

Wilfried Schmitz

Rechtsanwalt

RA Wilfried Schmitz, Mitglied der RA-Kammer Köln

An das

Bundesverwaltungsgericht
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Selfkant, den 14.4.2022

**In the military appeal proceedings
of the Mr ...**

AZ.

and

of the Mr ...

AZ. ...

I would like to clarify once again that we will be **applied for in** the respective interim relief proceedings:

- 1. The suspensive effect of the appellant's appeal dated 10.12.2021 is ordered.**
- 2. The obligation to tolerate the COVID-19 vaccination in accordance with the basic vaccination scheme of the German Armed Forces dated 24 November 2021 "General Regulation (AR) A1-840/8-4000 Vaccination and Selected Prophylactic Measures - Technical Part" of the German Armed Forces Medical Service Command is temporarily suspended until the conclusion of the main proceedings.**
- 3. In the alternative: It is determined that appellant is preliminarily not required to comply with a Covid 19 vaccination order.**

II.

And in the main proceedings will be **requested in** each case:

- 1. The directive of the Secretary of Defense dated November 24, 2021, to include Covid-19 vaccination in the Armed Forces Basic Vaccination Schedule "General Regulation (AR) Vaccination and Selected Prophylactic Measures - Special Part- A1-840/8-4000" is rescinded.**
- 2. The daily order of the Federal Minister of Defence, Annegret Kramp-Karrenbauer, dated 29.11.2021 is cancelled.**
- 3. The daily order of the Inspector General of the Bundeswehr, General Eberhard Zorn, dated 31.01.2022 is cancelled.**

In addition, a few general remarks will be made to promote understanding of the interrelationships.

1. mRNA agents as experimental preventive gene therapy

Pursuant to Section 17a, Paragraph 1, Sentence 1 of the General Medical Conditions (SG), Bundeswehr servicemen and women are obliged to do everything in their power to maintain or restore their health. This is intended to ensure the operational capability of the armed forces. Our colleague Prof. Martin Schwab has commented on this in detail in his written submission. The duty to maintain health is considered to be a special form of the duty to serve faithfully pursuant to § 7 of the General Service Regulations (see Eichen/Metzger/Sohm, Soldatengesetz, 4th ed. 2021, on § 17a, marginal no. 7). Insofar as therapeutic measures for the prevention of a transmissible disease - as is the case here - are the subject of dispute, these are only proportionate and thus permissible if they do not have any unacceptable side effects that have the value of a disease (see Eichen/Metzger/Sohm, on § 17a, marginal no. 17).

This requires that the therapeutics used have been well studied and conclusively tested for safety in animals and humans. Furthermore, it must not be an experiment to which the soldier is unknowingly exposed. Extensive arguments have already been presented in this regard.

In fact, the vector and mRNA active substances used against COVID19 in particular are experimental active substances, as is the active substance of the company Novavax.

Using the example of the mRNA active ingredient of the company BioNTech from Mainz, it will be shown that the COVID19 vaccines included as "vaccines" in the basic vaccination scheme of the German Federal Armed Forces, to which "Comirnaty" belongs, were developed in far too short a time under great time pressure, so that the safety regulations that had existed for decades were in fact largely abolished. And this is for an entirely new drug technology, operated and understood by only a few tech companies, which did not result

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in any approved drug by 2020, despite billions of dollars in funding from investors and government institutions. The company of Ugur Sahin and his wife Özlem Türeci as shareholders of the company BioNTech is a prime example of the fact that for years unsuccessful tinkering and research, money was destroyed and new money was needed again and again.

Should the court consider this to be an exaggeration or even a misrepresentation, each member of the Senate should thoroughly and critically read the book by the owners of BioNTech entitled "**Project Lightspeed**", subtitle "The Road to the BioNTech Vaccine - and to a Medicine of Tomorrow" by May 2, 2022.

This book, published in its first edition by Rohwolt Verlag at the end of 2021, co-authored by the probably more talented co-author Joe Miller of the Financial Times, shows quite precisely and in detail the path that led to the production of the active substance with the code name BNT162b2.9. If the information given there is correct, which the complainants and their lawyers may at least assume, there were less than 3 months between the idea in Mr. Ugur Sahin's head and the manufacture of the active ingredient. If one is more precise, not even 2 months.

Now all soldiers in the German armed forces are required to take an active substance into their bodies, the development time of which lasted less than a quarter. There is no need to mention that this circumstance alone entails a considerable risk potential.

The fact is that the authors Sahin and Türeci write several times in their book that it is

- an experimental compound

which had never been approved as part of a drug approval procedure and which only works technically when wrapped in lipids which had also not yet been approved for use in humans and which, when combined, exhibits extreme sensitivity.

The following other problems are meticulously described in the book:

- the production requires(s) 10,000 individual steps, all of which have to be perfectly coordinated
- the duration of efficacy in terms of antibody and T-cell immunity was already not known for certain in 2020
- the determination of the amount of active ingredient in the single dose to be found was a pure guessing game
- all approval steps have been abbreviated

In addition, the manufacturers have always been aware that severe side effects in the area of immune overreactions are always a major concern.

The bracket around all efforts was the hunt for fresh money. By its own admission, BioNTech had huge debts until 2020. Literally, the book says on page 259, "Yet when BioNTech began work on a Covid 19 vaccine, it was sitting on nearly half a billion in debt. "

The whole book therefore also impressively shows that it is essentially about money, about gigantic sums of money. It may be that Mr Sahin and Mrs Türeci also want to make a serious effort for people's health. However, as far as they were concerned about a vaccine against an infectious disease, they were simply clueless and quasi dilettantes. They were only interested in cancer research based on mRNA. They had been researching this for decades. Whoever does not want to believe this, may read the book.

The other employees of Biontech were also not specialists in the field of infectious diseases. The partnership entered into shortly before with Pfizer for the invention of a flu vaccine based on mRNA does not change this. In this respect, nothing tangible had yet been created.

Particularly worrying is the fact that the regulatory authority in Germany, the Paul Ehrlich Institute, as the higher federal authority according to § 62 AMG, accompanied the phase I study almost benevolently. This had a background that reads like a matter of course in the book, but which has enormous explosive power and calls into question the independence of the authority and its head. On page 70 of the book it states:

"In the late 2000s, the Paul Ehrlich Institute (PEI) unexpectedly became the focus of an mRNA vaccine research cluster. The agency, named after the scientist who had won the Nobel Prize for his groundbreaking work in the fields of immunology and chemotherapy, had taken two young companies under its wing. CureVac, founded in Tübingen in 2000, and BioNTech, founded eight years later in Mainz, were the world leaders in mRNA research and were just waiting to test their developments on humans. While the PEI was more known for being more cautious and conservative than its American counterpart, the agency was instrumental in developing regulatory frameworks for mRNA vaccines. For years, it worked closely with startups with the goal of testing and ensuring that the compound could be safely administered to humans. PEI staff co-authored scientific articles with the mRNA pioneers, including Ugur and Özlem. The pair attended research retreats organized by the agency - workshops where new areas of medical research were discussed in detail. Together, the innovators and regulators came up with new technologies such as mRNA. "

Thus, by the BioNTech owners' own admission, it is clear that there was an exceptionally close relationship between their company and a government agency (!). This close relationship also existed at the highest level, it says on page 71:

"Ugur had a collegial relationship with its president, biochemist Klaus Cichutek. That Tuesday, soon after the meeting with his fellow board member and before his conversation with Pfizer, Ugur picked up the phone and called Cichutek directly. He urgently needed a scientific consultation with experts from the PEI, he said. "

The further statements on pages 71 and 72 and in various places in the book also clearly show that BioNTech maintained an unusually close relationship with the PEI and its head of authority, Prof. Cichutek. This is unusual in that the PEI was not only responsible for the vaccine approval through the Phase I trial carried out in Germany, but also for its monitoring and, if necessary, the withdrawal of the approval according to § 5 Para. 2 AMG. If one were to compare this with other authorities, it would be as if the head of the Federal Central Tax Office were to meet with a private entrepreneur to discuss large tax saving models and to draw up regulations for this purpose, which would then be monitored by

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him and his authority. A completely unthinkable circumstance. The fact that this is supposed to be customary or sensible in the approval of pharmaceuticals is expressly denied. Prof. Cichutek and the PEI are solely committed to the health of the people of Germany, never to a company or a new technology, not even in a pandemic. Already in April 2020, the PEI made its newsroom available to BioNTech.

https://www.pei.de/SharedDocs/Downloads/DE/newsroom/dossiers/ppt-erste-studie-sars-cov-2-impfstoff.pdf?__blob=publicationFile&v=2

So it remains to be said that the soldiers should be obliged to take an active substance into their bodies, which was developed in an incredibly short time by a very small group of scientists with special knowledge without substantial knowledge in the development of infectious vaccines, which was only tested on rats until 22.04. 2020 and then on humans from 23.04.2020.2020 and then on humans from 23.04.2020 onwards, monitored and supervised by a higher federal authority which was and apparently still is in deep contact on a personal level with the BioNTech company, to which numerous safety tests were approved or partially waived in a kind of fast-track procedure.

In addition, at the beginning of 2020, BioNTech was almost crushed with a debt burden of 500 million euros. It urgently needed a breakthrough for its technology, which had repeatedly been sharply criticized by recognized experts, had not led to a marketable product in 12 years and had cost well over 1 billion euros.

Therefore, the soldiers are part of a gigantic human experiment. This is not changed by the fact that this also applies to all other people who have participated in it so far or who have been and will be indirectly committed in Germany via § 20a IfSG.

2. Why CureVac pulled out of developing a gene therapy against Covid19 and what this means in terms of BioNTech.

The company Curevac has also developed an mRNA active substance against Covid19 and has brought it into clinical phase I. As already mentioned in the book by Sahin and Türeci, CureVac was also under the wing of the PEI.

On 04/16/2021, a study was published in the prestigious journal Nature:

<https://www.nature.com/articles/s41541-021-00311-w>

This study can be read and translated into German by this court itself.

The fact is that Curevac made a crucial difference when it tested its active ingredient for efficacy and protection: it did not test on rats, but on the far more suitable Syrian hamster. The Syrian hamster is far more similar to humans than rats in its ability and structure in the respiratory tract.

Evidence: Testimony of Dr. med. Susanne Wagner, to be downloaded via msl-Management

Expert witness Dr. Wagner has been advising companies in the field of drug approval for approximately 25 years, with her focus today being in the field of nanotechnology.

In fact, the experiments on the Syrian hamster show that the mRNA-based agent studied there was by no means overly effective in protecting against infection.

Proof:as before

The results of this trial are likely to have been the ultimate reason why Curevac did not take its compound further to market and into Phase III.

BioNTech apparently shied away from testing on the Syrian hamster, and they are still shying away from it today, because no tests on the Syrian hamster have been published to date.

Proof:as before

Furthermore, there is reason to believe that BioNTech has chosen an excessively high active ingredient dose of 30 mg for the group of people under 55 years of age and an excessively low dose for older people. A correction has not taken place to date.

Proof:as before

The starting point was the phase I study with a total of 60 subjects in April and May 2020, in which 12 subjects each were administered amounts of 1 mg, 10 mg, 20 mg, 30 mg and 60 mg. The corresponding study by Sahin, Muik and Türeci (all appear frequently in the book) from 30.09.2020 in the journal Nature is cited here:

<https://www.nature.com/articles/s41586-020-2814-7>

This clearly shows that for people under 55, a drug dose of 20 mg or even 10 mg would also have been sufficient to obtain a sufficient immune response, but with lower side effect rates.

Proof:as before

In fact, due to the overdose, which BioNTech also does not seriously deny, a possible spike poisoning of people with intact immune systems takes place. In any case, it cannot be ruled out.

Proof:as before

This overdose affects virtually all servicemen and servicewomen, since they are among the healthy and younger ones.

With the acquiescence enforcement, the respondent thus forces the soldiers into a potential poisoning situation with the spike protein, which is toxic, which is completely undisputed in science. This weighs all the more heavily because 3 doses are now supposed to be mandatory. In fact, however, the determination of the amount of the active ingredient did not play a decisive role in the studies submitted to the EMA by the manufacturers - in this

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case BioNTech - because at the time of the 2020 approval procedure, a dose of 2 times was still assumed.

Proof:as before

This also applies to the nanolipids, which are absolutely necessary for the insertion of mRNA into human cell walls.

Proof:as before

In fact, all the studies were done only in relation to the alpha and beta variants of the SARS virus, the now prevailing omicron variant with subvariants was never the subject of the registration studies, not even in relation to the extension of the conditional approval.

Proof:as before

In fact, the current high incidence figures (merely assuming that these figures, which are based on unsuitable tests, have any significance at all) prove that the active substances against Omikron are virtually ineffective in terms of protection against infection with the SARS virus. Whether they can protect against serious illness or death - as repeatedly claimed by the proponents - is not to be discussed further here with regard to the servicemen and servicewomen, since these are not among the actual target group of active substances, if only because of their age and the known risk situation. These were clearly old and seriously pre-diseased people.

Proof:as before

In fact, even for chickens, vaccines have higher safety requirements than the currently conditionally licensed vaccines against SARS.

<https://www.msd-tiergesundheits.de/fokusthemen/infektioese-bronchitis-der-huehner/impfprogramme/>

There are individual vaccination programs for each herd.

Soldiers are entitled to expect their employer to do everything necessary to ensure that their health is not endangered or even destroyed by experimental active substances, which are primarily concerned with market opportunities for a new drug technology and profits running into billions.

3. The failure of the safety authority PEI

The PEI does not fulfil its control obligations.

According to § 13 para. 5 IfSG, the associations of panel doctors as well as the vaccination centres have to provide, among others, ICD codes for pharmacovigilance since the beginning of the vaccination campaign in Germany. To date, none of the addressees of the

law has fulfilled this obligation, not even the PEI as the responsible supreme safety authority. This proves that the PEI is only inadequately fulfilling its legal mandate, after having already only kindly accompanied the approval, as the explanations in Mr. Sahin's book prove.

This duty to contribute to vaccine safety also applies to physicians, including the military physicians of the Bundeswehr:

§ Section 6 (1) sentence 1 no. 3 IfSG regulates the obligation to report suspected health damage that goes beyond the usual extent of a vaccination reaction. In this regard, the commentary Kießling zum IfSG, 2nd edition 2021, § 6 Rz. 1 states: The norm states a duty to report for the diseases listed in it. According to § 6 Abs.1 Satz 1 Nr. 1 t also Covid19 belongs to it. According to § 6 para. 1 sentence 2, the duty to report suspected vaccination reactions is incumbent on the "ascertaining physician" according to § 6 as well as on the head of the pathology department (§ 8 para.1 no. 3), pursuant to § 8 para. 1 no. 1. The violation of this reporting obligation (non-reporting, incorrect reporting, incomplete reporting or reporting in an improper form) is an administrative offence in the sense of § 73 Para. 1 a No. 2 IfSG, and is subject to a fine of up to € 2,500.00 per violation. According to § 6 sentence 2 IfSG, the notification of the physician has to be made in accordance with § 8 Abs.1 Nummer 1 i.V.m. § 9 Abs. 1 Nr. 1 a-d, i (diagnosis or suspected diagnosis) as well as according to Nr. 4 information about the protective vaccination in the sense of § 22 IfSG "by name". According to § 9 para. 3 sentence 1 IfSG, the notification by name must be made to the public health department immediately, at the latest after 24 hours. Reports of vaccination reactions are obviously not exempt from this "immediacy regulation".

From this it can be concluded: the state wants immediate feedback on vaccination complications.

The legislator also commented on this in the joint draft by the CDU and SPD of 03.11.2020, BT-Drucksache 19/23944, p. 28.

The CDU and SPD, as the governing parties, knew from the RKI that the obligation of physicians to report vaccinations in § 6 Para.1 No. 3 IfSG is insufficient and that there is an under-reporting of vaccination complications.

The explanatory memorandum to the amendment of Section 13(5) IfSG of 03.11.2020 states:

"The limitation of drug safety monitoring based on individual case reports (passive surveillance) should therefore be compensated for with the help of the pseudonymised data of the Associations of Statutory Health Insurance Physicians. This additional database is particularly important for the introduction of new vaccines into the German market and for the publication of new vaccination recommendations, as these still lack broad empirical values.

As of 04.03.2021, sentence 2 was then introduced as a supplementary ordinance authorization.

In § 13 para. 5 sentence 1 IfSG it is regulated that the KVs and also the vaccination centres "...for the purpose of monitoring the safety of vaccines (pharmacovigilance)" had

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to transmit the data mentioned in no. 1-10 to the PEI in fixed time intervals. Thus also data according to No. 9: diagnosis code according to the International Statistical Classification of Diseases and Related Health Problems (ICD), diagnosis certainty and diagnosis type in the sense of an acute or permanent diagnosis.

Thus it is said in Kießling, 2nd ed. Rz. 36:

"The information already to be reported to the RKI for the purpose of vaccination surveillance is also helpful for the monitoring of pharmacovigilance by the PEI in order to be able to assess the frequency, severity and long-term course of vaccination complications and to investigate whether health damage and diseases related to vaccinations occur more frequently than in unvaccinated persons (BT-Drs. 19/23944,28). For this reason, the obligation to report to the PEI has been included here. "

The notification to the PEI is therefore made in the legislative sense. According to § 62 para. 1 AMG, the PEI is also responsible for the safety of vaccines and their monitoring.

In the commentary on Section 62 AMG, Zuck -Dettling, 1st ed. 2021, it is stated in this respect in para.7:

"As a result, care must be taken to ensure that the potential health hazards that may be associated with the use of the medicinal product do not exceed an acceptable level, taking into account the expected benefits (positive benefit-harm or benefit-risk ratio). Continuously assessing this represents the core activity of pharmacovigilance. "

Therefore, according to Section 62 (2) AMG, the PEI must record **all suspected** adverse reaction **reports of** which it becomes aware. The reporting deadlines to the EMA are clearly regulated in Section 62 (3) AMG.

The Zuck-Dettling states in this respect under para 18:

"The pharmacovigilance department of the BfArM and the PEI are regularly audited by quality assurance experts from within the authorities. The audit report and the findings contained therein are forwarded to the European Commission, which, however, does not publish these documents at present. "

§ Section 62 (2) AMG was introduced in 2012. The legislative materials state on page 61 (BT-Drs. 17/9341 of 18.04.2012):

Die bisherige Regelung, die zwischen erwarteten und unerwarteten Nebenwirkungen unterschieden hat, wird nicht mehr aufrecht erhalten. Titel IX der geänderten Richtlinie 2001/83/EG unterscheidet insoweit nicht mehr. Die Meldungen über die Verdachtsfälle von Nebenwirkungen an die zuständige Bundesoberbehörde haben bei Inlandsfällen von nicht schwerwiegenden Nebenwirkungen innerhalb von 90 Tagen und bei Inlands- und Drittstaatenfällen von schwerwiegenden Nebenwirkungen innerhalb von 15 Tagen zu erfolgen. Die Regelung in Absatz 3 stellt (in Umsetzung von Artikel 107 Absatz 1 Unterabsatz 2 der Richtlinie 2001/83/EG) sicher, dass an einer zentralen Stelle innerhalb der Europäischen Union alle Verdachtsfälle verfügbar sind. So können die zuständigen Bundesoberbehörden ohne erheblichen Aufwand im Bedarfsfall auf diese zugreifen. Die Regelung in Absatz 4 ist eine Folgeänderung der neuen Regelungssystematik der Pharmakovigilanz und im Übrigen redaktionelle Änderung auf Grund der Verschiebung entsprechender Vorschriften. Die bisher in § 63b Absatz 8 ge-

Therefore, all troop doctors are also legally obliged to report to the relevant authorities. So far, the complainants' lawyers are still waiting for the requested data and figures from the respondent providing clarification on the situation within the force.

Conclusion:

The servicemen and servicewomen take part in an experiment. They are not informed about this.

The active substances are wrongly dosed for the group of up to 55-year-olds, there is an overdose.

The active ingredients are largely ineffective against the omicron variant, against which they were not designed.

The regulatory authority PEI does not sufficiently fulfil its legal mandate to check the safety of vaccines.

This actively endangers the health of the servicemen and women.

Against this background alone, the obligation to tolerate violates § 17a.1 sentence 1 and sentence 2 of the SG.

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