Amazing product info on mRNA vaccines: fascinating questions for the vaccinator

by VisionBlue.info

If I were to sit across from a vaccinator one day and, after reading the educational leaflet for mRNA corona vaccines, he asked me if I still had any questions, I would not answer with a shake of my head as an attentive and critical citizen. For me, this is only a theoretically possible situation anyway, but since I am a lawyer, I see myself in a position to mentally play through this fictitious situation once and evaluate it legally. One should already inform oneself comprehensively before the vaccination appointment. At the European Medicines Agency (EMA) there are many interesting documents to read. Extensive information can also be obtained on the mRNA vaccines, which have now been inoculated billions of times. The "product information" is particularly interesting. The product information on Comirnaty (BioNTech/Pfizer) and Spikevax (Moderna) is available in many different languages, including German. I downloaded them and took a close look at them. You don't want to look stupid when you're in front of the vaccinator. At the actual vaccination appointment, there is a medical history and consent form in addition to the information sheet, and it is of immense importance to the person treating me (that's the name of the vaccinator in legalese) that I put the crosses in the right place and sign the paper. From a legal point of view, he enters into a treatment contract with me

and the information as well as the consent are mandatory by §§ 630d and 630e BGB in Germany. If he would not get consent, he would commit bodily injury and be exposed to civil claims for damages, which of course he presumably does not want! We consider now mentally the situation and - we say - it is not my family doctor (if one has a really competent one, he will refuse this vaccination) but a doctor med. taken under contract by the public health department who is active in the vaccination center. By the way, for the treatment contract it doesn't matter if the vaccinator - I'll call him Dr. X - gets his money for the prick from the office or the health insurance. He enters into this contract with the vaccinated person, at the latest when the latter signs and gives his consent. For most vaccinated people, this happens in a jiffy, after all, there is a queue out there and others want to get their hands on it, too. Well, with me it wouldn't go so quickly, but I would actually say:

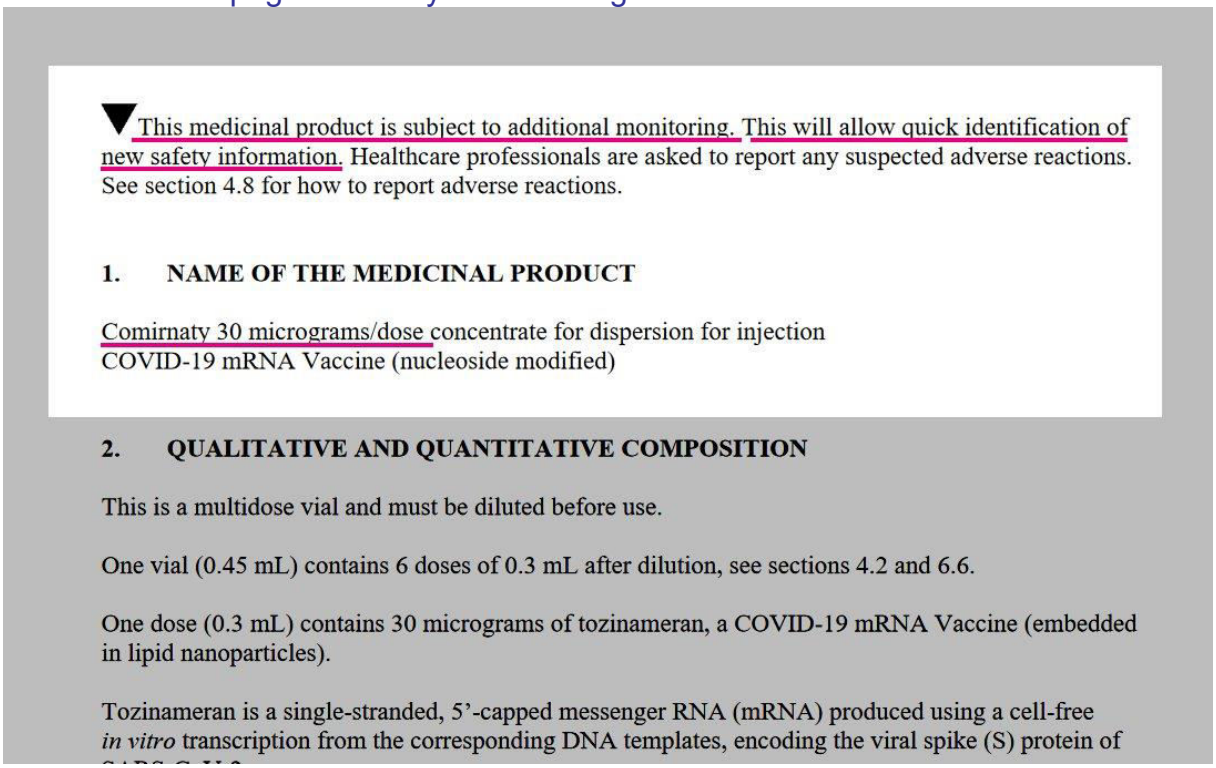
"Dr. X, I still have a few questions!"

He looks at me as if I had suddenly grown two horns on my head, but I'm not impressed by his furrowed brow and raised eyebrows.

I follow up with, "There are a few teeny inconsistencies ... I beg your indulgence but I'm a lawyer, I can't help it!"

He looks as if he has just bitten into a slice of lemon and growls, "If you must ... but hurry up and be brief!"

Ignoring this instruction, I calmly pull a stack of papers from my shoulder bag. Demonstratively, I place them on the table and say, "These are the product descriptions of the substances vaccinated here at the vaccination center. I took a close look at them and compared them with the information in the information sheet. After all, the manufacturers of the vaccines have submitted this information to the regulatory authority EMA, so that it can be assumed that it is not a matter of swearing! I notice thus on page 2 already the following ... "



▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1. NAME OF THE MEDICINAL PRODUCT

Comirnaty 30 micrograms/dose concentrate for dispersion for injection
COVID-19 mRNA Vaccine (nucleoside modified)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

This is a multidose vial and must be diluted before use.

One vial (0.45 mL) contains 6 doses of 0.3 mL after dilution, see sections 4.2 and 6.6.

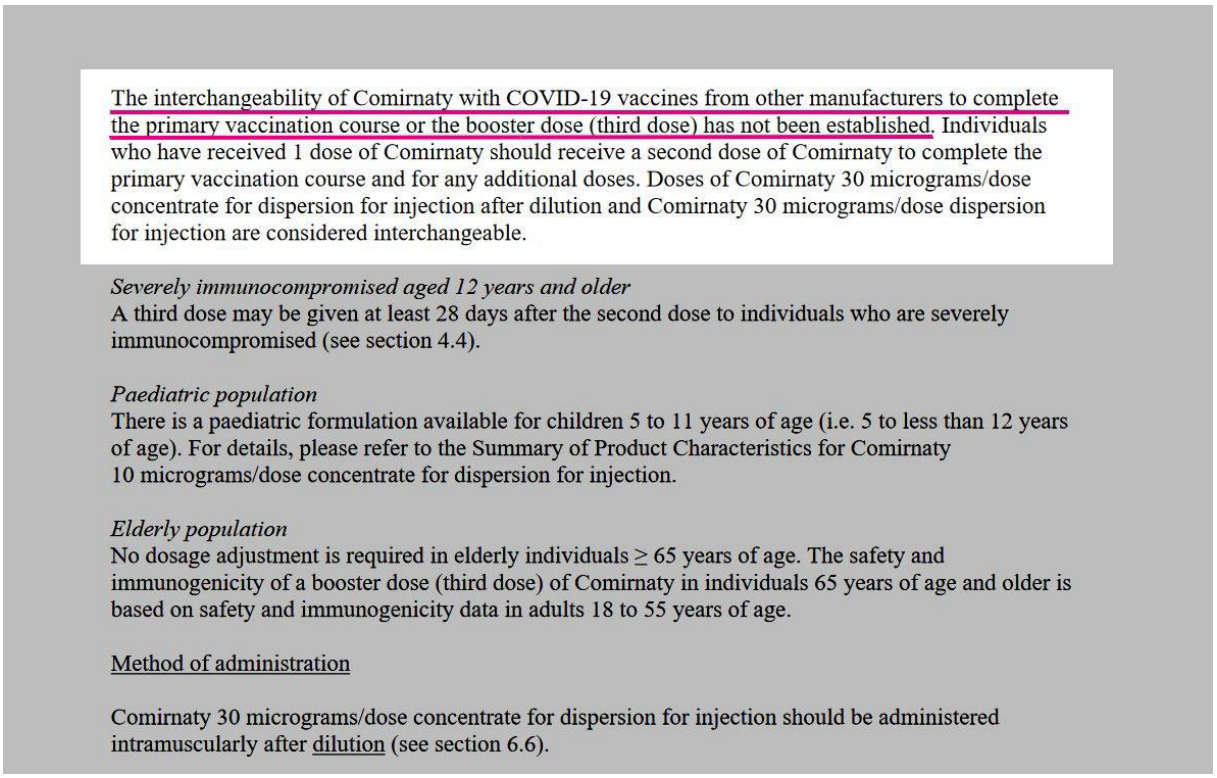
One dose (0.3 mL) contains 30 micrograms of tozinameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).

Tozinameran is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein of

I point to the open part of the paper and say, "Why does the vaccine actually need additional monitoring and why do new findings about its safety need to be identified? I thought the vaccine was safe?"

He rolls his eyes and replies indignantly, "The vaccine is safe! But it only has a conditional approval and that's where the manufacturer has to write something like this!"

Me: "All right, I can understand that. Only I do not understand that ... " I quote from the next pages and immediately ask the questions that arise from the information ...



The interchangeability of Comirnaty with COVID-19 vaccines from other manufacturers to complete the primary vaccination course or the booster dose (third dose) has not been established. Individuals who have received 1 dose of Comirnaty should receive a second dose of Comirnaty to complete the primary vaccination course and for any additional doses. Doses of Comirnaty 30 micrograms/dose concentrate for dispersion for injection after dilution and Comirnaty 30 micrograms/dose dispersion for injection are considered interchangeable.

Severely immunocompromised aged 12 years and older
A third dose may be given at least 28 days after the second dose to individuals who are severely immunocompromised (see section 4.4).

Paediatric population
There is a paediatric formulation available for children 5 to 11 years of age (i.e. 5 to less than 12 years of age). For details, please refer to the Summary of Product Characteristics for Comirnaty 10 micrograms/dose concentrate for dispersion for injection.

Elderly population
No dosage adjustment is required in elderly individuals ≥ 65 years of age. The safety and immunogenicity of a booster dose (third dose) of Comirnaty in individuals 65 years of age and older is based on safety and immunogenicity data in adults 18 to 55 years of age.

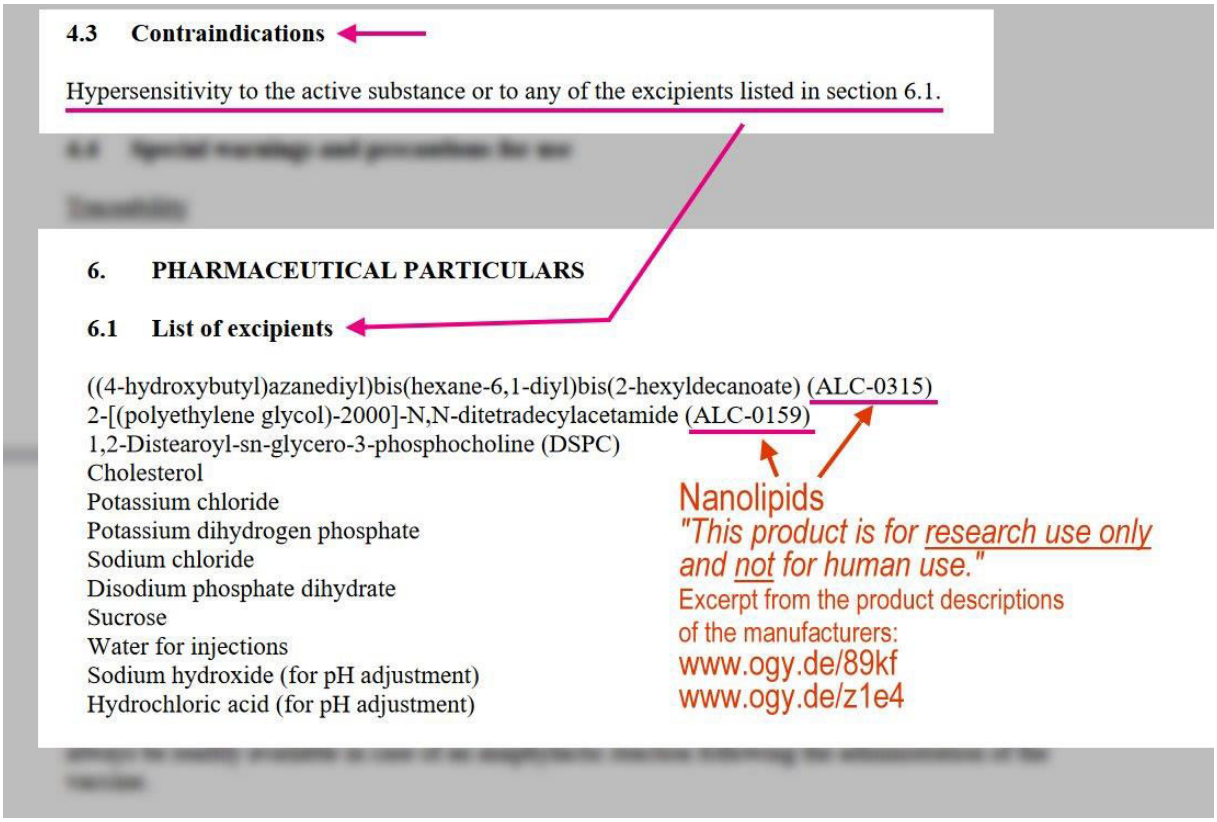
Method of administration

Comirnaty 30 micrograms/dose concentrate for dispersion for injection should be administered intramuscularly after dilution (see section 6.6).

Me: "Then why does the STIKO[1)], according to the information leaflet, recommend so-called cross-vaccinations with the Janssen vaccine, if the interactions have not been investigated by the manufacturers of Comirnaty and Spikevax?"

1) STIKO means Standing Commission on Vaccination

Dr. X: "I can't say anything about that! It is best to ask the STIKO!"



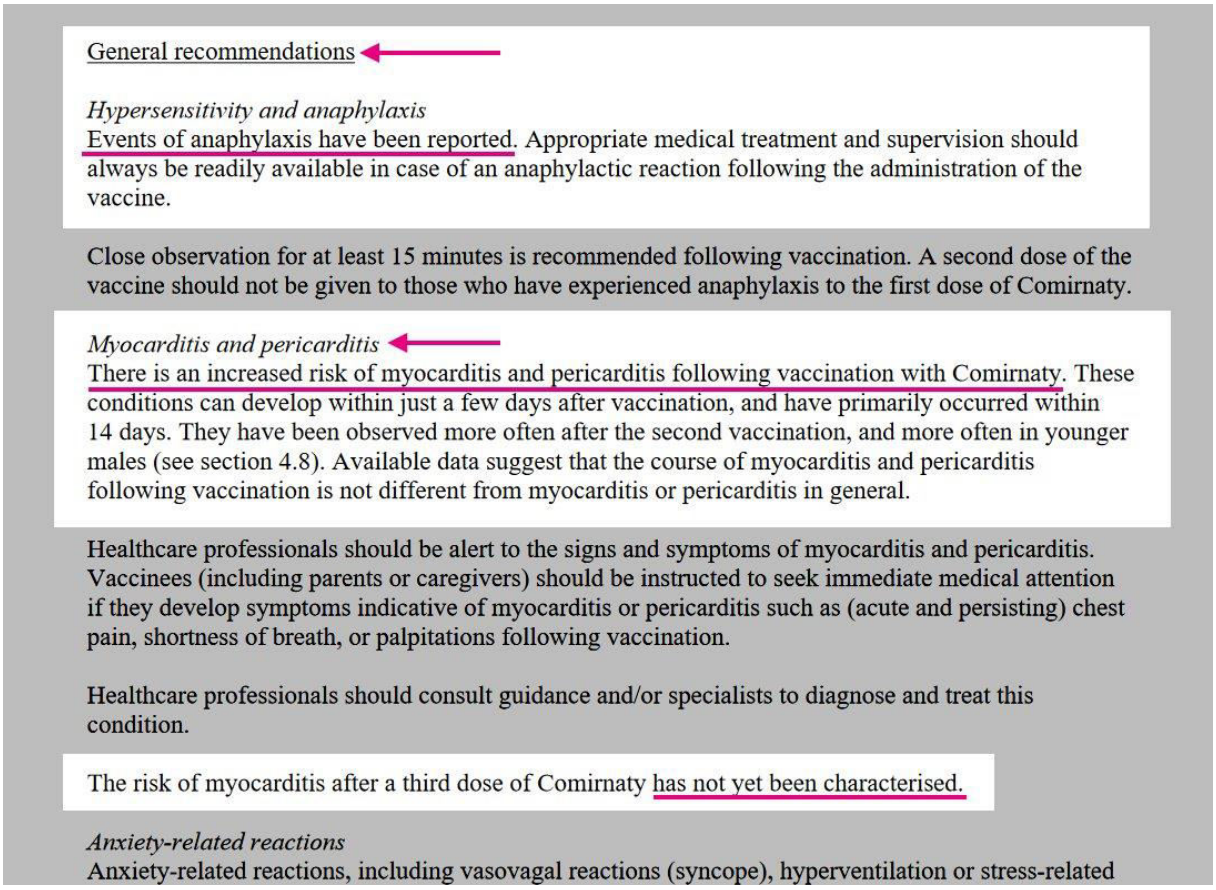
Me: "Are allergological examinations carried out on the vaccinated person before the injection with regard to a possible hypersensitivity to the ingredients mentioned in item 6.1 of the product description?"

Dr. X visibly annoyed: "No, there is no time for that here! The vaccinated person himself must disclose to us on the medical history form if he is allergic to certain substances!"

Me: "It's good to know that this will not be investigated here! But to the next question, which is related to this: Are you aware that the so-called nanolipids contained in the vaccine are labeled in the manufacturers' product descriptions as being for scientific use only and, in the case of some manufacturers, have additionally been declared as not to be used in humans?"

Dr. X growls, "No, that's completely new to me!" He is silent and thinks a bit, then he says: "But since the EMA has approved the vaccine with these nanolipids, this is also completely irrelevant!"

Me: "As a lawyer, however, I must tell you to this that it is not for you! Because you would at least have to inform the vaccinees that such substances are contained in the vaccines and that there are declarations on this from the manufacturers that they are only to be used for scientific purposes. This means that the vaccinated person is participating in a scientific experiment. At least this should be made clear. But well ... I come to the next question ... "



General recommendations

Hypersensitivity and anaphylaxis
Events of anaphylaxis have been reported. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine.

Close observation for at least 15 minutes is recommended following vaccination. A second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of Comirnaty.

Myocarditis and pericarditis
There is an increased risk of myocarditis and pericarditis following vaccination with Comirnaty. These conditions can develop within just a few days after vaccination, and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males (see section 4.8). Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general.

Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinees (including parents or caregivers) should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination.

Healthcare professionals should consult guidance and/or specialists to diagnose and treat this condition.

The risk of myocarditis after a third dose of Comirnaty has not yet been characterised.

Anxiety-related reactions
Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related

Me: "In the product description for the mRNA vaccines it is written that there is an increased risk of myocarditis and pericarditis after vaccination. That's a new warning, by the way, that didn't exist like that a year ago. How do you ensure that vaccinees who may be undiagnosed with these conditions or other heart problems are excluded from vaccination?"

Dr. X again visibly annoyed, "If he has heart problems, he has to put that on the medical history sheet. Then it will be decided whether I vaccinate him at all. But a cardiological examination before vaccination does not take place here. How can that be done?"

Me: "If it goes wrong, however, there is then a liability problem for you. Without clarification of the contraindications to which the manufacturers refer, you are acting grossly negligent in my opinion!"

Dr. X obviously does not like what I say at all, because his face is flushed with anger. With a loudly raised voice, he starts to yell at me: "Tell me what this is all about! Are you questioning my medical competence? I guess you don't want to be vaccinated, otherwise you wouldn't ask such strange questions! It's best you leave now and leave the vaccination center! I prefer to treat people who trust me!"

I had somehow expected that the conversation would take such a course. I don't want to annoy the good man any further, so I grab the product descriptions as well as my notes, stuff them into my shoulder bag and leave the vaccination center.

Now ... of course this conversation is purely fictional and didn't happen that way. I am also quite sure that there was no similar conversation anywhere. Of course, I can't say how other doctors would react to such questions. I also believe that some other doctors would listen to me carefully and have a factual conversation with me. The interested reader may now ask what else I would have asked, if the explanatory talk had not come to such an abrupt end. And so in the following I will formulate the right questions - among other things from the viewpoint of affected patient groups - to the statements in the product information ...

The risk of myocarditis after a third dose of Comirnaty has not yet been characterised.

Anxiety-related reactions
Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions (e.g. dizziness, palpitations, increases in heart rate, alterations in blood pressure, paraesthesia, hypoaesthesia and sweating) may occur in association with the vaccination process itself. Stress-related reactions are temporary and resolve on their own. Individuals should be advised to bring symptoms to the attention of the vaccination provider for evaluation. It is important that precautions are in place to avoid injury from fainting.

Concurrent illness
Vaccination should be postponed in individuals suffering from acute severe febrile illness or acute infection. The presence of a minor infection and/or low-grade fever should not delay vaccination.

Thrombocytopenia and coagulation disorders ←
As with other intramuscular injections, the vaccine should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.

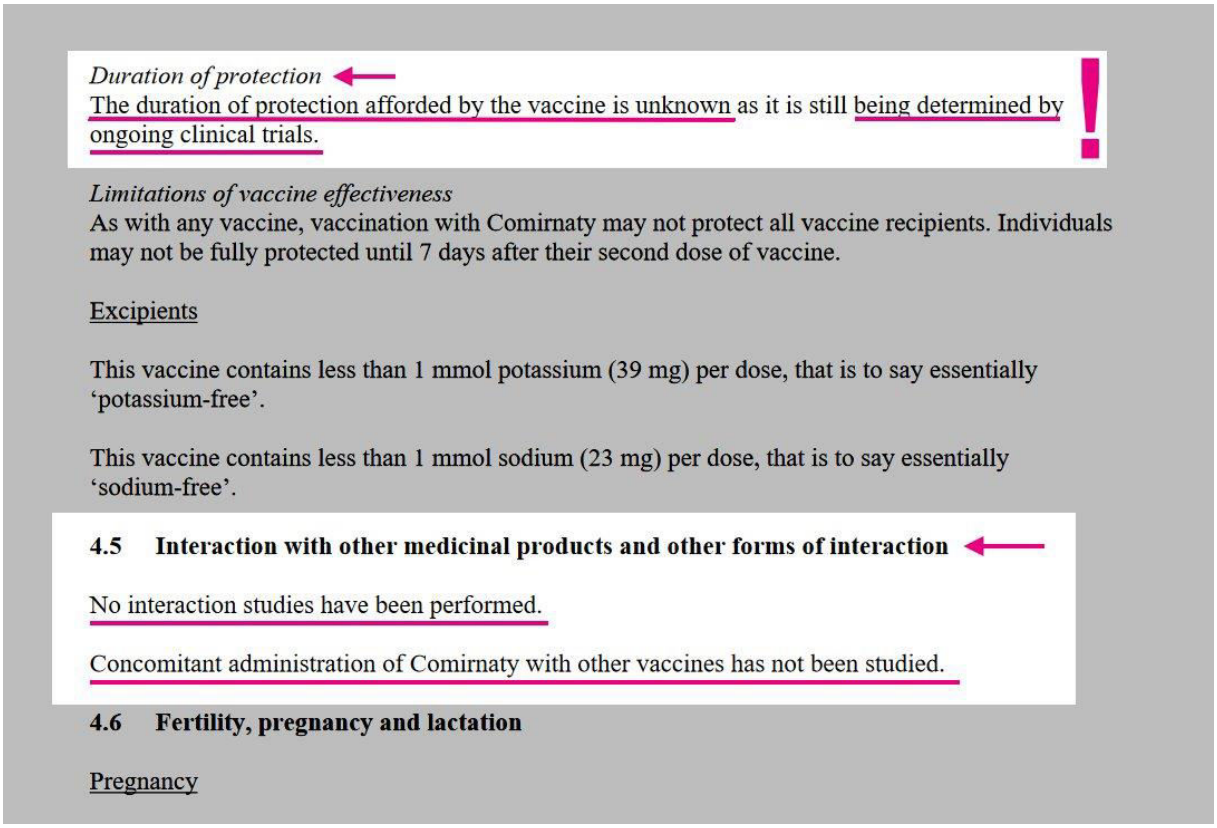
Immunocompromised individuals ←
The efficacy and safety of the vaccine has not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of Comirnaty may be lower in immunocompromised individuals.

The recommendation to consider a third dose in severely immunocompromised individuals is based on limited serological evidence from a case-series in the literature from the clinical management of patients with iatrogenic immunocompromisation after solid organ transplantation (see section 4.2).

Patient suffering from thrombocytopenia or coagulation disorder:
"I have thrombocytopenia / coagulation disorder and am being treated with XXX. According to the product info for the Comirnaty or Spikevax vaccines, the vaccine should be administered with caution in such a condition. I did not find anything about this in the educational fact sheet. However, the disease is asked about on the medical history form. How do you envision this caution in administration? Wouldn't it be better to refrain from vaccination altogether?"

Patient suffering from immunodeficiency or being treated with immunosuppressants:
"I have immunodeficiency / am being treated with immunosuppressants due to my XXX disease. According to the product information for the Comirnaty or Spikevax vaccines, the efficacy and safety of the vaccine has not been evaluated or studied with respect to individuals with immunodeficiency / being treated with

immunosuppressants. With such a gap in information, shouldn't vaccination be discouraged?"



Duration of protection
The duration of protection afforded by the vaccine is unknown as it is still being determined by ongoing clinical trials.

Limitations of vaccine effectiveness
As with any vaccine, vaccination with Comirnaty may not protect all vaccine recipients. Individuals may not be fully protected until 7 days after their second dose of vaccine.

Excipients

This vaccine contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially 'potassium-free'.

This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Concomitant administration of Comirnaty with other vaccines has not been studied.

4.6 Fertility, pregnancy and lactation

Pregnancy

"Doctor, I read in the product info for the Comirnaty or Spikevax vaccines that the duration of the vaccine's protective effect is unknown because it is still being determined in ongoing studies. According to the educational fact sheet, the STIKO recommends that all persons 12 years of age and older receive a booster vaccination with an mRNA vaccine at an interval of at least 3 months from the last vaccine dose of the basic immunization. This means that either the statement in the product information is wrong or the recommendation of the STIKO is wrong. If the effect of the basic immunization is so temporally limited that already after so short time must be inoculated again, then the sense of this inoculation, i.e. to reach a long protection against the illness, is questionable! The media are already talking about the next booster vaccinations. What do you say to that?"

Patient with hypertension:
"Doctor, I suffer from high blood pressure and take XXX regularly as prescribed by my family doctor. Now I read in the product info for the vaccines Comirnaty or Spikevax that no studies have been done to detect interactions with other drugs. There is nothing in the patient information leaflet about this either. Can I be vaccinated with Comirnaty / Spikevax at all without sufficient knowledge of the possible interactions?"

No interaction studies have been performed.

Concomitant administration of Comirnaty with other vaccines has not been studied.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is limited experience with use of Comirnaty in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development (see section 5.3). Administration of Comirnaty in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus.

Breast-feeding

It is unknown whether Comirnaty is excreted in human milk.

Fertility

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).

4.7 Effects on ability to drive and use machines

Comirnaty has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned under section 4.8 may temporarily affect the ability to drive or use machines.

Pregnant patient:

"Doctor, I am 27 weeks pregnant. I read in the product info for the Comirnaty or Spikevax vaccines that there is limited experience with the use of the mRNA vaccines in pregnant women. Reference is made to animal studies that would have shown no evidence of direct or indirect adverse effects related to pregnancy, embryonic/fetal development, birth, or postnatal development. For further details, reference is made to section 5.3, where experiments with pregnant rats are cited. According to the information leaflet, the STIKO recommends vaccination with Comirnaty for pregnant women from the 2nd trimester of pregnancy. According to current studies, severe side effects do not occur frequently after vaccination during pregnancy. If this study situation is based only on experiments with rats, then the statement of the STIKO is to be taken with caution. If there is a study situation with pregnant women, why is this not mentioned in the product information? What do you say to this?"

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: vaccines, other viral vaccines, ATC code: J07BX03

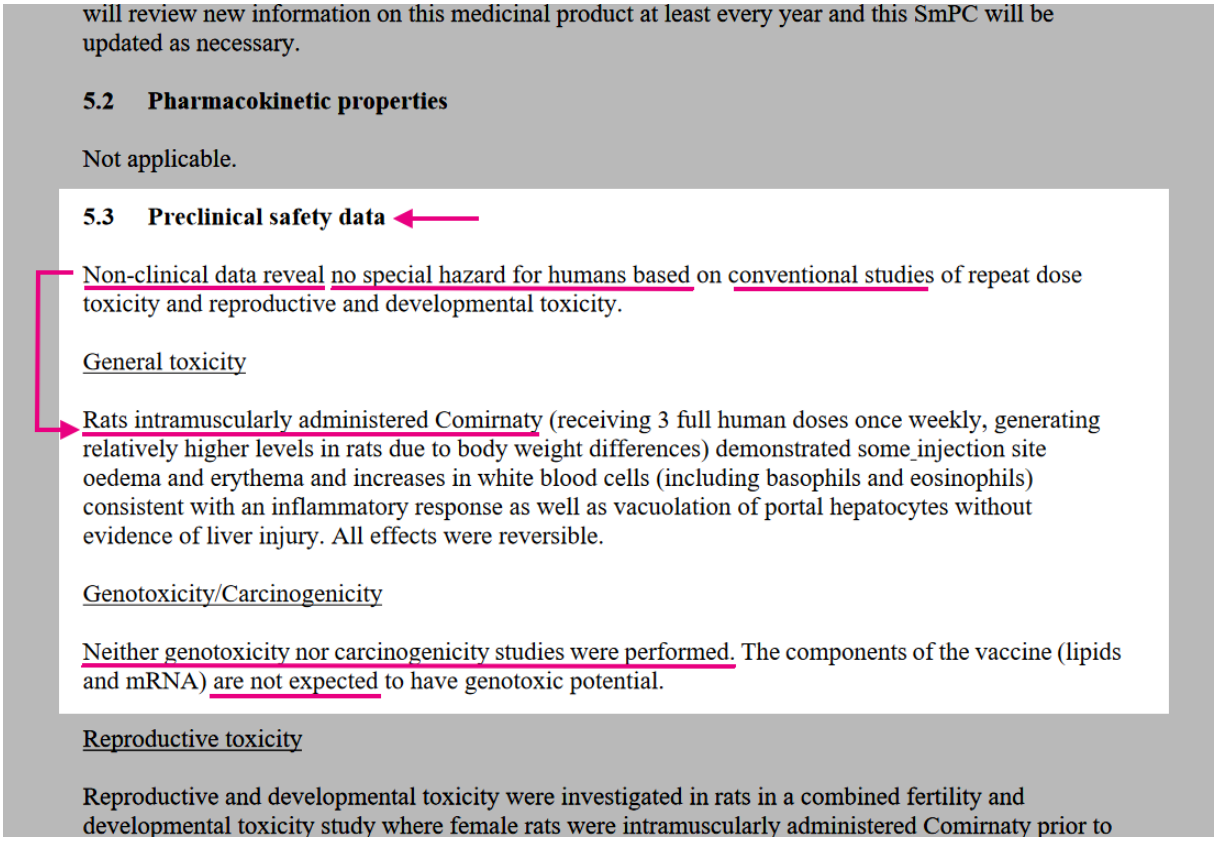
Mechanism of action

The nucleoside-modified messenger RNA in Comirnaty (tozinameran) is formulated in lipid nanoparticles, which enable delivery of the non replicating RNA into host cells to direct transient expression of the SARS-CoV-2 S antigen. The mRNA codes for membrane-anchored, full-length S with two point mutations within the central helix. Mutation of these two amino acids to proline locks S in an antigenically preferred prefusion conformation. The vaccine elicits both neutralizing antibody and cellular immune responses to the spike (S) antigen, which may contribute to protection against COVID-19.

Efficacy

Study 2 is a multicentre, multinational, Phase 1/2/3 randomised, placebo-controlled, observer-blind dose-finding, vaccine candidate selection and efficacy study in participants 12 years of age and older. Randomisation was stratified by age: 12 to 15 years of age, 16 to 55 years of age, or 56 years of age and older, with a minimum of 40% of participants in the ≥ 56-year stratum. The study excluded participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19. Participants with pre-existing stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrolment, were included as were participants with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV) or hepatitis B virus (HBV).

"Doctor, the product info for the Comirnaty or Spikevax vaccines states about the mechanism of action of the mRNA vaccines that they would induce neutralizing antibodies as well as cellular immune responses againstthe spike (S) antigen, which may contribute to protection against COVID-19. However, from the wording 'may contribute', I understand that this is by no means certain, but only a possibility. How do you evaluate this statement?"



will review new information on this medicinal product at least every year and this SmPC will be updated as necessary.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of repeat dose toxicity and reproductive and developmental toxicity.

General toxicity

Rats intramuscularly administered Comirnaty (receiving 3 full human doses once weekly, generating relatively higher levels in rats due to body weight differences) demonstrated some injection site oedema and erythema and increases in white blood cells (including basophils and eosinophils) consistent with an inflammatory response as well as vacuolation of portal hepatocytes without evidence of liver injury. All effects were reversible.

Genotoxicity/Carcinogenicity

Neither genotoxicity nor carcinogenicity studies were performed. The components of the vaccine (lipids and mRNA) are not expected to have genotoxic potential.

Reproductive toxicity

Reproductive and developmental toxicity were investigated in rats in a combined fertility and developmental toxicity study where female rats were intramuscularly administered Comirnaty prior to

"Doctor, I read in the product info for the Comirnaty or Spikevax vaccines that only non-clinical data was used to test the toxicity of the mRNA vaccines. To the best of my knowledge, this means that no human toxicity testing has been done, and that this testing has instead been done via animal studies or with cell tissue testing. But how can one deduce from this that there is no particular danger to humans?"

"Doctor, the product information for the Comirnaty or Spikevax vaccines states that no studies have been conducted on the genotoxicity and carcinogenicity of the mRNA vaccines. It also states that the components of the vaccines, namely the lipids and the mRNA, are not expected to have a genotoxic potential. There is no information on this in the fact sheet. But how can something not be expected if it has not been investigated? After all, we are talking about possible hereditary damage to DNA or carcinogenic effects. What do you say to that?"

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

E. SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE CONDITIONAL MARKETING AUTHORISATION

This being a conditional marketing authorisation and pursuant to Article 14-a of Regulation (EC) No 726/2004, the MAH shall complete, within the stated timeframe, the following measures:

Description	Due date
In order to complete the characterisation of the active substance and finished product, the MAH should provide additional data.	July 2021. Interim reports: 31 March 2021
In order to ensure consistent product quality, the MAH should provide additional information to enhance the control strategy, including the active substance and finished product specifications.	July 2021. Interim reports: March 2021
In order to confirm the efficacy and safety of Comirnaty, the MAH should submit the final Clinical Study Report for the randomized, placebo-controlled, observer-blind study C4591001.	December 2023
In order to confirm the efficacy and safety of Comirnaty, the MAH should submit the final Clinical Study Report for the randomized, placebo-controlled, observer-blind study C4591007.	July 2024

"Doctor, one last question ... the product info for the Comirnaty or Spikevax vaccines states that the marketing authorization holders must submit a final clinical study report to the EMA for a randomized, placebo-controlled, observer-blind study to confirm the efficacy and safety of Comirnaty or Spikevax, respectively. BioNTech even has until July 2024 to do so! Doesn't this mean that the mRNA vaccines are still in an experimental phase and all vaccinees are de facto participants in this trial? Are you actually educating patients about this experimental nature of the vaccine?"

I have to admit, it has become a lot of questions. But they do arise when you take a closer look at the information in the product information. From a legal point of view, it is significant which information is given on which topics. Thus, if it is stated that no studies or examinations have been carried out on a certain topic, every mRNA vaccination of a person who should have contraindications due to his pre-existing conditions is a unique medical blind flight that could have consequences under liability law. When deciding whether to give consent for an injection, haste and pressure should never prevent thorough education and asking the right questions. The vaccinator who lacks understanding and pressures the patient to make a quick decision is acting irresponsibly. In the end, the same should apply to the Corona vaccination as we hear every day in the advertising for medicines ...

"For risks and side effects, read the package insert and ask your doctor or pharmacist!"

Addendum of 01/25/2022 (00:23).

How important the correct procedure for the research and application of a only conditionally approved drug (this includes the so-called Corona vaccines) and how

high the responsibility of the medical profession is, is shown in retrospect by the affected people who, trusting in the safety and in ignorance of the exact contraindications and missing data, have had the mRNA and vector vaccines injected; in which now health impairments up to a life-threatening disease occurred. One of those affected is Rolf Merk, a fully qualified lawyer and Chairman of the Municipal Law Committee of the City of Mainz. He writes in his article "Since my vaccination, nothing is as it was" in the Berliner Zeitung of Jan. 24, 2022, about his ordeal after the second vaccination with BioNTech (meaning the vaccine Comirnaty, whose product characteristics I analyzed above).

"Since I was vaccinated against Corona, nothing has been the same. A few days after the second vaccination with Biontech, the problems started. Muscle and joint pain, numbness in arms and hands, severe fatigue and permanent headaches. After the complaints did not get better, I visited a neurologist after four weeks. This is an exaggerated immune response, it will pass, you just have to wait and see, the neurologist said. Shortly thereafter, I suffered an ischemic stroke. And I will be eternally grateful to the paramedics and Limburg Hospital for the fact that I survived because of their quick and professional help.
...
After I was discharged from the hospital, I visited many doctors. Since I naturally wanted to know what had happened to my body since the vaccination. How all this could happen. I was convinced to be an exciting case for medicine, which in the best case would advance science - oh, how naive I was! Not only was (almost) no doctor interested in my story. No, I was not even taken seriously. I saw distrust, incomprehension and boredom in the faces of the doctors from whom I had hoped so much. And the reaction of friends and acquaintances was often sobering. It was as if a taboo had been broken, as if something sacred had been called into question by complaints that could be traced back to the vaccination. A social betrayal had been committed. And only then did I understand the sentence of an acquaintance who also suffered severe side effects: first you lose your health and then your dignity."

A FB friend wrote the following in a comment on one of my analyses made from the Corona vaccine product information:
"Totally true what you are posting. I am affected by the vaccine damage myself. 2 weeks after the 2nd vaccination, I suddenly had a drop in performance in sports, which I could not explain. One week later it was already so bad that I could not climb any stairs without stopping. The cardiologist then diagnosed: massive myocarditis as a result of the vaccination. Since that time I have always had shortness of breath or air problems. It is indeed the case that what they injected us with is a very devilish thing. And the worst thing about it, you can't sue anyone for recourse."

But now I could give him the hint that his declaration of consent according to § 630d BGB for vaccination with an mRNA substance might be invalid if the explanation according to § 630e BGB, which already has to meet very high requirements according to the wording of the law, was incomplete or even wrong. After all, the law already writes so clearly what it understands by such an explanation:

"The treating party is obliged to inform the patient about all circumstances essential for the consent. This includes, in particular, the nature, scope, implementation, expected consequences and risks of the measure, as well as its necessity, urgency, suitability and prospects of success with regard to the diagnosis or therapy. In the

explanation, reference must also be made to alternatives to the measure if several medically equally indicated and customary methods can lead to substantially different burdens, risks or chances of cure."

Whether this obligation was fulfilled by the vaccinator or one of it assigned and for it suitable executing aides with the so-called Bratwurst, - Drive Inn or church inoculations with long queues, may be strongly doubted!

PS: Finally, no one will be able to talk his way out of it, because what I as an "Otto normal Internet user" could call up in a few minutes at the EMA, download and then analyze thoroughly in peace, must also "occur" to every physician who injects the experimental Corona vaccines. One cannot even reproach the EMA in the matter of information abundance! They are all highly official documents and if you take the time, you will get the necessary information that should make you decide very quickly to refrain from such a vaccination, unless you absolutely want to become a participant in the medical experiment to test these genetic techniques. And should the decision makers of the policy continue to put a vaccination obligation on the agenda, I must refer repeatedly to opposing international and constitutional law. By the way, everyone can refer to this:

Art. 3 of the Charter of Fundamental Rights of the European Union (2010/C 83/02).
"Right to the integrity of the person
1. Everyone has the right to physical and mental integrity.
2. In the context of medicine and biology, the following must be respected in particular:
a. the free consent of the person concerned after prior information in accordance with the legally established
details ... "

Article 7 of the International Covenant on Civil and Political Rights (ICCPR).
"No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected to medical or scientific experimentation without his voluntary consent."

Art. 25 GG
"The general rules of international law are part of federal law. They take precedence over the laws and generate rights and obligations directly for the inhabitants of the federal territory."

Declaration of assumption of liability

I, the undersigned, am the attending physician within the meaning of Section 630d of the German Civil Code (BGB) and, in order to obtain consent from the patient in accordance with Section 630d, Paragraph 1, Sentence 1 of the German Civil Code (BGB), declare the following
……., born on ……,
resident: ……., as follows:

1. I am aware that the mRNA vaccine Comirnaty /Spikevax (delete as applicable) to be used by me for preventive treatment against COVID-19 has received only an emergency marketing authorization from the European Medicines Agency (EMA) and that the final evaluation of the safety and efficacy of these vaccines according to Section II, Letter E. of the EPAR Product Information has yet to be demonstrated by the manufacturers of the above vaccines by submitting to the EMA a final clinical study report on the randomized, placebo-controlled and observer-blind studies by July 31, 2024 by BioNTech and September 30, 2022 by Moderna.

2. Thus, I am aware that this is an experimental preventive medical treatment.

3. I am aware through the product information for the above-mentioned mRNA vaccines that the use of the same is to be refrained from in patients who are allergic to the ingredients listed in section 6 of the product information. In this respect, I declare that I have not examined the vaccination capability of the above-mentioned patient and waive the presentation of a certificate of vaccination capability by a specialist in allergology prior to treatment.

4. I am aware that the nanolipids ALC 0315 and ALC 0159 (Comirnaty) and SM-102 (Spikevax) used in the vaccines are labeled by various manufacturers in the safety data sheets as not to be used in humans or to be used for experimental purposes only.

5. I am also aware that there are no studies on the part of the manufacturers on possible interactions of the vaccines with other medicines, which are currently to be taken on medical prescription. I am also aware that the mRNA vaccines should be used with caution in patients suffering from thrombocytopenia or coagulopathy, and that no studies of possible interactions with the mRNA vaccines have taken place in patients with immunodeficiency or patients treated with immunosuppressants. I also refrain from preliminary cardiological examinations of the vaccinee, although the manufacturers of the mRNA vaccines have pointed out an increased risk of contracting myocarditis and pericarditis after administration of the respective mRNA vaccine.

6. In view of the above, I am nevertheless willing to perform the preventive experimental treatment by injection of the selected mRNA vaccine on the patient subject to the following declaration of liability.

7. I assume liability for all possible physical and financial consequences for the above-mentioned patient in the event of adverse reactions and/or side effects caused by the vaccine used, such as possible disability, reduction in quality of life and possible chronic suffering. This liability is also assumed if, in addition to myself, an official liability of the authority commissioning me with the vaccination comes into consideration. The liability also exists in the case of non-provided coverage of a possibly existing liability insurance.

8. In case of death of the patient as a result of the vaccination, I will fulfill all claims for damages against the patient's heirs.

9. In case of adverse reactions and/or side effects caused by the vaccine used, it is my responsibility to prove that these were not caused by the preventive experimental treatment with the above-mentioned vaccine.

……., the ……. addressable address of the treating person(s)

…… ……
Signature of the treating person(s)

Why actually do I, since I do not want to be injected with genes, suggest such a thing? Well ... it may well be a wake-up call for the doctor you trust! Something like this just happened to a good friend of mine, to whom I had dictated this declaration of liability into her PC. What happened? The good friend, who is being bullied by her employer

for being unvaccinated, jumped over her shadow today. She presented her family doctor, who had made a vaccination appointment with her, with the liability assumption statement I had written and said that the statement written by her lawyer friend needed to be signed to make it legally safe. The doctor read it and got wide eyed. Then said she couldn't sign that. But she then got friendly as shit and gave my good friend her sick note for burn out, the real reason for the presentation. The doctor was visibly thrown in at the deep end and will surely now wonder if she now has a problem since she had previously vaccinated umpteen other patients with the mRNA vaccines.

Yes, I would present this liability assumption statement to any physician who is thinking of putting the needle in and injecting these mRNA vaccines. I reproduce it below in its entirety:

Liability Assumption Statement

I, the undersigned, am a treating physician in the sense of § 630d BGB (German Civil Code) and declare, in order to obtain consent according to § 630d paragraph 1 sentence 1 BGB, from the patient
....., born on ....., resident: ....., as follows:

1. I am aware that the mRNA vaccine Comirnaty /Spikevax (delete as applicable) to be used by me for preventive treatment against COVID-19 has received only an emergency marketing authorization from the European Medicines Agency (EMA) and that the final evaluation of the safety and efficacy of these vaccines according to Section II, Letter E. of the EPAR Product Information has yet to be demonstrated by the manufacturers of the above vaccines by submitting to the EMA a final clinical study report on the randomized, placebo-controlled and observer-blind studies by July 31, 2024 by BioNTech and September 30, 2022 by Moderna.

2. Thus, I am aware that this is an experimental preventive medical treatment.

3. I am aware through the product information for the above-mentioned mRNA vaccines that the use of the same is to be refrained from in patients who are allergic to the ingredients listed in section 6 of the product information. In this respect, I declare that I have not examined the vaccination capability of the above-mentioned patient and waive the presentation of a certificate of vaccination capability by a specialist in allergology prior to treatment.

4. I am aware that the nanolipids ALC 0315 and ALC 0159 (Comirnaty) and SM-102 (Spikevax) used in the vaccines are labeled by various manufacturers in the safety data sheets as not to be used in humans or to be used for experimental purposes only.

5. I am also aware that there are no studies on the part of the manufacturers on possible interactions of the vaccines with other medicines, which are currently to be taken on medical prescription. I am also aware that the mRNA vaccines should be used with caution in patients suffering from thrombocytopenia or coagulopathy, and that no studies of possible interactions with the mRNA vaccines have taken place in patients with immunodeficiency or patients treated with immunosuppressants. I also

refrain from preliminary cardiological examinations of the vaccinee, although the manufacturers of the mRNA vaccines have pointed out an increased risk of contracting myocarditis and pericarditis after administration of the respective mRNA vaccine.

6. In view of the above, I am nevertheless willing to perform the preventive experimental treatment by injection of the selected mRNA vaccine on the patient subject to the following declaration of liability.

7. I assume liability for all possible physical and financial consequences for the above-mentioned patient in the event of adverse reactions and/or side effects caused by the vaccine used, such as possible disability, reduction in quality of life and possible chronic suffering. This liability is also assumed if, in addition to myself, an official liability of the authority commissioning me with the vaccination comes into consideration. The liability also exists in the case of non-provided coverage of a possibly existing liability insurance.

8. in case of death of the patient as a result of the vaccination, I will fulfill all claims for damages against the patient's heirs.

9. in case of adverse reactions and/or side effects caused by the vaccine used, it is my responsibility to prove that these were not caused by the preventive experimental treatment with the above-mentioned vaccine.

....., the ..... summonable address of the treating person(s)

..... *.....*

Signature of the treating person(s)

In conclusion, it must be said that both the manufacturers of the mRNA vaccines and the government are abdicating their responsibility if they place the responsibility for any vaccine damage solely on the physicians. The physicians, in turn, will want to exclude their liability via patient consent forms and the educational fact sheet. The loser would ultimately be the patient, who gave his consent in good faith and would have to explain and prove afterwards that the vaccination was the cause of his suffering. Now, as a lawyer, I would want to establish a little parity here, because if the doctor is so convinced of the efficacy and harmlessness of the drug he administered (Corona vaccine), then he should also be obligingly responsible for it by way of assumption of liability.