UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY, Plaintiff, -against- FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. 4:21-cv-01058-P

OPPOSITION TO FDA'S REQUEST FOR AT LEAST 75 YEARS TO RELEASE PFIZER'S BLA DOCUMENTS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

Plaintiff, Public Health and Medical Professionals for Transparency ("**PHMPT**"), by and through its attorneys, Siri & Glimstad LLP, respectfully submits this brief in opposition to the FDA's request for at least 75 years to release documents submitted by Pfizer Inc. ("**Pfizer**") to the U.S. Food and Drug Administration (the "**FDA**") to license its COVID-19 vaccine (the "**Pfizer vaccine**").

PRELIMINARY STATEMENT

Defendant, incredibly, focuses its opening brief on the idea that fairness requires it to take decades to produce the Pfizer vaccine licensure documents. Fairness? Fairness would be giving millions of Americans who are mandated to receive this liability-free vaccine today assurance regarding the FDA's review by allowing independent scientists access to the same data the FDA reviewed, without making them wait decades. Fairness would be allowing Americans injured by the vaccine today, who cannot sue Pfizer or anyone else for the harm, hope that independent scientists with access to that data can more readily develop treatments for their ailments. Fairness would be our federal health authorities allocating more than one person spending a few hours each month to review Pfizer's documents for public disclosure after having given Pfizer over $17 billion of taxpayer money to develop and market the product. Fairness would be releasing the documents so that independent scientists can have this data to assist in addressing serious issues of waning immunity, diminished efficacy, vaccine-immunity evading variants, etc. Fairness would be producing documents that the American taxpayers paid for while those same people are still alive, not decades after most are dead. That would be fairness to the American people.

All of the FDA's griping about fairness comes down to one thing, and one thing alone: it has not sufficiently staffed its FOIA office to properly meet its legal obligations to respond to the requests it receives. In passing FOIA, Congress made the policy decision that it wanted to ensure

transparency, and it knew that transparency delayed is transparency denied, therefore it required agencies like the FDA to produce documents as soon as practicable where the request qualifies for expedited processing. That is the FDA's legal obligation: to promptly produce records. The FDA is not permitted to thwart Congress' policy choice by understaffing its FOIA response office. Numerous cases show how other agencies, when dealing with a production that is eligible for expedited processing, have transferred staff, or hired more staff, in order to promptly comply with its statutory obligations. Here, for the reasons explained in PHMPT's opening brief, the instant FOIA request is the prime example of one that requires expedited processing, and as a result, the FDA cannot be heard to claim that it has too few people to meet its statutory obligations.

Law journal articles, ABA publications, and legal decisions all reflect a document review rate of at least 50 pages per hour per reviewer, and often far more, for reviewing documents for production in litigation – where those reviewers are also searching the documents for relevance, responsiveness, privilege, hot documents, confidentiality designations, attorney-eyes only designation, trade secrets, certain personal information, coding by category, etc. Those are tasks far more complex than called for here. For the simpler task of reviewing for only personally identifiable information and trade secrets under FOIA, assuming a low average of 50 pages per hour per person, even to review the hundreds of thousands of pages the FDA estimates, the agency would need just 19 reviewers to work full time for 12 weeks to review and produce these documents – which is a tiny fraction of its approximately 18,000 employees or, if it outsources the review as is common in litigation reviews, a mere rounding error in its approximately $6.5 billion budget and an even smaller rounding error of the over $17 billion given by the federal government to Pfizer. Plaintiff, in fact, obtained a quote from the e-discovery company BIA dated December 10, 2021 to conduct this precise review of 400,000 pages. BIA concluded that the review could

be completed in a period of 6-8 weeks with 10 reviewers and 1 team leader for a total price tag of approximately $132,000. (App000634 ¶ 5.) **The FDA should be directed to do precisely that.** It should do what everyone else in this country must do – **follow the requirements of federal law**.

Companies do not get to delay paying taxes because they don't have enough tax personnel. They don't get to avoid complying with environmental regulations because they don't have enough compliance officers. They don't get to avoid responding to a U.S. Attorney's subpoena because they don't have enough staff to review the documents. They must follow the law, and so must federal agencies. And here the law says "promptly" and "as soon as practicable," and the regulation says, "immediately available." All of this statutory and regulatory language is intended to ensure transparency. These requirements are utterly defeated if the documents are not produced forthwith. Waiting for transparency until almost everyone alive today is dead makes a mockery of FOIA and of the promise of transparency.

Showing just how misguided the FDA is in its approach, in its brief and declaration in support of same, the FDA ignores all the arguments made by Plaintiff with regard to fairness in the parties' First Joint Report and Second Joint Report. (Dkt 18 ¶ 15; Dkt 20 ¶¶ 2-3.) It ignores the incredible unfairness to the American people to not have access to the Pfizer documents.

Instead, the FDA repeatedly discusses in its motion papers what is fair to the vaccine sponsor, meaning Pfizer, and "the interests of the vaccine sponsor." (Dkt 18 ¶ 15; Dkt 20 ¶ 2.) Putting aside that this is not a real concern in this case, if Pfizer is concerned about its trade secrets, then it has more than sufficient resources to perform the necessary review and inform the FDA what it believes should be withheld from disclosure in a timely manner. This is not a novel concept as other FOIA matters have been resolved in this manner wherein the FDA has adopted redactions proposed by the creator of the documents based on the company's representations that the

documents covered confidential commercial information that would cause harm if disclosed. In fact, if Pfizer spent just .01% of the $17 billion in taxpayer money it received from the federal government for its liability-free mandated product, it could complete this review in less than a week. At a minimum, Pfizer's interests must be viewed through the lens of its obligation to the American people who are underwriting its profits for a product the government has marketed for Pfizer, given immunity from harm, and mandated American take under penalty of exclusion from civil society.

The FDA also says it is unfair to other pending FOIA requesters to prioritize this request. First, since this request qualifies for expedited processing, it must by statute take priority over all other requestors. Second, any unfairness to other requestors is outweighed by the interest of millions of Americans who are being affected by the Pfizer vaccine in having independent scientists review the Pfizer data. Third, any unfairness falls squarely on the shoulders of the FDA for *choosing*, even now during a pandemic, to only have 10 people in its FOIA office (only 8 of whom with experience) despite a budget of over $6.5 billion and over 18,000 employees. Regardless of whether the FDA has made FOIA or transparency a priority, it is an obligation imposed by law and one that must be upheld by the courts despite any claimed hardship it may impose. For the hardship suffered by the American people in the alternative far outweighs any felt by the agency.

ARGUMENT

I. THE FDA ASKS THE COURT TO GIVE IT OVER 75 YEARS TO PROCESS THE FULL REQUEST

The FDA initially disclosed that responding to the instant FOIA request would involve producing 329,000+ pages. As stated in PHMPT's opening brief, at the FDA's proposed 500 pages per month, it would take 54 years and 10 months to process the instant request. The FDA

has since clarified its estimated pages and, with its revised figures, the FDA's current production schedule will require at least 75 years to complete.

The FDA has clarified that, in addition to the previously estimate, the response includes another "approximately 39,000 pages" of BLA "supplements, amendments, and product correspondence" (App000633 ¶ 3), plus "tens of thousands of additional pages" of "records that may be supportive of the BLA" (*Id.*), plus at least 126 data files from Pfizer, many of which the FDA says have over ten thousand rows. (Dkt. No. 22 p. 3.) The FDA states it would like to treat twenty rows in each data file as one page for its monthly production quota. (Dkt. No. 22 p. 9 n.6.) The page counts increased because the agency initially inappropriately limited the scope of Plaintiff's request without any agreement from Plaintiff. Now they have chosen to provide a more accurate page count based on the initial, plainly worded request seeking all documents enumerated in 21 C.F.R. § 601.51(e). However, the FDA has so far refused to provide a more precise count of the "tens of thousands of additional pages" or the total rows in all spreadsheets. (App000633 ¶¶ 3-4.) Instead, the agency argues that Plaintiff's request is overly broad – despite it asking for precisely what is enumerated in 21 C.F.R. § 601.51(e), nothing more. In fact, Plaintiff excluded from the documents any of those already made public via the Vaccine Adverse Event Reporting System. The scope of Plaintiff's request is clear and has been consistent; any misinterpretation or one-sided narrowing of same is on the FDA's part.

The FDA's 20 lines per page estimate is ridiculous in terms of estimating how long it will take to review a spreadsheet. The reason why data is put in a spreadsheet is so that different types of data can be easily identified and separated by columns. If there is either personally identifiable or trade secret information in a column which needs redaction, which as explained below is unlikely, then the FDA can identify same and, as already proposed by Plaintiff, the parties can

discuss redacting the entire column. In that case, a line-by-line review is unnecessary or at the very least can be performed very quickly.

Putting aside that 20 rows per page is an inflated estimate of the time to review, at an average of 12,000 rows per data file, at the FDA's proposed 20 rows per page, the 126 data files adds around 75,000 additional pages. (Dkt. No. 22 pp. 3, 9 n.6.) And assuming the FDA's amorphous "tens of thousands of additional pages" amounts to 20,000 additional pages, then the grand total appears to be at least 451,000 pages. This is the best estimate Plaintiff has at this time.

Even assuming the FDA produces the 12,000 pages it claims it will produce by the end of January, that still leaves at least 439,000 pages to be produced. This number pales in comparison to the millions of pages regularly produced in commercial litigations. Nevertheless, at the rate of 500 pages per month proposed by the FDA, the agency is asking that this Court give it at least **75 years** to produce all the documents. The average life expectancy in the United States in 2020 was 77.8 years. (App000634 ¶ 6.) Thus, the FDA is asking this Court to wait until almost everyone alive today is dead to produce documents that are supposed to be "immediately released" after approval.

II. FEDERAL LAW REQUIRES THE FDA TO "IMMEDIATELY RELEASE" THE REQUESTED DOCUMENTS

Federal regulation requires that upon licensure of a vaccine, the agency is to make "the biological product file … immediately available for public disclosure." 21 C.F.R. § 601.51(e). The FDA obviously adopted this regulation when it still believed in transparency, accountability, and open government. That it has retreated from these positions does not mean it can ignore the same federal laws every American must follow.

The FDA previously argued that this regulation creates no right for the public to obtain these documents, rather it merely allows the agency to produce what are otherwise private

documents. However, that argument is belied by the language of the regulation itself. The request here seeks the information listed in 21 C.F.R. § 601.51(e). Directly above section (e) is another section that concerns obtaining documents. That section, section (d), provides that the "FDA will make available to the public upon request" other documents concerning pre-licensure applications, and that "[p]ersons wishing to request this information shall submit a request under the Freedom of Information Act [FOIA]." 21 C.F.R. § 601.51 (d)(2). In stark contrast, paragraph (e) says nothing about a member of the public needing to make a FOIA request. Rather, it enumerates that the information that must be made "immediately available" to the public upon licensure. This difference reflects that paragraph (e) obligates the FDA, separate and apart from FOIA, to make those documents (i.e., the documents sought in the current request) "immediately available" just as it says.

This is also plain from the fact that paragraph (e) also sets its own standard as to what information should be redacted. For example, (e)(2) provides that the FDA is to make the study's "protocol" immediately public unless it contains "trade secrets and confidential commercial or financial information." Similarly, (e)(3) provides that "[a]dverse reaction reports" and "product experience reports" are to be made immediately available "after deletion of … names and any information that would identify the person using the product." If section (e) was not intending to create a right separate and apart from FOIA, there is no need for these redundant redaction obligations. Hence, this again further makes plain that the disclosure obligation under 21 C.F.R. § 601.51(e) is separate and apart from FOIA.

The Court should, therefore, respectfully require the FDA to abide by its own regulations, just as all Americans must abide by the FDA's regulations, and "immediately disclose" all the information required to be immediately disclosed under 21 C.F.R. § 601.51(e).

III. FOIA DEMANDS THE FDA TIMELY PRODUCE THE DOCUMENTS

The FDA also has a separate duty to disclose the documents requested under FOIA.

A. FOIA REQUIRES PRODUCTIONS TO BE MADE "PROMPTLY" AND EXPEDITED REQUESTS SUCH AS THE ONE AT ISSUE HERE MUST BE COMPLETED "AS SOON AS PRACTICABLE"

The FDA explains how it must take incredible care to abide by the statutory requirements to redact any information required by FOIA. That it must safeguard Pfizer's trade secrets by conducting a line-by-line, word-by-word review which will take decades because no shortcuts can be taken. That it must exactingly abide by the FOIA's redaction requirements. Taking the FDA at its word that the FOIA obligations must be strictly followed, the FDA must also give as much or more gravity to the primary requirement under FOIA – that it "shall make the records **promptly** available to any person" and that, when as here, a request qualifies for expedited processing, it is to be produced at even greater haste "**as soon as practicable**." 5 U.S.C. § 552(a)(3), 5 U.S.C. § 552 (a)(6)(E)(iii) (emphasis added). Congress made plain in FOIA that when there is an "urgency to inform the public concerning actual or alleged Federal Government activity," expedited processing beyond the routine "promptly" requirement is demanded. There frankly could not be an instance that more squarely falls into the criteria for expedited processing. At issue is a product for which the government has granted immunity to liability, has mandated millions of Americans to receive, has given Pfizer millions of dollars for, and was approved within 108 days. What Plaintiff seeks is to review the documents the government relied upon in its action of licensing this product for the public's use. There is, therefore, a dire urgency for the public to have full transparency and review of the FDA's quintessential government activity of licensing Pfizer's COVID-19 vaccine. *Id.* But still, where this need for expedited processing is crystal clear, the FDA shockingly appears to argue that this threshold is not met.

Incredibly, the FDA justifies asking for decades to produce documents by noting that FOIA does not have "a specific timeframe for the release of records." (Dkt. No. 22 p. 2.) Putting aside the elementary school understanding of the word "promptly" and "as soon as practicable," and the purpose of FOIA, courts have made clear that, "Congress recognized that delay in complying with FOIA requests is 'tantamount to denial.'" *Elec. Privacy Info. Ctr. v. Dept. of Justice*, 416 F. Supp. 2d 30, 40 (D.D.C. 2006) (quoting H.R. Rep. No. 93–876, at 6 (1974), 1974 U.S. Code Cong. & Admin. News, pp. 6267, 6271). Likewise, the D.C. Circuit, the circuit with the most experience concerning FOIA, has "acknowledged that 'stale information is of little value.'" *Id.* (quoting *Payne Enterprises, Inc. v United States*, 837 F.2d 486, 494 (D.C. Cir. 1988)). That is why "[t]he 1996 amendments to FOIA creating the statutory right to expedition in certain cases 'underlined Congress' recognition of the value in hastening release of certain information.'" *Id.* (quoting *Edmonds v F.B.I.*, 417 F.3d 1319, 1324 (D.C. Cir. 2005)).

As shown in PHMPT's complaint and in its opening brief, its instant FOIA request is exactly the type of request that Congress had in mind for expedited processing under the FOIA statue. 5 U.S.C. § 552 (a)(6)(E)(v); 21 C.F.R. § 20.44 (c)(2)-(3). PHMPT is unquestionably an organization engaged in the dissemination of information. (Dkt. No. 1 ¶ 4; Dkt. No. 26 p. 14.) The FDA has not challenged this fact. All the documents sought in the FOIA request are urgently needed to allow independent scientists to review the FDA's work and to provide assurance to the public that the liability-free vaccine they are being mandated to receive has truly passed the most rigorous review possible. (Dkt. No. 16 pp. 14-16.) Politicians, academics, and the scientific community all agree on this point. (*Id.*) Additionally, not only are the documents sought central to the largest media story of our time – the fight against COVID-19 and the vaccines deployed in that fight – but as shown, the FDA's claim that it would require decades to produce documents has

itself generated substantial media attention. (Dkt. No. 26 p. 16); *see also Brennan Ctr. for Justice at NYU School of Law v Dept. of Commerce,* 498 F. Supp. 3d 87, 97 (D.D.C. 2020) (requiring expedited processing of a FOIA request because the 2020 Census had generated substantial media attention and there was a need to establish the integrity of the Census). Furthermore, the need for this information will be lost if all the documents are not promptly produced because people and governments are making decisions regarding the Pfizer vaccine now, not in 75 years. (Dkt. No. 26 pp. 17-19.)

An agency like the FDA cannot satisfy Congress' expedited processing requirements solely by giving the FOIA request prompt administrative attention, or by giving priority to only the first 12,000 pages that PHMPT was seeking by November 17 in order to conduct a quick initial assessment. *Elec. Privacy Info. Ctr.*, 416 F. Supp. 2d at 41 (holding that, where a request is entitled to expedited processing, the agency must produce documents in a timely manner). "What matters … is … when the documents are actually released." *Id.* Notably, the FDA's brief is misleading as to the course of communications between the parties. It makes it appear as if Plaintiff agreed to some initial list of documents to the exclusion of others when, in reality, the list provided, with a request the FDA produce by November 17, 2021, was merely intended to get an initial sense of what was in the product file so that Plaintiff could create a priority list for the entire production to occur over a 30-day period and, later, its compromise position of no more than 108 days. The FDA knows that this information is useless in conducting an independent review and was merely intended to get an overview, yet treats it as if it's providing something valuable by the end of January when in reality is well aware that all this has done is create a two-month delay without adding value to the public. *See* full exchange between counsel included at App000633 ¶ 2. As such, the FDA cannot possibly claim that releasing a small subset of the documents when pressed

or the universe of responsive documents over the course of 75 years meets its statutory obligation to "process" the FOIA request "as soon as practicable." 5 U.S.C. § 552 (a)(6)(E)(iii).

Absent from the FDA's arguments is any acknowledgement of the declarant scientists and researchers' explanations that until the entire universe of documents is produced, Plaintiff will not be able to conduct a proper review to evaluate the government's licensure of the product at issue. "Attempting to recreate analyses on efficacy or safety without all the relevant data – data already limited by the short time period of the [Pfizer vaccine] trials – would prove useless." (Dkt. No. 26 p. 16.) Instead of acknowledging this issue, the FDA repeatedly demands that Plaintiff narrow its request to target only a subset or subsets of the entire biologic product file, ignoring the fact that all of the data is necessary in order to conduct an adequate analysis.

Nor can the FDA claim that it must take decades to process PHMPT's request because it received 329 other pending FOIA requests before PHMPT's request. (Dkt. No. 22 p. 11.) This is a specious claim given that, "[p]rocessing expedited FOIA cases takes precedence over processing other non-expedited FOIA cases." *Brennan Ctr. for Justice at New York Univ. School of Law v. United States Dept. of State*, 300 F. Supp. 3d 540, 549 (S.D.N.Y. 2018); *Brennan Ctr.*, 498 F. Supp. 3d at 100-01 (stating that because the request qualified for expedited processing the agency needed to move the request to the front of the line of requests to be processed); *Edmonds v F.B.I.*, No. 02-1294 (ESH), 2002 WL 32539613, at *2 (D.D.C. Dec. 3, 2002) (same). Simply put, the "hardship on other FOIA requesters is not a bar to relief" where the Court finds that expedited processing is warranted because the "substantial interests" of PHMPT in obtaining the requested documents regarding the Pfizer vaccine "outweigh the hardship to Defendant[] and other requesters." *Brennan Ctr.*, 498 F Supp 3d at 103 (internal quotations omitted); *see also Ctr. for*

Pub. Integrity, 411 F. Supp. 3d at 14 (noting that FOIA requests often overlap and that processing of documents for one FOIA requests will assist in responding to other similar requests).

Moreover, the FDA's obligations do not stop at simply putting PHMPT at the head of the line. *Elec. Privacy Info. Ctr.*, 416 F. Supp. 2d at 41. Expedited processing means that the agency is required to actually produce the documents as soon as practicable. *Id.* "Unless the requests are processed [i.e., the documents are produced] without delay, [PHMPT's] right to expedition will be lost." *Id.*; *see also Brennan Ctr.*, 498 F. Supp. 3d at 103 (finding that where the requestor had proven it was entitled to expedited processing, it was "entitled to expedited processing by a date certain"); *Open Socy. Justice Initiative v Cent. Intelligence Agency*, 399 F. Supp. 3d 161, 167 (S.D.N.Y. 2019) (focusing on the actual date of production after noting that meeting the date would put the request in priority over other requests).

Respectfully, "[t]he Court cannot 'simply ... take at face value an agency's determination that more time is necessary.'" *Brennan Ctr.*, 498 F. Supp. 3d at 100 (quoting *Elec. Privacy Info. Ctr. v Dept. of Justice*, 416 F. Supp. 2d at 37). The obligations under FOIA must be honored and hence, the FDA should review for information that needs redaction, but it must at the same time conduct that review in a manner that results in the documents being produced "as soon as practicable." *Brennan Ctr.*, 498 F. Supp. 3d at 103 (finding that, even though "inadvertent release of exempted documents" was a concern, that concern was not so great as to warrant dramatically slower production); *Diocesan Migrant & Refugee Services, Inc. v United States Immigration and Customs Enf't*, EP-19-CV-00236-FM, 2021 WL 289548, at *4 (W.D. Tex. Jan. 28, 2021) (noting that ICE had diverted resources and re-assigned 30% of its FOIA staff to first line review, and then 10-15 attorneys to spend half of every work day doing second line review in order to meet the court's expedited deadlines).

PHMPT is also willing to crowdsource sufficient funds for the FDA to hire contract attorneys to review the documents and produce them in less than 30 days. If the FDA would accept that help, it can produce these funds forthwith. However, the agency has declined this offer stating that "non-federal personnel…cannot perform federal work." (App000633 ¶ 4.) This claim rings hollow. When the FDA reviewed Pfizer's application to license its vaccine, the agency received at least $2,875,842 directly from Pfizer to expedite the licensing review. (App000634 ¶ 7.) As such, it is clear that the FDA's unprecedented quick approval time for Pfizer's vaccine was in many ways directly underwritten by Pfizer. (App000634 ¶ 8.) If the agency will now refuse to accept funds from Plaintiff to produce to the American people expeditiously the same documents it reviewed, then that decision makes crystal clear whose interests it really is serving.

It is embarrassing that our federal health agency gave Pfizer billions of taxpayer dollars, mandated Americans take its product, eliminated their ability to sue Pfizer for harms from this product, and then cries it is unfair to Pfizer if they have to produce these documents without a word-by-word review. Truly shameful. The pandemic is spiraling out of control and basic freedoms are receding in all directions. The solution is not for Plaintiff and the American people to wait until most people alive today are dead for the documents to be produced. Rather it is for the FDA to assign a few dozen of its 18,000+ employees *or* use a tiny rounding error fraction of its over $6.5 billion budget to hire professional document reviewers to get this done in less than 30 days, or at most Plaintiff's compromise position of no more than 108 days. Or it can allocate just .01% of the $17 billion the federal executive has given Pfizer which would be sufficient to hire enough contract attorneys to review and produce these documents in less than a week. *See Open Socy. Justice Initiative*, 399 F. Supp. 3d at 169 (directing expedited production "even if

meeting this demand calls upon DOD to augment, temporarily or permanently, its review resources, human and/or technological").

Plaintiff's request for production within 108 days is justified. If the FDA was able to review the universe of documents thoroughly enough to confirm and analyze Pfizer's data and conclusions, then certainly the agency can review the same universe looking only for the rare occurrence of trade secrets or personally identifying information. The FDA claims that Pfizer "submitted data to FDA on a rolling basis, even in advance of the formal BLA submission, meaning the substantive data review occurred over a longer period than the 108 days." (Dkt. No. 23 ¶ 35.) But Pfizer in a press release dated May 7, 2021, titled "Pfizer and BioNTech initiated the BLA by submitting the nonclinical and clinical data needed to support licensure…" of its COVID-19 vaccine announced that the "[d]ata to support the BLA **will be** submitted by the companies to the FDA on a rolling basis over the coming weeks, with a request for Priority Review." (App000634 ¶ 9) (emphasis added). Meaning, Pfizer began its rolling submission on May 7, 2021 and the vaccine was licensed on August 23, 2021, a total of 108 days from initial submission to licensure.

The only reason that the documents cannot be produced promptly is that the FDA has chosen to not properly allocate the resources to perform the required work. The FDA has repeatedly stated that the licensure of a COVID-19 vaccine and addressing the pandemic via same is its highest priority. This same branch of government reflected this priority by allocating enough resources to prioritize development, production, authorization, distribution, promotion, and licensing of the vaccine. It should now allocate adequate resources to transparency related to this vaccine. Releasing these documents is directly in line with this priority. It should act accordingly.

Corporations with a small fraction of the FDA's employees and resources must comply with all forms of statutory obligations. A company cannot claim that it only has 10 people in its accounting and tax departments and hence needs another 75 years to review its records in order to pay its taxes. But when it comes to the FDA's statutory obligation, the agency proposes to devote the equivalent of one person reviewing a few hours a month (even at its thumb-twiddling 8-minute-per-page rate) for the next 75+ years to fulfill its statutory obligation to produce these urgent records "as soon as practicable." It is a truly absurd position.

Putting this into perspective, private law firms manage to review and produce hundreds of thousands of pages per month in litigation when reviewing for far more than just the disclosure exemptions listed in FOIA, but also for relevance, responsiveness, privilege, hot documents, trade secrets, confidentiality designation, attorney-eyes only designation, coding by category, coding by request number, coding for second level reviews, certain personal information, etc. Law journal articles, ABA publications, and caselaw all reflect that at least 50 pages per hour, and often far more pages per hour, can be manually reviewed for this far more complex and involved review than the one required by FOIA, which here the Defendant submits only requires reviewing for trade secrets and personally identifiable information. (App000634 ¶ 10 – App000635 ¶ 13.) At this rate, it would take one reviewer just 10 hours to view the 500 pages that the FDA wants to produce in a month. Even at the FDA's ridiculous rate of 8 minutes per page, it would only take one reviewer 66 hours per month to review 500 pages. FDA also does not acknowledge the growing availability of artificial intelligence capable of almost completely automating privilege review. (App000635 ¶ 14.)

At bottom, the FDA does not treat its transparency obligations under FOIA to produce "as soon as practicable" as an actual statutory requirement. It instead just pays lip service to the

concept by saying that the "FDA is committed to transparency" but then does nothing to ensure that transparency. (Dkt. No. 18 ¶ 15.) "[M]erely paying lip service to [PHMPT's] statutory right does not negate the harm that results from the agency's failure to **actually** expedite its processing." *Elec. Privacy Info. Ctr.*, 416 F. Supp. 2d at 41 (internal quotations omitted, emphasis in original). In the end, whether the FDA values or is "committed" to transparency is irrelevant, Congress gave it a statutory obligation to produce expedited productions "as soon as practicable" and the Court must hold the agency to abide by that obligation – just as every other American must abide by federal statutes. *Payne Enterprises, Inc. v United States*, 837 F.2d 486, 494 (D.C. Cir. 1988) ("'unreasonable delays in disclosing non-exempt documents violate the intent and purpose of the FOIA, and the courts have a duty to prevent these abuses.'" (quoting *Long v U.S. I.R.S.*, 693 F.2d 907, 910 (9th Cir 1982))); *Clemente v Fed. Bur. of Investigation*, 71 F. Supp. 3d 262, 269 (D.D.C. 2014) (quoting *Payne* and concluding that a "court therefore may use its equitable powers to require the agency to process documents according to a court-imposed timeline").

For these reasons, any partial adoption of the FDA's current production proposal will not result in a prompt or immediate result for the American public and so should be rejected by this Court. That will instead result in a piecemeal, foot-dragging schedule for which the parties will undoubtedly need repeated Court intervention to settle.

B. CLAIMED NEED FOR REDACTIONS IS OVERBLOWN

It is also simply untrue that the review the FDA argues it must conduct is as arduous as it claims. The FDA claims it must review for two categories of information: personal information that constitutes "a clearly unwarranted invasion of privacy" and trade secrets. (Dkt. No. 22 at 2.) As for personally identifiable information, this information has already been redacted by Pfizer before submission because that is what is required by the FDA regulations. 21 C.F.R § 20.63(b). ("The names and other information which would identify patients or research subjects should be

deleted from any record before it is submitted to the Food and Drug Administration."). This likely explains why, when the FDA reviewed the two data files it produced to Plaintiff, the FDA found "that there was no exempt material in the data files" and hence "made no deletion or reductions in those files." (Dkt. No. 22 at 6.)

As for trade secrets, the FDA's regulations state that Pfizer was to designate trade secrets within its documents before submitting its documents or seek redactions in a "reasonable time thereafter." 21 C.F.R § 20.63(b). ("A person who submits records to the Government may designate part or all of the information in such records as exempt from disclosure under exemption 4 of the Freedom of Information Act. The person may make this designation either at the time the records are submitted to the Government or within a reasonable time thereafter. The designation must be in writing. … Any such designation will expire 10 years after the records were submitted to the Government.") In any event, most of the information submitted by Pfizer was clinical trial information – not trade secrets. It is deidentified patient level data.

As an example of how arbitrary and capricious the FDA acts regarding trade secret redactions, the FDA placed on its website its clinical trial review it conducted for the Pfizer vaccine which included an ingredient list for this product. One of the ingredients was redacted. Our firm submitted a FOIA request on behalf of a client to have that redaction lifted. (App000635 ¶ 15.) When it was finally lifted, it turned out that the redacted ingredient was "water for injection" (App000635 ¶ 16.) Literally "water."

The Court should respectfully not let the FDA play this same type of game here – pretending it must carefully review word-by-word to redact information and then finding something to redact to justify its review, when in reality almost everything submitted by Pfizer, without any review needed, will plainly not include trade secrets (*e.g.*, the hundreds of thousands

of pages of patient level data). In any event, Pfizer has already had an opportunity to designate any information it feels rises to the level of proprietary information.

If Pfizer has not already done so, the FDA can put the responsibility of designating information exempt from disclosure on Pfizer. Pfizer knows these documents and data inside and out. Pfizer has the responsibility to protect clinical trial participants' personally identifying information. Pfizer holds the interest in protecting trade secret information. Pfizer undoubtedly has the resources – as it expects to make $36 billion in sales on its COVID-19 vaccine this year alone (App000635 ¶ 17) – and the ability to promptly designate information it believes is exempt from disclosure and so, if the FDA cannot do so in an adequate period of time, the agency should notify Pfizer that it plans to produce the documents in full and lay the burden at Pfizer's feet to object to same.

C. THE FDA FAILED TO COMPLY WITH FOIA'S "DUE DILIGENCE" REQUIREMENT

An agency must show due diligence in responding to the request, even in situations where it is able to show exceptional circumstances exist for not being able to otherwise comply with statutory time frames. *See* 5 U.S.C. § 552(a)(6)(C). Here, the FDA has failed to show due diligence. Despite more than three months elapsing since Plaintiff's FOIA request was made, more than two months of communication through the parties' counsel, and the agency's own regulation which calls for these records to be made "immediately available" to the public, the agency has failed to do, *inter alia*, the following:

1. Provide a full index of the biological product file requested;
2. Provide a full index of the biologic license application within that file;
3. Provide approximate page counts/line counts for each portion of the biological product file;
4. Identify any documents or categories of documents which do not or are not expected to contain any exempt information;
5. Produce any documents that do not contain any exempt information;

6. Identify any documents or categories of documents which are expected to contain any exempt information;
7. Disclose any column headers for the data files so that the parties can discuss which columns may need review for potential redactions;
8. Confer with Plaintiff, proactively, about redactions or withholdings that may be needed to expedite that review now and to avoid disputes about redactions post-production;
9. Inform Plaintiff whether Pfizer has already designated information it believes is exempt from disclosure as proprietary trade secrets.

Instead, and only in response to specific prompting from Plaintiff, the agency has provided fractured and incomplete information regarding the volume of the responsive documents, has offered no information about redactions other than the general claim that redactions are needed and take time and resources to apply, and has provided only two tiny limited, piecemeal productions which are useless in isolation. The agency's actions fall far short of due diligence and have already violated its own regulation calling for these precise records to be made "immediately available" after licensure. In fact, the FDA could have performed the basic due diligence needed to provide almost all of foregoing information in less time than it took for it to draft the 19-page declaration filed in this action.

CONCLUSION

The FDA, so focused on its concern for Pfizer's purported trade secrets, simply ignores its obligations to make "immediately available" the requested documents under 21 C.F.R. § 601.51(e) as well as the entire purpose of FOIA – transparency – and its obligation to produce requested documents "as soon as practicable." All of these obligations are frustrated unless the requested documents are produced forthwith. Issues regarding waning immunity, need for boosters, vaccine immunity driving variants, and a host of others, need independent scientists to have transparency into the FDA's process today. Not 75 years from now. And without all the data, a proper analysis of the data cannot be done.

Transparency is also urgently needed here because millions of Americans are being mandated to receive this product under penalty of exclusion from work, school, the military, and everyday life in society. It is unconscionable that the FDA would not immediately assign sufficient personnel or resources to review these documents and release them to the public. It is in fact shocking that the agency did not anticipate this demand for these documents and had not done so prior to Plaintiff's request. Instead, prior to today and since the vaccine was licensed, the FDA has produced a total of 339 pages and two tiny data files. That is an average of producing 3 pages per day since Plaintiff submitted its request on August 27, 2021. Any other documentation released by federal health authorities regarding Pfizer's vaccine were documents generated by the government and were not Pfizer's documents which is what Plaintiff seeks to review. The whole purpose of FOIA and expedited treatment is to review government conduct.

True to form, and despite the passage of 112 days since licensure, the agency incredibly tells the Court in its papers that it still does not know how many pages are in the BLA file for Pfizer's vaccine, can't determine how many rows are in the 126 data files it identified, can't figure out which documents may be easily produced, can't disclose whether the documents were already deidentified by Pfizer, can't provide a full index of the documents, can't determine even how well its existing 10 reviewers can work since two of them are newer, etc. But there are two things the FDA is certain about: it is certain it can ignore the FOIA obligation to produce these documents "as soon as practicable" and it is certain it must put its obligation to redact trade secrets on Pfizer's behalf above the American peoples' right and need to see these documents.

But the FDA seeks to assure the Court that its choice to ignore its disclosure obligations is fine because when it reviewed the Pfizer data the agency "marshaled" all available resources to ensure that the public had access to "life-saving products" as soon as possible. (Dkt. No. 20 ¶ 2.)

That is precisely the issue at hand. The public is entitled to have independent scientists review the data underlying the federal government's decisions regarding this mandatory and liability-free COVID-19 vaccine. The FDA is essentially saying, "trust us, we know what we are doing, no one else needs to check our work." However, Congress made the policy decision decades ago that the American people may trust their government, but they also get to verify that trust through rigorous transparency.

The issue here is simply one of resources and for this issue, the FDA should be directed to produce at least the same speed it took to license the product given the importance of timely production, the obligation to "promptly" produce under FOIA to assure transparency, and the regulation calling for these documents to be "immediately available" to the public following licensure. The FDA should not be above the law. Nor should it be permitted to get away with its unconscionable approach and position with regard to disclosing Pfizer's documents for independent review.

For the foregoing reasons, during the upcoming scheduling conference, the Court should order the FDA to produce all documents responsive to the PHMPT's FOIA Request on or before March 3, 2022, which is 108 days from the parties Second Joint Report to the Court. Whether the FDA or Pfizer reviews the documents for proposed redactions is not of concern for Plaintiff and should not affect the requested production date of March 3, 2022.

Dated: December 13, 2021

SIRI & GLIMSTAD LLP

Aaron Siri, NY Bar No. 4321790
Elizabeth A. Brehm, NY Bar No. 4660353
Gabrielle G. Palmer, CO Bar No. 48948
200 Park Avenue
New York, New York 10166
Tel: (212) 532-1091
Fax: (646) 417-5967
aaron@sirillp.com
ebrehm@sirillp.com
gpalmer@sirillp.com

HOWIE LAW, PC
John Howie
Texas Bar Number: 24027239
2608 Hibernia Street
Dallas, Texas 75204
Tel: (214) 622-6340
jhowie@howielaw.net

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY, Plaintiff, -against- FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. 4:21-cv-01058-P

APPENDIX IN SUPPORT OF PLAINTIFF'S OPPOSITION TO FDA'S REQUEST FOR AT LEAST 75 YEARS TO RELEASE PFIZER'S BLA DOCUMENTS

Plaintiff Public Health and Medical Professionals for Transparency submits this Appendix in support of its Opposition to FDA's Request for at Least 75 Years to Release Pfizer's BLA Documents.

Dated: December 13, 2021

SIRI & GLIMSTAD LLP

Aaron Siri, NY Bar No. 4321790
Elizabeth A. Brehm, NY Bar No. 4660353
Gabrielle G. Palmer, CO Bar No. 48948
200 Park Avenue
New York, New York 10166
Tel: (212) 532-1091
Fax: (646) 417-5967
aaron@sirillp.com
ebrehm@sirillp.com
gpalmer@sirillp.com

HOWIE LAW, PC

John Howie
Texas Bar Number: 24027239
2608 Hibernia Street
Dallas, Texas 75204
Tel: (214) 622-6340
jhowie@howielaw.net

Attorneys for Plaintiff

Exhibit F

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY, Plaintiff, -against- FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. 4:21-cv-01058-P

DECLARATION OF AARON SIRI, ESQ.

I, Aaron Siri, declare as follows:

1. I am the Managing Partner of Siri & Glimstad LLP, counsel to Public Health and Medical Professionals for Transparency ("**PHMPT**"). I am admitted to practice *pro hac vice* in this action. I make this declaration in support of PHMPT's Opposition to FDA's Request for at Least 75 Years to Release Pfizer's BLA Documents.

2. Exhibit 1, attached hereto, is a true and correct copy of an email exchange between counsel for PHMPT and Courtney D. Enlow, counsel for the Food and Drug Administration ("**FDA**"). The most recent email in Exhibit 1 is dated November 5, 2021.

3. Exhibit 2, attached hereto, is a true and correct copy of an email exchange between counsel for PHMPT and Courtney D. Enlow, counsel for the FDA. The most recent email in Exhibit 2 is dated December 10, 2021.

4. Exhibit 3, attached hereto, is a true and correct copy of an email exchange between counsel for PHMPT and Antonia Konkoly, counsel for the FDA. The most recent email in Exhibit 3 is dated December 13, 2021.

5. Exhibit 4, attached hereto, is a true and correct copy of an email from Michael Kroeber of Business Intelligence Associates, Inc. to Nicky Tenney, a paralegal at my firm.

6. Exhibit 5, attached hereto, is a true and correct copy of a report by the National Center for Health Statistics titled "Provisional Life Expectancy Estimates for January through June, 2020" available at https://www.cdc.gov/nchs/data/vsrr/VSRR10-508.pdf.

7. Exhibit 6, attached hereto, is a true and correct copy of a page on the FDA's website titled "Prescription Drug User Fee Amendments" available at https://www.fda.gov/industry/fda-user-fee-programs/prescription-drug-user-fee-amendments.

8. Exhibit 7, attached hereto, is a true and correct copy of an article titled "Why is the FDA Funded in Part by the Companies It Regulates?" available at https://today.uconn.edu/2021/05/why-is-the-fda-funded-in-part-by-the-companies-it-regulates-2/.

9. Exhibit 8, attached hereto, is a true and correct copy of a press release titled "Pfizer and BioNTech Initiate Rolling Submission of Biologics License Application For U.S. FDA Approval of Their COVID 19 Vaccine" available at https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-initiate-rolling-submission-biologics.

10. Exhibit 9, attached hereto , is a true and correct copy of an article titled "Study Shows 'Traditional Linear Review' Almost Accounts for 73% of e-Discovery Costs" available at https://www.abajournal.com/advertising/article/reducing_costs_with_advance_review_strategies/

11. Exhibit 10, attached hereto, is a true and correct copy of an article titled "Advanced Analytics Value for Small Document Review Cases" available at https://www.biaprotect.com/blog/advanced-analytics-value-for-small-document-review-cases/.

12. Exhibit 11, attached hereto, is a true and correct copy of an article titled "Answering Your Questions about Legal Document Review" available at https://www.biaprotect.com/blog/legal-document-review-q-a/.

13. Exhibit 12, attached hereto, is a true and correct copy of a webpage titled "Document Review Calculator" available at https://percipient.co/electronic-discovery-and-esi-document-review-calculator/.

14. Exhibit 13, attached hereto, is a true and correct copy of an article titled "Privilege Analytics From H5: The Best Way To Handle Privilege Review" available at https://abovethelaw.com/2021/12/privilege-analytics-from-h5-the-best-way-to-handle-privilege-review/.

15. Exhibit 14, attached hereto, is a true and correct copy of a Freedom of Information Act ("**FOIA**") request submitted by my firm to the FDA on September 14, 2021.

16. Exhibit 15, attached hereto, is a true and correct copy of the FDA's response letter and the production made in response to the FOIA request attached hereto as Exhibit 14.

17. Exhibit 16, attached hereto, is a true and correct copy of an article titled "Pfizer raises Covid vaccine sales forecast to $36 billion for 2021" available at https://www.cnbc.com/2021/11/02/pfizer-raises-covid-vaccine-sales-forecast-to-36-billion-.html.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge.

Dated: December 13, 2021

Aaron Siri, Esq.

Exhibit 1

Aaron Siri

From: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Sent: Friday, November 5, 2021 8:39 AM
To: Aaron Siri
Cc: Elizabeth Brehm; Gabrielle Palmer
Subject: RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Aaron,

The FDA cannot agree to process and produce the non-exempt portions of more than 20,000 pages in less than a month. Again, I'm not aware of any court ever ordering such a processing schedule. We also disagree with your interpretation of the regulation and the other comments in your response, though I don't think it would be productive to continue a back-and-forth about those issues at this time.

Unfortunately, despite our best efforts to reach agreement on a schedule, I think we are too far apart and we should propose our own schedules in paragraph 16 of the Joint Report. One you have entered your proposal into the draft, please send it back to me so I can enter FDA's proposal. In the meantime, please also let me know if you had edits to the other sections, as I will need to run any language by folks on my end before we can file.

Thanks,
Courtney

From: Aaron Siri <aaron@sirillp.com>
Sent: Friday, November 05, 2021 11:23 AM
To: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Subject: [EXTERNAL] RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Courtney,

I would submit that the review by the FDA to license this product required it to engage in extensive statistical analysis, review, etc., that would have been more time consuming and involved than a review for exempt information. Also, with a product that the federal government is mandating that millions of Americans receive under penalty of being fired from their jobs while at the same time giving immunity to Pfizer for any injuries, this is a unique situation that demands the FDA (as its own regulations reflect) immediately make the data underlying the licensure of this product public.

That said, if the FDA will agree to produce everything on the priority list below (which you state is 20,000+ pages) by December 1, I will strongly recommend to my client accept that as an initial step.

I note that the product was licensed on November 23, 2021, and despite the passage of nearly two and a half months, the FDA has not abided by even its own regulations to make a single page of the data it relied upon to license this product available to the public. Not one page.

Thanks,
Aaron

From: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Sent: Friday, November 5, 2021 8:13 AM
To: Aaron Siri <aaron@sirillp.com>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Subject: RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Hi Aaron,

Can you clarify what you mean by "produce this initial list by December 1"? Are you referring to a subset of the priority list, or the entire 20,000+ pages?

Also, thanks for clarifying that PHMPT prioritized the CRFs. I had not understood that the top items were the items that PHMPT wanted first; I assumed the list was not in any particular order.

Finally, I appreciate you letting me know why they think their timing is reasonable, though I would point out that FOIA processing to ensure no exempt information is released is entirely different from the review cited by PHMPT.

Thanks,
Courtney

From: Aaron Siri <aaron@sirillp.com>
Sent: Friday, November 05, 2021 11:07 AM
To: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Subject: [EXTERNAL] RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Hi Courtney. I will need to confer with them but this proposal is not much different than what was originally proposed by the FDA which was not taken well. I pushed hard to get them to come back with something more limited than the entire file in 30 days which is reflected in the list below. Their repeated retort to me is that if the FDA can review the entire submission by Pfizer in three months and license the product, the FDA should be able to release it in far less than that amount of time. I also note that the list below was provided in the order of their priority but the FDA's proposal does not include the CRFs which are at the top of their list. Before I revert, can I tell them the FDA will produce this initial list by December 1? If so, I can push hard for agreement to same. Thanks.

From: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Sent: Friday, November 5, 2021 7:57 AM
To: Aaron Siri <aaron@sirillp.com>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Subject: RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Hi Aaron,

Thanks for providing PHMPT's desired priority list for processing responsive records. FDA has conducted an initial assessment and has determined that PHMPT has requested that FDA process and produce the non-exempt portions of over 20,000 pages by November 17. FDA cannot agree to such a schedule, nor am I aware of any court ever ordering the production of that many pages in such a short timeframe.

That being said, FDA can agree to produce the non-exempt portions of some of PHMPT's priority list by November 17. Specifically, FDA would agree to produce the non-exempt portions of the below records by November 17:

- From Section 5.2 (as shown on PDF page 1):
  - The Tabular Listing

- The Listing of Clinical Sites
- From Section 5.3.6 (as shown on PDF page 2): the Reports of Postmarketing Experience
- One SAS file (as shown on PDF page 10). As I've previously noted in my 11/3/21 3:08PM email, FDA is not used to producing SAS files and is unsure of what, if any technical difficulties may arise in the processing of an SAS file, so FDA would produce the non-exempt portions of one of the smaller SAS files.

FDA can also agree to produce the non-exempt portions of the remainder of Section 5.2 by December 1.

Because we received PHMPT's priority list at 4:00 yesterday afternoon, we do not yet have proposed dates for the rest of the items on the list. However, we are, of course, amenable to continuing our discussion on prioritizing and processing dates for the other sections PHMPT identified on its priority list.

Please let me know if PHMPT will agree to these initial processing dates. If so, we can include this in our Joint Report today and request to file a joint status report in 30 or 45 days to propose the next set of processing dates. If not, please let me know as soon as possible if PHMPT has an alternate proposal.

Thanks,
Courtney

Courtney Enlow
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W., Room 12102
Washington, D.C. 20005
(202) 616-8467
courtney.d.enlow@usdoj.gov

From: Aaron Siri <aaron@sirillp.com>
Sent: Thursday, November 04, 2021 4:06 PM
To: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Subject: [EXTERNAL] RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Also, CFRs for site 1085 which is on page 33 of the PDF.

From: Aaron Siri
Sent: Thursday, November 4, 2021 12:58 PM
To: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Subject: RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Hi Courtney,

Nice meeting yesterday. Based on our follow-up preliminary discussion with our client earlier today, they would like to know if the FDA will produce the following items by November 17:

1. Pdf page 27: CRFs for site 1055
2. Pdf page 31: CRFs for site 1081

3. Pdf page 38: CRFs for site 1096
4. Pdf page 46: CRFs for site 1128
5. Pdf page 10: Program Files/SAS files. They want 3 to 4 SAS files as a sample, in the first instance, so that they client can assess whether it would like to prioritize the complete universe of SAS files.
6. Pdf page 1: 5.2 - Tabular Listing of all Clinical Studies
7. Pdf page 1: 4 – Nonclinical Study Reports
8. Pdf page 2: 5.3.6 - Reports of Postmarketing Experience
9. Pdf page 3: 16.1.1 - Protocol and/or Amendment, and specifically, Final Analysis Interim Independent Oversight Committees
10. Pdf page 6: Under the Analysis Datasets (ADaM), the Analysis Data Reviewers Guide, Analysis Dataset Definition, and Analysis Dataset Definition Stylesheet
11. Pdf page 11: Tabulation Datasets

If we can get agreement on producing these limited items as noted, we can advise as much in our joint letter and that we are continuing to discuss a production schedule for the remaining data and information.

Please let us know if the FDA will agree to their proposal.

Thanks,
Aaron

From: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Sent: Thursday, November 4, 2021 11:07 AM
To: Gabrielle Palmer <gpalmer@sirillp.com>
Cc: Aaron Siri <aaron@sirillp.com>; Elizabeth Brehm <ebrehm@sirillp.com>
Subject: RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Hi Gabrielle and Aaron,

I've attached a draft joint report to address the court's questions in the October 18 order. Please let me know if you have a response to FDA's proposals as outlined in my below emails. If the parties can reach agreement on any of these proposals, we can include that agreement in the joint report. Otherwise, we can add our separate positions in paragraph 16 and request a conference with the judge to set a processing schedule. If we have no agreement on any issue, please let me know so I can draft FDA's position for our joint report.

Thanks,
Courtney

From: Enlow, Courtney D. (CIV)
Sent: Wednesday, November 03, 2021 3:08 PM
To: Gabrielle Palmer <gpalmer@sirillp.com>
Cc: Aaron Siri <aaron@sirillp.com>; Elizabeth Brehm <ebrehm@sirillp.com>
Subject: RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Hi Aaron,

It was nice to meet you in person this morning. To follow up on our conversation this morning and my emails from yesterday about SAS files, FDA has assessed as follows:

- FDA is willing to produce SAS files to PHMPT with the caveats as outlined in this email.
- FDA has not yet assessed whether it is feasible for FDA to redact or delete exempt information in SAS files. FDA does not usually produce SAS files in response to FOIA requests, so FDA does not know if it may experience any

technical difficulties during processing or whether any type of conversion of files will be necessary to process responsive records.

- For any SAS files that do not contain exempt information (and thus do not require redaction/deletion), FDA is willing to produce SAS files to PHMPT.
- For any SAS files that do contain exempt information that would need to be redacted/deleted, FDA is willing to produce SAS files if it is feasible for FDA to redact or delete in the SAS file. If it is not feasible to redact/delete in SAS files, FDA would need to produce those files in either Excel or PDF. We can update you if such a conversion is necessary.
- Again, because FDA is not used to producing SAS files and does not know what technical difficulties may arise, FDA proposes to produce the first SAS file to PHMPT on December 20. FDA has committed to producing that data to PHMPT earlier than December 20 if FDA is able to process it before that time. Once FDA has produced the first SAS file, we propose to confer about future processing dates for the remainder of the SAS files.
- If PHMPT wants FDA to prioritize certain files from the PDF that I emailed yesterday, please let me know.

Finally, I hope to have the draft joint report to you today or tomorrow morning.

Best regards,
Courtney

From: Enlow, Courtney D. (CIV)
Sent: Tuesday, November 02, 2021 6:37 PM
To: Gabrielle Palmer <gpalmer@sirillp.com>
Cc: Aaron Siri <aaron@sirillp.com>; Elizabeth Brehm <ebrehm@sirillp.com>
Subject: RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Hi Gabrielle,

As an update, FDA proposes a production date of December 1 for Section 5.2

FDA is amenable to producing documents in a format other than PDFs. However, the raw data files are in SAS format, which is a spreadsheet-like file type that isn't accessible to most people, and it appears difficult or perhaps even impossible for FDA to redact exempt material from SAS files. FDA would be amenable to converting those SAS files to Excel rather than PDF for FDA to review, delete the exempt information (as redacting is not possible in Excel), and provide the non-exempt portions of those files to PHMPT. Therefore, while this wouldn't be the "native" format that PHMPT requested, it would allow PHMPT to use a non-PDF format to manipulate the file.

Because FDA does not yet have a sense of how long the conversion from SAS files to Excel files would take, FDA proposes to produce the first raw data file to PHMPT by December 20 and then set a time to discuss future productions. FDA anticipates that future productions would not take 45 days per file to process and produce, but it does not have a good sense of how long it would take at this point because this is an atypical process for the agency.

Please let me know if this proposal is amenable to PHMPT. Also, please do let me know what time to meet Aaron in the morning. Does 6:15 work?

Thanks,
Courtney

From: Enlow, Courtney D. (CIV)
Sent: Tuesday, November 02, 2021 6:02 PM
To: Gabrielle Palmer <gpalmer@sirillp.com>

Cc: Aaron Siri <aaron@sirillp.com>; Elizabeth Brehm <ebrehm@sirillp.com>
Subject: RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Hi Gabrielle,

Yes, I can meet Aaron in the morning at the Starbucks near Terminal C at DCA. What time?

I'm still drafting a proposed joint report that I can send tomorrow. (Apologies for the delay, I've been tied up in emergency briefing this week.)

Best regards,
Courtney

From: Gabrielle Palmer <gpalmer@sirillp.com>
Sent: Tuesday, November 02, 2021 5:28 PM
To: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Cc: Aaron Siri <aaron@sirillp.com>; Elizabeth Brehm <ebrehm@sirillp.com>
Subject: [EXTERNAL] RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Courtney,

Will you please send us your proposed motion? Also, Aaron's plan is to take a 7am flight on American Airlines tomorrow morning. Are you able to meet him at DCA before his flight? There is a pre-security Starbucks near Terminal C, so if you're available, that could be a good meeting location.

Gabrielle G. Palmer, Attorney
Siri | Glimstad
200 Park Avenue
Seventeenth Floor
New York, NY 10166
Main: 212-532-1091
Facsimile: 646-417-5967
www.sirillp.com

This email may contain material that is confidential, privileged and/or attorney work product for the sole use of the intended recipient. Any review, reliance or distribution by others or forwarding without express permission is strictly prohibited. If you are not the intended recipient, please contact the sender and delete all copies.

From: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Sent: Tuesday, November 2, 2021 10:54 AM
To: Gabrielle Palmer <gpalmer@sirillp.com>
Cc: Aaron Siri <aaron@sirillp.com>; Elizabeth Brehm <ebrehm@sirillp.com>
Subject: RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Good afternoon Aaron and Gabrielle,

I'm writing to provide you an update on FDA's initial assessment of records responsive to PHMPT's FOIA request.

In terms of volume, FDA has determined that the original Cominarty BLA submission contains at least 329,000 pages. Of those pages, approximately 322,000 pages are contained in section 5 of the application.

FDA is still working on providing a proposed date for processing and production of the non-exempt portions of Section 5.2. I hope to have that proposed date to you today or tomorrow.

To help prioritize processing and production, FDA provides the attached "index" of several subsections of Section 5.3. As you will see, the FDA has provided estimates of the number of pages in various subsections. We would ask PHMPT to review that index and select the sections that they would like to prioritize. Once we understand their prioritization, we can offer production estimates for the subsections they prioritize.

Also, you had mentioned that PHMPT does not want anything that has been publicly released on any website. We are, of course, happy to narrow PHMPT's FOIA request, but we want to ensure that the parties are in agreement on which records do not need to be processed and produced. Accordingly, FDA requests that PHMPT provide a list of BLA sections that they wish to exclude from their FOIA request because they have obtained those sections from other sources.

With regard to the parties' joint motion for relief from the scheduling order, I'm concerned that since the parties' joint report is due Friday, we don't have sufficient time to seek relief from the order. Therefore, I propose that we file the joint report contemplated by the order and state that we don't believe certain sections are applicable to a FOIA case. This will also allow us to set forth different views on different issues if need be. I can take the lead on drafting.

Finally, Aaron, do you have any update on your availability to meet before you head back to New York? I have several meetings and a hearing tomorrow morning that I will need to work around.

Thanks,
Courtney

From: Gabrielle Palmer <gpalmer@sirillp.com>
Sent: Friday, October 29, 2021 5:31 PM
To: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Cc: Aaron Siri <aaron@sirillp.com>; Elizabeth Brehm <ebrehm@sirillp.com>
Subject: [EXTERNAL] RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Hi Courtney,

Our proposed revisions are attached. Aaron will respond to you separately about his trip to DC.

Gabrielle G. Palmer, Attorney
Siri | Glimstad
200 Park Avenue
Seventeenth Floor
New York, NY 10166
Main: 212-532-1091
Facsimile: 646-417-5967
www.sirillp.com

This email may contain material that is confidential, privileged and/or attorney work product for the sole use of the intended recipient. Any review, reliance or distribution by others or forwarding without express permission is strictly prohibited. If you are not the intended recipient, please contact the sender and delete all copies.

From: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Sent: Friday, October 29, 2021 1:55 PM
To: Gabrielle Palmer <gpalmer@sirillp.com>

Cc: Aaron Siri <aaron@sirillp.com>; Elizabeth Brehm <ebrehm@sirillp.com>
Subject: RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Hi Gabrielle,

Following up on my email below. Do you have any additional edits to the motion? Also, since it looks like we likely won't get this on file in time for it to be granted, can you please let me know if Aaron will be traveling to DC via Reagan National Airport (DCA)? It would be much more convenient to meet somewhere near there as opposed to anywhere near the Capitol.

Thank you,
Courtney

Courtney Enlow
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W., Room 12102
Washington, D.C. 20005
(202) 616-8467
courtney.d.enlow@usdoj.gov

From: Enlow, Courtney D. (CIV)
Sent: Thursday, October 28, 2021 3:47 PM
To: Gabrielle Palmer <gpalmer@sirillp.com>
Cc: Aaron Siri <aaron@sirillp.com>; Elizabeth Brehm <ebrehm@sirillp.com>
Subject: RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Hi Gabrielle,

I've attached some proposed edits to the joint motion. I thought it was necessary to provide a bit more explanation in the first paragraph. Please let me know if you have any additional edits.

Thank you,
Courtney

Courtney Enlow
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W., Room 12102
Washington, D.C. 20005
(202) 616-8467
courtney.d.enlow@usdoj.gov

From: Gabrielle Palmer <gpalmer@sirillp.com>
Sent: Wednesday, October 27, 2021 2:13 PM

To: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Cc: Aaron Siri <aaron@sirillp.com>; Elizabeth Brehm <ebrehm@sirillp.com>
Subject: [EXTERNAL] RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Hi Courtney,

Please see the attached letter and draft motion to excuse compliance with Rules 26 and 16.

Thanks,

Gabrielle G. Palmer, Attorney
Siri | Glimstad
200 Park Avenue
Seventeenth Floor
New York, NY 10166
Main: 212-532-1091
Facsimile: 646-417-5967
www.sirillp.com

This email may contain material that is confidential, privileged and/or attorney work product for the sole use of the intended recipient. Any review, reliance or distribution by others or forwarding without express permission is strictly prohibited. If you are not the intended recipient, please contact the sender and delete all copies.

From: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Sent: Monday, October 25, 2021 5:37 PM
To: Gabrielle Palmer <gpalmer@sirillp.com>
Cc: Aaron Siri <aaron@sirillp.com>; Elizabeth Brehm <ebrehm@sirillp.com>
Subject: RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Hi Gabrielle,

Thanks for your flexibility and for taking the lead on the motion. For Wednesday's 2:30 call, please use the below dial-in:

1-877-465-7975
15519379#

Thanks,
Courtney

Courtney Enlow
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W., Room 12102
Washington, D.C. 20005
(202) 616-8467
courtney.d.enlow@usdoj.gov

From: Gabrielle Palmer <gpalmer@sirillp.com>
Sent: Monday, October 25, 2021 7:34 PM
To: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Cc: Aaron Siri <aaron@sirillp.com>; Elizabeth Brehm <ebrehm@sirillp.com>
Subject: [EXTERNAL] RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Hi Courtney,

Sorry for the delay. We are available at 2:30pm EST on Wednesday. If that works for you, please let us know as soon as possible. Yes, we will take the lead on the motion.

Gabrielle G. Palmer, Attorney
Siri | Glimstad
200 Park Avenue
Seventeenth Floor
New York, NY 10166
Main: 212-532-1091
Facsimile: 646-417-5967
www.sirillp.com

This email may contain material that is confidential, privileged and/or attorney work product for the sole use of the intended recipient. Any review, reliance or distribution by others or forwarding without express permission is strictly prohibited. If you are not the intended recipient, please contact the sender and delete all copies.

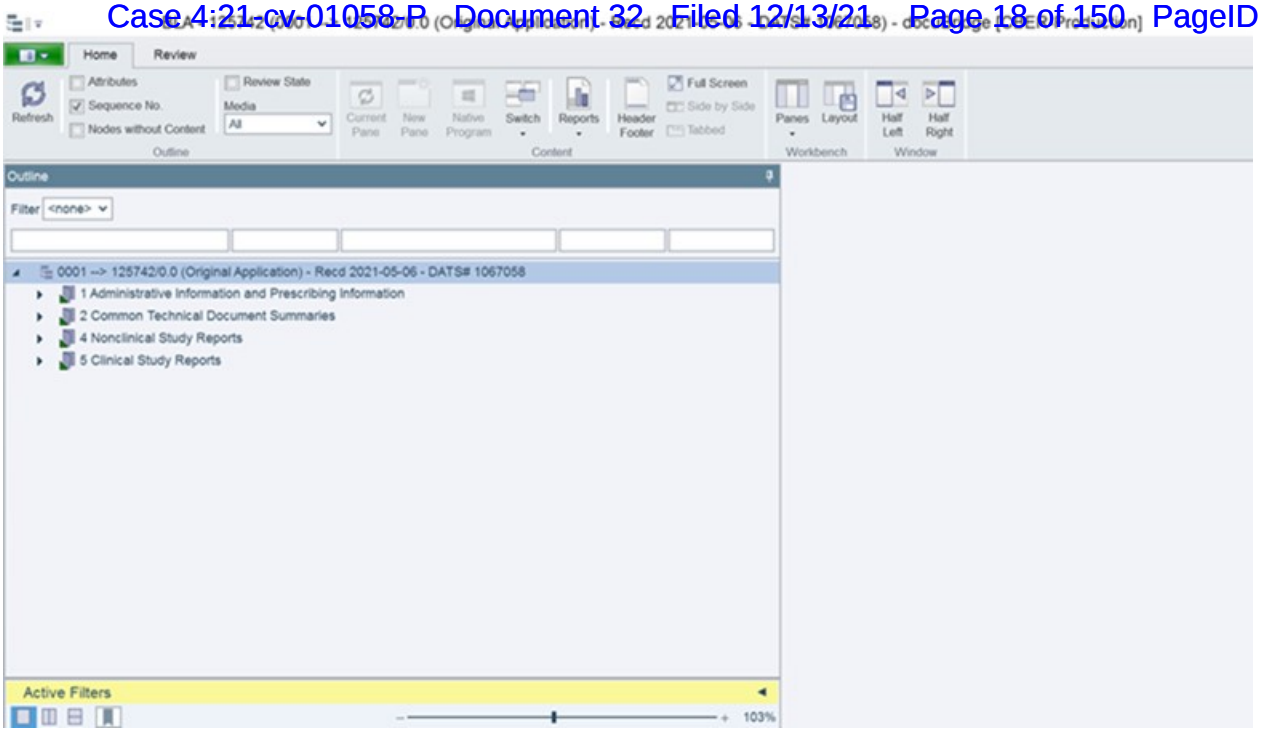
From: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Sent: Monday, October 25, 2021 2:46 PM
To: Gabrielle Palmer <gpalmer@sirillp.com>
Cc: Aaron Siri <aaron@sirillp.com>; Elizabeth Brehm <ebrehm@sirillp.com>
Subject: RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Hi Gabrielle and Aaron,

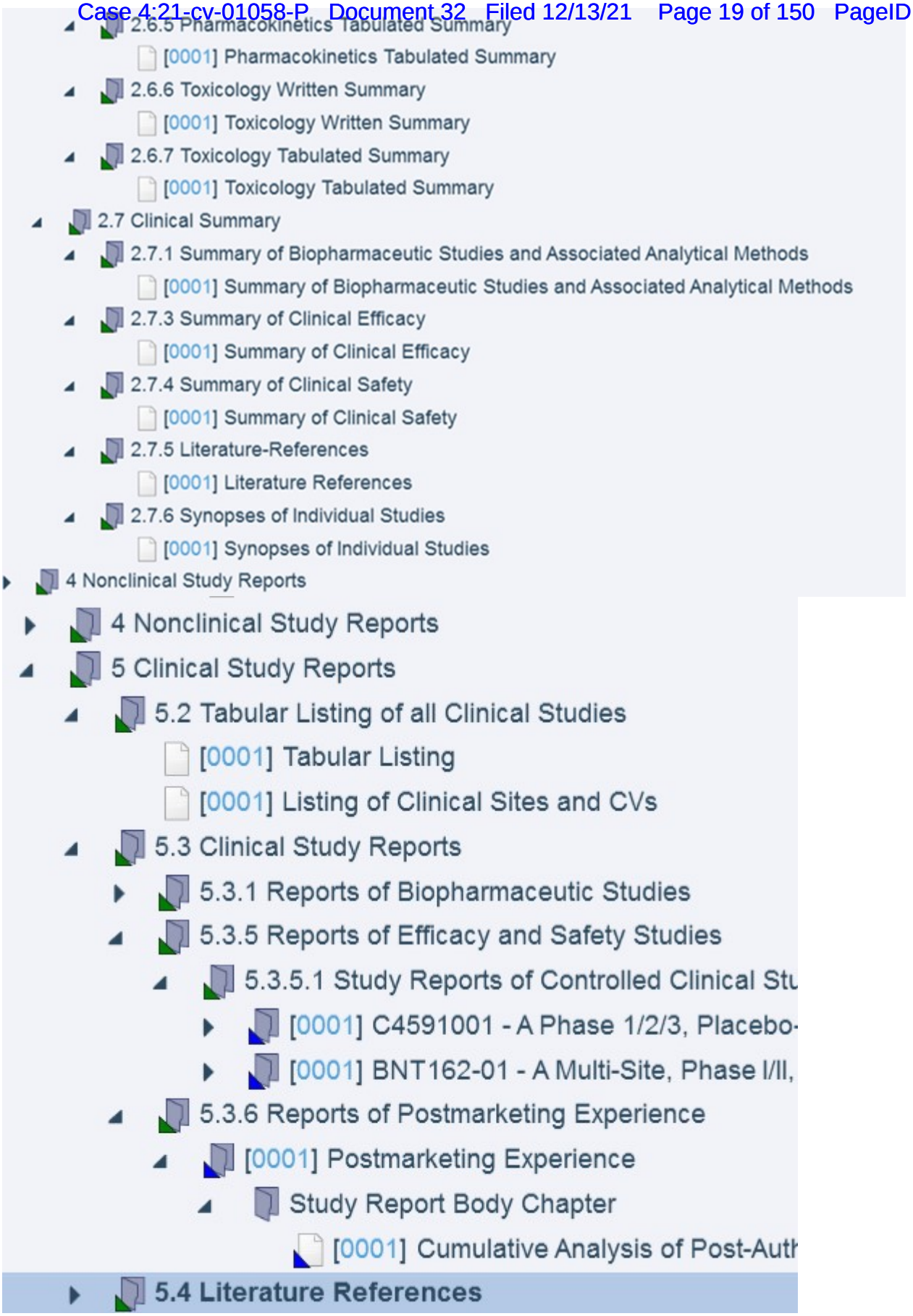
I write to follow up on our call from Friday afternoon and on my email below.

During Friday's call, you requested the "table of contents" from the BLA. Although BLA files generally may contain tables of contents, FDA's preliminary review has not identified a table of contents as part of the electronically filed Cominarty BLA. Although not obligated to do so, FDA provides below some non-privileged information from screenshots of FDA's internal filing system that show titles of different sections of the BLA. These screenshots have similar information as a table of contents and may help to inform the parties' discussions about reasonable prioritization and production schedule.

There are 4 Sections in the Original BLA submission (STN 125742/0/0) for Comirnaty (as shown below). When in the database, the arrows at the far left of the text can be clicked to expand the sections.



The following screenshots come from the same database showing partial expansion of sections 2 and 5. (Please note that the "sheet of paper" icon designates an individual record.)



You requested prioritization of raw data from the BLA and Pfizer's own analysis of its data. We think it would be more productive to discuss this request further with you once you have reviewed the Clinical Overview and the summaries of

clinical safety and efficacy section, which FDA plans to produce in the near future. But based on your request, we believe that the best prioritization may be as follows:

- *Initially (to provide you better insight into what is contained in the BLA to help inform discussions of prioritization):*

Section 2.5 Clinical Overview **334 pages – by approx. Nov. 5th**
Section 2.7.4 Summary of Clinical Safety **344 pages – by approx. Nov. 22nd**
Section 2.7.3 Summary of Clinical Efficacy **182 pages – by approx. Nov. 22nd**

- *Based on your most recent requests, we think it would make sense to prioritize the following reports from the BLA, which contain Pfizer's analysis and summaries of the data:*

Section 5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received Through 28-Feb-2021 **38 pages**
From Section 5.3.5.1 C4591001- Phase 1/2/3…; Study Report Body Chapter:
Final Analysis Interim Synopsis **31 pages**
Final Analysis Interim Report Body **2033 pages**
Final Analysis Interim Errata **1 page**

If you agree that this is an appropriate prioritization, we can estimate production dates for these sections.

Lastly, as it pertains to my below email, I am not able to have a call tomorrow, but I could discuss further on Wednesday. Also, please confirm that you are planning on taking the lead on drafting a motion for relief from the Court's Order.

Best regards,
Courtney

Courtney Enlow
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W., Room 12102
Washington, D.C. 20005
(202) 616-8467
courtney.d.enlow@usdoj.gov

From: Enlow, Courtney D. (CIV)
Sent: Friday, October 22, 2021 5:52 PM
To: Gabrielle Palmer <gpalmer@sirillp.com>
Cc: Aaron Siri <aaron@sirillp.com>; Elizabeth Brehm <ebrehm@sirillp.com>
Subject: RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Hi Gabrielle and Aaron,

I apologize, but something has come up on Tuesday. Are you available on Wednesday afternoon instead?

Also, were you planning on taking the lead on drafting a motion for relief from the Court's Order?

Thanks,
Courtney

Courtney Enlow
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W., Room 12102
Washington, D.C. 20005
(202) 616-8467
courtney.d.enlow@usdoj.gov

From: Enlow, Courtney D. (CIV)
Sent: Friday, October 22, 2021 3:15 PM
To: Gabrielle Palmer <gpalmer@sirillp.com>
Cc: Aaron Siri <aaron@sirillp.com>; Elizabeth Brehm <ebrehm@sirillp.com>
Subject: RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Hi Gabrielle and Aaron,

It was nice to speak to you today. For our call at 2:00 on Tuesday, please use the below dial-in:

1-877-465-7975
15519379#

I hope you both have a relaxing weekend.

Best regards,
Courtney

Courtney Enlow
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W., Room 12102
Washington, D.C. 20005
(202) 616-8467
courtney.d.enlow@usdoj.gov

From: Gabrielle Palmer <gpalmer@sirillp.com>
Sent: Wednesday, October 20, 2021 4:56 PM
To: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Cc: Aaron Siri <aaron@sirillp.com>; Elizabeth Brehm <ebrehm@sirillp.com>
Subject: [EXTERNAL] RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Hi Courtney,

We are available at 2pm EST on Friday. Will you kindly circulate dial-in information?

Gabrielle G. Palmer, Attorney
Siri | Glimstad
200 Park Avenue
Seventeenth Floor
New York, NY 10166
Main: 212-532-1091
Facsimile: 646-417-5967
www.sirillp.com

This email may contain material that is confidential, privileged and/or attorney work product for the sole use of the intended recipient. Any review, reliance or distribution by others or forwarding without express permission is strictly prohibited. If you are not the intended recipient, please contact the sender and delete all copies.

From: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Sent: Wednesday, October 20, 2021 2:49 PM
To: Gabrielle Palmer <gpalmer@sirillp.com>
Cc: Aaron Siri <aaron@sirillp.com>; Elizabeth Brehm <ebrehm@sirillp.com>
Subject: RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Hi Gabrielle,

Thanks for reaching out. I'm available between 1 and 3 on Friday afternoon. If that doesn't work for you, I can propose some times early next week.

I look forward to working with you all as well.

Best regards,
Courtney

Courtney Enlow
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W., Room 12102
Washington, D.C. 20005
(202) 616-8467
courtney.d.enlow@usdoj.gov

From: Gabrielle Palmer <gpalmer@sirillp.com>
Sent: Wednesday, October 20, 2021 4:43 PM
To: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Cc: Aaron Siri <aaron@sirillp.com>; Elizabeth Brehm <ebrehm@sirillp.com>
Subject: [EXTERNAL] Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Hi Courtney,

We are counsel for Public Health and Medical Professionals for Transparency in the above referenced action. Are you available to discuss this case at any time over the next few working days? If so, please propose some times that you are available.

We look forward to working with you.

Thanks,

Gabrielle G. Palmer, Attorney
Siri | Glimstad
200 Park Avenue
Seventeenth Floor
New York, NY 10166
Main: 212-532-1091
Facsimile: 646-417-5967
www.sirillp.com

This email may contain material that is confidential, privileged and/or attorney work product for the sole use of the intended recipient. Any review, reliance or distribution by others or forwarding without express permission is strictly prohibited. If you are not the intended recipient, please contact the sender and delete all copies.

Exhibit 2

From: Aaron Siri
To: Enlow, Courtney D. (CIV)
Cc: Elizabeth Brehm; Gabrielle Palmer
Subject: RE: PHMPT v. FDA, No. 21-cv-1058 (N.D. Tex.)
Date: Friday, December 10, 2021 11:23:12 AM

Good afternoon Courtney,

One additional question:

7. Will the FDA accept funds from the Plaintiff to hire sufficient reviewers to review the needed documents within the time requested by Plaintiff?

If you could kindly let me know the answers to these questions asap, it would be appreciated.

Best regards,
Aaron

From: Aaron Siri
Sent: Thursday, December 9, 2021 12:05 PM
To: 'Enlow, Courtney D. (CIV)' <Courtney.D.Enlow@usdoj.gov>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Subject: RE: PHMPT v. FDA, No. 21-cv-1058 (N.D. Tex.)

Good afternoon, Courtney,

Further to my emails below, please also:

5. Provide a list of the sections of the index that were not disclosed in the PDF index you provided.
6. An index for the documents in the BLA file that were not included in the index already provided (meaning, an index of the material that was not submitted as part of Comirnaty BLA application). The FOIA request, on its face, was for more than just the Comirnaty BLA submitted by Pfizer.

Once I have answers to these six questions, my client will be in a position to revert to the proposal made by the FDA.

Thanks,
Aaron

From: Aaron Siri
Sent: Wednesday, December 8, 2021 2:23 PM
To: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>

Subject: RE: PHMPT v. FDA, No. 21-cv-1058 (N.D. Tex.)

Good afternoon, Courtney,

Thank you for the response. Four hopefully simple questions/requests:

1. You claim it would take 1.5 days to determine the number of lines in the 126 data files, each similar to a spreadsheet. That estimate is difficult to understand since I would imagine it would require no more than someone opening each file, recording the total number of lines for each one, and then adding up the total number of lines. A paralegal at our firm could accomplish that task in less than an hour. Please explain why it would take 1.5 days to open each file and record the total number of lines in each file?

2. For the data files, please provide the column headers. My client would like to see these to determine if there is anything that can be streamlined.

3. Please provide a more precise number for the category you indicated has "tens of thousands of additional pages."

4. Would the FDA be interested in hiring qualified unpaid volunteers to assist with reviewing the documents requested by PHMPT?

Best regards,
Aaron

From: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Sent: Thursday, December 2, 2021 2:25 PM
To: Aaron Siri <aaron@sirillp.com>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Subject: RE: PHMPT v. FDA, No. 21-cv-1058 (N.D. Tex.)

Good afternoon Aaron,

With regard to your first two questions, FDA will not be able to make those assessments at this time. In order for FDA to determine (1) the number of lines of spreadsheet data or (2) the total number of pages for each line of the 87-page Index, FDA would need to perform a search by hand. In other words, an individual would have to click open each file listed on the 87-page Index to determine the size of the file, and then manually record the file's size. To perform that search for the number of lines of spreadsheet data, FDA estimates that it would take 1.5 days of a staff member's time; to provide the page counts for each entry in the Index, FDA estimates that it would take several days of a staff member's time. Due to the heavy burden such an effort would place on FDA's limited resources, it is not feasible for FDA to provide those estimates.

With regard to your third question, are you asking whether there is any data in the Comirnaty

biological product file that are not accounted for in the Index or the estimated 329,000+ page count? If so, the Cominarty biological product file also contains supplements, amendments, and product correspondence. FDA estimates that there are approximately 39,000 pages of records in that category. In addition, there may be investigational new drug records that may be supportive of the BLA. Although FDA cannot provide a precise count at this time, FDA estimates that there would be tens of thousands of additional pages in this category. These page counts are in addition to FDA's estimate of 329,000+ pages (plus data files) in the original Cominarty BLA.

If Plaintiff is amenable to the schedule I proposed yesterday, please let me know this week so that we can inform the Court.

Thanks,
Courtney

Courtney Enlow
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W., Room 12102
Washington, D.C. 20005
(202) 616-8467
courtney.d.enlow@usdoj.gov

From: Aaron Siri <aaron@sirillp.com>
Sent: Wednesday, December 01, 2021 5:56 PM
To: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Subject: [EXTERNAL] RE: PHMPT v. FDA, No. 21-cv-1058 (N.D. Tex.)

Good afternoon Courtney,

Thank you for the note. In order for me to have a meaningful conversation with my client, can you please let me know (1) approximately how many lines of spreadsheet data would need to be processed, (2) the approximate total number of pages for each line item in the Index of Comirnaty BLA you previously provided (copy attached) and (3) what else is in the biological product file for Comirnaty that is not reflected in the attached and is that included in the estimated 329,000 page count (and if not, how many pages does that consist of).

Thank you,
Aaron

From: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Sent: Wednesday, December 1, 2021 8:35 AM
To: Aaron Siri <aaron@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>
Subject: RE: PHMPT v. FDA, No. 21-cv-1058 (N.D. Tex.)

Good morning Aaron,

With regard to *PHMPT v. FDA*, No. 21-cv-1058 (N.D. Tex.), FDA has now had the opportunity to assess the number of responsive pages and to estimate processing times for additional portions of Plaintiff's priority list. In light of that assessment, FDA proposes that it produce the non-exempt portions of the following records by the below dates:

- By December 13, 2021, FDA plans to produce publicly releasable information from:
  - ***Plaintiff's priority item #1***- CRF files for site 1055 (~2,030 pages);
  - ***Completion of Plaintiff's priority item #5***-
    - Four additional .txt files that were listed on p. 10 of the index;
    - Four additional SAS files (not specifically listed on Plaintiff's priority list, but mentioned as something Plaintiff was interested in).
  - Publicly releasable information from the following additional sections of the original Comirnaty BLA:
    - Section 2.5 – Clinical Overview (~333 pages)
    - Section 2.7.3 – Summary of Clinical Efficacy (~182 pages)
    - Section 2.7.4 – Summary of Clinical Safety (~344 pages)
- By December 30, 2021, FDA plans to produce publicly releasable information from ***Plaintiff's priority item #2*** – CRF files for site 1081 (~3,380 pages);
- By January 18, 2022, FDA plans to produce publicly releasable information from ***Plaintiff's priority item #3*** – CRF files for site 1096 (~2,937 pages); and
- By January 31, 2022, FDA plans to produce publicly releasable information from ***Plaintiff's priority item #4*** – CRF files for site 1128 (~3,452 pages).

Under this schedule, by the end of January 2022, FDA expects to have produced publicly releasable information from more than 12,000 pages of records and 10 unpaginated .txt or SAS data files. (This page and file count includes records produced to Plaintiff on November 17, 2021, and records that will be produced to Plaintiff later today.) FDA will also have completed production of seven of the first eight items on the priority list Plaintiff provided to FDA on November 4, 2021.

After the January 31, 2022 production, FDA proposes to make one production at the end of each subsequent month totaling a minimum the non-exempt portions of 500 pages. (For purposes of calculating a "page count" of data records that are not paginated, FDA proposes considering twenty lines of spreadsheet data the equivalent of one page. For example, production of a spreadsheet containing 2,000 lines of data would be counted the equivalent of a 100-page PDF record.) To the extent feasible, FDA plans to continue to prioritize records from Plaintiff's priority list. Although FDA proposes a minimum rate of 500 pages a month, FDA will continue to produce records at a faster rate where feasible.

Please let me know if Plaintiff is amenable to this proposed schedule. If so, I propose that the parties file a joint status report setting out the agreed-upon schedule and requesting that the Court cancel the hearing set for December 14 and the briefing deadlines.

Thanks,
Courtney

Courtney Enlow
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W., Room 12102
Washington, D.C. 20005
(202) 616-8467
courtney.d.enlow@usdoj.gov

From: Enlow, Courtney D. (CIV)
Sent: Wednesday, November 17, 2021 1:40 PM
To: Aaron Siri <aaron@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>
Subject: PHMPT v. FDA, No. 21-cv-1058 (N.D. Tex.)

Good afternoon Aaron and Gabrielle,

I've attached correspondence from FDA and a release of records in *PHMPT v. FDA*, No. 21-cv-1058 (N.D. Tex.). Kindly confirm receipt.

Thanks,
Courtney

Courtney Enlow
Trial Attorney
U.S. Department of Justice

Civil Division, Federal Programs Branch
1100 L Street, N.W., Room 12102
Washington, D.C. 20005
(202) 616-8467
courtney.d.enlow@usdoj.gov

Exhibit 3

Aaron Siri

From: Aaron Siri
Sent: Monday, December 13, 2021 2:39 PM
To: 'Konkoly, Antonia (CIV)'
Cc: Enlow, Courtney D. (CIV); Elizabeth Brehm; Gabrielle Palmer
Subject: RE: PHMPT -- conferral questions

Good afternoon, Antonia,

Thanks, and let me reiterate that the list previously provided by Plaintiff was for initial documents to be produced by November 17 so that it could get a general sense of the overall biologic product file documents. The list was not a priority list of what was more, or less, relevant or useful. As Plaintiff has made clear numerous times – until everything is produced, it cannot conduct a meaningful review.

As for your responses below, it is unfortunate the FDA will not provide even the basic information regarding the file at issue, even withholding the index of its content. If the FDA will change its position on same, let me know, otherwise this will be a separate issue we will need to take up with the Court.

Thanks,
Aaron

From: Konkoly, Antonia (CIV) <Antonia.Konkoly@usdoj.gov>
Sent: Saturday, December 11, 2021 6:21 PM
To: Aaron Siri <aaron@sirillp.com>
Cc: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>; Elizabeth Brehm <ebrehm@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Subject: RE: PHMPT -- conferral questions

Hi Aaron –

I believe I did answer that question; see highlighted below. To the extent that the premise of your follow up is that there is a distinction between the Plaintiff paying a set of people directly, and Plaintiff giving money to the FDA to hire new employees to do this work, there is no such distinction. Plaintiff may not privately fund the hiring of additional FDA employees to do the processing work required by Plaintiff's request. That is simply not how the federal government works.

Thank you,
Toni

From: Aaron Siri <aaron@sirillp.com>
Sent: Saturday, December 11, 2021 8:13 PM
To: Konkoly, Antonia (CIV) <Antonia.Konkoly@usdoj.gov>
Cc: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>; Elizabeth Brehm <ebrehm@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Subject: [EXTERNAL] RE: PHMPT -- conferral questions

Good evening, Toni,

Thanks, welcome, and look forward to working with you on this matter as well.

I quickly glanced at your email below and noticed that there was one more question that was not answered:

7. Will the FDA accept funds from the Plaintiff to hire sufficient reviewers to review the needed documents within the time requested by Plaintiff?

As for the responses you sent below, I will review and revert. In the meantime, kindly let me know the answer to the above question.

Thank you,
Aaron

From: Konkoly, Antonia (CIV) <Antonia.Konkoly@usdoj.gov>
Sent: Friday, December 10, 2021 6:57 PM
To: Aaron Siri <aaron@sirillp.com>; Elizabeth Brehm <ebrehm@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Cc: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Subject: PHMPT -- conferral questions

Hi Aaron et al –

I assume you saw the NOA that I entered earlier this week; I'm a colleague of Courtney's and will be handling the hearing on Tuesday. I look forward to working with you. We've conferred with FDA regarding the various questions you've posed; please see below the agency's responses, in red.

1.) **You claim it would take 1.5 days to determine the number of lines in the 126 data files, each similar to a spreadsheet. That estimate is difficult to understand since I would imagine it would require no more than someone opening each file, recording the total number of lines for each one, and then adding up the total number of lines. A paralegal at our firm could accomplish that task in less than an hour. Please explain why it would take 1.5 days to open each file and record the total number of lines in each file?**

   - First, FDA derived the number 126 came from its search of a specific portion of the BLA file (within Section 5). However, FDA expects that there are data files in other sections of the application, so 126 is likely not the full number of SAS files for the entire BLA. Accordingly, some the time estimate accounts for the time that would be needed to search for and locate other files. Additionally, SAS files are large and can present technical difficulties for FDA staff to open and navigate. Both search time and expected technical difficulties are thus accounted for in the 1.5 day estimate.

2.) **For the data files, please provide the column headers. My client would like to see these to determine if there is anything that can be streamlined.**

   - Due to the same technical difficulties noted above – which, on the ground, would make this task quite time-consuming – FDA is not able to accommodate this request at this time. In short, the diversion of time this would involve would meaningfully undermine the agency's ability to focus on its processing work.

3.) **Please provide a more precise number for the category you indicated has "tens of thousands of additional pages."**

   - FDA knows that there are a number of records in the IND section of the biological product file; however, it would take a closer review of those pages to determine which information would be considered supportive of the BLA/licensure and, thus, publicly available (subject to disclosure review) under 21 C.F.R. 601.51(e).

     You may already be aware of this, but to make sure we're on the same page – IND files may include studies for several forms (different dose strengths, formulations, etc.) and/or indications (different disease conditions, age groups, etc.). It's possible for a biological product to be approved for only a

subset of the variations/indications for which it was originally studied. The portions of the IND file related to the approved conditions would become part of the biological product file that would be available for disclosure (subject to confidentiality review) once the product is approved; portions of the IND related to unapproved forms/indications would remain confidential (as would the existence of these portions).

To be clear, FDA disclosure staff have not yet determined whether portions of the IND section of the Comirnaty file refer to forms or conditions that are have not been approved under a BLA. Thus, this response should not be understood as an indication that any parts of the biological product file relate to INDs associated with a product that has not been approved. But, before performing that review (which would require a substantial investment of time from FDA), we cannot provide a precise page estimate. Because, again, the FDA assesses that that this effort does not justify the diversion of resources away from its processing work, it also cannot accommodate this request at this time.

4.) **Would the FDA be interested in hiring qualified unpaid volunteers to assist with reviewing the documents requested by PHMPT?**

- This is not an option. Non-federal personnel – whether they be unpaid volunteers, or per your later question, persons paid by the Plaintiff – cannot perform federal work.

5.) **Provide a list of the sections of the index that were not disclosed in the PDF index you provided.**

- FDA provided the high-level breakout of the entire original Comirnaty BLA. (See p. 1 of the Index provided on 11-4-21.) However, in accordance with the purpose of the index—ie, to assist PHMPT in honing in on the portions of the BLA that it is most interested in—FDA did not expand the index as to Sections that were not identified by PHMPT's Priority List. Additionally, other sections could not be expanded because to do so could have revealed confidential information.

6.) **An index for the documents in the BLA file that were not included in the index already provided (meaning, an index of the material that was not submitted as part of Comirnaty BLA application). The FOIA request, on its face, was for more than just the Comirnaty BLA submitted by Pfizer.**

- Creating the requested index would require FDA to create screen shots for each section, as it did for the index it provided in November. Given the nature of the documents in these sections, FDA anticipates that there would likely be confidential information in section titles, such that they could not be shared with PHMPT. Again, FDA assess that it cannot reasonably divert resources away from its processing efforts to this task at this time, in light of those circumstances.

Thanks,
Toni

Antonia Konkoly
Trial Attorney
U.S. Department of Justice
Civil Division | Federal Programs Branch
Direct line: (202) 514-2395
email: Antonia.Konkoly@usdoj.gov

Exhibit 4

From: Mike Kroeber - BIA <mkroeber@biaprotect.com>
Sent: Friday, December 10, 2021 8:20 PM
To: Nicky Tenney <ntenney@sirillp.com>
Subject: Review Pricing as requested

Hi Nicky,

The following is a breakdown of the pricing you requested for the Siri Glimstad project we spoke about earlier today. I've included some assumptions that we made based on the discussion we had this afternoon. Please review what I've included and let me know if you have any questions.

I will add that we have quite a bit of experience in IP and Medical and Healthcare related matters, having just finished a 30TB review last week which consisted of about 15 million or so pages of documents. So we are well skilled in dealing with this topic.

If you have any questions at all with the below, feel free to reach out.

Our pricing is as follows:

Known Information:

- 400,000 pages
- PDF & Excel Files
- Redacting for Trade Secret & PHI
- Privilege Log required

Assumptions:

- 400,000 pages = 65,000 documents = 75GB
- Estimate 25% (100,000 pages / 16,250 documents) will be fully automated redactions
- Estimate 75% (300,000 pages / 48,750 documents) will require manual redactions
- Estimate 1,700 hours of manual review
- Estimate 50 hour Team Lead
- Estimate 6-8 weeks

Item	Quantity	Price Per Unit	Total
PM Time	20 hours	$175/Hr.	$3,500

Data Processing	75 GB	$60/GB	$4,500
Relativity Site Setup	1 Time	$500	$500
Relativity Hosting	75GB	$8/Mo.	$600/Mo.
Relativity Users	10	$85/Mo.	$850/Mo.
Blackout	16,250 documents	$.75/Doc.	$12,187
Attorney Reviewers	1,700 hours	$50/Hr.	$85,000
Review Team Lead	50 hours	$95/Hr.	$4,750
Data Technician	20 hours	$150/Hr.	$3,000
Productions	400,000 pages	0.03/Pg.	$12,000
Privilege Log	1	$2500 Flat Fee	$2,500
Advisory Expert	10 hours	$300/Hr.	$3,000

Estimated Project Total - $132,387

As I mentioned, I've made my best attempt at the pricing based on the information known to me at this time and I've tried to be conservative in my estimates. The assumptions I've used are provided above. Once we receive the data and better understand the overall makeup of the collection, we may be able to further refine the assumptions, and even potentially reduce the overall cost estimates.

We anticipate that this project would take 6-8 weeks to complete, with a team of 10 reviewers and 1 team leader. We could shorten that time frame somewhat with additional reviewers if needed. We should be able to start the project fairly quickly, with the data collection and processing taking approximately 3-4 days, along with the time to prepare and set up the Relativity site and the Review starting directly after.

We would charge no extra fee for starting earlier or later.

As we mentioned on the call, if we are able to automate more of the process, if the data set lends itself to using Blackout to do more of the redactions, the cost and the time frame would be reduced significantly, but we won't know if that's possible until we see a sample set of data.

Again, thank you for allowing us to present pricing for this project, and I look forward to speaking with you and the team, and answering any questions you all might have.

Have a great night and a great weekend if I don't speak with you before.

Michael Kroeber, CEDS
National Account Director | BIA

D: 646.843.2266 | M: 516.263.2040 | F: 212.240.2298
mkroeber@biaprotect.com

Exhibit 5

NVSS Vital Statistics Rapid Release

Report No. 010 ■ February 2021

Provisional Life Expectancy Estimates for January through June, 2020

Elizabeth Arias, Ph.D., Betzaida Tejada-Vera, M.S., and Farida Ahmad, M.P.H.

Introduction

The National Center for Health Statistics (NCHS) collects and disseminates the nation's official vital statistics through the National Vital Statistics System (NVSS). NCHS uses provisional vital statistics data for conducting public health surveillance and final data for producing annual national natality and mortality statistics. NCHS publishes annual and decennial national life tables based on final vital statistics. In order to assess the effects on life expectancy of excess mortality observed during 2020, NCHS is publishing, for the first time, life tables based on provisional vital statistics data. Provisional data are early estimates based on death certificates received, processed, and coded but not finalized by NCHS. These estimates are considered provisional because death certificate information may later be revised and additional death certificates may be received until approximately 6 months after the end of the data year.

This report presents life expectancy estimates based on provisional death counts for the months January through June, 2020, by sex, for the total, Hispanic, non-Hispanic white, and non-Hispanic black populations. Abridged period life tables calculated to produce the provisional life expectancy estimates are also provided via Internet tables (see Technical Notes and Internet tables 1–15). Life expectancy estimates based on final data for 2019 by sex, Hispanic origin, and race are also provided in this report for purposes of comparison (see Technical Notes and reference 1 for description of methodology).

Keywords: life expectancy • Hispanic origin • race • National Vital Statistics System

Data and Methods

Provisional life expectancy estimates were calculated using abridged period life tables based on provisional death counts for the first half of 2020 from death records received and processed by NCHS as of October 26, 2020; provisional numbers of births for the same period based on birth records received and processed by NCHS as of October 27, 2020; and, April 1, 2020 monthly postcensal population estimates based on the 2010 decennial census. Provisional mortality rates are typically computed using death data after a 3-month lag following date of death, as completeness and timeliness of provisional death data can vary by many factors, including cause of death, month of the year, and age of the decedent (2,3). Mortality data used in this report include over 99% of the deaths that occurred from January through June, 2020, but certain jurisdictions and age groups may be underrepresented for the latter months in the period (3). Deaths requiring investigation, including infant deaths, deaths from external injuries, and drug overdose deaths may be underestimated (4,5). See Technical Notes for more information about the calculation of the abridged period life tables and 2019 life expectancy estimates by race and Hispanic origin.

Results

Life expectancy in the United States

The Table summarizes life expectancy by age, Hispanic origin, race, and sex. Life expectancy at birth represents the average number of years that a group of infants would live if they were to experience throughout life the age-specific death rates prevailing during a specified period. In the first half of 2020, life expectancy at birth for the total U.S. population was 77.8 years, declining by 1.0 year from 78.8 in 2019 (6). Life expectancy at birth for males was 75.1 years in the first half of 2020, representing a decline of 1.2 years from 76.3 years in 2019. For females, life expectancy declined to 80.5 years, decreasing 0.9 year from 81.4 years in 2019 (Figure 1).

The difference in life expectancy between the sexes was 5.4 years in the first half of 2020, increasing from 5.1 in 2019. Between 2000 and 2010, the difference in life expectancy between the sexes narrowed from 5.2 years to its lowest level of 4.8 years and then gradually increasing to 5.1 years in 2019 (Figure 1).

Life expectancy by Hispanic origin and race

Between 2019 and the first half of 2020, life expectancy decreased 2.7 years for the non-Hispanic black population (74.7 to 72.0) (Figure 2). It decreased by 1.9 years for the Hispanic population (81.8 to 79.9) and by 0.8 year for the non-Hispanic white population

Table. Expectation of life by age, Hispanic origin, race for the non-Hispanic population, and sex: United States, 2020

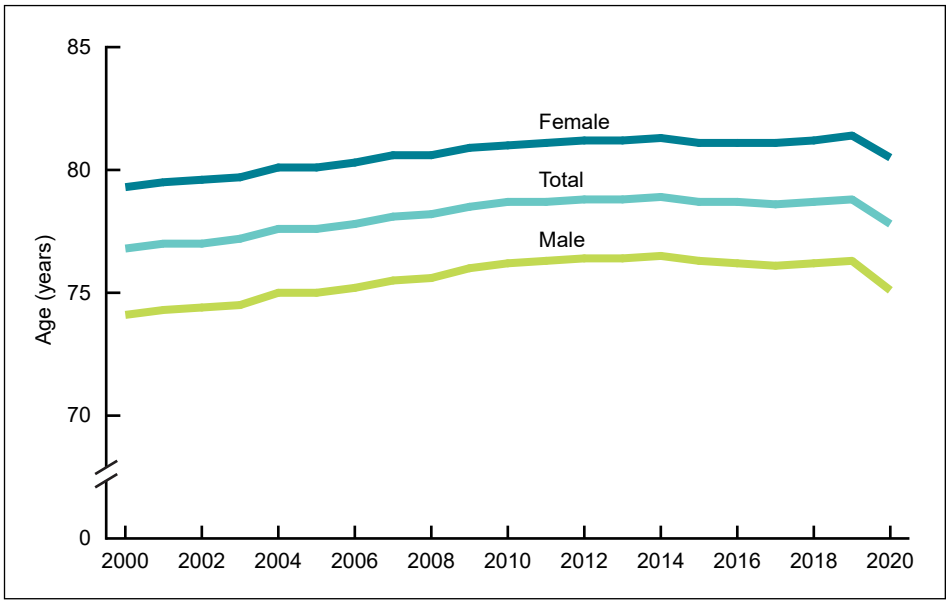
	All origins			Hispanic[1]			Non-Hispanic white[1]			Non-Hispanic black[1]		
Age (years)	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female
0	77.8	75.1	80.5	79.9	76.6	83.3	78.0	75.5	80.6	72.0	68.3	75.8
1	77.2	74.5	80.0	79.3	76.0	82.7	77.4	74.9	79.9	71.8	68.1	75.5
5	73.3	70.6	76.0	75.4	72.1	78.8	73.4	71.0	75.9	67.9	64.2	71.6
10	68.3	65.6	71.0	70.4	67.1	73.8	68.4	66.0	71.0	63.0	59.3	66.7
15	63.4	60.7	66.1	65.4	62.1	68.8	63.5	61.1	66.0	58.1	54.4	61.7
20	58.5	55.9	61.2	60.6	57.3	63.9	58.6	56.3	61.1	53.4	49.8	56.9
25	53.8	51.3	56.3	55.8	52.7	59.1	53.9	51.6	56.3	48.9	45.5	52.1
30	49.2	46.8	51.5	51.1	48.1	54.2	49.2	47.0	51.5	44.4	41.1	47.4
35	44.6	42.3	46.8	46.5	43.5	49.4	44.6	42.6	46.7	39.9	36.8	42.8
40	40.0	37.8	42.1	41.8	39.0	44.6	40.1	38.1	42.1	35.5	32.6	38.3
45	35.5	33.4	37.5	37.3	34.6	39.9	35.6	33.7	37.4	31.3	28.5	33.9
50	31.1	29.2	33.0	32.8	30.2	35.2	31.2	29.4	32.9	27.2	24.6	29.6
55	26.9	25.1	28.6	28.5	26.1	30.7	26.9	25.3	28.5	23.3	20.8	25.5
60	22.9	21.3	24.4	24.4	22.2	26.4	22.9	21.5	24.3	19.7	17.5	21.7
65	19.1	17.8	20.4	20.6	18.7	22.3	19.1	17.9	20.2	16.5	14.5	18.1
70	15.5	14.4	16.5	17.0	15.4	18.3	15.4	14.4	16.3	13.6	11.9	14.8
75	12.2	11.3	12.9	13.7	12.4	14.6	12.0	11.2	12.7	10.8	9.6	11.8
80	9.3	8.6	9.7	10.7	9.8	11.4	9.0	8.4	9.5	8.5	7.5	9.1
85	6.8	6.4	7.0	8.3	7.7	8.8	6.5	6.1	6.7	6.5	5.9	6.8

[1]Life tables by Hispanic origin are based on death rates that have been adjusted for race and ethnicity misclassification on death certificates. Updated classification ratios were applied; see Technical Notes.

NOTES: Estimates are based on provisional data from January 2020 through June 2020. Provisional data are subject to change as additional data are received.

SOURCE: National Center for Health Statistics, National Vital Statistics System, Mortality, 2020.

Figure 1. Life expectancy at birth, by sex: United States, 2000–2020



NOTES: Life expectancies for 2019 by Hispanic origin and race are not final estimates; see Technical Notes. Estimates are based on provisional data from January 2020 through June 2020.
SOURCE: National Center for Health Statistics, National Vital Statistics System, Mortality data.

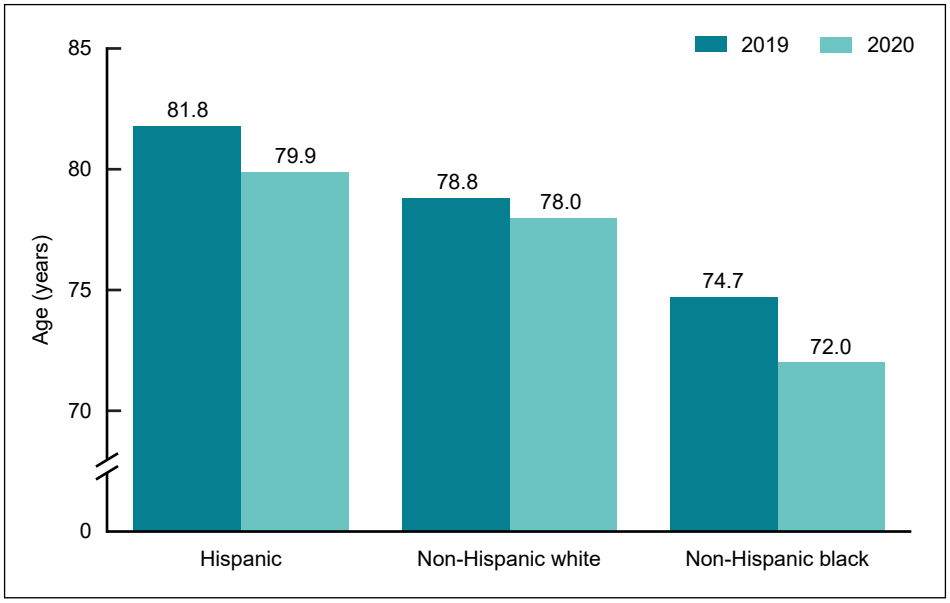
(78.8 to 78.0). In the first half of 2020, the Hispanic population had a life expectancy advantage of 1.9 years over the non-Hispanic white population, declining from an advantage of 3.0 years in 2019 (Figure 3). The Hispanic advantage relative to the non-Hispanic black population increased from 7.1 to 7.9 years between 2019 and the first half of 2020. The non-Hispanic white life expectancy advantage relative to the non-Hispanic black population increased from 4.1 to 6.0 years between 2019 and the first half of 2020.

Among the six Hispanic origin and race-sex groups (Figure 4), the decrease in life expectancy between 2019 and the first half of 2020 was highest for non-Hispanic black males whose life expectancy declined by 3.0 years (71.3 to 68.3), followed in order by Hispanic males with a decline of 2.4 years (79.0 to 76.6), non-Hispanic black females with a decline of 2.3 years (78.1 to 75.8), Hispanic females with a decline of 1.1 years (84.4 to 83.3), non-Hispanic white males with a decline of 0.8 year (76.3 to 75.5), and non-Hispanic white females with a decline of 0.7 year (81.3 to 80.6).

Discussion and Conclusions

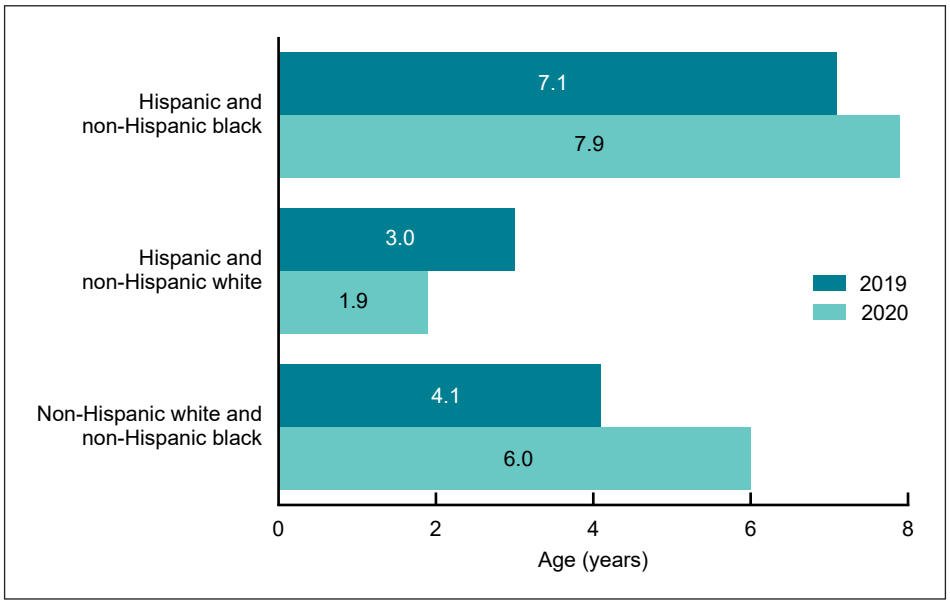
Provisional life expectancy at birth in the first half of 2020 was the lowest level since 2006 for both the total population (77.8 years) and for males (75.1), and was the lowest level since 2007 for females (80.5). Life expectancy for the non-Hispanic black population, 72.0, declined the most, and was the lowest estimate seen since 2001 (for the black population regardless of Hispanic origin). The Hispanic population experienced the

Figure 2. Life expectancy at birth, by Hispanic origin and race: United States, 2019 and 2020



NOTES: Life expectancies for 2019 by Hispanic origin and race are not final estimates; see Technical Notes. Estimates are based on provisional data from January 2020 through June 2020.
SOURCE: National Center for Health Statistics, National Vital Statistics System, Mortality data.

Figure 3. Differences between groups in life expectancy at birth: United States, 2019 and 2020



NOTES: Life expectancies for 2019 by Hispanic origin and race are not final estimates; see Technical Notes. Estimates are based on provisional data from January 2020 through June 2020.
SOURCE: National Center for Health Statistics, National Vital Statistics System, Mortality data.

second largest decline in life expectancy (79.9) reaching a level lower than what it was in 2006, the first year for which life expectancy estimates by Hispanic origin were produced (80.3). The levels observed for the non-Hispanic white population were last seen in 2005 for the white population (regardless of Hispanic origin) (7).

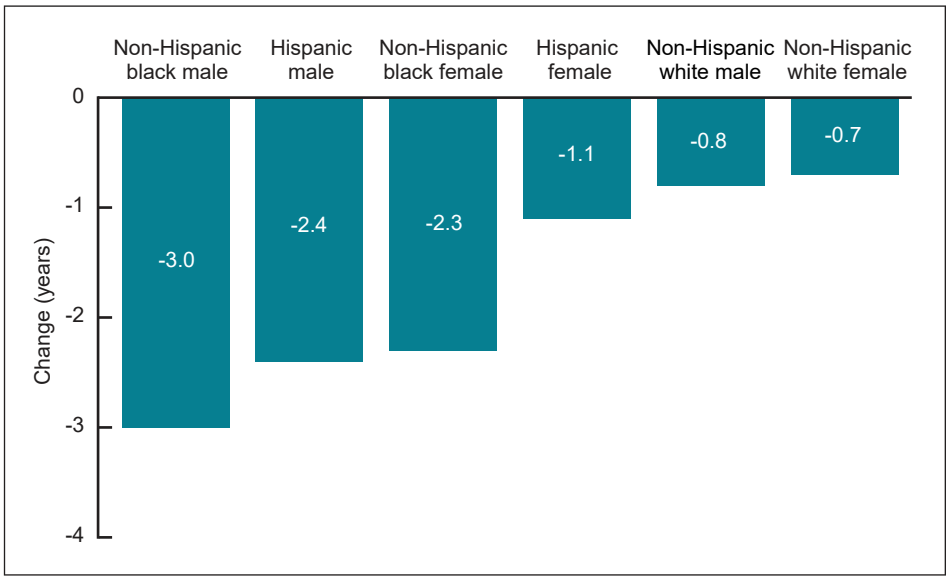
Another consequence of the decreased life expectancy estimates observed during the first half of 2020 was a worsening of racial and ethnic mortality disparities. For example, the gap in life expectancy at birth between the non-Hispanic black and white populations increased by 46% between 2019 and the first half of 2020 (from 4.1 to 6.0 years). Regardless of Hispanic origin, life expectancy for the black population has consistently been lower than that of the white population but the gap between the two races had generally been narrowing since 1993 when it was 7.1 (7). The gap of 6.0 observed in the first half of 2020 is the largest since 1998 (7).

Conversely, the gap between the Hispanic and non-Hispanic white populations decreased by 37% between 2019 and the first half of 2020 (from 3.0 to 1.9 years). This indicates that the Hispanic population lost some of the mortality advantage it has evidenced since 2006 relative to the non-Hispanic white population, despite experiencing generally lower socioeconomic status (8–10).

The provisional life expectancy estimates presented in this report are subject to important limitations. First, they are based on deaths that occurred during the first 6 months of the year and do not reflect the entirety of the effects of the COVID-19 pandemic in 2020, or other changes in causes of death, such as the increases in provisional drug overdose deaths through early 2020 (11). There is seasonality in death patterns in any given year, with winter months typically seeing more deaths than summer months, and this is not accounted for in the data. Second, the COVID-19 pandemic differentially affected certain geographic areas in the first half of 2020. The life table estimates may disproportionately represent mortality in those regions, which are more urban and have different demographic characteristics than areas affected by the pandemic in the latter part of the year. As a result, life expectancy at birth for the first half of 2020 may be underestimated since the populations more severely affected, Hispanic and non-Hispanic black populations, are more likely to live in urban areas.

The provisional mortality data on which the life tables are based also have a number of limitations. First, the timeliness of death certificate data varies by jurisdiction. Some jurisdictions

Figure 4. Change in life expectancy at birth, by Hispanic origin and race and sex: United States, 2019 and 2020



NOTES: Life expectancies for 2019 by Hispanic origin and race are not final estimates; see Technical Notes. Estimates are based on provisional data from January 2020 through June 2020.
SOURCE: National Center for Health Statistics, National Vital Statistics System, Mortality data.

have historically taken longer to submit death certificates because of paper records, staffing shortages, or other localized issues. More recently, jurisdictions were differently affected by the pandemic. Many jurisdictions increased their frequency of death certificate submissions, while some faced staffing challenges, data processing disruptions, or other issues. Some jurisdictions expanded their use of electronic death registration systems in 2020, which may have affected the timeliness of data submission. The effect of recent changes in timeliness will not be apparent until data are finalized. Another limitation is the variation in timeliness due to age and cause of death. Certain age groups, particularly under 5 years, may be underrepresented (3). Completion of death certificates takes longer for deaths from causes requiring investigation, including infant deaths, external injuries, and drug overdose deaths. As a result, these deaths may be underreported in the three to six months after the death occurred. Lastly, the timeliness of death certificate data by race or ethnicity has not been studied. Differences in timeliness by these factors may result in underestimation of deaths for specific groups. The underestimation of infant deaths, for example, will have a disproportionate effect on life expectancy at birth given that infant mortality has a large effect on life expectancy at birth due to it generally being higher than mortality at all other ages up to the mid-50s or so.

References

1. Arias E, Xu JQ. United States life tables, 2018. National Vital Statistics Reports; vol 69, no 12. Hyattsville, MD: National Center for Health Statistics. 2020. Available from: https://www.cdc.gov/nchs/data/nvsr/nvsr69/nvsr69-12-508.pdf.
2. Ahmad FB, Bastian B. Quarterly provisional estimates for selected indicators of mortality, 2018–Quarter 2, 2020. National Center for Health Statistics. National Vital Statistics System, Vital Statistics Rapid Release Program. 2020. Available from: https://www.cdc.gov/nchs/nvss/vsrr/mortality.htm.
3. Ahmad FB, Dokpesi P, Escobedo L, Rossen L. Timeliness of death certificate data by sex, age, and geography. Vital Statistics Rapid Release; no 9. Hyattsville, MD: National Center for Health Statistics. June 2020. Available from: https://www.cdc.gov/nchs/data/vsrr/vsrr009-508.pdf.
4. Rossen LM, Ahmad FB, Spencer MR, Warner M, Sutton P. Methods to adjust provisional counts of drug overdose deaths for underreporting. Vital Statistics Rapid Release; no 6. Hyattsville, MD: National Center for Health Statistics. 2018. Available from: https://www.cdc.gov/nchs/data/vsrr/report006.pdf.
5. Rossen LM, Womack LS, Spencer MR, Ahmad FB. Timeliness of infant death data for infant mortality surveillance and quarterly provisional estimates. Vital Statistics Rapid Release; no 5. Hyattsville, MD: National Center for Health Statistics. 2018. Available from: https://www.cdc.gov/nchs/data/vsrr/report005.pdf.
6. Kochanek K, Xu JQ, Arias E. Mortality in the United States, 2019. Data Brief, no 395. Hyattsville, MD: National Center for Health Statistics. 2020. Available from: https://www.cdc.gov/nchs/data/databriefs/db395-H.pdf.
7. Arias E, Xu JQ. United States life tables, 2017. National Vital Statistics Reports; vol 68, no 7. Hyattsville, MD: National Center for Health Statistics. 2019. Available from: https://www.cdc.gov/nchs/data/nvsr/nvsr68/nvsr68_07-508.pdf.
8. Arias E, Heron M, Hakes JK. The validity of race and Hispanic-origin reporting on death certificates in the United States: An update. National Center for Health Statistics. Vital Health Stat 2(172). 2016. Available from: http://www.cdc.gov/nchs/data/series/sr_02/sr02_172.pdf.
9. Arias E. United States life tables by Hispanic origin. National Center for Health Statistics. Vital Health Stat 2(152). 2010. Available from: http://www.cdc.gov/nchs/data/series/sr_02/sr02_152.pdf.

10. Markides KS, Coreil J. The health of Hispanics in the southwestern United States: An epidemiologic paradox. Public Health Rep 101(3):253–65. 1986.

11. Ahmad FB, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2020. Available from: https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.

12. Chiang CL. The life table and its applications. Malabar, FL: R.E. Krieger Publishing Company. 1984.

13. Silcocks PBS, Jenner DA, Reza R. Life expectancy as a summary of mortality in a population: Statistical considerations and suitability for use by health authorities. J Epidemiol Community Health 55:38–43. 2001.

Technical Notes

The methodology used to estimate the provisional 2020 life tables (Internet tables 1–12) on which the life expectancy estimates presented in this report are based differs from what is used to estimate the annual U.S. national life tables in several ways (1). First, the life tables presented in this report are based on provisional death counts for half a year rather than on final death counts for a full year. Second, they are based on monthly population estimates rather than annual mid-year population estimates. Third, they are abridged period life tables closed at ages 85 and over rather than complete period life tables closed at ages 100 and over. The main reason for the differences in methodology is data availability. Final death counts for the year 2020 will be not be available until late 2021. Similarly, census mid-year population estimates for 2020 are not yet available. The tables are closed at ages 85 and over because Medicare data, used to supplement vital statistics data at older ages, will not be available until mid-2021. Another difference is the use of provisional birth counts for the first half of 2020 rather than final birth counts and linked birth/infant death data used for life tables by Hispanic origin and race as these data are not yet available. Finally, abridged rather than complete life tables were used to address the effects of small death counts for some Hispanic origin-race-sex-age groups (Internet tables 1–12).

Standard errors of the two most important functions, the probability of dying and life expectancy (Internet tables 13–14), are estimated under the assumption that the data are only affected by random error because over 99% of deaths that occurred during the first half of 2020 are included. However, the possibility that certain jurisdictions and age groups may be underrepresented for later months in the period could potentially lead to biases not accounted for by the estimated standard errors. Other possible errors, including age, and Hispanic origin and race misreporting on death certificates are also not considered in the calculation of the variances or standard errors of the life table functions.

Life expectancy estimates presented in this report for 2019 are based on 2019 complete period life tables generated using the same methodology as that used each year to estimate annual U.S. life tables, with a minor modification (1). The standard 2018 and 2019 birth and 2019 mortality data files were used rather than the 2019 linked birth/infant death data file because the latter is not yet available. The final 2019 life tables by Hispanic origin and race will be updated once the linked birth/infant death data are available (Internet table 15).

Data for calculating life table functions

Vital statistics data

Mortality data used to estimate the life tables presented in this report include over 99% of the deaths that occurred from January through June, 2020, although certain jurisdictions and age groups may be underrepresented for later months in the period. Death data are typically over 99% complete 3 months after the date of death, but this can vary by jurisdiction, age of the decedent, and the cause of death. Most jurisdictions submit over 90% of death data by 3 months after the date of death, but some jurisdictions may take longer to submit death records. Death data for decedents under age 5 years are 90% complete 3 months after the date of death, and 95% complete by 6 months after the death occurred. Infant death records often take longer to complete because infant deaths often require additional investigation. As a result, provisional estimates of infant mortality are typically presented with a nine-month lag after death. Timeliness also varies by cause of death, with deaths due to external causes taking additional time to investigate and complete death certificates. Provisional estimates for most external causes of death (e.g., falls, suicides, unintentional injuries, etc.) are presented with a 6-month lag, while drug overdose deaths are presented with a 9-month lag.

Beginning with the 2018 data year, all 50 states and D.C. reported deaths based on the 2003 revision of the U.S. Standard Certificate of Death for the entire year (1). The revision is based on the 1997 Office of Management and Budget (OMB) standards (1). The 1997 standard allows individuals to report more than one race and increased the race choices from four to five by separating the Asian and Pacific Islander groups. The Hispanic category did not change, remaining consistent with previous reports.

The Hispanic origin and race groups in this report follow the 1997 standards and differ from the race categories used in reports for data years prior to 2018. From 2003–2017, not all deaths were reported using the 2003 certificate revision that allowed the reporting of more than one race based on the 1997 OMB race standard (1). During those years, multiple-race data were bridged to the 1977 standard single-race categories. Use of the bridged-race process was discontinued for the reporting of mortality statistics in 2018 when all states collected data on race according to 1997 OMB guidelines for the full data year.

Census population data

The population data used to estimate the life tables shown in this report are April 1, 2020 monthly postcensal population estimates based on the 2010 decennial census and are available from the U.S. Census website at https://www.census.gov/data/tables/time-series/demo/popest/2010s-national-detail.html.

Preliminary adjustment of the data

Adjustments for unknown age

An adjustment is made to account for the small proportion of deaths for which age is not reported on the death certificate. The number of deaths in each age category is adjusted proportionally to account for those with not-stated ages. The following factor (F) is used to make the adjustment. F is calculated for the

total and for each sex group within a racial and ethnic population for which life tables are constructed:

$$F = D / D^a$$

where D is the total number of deaths and D^a is the total number of deaths for which age is stated. F is then applied by multiplying it by the number of deaths in each age group.

Adjustment for misclassification of Hispanic origin and race on death certificates

The latest research to evaluate Hispanic origin and race reporting on U.S. death certificates found that the misclassification of Hispanic origin and race on death certificates in the United States accounts for a net underestimate of 3% for total Hispanic deaths, a net underestimate of less than one-half percent for total non-Hispanic black deaths, and no under or overestimate for total non-Hispanic white deaths (8). These results are based on a comparison of self-reported Hispanic origin and race on Current Population Surveys (CPS) with Hispanic origin and race reported on the death certificates of a sample of decedents in the National Longitudinal Mortality Study (NLMS) who died during the period 1999–2011 (8).

NLMS-linked records are used to estimate sex-age-specific ratios of CPS Hispanic origin and race counts to death certificate counts (9). The CPS/death certificate ratio, or "classification ratio," is specifically the ratio of the weighted count of self-reported race and ethnicity on the CPS to the weighted count of the same racial or ethnic category on the death certificates of the sample of NLMS decedents described above. It can be interpreted as the net difference in assignment of a specific Hispanic origin and race category between the two classification systems and can be used as a correction factor for Hispanic origin and race misclassification (8). The assumption is made that the race and ethnicity reported by a CPS respondent is more reliable than proxy reporting of race and ethnicity by a funeral director who has little personal knowledge of the decedent. Further, public policy embodied in the 1997 OMB standard mandates that self-identification should be the standard used for the collection and recording of race and ethnicity information (8).

The NLMS-based classification ratios discussed above are used to adjust the age-specific number of deaths for ages 1–85 years and over for the total, Hispanic, non-Hispanic white, and non-Hispanic black populations, and by sex for each group, as follows:

$$_nD_x = {}_nD_x^F \bullet {}_nCR_x$$

where ${}_nD_x^F$ is the age-specific number of deaths adjusted for unknown age as described above, ${}_nCR_x$ are the sex- and age-specific classification ratios used to correct for the misclassification of Hispanic origin and race on death certificates, and ${}_nD_x$ are the final age-specific counts of death adjusted for age and Hispanic origin and race misclassification.

Because NLMS classification ratios for infant deaths are unreliable due to small sample sizes, corrections for racial and ethnic misclassification of infant deaths are addressed by using infant death counts and live birth counts from the linked birth/infant death data files rather than the traditional birth and death data files (1). In the linked file, each infant death record is linked to its corresponding birth record so that the race and ethnicity of the mother reported on the birth record can be ascribed to the infant death record. Due to the unavailability of birth/infant death data at this time, the traditional birth and death data files are used instead for both the 2019 and 2020 life tables. Typically, infant mortality rates based on these data are overestimated by approximately 4% for the Hispanic population and 3% for the non-Hispanic black population and underestimated by 2% for the non-Hispanic white population (1).

Calculation of abridged life tables

Abridged life tables were constructed using the methodology developed by Chiang with minor modifications described below (12). The life table columns include:

Age

The age interval between two exact ages, x and $x + n$. The abridged life tables contain 19 age groups (in years): 0–1, 1–5, 5–10, 10–15, …, 80–85, and 85 and over.

Probability of dying, ${}_nq_x$

The first step in the calculation of an abridged period life table is the estimation of the age-specific probability of dying, ${}_nq_x$. The probability of dying between two exact ages, x and $x + n$, is defined as:

$$_nq_x = \frac{n_x \bullet {}_nM_x}{1+(1-a_x)\bullet n_x \bullet {}_nM_x}$$

where ${}_nM_x$ is the age-specific period death rate, $\frac{{}_nD_x}{{}_nP_x \bullet \frac{1}{2}}$, and ${}_nD_x$ is the age-specific provisional death count for January through June, ${}_nP_x$ is the April 1, 2020 age-specific monthly population estimates based on the 2010 decennial population census population count; n_x is the size in years of the age interval; and a_x is the fraction of life lived by those who died in the age interval.

Number surviving, l_x

The number of persons surviving to the beginning of the age interval from the original 100,000 hypothetical live births is defined as:

$$l_{x+n} = l_x - {}_nd_x$$

where the radix of the table l_0 = 100,000.

Number dying, ${}_nd_x$

The number of persons dying in the hypothetical life table cohort in the age-interval x and $x + n$ is defined as:

$$_nd_x = l_x \bullet {}_nq_x$$

Person-years lived, ${}_nL_x$

The number of person-years lived by the hypothetical life table cohort within an age interval x and $x + n$ is defined as:

$$ {}_nL_x = n_x \bullet (l_x - {}_nd_x) + a_x \bullet n_x \bullet {}_nd_x $$

where ${}_{85+}L_x$, the person-years lived in the final open-ended age interval, is defined as:

$$ {}_{85+}L_x = \frac{l_x}{{}_{85+}M_x} $$

Total number of person-years lived, T_x

The number of person-years that would be lived by the hypothetical life table cohort after the beginning of the age interval x and $x + n$ is defined as:

$$ T_x = \sum_{x=0}^{x=85+} {}_nL_x $$

Expectation of life, e_x

The average number of years to be lived by those in the hypothetical life table cohort surviving to age x is defined as:

$$ e_x = \frac{T_x}{l_x} $$

Variances and standard errors of the probability of dying and life expectancy

Variances are estimated under the assumption that the mortality data on which the life tables are based are not affected by sampling error and subject only to random variation. However, although over 99% of deaths that occurred from January through June, 2020 are included, the data may be biased by the possibility that certain jurisdictions and age groups may be underrepresented for later months in the period. These errors as well as those resulting from age, Hispanic origin and race misreporting on death certificates are not considered in the calculation of the variances or standard errors of the life table functions.

The methods used to estimate the variances of ${}_nq_x$ and e_x are based on Chiang (12) with a minor modification in the estimate of the variance of e_x in the closing age of the life table (13). Based on the assumption that deaths are binomially distributed, Chiang proposed the following equation for the variance of ${}_nq_x$:

$$ Var({}_nq_x) = \frac{{}_nq_x^2(1 - {}_nq_x)}{{}_nD_x} $$

where ${}_nD_x$ is the age-specific number of deaths, and for the variance of e_x for ages under 85:

$$ Var(e_x) = \frac{\sum_{x=0}^{x=75-84} l_x^2 \bullet [(1 - a_x) \bullet n_x + e_{(x+n)}]^2 \bullet Var({}_nq_x)}{l_x^2} $$

and for ages 85 and over:

$$ Var(e_{85+}) = \frac{l_{85+}^2}{M_{85+}^4} \bullet Var(M_{85+}) $$

Acknowledgments

The authors are grateful for the content review provided by Sherry L. Murphy, Mortality Statistics Branch (MSB). The authors thank Isabelle Horon, Division of Vital Statistics; Amy B. Branum, Office of the Director; and Robert N. Anderson, MSB for their reviews and comments. The report was edited and produced by NCHS Office of Information Services, Information Design and Publishing Staff: Yolanda L. Jones and Michael Jones.

Suggested citation

Arias E, Tejada-Vera B, Ahmad F. Provisional life expectancy estimates for January through June, 2020. Vital Statistics Rapid Release; no 10. Hyattsville, MD: National Center for Health Statistics. February 2021. DOI: https://dx.doi.org/10.15620/cdc:100392.

Copyright information

All material appearing in this report is in the public domain and may be reproduced or copied without permission; citation as to source, however, is appreciated.

National Center for Health Statistics

Brian C. Moyer, Ph.D., *Director*

Amy M. Branum, Ph.D., *Acting Associate Director for Science*

Division of Vital Statistics

Steven Schwartz, Ph.D., *Director*

Isabelle Horon, Dr.P.H., *Acting Associate Director for Science*

Exhibit 6

Prescription Drug User Fee Amendments

Latest News:

- On August 16, 2021, the Food and Drug Administration announced the Prescription Drug User Fee Rates for Fiscal Year 2022 (https://www.federalregister.gov/documents/2021/08/16/2021-17505/prescription-drug-user-fee-rates-for-fiscal-year-2022) in the Federal Register for fees assessed under the Federal Food, Drug, and Cosmetic Act. These fees apply to the period from October 1, 2021, through September 30, 2022. Please see the table below for Fiscal Year 2021 and Fiscal Year 2022 fee rates.
- The FY 2022 PDUFA program fee invoices were emailed on **Friday, August 20, 2021.** Full payment of the invoice is due October 01, 2021. If you do not receive your invoice by August 25, 2021, please contact PDUFA User Fee staff at CDERCollections@fda.hhs.gov (mailto:CDERCollections@fda.hhs.gov).
- CDER's Work to Meet User Fee Goals During the Pandemic (/industry/fda-user-fee-programs/cders-work-meet-user-fee-goals-during-pandemic/?utm_source=GDUFA&utm_medium=web&utm_campaign=FDA): This webpage will provide periodic updates on key user fee metrics related to application review and the pre-approval process throughout the COVID-19 pandemic.
- IMPORTANT NOTICE REGARDING PRESCRIPTION DRUG USER FEE STAFF CONTACT INFORMATION: Due to the COVID-19 pandemic, and until further notice, electronic mail is the Prescription Drug User Fee staff's preferred method of receiving communication over postal mail. If you have questions or documentation for the Prescription Drug User Fee staff regarding PDUFA Fee requirements, waivers, reductions or refunds, please send them by electronic mail to CDERCollections@fda.hhs.gov (mailto:CDERCollections@fda.hhs.gov). Please continue to contact the User Fee Helpdesk at userfees@fda.gov (mailto:userfees@fda.gov) for questions about making or confirming the status of a payment.

FY 2021 and FY 2022 User Fee Rates:

User Fee Type	2021	2022
Application Fee – Clinical Data Required	$2,875,842	$3,117,218

User Fee Type	2021	2022
Application Fee – No Clinical Data Required	$1,437,921	$1,558,609
Program Fee	$336,432	$369,413

Background and Legislation

The Prescription Drug User Fee Act (PDUFA) was created by Congress in 1992 and authorizes FDA to collect fees from companies that produce certain human drug and biological products. Since the passage of PDUFA, user fees have played an important role in expediting the drug approval process.

PDUFA must be reauthorized every five years, and was renewed in 1997 (PDUFA II (/industry/prescription-drug-user-fee-act-pdufa/pdufa-legislation-and-background-pdufa-ii)), 2002 (PDUFA III (/industry/prescription-drug-user-fee-act-pdufa/pdufa-legislation-and-background-pdufa-iii)), 2007 (PDUFA IV (/industry/prescription-drug-user-fee-act-pdufa/pdufa-legislation-and-background-pdufa-iv)), and 2012 (PDUFA V (/industry/prescription-drug-user-fee-act-pdufa/pdufa-v-fiscal-years-2013-2017)) and 2017 (PDUFA VI (/industry/prescription-drug-user-fee-act-pdufa/pdufa-vi-fiscal-years-2018-2022)). On August 18, 2017, the President signed into law the Food and Drug Administration Reauthorization Act (FDARA), which includes the reauthorization of PDUFA through September 2022. PDUFA VI (/industry/prescription-drug-user-fee-act-pdufa/pdufa-vi-fiscal-years-2018-2022) will provide for the continued timely review of new drug and biologic license applications.

Federal Register Documents and Guidances

Federal Register Documents

- Fee Rate for Using a Rare Pediatric Disease Priority Review Voucher in Fiscal Year 2021 (https://www.federalregister.gov/documents/2020/10/07/2020-22186/fee-rate-for-using-a-rare-pediatric-disease-priority-review-voucher-in-fiscal-year-2021)
- Fee Rate for Using a Tropical Disease Priority Review Voucher in Fiscal Year 2022 (https://www.federalregister.gov/documents/2021/09/30/2021-21328/fee-rate-for-using-a-tropical-disease-priority-review-voucher-in-fiscal-year-2022)
- Fee Rate for Using a Material Threat Medical Countermeasure Priority Review Voucher in Fiscal Year 2022 (https://www.federalregister.gov/documents/2021/09/30/2021-21317/fee-rate-for-

using-a-material-threat-medical-countermeasure-priority-review-voucher-in-fiscal-year)

- Genus Medical Technologies LLC Versus Food and Drug Administration; Request for Information and Comments (https://www.federalregister.gov/documents/2021/08/09/2021-16944/genus-medical-technologies-llc-versus-food-and-drug-administration-request-for-information-and)
- Establishment of Prescription Drug User Fee Rates for Fiscal Years 1998 – present (/industry/prescription-drug-user-fee-act-pdufa/pdufa-user-fee-rates-archive)

Guidances

- Guidance Documents and MAPPs (/industry/prescription-drug-user-fee-act-pdufa/guidance-documents-and-mapps-pdufa)

To find older Federal Register Documents, please visit the Archive Page (/industry/prescription-drug-user-fee-act-pdufa/regulations-and-federal-register-documents-pdufa).

Application Fees

What is a human drug application?
PDUFA levies a user fee on certain human drug applications. Under PDUFA, the term human drug application means an application for

- approval of a new drug submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), or
- licensure of certain biological products under section 351(a) of the Public Health Service Act (PHS Act).

What are application fees?
Each person that submits a human drug application is assessed an application fee as follows:

- A human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required for approval is assessed a full application fee.
- A human drug application for which clinical data with respect to safety or effectiveness are not required for approval is assessed one-half of a full fee.

Human drug application fees are due when the application is submitted.

How do I pay a fee?
Visit our Payment Information and Cover Sheet tab for all the information you will need to pay your application fee.

Are there any exceptions to the fee requirements?

Previously Filed Applications:

- An application fee is not required for the resubmission of an application if the original application of the same product
  - was submitted by a person that paid the fee for the application,
  - was accepted for filing, and
  - was not approved or was withdrawn (without a waiver).

Designated Orphan Drug or Indication

- An application for a prescription drug product that has been designated as a drug for a rare disease or condition, under section 526 of the FD&C Act, is not subject to an application fee unless the application includes an indication for other than a rare disease or condition.

For more information about application fees, please read FDA's guidance for industry Assessing User Fees Under the Prescription Drug User Fee Amendments of 2017 (/media/108233/download).

Program Fees

What are prescription drug program fees?
Prescription drug program fees are assessed annually for eligible products. The program fees are assessed for each prescription drug product that is identified in such a human drug application approved as of October 1st of such fiscal year.

Applicants may not be assessed more than five prescription drug program fees for a fiscal year for prescription drug products identified in a single approved application.

What is the definition of a prescription drug product?
Prescription drug product means a specific strength or potency of a drug in final dosage form for which a human drug application has been approved and which may be dispensed only by prescription under section 503(b) of the FD&C Act, and is also on the list of

products described in section 505(j)(7)(A), or is on a list created and maintained by the Secretary of products approved under human drug applications under section 351 of the Public Health Service Act.

Are there drugs that are not included in the term prescription drug product?
Yes. The term prescription drug product does not include the following drugs:

- Whole blood or a blood component for transfusion,
- A bovine blood product for topical application licensed before September 1, 1992, an allergenic extract product, or an in vitro diagnostic biologic product licensed under section 351 of the PHS Act,
- A biological product that is licensed for further manufacturing use only,
- A drug that is not distributed commercially AND is the subject of an application or supplement submitted by a State or Federal Government entity.

How do I pay a fee?
Visit our Payment Information and Cover Sheet tab for all the information you will need to pay your program fee.

Are there any exceptions to the fee requirements?
Yes, there are. An annual program fee is not assessed if the prescription drug product is:

- listed in the Orange Book with a potency described in terms of per 100 mL, or,
- the same product as another product that –
  - was approved under an application filed under sections 505(b) or 505(j) of the FD&C Act,
  - is not in the list of discontinued products compiled under section 505(j)(7) of the FD&C Act.

For more information about program fees, please read FDA's guidance for industry Assessing User Fees Under the Prescription Drug User Fee Amendments of 2017 (/media/108233/download).

Payment Information and Cover Sheet

When are user fees due?

- An application fee is due when the application is submitted to FDA.

- FDA issues invoices for annual program fees for the coming fiscal year in August of each year using the fee schedule for the coming fiscal year. Payments are due either on the first business day on or after October 1 of each fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for that fiscal year, whichever occurs later.
- FDA may issue additional invoices as needed. These invoices are also known as clean-up invoices to capture program fees that were not previously invoiced. The clean-up invoices are generally issued in mid-December of the fiscal year and the fees are generally due by mid-January of the fiscal year.

What is the Federal government's fiscal year?

The Federal government's fiscal year begins on October 1 and ends on September 30. For example, fiscal year 2022 begins October 1, 2021, and ends September 30, 2022.

What is the PDUFA User Fee Cover Sheet?

Form FDA 3397, the PDUFA user fee cover sheet, is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to help FDA track payments. The PDUFA Cover Sheet Form FDA 3397 should be completed for the following:

- 505(b) and 351(a) Original Applications
- Resubmission of 505(b) and 351(a) Original Application after a Refuse to File
- Resubmission of 505(b) and 351(a) Original Applications Withdrawn before the filing date.

The form provides a cross-reference of the fee submitted for an application with the actual application by using a unique number tracking system to assign the user fee payment identification number (PIN). The information collected is used by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new drug applications and biologics license applications. Note: You do not need to fill out a Form 3397 for annual program fee payments.

How do I fill out the PDUFA User Fee Cover Sheet Online?

FDA offers you the ability to complete a PDUFA User Fee Cover Sheet online and submit it electronically. Please visit PDUFA User Fee Coversheet webpage (https://userfees.fda.gov/OA_HTML/pdufaCAcdLogin.jsp) to fill out the form. To fill out the form online, you need Microsoft Internet Explorer 5.5 or higher. For Step-by-Step Instructions on how to fill out the cover sheet, please visit:

https://userfees.fda.gov/OA_HTML/PDUFACScreation.pdf (https://userfees.fda.gov/OA_HTML/PDUFACScreation.pdf)

How do I submit payment after completing the PDUFA User Fee Cover Sheet?
A payment may be submitted electronically via the User Fees Payment Portal (https://userfees.fda.gov/OA_HTML/fdaExternalBanner.jsp?redirectURL=/OA_HTML/fdaUPPInvSearch.jsp) or by mailing a check, bank draft, U.S. postal money order, or by wire transfer made payable to the order of the U.S. Food and Drug Administration. For all payment options, the payment must be made in U.S. currency drawn on a U.S. financial institution.

If mailing your payment, please send a printed copy of the completed PDUFA User Fee Cover Sheet along with a check, bank draft, or U.S. Postal money order made payable to the Food and Drug Administration for the fee amount due. Remember to include the user fee payment identification number, beginning with "PD," the BLA/NDA number, and the FDA P.O. Box on the enclosed check.

Mail payment and copy of PDUFA user fee cover sheet to:

Food and Drug Administration
P.O. Box 979107
St. Louis, MO 63197-9000
Note: In no case should payment be submitted with the actual application to CDER/CBER.

If checks are to be sent by a courier that requires a street address, the courier can deliver the checks to:

U.S. Bank
Attn: Government Lockbox 979107
1005 Convention Plaza
St. Louis, MO 63101
Note: This address is for courier delivery only.

Wire Transfer Payment

US Department of Treasury
TREAS NYC
33 Liberty Street
New York, NY 10045
FDA Deposit Account Number: 75060099
US Department of Treasury routing/transit number: 021030004
SWIFT Number: FRNYUS33
Beneficiary: FDA

8455 Colesville Road
COLE-14-14253
Silver Spring, MD 20993-0002

Note: For wire transfers, please include the user fee payment identification number (PIN), beginning with "PD", the BLA/NDA number and ensure that the fee that your bank will charge for the wire transfer is added to your fee payment.

Please note for payments for annual program fees, it is helpful to include the invoice sheet that was sent to you for the annual program fees (or product or establishment fees).

If you have problems or if you are unsure on whether or not you need to file an application with FDA or are unsure what type of application to file:

Prescription Drug User Fee Staff Contact:
CDERCollections@fda.hhs.gov or 301-796-7900

Center for Biologics Evaluation and Research Contact:
Carla Vincent at 240-402-8177

If you need technical assistance with your cover sheet or are unsure how to proceed:

Contact: FDA User Fee Financial Support Team at (301) 796-7200 or userfees@fda.gov.
PDUFA User Fee Cover Sheet
OMB No. 0910-0297
Form FDA 3397 (03/19)

Waivers, Reductions, and Refunds

Are there any waivers of user fees?
Under section 736(d) of the FD&C Act, a waiver may be granted for one or more fees where:

- a waiver or reduction is necessary to protect the public health
- assessment of the user fees would present a significant barrier to innovation due to limited resources or other circumstances, or
- the applicant involved is a small business submitting its first human drug application for review

Is there a reduction of fees for human drug applications that are refused for filing or are withdrawn before or after filing?
Yes. The following reductions or refunds are available:

- 75 percent of the application fee is refunded for any application that is refused for filing or is withdrawn before filing.
- if an application is withdrawn after it is filed, FDA may refund the fee or a portion of the fee if no substantial work was performed on the application or supplement. FDA has the sole discretion to refund a fee or a portion of the fee. FDA's determination concerning a refund is not reviewable.

To be granted a waiver, the human drug applicant must submit a written request for the waiver.

What is the timeframe for requesting a waiver, reduction, or refund of fees?
To qualify for consideration, a written request for waiver, reduction or refund must be submitted not later than 180 days after such fee is due.

How do I request a small business waiver and refund? An applicant should submit Form FDA 3971 (https://www.fda.gov/media/108984/download) (Small Business Waiver and Refund Request) to CDERCollections@fda.hhs.gov (mailto:CDERCollections@fda.hhs.gov) to see if they qualify for a small business waiver.

Who should I contact with questions about how to submit a waiver, refund, or reduction request?
Please contact CDERCollections@fda.hhs.gov (mailto:CDERCollections@fda.hhs.gov) with any questions about submitting your request.

Where should I send my request?
Please submit a refund or waiver request by electronic mail to the Prescription Drug User Fee staff at CDERCollections@fda.hhs.gov. (mailto:CDERCollections@fda.hhs.gov)

What information should I include in my request?
For more information about submitting a request for a waiver, refund or reduction request, please read FDA's guidance for industry User Fee Waivers, Reductions, and Refunds for Drug and Biological Products (/media/131797/download).

Reauthorization Activities

- PDUFA VII: Fiscal Year 2023 - 2027 (https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027)
- PDUFA VI Five-Year Financial Plan (/media/112325/download) (PDF - 480 KB)
- PDUFA Meetings (/industry/prescription-drug-user-fee-act-pdufa/pdufa-meetings)

- PDUFA VI Information Technology Goals and Progress (/industry/prescription-drug-user-fee-act-pdufa/pdufa-vi-information-technology-goals-and-progress)
- PDUFA VI: Fiscal Years 2018 - 2022 (/industry/prescription-drug-user-fee-act-pdufa/pdufa-vi-fiscal-years-2018-2022)
- Federal Register Notice: Public Meeting on Proposed Recommendations for PDUFA Reauthorization (https://www.federalregister.gov/documents/2016/07/19/2016-16916/prescription-drug-user-fee-act-public-meeting-request-for-comments)
- PDUFA VI Proposed Commitment Letter (/media/99140/download)
- PDUFA V: Fiscal Years 2013-2017 (/industry/prescription-drug-user-fee-act-pdufa/pdufa-v-fiscal-years-2013-2017)

Related Information

- CDER & CBER Net Hiring Data (/industry/prescription-drug-user-fee-amendments/center-drug-evaluation-and-research-center-biologics-evaluation-and-research-net-hiring-data)
- PDUFA 5 Year Financial Plan (2018) (/media/112325/download) (PDF - 540KB)
- PDUFA Letters (/industry/prescription-drug-user-fee-act-pdufa/letters-pdufa)
- Annual Reports and Plans (/industry/prescription-drug-user-fee-act-pdufa/pdufa-annual-reports-and-plans)
- Orange Book (http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm)
- CDER Therapeutic Biologic Products List (/media/76650/download)
- CBER Billable Biologics List (/media/113210/download)
- PDUFA User Fee Rates Archive (/industry/prescription-drug-user-fee-act-pdufa/pdufa-user-fee-rates-archive)
- Complete Response Letter Final Rule (/drugs/laws-acts-and-rules/complete-response-letter-final-rule)
- PDUFA Financial Reports (/about-fda/user-fee-financial-reports/pdufa-financial-reports)

Contact Us

Questions for the Prescription Drug User Fee staff? Contact us at CDERCollections@fda.hhs.gov (mailto:CDERCollections@fda.hhs.gov) or 301-796-7900.

Refund or waiver request? Please email them to CDERCollections@fda.hhs.gov (mailto:CDERCollections@fda.hhs.gov).

Questions about making a payment or confirming the status of a payment? Email the User Fee Helpdesk at userfees@fda.gov (mailto:userfees@fda.gov) or call 301-796-7200.

Questions about Pay.gov? Email them at pay.gov.clev@clev.frb.org (mailto:pay.gov.clev@clev.frb.org) or call 800-624-1373.

Questions about the Orange Book? Email them at OrangeBook@fda.hhs.gov (mailto:OrangeBook@fda.hhs.gov).

Exhibit 7

DECEMBER 13, 2021

May 21, 2021 | ***C. Michael White, UConn School of Pharmacy***

Why is the FDA Funded in Part by the Companies It Regulates?

Nearly half the agency's budget now comes from 'user fees' paid by companies seeking approval for medical devices or drugs

The Food and Drug Administration has become more reliant on fees paid by companies regulated by the agencies than on public dollars (Adobe Stock).

he Food and Drug Administration has moved from an entirely taxpayer-funded entity to one increasingly funded by user fees paid by manufacturers that are being regulated. Today, close to 45% of its budget comes from these user fees that companies pay when they apply for approval of a medical device or drug.

As a pharmacist and medication and dietary supplement safety researcher, I understand the vital role that the FDA plays in ensuring the safety of medications and medical devices.

But I, along with many others, now wonder: Was this move a clever win-win for the manufacturers and the public, or did it place patient safety second to corporate profitability? It is critical that the U.S. public understand the positive and negative ramifications so the nation can strike the right balance.

The FDA Blocks Thalidomide

Americans in the early 20th century were outraged when they found out that manufacturers used poor-quality methods for producing food and medication, and used unsafe, ineffective and undisclosed addictive ingredients in medications. The resulting Food, Drug and Cosmetic Act of 1938 gave the taxpayer-funded Food and Drug Administration new authority to protect the U.S. consumer.

One of the FDA's most shining successes occurred in the late 1950s when the agency refused to approve thalidomide. By 1960, 46 countries allowed pregnant women to use thalidomide to treat morning sickness, but the FDA refused on the grounds that the studies were insufficient to demonstrate safety. Debilitating birth defects resulting from thalidomide arose in Europe and elsewhere in 1961. President John F. Kennedy heralded the FDA in 1962 for its stance. An FDA driven by the data – and not corporate pressure – prevented a major tragedy.

How AIDS Changed How the FDA is Funded

The FDA continued its work fully funded by U.S. taxpayers for many years until this model was upended by a new infectious disease. The first U.S. case of HIV-induced AIDS occurred in 1981. It was rapidly spreading, with devastating complications like blindness, dementia, severe respiratory diseases and rare cancers. Well-known sports stars and celebrities died of AIDS-related complications. AIDS activists were incensed about long delays in getting experimental HIV drugs studied and approved by the FDA.

In 1992, in response to intense pressure, Congress passed the Prescription Drug User Fee Act. It was signed into law by President George H.W. Bush.

With the act, the FDA moved from a fully taxpayer-funded entity to one funded through tax dollars and new prescription drug user fees. Manufacturers pay these fees when submitting applications to the FDA for drug review and annual user fees based on the number of approved drugs they have on the market. However, it is a complex formula with waivers, refunds and exemptions based on the category of drugs being approved and the total number of drugs in the manufacturers portfolio.

Over time, other user fees for generic, over-the-counter, biosimilar, animal and animal generic drugs, as well as for medical devices, were created. As time passed, the FDA's funding has increasingly come from the industries that it regulates. Of the FDA's total US$5.9 billion budget, 45% comes from user fees, but 65% of the funding for human drug regulatory activities are derived from user fees. These user fee programs must be reauthorized every five years by Congress, and the current agreement remains in effect through September 2022.

Have User Fees Worked?

The FDA and the drug or device manufacturers negotiate the user fees. They also negotiate performance measures that the FDA has to meet to collect them, and proposed changes in FDA processes. Performance measures include things such as how quickly the FDA responds to meeting requests, how quickly it generates correspondence, and how long it takes from submission of a new drug application until the FDA approves or refuses to approve a drug or product.

Because of the additional funding generated by user fees and performance measures that the FDA has to meet, the FDA is quicker and more willing to discuss what it wants to see in an application with manufacturers. It also offers clearer guidance for manufacturers. In 1987, it took 29 months from the time a new drug application was filed by the manufacturer for the FDA to decide whether to approve a medication in the U.S. In 2014, it only took 13 months and by 2018, it was down to 10 months.

Changes in more recent years have also increased the number of standard new drug applications approved the first time around by the FDA from 38% in 2005 to 61% in 2018. In diseases where there are not many medication options for patients, the FDA has a priority

review process, where 89% of new drug applications were approved the first time around and the approvals were completed in eight months in 2018. All this occurred while the number of new drug applications have been increasing over time.

Most recently, the COVID-19 pandemic has seen the FDA provide emergency use authorization for potential treatments in a matter of weeks, not months. The infrastructure and capacity to review the available information so rapidly is due in large part to the funding from user fees.

While the number and speed of drug approvals have been increasing over time, so have the number of drugs that end up having serious safety issues coming to light after FDA approval. In one assessment, investigators looked at the number of newly approved medications that were subsequently removed from the market or had to include a new black box warning over 16 years from the year of approval. These black box warnings are the highest level of safety alert that the FDA can employ, warning users that a very serious adverse event could occur.

Before the user fee act was approved, 21% of medications were removed or had new black box warnings as compared to 27% afterwards.

Some potential reasons that more adverse effects are coming to light after drug approval include senior FDA officials overturning scientist recommendations, a lower burden of proof for medication approval, and more clinical data in new drug applications coming from foreign clinical trial sites that require additional time to assess in an environment where regulators are rushing to meet tight deadlines.

Lack of Money Limits FDA

User fees are a viable way to shift some of the financial burden to manufacturers who stand to make money from the approval and sale of drugs in the lucrative U.S. market. Successes have occurred and provided U.S. citizens with medication more quickly than before.

However, without careful consideration of what is being negotiated, the FDA can become weak and ineffective, unable to protect its citizens from the next thalidomide. There are some signs that the pendulum may be swinging too far in the direction of the manufacturers. Additionally, while drug approval functions at the FDA are well funded, the FDA is

insufficiently funded to protect consumers from other issues such as counterfeit drugs and dietary supplements because they cannot collect user fees to do so. In my view, these functions need to be identified and require additional taxpayer funding.

Originally published in *The Conversation*.

Recent Articles

December 13, 2021

STEP-HI Study Providing Physical and Mental Strength to Older Women

READ THE ARTICLE

December 13, 2021

Women Are Facing Greater Interruption Challenges with Remote Work Than Their Male Colleagues

READ THE ARTICLE

editor@uconn.edu | (860) 486-3530

SUBSCRIBE

© 2021 University of Connecticut

Disclaimers, Privacy & Copyright

Accessibility

Exhibit 8

PFIZER AND BIONTECH INITIATE ROLLING SUBMISSION OF BIOLOGICS LICENSE APPLICATION FOR U.S. FDA APPROVAL OF THEIR COVID 19 VACCINE

Friday, May 07, 2021 - 06:45am EST

We look forward to working with the FDA to complete this rolling submission and support their review, with the goal of securing full regulatory approval of the vaccine in the coming months.

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer Inc. (www.pfizer.com) (NYSE: PFE) and BioNTech SE (www.biontech.de) (Nasdaq: BNTX) today announced the initiation of a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) for approval of their mRNA vaccine to prevent COVID-19 in individuals 16 years of age and older. Data to support the BLA will be submitted by the companies to the FDA on a rolling basis over the coming weeks, with a request for Priority Review. The Prescription Drug User Fee Act (PDUFA) goal date for a decision by the FDA will be set once the BLA is complete and formally accepted for review by the agency.

The Pfizer-BioNTech COVID-19 Vaccine is currently available in the U.S. under an Emergency Use Authorization (EUA) granted (https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-celebrate-historic-first-authorization) by the FDA on December 11, 2020. Since then, the companies have delivered more than 170 million doses of the vaccine across the U.S. Submission of a BLA, which requires longer-term follow-up data for acceptance and approval, is the next step in the rigorous FDA review process.

“We are proud of the tremendous progress we’ve made since December in delivering vaccines to millions of Americans, in collaboration with the U.S. Government,” said Albert Bourla, Chairman and Chief Executive Officer, Pfizer. “We look forward to working with the FDA to complete this rolling submission and support their review, with the goal of securing full regulatory approval of the vaccine in the coming months.”

"Following the successful delivery of more than 170 million doses to the U.S. population in just a few months, the BLA submission is an important cornerstone of achieving long-term herd immunity and containing COVID-19 in the future," said Ugur Sahin, M.D., CEO and Co-founder of BioNTech. "We are pleased to work with U.S. regulators to seek approval of our COVID-19 vaccine based on our pivotal Phase 3 trial and follow-up data."

Pfizer and BioNTech initiated the BLA by submitting the nonclinical and clinical data needed to support licensure of the COVID-19 vaccine for use in individuals 16 years of age and older. This includes the most recent analyses (https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-confirm-high-efficacy-and-no-serious) from the pivotal Phase 3 clinical trial, where the vaccine's efficacy and favorable safety profile were observed up to six months after the second dose. The companies will submit the required manufacturing and facility data for licensure in the coming weeks to complete the BLA.

Pfizer and BioNTech also have submitted an application to expand the current EUA for their COVID-19 vaccine to include individuals 12 to 15 years of age. The companies intend to submit a supplemental BLA to support licensure of the vaccine in this age group once the required data six months after the second vaccine dose are available.

Hide

The Pfizer-BioNTech COVID-19 Vaccine, which is based on BioNTech proprietary mRNA technology, was developed by both BioNTech and Pfizer. BioNTech is the Marketing Authorization Holder in the European Union, and the holder of emergency use authorizations or equivalent in the United States (together with Pfizer), United Kingdom, Canada and other countries in advance of a planned application for full marketing authorizations in these countries.

The Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by the U.S. Food and Drug Administration (FDA), but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564 (b) (1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner. Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Full EUA Prescribing Information available at www.cvdvaccine-us.com (http://www.cvdvaccine-us.com).

AUTHORIZED USE IN THE U.S.:

The Pfizer-BioNTech COVID19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

IMPORTANT SAFETY INFORMATION FROM U.S. FDA EMERGENCY USE AUTHORIZATION PRESCRIBING INFORMATION:

- Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine.
- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer- BioNTech COVID-19 Vaccine.
- Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/ (https://www.cdc.gov/vaccines/covid-19/)).
- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.
- The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.
- In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%).
- Severe allergic reactions, including anaphylaxis, have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials.
- Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine.
- Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.
- Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion.
- There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.
- Vaccination providers must report Adverse Events in accordance with the Fact Sheet to VAERS at https://vaers.hhs.gov/reportevent.htmlor (https://vaers.hhs.gov/reportevent.htmlor) by calling 1-800-822-7967. The reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report.
- Vaccination providers should review the Fact Sheet for Information to Provide to Vaccine Recipients/Caregivers and Mandatory Requirements for Pfizer-BioNTech COVID-19 Vaccine Administration Under Emergency Use Authorization.

Hide

Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information available at www.cvdvaccine-us.com (http://www.cvdvaccine-us.com).

ABOUT PFIZER: BREAKTHROUGHS THAT CHANGE PATIENTS' LIVES

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com (http://www.Pfizer.com). In addition, to learn more, please visit us on www.Pfizer.com (http://www.Pfizer.com) and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

PFIZER DISCLOSURE NOTICE

The information contained in this release is as of May 7, 2021. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

Hide

This release contains forward-looking information about Pfizer's efforts to combat COVID-19, the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine, the BNT162 mRNA vaccine program and the Pfizer-BioNTech COVID-19 Vaccine (BNT162b2) (including qualitative assessments of available data, potential benefits, expectations for clinical trials, a rolling submission of a Biologics License Application (BLA) with the FDA for BNT162b2, the anticipated timing of regulatory submissions, regulatory approvals or authorizations and anticipated manufacturing, distribution and supply), involving substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data (including the Phase 3 data), including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the ability to produce comparable clinical or other results, including the rate of vaccine effectiveness and safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial and additional studies or in larger, more diverse populations upon commercialization; the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; the risk that more widespread use of the vaccine will lead to new information about efficacy, safety, or other developments, including the risk of additional adverse reactions, some of which may be

serious; the risk that preclinical and clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether and when additional data from the BNT162 mRNA vaccine program will be published in scientific journal publications and, if so, when and with what modifications and interpretations; whether regulatory authorities will be satisfied with the design of and results from these and any future preclinical and clinical studies; whether and when the submission of the BLA for BNT162b2 in the U.S. will be completed and accepted for review and whether and when other biologics license and/or emergency use authorization applications or amendments to any such applications may be filed in particular jurisdictions for BNT162b2 or any other potential vaccines that may arise from the BNT162 program, and if obtained, whether or when such emergency use authorization or licenses will expire or terminate; whether and when the BLA for BNT162b2 in the U.S. and any other applications that may be pending or filed for BNT162b2 (including any requested amendments to the emergency use or conditional marketing authorizations) or other vaccines that may result from the BNT162 program may be approved by particular regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine's benefits outweigh its known risks and determination of the vaccine's efficacy and, if approved, whether it will be commercially successful; decisions by regulatory authorities impacting labeling or marketing, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of a vaccine, including development of products or therapies by other companies; disruptions in the relationships between us and our collaboration partners, clinical trial sites or third-party suppliers; the risk that demand for any products may be reduced or no longer exist; risks related to the availability of raw materials to manufacture a vaccine; challenges related to our vaccine's ultra-low temperature formulation, two-dose schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by Pfizer; the risk that we may not be able to successfully develop other vaccine formulations, booster doses or new variant-specific vaccines; the risk that we may not be able to create or scale up manufacturing capacity on a timely basis or maintain access to logistics or supply channels commensurate with global demand for our vaccine, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine within the projected time periods as previously indicated; whether and when additional supply agreements will be reached; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; challenges related to public vaccine confidence or awareness; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

Hide

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov (http://www.sec.gov) and www.pfizer.com (http://www.pfizer.com).

ABOUT BIONTECH

Biopharmaceutical New Technologies is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor T cells, bi-specific checkpoint immuno-modulators, targeted cancer antibodies and small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including Genmab, Sanofi, Bayer Animal Health, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, and Pfizer. For more information, please visit www.BioNTech.de (http://www.BioNTech.de).

Hide

BIONTECH FORWARD-LOOKING STATEMENTS

This press release contains "forward-looking statements" of BioNTech within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to, statements concerning: BioNTech's efforts to combat COVID-19; the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine (including a potential second booster dose of BNT162b2 and/or a potential booster dose of a variation of BNT162b2 having a modified mRNA sequence); the potential of BNT162b2 for adolescents 12 to 15 years of age, evaluation of BNT162b2 in children 6 months to 11 years old, anticipated timing of regulatory submissions, regulatory approvals or authorizations, including the Biologics License Application, and anticipated manufacturing, distribution and supply); our expectations regarding the potential characteristics of BNT162b2 in our clinical trials and/or in commercial use based on data observations to date; the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; the expected time point for additional readouts on efficacy data of BNT162b2 in our clinical trials; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; the timing for submission of data for, or receipt of, any marketing approval, including the Biologics License Application, or Emergency Use Authorization; our contemplated shipping and storage plan, including our estimated product shelf life at various temperatures; the

risk that demand for any products may be reduced or no longer exist; the ability of BioNTech to supply the quantities of BNT162 to support clinical development and market demand, including our production estimates for 2021; and challenges related to public vaccine confidence or awareness. Any forward-looking statements in this press release are based on BioNTech's current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: the ability to meet the pre-defined endpoints in clinical trials; competition to create a vaccine for COVID-19; the ability to produce comparable clinical or other results, including our stated rate of vaccine effectiveness and safety and tolerability profile observed to date, in the remainder of the trial or in larger, more diverse populations upon commercialization; the ability to effectively scale our productions capabilities; and other potential difficulties.

For a discussion of these and other risks and uncertainties, see BioNTech's Annual Report on Form 20-F for the Year Ended December 31, 2020, filed with the SEC on March 30, 2021, which is available on the SEC's website at www.sec.gov (http://www.sec.gov). All information in this press release is as of the date of the release, and BioNTech undertakes no duty to update this information unless required by law.

Hide

CONTACTS

Pfizer Contacts:
Media Relations
Amy Rose
+1 (212) 733-7410
Amy.Rose@pfizer.com (mailto:Amy.Rose@pfizer.com)

Investor Relations
Chuck Triano
+1 (212) 733-3901
Charles.E.Triano@Pfizer.com (mailto:Charles.E.Triano@Pfizer.com)

BioNTech Contacts:
Media Relations
Jasmina Alatovic
+49 (0)6131 9084 1513
Media@biontech.de (mailto:Media@biontech.de)

Investor Relations

Sylke Maas, Ph.D.

+49 (0)6131 9084 1074

Investors@biontech.de (mailto:Investors@biontech.de)

Pfizer (/)

Copyright © 2002-2021 Pfizer Inc. All rights reserved. This information—including product information—is intended only for residents of the United States.
The products discussed herein may have different labeling in different countries.

Hide

Exhibit 9

This article is advertising content.

A MESSAGE FROM RECOMMIND

Study Shows "Traditional Linear Review" Almost Accounts for 73% of e-Discovery Costs

FEBRUARY 19, 2013, 4:58 PM CST

Tweet

Many legal departments are struggling for ways to reduce, or at least stop growth in their legal budgets. One of the obvious targets for cost reduction in any legal department is the cost of responding to eDiscovery, including the cost of in-house or external attorney review for relevance and privilege. Per a Compliance, Governance and Oversight Counsel (CGOC) survey, the average legal department spends approximately $3 million per discovery to gather and prepare information for opposing counsel in litigation. The RAND Institute for Civil Justice has published a 2012 study that points out the cost of legal review for privilege and responsiveness costs an average of $0.73 for every dollar spent on eDiscovery.

The top four cost reduction strategies legal departments are considering are:

- 1) Bring more evidence collection and analysis in-house to do more **Electronically Stored Information (ESI)** processing internally
  2) Keep more of the review of ESI in-house rather that utilize outside law firms
  3) Explore off-shore review
  4) Pressure external law firms for lower rates

Many law firms are also looking for ways to reduce the cost of document review based on number 4 above; pressure from their clients to reduce the fees they charge for eDiscovery review.

The average civil eDiscovery matter can include between 3 and 5 GB of potentially responsive ESI per employee. To put that in context, 1 GB of data can contain between 10,000 and 75,000 pages of content. Multiply that by 3 and you are conservatively looking at between 30,000 and 50,000 pages of content that should be reviewed for relevancy and privilege per employee. Now consider that litigation and eDiscovery usually includes more than one employee…ranging from two to hundreds.

Traditional linear review, the process used for discovery review for decades, is a manual, expensive, time-consuming and error-prone process requiring teams of legal professionals to review hundreds of thousands or millions of documents one page at a time to determine relevance to a specific case. This review step drives the largest cost of eDiscovery.

In the linear review process, documents are usually split up and given to individual reviewers haphazardly; the first 200,000 go to Bob, the second 200,000 go to Judy, the third 200,000 go to Charles in London and so on. Because of this practice and the lack of document prioritization, potentially critical documents are spread across several reviewers and are not reviewed at the same time and by the same person, greatly reducing consistency.

Traditional linear review is usually accomplished in the following manner (simplified process):

1. 1) Data is collected from affected custodians
   2) Data is collected from enterprise repositories
   3) Keyword searches are run on collected data to build a "potentially responsive data set"
   4) The potentially responsive data set of 112 GB (1.12 million documents) is sent to outside counsel for review and tagging
   5) Outside counsel assigns a team(s) of attorneys to review 1.12 million documents for privilege and relevance
   6) At $70/hour and a review rate of 55 documents per hour, total document review costs $1.425 million

In the white paper, Reducing Costs with Advanced Review Strategies – Prioritization for 100% Review (http://www.recommind.com/resources/knowledge_library/reducing-costs-advanced-review-strategies-prioritization-100-review?utm_medium=advert&utm_source=abajournal-site&utm_campaign=content-prioritization_wp_abajournal)learn how organizations are utilizing advanced review strategies to prioritize documents for more comprehensive Early Case Assessment (ECA) and to save money when performing the review of an entire document corpus.

Advanced review strategies covered in this white paper include:

- A typical linear review process
- Predictive Coding workflows
- Document Prioritization for 100% Review
- The cost savings of Prioritization vs. Linear Review

This content is advertising.

Give us feedback, share a story tip or update, or report an error.

Copyright 2021 American Bar Association. All rights reserved.

Exhibit 10

Advanced Analytics Value for Small Document Review Cases

BLOG June 18, 2020 by Aaron Boone, Esq. and Maureen Murchie, CEDS | 5 min read

Can I Use Advanced Analytics For a Small Case?

There is a common misconception that advanced analytics value is derived only on large document sets and that not all cases are big enough to truly benefit from them. So many times, I've been on calls with outside or in-house counsel and heard the questions: "Will advanced analytics be useful on such a small set?" or "Is this really enough documents to make advanced analytics worth it?"

In short, the answer is YES!

I understand and can appreciate the misconception; TAR, in its earlier days, used to require a good amount of documents in order to feed and seed them. If we'd had this conversation

three years ago and you didn't have that initial volume to start, then the answer may well have been that we couldn't make much use out of advanced analytics on your small document set. However, to borrow (clumsily) from Bob Dylan:

The Tools They Are A-Changin'

TAR 1.0 takes a set of documents reviewed by attorneys and then uses those decisions to make a prediction on the remaining docs—end of story. Since 2017, Brainspace and Relativity have introduced Active Learning and CMML (Continuous Multimodal Learning), also known as TAR 2.0 or supervised analytics, which takes the docs we feed and *continuously* reviews and continuously scores. Every scoring decision is applied to future documents, so the predictions get smarter and more accurate as the review moves forward.

Today we have advanced analytics capabilities that extend beyond TAR, and it is these tools that can result in the biggest savings for your smaller cases. Most advanced analytics tools come in a bundled deal, meaning that if you use one tool in the platform, you have access to all of the tools. **Email Threading**, **Near-Duplicate Identification**, and **Textual Duplicate Identification** are three of the primary tools you've probably already encountered.

Here are some lesser-known advanced analytics tools that can come in handy as well:

- **Name Normalization** will gather all variations of someone's email and put their name in a field. For example, I have my work email, a google email, a yahoo email, and probably some others. The analytics would identify all those emails as mine and put my name in a field. This is especially helpful for privileged logs.
- **Language Identification** is just that: a tool that identifies the primary and secondary languages used in your data set. This is great to run at the start of a case to figure out staffing needs, like whether you'll need to hire Spanish, German, or Japanese reviewers for a foreign language document review.
- **PII Identification** will flag documents for social security account numbers or anything else that may be confidential so you can redact that information.

Since these tools come in a bundled deal, some clients may think: *I only need one tool. If I'm not going to use all the tools, is it worth having the whole bundle?*

The short answer is YES. But to address this question with another question, let's return to the original discussion topic: *Does this case have enough documents to use analytics?*

Some Easy Math…

Let's look at **a case of 1,000 documents**. Let us also assume that this is a sole practitioner, so only one person is reviewing the documents. I will use some industry averages to show the advanced analytics value.

1. The average attorney will review 50 documents per hour.
2. The average attorney will charge $200 per hour.
3. The average document reduction from email threading, if looking only at the unique threads, is 20%.
4. The average increase of review speed, from viewing threads together, is at least 10%.

Let's say you have a vendor who charges 4 cents per doc for advanced analytics.

Cost of Review Without Email Threading:

- 1,000 documents reviewed at 50 documents per hour is 20 hours.
- 20 hours at $200 per hour is $4,000.
- *Total cost of review:* ***$4,000****.*

Cost of Review with Email Threading:

- 800 documents reviewed at 55 documents per hour is 14.5 hours.
- 14.5 hours at $200 per hour is $2,900.
- Cost to run advanced analytics is 1,000 x $.04 which equals $40.
- Cost of a tech to run advanced analytics $200 per hour x 0.5 hours is $100.
- *Total cost of review:* ***$3,040.***

Total Savings: $960

As you can see, advanced analytics value can have a tremendous impact, regardless of the size of your case. Keep in mind that the above scenario uses only one of the many tools available

through the advanced analytics bundle. Our BIA team of lit tech experts working on your document sets might find, for instance, that we are able to mass tag a number of near or textual duplicates together. Using other tools in the bundle could easily increase the average review rate to 60 documents per hour, saving you or your client another 300 dollars.

Of course, the definition of “a small case” is different for everyone. It could mean one thousand documents for one client or ten thousand for another. But those smaller cases are where you’ll start to see the biggest savings and the highest advanced analytics value when you choose a review company that will use advanced analytics on your document review sets. At BIA, our tools are top-shelf, and our people have the top levels of training and certifications needed to run these tools at their maximum capacity for speed, accuracy, and efficiency.

So the next time you find yourself wondering if you have enough documents, or if you can convince your client of the advanced analytics value for your case, I hope you’ll stop wondering and give BIA a call. Our answer is YES.

Exhibit 11

Answering Your Questions about Legal Document Review

BLOG October 10, 2019 by BIA | 9 min read

Back in 2017, we partnered with Emily Cobb from Ropes & Gray, LLC and the team at ACEDS to host a webinar covering the ins and outs of successful document review. It was a thoughtful, helpful discussion on strategies and tips for improving the document review process, and we covered a lot of ground during the one-hour program, from modern approaches to managed review, technology-assisted review (TAR), putting together a review team and more.

Attendees posed a lot of great questions and we shared them on the BIA Blog. Since managed review tools and strategies are always changing for the better, we thought it would be beneficial to refresh and re-share the Q&A to keep the discussion fresh and ongoing. We hope you find this information helpful!

1. What is the average rate of legal document review, per reviewer, on an hourly basis?

It all depends on the complexity of the legal document review protocol, really. Reviews with simple protocols and easy "yes" or "no" questions will go very quickly, but if your review project is highly complex, then the review rate will be slower.

For example, the average rate of legal document review for emails only, if you're only coding for responsiveness, could be anywhere from 70-80 documents per hour. However, if your reviewers are sifting through formulas in spreadsheets, you can expect them to spend a lot more time on each document, not only to review the information but to open the document in its native software. While some review platforms provide a decent spreadsheet view, the best way to view all the information in a spreadsheet is still to open it in Excel or Google Sheets. That means a reviewer may only look at 20-30 documents in an hour.

In general, assuming that reviewers are looking at a mix of documents that include some spreadsheets, most reviewers average 40-50 documents per hour.

2. When a law firm associate is overseeing an eDiscovery/managed legal document review project, what is the role of the project manager at the vendor or corporate client?

Put simply, the role of the project manager is to work with a law firm associate to keep him or her informed on the status of each step of the project, including document collection, processing, search results, review and production. In addition to providing reports and metrics on the case, the project manager is also there to troubleshoot any issues or facilitate things like complicated search term requests.

A project manager at the corporate client would be in a similar position. There's usually a point person at the corporation who takes the lead in facilitating data collections. During the webinar, our colleague and fellow presenter Emily Cobb pointed out that it's the law firm's neck on the line in terms of what's reported out. As such, it's the law firm associate that has the final say on most substantive issues.

We also did a previous webinar on the role of the eDiscovery project manager, which goes more in-depth, and can be seen here.

3. Does outside counsel need to do 100% of the quality control of documents reviewed by contract attorneys or the managed review vendor?

Generally speaking, no. Of course, that assumes that you have a reasonable level of confidence in the process, the people and the vendor. Whether done in-house with contract attorneys or outsourced to a vendor, quality results depend on a quality process from the outset. It helps to have an ongoing dialogue between the review team and counsel so there is a process to track questions asked and answered. This promotes consistency and quality in the review product.

Quality control in document review typically involves random samplings throughout the review process. If the review is being handled by a vendor's review team or contract attorneys, they usually have their own QC process, in addition to what outside counsel will do.

We suggest that the samplings happen more often and are more encompassing at the beginning of the process, looking at the results on an individual reviewer basis to get a sense of how accurately each person is coding. Also look to see if any problems are widespread, as this could mean the review protocol was not properly explained or understood.

It's also good to look at overturn reports, which show when document coding was overturned by the QC person. If there are patterns there – such as certain types of documents that get changed often, or if one reviewer's coding calls are overturned more regularly – you can gain insight into any potential issues and make adjustments as needed.

With a strong focus on quality, combined with both general and individual feedback addressing any quality concerns from the outset, you can help ensure that the overall process is a success. As that proceeds and you become comfortable with your reviewers and the protocols for that review project, the QC process can be scaled back a bit, but should still include random samplings of the entire document set throughout the review.

That said, there are certain documents for which we do recommend to have a 100% quality-check review, whether it's done by outside counsel or senior level reviewers at your vendor (or

a combination of both). At BIA, for example, we always make sure there is a second set of eyes from our team on all documents coded as privileged or "hot."

4. How has the quality control process matured over time with the "modern" approach? How can we best leverage technology to track errors, etc.?

Technology now allows us to more easily locate items that need to be quality controlled. For example, we utilize TAR technologies not just in review, but also in our QC processes, helping to quickly highlight any quality concerns. In the past, we would have had to go through the entire document review process before there were insights to pull. Now, we can quickly and easily glean valuable insights, such as specific areas of documents that need to be quality controlled.

5. What kind of supervision do you give to a first or second-year associate managing an eDiscovery/managed legal document review project?

We do give more training and support to people who are new to the process. We believe it is BIA's responsibility to our clients to make sure all associates – and really everyone involved – fully understand and are comfortable with the proven processes that we have established. We don't want anyone to fail.

6. Why do firms not utilize eDiscovery staff attorneys more?

This is an interesting question. Before BIA, I (Barry) worked at a law firm that managed document review projects with more than 160 contract attorneys on multiple projects. What we found was that having so many contract attorneys on multiple projects kept us from building institutional knowledge for a case or client. We changed that process to employ 10-11 staff attorneys and recruited out of our existing talent pool of 160+ contract attorneys.

Staff attorneys cost less because they're not on the partner track at a firm, but they still bill higher than contract attorneys – so there are two sides at play. But in general, staff attorneys *build cost-effective institutional knowledge*, and they provide consistent coding.

That's the same philosophy that we use at BIA with our Managed Document Review Services team, which provides the benefits of staff attorneys – including being cost-effective and maintaining institutional knowledge – with the ability for our clients to use our attorneys as needed like one would with a contract attorney review team.

7. Are there any quality issues with the per-doc model's incentive to get through legal document review quickly?

No, quite the opposite. With the per-document pricing model, the incentive is directly built into the model to get it right the first time around.

BIA's preferred practice is to bill per document versus per hour, as we find it's not only more predictable for the client, but easier for everyone to manage. We touched on this somewhat during the webinar, and it is discussed in more depth here.

Simply put, legal document review must be done accurately, or, regardless of how quickly it was done or how it was billed, it will have to be done again. Our per-doc model of review puts that burden where it should be – on us. If we don't maintain the highest quality, then documents will need to be re-reviewed, which negatively impacts our profit on the project. Thus, inherent in the very model is the incentive for quality from the outset.

BIA's well-designed process allows for reviewers to take the necessary time to code documents correctly the first time and includes both team management and our comprehensive quality control process all in one simple price. We are convinced of this model's effectiveness for several reasons, but our favorite is that not a single BIA client utilizing this model has ever looked back.

8. If the other party does not specify format can you produce in the format you deem reasonable?

Per the federal rules, the answer is yes. However, what one side deems reasonable isn't necessarily what the other side will agree upon. It's good to confirm – more than once – what the specified format will be, just to avoid any back-and-forth in court. It's not worth the money or time on either side to argue about the format. We suggest agreeing on an ESI production protocol at the outset of a matter to minimize ambiguity when completing productions.

9. How do you measure, monitor and track productivity and quality?

This is a good sum-up question. At BIA, we look at each individual reviewer's rate of review (documents per hour) and then measure speed, accuracy, the difficulty of the review material, amount of errors per set and time spent reviewing. Conducting these measurements gives us a good indication of how the review is going and points out areas for improvement, be that for an individual or an entire team.

Want to streamline your document review? Check out our webinar, **Document Review: The EDRM's Final Frontier**, that discusses how to approach, plan for and execute a successful document review.

Want to learn about using analytics in document review? In our recent Practical Uses of Brainspace webinar, we discuss how we leverage their technology to deliver unparalleled accuracy and cost savings to our Managed Document Review offering.

Exhibit 12

Document Review Calculator

How much does an eDiscovery document review cost?

What does managed review cost per document?

How many documents can an attorney review in an hour? In a day?

Electronic discovery costs and document review speed turns on several variables:

- The review type (is it a first pass review for relevance, or are documents coded for legal issues)?
- Is redaction needed? (Does the ESI (electronically stored information) contain personally identifiable information or sensitive information that needs to be kept confidential?)
- Is it a linear attorney review with eyes on every document, or a technology assisted review (TAR --the use of eDiscovery analytics, artificial intelligence or machine learning)?
- What eDiscovery document review software is being used and is there a monthly cost per gb (gigabyte) for data hosting?

How do these factors impact document review cost?

Speed: The number of coding decisions for each document decreases document review speed. Simple yes/no, (is it relevant?) first pass review
document review. However, if reviewers must apply is
increases.

Redaction: Redacting documents also slows docume

LIKE WHAT YOU SEE?

Receive email updates on legal tech, legal ops, and e-discovery

Sign Up Now!

identify and hide sensitive information than it does to make relevance decisions about ESI.

Thus, the average document review speed varies. From 25 documents an hour per reviewer for heavy redaction to 100 documents per hour (or more) if coding decisions are limited. Assuming an eight-hour day, the number of documents reviewed per day (by reviewer) is 200 on the low end to 800+ on the high end.

Linear Review or TAR: If attorney document reviewers need to code every document, the hourly costs and review cost per document increase. If technology is used to reduce the volume of ESI reviewed, costs decrease.

eDiscovery Software Pricing: eDiscovery software costs also impact total document review charges. Historically, billing for eDiscovery tools is based on monthly per gigabyte charges. But eDiscovery pricing structures are changing. Flat fees and other pricing models are offered.

So, what is your document review going to cost? Use the calculator below to get a ballpark estimate. (NOTE: the estimate does not include pre or post-review processing costs that many eDiscovery vendors charge).

ESI Document Review Cost Calculator

Number of Files to Review

If using technology assisted review (TAR) deduct lower ranking files not subject to actual review.

Type of Review and Level of Redaction

Use slider to adjust review characteristics

Little to no Redaction & Broad Relevance Coding

LIKE WHAT YOU SEE?

Receive email updates on legal tech, legal ops, and e-discovery

Sign Up Now!

Significant Redaction or Heavy Issue Coding

Number of Months Review Data Hosted

Gigabytes of Data to Host

Leave blank if unknown and industry average will be used.

Document Reviewer Hourly Rate ($)

Hours Needed to Complete Review 0.00

Total Cost $0.00

Enter Address to Receive Results via Email.*

PERCIPIENT

Learn

Articles & Resources

Technically Legal Podcast

Company

About

Servi

Conta

Talk to Us

LIKE WHAT YOU SEE?

Receive email updates on legal tech, legal ops, and e-discovery

Sign Up Now!

(c) Percipient, LLC – not a law firm and
not licensed to practice law in any jurisdiction.
Privacy Policy
Website construction by WorkSite, LLC

LIKE WHAT YOU SEE?

Receive email updates on legal tech, legal ops, and e-discovery

Sign Up Now!

Exhibit 13

Subscribe Send Tips

SPONSORED CONTENT, TECHNOLOGY

Privilege Analytics From H5: The Best Way To Handle Privilege Review

Privilege review and logging no longer has to be a chore you dread.

By Above the Law

December 6, 2021 at 4:40 PM

H5 is now Lighthouse, which strengthens our ability to modernize the eDiscovery and information governance space with a technology-first focus, meet accelerated demand for technologies and services that span the entire client data life cycle, and fully embrace the rapid shifts to cloud and hybrid environments. For more details, visit:

https://www.lighthouseglobal.com/news-events/lighthouse-completes-acquisition-of-h5

Protecting privilege is one of the most critical aspects of any legal matter. Unfortunately, it can also be one of the most confusing and time-consuming. While eDiscovery has seen significant advances in recent years, identifying potentially privileged documents, reviewing them, and ultimately logging them remains an arduous task.

H5 is finally changing all that. H5's sophisticated Matter Analytics application was built from the ground up to give you a better eDiscovery experience from within Relativity. The Privilege Analytics solution within Matter Analytics blends together analytics capabilities and proprietary, pre-trained linguistics models to help you more easily identify privileged content, create better workflows for reviewing it, focus in on potential privilege-breaking scenarios, and seamlessly create privilege logs.

Simply put, privilege review and logging no longer has to be a chore you dread.

How It Works

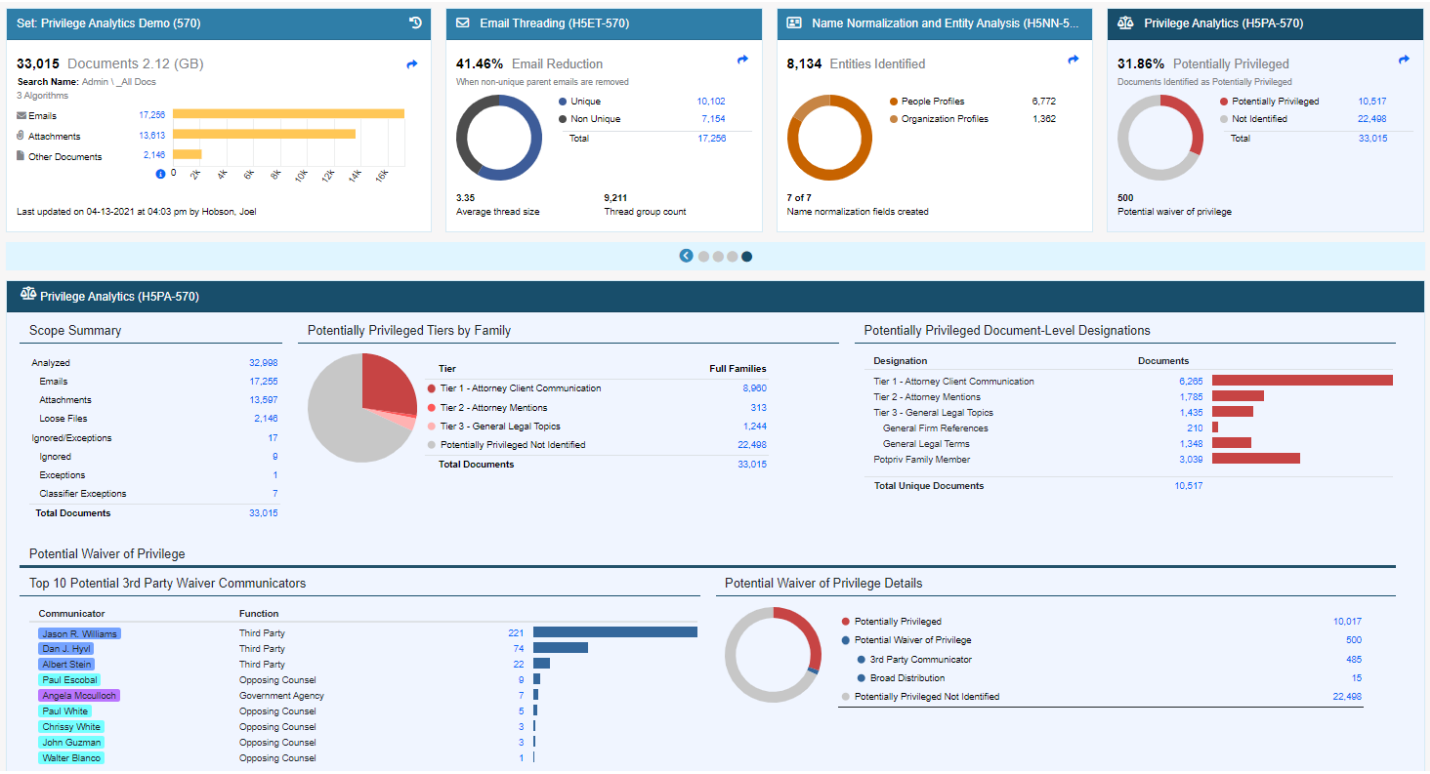
One of the key things to know about Matter Analytics and Privilege Analytics from H5 is that these tools exist inside Relativity. They don't require navigating to outside applications like some other eDiscovery solutions – all of your data stays within Relativity and the privilege analysis happens there, making for significantly streamlined workflows and maximum functionality.

H5 has heavily refined its proprietary algorithms over the years, as well as worked hard to seamlessly integrate their analytics into Relativity to improve the privilege review experience, with the help of functions like their proprietary threading and name normalization (more on that in a bit). Better yet, H5's staff uses the software itself every day – so they're not just blindly developing it, they're developing it to actually work. And they've succeeded.

Privilege Identification

Privilege Analytics' core functionalities target the two main facets of privilege – understanding who the privileged actors are and what legal concepts are at issue (the "who" and the "what" of privilege).

Identifying privileged documents starts with tackling the "who" through threading and name normalization. On your main Privilege Analytics screen, you start with an analytics set of all documents that have been analyzed, broken down into useful graphic cards that give you a high-level snapshot of exactly what you're dealing with.



You can click into any card to get more detail about the analysis, including insight into threading and name normalization.

Threading is an intuitive and powerful way of analyzing and viewing communications in your potential production. You can think of every thread as a tree with branches. Privilege Analytics makes it easy to see last-in-time messages, or the ends of the branches where privilege is often broken.

It also performs a full attachment analysis to find all inclusive attachments for every thread and a full recipient analysis that includes BCCs, which many solutions don't take into consideration.

Name normalization is the next step, and it's aimed at trying to really understand not just who the people are in your document set, but also what organizations they belong to and what function they play in the data population. Names can be associated with roles like in-house or outside counsel, or adversarial organizations and government agencies that might be privilege-breakers.

Privilege Analytics allows you to pre-categorize individuals based on their function, and you can reuse those categorizations from one matter to the next. If you do a lot of work on behalf of the same client, this feature is a great way to carry your knowledge base over, ensure consistency, and accelerate your privilege identification in subsequent matters.

Name normalization doesn't stop at a party's function. It takes into account all the different variations in how a person is addressed and the different email addresses they might use. Domain names are also parsed to better understand the organizations at play in your document set. Accounting for all these variances is usually a painful slog of merging profiles and cleaning up details that takes significant time in its own right. Privilege Analytics makes it easy, and this is yet another useful feature that you can carry forward into other matters.

Running threading and name normalization together is a powerful combination that gets you to the "who" of your privilege review much more quickly and accurately than other eDiscovery solutions on the market.

Once you know the "who," you can focus on the "what." Privilege Analytics is pre-trained on over 500 privilege concepts to parse the subject of communications. Using linguistic modeling, the system can hone in on specific aspects of communications, rather than just recognizing likely patterns for privileged documents – so if you have two privileged lines in an email that's otherwise about holiday plans, the system will still catch it.

The results of the threading and name normalization are then paired with the privilege concepts to quickly identify and tier levels of privilege in the data population.

Tier one communications are those that involve both identified privileged actors and privileged legal topics.

One of the tricky but critical aspects of any privilege review is identifying when an existing privilege scenario has been broken. Privilege Analytics makes this complicated task much easier. The system looks not only for privileged actors in email threads, but also for third parties on otherwise privileged communications. When such a potential privilege-breaker is identified, the documents are flagged as being potential third-party waivers.

Privilege Review

The tiering feature creates an ideal starting point for your privilege review because it allows you to get at the most sensitive material right out of the gates.

The H5 Matter Analytics thread viewer takes your privilege review to the next level. Color coding of thread branches (red for privileged actors, blue for third parties) makes it easy to see if privilege was broken, and you get to graphically see the branches of how a communication evolved.

If you see a blue branch, you know your privilege might have been broken. This view is available right in Relativity, even though it's a feature you don't normally get in Relativity itself. It will also pull in flags from Relativity for things like redactions.

Privilege Analytics pulls together all parts of a thread into a comprehensive conversation view of the communication, with every segment in order. You can see exactly when people joined or left the conversation. In addition to the branch color coding, the privileges subjects that were identified via the linguistic modeling are highlighted.

Once you finish reviewing a thread and have made your privilege decision, you can simply advance to the next thread, rather than moving document by document.

Whether you're engaged in second-pass review or the QC stage, Privilege Analytics is the easiest way to make informed coding decisions that eliminate some of the most common mistakes that increase the risk of privilege exposure.

Privilege Logging

Unfortunately, your job's not done when you finish your privilege review. Creating privilege logs usually ranks low on the list of any attorney's favorite tasks. Thankfully, Privilege Analytics makes that easier, too.

As the system identifies potentially privileged documents, it also assigns auto-reasons for the privilege identification, which are a great starting point for your privilege log. While you may need to add more detail or make a few tweaks, the system gives you the building blocks to log your documents quickly and accurately.

To create a log, select a saved set of documents and select a template (or create a new one yourself). Privilege Analytics generates the document list populated with all the requisite fields, all the individuals identified in every branch of the thread, and the auto-reasons for privilege.

If you need to see an individual document, you can navigate to it with just a click.

You can edit the log just as you would in Excel to make the final version look exactly the way you need it to look. Your final output can exist as either an object directly in Relativity or it can be exported to Excel. You get a beautiful and, more importantly, accurate privilege log without all the intensive manual labor you're used to.

Installing Privilege Analytics usually takes less than 15 minutes and H5 has a great evaluation offer where you can try it for yourself. Chances are, you'll be sold. If you're interested in trying Privilege Analytics with your H5 hosted matter, please contact H5 for more information".

With something as important as privilege on the line, you can't afford to keep doing things the old way.

TOPICS

Above the Law daily newsletter

Enter your email address

Subscribe Now

We will never sell or share your information without your consent. See our privacy policy.

Exhibit 14

Siri | Glimstad

200 Park Avenue, Seventeenth Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

FREEDOM OF INFORMATION ACT REQUEST
EXPEDITED PROCESSING REQUESTED

VIA ONLINE PORTAL September 14, 2021

Food and Drug Administration
Division of Freedom of Information
Office of the Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: *Ingredients in Pfizer Vaccine (IR#0558)*

Dear Sir or Madam:

This firm represents the Informed Consent Action Network ("**ICAN**").

On August 23, 2021, the Food and Drug Administration ("**FDA**") approved the Pfizer-BioNTech COVID-19 Vaccine, Comirnaty (the "**Pfizer Vaccine**"). On behalf of ICAN, please provide the following records to foia@sirillp.com in electronic form:

> **Please provide a copy of page 8 of the document available at https://www.fda.gov/media/151733/download, without any redaction of the ingredients listed at the top of that page. For the avoidance of doubt, the redactions that this request seeks to lift are as follows:**

Ingredients	Quantity after Dilution (per vial)	Function
(UNII: 451W47IQ8X)		
Dibasic sodium phosphate dihydrate (UNII: GR686LBA74)	0.49 mg	Excipient
Sucrose (UNII: C151H8M554)	46.0 mg	Excipient
(b) (4) (UNII: (b) (4))	0.450 mL	Excipient

UNII: Unique Ingredient Identifier

ICAN requests expedited processing for this request. ICAN is "primarily engaged in disseminating information to the general public" and there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II). Specifically, ICAN's mission is to raise public awareness about public health and safety and to

provide the public with information to give informed consent regarding related health interventions and precautions. As part of its mission, ICAN disseminates information to an audience of approximately 5 million people.

The FDA "is responsible for protecting public health by ensuring the safety[] [and] efficacy . . . of . . . biological products[.]"[1] As part of that responsibility, the FDA approves drugs and biologics, typically, before they become available to the public.[2] Congress mandated that the FDA only approve a product if its sponsor has proven it to be "safe and effective." *See, e.g.*, 21 U.S.C. § 393.

The FDA claims that it is committed to "open[ing] the doors of the agency." In that regard, it maintains an entire section on its website dedicated to transparency.[3] However, in approving the Pfizer Vaccine for individuals 16 years of age and older, the FDA refused to release much of the information necessary to inform the public as to the composition of the Pfizer Vaccine, including the names of certain ingredients and their unique ingredient identifier (UNII).[4] This information is a matter of current exigency to the American public for two reasons.

First, there is an ongoing, public national debate regarding the adequacy of the data and information, and analyses of same, relied upon by the FDA to license the Pfizer Vaccine. On the one hand, there are numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms that have declared that the data and information underlying the licensure of the Pfizer Vaccine is more than sufficient for licensure.

For example, in a press release issued on August 23, 2021, acting FDA Commissioner Janet Woodcock stated that "the public can be very confident that [the Pfizer Vaccine] meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product."[5] Peter Marks, the director of FDA's Center for Biologics Evaluation and Research, made similar remarks, stating that

> **[The FDA's] scientific and medical experts conducted an incredibly thorough and thoughtful evaluation of [the Pfizer Vaccine]. We evaluated scientific data and information included in hundreds of thousands of pages, conducted our own analyses of [the Pfizer Vaccine's] safety and effectiveness, and performed a detailed assessment of the manufacturing**

[1] https://www.fda.gov/about-fda/what-we-do (last visited 8/25/2021).

[2] https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved (last visited 8/23/2021).

[3] https://www.fda.gov/about-fda/transparency (last visited 9/14/2021).

[4] https://www.fda.gov/media/151733/download (last visited 9/14/2021).

[5] https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited 9/8/2021).

> **processes, including inspections of the manufacturing facilities[.][6]**

Peter Marks further stated that "although [the FDA] approved [the Pfizer Vaccine] expeditiously, it was fully in keeping with [the FDA's] existing high standards for vaccines in the U.S."[7] President Biden also stated that the FDA's approval meets the "gold standard."[8] Even prior to FDA approval of the Pfizer Vaccine, government officials, public health authorities, and medical professionals repeatedly claimed that COVID-19 vaccines are "safe and effective."[9]

On the other hand, numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms have publicly raised questions regarding the sufficiency of the data and information, adequacy of the review, and appropriateness of the analyses relied upon to license the Pfizer Vaccine. For example, on June 1, 2021, a group of 27 clinicians and scientists filed a Citizen Petition[10] with the FDA, claiming that the available evidence for licensure of the Pfizer Vaccine "is simply not mature enough at this point to adequately judge whether clinical benefits outweigh the risks in all populations."[11]

Peter Doshi has publicly questioned the lack of transparency regarding the vaccine approval process,[12] which Peter Marks publicly disputed.[13] Peter Doshi has also questioned the adequacy of the data on the basis that the Pfizer Vaccine is only "13 months into the still ongoing, two year pivotal trial, with no reported data past 13 March 2020, unclear efficacy after six months

---

[6] *Id.*

[7] *Id.*

[8] https://www.cbsnews.com/news/biden-address-covid-19-vaccine-pfizer-fda-approval-watch-live-stream-today-2021-08-23/ (last visited 9/8/2021).

[9] *See, e.g.*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html#:~:text=COVID%2D19%20vaccines%20are%20safe,vaccine%20as%20soon%20as%20possible. (last visited 9/8/2021). *See also* https://www.hhs.gov/ ("COVID-19 vaccines are safe, effective, and free) (last visited 9/8/2021); https://www.who.int/news-room/feature-stories/detail/vaccine-efficacy-effectiveness-and-protection ("COVID-19 vaccines have proven to be safe, effective and life-saving.") (last visited 9/8/2021); https://www.doh.wa.gov/Emergencies/COVID19/VaccineInformation/SafetyandEffectiveness ("COVID-19 vaccines are safe") (last visited 9/8/2021); https://www.wlns.com/news/gov-whitmer-and-dr-khaldun-respond-to-the-fda-approval-of-pfizers-covid-19-vaccine/ (quoting Governor Whitmer referring to the Pfizer Vaccine as a "safe, effective COVID-19 vaccine") (last visited 9/8/2021).

[10] https://www.regulations.gov/document/FDA-2021-P-0521-0001 (last visited 9/8/2021).

[11] *See* https://blogs.bmj.com/bmj/2021/06/08/why-we-petitioned-the-fda-to-refrain-from-fully-approving-any-covid-19-vaccine-this-year/ (last visited 9/8/2021).

[12] *See* https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/ (last visited 9/8/2021); https://blogs.bmj.com/bmj/2021/01/04/peter-doshi-pfizer-and-modernas-95-effective-vaccines-we-need-more-details-and-the-raw-data/ (last visited 9/8/2021); https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-and-first-see-the-full-data/ (last visited 9/8/2021).

[13] https://www.statnews.com/2020/12/17/did-the-fda-understaff-its-review-of-the-pfizer-biontech-vaccine/ (last visited 9/8/2021).

due to unblinding, evidence of waning protection irrespective of the Delta variant, and limited reporting of safety data."[14]

Andrew Kheriaty, professor of psychiatry at UCI School of Medicine, Director of the Medical Ethics Program at UCI Health,[15] has also questioned the FDA's approval process. For example, in an article published in the Wall Street Journal, Dr. Kheriaty questioned the need for student vaccination requirements based on, among other things, a review[16] by the FDA's Vaccines and Related Biological Products Advisory Committee ("**VRBPAC**") that indicates a risk of heart inflammation after vaccination.[17]

Government officials have raised similar concerns about the lack of transparency in the review process, arguing that it is "essential" for the FDA to, among other things, "make the data generated by clinical trials and supporting documents submitted to the FDA by developers available to the public[.]"[18] Despite all eyes on the COVID-19 vaccines and calls for transparency regarding the FDA's actions, the FDA did not convene its advisory group, VRBPAC, to have a public meeting prior to licensure. Those interested were denied the opportunity to both hear discussion about the data and to offer public comment about same.

The public debate regarding the adequacy of the FDA's review process and the safety and efficacy of the Pfizer Vaccine is unlikely to be settled without full disclosure of the ingredients in the same.

The second reason that this request is of a matter of current exigency is that the Pfizer Vaccine is being mandated to individuals across the country by the federal government,[19] local

---

[14] https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/ (last visited 9/8/2021).

[15] https://www.aaronkheriaty.com/bio (last visited 9/8/2021).

[16] https://www.fda.gov/media/150054/download (last visited 9/8/2021).

[17] https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220 (last visited 9/8/2021).

[18] https://www.warren.senate.gov/imo/media/doc/2020.09.14%20Letter%20to%20FDA%20re%20transparency%20in%20vaccine%20review%20process_.pdf (last visited 9/8/2021). *See also* https://www.washingtontimes.com/news/2021/aug/23/editorial-the-coincidental-timing-of-pfizers-vacci/ (last visited 9/8/2021).

[19] *See, e.g.*, https://www.natlawreview.com/article/covid-19-vaccine-added-to-requirements-green-card-processing-effective-oct-1 (last visited 9/8/2021); https://apnews.com/article/business-health-coronavirus-pandemic-coronavirus-vaccine-4cf7451267919302de4a7b591508e80c (last visited 9/8/2021); https://www.forbes.com/sites/joewalsh/2021/08/09/us-military-will-require-covid-vaccinations-by-mid-september/?sh=78defacd6c9f (last visited 9/8/2021); https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/29/fact-sheet-president-biden-to-announce-new-actions-to-get-more-americans-vaccinated-and-slow-the-spread-of-the-delta-variant/ (last visited 9/8/2021).

governments,[20] public and private employers,[21] universities, [22] schools,[23] and various other institutions,[24] and many more entities are expected to follow suit.[25] At the federal level, legislation was recently introduced that would require COVID-19 vaccines for air travel into or out of the

---

[20] *See, e.g.*, https://www.cnn.com/2021/08/12/us/san-francisco-vaccine-requirement/index.html (last visited 9/8/2021); https://www1.nyc.gov/site/doh/covid/covid-19-vaccines-keytonyc.page (last visited 9/8/2021); https://news.yahoo.com/orleans-now-requires-proof-vaccination-230433492.html (last visited 9/8/2021).

[21] *See, e.g.*, https://www.cnbc.com/2021/08/06/united-airlines-vaccine-mandate-employees.html (last visited 9/8/2021); https://sanfrancisco.cbslocal.com/2021/08/02/covid-kaiser-permanente-makes-vaccination-mandatory-for-all-employees/ (last visited 9/8/2021); https://abcnews.go.com/Health/wireStory/walmart-mandates-vaccines-workers-headquarters-79177220 (last visited 9/8/2021); https://www.kpbs.org/news/2021/aug/17/encinitas-covid-19-vaccine-negative-test-employees/ (last visited 9/8/2021); https://www.cnbc.com/2021/08/09/covid-vaccine-mandates-sweep-across-corporate-america-as-delta-surges.html (last visited 9/8/2021); https://www.reuters.com/business/energy/chevron-begins-covid-19-vaccination-mandates-wsj-2021-08-23/ (last visited 9/8/2021); https://thehill.com/policy/healthcare/569051-pfizers-full-approval-triggers-new-vaccine-mandates (last visited 9/8/2021); https://cvshealth.com/news-and-insights/statements/cvs-health-will-require-covid-19-vaccinations-for-clinical-and-corporate-employees (last visited 9/8/2021).

[22] *See* https://universitybusiness.com/state-by-state-look-at-colleges-requiring-vaccines/ (last visited 9/8/2021). *See also, e.g.*, https://www.nbcnews.com/health/health-news/colleges-universities-covid-vaccination-mandates-facing-pushback-n1273916 (last visited 9/8/2021); https://www.colorado.edu/covid-19-updates/covid-19-vaccination (last visited 9/8/2021); https://uhs.berkeley.edu/requirements/covid19 (last visited 9/8/2021); https://huhs.harvard.edu/covid-19-vaccine-requirement-faqs (last visited 9/8/2021); https://www2.gmu.edu/safe-return-campus/vaccination-requirements (last visited 9/8/2021); https://www.pc.pitt.edu/news/vaccine-disclosure-requirements-2021-2022-campus-housing (last visited 9/8/2021)

[23] *See, e.g.*, https://www.npr.org/sections/back-to-school-live-updates/2021/08/20/1029837338/a-california-school-district-mandates-vaccines-for-eligible-students (last visited 9/8/2021); https://patch.com/massachusetts/salem/salem-school-committee-approves-vaccine-mandate-sports-band (last visited 9/8/2021); https://www.nbcnewyork.com/news/coronavirus/nyc-will-require-vaccination-for-high-risk-school-sports/3232745/ (last visited 9/8/2021); https://www.nj.com/hudson/2021/08/hoboken-believed-to-be-first-in-state-to-issue-mandate-for-students-12-and-up-get-vaccine-or-face-weekly-testing.html (last visited 9/8/2021); https://www.mercurynews.com/2021/08/19/la-county-school-district-mandates-covid-vaccines-for-k12-kids-others-soon-may-follow/ (last visited 9/8/2021).

[24] *See, e.g.*, https://www.reuters.com/world/us/new-york-city-mandates-covid-19-vaccine-public-school-teachers-staff-mayor-2021-08-23/ (last visited 9/8/2021); https://www.cbsnews.com/news/california-covid-vaccine-teachers-mandate/ (last visited 9/8/2021); https://www.nytimes.com/2021/08/18/us/washington-state-teacher-vaccine-mandate.html (last visited 9/8/2021); https://www.governor.ny.gov/news/governor-cuomo-announces-covid-19-vaccination-mandate-healthcare-workers (last visited 9/8/2021); https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/FAQ-Health-Care-Worker-Vaccine-Requirement.aspx (last visited 9/8/2021); https://www.nytimes.com/2021/08/09/us/washington-state-workers-vaccine-mandate.html (last visited 9/8/2021); https://www.denvergov.org/Government/COVID-19-Information/Public-Health-Orders-Response/News-Updates/2021/Mayor-Hancock-Announces-COVID-19-Vaccine-Requirement-for-Employees (last visited 9/8/2021); *See* https://www.bostonherald.com/2021/08/19/baker-issues-vaccine-mandate-for-42000-state-employees/ (last visited 9/8/2021).

[25] *See* https://www.mississippifreepress.org/15126/fda-fully-approves-pfizer-biontech-vaccine-mandates-to-follow/ (last visited 9/8/2021); https://www.huffpost.com/entry/vaccine-mandates-roll-out-fda-approval_n_6123e028e4b0df3eacd5d657 (last visited 9/8/2021); https://www.theadvocate.com/baton_rouge/news/coronavirus/article_9be6d02c-0434-11ec-b7b1-cb17d8495274.html?utm_medium=social&utm_source=twitternoladotcom&utm_campaign=snd (last visited 9/8/2021). *See also* https://www.latimes.com/california/story/2021-08-26/california-lawmakers-grapple-with-statewide-covid-19-vaccine-mandate (last visited 9/8/2021).

United States[26] and the Pentagon has mandated COVID-19 vaccines for all military personnel.[27] In addition, Present Biden recently announced vaccine mandates for all employers with 100 or more employees, all federal employees, and all employees of federal contractors.[28] At the state level, legislation has been introduced to require COVID-19 vaccines for all post-secondary students,[29] all state employees, [30] and even for all citizens of the state.[31] As explained by Dr. Anthony Fauci, "a flood" of vaccine mandates will follow FDA approval of a COVID-19 vaccine[32] and President Biden is actively encouraging "companies in the private sector to step up the vaccine requirements[.]"[33] More recently, it appears that mandates may now encompass additional booster shots of the vaccine in order to retain a "fully vaccinated" status.[34]

Delaying public access to the requested information would compromise a number of significant recognized interests, including ICAN's right, as a media outlet, to timely contribute to the public's understanding of the Pfizer Vaccine and the public's right to have a full understanding of a product being mandated in numerous settings by both governments and private businesses.

---

[26] https://www.congress.gov/bill/117th-congress/house-bill/4980?q=%7B%22search%22:%5b%224980%252 (last visited 8/23/2021).

[27] https://thehill.com/policy/defense/568996-pentagon-to-mandate-covid-19-vaccine-for-military (last visited 8/23/2021).

[28] https://www.whitehouse.gov/covidplan/ (last visited 9/13/2021). *See also* https://www.cnn.com/2021/09/09/politics/joe-biden-covid-speech/index.html (last visited 9/13/2021).

[29] *See* New York bill S6495 available at https://www.nysenate.gov/legislation/bills/2021/S6495 (last visited 9/8/2021).

[30] *See, e.g.*, https://www.nj.com/coronavirus/2021/08/murphy-orders-vaccination-requirement-for-all-nj-state-workers-including-at-public-colleges.html (last visited 9/8/2021).

[31] *See* New York bill A11179 available at https://www.nysenate.gov/legislation/bills/2019/A11179. *See generally* https://eastcountytoday.net/buffy-wicks-transportation-bill-could-become-california-vaccine-passport-bill/ (last visited 9/8/2021).

[32] https://www.usatoday.com/story/news/health/2021/08/06/anthony-fauci-covid-vaccine-mandates-fda-full-approval/5513121001/ (last visited 9/8/2021).

[33] https://www.msn.com/en-us/news/us/biden-urges-private-companies-to-implement-covid-19-vaccine-requirements-following-pfizer-e2-80-99s-fda-approval/ar-AANEcYs?ocid=uxbndlbing (last visited 9/8/2021). *See also* https://www.nytimes.com/2021/08/23/us/pfizer-vaccine-mandates.html (noting that FDA approval of the Pfizer Vaccine "is opening the way for institutions like the military, corporate employers, hospitals and school districts to announce vaccine mandates for their employees") (last visited 8/23/2021); https://www.msn.com/en-us/news/us/now-that-a-covid-19-shot-is-fully-approved-employer-mandates-are-rolling-in-but-will-vaccination-rates-in-the-us-go-up/ar-AANGDTy?ocid=uxbndlbing (last visited 8/23/2021); https://news.yahoo.com/surgeon-general-vivek-murthy-says-205530053.html (quoting the Surgeon General referring to vaccine mandates as "reasonable") (last visited 8/23/2021).

[34] *See* https://www.nbcnews.com/health/health-news/u-s-announces-plan-offer-boosters-all-americans-starting-late-n1277059 (quoting the U.S. Surgeon General stating "it is our clinical judgment that the time to lay out a plan for Covid-19 boosters is now") (last visited 9/13/2021); https://www.youtube.com/watch?v=ciVGAPuruoQ at 17:21 (video of Rochelle P. Walensky, Director of the CDC, stating "we are planning for Americans to receive booster shots") (last visited 9/13/2021).

ICAN incorporates all articles and information regarding the COVID-19 pandemic, the Pfizer Vaccine, and the sweeping mandates being implemented across the country as if set forth fully herein.

ICAN certifies that the information in this request is true and correct to the best of its knowledge and belief.

We ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552 (a)(4)(A)(iii). ICAN is a not-for-profit 501(c)(3) organization whose mission is to raise public awareness about vaccine safety and to provide the public with information to give informed consent. As part of its mission, ICAN actively investigates and disseminates information regarding vaccine safety issues, including through its website, and through press events and releases. ICAN is seeking the information in this FOIA request to allow it to contribute to the public understanding of the government's vaccine safety programs, including the government's efforts to promote vaccine safety. The information ICAN is requesting will not contribute to any commercial activities.

Please note that the FOIA provides that if only portions of a requested file are exempted from release, the remainder must still be released. We, therefore, request that we be provided with all non-exempt portions which are reasonably segregable. We further request that you describe any deleted or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. ICAN of course reserves all rights to appeal the withholding or deletion of any information.

Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and ICAN may immediately file an administrative appeal.

If you would like to discuss our requests or any issues raised in this letter, please feel free to contact me at (212) 532-1091 or via email at foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,

Aaron Siri
Elizabeth Brehm
Gabrielle Palmer

Exhibit 15

September 29, 2021

Gabrielle Palmer
Informed Consent Action Network
Siri & Glimstad LLP
200 Park Avenue, 17th Floor
New York, NY 10166

In reply refer to file: 2021-6184 (IR#0558)

Dear Ms. Palmer,

This is in reply to your Freedom of Information Act request dated September 14, 2021, in which you requested "a copy of page 8 of the document available at https://www.fda.gov/media/151733/download, without any redaction of the ingredients listed at the top of that page." Your request was received in the Center for Biologics Evaluation and Research on September 20, 2021.

Enclosed please find 2 pages from the document found at the link you provided (the Summary Basis for Regulatory Action for BLA STN 125742/0), that contain Table 2 titled "*Composition of COMIRNATY Multiple Dose Vial*".

We interpret your request, "the ingredients listed at the top of that page," to be a request for the content in Table 2 of the Summary Basis for Regulatory Action (SBRA). In order to provide you with all of Table 2, we are providing you with the 2 enclosed pages. Please note that while there are some redactions on the 2 provided pages, there are no redactions to Table 2.

We have withheld portions of pages under Exemption (b)(4), 5 U.S.C. § 522(b)(4). That exemption permits the withholding of trade secrets and commercial or financial information that was obtained from a person outside the government and that is privileged or confidential.

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision.

Your appeal must be mailed within 90 days from the date of this response, to:

Director, Office of the Executive Secretariat
US Food & Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
E-mail: FDAFOIA@fda.hhs.gov

Please clearly mark both the envelope and your letter "FDA Freedom of Information Act Appeal."

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact Katherine Uhl at 301-796-8975.

If you are not satisfied with any aspect of the processing and handling of this request, please contact me:

Ms. Beth Brockner-Ryan
Chief, Access Litigation and Freedom of Information Branch
Division of Disclosure and Oversight Management
Office of Communication Outreach and Development
Center for Biologics Evaluation and Research (CBER)
U.S. Food and Drug Administration (FDA)
10903 New Hampshire Avenue
E-mail: beth.brocknerryan@fda.hhs.gov
Direct Phone: 240-402-8026
Main Phone: 240-402-7800

You may also contact the FDA FOIA Public Liaison for assistance at:

Office of the Executive Secretariat
US Food & Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
E-mail: FDAFOIA@fda.hhs.gov

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is:

Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road–OGIS
College Park, MD 20740-6001
Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
Fax: 202-741-5769
E-mail: ogis@nara.gov

If you have any questions or if we can be of further assistance, please let us know by referencing the above file number. You can contact Elizabeth Sly by phone at 240-402-8001 or by e-mail at Elizabeth.Sly@fda.hhs.gov.

Sincerely,

Beth A. Brockner Ryan -S

Digitally signed by Beth A. Brockner Ryan -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300052489, cn=Beth A. Brockner Ryan -S
Date: 2021.09.29 13:34:45 -04'00'

Beth Brockner Ryan
Chief, Access Litigation and Freedom of Information Branch

Drug Product (DP)

The manufacturing process of the DP is divided into the following critical steps:

- **Preparation of the DS:** (b) (4) (b) (4)
- **Formation of LNP:** In this step, (b) (4) (b) (4)
- **Formulation of the bulk DP:** The bulk DP is formulated by (b) (4) (b) (4)
- **Filling:** The bulk DP is sterile filtered and aseptically filled into 2 mL Type I borosilicate glass vials manufactured by (b) (4) (b) (4)
- **Labeling and storage:** The filled vials are visually inspected, labeled, and frozen at -90°C to -60°C.

Composition

The composition of the formulation of COMIRNATY and the function of the ingredients are provided in Table 2.

Table 2. Composition of COMIRNATY Multiple Dose Vial

Ingredients	Quantity after Dilution (per vial)	Function
SARS-CoV-2 spike glycoprotein mRNA (UNII: 5085ZFP6SJ)	225 µg	Active Ingredient
ALC-0315 [4-hydroxybutyl)azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate) (UNII: AVX8DX713V)	3.23 mg	Lipid component
ALC-0159 [2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide] (UNII: PJH39UMU6H)	0.4 mg	Lipid component
DSPC [1,2-distearoyl-sn-glycero-3-phosphocholine] (UNII: 043IPI2M0K)	0.7 mg	Lipid component
Cholesterol (UNII: 97C5T2UQ7J)	1.4 mg	Lipid component
Potassium chloride (UNII: 660YQ98I10)	0.07 mg	Excipient
Monobasic potassium phosphate (UNII: 4J9FJ0HL51)	0.07 mg	Excipient
Sodium Chloride	2.7 mg	Excipient

Ingredients	Quantity after Dilution (per vial)	Function
(UNII: 451W47IQ8X)		
Dibasic sodium phosphate dihydrate (UNII: GR686LBA74)	0.49 mg	Excipient
Sucrose (UNII: C151H8M554)	46.0 mg	Excipient
Water for Injection (UNII: 059QF0KO0R)	0.450 mL	Excipient

UNII: Unique Ingredient Identifier

Stability of COMIRNATY in Multiple Dose Vial

For the long-term storage condition study, parameters monitored are Appearance, (b) (4) by (b) (4) LNP (b) (4) RNA content and (b) (4) Assay, Lipid (ALC-0315, ALC-0159, DSPC, and Cholesterol) Content by (b) (4) (b) (4) (b) (4) Container closure integrity test by (b) (4) (b) (4) Endotoxin content by (b) (4) and Sterility.

The stability data provided in the submission support a dating period of 9 months from the date of manufacture when stored at -90°C to -60°C for the COMIRNATY DP filled in 2 mL Type I borosilicate glass vials. Stability data on emergency use and process performance qualification lots also support storage at -20°C ± 5°C for up to 2 weeks as well as short term storage at 5°C ± 3°C for up to one month (within the 9-month expiry dating period).

The Diluent for COMIRNATY

The contents of the vaccine vial are diluted with sterile 0.9% Sodium Chloride Injection, USP. Vials of sterile 0.9% Sodium Chloride Injection, USP are provided but shipped separately. The provided diluent or another sterile 0.9% Sodium Chloride Injection, USP should be used as the diluent.

The provided 0.9% Sodium Chloride Injection, USP diluent will be supplied either as cartons of 10 mL single-use vials manufactured by Hospira, Inc (NDC 0409-4888-10), or 2 mL single-use vials manufactured by Fresenius Kabi USA, LLC (NDC 63323-186-02). The composition of the saline diluent and the function of the ingredients are provided in Table 3.

Table 3. Composition of the Diluent

Ingredients	Quantity (per 0.3 mL dose)	Function
SODIUM CHLORIDE (UNII: 451W47IQ8X)	2.16 mg	Excipient
Water for Injection (UNII: 059QF0KO0R)	0.3 mL	Excipient

UNII: Unique Ingredient Identifier

Exhibit 16

LIVE Watch now: ETF Edge on this year's

BREAKING Stocks making the biggest moves midday: Harley-Davidson, C

WATCH LIVE

HEALTH AND SCIENCE

Pfizer raises Covid vaccine sales forecast to $36 billion for 2021

PUBLISHED TUE, NOV 2 2021•6:52 AM EDT UPDATED TUE, NOV 2 2021•7:52 AM EDT

REUTERS

WATCH LIVE

KEY POINTS

Pfizer on Tuesday raised the full-year sales forecast for its Covid-19 vaccine by 7.5% to $36 billion, as it signs deals with countries for booster doses and receives clearances for using its shots in children.

The company said it is also on track to deliver 2.3 billion doses of the vaccine, out of the roughly 3 billion it plans to make this year.

The vaccine brought in sales of $13 billion in the third quarter. Analysts had expected $10.88 billion on average, according to seven analysts polled by Refinitiv.

In this article

PFE +2.72 (+5.14%)

LIVE Watch now: ETF Edge on this year's

BREAKING Stocks making the biggest moves midday: Harley-Davidson, C

WATCH LIVE

VIDEO 01:30

Pfizer raises full-year sales guidance after earnings beat estimates

Pfizer on Tuesday raised the full-year sales forecast for its Covid-19 vaccine by 7.5% to $36 billion, as it signs deals with countries for booster doses and receives clearances for using its shots in children.

The company said it is also on track to deliver 2.3 billion doses of the vaccine, out of the roughly 3 billion it plans to make this year.

Driven by an unprecedented vaccination drive against the Covid-19 pandemic globally, Pfizer's shot has quickly become one of the best-selling products in the company's roughly 172-year history. The company equally splits expenses and profit from the vaccine with its German partner BioNTech.

Other rivals such as Moderna and Johnson & Johnson have faced production snags, helping Pfizer extend its lead in signing supply deals with countries.

Pfizer is also rolling out booster doses of the vaccine, while waiting for the outcome of a U.S. regulatory meeting later in the day on using its shots in children aged five to 11.

The vaccine brought in sales of $13 billion in the third quarter. Analysts had expected $10.88 billion on average, according to seven analysts polled by Refinitiv.

Pfizer's shares rose over 1% in premarket trading.

In this article

LIVE Watch now: ETF Edge on this year's

BREAKING Stocks making the biggest moves midday: Harley-Davidson, C

WATCH LIVE

TRENDING NOW

Omicron can hit fully vaccinated, Oxford study says, as UK prepares for tidal wave of cases

Meme stocks AMC and GameStop tumble to lowest levels in months as investors take off risk

Hawaii's ultra-luxury real estate market smashes records, as sales soar 600%. Here's what's selling

Peloton fires back at its portrayal in 'Sex and the City' reboot with own parody ad: 'He's alive'

Elon Musk says dogecoin is better to buy things with than bitcoin

Subscribe to CNBC PRO
CNBC Councils
CNBC on Peacock
Join the CNBC Panel
Licensing & Reprints
Supply Chain Values
Advertise With Us
Digital Products

LIVE Watch now: ETF Edge on this year's

BREAKING Stocks making the biggest moves midday: Harley-Davidson, C

WATCH LIVE

Careers Help

Contact

News Tips

Got a confidential news tip? We want to hear from you.

GET IN TOUCH

CNBC Newsletters

Sign up for free newsletters and get more CNBC delivered to your inbox

SIGN UP NOW

Get this delivered to your inbox, and more info about our products and services.

Privacy Policy

Do Not Sell My Personal Information

CA Notice

Terms of Service

© 2021 CNBC LLC. All Rights Reserved. A Division of NBCUniversal

Data is a real-time snapshot *Data is delayed at least 15 minutes. Global Business and Financial News, Stock Quotes, and Market Data and Analysis.

Market Data Terms of Use and Disclaimers

Data also provided by

MARKETS CNBC TV WATCHLIST MENU

Exhibit G

Neutral

As of: December 14, 2021 12:04 AM Z

Diocesan Migrant & Refugee Servs. v. United States Immigration & Customs Enforcement

United States District Court for the Western District of Texas, El Paso Division

January 28, 2021, Decided; January 28, 2021, Filed

EP-19-CV-00236-FM

Reporter

2021 U.S. Dist. LEXIS 16469 *; 2021 WL 289548

DIOCESAN MIGRANT & REFUGEE SERVICES, INC., Plaintiff, v. UNITED STATES IMMIGRATION AND CUSTOMS ENFORCEMENT, Defendant.

Core Terms

documents, records, attorney's fees, redactions, exemptions, immigration, requests, Sheet, pages, deadline, field office, hourly rate, costs, asylum, email, billing, seekers, reasonable basis, disclosure, searches, withhold, inlaw, prevailed, lodestar, thirty-three, calculate, practices, uncover, reasonable attorney's fees, privileges

Counsel: [*1] For Diocesan Migrant & Refugee Services, Inc., Plaintiff: Christopher Benoit, LEAD ATTORNEY, Law Office of Lynn Coyle, PLLC, El Paso, TX; Lynn A. Coyle, The Law Office of Lynn Coyle, PLLC, El Paso, TX.

For United States Immigration and Customs Enforcement, Defendant: Manuel Romero, LEAD ATTORNEY, U.S. Attorney, Western District of Texas, El Paso, TX.

Judges: FRANK MONTALVO, UNITED STATES DISTRICT JUDGE.

Opinion by: FRANK MONTALVO

Opinion

ORDER GRANTING APPLICATION FOR ATTORNEY FEES AND COSTS

Before the court are "Plaintiff's Opposed Application for Attorney Fees and Costs" ("Motion") [ECF No. 56], filed November 2, 2020 by Diocesan Migrant & Refugee Services, Inc. ("DMRS"); "Response to Plaintiff's Application for Attorney Fees and Costs" [ECF No. 65], filed November 23, 2020 by United States Immigration and Customs Enforcement ("ICE"); and "Plaintiff's Reply to Defendant's Response to Plaintiff's Application for Attorney Fees and Costs" ("Reply") [ECF No. 66], filed November 25, 2020. After due consideration of the Motion, Response, Reply, and applicable law, the Motion is **GRANTED**.

I. BACKGROUND

A. Pre-Trial

In 2019, the United States government implemented a policy titled the Migrant Protection Protocols ("MPP"). Pursuant [*2] to the MPP, selected asylum seekers

must remain in Mexico while they wait for U.S. immigration judges to hear their asylum cases.[1] The MPP was first implemented at the San Ysidro port of entry in January 2019.[2] It was then implemented at the El Paso port of entry in May 2019 and at the Laredo and Brownsville ports of entry later in 2019.[3]

DMRS is a non-profit organization that provides know-your-rights information and legal representation for asylum seekers prior to their appearances before an immigration judge.[4] It provided know-your-rights information to asylum seekers subject to the MPP during the brief time the asylum seekers were in the United States prior to immigration hearings.[5] In June 2019, ICE and the United States Department of Justice Executive Officer for Immigration Review ("DOJ-EOIR") informed DMRS that it would no longer be permitted to provide know-your-rights-information to asylum seekers waiting for immigration hearings.[6]

On July 1, 2019, DMRS submitted a request for information to ICE pursuant to the *Freedom of Information Act ("FOIA"), 5 U.S.C. §§ 552 et seq.*[7] It sought records related to the implementation of the MPP and asylee access to attorneys prior to immigration hearings. [*3] [8] ICE did not produce any responsive documents within the twenty-day statutory deadline.[9] DMRS filed suit to compel production on August 22, 2019.[10]

Toni Fuentes ("Fuentes"), a Deputy FOIA Officer for ICE, was immediately responsible for supervising ICE responses to requests for records under FOIA.[11] Due to an ICE administrative error, ICE did not become aware of DMRS's FOIA request until after the initiation of this lawsuit.[12] Fuentes assisted in locating DMRS's FOIA request, at which time she assigned the request to the litigation team of the ICE FOIA Office for expedited processing of the request.[13]

Approximately four-and-a-half months after the statutory deadline to respond, on December 16, 2019, ICE notified DMRS it identified ninety-two pages of potentially responsive records.[14] Ten pages were provided in full, twenty-eight pages contained redacted information, fourteen pages were deemed non-responsive or duplicates, and the remaining forty pages required "consultation with other agencies or components" and ICE stated they would "be produced

---

[1] "Findings of Fact and Conclusions of Law" 3, ECF No. 44, entered Oct. 19, 2020.

[2] *Id.*

[3] *Id.*

[4] "Plaintiff's Original Complaint" ("Compl.") 2 ¶ 6, ECF No. 1, filed Aug. 22, 2019; "FOIA Request," Ex. 1. *See also* Plaintiff's Opposed Application for Attorney Fees and Costs" ("Mot."), ECF No. 56, filed Nov. 2, 2020, "Declaration of Melissa M. Lopez" 3, ECF No. 56-1, Ex. 3.

[5] *Id.*

[6] *Id.* at 2 ¶ 7.

[7] Findings of Fact and Conclusions of Law 3.

[8] *Id.*

[9] *See id.* at 5. *See also 5 U.S.C. § 552(a)(6)(A)(i)*.

[10] *See generally* Compl.

[11] *Id.* at 2-3.

[12] "Transcript of Bench Trial" 15, ECF No. 63, filed Nov. 16, 2020.

[13] *Id.* at 13.

[14] Findings of Fact and Conclusions of Law 2.

at a later date."[15] On May 22, 2019, DMRS filed its motion for summary judgment arguing ICE had not conducted a search reasonably [*4] calculated to uncover responsive records and had not met its burden to show that records it withheld were exempt from disclosure.[16]

On May 29, 2020, nine months after Plaintiff filed suit and almost eleven months after Plaintiff sent its original FOIA request, ICE forwarded the pages requiring consultation to other agencies for review.[17] ICE admitted that a second administrative error prevented timely referral of these documents.[18] While the consultations were pending, ICE filed five motions for extensions of the deadline to respond to DMRS's motion for summary judgment. ICE finally responded on June 25, 2020, twenty days after the original deadline. That same day, almost eleven months after the statutory deadline, ICE produced thirty-three of the forty pages requiring consultation.[19] ICE did not address these documents in its response. DMRS challenged redactions to the thirty-three pages produced after its motion for summary judgment but withdrew its objections to previously produced materials.[20]

B. Trial

On October 5, 2020 the court held a bench trial to resolve two issues: 1) whether ICE conducted a search reasonably calculated to uncover responsive records; and 2) whether [*5] redactions pursuant to 5 U.S.C. § 552(b)(5) ("exemption (b)(5)") to the thirty-three pages produced June 25, 2020 were exempt from disclosure.[21] The parties were present and represented by counsel. Fuentes was ICE's sole witness.

One subdivision of ICE Enforcement and Removal Operations ("ERO") is ERO Field Operations ("FOPS"), the office responsible for providing MPP guidance to all ERO field offices.[22] After consideration of Fuentes's testimony, the court found ICE was on notice that DMRS's request sought communications between ICE ERO agents and their contractors at the field office level about implementation of the MPP; correspondence to ICE ERO officers and, their contractors who were responsible for movement and custody of respondents subjected to the MPP; emails by or between ERO field offices where the MPP was implemented; and emails of guidance between officers and contractors at the field office level regarding the MPP participants' access to counsel before their immigration court hearings.[23]

The court also found:

- ICE program offices have no written guidelines on how to conduct searches for records responsive to

[15] *Id.*

[16] *See generally* "Plaintiff's Motion for Summary Judgment," ECF No. 14, filed May 22, 2020.

[17] Findings of Fact and Conclusions of Law 11.

[18] "Transcript of Bench Trial" 61, ECF No. 63, filed Nov. 16, 2020.

[19] Findings of Fact and Conclusions of Law 2. *See also* 5 U.S.C. § 552(a)(6)(A)(i) (providing a twenty-day deadline, excluding weekends and holidays for agencies to respond to FOIA requests).

[20] "Plaintiff's Reply to Defendant's Response to Plaintiff's Motion for Summary Judgment" 2-3, ECF No. 29, filed July 29, 2020.

[21] Findings of Fact and Conclusions of Law 2.

[22] *Id.* at 9.

[23] *Id.* at 4-5.

FOIA requests.[24]

• Each program office within ICE has its own guidelines for record keeping, [*6] retention schedule, and records liaison officers.[25]

• Fuentes instructed her points of contact ("POCs") in three program offices to conduct searches for responsive documents: the ICE Office of Policy, ICE Office of the Principal Legal Advisor ("OPLA"), and ICE ERO.[26]

• No uniform set of search terms was used across the various ICE program offices.[27]

• No POC described to what extent, if any, they took into consideration the particular record keeping practices of their respective program offices in searching for responsive documents.[28]

• ERO FOPS, the office responsible for providing MPP guidance to all ERO field offices, determined the requested information did not fall in its area of responsibility and did not conduct any search for responsive documents.[29]

The court then turned to the thirty-three pages of redacted documents produced to Plaintiff after consultation with Customs and Border Patrol and the Department of Homeland Security Office of Privacy.[30] ICE provided only a letter to accompany the produced documents.[31] Two paragraphs in the letter address the redactions made pursuant to *exemption (b)(5)*.[32] The letter did not identify which privilege supported each redaction made under [*7] redaction *(b)(5)*.[33] Nor did either provide DMRS with any factual basis for the application of *exemption (b)(5)* to any individual redaction.[34] Fuentes's testimony was equally inadequate.

Upon conclusion of ICE's case, DMRS moved for judgment as a matter of law as to both issues. The court granted the motion and, on October 19, 2020, entered corresponding "Findings of Fact and Conclusions of Law" [ECF No. 44]. The court ordered that the thirty-three pages originally produced to DMRS on June 25, 2020 be unredacted and produced to DMRS by October 26, 2020.[35] It also ordered ICE to conduct a new search for documents responsive to DMRS's FOIA request by November 2, 2020.[36]

C. Post-Trial

On November 2, 2020, the deadline for ICE to conduct its new search, ICE informed the court it had not yet conducted any search and moved for an extension of

---

[24] *Id.*

[25] *Id.* at 6.

[26] *Id.*

[27] Findings of Fact and Conclusions of Law 6.

[28] *Id.*

[29] *Id.* at 9. *See also* Memorandum from Nathalie R. Asher, Acting Executive Associate Director, U.S. Immigration and Customs Enforcement, to Field Office Directors, Enforcement and Removal Operations, "Migrant Protection Protocols Guidance" (Feb. 12, 2019).

[30] Findings of Fact and Conclusions of Law 11.

[31] *Id.* at 12.

[32] *Id.*

[33] *Id.* at 12.

[34] *Id.*

[35] "Final Judgment" 1, ECF No. 45, entered Oct. 19, 2020.

[36] *Id.*

time do so.[37] ICE requested the deadline be extended to November 23, 2020 with respect to a search for responsive records from the El Paso Field Office and asked for an additional thirty days upon completion of a search of the El Paso Field Office to search for responsive records from the San Antonio and San Diego Field Offices.[38] ICE did not express any concern [*8] about the procedural feasibility of the deadline, merely citing counsel's personal circumstances. The court granted ICE an additional extension of all search deadlines to November 23, 2020.[39]

A week after the second deadline, on November 30, 2020, ICE moved for yet another extension of time to comply with the court's order.[40] For the first time, ICE informed the court of the procedure it intended to follow in conducting its new, more thorough, search for responsive documents. ICE also expressed concern for the impossibility of the court's deadline in light of the search requirements. ICE informed the court it conducted an examination of its records utilizing thirteen search terms in records from forty-nine custodians. That examination identified approximately 2.3 million potentially responsive documents.[41] After using software to extract irrelevant and duplicative documents, approximately 86,000 potentially responsive documents remained.[42] ICE then assigned thirty percent of its FOIA staff to conduct first-line review full-time.[43] Ten to fifteen attorneys would dedicate half of every work day to second-line review.[44] ICE estimated staff would require four months to produce all responsive records [*9] from the El Paso field office.[45] Thereafter, the parties would confer to present a new scheduling order for remaining documents.[46] The court entered an order granting the extension.[47] ICE did not appeal any part of the court's judgment. As a result, the court's Findings of Fact and Conclusions of Law are now the law of the case. ICE cannot contest either.[48]

II. LEGAL STANDARD

FOIA states "[t]he court may assess against the United

---

[37] "Defendant's Unopposed Motion for Extension of Time, or in the Alternative, Motion to Alter or Amend a Judgment," ECF No. 53, filed Nov. 2, 2020.

[38] *Id.* at ¶ 8.

[39] "Order Granting in Part and Denying in Part Motion for Extension of Time" 2, ECF No. 57, entered Nov. 3, 2020.

[40] *See generally* Defendant's Amended Unopposed Motion for Extension of Time to Produce Documents," ("Nov. Mot. For Extension") ECF No. 70, filed Nov. 30. 2020.

[41] *Id.* at ¶¶ 7-8.

[42] *Id.* at ¶ 11.

[43] *Id.* at ¶ 47.

[44] *Id.* at ¶ 48.

[45] *Id.* at ¶ 59.

[46] Nov. Mot. For Extension ¶ 59.

[47] *See generally* "Order Granting Second Motion for Extension of Time," ECF No. 71, entered Dec. 1, 2020.

[48] *See* Arizona v. California, 460 U.S. 605, 618, 103 S. Ct. 1382, 75 L. Ed. 2d 318 (1983) (The law-of-the-case doctrine "posits that when a court decides upon a rule of law, that decision should continue to govern the same issue in subsequent stages in the same case.") *See also* Ashe v. Swenson, 397 U.S. 436, 443, 90 S. Ct. 1189, 25 L. Ed. 2d 469 (1970) (The collateral estoppel doctrine stands for the principle that "when an issue of ultimate fact has once been determined by a valid and final judgment, that issue cannot again be litigated between the same parties in any future lawsuit.")

States reasonable attorney fees and other litigation costs reasonably incurred in any case under this section in which the complainant has substantially prevailed."[49] Accordingly, the court must apply a two-prong test to determine: (1) "whether a plaintiff has substantially prevailed" and, if so, (2) "whether the plaintiff *should* receive fees."[50]

A Plaintiff has "substantially prevailed" and therefore satisfied the first prong if it obtained requested relief through a judicial order.[51] The second prong, also known as the "entitlement" prong, requires courts to consider: "(1) the benefit to the public deriving from the case; (2) the commercial benefit to the complainant; (3) the nature of the complainant's interest in the [*10] records sought; and (4) whether the government's withholding of the records had a reasonable basis in law."[52] The entitlement prong requires courts to conduct analysis through the lens of the three fundamental purposes of FOIA's legal fee provision. The provision is designed: (1) "as an incentive for private individuals to pursue vigorously their claims for information" and overcome barriers "that government may erect in an effort to escape compliance with the law;" (2) to "deter the government from opposing justifiable requests;" and (3) "to punish the government where such opposition is unreasonable."[53] An award of attorneys' fees is particularly appropriate where "'government officials have been recalcitrant in their opposition to a valid claim or have been otherwise engaged in obdurate behavior.'"[54]

III. DISCUSSION

A. Whether DMRS Should Receive Attorney Fees

The Final Judgment entered in this action definitively establishes DMRS substantially prevailed in its FOIA action as this court granted all of the requested relief.[55] This is not contested. Accordingly, the court proceeds to a determination of whether DMRS should receive attorney fees in light of the circumstances of the case and the [*11] essential purposes of the FOIA legal fee provision.

1. The Benefit to the Public Deriving from the Case

"The basic purpose of FOIA is to ensure an informed citizenry, vital to the functioning of a democratic society, needed to check against corruption and to hold the government accountable to the governed."[56] Viewing the public benefit factor through the lens of FOIA's high-minded central purpose, attorneys fees are more appropriate "where the complainant's victory is likely to add to the fund of information that citizens may use in

---

[49] *5 U.S.C. § 552(a)(4)(E)(i)*.

[50] *Batton v. IRS, 718 F.3d 522, 525 (5th Cir. 2013)* (emphasis in original).

[51] *5 USC § 552(a)(4)(E)(ii)*; *Batton, 718 F.3d at 525*.

[52] *Texas v. ICC, 935 F.2d 728, 730 (5th Cir. 1991)*.

[53] *Cazalas v. Dep't of Justice, 709 F.2d 1051, 1057 (5th Cir. 1983)*.

[54] *Id. at 1054* (quoting S.Rep. No. 93-854, at 19 (1974)).

[55] *See 5 USC § 552(a)(4)(E)(ii)(I)* ("a complainant has substantially prevailed if the complainant has obtained relief through . . . a judicial order . . ."); *Batton, 718 F.3d at 525*.

[56] *NLRB v. Robbins Tire & Rubber Co., 437 U.S. 214, 242, 98 S. Ct. 2311, 57 L. Ed. 2d 159 (1978)*.

making vital political choices."[57] Courts take into consideration "the degree of dissemination and the likely public impact that might be expected from a particular disclosure."[58]

DMRS requested information about ICE's decision to prohibit asylum seekers' access to attorneys and to know your rights information. Denial of access to counsel and rights information has broad-ranging due process consequences for asylum seekers fleeing persecution. The documents responsive to DMRS's FOIA request are very likely to be of significant consequence to the large numbers of asylees and their advocates. As DMRS intends to use the requested records to "determine how to move [*12] forward with providing information and representation to asylum seekers in the MPP program,"[59] it has already begun the process of making documents obtained through this litigation available to other non-profit legal service organizations in the El Paso area, fellow advocates, and members of the press.[60]

Our nation's comprehensive immigration policy has been part of the national dialogue for well over a decade. In the recently concluded presidential cycle it figured prominently in the campaigns of every presidential candidate and most candidates seeking federal office. An element of that policy is the treatment of refuge and asylum seekers. Responsive documents would provide valuable insight into the execution of a rapidly evolving and controversial policy dealing with that segment of the immigrants pursuing admission to our country. As this information is both of public concern and useful to political decision making, the diffusion of documents will spread beyond legal service providers to the wider public. An award of attorney fees will foster the spirit of private litigants to vigorously pursue claims for information vital for democratic society and discourage the government from the [*13] cavalier treatment of appropriate and lawful requests such as DMRS is pursuing.

The public benefit is not reduced by the change in administration since the initiation of this lawsuit and before ICE has finished reviewing and producing all responsive documents. The delays are completely attributable to ICE's own administrative errors, absence of clearly defined methods and procedures to determine places and databases to search, lack of effective and comprehensive procedures for adequately processing FOIA requests, and repeated requests for extensions of deadlines. ICE's ineptitude in responding to valid requests for information and failure to comply with this court's deadlines cannot be counted in its favor. To do so would make a mockery of the accountability principles underlying FOIA.

ICE's handling of this FOIA request is precisely encompassed in the Fifth Circuit's holding that attorney fees are particularly appropriate where "'government officials have been recalcitrant in their opposition to a valid claim or have been otherwise engaged in obdurate behavior.'"[61] Potential FOIA complainants must be incentivized to pursue meritorious claims without fear that the duration of the lawsuit [*14] would make the information sought "old news," no longer in the public

---

[57] *Blue v. Bureau of Prisons, 570 F.2d 529, 534 (5th Cir. 1978)*.

[58] *Id. at 533*.

[59] Mot. 5.

[60] Mot., "Declaration of Melissa M. Lopez" 3, ECF No. 56-1, Ex. 3.

[61] *Cazalas v. Dep't of Justice, 709 F.2d 1051, 1054 (5th Cir. 1983)* (quoting S.Rep. No. 93-854, at 19 (1974)).

eye, and defeat a motion for compensation by simply delaying response. Therefore, this factor weighs strongly in favor of granting attorney fees.

2. The Commercial Benefit to the Complainant and Nature of Complainant's Interest in the Records Sought

When the commercial benefit to a plaintiff and the nature of the plaintiff's interest in records sought are similar it is useful to consider these factors together.[62] In weighing the commercial benefit factor, courts consider whether the party requesting fees is indigent or a non-profit organization rather than a large corporate interest.[63] Similarly, the nature of the complainant's interest weighs in favor of granting attorney fees if the plaintiff seeks to protect the public interest, rather than merely a private interest.[64] These factors further congressional intent that the prohibitive costs of litigation not exclude the indigent and public interest groups from pursuing relief.[65]

There is no commercial benefit to DMRS in the records sought. DMRS is a non-profit organization that provides know-your-rights information and legal representation to indigent asylum seekers. [*15] Its central purposes in seeking the documents are to protect its constituents' due process rights and to facilitate the fair adjudication of political asylum claims. Receipt of responsive records furthers DMRS's organizational purpose by bolstering its ability to protect the public interest in the administration of justice in the immigration system. Responsive records are also likely to raise public awareness of issues of political importance through the distribution of responsive records to other immigrant advocacy groups and the media. As such, both factors weigh in favor of granting attorney fees.

3. Whether the Government's Withholding of the Records had a Reasonable Basis in Law.

FOIA requires federal agencies to make their records promptly available to any person who makes a proper request for records.[66] "[T]he threshold question in any FOIA suit is whether the requester can even *see* the documents the character of which determines whether they can be released."[67] Accordingly, the FOIA statute provides that, when the government withholds information from disclosure, the agency has the initial burden to prove *de novo* that the information is exempt from disclosure.[68] This court's findings [*16] of fact document the abysmal inadequacy of the search and the unsupported redactions. In considering whether to award attorney fees, the threshold is lower. The government's withholding needs only to have had a reasonable basis in law for ICE to avoid attorney fees.[69] ICE showed no reasonable basis to withhold the documents.

a. Adequacy of Search

ICE failed to establish even a colorable basis in law exists to support the adequacy of its search for

---

[62] *Id.*

[63] *Blue v. Bureau of Prisons, 570 F.2d 529, 533-34 (5th Cir. 1978)*.

[64] *Id. at 534*

[65] *Id.* (citing S.Rep. No. 854, 93d Cong., 2d Sess. 19 (1974)).

[66] *5 U.S.C. § 552(a)(3)(A)*.

[67] *Cooper Cameron Corp. v. U.S. Dep't of Labor, OSHA, 280 F.3d 539, 543 (5th Cir. 2002)*.

[68] *5 U.S.C. § 552(a)(4)(B)*; *Batton v. Evers, 598 F.3d 169, 175 (5th Cir. 2010)*.

[69] *See Texas v. ICC, 935 F.2d 728, 730 (5th Cir. 1991)*.

documents responsive to DMRS's FOIA request. "Even when an agency does not deny a FOIA request outright, the requesting party may still be able to claim 'improper' withholding by alleging that the agency has responded in an inadequate manner."[70] An agency's search is adequate if it is "reasonably calculated to uncover all relevant documents."[71] "The adequacy of an agency's search is measured by a standard of reasonableness and is dependent upon the circumstances of the case."[72] The focus is on the reasonableness of the search, not the result.[73] An agency must "make more than perfunctory searches and, indeed, [] follow through on obvious leads to discover requested documents."[74]

There is no reasonable basis in law to believe ICE's search [*17] was reasonably calculated to uncover all responsive documents. Testimony about ICE's search was inconsistent and generalized. Fuentes described general ICE procedure for responding to FOIA requests without knowledge of the specifics. Fuentes did not conduct any search herself.[75] Nor could she testify as to the precise search procedure—Fuentes conceded her knowledge was limited to information on search forms POCs provided to her office.[76] ICE had all the time it requested to prepare for trial and to marshal all evidence it deemed appropriate. Even so, it did not call a single witness able to explain the rationale for the search conducted at any single program office.

In explanation of ICE's failure to conduct a methodical agency-wide search for responsive records, Fuentes stated the agency was "young" and "playing catch-up," seemingly acknowledging deficiencies.[77] In an apparent contradiction, she then said the reason for the lack of uniformity was to honor the subject-matter expertise within individual program offices.[78] Since record keeping practices vary across program offices, Fuentes reasoned, ICE conducts non-uniform searches.

Due to this model, Fuentes could not testify as to either the [*18] record keeping or searching practices of any program offices or their subdivisions. POCs did not provide that information in their search forms. The returned search forms indicate different search terms were used across program offices without any apparent reason for the lack of uniformity. Fuentes could not say whether a given search was reasonable in the context of the recordkeeping practices of a program office as she was not familiar with those practices and the POCs provided no explanation.

ICE's deference to the subject-matter expertise of

---

[70] *U.S. Dep't of Justice v. Tax Analysts, 492 U.S. 136, 151 n.12 (1991), 109 S. Ct. 2841, 106 L. Ed. 2d 112* (citations omitted). *See also Kissinger v. Reporters Comm. for Freedom of the Press, 445 U.S. 136, 150, 100 S. Ct. 960, 63 L. Ed. 2d 267 (1980)* (recognizing the judicial authority conferred by the FOIA to devise remedies for agencies contravening the statute through improper withholdings).

[71] *Weisberg v. U.S. Dep't. of Justice, 705 F.2d 1344, 1351, 227 U.S. App. D.C. 253 (D.C. Cir. 1983)*; *Batton v. Evers, 598 F.3d 169, 176 (5th Cir. 2010)*.

[72] *Id.*

[73] *Steinberg v. U.S. Dep't of Justice, 23 F.3d 548, 551, 306 U.S. App. D.C. 240 (D.C. Cir. 1994)*.

[74] *Valencia-Lucena v. U.S. Coast Guard, 180 F.3d 321, 325, 336 U.S. App. D.C. 386 (D.C. Cir. 1999)*.

[75] Findings of Fact and Conclusions of Law 6.

[76] "Transcript of Bench Trial" 35-36, 83-84, ECF No. 63, filed Nov. 16, 2020.

[77] *Id.* at 19-20.

[78] *Id.* at 20.

individuals within each program office is neither strategic nor efficient. It shows indifference to the purpose of the search. Without testimony about each program office's record keeping practices, ICE cannot show the search process was reasonably calculated to uncover all responsive documents.

The search was too narrow to be expected to uncover all responsive documents. Only five individuals in an agency of several thousand searched their email accounts for responsive correspondence.[79] These individuals used a variety of inconsistent search terms. The entirety of the search within the ERO Enforcement Division records was for a single search term [*19] within the Deputy Assistant Director's email account: the acronym "MPP."[80] Fuentes could not say with any level of assurance that this search uncovered responsive documents containing the spelled-out acronym.[81] Some individuals may have searched only within specific folders.[82] Some may have excluded deleted, archived, or sent emails by searching only within their inboxes.[83] Fuentes could not be sure and could only interpret the returned search forms.

ICE failed to show it conducted a reasonable search within ERO FOPS. DMRS's request sought communications about guidance and instruction to employees regarding day-to-day movement of MPP participants wherever the MPP was established. FOPS is responsible for providing guidance and coordination to the twenty-four ERO field offices.[84] ERO field offices are responsible for the custody of all MPP participants from the port of entry to the immigration court.[85] A publicly available memorandum by the Acting Executive Associate Director of ICE instructs field office directors to assign a lead POC for MPP issues within their offices.[86] The memorandum tasks these POCs with issuing local operational guidance applicable to the MPP.[87] These facts conclusively indicate [*20] FOPS is reasonably likely to have records responsive to DMRS's FOIA request. They also indicate ICE was aware that field offices possess records responsive to FOIA requests for information related to the MPP.

Inexplicably, FOPS determined DMRS's FOIA request did not fall within its area of responsibility and declined to conduct any search. It is troubling FOPS disregarded the plain language of a publicly available memo in determining it had no records responsive to DMRS's FOIA request. There is no reasonable basis in law to support ICE's inadequate search.

b. Exemptions

ICE gave no reasonable basis in law to redact the thirty-three pages it produced on June 25, 2020. When the applicability of an exemption to disclosure under FOIA is in dispute, an agency is required to provide a detailed

---

[79] "Transcript of Bench Trial" 77, ECF No. 63, filed Nov. 16, 2020.

[80] *Id.* at 95.

[81] *Id.* at 96.

[82] *Id.* at 87.

[83] *Id.* at 88.

[84] Findings of Fact and Conclusions of Law 9.

[85] "Transcript of Bench Trial" 68, ECF No. 63, filed Nov. 16, 2020.

[86] Memorandum from Nathalie R. Asher, Acting Executive Associate Director, U.S. Immigration and Customs Enforcement, to Field Office Directors, Enforcement and Removal Operations, "Migrant Protection Protocols Guidance" (Feb. 12, 2019).

[87] *Id.*

justification for exemption claims, correlating justifications for refusal to disclose with actual portions of records claimed to be exempt.[88] A common way in which agencies do so is through a *Vaughn* index.[89] In *Vaughn*, the D.C. Circuit held that a system of itemizing and indexing exemptions' legal and factual bases would easily remedy the problem of conclusory and generalized allegations of exemptions. [*21] [90] This procedure makes clear the factual nature of the information sought and the specific reason it falls within the statutory exemption asserted.[91] Since *Vaughn*, it has become standard practice for agencies to supply the court with a *Vaughn* index.[92]

Under *FOIA exemption (b)(5)*, an agency can withhold information covered by a recognized evidentiary or discovery privilege.[93] *Exemption (b)(5)* protects from disclosure:

> inter-agency or intra-agency memorandums or letters that would not be available by law to a party other than an agency in litigation with the agency, provided that the deliberative process privilege shall not apply to records created 25 years or more before the date on which the records were requested.[94]

Thus, "*[e]xemption 5* incorporates the privileges which the government enjoys under the relevant statutory and *case law* in the pretrial discovery context."[95] Three common law privileges encompassed in *exemption (b)(5)* include: (1) the attorney work-product privilege; (2) the attorney-client privilege; and (3) the governmental deliberative process privilege.[96]

After repeated opportunities to demonstrate to this court how *exemption (b)(5)* applies to the records ICE sought to [*22] withhold, ICE did not meet its burden to support exempting any information redacted pursuant to *exemption (b)(5)* from disclosure. ICE presented no evidence at either the summary judgment phase or at trial supplying the factual or legal basis for any application of *exemption (b)(5)*. Although settled law establishes the preparation of a Vaughn index, ICE did not generate one. ICE simply provided a brief letter to accompany the thirty-three pages of responsive documents at issue. The letter stated that redactions under *exemption (b)(5)* qualified for protection under one or more of the three named privileges, without specifying which, and without any factual basis for the application of *exemption (b)(5)* to any individual redaction.

ICE's only witness shed no more light on the factual

---

[88] *Batton v. Evers, 598 F.3d 169, 175 (5th Cir. 2010)* (citing *Vaughn v. Rosen, 484 F.2d 820, 157 U.S. App. D.C. 340 (D.C. Cir. 1973)*.

[89] *See Vaughn, 484 F.2d at 827*.

[90] *Id. at 826-27*.

[91] *Stephenson v. IRS, 629 F.2d 1140, 1144 (5th Cir. 1980)*.

[92] *See, e.g., Batton, 598 F.3d at 178-79*; *Flight Safety Servs. Corp. v. Dep't of Labor, 326 F.3d 607, 613 (5th Cir. 2003)*; *Stephenson, 629 F.2d at 1145*.

[93] *Judicial Watch, Inc. v. U.S. Dep't of Def., 847 F.3d 735, 738-39, 427 U.S. App. D.C. 356 (D.C. Cir. 2017)*.

[94] *5 U.S.C. § 552(b)(5)*.

[95] *United States v. Weber Aircraft Corp., 465 U.S. 792, 799, 104 S. Ct. 1488, 79 L. Ed. 2d 814 (14)* (citations omitted) (emphasis in original).

[96] *Tax Analysts v. IRS, 294 F.3d 71, 76, 352 U.S. App. D.C. 273 (D.C. Cir. 2002)*.

basis for the exemptions. Fuentes admitted she was not involved in redacting the documents at issue and therefore had no personal knowledge to speak of.[97] Nor did she seem to have secondary knowledge on which the court could rely due to her role as agency representative. Fuentes stated she reviewed the exemptions claimed and agreed with them.[98] However, when asked directly about why entire pages had been subject [*23] to *exemption (b)(5)*, she stated she did not know what the pages contained.[99] When asked about a specific redacted page, she could not say whether it was the end of the preceding document, an attachment, or part of a subsequent document.[100]

Fuentes's lack of knowledge regarding the substance of the redactions often led her to speculate to fill in the gaps. When asked whether redacted emails were sent to agents executing the MPP on-the-ground, she responded, "they do not appear that way as redacted."[101] In reference to another redacted email, Fuentes stated that, as two attorneys were included among other undisclosed recipients, she believed the email to contain legal advice.[102] She later admitted she did not know who else received the email and was aware emails are not necessarily privileged just because an attorney is included in an email chain.[103]

Fuentes was not only uncertain of the content of responsive records; she was uncertain and inconsistent in providing underlying reasons for redactions. She alternated between identifying the specific privilege applied and admitting she could not state with any confidence which privilege supported each redaction. She openly speculated about which privilege [*24] may have applied based on context clues in the released portions. More than once, she equivocated, stating perhaps the redactor had relied on one of the three privileges cited or perhaps on all three.[104] Fuentes's testimony was not reliable. Even had Fuentes confidently testified as to the privileges relied upon by the redactors, she is not a lawyer.[105] She therefore does not have the education or training to provide an explanation as to *why* a particular privilege was invoked.

While Fuentes was knowledgeable about the procedure ICE uses to apply exemptions generally, she was unable to bridge the gap between that procedure and the factual basis for exemptions applied in this case. Both the fundamental principle of public access to government documents and the general principle of full agency disclosure require agency representatives to have more than mere confidence in the procedure followed. They require clear statements of both the factual nature of the information withheld and whether it falls within a specific statutory exemption.[106] Without

---

[97] "Transcript of Bench Trial" 57-58, ECF No. 63, filed Nov. 16, 2020.

[98] *Id.* at 120.

[99] *Id.* at 144.

[100] *Id.*

[101] *Id.* at 103.

[102] *Id.* at 140-41.

[103] "Transcript of Bench Trial" 146, ECF No. 63, filed Nov. 16, 2020.

[104] *Id.* at 146-47.

[105] *Id.* at 132-33.

[106] *See Batton v. Evers, 598 F.3d 169, 176 (5th Cir. 2010)* ("The central issue . . . is whether the [evidence] submitted by [the agency] . . . sufficiently identif[ies] the documents at issue, including the relevant information contained in each document, and explain[s] why the asserted exemptions justify

either, the explanation is not only legally insufficient, it lacks any reasonable basis in the law. ICE did less than the bare minimum to justify its [*25] exemptions and instead attempted to shift the burden to the court and to DMRS. This forced DMRS to expend considerably more in attorney labor and fees to litigate exemptions to documents produced at the eleventh hour and without the easy remedy of a *Vaughn* index. Therefore, the final factor in the entitlement prong, like all others, weighs in favor of granting attorney fees.

B. Whether the Amount of Attorney Fees Requested is Reasonable

As DMRS substantially prevailed and is entitled to attorney fees, the court must consider whether the amount requested is reasonable.[107] District courts have broad discretion in calculating reasonable attorney fee awards.[108] Reasonable attorney fees are determined in two steps. First, the court calculates the "lodestar."[109] The lodestar is the product of the reasonable hourly rate multiplied by the number of hours reasonably expended on the litigation.[110] The party requesting fees bears the burden of establishing the reasonableness of fees, hours billed, and billing judgment exercised.[111] There is a presumption that the lodestar amount is a reasonable fee.[112]

In step two, the court may adjust the fee award up or down after consideration of the factors articulated [*26] in *Johnson v. Georgia Highway Express, Inc.* not already included in the calculation of the lodestar.[113] However, neither party requests attorney fees depart from the lodestar. Accordingly, the court will not advance to the second step of the attorney fee inquiry and calculation of the lodestar alone will determine the amount of the attorney fee award.

1. Compensable Hours

To calculate the lodestar, a district court must first determine the compensable hours from the attorney's time records, including only hours reasonably spent.[114] Each hour claimed must be supported by attorney billing records.[115] The court must exclude "excessive,

---

withholding.").

[107] *See* 5 U.S.C. § 552(a)(4)(E)(i) ("The court may assess against the United States reasonable attorney fees and other litigation costs reasonably incurred . . .").

[108] *Hensley v. Eckerhart, 461 U.S. 424, 434, 103 S. Ct. 1933, 76 L. Ed. 2d 40 (1983)*; *Watkins v. Fordice, 7 F.3d 453, 457 (5th Cir. 1993)*.

[109] *League of United Latin Am. Citizens No. 4552 v. Roscoe Indep. Sch. Dist., 119 F.3d 1228, 1232 (5th Cir. 1997)*.

[110] *Hensley, 461 U.S. at 434*.

[111] *Saizan v. Delta Concrete Pro. Co., 448 F.3d 795, 799 (5th Cir. 2006)*.

[112] *City of Burlington v. Dague, 505 U.S. 557, 562, 112 S. Ct. 2638, 120 L. Ed. 2d 449 (1992)*. *See also* *Walker v. U.S. Dep't. of Hous. and Urban Dev., 99 F.3d 761, 771-72 (5th Cir. 1996)* (describing the limited circumstances in which an adjustment to the lodestar is permitted).

[113] *488 F.2d 714, 717-19 (5th Cir. 1974)*. *See also* *Pennsylvania v. Del. Valley Citizens' Council for Clean Air, 478 U.S. 546, 565, 106 S. Ct. 3088, 92 L. Ed. 2d 439 (1986)* (holding that *Johnson* factors that are subsumed in the calculation of the lodestar may not provide an independent basis for increasing the fee award).

[114] *Hensley, 461 U.S. at 436-37*.

[115] *Watkins v. Fordice, 7 F.3d 453, 457 (5th Cir. 1993)*.

redundant, or otherwise unnecessary" hours.

DMRS requests compensation for 125.7 hours worked by lead counsel, Christopher Benoit ("Benoit").[116] In support, it submits a billing statement detailing hours worked by Benoit. According to the billing statement, the billed hours are reduced from a total of 132 hours to eliminate redundant or administrative hours.[117] In order to prevent duplication of work, DMRS also does not request compensation for hours worked by co-counsel or counsel's administrative assistant.[118] At the time DMRS filed its Motion DMRS estimated [*27] an additional ten hours of work would be performed to cooperate with ICE in creating and completing a new search in compliance with this court's order.[119] ICE disputed only that the FOIA fee shifting provision permitted compensation for work yet to be performed.[120] DMRS then submitted documentation of an additional 12.8 hours worked in compliance with the court's order to construct a new search and amended its request to substitute these hours for the prospective fees.[121] These hours are therefore no longer speculative and will be considered alongside all other hours.

The hours billed reasonably reflect the time spent on litigation and are compensable. FOIA matters present legal complexities requiring a significant investment of time to fully research and brief. This case proceeded to trial, which required significant time to prepare opening and closing statements, exhibits, an expert witness, and cross-examination. The quality of pleadings submitted and trial advocacy displayed by Mr. Benoit was of the first order. It is remarkable that he and his litigation team did so much quality work in the time claimed.

Benoit represents DMRS on a contingent fee basis.[122] He charged no hourly rate and will [*28] not be compensated beyond court awarded attorney fees. Benoit exercised reasonable billing judgment by omitting any charge for time contributed by co-counsel and his administrative assistant. The court finds no excessive, redundant, or otherwise unnecessary hours in counsel's billing statement.

Besides the usual time requirement for actions proceeding to trial, this case presented unusual complications resulting from the government's own obstructionist behavior. ICE's repeated delays and administrative errors needlessly extended the duration of this action and required numerous phone calls, emails, and conferences that would otherwise have been unnecessary. ICE also complicated the summary judgment phase by untimely producing responsive documents after DMRS filed its motion and the dispositive motion deadline had passed, thereby preventing DMRS from disputing redactions to those documents before its reply. In turn, as both parties had not had an opportunity to brief the issue, this court was unable to address the contested redactions at that phase and carried the issue over to trial.[123]

---

[116] Mot. 10.

[117] Mot., "19-cv-00236 Billing Statement" 2, ECF No. 56-1, Ex. 1-B.

[118] Mot. 8.

[119] *Id.* at 10.

[120] Resp. 3 fn. 2.

[121] *See* "Plaintiff's Reply to Defendant's Response to Plaintiff's Application for Attorney Fees and Costs" 6, ECF No. 66, filed Nov. 25, 2020.

[122] Mot. 7.

[123] *See* "Order Denying Motion for Summary Judgment" 6, ECF No. 30, entered Aug. 25, 2020; *Medina Cnty. Envtl.*

Even now, ICE continues to stall and delay its search for responsive documents. For the first time, [*29] ICE claims the substantial backlog of FOIA requests and its limited personnel makes timely compliance impossible. However, administrative backlog does not form a reasonable basis in law to withhold responsive documents.[124]

As ICE did not have a faintly colorable claim that its search complied with the statute, this newfound claim of impossibility proves how indifferent ICE was to its statutory duty. Had ICE responded in conformity with the statute, the enormity of the task they now claim would have been identified in the summer of 2019 and not in the winter of 2020. Meanwhile, DMRS and its counsel must continue to expend time and resources pursuing its claim, even after completely prevailing at trial. DMRS has met its burden to show the reasonableness of the 138.5 hours billed by Benoit.

2. Hourly Rate

Next, the district court must "select an appropriate hourly rate based on prevailing community standards for attorneys of similar experience in similar cases."[125] "Generally, the reasonable hourly rate for a particular community is established through affidavits of other attorneys practicing there."[126]

DMRS requests an hourly rate of $325-375.[127] In support of its requested rate, DMRS provides a [*30] declaration from Benoit, expanding on the time and effort expended by counsel;[128] a declaration from attorney Lynn Coyle, attesting to both the work done by Benoit in this case and the prevailing rate for comparable legal work;[129] and a declaration from John P. Mobbs ("Mobbs"), a seasoned El Paso attorney qualified as an expert in attorney fees, opining that the fees requested in this case are below the reasonable contingency fee range in El Paso.[130]

ICE contends the proposed rate is excessive and unreasonable as it exceeds the hourly rate of El Paso attorneys with comparable experience as listed in the 2015 State Bar of Texas Hourly Rate Fact Sheet ("Fact Sheet").[131] ICE cites to a string of unreported district court opinions relying on the Fact Sheet to calculate reasonable attorney fees according to various statutory fee-shifting provisions.[132] The line of cases relying on

---

Action Ass'n v. Surface Transp. Bd., 602 F.3d 687, 702 (5th Cir. 2010).

[124] *See* *Miller v. U.S. Dep't of State, 779 F.2d 1378, 1390 (8th Cir. 1985)*(holding that attorney fees cannot be denied on the reasonableness of the government's position where the government cites processing backlogs, confusion, and administrative error, because these "are practical explanations, not reasonable bases.").

[125] *Shipes v. Trinity Indus., 987 F.2d 311, 319 (5th Cir. 1993)*.

[126] *Tollett v. City of Kemah, 285 F.3d 357, 368 (5th Cir. 2002)*.

[127] *Id.* at 7.

[128] *See generally* Mot., "Declaration of Christopher Benoit," ECF No. 56-1, Ex. 1.

[129] *See generally* Mot., "Declaration of Lynn Coyle Pursuant to *28 U.S.C. § 1746*." ECF No. 56-1, Ex. 5.

[130] *See generally* Mot., "Declaration of John P. Mobbs," ECF No. 56-1, Ex. 2.

[131] Resp. 5. *See also*, Resp., "State Bar of Texas 2015 Hourly Fact Sheet" ("Fact Sheet") ECF No. 65-1, Ex. A.

[132] *See e.g.,* [*31] *Alvarez v. McCarthy, No. 6:16-CV-00172-ADA, 2020 U.S. Dist. LEXIS 59790, 2020 WL 1677715, at *6*

the Fact Sheet is unpersuasive. First, the Texas Bar has not published an updated Fact Sheet since 2015. Five-year-old fee data is unreliable and likely to skew lower than current attorney fees. The Fact sheet itself notes a 7.4% increase in median rates from 2013 to 2015.[133]

Second, it is uncertain that even a 2021 Fact Sheet would accurately represent the reasonable hourly rate for the El Paso legal community. DMRS included with its motion a Review of the State Bar of Texas *2015 Hourly Fact Sheet* by Statistician N. Shirlene Pearson, Ph.D. ("Dr. Pearson").[134] Dr. Pearson stated the Texas Bar survey underlying the Fact Sheet data suffered from the fatal defects of a limited sample size, selection bias, and suboptimal methodology.[135] Moreover, the hourly rates listed on the Fact Sheet do not distinguish between reported billing method: hourly fees, flat rates, contingency fees, or discounted fees for volume clients.[136] Dr. Pearson concluded the Fact Sheet does not reliably reflect the hourly rates of attorneys in Texas.[137] Tellingly, the Texas Bar itself warns against using the Fact Sheet to set attorney fees.[138]

Finally, the Fifth Circuit has not adopted the Fact Sheet as a determinative measure of reasonable attorney fees in a given community. Instead, Fifth Circuit jurisprudence is based on trial court reliance on attorney affidavits.[139] ICE does not dispute the unreliability of the Fact Sheet [*32] or offer its own attorney affidavits. Instead, it merely points to non-binding law and argues the court should blindly follow it. After consideration of the significant limitations of the Fact Sheet, this court relies on the three attorney declarations supporting the Motion, which compellingly concur that the requested rate is reasonable.

The large amount of work done in such a low number of hours is the direct result of Benoit's high level of litigation skills and accompanying effectiveness. Given the delays and conduct of ICE in this case, a less experienced attorney would have easily spent a substantially higher number of hours. By way of illustration, 190 compensable hours at $275 would yield a total of $52,250 in attorney fees—more than Benoit requested. ICE's objection to the proposed hourly rate is solely based on a much-discredited study and not on Fifth Circuit jurisprudence. To follow ICE's rationale would simply discourage highly skilled attorneys like Benoit from taking on difficult cases like this one. DMRS has met its burden to show the reasonableness of its requested fee.

Considering the applicable law and pertinent facts before this court, an hourly rate of $375 will [*33] be applied to calculate the lodestar. After multiplying this rate by the 138.5 compensable hours, reasonable attorney fees in this case are $51,937.50.

(W.D. Tex. Apr. 6, 2020).

[133] Fact Sheet 4.

[134] *See generally* Mot. "Review of the State Bar of Texas *2015 Hourly Fact Sheet* report and its Use by the Texas Judiciary in Deciding Plaintiff Attorney Hourly Fees in Labor-Employment Cases" ("Review of Fact Sheet") ECF No. 56-1, Ex. 1-C.

[135] *Id.*

[136] *See generally* Fact Sheet. *See also* Review of Fact Sheet 5.

[137] Review of Fact Sheet 6.

[138] Texas State Bar, Demographic & Economic Trends: Economic Trends, available at https://www.texasbar.com/AM/Template.cfm?Section=Demographic_and_Economic_Trends (last accessed Jan. 20, 2021).

[139] *See Tollett v. City of Kemah, 285 F.3d 357, 368 (5th Cir. 2002)*.

UNITED STATES DISTRICT JUDGE

End of Document

C. Plaintiff's Bill of Costs

Pursuant to *28 U.S.C. § 1920*, a judge may include costs for fees of the clerk of court and service of summons of subpoena in a judgment upon filing of a bill of costs. In its bill of costs, DMRS requests such reimbursement in the amount of $432.20.[140] ICE does not challenge these costs.[141] After due consideration, the court finds it in the interest of justice to grant DMRS's bill of costs.

IV. CONCLUSION

Accordingly, the court enters the following orders:

1. **IT IS HEREBY ORDERED** that "Plaintiff's Opposed Application for Attorney Fees and Costs" [ECF No. 56] is **GRANTED**.

2. **IT IS FURTHER ORDERED** that Plaintiff Diocesan Migrant & Refugee Services shall **RECOVER** from Defendant United States Immigration and Customs Enforcement **$51,937.50** for work performed in this case.

3. **IT IS FURTHER ORDERED** that Plaintiff Diocesan Migrant & Refugee Services shall **RECOVER** from Defendant United States Immigration and Customs Enforcement costs of the court in the amount of **$432.20**.

SIGNED AND ENTERED this **28th** day of **January 2021**.

/s/ Frank Montalvo

FRANK MONTALVO [*34]

---

[140] "Bill of Costs" 1, ECF No. 55, filed Nov. 2, 2020.

[141] Resp. 1 fn. 1.

Caution

As of: December 14, 2021 12:04 AM Z

Edmonds v. FBI

United States District Court for the District of Columbia

December 3, 2002, Decided ; December 3, 2002, Filed

Civil Action No. 02-1294 (ESH)

Reporter

2002 U.S. Dist. LEXIS 26578 *; 2002 WL 32539613

SIBEL D. EDMONDS, Plaintiff, v. FEDERAL BUREAU OF INVESTIGATION, Defendant.

Disposition: [*1] Plaintiff's Motion for partial summary judgment granted, defendant's Motion for an Open America stay denied.

Core Terms

requests, processing, expedited, regulation, exceptional circumstances, due diligence, compelling need, responding, documents, media, public confidence, allegations, questions, backlog

Case Summary

Procedural Posture

Plaintiff whistleblower filed suit, asserting that she was entitled to expedited processing of her Freedom of Information Act (FOIA), *5 U.S.C.S. § 552 et seq.*, request under *28 C.F.R. § 16.5(d)(1)(iv)*. Defendant Federal Bureau of Investigations (FBI) disputed the whistleblower's entitlement to expedited processing and moved for an Open America stay. The whistleblower moved for partial summary judgment.

Overview

Even though the FBI had satisfied the exceptional circumstances-due diligence test, it was not entitled to an Open America stay because the whistleblower was entitled to expedited processing of her request. Under the Department of Justice's regulations, *28 C.F.R. § 16.5(d)(1)(iv)*, the whistleblower did not need to show prejudice or a matter of current exigency to the American public; she only needed to demonstrate that the subject matter of her request involved a matter of widespread and exceptional media interest in which there existed possible questions about the integrity of the government that affect public confidence. The whistleblower easily met that standard and was thus entitled to expedited processing. The whistleblower had offered ample evidence that her allegations had been (1) the subject of widespread and exceptional media interest, and (2) had called into question the integrity of the FBI which affected public confidence in that institution.

Outcome

The whistleblower's motion for partial summary judgment was granted, and the FBI's motion for an Open America stay was denied.

LexisNexis® Headnotes

Administrative Law > ... > Compliance With Disclosure Requests > Delays > Exceptional Circumstances

Administrative Law > Governmental Information > Freedom of Information > General Overview

Administrative Law > ... > Freedom of Information > Compliance With Disclosure Requests > General Overview

Administrative Law > ... > Freedom of Information > Defenses & Exemptions From Public Disclosure > General Overview

Administrative Law > ... > Judicial Review > Reviewability > Jurisdiction & Venue

HN1[] **Delays, Exceptional Circumstances**

Under the Freedom of Information Act (FOIA), *5 U.S.C.S. § 552 et seq.*, a court may retain jurisdiction and give an agency additional time to respond to a FOIA request if the Government can show exceptional circumstances exist and that the agency is exercising due diligence in responding to the request. *5 U.S.C.S. § 552(a)(6)(C)(i)*. Exceptional circumstances exist when an agency is deluged with a volume of requests for information vastly in excess of that anticipated by Congress, when the existing resources are inadequate to deal with the volume of such requests within the time limits of *5 U.S.C.S. § 552(a)(6)(A)*, and when the agency can show that it is exercising due diligence in processing the requests. Such exceptional circumstances do not include a delay that results from a predictable agency workload of requests unless the agency demonstrates reasonable progress in reducing its backlog of pending requests. *5 U.S.C.S. § 552(a)(6)(C)(ii)*.

Administrative Law > Governmental Information > Freedom of Information > General Overview

Civil Procedure > ... > Entry of Judgments > Stays of Judgments > General Overview

HN2[] **Governmental Information, Freedom of Information**

In the context of an Open America stay, where a requester shows exceptional need or urgency, that requester may be given priority over other requesters.

Administrative Law > ... > Compliance With Disclosure Requests > Delays > Expedited Processing

Administrative Law > Governmental Information > Freedom of Information > General Overview

Administrative Law > ... > Freedom of Information > Compliance With Disclosure Requests > General Overview

HN3[] **Delays, Expedited Processing**

The Freedom of Information Act, *5 U.S.C.S. § 552 et seq.*, directs agencies to provide for expedited processing, not only in cases in which the person requesting the records demonstrates a compelling need, but also in other cases determined by the agency. *5 U.S.C.S. § 552(a)(6)(E)(i)*. This latter provision gives an agency latitude to expand the criteria for expedited access beyond cases of compelling need.

Administrative Law > Agency Rulemaking > Rule Application & Interpretation > General Overview

Administrative Law > Judicial Review > Standards of Review > Rule Interpretation

HN4[] **Agency Rulemaking, Rule Application & Interpretation**

An agency is required to follow its own regulations.

Administrative Law > Governmental Information > Freedom of Information > General Overview

HN5[] **Governmental Information, Freedom of Information**

The specific motives of the party making the Freedom of Information Act, *5 U.S.C.S. § 552 et seq.*, request are irrelevant. If the general public has a legitimate, albeit abstract, interest in the requested information and that disclosure is warranted, disclosure must be made despite the fact that the party actually requesting and receiving the information may use it for less-than-lofty purposes.

Counsel: For S D Edmonds, PLAINTIFF: Stephen Martin Kohn, David Keith Colapinto, Kohn, Kohn & Colapinto, PC, Washington, DC USA.

For Federal Bureau of Investigation, FEDERAL DEFENDANT: John R Griffiths, Vesper Mei, US Department of Justice, Pamela D Huff, US Attorney's Office, Washington, DC USA.

Judges: ELLEN SEGAL HUVELLE, United States District Judge.

Opinion by: ELLEN SEGAL HUVELLE

Opinion

ORDER

Before the Court are plaintiff's Motion for Partial Summary Judgment [11-1] and defendant's opposition and Cross Motion for Stay of Proceedings [18-1] pursuant to *Open America v. Watergate Special Prosecution Force, 178 U.S. App. D.C. 308, 547 F.2d 605 (D.C. Cir. 1976)*. At issue before the Court is the speed with which defendant must comply with plaintiff's Freedom of Information Act ("FOIA") request. *See 5 U.S.C. § 552 et seq.*

Plaintiff asserts that she is entitled to expedited processing of her FOIA request under *28 C.F.R. § 16.5(d)(1)(iv)*, which provides for expedited processing where a request involves "[a] [*2] matter of widespread and exceptional media interest in which there exist possible questions about the government's integrity which affect public confidence." Defendant disputes plaintiff's entitlement to expedited processing and moves for an *Open America* stay on the grounds that the FBI is exercising due diligence in responding to plaintiff's requests but that exceptional circumstances have prevented it from processing the requests within the statutory time limit.

BACKGROUND

Plaintiff is a whistleblower who worked as a contract linquist for the FBI in counter-terrorism and counter-intelligence investigations at the FBI Washington Field Office after September 11, 2001. By letter dated April 19, 2002, Ms. Edmonds has requested documents relating to herself, her allegations of wrongdoing at the FBI, and investigations of persons related to her.

Plaintiff made a second FOIA request on April 29, 2002, seeking information pertaining to her security clearance and the purported investigation and/or adjudication thereof. In both requests, plaintiff asked for expedited processing. However, in response to these requests, defendant has failed to make any determination regarding [*3] whether her requests are entitled to expedited processing. *See* 28 C.F.R. § 16.5(d)(4); *see also* 5 U.S.C. § 552(a)(6)(E)(i)-(ii). Having exhausted her administrative remedies, plaintiff now moves for partial summary judgment, requesting that this Court order the FBI to expedite the processing of her requests.

In response, defendant argues that plaintiff does not qualify for expedited processing because her requests are "personal to her, and the documents that she seeks have nothing to do with any wider concerns of the American public." (Def.'s Opp. at 8.) According to defendant, her requests are being made in order to obtain information for her civil suit, *Edmonds v. Department of Justice,* Civil Action No. 02-1448 (JR). Further, defendant seeks an *Open America* stay until April 1, 2003, on the grounds that although the FBI is exercising due diligence in responding to plaintiff's requests, there are exceptional circumstances, especially in light of September 11, 2001, that have prevented defendant from processing plaintiff's requests in a timely manner.

LEGAL ANALYSIS

I. *Open America Stay*

Defendant [*4] FBI moves for an *Open America* stay until April 1, 2003. [1] HN1[↑] Under FOIA, a court may retain jurisdiction and give an agency additional time to respond to a FOIA request "if the Government can show exceptional circumstances exist and that the agency is exercising due diligence in responding to the request …." 5 U.S.C.A. § 552(a)(6)(C)(i). Exceptional circumstances exist when an agency "is deluged with a volume of requests for information vastly in excess of that anticipated by Congress, when the existing resources are inadequate to deal with the volume of such requests within the time limits of … [5 U.S.C. § 552(a)(6)(A)], and when the agency can show that it 'is exercising due diligence' in processing the requests." *Open America, 547 F.2d at 616*. Such exceptional circumstances do not include "a delay that results from a predictable agency workload of requests … unless the agency demonstrates reasonable progress in reducing its backlog of pending requests." 5 U.S.C.A. § 552(a)(6)(C)(ii).

[*5] The FBI has demonstrated that exceptional circumstances do exist, the agency is exercising due diligence in processing requests, and it is making reasonable progress in reducing its backlog. According to the declaration of Christine Kiefer, Acting Chief of the Litigation Unit, Freedom of Information Privacy Acts Section, Records Management Division at FBI Headquarters in Washington, D.C., the FBI is still confronted by over 1,300 requests each month even though it has drastically reduced its backlog. The FOIA personnel also spend time on administrative appeals, litigation, and large projects. For instance, as of September 30, 2002, the FBI was involved in 142 pending requests in various federal courts throughout the United States involving 650 FOIA requests. Finally, in response to the events of September 11, 2001, the

[1] Plaintiff incorrectly argues that defendant has waived its right to an *Open America* stay by not raising it before now. *See* Pl.'s Opp. at 12. A request for a temporary stay does not constitute an affirmative defense, since it is unrelated to defendant's defenses to the merits of plaintiff's FOIA claims, and thus, there is no basis for plaintiff's waiver argument.

FBI has had to divert personnel to assist in ongoing investigations of terrorist attacks. For these reasons, the FBI faces exceptional circumstances warranting an *Open America* stay. [2]

[*6] In addition to demonstrating "exceptional circumstances," defendant has also shown that it is exercising due diligence in responding to plaintiff's FOIA requests and has made reasonable progress in reducing its backlog despite the burdens on its resources. As attested to by Kiefer, the FBI's backlog has decreased significantly since 1996 (declining approximately 26%). Further, as evidenced by her declaration, the FBI has identified approximately 774 pages of responsive documents and it is in the process of reviewing these documents at this time. Based on the efforts to date, the Court is satisfied that the FBI is exercising due diligence in responding to plaintiff's requests.

Having found that defendant has satisfied the exceptional circumstances-due diligence test, however, this Court's inquiry is not complete, for *Open America* also recognized that HN2[↑] where a requester shows exceptional need or urgency, that requester may be given priority over other requesters. *Open America, 547 F.2d at 615-16*. In particular, defendant itself has recognized several specific grounds for expediting requests, only one of which is relevant here, and it is this ground for expedition [*7] to which the Court must turn its attention.

II. Expedited Processing

As noted, plaintiff moves for partial summary judgment, arguing that her requests involve "[a] matter of widespread and exceptional media interest in which there exist possible questions about the government's integrity which affect public confidence" and therefore are entitled to expedited processing under the Department of Justice's ("DOJ") regulations. *28 C.F.R. § 16.5(d)(1)(iv)*. Defendant responds that plaintiff has not satisfied this standard because she has failed to show that her requests concern a matter of current exigency to the American public, and she has not shown that "'a delay in obtaining information can reasonably be foreseen to cause a significant adverse consequence to a recognized interest.'" (Def.'s Opp. at 9, quoting *Al-Fayed v. CIA, 349 U.S. App. D.C. 223, 254 F.3d 300, 311 (D.C. Cir. 2001)*.)

The problem with defendant's position is that it is attempting to graft onto the DOJ's regulation FOIA's definition of "compelling need." *See 5 U.S.C. § 552(a)(6)(E)(v)(I)and (II)*. However, the regulation at issue here was [*8] not issued pursuant to this "compelling need" standard. As the D.C. Circuit recognized in *Al-Fayed,* HN3[↑] FOIA directs agencies to provide "for expedited processing, not only 'in cases in which the person requesting the records demonstrates a compelling need,' but also 'in other cases *determined by the agency.*'" *Al-Fayed, 254 F.3d at 307 n.7*, quoting *5 U.S.C. § 552(a)(6)(E)(i)* (emphasis in original). Citing the statute's legislative history, the Court explained that this "latter provision gives an agency 'latitude to expand the criteria for expedited access' beyond cases of 'compelling need.' H.R. Rep. No. 104-795, at 26." *Id; see also Aguilera v. FBI, 941 F. Supp. 144, 149 (D.D.C. 1996)*; *Electronic Privacy*

---

[2] As indicated by the many cases cited by the defendant in its Opposition at 15-16 and 18-19, *Open America* stays of far greater time periods than requested here have been ordered by this Court on numerous occasions, and these stays have been granted subsequent to the passage of the Electronic FOIA Amendments of 1996. *See, e.g., Emerson v. CIA, 1999 U.S. Dist. LEXIS 19511, at *4 (D.D.C. Dec. 16, 1999)* (Hogan, J.).

Information Center v. FBI, 865 F. Supp. 1, 2 (D.D.C. 1984); *Whitehurst v. FBI,* Civil Action No. 96-572 (Feb. 5, 1997) (Kessler, J.).

DOJ promulgated the standard pertinent to this case pursuant to this discretionary authority. Because that standards falls outside and goes beyond FOIA's definition of "compelling need," the Court has no basis to demand that the requester satisfy the compelling need test in [*9] order to satisfy the regulation. [3] Under DOJ's regulation, plaintiff need not show prejudice or a matter of current exigency to the American public; she need only demonstrate that the subject matter of her request involves "[a] matter of widespread and exceptional media interest in which there exist possible questions about the integrity of the government that affect public confidence." Plaintiff easily meets this standard and is thus entitled to expedited processing.

[*10] First, as even defendant concedes (Def.'s Op. at 7-8) and is as amply demonstrated by the record before the Court, plaintiff's allegations have received extensive media coverage, including numerous newspaper articles in the printed press -- *Associated Press, The Washington Post, Chicago Tribune* -- and on TV. (*See, e.g.,* Pl.'s Mot. Exs. 5, 8, 9, 12, 13, 17-19.) Plaintiff's allegations regarding security lapses in the FBI's translator program have also fueled the interest of Senators Leahy and Grassley, both of whom have written to the Attorney General and spoken on the floor of the Senate about their concerns regarding the significant security issues raised by plaintiff's allegations and the integrity of the FBI. (*Id.* Ex. 10.) [4] This flurry of articles and television coverage, which has continued at least until last month, cannot be cast aside by a sleight-of-hand as defendant attempts to do by categorizing plaintiff's requests as being merely "personal to her" and of no "wider public concern." (Def.'s Opp. at 8.)

[*11] While it is true -- as defendant argues (Def.'s Opp. at 8) -- that plaintiff's pending lawsuit against the DOJ may be the motivating force for her requests and that the documents that she seeks undoubtedly relate to that suit, these requests also relate to matters of wider public concern that directly implicate "possible questions about the government's integrity which affect public confidence." *28 C.F.R. § 16.5(d)(1)(iv)*. Nothing in the DOJ's regulation disqualifies a plaintiff from obtaining expedited processing where the documents may assist her in another lawsuit, nor is there any basis to conclude that a whistleblower who has brought suit against a government agency as a result of her firing cannot also satisfy the DOJ's regulations for expedited processing. Indeed, it would be illogical to conclude that where a whistleblower's allegations trigger "widespread and exceptional media interest" because of the questions raised regarding the "government's integrity," that person's requests can be rejected for expedited handling because they are also personal to her and her lawsuit against the defendant. *Cf. Halloran v. Veterans Admin., 874 F.2d 315, 323 (5th Cir. 1989)* [*12] ("The *HN5*[↑] specific motives of the party making the FOIA

---

[3] It is, of course, axiomatic that *HN4*[↑] an "agency is required to follow its own regulations." *Cherokee National of Okla. v. Babbitt, 326 U.S. App. D.C. 139, 117 F.3d 1489, 1499 (D.C. Cir. 1997)*. In addition, the Court has no basis to accord deference to the agency's reasonable interpretation of its own regulations, *see Al-Fayed, 254 F.3d at 307 n.7*, since defendant has not cited any interpretation of its regulations but only argues that plaintiff does not meet the standard because the "requests are personal to her, and the documents that she seeks have nothing to do with any wider concerns of the American public." (Def.'s Opp. at 8.)

[4] As is clear from Pl.'s Reply Mem., her allegations continue to receive coverage in the press, including on *60 Minutes* (Pl.'s Reply Mem. Ex. 23), and attention from Senator Grassley. (*Id.* Ex. 24.)

request are irrelevant. If the general public has a legitimate, albeit abstract, interest in the requested information and that disclosure is warranted, disclosure must be made despite the fact that the party actually requesting and receiving the information may use it for less-than-lofty purposes.")

In sum, plaintiff has satisfied the criteria established by the DOJ for expediting FOIA requests. Plaintiff has offered ample evidence that her allegations have been (1) the subject of "widespread and exceptional media interest," and (2) call into question "the integrity of the … [FBI] which affect[s] public confidence" in that institution. While defendant could justifiably argue that the Court's application of the relevant regulation will result in an even greater burden on its already strained resources and will disadvantage other FOIA requesters, [5] the Court is constrained to enforce the regulation as written.

[*13] **CONCLUSION**

Accordingly, plaintiff's motion for partial summary judgment is **GRANTED,** defendant's Motion for *Open America* Stay is **DENIED,** and a status hearing is set for December 13, 2002, at 11:00 a.m., at which time defendant must inform the Court of the date when the request will be processed consistent with *5 U.S.C. § 552(a)(6)(E)(iii)* and *28 C.F.R. § 16.5(d)(4)* ("as soon as practicable").

ELLEN SEGAL HUVELLE

United States District Judge

Dated: 12/3/02

End of Document

[5] In this regard, the Court is mindful of the admonition in *Al-Fayed* that an "'unduly generous use of the expedited processing procedure would unfairly disadvantage other requesters'" whether they qualify for expedited treatment or not. *254 F.3d at 310* (citation omitted). Unlike *Al-Fayed,* the statutory requirement of "compelling need" is not applicable here, since the DOJ has "'expanded the criteria for expedited access' beyond cases of 'compelling need.'" *Id. at 307 n.7* (citation omitted).