WELT+ CORONA VACCINE

The many inconsistencies in the Pfizer approval study

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Responsible Editor

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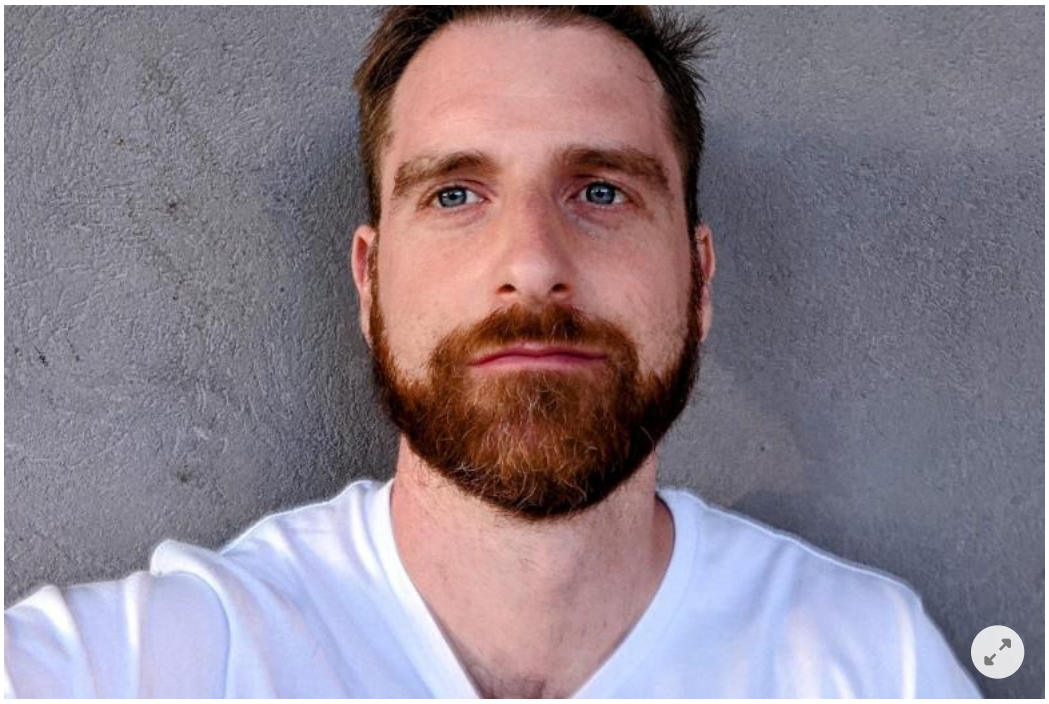
Biontech/Pfizer's mRNA vaccine approval may have been based on incorrect documentation. There are increasing doubts about the data from the pivotal phase 3 study. Pfizer dodges the allegations and refuses to review.

When the patient with the number 12312982 went public, the managers at the US pharmaceutical company Pfizer suspected that things could get very uncomfortable. Number 12312982 was hospitalized with severe symptoms in September 2020 during the final testing phase for approval of the mRNA vaccine. The patient pulled the ripcord, he got out of the test procedure.

Number 12312982 is called Augusto Roux. He is a lawyer, 36 years old, he lives in Buenos Aires. With almost 6,000 of the 43,548 subjects worldwide, the metropolis was by far the most important location for the third, decisive test phase of the Biontech/Pfizer vaccine. But in Buenos Aires things did not go as they should, and

not only in the Roux case. There were significant irregularities with serious consequences. They now put the entire study on the efficacy and side effects of the Biontech/Pfizer vaccine in a different light.

Roux received the first test dose of the mRNA vaccine in August 2020 at the military hospital, the Pfizer study center in Buenos Aires. Roux's arm began to hurt and swell up. Later came nausea and difficulty swallowing, Roux felt hung over. His sense of smell changed over the next few days, his stools turned white and his urine dark. Two days after the vaccination, Roux contacted his test doctors, who noted in the protocol that WELT has: "Undesirable effect of toxicity level 1".



Argentine lawyer Augusto Roux, 36

Which: Roux

Three weeks later, test candidate Roux received the second dose. He remained under observation for 40 minutes, then left the hospital feeling good. In the taxi home he felt uncomfortable, and later he had shortness of breath, burning chest pain, nausea and fever. His urine turned black like cola and he passed out. Three days later, Roux was in the Alemán Hospital, several PCR tests for Covid were negative. Senior physician Gisela di Stilio noted in the discharge report, which is available to WELT: "Adverse reaction to the coronavirus vaccine (high probability)". The computer tomograph had provided images of fluid in Roux's heart. A pericardial effusion.

Over the next few months, Roux lost 14 kilos, he had liver problems, and his heart sometimes beat irregularly. His liver was examined for suspected toxic hepatitis. As it turned out later, he suffers from a genetic defect that may make him sensitive to vaccinations. The American doctor Gemma Torrell, who knows Roux's medical records and questioned him extensively in spring 2021, noted: The diagnosis for the symptoms after the second vaccination is very likely to be "pericarditis", inflammation of the heart. All of this fits exactly with a clinical picture that the Paul Ehrlich Institute also has in its list of "rare side effects" for mRNA vaccines.

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Roux's case took a surprising turn when he was the attorney for Fernando Polack, study director in Buenos Aires and lead author of the global phase 3 pivotal study, forced access to his file. He found amazing things there. His story, one might think, should appear in Pfizer's pivotal study papers, but it doesn't. The pharmaceutical company's papers say Roux informed the research team that he was hospitalized with pneumonia on both sides, following the initial report, which was classified as an "adverse event of toxicity level 1". That could have nothing to do with the vaccine, the file goes on to say, it is probably a Covid infection. Not a word that Roux had tested negative for Corona in several PCR tests.

Reinterpretation of the Covid patient

Roux found out other things about himself that he didn't know himself: On September 23, study director Polack noted that he had a "severe anxiety attack". Roux suffers from anxiety (which is not caused by the vaccine).

The reinterpretation of Roux' from a vaccine victim to a Covid patient and mental problem raises questions. His medical history is not mentioned in the approval study from December 2020, and his case does not appear in later evaluations either. In a summary of all study data for the US Food and Drug Administration as of August 11, 2021, only one case of pericarditis was recorded among the vaccinated subjects. A man older than 55 is affected, it says. Augusto Roux is not mentioned. Was he registered as a Covid case and therefore as an unvaccinated person?

Almost at the same time as the Roux case, there must have been an incident in the Buenos Aires test center. In one fell swoop, the test management said goodbye to 53 subjects on August 31, 2020. The test candidates were "unblinded", which means they were informed about their vaccination status, a process that the Pfizer study protocol expressly only provides for "in emergencies". But there is nothing about it in the approval study. In protocol documents that are available to WELT, and which are actually not intended for the public, those responsible get caught up in contradictions. "Three different explanations can be found in three different documents for the exclusion of the 53 subjects," complains David Healy, professor of psychiatry and expert in pharmacology as well as head of the "Data Based Medicine" network and the React-19 help for victims in the USA. "One document notes that all participants received the standard dose at the correct time, a second states that there was an error in the dose for all, and the third mentions irregularities for all but does not say which." The participants were about excluded because they had reported serious side effects?

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A total of 302 volunteers from the vaccine group were eliminated from the study after the second vaccination and were therefore not included in the assessment. 200 of them came from Buenos Aires. Have unpleasant results been suppressed here? The Argentine health authority ANMAT had apparently also noticed that things were not going as they should in the military hospital: their inspectors stopped by twice to check. This has not been the case in any other place of study in the world.

The fate of a test participant who did not survive the procedure is also strange. The man was a subject in the placebo group, came to the Aleman hospital shortly after the start of the study with a heart attack and died. But the death was kept secret from the ANMAT inspectors. The protocol of the health authority, which is available to WELT, also expressly states that there were no deaths, neither in the vaccine nor in the placebo group. Only in the approval study does the dead person suddenly appear again under ID 12313972. ″Polack obviously kept this dead person a secret from the health authorities,″ Roux suspects. But what reason was there to conceal a dead person if he allegedly could not have received the vaccine?

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Eventually, what happened in Buenos Aires was enough for the respected Argentinian neurologist Ruben Horecio Manci. The clinical trials expert wrote a fire letter to the Argentine Minister of Health on April 15, 2021. In October 2022, Parliament set up a committee of inquiry, which to date has not provided any answers. Among other things, it is about these questions: How many serious side effects, how many deaths have there really been? What happened the day 53 subjects dropped out of the study?

The negotiations between Pfizer and the Argentine government on the country's vaccine supply should also be examined. According to the contract, the manufacturer did not want to guarantee anything with its vaccine. Government officials should sign a liability waiver even for Pfizer's negligence and for ″fraud or bad faith on the part of Pfizer itself.″ These clauses, which are also considered unusual by experts, ensured that Argentina relied entirely on the Russian vaccine Sputnik until spring 2021.

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Beyond the Augusto case and what happened in Buenos Aires, David Healy has other questions about the pivotal study. He wonders about a total of 21 vaccine group deaths, which are said to be ″not due to the vaccine″. In at least two of those deaths, things may not have been quite as presented in the study. WELT has documents according to which patient no. 11621327 was found dead in his apartment three days after the 2nd dose, apparently a stroke. Patient #11521497 died 20 days

after vaccination, diagnosis of cardiac arrest. ″According to the current state of science, these two cases would be assigned to the vaccination,″ says the Berlin pharmaceutical specialist Susanne Wagner, ″especially since the US health authority CDC is currently investigating strokes in vaccinated people and it is known

The Danish physician Peter Gøetzsche, former professor for clinical studies at the University of Copenhagen, stated resignedly in an interview with WELT that ″the manufacturers′ approval studies are unreliable, even if they appear in renowned scientific journals″. He generally observes ″fraud and suppression of the publication of harms in the clinical trials″. Gøetzsche considers the Biontech/Pfizer publication to be typicalon the ″Safety, Immunogenicity and Efficacy of the Covid-19 Vaccine BNT162b2 in Adolescents″. In it, the authors, including Biontech founder Uğur Şahin, conclude, among other things, that the mRNA vaccine “shows a favorable safety profile” in 12- to 15-year-olds and that there were “no serious vaccine-related events” among the participants. In the appendices at the end, under “serious events” there is a number 4. Of these, 0 are vaccine-related. One of the four is 13-year-old Maddie De Garay. The girl suffered a serious neurological disorder after the second injection. Since then she has not been able to get out of the wheelchair on her own. She is fed through a nasogastric tube.

60%

“The allegations should be properly clarified”

″Irregularities in studies must be clarified,″ says the health policy spokesman for the FDP Andrew Ullmann to WELT. ″Errors in individual parts of the study″ are no reason to question the entire approval. The epidemiologist Klaus Stöhr , who managed the Novartis vaccine program from 2007 to 2017, points out to WELT that such incidents cannot always be avoided: ″It is crucial that they are discovered and taken into account in the study evaluation″. Whether the study needs to be corrected ″can only be said conclusively by looking at the original documents of the entire study″. The Charité immunologist Andreas Radbruchcalls for strong sanctions, it is about ″vaccination acceptance in society, trust in the approval authorities″. The head of the Standing Vaccination Commission (Stiko) Thomas Mertens also demands: “The allegations should be correctly clarified”.

WELT asked Pfizer to comment on the cases of Augusto Roux, Maddie de Garay, the events in Buenos Aires and the role of Fernando Polack. It came promptly: “Regulatory authorities around the world have approved our COVID-19 vaccine. These approvals are based on a robust and independent assessment of quality, safety and efficacy scientific data, including the Phase 3 clinical trial .”

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But was there even time for such a solid assessment by the authorities? E-mails from the EMA, which are available to WELT, show that the FDA, the British MHRA and the EMA itself had already agreed on the date of approval before they could even take a look at the Pfizer papers. Time was pressing, the corona virus caused suffering and terror. It seems there was no time for meticulous checks back then.

WELT also asked the head of the Pfizer approval study, Fernando Polack, for clarification. Polack also preferred to remain silent.


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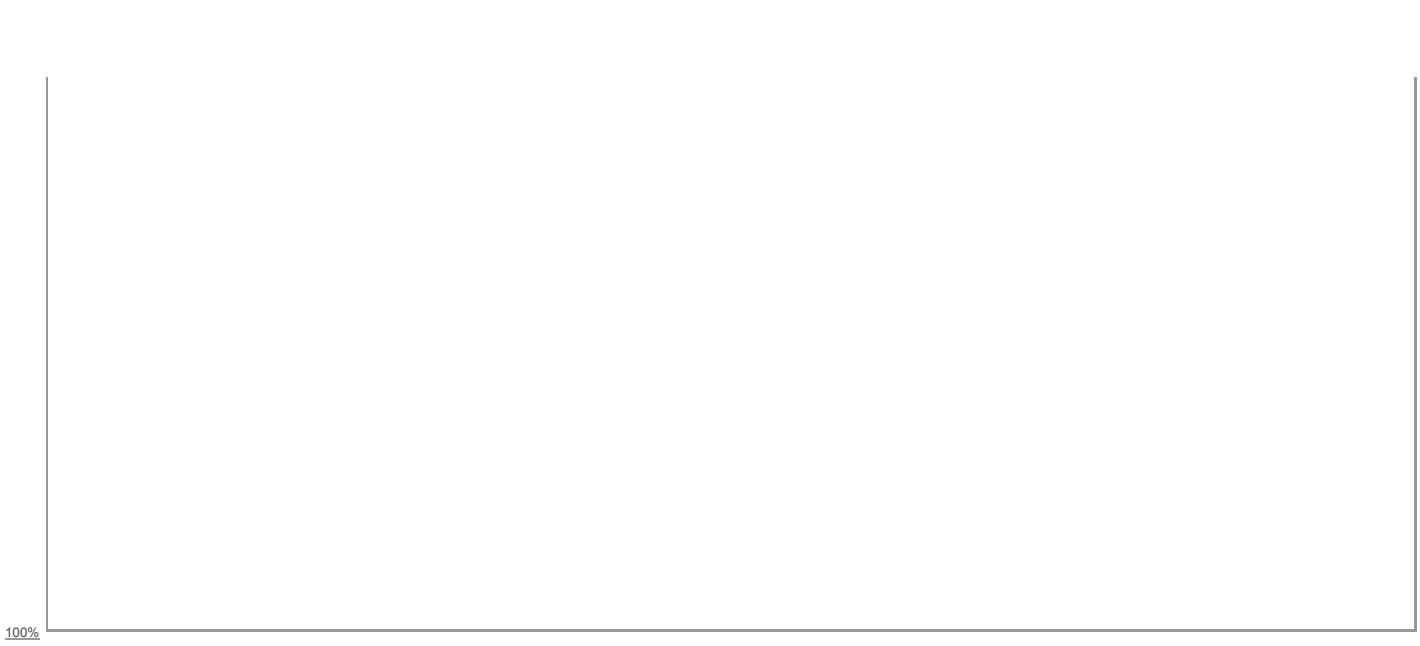
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