

District Court of the Northern Netherlands,
Leeuwarden branch Case and roll number:
C/17/190788 / HA ZA 23/172 Hearing: 21 February
2024

STATEMENT OF DEFENCE

concerning:

Albert BOURLA,
residing in Greenwich, United States of America

Defendant No. 11,
lawyers: D.C. Roessingh, LL.M., and M. Bredenoord-Spoek, LL.M.

against:

1. [REDACTED]
2. [REDACTED]
3. [REDACTED]
4. [REDACTED]
5. [REDACTED]
6. [REDACTED]
7. [REDACTED]

(collectively [REDACTED] et al.' and referred to individually by their surnames)

claimants,

DE BRAUW
BLACKSTONE
WESTBROEK

following deliberation on suspension pursuant to Article 225(2) of the Code of Civil Procedure
dated 10 January 2024.

solicitors: Mr A.G.W. van Kessel and Mr P.W.H.
Stassen

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Dr Albert Bourla (“Bourla”) submits the following in his defence.

1 INTRODUCTION

1. The SARS-CoV-2 virus (the “**Coronavirus**”) is very real. Equally real is COVID-19, the highly contagious and potentially life-threatening respiratory disease caused by the Coronavirus.
2. Shortly after its emergence, on 11 March 2020, the infection had spread to 114 countries worldwide, and the World Health Organisation (the “WHO”) declared the Coronavirus outbreak a global pandemic.* As a result of this pandemic, approximately 700 million people worldwide have been infected with COVID-19 and nearly seven million people have died.³ In the Netherlands alone, more than eight million confirmed COVID-19 infections have been recorded, resulting in more than 22,000 deaths.⁴
3. Unsurprisingly, the COVID-19 pandemic became the primary concern for governments, businesses and civil society organisations around the world almost immediately after it emerged in early 2020. Governments around the world called on pharmaceutical companies to develop a vaccine. Pfizer and BioNTech were among the first to take on this responsibility, alongside other pharmaceutical companies such as Moderna, Janssen and AstraZeneca.⁵ In the course of 2020, Pfizer conducted clinical trials and, in the same year, succeeded in obtaining conditional marketing authorisation from regulatory authorities, including those in the EU. These authorisations were granted on the basis of extensive data obtained during the clinical trials, which demonstrated that the Pfizer/BioNTech vaccine

WHO, *WHO Director-General's opening remarks at the media briefing on COVID-19*, 11 March 2020 (Bourla-1), available at www.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/nl
For a full list of COVID-19 vaccines authorised by the EMA, see EMA, *COVID-19 medicines* (Bourla-2), available at www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/coronavirus-disease-covid-19/covid-19-medicines

("Comirnaty")⁶ met the regulatory standards for safety, efficacy and manufacturing quality.

4. The devastation and loss of life caused by the pandemic were mitigated and ultimately largely overcome through a joint effort by governments, citizens, businesses and the scientific community. In particular, vaccines, including Comirnaty, contributed significantly to curbing the pandemic. On 5 May 2023, the WHO declared that the COVID-19 pandemic was officially over.⁷ Scientific analyses show that, during the first two years of the pandemic alone, the COVID-19 vaccines prevented approximately 14 to 19 million deaths worldwide.⁸
5. Nevertheless, a (fortunately small) section of the population embraced various conspiracy theories, including the idea 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 objective.
6. Unfortunately, [REDACTED] and others can be counted amongst this section of the population — as, incidentally, can GP Van Walraven, who has apparently been found willing to issue 'medical certificates' for the purposes of these proceedings. [REDACTED] et al. claim that COVID-19 is not a disease, but that this phenomenon has been fabricated as part of a project called The Great Reset, which was planned and aimed at forcing a total reorganisation of the world. According to [REDACTED] et al., 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 is said to have formed part of this project. The specific basis for these theories put forward by [REDACTED] et al. appears to be the book 'The Great

" 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), available at [www.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](https://www.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, *'Global impact of the first year of COVID-19'*, 23 June 2022 (Bourla-4), available at www.thelancet.com/action/showPdf?pii=S1473-3099%2822%2900320-6
See, inter alia, the writ of summons, nos. 2, 61–65, 117–125, 186 and 198.

‘Reset’, which outlines what the authors believe the world *might* look like after COVID-19.⁴⁰ Nothing more and nothing less. The conspiracy theory put forward by [REDACTED] et al. therefore has absolutely no factual basis.

7. In these proceedings, [REDACTED] et al. specifically allege that (i) Bourla and the other defendants deliberately and unlawfully misled them by urging the Dutch public (including [REDACTED] et al.) to get vaccinated against COVID-19, whilst they knew or ought to have known that the vaccine was neither safe nor effective, and (ii) they have suffered damage as a result.
8. These allegations are incorrect. Bourla did not mislead [REDACTED] and others, nor did he act unlawfully towards them in any other way. In reality, Bourla, in his role as CEO of Pfizer, contributed to the development of a COVID-19 vaccine that is effective and has a favourable safety profile. This makes it all the more bitter that Bourla is now being personally sued and confronted with the aforementioned allegations. The claims put forward by [REDACTED] et al. are fundamentally flawed in both procedural and substantive terms. From a procedural perspective, it is notable that the claims against the various defendants are scarcely — or, in many cases, not at all — related to one another, meaning that, under Dutch procedural law, a claim against Bourla, who is resident in the United States, cannot, in principle, be brought before a Dutch court.⁴¹ Furthermore, [REDACTED] and others have failed to fulfil their burden of proof. On the merits, the claims also have no prospect of success. [REDACTED] and others have presented the court with a jumble of allegations—some of which are incomprehensible—that are unrelated to one another and to the claim itself, unsubstantiated and incorrect. The claims of [REDACTED] et al. must therefore be dismissed.

9. In this statement of defence, Bourla will
e.a. , in so far as they are comprehensible and relate

⁴⁰ This book was co-authored by Mr Schwab, the chairman of the WEF. The WEF is an organisation dedicated to fostering 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 to Proceedings II 2021/22*, 2541, answer to question 4).
See also section 2.1 on jurisdiction.

against him, against Pfizer and/or against the qualities of Comirnaty.
The following structure is used:

- in Chapter 2, Bourla will highlight some of the most striking procedural flaws in the claims brought by Minks et al.;
- in Chapter 3, Bourla will refute the factual allegations made by [REDACTED] et al.; and
- Chapter 4 will explain why the claims have no legal basis.

2 PROCEDURAL OBSERVATIONS

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

10. The District Court of the Northern Netherlands, Leeuwarden division, lacks jurisdiction to hear the claims against Bourla. In paragraphs 296–297 of the writ of summons, [REDACTED] et al. refer only to Article 107 of the Code of Civil Procedure, which concerns internal or relative jurisdiction. [REDACTED] et al. have not explained — let alone substantiated — why and on what basis the court would have international jurisdiction over the claims against Bourla. Had they taken Article 7(1) of the Code of Civil Procedure (which provides the correct framework) into consideration, they would not have been successful. They have, in fact, come nowhere near establishing such a connection between their claims against the intended anchor defendant, Mr Hofstra, and their claims against Bourla. The District Court of the Northern Netherlands, Leeuwarden division, could therefore – following its ex officio assessment – simply declare itself to lack jurisdiction in respect of the claims against Bourla. That said, the claims brought by [REDACTED] et al. are so manifestly unfounded that Bourla will not raise a defence of lack of jurisdiction, thereby allowing the claims to be dealt with on their merits once and for all.¹²

¹² Consequently, Bourla cannot be deemed to have consented to any of the requirements for the jurisdiction of the Dutch court, such as that there is a connection between the claims against Bourla and those against the other defendants within the meaning of Article 7 of the Code of Civil Procedure.

2.2 Claims must be dismissed for lack of substantiation

11. [REDACTED] et al. should have set out the necessary facts and, where these were disputed, proved them, in order to be able to invoke the legal consequences they sought. Relying on Article 6:162 of the Dutch Civil Code, they argue that (i) they were misled; (ii) they would not have received the COVID-19 vaccine had it not been for that misrepresentation; and (iii) they have suffered damage as a result of the vaccine.
12. These submissions apparently imply that [REDACTED] et al. received a COVID-19 vaccine. In that case, one would at least have expected them to state (i) *which* vaccine they received and *when*, and (ii) that they received these vaccines as a result of the alleged misrepresentation. [REDACTED] et al. have failed to make even these basic points. For that reason alone, their claims cannot be upheld. Furthermore, there is a lack of sound arguments and proper substantiation regarding (i) the nature of the alleged misrepresentation and (iii) their alleged loss.
13. Notwithstanding the foregoing, Bourla considers that the court is nevertheless able to rule on the arguments that are actually put forward by [REDACTED] et al. Although the 65-page writ is replete with fabricated arguments that sometimes make no sense whatsoever and whose relevance is not always clear, it is clear to Bourla what [REDACTED] et al. are seeking to achieve. Bourla disputes everything set out by [REDACTED] et al. in the writ of summons, except in so far as it is apparent from this statement of defence that Bourla acknowledges the accuracy of any assertion made by [REDACTED] et al. Bourla responds as best it can to the suggestions made by [REDACTED] et al.

3 THE CLAIMS HAVE **NO FACTUAL BASIS**

14. In this chapter, we will examine the general authorisation process for vaccines in the EU (section 3.1) and the specific development of Comirnaty

¹³ Only in the case of Oudakker-Bekkers does Exhibit 91 indicate which vaccine she would have received and when.

(section 3.2) will be discussed. Subsequently, the specific claims made by [REDACTED] et al. will be refuted (section 3.3).

%0.1 General authorisation process for vaccines in the EU

%0.1.1 Obtaining a marketing authorisation

15. All Pfizer vaccines are initially developed and tested in a laboratory. If the initial tests are favourable, these are followed by clinical trials of increasing scale, including randomised controlled trials that compare the new vaccine with an existing vaccine or a placebo.¹⁴
16. The results of the development programme are submitted to the relevant competent authority, together with comprehensive pharmaceutical data relating to the manufacture of the vaccine, in support of the application for a marketing authorisation.
17. At European level, the European Commission decides on the granting of a marketing authorisation, following 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, following a thorough review, the EMA concludes that the balance of benefits and risks associated with the use of the vaccine is favourable, it may decide to grant a marketing authorisation for the product. The vaccine and the approved product information for healthcare professionals and vaccine recipients will then become available on the market.
19. That marketing authorisation may also be granted on a conditional basis, for example in emergency situations relating to a public health threat identified by the World Health Organisation

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

¹⁵ The legal framework for the authorisation, manufacture and distribution of medicinal products in the EU is primarily 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 authorisation 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 1 of Regulation (EC) No 507/2006 provides as follows:

“A conditional marketing authorisation may be granted where the Committee determines that, although complete clinical data on the safety and efficacy of the medicinal product have not been provided, all the following requirements are met:

- a) the benefit-risk balance of the medicinal product, as defined in Article 1(28a) of Directive 2001/83/EC, is favourable,*
- b) it is likely that the applicant will be able to provide complete clinical data;*
- c) unmet medical needs are addressed;*
- d) the public health benefits of the immediate availability of the medicinal product on the market outweigh the risk associated with the fact that additional data still needs to be provided.”*

20. The EMA confirms that the conditional marketing authorisation is a pragmatic tool for the authorisation of a medicinal product that meets an unmet medical need.” Early authorisation via a conditional marketing authorisation does not detract from the guarantees that the medicinal product meets the strict EU standards for safety, efficacy and quality, and that comprehensive data will continue to be generated following authorisation. Additional information may, *however*, be provided, such as on safety in specific groups, for example children and pregnant women. A conditional marketing authorisation is valid for one year and may subsequently be renewed annually. Once comprehensive clinical data have been submitted, the CHMP may recommend converting the conditional marketing authorisation into a standard marketing authorisation.

¹⁶ Commission Regulation (EC) No 507/2006 provides for the granting of a “conditional marketing authorisation” for certain medicinal products falling within the scope of Regulation (EC) No 726/2004.

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

%0.1.2 Post-authorisation pharmacovigilance

21. The safety profile of a medicinal product cannot be fully established during pre-authorisation development. In particular, it is possible that very rare adverse reactions may not be identified even in large clinical trials. In order to identify new safety information as quickly as possible, advanced pharmacovigilance procedures are therefore implemented for all medicinal products after they have been placed on the market.¹⁸
22. A draft risk management plan (an 'RMP') is submitted with every application for a marketing authorisation in the EU. Once approved, the RMP forms part of the marketing authorisation. An RMP may also include additional pharmacovigilance activities that constitute conditions of the marketing authorisation.¹
23. Routine pharmacovigilance activities require the marketing authorisation holder to record and report any adverse reactions of which they become aware to the competent regulatory authorities.²⁰ Where reports of suspected adverse reactions result in a confirmed safety signal, this leads to appropriate action, including the updating of product information, as approved by the regulatory authorities.

The main EU legislation relating to marketing authorisation holders' pharmacovigilance obligations is Directive 2001/83/EC, Regulation (EC) No 726/2004 and Commission Implementing Regulation (EU) No 520/2012. The EU legislation is supplemented by detailed guidelines issued by the EMA in collaboration with the heads of the medicines authorities on good pharmacovigilance practices for both regulators and industry. See EMA, *Good pharmacovigilance practices* (Bourla-6), available via ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/good-pharmacovigilance-practices

See EMA, *Comirnaty risk management plan*, October 2023 (excerpt) (Bourla-7) for the current version of the Comirnaty RMP. Available, as updated from time to time, at ema.europa.eu/en/documents/rmp-summary/comirnaty-epar-risk-management-plan_en.pdf. For further information, see EMA, Periodic Safety Update Reports (PSURs) (Bourla-8), available at ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/periodic-safety-update-reports-psurs#:-text=PSURs%20are%20pharmacovigilance%20documents%20intended,time%20points%20after%20its%20authorisation

%0.2 Development, authorisation and pharmacovigilance of Comirnaty and other COVID-19 vaccines

24. The procedure outlined above was followed in the development, authorisation and pharmacovigilance of Comirnaty. To the best of Bourla's knowledge, based on publicly available information, the same applies to COVID-19 vaccines produced by other manufacturers.²¹

%0.2.1 Clinical trials (prior to authorisation)

25. On 13 March 2020, Pfizer issued a statement calling on the biopharmaceutical industry to work together in the fight against COVID-19. In that statement, Pfizer had already referred to its contact with BioNTech regarding the development of a potential mRNA vaccine against the coronavirus.²² A formal letter of intent between the two parties was announced on 17 March 2020.²³ On 9 April 2020, they provided further details of their collaboration, including their intention to commence clinical trials of vaccine candidates by the end of April 2020, subject to regulatory approval.²⁴
26. On 23 April 2020, a study was launched to select vaccine candidates based on dosage. This resulted in the selection of one of the four vaccine candidates, BNT162b2 (Comirnaty), administered in a two-dose regimen of 30 micrograms.²⁵
27. The efficacy and safety of BNT162b2 were subsequently investigated in a large clinical trial conducted in the

²¹ EMA, *COVID-19 vaccines development, evaluation, approval and monitoring* (Bourla-9), available via 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

²² Pfizer, *'Pfizer Outlines Five-Point Plan to Battle COVID-19'*, 13 March 2020 (Bourla-10), available at www.pfizer.com/news/press-release/press-release-detail/pfizer-outlines-five-point-plan-battle-COVID-19

²³ Pfizer, *Pfizer and BioNTech to Co-Develop Potential COVID-19 Vaccine*, 17 March 2020 (Bourla-11), available at investors.pfizer.com/Investors/News/news-details/2020/Pfizer-and-BioNTech-to-Co-Develop-Potential-COVID-19-Vaccine-17-March-2020/default.aspx

²⁴ Pfizer, *Pfizer and BioNTech Announce Further Details on Collaboration to Accelerate*, 9 April 2020 (Bourla-12), available at www.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-19 in Healthy and Immunocompromised Adults*, 13 January 2022 (Bourla-13), available at clinicaltrials.gov/ct2/show/study/NCT04380701

The United States, Germany, South Africa, Turkey, Argentina and Brazil.*⁶ Nearly 44,000 people took part in this trial, of whom approximately 50 per cent received Comirnaty and approximately 50 per cent received a placebo.*⁷ The results showed that the vaccine's efficacy against a laboratory-confirmed symptomatic COVID-19 infection — which occurred at least seven days after the second dose, and with no evidence of a previous COVID-19 infection — was 95 per cent in individuals aged 16 years or older (with eight cases of COVID-19 in the vaccine group compared with 162 cases of COVID-19 in the placebo group).*

28. Of the nearly 44,000 enrolled participants recorded in the safety database as at the data cut-off date (14 November 2020), the proportion who were withdrawn due to adverse reactions was very small (0.2% in the vaccine group and 0.1% in the placebo group).² There were no reported deaths among trial participants that were considered to be related to the vaccine.³⁰

%0.2.2Authorisation

29. During the COVID-19 pandemic, various mechanisms available to the EMA were utilised to accelerate the regulatory assessment of medicines in the context of public health crises. These included:
 - the procedure under Regulation (EC) No 726/2004, which provides for a regulatory assessment with a 150-day deadline for issuing an opinion following receipt of a

Study C4591001; see ClinicalTrials.gov, *Study to Describe the Safety, Tolerability, Immunogenicity* [...], 28 February 2023 (Bourla-14), available at clinicaltrials.gov/ct2/show/NCT04368728

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

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

²⁹ EMA, *Comirnaty Assessment Report*, 19 February 2021 (Bourla-15), available at ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf, p. 94 ff.

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

an application for a marketing authorisation, rather than the 210 days the EMA is usually given;

- a 'rolling review' whereby the EMA can assess clinical trial data as it becomes available and before a formal application for a marketing authorisation has been submitted; and
- the establishment of a task force by the EMA to ensure a rapid and coordinated response to the pandemic.³¹

30. These fast-track procedures do not alter the substantive product requirements or the established assessment principles, but are designed to organise the product assessment in a highly efficient manner, within timeframes appropriate to the specific situation.
31. The first data on Comirnaty were submitted to the EMA by BioNTech on 5 October 2020 as part of the rolling review process, followed by the formal application for a marketing authorisation on 30 November 2020.^{*Z}
32. The CHMP carried out a rigorous evaluation of the pharmaceutical, pre-clinical and clinical data on Comirnaty and concluded that the available data on the quality, safety and efficacy of Comirnaty demonstrated that the balance of benefits and risks was favourable.³³
33. Following the CHMP's positive opinion, the European Commission granted a conditional marketing authorisation for Comirnaty on 21 December 2020.³⁴ The conditional marketing authorisation was extended by the European Commission on 3 November 2021 and converted into a standard marketing authorisation on 10 October 2022, following the conclusion that all

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

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

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

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

the specific obligations imposed when the conditional authorisation was originally granted had been met or had been reclassified, and that there were no longer any grounds for maintaining the conditional nature of the authorisation.³⁵

%0.2.3 Additional pharmacovigilance for COVID-19 vaccines

34. In view of the exceptional circumstances surrounding 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 for pharmacovigilance”).³⁶ The EMA plan for pharmacovigilance included the active collection of data on rare potential risks, rapid assessment of new safety information, rapid evaluation of safety issues that could influence the benefit-risk balance, active monitoring of vulnerable groups, and rapid communication of new safety information. In addition to the application of existing procedures, the EMA’s pharmacovigilance plan stipulated that marketing authorisation holders were required to submit monthly summary safety reports and periodic safety update reports, containing information on reported adverse reactions, adverse events of special interest and sales data. EU Member States were tasked with collecting data on exposure to the vaccines, which was to be used for the interpretation of the safety data.³⁷
35. The suspected adverse reactions have been recorded, investigated and reported to the relevant regulatory authorities, including the EMA and the Dutch Ministry of Health, Welfare and

³⁵ OJEU, 24 December 2020 (Bourla-17), available at eur-lex.europa.eu/legal-content/NL/TXT/PDF/?uri=OJ:C:2022:457:FULL, p. 3.

³⁶ See EMA, *Pharmacovigilance Plan of the EU Regulatory Network for COVID-19 Vaccines* (Bourla-18), available at ema.europa.eu/en/documents/other/pharmacovigilance-plan-eu-regulatory-network-covid-19-vaccines_en.pdf

³⁷ See EMA, *Pharmacovigilance Plan of the EU Regulatory Network for COVID-19 Vaccines* (Bourla-18), available at ema.europa.eu/en/documents/other/pharmacovigilance-plan-eu-regulatory-network-covid-19-vaccines_en.pdf, p. 3, point 5.3.

Sport, in accordance with the applicable pharmacovigilance requirements. Such data have been independently analysed 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 medicinal product and requires further investigation). Following investigation, appropriate measures are taken, including, if approved by the regulatory authorities, an amendment to the product information. Pfizer and BioNTech have at all times cooperated with the competent authorities and fulfilled their pharmacovigilance obligations in relation to Comirnaty.^{3®}

%0.2.4 Interim conclusion

36. Comirnaty underwent rigorous testing and regulatory assessments before it was introduced in the EU. The outcome of this assessment was clear: Comirnaty was found to be highly effective (95%) in preventing symptomatic COVID-19 infections. Scientific research suggests that COVID-19 vaccines, including Comirnaty, have prevented nearly 20 million deaths from COVID-19 worldwide, which, on a proportional basis, would translate to approximately 44,500 lives saved in the Netherlands alone.³
37. Since its market launch, the efficacy, safety and manufacturing quality of Comirnaty have been closely monitored by both Pfizer and the relevant regulatory authorities. These ongoing assessments continue to confirm that Comirnaty, as updated to take account of coronavirus variants, meets all legal requirements, including those relating to safety: Comirnaty was found to cause few side effects, which were generally mild and short-lived.^{4⁰} The

[^] See also section 3.3.4.

^{'''} Watson O. et al., 'Global impact of the first year of COVID-19 vaccination: a mathematical modelling study', 23 June 2022 (Bourla-19), available at <https://www.thelancet.com/action/showPdf?pii=S1473-3099%2822%2900320-6>

^{o''} 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 tend to improve within a few days after vaccination. These include pain and swelling at the injection site, tiredness, headache, muscle and joint pain, chills, fever and diarrhoea."

The health benefits of the vaccination therefore outweighed the side effects.⁴¹

%0.3 The argument put forward by █████ et al. is a collection of conspiracy theories and falsehoods already established as such, disguised as facts

38. █████ et al. ignore the fact that new infectious diseases emerge from time to time and that measures may need to be taken to save lives. Instead, █████ et al. claim that the phenomenon which dominated almost everyone's lives for at least two years – the coronavirus – was not real.

39. In an attempt to explain these measures, █████ et al. put forward vague and far-fetched conspiracy theories allegedly involving NGOs, governments, the media, international organisations and companies. In this section, Bourla will address the factual claims made by █████ et al. Bourla reiterates that claims described as incomprehensible or not directly addressed must be regarded as disputed.

%0.3.1 Misrepresentation of the development process of Comirnaty

40. Essentially, █████ et al. appear to argue that Pfizer began testing a coronavirus vaccine too soon. In particular, they emphasise that Pfizer began testing just a few days after the Chinese authorities had released the genetic code of the coronavirus on 10 January 2020.⁴² █████ et al. do not substantiate this claim. In this context, they refer to Exhibit 47. However, this exhibit contains only unsubstantiated assertions which do not appear to originate from an external source, and in any event contain no information about the development process of a COVID-19 vaccine. █████ et al.

⁴¹ See also the Health Council of the Netherlands, *Advice on COVID-19 vaccination with BioNTech-Pfizer*, 24 December 2020 (Bourla-20), available at www.gezondheidsraad.nl/binaries/gezondheidsraad/documenten/adviezen/2020/12/24/covid-19-vaccination-biontech-pfizer/Advice-on-COVID-19-vaccination-BioNTech-Pfizer.pdf, p. 4. See the writ of summons, nos. 41, 148, 163, 165 and 200. In no. 41, the date of release of the genetic code is incorrectly stated as 8 January 2020.

Furthermore, they have not explained — and Bourla has not understood — why the aforementioned argument would be relevant to the claims brought.

41. Nevertheless, Bourla will briefly explain (i) how Pfizer and its commercial partner BioNTech, alongside other pharmaceutical companies, were able to begin testing a COVID-19 vaccine shortly after receiving the genetic code of the coronavirus, and (ii) how it became possible to launch the vaccination campaign within approximately one year of the start of the pandemic.⁴³

Re (i): Rapid launch of initial trials

42. Put simply, Comirnaty did not need to be developed from scratch. In developing Comirnaty, Pfizer and its commercial partner BioNTech were able to draw on a number of solutions for the use of mRNA technology and the rapid achievement of effective vaccine delivery, which had already been researched and tested for decades.⁴⁴ This includes, amongst other things, (a) the use of mRNA technology, and (b) the delivery system for the active substance into the cells (lipid nanoparticles).

(a) mRNA

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

⁴³ Incidentally, there are many publicly available publications on the development process of Comirnaty. See, for example, Lewis, L.M. et al., *The Race to Develop the Pfizer-BioNTech COVID-19 Vaccine. From the Pharmaceutical Scientists’ Perspective*, 18 September 2022 (**Bourla-21**), available at www.ncbi.nlm.nih.gov/pmc/articles/PMC9482796

⁴⁴ Incidentally, Minks et al. themselves appear to acknowledge that a considerable amount of work had already been carried out in this field prior to 2020. This is evident from their assertion that Pfizer “*had been working on the development of mRNA vaccines for the beta coronavirus since mid-2011*”, and from their reference to a series of patent applications by Moderna for the period 2015–2020 (summons, para. 215, referring to Exhibit 72). Although these patents have nothing to do with Pfizer and do not align chronologically with the claim made by Minks et al., they do at least demonstrate that earlier scientific research – in this case into other coronaviruses – can be useful for subsequent research, in this instance 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 then, many researchers have investigated its therapeutic potential, including its possible use in vaccines. In particular, the founders of BioNTech and other researchers have been investigating the therapeutic potential of mRNA for over 30 years.^{46 47}
45. Comirnaty contains a form of mRNA that was prepared in a laboratory to encode the SARS-CoV-2 spike protein. Following administration of Comirnaty, cells use the mRNA to produce this viral spike protein. This, in turn, is recognised by the immune system as a foreign protein, prompting the production of antibodies. Once the body has produced antibodies against the viral spike protein, these remain in the body and the immune system can respond rapidly to protect the vaccine recipient from infection if they are exposed to SARS-CoV-2.⁴⁸ For the sake of completeness: individuals who are administered Comirnaty or another mRNA vaccine are only exposed to the target antigen or protein encoded by the mRNA. Administration of the vaccine does not lead to infection with the virus itself.
46. The above means that, at the start of the pandemic, it was already technologically possible to produce mRNA encoding the SARS-CoV-2 spike protein.
47. Pfizer/BioNTech were able to produce several candidate vaccines shortly after the Chinese authorities had released the genetic code of SARS-CoV-2. They were then able to carry out the first laboratory tests and — subject to obtaining the necessary regulatory approvals — the first

⁴⁵ Institut Pasteur, *Discovery of messenger RNA in 1961*, 15 February 2021 (**Bourla-22**), available via www.pasteur.fr/en/home/research-journal/news/discovery-messenger-ma-1961#:~:text=We%20can%20be%20sure%20that,protect%20them%20against%20COVID%20D19

⁴⁶ BioNTech, *The History of BioNTech – The Road to a New Era of Immunotherapy* (**Bourla-23**), available at www.biontech.com/int/en/home/about/who-we-are/history.html

⁴⁷ For example, the 2023 Nobel Prize in Physiology or Medicine was awarded to researchers whose work Pfizer drew upon when modifying the coronavirus's mRNA for Comirnaty; see the press release '*The Nobel Prize in Physiology or Medicine 2023*', 2 October 2023 (**Bourla-24**), available via www.nobelprize.org/prizes/medicine/2023/press-release/

⁴⁸ Bettini, E., *SARS-CoV-2 mRNA Vaccines: Immunological Mechanism and Beyond*, 2021 (**Bourla-26**), available at www.ncbi.nlm.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 it enters the cells. Consequently, a great deal of research was carried out into improving the stability of the RNA and overcoming the challenges associated with its administration through a range of possible approaches,⁴⁹ including the use of lipids and lipid nanoparticles. A lipid nanoparticle (an 'LNP') is, in effect, a delivery system that ensures the active substance — in the case of Comirnaty, mRNA encoding the SARS-CoV-2 spike protein — remains intact until it enters the cell.⁵⁰ LNP technology had been known for over a decade and was already in widespread use for the effective delivery of a number of medicines.⁵¹ Pfizer/BioNTech therefore did not need to reinvent the wheel in this respect.
49. That is why Pfizer/BioNTech were able to begin developing vaccine candidates shortly after they had determined the genetic code of SARS-CoV-2 in January 2020.

Ad (ii): Accelerated progress through the vaccine development stages

50. The vaccine candidate that would eventually become known as Comirnaty went through all the standard development and testing phases.⁵² The development process was not accelerated by skipping these stages — which are designed to ensure the safety and efficacy of the vaccine — but by eliminating bottlenecks and pursuing parallel pathways. Without wishing to be exhaustive,

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', 29 June 2021 (Bourla-25), available at www.sciencenews.org/article/covid-coronavirus-vaccine-development-speed

⁵² See section 3.2.

Bourla will outline some of the key factors that contributed to Comirnaty's shorter development time.

- (a) Rapid results thanks to a large number of volunteers and the rapid spread of the coronavirus

51. Pfizer was able to recruit nearly 44,000 volunteers in less than four months for the final phases of the clinical trial. This compares favourably with previous experiences of recruiting volunteers; for example, it took more than two years to recruit just 101 volunteers for the clinical trials of the rabies vaccine in 2013. This alone saved approximately two years of development time.⁵³

52. Furthermore, the rapid spread of the coronavirus meant that the number of cases required to draw a statistically sound conclusion about the efficacy of Comirnaty was reached much more quickly than usual.⁵⁴ 'The infection rate required to assess the efficacy of Comirnaty was reached approximately 1.5 years sooner than has been the case in the past with some other viruses.'⁵⁵

- (b) Prioritisation by the competent regulatory authorities

53. It is widely known that regulatory authorities in the US, the EU and elsewhere have given high priority to the development of coronavirus vaccines since early 2020.⁵⁶ Put simply, candidate coronavirus vaccines were at the front of the queue. Among other things, this meant that priority was given to assessing

⁵³ See Science News, 'How COVID-19 vaccines were made so quickly without cutting corners', 29 June 2021 (**Bourla-25**), available at www.sciencenews.org/article/covid-coronavirus-vaccine-development-speed
The effectiveness of a vaccine is measured by comparing the number of (severe) cases of COVID-19 within a specific timeframe following vaccination between the vaccine and placebo groups. Therefore, a sufficient number of clinical trial participants must fall ill before a statistically sound conclusion can be drawn about the vaccine's efficacy.
See Science News, 'How COVID-19 vaccines were made so quickly without cutting corners', 29 June 2021 (**Bourla-25**), available at www.sciencenews.org/article/covid-coronavirus-vaccine-development-speed
See Science News, 'How COVID-19 vaccines were made so quickly without cutting corners', 29 June 2021 (**Bourla-25**), available at www.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', 4 May 2020 (**Bourla-28**), available 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 coronavirus vaccines. Given that regulatory assessments typically represent a major bottleneck in the vaccine development process, this prioritisation is estimated to have saved approximately 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 authorisations had been obtained, to ensure that a large number of doses would be available immediately upon authorisation.⁵ Pfizer was prepared to take this risk for the sake of global public health.
55. In summary, the success of BioNTech and Pfizer in delivering an approved vaccine to millions of patients within a year can only be described as an unprecedented achievement, made possible by the joint efforts of the scientific community, companies and regulatory authorities around the world.

%0.3.2 The purpose and effects of Comirnaty have been consistently and **transparently communicated to the public**

56. In essence, [REDACTED] et al. claim that (i) they were told that people should get vaccinated not only for their own safety but also for that of others, (ii) that this was misleading, and (iii) that they would not have been vaccinated had they been properly informed that Comirnaty does not prevent the transmission of the coronavirus.⁵ Bourla will now address these false allegations.

⁷ See Science News, 'How COVID-19 vaccines were made so quickly without cutting corners', 29 June 2021 (Bourla-25), available at www.sciencenews.org/article/covid-coronavirus-vaccine-development-speed

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

⁵ Statement of Claim, paras. 145 et seq. At the same time, none of the claimants has alleged that they suffered damage as a result of Comirnaty's failure to prevent the transmission of the coronavirus to or from any of the claimants.

The primary aim of Comirnaty

57. The aim of Comirnaty was to prevent vaccinated people from becoming seriously (symptomatically) ill and to minimise the number of deaths resulting from COVID-19. This was made clear from the outset by the regulatory authorities, who in early 2020 called for a COVID-19 vaccine to be developed as quickly as possible.
58. For example, a presentation by the EMA on the development of COVID-19 vaccines states that the '*main measure of benefit*' of a COVID-19 vaccine is the '*prevention of symptomatic disease*'. In the same presentation, the EMA states that it is not possible to determine, by the time a vaccine is authorised, whether it will have the effects of '*prevention of infection*' and '*prevention of virus transmission*'.⁶⁰

Clinical studies — efficacy and safety

MEASURING THE BENEFIT OF COVID-19 VACCINES

Prevention of symptomatic disease as the main measure of benefit

Less disease with symptoms in people who received the vaccine compared with those who received a placebo

Other benefits are likely to be uncertain at the time of approval and will only become clearer once the vaccine is in use:

Long-term protection

Prevention of infection (asymptomatic cases)

Prevention of virus transmission in the community – requires specific studies following approval



Efficacy levels

Studies designed to show efficacy of 50% or more

50% efficacy means the vaccine prevents half of the cases of symptomatic COVID-19 compared with placebo

90 per cent efficacy means the vaccine prevents nine out of 10 cases of symptomatic COVID-19 compared with placebo

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59. Numerous academic papers published in the run-up to the authorisation of Comirnaty similarly

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.

that the primary endpoint⁶¹ of the clinical trials is the vaccine's ability to prevent *severe* cases of COVID-19:

*"The primary endpoint for all phase 3 vaccine trials is the alleviation of COVID-19."*⁶²

60. Preventing transmission was not a characteristic of the COVID-19 vaccines (including Comirnaty) that had to be tested and demonstrated before the vaccine could be brought to market.
61. It was therefore clear from the outset that the primary aim of Comirnaty was to reduce the risk of severe COVID-19 disease, and not to prevent the transmission of the coronavirus. As explained in section 3.2, the data at the time indicated that Comirnaty was 95 per cent effective in preventing symptomatic COVID-19 disease, which can undoubtedly be regarded as achieving the aforementioned objective.

Public statements on the purpose and efficacy of Comirnaty

62. As mentioned, █████ et al. allege, amongst other things, that they were misled by Bourla into believing that Comirnaty had been developed to prevent vaccinated people from contracting the coronavirus and subsequently passing it on.
63. However, Bourla did not mislead █████ et al. Even before Comirnaty was granted 21 December 2020, Bourla had been transparent about the fact that its effect in preventing transmission had not been tested during the clinical trials and was unknown.⁶³

Put simply, endpoints are specific outcomes of a clinical trial that are statistically analysed to help determine the efficacy and safety of the therapy under investigation.

See, for example, Nature, 'Whither COVID-19 vaccines', 28 September 2020 (Bourla-30), available at www.nature.com/articles/s41587-020-0697-7

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

64. In an interview with NBC News published on 3 December 2020, Bourla says, for example, that it is not known whether people who have been vaccinated can still carry the coronavirus and pass it on to others:

*"I think this is something that needs to be examined. We are not certain about that right now."*⁶⁴

65. In an interview with The Journal published on 13 January 2021, Bourla reiterated that whilst there were "*encouraging*" initial data on Comirnaty's ability to prevent the transmission of the coronavirus, these data were "*not conclusive*". Bourla further cautioned that Pfizer had not yet proven the existence of a transmission-preventive effect:

*"This is not conclusive yet. We know that in animals, [there is] significant protection against transmission of the virus.... We haven't [proven that in] humans yet."*⁶⁵

66. Regulatory authorities have been equally clear that no trials have been conducted, and that no empirical data has yet been collected, on whether Comirnaty has a transmission-preventing effect.
67. For example, on 21 December 2020, the EMA published a document accompanying its recommendation to grant Comirnaty a conditional marketing authorisation. In it, the EMA explained that Comirnaty was 95 per cent effective in preventing symptomatic COVID-19, thereby fulfilling its objective. At the same time, the EMA warned:

*A description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the financial year ended 31 December 2019 and in its subsequent reports on Form 10-O, including in the sections thereof entitled "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 US 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', 13 March 2020 (**Bourla-10**), available at www.pfizer.com/news/press-release/press-release-detail/pfizer-outlines-five-point-plan-battle-covid-19*

⁶⁴ NBC News, *3 vaccine executives say that after approval, distribution will be the main challenge*, 3 December 2020 (**Bourla-31**), available at www.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*, 13 January 2021 (**Bourla-32**), available 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 to what extent vaccinated people may still be able to carry and spread the virus."*⁶⁶

- 68 The US Food and Drug Administration ("FDA") also stated in a press release on 11 December 2020 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 applies to the WHO, which warned on 8 January 2021 that there was *"not yet any evidence of the effect of the vaccine on virus transmission"*. It identified this issue at the time as a recommended area for further research.⁶⁸
70. The foregoing makes it clear that, during a hearing at the European Parliament on 10 October 2022, it was by no means 'revealed' that Comirnaty's effects in preventing transmission had not been tested during clinical trials, as █████s et al. suggest.⁶ At that point, this had already been an established and transparently published fact for almost two years.

The actual effect of Comirnaty in preventing transmission

71. At the same time, Comirnaty did in fact contribute to reducing the transmission of at least the earlier variants of the coronavirus that were circulating during the early stages of the COVID-19 pandemic.⁷⁰

EMA, *Comirnaty, COVID-19 mRNA vaccine (nucleoside-modified)*, 21 December 2020 (Bourla-33), available 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 Authorisation for First COVID-19 Vaccine'*, 11 December 2020 (**Bourla-34**), available at www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorisation-first-covid-19

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

Summons, No. 147.

¹⁰ See, for example, Reuters, *Fact Check: Preventing transmission never required for COVID vaccines' initial approval* (Bourla-36), available at www.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-idUSL1N31F20E/

72. It is clear that the vaccine has helped to 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. Furthermore, by preventing severe COVID-19 symptoms, COVID-19 vaccines, including Comirnaty, have helped to manage the burden on national healthcare systems, including those in the Netherlands.
74. In short, COVID-19 vaccines have had tangible positive effects on public health that went beyond individual protection. The repeated claims by [REDACTED] et al. that they were misled about the purpose of Comirnaty are unfounded.⁷²

%0.3.3 The chemical composition of Comirnaty has long been known

75. [REDACTED] et al. claim that Comirnaty contains '*graphene oxide*'.⁷³ This is incorrect.
76. In reality, the chemical composition of Comirnaty has been public since the conditional marketing authorisation was granted in the EU, including the Netherlands. For example, the full list of ingredients in Comirnaty is always stated in the product information (the summary of product characteristics intended for healthcare professionals and the patient information leaflet for those receiving the vaccine) which has been approved by the EMA and made available from the date the conditional marketing authorisation was granted on 21 December 2020.⁷⁴ This list of ingredients has also been published in numerous other media, as well as in government and academic sources, such as by the FDA in its Emergency Use Authorisation review memorandum of 11 December

⁷¹ See, for example, ECDC, '*Risk of SARS-CoV-2 transmission from newly-infected individuals with documented previous infection or vaccination*', 29 March 2021 (Bourla-37), available at ecdc.europa.eu/en/publications-data/sars-cov-2-transmission-newly-infected-individuals-previous-infection

⁷² See also the conclusion of the response from S1aa1 et al. dated 10 January 2024, no. 6.2.

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

2020.⁵ Information on the chemical composition of Comirnaty had therefore been made public and was readily available to [REDACTED] et al. prior to their alleged vaccinations.

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

The active substance

78. The active ingredient in Comirnaty is called Tozinameran. Put simply, Tozinameran consists of mRNA that encodes the viral spike protein of SARS-CoV-2. It causes cells to produce the 'spike' protein, a protein found 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, the cells are 'trained' to produce antibodies when they encounter the coronavirus spike protein, so that the recipient of the ferret vaccine is protected against infection when exposed to the virus.¹⁶

The lipids (protective spheres)

79. Comirnaty contains four lipids. These form small fatty spheres that envelop the mRNA to protect it from destruction before it enters the cells. These protective spheres are known as lipid nanoparticles or LNPs.
80. The first lipid is usually referred to by the code name ALC-0315.⁷⁷ As ALC-0315 can become ionised during the production process – that is, it acquires a positive charge – it can 'stick' to the mRNA, which has a negative charge. This enables ALC-0315 to encapsulate the mRNA and thus protect it. The lipid droplets

⁷⁷ FDA, *Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorisation Review Memorandum*, 20 November 2020 (Bourla-39), available at www.fda.gov/media/144416/download, p. 11. "See also footnote 45 above.

⁷⁸ The full scientific name of the compound ALC-0315 is ((4-hydroxybutyl)azaandiyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate).

The active substance, the mRNA, is then transported through the cell wall into the cell's cytoplasm.⁷

81. The second lipid is usually referred to by the code name 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 shelf life of Comirnaty.⁰
82. The third and fourth lipids in Comirnaty are cholesterol and DSPC.¹ These are conventional lipids used in numerous authorised medicines and serve to further enhance the stability of the LNP.⁸²

Other ingredients

83. Finally, Comirnaty contains several other ingredients, all of which are very common. Firstly, Comirnaty contains sucrose, a common form of sugar. Its function is to prevent LNPs from sticking together when frozen.⁸ * Secondly, Comirnaty contains a mixture of salts (including sodium chloride, or table salt) commonly known as phosphate-buffered saline, or trometamol, a widely used buffer to improve stability.⁴ The purpose of these salts is to ensure that the vaccine's pH is similar to that of the human

⁷⁸ See Gov.UK, *Summary of the Public Assessment Report on the COVID-19 Vaccine*, December 2020 (Bourla-40), available 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-[(polyethylene glycol)-2000-N,N-ditetradecylacetamide].

⁸⁰ See, for example, Gov.UK, 'Summary of the Public Assessment Report on the COVID-19 Vaccine', December 2020 (Bourla-40), available at www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/summary-public-assessment-report-for-pfizer-biontech-covid-19-vaccine

⁸¹ The full scientific name of DSPC is 1,2-Distearoyl-sn-glycero-3-phosphocholine.

⁸² See, for example, Gov.UK, *Summary of the Public Assessment Report on the COVID-19 Vaccine*, December 2020 (Bourla-40), available at www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/summary-public-assessment-report-for-pfizerbiontech-covid-19-vaccine

⁸³ MIT Technology Review, 'What are the ingredients of Pfizer's COVID-19 vaccine?', 9 December 2020 (Bourla-41), available at www.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 Authorisation Review Memorandum*, 20 November 2020 (Bourla-39), available at www.fda.gov/media/144416/download, p. 11.

body. Thirdly, Comirnaty contains water, as the vaccine is an aqueous solution.

84. The list of ingredients described in the preceding paragraphs is exhaustive: Comirnaty contains no other constituents, including ‘*graphene oxide*’. This has been confirmed time and again by the EMA and other authorities.⁸⁵ Graphene oxide is not used in the manufacturing process of Comirnaty and cannot 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 8 March 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 writ of summons, █████ et al. acknowledge that a number of independent third parties have investigated the claim that graphene oxide is present in Comirnaty. █████ et al. are also correct in stating that the outcome of these *fact-checks* was consistently the same: Comirnaty does not contain graphene oxide. Nevertheless, █████ et al. dismiss these reports as ‘*false*’, without providing any evidence to support this claim.⁸⁷ █████ et al. then refer to “*videos and scientific reports by highly reputable individuals*” in which these individuals allegedly state, “*on the basis of highly precise evidence*”, “*that graphene oxide is present as the main component in all mRNA injections*”. The only thing █████ et al. refer to in this context is a video clip from an episode of an American online programme called “*The Stew Peters Show*”.⁰ In this clip, a guest — Ms Karen Kingston — suggests that all mRNA vaccines, including Comirnaty, contain graphene oxide. She attempts to

⁸⁵ See, for example, European Parliament, *Answer given by Ms Kyriakides on behalf of the European Commission*, 26 October 2021 (Bourla-42), available via www.europarl.europa.eu/doceo/document/P-9-2021-003980-ASW_EN.html#ref1

87. European Parliament, *Answer given by Ms Kyriakides on behalf of the European Commission*, 8 March 2022 (Bourla-43), available at www.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*’, 23 July 2021 (Bourla-44), available at www.reuters.com/article/factcheck-grapheneoxide-vaccine-idUSL1N2OZ14F/ and AP, ‘*Pfizer vaccine does not contain graphene oxide*’, 8 July 2021 (Bourla-45), available at apnews.com/article/fact-checking-430816913228

[^] Subpoena, no. 152.

[^] Summoning, no. 153.

Statement of Claim, Exhibit 44.

to support this conclusion by referring, in a misleading manner, 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 is, in any event, disputed.

86. There is absolutely no evidence that Ms Kingston has any expert knowledge of the chemical composition, the development process, the effects or any other aspect of Comirnaty, let alone that she is a “highly respected individual”. Ms Kingston is a former employee of Pfizer. However, she was not involved in the research, development or manufacture of Comirnaty. In any case, Comirnaty simply does not contain graphene oxide.

87. The claim by █████ et al. that graphene oxide is present in Comirnaty — even “as the main ingredient” — is incorrect. ¹ The same therefore applies to the claim that Bourla “deliberately allowed this misrepresentation to persist”. ²

%0.3.4 █████ et al. fundamentally misinterpret Pfizer’s report of 30 April 2021

88. In the writ of summons, █████ et al. refer no fewer than eight times to Pfizer’s report No. FDA-CBER-2021-5683-0000054 dated 30 April 2021 (the “Pfizer report”). They present the Pfizer report as a “smoking gun” proving that Comirnaty is dangerous. Specifically, █████ et al. claim that 42,086 people allegedly took part in a Comirnaty trial (“mia”) which ran from November 2020 to February 2021, and that of these, 1,223 people allegedly died and 11,361 people allegedly suffered serious and permanent injury.

89. The Pfizer report proves nothing of the sort.

90. Firstly, the Pfizer report does not relate to a clinical trial. Instead, it is an integrated analysis of *post-authorisation* safety data for Comirnaty, as the report itself describes. ³ Put simply, the Pfizer report

¹ Subpoena, No. 153.

² Subpoena, No. 152.

³ Exhibit 40, p. 5.

suspected adverse reactions that have been reported, mostly via national authorities, before the deadline of 28 February 2021. The Pfizer report is a US report. The equivalent under EU medicines legislation is the Periodic Safety Update Report ('PSUR'). This is a report drawn up by the holder of a marketing authorisation for a medicinal product, which describes the global safety experience with that product at a specific point in time following its authorisation.⁴

91. Secondly, ████████ et al. misrepresent the figures presented in the Pfizer report. During the relevant period, 42,086 recipients of Comirnaty reported adverse reactions.⁵ In order to assess the safety of Comirnaty in any meaningful way, this figure must be set against the total number of people who have been administered Comirnaty. This confirms Comirnaty's strong safety profile: according to the EMA, more than 330 million doses of Comirnaty had been administered worldwide by 29 April 2021,⁶ which indicates that only a very small proportion of vaccinations resulted in a report of a suspected adverse reaction.'
92. Thirdly, ████████ et al. misrepresent the significance of the reported adverse reactions analysed in the Pfizer report. The report does not suggest that these adverse reactions were *caused* by Comirnaty. The Pfizer report merely states that such adverse reactions occurred at a certain

⁹⁴ The original English text reads as follows: "A report prepared by the marketing authorisation holder describing the worldwide safety experience with a medicinal product at a defined time after its authorisation." See EMA, *Periodic Safety Update Report* (Bourla-46), available via www.ema.europa.eu/en/glossary/periodic-safety-update-reports:
:text=A%20report%20prepared%20by%20the,reports%3A%20questions%20and%20answer
s%. See, for example, EMA, *Comirnaty periodic safety update report assessment 19 June 2022 to 18 December 2022* (selection) (Bourla-47), available at www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/comirnaty-periodic-safety-update-report-assessment-19-june-2022-18-december-2022_en.pdf Volume 40, p. 8.

⁹⁶ EMA, *Assessment report on the annual renewal of the conditional marketing authorisation (Comirnaty), 2021* (Bourla-48), available at www.ema.europa.eu/en/documents/variation-report/comirnaty-h-c-5735-r-0046-epar-assessment-report-renewal_en.pdf, p. 16. Although the period covered by the EMA report is longer than that covered by the report cited by Minks et al. (29 April 2021 and 28 February 2021 respectively), this shows that the number of reported deaths and the number of reported cases of serious permanent physical injury — relative to the total number of doses — is very limited, and also significantly lower than Minks et al. suggest.

are said to have occurred shortly *after* the injection. This does not, however, mean that the side effects mentioned in the report are actually caused *by* vaccination. This is all the more true given that, during the early stages of the vaccination programme — which this report covers — it was primarily the elderly and vulnerable who were vaccinated. [REDACTED] et al. make a fundamental error by confusing correlation with causation, whilst the former does not prove the latter or even necessarily suggest it. Instead, reports of this kind are usually used as part of post-authorisation pharmacovigilance to determine whether there are any safety signals that warrant further investigation.

93. Fourthly, [REDACTED] et al. misrepresent even the most basic statistical and demographic data in the report.
 - For example, they suggest that 2,990 children ‘took part’ in the analysis. In reality, the Pfizer report refers to 2,990 individuals whose gender was not specified in the adverse reaction report. Furthermore, it states that there were 175 individuals under the age of 18 for whom adverse reactions were reported.¹⁰⁰
 - Furthermore, [REDACTED] et al. claim, for example, that 11,361 individuals are said to have suffered serious, permanent physical injury. Nothing in the report indicates serious, permanent injury, or even the physical nature of an adverse reaction.
94. The claim that the report was ‘concealed’ by Bourla is also incorrect, as is the date on which the report was allegedly made public.¹⁰¹ Pharmaceutical companies, including Pfizer, do not publish their reports to the public, but submit them to the relevant regulatory authorities. To be clear: neither Bourla nor Pfizer has taken any steps to prevent the eventual publication of the

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

¹⁰⁰

Exhibit 40, p. 7.

¹⁰¹

Exhibit 40, p. 7.

Summon, No. 144.

To prevent the disclosure of the Pfizer report under the Freedom of Information Act proceedings in the US.¹⁰² Furthermore, the equivalent document in the EU — the PSUR — is publicly available on the EMA's website.¹⁰³

%0.3.5 The vague comments by █████ et al. regarding alleged differences in the quality of vaccine batches are irrelevant and **incorrect**

95. █████ et al. claim that Pfizer has not maintained consistent production quality across the various batches of Comirnaty.¹⁰⁴ Specifically, they refer to batch EM0477 as a “*non-lethal*” variant.¹⁰⁵ These assertions are incorrect.

96. To begin with, █████ et al. have not stated that they were vaccinated against COVID-19, let alone which batch of Comirnaty they might have received.¹⁰⁶ Nor have they claimed that their vaccinations came from a batch which they consider to be of inferior quality. The assertions made by █████ et al. regarding the alleged differences in the quality of vaccine batches are therefore apparently unrelated to the claim for damages, and are consequently irrelevant. Furthermore, █████ et al. have not adequately substantiated that batch EM0477 differed from other batches of Comirnaty.¹⁰⁷

97. More importantly, a large part of the argument put forward by █████ et al. is based on a misinterpretation of a scientific report by Peter Riis Hansen (“Hansen”),¹⁰⁸ and the subsequent question put to the European Commission by a Member of the European Parliament, which refers to Hansen's report.¹⁰⁹ █████ et al. wrongly claim that Hansen's report proves “*[that there are very large differences in mortality and side effects of Pfizer's Covid-19*

¹⁰² Requests under the US Freedom of Information Act are comparable to requests under the Open Government Act (Woo) in the Netherlands.

¹⁰³ See above, no. 90. Summons, nos. 245 et seq. Summons, no. 246.

¹⁰⁴ The only exception is Ms Oudakker-Bekkers, in respect of whom it is stated on page 7 of Exhibit 91 that she was administered Comirnaty doses from batches FC3143 and FF0688. Subpoena, nos. 245 et seq.

¹⁰⁵ Exhibit 83, second document. Hansen is, incidentally, one of the three authors. Exhibit 83, first document.

¹⁰⁶

injection batches [exist].” In reality, the conclusion of Hansen is:

“In conclusion, the results suggest the existence of a batch-dependent safety signal for the BNT162b2 vaccine, and further studies are warranted to explore this preliminary observation and its consequences.”¹¹⁰

98. Hansen’s report also reflects the fundamental scientific understanding that analyses of adverse reactions are not intended to establish a causal link between the vaccine and health problems. This is all the more true in the case of self-reporting systems, which are by definition susceptible to reporting biases and data deficiencies. Hansen rightly 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 the potential for both under- and over-reporting, as well as incomplete data and variable quality of the reported information. Owing to these inherent limitations, signals detected by these systems must be considered to be hypothesis-generating and generally cannot be used to establish causality. In addition, in the present study, the history of prior COVID-19 in relation to SAEs was unknown, and specific types of SAEs (...) were not examined. Notably, to our knowledge, the Danish Serum Institute has not issued any recalls of BNT162b2 vaccine batches.”¹¹ 11
(underlining added, lawyer)

99. As well as misrepresenting this preliminary conclusion by Hansen as evidence of Comirnaty’s alleged ‘*lethality*’, [REDACTED] et al. ignore the fact that the relevant European authorities have carried out further investigations into the Danish parties mentioned by Hansen. This is evident from the reply by the European Commissioner for Health and Food Safety¹¹ * to a question from a Member of the European Parliament – a *question* to which, as mentioned, [REDACTED] et al. do indeed

¹¹⁰ Exhibit 83, second document, p. 3.
Exhibit 83, second document, p. 3.
That reply was given on 3 July 2023. That is prior to the date on which the summons was issued.

refer to.”* That reply shows that no increased risk of adverse effects for specific batches has been demonstrated:

“As regards literature monitoring, if various sources of information point to a potential issue, a more in-depth review is initiated. This was not the case for the aforementioned Danish study.”

“In addition to the limitations mentioned in the study, analyses carried out by the European Medicines Agency on the batches reported in suspected adverse reaction cases did not reveal an increased risk of side effects for specific batches.”¹¹⁴

100. The European Commission further reiterated that every batch undergoes rigorous quality testing before being placed on the EU market. Each batch is first carefully tested by the manufacturer. The national competent authority then carries out an additional independent check, known as the Official Control Authority Batch Release test:

“As with any other medicinal products authorised in the EU, once a COVID-19 vaccine has been approved, each vaccine batch can only be released following quality control testing to confirm that the product complies with the specifications approved as part of the relevant marketing authorisation.”

This control is carried out by the manufacturer. However, for most centrally authorised vaccines, EU legislation requires that a Member State’s Official Medicines Control Laboratory carries out an additional independent control on each batch before it is placed on the EU market.

This independent control is referred to as Official Control Authority Batch Release testing and includes testing of agreed quality parameters and a compliance check of the manufacturer’s own test results.”¹¹⁵

101. As mentioned in the MEP’s question, both vaccine manufacturers and regulatory authorities are extremely rigorous when it comes to ensuring consistently high production quality

¹¹³ Subpoena, No. 248, with reference to production 83, first document.

¹¹⁴ European Parliament, *Answer given by Ms Kyriakides on behalf of the European Commission*, 3 July 2023 (Bourla-50), available at www.europarl.europa.eu/doceo/document/E-9-2023-001537-ASW_EN.html

¹¹⁵ European Parliament, *Answer given by Ms Kyriakides on behalf of the European Commission*, 3 July 2023 (Bourla-50), available at www.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), available at www.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 instance, for example, 1.6 million doses were recalled by Moderna because a foreign substance was found in just 39 doses.¹¹⁶

102. Furthermore, the data and methodology used in Hansen's report contain serious shortcomings, as a representative of the Danish national competent authority — the Danish Serum Institute — pointed out in a letter to the editor. That letter explains that Hansen's report fails to take into account the fact that some of the batches he examined were not (or hardly) used, whilst those batches logically had no or very few reports of suspected adverse reactions. This makes the various batches examined incomparable. Furthermore, when the first batches were administered, healthcare professionals were encouraged to report all suspected adverse reactions; later in the pandemic, however, the authorities no longer encouraged the reporting of mild adverse reactions. As explained in the letter from the representative of the Danish Serum Institute, Hansen's report does not take this into account either. For this reason too, the study cannot provide 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 anywhere in the EU, nor worldwide, on safety grounds. This in itself is sufficient to allay any reasonable concerns about the quality of individual batches.
104. In short, the claims made by ██████████ et al. regarding alleged variations in the quality of the various Comirnaty batches are irrelevant and incorrect.

¹¹⁶ Exhibit 83, first document.
¹¹⁷ The letter is from Anders Hviid, received on 20 June 2023 and accepted on 9 July 2023. See Hviid, A., *Inaccurate representation of shipped vaccines as administered*, 20 June 2023 (Bourla-52), available at factreview.gr/wp-content/uploads/2023/07/Eur-J-Clin-Investigation-2023-Hviid-Inaccurate-representation-of-shipped-vaccines-as-administered.pdf

%0.3.6 Inaccurate statements regarding the relationship with the European Commission

105. [REDACTED] et al. make a number of unsubstantiated and incorrect statements regarding the contractual relationship between Pfizer and the European Commission in relation to Comirnaty."⁸ Nor have [REDACTED] et al. explained what relevance this would have to their claims.
106. [REDACTED] et al. claim that the European Commission purchased Comirnaty for EUR 71 billion. This is incorrect. This amount represents the value of the EU's vaccine orders from eight manufacturers. Furthermore, this amount includes purchase options that have not been exercised and which relate to almost half of the 4.6 billion doses that were actually purchased."⁹ [REDACTED] et al. also argue that the EU Member States are jointly and severally liable as guarantors for this alleged payment. That is also incorrect. Finally, [REDACTED] et al. claim that the EU, represented by the European Commission, has not paid Pfizer for the vaccines. That, too, is incorrect.

%0.3.7 Comirnaty is not a gene therapy

107. [REDACTED] et al. repeatedly claim that Comirnaty is '*based on gene therapy*'.¹²⁰ They do not substantiate this claim. Moreover, this claim is incorrect.
108. The term 'gene therapy' has a specific and established meaning under EU legislation. Annex I to Directive 2001/83/EC defines a '*gene therapy medicinal product*' as follows:

"a) the medicinal product contains an active substance consisting wholly or partly of recombinant nucleic acid which is used in or administered to humans to regulate, repair, replace, insert or delete a genetic sequence;

(b) the therapeutic, prophylactic or diagnostic action of the medicinal product is directly related to the

⁸⁸⁸ Summoning, nos. 165 et seq.

⁸⁸⁹ ECA, *Special Report, 'EU COVID-19 vaccine procurement: Sufficient doses secured after initial challenges but performance of the process not sufficiently assessed'*, 2022 (Bourla-53), available at [Nw.eca.europa.eu/Lists/ECADocuments/SR22_19/SR_EU_COVID_vaccine_procurement_E](https://www.eca.europa.eu/Lists/ECADocuments/SR22_19/SR_EU_COVID_vaccine_procurement_E)

¹²⁰ o/gvaarding, nos. 131 et seq., no. 169.

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

Vaccines against infectious diseases are not regarded as medicinal products for therapeutic purposes. (underlining added by the lawyer)

109. Comirnaty does not fall under this definition, as it does not regulate, repair, replace, add to or remove the genetic sequence of vaccine recipients — nor is it capable of doing so. The mRNA in the vaccine does not enter the cell nucleus, where the human genome, i.e. DNA, is located. Instead, the mRNA is rapidly broken down by the vaccine recipient's body.¹²¹ Furthermore, the definition expressly excludes vaccines against infectious diseases.

4 **██████ ET AL. HAVE NOT ESTABLISHED ANY ELEMENT OF A TORTIOUS ACT**

110. ██████ et al. are asking your court to assess the damages on a provisional basis.¹²² This means that these proceedings must establish that Bourla acted unlawfully and with culpability towards ██████ et al., and that it is plausible that the latter may have suffered damage as a result.
111. Neither of these requirements has been met. Bourla did not mislead ██████ et al., let alone do so intentionally. Comirnaty, incidentally, just like the other COVID-19 vaccines, was developed through the usual rigorous process and meets the statutory standards for safety, efficacy and manufacturing quality (see paragraph 3.2).
112. In so far as the claims made by ██████ et al. would amount to (derivative) liability on the part of Bourla in his capacity as CEO of Pfizer, there is no relevant claim regarding Pfizer's alleged liability. Those claims therefore fail on that ground alone. In so far as Bourla is being sued by ██████ et al. in any other capacity, Bourla sets out his defence below.

¹²¹ See, for example, Reuters, 'mRNA vaccines are distinct from gene therapy', 10 August 2021 (Bourla-54), available at www.reuters.com/article/idUSL1N2PH16N.

¹²² See paragraph 7 for the claim by Minks et al.

4.1 No unlawful act

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

113. Bourla understands the arguments put forward by █████ et al. regarding Article 7 of the ICCPR to mean that only the State would have committed a breach thereof. The State is alleged to have tortured its citizens, or subjected them to cruel, inhuman or degrading treatment or punishment, by subjecting them to an ongoing medical and scientific (behavioural) experiment.¹² * Although Bourla is apparently not being accused by █████ et al. of violating Article 7 of the ICCPR, he wishes to make the following comment on this matter.
114. Comirnaty does not qualify as a medical or scientific experiment.¹ *⁴ Although the development process was accelerated, the vaccine has undergone all the standard development and testing phases, including clinical trials. Furthermore, the vaccine was only placed on the market following the granting of conditional authorisation by the European Commission in December 2020.¹ *⁵ The term '*conditional* authorisation' could lead to misunderstandings, but simply means that the vaccine meets all requirements regarding safety, efficacy and manufacturing quality, whilst additional data still needs to be provided (see footnotes 19–20 and 50–55).¹ *⁶
115. Nor is there any question of torture or inhuman or degrading treatment or punishment. The government has offered its citizens the opportunity to be vaccinated. There is no question of violence, no question of deprivation of liberty, and █████ et al. have had the choice as to whether or not to be vaccinated against COVID-19.

¹²³ Summons, nos. 254–255.

See also District Court of The Hague, 5 March 2021, ECLI:NL:RBDHA:2021:1920, para. 4.7 in conjunction with 4.5, and upheld on appeal by the Court of Appeal, The Hague, 22 June 2021, ECLI:NL:GHDHA:2021:1094, para. 5.6.

¹²⁵ In October 2022, the conditional marketing authorisation granted to Comirnaty was converted into a standard marketing authorisation; see point 33 above.

¹²⁶ See also CBG-MEB, *Column 'About medicines': 'Are coronavirus vaccines experimental?'*, 2 June 2021 (Bourla-55), available at www.cbg-meb.nl/actueel/nieuws/2021/06/02/column-over-medicijnen-coronavaccins-experimenteel.

4.1.2 No breach of a statutory obligation

Article 97a of the Dutch Criminal Code – seeking support abroad for a revolution

116. █████ et al. apparently argue that Bourla, just like the other defendants, intended to support the alleged interests of Schwab and the WEF in The Great Reset.¹²⁷ In doing so, he is alleged to have contravened Article 97a of the Dutch Criminal Code.*²⁸ This argument makes no sense whatsoever.
117. 'Article 97a of the Criminal Code is intended to protect the Dutch constitutional form of government and the order of succession to the throne against unlawful alteration or abolition.'² █████ et al. have failed entirely to explain why such an upheaval would occur, what Bourla's role in it would be, and why a breach of this provision would constitute grounds for compensation for alleged damage suffered as a result of a COVID-19 vaccine.

Article 300 of the Dutch Criminal Code – simple assault

118. █████ et al. further claim that Bourla is guilty of assault within the meaning of Article 300 of the Dutch Criminal Code.⁽¹³⁰⁾ This is incorrect.
119. Assault consists of the deliberate infliction of physical pain or bodily harm without any justifiable grounds.¹³¹ Assault presupposes that the conduct is unlawful. As explained earlier, Comirnaty meets the legal standards for safety, efficacy and manufacturing quality (section 3.2), and the purpose and effects of the vaccine have been communicated consistently and transparently to the general public (section 3.3.2). Furthermore, █████ et al. have given their consent to be vaccinated, insofar as they were indeed vaccinated

* *
* *
* *
See also margin note 6.
Summons, nos. 58–59 in
conjunction with 155.

Van der Woude, *T&C Criminal Law*, commentary on Article 97a of the Dutch Criminal Code, under 1 (online, updated 1 August 2023). See also Article 80bis of the Criminal Code, which states that 'revolution' is defined as 'the destruction or unlawful alteration of 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*, Article 300 of the Dutch Criminal Code, notes 1 and 9 (online, updated on 1 August 2023).

. Consequently, the administration of a vaccine does not, even in a general sense, constitute assault.

120. Even if the administration of COVID-19 vaccinations were to constitute assault (*which it does not*), this act cannot be attributed to Bourla. Bourla did not administer any COVID-19 vaccinations himself. Moreover, [REDACTED] cannot, in any event, have been assaulted within the meaning of Article 300 of the Dutch Criminal Code, given that, by their own account, they have not suffered any after-effects from the vaccinations.¹³²

Article 308 of the Dutch Criminal Code – grievous bodily harm through negligence

121. [REDACTED] et al. allege that Bourla is guilty of causing grievous bodily harm to [REDACTED] and [REDACTED] within the meaning of Article 308 of the Dutch Criminal Code.¹³³ That too is incorrect. Even if they were to have a medical condition (i.e. Parkinson's or a TIA), they have not substantiated that this was caused by Bourla's actions (see section 4.3 for further details on causal link), or at least that it is attributable to his fault.

Section 3 of the WIM – genocide

122. [REDACTED] et al. further argue that it is "*plausible*" that Bourla (and the other defendants) are guilty of contravening Article 3(1)(b) and (c) of the International Crimes Act.¹³⁴ This is utter nonsense and, moreover, has not been substantiated.

4.1.3 No conduct contrary to what is deemed proper in social intercourse under unwritten law

123. [REDACTED] et al. further argue that the pharmaceutical industry has collaborated in the implementation of The Great Reset and the widespread deception of the public required for this, thereby grossly breaching the public's trust. This behaviour

¹³² They have not suffered any material damage (see paragraph 4.2.2). The alleged non-material damage is apparently merely the result of the alleged deception and not of the vaccinations themselves, and a lack of knowledge regarding the precise consequences of the vaccinations does not constitute damage (see paragraph 134).

¹³³ Statement of Claim, para. 278.

¹³⁴ Statement of claim, nos. 280–281.

would be contrary to what is deemed proper in social intercourse under unwritten law.¹³⁵ No explanation is given as to why Bourla's actions can be attributed to the entire 'pharmaceutical industry'. For that reason alone, the claims of █████ et al. on this ground must be dismissed.

124. Nor is there any question of unlawful conduct. As mentioned earlier, █████ et al. base their arguments on a conspiracy theory surrounding The Great Reset (see paragraph 6) which is not based on any truth. Furthermore, neither Bourla nor the pharmaceutical industry has been guilty of deception. See paragraphs 3.2–3.3, which explain, amongst other things, that Comirnaty has been extensively tested and found to be safe and effective.

4.2 No damage

125. For a case to be referred to damages proceedings, the possibility of damage must be plausible (and the basis for liability must be established).¹³⁶ At first glance, this does not sound like a high threshold. However, Tjong Tjin Tai makes it clear that the threshold must not be too low either. The extent of the damage need not yet be entirely clear, but it must be clear that damage has been suffered.^{13 *} █████ et al. do not meet this threshold.

4.2.1 Graphene oxide is not a component of the COVID-19 vaccines

126. █████ et al. claim that, as a result of the COVID-19 vaccines, they have been injected with '*toxic graphene oxide*', which is '*plausibly*' likely to cause lasting adverse health effects in humans.¹³ This alone would make it plausible that █████ et al. have suffered harm. However, this assertion by █████ et al. is incorrect. As explained in section 3.3.3, the COVID-19 vaccines do not contain graphene oxide.

¹³⁵ Summon, No. 284.

¹³⁶ See also writ of summons, no. 268.

¹³⁷ T.F.E. Tjong Tjin Tai, *Proceedings for Damages*, Deventer: Kluwer 2012, nos. 422–423.

¹³⁸ Summon, no. 265.

4.2.2 [REDACTED] et al. **have failed to fulfil their burden of proof; moreover, the majority of them admit that they have not suffered any material damage** ¹³⁹

127. Two of the six claimants allege that they have suffered serious physical injury.¹⁴⁰ The remaining four claimants do not allege that they have suffered serious physical injury, but do claim to have less severe symptoms.^{*41} It is also plausible that the health of claimants' health may suffer in the long term as a result of the COVID-19 injections. ¹⁴²

128. It has not been stated what the serious physical injury, the less severe symptoms and the long-term effects consist of. Reference has merely been made to Exhibit 91, which is said to contain '*diagnoses*' by '*medical specialists*'. However, those '*diagnoses*' cannot be regarded as neutral, objective, reliable or expert and must therefore be disregarded.

Statements by Van Walraven

129. Exhibit 91 contains seven statements by company doctor A.H. van Walraven ("Van Walraven"), which are largely identical.¹⁴³

130. In his '*diagnoses*', [REDACTED] does not hesitate to voice his own views on the COVID-19 vaccinations and government policy, and apparently subscribes to the same theories as [REDACTED] and others¹⁴⁴ For instance, he states that [REDACTED] and others are *right* to feel misled by the government; he suggests that the government does not have its people's best interests at heart, that there would never have been an emergency, and that the mortality rate from COVID-19 would have been in line with that of the flu, and that this figure alone would not justify any of the measures taken by the government. Such passages have no place

¹³⁹ Minks et al. apparently base this claim on Article 6:106(b) of the Dutch Civil Code.

¹⁴⁰ Oudakker-Bekkers and Vlegels ("*Dijkstra*" according to the "diagnosis" in Exhibit 91).

¹⁴¹ Minks, Bosma, De Vries and Oudakker.

¹⁴² Summons, no. 265.

¹⁴³ Those by Minks, Bosma, De Vries and Oudakker are even completely identical.

¹⁴⁴ See also, if applicable, Van Walraven's Manifesto to all doctors in the Netherlands; available via www.youtube.com/watch?v=sOpfZOaqmU

familiar with medical certificates and forms, and this in itself is sufficient grounds to disregard them.

131. Furthermore, [REDACTED] arguments are insufficient, both medically and legally, to establish a causal link. Firstly, [REDACTED] tends to conflate correlation and causation all too readily. As a doctor, he ought to know better. It follows from [REDACTED] 'diagnoses' that [REDACTED] is said to have developed Parkinson's disease and Vlegels a TIA. According to Van [REDACTED] these conditions can be attributed to the COVID-19 vaccination because (i) the symptoms arose (shortly) after the vaccination (in [REDACTED] case) and (ii) no other causes have been identified (in the cases of [REDACTED] and [REDACTED]). In [REDACTED] case, it has not been claimed at all that his symptoms arose *following* a COVID-19 vaccination. Nevertheless, Van Walraven concludes with regard to [REDACTED] that there is "*a vaccine side-effect until proven otherwise*". This is incorrect — and merely serves to invalidate all the assertions made by Van Walraven. The assertion that the symptoms arose shortly after the vaccinations is merely a prerequisite, but does not substantiate the claim that the alleged symptoms were caused *by* the vaccination.¹⁴⁵ Bourla therefore disputes this. Secondly, Van Walraven's assertions are largely unsubstantiated (in further detail) and are therefore unverifiable. See, for example, the claim regarding [REDACTED] that no other causes were found, and the claims regarding [REDACTED] concerning the negative family history and the rapid progression of the illness. Incidentally, causes for such clinical presentations are often not found; therefore, the mere absence of an '*other*' cause in no way serves as an indication that the clinical presentations were consequently caused by a vaccine.
132. Furthermore, Van Walraven appears to be uninformed regarding the side effects of Comirnaty. He points out that Parkinson's disease and coagulation problems, including TIAs, are included on the list of side effects for the

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

vaccines, but this is incorrect, as is evident from the lists of side effects published on the websites of the EMA and Lareb.’¹⁴⁶

133. Incidentally, even if a side effect were to appear on the list of side effects, this does not necessarily mean that the vaccine causes that side effect. And even if it can be demonstrated that a side effect is caused by the vaccine, this still does not give rise to liability if the vaccine complies with the prescribed safety standards and is not defective. Safety is not an absolute concept, particularly in the case of medicines, as they always entail both risks and benefits and are expressly authorised on the basis of evidence that the balance between them is favourable. Comirnaty complies with the applicable safety standards. This is evident from the granting of the marketing authorisation after the EMA had confirmed that the balance of benefits and risks of Comirnaty was favourable, and from post-authorisation pharmacovigilance. [REDACTED] et al. have not contested this: they have neither alleged nor explained that the vaccines allegedly administered were deficient in any way.

4.2.3 Alleged non-pecuniary damage is not eligible for compensation

134. In addition to material damage, [REDACTED] et al. claim to have suffered non-material damage. This is said to consist of (i) the psychological distress resulting from the deception caused by the defendants (feelings of pain, suffering, shame, powerlessness and uncertainty about their health) and (ii) a lack of knowledge regarding the precise consequences of the vaccinations.¹⁴⁷
135. [REDACTED] et al. appear to base these claims, first and foremost, on Article 6:106(b) of the Dutch Civil Code. Mental injury falls within the category referred to therein as ‘*harm to a person in any other way*’.¹⁴⁸

¹⁴⁶ EMA, *Comirnaty product information* (selection) (Bourla-38), available via www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_nl.pdf and LAREB, *Side effects of COVID-19 vaccines* (Bourla-56), available at www.lareb.nl/bijwerkingen-coronavaccins#pfizer

¹⁴⁷ Summons, no. 266.

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

136. The legislative history shows that psychological injury must be ‘*sufficiently serious*’ to qualify for compensation.¹⁴ A greater or lesser degree of psychological distress is insufficient, which is also established case-law.¹⁰ For this reason alone, the claims of [REDACTED] and others must be dismissed. Furthermore, the Supreme Court has held that a person claiming ‘*harm to their person in some other way*’ must adduce sufficiently concrete facts from which it can be inferred that psychological harm has arisen in connection with the circumstances of the case, which requires that the existence of psychological injury can be established according to objective criteria.¹⁵¹ [REDACTED] et al. have not done so. The mere assertion that they are experiencing psychological harm and are unaware of the precise consequences of the vaccinations is insufficient for this purpose. In so far as [REDACTED] et al. might also refer to Exhibit 91 in the context of non-pecuniary damage, Bourla refers to paragraph 128 et seq., in which it is explained that these statements are not neutral, objective, reliable or expert in nature.
137. Secondly, [REDACTED] et al. appear to rely on Article 6:106(a) of the Dutch Civil Code. They state, in fact, that “*they have argued, with reasons, that the defendants had the intention of causing them harm*”.¹⁵² However, [REDACTED] et al. have not asserted this anywhere, let alone in a substantiated manner. This assertion is unfounded and incorrect.¹⁵³ Thirdly, [REDACTED] et al. refer to Article 6:106(c) of the Dutch Civil Code and state that some of the claimants are married.¹⁵⁴ The relevance of this is not clear from the writ of summons.

¹⁰⁸ Parliamentary History of the Dutch Civil Code, Book 6, 1981, p. 389 (EV I).
¹¹⁰ S.D. Lindenbergh, “Compensation for pain and suffering due to stress, frustration, annoyance and (other) distress? On the concept of ‘infringement of personal dignity’ beyond physical and mental injury”, *NTBR* 2019/20, pp. 122–130, p. 124, with reference to Supreme Court 13 January 1995, *NJ* 1997/366, with commentary by C.J.H. Brunner (*Ontvanger/B.*) and Supreme Court 21 February 1997, *NJ* 1999/145, with commentary by C.J.H. Brunner (*Wrongful birth*). Supreme Court 15 March 2019, ECLI:NL:HR:2019:376, *NJ* 2019/162 *EBS*.
¹⁵¹ Summons, no. 267.
¹⁵² Furthermore, with this argument, Minks et al. fail to recognise that the intention must be specifically directed at causing *non-pecuniary* damage. The mere fact that someone has deliberately created a situation – which, incidentally, is not even the case here – as a result of which harm other than financial loss has been caused, cannot support the conclusion that that person intended to cause such harm. (See Supreme Court 26 May 2020, ECLI:NL:HR:2020:868, *VJ* 2020/231, paras. 2.3.2–2.4. See also S.D. Lindenbergh, in: *T&C BW*, Art. 6:106 BW, note 2 (online, updated up to and including 1 September 2023)). The scope of application of this provision is therefore limited in practice.
¹⁵³ Summons, no. 267.

4.3 No causal link

138. [REDACTED] et al. have not claimed that:

- (a) they had taken Comirnaty once or on more than one occasion;^{15 *}
- (b) that, had it not been for the alleged misrepresentation, they would not have been vaccinated (i.e. what information guided their decision to have the vaccines);
- (c) Comirnaty may have caused the alleged harm (generic causation); and
- (d) Comirnaty, in the case of [REDACTED] et al., has led to the alleged damage suffered (specific causation).

139. Bourla points out once again that Van Walraven's assertions are insufficient, both medically and legally, to establish (specific) causation (see paragraphs 128 et seq.) and that the assertions which Van Walraven appears prepared to make also mean that the probative value of his statements is very low or nil.

140. Nor is the alleged non-material damage suffered – which, as explained, is not eligible for compensation in the first place (see section 4.2.3) – causally linked to Comirnaty or any of the other COVID-19 vaccines. [REDACTED] et al. have not put forward any arguments on this point. Furthermore, it is common knowledge that psychological symptoms can also be – and indeed have been on a large scale

caused by the coronavirus crisis, rather than by the coronavirus vaccines¹⁵⁶

^{**} With the exception of Oudakker-Bekkers.

^{***} See, for example, Trimbos Institute, 'Ongoing coronavirus crisis leads to an increase in mental health issues and a need for perspective', 25 February 2021 (Bourla-57), available at www.trimbos.nl/actueel/news/ongoing-covid-crisis-leads-to-increase-in-mental-health-problems-and-need-for-prospects/#:~:text=health%20of%20adults,-Increase%20in%20mental%20health%20issues,%20the%20age%20group%20with%20the%20most%20issues and the Netherlands Youth Institute, *Research into COVID-19 and mental wellbeing* (Bourla-58), available at www.nji.nl/coronavirus/onderzoek-naar-corona-en-mentaal-welbevinden

4.4 No **collective liability** (Article 6:166 of the Dutch Civil Code)

141. The alleged claims brought under Article 6:166 of the Dutch Civil Code also fail. In order to successfully rely on Article 6:166 of the Dutch Civil Code, █████ et al. would have had to allege and prove:

- (a) that Bourla participated in;
- (b) conduct as part of a group;
- (c) the likelihood of causing damage in this way should have deterred the participants;
- (d) that his participation in this conduct can be attributed to him; and
- (e) that one of the participants █████ in that conduct caused unlawful damage to the injured party.¹⁵⁷

142. As explained, Bourla did not act unlawfully (see paragraph 4.1). The same applies to the other defendants. Nor did Bourla and the other defendants cause any damage to █████ et al. (see paragraph 4.2). For that reason alone, Bourla cannot be held (jointly and severally) liable under Article 6:166 of the Dutch Civil Code.

5 BURDEN OF PROOF AND PRESENTATION OF EVIDENCE

143. In support of the grounds for his defence, Bourla has the following evidence at his disposal:

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

¹⁵⁷ R.J.B. Boonekamp, *Stelplicht & Bewijslast*, commentary on Article 6:166 of the Dutch Civil Code (online, updated up to and including 2 October 2017).

- Bourla-9 EMA, *COVID-19 vaccine development, evaluation, approval and monitoring*
- Bourla-10 Pfizer, *Pfizer Outlines Five-Point Plan to Battle COVID-19*, 13 March 2020
- Bourla-11 Pfizer and BioNTech to jointly develop a potential COVID-19 vaccine, 17 March 2020
- Bourla-12 Pfizer and BioNTech Announce Further Details on Collaboration to Accelerate, 9 April 2020
- Bourla-13 ClinicalTrials.gov, *A trial investigating the safety and effects of four BNT162 vaccines against COVID-19 in healthy and immunocompromised adults*, 13 January 2022
- Bourla-14 ClinicalTrials.gov, *Study to Describe the Safety, Tolerability, Immunogenicity [...]*, 28 February 2023
- Bourla-15 EMA, *Comirnaty Assessment Report*, 19 February 2021
- Bourla-16 EMA, *'EMA starts second rolling review of a COVID-19 vaccine'*, 6 October 2020
- Bourla-17 OJEU, 24 December 2020
- Bourla-18 EMA, *Pharmacovigilance Plan of the EU Regulatory Network for COVID-19 Vaccines*
- Bourla-19 Watson et al., *Global impact of the first year of COVID-19 vaccination: a mathematical modelling study*, 23 June 2022
- Bourla-20 Health Council of the Netherlands, *Advice on COVID-19 vaccination with 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*, 18 September 2022
- Bourla-22 Institut Pasteur, *Discovery of messenger RNA in 1961*, 15 February 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*, 2 October 2023
- Bourla-25 Science News, *How COVID-19 vaccines were developed so quickly without cutting corners*, 29 June 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-19: how the EMA fast-tracks development support and approval of medicines and vaccines*, 4 May 2020
- Bourla-29 EMA, *How are COVID-19 vaccines developed*
- Bourla-30 Nature, *'Whither COVID-19 vaccines'*, 28 September 2020
- Bourla-31 NBC News, *3 vaccine executives say that after approval, distribution will be the main challenge*, 3 December 2020

- Bourla-32 The Journal, *Pfizer CEO says there is 'encouraging' data on whether its vaccine stops Covid transmission*, 13 January 2021
- Bourla-33 EMA, *Comirnaty, COVID-19 mRNA vaccine (nucleoside-modified)*, 21 December 2020
- Bourla-34 FDA, *'FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorisation for First COVID-19 Vaccine'*, 11 December 2020
- Bourla-35 WHO, *Interim recommendations for the use of the Pfizer-BioNTech COVID-19 vaccine*, 8 January 2021
- Bourla-36 Reuters, *Fact Check: Preventing transmission was never a requirement for the initial approval of COVID vaccines*
- Bourla-37 ECDC, *Risk of SARS-CoV-2 transmission from newly-infected individuals with documented previous infection or vaccination*, 29 March 2021
- Bourla-38 EMA, *Comirnaty product information (selection)*
- Bourla-39 FDA, *Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorisation Review Memorandum*, 20 November 2020
- Bourla-40 Gov. UK, *Summary of the Public Assessment Report on the COVID-19 Vaccine*, December 2020
- Bourla-41 MIT Technology Review, *What are the ingredients of Pfizer's COVID-19 vaccine*, 9 December 2020
- Bourla-42 European Parliament, *Answer given by Ms Kyriakides on behalf of the European Commission*, 26 October 2021
- Bourla-43 87. European Parliament, *Answer given by Ms Kyriakides on behalf of the European Commission*, 8 March 2022
- Bourla-44 Reuters, *'COVID-19 vaccines do not contain graphene oxide'*, 23 July 2021
- Bourla-45 AP, *'Pfizer vaccine does not contain graphene oxide'*, 8 July 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 authorisation (Comirnaty)*, 2021
- Bourla-49 Reuters, *Pages detailing suspected side effects released regarding Pfizer's COVID-19 vaccine [...]*, 17 March 2022
- Bourla-50 European Parliament, *Answer given by Ms Kyriakides on behalf of the European Commission*, 3 July 2023
- Bourla-51 EMA, *COVID-19 vaccines: development, evaluation, approval and monitoring*
- Bourla-52 Hviid, A., *Inaccurate representation of shipped vaccines as administered*, 20 June 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'*, 10 August 2021

- Bourla-55 CBG-MEB, *Column 'About medicines': Are coronavirus vaccines experimental?*, 2 June 2021
- Bourla-56 LAREB, *Side effects of COVID-19 vaccines*
- Bourla-57 Trimbo's Institute, *Ongoing coronavirus crisis leads to an increase in mental health issues and a need for perspective*, 25 February 2021
- Bourla-58 Netherlands Youth Institute, *Research into coronavirus and mental wellbeing*

144. Bourla does not wish to be regarded, on the basis of the foregoing, as having voluntarily assumed any burden of proof that does not legally rest with Bourla.
145. Bourla takes the view that the burden of proof in these proceedings rests with [REDACTED] et al. Bourla expressly offers counter-evidence.
146. In so far as, in the court's view, the burden of proof in respect of any assertion may rest with Bourla, Bourla shall adduce evidence to that effect by all lawful means, in particular by calling witnesses.

ON THESE GROUNDS, BOURLA CONCLUDES:

that the court, by judgment, in so far as legally possible with provisional enforceability:

- (a) declare the claims of [REDACTED] et al. inadmissible, or at least dismiss those claims;
- (b) order [REDACTED] et al. jointly and severally to pay the costs of the proceedings, as well as the customary subsequent costs (both with and without service), plus statutory interest as referred to in Article 6:119 of the Dutch Civil Code from fourteen days after the date of the judgment, in which case payment by one claimant shall discharge the other claimants.

Solicitor

loco

N. Vonk



This case is being handled by [REDACTED] Lessing, LL [REDACTED] 892,
[REDACTED] 162 1874, E Davine.Roe [REDACTED].com, and M.

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