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The Moderna Spikevax Covid-19 Vaccine. Nonprofit Sues FDA to Obtain Documents Related to Approval

A nonprofit group is suing the U.S. Food and Drug Administration in an effort to obtain documents relating to the FDA's approval of Moderna's Spikevax COVID-19 vaccine after the agency told the group there was "no compelling need" to expedite the release of the documents.

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A nonprofit group is suing the U.S. Food and Drug Administration (FDA) in an effort to obtain documents relating to the FDA's approval of Moderna's Spikevax COVID-19 vaccine after the agency told the group there was "no compelling need" to expedite the release of the documents.

Dallas, Texas-based Defending the Republic on June 7 filed the lawsuit in the U.S. District Court for the Northern District of Texas.

This is the same court that previously ordered the release of the FDA's documents pertaining to the approval of the Pfizer COVID-19 vaccine, rejecting the FDA's proposed release schedule that would have meant those documents would be made public over a period of 75 years.

The FDA granted full approval of Spikevax on Jan. 31. Just a few days later, on Feb. 3, Defending the Republic filed a Freedom of Information Act (FOIA) request with the FDA, "seeking the expedited production of records relating to the FDA's approval of the Moderna COVID-19 vaccine."

According to the lawsuit, Defending the Republic:

> "… is a public interest group committed to the rule of law and the principles on which this country was founded.
>
> "It defends victims of unlawful governmental actions, informs Americans on matters of

> public concern, and works tirelessly on behalf of those who are subject to unlawful government actions and mandates."

The lawsuit notes the organization previously filed an amicus brief relating to the Biden administration's vaccine mandate for private businesses.

Two FDA rejections led to Defending the Republic's lawsuit

According to Defending the Republic's lawsuit:

> "On February 3, 2022, Defending the Republic made a FOIA request for all documents, data, and records submitted by Moderna to the FDA concerning the approval of Spikevax. Defending the Republic asked for expedited processing for this request.
>
> "The request was made consistent with, and in furtherance of, Defending the Republic's mission to ensure public access to essential information relating to COVID-19."

The original FOIA request made the following request:

> "Please provide all data and information submitted by Moderna relating to the FDA review and approval of Spikevax.
>
> "This includes, but is not limited to, all safety and effectiveness data and information; all data and information in the biological product file; and all ingredients."

The FDA on Feb. 9 refused this initial request for expedited production of the Spikevax records, arguing the group had not demonstrated "urgency" or a "compelling need" for the swift release of the documents.

Sarah Kotler, director of the FDA's Division of Freedom of Information, wrote:

> "I have determined that your request for expedited processing does not meet the criteria under the FOIA.
>
> "You have not demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual. Neither have you demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity.
>
> "Therefore, I am denying your request for expedited processing. The responding agency office will process your request in the order in which it was received."

Defending the Republic appealed the decision, stating in its lawsuit:

> "The public deserved to know the requested information when making life-altering decisions including whether and when to vaccinate, and which vaccine—if any—to take, considering facts such as vaccine mandates affecting millions of Americans and the waning effectiveness of the Moderna vaccine."

The Feb. 9 appeal also claimed:

> "It is without question that the public and the medical community have an urgent and

> compelling interest in analyzing the data and information underlying the FDA's approval of Moderna's COVID-19 vaccine. There is no debate that COVID-19 has touched every single American life.
>
> "The FDA promises 'Spikevax meets the FDA's rigorous standards for safety, effectiveness and manufacturing quality required for approval.'
>
> "The American people deserve to know whether that statement is true, especially since there are legitimate issues with Spikevax. And Americans deserve to have that information now, not years down the road."

In their appeal, Defending the Republic also described evidence about the "waning protection" of the COVID-19 vaccines and their "decreased effectiveness" against certain variants, such as Omicron.

The group also addressed the "serious risks of myocarditis and pericarditis," acknowledged by the FDA, and "insufficient" data regarding "vaccine-associated risks in pregnancy."

However, the FDA on June 6 again denied Defending the Republic's appeal, claiming:

> "After conducting a thorough review of your appeal, we have determined that you have not demonstrated a compelling need for expedited processing.
>
> "Therefore, we have decided to uphold the FDA's decision to deny the request for expedited processing.
>
> "You have not demonstrated that there is an "urgent need for the requested information and that [it] has a particular value that will be lost if not obtained and disseminated quickly."

The FDA claimed it is already providing a sufficient amount of information about the Spikevax vaccine, stating:

> "Since approval of the product, the following records are available on FDA's website — Spikevax information approval package and reviews, advisory committee documents and a host of related information, including Frequently Asked Questions for Spikevax, information sheets for healthcare providers, regulatory information, and media materials.
>
> "The website even includes translations of certain information in multiple languages, including Spanish, Chinese, Korean, Vietnamese, and Tagalog."

According to the FDA, Defending the Republic had "not shown that receiving data and information not already posted to the FDA webpage regarding this approved product has particular urgency," nor had it "demonstrated that these records have a particular value that would be lost if not obtained and disseminated quickly."

As a result, the FDA determined that Defending the Republic's request "does not satisfy the 'urgency to inform the public' standard."

The group's FOIA request was placed "in the complex queue" by the FDA's Center for Biologics Evaluation and Research, with a response to be expected from the FDA "within

approximately 18-24 months."

Rejections lead to lawsuit

In response, Defending the Republic sued the FDA, asking the court to "order expedited briefing and proceedings in this matter" and to "order the FDA [to] produce all documents responsive to Defending the Republic's FOIA request on an expedited schedule," in addition to attorney fees and any other relief the court may deem appropriate.

In the lawsuit, Defending the Republic said "COVID-19 and the approval of COVID-19 vaccines is a matter of current exigency to the American public."

The lawsuit cites Public Health & Medical Professionals for Transparency v. Food & Drug Administration — the case that led to the release of the Pfizer vaccine documents by the FDA — in justifying its lawsuit against the agency:

> "The information requested — just like the data the FDA reviewed to approve Comirnaty — is information the American people need to know now. It is an urgent matter of public health.
>
> "The FDA declined the appeal, leaving Defending the Republic with no choice but to file this action seeking a court order requiring the FDA produce the requested records on an expedited schedule — just as those who obtained a court order for the expedited production of records relating to the FDA approved Pfizer-BioNTech vaccine."

The lawsuit also refers to various judicial precedents and legal statutes which the group argues support its claim.

In reference to its FOIA request, Defending the Republic said federal statute states, "FOIA allows for the 'expedited processing of request for records' where there is shown to be a 'compelling need.'"

In turn, the term "compelling need," according to federal statute, means "with respect to a request made by a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity."

Defending the Republic claims "a closer inspection of the Spikevax approval reveal there may be glaring issues in the approval process," including insufficient data related to the vaccine's risks for pregnant women.

The organization further argued the FOIA request should be expedited in light of federal and local vaccine mandates.

Plaintiffs' attorney: FDA wants to control what the public sees and doesn't see

Travis Miller, one of the lawyers representing Defending the Republic, told The Defender:

> "The FDA has the audacity to claim there is no 'compelling need' for the expedited processing of the data underlying the FDA's approval of Moderna's Spikevax COVID-19 vaccine.

> "In doing so, the FDA ignored our arguments that a Fort Worth federal court had already found there to be a compelling need for the expedited production of the Comirnaty records. The FDA just pretended that the court order to produce the Comirnaty records didn't exist."

According to Miller, by denying Defending the Republic's FOIA request, the FDA is seeking to obfuscate data related to the Spikevax vaccine and its own actions:

> "They don't want outside experts or the common man looking through this data for themselves.
>
> "The FDA would rather control what the public sees — and doesn't see — by repackaging data or otherwise hiding information that might just cast doubt on FDA actions."
>
> When asked whether the FDA might have been influenced by Moderna in issuing its denials, Miller said, "We've seen no response from Moderna. But it's possible that Moderna attempts to intervene in this lawsuit," adding that Pfizer had done something similar previously.

"Pfizer moved to intervene in the Comirnaty FOIA lawsuit 'for the limited purpose of helping FDA and the court ensure expeditious production,'" Miller said.

Ultimately, Miller hopes the court will decide in favor of a release schedule for the Spikevax documents that would be similar to that of the Pfizer documents, stating:

> "We hope that the production timeline will be similar to the timeline issued in the Comirnaty FOIA case.
>
> "That court ordered 12,000 pages to be produced in January 2022, and then rolling production of 55,000 pages every 30 days beginning March 1, 2022 until production was complete."
>
> If and when the FDA provides the Spikevax documents, Defending the Republic intends to make them available to the public, just as Public Health and Medical Professionals for Transparency, a group of doctors and public health professionals that filed the lawsuit against the FDA concerning the Pfizer vaccine documents, has publicized those documents on its website.

As stated in Defending the Republic's lawsuit, it will "publicly disseminate" any information that is revealed about the Spikevax vaccine as a result of its FOIA request.

According to the lawsuit:

> "Any delayed response to the FOIA request would compromise and otherwise inhibit Defending the Republic's recognized interest to inform the public of the Moderna vaccine. It would also compromise the significant recognized interest of the American public, including parents, physicians, independent experts, and policy makers, in reviewing and analyzing the Moderna data for themselves.
>
> "Millions of Americans would be subject to vaccine requirements for vaccines they are prevented from fully understanding. Stale information will not serve Defending the

Republic or the American public.”

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