SECOND JOINT REPORT

Description

IN THE UNITED STATES DISTR
NORTHERN DISTRICT OF

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY,

Plaintiff,

-against-

FOOD AND DRUG ADMINISTRATION,

Defendant.

Civ

SECOND JOINT REPO

Plaintiff, Public Health and Medical Professionals f

through its attorneys, and Defendant, the U.S. Food and I

"**FDA**"), by and through its attorney, hereby submit this

Court's Order of November 10, 2021, ECF No. 19 (the "**Or**

1. The Order asked the parties to "appraise

conference is needed" and if not to "propose[] deadlines f

necessary."

Case 4:21-cv-01058-P Document 20 Filed 11/15/

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necessary."

resources are finite. Increasing the volume to more than 8
even possible – and it likely is not), as Plaintiff requests, w
essentially all of FDA's resources and leaving little resou
Indeed, the D.C. Circuit has recognized that another agency
request per month "serves to promote efficient responses to
Sec. Counselors v. Dep't of Justice, 848 F.3d 467, 471–72 (I
Info. Ctr. v. Dep't of Justice, 15 F. Supp. 3d 32, 47 (D.D.C. 2
injunction requesting immediate production of documents
that allowing the plaintiff "to jump to the head of the line w
be detrimental to the other expedited requesters"); *Daily Cal*
"the plaintiff's effort to jump to the head of the FOIA proc
burden on both the agency and numerous interested parties"

Third, the Court should flatly reject Plaintiff's specio
reviewing Pfizer's Biologics License Application could d
government information specialists should be able to do so
be apparent, the review conducted by FDA scientists when

approved. When read in context, it is clear that FDA's regu
a biological product file is held in strict confidence by the
released to the public, for instance in response to standard pr
the Freedom of Information Act. *See generally* 21 C.F.
regulations establish the point in time when records that may
public disclosure lose their status as confidential and thus
"immediately" upon occurrence of the triggering event. Sp
the existence of a biological product file will not be discl
unless it has been previously disclosed or acknowledged, an
available for public disclosure. 21 C.F.R. § 601.51(b, c). If
file has been acknowledged before a license has been issue
information and data in the file available for public dis
license. 21 C.F.R. § 601.51(d). Once a license has bee
information in the biological product file become "
disclosure. 21 C.F.R. § 601.51(e). That means that if a
received for data and information listed in 21 C.F.R. § 601.

6299966, at *3 (D.D.C. Sept. 3, 2018) (permitting a proces
71,000 responsive records). FDA has invited Plaintiff to na
it no longer wants FDA to process and release, and Plaint
decides to request fewer records, then FDA will be able to
date.

Finally, this case is not about a vaccine mandate or w
is a FOIA case where the only relevant issue at this stage i
processing schedule. FDA's proposed schedule of 500
schedules set by courts across the country, including in cas
of national significance. It adequately balances the interest
with the interests of the vaccine sponsor in the protectio
interests of clinical trial participants in the protection of th
the interests of other FOIA requesters whose requests are be

3. **Plaintiff's Position:** Plaintiff agrees with th
may enter a production schedule based on the argument
conference. Plaintiff seeks the records submitted to the FD

responsive to its FOIA request no later than March 3, 202
amount of time it took the FDA to review the responsive do
of licensing Pfizer's Covid-19 vaccine (the "**Pfizer vaccine**

Plaintiff is an organization comprised of over 30 acc
scientists from the medical schools and related departments
including Yale, Harvard, UCLA, and Brown. These acade
section of every discipline relevant to the licensure of the P
best our country has to offer when it comes to reviewing a
validity of the FDA's decision-making in licensing this proc

The ability of a majority of Americans to participa
basic liberty rights, are now contingent on receiving this proc
recent Covid-19 Action Plan[5] and executive orders[6] have m
of employment[7] for more than 6 million federal workers a
professionals,[9] 84 million private sector employees,[10] and th

[5] https://www.whitehouse.gov/covidplan/#testing-masking (last visited

armed forces.[11] There are few whose livelihood, education, se
are not contingent on a government requirement to receive th
liberty and government transparency demand that the docum
license this product be made available to Plaintiff and the publ
by federal regulations.[12]

The acute need for transparency regarding this prod
secretary of Health and Human Services ("**HHS**"), the Fl
Pfizer complete immunity from financial liability for any in
-- including suffering one of the injuries even federal health
product -- the injured individual effectively has no recourse
secretary of HHS, Pfizer cannot be sued by anyone receiving
§ 247d-6d. Pfizer also cannot be sued for willful misconduc
which has been promoting this product, agrees to bring such
It should not be that the public is deprived accessing the do
to license this product when at the same time the public are b
with no ability to sue Pfizer for compensation if they suffer

appropriate analysis by the independent scientists that are
Would the FDA agree to review and license this product w
not. These independent, world-renowned scientists should

The entire purpose of the FOIA is to assure gover
imagine a greater need for transparency than immediate dis
by the FDA to license a product that is now being mandated
penalty of losing their careers, their income, their military s

It took the FDA precisely 108 days from when Pfi
licensure on May 7, 2021,[14] to when the product was license
as the FDA has stated, that it conducted an intense, robus
analysis of those documents in order to assure that the Pfiz
licensure. The FDA now has an equally important task of
the Plaintiff in this case and the public at large in at least the

The FDA's own regulations envision and reflect
information public as soon as a vaccine is licensed. Its
"immediately available" all documents underlying licensure

licensure, the FDA has not released a single document subm
Covid-19 vaccine. Not one page.

Mandates of this liability-free product are ongoing ar
Report. School-age children are now being mandated to tak
today to produce is far too long, hence Plaintiff respectfully
absolute outside date by which the FDA be compelled to pr
an organization comprised of more than 18,000 people[17] wit
said that there is nothing more important than the licensure
about this vaccine. This request is precisely why the need f
Congress enacted FOIA. If the FDA claims its obligation
should take its complaints to Congress – not this Court.

For the Americans that will lose their job, income,
worse, for refusing a federal mandate requiring this product
burdensome to comply with federal law. That is not an exc
a federal law requires them to do something. The FDA sho
harbor. Certainly not on an issue this important. Again, if t

and taken such an absurd and unconscionable position of w
the production further heightens the grave need to have thes

Plaintiff respectfully requests that the Court enter a
all documents and data submitted by Pfizer on a rolling bas
on or before March 3, 2022, which is 108 days from toda
meaningless, the FDA's promise of transparency a lie, and t
while the federal executive branch is shielding Pfizer from a
and requiring employers, schools, hospitals and the military
product, it is protecting the very documents Pfizer provided
to obtain licensure to be able to sell this product. That sim
FOIA and equity demand the relief Plaintiff requests herein

Dated: November 15, 2021

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requestor. 5 U.S.C. § 552(a)(4)(B). Once a case is filed a complaint, the parties usually negotiate a schedule by wh process, and produce records responsive to the plaintiff's F to agree upon a schedule, courts typically enter a processing for each party's proposed schedule that were presented i conference.

A processing schedule is necessary because many dif from the FOIA, such that the government must redact that inf records to the plaintiff. *See* 5 U.S.C. § 552(b)(1)–(b)(9). exempt information is a time-consuming process that oft specialists to review each page line-by-line. When a party re Plaintiff did here, courts typically set a schedule whereby non-exempt portions of records is made on a rolling basis.

After the government has completed processing and responsive records to the plaintiff, the parties typically confe

merits of the case. Summary judgment briefing in a FOIA set a schedule for the release of records.[1]

In this case, FDA has assessed that there are m responsive to Plaintiff's FOIA request. (This page cour responsive to the request, as it does not include certain types paginated, such as data captured in spreadsheets that cont parties have conferred in good faith concerning a processi reach agreement for the reasons set forth in the parties' Join

Defendant respectfully requests a scheduling confere a schedule for the processing of documents. Defendant p Joint Report and resubmits it here for ease of reference. FD non-exempt portions of the following records by the follow

- November 17:
  - From Section 5.2 of the Biologics Li
    - The Tabular Listing
    - The Listing of Clinical Sites

- December 1: remainder of section 5.2 of the

After the December 1 production, FDA proposes to worl Plaintiff requested FDA prioritize for production in order c non-exempt portions of those records to Plaintiff on a rollin produce the non-exempt portions of responsive records at a r is consistent with processing schedules entered by courts ac

Plaintiff's request (as set forth below) that FDA p portions of more than 329,000 pages in four months would fo pages per month. Undersigned counsel is not aware of any c Court should decline to enter Plaintiff's schedule for numer

First, "[r]equiring the agency to process and produce deadline raises a significant risk of inadvertent disclosure of under FOIA." *Daily Caller v. Dep't of State*, 152 F. Supp. requested records that comprise information submitted by th From FDA's experience with other FOIA requests, such re

confidential business and trade secret information of Pfize
information of patients who participated in clinical trials.
information under the law and this type of information is exe
See 5 U.S.C. § 552(b)(4), (b)(6); *F.B.I. v. Abramson*, 456 U.S
that legitimate governmental and private interests could be
information and provided nine specific exemptions under
To ensure protection of this information, and other informa
FOIA exemptions, FDA must carefully review and, if neces
line-by-line basis. *See Daily Caller*, 152 F. Supp. 3d at 1
"responsibility" when processing FOIA requests to
information"). This type of review for more than 329,000
the agency is going to be able to perform the careful an
information.

Second, the FDA does not have the personnel or re
Plaintiff's FOIA request at a rate of more than 80,000 pages
is being processed by the Access Litigation and Freedom of

Category

1. Main

Tags

1. Iran
2. Kondolence
3. Menšiny
4. Židé

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