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COMMITTEE ON THE JUDICIARY

COMMITTEE ON
OVERSIGHT AND REFORM

Congress of the United States
House of Representatives
Washington, DC 20515–0305

December 29, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington, D.C. 20201

Janet Woodcock, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, M.D. 20993

Dear Secretary Becerra and Acting Commissioner Woodcock,

The lack of transparency from the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) surrounding the information that was relied on to license the COVID-19 vaccines is astonishing. I urge you to commit significant departmental resources to ensure that the American public has full access to all information that FDA regulators relied upon in approving the COVID-19 vaccines.

In September, the non-profit Public Health and Medical Professionals for Transparency (PHMPT) submitted a Freedom of Information Act (FOIA) request to FDA requesting all data contained within Pfizer's COVID-19 vaccine biological product file.[1] PHMPT is a group of more than 30 professors and scientists from colleges and universities around the country. [2] The group's website states that they are a non-profit made up of "public health professionals, medical professionals, scientists, and journalists" that exists solely to obtain and disseminate the data relied on by FDA in licensing the COVID-19 vaccines.[3]

PHMPT simply believes that the data relied upon by FDA should be made available to the public. This position is common-sense and something I firmly support.

On November 15th, PHMPT and FDA filed a Joint Status Report (JSR) in a federal district court in Texas regarding PHMPT's FOIA request. In the JSR, FDA asserted that there are more than 329,000 pages that are potentially responsive to PHMPT's request.[4] In a December update to the court, FDA agreed to produce 12,000 pages by January 31, 2022 but admitted that there are an additional 59,000 potentially responsive pages that it had not previously identified.[5]

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[1] Letter from Aaron Siri et al., to Food and Drug Administration, Office of the Secretariat, (Aug. 27, 2021) https://phmpt.org/wp-content/uploads/2021/10/IR0546-FDA-Pfizer-Approval-FINAL.pdf.
[2] Wesley J. Smith, *FDA Will Take 55 Years to Answer FOIA on Vaccine-Approval Data*, NATIONAL REVIEW, Nov. 22, 2021, https://www.nationalreview.com/corner/fda-will-take-55-years-to-answer-foia-on-vaccine-approval-data/.
[3] Public Health and Medical Professionals for Transparency, https://phmpt.org/ (last visited Dec. 20, 2021).
[4] *Public Health and Medical Professionals for Transparency v. U.S. Food and Drug Administration*, No. 4:21-cv-01058-P, Second Joint Report (N.D. Tex. Nov. 15, 2021) https://fingfx.thomsonreuters.com/gfx/legaldocs/egvbkaeggpq/vaccine%20foia%20status%20report.pdf.
[5] Zachary Stieber, *FDA says It Now Needs 75 Years to Fully Release Pfizer COVID-19 Vaccine Data*, THE EPOCH TIMES, Dec. 8, 2021, https://www.theepochtimes.com/fda-says-it-now-needs-75-years-to-fully-release-pfizer-covid-19-vaccine-data_4145410.html?utm_source=partner&utm_campaign=allsides.

Rather than choosing to recognize the importance of transparency and ensure that Americans have access to the information relied on in approving the COVID-19 vaccine, FDA proposed to the court that it process only 500 pages per month after its initial production of 12,000 pages. If FDA sticks to its proposal, then PHMPT's FOIA request would not be complete for another 75 years.[6] As justification for this outrageous timeline, FDA complained in November that it is also processing an additional 400 FOIA requests and only has ten employees dedicated to FOIA review.[7]

The excuses that HHS and FDA have put forth to the court for its prolonged document production timeline are inexcusable and characteristic of bureaucratic delay.

There is an understandably high degree of public interest in the information and data that was used by FDA to approve the COVID-19 vaccines. President Biden and his administration have repeatedly overstepped their authority as they have sought to implement vaccine mandates across the federal workforce and the private sector. In November, the U.S. Court of Appeals for the Fifth Circuit stated that the Occupational Safety and Health Administration's (OSHA) vaccine mandate for the private sector raised "serious constitutional concerns."[8] The appeals court did not hold back in criticizing President Biden's vaccine mandate, and wrote that OSHA's order involves "separation of powers principles" that "cast doubt over the Mandate's assertion of virtually unlimited power to control individual conduct under the guise of a workplace regulation."[9]

I have consistently been opposed to this administration's extreme overreach of Executive Branch authority and will continue to fight against unconstitutional and draconian vaccine mandates.

The American people deserve complete transparency surrounding the information that was relied on by FDA regulators in approving the COVID-19 vaccines. Your failure to commit adequate Department resources to timely processing FOIA requests represents another failure of political leadership from your agencies.

In order to address these concerns, please provide an immediate response outlining the steps HHS and FDA are taking to address the backlog of FOIA requests at FDA pertaining to COVID-19 vaccines.

Sincerely,

Andy Biggs
Member of Congress

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[6] *Id.*
[7] Jenna Greene, Wait what? FDA wants 55 years to process FOIA request over vaccine data, REUTERS, Nov. 18, 2021 https://www.reuters.com/legal/government/wait-what-fda-wants-55-years-process-foia-request-over-vaccine-data-2021-11-18/.
[8] *In re: MCP No. 165, Occupational Safety & Health Admin. Rule on COVID-19 Vaccination and Testing, 86 Fed. Reg. 61402*, (5th Cir. Nov. 12, 2021) https://www.ca5.uscourts.gov/opinions/pub/21/21-60845-CV0.pdf.
[9] *Id.*