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FDA Asks the Court to Delay First 55,000 Page Production Until May and Pfizer Moves to Intervene in the Lawsuit

Somewhere on the other side of the growing heap of government and pharma lawyers is transparency.

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As explained in prior posts, in a lawsuit seeking all of the documents the FDA relied upon to license Pfizer's COVID-19 vaccine, a federal judge shot down the FDA's requested rate of 500 pages per month and instead ordered the FDA to produce at the rate of 55,000 pages per month starting on March 1.

Since the government has trillions of dollars of our money, it is putting it to good use by fighting to assure that the public has the least amount of transparency possible. To that end, it has now asked the Court to make the public wait until May for it to start producing 55,000 pages per month and, even then, claims it may not be able to meet this rate.

The FDA's excuse? As explained in the brief opposing the FDA's request, the FDA's defense effectively amounts to claiming that the 11 document reviewers it has already assigned and the 17 additional reviewers being onboarded are only capable of reading at the speed of preschoolers.

Meanwhile…

As the FDA tries to obtain months of delay, guess who just showed upon in the lawsuit? Yep, Pfizer. And it is represented by a global chair and team from a law firm with thousands of lawyers. Pfizer's legal bill will likely be multiple times what it would cost the FDA to simply hire a private document review company to review, redact, and produce the documents at issue. Within weeks, if not days.

Pfizer is coming in as a third party. But Pfizer assures the Court it is here to help expedite production of the documents. Sure it is! Where was Pfizer before the Court ordered the 55,000 pages per month? Right, doing what it normally does: letting the government work

on its behalf – like the way the government mandates, promotes, and defends Pfizer's product.

But the government did not please Pfizer this time and so here it comes, likely looking for a second bite at the apple. Of course the FDA consented to Pfizer appearing. You can read the response my firm filed to Pfizer's motion, as well as all of the other relevant recent filings in the link provided below.

Let me end by noting that all of this insanity is simply in response to an attempt to obtain some basic transparency. This should again bring into sharp focus why the government should never coerce or mandate anyone to get an unwanted medical product or procedure. Just look at this circus – the government mandates Pfizer's product, gives it immunity for any safety or efficacy issues, promotes its product using taxpayer money, gives Pfizer over $17 billion and then uses taxpayers' money to fight to avoid providing even the most basic level of transparency to the public.

The introduction from the brief opposing the FDA's request is below and you can find copies of all the relevant court filings (FDA Motion to Modify Scheduling Order, January 18, 2022 / Plaintiff Opposition to Motion to Modify, January 24, 2022 / Pfizer Motion to Intervene, January 21, 2022 / FDA Response to Pfizer Motion, January 25, 2022 / Plaintiff Response to Pfizer Motion, January 25, 2022) here:

Introduction to Opposition to FDA's Motion

> It is understandable that the FDA does not want independent scientists to review the documents it relied upon to license Pfizer's vaccine given that it is not as effective as the FDA originally claimed, does not prevent transmission, does not prevent against certain emerging variants, can cause serious heart inflammation in younger individuals, and has numerous other undisputed safety issues.[1] However, the FDA's potential embarrassment over its decision to license this product must take a back seat to the transparency demanded by FOIA and the urgent need and interests of the American people to review that licensure data. The Court already recognized this unprecedented urgent need in its January 6th order directing the FDA to produce 55,000 pages per month.
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> The FDA now insists it must delay its first 55,000-page production until May 1, 2022 – four months after the Court entered its order. However, the FDA's own papers seeking this delay make plain it can produce at a rate of 55,000 pages per month in February and March. The FDA affirms it has already "allocated the equivalent of nearly 11 full-time staff to this project" and that "a review speed of 50 documents per hour was within the normal range for document review in a complex matter" in private practice; and here the 50 document per hour rate would be faster since there is only a need to review for personally identifying information ("PII") for most pages. Hence, if the FDA's 11 full-time reviewers work only 7.5 hours per day and review 50 pages (not documents) per hour, the FDA could review over 88,000 pages per month in February and March. That is more than sufficient to produce the 55,000 pages per month currently ordered for these two months.
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> Instead of complying with this Court's reasoned order, the FDA claims these 11 reviewers can only review a total of 10,000 pages per month. What the FDA does not say, and what basic math shows, is that a rate of 10,000 pages a month for 11 full-time

reviewers amounts to only 5 pages per hour! This rate is made even more absurd because most of the pages the FDA will be reviewing during this period are repetitive data files that only require second level review to redact minimal amounts of PII that Pfizer may have left in the documents. FDA's reality defying claim and contemptuous approach to its production obligations should not be countenanced. (*Infra* § I.)

It is also apparent that the instant demand is just the start of a campaign to delay the production ordered by the Court. In this first salvo, the FDA is not really asking the Court. It is instead expressly *telling* the Court it does not intend to produce more than 10,000 pages per month for February and March, and despite claiming it is making "unprecedented" efforts, the FDA repeatedly tells the Court: "It is not possible to guarantee that FDA will be able to fully comply" with the 55,000-page production rate thereafter. (Dkt. No. 38 at APPX004, APPX008.) Americans must follow the law and the FDA, a multi-billion-dollar agency, should similarly be given no safe harbor from complying with the orders of this Court. (*Infra* § II.)

The FDA should also be held to what it attests. The FDA, with over 18,000 employees and an over $3 billion discretionary budget, repeatedly assures the Court that it is taking steps to "marshal every possible resource available to it," "acting with maximal urgency to assemble every possible resource available to it" and "putting every available resource at its disposal into its efforts to achieve compliance." (Dkt. No. 37 at 10, 3, 10.) The FDA also attests that over the coming weeks, it will have 28.5 full-time people reviewing the documents. Working 7.5 hours per day for 20 business days per month, 28.5 people reviewing 50 pages per hour can review a total of approximately 213,750 pages per month. Putting aside that most of this production can be reviewed far faster than the rate of 50 pages per hour, Plaintiff asks that the FDA be held to its representations and be directed to produce at the rate of 180,000 pages per month starting in April. (*Infra* § III.)

The Court is, other than Congress, the only check on the FDA. In a free country, transparency is paramount, and the FDA has chosen to thwart transparency and the requirements of FOIA by anemically understaffing the office it maintains to respond to FOIA requests. It is akin to the boy that kills his parents and asks for sympathy for being an orphan. Decrying that this Court is now making it comply with the law – by actually producing documents in a timely manner – is ridiculous. It is also incredible for the FDA to claim that compliance here would harm its health policy objectives. Even if the FDA really does need to spend $4 to $5 million which, as shown below, is an absurd overestimate, that is an inconsequential amount of its overall $3.41 billion discretionary budget. Moreover, the issues with the Pfizer vaccine – including waning immunity, variants evading immunity, the failure to prevent transmission, myocarditis, and pericarditis – show that the FDA's priority should be to address this product before rushing off to engage in other activities. (*Infra* § IV.)

For these reasons, as explained below, the Court should refuse to reduce the rate of production in February and March and should increase the rate of production for April and thereafter to 180,000 pages per month consistent with the FDA employing 28.5 full-time reviewers in the coming weeks to conduct the review and the fact that most of the pages need only be reviewed for PII.

…you can read the rest of the brief here

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Notes

[1] Reflecting the issues with this product, the FDA failed to send a representative to a federal court hearing in this matter on December 14th because of the “FDA’s protocols” regarding COVID-19. Meaning, despite the FDA’s claim the vaccine is “effective,” the FDA is apparently still scared to send a representative to the hearing. Its actions speak volumes and cast serious doubt on its words.

Featured image is from Children’s Health Defense

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