Rechtbank Noord-Nederland, location Leeuwarden
Case and role number: C/17/190788 / HA ZA
23/172 Session: February 21, 2024

CONCLUSION OF REPLY

concerning:

Albert BOURLA,
Residing in Greenwich, United States of America

Defendant sub 11,
lawyers: mr. D.C. Roessingh and mr. M. Bredenoord- Spoek

against:

1. , residing in Sneek, municipality of Súdwest-Fryslân,
2. , living in Sneek, Municipality of Súdwest-Fryslân,
3. , living in Sneek, Municipality of Súdwest-Fryslân,
4. , residing at Doetinchem,
5. , residing at Doetinchem,
6. , last residing in Zaandam, municipality of Zaanstad,[1]
7. , residing at Leeuwarden,

(collectively " et al." and designated separately by their surnames)

plaintiffs,

[1] Suspended due to death. See deed deliberating suspension under Article 225(2) Rv (...) dated November 22, 2023 and deed after deliberating suspension under Article 225(2) Rv dated January 10, 2024.

lawyers: mr. A.G.W. van Kessel and mr. P.W.H. Stassen

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Dr. Albert Bourla ("Bourla") concludes for answer as follows.

1 INTRODUCTION

1. The SARS-CoV-2 virus (the **"Coronavirus")** is real. Just as real is COVID-19, the highly contagious and potentially life-threatening respiratory disease caused by the Coronavirus.

2. Shortly after its emergence, on March 11, 2020, the infection had spread to 114 countries worldwide and the World Health Organization (the "WHO") declared the Coronavirus outbreak a global pandemic.* As a result of this pandemic, approximately 700 million people worldwide have become infected with COVID-19 and nearly seven million people have died.[3] More than eight million confirmed COVID-19 infections have been recorded in the Netherlands alone, resulting in more than 22,000 deaths.[4]

3. Needless to say, the COVID-19 pandemic almost immediately became the top concern of schemes, companies and civil society organizations around the world when it emerged in the early 2020s. Governments from around the world called on pharmaceutical companies to develop a vaccine. Pfizer and BioNTech were among the first to take on this responsibility, along with other pharmaceutical companies such as Moderna, Janssen and AstraZeneca.[5] Al during 2020, Pfizer conducted clinical trials and that same year succeeded in obtaining conditional marketing approval from regulatory authorities, including in the EU. These approvals were granted based on extensive data obtained during the clinical trials, which demonstrated that the Pfizer/BioNTech vaccine

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WHO, *WHO Director-General's opening remarks at the media briefing on COVID- 19* , 11 March 2020 (Bourla-1), accessed atwww.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-COVID-19 11-march-2020
data.who.int/dashboards/covid19/cases?n=c
covid19.who. int/region/euro/country/en
For a complete list of COVID-19 vaccines approved by the EMA, see EMA, *COVID- 19 medicines* (Bourla-2), accessible atwww.ema.europa.eu/en/human-regulatory-overview/public-health-threats/coronavirus-disease-covid-19/covid-19-medicines

("Comirnaty")[6] met regulatory standards for safety, efficacy and production quality.

4. The devastation and loss of life caused by the pandemic was limited and ultimately largely overcome by a concerted effort by governments, citizens, businesses and the scientific community. In particular, vaccines, including Comirnaty, contributed greatly to slowing the pandemic. On May 5, 2023, WHO declared that the COVID-19 pandemic was officially over.[7] Scientific analyses show that COVID-19 vaccines prevented approximately 14 to 19 million deaths worldwide during the first two years of the pandemic alone.[8]

5. Nevertheless, a (thankfully, small) segment of the population embraced various conspiracy theories, including that the Coronavirus itself is a hoax, that the vaccines against it are toxic, or that the COVID-19 pandemic is a conspiracy by "the global elite" to achieve some illegal and/or immoral goal.

6. et al. can unfortunately be classed among this segment of the population - as, incidentally, can GP Van Walraven, who has apparently been found willing to provide "medical statements" for the purpose of these proceedings. et al. claim that COVID-19 is not a disease, but that this phenomenon was invented as part of a project called The Great Reset, which was planned and aimed at forcing a total reordering of the . According to e.a., this project was initiated by NGOs, in particular the World Economic Forum ("WEF"), funded by the World Bank and implemented in the Netherlands by the defendants in these proceedings. Vaccinating the entire population with a COVID-19 vaccine was allegedly part of this project. The concrete reason for these theories of et al. apparently constitutes the book "The Great

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" The Pfizer/BioNTech COVID-19 vaccine is also known as BNT162b2. These names may be used interchangeably.
WHO, *Statement on the fifteenth meeting of the IHR (2005i),* 5 May 2023 (Bourla-3), , accessed atwww.who.int/news/item/05-05-2023-statement-on-the-fifteenth-meeting-of-the- international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus- disease-(covid-19)-pandemic
The Lancet, *f lobal impact of the first year of COVID- 19,* June 23, 2022 (Bourla-4), accessed via www.thelancet.com/action/showPdf?pii=S1473-3099%2822%2900320-6
See, inter alia, writs, nos. 2, 61-65, 117-125, 186 and 198.

Reset,' which outlines what the authors believe the world *might* look like after COVID-19.'[0] Nothing more, nothing less. The conspiracy theory of et al. therefore has no factual basis whatsoever.

7. In these proceedings, the et al. specifically that (i) Bourla and the other defendants intentionally and unlawfully misled them by calling upon the Dutch population (including e.a.) calling on them to be vaccinated against COVID-19, when they knew or should have known that the vaccine was not safe and not effective and (ii) they suffered damages as a result.

8. These accusations are false. Bourla has et al. not misled them or otherwise acted unlawfully toward them. In reality, Bourla, in his role as CEO of Pfizer, contributed to the development of a vaccine against COVID-19 that is effective and has a favorable safety profile. This makes it especially galling that Bourla is now being personally sued and facing the aforementioned allegations. The claims formulated by et al. present fundamental procedural and substantive defects. Procedurally, it is striking that the claims against the various defendants are hardly - or in many cases not at all - connected to each other, so that a claim against Bourla, who resides in the United States, cannot in principle be brought before the Dutch court on the basis of Dutch procedural law.[1'] In addition, the et al. do not meet their burden of proof. On the merits, the claims also have no chance of success. e.a. present the court with an incomprehensible hotchpotch of unrelated, unsubstantiated and erroneous allegations (among themselves and with the claim). The claims of et al. should therefore be dismissed.

9. In this conclusion of reply, Bourla will address the contentions of e.a. refute, insofar as they are understandable and relate

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[40] This book was written in part by Mr. Schwab, the president of the WEF. The WEF is an organization aimed at bringing about international cooperation and, under the banner of The Great Reset, initiates the sharing of insights and information on a global approach to the social and economic crisis following the pandemic *(Appendix Proceedings II* 2021/22, 2541, response to question 4).
See further section 2.1 on jurisdiction.

have on him, on Pfizer and/or on the qualities of Comirnaty. In doing so, the following structure is used:

- in Chapter 2, Bourla will identify some of the most glaring procedural defects in the claims of et al. highlight;
- In chapter 3, Bourla will discuss the factual claims of e.a. refute; and
- Chapter 4 will explain why the claims have no legal basis.

2 PROCEDURAL REMARKS

2.1 Bourla will not contest the court's jurisdiction, but cannot be deemed to accept the jurisdictional requirements

10. The District Court of North Netherlands, Leeuwarden location has no jurisdiction to hear the claims against Bourla. In margin numbers 296-297 of the writ of summons, refer et al. only refer to article 107 Rv, which deals with internal or relative jurisdiction. et al. have not explained - let alone justified - why and on what basis the court would have international over the claims against Bourla. Had they Article 7(1) Rv (which provides the proper framework), they would not have successful. Indeed, they did not come close to asserting such a connection between their claims against the intended anchor defendant, Mr. Hofstra, and their claims against Bourla. The District Court of Northern Netherlands, Leeuwarden location - after its ex officio assessment - could therefore easily declare itself incompetent with respect to the claims against Bourla. That said, the claims of et al. are so obviously unfounded that Bourla will not raise a jurisdictional defense in favor of dealing with the merits of the claims once and for all.[12]

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[*] With this, Bourla cannot be deemed to have consented to any of the requirements for jurisdiction of the Dutch court, such as that between the claims against Bourla and those against the other defendants, there is such consistency within the meaning of Section 7 Rv.

2.2 Claims should be dismissed for lack of substantiation

11. et al. should have stated the necessary facts, and, if contested, proved those facts, in order to invoke the legal consequences they sought. Relying on Section 6:162 of the Civil Code, they contend that (i) they were misled; (ii) they would not have taken the COVID-19 vaccine without that misrepresentation; and (iii) they suffered damages as a result of the vaccine.

12. These contentions apparently imply that et al. took a COVID-19 vaccine. In that case, they should at least have been expected to have stated (i) *which* vaccine they allegedly took *when*[t3] and (ii) that they took these vaccines as a result of the alleged deception. et al. have failed to state even these elementary points. Their claims cannot be for this reason alone. In addition, they lack proper contentions and substantiation as to (i) the nature of the alleged deception and (iii) their alleged damages.

13. Bourla, notwithstanding the foregoing, believes that the court does have discretion to rule on the contentions that are, however, by et al. Although the 65-page subpoena is replete with fabricated assertions, some of which make no sense and the relevance of which is not always clear, Bourla is clear what et al. attempt to achieve. Bourla disputes all that et al. asserted in the preliminary subpoena, except to the extent that it appears from this claim that Bourla disputes the correctness of any assertion of e.a. acknowledges.Bourla is responding as best as it can to the suggestions of e.a..

3 THE CLAIMS **HAVE NO FACTUAL BASIS**

14. In this chapter, the general vaccine authorization process in the EU (section 3.1) and the specific development of Comirnaty

[t3] Only for follows from production 91 which vaccine she would have when taken.

(section 3.2) will be . Next, the specific contentions of et al. will be refuted (section 3.3).

General approval process for vaccines in the EU

Obtaining a trade license

15. All of Pfizer's vaccines are initially developed and tested in a laboratory. If initial tests are favorable, they are followed by clinical trials of increasing size, including randomized controlled trials comparing the new vaccine to an existing vaccine or placebo.[14]

16. The results of the development program are submitted to the appropriate competent authority, along with comprehensive pharmaceutical data related to the production of the vaccine, for marketing authorization application.

17. At the European level, the European Commission decides on granting a marketing authorization after regulatory and scientific assessment by the European Medicines Agency (the "EMA") and its advisory committee, the Committee for Medicinal Products for Human Use (the "CHMP").'[5]

18. If, after thorough investigation, the EMA concludes that the balance of benefits and risks associated with the use of the vaccine is positive, the EMA may decide to grant marketing authorization to the product. The vaccine and approved product information for healthcare professionals and vaccine recipients will then become available in the marketplace.

19. That marketing authorization may also be granted conditionally, such as in emergency situations related to a public health threat identified by the World Health Organization

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In this case, the candidate vaccine Comirnaty was compared with a placebo because there were no existing COVID-19 vaccines.

15 The legal framework for the authorization, manufacture and distribution of medicinal products in the EU is mainly laid down in Directive 2001/83/EC on the Community code relating to medicinal products for human use and Regulation (EC) No. 726/2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

or by the EU under Decision No. 2119/98/EC.[16] Article 4 paragraph 1 of Regulation (EC) No. 507/2006 provides as follows in this regard:

> *"A conditionly authorization may be granted when the Committee determines that, although complete clinical data concerning the safety and efficacy of the drug have not been provided, all of the following requirements have been met."*
>
> *a) the risk-benefit balance of the medicinal product as defined in Article 1(28a) of Directive 2001/83/EC is positive,*
>
> *b) it is likely that the applicant can provide that complete clinical data;*
>
> *c) unmet medical needs are met;*
>
> *d) the public health benefits of the immediate availability of the drug on the market outweigh the risk associated with the need to additional data."*

20. The EMA confirms that the conditional marketing authorization is a pragmatic tool for approval of a drug that addresses an unmet medical need." Earlier approval through a conditional marketing authorization does not diminish the guarantees that the drug meets the EU's strict standards for safety, efficacy and quality and that comprehensive data will be generated on an ongoing basis after approval. *However,* additional information can be , such as for example on protection in specific groups such as children and pregnant women. A conditional marketing authorization is valid for one year and can then be renewed annually. Once comprehensive clinical data have been submitted, the CHMP may recommend converting the conditional marketing authorization to a standard marketing authorization.

"' Commission Regulation (EC) No. 507/2006 provides for the granting of a *" conditional* marketing *authorization"* for certain medicinal products falling the scope of Regulation (EC) No. 726/2004.

17 EMA, *Conditional marketing authorisation* (Bourla-5), accessible atwww.ema.europa.eu/en/human-regulatory/marketing-authorisation/conditional-marketing-authorisation

Post-authorization pharmacovigilance

21. The safety profile of a drug may not be fully established during pre-authorization development. In particular, very rare side effects may not be identified even in large clinical trials. Therefore, in order to identify new safety information as quickly as possible, advanced pharmacovigilance procedures are implemented for all drugs after it is marketed.[18]

22. A draft risk management plan (an "RMP") is submitted with each application for a marketing authorization in the EU. Once approved, the RMP becomes part of the marketing authorization. An RMP may also include additional pharmacovigilance activities that are conditions of the marketing authorization.[1]

23. Routine pharmacovigilance activities require the marketing authorization holder to record and report to the appropriate regulatory authorities any adverse reactions of which he becomes aware.[20] In cases where reports of suspected adverse reactions result in a confirmed safety signal, this triggers appropriate action, including updating the product information, as approved by the regulatory authorities.

The main EU legislation related to the pharmacovigilance obligations of marketing authorization holders is Directive 2001/83/EC, Regulation (EC) No. 726/2004 and Commission Implementing Regulation (EU) No. 520/2012. EU legislation is complemented by detailed guidance issued by the EMA together with the Heads of Medicines Authorities on good pharmacovigilance practices for both regulators and . See EMA, *Good pharmacovigilance practices* (Bourla- 6), accessible at ema.europa.eu/en/human-regulatory-overview/post-authorization/pharmacovigilance-post-authorization/good-pharmacovigilance-practices

See EMA, *Comirnaty risk management plan,* October 2023 (selection) (Bourla-7) for the current version of Comirnaty RMP. Findable, as updated from time to time, at ema.europa.eu/en/documents/rmp-summary/comirnaty-epar-risk-management-plan_en.pdf.

20 For more information, see EMA, Periodic safety update reports (PSURs) (Bourla-8), accessible at ema.europa.eu/en/human-regulatory-overview/post-authorization/pharmacovigilance-post-authorization/periodic-safety-update-reports-psurs#:-:text=PSURs%20are%20pharmacovigilance%20documents%20intended,time%20points%20after%20its%20authorization.

Development, approval and pharmacovigilance of Comirnaty and other COVID-19 vaccines

24. The procedure outlined above was followed in the development, approval and pharmacovigilance of Comirnaty. To Bourla's knowledge based on publicly available information, the same is true for COVID-19 vaccines produced by other manufacturers.[21]

Clinical trials (before approval)

25. On March 13, 2020, Pfizer issued a statement calling on the biopharmaceutical industry to cooperate in the fight against COVID-19. In that statement, Pfizer already referred to its contact with BioNTech in connection with the development of a potential mRNA vaccine against the Coronavirus.[22] An actual letter of intent between these two parties was announced on March 17, 2020.[23] On April 9, 2020, they provided further details of their collaboration including the intention to begin clinical trials of vaccine candidates by the end of April 2020, subject to regulatory approval.*[4]

26. On April 23, 2020, a dose-based vaccine candidate selection study was initiated. This resulted in the selection of one of four candidate vaccines, BNT162b2 (Comirnaty), administered in a schedule of two doses of 30 micrograms.[25]

27. The efficacy and safety of BNT162b2 was then investigated in a large clinical trial conducted in the

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'" EMA, *COVID-19 vaccines development, evalua lion, approval and monitoring* (Bourla-9), accessed at www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-COVID-19/treatments-vaccines/vaccines-COVID-19/COVID-19-vaccines-development-evaluation-approval-monitoring

** Pfizer, *Pfizer Outlines Five-Point Plan* fo *Battle COVID-19,* March 13, 2020 (Bourla-10), accessible atwww.pfizer.com/news/press-release/presS-release-detail/pfizer-outlines-five-point-plan-battle-COVID-19

Pfizer, *Pfizer and BioNTech to Co-Develop Potential COVID-19 Vaccine,* March 17, 2020 (Bourla-11), accessed at investors.pfizer.com/Investors/News/news-details/2020/Pfizer-and-BioNTech-to-Co-Develop-Potential-COVID-19-Vaccine-03-17-2020/default.aspx

24 Pfizer, *Pfizer and BioNTech Announce Further Details on Collaboration* to *Accelerate, April 9*, 2020 (Bourla-12), accessed atwww.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-further-details-collaboration

ClinicalTrials.gov, *A Trial Investigating the Safety and Effects of Four BNT162 Vaccines Against COVID-2D19 in Health)/ and Immunocompromised Adults,* Jan. 13, 2022 (Bourla-13), accessed via clinicaltrials.gov/ct2/show/study/NCT04380701

United States, Germany, South Africa, Turkey, Argentina and Brazil.*[6] This involved nearly 44,000 people, about 50% of whom received Comirnaty and about 50% of whom received a placebo.*[7] The results showed that the efficacy of the vaccine against laboratory-confirmed symptomatic COVID-19 infection - which occurred at least seven days after the second dose, and with no evidence of previous COVID-19 infection
- 95% were in persons aged 16 years or older (with eight COVID-19 cases in the vaccination group compared with 162 COVID-19 cases in the placebo group).*

28. Of the nearly 44,000 enrolled proet subjects in the safety database by the data cut-off date (Nov. 14, 2020), the percentage withdrawn due to adverse events was very small (0.2% in the vaccine group and 0.1% in the placebo group).[2] There were no reported deaths among study participants that were considered to be vaccine-related.[30]

Approval

29. During the COVID-19 pandemic, several mechanisms available to the EMA were used to expedite the regulatory assessment of medicines in the context of public health emergencies. These include:

    • the procedure under Regulation (EC) No. 726/2004, which provides for a regulatory review with a 150-day deadline to issue an opinion after receiving a

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Study C4591001 ; see ClinicalTrials.gov, *Study* fo *Describe the Safety, Tolerability, Immunogenicity [... j,* Feb. 28, 2023 (Bourla-14), retrievable at clinicaltrials.gov/ct2/show/NCT04368728

EMA, *Comirnaty Assessment report,* Feb. 19, 2021 (Bourla-15), accessible at ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf, pp. 75-76.

28 EMA, *Comirnaty Assessment report,* Feb. 19, 2021 (Bourla-15), accessed at ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf, p. 131.

29 EMA, *Comirnaty Assessment report,* Feb. 19, 2021 (Bourla-15), accessed at ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf, p. 94 et seq.

30 EMA, *Comirnaty Assessment report,* Feb. 19, 2021 (Bourla-15), accessed at ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf, p. 109.

application for marketing authorization, rather than the 210 days usually given to the EMA;

- a "rolling review" in which the EMA may review data from clinical trials as they become available and before a formal marketing authorization application has been submitted; and
- the creation of a task force by the EMA to ensure a rapid and coordinated response to the pandemic.[31]

30. These expedited procedures do not change the substantive product requirements and established assessment principles, but are designed to make product assessment highly efficient, within timeframes appropriate to the specific situation.

31. Initial data on Comirnaty were submitted by BioNTech to the EMA as part of the rolling review process on Oct. 5, 2020, followed by the formal application for marketing authorization on Nov. 30, 2020.*[z]

32. The CHMP conducted a rigorous review of the pharmaceutical, preclinical and clinical data on Comirnaty and concluded that the available data regarding the quality, safety and efficacy of Comirnaty showed that the balance of benefits and risks was favorable.[33]

33. Following the positive opinion of the CHMP, the European Commission granted a conditional marketing authorization for Comirnaty on December 21, 2020.[34] The conditional authorization was renewed by the European Commission on November 3, 2021 and converted into a standard marketing authorization on October 10, 2022, based on the determination that all

31 EMA, *Comirnaty Assessment report,* Feb. 19, 2021 **(Bourla-15),** accessible at ema.europa.eu/en/documents/assessmenl-report/comirnaty-epar-public-assessment-report_en. pdf

32 EMA, *EMA starts second rolling review of a COVID-19 vaccine,* Oct. 6, 2020 (Bourla-16), accessed at ema.europa.eu/en/news/ema-starts-second-rolling-review-covid-19-vaccine

33 EMA, *Comirnaty Assessment report,* Feb. 19, 2021 (Bourla-15), accessed at ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf, p. 138.

34 OJEU, Dec. 24 2020 **(Bourla-17),** accessible via eur-lex.europa.eu/legal-content/NL/TXT/PDF/?uri=OJ:C:2020:4471:FULL

specific obligations imposed when the conditional permit was originally granted had been met or had been reclassified and that there were no longer reasons to leave the permit conditional.[35]

Additional pharmacovigilance for COVID-19 vaccines

34. Given the special circumstances of the COVID-19 pandemic, the EMA, together with the national competent authorities in the Member States - including the Health and Youth Care Inspectorate of the Dutch Ministry of Health, Welfare and Sport - has drawn up a specific pharmacovigilance plan for COVID-19 vaccines drawn up (the "EMA plan Pharmacovigilance Plan").[36] The EMA plan for pharmacovigilance included active collection of data on rare potential risks, rapid assessment of new safety information, rapid evaluation of safety issues that could affect the balance of benefits and risks, active surveillance of vulnerable groups of people, and rapid communication of new safety information. In addition to applying existing procedures, the EMA pharmacovigilance plan required marketing authorization holders submit monthly summary safety reports and periodic safety reports, which included information on reported adverse reactions, adverse events of special interest and sales data. EU member states were charged with collecting vaccine exposure data to be used in interpreting the veil safety data.[37]

35. The suspected side effects have been recorded, investigated and reported to the relevant regulatory authorities, including EMA and the Dutch Ministry of Health, Welfare and

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" OJEU, December 24, 2020 (Bourla-17), accessed at eur-lex.europa.eu/legal-content/NL/TXT/PDF/?uri=OJ:C:2022:457:FULL, p. 3.

*" See EMA, *Pharmacovigilance Plan of the EU Regulatory Network for COVID-19 Vaccines* (Bourla-18), accessed through ema.europa.eu/en/documents/other/pha macovigilance-plan-eu-re9ulatory-network-covid-19-vaccines_en.pdf

" See EMA, *Pharmacovigilance Plan of the EU Regulatory Network for COVID-19 Vaccines* (Bourla-18), accessible at ema.europa.eu/en/documents/other/pharmacovigilance-plan-eu-regulatory-network-covid-19-vaccines_en.pdf, p. 3, section 5.3.

Sport, in accordance with applicable pharmacovigilance requirements. Such data have been independently analyzed by regulatory authorities and by Pfizer/BioNTech to identify any new safety signals (i.e., information about a new or known adverse event that may be caused by a drug and requires further investigation). After investigation, appropriate action is taken, including, if approved by regulatory authorities, a change in product information. Pfizer and BioNTech have at all times cooperated with competent authorities and fulfilled their pharmacovigilance obligations with respect to Comirnaty. 3®

Interim conclusion

36. Comirnaty was subjected to rigorous testing and regulatory assessments before it was introduced in the EU. The result of this assessment was clear: Comirnaty was found to be highly effective (95%) in preventing symptomatic COVID-
19 infections. Scientific research suggests that COVID vaccines, including Comirnaty, have prevented nearly 20 million deaths from COVID-19 worldwide, which would translate proportionally to about 44,500 lives saved in the Netherlands alone.[3]

37. Since its market launch, Comirnaty's efficacy, safety and manufacturing quality have been closely monitored by both Pfizer and the appropriate regulatory authorities. These ongoing reviews continue to confirm that Comirnaty, as now updated to take into account Coronavirus mutations, meets all regulatory requirements, including with respect to safety: Comirnaty was found to cause few and generally mild and short-lived side effects.4[0] The

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^ See also section 3.3.4.

"' Watson 0. et al, *Global impact of the first year of COVID-19 vaccination." a mathematical modeling study,* June 23, 2022 (Bourla-19), accessed at https://www.thelancet.com/action/showPdf?pii=S1473-3099%2822%2900320-6

°" See www.ema.europa.eu/en/medicines/human/EPAR/comirnaty: under What are the risks associated with Comirnaty: "*The most common side effects with Comirnaty are usually mild or moderate and pet beiter within a few days after vaccination. These include pain and swelling at the injection site, tiredness, headache, muscle and joint pain, chills, fever and diarrhea."*

health benefits of vaccination therefore outweighed the side effects.[41]

The argument of et al. is a collection of conspiracy theories and already established falsehoods disguised as facts

38. et al. ignore that new infectious diseases emerge from time to time and that measures may need to be taken to lives. Instead, they claim et al. that the phenomenon that dominated almost everyone's life for at least two years lang - the Coronavirus - was not real.

39. In an attempt to explain these measures, et al with vague and far-fetched conspiracy theories allegedly involving NGOs, governments, media, international organizations and corporations. Bourla will address the factual claims of et al. Bourla reiterates that claims that are called unintelligible or otherwise not directly addressed should be considered disputed.

Misrepresentation of Comirnaty's development process

40. At its core, the et al. argue that Pfizer began testing a vaccine against the Corona virus too soon. In particular, they highlight that Pfizer began testing just days after Chinese authorities released the genetic code of the Corona virus on Jan. 10, 2020.[42] et al. do not substantiate this claim. They refer in this context to production 47. However, this production contains only bare assertions without appearing to come from an external source, and in any case no information about the process of developing a COVID-19 vaccine. et al.

See also Health Council, *Opinion-COVID- 19 vaccination BioNTech-Pfizer,* Dec. 24, 2020 (Bourla-20), accessed at www.gezondheidsraad.nl/binaries/gezondheidsraad/documenten/adviezen/2020/12/24/covid-19-vaccination-biontech-pfizer/Advice-COVID-19-vaccination-BioNTech-Pfizer.pdf, p. 4.

°* See Subpoena, Nos. 41, 148, 163, 165 and 200. In No. 41, the release date of the genetic code is incorrectly stated as January 8, 2020.

Moreover, they did not explain - and Bourla did not understand - why the aforementioned contention would be relevant to the claims brought.

41. Nonetheless, Bourla will briefly explain (i) how Pfizer and its commercial partner BioNTech, among other pharmaceutical companies, were able to begin testing a Corona vaccine shortly after receiving the genetic code of the Corona virus, and (ii) how it became possible to start the vaccination campaign within about a year of the start of the pandemic.[43]

Re (i): Rapid start-up of initial tests.

42. Simply put, Comirnaty did not have to developed from scratch. Pfizer and its commercial partner BioNTech were able to leverage a number of solutions for the use of mRNA technology and ferret attainment of effective ferret vaccine delivery that had been researched and tested for decades in the development of Comirnaty.[44] These include (a) the use of mRNA technology, and (b) the delivery system of the active ingredient into cells (lipid nanoparticles).

(a) mRNA

43. Messenger ribonucleic acid ("mRNA") is a nucleic acid present in all living cells. It contains instructions for making specific proteins. Human cells make many thousands of proteins necessary for the body to function. Each of these proteins is associated with a unique mRNA sequence.

" Incidentally, there are many publicly available publications on the Comirnaty development process. See, for example, Lewis, L.M. et al, *The Race to Develop the Pfizer-BioNTech COVID-19 Vaccine. From the Pharmaceutical Scientists' Perspective,* Sept. 18, 2022 **(Bourla-21),** accessed at www.n cbi.nlm.nih.gov/pmc/articles/PMC9482796

°^ Incidentally, even [redacted] et al. themselves acknowledge that a considerable amount of work had already been done on this ge ied before 2020. This is evident from their assertion that Pfizer *"had been developing mRNA vaccines for beta coronavirus since mid-2011,"* and from their reference to a series of patent applications by Moderna for the period 2015-2020 (Subpoena, No. 215, citing Production 72). While these patents have nothing to do with Pfizer and are temporally inconsistent with the allegation of et al, it does at least show that earlier scientific research, in this geva on other coronaviruses, may be useful for later research, in this case for the development of a vaccine against COVID-19. See also https://www.pfizer.com/science/innovation/mrna-technology

44. mRNA was first discovered in 1961 at the Institut Pasteur in France.[45] Since that time, many researchers have explored its therapeutic potential, including possible use in vaccines. In particular, the founders of BioNTech and other researchers have been researching the therapeutic potential of mRNA for more than 30 years.[46] [47]

45. Comirnaty contains a form of mRNA prepared in a laboratory to encode for the spike protein of SARS-CoV-2. After administration of Comirnaty, cells use the mRNA to produce this viral spiking protein. This, in turn, is recognized by the immune system as a foreign protein, causing antibodies to be produced. Once the body has made antibodies to the viral spike protein, these remain in the body and the immune system can respond quickly to protect the vaccine recipient from infection if exposed SARS-CoV-2.[48] For completeness, individuals to whom Comirnaty or any other mRNA vaccine is administered are exposed only to the target antigen or protein encoded by the mRNA. Administration of the vaccine does not result in infection with the virus itself.

46. The above means that at the beginning of the pandemic, it was already technologically possible to make mRNA encoding the spike protein of SARS-CoV-2.

47. Pfizer/BioNTech were able to produce several vaccine candidates shortly after the Chinese authorities released the genetic code of SARS-CoV-2. Thereafter, Pfizer/BioNTech were able to conduct the first laboratory tests and - subject to obtaining the required regulatory approvals - the first

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[45] Institut Pasteur, *Discovery* or *messenger RNA in 1961,* Feb. 15, 2021 **(Bourla-22),** accessed viawww.pasteur.fr/en/home/research-journal/news/discovery-messenger-rna-1961#:-:text=We%20can%20be%20sure%20that,protect%20them%20against%20COVID %2D19

[46] BioNTech, *The History of BioNTech - The Road io a New Era ot Immunotherapy* **(Bourla-23),** accessible www.biontech.com/int/en/home/about/who-we-are/history.html

[47] For example, the 2023 Nobel Prize in Physiology and Medicine was given to researchers whose work Pfizer built on in modifying the Coronavirus mRNA for Comirnaty; see Press release *The Nobel Prize in Physiology or Medicine 2023,* 2 October 2023 (Bourla-24), accessible at www.nobelprize.org/prizes/medicine/2023/press -release/

[48] Bettini, E., *SARS-CoV-2 mRNA Vaccines: Immunological Mechanism and Beyond,* 2021 (Bourla-26) , accessed www.ncbi.nim.nih.gov/pmc/articles/PMC7918810

Conduct clinical trials to identify the most promising candidate.

(b) Lipid nanoparticles

48. The use of mRNA technology in vaccines was initially limited by the fact that mRNA is susceptible to enzymatic degradation before entering cells. Therefore, much research was devoted to improving the stability of the RNA and overcoming the problems of delivery through a range of possible approaches,[4] including the use of lipids and lipid nanoparticles. A lipid nanoparticle (an "LNP") is essentially a delivery system that ensures that the active substance - in the case of Comirnaty mRNA encoding the SARS-CoV-2 spike protein - remains intact until it enters the cell. [0] LNP technology had been known for more than a decade and was already widely used for the effective delivery of a number of drugs.[51] Pfizer/BioNTech therefore did not need to reinvent the wheel in this regard.

49. Therefore, Pfizer/BioNTech could begin developing vaccine candidates shortly after finding out the genetic code of SARS-CoV-2 in January 2020....

Re (ii): Accelerated progress in vaccine development stages.

50. The vaccine candidate that would eventually become known as Comirnaty went through all the regular development and testing stages.[52] The development process was not accelerated by skipping these stages - which are intended to ensure the vaccine's safety and efficacy - but by eliminating bottlenecks and going through parallel pathways. Without wishing to be exhaustive,

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49 Wadhwa et al, *Opportunities and Challenges in the Delivery of mRNA-Based Vaccines,* January 2020 (Bourla-27).

*" See also section 3.3.3.

*' See Science News, *How COVID- 19 vaccines were made so quickly without cutting corners,* June 29, 2021 (Bourla-25), accessed atwww.sciencenews.org/article/covid-coronavirus-vaccine-development-speed

'* See section 3.2.

Bourla will list some of the key factors that have contributed to shorter Comirnaty development time.

(a) Fast results thanks to large number of volunteers and rapid spread of Coronavirus

51. Pfizer was able to recruit nearly 44,000 volunteers in a time frame of less than four months for the late stages of the clinical trial. This compares favorably with previous volunteer recruitment experiences; for example, it took more than two years to recruit only 101 volunteers for the 2013 rabies vaccine clinical trials. This alone saved about two years of development time.[53]

52. In addition, the rapid spread of Coronavirus meant that the number of cases of disease needed to make a statistically sound conclusion about the efficacy of Comirnaty was reached much more quickly than usual.[54] The infection rate needed to assess the efficacy of Comirnaty was reached about 1.5 years faster than what has been done in the past with some other viruses.'[5]

(b) Prioritization by relevant government agencies

53. It is well known that regulators in the US, EU and elsewhere heavily prioritized the development of vaccines against Coronavirus starting in the early 2020s.[56] Simply put, candidate vaccines against Coronavirus were at the front of the queue. This included giving priority to assessing

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[53] See Science News, *How COVID- 19 vaccines were made so quickly without cutting corners,* June 29, 2021 **(Bourla-25),** accessed atwww.sciencenews.org/article/covid-coronavirus-vaccine-development-speed
The effectiveness of a vaccine is measured by the number of (severe) cases of COVID-19 within a given time frame after vaccination to compare vaccine and placebo groups. Therefore, enough participants in clinical trials must become ill before a statistically valid conclusion about vaccine efficacy can be drawn.
See Science News, *How COVID- 19 vaccines were made so quickly without cutting corners,* June 29, 2021 (Bourla-25), accessed atwww.sciencenews.org/article/covid-coronavirus-vaccine-development-speed
See Science NewS, *How COVID- 19 vaccines were made so quickly without cutting corners,* June 29, 2021 (Bourla-25), accessed atwww.sciencenews.org/article/covid-coronavirus-vaccine-development-speed; see also EMA, *coViD-1s: how EMA fast-tracks development support and approval of medicines and vaccines,* May 4, 2020 (Bourla-28), accessed at https://www.ema.europa.eu/en/news/covid-19-how-ema-fast-tracks-development-support-and-approval-medicines-and-vaccines

the results of future trials of Corona vaccines. Since regulatory reviews are usually a major bottleneck in the vaccine development process, this prioritization is estimated to have saved about four years of development time.'[7]

(c) Stepping up production pending regulatory approval

54. Furthermore, Pfizer began large-scale production of Comirnaty *before* (conditional) marketing authorizations had been obtained, to ensure that a large number of doses were available immediately after authorization.[5] Pfizer was willing to take this risk for the sake of global public health.

55. In summary, then, BioNTech and Pfizer's success in bringing an approved vaccine to millions of patients within a year can only be described as an unprecedented achievement made possible by the combined efforts of the scientific community, companies and regulatory agencies around the world.

The purpose and effects of Comirnaty are consistent and **transparently communicated to the public**

56. In essence, they allege et al. that (i) they were told that one should be vaccinated not only for his/her own safety but also for the safety of others, (ii) that this was misleading, and (iii) they would not have left themselves to be vaccinated if they had been properly informed that Comirnaty does not prevent Coronavirus transmission.[5] Bourla will now address these false allegations.

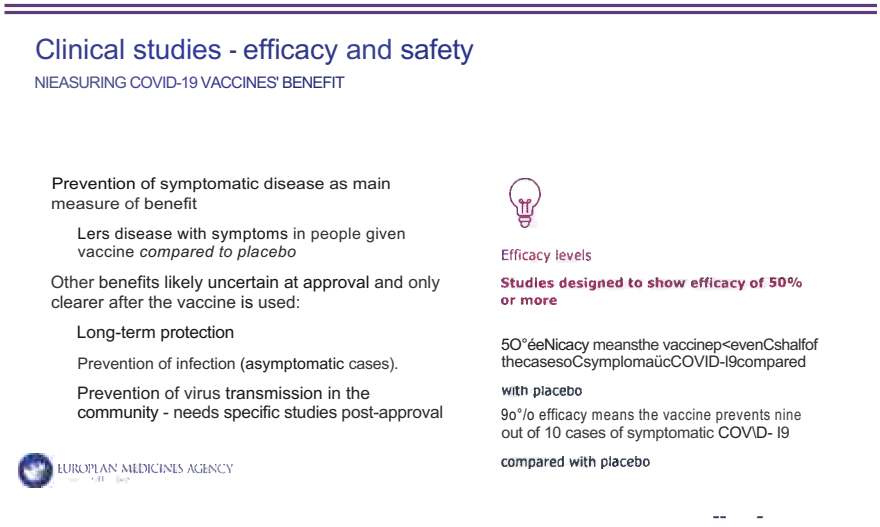
" See Science News, *How COVID-19 vaccines were made so quickly without culling corners,* June 29, 2021 (Bourla-25), accessed atwww.sciencenews.org/article/covid-coronavirus-vaccine-development-speed
See Science News, *How GOVID-19 vaccines were made so quickly without cutting corners,* June 29, 2021 (Bourla-25), accessed atwww.sciencenews.org/article/covid-coronavirus-vaccine-development-speed

*' Subpoena, Nos. 145 et seq. At the same time, none of the plaintiffs has alleged that they suffered damages as a result of Comirnaty's failure to the transmission of the Coronavirus from or to any of the plaintiffs.

The primary purpose of Comirnaty

57. Comirnaty's goal was to prevent vaccinated people from becoming seriously (symptomatically) ill and to minimize deaths from COVID-19. This was made clear from the outset by the regulatory agencies that called for the development of a COVID-19 vaccine as soon as possible in early 2020.

58. For example, in a presentation on COVID-19 vaccine development from the EMA, it states that the *"main measure of benefif"* of a COVID-19 vaccine is the *"prevention of symptomatic disease*. In that same presentation, the EMA indicates that it is not possible to determine, by the time a vaccine is approved, whether it will have the effects of *"prevention of infection"* and *"prevention of virus transmission*."[60]



59. Numerous academic contributions published in the run-up to Comirnaty's admission similarly explained

60 EMA, *How are COVID-19 vaccines developed* (Bourla-29), accessible via ema.europa.eu/en/documents/presentation/presentation-how-are-covid-19-vaccines-developed-marco-cavaleri_en.pdf, p. 8.

out that the primary endpoint[61] of the clinical trials is the vaccine's ability to prevent *severe* cases of COVID-19:

> *" The primary endpoint for all the phase 3 vaccine trials is amelioration of COVID- 19* disease. "[62]

60. Prevention of transmission was not a feature of the COVID-19 vaccines (including Comirnaty) that had to be tested and demonstrated before the vaccine could be marketed.

61. Thus, it was clear from the beginning that the primary goal of Comirnaty was to reduce the risk of severe COVID-19 disease, not to prevent Coronavirus transmission. As explained in Section 3.2, the data at the time indicated that Comirnaty was 95% effective in preventing symptomatic COVID-19 disease, which can undoubtedly be regarded as achieving the aforementioned goal.

Public communications about the purpose and effect of Comirnaty

62. As stated above, the et al. were misled in part by Bourla by believing that Comirnaty was developed to prevent vaccinated people from contracting and then transmitting the Coronavirus.

63. Bourla did e.a., however, did not mislead. Al before Comirnaty on received a conditional marketing authorization December 21, 2020, Bourla was transparent about the fact that its transmission-preventive effect had not been tested during clinical trials and was not known.°'

Simply put, endpoints are targeted outcomes of a clinical trial that are statistically analyzed to help determine the efficacy and safety of the therapy being studied.

See, for example, Nature, *Whither COVID-19 vaccines,* Sept. 28, 2020 (Bourla-30), accessed via www.nature.com/articles/s41587-020-0697-7

63 Incidentally, in a March 13, 2020 press release, Bourla said the following: "Many *companies, including Pfizer, are working to develop antiviral therapies* fo *help infected patients right this emerging virus as well as new vaccines to present infection and hall the rurther spread of this disease."* However, the press release also includes a detailed disclaimer saying that this is all very uncertain and thus no rights can be derived from it: *" This release contains forward-looking information about Pfizer's efforts to baltle COVID- 19 that involves substantial risks and uncertainties that could cause actual results* to *diirer materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development (...). A further description*

64. For example, in an interview with NBC News on Dec. 3, 2020, Bourla said it is unknown whether people who have been vaccinated can still be carriers of the Coronavirus and transmit it to others:

> *"I think this is something that needs* /o *be examined. We are not certain about that right now*."^(4)

65. In an interview with The Journal published on Jan. 13, 2021, Bourla again stated that while there was *"encouraging"* initial data on Comirnaty's ability to prevent Coronavirus transmission, these data "not *conclusive*." Bourla further cautioned that Pfizer had not yet proven the existence of a transmission-preventing effect:

> *" This is not conclusive* ye/. *We know that in animals,* [there is] *significant protection from transferring the virus.... We haven't* [proven that in] *hUmans* yet. "[65]

66. Regulators have been equally clear about the fact that no tests have been conducted, and no empirical data have yet been collected, on whether Comirnaty has a transfer-preventive effect.

67. For example, on Dec. 21, 2020, the EMA published a document accompanying its recommendation to grant Comirnaty a conditional marketing authorization. In it, the EMA explained that Comirnaty was 95% effective in preventing symptomatic COVID-19 disease, fulfilling its purpose. At the same time, the EMA warned:

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of risks and uncertainties can be found in Pfizer's Annual Report on *Form 10- K for the fiscal year ended December 31, 2019 and* in its subsequent *reports* on Form *10-O,* inc/uding in the *sections thereof captioned "Risk Factors" and Forward-Looking Information and Factors That May Affect Future Results," as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com."* See Pfizer, *Pfizer Outlines Five-Point Plan to Battle COVID-19,* March 13, 2020 **(Bourla-10),** accessed atwww.pfizer.com/news/press-release/press-release-detail/pfizer- outlines-five-point-plan-battle-covid-19

"° NBC News, *3 vaccine executives say that after approval, distribution will be the main challenge,* Dec. 3, 2020 **(Bourla-31),** accessed atwww.nbcnews.com/news/us-news/3-vaccine- executives-say-after-approval-distribution-will-be-main-n1249928

The Journal, *Pfizer CEO says there is 'encouraging' data on whether its vaccine stops Covid transmission,* Jan. 13, 2021 (Bourla-32), accessed at www.thejournal.ie/pfizer-ceo-5323949-Jan2021/

> *" The impact of vaccination with Comirnaty on the spread of the SARS-CoV-2 virus in the community is not yet known. It is not yet known how much vaccinated people may still be able to carry and spread the* virUs."[66]

68 The U.S. Food and Drug Administration ("FDA") also stated in a December 11, 2020 press release that *"at this time, [...] nor is there evidence that the vaccine prevents transmission of SARS-CoV-2 from person to person."*[67]

69. The same goes for the , which warned on Jan. 8, 2021 that was *"not yet any evidence of the effect of the vaccine on virus transmission*." It then flagged this issue as a recommended area for further research.[68]

70. The foregoing makes clear that at a hearing in the European Parliament on October 10, 2022, it was not at all *"disclosed"* that the effects of Comirnaty to prevent transmission had not been tested during clinical trials, as et al. suggest.[6] At that time, this had been an established and transparently published fact for almost two years.

Actual effect of Comirnaty to prevent transmission

71. At the same time, Comirnaty actually did help reduce transmission of at least the earlier variants of Coronavirus that occurred during the early stages of the COVID-19 pandemic.[70]

EMA, *Comirnaty, GOVID- 19 mRNA vaccine (nucleoside modified),* December 21, 2020 (Bourla-33), accessed at ema.europa.eu/en/documents/smop-initial/chmp-summary-positive-opinion-comirnaty_en.pdf

FDA, *FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID- 19 Vaccine,* December 11, 2020 **(Bourla-34),** accessed atwww.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19- issuing-emergency-use-authorization-first-covid-19

WHO, *Interim recommendations for use* of *the Pfizer-BioNTech COVID-19 vaccine,* January 8, 2021 (Bourla-35), accessed at iris.who.int/bitstream/handle/10665/338484/WHO-2019- nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1-eng.pdf?isAIlowed=y&sequence=1#page=5, p. 5.

Subpoena, No. 147.

10 See, for example, Reuters, *Fact Check: Preventing* transmission-never-required-for *COVID vaccines' initial approval* (Bourla-36), accessible atwww.reuters.com/article/factcheck-pfizer-vaccine-transmission/fact-check-preventing-transmission-never-required-for-covid-vaccines-initial-approval-pfizer-vax-did-reduce-transmission-of-early-variants-idUSL1 N31F20E/

72. It is clear that the vaccine helped slow the spread of the virus by reducing viral load and (symptomatic) infections in vaccinated individuals, which in turn leads to reduced transmission.[71]

73. In addition, COVID-19 vaccines, including Comirnaty, by preventing severe COVID-19 symptoms, have helped control the burden on national health care systems, including those in the Netherlands.

74. In short, COVID-19 vaccines had tangible positive public health effects beyond individual protection. The repeated assertions by et al. that they were misled about the purpose of Comirnaty are unfounded.[72]

The chemical composition of Comirnaty has been known for a long time

75. et al. claim that Comirnaty contains *"graphene oxide*."[73] This is incorrect.

76. In reality, the chemical composition of Comirnaty has been publicly available since the conditional marketing authorization was granted in the EU, including the Netherlands. For example, the full list of ingredients in Comirnaty has been listed at all times in the product information (the summary of product characteristics aimed at health care professionals and the package insert for patients a vaccine) approved by the EMA and made available from the date of granting the conditional marketing authorization on Dec. 21, 2020.'[4] This list of ingredients has also been published in numerous other media, and government and academic sources, such as by the FDA in its Emergency Use Authorization review memorandum of Dec. 11

" See, e.g., ECDC, *Risk of SARS-CoV-2 transmission from newly-infected individuals with documented previous infection or vaccination,* March 29, 2021 (Bourla-37), accessed at ecdc.europa.eu/en/publications-data/sarS-cov-2-transmission-newly-infected-individuals-prior-infection

72 See also concurrence of reply of the S1aa1e.a.of January 10, 2024, no. 6.2.

73 Subpoena, nos. 150 et seq.
EMA, *Comirnaty product intorma tion* (selection) (Bourla-38), accessible via ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf, p. 345.

2020. [5] Information about the chemical composition of Comirnaty was for et al. thus before their alleged vaccinations were made public and readily available.

77. For completeness, the following is a brief description of each of the ingredients in Comirnaty and their role in ensuring the safety, efficacy and manufacturing quality of the vaccine.

The active ingredient

78. Comirnaty's active ingredient is called Tozinameran. Simply put, Tozinameran consists of mRNA encoding the viral spike protein of SARS- CoV-2. It causes cells to produce the "spi/'e" protein, a protein present on the surface of the SARS- CoV-2 virus. The protein itself is not infectious or otherwise harmful. However, the body reacts to it as a "foreign" protein. In this way, cells are "trained" to produce antibodies when they encounter the spike protein of the Coronavirus, so that the recipient of ferret vaccine is protected from infection when he or she is blooted to the virus."[6]

The lipids (protective globules)

79. Comirnaty contains four lipids. These form tiny fatty spheres that envelop the mRNA to protect it from destruction before it enters cells. These protective globules are known as lipid nanoparticles or LNPs.

80. The first lipid is usually referred to by the code name ALC- 0315.[77] Because ALC-0315 can be ionized during the production process, that is, it acquires a positive charge, it can "stick" to the mRNA, which has a negative charge. This allows ALC- 0315 to encapsulate the mRNA and thus protect it.... The fat globules

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*' FDA, *Plizer-BioNTech COVID-19 Vaccine Emergenoy Use Authorization Review Memorandum,* Nov. 20, 2020 (Bourla-39), accessed at www.fda.gov/media/144416/download, p. 11. "
See also margin number 45 above.

" The complete scientific name of the compound ALC-0315 is *((4-hydroxybutyl)azaandiyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate).*

then transport the active substance, the mRNA, through the cell wall into the cell's cytoplasm.[7]

81. The second lipid is usually codenamed ALC- 0159.[7] The main function of ALC-0159 is to form a protective layer around the LNP. This increases the stability of the mRNA and thus the storability of Comirnaty. [0]

82. The third and fourth lipids in Comirnaty are cholesterol and DSPC. [1] These are conventional lipids used in numerous permitted drugs and serve to further enhance the stability of the LNP [82]

Other ingredients

83. Finally, Comirnaty contains several other ingredients, all of which are quite common. First, Comirnaty contains sucrose, a common sugar. Its function is to ensure that LNPs do not stick together when frozen.[8]* Second, Comirnaty contains a mixture of salts (including sodium chloride or table salt) commonly known as phosphate-buffered saline, or thrometamol, a commonly used buffer for improved stability. [4] The purpose of these salts is to ensure that the acidity of the vaccine is similar to that of human

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78 See Gov.UK, Summary *of the Public Assessment Repon COVID- 19 Vaccine,* December 2020 (Bourla-40), accessible at, for example,www.gov.uk/government/publications/regulatory- approval-of-pfizer-biontech-vaccine-for-covid-19/summary-public-assessment-report-for-pfizerbiontech-covid-19-vaccine

79 The full scientific name of the compound ALC-0159 is *2-[(polyethyleneenglycol)- 2000j-N, N-ditetradecylacetamide.*

80 See, for example, Gov.UK, Summa/}' *of the Public Assessment Report COVID-19 Vaccine,* December 2020 (Bourla-40), accessible atwww.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/summary-public-assessment-report-for-pfizerbiontech-covid-19-vaccine

''' The full scientific name of DSPC is *1,2-Distearoyl-sn-glycero-3-roscholine.*

''* See, for example, Gov.UK, Summary of the *Public Assessment Report COVID-19 Vaccine,* December 2020 (Bourla-40), accessed atwww.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/summary-public-assessment-report-for-pfizerbiontech-covid-19-vaccine

B3 MIT Technology Review, *What are the ingredients of Pfizer's covid- 19 vaccine,* December 9, 2020 (Bourla-41), accessible atwww.technologyreview.com/2020/12/09/1013538/what-are-the-ingredients-of-pfizers-covid-19-vaccine/

84 Specifically, these salts are: potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate. See FDA, *Pfizer-BioNTech COVID- 19 Vaccine Emergency Use Authorization Review Memorandum,* Nov. 20, 2020 (Bourla-39), accessed at www.fda.gov/media/144416/download, p. 11.

body. Third, Comirnaty contains water because the vaccine is an aqueous solution.

84. The list of ingredients described in the preceding paragraphs is exhaustive: Comirnaty contains no other ingredients, including *"graphene oxide."* This has been confirmed time and again by the EMA and other authorities.[85] Graphene oxide is not used in the production process of Comirnaty and could not have been accidentally present in a dose of Comirnaty. This has also been confirmed by the European Commissioner for Health and Food Safety, who stated on March 8, 2022 that *"graphene oxide is not used in the manufacture or formulation of any of the COVID- 19 vaccines or other* medicines."[86]

85. In the subpoena, the e.a. that a number of independent third parties have checked the allegation that graphene oxide is present in Comirnaty. e.a. are also correct that the outcome of these *fact-checks* was always the same: Comirnaty does not contain graphene oxide. e.a. nevertheless dismiss these reports as *"valselyF,"* without offering any substantiation.[8®] Next, e.a. refer e.a. to *"videos and scientific reports by very reputable persons"* in which they would state *"by means of proofs of great precision" "that graphene oxide* is present *as the main component in all mRNA injections*." The only thing that e.a. refer to in this context is a video excerpt from an episode of an American online program called "*The Stew Peters Show."* [0] In this excerpt, a guest - Ms. Karen Kingston - suggests that all mRNA vaccines, including Comirnaty, contain graphene oxide. She attempts

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®' See, for example, EU Parliament, *Answer given by Ms. Kyriakides on behalf of the European Commission,* 26 October 2021 (Bourla-42), accessible viwww.europarl.europa.eu/doceo/document/P-9-2021-003980-ASW_EN.html#ref1
87. EU Parliament, *Answer given by Ms. Kyriakides on behalt ot the European ,* March 8, 2022 (Bourla-43), accessible atwww.europarl.europa.eu/doceo/document/P-9-2022- 000303-ASW_EN.pdf

87 Subpoena, No. 152. Some examples of such fact-checking: Reuters, *COVID- 19 vaccines do not contain graphene oxide,* July 23, 2021 (Bourla-44), accessed atwww.reuters.com/article/factcheck-grapheneoxide-vaccine-idUSL1 N2OZ14F/ and AP, *Pfizer vaccine does not contain graphene oxide,* July 8, 2021 (Bourla-45), accessed at apnews.com/article/fact-checking-430816913228

^ Subpoena, no. 152.

^' Subpoena, No. 153.
Subpoena, Production 44.

support this conclusion by misleadingly referring to a number of patents, none of which belong to Pfizer or any of its group companies, and whose connection to Comirnaty is not understood and in any event disputed.

86. There is no indication that Ms. Kingston has expert knowledge of the chemical composition, development process, effects or any other aspect of Comirnaty, let alone that she is a "highly reputable person." Ms. Kingston is a former employee of Pfizer. However, she was not involved in the research, development or production of Comirnaty. Regardless, Comirnaty simply does not contain graphene oxide.

87. The proposition of et al. that graphene oxide is present in Comirnaty - even *"as a principal element"* - is incorrect. [1] The same is thus true of the contention that Bourla *deliberately [allowed]* this *" misrepresentation to continue.* [2]

et al. fundamentally misinterpret Pfizer's April 30, 2021 report

88. In the subpoena, the et al. no less than eight times to Pfizer's report No. FDA-CBER-2021-5683-0000054 dated April 30, 2021 (the "Pfizer Report"). They present the Pfizer Report as a *"smoking gun"* that proves Comirnaty is dangerous. Specifically, they state

et al. that 42,086 people would have participated in a Comirnaty trial *("mia/")* that ran from November 2020 to February 2021, and of those, 1,223 people would have died and 11,361 people would have suffered serious and permanent injuries.

89. The Pfizer report proves nothing of the .

90. First, the Pfizer report does not refer to a clinical trial. Instead, it is an integrated analysis of *post-authorization* Comirnaty safety data, as the report itself describes. [3] Simply said records the Pfizer report

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"' Subpoena, No. 153.
"* Subpoena, No. 152.
"* Production 40, p. 5.

suspected adverse reactions reported, mostly through national authorities, before the cut-off date of *February 28*, 2021. The Pfizer report is a U.S. report. The equivalent in EU drug regulations is the Periodic Safety Update Report ("PSUR"). This is a report prepared by the marketing authorization holder of a drug that the global safety experiences with it at a particular point in time after authorization. [4]

91. Second, distort et al. the figures presented in the Pfizer report. During the relevant period, 42,086 recipients of Comirnaty reported adverse reactions. [5] To even meaningfully assess the safety of Comirnaty, this number must be compared to the total number of people to whom Comirnaty was . This confirms Comirnaty's strong safety profile: according to the EMA, more than 330. million doses of Comirnaty were administered worldwide through April 29, 2021, (6) indicating that only a very small proportion of vaccinations resulted in a report of an alleged adverse reaction. '

92. Third, the et al. misrepresent the significance of the reported side effects analyzed in the Pfizer report. The report does not suggest that these side effects were *caused* by Comirnaty. The Pfizer report only states that such side effects occurred at a certain

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94 The English original reads as follows: *"A report prepared by the marketing-authorization holder describing the worldwide safety experience with a medicine at a defined time after its authorization."* See EMA, *Periodic* safely *update report* (Bourla-46), accessed at www.ema.europa.eu/en/glossary/periodic-safety-update-reports:-:text=A%20report%20prepared%20by%20the,reports%3A%20questions%20and%20answers%27. See, for example, EMA, *Comirnaty periodic safety update report assessment 19 June 2022 to 1B December 2022* (selection) (Bourla-47) findable atwww.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/comirnaty-periodic-safety- update-report-assessment-19-june-2022-18-december-2022_en. pdf Production 40, p. 8.

96 EMA, Assessment report on the annual renewal of the conditional marketing authorization (Comirnaty), 2021 (Bourla-48), accessed atwww.ema.europa.eu/en/documents/variation-report/comirnaty-h-c-5735-r-0046-epar-assessment-report-renewal_en.pdf, p. 16. Although the period in the EEA report is longer than the period covered by the report cited by et al. mentioned (April 29, 2021 and February 28, 2021, respectively), this shows at the number of reported deaths and the number of reported persons with serious permanent physical injuries - as compared to the total number of doses - is very limited, and also significantly smaller than et al.

moment *after* the injection would have occurred. This does not mean that the side effects mentioned in the report are actually *due to* vaccination. This is all the more true since in the early days of vaccination - which is the subject of this report - the elderly and vulnerable were vaccinated. et al. make a fundamental mistake by confusing correlation with causation, when one does not prove or even necessarily suggest the other. Instead, such reports are typically used as part of post-authorization pharmacovigilance to determine if there are safety signals that warrant further investigation.

93. Fourth, the et al. misrepresent even the most basic statistical and demographic data in the report.

- For example, they suggest that 2,990 children *"participated"* in the analysis. In reality, the Pfizer report refers to 2,990 individuals whose was not mentioned in the adverse reaction report. In addition, it states that there were 175 persons under 18 years of age for whom adverse reactions were reported.[100]

- In addition et al, for example, that 11,361 persons would have suffered serious permanent physical injury. Nothing in the indicates serious permanent injury, or even the physical nature of an adverse reaction.

94. The assertion that the report was *"*concealed*"* by Bourla is also false, as is the date the report was allegedly released publicly.[10' Pharmaceutical companies, including Pfizer, do not release their reports to the public, but to the relevant regulatory authorities. To be clear, neither Bourla nor Pfizer took any steps to prevent the eventual release of the

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The FDA confirmed that *"In tact, reviews by FDA and CDC have determined ihat the vast majority of deaths reported are not directly attributable to the vaccines. FDA requires healthcare providers* to *report any death after COVID-19 vaccination to VAERS, even if it's unclear whether the vaccine was the cause."* See Reuters, *Pages of suspected side effects* released about Pfizer's *COVID-19 vaccine (...),* March 17, 2022 (Bourla-49), accessed at www.reuters.com/article/factcheck-coronavirus-pfizer-idUSL2N2VK1G1/.

Production 40, p. 7.

"°° Production 40, p. 7.

"" Subpoena, No. 144.

Pfizer report under the Freedom of Information Act proceedings in the U.S. to avoid.[102] Moreover, the analogous document in the EU - the PSUR - is publicly available on the EMA website.[103]

The vague comments from et al. about allegedly different qualities of batches of vaccines are irrelevant and **incorrect**

95. et al. allege that Pfizer has not maintained consistent production quality across the various batches of Comirnaty.[104] Specifically, they refer to batch EM0477 as a *"bj "without deadlj "k[e]"* variant.[105] These contentions are incorrect.

96. Premise, 'e.a. have not alleged that they were vaccinated against COVID-19, late what batch of Comirnaty they allegedly received.'** Nor have they alleged that their vaccinations came from a batch they consider to be of inferior quality. The contentions of et al. about the allegedly different qualities of batches of vaccines are thus apparently unrelated to the damages claimed, and are therefore irrelevant. In addition, the e.a. have failed to properly substantiate that batch EM0477 differed from other batches of Comirnaty.[10']

97. More importantly, much of the story of et al. rests on a misinterpretation of a scientific report by. Peter Riis Hansen ("Hansen"),[108] and an MEP's subsequent question to the European Commission referring to Hansen's report.[10] et al. falsely claim that Hansen's report proves *"[djat there are very large differences in lethality and side" effects of Pfizer Covid-19*

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102 Requests under the U.S. Freedom of Information Act are similar to requests under the Open Government Act (Woo) in the Netherlands.

103 See supra, no. 90.

Subpoena, nos. 245 et seq.

105 Subpoena, no. 246.

The only exception is Mrs. in respect of whom it is stated on page 7 of production 91 that she administered Co irna y oses from batches FC3143 and FF0688.

'0* Subpoena, nos. 245 et seq.

''' Production 83, second document. Hansen, by the way, is one of three authors.

'''' Production 83, first document.

injectionbatches [existj." In reality, the conclusion of Hansen:

> *"In conclusion, the results suggest the existence of a batch-dependent safety signal for the BNT162b2 vaccine, and more studies are warranted* to *explore this preliminary observation and í/s* consequences. "[110]

98. Hansen's report also reflects the basic scientific understanding that analyses of adverse events are not intended to establish a causal relationship between the vaccine and health problems. This is all the more true when it comes to self-reporting systems, which by definition are prone to reporting biases and data deficiencies. Hansen correctly acknowledges that the purpose of such systems, and of his report, is to identify a potential safety signal for further investigation:

> *" The present preliminary findings must be interpreted in the light of several limitations. The DKMA-managed spontaneous SAE reporting system in Denmark is a passive surveillance system (...), and reports from these systems are subject to reporting biases, with Dotential for both under- and over-reporting, as well as incOmDlełe data and variable oualitv of the reDorted information. Owing to these inherent limitations, signals detected bY these systems must be considered to be h'/Qothesis-aeneratina and generally cannot be used to establish causalit'Y. In addition, in the present study, the SAE case history of prior COVID-19 was unknown, and specific SAE types (.... j were not examined. Notably, to our knowledge, the Danish Serum Institute has not issued recalls of BNT162b2 vaccine* batches."[111] (emphasis added, lawyer)

99. Besides misrepresenting this preliminary conclusion of Hansen as evidence of the alleged *"lethality"* of Comirnaty, ignoreet al. that further research has been conducted by the relevant European authorities on the Danish batches mentioned by Hansen. This follows from the response of the Eurocommissioner for Health and Food Safety[11]* to the question of an MEP, to which *questione*t al. as noted above did

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110 Production 83, second document, p. 3.
Production 83, second document, p. 3.
That answer came on July 3, 2023. That is before the date the subpoena was issued.

refer."* That response shows that no increased risk of side effects for specific lots has been demonstrated:

> *"As regards literature monitoring, if various sources of information point to a potential issue more in-depth review is initiated. This was not the case for the mentioned Danish study.*
>
> *In addition to the limitations mentioned in the study, analyses performed by the European Medicines Agency on the batches reported in suspected AR cases did not reveal an increased risk of side effects for specific* batches."[114]

100. The European Commission further reiterated that each batch is subjected to rigorous quality testing before being released into the EU market. Each batch is first carefully tested by the manufacturer. And then the national competent authority conducts an additional independent check, called the Official Control Authority Batch Release Test:

> *"As for any other medicinal products authorized in the EU, once a COVID- 19 vaccine has received approval, each vaccine batch can only be released following quality control testing to confirm that the product is in line with the specifications that were approved as part of the respective marketing authorization.*
>
> *This control is carried out by the manufacturer. However, for most centrally authorised vaccines, the EU legislation requires that a Member* State *Official Medicines Control Laboratory performs an additional independent control for each batch before it is put on the EU market.*
>
> *This independent control is referred* /o *as Official Control Authority Batch Release testing and includes testing of agreed quality parameters and a compliance check of the manufacturer's own* lest results. "[115]

101. As mentioned in the MEP's question, both vaccine manufacturers and regulators are extremely strict when it comes to ensuring consistently high production quality

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113 Subpoena, No. 248, citing production 83, first document.

114 EU Parliament, *Answer given by Ms. Kyriakides on behalf ot the European* , 3 July 2023 (Bourla-50), accessible atwww.europarl.europa.eu/doceo/document/E-9-2023- 001537-ASW_EN.html

115 EU Parliament, *Answer given by Me Kyriakides on behalf of the European Commission,* 3 July 2023 (Bourla-50), accessible atwww.europarl.europa.eu/doceo/document/E-9-2023-001537-ASW_EN.html; see also EMA, *COVID-19 vaccines: development, evaluation, approval and monitoring* (Bourla-51), accessible atwww.ema.europa.eu/en/human-regulatory- overview/public-health-threats/coronavirus-disease-covid-19/covid-19-public-health- emergency-international-concern-2020-23/covid-19-vaccines-development-evaluation-approval-and-monitoring

of vaccines. In one situation, for example, 1.6 million doses were recalled by Moderna because a foreign substance was found in only 39 doses.[116]

102. In addition, the data and methodology used for Hansen's report are seriously flawed, as a representative of the Danish national competent authority - the Danish Serum Institute - pointed out in a letter sent in. That letter explains that Hansen's report does not take into account the fact that some of the batches he examined were not used (or were used very infrequently), while those batches logically had no or very few reports of suspected side effects. This makes the various batches studied incomparable. Moreover, when the first batches were administered, practitioners were encouraged to report all suspected side effects; however, later in the pandemic, authorities no longer encouraged the reporting of minor side effects. As explained in the letter from the representative of the Danish Serum Institute, Hansen's report does not take this into account either. Again, the study cannot offer meaningful insights into the variability of batches.[117]

103. At the same time, the Danish Serum Institute has not recalled any batches of Comirnaty, as Hansen confirms in his report. Indeed, no batches of Comirnaty have been recalled for safety reasons anywhere in the EU or worldwide. This in itself is enough to allay any meaningful concerns about the quality of individual batches.

104. In short, the claims of et al. regarding alleged variations in quality of different batches of Comirnaty are irrelevant and incorrect.

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[116] Production 83, first document.

[117] The letter is from Anders Hviid, received June 20, 2023 and accepted July 9, 2023. See Hviid, A., *Inaccurate representation of shipped vaccines as administered,* June 20, 2023 (Bourla- 52), accessed via factreview. gr/wp-content/uploads/2023/07/Eur-J-Clin-Investigation-2023- Hviid-Inaccurate-representation-of-shipped-vaccines-as-administered.pdf

Incorrect statements about the relationship with the European **Committee**

105. et al. make a number of unsupported and incorrect statements about the contractual relationship between Pfizer and the European Commission with respect to Comirnaty."[8] et al. also failed to explain what relevance this would have to their claims.

106. et al. claim that the European Commission bought Comirnaty for EUR 71 billion. This is incorrect. This amount represents the value of EU orders for vaccines from eight manufacturers. Moreover, this amount includes purchase options that have not been lifted and that see almost half of the 4.6 billion doses that have been purchased."[9]

et al. also argue that EU member states are jointly and severally liable as guarantors for this alleged payment. This is also incorrect. Finally, they argue
et al. that the EU, represented by the European Commission, did not pay Pfizer for the vaccines. That, too, is false.

Comirnaty is not a gene therapy

107. et al. repeatedly state that Comirnaty is *"gene therapy based."*[120] They do not substantiate this contention. Moreover, this contention is incorrect.

108. The term gene therapy has a defined and established meaning under EU law. Annex I of Directive 2001/83/EC defines a *"gene therapy medicinal product"* as follows:

> *"(a) the medicinal product contains an active stoi which consists wholly or partly of recombinant nucleic acid used in" or administered to human beings for the purpose of regulating, repairing,* le *replacing,* le *adding or* le *removing a genetic sequence;*
>
> *(b) the therapeutic, prophylactic, or diagnostic effect of the drug is directly related to the contained*

"" Subpoena, nos. 165 et seq.

"' ECA, *Special report, EU GOVID-19 vaccine procurement." Surficient doses secured after initial challen es but performance of the process not sufficiently assessed* 2022 (Bourla-53) findable via Nw .eca.europa.eu/Lists/ECADocuments/SR22 19/SR_EU_COVID_vaccine_procurement_E :f

120 o/w summons, nos. 131 et seq., no. 169.

recombinant nuclei "nucleic acid sequence or with the genetic expression product of that sequence.

Vaccines te0en infectious diseases are not drugs for oentheraDie."
(emphasis added by attorney)

109. Comirnaty does not fall under this because it does not - and cannot - regulate, repair, replace, add or remove the gene sequence of vaccinees. The mRNA in the vaccine does not enter the cell nucleus, where the human genome, that is, DNA, is located. Instead, the mRNA is rapidly degraded by the body of the vaccinated person.[121] Moreover, the definition explicitly excludes vaccines against infectious diseases.

4 E.A. HAVE **NO SINGLE ELEMENT** OF ONE TORT **ESTABLISHED**

110. e.a. ask your court to assess the damages.[122] This means that in these proceedings it must be established that Bourla acted imputably unlawfully towards e.a. and that it is plausible that the latter may have suffered damages as a result.

111. None of these requirements were met. Bourla did e.a. not misled, late intentionally. Comirnaty, incidentally, like the other COVID-19 vaccines, was developed during the usual careful process and meets regulatory standards for safety, efficacy and manufacturing quality (see section 3.2).

112. To the extent that the contentions of et al. would amount to (derivative) liability of Bourla in his capacity as CEO of Pfizer, any relevant assertion of alleged liability of Pfizer is lacking. That is where these claims already . To the extent Bourla is sued in other capacities by e.a., Bourla raises defenses below.

"" See, for example, Reuters, *mRNA vaccines are dislinct from gene therapy,* Aug. 10, 2021 (Bourla-54), accessed at www.reuters.com/article/idUSL1N2PH16N.
For the claim of et al.

4.1 No unlawful conduct

4.1.1 No torture or cruel, inhuman or degrading treatment or punishment under Article 7 ICCPR

113. Bourla understands the contentions of et al. on Article 7 ICCPR to mean that only the State would have violated it. Namely, the State would have tortured its citizens, or subjected them to cruel, inhuman or degrading treatment or punishment, by subjecting them to continuous medical and scientific (behavioral) experimentation.[12]* Despite the fact that Bourla is apparently not challenged by et al. apparently does not allege a violation of Article 7 ICCPR, he wishes to make the following observations in this regard.

114. Comirnaty does not qualify as a medical or scientific experiment.[1]*[4] Although the development process has been accelerated, the vaccine has passed all regular development and testing stages, including those of clinical trials. Moreover, the vaccine was only marketed after the granting of a conditional approval by the European Commission in December 2020.'*[5] The term *"conditional* approval" could lead to misunderstandings, but means nothing other than that the vaccine meets all requirements in terms of safety, efficacy and manufacturing quality, but that additional data still need to be provided (see marginal numbers 19-20 and 50-55).[1]*[6]

115. Nor has there been torture or inhuman or degrading treatment or punishment. The government has given its citizens the opportunity to I get vaccinated. There is no question of violence, there is no question of deprivation of liberty and e.a. have had the choice of whether or not to Ibe vaccinated against COVID-19.

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[123] Subpoena, nos. 254-255.
See thus also Rb. Den Haag March 5, 2021, ECLI:NL:RBDHA:2021 :1920, r.o. 4.7 jo. 4.5 and affirmed on appeal by Hof Den Haag June 22, 2021, ECLI:NL:GHDHA:2021:1094, r.o. 5.6.

[125] In October 2022, the conditional marketing authorization granted to Comirnaty was converted to a standard marketing authorization; see No. 33 above.

'*" See also CBG-MEB, *Column "On medicj "ns. Coronavaccines experimental?",* June 2, 2021 (Bourla-55), accessed atwww.cbg-meb.nl/actueel/nieuws/2021/06/02/column-over-medicines-coronavaccines-experimental.

4.1.2 No violation of a legal obligation

Article 97a Sr - seeking support abroad for revolution

116. et al. apparently argue that Bourla, like the other defendants, had the intent to support Schwab's and WEF's alleged interests in The Great Reset.[127] In doing so, he is alleged to have violated Article 97a Sr.*[28] That misses the point.

117. Article 97a Sr seeks to protect the Dutch constitutional form of government and the order of succession to the throne from unlawful alteration or destruction.'[2] Why there would be such an alteration, what Bourla's role in it would be, and why violation of this provision would provide a basis for compensation for allegedly suffered damages as a result of a COVID-19 vaccine, have et al. not explained at all.

Article 300 Sr - simple assault

118. et al. further argue that Bourla is guilty of assault within the meaning of section 300 Sr.[130] That is incorrect.

119. Maltreatment consists of the intentional infliction of bodily pain or bodily injury without justification.[131] Maltreatment presupposes the unlawfulness of the conduct. As previously explained, Comirnaty complied with regulatory standards for safety, efficacy and manufacturing quality (Section 3.2) and the purpose and effects of the vaccine were consistently and transparently communicated to the general public (Section 3.3.2). et al. additionally consented to their vaccination to the extent that they were indeed vaccinated

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'*' See also supra note 6.'*®
Subpoena, nos. 58-59 jo. 155.

'*'' Van der Woude, *T& C Criminal Law,* Commentary on Article 97a Sr, at 1 (online, updated tim Aug. 1, 2023). See also article 80bis Sr which shows that *"revolution"* means *"destroying or unlawfully changing the constitutional form of government or the order of succession to the throne."*

130 Subpoena, no. 277.
C.P.M. Cleiren, in: 7&C *Criminal Law,* art. 300 Sr, annotations. 1 and 9 (online, updated tim Aug. 1, 2023).

are. With that, administering a vaccine also does not qualify as mistreatment in a general sense.

120. Even if the administration of COVID-19 vaccinations were to qualify as mistreatment *(quod non),* this action cannot be imputed to Bourla. Bourla himself did not administer COVID-19 vaccinations. For that matter,
in any case, have not been mistreated within the meaning of Article 300 Sr, since they have already said that they have had no complaints from the vaccinations."[32]

Article 308 Sr - serious bodily /e/se/ *through fault*

121. et al. argue that Bourla would be guilty of causing grievous bodily harm to within the meaning of section 308 Sr.[133] That too is incorrect. Even if they had a medical condition (read: Parkinson's or a TIA), they have not substantiated that it was caused by Bourla's actions (see further section 4.3 on causation), or at least that it was due to his fault.

Article 3 SMO - genocide

122. et al. further argue that it is *"plausible"* that Bourla (and the other defendants) are guilty of violating Section 3(1)(b) and (c) of the International Crimes Act.[134] This is hogwash and, moreover, not explained in detail.

4.1.3 No acting contrary to what is required by unwritten law in the public interest

123. et al. further argue that the pharmaceutical industry collaborated in the implementation of The Great Reset and the widespread deception of citizens required for it, thereby grossly violating their trust. This behavior

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132 They suffered no material harm (see section 4.2.2). The intangible harm allegedly suffered is apparently due only to the alleged deception and not to the vaccinations themselves, and ignorance of the exact consequences of the vaccinations is not a harm (see marginal 134). Subpoena, no. 278.

133 Subpoena, no. 280-281.

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would contravene what is proper under unwritten law in society.[135] Why Bourla can be blamed for the actions of the entire "pharmaceutical industry" is not explained. For this reason alone, the claims of et al. should be dismissed on this ground.

124. Nor, for that matter, is there any unlawful conduct. As mentioned earlier, the e.a. assume a conspiracy theory surrounding The Great Reset (see margin number 6) that is not based on any truth. Moreover, neither Bourla nor the pharmaceutical industry has been guilty of deception. See paragraphs 3.2-3.3, which explain, among other things, that Comirnaty has been extensively tested and found to be safe and effective.

4.2 No damage

125. For referral to the damages state procedure, the possibility of damage must be plausible (and the basis for liability must be).[136] At first glance, that does not sound like a heavy threshold. However, Tjong Tjin Tai makes it clear that the threshold should not too low either. The extent of the damage does not yet have to entirely clear, but it must be clear that damage has been suffered.[13]* That threshold is not met by the parties. et al. do not.

4.2.1 Graphene oxide is not part of COVID-19 vaccines

126. et al. claim to have been injected by the COVID-19 vaccines with *"the toxic graphene oxide,"* which would be *"plausible"* to cause permanent adverse health consequences in humans.[13] This alone would make it plausible that et al suffer harm. This contention of et al, however, is incorrect. As explained in Section 3.3.3, COVID-19 vaccinations do not contain graphene oxide.

'3' Subpoena, no. 284.
'3" See also subpoena, no. 268.
'^' T.F.E. Tjong Tjin Tai, *The damages state procedure,* Deventer: Kluwer 2012, no. 422-423. '*" Subpoena, no. 265.

4.2.2 et al. **do not satisfy their burden of proof; moreover, the majority of them admit that they have not** suffered **material damage** [139]

127. Two of the six claimants claim to have suffered serious physical injuries.[140] The other four claimants claim not to have suffered serious physical injuries, but would have minor complaints.*[41] It would also be plausible that the health of

plaintiffs would suffer long-term under the COVID-19 injections. \(4)2

128. What the serious physical injuries, minor complaints and long-term effects consist of was not stated. Only bare reference has been made to production 91, which allegedly *"diagnoses"* by *"medical specialists*." However, those *"diagnoses"* cannot be considered neutral, objective, reliable and expert and should therefore be disregarded.

Statements by Van Walraven

129. Production 91 contains seven statements by company physician A.H. van Walraven ("Van Walraven"), which are substantially identical.[143]

130. Van Walraven, in his *"diagnoses,"* does not hesitate to also air his own opinions about COVID-19 vaccinations and government policies pursued and apparently adheres to the same theories as e.a.'[44] For example, he says that e.a. feel *rightly* misled by the , suggests that the government does not have the best interests of its people at heart, that there was never an emergency, and that the mortality rate of corona compliant influenza would have been and this rate in itself does not justify any action taken by the government. Such passages do not belong

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13 e.a. baseren deze vordering kennical on article 6:106 sub b BW.
9 (according to the "diagnosis" in production 91).
140
141 Dagvaarding, nr. 265.
143 The ones from are even completely identical.
144 See eventuee oo e an es an aven to all physicians in the Netherlands; available at www.youtube.com/watch?v=sOpflZOaqmU

at home in medical statements and are in themselves sufficient grounds for their disregard.

131. In addition, Van Walraven's contentions are insufficient both medically and legally to causation. First, Van Walraven lumps correlation and causation together very simply. As a doctor, he should know better.It follows from Van Walraven's *"diagnoses"* that Parkinson's would have suffered and a TIA. According to Van Walraven, these illnesses can be attributed to the COVID-19 vaccination because (i) the symptoms arose (shortly) after the vaccination (in the situation of and (ii) other causes have not been found (in the situations of For has not been stated at all that his symptoms *after* COVID-19 vaccination. Nevertheless, Van Walraven concludes with regard of that thereis *"a vaccine biy effect until proven otherwise."* This is incorrect - and only leads to devalidation of all the contentions taken by Van Walraven. The assertion that the complaints arose shortly after the vaccinations is merely an entry requirement, but not a substantiation of the claim that the alleged complaints arose *from* the vaccination.[145] Bourla disputes this. Second, Van Walraven's statements are mostly not (further) substantiated and therefore unverifiable. See for example the statement with respect to that no other causes were found and the statements with respect to about the negative family anamnesis and the rapid course. Incidentally, no causes can often be found for such syndromes, so the mere lack of a *"other"* cause is in no way an indication that the syndromes were therefore by a vaccine.

132. Furthermore, Van Walraven appears incompetent regarding the side effects of Comirnaty. He points out that Parkinson's and clotting problems including TIAs are on the side effect list of the

[145] This is also a well-known fallacy: *post hoc ergo propter hoc*.

vaccines are listed, but that is incorrect, according to side effect lists published on the EMA and Lareb websites."[46]

133. By the way, even if a side effect were on the side effect list, it is not necessarily true that the vaccine causes that side effect. And even if it can be shown that an adverse reaction is caused by the vaccine, that still does not lead to liability if the vaccine meets prescribed safety standards and is not defective. Safety is not an absolute concept, especially with drugs, since they always carry both risks and benefits and are expressly authorized based on evidence that the relationship between them is favorable. Comirnaty meets the applicable safety standards. This is evidenced by the granting of the marketing authorization after the EMA confirmed that the benefit-risk balance of Comirnaty was favorable, and by post-authorization pharmacovigilance. et al. did not argue against this: they neither claimed, nor explained, that the allegedly administered vaccines were defective in any way.

4.2.3 Alleged intangible damages not eligible for compensation

134. In addition to material damage, the et al. have suffered intangible damages. These would consist of (i) the mental perceived harm resulting from the deception brought about by defendants (feelings of pain, suffering, embarrassment, helplessness and uncertainty about their health) and (ii) being unaware of the exact consequences of the vaccinations.[147]

135. et al. apparently base these claims, first, on Section 6:106(b) of the Civil Code. Indeed, mental injury falls under the category of *impairment in his person in other* w'ze mentioned therein.[148]

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146 EMA, *Comirnaty product information* (selection) (Bourla-38), accessible viawww.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_nl.pdf and LAREB, respectively, *Bywerkingen corona vaccines* (Bourla-56), accessible at www.lareb.nl/bijwerkingen-coronavaccins#pfizer

147 Subpoena, no. 266.

148 S.D. Lindenbergh, in: *T& C BW,* Art. 6:106 BW, infra. 3 (online, updated through September 1, 2023).

136. The legislative history shows that mental injury must be *"sufficiently serious"* to be eligible for compensation.[14] More or less strong psychological discomfort is insufficient, which is also established case law.[1 0] For this reason alone, the claims of et al. should be rejected. Moreover, the Supreme Court has held that a person who relies on *"impairment of his person in another manner"* will have to adduce sufficiently concrete facts from which it can follow that, in connection with the circumstances of the case, psychological damage has occurred, which requires that the existence of mental injury can be established according to objective standards."[51] et al. failed to do so. The bare assertion that they experienced mental harm and were unaware of the exact consequences of the vaccinations is insufficient for this purpose. Insofar as

et al. would also refer to production 91 in the context of immaterial damages, Bourla refers to marginal number 128 et seq. which explained that these statements are not neutral, objective, reliable and expert.

137. et al. secondly apparently invoke Section 6:106(a) of the Civil Code. They argue that *they have "substantiated //e/ that bj" the defendants had the intention to* inflict *damage on them*.[152]

et al. have nowhere stated this, let alone substantiated it. This assertion is unsubstantiated and incorrect.[153] Third, the et al. to article 6:106 sub c of the Civil Code and argue that some plaintiffs are married.[154] The relevance is not clear from the summons.

'°" Parl. Gesch. Civil Code Book 6 1981 p. 389 (EV I).

"° S.D. Lindenbergh, "Compensation for stress, frustration, annoyance and (other) discomfort? On the concept of 'personal impairment' beyond physical and mental injury," *NTBR* 2019/20, pp. 122-130, p. 124, citing HR 13 January 1995, *NJ* 1997/366, m.nt. C.J.H. Brunner *(Ontvanger/B.)* and HR February 21, 1997, *NJ* 1999/145, m.nt. C.J.H. Brunner *(Wrongful birth)*.

t 51 HR March 15, 2019, ECLI:NL: HR:2019:376, *NJ* 2019/162 *EBS.*

152 Dagvaarding, no. 267.

153 [redacted] et al. also fail to recognize with this argument that the intention must have been aimed at specifically inflicting *immaterial* damage. The mere circumstance that someone intentionally created a situation - which incidentally is not the case - as a result of which harm other than pecuniary damage was inflicted, cannot carry the conclusion that this person had the intention to inflict such harm. (See HR 26 May 2020, ECLI:NL:HR:2020:868, /VJ 2020/231, r.o. 2.3.2-2.4. See thus also S.D. Lindenbergh, in: *T& C BW,* art. 6:106 BW, ann. 2 (online, updated through September 1, 2023)). The scope of application of this provision is therefore limited in practice.
Subpoena, No. 267.

4.3 No causal relationship

138. et al. did not argue that:

(a) they have Comirnaty once or more often;[15]"

(b) they would not have taken those vaccinations without the alleged deception (read: what information guided them in taking the vaccines);

(c) Comirnaty may lead to the alleged injury suffered (generic causation); and

(d) Comirnaty at et al. led to the alleged injury (specific causation).

139. Bourla again points out that Van Walraven's assertions are both medically and legally insufficient to assume (specific) causation (see margin numbers 128 and further) and the assertions that Van Walraven is apparently willing to take also incidentally makes probative value of his statements very low to nil.

140. Nor is the allegedly suffered intangible harm - which, as explained, is not at all a harm (see section 4.2.3) - causally related to Comirnaty or any of the other COVID-19 vaccines. et al. have no contentions in this regard. Moreover, it is well known that psychological symptoms can also be - and indeed have been widely caused by the corona crisis, rather than by the corona vaccines [156]

"5 With the exception of
See, for example, Trim os ns uu *ort sustained corona crisis leads to increase in mental health complaints and* need for *perspective,* Feb. 25, 2021 (Bourla-57), accessed atwww.trimbos.nl/actueel/nieuws/voortdurende-coronacrisis-leidt-tot-toename-psychische-complaints-and-need-for-perspective/#:-:text=health%20of%20volwassenen.-,Increase%20psychic%20klachten,year%20have%20the%20most%20klachten and Nederlands Jeugdinstituut, *Research on corona and mental wellbeing* (Bourla-58), accessed through www.nji.nl/coronavirus/onderzoek-naar-corona-en-mentaal-welbevinden

4.4 No **group liability** (Article 6:166 BW)

141. The alleged claims brought on the basis of Article 6:166 DCC also fail. For a successful reliance on Section 6:166 DCC, the e.a. must state and prove:

(a) That Bourla participated in;

(b) behaviors in groups;

(c) from which the likelihood of harm thus inflicted should have deterred the participants;

(d) that his participation in such conduct can be imputed to him; and

(e) That one of the participants in that conduct unlawfully harmed the injured party.[157]

142. As explained, Bourla did not act unlawfully (see section 4.1). The same is true of the other defendants. Bourla and the other defendants have et al. also caused no damage (see Section 4.2). For that reason alone, Bourla cannot be held (jointly and severally) liable pursuant to Section 6:166 of the Dutch Civil Code either.

5 BURDEN OF PROOF AND OFFER OF PROOF

143. In support of the grounds of his defense, Bourla has the following evidence:

Number	**Description**
Bourla-1	WHO, *WHO Director-General's opening remarks at the media briefing on COVID- 19 ,* 11 March 2020
Bourla-2	EMA, *COVID- 19 medicines*
Bourla-3	WHO, *Statement on the fifteenth meeting of the IHR (2005),* May *5*, 2023
Bourla-4	The Lancet, *Global impact of the first year of COVID- 19,* June 23, 2022
Bourla-5	EMA, *Conditional marketing authorization*
Bourla-6	EMA, *Good pharmacovigilance practices*.
Bourla-7	EMA, *Comirnaty risk management plan,* October 2023 (selection)
Bourla-8	EMA, Periodic safety update reports (PSURs)

[157] R.J.B. Boonekamp, *Stelplichl & Bewijslast,* Commentary on Art. 6:166 BW online, updated Oct. 2, 2017).

Bourla-9	EMA, *COVID-19 vaccines development, evaluation, approval and monitoring*
Bourla-10	Pfizer, *Pfizer Outlines Five-Point Plan to Battle COVID-19,* March 13, 2020
Bourla-11	Pfizer, *Pfizer and BioNTech to Co-Develop Potential COVID-19 Vaccine,* March 17, 2020
Bourla-12	Pfizer, *Pfizer and BioNTech Announce Further Details on Collaboration to Accelerate,* April 9, 2020
Bourla-13	ClinicalTrials.gov, *A Trial Investigating the Safety and Effects of Four BNT162 Vaccines Against COVID-2019 in Healthy and Immunocompromised Adults,* Jan. 13, 2022
Bourla-14	ClinicalTrials.gov, *Study to Describe the Safety, Tolerability, Immunogenicity [... j,* Feb. 28, 2023
Bourla-15	EMA, *Comirnaty Assessment report,* Feb. 19, 2021
Bourla-16	EMA, *EMA starts second rolling review of a COVID-19 vaccine,* Oct. 6, 2020
Bourla-17	OJEU, Dec. 24, 2020
Bourla-18	EMA, *Pharmacovigilance Plan of the EU Regulatory Network for COVID-19 Vaccines*
Bourla-19	Watson 0. et al, *Global impact of the first year of COVID-19 vaccination: a mathematical modeling study,* June 23, 2022
Bourla-20	Health Council, *Opinion-COVID- 19 vaccination BioNTech-Pfizer,* 24 December 2020
Bourla-21	Lewis, L.M. et al, *The Race to Develop the Pfizer-BioNTech COVID-19 Vaccine: From the Pharmaceutical Scientists' Perspective,* September 18, 2022
Bourla-22	Institut Pasteur, *Discovery of messenger RNA in 1961,* Feb. 15, 2021
Bourla-23	BioNTech, *The History of BioNTech - The Road to a New Era of Immunotherapy*
Bourla-24	Press release *The Nobel Prize in Physiology or Medicine 2023,* Oct. 2, 2023
Bourla-25	Science News, *How CoViD-1s vaccines were made so quickly without cutting corners,* June 29, 2021
Bourla-26	Bettini, E., *SARS-CoV-2 mRNA Vaccines: Immunological Mechanism and Beyond,* 2021
Bourla-27	Wadhwa et al, *Opportunities and Challenges in the Delivery of mRNA-Based Vaccines,* January 2020
Bourla-28	EMA, *COVID- I9: how EMA fast-tracks development support and approval of medicines and vaccines,* May 4, 2020
Bourla-28	EMA, *How are COVID-19 vaccines developed*
Bourla-29	Nature, *Whither COVID-19 vaccines,* Sept. 28, 2020
Bourla-30	NBC News, *3 vaccine executives say that after approval, distribution will be the main challenge,* Dec. 3, 2020
Bourla-31	

Bourla-32 The Journal, *Pfizer CEO says there is 'encouraging' data on whether its vaccine stops Covid transmission,* Jan. 13, 2021
Bourla-33 EMA, *Comirnaty, COVID-19 mRNA vaccine (nucleoside modified),* December 21, 2020
Bourla-34 FDA, *FDA Takes Key Action in Fight Against COVID- 19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine,* December 11, 2020
Bourla-35 WHO, *Interim recommendations for use of the Pfizer-BioNTech COVID-19 vaccine,* Jan. 8, 2021
Bourla-36 Reuters, *Fact Check: Preventing transmission never required for COVID vaccines' initial approval*
Bourla-37 ECDC, *Risk of SARS-CoV-2 transmission from newly-infected individuals with documented previous infection or vaccination,* March 29, 2021
Bourla-38 EMA, *Comirnaty product information* (selection)
Bourla-39 FDA, *Pfizer-BioNTech COVID- 19 Vaccine Emergency Use Authorization Review Memorandum,* November 20, 2020
Bourla-40 Gov. UK, Summary *of the Public Assessment Report COVID- 19 Vaccine,* December 2020
Bourla-41 MIT Technology Review, *What are the ingredients of Pfizer's covid-19 vaccine,* Dec. 9, 2020
Bourla-42 EU Parliament, *Answer given by Ms. Kyriakides on behalf of the European Commission,* Oct. 26, 2021
Bourla-43 87. EU Parliament, *Answer given by Ms. Kyriakides on behalf of the European Commission,* March 8, 2022
Bourla-44 Reuters, *COVID-19 vaccines do not contain graphene oxide,* July 23,
Bourla-45 2021 AP, *Pfizer vaccine does not contain graphene oxide,* July 8, 2021
Bourla-46 EMA, *Periodic safety update report*
Bourla-47 EMA, *Comirnaty periodic safety update report assessment 19 June 2022 to 18 December 2022* (selection)
Bourla-48 EMA, Assessment report on the annual renewal of the conditional marketing authorization (Comirnaty), 2021
Bourla-49 Reuters, *Pages of suspected side effects released* a6ou/ *Pfizer's COVID-19 vaccine [...],* March 17, 2022
Bourla-50 EU Parliament, *Answer given by Ms. Kyriakides on behalf of the European Commission,* July 3, 2023
Bourla-51 EMA, *COVID- 19 vaccines. development, evaluation, approval and monitoring*
Bourla-52 Hviid, A., *Inaccurate representation of shipped vaccines as administered,* June 20, 2023
Bourla-53 ECA, *Special report, EU COVID- 19 vaccine procurement: Sufficient doses secured after initial challenges, but performance of the process not sufficiently assessed,* 2022
Bourla-54 Reuters, *mRNA vaccines are distinct from gene therapy,* Aug. 10, 2021

Bourla-55	CBG-MEB, *Column "On medicynen: Corona vaccines experimental?",* June 2, 2021
Bourla-56	LAREB, *Biywerkingen corona vaccines*
Bourla-57	Trimbos Institute, *Ongoing corona crisis leads to increase in psychological symptoms and need for perspective,* Feb. 25, 2021
Bourla-58	Netherlands Youth Institute, *Research on corona and mental well-being*

144. By the foregoing, Bourla does not wish to be deemed to have assumed any burden of proof that is not incumbent on Bourla as a matter of law.

145. Bourla takes the position that the burden of proof in these proceedings is on et al. Bourla expressly rebuttal evidence.

146. To the extent the burden of proof of any contention was, in the opinion of the court, allowed to rest on Bourla, Bourla offers proof thereof by all means in law, in particular by hearing witnesses.

ON THESE GROUNDS CONCLUDES BOURLA:

That the court by judgment, so far as legally possible enforceable on a provisional basis:

(a) et al. in their claims , or at least deny them these claims;

(b) e.a. shall jointly and severally pay the costs of the proceedings, as well as the usual subsequent costs (both without and with service of process), to be increased by the statutory interest as referred to in Section 6:119 of the Dutch Civil Code from fourteen days after the date of the judgment, the one plaintiff paying the other plaintiffs shall be released.

attorney [redacted]

This case is handled by Mr. D.C. Roessingh, T +31 20 577 1892,
M +31 6 5162 1874, E Davine.Roessingh @ debrauw.com, and mr. M.

Bredenoord-Spoek, T +31 20 577 1066, M +31 6 5043 1078, E
Marieke.Bredenoordõ debrauw.com. De Brauw Blackstone Westbroek N.V.,
P.O. Box 75084, 1070 AB Amsterdam