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by **Brian Shilhavy**, *Health Impact News*
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As the news cycle continues to focus on the Ukraine situation, the FDA complied with a court order to begin releasing 55,000 pages of Pfizer data per month that was used to authorize their COVID-19 vaccine produced with BioNTech, with the first batch quietly released yesterday, March 1st.

There are 150 documents that the public can now download here.

One of the documents released was the “Prescription Drug User Fee Payment” that BioNTech paid to the FDA on 4/20/2021 for the “COMIRNATY COVID-19 mRNA Vaccine” which the FDA subsequently approved in August of 2021.

That “Prescription Drug User Fee Payment” was $2,875,842.00. (Source.)

Another interesting document I found was the “EXTERNAL DATA MONITORING COMMITTEE” found here.

Here is the stated purpose of this “External Data Monitoring Committee”:

> *This External Data Monitoring Committee (E-DMC) (hereafter referred to as "the committee") is a single,* ***external, independent, expert advisory group established to oversee safety and efficacy data*** *from the BNT162 Vaccine Program. The primary rationale for establishing the committee is to* ***make certain that appropriate external safeguards are in place to help ensure the safety of subjects and to maintain scientific rigor and study integrity*** *while the trial is on-going.*
>
> *The committee will review accumulating safety data across all studies, as well as efficacy data in the Phase 2/3 portion of the C4591001 study. The committee will advise Pfizer regarding the safety of current participants and those yet to be recruited, as well as the continuing scientific validity of the trial. In addition to safety review by the committee, qualified Pfizer personnel will review safety data as specified in the safety surveillance review plan and will inform the committee of significant findings. Efficacy data from the C4591001 study will be available to the committee when there is a planned interim analysis of efficacy or if this is considered necessary to conduct a risk-benefit assessment.*

And to make sure that this Committee is doing their job properly to ensure "*the safety of subjects and to maintain scientific rigor*," who at the FDA is responsible to make sure this happens?

Well, that would be no one. Pfizer is the one who was responsible, and BioNTech funded it.

> ***"Pfizer is responsible for conducting this study. BioNTech is the regulatory sponsor of this study."***

The committee members are to be free from "conflicts of interest."

> *The committee members will complete a CT22-GSOP-RF01 Independent Oversight Committee Member Conflict of Interest Form. Committee members should be free of apparent significant conflicts of interest. Any potential conflict of interest that develops during a member's tenure on the committee must be disclosed by the committee member.*

And who at the FDA is responsible for assuring that this committee who is overseeing "safety and efficacy data" is free from conflicts of interest?

Well, that would be no one. Again, Pfizer is responsible for that.

> ***"Pfizer will determine if any potential conflict requires termination of committee membership."***

The question that then begs to be answered here is, what role did the FDA play, if any, in the "external" monitoring of the data to ensure integrity and safety of a new vaccine about to be injected into hundreds of millions people in the U.S.?

It would appear that all they did was rubber stamp the process that was completely managed by Pfizer, and funded by BioNTech.

Here are the members of the "*External Data Monitoring Committee*" that apparently were chosen by Pfizer, monitored by Pfizer, and investigated by Pfizer to make sure they were doing their job and that there were no "conflicts of interest."

The other interesting thing this document reveals is that a significant number of people compiling the data for this committee to review were located in China.

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I wonder if the raw data is also located in China?

There is a lot more data I am still reviewing, and tens of thousands of more pages of data still to be released by the FDA.

But with everyone watching what is happening in the Ukraine right now, I wonder if anyone is even noticing this?

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