BioNTech Gave FDA $2,8 Million ‘’Drug User Fee’’ For C-19 Vaccine Approval!

Description

USA: While the entire world is obsessed with the Russia-Ukraine war, the Pfizer document release is unnoticed!

Does the C-19 virus disappear with the war?

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We can now tell you how corrupt Pfizer, BioNTech, and FDA are! Among the most incriminating discoveries is the document called ‘’Prescription Drug User Fee Payment.’’

BioNTech paid $2.8 million on 4/20/21 for the Comirnaty C-19 mRNA Vaccine.

Check this out:

Form Approved: OMB No. 0910 - 0297 Expiration Date: March 31, 2022. See instructions for OMB Statement, below.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	PRESCRIPTION DRUG USER FEE COVERSHEET FY 2021

A completed form must be signed and accompany each new drug or biologic product application. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment instructions and fee rates can be found on FDA's website:
http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119184.htm

1. APPLICANT'S NAME AND ADDRESS BioNTech Manufacturing GmbH An der Goldgrube 12 55131 Mainz Germany	4. BLA SUBMISSION TRACKING NUMBER (STN) / NDA NUMBER 125742
2. NAME AND TELEPHONE NUMBER OF REPRESENTATIVE Neda Aghajani Memar 212-733-2613	5. DOES THIS APPLICATION REQUIRE CLINICAL DATA FOR APPROVAL? [X] YES [ ] NO IF YOUR RESPONSE IS "NO", STOP HERE AND SIGN THIS FORM. IF RESPONSE IS "YES", CHECK THE APPROPRIATE RESPONSE BELOW: [X] THE REQUIRED CLINICAL DATA ARE CONTAINED IN THE APPLICATION [ ] THE REQUIRED CLINICAL DATA ARE SUBMITTED BY REFERENCE TO:
3. PRODUCT NAME COMIRNATY (COVID-19 mRNA Vaccine (nucleoside modified))	6. USER FEE I.D. NUMBER PD3017966

7. ARE YOU REDEEMING A PRIORITY REVIEW VOUCHER FOR THE TREATMENT OF TROPICAL DISEASES? [ ] YES [X] NO

PRIORITY REVIEW VOUCHER NUMBER:

8. ARE YOU REDEEMING A PRIORITY REVIEW VOUCHER FOR MEDICAL COUNTER MEASURES? [ ] YES [X] NO

PRIORITY REVIEW VOUCHER NUMBER:

9. IS THIS APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] THE APPLICATION QUALIFIES FOR THE ORPHAN EXCEPTION UNDER SECTION 736(a)(1)(F) of the Federal Food,Drug, and Cosmetic Act

FDA-CBER-2021-5683-0013734

[ ] THE APPLICATION IS SUBMITTED BY A STATE OR FEDERAL GOVERNMENT ENTITY FOR A DRUG THAT IS NOT DISTRIBUTED COMMERCIALLY

10. HAS A WAIVER OF AN APPLICATION FEE BEEN GRANTED FOR THIS APPLICATION?
[ ] YES [X] NO
If a waiver has been granted, include a copy of the official FDA notification with your submission.

Privacy Act Notice:
This notice is provided pursuant to the Privacy Act of 1974, 5 U.S.C. 552a. The collection of this information is authorized by 21 U.S.C. 371, 379, 379e, 379h, 379h-1, 379j, 379j-12, 379j-21, 387s, and 393(d)(2); 42 U.S.C. 263b(r)(1); 5 U.S.C. 301 and 552; and 42 U.S.C. 3101. FDA will use the information to assess, collect and process user fee payments, and, facilitate debt collection under the Debt Collection Improvement Act. FDA may disclose information to courts and the Department of Justice in the context of litigation and requests for legal advice; to other Federal agencies in response to subpoenas issued by such agencies; to HHS and FDA employees and contractors to perform user fee services; to the National Archives and Records Administration and General Services Administration for records management inspections; to the Department of Homeland Security and other Federal agencies and contractors in order to respond to system breaches; to banks in order to process payment made by credit card; to Dun and Bradstreet to validate submitter contact information, and to other entities as permitted under the Debt Collection Improvement Act. Furnishing the requested information is mandatory. Failure to supply the information could prevent FDA from processing user fee payments. Additional detail regarding FDA's use of information is available online: http://www.fda.gov/RegulatoryInformation/FOI/PrivacyAct/default.htm.

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PRINTED NAME AND SIGNATURE OF AUTHORIZED REPRESENTATIVE	TITLE	DATE
Neda Aghajani Memar	Director, Global Regulatory Affairs	4/20/2021

11. USER FEE PAYMENT AMOUNT FOR THIS APPLICATION
$2,875,842.00

Form FDA 3397 (04/19)

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Health Impact News reported:

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.

The FDA didn't have this task. Pfizer was in charge of conducting the study, and BioNTech was the regulatory sponsor of the study.

Section 1 Introduction says:

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

Section 2.1 Conflicts of Interest reads:

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

Each time the committee meets, the study team will ask the committee members to consider whether or not any changes in their conflict of interest status have emerged. Status must be recorded in the committee open meeting minutes and any potential conflicts must be reported using CT22-GSOP-RF01.

Below you can see the members of the ''External Data Monitoring Committee'', according to the document, chosen monitored, and investigated by Pfizer to conclude that there were no conflicts of interest.

EXTERNAL DATA MONITORING COMMITTEE

Member	Affiliation/Address	Role	*Dates of Membership	Biography
Jonathan Zenilman, MD	Infectious Diseases Division Johns Hopkins Bayview Medical Center Baltimore, MD, US Tel: +1 410 440 9729	Chair	03-April-2020	Infectious Diseases
Kathryn Edwards, MD	Vanderbilt University School of Medicine 1300 Falkirk Court, Nashville, TN 37221 Tel: +1 615-429-3226	E-DMC member	07-April-2020	Pediatric infectious Diseases
Robert Belshe, MD	Division of Infectious Diseases & Immunology Saint Louis University Medical Center 714 Schiele Ave, San Jose, CA 95126 Tel: +1 314 496 1033	E-DMC member	03-April-2020	Infectious Diseases and Immunology
Lawrence Stanberry, MD	Columbia University 456 Riverside Drive, Apt 8A, New York, NY, 10027 Tel: +1 646-330-8329	E-DMC member	07-April-2020	Pediatric Infectious Diseases
Steve Self, PhD	Fred Hutchinson Cancer Research Center Vaccine and Infectious Disease Division 1100 Fairview Avenue North, M2- C200, Seattle, WA 98109, USA Tel: +1 206-915-9617	E-DMC Biostatistician	02-April-2020	Professor Emeritus, Biostatistics

Health Impact News reported:

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

by Addison Wilson
Category

1. Health-Wellness-Healing-Nutrition & Fitness
2. Main

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