BioNTech and the US Securities and Exchange Commission (SEC)

The Approval

Anyone who wants to develop and market a drug must prove the efficacy, consistent quality and biological safety. To this end, the legislator has prescribed a series of preclinical and 4 clinical trials: In phases 1-3, tolerability and safety are first tested on healthy volunteers, and from phase 2 onwards on patients. If a drug successfully passes phases 1-3, it is approved. The entire process from preclinical to clinical to approval can take 10 years. Phase 4 is a post-marketing study. The drug is already approved and now the monitoring begins: recording all adverse events.

Usually, clinical trials start only after sufficient preclinical testing in the laboratory, in cell cultures and animal models. The active principle is analysed, and the production process is defined. Toxicological studies are a focal point. The preclinical data are the basis for applying to the authorities for a clinical trial.

In the case of the emergency approvals of the vaccines against SARS-CoV 2, the manufacturers do not need to demonstrate extensive animal experiments. Little preclinical, but right away studies with patients. After only 10 months of development, BioNTech has delivered.

The Lie

BioNTech has always emphasized the good efficacy and high safety of its Corona vaccine, pointing to regulatory agencies such as EMA (Europe) and FDA (USA). Vaccine side effects would be rare, moderate and comparable to side effects of other vaccines.

The EMA is led by Dr. Emer Cooke, an Irish pharmacist. She was a lobbyist for years for AstraZeneca and Pfizer, among others, in the European pharmaceutical industry umbrella organization: The interests of the pharmaceutical industry are the focus here, not the patient.

US Securities and Exchange Commission (SEC)

The stock exchange supervisory authority is different. It protects the economic interests of investors and makes sure that a company puts all its data on the table and does not lie to investors. Lying to the SEC can mean economic ruin for a publicly traded company. It was the U.S. Securities and Exchange Commission (SEC) that forced BioNTech to disclose the truth about its mRNA Corona vaccine.

(https://www.sec.gov/Archives/edgar/data/1776985/000156459021016723/bntx-20f_20201231.htm#ITEM_3_D)

BioNTech buckles:

- ***We may not be able to demonstrate sufficient efficacy or safety of our COVID-19 vaccine*** *and/or variant-specific formulations* ***to obtain permanent regulatory approval in the United States, the United Kingdom, the European Union or other countries*** *where the vaccine has been approved for emergency use or granted conditional marketing approval.*

- ***Serious adverse events may occur during our clinical trials or even after we receive regulatory approval, which could delay or terminate the clinical trials*** *and delay or prevent regulatory approval or market acceptance of any of our product candidates.*

(https://investors.biontech.de/static-files/50d0cafc-b2c1-4392-a495-d252f84be105 - Seite 8: Risk Factors)

3 million side effects

Since the introduction of the Corona vaccines, WHO counts more than 3 million severe side effects worldwide. In the EU, it is assumed that at least 300,000 deaths are related to this vaccination. A regularly approved vaccine with such a negative record would have lost its approval long ago and those responsible would be facing legal action.

mRNA vaccines are toxic

The RNA vaccine does not produce a stable and sterile immune response. Most importantly, it does not protect against a severe course. A fairy tale that is repeatedly strained. Evidence-based studies are lacking on this. Neither self-protection nor protection from others is given. One of the severe side effects is that the RNA vaccine massively interferes with the innate immune system and provokes serious disorders.

(https://www.sciencedirect.com/science/article/pii/S027869152200206X)