EUROPEAN COURT

*

IMPORTANCE CLAIM according to Art. 263 TFEU

*

Plaintiff:
The present action for annulment is brought on behalf of the following applicants:

1) Faller Sonja, born in Bruneck, on 06.01.1973 and residing in Blestrasse 3/ Brixen, Italian citizen, in her capacity as parent of Felix Amort born on 12.05.2007 and Sabine Amort born on 06.02.2010;

2) Vasilyeva Nadezda, born in Russia on 29.10.1978 Italian citizen, and Walter Amplatz, born in Bolzano on 22.01.1965, Italian citizen, both residing in Bolzano, Palermo Street 54/a, in their capacity as parents of Valentina Amplatz born on 16.08.2011 and Nicole Amplatz born on 17.11.2005;

3) Steck Karin Maria, born in Silandro on 31.01.1965, Italian citizen, residing in 39024 Malles Bahnhofstr. 9A and Angerer Günther Josef, born in Graun i.V. on 19.03.1970, residing in 39027 St. Valentin a.d. Heide, in her capacity as parent of Jana Angerer born on 15.08.2006 and Lia Angerer born on 15.07.2008;

4) Atz Carlo, born in Bolzano on 25.05.1972, Italian citizen and Pontalti Chiara, born in Trento on 03.09.1972, Italian citizen, both residing in Altopiano della Vigolana, Via Canaletta 5, in their capacity as parents of Atz Alice born on 25.07.2008 and Atz Arianna born on 23.12.2010;

5) Wild Edith Maria, born in Brixen on 20.06.1970, Italian citizen and Baumgartner Heinz Johann, Italian citizen, both residing in 39030 Rasen/Antholz, Sonnweg 10b, in their capacity as parents of Baumgartner Johannes, born on 08.09.2011 and Baumgartner Lara born on 14.01.2005;

6) Schneider Waltraud, born in Sterzing on 25.05.1965, Italian citizen and Bendinoni Oscar, born in Brixen on 13.01.1972, Italian citizen, both residing in 39045 Franzensfeste, Risolstrasse 3, in their capacity as parents of Bendinoni Schneider Heberth born on 15.09.2006;

7) Bertassi Paolo, born in Brescia on 01.03.1966, Italian citizen, residing in Levico Terme, Piazza San Rocco and Zampatti Rachele, born in Como on 15.01.1970, Italian citizen, residing in Levico Terme, Via Regia n19/A, in her capacity as parent of Bertassi Alice born on 04.01.2009;

8) Berti Irene, born in Innsbruck on 23.11.1974, Italian citizen and Hörnemann Björn, born in Ründeroth on 12.04.1970, German citizen, both resident in 39042 Brixen, Vedistrasse 8, in their capacity as parents Berti Maya born on 15.03.2009 and Berti Giona born on 12.04.2007;

9) Bianchi Andrea, born in Rovereto on 25.11.1971, Italian citizen and Gregori Francesca Maria, born in Trento on 31.10.1971, Italian citizen, both residing at 38121 Trento, Via Don Milani 9, of her capacity as parent Bianchi Alice born on

22.11.2007;

10) Brunelli Layla, born in Zevio on 30.05.1970, Italian citizen and Brenn Georg, born in Merano on 23.12.1962, Italian citizen, both resident in 39013 Merano, Meinhardstrasse 190, in their capacity as parents Brenn Yannic born on 17.09.2008;

11) Pföstl Edeltraud, born in Merano on 22.06.1986, Italian citizen and Buchschwenter Christoph born in Merano on 04.03.1969, Italian citizen, both residing in 39010 St. Martin in Passeier. Martin in Passeier, in their capacity as parents of Buchschwenter Antonia, born on 03.04.2013;

12) Kinzner Katrin, born in Bruneck on 16.04.1971, Italian citizen and Campidell Josef born in Bruneck on 28.07.1976, Italian citizen, both residing in 39030 Percha, Sonnbergstraße 4B, in their capacity as parents of Campidell Hannes, born on 15.08.2009;

13) Cappello Sergio, born in Borgo Valsugana on 02.01.1972, Italian citizen round Borgogno Elisabetta, born in Borgo Valsugana on 20.03.1973, Italian citizen, both resident in Borgo Valsugana Fraz. Olle, Via die Pozzi 14/A, in her capacity as parent of Cappello Francesco born on 29.08.2010;

14) Sommadossi Orietta, born in Trento on 17.06.1968, Italian citizen and resident at 38121 Trento, Via Papiria 7, in her capacity as parent of Carli Ian born on 17.08.2007;

15) Casatta Andrea, born in Trento on 08.12.1970, Italian citizen and Potrich Cristina born in Rovereto on 08.02.1974, Italian citizen, both resident in Rovereto, via Cittadella 12, in her capacity as parent of Casatta Martino born on 01.01.2009;

16) Comai Christian, born in Trento on 11.07.1970, Italian citizen and Altava Paula Mora born in Valencia (Spagna) on 08.03.1978, Spanish citizen, both residing at 39121 Trento, via Brennero 132, in their capacity as parents of Comai Mora Nicolas born on 24.08.2008;

17) Costanzi Alberto, born in Bolzano on 04.10.1969, Italian citizen and Demetz Lea born in Bolzano on 27.05.1971, Italian citizen, both residing in 39046 Ortisei, Via Resciesca 44, in their capacity as parents of Costanzi Giovanni born on 04.10.2006;

18) De Masi Emanuele, born in Bologna on 18.01.1972, Italian citizen and Nicolini Liliana born in Este on 14.12.1970, Italian citizen, both residing in 37022 Fumane, in their capacity as parents of De Masi Davide born on 10.12.2006;

19) Debonis Sabino, born in Altamura on 16.02.1976, Italian citizen and Barzini Maria Teresa born in Bologna on 09.11.1987, Italian citizen, both residing in Casalgrande, Via Aosta n. 72-5, in their capacity as parents of Debonis Arminio born on 28.01.2009, Debonis Pancrazio born on 27.01.2001, Debonis Kassandra born on 20.01.2013, Debonis Sigfried born on 08.02.2015 and Debonis Ragnar born on 01.04.2019;

20) Dongili Paolo born in Bolzano on 26.05.1972, Italian citizen and Pierucci Tiziana born in Bolzano on 21.08.1973, Italian citizen, both residing at 39100

Bolzano, Via N. Rasmo 62, in their capacity as parents of Dongilli Samuel born on 08.02.2011 and Dongilli Sofia born on 02.10.2014;

21) Agreiter Karin, born in Brixen on 10.06.1976, Italian citizen, resident in 39012 Meran, Karl Wolf Str. 55, in her capacity as parent of Dorfmann Sophia born on 07.04.2009 and Dorfmann Jakob born on 18.03.2007;

22) Hober Michaela, born in Merano on 13 December 1969, Italian citizen and Erb Reinhart, born in Cermes on 28 October 1946, Italian citizen, both resident in 39012 Merano, Winkelweg 79, in their capacity as parents of Erb Jonas born on 9 September 2004;

23) Fabrocile Francesco Maria born in Rome on 22/02/1976 and residing in Rome, via monte Serrone 11, Italian citizen, in her capacity as parent Fabrocile Maddalena born on 28/07/2008, Fabrocile Susanna born on 09/02/2011 and Fabrocile Davide born on 14/08/2014;

24) Faccenda Stefano born in Trento on 02.04.1968, Italian citizen and Ognibeni Monica born in Trento on 20.01.1976, Italian citizen, both residing at Altopiano della Vigolana, Via Marzola n.19, in their capacity as parents Faccenda Alice born in Trento on 14.02.2007 and Faccenda Jacopo born in Trento 14.02.2010;

25) Filippi Renato, born in Trento on 26.01.1972, Italian citizen and Gaiotto Stefania born in Trento on 15.07.1976, Italian citizen, both residing at 38045 Civezzano, Via Strada Avisio 25, in her capacity as parent Filippi Leonardo born on 04.07.2009;

26) Jocher Adele, born in Bressanone on 21.01.1972, Italian citizen and Fischer Erwin born in Bressanone on 15.05.1966, Italian citizen, both residing in 39042 Bressanone, St. Leonhard 64, in their capacity as parents Fischer Max born on 09.03.2010 and Fischer Pia born on 30.11.2006;

27) Franchetto Federico born in Verona on 21.07.1966, residing in Pescantina, Via Santa Chiara n.4, Italian citizen and Di Pumpo Teresa born in Verona on 20.06.1964, residing in Verona, Via fra Giocondio 62, Italian citizen, in her capacity as parent of Franchetto Jacopo born on 02.03.2006;

28) Durcakova Katarino born in Trstena (SK) on 20.04.1974, Slovakian citizen and Franzelin Georg born in Aldein on 19.05.1971, Italian citizen, both residing in Aldein, Dorf, Krone 3, in their capacity as parents Franzelin Amelie born on 15.10.2008 and Franzelin Greta born on 14.08.2011;

29) Predrotti Milena, born in Trento on 15.06.1972, Italian national, resident in Pergine Valsugana, loc. Valar 8, in her capacity as parent of Frisinghelli Teresa born on 09.07.2005 and Frisinghelli Pietro born on 16.03.2007;

30) Gaioni Valentino born in Riva del Garda on 18/03/1971, Italian citizen and Franchetto Silvia born in Verona on 07/11/1964, Italian citizen, both residing in Fumane, Via Giovanni XXII 58, in their capacity as parents of Gaioni Nicolo born on 09/08/2006 and Gaioni Giulio 19/11/2007;

31) Spiess Hildegard, born in Silandro on 7.11.1964, Italian citizen and Mr. Gamper Peter, born in Bolzano on 17.01.1968, Italian citizen, both residing in

39039 Villabassa, Parkweg 14, in their capacity as parents of Gamper Ruth, born on 3.8.2004 and Gamper Sarah, born on 26.4.2006;

32) Montesel Silvia, born in Bolzano on 14.11.1981, Italian citizen and Gamper Lorenz, born in Bressanone on 07.08.1980, Italian citizen, both residing in 39040 Feldthurns, pedratz 13/A, in their capacity as parents of Gamper Irene born on 23.02.2007, Gamper Laura born on 29.06.2009 and Gamper Lukas born on 29.07.2017;

33) Waldner Nicol born in Silandro on 18.06.1986, Italian citizen and Gapp Patrik Arthur born in Silandro on 17.03.1986, Italian citizen, both resident in 39026 Prad am Stilfserjoch, Agums 14/A, in their capacity as parents of Gapp Annalena born on 02.10.2010 and Gapp Julian born on 13.07.2015;

34) Giacchino Carmelo born in Morano Calabro on 04.05.1973, Italian citizen and Ddelaiti Karin born in Bolzano on 01.09.1979, Italian citizen, neide resident in Laives, Via A. Hofer 46/B, in her capacity as parent of Giacchino Linda born on 22.07.2003, Giacchino Noel born on 03.03.2005, Giacchino Sophie born on 20.02.2008 and Giacchino Maia born on 19.05.2011;

35) Bratschko Caroline born in Graz on 13.05.1977, Austrian citizen and Giatti Gottardo born in Bolzano on 11.08.1969, Italian citizen, both residing in 39100 Bolzano, Oswaldleiten 14, in their capacity as parents of Giatti Lyla born on 26.04.2009, Giatti Elia born on 19.07.2003, Giatti Leny born on 21.04.2005 and Giatti Enea born on 24.03.2007;

36) Giovannini Enzo, born in Bolzano on 18.02.1958, Italian citizen and Bolognani Mara born on 19.12.1972, Italian citizen, both residing in Laives, Via F. Kennedy 251, in their capacity as parents of Giovannini Samantha born on 03.01.2007;

37) Winkler Doris, born in Bolzano on 02.03.1972, Italian citizen and resident in 39100 Bolzano, Palermostr. 95 and Gitzl Lukas, born in Brunico on 07.04.1971, Italian citizen and resident in 39035 Welsberg-Taisten, Unterrainerstr. 13 a, in her capacity as parent of Gitzl Tina born on 12.08.2010;

38) Kofler Silke, born in Bolzano on 21.01.1975, Italian citizen and Graf Günther, born in Bolzano on 08.10.1973, Italian citizen, both residing in 39054 Unterinn Ritten, Seestrasse 10A, in their capacity as parents of Matthias Graf born on 20.09.2007, Katharina Graf born on 21.06.2009, Valentina Graf born on 14.03.2011 and Armin Graf born on 08.02.2014;

39) Groff Luca, born in Trento on 01.09.1963, Italian citizen and Obrelli Claudia born in Trento on 21.02.1970, Italian citizen, both residing at 38123 Trento, Via Castel di San Rocco 7, in their capacity as parents Groff Lorenzo born on 15.11.2006 and Groff Davide born on 03.08.2008;

40) Stoll Martina, born in San Candido on 07.07.1970, Italian citizen and Gruber Heinrich born in Ahrntal on 13.08.1967, Italian citizen, both resident in 39030 Luttach/Ahrntal, Lichtegg 39 in their capacity as parents of Gruber Alexandra born on 24.04.2004;

Respondent:
European Commission

Subject:
IMPLEMENTING DECISION OF THE EUROPEAN COMMISSION of 31.05.2021 amending the conditional marketing authorisation granted by Decision C(2020) 9598 (final) for the medicinal product for human use "Comirnaty - COVID-19 mRNA vaccine (nucleleioside-modified)" together with its successive amendments and integrations, and the previous implementing decisions required by this Decision

*

The above-mentioned plaintiffs, all in their capacity as parents of minor children, are represented and defended by Renate Holzeisen, a lawyer admitted to the Italian Supreme Courts, registered with the Bolzano Bar Association and with an office in I-39100 Bolzano, Bahnhofallee no. 7,

PROVIDED THAT

1. **By implementing Decision of 31 May 2021 amending the conditional marketing authorisation granted by Decision C(2020) 9598 (final) for the medicinal product for human use 'Comirnaty' - COVID-19 mRNA vaccine (nucleoside-modified)',** the European Commission, following opinions of the European Medicines Agency delivered on 20 May 2021 and 28 May 2021 by the Committee for Medicinal Products for Human Use, amended the **conditional marketing authorisation granted by Decision C(2020) 9598 (final).** May 2021 and 28 May 2021 by the Committee for Medicinal Products for Human Use, the European Commission, amending the original decision, **conditionally authorised the** substance "Comirnaty - COVID-19 mRNA vaccine" **also for children aged 12 years and over**. (Doc**. A. 1).**

2. Four (IV) annexes are attached to the above-mentioned European Union Implementing Decision - Annex I (Summary of Product Characteristics), Annex II (A. Manufacturer of the active substance(s) of biological origin and manufacturer responsible for batch release), Annex III (Labelling and Package Leaflet), Annex IV (Conclusions of the European Medicines Agency on the granting of marketing authorisation under "special conditions") (Doc. **A.2.**).

3. On 21.12.2020, the European Commission had

*"Having regard to the **Treaty on the Functioning of the European Union, Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human** and veterinary use and establishing a European Medicines Agency, and in particular Article 10(2) and Article 14-a thereof, Having regard to **Commission Regulation (EC) No 507/2006 concerning** the **conditional marketing authorisation for medicinal products for human use falling within the** scope of Regulation (EC) No. 726/2004 of the European Parliament and of the Council, Having regard to the application submitted by BioNTech Manufacturing GmbH on 1 December 2020 pursuant to Article 4(1) of Regulation (EC) No 726/2004, **Having regard to the opinion of the European Medicines Agency delivered on 21 December 2020** (1) The medicinal product 'Comirnaty' - COVID-19 mRNA vaccine (nucleoside modified)' satisfies the requirements of Direc-*

tive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for ***human use.*** *(2)* ***"Comirnaty" - COVID-19 MRNA vaccine (nucleoside-modified)" falls within the scope of Regulation (EC) No 507/2006, and in particular Article 2(1) thereof. Furthermore, the medicinal product fulfils the conditions laid down in Article 4 of that Regulation for the granting of a conditional marketing authorisation****, as set out in Annex IV.** *(3) The marketing authorisation for 'Comirnaty' - COVID 19 mRNA vaccine (nucleoside-modified)' should therefore be granted subject to certain conditions laid down in Article 14-a of Regulation (EC) No 726/2004 and in Regulation (EC) No 507/2006. (4) The Committee for Medicinal Products for Human Use considered that 'Single-stranded, 5'-capped messenger RNA (mRNA) produced using cell-free in vitro transcription from the appropriate DNA templates and encoding the viral spike (S) protein of SARS-CoV-2' is a new active substance. (5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use".*

decided to authorise **"Comirnaty" for persons aged 16 and over.**

4. An action for annulment has already been brought against the EU Commission's original implementing decision of 21 December 2020 by a group of members of the Italian health and care sector, which has been hung before this honourable court with **T-96/21,** and to which, together with the documents referred to therein, reference is made here as an essential and integral part of this action (**Doc. 3**).

5. **<u>Legal standing according to Art. 263 TFEU</u>**

6. The plaintiffs are all parents of minor children.

7. With **Art. 3 Legislative Decree No. 105 of 23 July 2021 (Decreto Legge 23 Luglio 2021 n. 105** - **Doc. 4**), the Italian government has decreed that, **as of 6 August 2021, access to restaurants, indoor events of any kind, indoor swimming pools and other indoor sports facilities, indoor spaces of** amusement **parks, thermal centres, cultural centres, etc. will be denied unless the so-called "*green pass*" is presented.**

This "green certificate" (certificazione verde COVID-19) can only be obtained if one has **either been vaccinated against Covid-19** (**<u>for children aged 12 years and older, the experimental mRNA substances "Comirnaty by Pfizer-BioNTech and Moderna are currently conditionally approved</u>**), has a negative PCR or antigen rapid test (must not be older than 48 hours), or is considered to have recovered from Covid-19 disease (which must not have occurred more than 6 months previously and must have been detected with a previously positive PCR test).

8. The **misuse of PCR tests in particular and their lack of legally binding significance** has already been explained in detail in the action for annulment filed against the original implementing decision of the European Commission under T-96/21. The latest findings on this topic can be found in the enclosed expert report on molecular biology by Prof. Dr. Ulrike Kämmerer, Dipl.Biol. (Virology/Molecular Biology) Dr.rer.hum.biol. (Human Biology) (**Doc. 5**).

9. **<u>In Italy, the Association of School Principals has called for the introduction of compulsory Covid 19 vaccination from the start of the next school year</u>** (**<u>beginning of September 2021) for pupils aged 12 and over</u>** (**Doc. 6**).

This means that **not only will there be a de facto exclusion from social life (sports, culture) of children over 12 years of age from 6 August 2021, unless** they are treated with the experimental Covid-19 vaccines approved for them (Comirnaty and Moderna), or they are subjected every 48 hours to the not only degrading and also harmful procedure of the antigen test or PCR test, by an invasive deep penetration of the nasopharynx, or they are deemed to have recovered from a Covid-19 disease, which in turn will only be diagnosed as infectious. PCR test, by invasive deep penetration into the nasopharynx, or they are considered to have recovered from a Covid 19 disease, which in turn can only be detected on the basis of a positive PCR test), **but also to the exclusion of children from 12 years of age from school!**

This means that in <u>Italy there will be a clear legal obligation to vaccinate children aged 12 and over from 6 August 2021 and therefore, on the basis of the grounds set out in this action for annulment, there will be an absolute risk of imminent danger.</u>

The parents complaining here are faced with the alternative: either they have their children from the age of 12 "vaccinated" with these experimental substances, the medium and long-term effects of which have not been researched and which have already been proven to lead to the most serious side effects (up to and including death) in the short term, and thus expose their children to the concrete risk of the most serious immediate side effects and, in addition, to medium and long-term effects, the enormous dimensions of which cannot yet be assessed as a whole, or they do not allow their children access to sports, leisure and cultural facilities, and above all to school lessons!

10. "**COVID-19 Vaccine Comirnaty**" is the first substance centrally **approved** by the European Commission in the EU based on genetic engineering, which was **<u>conditionally</u> approved** as a so-called Covid "vaccine" first for persons aged 16 years and older and then on 31 May 2021 also for children aged 12 years and older. The other substance that has now been approved as a so-called Covid "vaccine" for children from 12 years of age (manufacturer: Moderna) is also of an experimental nature and, as an mRNA substance, has nothing in common with a conventional vaccine.

11. **Due to the centralised authorisation of "COVID-19** Vaccine **Comirnaty" on 31.05.2021 for children aged 12 years and older, this active substance is automatically authorised by the European Commission in every Member State for children aged 12 years and older, i.e. no further decision by the Italian Member State was required to authorise this active substance on Italian territory as well.**

12. **The experimental substance Comirnaty has been "**inoculated**" on a large scale to children aged 12 and over for two months now.**

<u>CLAIM REASONS</u>

13. <u>Premise</u>

"Comirnaty" is an experimental mRNA-based substance that has absolutely nothing to do with conventional vaccines in terms of its mode of action and production.

Since children are injected with the same substance as adults, reference is made here to all the pleas already put forward in the action for annulment T-96/21 as an integral part of this action (Doc. **A.3**).
In the following, only the child-specific aspects as well as the most current scientific knowledge on this experimental substance based on genetic engineering will be explained and documented.

14. 1. annulment for infringement of Article 2 (scope) of Commission Regulation (EC) No 507/2006 of 29 March 2006

15. 1.1 Violation of Article 2 point 1. EU Regulation No. 507/2006

See the attached action for annulment pending with T-96/21 (Doc. **A.3**), and in particular:

16. **Children have ZERO (O) risk of infection with SARS-CoV-2.**

For healthy children, there can therefore be no positive risk-benefit ratio at all for this reason alone, and the use of this experimental substance based on genetic engineering is thus grossly contrary to EU law for this reason alone.

17. **1.2 Invalidity due to infringement of Regulation (EC) No 507/2006 Art. 2 point 2.**

18. See the attached action for annulment pending with T-96/21 (Doc**. A.3**), and in particular:

19. The molecular biology expert report (Doc. **A.5**) by Prof.Dr. Ulrike Kämmerer, Dipl.Biol. (Virology/Molecular Biology) Dr.rer.hum.biol. (Human Biology) presents the latest scientific evidence of the gross misuse of the PCR tests and thus the absolute untenability of the so-called COVID-19 cases determined exclusively by the laboratory tests.

20. To date, therefore, neither WHO nor the European Community has made a proper determination of an alleged public health emergency.

For this reason alone, the implementing decision contested here is null and void.

21. 2. annulment for infringement of Article 4 Regulation (EC) No 507/2006

22. 2.1. invalidity due to the absence of a positive risk-benefit balance according to Article 1(28a) of Directive 2001/83/EC

23. 2.1.1. absence of demonstrable benefit

24. See the attached action for annulment pending with T-96/21 (Doc. **A.3**), and in particular:

25. Since SARS-CoV-2 infection for children usually carries de facto zero risk, a substance that is (allegedly) effective solely for preventing a more severe course of the disease, but which has not been developed and approved for preventing the viral infection, can never have any benefit for application to a fundamentally healthy broad population of children.

26. 2.1.2 Material risks not recorded and therefore undetermined and currently indeterminable risk

27. See the attached action for annulment pending with T-96/21 (Doc. **A.3**).

28. **2.1.3. <u>failure to take into account significant risks that would never allow a conditional marketing authorisation of a medicinal product intended for a fundamentally healthy population.</u>**

29. See the attached action for annulment pending with T-96/21 (Doc**. A.3.**), and in particular:

30. From the Expert Statement of Prof.em Sucharit Bhakdi, M.D. former Head of the Institute for Microbiology and Hygiene of the Johannes-Gutenberg University of Mainz, Prof.Dr. Stefan Hockertz, European Toxicologist and Immunologist, Prof.Dr.med. Michael Palmer, Specialist in Medical Microbiology and Infectious Disease Epidemiology, Department of Chemistry University of Waterloo, Canada, and Dr. Wolfgang Wodarg, Specialist in Internal Medicine, Lung and Bronchial Diseases, Specialist in Hygiene and Environmental Medicine and Public Health (Doc**. A.7.**), the following emerges:

"Summary

This expertise on the use of the Pfizer COVID-19 vaccine (Comirnaty, BNT162b2) in adolescents is divided into three sections, which will deal with the following questions, in order:

1. Is vaccination of adolescents against COVID-19 necessary?
2. Is the Pfizer COVID-19 vaccine effective?
3. Is the Pfizer COVID-19 vaccine safe?

The arguments presented in Section <u>1</u> pertain to all COVID-19 vaccines, whereas those in Sections <u>2</u> and <u>3</u> apply specifically to the Pfizer vaccine.
Section <u>1</u> will show that vaccination of adolescents COVID-19 is unnecessary, because

- in this age group the disease is almost always mild and benign;
- for the rare clinical cases that require it, treatment is readily available;
- immunity to the disease is now widespread, due to prior infection with the virus (SARS-CoV-2) or with other coronavirus strains; and
- asymptomatic adolescents will not transmit the disease to other individuals who might be at greater risk of infection.

Section <u>2</u> will demonstrate that the claims of efficacy which Pfizer attaches to its vaccine-namely, 95% efficacy in adults, and 100% in adolescents-are

- misleading, because these numbers pertain to *relative*, not *absolute* efficacy, the latter being on the order of only 1%;
- specious, because they refer to an arbitrarily defined, clinically meaningless evaluation endpoint, whereas no efficacy at all has been demonstrated against severe disease or mortality;
- most likely altogether fraudulent.

Section <u>3</u> will show that the safety profile of the Pfizer vaccine is catastrophically bad. It will be discussed that

- Pfizer, the EMA, and the FDA have systematically neglected evidence from preclinical animal trials that clearly pointed to grave dangers of adverse events;

- the Pfizer vaccine has caused thousands of deaths within five months of its introduction;
- The agencies that granted emergency use authorisation for this vaccine committed grave errors and omissions in their assessments of known and possible health risks.

The only possible conclusion from this analysis is that the use of this vaccine in adolescents cannot be permitted, and that its ongoing use in any and all age groups ought to be stopped immediately.

1. vaccination of adolescents against COVID-19 is unnecessary

1.1 What does the available evidence show?

There are several lines of evidence that show vaccination of adolescents against COVID-19 to be unnecessary.

1.1.1 The case fatality rate of COVID-19 in the general population is low

The vast majority of all persons infected with COVID-19 recovers after minor, often uncharacteristic illness. According to world-leading epidemiologist John Ioannidis [1,2], the infection fatality rate of COVID-19 is on the order of 0.15% to 0.2% across all age groups, with a very strong bias towards old people, particularly those with comorbidities. This rate does not exceed the range commonly observed with influenza, against which a vaccination of adolescents is not considered urgent or necessary.

1.1.2. COVID-19 has a particularly low prevalence and severity in adolescents

In the U.S. and as of April 2020, those younger than 18 years accounted for just 1.7% of all COVID-19 cases [3,4]. Within this age group, the most severe cases were observed among very young infants [4]. This is consistent with the lack in infants of cross-immunity to COVID-19, which in other age groups is conferred by preceding exposure to regular respiratory human coronaviruses (see Section 1.2.1). Among slightly older children, a peculiar multisystem inflammatory syndrome was observed in early 2020 [5]; conceivably, these patients, too, were still lacking cross-immunity.
Essentially no severe cases of COVID-19 were observed in those above 10 but below 18 years of age [4]. This group accounted for just 1% of reported cases, almost all of which were very mild. Thus, adolescents are at particularly low risk of harm from COVID-19 infection. Vaccination of this age group is therefore unnecessary.

1.1.3. COVID-19 can be treated

Numerous experienced physicians have collaborated on establishing effective treatment guidelines for clinically manifest COVID-19 [6]. Treatment options are available both for the early stage of the disease, at which emphasis is placed on inhibiting viral replication, and for the later stage, at which anti-inflammatory treatment is paramount. Two drugs that have been used successfully at the early stage are hydroxychloroquine and ivermectin. Both drugs have been, and continue to be, in use against a variety of other diseases. Ivermectin, for example, is considered safe enough to be used not only for treating manifest scabies-a parasite infection of the skin that is unpleasant but not severe-but even prophylactically in asymptomatic contacts of scabies-infected persons [7].
Ivermectin is also widely used in the treatment of tropical parasitic diseases such as onchocerciasis (river blindness), and for this reason it is on the WHO's list of essential medicines. Yet, with COVID-19, the WHO sees fit to warn against the use of this

very same well-known and safe drug outside of clinical trials[8]. This policy cannot be rationally justified, and it has quite appropriately been overridden by national or regional health authorities and ignored by individual physicians worldwide.
The availability of effective treatment voids the rationale for the emergency use of vaccines on any and all age groups, including also adolescents.

1.1.4 Most people, particularly adolescents, are by now immune to SARS-CoV-2

Due to the many inherent flaws and shortcomings of the diagnostic methods in common use (see Section 1.2), it is impossible to accurately determine the proportions of those who have already been infected with SARS-CoV-2 and those who have not. However, there are indications that the proportion of those who have been infected and recovered is high:

- The incidence of multisystem inflammatory syndrome in children (see Section 1.1.2) peaked in early to mid 2020, and then receded, with some slight delay after the initial wave of the COVID-19 respiratory disease itself[9].
- Approximately 60% of randomly selected test persons from British Columbia have detectable antibodies against multiple SARS-CoV-2 proteins (personal communication by Stephen Pelech, University of British Columbia), indicating past infection with the virus-as opposed to vaccination, which would induce antibodies to only one (the spike) protein.

Past COVID-19 infection has been found to protect very reliably from reinfection [10], and strong specific humoral and cellular immunity is detected in almost all recovered individuals, and also in those who remained asymptomatic throughout the infection [11]. Thus, a large proportion of individuals in all age groups, including adolescents, already have specific, reliable immunity to COVID-19. As mentioned above, most of those who do not have such specific immunity nevertheless are protected from severe disease by cross-immunity[12,13]. This immunity will be particularly effective in healthy adolescents and young adults. Individuals with specific immunity or sufficient cross-immunity cannot possibly derive any benefit from undergoing an experimental vaccination.

1.1.5 Asymptomatic transmission of COVID-19 is not real

An oft-cited rationale for vaccinating individuals who are not themselves at risk of severe disease is the need to induce "herd immunity:" the few who are at high risk should be protected by preventing the spread of the virus in the general population.
A subtext of this rationale is the idea of "asymptomatic spread"-persons who have been infected but who show no signs of it other than a positive PCR test are assumed to transmit this infection to other susceptible individuals. If we accept the idea of such asymptomatic spread, then preventative mass vaccination might indeed appear as the only means of reliable protection of those at risk.
It has, however, been unambiguously determined that such asymptomatic transmission does not occur. In a large-scale study, which involved almost 10 million Chinese residents, no new infections could be traced to persons that had tested positive for SARS-CoV-2 by PCR, but who did not exhibit any other signs of infection [14]. This agrees with several studies that compared PCR to virus isolation in cell culture among patients with acute COVID-19 disease. In all cases, growth of the virus in cell culture ceased as symptoms subsided, or very shortly thereafter, whereas PCR remained positive for weeks or months afterwards [15,16]. It was accordingly proposed to use cell culture rather than PCR to assess infectiousness and to determine the du-

ration of isolation [16].
These findings indicate that restricting contact of persons at risk with those who show, or very recently showed, symptoms of acute respiratory disease would be effective and sufficient as a protective measure. Indiscriminate mass vaccinations of persons who are not themselves at risk of severe disease are therefore not required to achieve such protection. …

2 The Pfizer COVID-19 vaccine lacks efficacy

2.1 What does the evidence show?

Pfizer persistently touts the 95% efficacy of its vaccine, based on the clinical trials that formed the basis of the emergency approvals granted by the FDA[29] and the European Union [30]. In a more recent study on adolescents [31], the claimed efficacy has been raised to no less than 100%. However, these claims cannot be taken at face value.

2.1.1 Absolute vs. relative efficacy

In Pfizer/BioNTech's first reported clinical trial, 43,548 participants underwent randomisation, of whom 43,448 received injections. The experimental vaccine (BNT162b2) was administered to 21,720 persons, and 21,728 received placebo. Across both groups, a total of 170 COVID-19 "cases" was recorded, of which 162 occurred in the placebo group, whereas 8 cases were observed in the BNT162b2 group. Based on these figures-8/162 ≈ 5%-Pfizer proceeded to claim 95% efficacy. Clearly, however, this efficacy is only a *relative* value-in absolute terms, less than 1% of the placebo group developed COVID-19, and therefore less than 1% of the vaccine group was protected from it.
The situation is similar with the subsequent, smaller test carried out on 12-15 year old adolescents [31]. Here, the vaccine group comprised 1131 individuals, whereas the placebo group included 1129 persons. In the latter group, 16 individuals were subsequently diagnosed with COVID-19, whereas no such cases occurred in the vaccine group. True to form, Pfizer/BioNTech converted this absolute efficacy of 1.4% to a relative one of 100%; only the latter value is highlighted in the abstract of the published study.

2.1.2 Negative impact of BNT162b2 on overall morbidity in adolescents

In the cited vaccine study on adolescents, a "case" of COVID-19 was determined as follows:

> The definition of confirmed COVID-19 included the presence of ≥ 1 symptom (i.e., fever, new or increased cough, new or increased shortness of breath, chills, new or increased muscle pain, new loss of taste or smell, sore throat, diarrhea, vomiting) and being SARS-CoV-2 NAAT-positive [= PCR-positive] during, or within 4 days before or after, the symptomatic period (either at the central laboratory or at a local testing facility and using an acceptable test).

Thus, a single symptom from a laundry list of non-characteristic symptoms, plus a positive finding from an unreliable laboratory test (cf. Section 1.2.6), was deemed sufficient to establish the diagnosis. While the study goes on to list several clinical criteria of severe disease, it gives no indication that any test persons actually suffered any of those. It can therefore be assumed that very few non-severe, and no

clinically severe cases of COVID-19 occurred in the entire test population.
In stark contrast to these numbers pertaining to the disease from which the vaccination is supposed to protect, side effects from the vaccination were exceedingly common. Apart from injection site pain occurring in a high percentage of the vaccine group (79% to 86%), fatigue (60% to 66%) and headache (55% to 65%) abounded. Severe fatigue and headache were reported by several percent of the test persons. Severe headache, in particular, may be associated with underlying thrombotic events (see Section 3.1.3.2). It is therefore clear that, if we consider both COVID-19 and vaccine adverse effects, overall morbidity was far greater in the vaccinated than in the placebo group.

2.1.3 Unlikely claims and contradictions in Pfizer's evidence on efficacy

We saw above that the reported efficacy of Pfizer's vaccine is very modest when expressed in absolute terms. Even this low efficacy, however, cannot be accepted at face value. This is apparent from the assessment reports prepared by the FDA [29] and the EMA [30]. ...A key illustration that occurs in both reports compares the cumulative incidence of COVID-19 among the vaccinated and the placebo group. This graph, which is shown as Figure 9 in the EMA report, is reproduced here in Figure 1B. Up to day 12 after the first injection, the cumulative incidences in the two groups track each other closely. After day 12, however, only the placebo group continues to accumulate further new cases at a steady pace, whereas the slope of the graph drops to almost zero in the vaccine group.
This remarkable observation suggests that immunity sets in very suddenly and uniformly on day 12 exactly among the vaccinated. Since the second injection occurred 19 or more days after the first one, this would imply that one injection is enough to establish full immunity. This conclusion, however, is not stated, and in fact Pfizer does not report any data at all on test persons who received one injection only.
A sudden onset of full immunity on day 12 after the first exposure to the antigen is not at all a biologically plausible outcome. Typically, immunity develops more slowly and gradually; and such a pattern is in fact reported for this very same vaccine (BNT162b2) in Figure 7 of the EMA report, reproduced here as Figure 1A. The figure shows the increase of neutralising antibodies to SARS-CoV-2 as a function of time after the first injection of the vaccine.
The induction of neutralizing antibodies is the declared purpose of the Pfizer vaccine. Generally speaking, antibodies are protein molecules produced by our immune system when it encounters *antigens-macromolecules* that do not occur within our own bodies. These antigens are often part of infectious microbes, including viruses. An antibody binds to a specific feature on the surface of its antigen; this feature is called the *epitope of the* antibody in question.
In the context of virus infections, antibodies can be neutralizing or non-neutralizing. A neutralizing antibody recognizes an epitope that is essential for the function of the virus, for example because this epitope must make contact to a *receptor* molecule on the surface of the host cell which the virus must enter in order to replicate. A non-neutralizing antibody simply happens to recognise a surface feature (epitope) that plays no essential role in the infectiousness of the virus.
Considering the foregoing, we should expect that the blood level of neutralising antibodies should reflect the degree of clinical immunity to the virus. This is, however, not at all what we see in Figure 1A. On day 21 after the first injection, that is, a full 9 days after the purported sudden onset of full clinical immunity, the amount of neutralizing antibodies in the blood has barely risen above the background level. The maximal

level of neutralizing antibodies is observed only on day 28 after the first injection, at which time most test persons would have already had their second injection. The time course of cellular (T-cell) immunity was not reported, but in the absence of proof positive to the opposite it can be assumed to resemble that of the antibody response.
It is very difficult to reconcile the two contrasting observations of sudden onset of full clinical immunity on day 12, but neutralizing antibodies appearing only weeks later. Yet, neither the EMA reviewers nor those of the FDA appear to have been interested in the problem.

2.1.3.2 The Pfizer documentation contradicts itself on COVID-19 incidence after vaccination

…

Table 0.1: Subjects without evidence of infection in vaccine and placebo groups at various time points in the clinical trial. Data excerpted from Table 4 in [30]. See text for discussion.

	Vaccine	Placebo
No evidence of infection before dose 1	93.1%	93.0%
No evidence of infection prior to 14 days after dose 2	85.6%	85.0%
Difference (= infection between day 0 and day 14 after dose 2)	7.5%	8.0%

….
Table 1 lists the percentages of subjects in the vaccine group and the placebo group who showed no evidence of SARS-CoV-2 infection on day 0 (before the first dose) and on day 14 after the second dose, respectively. From the differences between the two time points, we can work out that 7.5% of the subjects in the vaccine group and 8% in the control group converted from negative to positive-that is, became infected-between the two time points.
According to [29], the second dose was administered approximately 21 days after the first, although all subjects who received it between days 19 and 42 after the first injection were included in the evaluation. If we take day 35 after the first injection as the approximate time point of the comparison, we see from Figure 1B that the cumulative incidence between day 0 and day 35 is more than twice higher in the placebo group than in the vaccine group; but from Table 1, we see that it is almost the same. Moreover, with both groups the numbers are substantially higher in the table than in the figure.
These two sets of data cannot possibly be reconciled; one must be false. Since, as discussed, the sudden onset of immunity implied by Figure 1B lacks any biological plausibility, it is most likely that it is this data set which was fabricated.

2.1.3.3 Pfizer's data imply that the vaccine protects from COVID more effectively than does prior infection with the virus

We can also scrutinize Pfizer's reported data in order to compare the immunity conferred by the vaccine to that induced by prior natural infection with the virus. The relevant data are summarized in Table 2. The reported 8 cases of COVID-19 among vaccinated persons who had initially tested negative for the virus amount to an incidence of 0.044%. Pfizer also reports 7 cases among persons who had initially tested

positive but were not vaccinated. Since this group is considerably smaller, those 7 cases translate into an almost ninefold higher incidence (0.38%).
It is common knowledge that vaccines will at best approach, but not surpass the immunity conferred by the corresponding natural infection. Very robust immunity after prior natural infection with SARS-CoV-2 has recently been reported[10]; in that study, not a single case of COVID-19 was observed among 1359 individuals who had remained unvaccinated. Robust immunity after infection is also confirmed by comprehensive laboratory investigations [11]. Therefore, the above analysis corroborates yet again that the trial results reported by Pfizer cannot be trusted. That neither the FDA nor the EMA picked up on any of these inconsistencies does not instil confidence in the thoroughness and integrity of their review processes.

Table 0.2: Incidence of COVID-19 among subjects not previously infected but vaccinated, or previously infected but not vaccinated. Data excerpted from Tables 6 and 7 in [29]. See text for discussion.

	Vaccine			Placebo		
	Total	Cases	Incidence (%)	Total	Cases	Incidence (%)
All subjects	19965	9		20172	169	
Initially negative	**18198**	**8**	**0.044**	18325	162	
Previously infected	1767	1		**1847**	**7**	**0.38**

…

2.2 What evidence is lacking to make the case?

We had already mentioned the specious and contrived character of the endpoint used in Pfizer's clinical trials-namely, the counting of a COVID-19 "case" based on nothing more than a positive PCR result, together with one or more items from a list of mostly uncharacteristic clinical symptoms. We must therefore ask if the vaccine provides any benefits that are more substantial than the claimed-but, as discussed above, most likely fabricated-reduction in the count of such trivial "cases".

2.2.1 Prevention of severe disease and mortality

Page 48 of the FDA report sums up this question as follows: "A larger number of individuals at high risk of COVID-19 and higher attack rates would be needed to confirm efficacy of the vaccine against mortality."
We note that this quote not only answers the posed question in the negative, but it also disposes of the entire pretext for granting emergency use authorisation for this experimental vaccine. If in a study that involves 40,000 individuals the number of fatal outcomes is too small to permit the detection of any benefit of the vaccine, then surely no "emergency" exists that would justify the very grave risks, and meanwhile manifest harm, associated with the extraordinarily rushed introduction of this and other COVID-19 vaccines.
No fatalities at all occurred in the cited study on adolescents [31]; and we already

noted that this study does not report any cases of severe disease either. Therefore, in this specific age group, too, neither a meaningful benefit nor an emergency are in evidence.

2.2.2 Effectiveness for those at high-risk of severe COVID-19

Here, the FDA report has this to say: "Although the proportion of participants at high risk of severe COVID-19 is adequate for the overall evaluation of safety in the available follow-up period, the subset of certain groups such as immunocompromised individuals (e.g., those with HIV/AIDS) is too small to evaluate efficacy outcomes".
The report shirks the question of risk reduction among those with more common predisposing conditions, such as for example chronic heart or lung disease. Naturally, the clinical study on adolescents[31] is completely barren in this regard. Overall, no evidence has been adduced by Pfizer's clinical studies to prove clinical benefit in those at high risk of severe COVID-19.

2.2.3 Effectiveness against long-term effects of COVID-19 disease

The FDA report's verdict is as follows: "Additional evaluations will be needed to assess the effect of the vaccine in preventing long-term effects of COVID-19, including data from clinical trials and from the vaccine's use post-authorisation." In other words, the clinical trials provided no such evidence.

2.2.4 Reduction of transmission

On this topic, the FDA report offers only that "additional evaluations including data from clinical trials and from vaccine use post-authorization will be needed to assess the effect of the vaccine in preventing virus shedding and transmission, in particular in individuals with asymptomatic infection".
In plain language, there is no evidence that transmission is reduced, and in fact the trials were simply not even designed to prove or disprove such an effect.

2.2.5 Duration of protection

The FDA report correctly states (on page 46) that "as the interim and final analyses have a limited length of follow-up, it is not possible to assess sustained efficacy over a period longer than 2 months". Even if we choose to believe that any efficacy at all has been demonstrated pertaining to the two-month study period, such a short duration of protection does not justify the risks associated with vaccination.

2.2.6 Inadequate efforts to determine the optimal dose

Figure 1A shows that the level of neutralizing antibodies is virtually the same with vaccine (mRNA) doses of 20 µg and 30 µg, respectively. This raises the question why the higher dose was employed throughout-and not only with adults, on whom these data were obtained, but also with children, whose lower body weights should suggest a dose reduction. Furthermore, the data in Figure 1B suggest that full immunity is induced already by the first dose; application of the second dose does not change the pace at which new cases accrue in the vaccine group, and therefore apparently has no effect on immunity. This would imply that a one-dose regimen should have been evaluated, which would reduce the overall likelihood of adverse events.

2.2.7 Summary

The clinical trials carried out by Pfizer contain no proof of any benefit conferred by the vaccine with respect to any clinically relevant endpoints. This applies to all tested

age groups, and in particular also to adolescents.

3 The Pfizer COVID-19 vaccine lacks safety

3.1 What does the evidence show?

The clinical trials for Comirnaty (BNT162b2), as well as for the other COVID-19 vaccines, were rushed through in a very short time; this has meant that proper precautions to ensure their safety were not taken. However, animal experiments carried out before the start of clinical testing already gave reason to expect severe toxicity. Unfortunately, this expectation has been abundantly borne out in practice since the beginning of mass vaccinations.

3.1.1 Preclinical data from animal experiments indicate potential for grave harm

Comirnaty, like all other gene-based COVID-19 vaccines, causes the expression in vivo of one specific protein of SARS-CoV-2-namely, the so-called spike protein, which is located on the surface of the virus particle. The spike protein mediates the virus particle's initial attachment to the host cell and also its subsequent entry into the cell. The key idea behind the Comirnaty vaccine is as follows:

1. a synthetic mRNA that encodes the spike protein is complexed with a mixture of neutral and cationic (positively charged) synthetic lipids, which cluster together in lipid nanoparticles (LNPs);
2. after injection, the LNPs facilitate the uptake of the mRNA into host cells, where the mRNA will cause the expression (synthesis) of the spike protein;
3. the spike protein will appear on the surface of the host cells and induce an immune reaction to itself.

The immune reaction to the spike protein will comprise both antibodies, which may or may not be neutralising (see Section 2.1.3.1), and T-lymphocytes (T-cells). Some of these T-cells are cytotoxic (also known as T-killer cells); their function is to kill virus-infected body cells.
While this vaccination strategy may look good on paper, it has a number of drawbacks and risks. These arise both from the lipid mixture and from the spike protein, both of which have known toxic activities.

3.1.1.1 Toxic and procoagulant activities of the spike protein

Severe clinical COVID-19 disease is often accompanied by a pathological activation of blood clotting[32]. The central role of the spike protein in this complication is recognised [33]. Notably, there are at least two different mechanisms for triggering blood coagulation:

1. If the spike protein is expressed within vascular endothelial cells-the innermost cell layer of the blood vessels-then an immune reaction to the spike protein can destroy these cells. The resulting vascular lesion will activate blood clotting. This immune reaction can involve cytotoxic T-cells, but also antibodies that trigger the complement system and other immune effector mechanisms.
2. Spike protein molecules that are formed within the circulation, or which enter it after being synthesised elsewhere in the body, can directly bind to blood platelets (thromboycytes) and activate them. This will again set off blood clotting.

The second mechanism is significant because it does not involve an immune reaction; therefore, it can be triggered right away even in those persons who have no pre-

existing immunity. The first mechanism will be most effective in those who already have immunity to the spike protein, due to either infection with the virus or a previous injection of vaccine. Note that the underlying mechanism of cell damage will also operate in other tissues-any cell in the body that expresses the spike protein will thereby become a target for the immune system.
Since Comirnaty and other gene-based vaccines induce the synthesis of active, and therefore potentially toxic, spike protein, it is important to understand how this protein with be distributed within the body. Toxicity might be limited if the vaccine, and therefore the synthesis of the spike protein, remained confined to the site of injection, within the muscle tissue but outside the circulation. On the other hand, if the vaccine were to enter the bloodstream, then one would have to expect expression of the spike protein within the blood vessels and toxicity through the activation of blood clotting.

3.1.1.2 Distribution of the vaccine in animal experiments

As it turns out, the vaccine does indeed appear in the bloodstream very rapidly after intramuscular injection. In experiments which Pfizer reported to the Japanese health authorities [34], rats were injected with a mock vaccine sample. This material was chemically similar to Comirnaty, but it contained an mRNA molecule that encoded an easily traceable, non-toxic model protein (luciferase) rather than the SARS-CoV-2 spike protein. The lipid mixture used to form the LNPs was the exact same as with Comirnaty. One of the lipids in this mixture was radioactively labelled, which permitted the distribution of the sample within the body to be traced and quantified sensitively and accurately. Several remarkable observations were made:

1. The radioactive lipid appeared rapidly in the bloodstream. The blood plasma concentration peaked after 2 hours; but even at only 15 minutes into the experiment, the plasma level had already reached 45% of that maximal value.
2. Very high levels of the radioactive lipid accumulated in the liver, the spleen, the adrenal glands, and the ovaries.
3. Comparatively low levels accumulated in the central nervous system (the brain and the spinal cord).
4. Expression of the model protein encoded by the mRNA was studied only in the liver, where it was readily detected.

3.1.1.3 Mechanism of vaccine uptake into the bloodstream

Considering that the complex consisting of mRNA with bound LNPs has a rather large molecular size, we must ask how it managed to enter the bloodstream so rapidly. After intramuscular injection, the bulk of the vaccine should end up in the "interstitial" space, that is, the extracellular space outside the blood vessels. This space is separated from the intravascular space (the circulation) by the capillary barrier, which permits free passage only to small molecules such as oxygen or glucose (blood sugar) but is impermeable to large molecules such as plasma proteins; and the vaccine particles would be even larger than those.
The fluid within the interstitial space is continuously drained through the lymphatic system; all lymph fluid ultimately enters the bloodstream through the thoracic duct. Particles which are too large for traversing the capillary barrier can ultimately reach the circulation by way of this lymphatic drainage. However, this process tends to be considerably slower[35] than was observed here with the model vaccine. We must therefore ask if the model vaccine may have broken down the capillary barrier and thereby gained direct entry to the bloodstream.

Lipid mixtures similar to those contained in the Pfizer vaccine have been used experimentally to penetrate the blood brain barrier after intravenous injection [36]. The blood brain barrier can be described as a "fortified version" of the regular capillary barrier-if it can be broken down, then we must expect the same with a regular capillary barrier, too. The high local concentration of the lipid nanoparticles that will result after intramuscular injection will further promote the breakdown of the barrier. The upshot of this is that the vaccine *will* appear in the bloodstream, in large amounts and on short order. Complications due to blood clotting must therefore be expected.

3.1.1.4 Other indications of LNP toxicity

The proposed breakdown of the capillary barrier by the LNPs implies a cytotoxic effect on the endothelial cells, which form the only cellular element of the capillary walls. Cytotoxic effects of the LNPs are also evident from damage to muscle fibres at the injection site [30] and to liver cells [30]. Note that these data, too, were obtained with the model mRNA encoding the presumably non-toxic luciferase enzyme. Therefore, these cytotoxic actions are not due to any direct action of the spike protein. An immunological component of the cell damage cannot be completely ruled out, but it is likely not dominant in this case, since luciferase, unlike spike protein, is not transported to the cell surface.

3.1.1.5 Mechanisms of accumulation in specific organs

The high rates of accumulation of the vaccine in the liver and the spleen suggest uptake by macrophage cells, which abound in both organs and are generally in charge of clearing away unwanted debris. The accumulation in the adrenal glands, the ovaries, and again the liver suggests a role of lipoproteins in cellular uptake within these organs. Lipoproteins are complexes of lipids and specific protein molecules (apolipoproteins) that function as lipid carriers in the bloodstream. The liver has a central role in lipid and lipoprotein metabolism generally, whereas the adrenal glands and the ovaries take up lipoproteins to acquire cholesterol, which they then convert to their respective steroid hormones. Such a role of lipoproteins in the transport and cellular uptake of lipid nanoparticles is in fact accepted[37]. We must therefore expect that other organs with a high rate of lipoprotein uptake will be similarly affected. This includes in particular the placenta, which like the ovaries produces large amounts of steroid hormone (progesterone), and the lactating mammary glands, which acquire cholesterol contained in lipoproteins for secretion into the breast milk.

3.1.1.6 Correlation of lipid uptake and mRNA expression

In the experimental study in question, the liver was also shown to express the mRNA that is associated with the LNPs (see [30], Section 2.3.2). As stated above, the mRNA used in this study encoded the firefly enzyme *luciferase*, which is the very protein that enables these animals to glow in the dark. Mammalian tissues expressing this enzyme will also become luminescent, in proportion to the amount of luciferase protein which they synthesize. Measurements of this luminescence are not very sensitive, though, which was most likely the reason why Pfizer carried them out only with the liver but not with other, smaller organs. However, in the absence of proof positive to the opposite, we must assume that the correlation between efficient LNP uptake and mRNA expression that applies to the liver will also hold with other organs. If the cargo mRNA encodes the spike protein, then these organs will be exposed to the toxicity of the spike protein, and to the immune reaction against it, in proportion to the level of LNP and mRNA uptake.

3.1.1.7 Potential risks to fertility and to the breastfed newborn

A high level of expression of spike in the ovaries raises the prospect of significant damage to that organ, with possible consequences for female fertility. Uptake of the vaccine by mammary gland cells opens two possible pathways of toxicity to the breastfed child: firstly, the expression of spike protein and its secretion into the breast milk, and secondly, the wholesale transfer of the vaccine into the milk. The mammary glands are *apocrine*, which means that they pinch off and release fragments of their own cytoplasm into the milk; thus, anything that has reached the cytoplasm might also reach the breast milk. In this connection, we note that both the VAERS database and the EU drug adverse events registry (EudraVigilance) report fatalities in breastfed newborns after vaccination of their mothers (see Section 3.1.3.6).

3.1.1.8 Pfizer's failure to investigate risks evident from preclinical investigations

With the exception of fertility, which can simply not be evaluated within the short period of time for which the vaccines have been in use, all of the risks discussed above have been substantiated since the vaccines have been rolled out-all are manifest in the reports to the various adverse event registries (see Section 3.1.3). We must stress again that each of these risks could readily be inferred from the cited limited preclinical data, but were not followed up with appropriate in-depth investigations. In particular, the clinical trials did not monitor any laboratory parameters that could have provided information on these risks, such as those related to blood coagulation (e.g. D-dimers/thrombocytes) or liver damage (e.g. -glutamyltransferase).

3.1.2 Contaminations arising from the manufacturing process

The commercial scale manufacturing process of BNT162b2 gives rise to several contaminations that may compromise vaccine safety and effectiveness. For brevity, we will here mention only two such contaminants.

3.1.2.1 Contaminating bacterial DNA

The mRNA is produced in vitro using a DNA template, which in turn is obtained from bacterial cells. While steps are taken to remove this DNA afterwards, they are not completely effective, which is acknowledged in the EMA report (pages 17 and 40). Contaminating DNA injected with the vaccine may insert into the genomes of host cells and cause potentially harmful mutations. Bacterial DNA also non-specifically promotes inflammation.

3.1.2.2 Lipid impurities

The EMA report also observes impurities originating from the synthesis of the lipid ingredients of the vaccine (page 24):

> Lipid-related impurities have been observed in some recently manufactured finished product batches, correlated with ALC-0315 lipid batches. The quality of ALC-0315 excipient is considered acceptable based on the available data on condition that specific impurities in the finished product will be further evaluated.

Considering that the synthetic lipid referred to as ALC-0315 has never before been used on humans, there is no sound empirical basis for deciding on "acceptable" levels of impurities. Furthermore, it appears that the contaminating species have not even been identified. EMA's arbitrary blanket approval of unknown contaminants of

an unproven vaccine ingredient is completely unacceptable.

3.1.3 Adverse events after the onset of vaccinations

Since the introduction of the vaccines, numerous adverse events have been reported to registries around the world. We will here focus on two registries, namely, the U.S. vaccine adverse events reporting system (VAERS) and the EU monitoring system for 21s-drug adverse events (EudraVigilance). All numbers quoted below are as of May tunless stated otherwise.

3.1.3.1 Fatalities reported in connection with COVID vaccines

Within just five months of the onset of vaccinations, EudraVigilance has accumulated 12,886 deaths in connection with the COVID-19 vaccines, of which the Pfizer vaccine accounted for almost half (6,306). In the same time period, VAERS has run up 4,406 deaths in all; of these, 91% were associated with the mRNA vaccines, with Pfizer accounting for 44% and Moderna for 47% of the total.

It is impossible to know what percentage of all fatalities that occur after vaccination will actually be reported to VAERS or EudraVigilance. However, note that the 4,406 COVID vaccine-related fatalities accrued by VAERS during just the past 5 months exceed the cumulative total of all other vaccines combined, over the entire previous 20 years. It is therefore clear that these vaccines are far and away the most deadly ones in history-quite predictably so, and all for a disease whose case fatality rate does not exceed that of influenza[1,38].

3.1.3.2 Severe events related to disrupted blood clotting

The litany of diagnoses in both databases that indicate pathological activation of blood clotting is almost endless-hart attacks, strokes, thromboses in the brain and in other organs, pulmonary embolism; but also thrombocytopenia and bleeding, which result from excessive consumption of thrombocytes and of coagulation factors in disseminated intravascular coagulation. These disease mechanisms caused many of the fatalities summarized above; in other cases, they caused severe acute disease, which will in many cases leave behind severe disability.

3.1.3.3 Other severe reactions

Severe reactions also include seizures, other neurological symptoms, particularly related to motor control, and severe systemic inflammation with damage to multiple organs. Again, in many of these patients, long-lasting or even permanent residual damage is highly likely.

3.1.3.4 Severe adverse reactions among adolescents

In the age group of 12-17 years, two deaths likely related to the Pfizer vaccine were already reported to EudraVigilance. Also in this age group, there were 16 cases of myocarditis, all in males, and 28 cases of seizures among both sexes, 3 of them reported as life-threatening. There were also a few cases of stroke, myocardial infarction, and severe inflammatory disease.

While the numbers of adverse events are much lower than those among adults, this is simply due to the hitherto far lower rates of vaccination in this age group. Should

systematic vaccination be green-lighted for adolescents, we must expect these numbers to rapidly climb to a level resembling that seen in adults.

3.1.3.5 Miscarriages

As of June 21st, 2021, EudraVigilance lists 325 cases of miscarriage among vaccinated pregnant women. While it is difficult to ascertain by just how much vaccination will raise the rate of miscarriage, most of these cases were reported by healthcare professionals, who evidently considered a connection to the vaccine at least plausible. This series of cases alone would be reason enough to pause the vaccinations and investigate.

3.1.3.6 Deaths among breastfed infants

Although it does not directly relate to the age group which is the focus of this lawsuit and this expert opinion, it bears mention that both VAERS and EudraVigilance contain reports of death among breastfed children shortly after their mothers had received the Pfizer vaccine.
In Section 3.1.1.5, we discussed the possibility of vaccine uptake into the placenta and the breast glands. The reported miscarriages and fatalities in newborns indicate that these risks must be taken very seriously, and that Pfizer acted negligently in not investigating them in any of their reported preclinical and clinical trials.

3.2 Missing evidence

We saw above that significant positive indications of risk were neglected in the clinical trials and subsequent rushed emergency approval of the Pfizer vaccine, with unfortunate yet predictable outcomes. Equally damning is the list of omissions-potential risks that should have been investigated in preclinical or clinical trials but never were.

3.2.1 Proper pharmacokinetics

Section 3.1.1.2 described some experiments pertaining to the distribution of a surrogate vaccine. While these studies did provide important and useful information, it must be noted that the expression of the spike protein instead of the presumably inert luciferase enzyme might affect the distribution due to its interference with vascular integrity, including at the blood brain barrier, and with blood clotting. EMA and other regulators should have insisted that such experiments be carried out and documented.

3.2.2 Drug interactions

The EMA report states (page 110):

> Interaction studies with other vaccines have not been performed, which is acceptable given the need to use the vaccine in an emergency situation.

Since it is clear that mortality due to COVID-19 is low (see Section 1.1.1) and therefore that no emergency exists, this argument must be rejected as specious.
Immunosuppressive effects of BNT162b2 are apparent from a drop of blood lymphocyte numbers among those vaccinated, as well as from clinical observations of herpes zoster (shingles), which arises through the reactivation of persistent varicella-zoster virus [39]. This suggests that the desired immune response to other vaccines simultaneously administered may be impaired.
Furthermore, studies of interactions should not have been limited to vaccines alone, but also been extended to other drugs. One area of concern is the experimentally

apparent liver toxicity of BNT162b2. The liver is central in the metabolic inactivation and disposal of many drugs; any interference with the function of this organ immediately creates numerous possibilities of adverse drug interactions.

3.2.3 Genotoxicity

No studies have been carried out regarding genotoxicity, that is, damage to the human genetic material, which could lead to heritable mutations and cancer. In the EMA report[30], this is justified as follows:

> No genotoxicity studies have been provided. This is acceptable because the components of the vaccine formulation are lipids and RNA, which are not expected to have genotoxic potential. The risk assessment performed by the applicant shows that the risk of genotoxicity related to these excipients [i.e. the synthetic lipids] is very low based on literature data.

In reality, it is known that the LNPs contained in BNT162b2 can enter all kinds of cells-that is, after all, the purpose of their inclusion in this vaccine preparation. It is also known that, once inside the cell, cationic lipids disrupt mitochondrial function (cell respiration) and cause oxidative stress, which in turn leads to DNA damage.

It should be mentioned that two of the lipids used by Pfizer-namely, the cationic lipid ALC-0315 and the PEGylated lipid ALC-0159, which account for 30-50% and for 2-6%, respectively, of the total lipid content-had not previously been approved for use in humans. Pfizer's and EMA's cavalier attitude to the use of novel and so far unproven chemicals as components in drug or vaccine preparations without comprehensive studies on toxicity, including genotoxcicity, is completely unscientific and unacceptable.

3.2.4 Reproductive toxicity

Reproductive toxicity was assessed using only one species (rats) and on only small numbers of animals (21 litters). A greater than twofold increase in pre-implantation loss of embryos was noted, with a rate of 9.77% in the vaccine group, compared to 4.09% in the control group. Instead of merely stating [30] that the higher value was "within historical control data range," the study should have stated unambiguously whether or not this difference was statistically significant; and if it was not, the number of experiments should have been increased to ensure the required statistical power. The same applies to the observations of "very low incidence of gastroschisis, mouth/jaw malformations, right sided aortic arch, and cervical vertebrae abnormalities". Overall, these studies are inadequately described and apparently were also inadequately carried out.

3.2.5 Autoimmunity

Exposure to the vaccine will lead to cell damage due to the cationic lipids, and also to the immune attack on cells producing the spike protein. From the cells undergoing destruction, proteins and other macromolecules will be released; such material must then be cleared away by macrophages.

When the clearing system is overloaded because of excessive cell damage and apoptosis (cell death), then the accumulation of cellular debris will lead to chronically excessive type I interferon release; this, in turn, will trigger further inflammation. With time, some macromolecules in the debris will become targets for the formation of autoantibodies and the activation of autoreactive cytotoxic T cells-they will begin to function as auto-antigens. This then leads to further tissue damage and the release of more auto-antigens-autoimmune disease will develop. Such an outcome is particu-

larly likely in immunocompromised people or in those who are genetically predisposed to autoimmune disease (e.g. those with the HLA-B27 allele).
The risk of autoimmunity induced by BNT162b2 could be adequately addressed only in long-term studies; as with fertility or cancer, the very short period of preclinical and clinical testing means that we are flying blind. It should go without saying that all of these risks are particularly grave with children, adolescents, and young adults.

3.2.6 Antibody-dependent enhancement

While antibodies in principle serve to protect us from infections, in some cases they can increase disease severity. This phenomenon is referred to as antibody-dependent enhancement.

3.2.6.1 The principle

In Section 2.1.3.1 above, we saw that antibodies may or may not neutralize the virus that elicited them. While in most cases non-neutralizing antibodies are not harmful, with some viruses they can actually make matters worse by facilitating entry of these viruses into host cells. This occurs because certain cells of the immune system are supposed to take up antibody-tagged microbes and destroy them. If a virus particle to which antibodies have bound is taken up by such a cell but then manages to evade destruction, then it may instead start to multiply within this cell. Overall, the antibody will then have enhanced the replication of the virus. Clinically, this antibody-dependent enhancement (ADE) can cause a hyperinflammatory response (a "cytokine storm") that will amplify the damage to our lungs, liver and other organs of our body.
ADE can occur both after natural infection and after vaccination, and it has been observed with several virus families, including Dengue virus, Ebola virus, respiratory syncytial virus (RSV), and HIV [40]. Importantly, ADE also occurs with coronaviruses, and in particular with SARS, whose causative agent is closely related to SARS-CoV-2. Attempts to develop vaccines to SARS repeatedly failed due to ADE-the vaccines did induce antibodies, but when the vaccinated animals were subsequently challenged with the virus, they became more ill than the unvaccinated controls (see e.g. [41]).

3.2.6.2 SARS-CoV-2 and ADE

The possibility of ADE in the context of natural infection with SARS-CoV-2, as well as of vaccination against it, has been acknowledged [42]. More specifically, ADE due to spike protein antibodies elicited by other coronavirus strains has been invoked to account for the peculiar geographical distribution of disease severity within China[43]. However, the experimental research required to address it remains missing, even after more than one year into the pandemic.
With some experimental SARS vaccines, ADE could be mitigated through the use of inulin-based adjuvants [44]. This approach might be feasible for avoiding ADE with COVID-19 vaccines also, but so far this appears not to have been investigated with any of the existing COVID vaccines.
Pfizer and the regulatory bodies are well aware of the risk of ADE as well. The FDA notes in its briefing document [29]:

> Pfizer submitted a Pharmacovigilance Plan (PVP) to monitor safety concerns that could be associated with Pfizer-BioNTech COVID-19 Vaccine. The sponsor identified vaccine-associated enhanced disease including

> vaccine-associated enhanced respiratory disease as an important potential risk.

Here, the term "vaccine-associated enhanced disease" refers to ADE. EMA has likewise acknowledged that this risk must be investigated further[30]:

> Any important potential risks that may be specific to vaccination for COVID-19 (e.g. vaccine associated enhanced respiratory disease) should be taken into account. The Applicant has included VAED/VAERD as an important potential risk and will further investigate it in the ongoing pivotal study and a post-authorization safety study.

Overall, it is clear that the risk of ADE is recognised in theory but is not addressed in practice. Given the abundant evidence of ADE with experimental SARS vaccines, this is completely irresponsible. ”

31. The risks pointed out by the experts are serious and so is the lack of beneficial effects. The widespread use of the substance on healthy children - if most EU governments have their way, on all children - is absolutely irresponsible!

*

32. 2.2 Invalidity due to non-existence of the requirement according to Regulation (EC) No 507/2006 Article 4 (1) b) - Applicant is not able to provide the comprehensive clinical data.

33. See the attached action for annulment pending with T-96/21 (Doc**. A.3**).

34. In addition, it became known that the **participants in the clinical trials belonging to the placebo group have meanwhile been treated with Comirnaty. An assessment of the effect of the substance and thus the provision of comprehensive clinical data is definitely no longer possible** (Doc. **A.8).**

*

35. 2.3 Invalidity due to non-existence of the requirement according to Regulation (EC) No 507/2006 - Article 4 (1) c) - non-existence of a medical supply gap which can be filled by the authorised medicinal product.

See the attached action for annulment pending with T-96/21 (Doc. **A.3**).

*

36. 2.4 Invalidity due to non-existence of the condition according to Regulation (EC) No 507/2006 -Article 4 (1) d) - non-existence of the benefit for public health brought about by the immediate availability of the medicinal product on the market and outweighing the risk due to still missing additional data.

See the attached action for annulment pending with T-96/21 (Doc. **A.3**).

*

37. (3) Invalidity for breach of Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007, Directive 2001/83/EC of the European Parliament and of the Council of 6 Novem-

ber 2001 on the Community code relating to medicinal products for human use, and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human use.

38. **3.1 Violation of the EU legal provisions for the authorisation of "advanced therapy medicinal products".**

39. See the attached action for annulment pending with T-96/21 (Doc. **A.3**).

40. **3.2 Violation of EU legal provisions regarding the correct indication of the characteristics of the medicinal product and a correct package leaflet**

41. See the attached action for annulment pending with T-96/21 (Doc. **A.3**).

42. **3.3 Invalidity due to violation of the EMA's own criteria for the surveillance of a "pandemic medicinal product" with enormous short-term exposure figures.**

43. See the attached action for annulment pending with T-96/21 (Doc**. A.3**).

44. According to Art. 2 of the implementing decision contested here, the placing on the market is subject to obligations listed in Annex II, which are reassessed annually. These include, inter alia, Annex II, point C *"Other terms and conditions of the marketing authorisation",* the submission of Periodic Safety Update Reports (PSURs).

45. It is absolutely inadmissible that safety reports on a medicinal product with short-term enormous exposure figures do not have to be submitted until 6 months after authorisation, further exacerbating the threat to public health.

46. In this context, the approval of the pre-pandemic influenza vaccine *Aflunov* should be mentioned. In this regard, the EMA has requested a tighter submission of safety reports:

47. "*During a pandemic situation, the frequency of submission of periodic safety update reports (PSURs), as specified in Article 24 of Regulation 726/2004/ EC, is not sufficient for monitoring the safety of a pandemic vaccine where high numbers of exposures are expected within a short period of time. Such a situation requires a rapid display of drug safety information, which is of utmost importance for the risk-benefit balance in a pandemic. The immediate assessment of cumulative safety information, taking into account the extent of exposure, will be crucial for regulatory decisions and for the protection of the population to be vaccinated. Furthermore, during a pandemic, the resources needed for a thorough assessment of PSURs in the format set out in Book Volume 9a of the Rules Governing Medicinal Products in the European Union may not be sufficient for rapid identification of new safety issues*. "

48. Although these "orientations" or "guidelines" are not legally binding, they can be taken into account to a certain extent as supplementary considerations in the risk-benefit assessment of a medicinal product (see, accordingly,

judgment of 16 October 2003, AstraZeneca, C-223/01, EU:C:2003:546, para. 28).

49. Against this background, the EMA itself understandably confirms the view that the submission of PSURs of pandemic vaccines as gene therapy products after 6 months is too late.

50. The actual "special conditions" (according to Art. 14a para. 4 of the Regulation 726/2004) concern, among other things, specific obligations to complete product and manufacturing quality of the active substance (Annex II), which have to be verified within the first 6 months, as well as, with regard to confirmation of efficacy and safety, the submission of the final clinical study report under point E "Specific obligation to complete post-authorisation measures under "special conditions"", which obliges the marketing authorisation holder to submit the final clinical study report for the study VAC31518COV3001, for the purpose of confirming the efficacy and safety of "COVID-19 Vaccine Janssen" only on 31.12.2023! This deadline is clearly outside a valid assessment period for the review regarding efficacy and safety etc. at the extension date.

51. The health-threatening problem lies in the proof of efficacy and safety to be provided by the authorisation holder, which is not to be provided until the end of December 2023, although an annual review is to take place according to the implementation decision. This results in an irresolvable contradiction that calls into question the legality of this condition and thus the authorisation itself.

*

52. **<u>3.4 Annulment of the implementing decision due to the Commission's misuse of powers concerning the violation of the child protection provisions for clinical trials and the Declaration of Helsinki respectively, while at the same time adopting legislative measures to establish de facto compulsory vaccination - violation of the Nuremberg Code.</u>**

53. **The implementing decision is void because Annex I (Summary of Product Characteristics) and Annex III (Labelling and Package Leaflet) do not contain sufficient information within the meaning of Article 8 of Regulation 507/2006 on patient safety, information and education in connection with the specific protection provisions for minors pursuant to Article 3 in conjunction with Article 4 of Directive 2001/20/EC and Article 107m(2) of Directive 2001/83/EC. 3 in connection with 4 Directive 2001/20, Art. 7 (1) lit. a Regulation 1901/06 as well as Art. 107m para. 2 Directive 2001/83, which enable information in the sense of the prerequisite of consent, i.e. *informed consent,* about the direct or indirect study participation or the parallel clinical studies and largely missing study results, which would guarantee a safe use of the substrate. In fact, there is no valid consent according to the cited protection regula-**

tions of the age group of 12-15 years, who are administered the substrate due to the de facto compulsory vaccination.

54. The implementation decision in question is based, among other things, on Regulation 1901/06, according to which Art. 7 (1) lit a. authorisation is only possible if the results of **all studies, i.e. sufficient data security, are** available. However, the clinical study C4591001, on which the approval documents are based, is an ongoing study and not a fully completed study. In addition, essential safety data on, for example, toxicology or study results on fertility in humans, data on long-term safety, interactions with other drugs, VAED/VAERD, etc. are still missing, as can be seen from the RMP.

55. In this tension, in the sense of the precautionary principle and the safety of medicinal products, the other legal requirements concerning clinical studies remain unaffected (cf. Directive 2001/20 as well as Art. 107m para. 2 Directive 2001/83).

56. The amendment of the paediatric indication according to Regulation 1901/06 requires mandatory compliance with the provisions concerning the participation of minors in trials according to Directive 2001/20. As minors are a particularly protected population group under European pharmaceutical law, there can be no parallel studies in minors with simultaneous free availability of the gene-based substrate, as this would run counter to the protection of trial subjects by the provisions of Directive 2001/20.

57. This means that in particular the provisions of Art. 4 of Directive 2001/20 must be applied when Comirnaty is given to 12-17 year olds. Therefore, according to Art. 4 of Directive 2001/20, clear, informed consent must be obtained from the parents or legal guardians as well as the minor about the lack of study results and the associated health risks as well as about the actual participation in the study.

58. Accordingly, a clinical trial must be associated with a direct benefit for the trial subject according to Art. 4 lit. e Directive 2001/20, which can only result from an individual risk of the minor contracting a severe course of Covid-19. The risk situation for minors is hardly given, as admitted in the PAR: "Covid-19 in adolescents is mostly a mild disease although severe cases also occur rarely", PAR, p. 7. From the enclosed scientific opinion, under point 1.1.4 "Most people, particularly adolescents, are by now immune to SARS-CoV-2", it emerges, citing scientific sources, that most adolescents have an immunity to SARS Cov-2 anyway. (Doc. **A.10** p. 4)**.**

59. **In the sense of a serious overall scientific assessment in terms of patient safety and information, this fact of the ongoing and missing studies and results resulting from the conditional marketing authorisation according to Regulation 507/2006 must be clearly communicated, and in particular minors must be informed about the actual study participation and, in the case of administration, they must give their explicit consent together with their parents or legal guardians.**

60. In addition, in Part III.2 RMP (p. 96ff), Tables 40 and 41, all studies that obtain secondary data from electronic health database portals were approved.

61. This **procedure contradicts the requirements of Union law with regard to the welfare and rights of the participants, as there is no consent and the study design is not suitable to measure all identified missing safety information due to the secondary and thus highly error-dependent data analysis, which poses an irresponsible risk to the health and life of the minors. Moreover, it is a prophylactic vaccination of healthy persons whose health status must not be jeopardised under any circumstances by identifying significant safety risks only after realisation through a non-interventional PASS. Secondary aggregation of adverse reaction data is reactive and, from the point of view of patient safety and the precautionary principle, inflicts enormous damage to health and leaves the health-damaged persons "unprotected".**

62. These serious scientific misjudgements, in particular the neglect of the fact that the vaccination is administered as a prophylaxis, as already sufficiently explained under the above points of complaint, must be **qualified as a violation of the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects of the World Medical Association when systematically considered as a whole**. Point 25 states: "*The participation of persons capable of giving consent in medical research must be voluntary. Although it may be appropriate to involve family members or community leaders, no person capable of giving consent may be included in a research project unless he or she consents voluntarily.*"

63. This declaration was also recognised in the second recital of Directive 2001/20 as an applicable part of Union law: *"The recognised principles for the conduct of clinical trials on human subjects are based on the protection of human rights and dignity of the human being with regard to the application of biology and medicine, as stated, for example, in the Helsinki Declaration as amended in 1996. The protection of trial subjects is ensured by a risk assessment based on the results of toxicological studies prior to the start of each clinical trial, the reviews of the ethics committees and the competent authorities of the Member States, and the provisions on the protection of personal data."*

64. In the case at hand, the marketing authorisation and thus the use in humans is not based on the legally required basis of comprehensive study results, as laid down in detail in Annex I "Analytical, toxicological-pharmacological and medical or clinical standards and evidence concerning the testing of medicinal products" of Directive 2001/83/EC. **As can be seen from the scientific opinion (**doc. **A7), essential study data are missing, which would have had to be provided unconditionally in the case of a regular medicinal product authorisation**. On the other hand, according to the expert opinion, there are serious scientific errors and undeclared safety concerns, so that,

viewed as a whole, the limit for mass vaccination without sufficient study results for human trials was absolutely exceeded.

65. At the same time, the Commission is pursuing a policy of establishing de facto compulsory vaccination for European citizens, as is undoubtedly evident, inter alia, from the European Vaccine Strategy of 17.6.2020, COM(2020) 245 final, as well as from the total procurement volume of 2.6 billion doses of vaccine and the Commission Communication on "Arrangements for COVID-19 vaccination strategies and vaccine supply" of 15.10.2020, COM(2020) 680 final. The recent effort to introduce "digital green certificates" with the legislative proposal COM/2021/130 final, is another push to establish de facto Europe-wide vaccination obligation in order to be able to claim fundamental rights, in particular freedom of movement.

66. The lack of information and education, as shown above, in combination with the fact that the Commission is at the same time the licensing authority of Covid vaccines, objectively of Comirnaty, and establishes legislative measures that oblige the individual citizen of the European Union to be vaccinated, violates mandatory legal principles of international law, which are referred to as *ius cogens.*

67. The principles on consent requirements in medical studies of the Helsinki Declaration go back to the Nuremberg Code, which has also found its way into the offences of the Rome Statute of the International Criminal Court.

68. International law is not only an "integral part" of the Union legal order. **Legal acts of the Commission that systematically and collectively violate *ius cogens* are *ipso iure* null and void in accordance with Article 53 of the Vienna Convention on the Law of Treaties, which is recognised under customary international law** (see further references in the literature: *Schmalenbach*, in: Calliess/Ruffert, EUV/AEUV (Fn. 1), Art. 216, marginal no. 50; *Tomuschat*, in: von der Groeben/Schwarze, EUV/EGV (fn. 10), Art. 281, marginal no. 43; in detail *Schmalenbach*, in: Europarecht als Mehrebenensystem (fn. 4),67 (75 ff.))

69. Apart from this, the Agreement between the International Criminal Court and the European Union on Cooperation and Assistance of 10.4.2006, OJ 2006 L 115, p. 50) regulates in Art. 4 that the respective provisions of the Statute are to be observed for the EU.

70. **The performance of medical or scientific experiments on human beings in peacetime, which violate the principles of medical ethics, constitute a violation of the Rome Statute of the International Criminal Court, since they are the result of the actions of the Commission or of Union policy. Under the alternative offence of Art. 7 para. 1 lit k of the Rome Statute of the International Criminal Court with reference to the prohibition in wartime concerning "inhumane treatment including biological experiments" as well as "intentional infliction of great suffering or serious impairment of physical integrity or health" according to Art. 8 para. 2 lit**

a of the Rome Statute of the International Criminal Court, the Commission and the Union policy are in violation of the Rome Statute of the International Criminal Court. 8 para. 2 lit. a of the Rome Statute on the deliberate commission of "other inhuman acts of a similar nature" can be sanctioned as "crimes against humanity" if great suffering or serious impairment of physical integrity is caused as a result of state action or the Union institutions.

*

71. **3.5 Annulment of the Commission's implementing decision of 31 May 2021 due to lack of reasoning or manifest error of assessment of the CHMP(Committee for Medicinal Products for Human Use)opinion of 28 May 2021 or CHMP assessment report of 28 May 2021 concerning the change of paediatric indication.**

72. Intermediate documents such as CHMP opinions and the CHMP Public Assessment Report (PAR) may be taken into account, provided that the Commission has adopted and confirmed them by a positive decision, in order to determine whether the scientific conclusions ultimately reached by the CHMP in the context of the procedure for the examination of the marketing authorisation application at issue here are vitiated by a lack of reasoning and/or manifest errors of assessment. (see judgment of 19 December 2019, Vanda Pharmaceuticals Ltd, T-211/18, ECLI:EU:T:2019:892, para. 135)).

Since the Commission's implementing decision in question approved BioNtech's application on the basis of the positive decision of the CHMP pursuant to Article 17(2) 1234/08, it must be shown that the CHMP opinion or, in particular, the PAR is vitiated by deficiencies in the statement of reasons and/or manifest errors of assessment which cause the decision to be annulled.

73. **3.5.1 Invalidity for breach of compliance with the ethical requirements of US Study Directive 2001/20.**

74. Art. 6 (1) of Regulation 726/2006 requires that, with regard to clinical trials conducted outside the European Union, the applicant must provide confirmation of compliance with the ethical requirements of Directive 2001/20/EC.

75. According to the PAR, p. 8-9, the applicant confirmed that the ethical standards according to Directive 2001/20 were met. **However, the CHMP should have recognised that in the clinical trial C4591001 in question, the fundamental ethical standards of children between 12-15 years of age according to the European legal system were grossly disregarded**. **The European legal system has recognised a particularly high standard of protection with regard to the participation of children in clinical studies and has established the principle that the subject status of minors is fundamentally excluded in the absence of legally valid consent and that only minors without benefit may not participate in clinical studies.**

76. Recital 2 of Directive 2001/20 indicates that the recognised principles for the conduct of clinical trials on human subjects are based on the protection of

human rights and dignity of the human being with regard to the application of biology and medicine, as stated, for example, in the 1996 version of the Declaration of Helsinki. The protection of trial subjects is ensured by a risk assessment based on the results of toxicological studies prior to the start of each clinical trial, the reviews of the ethics committees and the competent authorities of the Member States, and by the provisions on the protection of personal data.

77. Recital 3 of the Directive states: "Persons who are unable to give legally valid consent to a clinical trial should be given special protection. It is the responsibility of the Member States to adopt appropriate provisions. These persons must not be included in clinical trials if the same knowledge can also be obtained through clinical trials with persons capable of giving consent. As a rule, these persons should only be included in clinical trials if there is a reasonable assumption that the administration of the medicinal product will have a direct benefit for the patient concerned that outweighs the risks. But especially in children, it is necessary to conduct clinical trials in order to improve the treatment of this population group. **Children form a particularly vulnerable population group. They are developmentally, physiologically and psychologically different from adults, so research that takes into account age and developmental stage is important for the benefit of this population. Medicines for children, including vaccines, need to be scientifically tested before general use. This can only be achieved by thoroughly testing medicines that may be of significant clinical value in children. The clinical trials required for this purpose should take place under optimal protection of the trial subjects. It is therefore necessary to establish criteria for the protection of children in clinical trials.**"

78. In addition to the protective provisions pursuant to Art. 3 of Directive 2001/20/EC, such as the obligation of the Member States to enact detailed regulations to protect persons who are incapable of giving consent from abuse, the explicit requirements pursuant to Art. 4 of Directive 2001/20/EC with regard to minors must be observed.

79. Art. 4 (e) of Directive 2001/20 stipulates that the clinical trial must be of direct benefit to the patient group and that it must relate directly to a clinical condition from which the minor concerned suffers or, by its nature, can only be carried out on minors. According to Art. 4 (h) RL 2001/20, an ethics committee with knowledge in the field of paediatrics or which has been advised on clinical, ethical and psychosocial issues in the field of paediatrics must be endorsed.

80. This means that **a clinical trial must be associated with a direct benefit for the trial subject according to Art. 4 lit. e of Directive 2001/20, which can only result from an individual risk of the minor contracting a severe course of Covid-19. However, only "healthy" subjects were recruited for the clinical trial C4591001, as can be seen from the PAR, p. 32, among**

others, which means that a severe course in the age group between 12-15 years can already be excluded in principle. The risk situation for minors is hardly given, as even the PAR admits: *"Covid-19 in adolescents is mostly a mild disease although severe cases also rarely occur",* PAR, p. 7. The enclosed scientific opinion states in point 1.1.4 *"Most people, particularly* adolescents*, are by now immune to SARS-CoV-2",* citing scientific sources, that most adolescents have an immunity to SARS Cov-2 anyway. (Doc. **A.11** p. 4).

81. This means that **the US clinical trial C4591001 contradicts the ethical requirements of Directive 2001/20/EC, since, among other things, the underage subjects themselves would have had to derive a direct health benefit from participation in the administration of the prophylactic gene-based substance, which can be ruled out *per se in the case* of basically healthy subjects. Thus, the mandatory application requirement according to Art. 6 (1) of Regulation 726/2006 is not fulfilled and the CHMP should not have issued a recommendation for a change of indication**.

82. **3.5.2 Invalidity due to violation of the provisions of Regulation No. 1234/2008 and Regulation No. 1901/2006** https://eur-lex.europa.eu/legal-content/de/ALL/?uri=CELEX%3A32006R1901)

83. The application in question is a **variation of a paediatric indication using an existing marketing authorisation**. This is to be classified as a Type II variation in accordance with Article 16 of Regulation 1234/08 and its content is based on the provisions of Regulation 1901/06. These provisions were infringed by the CHMP in various ways, so that there is a lack of reasoning or a manifest error of assessment on account of the following infringements:

84. Biontech has submitted an application under Article 8 of Regulation 1901/06, as can be seen from PAR S. 5, for which "the results of all studies and details of all information conducted or collected in compliance with an agreed paediatric investigation plan" are to be submitted under Article 7 (1) lit a of Regulation 1901/06.

85. The applicant shall include with the application for a variation for a paediatric indication a statement under Article 23a of Regulation (EC) No 1234/08 in which the applicant confirms that the application complies with the agreed and completed paediatric investigation plan referred to in Article 28(3) of Regulation (EC) No 1901/2006.

86. This is the approved paediatric investigation plan dated 23.04.2021, P/0179/2021, which amended the paediatric investigation plan (PIP) deferral authorisation dated 27.11.2020, P/0480/2020.

87. According to Article 15(2) of Regulation 1901/08, each PIP must contain details of the timetable **and** measures to demonstrate the **quality, safety and efficacy of the** medicinal product in all subsets of the paediatric population

that may be affected, in order to be authorised in accordance with Article 16(2) of Regulation 1901/08.

88. In the current approved PIP, the timetable for completion of the studies is given as July 2024, with no provision for a phased completion of the four clinical studies. Against this background, the following erroneous statement of the CHMP from the PAR should be highlighted "(a)t the time of submission of the application, the PIP P/0179/2021 was not yet completed as some measures were deferred." (PAR, P. 5).

89. However, a lawful deferral of measures of the PIP or a phased implementation can only be obtained through a due process according to the provisions of Regulation 1901/06 by the authorising authority itself. An informal, unauthorised amendment through statements by the CHMP in the PAR in question is contrary to the applicable procedural provisions and thus unlawful.

90. Consequently, the application to change the paediatric indication is not in compliance with the PIP, as it was not completed, which, among other things, realised a formal deficiency with reference to Art. 23a of Regulation 1234/08. In addition, the application contradicted the requirement for authorisation under Art. 7 (1) lit a VO 1901/06, which provides for the results of **all studies** and details of all information.

- The study C4591001 for children aged 12-15 years shown in the PAR is not a fully completed study but only a partial section for which relevant aspects are missing. The provisions of the paediatric regulation do not allow for a shortening of the study in the sense of drug safety for children (cf. 10th recital of Directive 2001/20 "Clinical trials are complex activities that usually last longer than one year and may even extend over several years;").
- serious flaws in the study "it will however not be possible to detect rare adverse reactions if such would occur specifically in adolescents" (PAR p. 34); "The study is not large enough to determine whether there is rare adverse reaction with a higher frequency in adolescents compared to what has been seen in trials and real-life use in an older population". (PAR p. 61), no dose-finding study (preclincal) (compare https://www.ema.europa.eu/en/documents/pip-decision/p/0341/2019-ema-decision-10-september-2019-acceptance-modification-agreed-paediatric-investigation-plan_en.pdf-9)
- The provisions of Directive 2001/20 are to be used to assess whether a fully-fledged study exists. https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=CELEX%3A32001L0020

*

91. **3.6 Annulment of the implementing decision on the basis of the manifest error of assessment and the inadequate reasoning of the authorisation dossier due to the risk management plan which cannot be approved,**

which contains no or inappropriate risk mitigation measures and which infringes the principle of proportionality pursuant to Article 5 TEU.

92. The applicant has not proposed any risk mitigation measures (RMMs) in the updated risk management plan (RMP) for important potential safety concerns and missing information, or has proposed inappropriate RMMs for identified safety concerns and missing information. proposed inappropriate RMMs for identified safety concerns and missing information, so that the RMP is grossly flawed as safety was not sufficiently demonstrated by the applicant, so that the application for conditional marketing authorisation should have been rejected (see judgment of 19 December 2019, Vanda Pharmaceuticals Ltd, T-211/18, ECLI:EU:T:2019:892, paras 64, 131) (Doc **A. 9).**

93. In principle, RMM measures are generally aimed at preventing or reducing the occurrence of adverse reactions that are unavoidable and associated with exposure to a medicinal product or, in the event of the occurrence of adverse reactions, reducing their severity or impact on the patient. All safety concerns mentioned in the RMP must be managed by appropriate RMMs in accordance with Art. 30 (1) lit c Implementing Regulation 520/2012, which must also be given special consideration in the summary of the RMP in accordance with Art. 31 (1) Implementing Regulation 520/2012. The risk minimisation measures are intended to optimise the safe and effective use of a pharmaceutical product. Both the planning and implementation of risk minimisation measures and the evaluation of their effectiveness are central elements of risk management and crucial for the positive benefit-cost assessment. Whether proposed risk minimisation measures are sufficient or not can therefore be decisive for any decision on the authorisation of a medicinal product. (Vanda Pharmaceuticals Ltd, T-211/18, para 120).

94. The flaw in the updated Public Assessment Report (PAR) EMA/343389/2021, (Doc **A. 10)** refers to the fact that the RMMs, including routine measures and pharmacovigilance activities according to the RMP submitted by the applicant under point 2.6 (p.62ff) were considered sufficient on the basis of the opinion of the Committee for Medicinal Products for Human Use and the recommendation of the Pharmacovigilance Risk Assessment Committee (PRAC) without adequate justification. In fact, however, according to Art. 30 (1) lit c Implementing Regulation 520/2012, an appropriate RMM, the effectiveness of which is to be assessed by pharmacovigilance, must be taken for each risk or safety concern. This means that the pharmacovigilance system can only be activated once RMMs have been taken. Thus, in accordance with the *aforementioned* provision a *contrario, there is in* any case a mandatory obligation to take RMMs for important identified as well as potential and missing information. If no RMMs are taken with regard to important security concerns, there is also **no RMP** that **can be approved.**

95. The significant safety risk of "Vaccine-associated enhanced disease (VAED) including vaccine-associated enhanced respiratory disease (VAERD)" was

again not sufficiently excluded by the applicant in the updated RMP or no study endpoints were defined in this regard in the present study C4591001 to actually investigate this theoretical risk in a controlled manner. The RMP in Table 32 assumes, based on the presentation of the data from the leading clinical study of the cohort of 12-15 year-olds, that this risk does not exist. However, this conclusion is not logical due to the lack of controlled infection with the SARS CoV-2 pathogen ("human challenge study"), as the endpoints of the present study do not examine this question and the study will only be completed in approx. 3 years.

96. With regard to the significant safety risk of VAED/VAERD, which is also referred to as "antibody-dependent enhancement" (ADE), reference is made to the relevant scientific explanations in the enclosed expert opinion (Doc. **A. 7**). In section 3.2.6, p. 24-25, the report consistently explains why the risk is to be classified as extremely high and comes to the following conclusion:

97. *"Overall, it is clear that the risk of ADE is recognised in theory but is not addressed in practice. Given the abundant evidence of ADE with experimental SARS vaccines, this is completely irresponsible.*"

98. In addition, a variety of other scientific papers exist, notably Cardozo et al, *Informed consent* disclosure to vaccine trial subjects of risk of COVID 19 vaccines worsening clinical disease, The International Journal of Clinicial Practice, Oct 2020, https://doi.org/10.1111/ijcp.13795 .The conclusions of the article call for comprehensive disclosure of VAED/VAERD risk to trial subjects and post-approval, as it is a significant safety risk, *"The specific and significant COVID19 risk of ADE should have been and should be prominently and independently disclosed to research subjects currently in vaccine trials, as well as those being recruited for the trials and future patients after vaccine approval, in order to meet the medical ethics standard of patient comprehension for informed consent."*

99. On the other hand, **due to the mass vaccination campaign, which provides for nationwide exposure of the population, as well as the increased occurrence of virus mutations, there is a particularly high risk of a massive health impairment of the European population by VAED/VAERD, as is also conceded in Table 32. The suggestion that an actual VAED/VAERD risk could have a negative impact on the risk/benefit ratio or have a negative effect on public health is irresponsible in view of the fact that no study is required that effectively rules out this risk. This blatantly contradicts the general principle of protection of public health established by the case-law and the precautionary principle of the Union** (Vanda Pharmaceuticals Ltd, T-211/18, para 46).

100. Consequently, there **is a serious error of reasoning and assessment in the implementing decision in that the applicant did not propose an RMM, which is contrary to the wording of the aforementioned provision**. It would not have been a disproportionate effort compared to the risk to the

health and life of the people receiving the experimental substance if it had been included in the Summary of Product Characteristics - Doc **A.2** - as well as in the package leaflet. This would have made the real and serious health threat apparent. **Due to the omission, which consequently also includes pharmacovigilance, no one becomes aware of this serious safety concern and there is also no risk control through pharmacovigilance measures**.

101. **Further errors of judgement and reasoning in the RMP, pp. 79-80, lie in the fact that the new *adverse events of special interest (AESI*) reported in the post-authorisation adverse event reports, namely *"immune/autoimmune-mediated neurological, haematological and vasculitis events; events associated with severe COVID-19; serious thrombotic and embolic events.* were not included in the list of safety concerns in Table 32. Furthermore, the RMP states that with regard to these AESIs *"are taken into consideration for all routine and additional pharmacovigilance activities"* without any correspondence in the RMP. Moreover, the CHMP would have had the duty to include the safety report of 11 May 2020 on facial swelling and myocarditis and pericaditis at the time of drafting the PRAC, as these side effects occur especially in younger people.** No justification is provided in the RMP as to why these identified safety concerns were not included under item SVII.1.2. regarding the important safety concerns in the RMP. Against this background, the RMP version 2.0 should not have been approved by the CHMP, as these newly emerged safety risks AESI cannot include in the summary of product characteristics as RMMs are not sufficient risk mitigation measures and the CHMP would have been obliged to adequately address this risk through RMMs in terms of patient safety.

102. **In addition, the following missing information was identified in the RMP (pp. 80-81): use during pregnancy and lactation, use by immunosuppressed patients, use by people with fragile health status with comorbidities, interaction with other medicines and vaccinations, and long-term safety data. Since these are not concrete safety risks but, in general clause terms, an unmanageable area without a robust side effect profile, this RMP is in any case an obstacle to approval.**

103. According to established case law, the identified risk must be set against "simple" RMMs, such as warnings in the summary of product characteristics and in the package leaflet. In the case of a materiality of risk, the relevance of simple RMMs is often not sufficient (Vanda Pharmaceuticals Ltd, T-211/18, para 132). **In the case at hand, however, the materiality of the identified unforeseeable risks is exceptionally high, which has a negative impact on the benefit-cost profile, so that the non-inclusion of simple RMMs and not a single "additional" RMM constitutes a particularly serious error of assessment and lack of reasoning and results in the nullity of the act**.

104. This means that, **given the potential for side effects that cannot be assessed, safe and effective use of "Comirnaty" for the** paediatric **indication of 12-15 year olds** must be **ruled out *a priori with* regard to the identified safety risks for which no RMMs have been set.**

105. **In the overall view of the mass vaccination of the population prescribed by the European Vaccination Strategy, which results in a high number of exposures in the shortest possible time, compared to the medically absolutely incalculable health risks, in particular VAED/VAERD, the newly added side effects of special interest, as well as the lack of long-term safety data, for which no risk minimisation whatsoever was provided, the Commission, or rather the EMA, exercised its discretion in the adoption of the legal act in a grossly erroneous and unjustified manner** (PAR p.80 ff - Doc.ff - Doc. **A.10**), **since the regular health status of the adolescent population is massively and incalculably endangered by the prophylactic gene immunisation, without the risks having been declared, explained or correlatively minimised (**Vanda Pharmaceuticals Ltd, T-211/18, para. 53).

106. **The plea of violation of the principle of proportionality**

107. The implementing decision adopted is unlawful on the basis of the measures taken, since it is manifestly inappropriate to achieve the objective pursued by the competent institutions, namely the safe and effective use of the gene therapy medicinal product at issue against infectious diseases (see, to that effect, judgments of Pillbox 38, EU:C:2016:49 and the case-law cited). in this sense, judgments of 4 May 2016, Pillbox 38, C-477/14, EU:C:2016:324, para 49 and the case-law cited therein, and of 16 March 2016, Dextro Energy v Commission, T-100/15, EU:T:2016:150, para 80).

108. **The principle of proportionality in the area of public health means that, among the goods and interests protected by the TFEU, the health and life of humans rank highest** (see, to that effect, judgment of 19 April 2012, Artegodan v Commission, C-221/10 P, EU:C:2012:216, para. 99 and the case-law cited there; see also, mutatis mutandis, on the respect of that principle by the Member States in the field of public health, judgment of 8 June 2017, Medisanus, C-296/15, EU:C:2017:431, para. 82 and the case-law cited there).

109. **For the control of safety risks due to the complete absence or partial simplicity of RMMs, considered both in isolation and in combination, less burdensome alternatives for the achievement of these objectives would have been available in accordance with the enshrined principles of medicinal products law, in particular those of Regulation 1901/2006 "Safety, efficacy and quality", which correlate with the protection of health and life, in particular of children as a population group requiring special protection, by refusing to grant marketing authorisation under Article 5 TEU as an inappropriate measure**. Therefore, the act at issue,

which amends the authorisation of the applicant's proposed change of paediatric indication to include 12-15 year olds, constitutes an inappropriate measure with regard to the principles of medicinal product authorisation and public health mentioned above.

*

110. **<u>3.7 Violation of EU legal provisions regarding the correct indication of the characteristics of the medicinal product and a correct package leaflet.</u>**

111. According to Art. 9 para. 1 lit. c) Regulation (EC) No. 726/2004 as well as Art. 62 Directive 2001/83/EC, the characteristics of the medicinal product, in particular the associated risks or information on groups of persons for whom the medicinal product is not recommended, must be correctly included and the package leaflet must comply with this.

112. According to Art. 11 point 4.4. Directive 2001/83 EC, the summary of product characteristics must contain the special warnings and precautions for use and, in the case of immunological medicinal products, any special precautions to be taken by persons dealing with immunological medicinal products and by persons administering these medicinal products to patients, as well as any precautions to be taken by the patient, where appropriate.

113. **According to Art. 11 point 4.5. Directive 2001/83 EC, the summary of** product **characteristics must contain the drug and other interactions.**

114. According to Art. 59 para. 1 lit. c) Directive 2001/83 EC, the package leaflet shall be drawn up in accordance with the summary of product characteristics and shall contain the following list of information which must be known before the medicinal product is taken: i) contra-indications, ii) appropriate precautions for use, iii) interactions with other medicinal products and other interactions which may affect the action of the medicinal product, iv) special warnings.

115. Due to the gross error of assessment set out above under point 3.2, which led to a non-observance of significant safety risks, there is automatically also a violation of the EU legal provisions regarding the correct statement of the characteristics of the medicinal product and a correct package leaflet.

*

116. **<u>4. annulment of the contested implementing decision on the ground of gross violation of Articles 168 and 169 TFEU and Articles 3, 35 and 38 EU Charter</u>**

117. **On the** basis of the facts and circumstances set out above and documented in this application, it is obvious that the implementing decision of the EU Commission contested here grossly violates the principles enshrined in Article 168 TFEU (Public Health) of the EU legislator. **The EU legislator has guaranteed EU citizens that a high level of health protection is to be ensured in the definition and implementation of all Union policies and measures.**

118. Union action should be directed towards improving public health, preventing human illness and diseases, and **obviating sources of danger to physical and mental health.**

119. **The EU has to set measures to establish high quality and safety standards for medicines and medical devices**.

120. The European Commission has grossly violated all of these obligations entered into under Article 168 TFEU with the implementing decision contested here and is concretely putting the applicants in a situation that endangers their health.

121. **Article 3 of the EU Charter (right to the integrity of the** person**)** guarantees the following to every person present in the EU: (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: the free informed consent of the person concerned**, in **accordance with the modalities established by law**, ..., **the prohibition of using the human body and parts thereof as such for profit**.

122. **Article 35 of the EU Charter (health protection)** guarantees everyone in the EU that **a high level of** human **health protection shall be ensured in the definition and implementation of all Union policies and activities.**

123. **Article 169 TFEU (consumer protection**) guarantees consumers that, in order to ensure a high level of consumer protection, the EU shall contribute to **protecting the health** and safety of consumers and to promoting their **right to information**.

124. And according to Art. 38 of the EU Charter (consumer protection), the Union's policies should represent a high level of consumer protection.

125. On the basis of the foregoing, it is obvious that the European Commission has also grossly violated the plaintiffs' fundamental right to consumer protection and the obligations under Article 169 TFEU, which also apply to the Commission in particular, with the implementing decision challenged here.

*****

126. The above-mentioned applicants therefore request that this honourable European Court, on the basis of the multiple gross violations of applicable EU law cited, which directly and personally affect the applicants in their capacity as parents of minor children and their minor children, recognise and declare the implementing decision contested here, together with subsequent integrations and amendments, to be null and void.

Bolzano, 30 July 2021

RA DDr. Renate Holzeisen

The following documents are deposited:

1. European Commission, Implementing Decision of 31.5.2021 amending the conditional marketing authorisation granted by Decision C(2020) 9598 (final) for

the medicinal product for human use 'Comirnaty - COVID-19 mRNA vaccine (nucleoside modified)' paragraph 1, pages 1 to 4 of the Annexes;

2. Annexes I, II, III and IV to the Implementing Decision of 31.5.2021; paragraph 2, pages 5 to 41 of the Annexes;

3. Action for annulment T-96/21 - together with annexes; paragraph 13, pages 42 to 1485 of the annexes, (colour print);

4. Decreto Legge 23 Luglio 2021 n. 105, art. 3; para. 7, pages 1486 to 1488 of the Annexes;

5. Prof.Dr.Ulrike Kämmerer Dipl.Biol (Virology/Molecular Biology) Dr.rer.hum.biol. (Human Biology) - Expert opinion; paragraph 8, page 1489 to 1545 of the Annexes

6. I presidi chiedono a Bianchi la vaccinazione obbligatoria per gli studenti: "L'alternativa è la Dad". Paragraph 9 , pages 1546 to 1550 of the Annexes;

7. Expert Statement by Prof.em Sucharit Bhakdi, M.D. former Head of the Institute of Microbiology and Hygiene, Johannes-Gutenberg University of Mainz, Prof.Dr. Stefan Hockertz, European Toxicologist and Immunologist, Prof.Dr.med. Michael Palmer, Specialist in Medical Microbiology and Infectious Disease Epidemiology, Department of Chemistry University of Waterloo, Canada, and Dr. Wolfgang Wodarg, Specialist in Internal Medicine, Lung and Bronchial Diseases, Specialist in Hygiene and Environmental Medicine and Public Health; paragraph 30, page 1551 to 1579 of the Annexes, (colour print);

8. Pfizer-BioNTech Covid-19 Vaccine Trial Overview; paragraph 34, pages 1580 to 1586 of the appendices, (colour print);

9. COVID-19 Vaccine (Ad26.COV2-S [recombinant]) updated RISK MANAGEMENT PLAN (RMP); pp. 1587 to 1720 of the appendices; paragraph 92 (colour print);

10. EMA Public Assessment Report, Comirnaty PAR) EMA/343389/2021; pp. 1721 to 1800 of the appendices; paragraph 58; (colour print);