submitted a Citizen Petition to the FDA, showing that NDMA accumulates in ranitidine at unsafe rates when exposed to heat levels that would occur during transport and storage.

OTC branded Zantac to Pfizer in 1998, GSK still manufactured the API as well as other forms of the drug for decades. E.g., GSK did not cease selling prescription Zantac until 2018.

[8] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine; https://www.ema.europa.eu/en/news/ema-review-ranitidine-medicines-following-detection-ndma.

29. Emery's Citizen Petition outlined its concern that ranitidine is a time- and temperature-sensitive pharmaceutical product that develops a known carcinogen, NDMA, when exposed to heat and humidity, a common occurrence during shipping, handling, and storage. In addition to warning about this condition, Emery requested agency directives to manufacturers and distributors to ship Ranitidine Containing Drugs in temperature-controlled vehicles.

30. The FDA found its stability testing raised concerns that NDMA levels in some ranitidine products stored at room temperature can increase with time to unacceptable levels. Other testing conducted by FDA revealed a correlation between NDMA levels and expiration date. The FDA's testing eroded the agency's confidence that any ranitidine product could remain stable through its labeled expiration date. Consequently, the FDA ordered the products off the market.

31. On April 1, 2020, the FDA issued a public statement requesting the immediate removal of all Ranitidine Containing Drugs from the market due to the risk to public health.[9] "The agency has determined that the impurity in some ranitidine products increases over time and when stored at higher than room temperatures and may result in consumer exposure to unacceptable levels of this impurity." Based upon its own testing and evaluation, the FDA concluded that "NDMA levels increase in ranitidine even under normal storage conditions and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during distribution and handling by consumers."

32. The FDA's reaction to the NDMA crisis involving ranitidine has come under attack. Over 43 different countries and jurisdictions took action to restrict or ban ranitidine-containing products before the FDA took any action.[10] Indeed, despite being notified of the problem by Valisure in June 2019, the FDA left the drug on the market for nearly an entire year, during which time

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[9] Press Release, *FDA Requests Removal of All Ranitidine Products (Zantac) from the Market*, U.S. Food and Drug Administration (April 1, 2020), *available at* https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market

[10] Margaret Newkirk and Susan Berfield, *FDA recalls are always voluntary and sometimes haphazard—and the agency doesn't want more authority to protect consumers*, Bloomberg Businessweek (Dec. 3, 2019), *available at* https://www.bloomberg.com/graphics/2019-voluntary-drug-recalls-zantac/.

countless more individuals were exposed to a potent carcinogen against their will.

The Underlying JCCP Litigation

33. Plaintiff's case is one of over a thousand individual cases in California state court that are centralized in Alameda County Superior Court, California JCCP No. 5150, *Ranitidine Products Cases*. Mr. Goetz's California Complaint is attached as an example of the JCCP Plaintiffs' claims. *See* Exh. 5. Each and every one of these JCCP cases, including Mr. Goetz's, alleges that Ranitidine Containing Drugs caused their cancer (or a loved one's).

34. The JCCP, owing to the importance and sheer number of these cases, has an aggressive bellwether trial process with the first trial, Mr. Goetz's trial, set to begin on February 13, 2023. Three other bellwether trials are slated to serially follow Mr. Goetz's case.

35. In the JCCP litigation the Drug Companies have signaled their intent to leverage the FDA Study to the maximum possible extent in order to defend these lawsuits. Indeed, they already have to the JCCP Court.

The FDA Study and the FDA's Actions Since the Recall

36. Shortly after the April 2020 recall, the FDA began the subject FDA Study on June 8, 2020.[11] Remarkably, in 2016, a similar study had been conducted by researchers at Stanford University, and that study had shown significant endogenous formation of NDMA following ranitidine ingestion, as measured in the urine. Ultimately, the Journal of the American Medical Association ("JAMA") published the FDA Study on June 28, 2021. The vast majority of the FDA Study's team of authors was FDA personnel, but also included a Spaulding Clinical Research, LLC ("Spaulding") scientist located in West Bend, Wisconsin. Spaulding was the actual laboratory that conducted tests for the FDA Study. The FDA sponsored, designed, and paid for the study. As it relates to ranitidine and carcinogenicity, the FDA Study stated: "The findings do not support that ranitidine is converted to NDMA in a general, healthy population."[12] The FDA Study also goes out of its way to impugn other scientists and researchers who have linked ranitidine with cancer. This is

[11] https://clinicaltrials.gov/ct2/show/NCT04397445
[12] https://jamanetwork.com/journals/jama/fullarticle/2781670

not the only FDA study or statement to do so.[13]

The JCCP Plaintiffs' FOIA Request

37. Plaintiffs submitted their FOIA Request[14] on April 21, 2022. The FOIA Request made five, and only five, targeted document requests. As alluded to previously, these requests all sought correspondence on the FDA Study and draft versions of the FDA Study:

a. (1) Between January 1, 2020 and January 1, 2022, email correspondence and attachments of Jeffery Florian, David G. Strauss, Murali K. Matta, Victoria Gershuny, Vikram Patel, Robbert Zusterzeel, Rodney Rouse, Kristin Prentice, Insook Kim, Sojeong Yi, Liang Zhao, Miyoung Yoon, Susan Selaya, David Keire, and Joyce Korvick, relating to the "concept and design" of the FDA-funded (tax-payer funded) & sponsored study, "Effect of Oral Ranitidine on Urinary Excretion of N-Nitrosodimethylamine (NDMA)," published in the Journal of the American Medical Association in 2021.

b. (2) Between January 1, 2020 and January 1, 2022, email correspondence and attachments of Jeffery Florian, David G. Strauss, Murali K. Matta, Victoria Gershuny, Vikram Patel, Robbert Zusterzeel, Rodney Rouse, Kristin Prentice, Insook Kim, Sojeong Yi, Liang Zhao, Miyoung Yoon, Susan Selaya, David Keire, and Joyce Korvick, relating to the diet of participants in the FDA-funded (tax-payer funded) & sponsored study, "Effect of Oral Ranitidine on Urinary Excretion of N-Nitrosodimethylamine (NDMA)," published in the Journal of the American Medical Association in 2021.

c. (3) Between January 1, 2020 and January 1, 2022, email correspondence and attachments, between Jeffery Florian and/or David G. Strauss with editors of Journal

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[13] *See* Gao Z, Karfunkle M, Ye W, et al. *In Vitro Analysis of N-Nitrosodimethylamine (NDMA) Formation From Ranitidine Under Simulated Gastrointestinal Conditions*. JAMA NETW OPEN. 2021;4(6):e2118253. doi:10.1001/jamanetworkopen.2021.18253. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2781455

[14] A copy of the FOIA Request papers are attached as Exhibit 1.

of the American Medical Association regarding the publication of the FDA-funded (tax-payer funded) & sponsored study, "Effect of Oral Ranitidine on Urinary Excretion of N-Nitrosodimethylamine (NDMA)," published in the Journal of the American Medical Association in 2021

d. (4) Between June 1, 2019 and January 1, 2022, email correspondence and attachments, between Jeffery Florian, Murali K. Matta, Ryan DePalma, Victoria Gershuny, Vikram Patel, Cheng-Hui Hsiao, Robbert Zusterzeel, Rodney Rouse, Kristin Prentice, Colleen Gosa Nalepinski, Insook Kim, Sojeong Yi, Liang Zhao, Miyoung Yoon, Susan Selaya, David Keire, Joyce Korvick, David G. Strauss, and any third-party (non-FDA) regarding the FDA-funded (tax-payer funded) & sponsored study, "Effect of Oral Ranitidine on Urinary Excretion of N-Nitrosodimethylamine (NDMA)," published in the Journal of the American Medical Association in 2021.

e. (5) All drafts of the manuscript of the FDA-funded (tax-payer funded) & sponsored study, "Effect of Oral Ranitidine on Urinary Excretion of N-Nitrosodimethylamine (NDMA)," published in the Journal of the American Medical Association in 2021.

38. In crafting these document demands, the JCCP Plaintiffs followed what they viewed as the clear suggestions—arguably directives—of the Federal MDL magistrate judge, the Hon. Judge Bruce E. Reinhart, when he suggested to the MDL plaintiffs who wanted similar documents—but instead subpoenaed Spaulding and did not issue a FOIA request—to avail themselves of the FOIA process. Exh. 6 at 12–13. Judge Reinhart issued his initial order in April 2021 and then his final order on the matter in July 2021. Exhs. 6, 7.

39. Here, not only did the JCCP Plaintiffs follow Judge Reinhart's suggestions by submitting a tailored and focused FOIA Request to the FDA, but the JCCP Plaintiffs also issued a revised, more tailored subpoena (as compared to the MDL plaintiffs) to Spaulding in cover-all-bases fashion. Spaulding answered the JCCP Plaintiffs' subpoena to the extent they could, providing some valuable information and documents, but made it crystal clear, again, to the JCCP Plaintiffs this time that all correspondence and draft work for the FDA Study—the documents sought by the FOIA Request—were within the exclusive custody and control of the FDA. In other words, the JCCP

Plaintiffs did everything they could to avoid burdening the government.

40. A month after Plaintiffs submitted their FOIA Request to the FDA, i.e., past twenty working days as is required by FOIA, the JCCP Plaintiffs received no reply from the FDA. So, with the time to respond expired, counsel for the JCCP Plaintiffs called the FDA on May 20, 2022 to get an update on the FOIA Request. Counsel was provided a contact name at the FDA to which Plaintiffs sent an email that same day. Exh. 2 at 3. Plaintiffs received no reply. Exh. 2 at 2–3. So, Plaintiffs' counsel reached out a second time on May 26, 2020, about a week later. Exh. 2 at 1–2. Finally, the FDA communicated with the JCCP Plaintiffs, well after expiration of its deadline to respond. *Id.*

41. On May 26, 2022, in response to Plaintiffs' second follow-up, an FDA official, Mr. Guruprasad Udapi ("Udapi"), telephonically attempted to contact counsel for the JCCP Plaintiffs. *Id.* Mr. Udapi and counsel arranged for a telephonic meeting for the next day, May 27, 2022, at which two BHAG attorneys of the JCCP Plaintiffs attended. *Id.*

42. On the May 27, 2022 telephonic call, Mr. Udapi, on behalf of the FDA, informed the JCCP Plaintiffs that it would be a minimum of 24 months (two years) to process the JCCP Plaintiffs' FOIA Request. The JCCP Plaintiffs sought clarification as to what "processing" meant. Mr. Udapi explained that this 24-month period was to evaluate the FOIA Request and provide the JCCP Plaintiffs with an affirmative or negative response to the FOIA Request's five categories of requests. No specific explanation was provided as to why the FOIA Request was complex or why it would take so long for the FDA to comply with the FOIA Request with despite its very tailored nature.[15] After that, assuming the FOIA Request was approved (in whole or in part) Mr. Udapi stated that it would take a year, probably more, to gather the documents and produce them to the JCCP Plaintiffs. No specific explanation was given for why it would take such a long time to produce documents that

[15] Indeed, the FOIA Request is anything but complex. The FOIA Request seeks specific documents (namely emails) from itemized custodians on a discrete topic (the FDA Study) concerning a limited timeframe on a public issue which the FDA voluntarily opined on. The JCCP Plaintiffs did not request large amounts of data, protected health information, or issue roaming requests. The JCCP Plaintiffs' FOIA Request asked for email correspondence on specific FDA Study topics and drafts.

were ostensibly already gathered, reviewed, and vetted. To be clear, Mr. Udapi did not claim to have reviewed a single request, talked to a single custodian, or looked for a single document.

43. On May 31, 2022, Mr. Udapi emailed the JCCP Plaintiffs to memorialize the May 27, 2022 conversation.[16] Exh. 2 at 1.

44. On June 27, 2022, the JCCP Plaintiffs timely appealed the FDA's decision, contending that the FDA's 24-month "processing" time amounted to constructive denial. Exh. 2 at 1, Exh. 3.

45. Nearly immediately, on July 1, 2022, the FDA denied the JCCP Plaintiffs' appeal saying that there was "no adverse determination" and that "there is no action to consider under appeal and, thus, would "close your appeal." Exh. 4. The FDA ended: "You have the right to judicial review of this action in a United States District Court in accordance with 5 USC § 552(a)(4)(B)." Exh. 4. Accordingly, Mr. Goetz, on behalf of all JCCP Plaintiffs, filed this lawsuit.

FIRST CAUSE OF ACTION

Failure to Make Reasonable Search for Records

46. Plaintiffs repeat, reallege, and incorporate the allegations in the foregoing paragraphs as though fully set forth herein.

47. The FDA did nothing to search for or even evaluate the document requests of the JCCP Plaintiffs in the FOIA Request within the required, twenty-day timeframe. Indeed, the timeframe had already expired by the time the JCCP Plaintiffs were contacted by the FDA. The response of the FDA, as described above, was not a FOIA-compliant response.

48. Two years to process a request constitutes constructive denial. Given the urgency of the underlying JCCP litigation, as well as the narrowly tailored requests with specific topics, named custodians, and short timeframes in the FOIA Request, the FDA's "minimum 24 months" processing period is not reasonable or permissible under FOIA.

49. Defendant's failure to make a reasonable search for records requested by

[16] All correspondence between counsel and the FDA regarding the FOIA Request is attached as Exh. 2.

Plaintiffs violates FOIA, 5 U.S.C. § 552(a)(3), and corresponding regulations.

SECOND CAUSE OF ACTION

Failure to Make Records Available

50. Plaintiff repeats, realleges, and incorporates the allegations in the foregoing paragraphs as though fully set forth herein.

51. Defendant's failure to make a reasonable search for records and make the records available that were requested by Plaintiffs violates FOIA, 5 U.S.C. § 552(a)(3)(A), and corresponding regulations.

THIRD CAUSE OF ACTION

Wrongful Withholding of Records

52. Plaintiff repeats, realleges, and incorporates the allegations in the foregoing paragraphs as though fully set forth herein.

53. Defendant's failure to make a reasonable search for records requested by Plaintiffs violates FOIA, 5 U.S.C. § 552(a)(3)(A) and 5 U.S.C. § 552(a)(6)(A), and corresponding regulations.

PRAYER FOR RELIEF

54. WHEREFORE, Plaintiff respectfully prays to this Court:

a. Expedite consideration of this Complaint pursuant to 28 U.S.C. § 1657;

b. Declare that Defendant improperly and untimely failed to conduct and complete a thorough search for all responsive records;

c. Order Defendant to immediately and expeditiously provide copies of the requested records to Plaintiff within 30 days;

i. Order Defendants to provide copies of the records in their native electronic format or other electronic format, as requested, to Plaintiff;

d. Enjoin Defendant from unlawfully withholding records, or portions thereof;

e. Enjoin Defendant from assessing any unreasonable fees against Plaintiff in relation to the processing of the FOIA Request;

f. Award Plaintiff the costs of this proceeding, including reasonable attorneys' fees and

costs, pursuant to 5 U.S.C. § 552(a)(4)(E); and

g. Grant such other and further relief as the Court deems just and proper.

Dated: August 19, 2022

Respectfully submitted by,

/s/ R. Brent Wisner

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