



# the Defender™

CHILDREN'S HEALTH DEFENSE NEWS & VIEWS

**BUY TODAY:** Robert F. Kennedy, Jr.'s New Book — 'The Real Anthony Fauci'

12/10/21 • [BIG PHARMA](#) › [NEWS](#)

## FDA Now Wants 75 Years to Release Pfizer Vaccine Documents

*“ ... it is dystopian for the government to give Pfizer billions, mandate Americans to take its product, prohibit Americans from suing for harms, but yet refuse to let Americans see the data underlying its licensure.”*

By [Michael Nevradakis, Ph.D.](#)

  
115



*Miss a day, miss a lot. [Subscribe to The Defender's Top News of the Day. It's free.](#)*

The U.S. Food & Drug Administration (FDA) now says it needs 75 years — up from the [55 years](#) the agency initially requested — to fully release redacted versions of all documents related to the agency's [approval](#) of Pfizer's Comirnaty COVID-19 vaccine.

In a [legal brief](#) filed Dec. 7, the FDA said 59,000 additional pages of documents, not included in the agency's earlier filings, need to be processed. The agency did not offer an explanation for why those documents initially were overlooked.

The agency [said](#) it can release an initial batch of approximately 12,000 pages by the end of January. Past that date, the FDA said it can process and disclose only 500 pages of documents per month.

This would mean the entire cache of documents would not be fully released until 2096. The FDA's initial timeline would have meant the release of the documents would not be completed until 2076, or 55 years from now.

The FDA did not divulge the criteria it will use to select the initial 12,000 pages of documents, or how the agency will prioritize the release of those pages, or of additional pages going forward.

The documents in question stem from a Freedom of Information Act (FOIA) request filed in August by [Public Health and Medical Professionals for Transparency](#) (PHMPT).

## **BUY TODAY: Robert F. Kennedy, Jr.'s New Book** **— 'The Real Anthony Fauci'**

In its FOIA [request](#), the group asked the FDA to release “all data and information for the [Pfizer](#) vaccine,” including safety and effectiveness data, [adverse reaction](#) reports, and a list of active and inactive ingredients.

In a [filing](#) submitted to a federal judge in November, the U.S. Department of Justice (DOJ), arguing on behalf of the FDA, initially claimed the agency could process some 329,000 pages of documents at a rate of only 500 pages per month, in order to have time to [redact](#) legally exempt material.

According to the DOJ, such material includes “confidential business and trade secret information of Pfizer or BioNTech and personal privacy information of patients who participated in clinical trials.”

Attorney Aaron Siri, who represents PHMPT, [requested](#) the FDA release the documents within 108 days — the amount of time needed by the FDA to license the Comirnaty vaccine.

Remarking on the FDA's latest request to extend the timeline from 55 to 75 years, Siri [stated](#):

“[I]f you find what you are reading difficult to believe — that is because it is dystopian for the government to give Pfizer billions, mandate Americans to take its product, prohibit Americans from suing for harms, but yet refuse to let Americans see the data underlying its licensure.

“The lesson yet again is that civil and individual rights should never be contingent upon a medical procedure.”

Prior to the FDA's request for the additional 20 years, U.S. Rep. Ralph Norman (R-S.C.), on Dec. 2, [introduced legislation](#) that would require the agency to release all records of information related to Pfizer [COVID vaccines](#) within 100 days.

**Oral arguments set for Dec. 14**

PHMPT, a group [comprised](#) of more than 30 medical and public health professionals and scientists from institutions such as Harvard, Yale, and UCLA, initially requested expedited processing of its FOIA submission on the basis there is a “compelling need” for the swift release of the documents in question.

When, in September, the FDA declined the request, Siri’s firm, Siri & Glimstad, filed a [lawsuit](#) against the agency on behalf of PHMPT. The lawsuit was filed in U.S. District Court for the Northern District of Texas.

PHMPT [argued](#) the release of the documents is a matter of urgency at a time where millions of Americans are facing mandates to get vaccinated or face repercussions.

As stated in PHMPT’s most recent [brief](#) demanding timely production of the documents:

“The entire purpose of FOIA is government transparency. In multiple recent cases, in upholding the FOIA’s requirement to ‘make the records promptly available,’ courts have required agencies, including the FDA, to produce 10,000 or more pages per month, and those cases did not involve a request nearly this important — i.e., the data underlying licensure of a liability-free product that the federal government requires nearly all Americans to receive.”

In its latest brief, the FDA [cited](#) several reasons justifying its proposed disclosure schedule.

The FDA [claimed](#) its Center for Biologics Evaluation and Research, which maintains the records in question, has only 10 staff members, two of whom are “new.”

Additionally, the FDA argued an accelerated rate of release for the documents in question will divert “significant resources away from the processing of other FOIA requests that are also in litigation,” as well as other pending FOIA requests submitted prior to that of PHMPT.

[According](#) to Siri, response briefs from both sides are due on Dec. 13, and an oral argument will follow in court on Dec. 14.

## Urgent: 3 Ways to Help Stop Biden’s Vaccine Mandates

### FDA promised ‘full transparency’ prior to authorizing vaccines

As [previously reported by The Defender](#), a [study](#) examining the processing of FOIA requests by the FDA and other federal public health agencies between 2008 and 2017 found the FDA processed 114,938 such requests, fully or partially granting 72.4% of them.

Of these requests, 39.8% were considered “complex.”

By contrast, the FDA now [claims](#) a backlog of 400 FOIA requests. It’s unclear how many pending requests are considered complex

[Federal law](#) prescribes a 20-day period for processing “complex” FOIA requests, although this timeframe is frequently [exceeded](#).

[According](#) to the FDA, “complex requests,” such as “510K, PMA, and De novo records,” require “approximately 18-24 months to process,” a far cry from 55 (or 75) years.

Prior to authorizing or licensing COVID vaccines, the FDA promised [full transparency](#) on the process.

The federal government's [FOIA request guidelines](#) outline two conditions under which a FOIA request may be processed on an expedited basis. The first is "if the lack of expedited treatment could reasonably be expected to pose a threat to someone's life or physical safety."

The second condition is "if there is an urgency to inform the public about an actual or alleged federal government activity if made by a person who is primarily engaged in disseminating information."

In its legal brief, the FDA did not explain how the agency was able to review the nearly 400,000 Pfizer documents in order to expedite the approval of Pfizer's vaccine in just 108 days.

The FDA also did not explain why the agency cannot expand its staffing capacity to better respond to FOIA requests, or why it can't enlist the help of other federal agencies, such as the DOJ, which is handling the FDA's legal defense against the PHMPT lawsuit.

## Subscribe to The Defender – It's Free!

SIGN UP

### SUGGEST A CORRECTION

---



#### **Michael Nevradakis, Ph.D.**

Michael Nevradakis, Ph.D., is an independent journalist and researcher based in Athens, Greece.

[Sign up](#) for free news and updates from Robert F. Kennedy, Jr. and the Children's Health Defense. CHD is planning many strategies, including legal, in an effort to defend the health of our children and obtain justice for those already injured. Your [support](#) is essential to CHD's successful mission.

[Republishing Guidelines](#)

### Get FREE News & Updates!

Email..

SIGN UP

**Donate Now**

You make the difference.



### Latest News



**Supreme Court Judges Spar Over Vaccine Mandates, Twitter Erupts Over False Claims**



**Judge Gives FDA 8 Months, Not 75 Years, to Produce Pfizer Safety Data**



**7-Year-Old Dies 11 Days After Pfizer Shot, VAERS Report Shows**

[MORE NEWS](#)

### Latest Views

**Children at Risk for Lifelong Health Problems From**



## COVID Vaccine



## International Finance Leaders Hold 'War Game' Exercise Simulating Global Financial Collapse. Should We Be Worried?



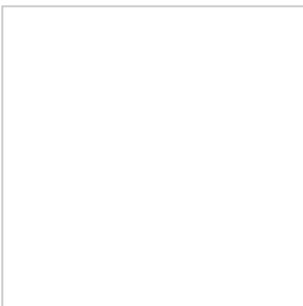
## The Day Jake Tapper Sold His Soul to Pharma

[MORE VIEWS](#)

### Latest Community



## Community Calendar: Upcoming Shows, Live Events and More!



## 4,000 Health Freedom Advocates Tell New York Lawmakers: 'We Will Not Comply'

## 'This Week' With Mary + Polly: Video 'Sent Shivers

**Down My Spine' + More**



[MORE COMMUNITY](#)



**Children's Health Defense**<sup>®</sup> is a 501(c)3 non-profit organization. Its mission is to end childhood health epidemics by working aggressively to eliminate harmful exposures, hold those responsible accountable, and to establish safeguards so this never happens again.

[EN](#) [ES](#)

**SUBSCRIBE - IT'S FREE!**

**BECOME A MEMBER**

**MEMBER LOGIN**



**Donations are tax deductible to the full extent of the law. EIN #26-0388604**

[Children's Health Defense](#) • [Legal Disclaimer](#) • [Terms of Use](#) • [Privacy Policy](#) • [Donate](#) • [Work for CHD](#) • [Contact](#) • [Social](#) • [Sitemap](#)

© 2016 - 2022 Children's Health Defense<sup>®</sup> • All Rights Reserved