IN THE HIGH COURT OF SOUTH AFRICA
(GAUTENG DIVISION, PRETORIA)

CASE NO.: _____

In the matter between:

FREEDOM ALLIANCE OF SOUTH AFRICA	Applicant
and	
THE MINISTER OF HEALTH	First Respondent
THE DEPARTMENT OF HEALTH	Second Respondent
THE DEPARTMENT OF HEALTH, EASTERN CAPE PROVINCE	Third Respondent
MEMBER OF THE EXECUTIVE COUNCIL: DEPARTMENT OF HEALTH, EASTERN CAPE PROVINCE	Fourth Respondent
THE DEPARTMENT OF HEALTH, FREE STATE PROVINCE	Fifth Respondent
MEMBER OF THE EXECUTIVE COUNCIL: DEPARTMENT OF HEALTH, FREE STATE PROVINCE	Sixth Respondent
THE DEPARTMENT OF HEALTH, GAUTENG PROVINCE	Seventh Respondent
MEMBER OF THE EXECUTIVE COUNCIL: DEPARTMENT OF HEALTH, GAUTENG PROVINCE	Eighth Respondent
THE DEPARTMENT OF HEALTH, KWAZULU-NATAL PROVINCE	Ninth Respondent
MEMBER OF THE EXECUTIVE COUNCIL: DEPARTMENT OF HEALTH, KWAZULU NATAL	Tenth Respondent
THE DEPARTMENT OF HEALTH, LIMPOPO PROVINCE	Eleventh Respondent

REGISTRAR OF THE HIGH COURT OF SOUTH AFRICA
GAUTENG DIVISION,
PRETORIA
Private Bag X67, Pretoria 0001
REGISTRAR OF THE HIGH COURT OF SOUTH AFRICA
GAUTENG DIVISION,
PRETORIA

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MEMBER OF THE EXECUTIVE COUNCIL: DEPARTMENT OF HEALTH, LIMPOPO PROVINCE	Twelfth Respondent
THE DEPARTMENT OF HEALTH, MPUMALANGA PROVINCE	Thirteenth Respondent
MEMBER OF THE EXECUTIVE COUNCIL: DEPARTMENT OF HEALTH, MPUMALANGA PROVINCE	Fourteenth Respondent
THE DEPARTMENT OF HEALTH, NORTHERN CAPE PROVINCE	Fifteenth Respondent
MEMBER OF THE EXECUTIVE COUNCIL: DEPARTMENT OF HEALTH, NORTHERN CAPE	Sixteenth Respondent
THE DEPARTMENT OF HEALTH, NORTH-WEST PROVINCE	Seventeenth Respondent
MEMBER OF THE EXECUTIVE COUNCIL: DEPARTMENT OF HEALTH, NORTH-WEST PROVINCE	Eighteenth Respondent
THE DEPARTMENT OF HEALTH, WESTERN CAPE PROVINCE	Nineteenth Respondent
MEMBER OF THE EXECUTIVE COUNCIL: DEPARTMENT OF HEALTH, WESTERN CAPE PROVINCE	Twentieth Respondent
THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA	Twenty-first Respondent
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY	Twenty-second Respondent
PFIZER	Twenty-third Respondent

REGISTRAR OF THE HIGH COURT OF SOUTH AFRICA
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GAUTENG DIVISION,
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FOUNDING AFFIDAVIT

I, the undersigned

HERMAN JACOBUS EDELING

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do hereby make oath and state that:-

1. I am an adult male specialist neurosurgeon, medico-legal practitioner, and mediator. I have been engaged in private practice for 40 years.

2. This application has been duly authorised by the Board of the applicant. Pursuant to section 38 of the Constitution, 1996, the applicant brings this case in its own interest, in the interests of its members, and in the public interest. As these papers make clear, the public are being adversely effected by what the applicant (and its members) believes to be a defective exercise of administrative power, and their rights are being infringed. A resolution of the Board of the applicant confirming the authorisation of this application is annexed as "**HE1**", and a confirmatory affidavit of Dr Paolo Brogneri, one of the Directors of the applicant, is annexed as "**HE2**".

3. The facts in this affidavit are, to the best of my knowledge, both true and correct, and, unless the contrary appears from the context of this document, they fall within my personal knowledge. Where I make legal submissions, I do so on the advice of the legal team in this case, and I accept their advice as correct.

4. In this matter, my testimony is predominantly that of a factual nature. To the extent that I opine as an expert, I do so based on my qualifications which are detailed in my *curriculum vitae* annexed as "**HE3**", and my established expertise in medical ethics, general medical science, evidence-based medicine and rational interpretation of clinical studies, scientific and medical articles, and scientific and medical data.

5. In the aforementioned areas of expertise, I have provided evidence to South African Courts in two hundred and thirty-five (235) cases.

6. The opinions I express in this document are based on conclusions I have drawn from a careful consideration of available facts. Where I reference peer-reviewed journal articles, I ask the Court to accept them on the basis that I have satisfied myself of the correctness of the views and conclusions expressed in those articles, given that I have carefully scrutinised and assessed them by applying my aforementioned skillset.

SUMMARY OF THE CASE AND NECESSITY FOR A JUDICIAL CASE MANAGEMENT

7. I am advised that the applicant's legal representatives will, in due course, seek to have this application assigned to judicial case management. In this section, I set out – broadly – the significance of this matter.

8. The SARS CoV-2 (severe acute respiratory syndrome coronavirus 2) virus, which is a strain of coronavirus that causes Covid-19 (coronavirus disease 2019) was first identified in an outbreak in the Chinese city of Wuhan in December 2019. From that point on, it spread rapidly throughout the world causing illness, death and global panic.

9. Following what was trumpeted as a necessary, herculean, and collaborative scientific effort, numerous vaccines flooded the market in the hopes of providing a panacea to the Covid-19 pandemic. Those vaccines were all developed and trialed

under severely truncated time periods. These vaccines were developed and trialed in a matter of months.

10. Vaccines normally take between ten to fifteen years from trial to market.

11. Amongst these vaccines was the Pfizer BioNTech BNT162b2 mRNA Covid-19 Vaccine, branded in South Africa as "Comirnaty" ("Comirnaty"). According to a press release by SAHPRA, the Comirnaty vaccine is authorised for use in South Africa by SAHPRA in adults and children aged 12 years and older". Comirnaty was (and continues to be) marketed as "safe" and "effective".

12. Comirnaty has now been supplemented by the authorisation of the adult "Ready to Use" vaccine ("RTU vaccine"), and the paediatric "Dilute to Use" vaccine ("DTU vaccine") – both based on the same mRNA technology.

13. South Africa did not conduct its own independent trials of Comirnaty, the RTU vaccine or the DTU vaccine. My understanding is that SAHPRA relied solely on datasets provided by the very party contractually responsible for *commercializing* these vaccines – Pfizer. There is a fundamental conflict of interest at play, cloaking the registration of these vaccines in irrationality.

14. Prior to the release of Comirnaty, mRNA had never been successfully tested – let alone used – in combatting infectious diseases such as Covid-19. It had been tested as a possible intervention against cancers, and, to a limited and unsuccessful extent, as a potential intervention against HIV-1. It had not previously been tested in any human trials against SARS-CoV-2, the causative agent of Covid-19, or against any other coronaviruses.

15. In this case, I set out – in this affidavit - clear evidence showing that Pfizer's vaccine trial for Comirnaty was a whitewash – mired by what appears to be substantial data manipulation, data inaccuracies, and inaccurate outcomes. It is difficult to avoid the conclusion that this misled global regulators, like the twenty-second respondent ("**SAHPRA**") into granting authorization for Comirnaty, to the detriment of public health.

16. Global real-world data, in the form of official data from Governments around the World, as well as vaccine adverse event monitoring systems, and scientists and doctors on the ground are sounding the alarm about serious adverse events (including blood clotting disorders, cardiac disorders, neurological disorders, autoimmune disorders, pregnancy and fertility issues and aggressive cancers) arising out of the inadequately tested Comirnaty vaccine.

17. Battling the tide of information suppression and "cancellation" of unpopular opinions, medical and scientific experts around the world are now succeeding in publishing these adverse events, as well as the mechanisms causing them, in established peer-reviewed journals.

18. This application is a call on Pfizer to explain its conduct for public scrutiny. It is also a call on the South African regulators and Government to hold Pfizer to account and to act in the best interests of the South African public. As a last resort, the applicant humbly requests this Court to come to the aid of bodies like the applicant, in the interests of the health of the South African public.

19. I will, in this affidavit, demonstrate that the Comirnaty vaccine is not (and should never have been branded as) "safe" and/or "effective".

THE STRUCTURE OF THESE PAPERS

20. These papers are structured a follows:

20.1. First, I set out the parties to the litigation.

20.2. Second, I deal with the admission of the hearsay evidence contained in these papers.

20.3. Third, I apprise the Court of the various experts whose testimony stands in support of this case.

20.4. Fourth, I deal with the Vaccine Adverse Events Reporting System ("VAERS") and the alarming safety signals that it is showing regarding adverse events associated with Pfizer's vaccines. VAERS was created in the United States in 1990 by the Food and Drug Administration (FDA) and Centres for Disease Control and Prevention (CDC) to receive reports of Adverse Events ("AEs") that may be associated with any vaccine that goes to market. It is widely known as one of the world's foremost adverse events reporting systems. In relation to Pfizer's vaccines, it is already showing drastic increases (of hundreds or thousands of percentage points) in adverse events such as cancers, deaths, disability, fertility issues, and adverse events in children compared to all other vaccines over a decade long period. I put this section upfront in order to apprise the Court of the gravity of the problem that the remainder of the papers tackle.

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20.5. Fifth, I detail the collaboration between Pfizer and BioNTech that led to the development and mass marketing of Pfizer's vaccines. In this section, I apprise the court of the reasons that Pfizer's intentions and motivations, as they pertain to the conduct of the clinical trial in question, fall to be treated with substantial skepticism.

20.6. Sixth, via information provided by an mRNA expert, I explain the mRNA technology in the Comirnaty vaccine, and the mechanisms through which it operates in the human body. This section details the potential harms and unknowns associated with the vaccine. With reference to peer-reviewed articles (contained in the relevant supporting affidavit) the section demonstrates links between the mRNA technology and conditions such as autoimmune diseases, aggressive deadly cancers, severe inflammatory conditions, prion diseases (contagious untreatable diseases resulting in the gradual decline of brain function leading to personality changes and death), myocarditis, blot clotting, impaired fertility, miscarriages and spontaneous abortions.

20.7. Seventh, I detail the Pfizer trial. I set out the trial protocol and explain what was trialed and what was not trialed, and compare this to the stated outcomes and the government narrative. I detail Pfizer's 2-month trial data and their 6-month trial data, and highlight data anomalies and factual inaccuracies. In particular, I detail evidence in the trial data that shows lack of effectiveness at preventing disease or death, as well as subsequent surveillance data that shows lack of effectiveness at preventing disease or death. I also detail evidence of severe adverse

events as per post-authorization pharmacovigilance, and explain how Pfizer has torpedoed the collection of any adequate long-term safety data in their "randomized controlled trial".

20.8. Eighth, I set out reports from two local medical practitioners to demonstrate to the Court that the adverse events that are signaled by the data canvassed elsewhere in the papers, are manifesting on the ground locally. I can attest to the fact that many medical practitioners are scared to speak up about what they diagnose or suspect as vaccine injuries. In the preparation of these papers, we approached twenty-two doctors from around the country who confirmed vaccine injuries seen in their practices. Only two of those doctors were willing to provide evidence on affidavit due to fear of reprisal. They explained that they had seen what had happened to those doctors (such as Dr Susan Vosloo) who had warned against the Pfizer injections: they had been sidelined, attacked viciously in the press, and harassed by their professional bodies, and explained further that they were not willing to subject themselves to that onslaught for the sake of this case. They had not even reported the adverse events to SAHPRA because of the same fear, and because SAHPRA's pharmacovigilance reporting system is so complicated and time consuming as to be prohibitive. Over and above this, it has been difficult terrain for doctors to navigate because the State's official narrative has been that these vaccines are "*safe and effective*", and any information to the contrary has been heavily suppressed. This means that no official guidance has been forthcoming

to doctors in terms of how to diagnose and treat vaccine injuries. I ask the Court to bear this in mind when dealing with this leg of the evidence.

THE PARTIES TO THE LITIGATION

21. The applicant is the Freedom Alliance of South Africa ("FASA"), a registered non-profit company domiciled and headquartered at 49 Victoria Rd Camps Bay Cape Town South Africa, 8005. As detailed more fully in Dr Brogneri's affidavit, FASA is an organisation principally committed the promotion and protection of human rights, and its core objectives include the promotion of equal rights, the expansion of freedoms, access to information without censorship and one-sided narratives, and equality and protection for all independent men and women of South Africa.

22. The first respondent is the Minister of Health, the member of the national executive responsible for the national Department of Health and National Health Policy as well as the administration of Public Health ("the Minister"). The Minister's principal place of administration is at Civitas Building, Floor 20, corner Struben and Thabo Sehume Streets, Pretoria and in the care of the State Attorney, Pretoria, at 316 Thabo Sehume Street, Pretoria. The incumbent Minister is Dr Joe Phaala.

23. The second respondent is the Department of Health. It is the executive department of the national government that is assigned to oversee healthcare in South Africa. Of relevance to this case, and pursuant to GN 1502 in Government Gazette 45487 of 15 November 2021, it is the authorised seller of all vaccines, including the Comirnaty vaccine, the Pfizer Ready To Use Adult vaccine and Pfizer's Dilute To Use Paediatric vaccine. The second respondent's place of business is 1112

Voortrekker Rd, Pretoria care of the State Attorney, Pretoria, at 316 Thabo Sehume Street, Pretoria.

24. The third respondent is the Eastern Cape Department of Health. It is the executive department responsible for healthcare in the Eastern Cape. Its place of business is in Bisho, Eastern Cape.

25. The fourth respondent is the Member of the Executive Council of the Eastern Cape Department of Health cited in her capacity as the head of the Department of Health in the Eastern Cape, and having the responsibilities as set out in section 25 of the National Health Act 61 of 2003. Her place of business is in Bisho, Eastern Cape.

26. The fifth respondent is the Free State Department of Health. It is the executive department responsible for healthcare in the Free State. Its place of business is at Cnr. Charles & Harvey Rd, City Centre, Bloemfontein.

27. The sixth respondent is Member of the Executive Council of the Free State Department of Health cited in his capacity as the head of the Department of Health in the Free State, and having the responsibilities as set out in section 25 of the National Health Act 61 of 2003. His place of business is at Cnr. Charles & Harvey Rd, City Centre, Bloemfontein.

28. The seventh respondent is the Gauteng Department of Health. It is the executive department responsible for healthcare in Gauteng. Its place of business is 45 Commissioner St, Johannesburg, 2000.

29. The eighth respondent is the Member of the Executive Council of the Gauteng Department of Health cited in her capacity as the head of the Department of Health in Gauteng, and having the responsibilities as set out in section 25 of the National Health Act 61 of 2003. Her place of business is 45 Commissioner St, Johannesburg, 2000.

30. The ninth respondent is the KwaZulu Natal Department of Health. It is the executive department responsible for healthcare in KwaZulu Natal. Its place of business is Magwaza Maphalala St, Dalbridge, Durban.

31. The tenth respondent is the Member of the Executive Council of the KwaZulu Natal Department of Health cited in his capacity as the head of the Department of Health in Gauteng, and having the responsibilities as set out in section 25 of the National Health Act 61 of 2003. His place of business is Magwaza Maphalala St, Dalbridge, Durban.

32. The eleventh respondent is the Limpopo Department of Health. It is the executive department responsible for healthcare in Limpopo. Its place of business is College Ave, Hospital Park, Polokwane.

33. The twelfth respondent is the Member of the Executive Council of Limpopo cited in her capacity as the head of the Department of Health in Limpopo, and having the responsibilities as set out in section 25 of the National Health Act 61 of 2003. Her place of business is 46 Hans van Rensburg Street, Polokwane.

34. The thirteenth respondent is Mpumalanga Department of Health. It is the executive department responsible for healthcare in Mpumalanga. Its place of business is office 14, Jaspis St, Aeorand, Middelburg.

35. The fourteenth respondent is the Member of the Executive Council of Mpumalanga cited in her capacity as the head of the Department of Health in Mpumalanga, and having the responsibilities as set out in section 25 of the National Health Act 61 of 2003. Her place of business is 7 Government Boulevard, Building 3, Riverside Park, Extension 2, Nelspruit.

36. The fifteenth respondent is the Northern Cape Department of Health. It is the executive department responsible for healthcare in the Northern Cape. Its place of business is at James Exum Building Du Toit Span Road Kimberley.

37. The sixteenth respondent is the Member of the Executive Council of the Northern Cape cited in his capacity as the head of the Department of Health in the Northern Cape , and having the responsibilities as set out in section 25 of the National Health Act 61 of 2003. His place of business is James Exum Building Du Toit Span Road Kimberley.

38. The seventeenth respondent is the North West Department of Health. It is the executive department responsible for healthcare in the North West. Its place of business is Cnr 1st Street & Sekame Street, Mahikeng.

39. The eighteenth respondent is the Member of the Executive Council of the North West cited in his capacity as the head of the Department of Health in the North West, and having the responsibilities as set out in section 25 of the National Health Act 61 of 2003. His place of business is Cnr 1st Street & Sekame Street, Mahikeng.

40. The nineteenth respondent is the Western Cape Department of Health. It is the executive department responsible for healthcare in the Western Cape. Its place of business is 4 Dorp Street, Cape Town.

41. The twentieth respondent is the Member of the Executive Council of the Western Cape cited in her capacity as the head of the Department of Health in the Western Cape, and having the responsibilities as set out in section 25 of the National Health Act 61 of 2003. Her place of business is 4 Dorp Street, Provincial Administration Building, 21st Floor, Cape Town.

42. The twenty first respondent is President of the Republic of South Africa, cited in his capacity as head of state and head of the national executive with his principal place of administrative business at the Union Buildings, Government Avenue, Pretoria.

43. The twenty second respondent is the South African Health Products Regulatory Authority ("SAHPRA"), established as an organ of state under section 2 of the Medicines and Related Substances Act 1010 of 1965. It has its principal place of business at Building A, Loftus Park, 402 Kirkness St, Arcadia, Pretoria.

44. The twenty third respondent is Pfizer, a company registered and incorporated in terms of the company laws of South Africa. It is the manufacturer of the vaccines sought to be interdicted in this application. Its registered place of business is 85 Bute Rd, Sandown, Sandton.

ADMISSION OF HEARSAY EVIDENCE

45. These papers contain hearsay evidence. The applicant humbly requests that the Court admit that evidence in the interests of justice under section 3(c) of the Law of Evidence Amendment Act 45 of 1988 ("ELAA").

45.1. **First**, reference is made to peer-reviewed journal articles without direct evidence from the authors of those articles. This evidence demonstrates that the vaccines are ineffective and unsafe. There is no prejudice to any of the respondents in admitting this evidence. They, no doubt, will adduce peer-reviewed articles to bolster their argument, and the applicant will not object to the introduction of that evidence. The reasons why the authors of the articles have not given direct evidence in this application follow. The relevance to the case is beyond question, and there are safeguards around its reliability and credibility because the articles are sourced from peer-reviewed journals. The peer-review process helps to ensure the accuracy, reliability, and credibility of scientific papers by subjecting them to rigorous scrutiny by experts in the same field. The peer-review process is sufficient to secure the probative value of the articles annexed. The process involves a number of steps:

45.1.1. Submission: The author(s) submit their paper to a journal for consideration.

45.1.2. Editorial evaluation: The editor of the journal evaluates the paper to see if it meets the minimum requirements for publication. If it does not meet the requirements, it may be rejected at this stage without being sent for peer review.

45.1.3. Selection of reviewers: If the paper passes the initial evaluation, the editor will select two or more experts in the same field as the paper to review it.

45.1.4. Peer review: The reviewers read the paper and evaluate its quality, relevance, and originality. They may suggest changes or improvements, or they may recommend that the paper be rejected if they find major flaws or if it does not meet the journal's standards.

45.1.5. Decision: Based on the feedback from the reviewers, the editor makes a decision on whether to accept or reject the paper. The author(s) are informed of the decision and, if necessary, are given the opportunity to revise the paper and resubmit it for further consideration.

45.2. **Second**, comprehensive reference is made to read-world data sets without the direct evidence of the statisticians responsible for producing or compiling that data. One such set of data, for example, is data released by the UK government. In assessing whether it is in the interests of justice to admit this category of evidence, it is important to understand why it has been necessary to rely on the data published from other governments. The primary reason for this is that our own government has not been publishing the relevant vaccine-related statistics. On 10 August 2021, I wrote to the Honourable President requesting the publication of relevant vaccine-related statistics. I attach that email (which I sent five times) and the four responses I received collectively as "**HE5**". Specifically, I asked for the following:

> *"Track and publish daily statistics on the numbers (and proportions) of vaccinated individuals who (a) have any serious health issue; (b) have been admitted to hospital for any reason; and (c) who have died for any reason; as well as (d) the number (and proportion) of hospitalized individuals who have been vaccinated."*

> *Direct the authorities to immediately ensure full transparency in the collection of data and the reporting of adverse events, as well as numbers of all deaths, the causes thereof and contextual information, such that simple, easy to understand reports become openly available on the official SA Coronavirus website on a daily and annualized basis."*

45.3. The Presidency responded to me promising that they would make contact. This did not happen. Despite pleas for the relevant vaccine-related data, none was forthcoming.

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45.3.1. On 7 September 2021, having not heard back from the Presidency, I wrote to the Minister of Health and echoing the pleas made to the President. In that letter, annexed as "**HE6**", I made it clear that my requests for data were supported by 3510 other concerned citizens. I received no reply.

45.3.2. In the context of the South African Government having chosen to not make vaccine-related data publicly available, it would be unjust to prevent the applicants from relying on data from other countries who have published such data. Those data sets are simply the best we have.

45.3.3. In the context of the absence of South African data, the international data is highly probative and should be admitted.

45.3.4. The respondents are free to counter it with local datasets should they choose a level of transparency before this Court that they were not inclined to afford to the South African people.

45.4. **Third**, Pfizer's 2-month and 6-month reports containing the data supporting the safety and efficacy profiles of the relevant vaccines are also referenced. Pfizer is a party in this application.

DELAY AND THE EXHAUSTION OF INTERNAL REMEDIES

46. The Comirnaty vaccine was registered in January 2022. In February 2022, an organisation called "Free the Children Save the Nation" ("FCSN") instituted an appeal process under the Medicines and Related Substances Act against the registration of the Comirnaty vaccine.

47. FCSN's grounds of appeal were similar to the grounds on which the applicant relies in this application – irrationality. To date, a year later, an appeal panel still has not been constituted under the Act, due to delays occasioned primarily at the hands of the Minister of Health and SAHPRA, who have still not nominated members for the appeal panel.

48. The applicant was aware of the FCSN's internal appeal, and decided that the most responsible course of action was to allow that process to unfold.

49. However, the severe, unwarranted, and inexplicable delays in the finalization of that appeal left the applicant with no option, but to approach this Court.

50. A further reason the applicant has decided to approach this Court is that the vaccination campaign is now being heavily targeted at children. The safety and efficacy concerns raised by the evidence in this case merited a direct approach to this Court. This is because it is unlikely that the internal appeal process will definitely resolve the issues arising from the impugned decisions. On the contrary, findings of our courts are binding on all.

51. The issue of delay does not arise in the context of the RTU and DTU products. Those products were authorised on 15 November 2022.

52. Given the scope of these papers, and the length of time required to prepare them, there is also no unreasonable delay that could possibly bar the applicant from a review.

53. With the internal appeal (referred to above) having ground to a halt, consultations for this case commenced in late November 2022. The process of assembling the relevant evidence and expert testimony commenced in late December 2022, and commencement of the drafting of these papers began in earnest in or around January 2022.

54. The process of reading all the relevant documentation, (and then detailing, and simplifying) what is extremely complex medical and data-based evidence, demanded months of dedicated work.

55. Over and above that, consultations had to be set up with expert witnesses overseas. Those consultations involved complex medical and scientific evidence and occurred over weeks.

56. What therefore emerges from the above is that the interests of justice permit the:

56.1. Condonation of any late institution of the review application, in respect of one or more of the impugned decisions, and the extension of the period prescribed for the institution of a review application to the date in which this application is actually instituted; and

56.2. Exemption of the applicant from any obligation(s) to exhaust internal remedies, in respect of the decisions impugned in this application.

EXPERT TESTIMONY SUPPORTING THE APPLICANT'S CASE

57. This affidavit is supported by evidence from domestic and international independent experts. Prior to including their evidence in these papers, I have consulted with all of these experts, I have taken the effort to:

57.1. verify the accuracy of the information that appears in this document; and

57.2. prior to finalization of the document, I circulated a draft of this document to the relevant experts in order to ensure that they were satisfied with the accuracy of its contents.

58. In circumstances where I have made use of the evidence of other independent expert witnesses, their confirmatory affidavits together with their *curriculum vitaes* are annexed, and their qualifications, their expertise, and the bases for their independent conclusions and opinions are available for the scrutiny of the Court. The expert affidavits attached to these papers are as follows:

58.1. **Dr Jessica Rose:** Dr Jessica Rose is an expert computational biologist, whose affidavit and *curriculum vitae* are annexed as "**HE8**". A computational biologist is a highly trained expert specializing in developing and/or analysing data to obtain useful results and models.

This includes a knowledge of the data itself, and understanding where it comes from and how it is to be used. Dr Rose pursued a Bachelor of Science in Applied Mathematics at Memorial University of Newfoundland, and a Master of Science in Medicine in Immunology at the same institution. She continued with her studies in Israel, having been invited to pursue a PhD in Computational Biology (Viral Kinetic studies on Cytomegalovirus (CMV) and Hepatitis B Virus (HBV)) at Bar Ilan University. Since its completion, she has successfully completed two Post-Doctoral degrees in Molecular Biology, with a focus on Rickettsiology at the Hebrew University of Jerusalem, and Biochemistry, with a focus on Anisotropic Network modeling of ATP-Cassette-Binding Transporter molecule mechanisms at the Technion Institute of Technology. Since completion of the second Post Doctoral degree in December 2019, and the declaration of the global 'pandemic', she has applied her mathematical, computational and modelling expertise to analyzing the Vaccine Adverse Event Reporting System (VAERS) data from the United States. VAERS is a pharmacovigilance tool launched by the U.S. Government in 1990 to provide safety signals not detected in pre-market testing in the context of pharmaceuticals and biologicals such as the COVID-injectable products. She has published her findings twice in the journal "Science, Public Health Policy and the Law" and has another publication co-authored with Dr. Peter McCullough. The first publication is a general analysis, the second is a critical appraisal of VAERS pharmacovigilance and the third is an analysis of myocarditis adverse events reported to VAERS in the context of the Moderna, Pfizer

and Janssen COVID19 injectable products. Her evidence shows alarming increases in adverse events associated Pfizer's vaccines compared to all other vaccines over the course of a decade.

58.2. **Dr Anthony Kyriakopoulos**: Dr Kyriakopoulos is a medical microbiologist and mRNA expert. His supporting affidavit and his *curriculum vitae* are annexed collectively as "**HE9**". His CV shows that he has been researching the molecular genetics of aging and cancer for more than 20 years. During that research he has used mRNA technology extensively in producing two Ph.D. theses and sustaining postdoctoral positions for other colleagues. He graduated from the Faculty of Medicine of the University of London UK, and received a Postgraduate Diploma in Medical Microbiology from The London School of Hygiene and Tropical Medicine London, UK, and a Master's Degree from the Faculty of Medicine, Medical School, University of London UK. In Greece, he completed medical training in Medical - Molecular Microbiology and obtained a Doctorate in Medicine, from the Medical School of the University of Athens. This has been recognised after official panel examination as a Doctorate of Philosophy in Medical Microbiology from The Institute of Biomedical Sciences in the United Kingdom (UK). Currently he is the President of the Hellenic Society of Turin and Fellow of the Institute of Biomedical Sciences UK. He explains that in his expert opinion, the mRNA technology was used prematurely as a weapon against infectious diseases, and that it is causing severe health harms. With reference to peer-reviewed papers, he sets out links

between the mRNA technology and conditions such as autoimmune diseases, aggressive deadly cancers, severe inflammatory conditions, prion diseases (contagious untreatable diseases resulting in the gradual decline of brain function leading to personality changes and death), myocarditis, blood clotting, impaired fertility, miscarriages and spontaneous abortions.

58.3. **Professor Norman Fenton**, whose affidavit and *curriculum vitae* are annexed as "**HE10**" is Professor Emeritus of Risk at Queen Mary University of London (retired as Full Professor December 2022). He is also a Director of Agena Ltd, a company that specialises in artificial intelligence and Bayesian probabilistic reasoning. He is a mathematician by training with a current focus on quantifying risk and uncertainty using causal, probabilistic models that combine data and knowledge (Bayesian networks). He has published 7 books and over 400 peer reviewed articles, and his works cover multiple domains including law and forensics and health. He has been an expert witness in major criminal and civil cases throughout his career. He holds a PhD (1981) in Mathematics, Sheffield University; an MSc (1979) in Mathematics, Sheffield University; a BSc (Class I) in Mathematics, University of London (LSE) 1978; a CEng Chartered Engineer, Member of the IET (since 1987); and a CMath Chartered Mathematician. He is a Fellow of the IMA (AFIMA 1988, FIMA 1998); a FBCS Fellow of the BCS (British Computer Society) since 2005; and a FHEA Fellow of the Higher Education Academy, since June 2019. He completed Expert Witness

Training with Bond Solon under the auspices of Cardiff University Law Dept (2007-2008). He gives evidence confirming my interpretation of the Pfizer data and my interpretation of real world data (including data from the UK). He confirms my assessment of the Pfizer trial data.

58.4. **Dr James Thorp**: Dr Thorp, whose supporting affidavit and curriculum vitae are annexed collectively as "**HE11**" is a Obstetrician-Gynaecologist (OBGYN) practising in the sub-speciality of Maternal Foetal Medicine in the United States. He has been a practising Medical Doctor (M.D.) for forty-three (43) years. He obtained his undergraduate degree (B.A.) in 1975 from Western Michigan University, which is in Kalamazoo, Michigan, majoring in Chemistry, with Biology minor and Math minor, and his Doctor of Medicine in 1979 from Wayne State University School of Medicine, which is in Detroit, Michigan. He has called for a world-wide ban and moratorium on the use of any Covid-19 mRNA vaccines, including the Pfizer vaccine products, in pregnancy until long-term safety data are irrefutable. He agrees with my analysis of Pfizer's protocol and data showing that the Comirnaty vaccine's safety was not tested in pregnant or breastfeeding women. The fact that, despite this, the relevant Government and regulatory authority recommended the product to pregnant or breastfeeding women, or for that matter, to any woman who wants to have children, violates the long-standing golden rule of pregnancy: never ever use an investigational drug, a new substance, a new vaccine, in pregnancy even if there is a potential benefit. To the best of his knowledge and experience, he testifies that there is an increased

risk of the following complications related to the COVID-19 "vaccines": menstrual irregularities, miscarriage, fetal deaths (also known as stillbirths), fetal growth abnormalities, abnormal fetal vascular abnormalities, fetal malformations, fetal arrhythmias and fetal cardiac arrests.

58.5. **Dr Aseem Malhotra**:, whose affidavit and curriculum vitae are annexed as "**HE12**" is an NHS Trained Consultant Cardiologist, and visiting Professor of Evidence Based Medicine. He is twice vaccinated, and stood in public support of the Covid-19 vaccines until the circumstances surrounding the death of his double-vaccinated Father led him to investigate the safety and efficacy of the Comirnaty vaccine. Relying on his assessment of the Pfizer data (which accords with my own), and global data sources, his evidence focuses on his conclusion that Comirnaty is not as safe and effective as we have been told, as well as the rationale supporting his conclusion. Dr Malhotra also testifies to the corruption of the medical fraternity, academia, the mainstream media and health policy makers that led to the perpetuation of the distorted narrative around the Pfizer vaccines.

58.6. **Dr Stephen Schmidt**: Dr Schmidt, whose curriculum vitae and supporting affidavit are annexed collectively as "**HE13**", is a specialist physician and gastroenterologist, and an expert drug trialist. He has been involved in drug trials for over thirty (30) years and has completed trails for the following manufacturing companies: Pfizer, Astra Zeneca,

Janssen Cilag, Novavax, Gilead, Johnson and Johnson, Glaxo Smith, Adcock-Ingram, and the US Defence Force. He holds an MBChB and MMed(Int) from the University of Stellenbosch. From 1990 to 2022 he was part of, or was the responsible principal investigator in, fifty-seven clinical drug trials. His experience as a training trialist and eventual Principal Investigator taught him every skill needed to conduct clinical trials, including the complete administrative management of the trial site, logistics, pharmacy control, dispensing and drug accountability, blood and tissue sampling and shipping, writing of- and updating 72 standard operative procedures detailing every action at the trial site, assessing and understanding novel drug protocols, continuous training of staff and refresher courses in Good Clinical Practice every 2 years, attending international trial commencement meetings, receiving clinical trial monitors and auditors, assessing and management of adverse events of any type, acting as first responder to safety signals observed at the site. He acted as national investigator in several studies and was audited by sponsors' auditors, CRO auditors, the Medical Control Council, SAHPRA and the FDA. Neither of his trial sites ever received a negative audit report. His conduct as a Principal Investigator was based on the ethical principles of national and international institutions . He conducted his trial work in South Africa following the strict ethical guidelines of SA-GCP (South African Good Clinical Practice), the DOH research guidelines and the Constitution of South Africa. He is perfectly placed, therefore, as an expert to comment on Pfizer's trial procedures, and irregularities therein.

27

THE WORLD'S MOST COMPREHENSIVE AND RELIABLE ADVERSE EVENTS REPORTING SYSTEM SHOWS THAT THE PFIZER COMIRNATY VACCINE CAUSES FAR MORE SERIOUS ADVERSE EVENTS THAN ALL PREVIOUS VACCINES

59. The Vaccine Adverse Events Reporting System ("VAERS") was created in the United States in 1990 by the Food and Drug Administration (FDA) and Centres for Disease Control and Prevention (CDC) to receive reports of Adverse Events ("AE") that may be associated with any vaccine that goes to market. It is widely known as one of the World's foremost adverse events reporting systems.

60. VAERS was created because vaccines can cause adverse events, including death, that may not have been detected in clinical trials. Many times, serious adverse effects of vaccines only emerge once they have been released onto the market.

61. The main goal of VAERS is to act as an early warning system for such events. The reports onto the system are filed primarily by medical practitioners (approximately 70%) who have, as a result of their medical expertise and in their best judgments, concluded that the relevant adverse effect was related to vaccine.

62. The remaining reports stem primarily from family members. In analysing the below data, I ask the Court to bear in mind that false reporting to VAERS would constitute making a false and misleading statement to the US Government which is, in turn, a federal crime. Therefore, the data has a high probability of accuracy.

28

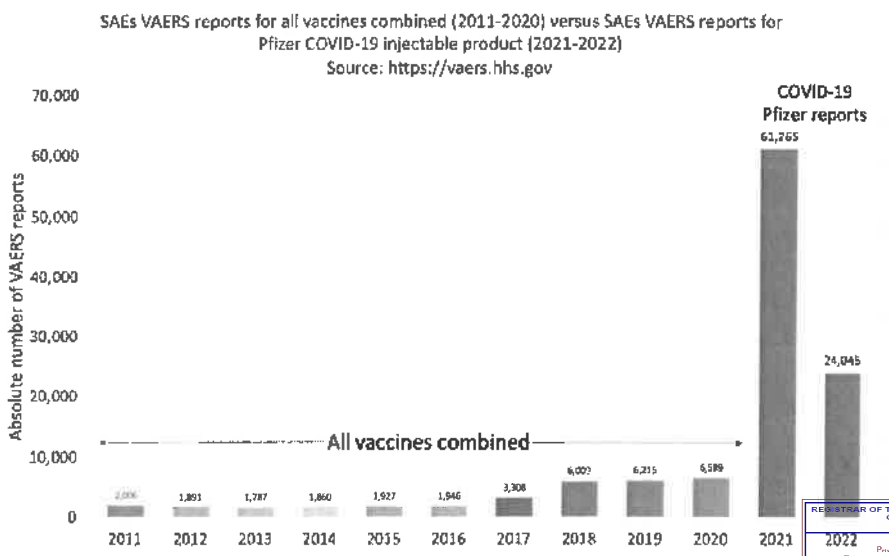
63. False reporting is simply not incentivised in any way. If anything, the risk is of under-reporting, not over-reporting. In any event, the data once filed is vetted by data analysts hired specifically for that purpose. Only those reports that are fully vetted make it onto the system which is where Dr Rose accesses it and analyses it.

64. Despite the fact that the National Childhood Vaccine Injury Act of 1986 (NCVIA) requires health care providers and vaccine manufacturers to report to the Department of Health and Human Services specific AEs following the administration of vaccines outlined in the Act, underreporting is a known imperfection of the VAERS system.

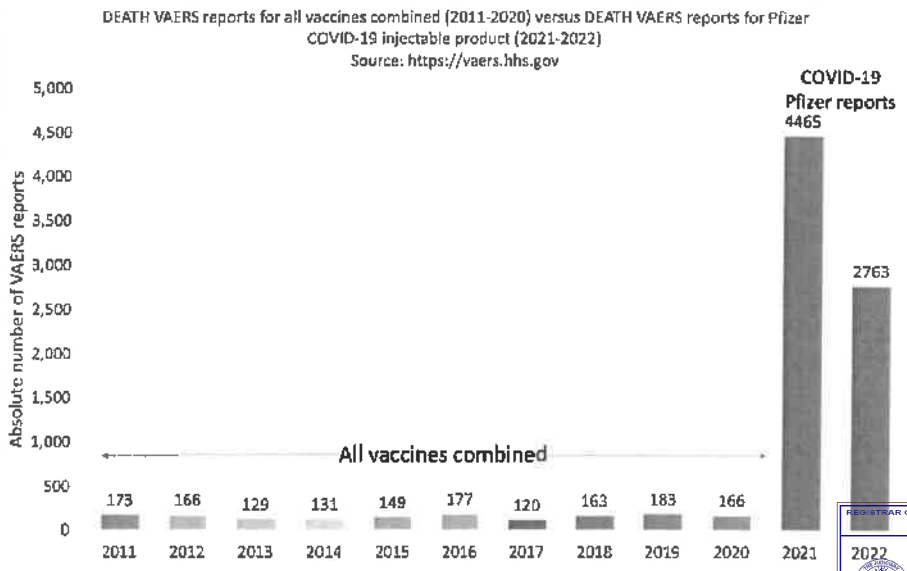
65. There is no consensus on the exact rate of under-reporting, but there is a consensus on the fact that under-reporting exists.

66. Dr. Rose (whose CV and affidavit are annexed above) has been studying VAERS data on Covid-19 vaccines for 2 years and has found alarming results. The Covid-19 Pfizer vaccine reports show higher rates of adverse events than all other vaccines combined over the past decade in every metric analysed. For example:

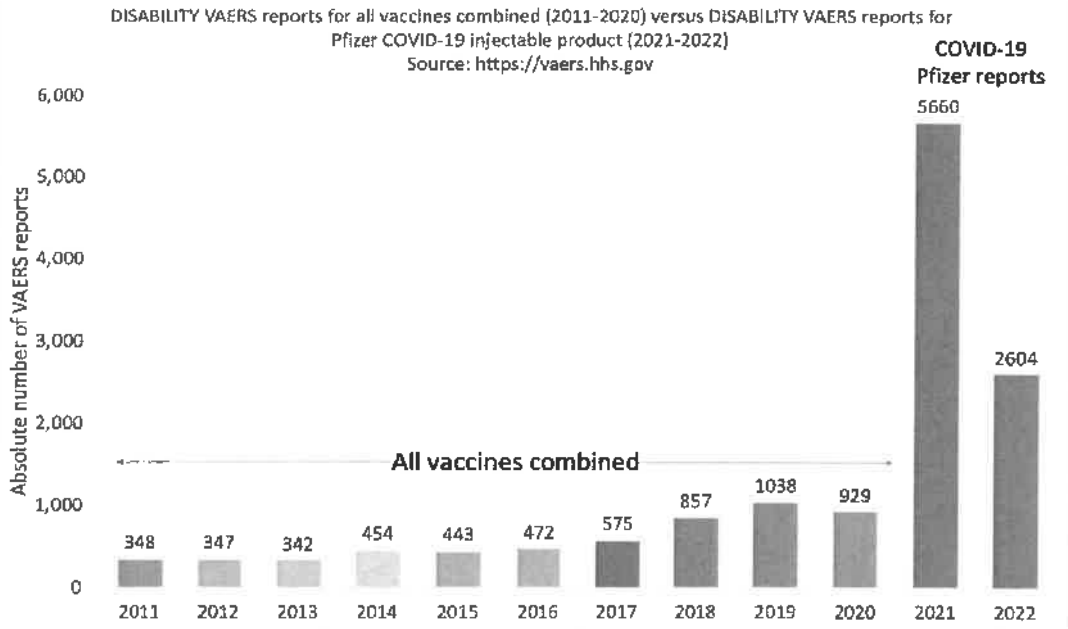
66.1. The severe adverse event reports for Pfizer's Covid-19 vaccine in 2021 and 2022 are 1,727% higher than all other vaccines combined from 2011 to 2020. This data is still being updated for 2022.



66.2. Death reports for the Pfizer Covid-19 in 2021 and 2022 are 2,768% higher than all other vaccines combined from 2011 to 2020. This data is still being updated for 2022. According to the precautionary principle, when a death is linked to a biological or pharmaceutical product, it should be removed from distribution. The precautionary principle is a risk management approach that states that, when an action or policy has the potential to harm human health or the environment, in the absence of scientific consensus, the burden of proof falls on those advocating for the action or policy. This principle calls for cautious action to be taken to prevent harm, even if the cause-and-effect relationships are not fully established scientifically. In the context of the vaccine report, it suggests that if a death is associated with a vaccine, the vaccine should be removed from distribution as a precautionary measure.



66.3. Reports of disability after receiving the Pfizer Covid-19 vaccine in 2021 and 2022 are 875% higher than all other vaccines combined from 2011 to 2020. The data is still being updated for 2022. Disability can include serious conditions such as a loss of walking ability or tremors from neurological damage, and they often persist.



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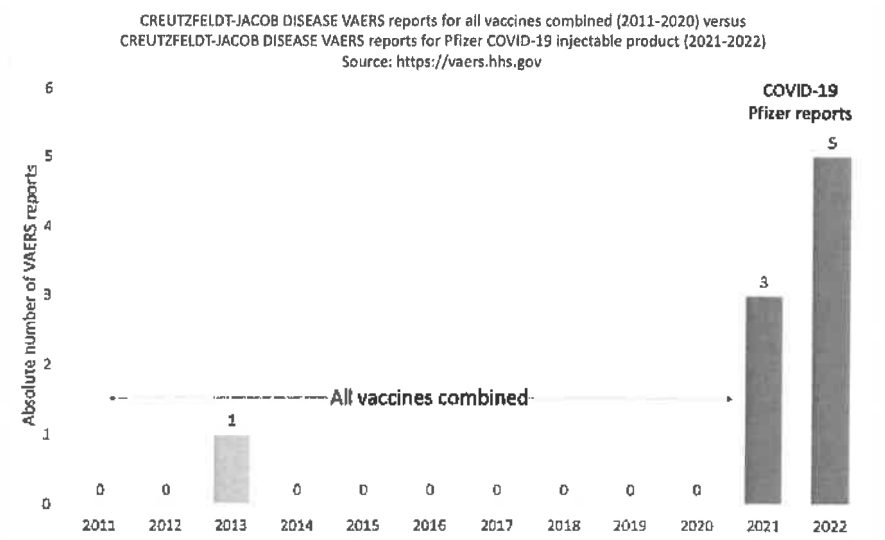
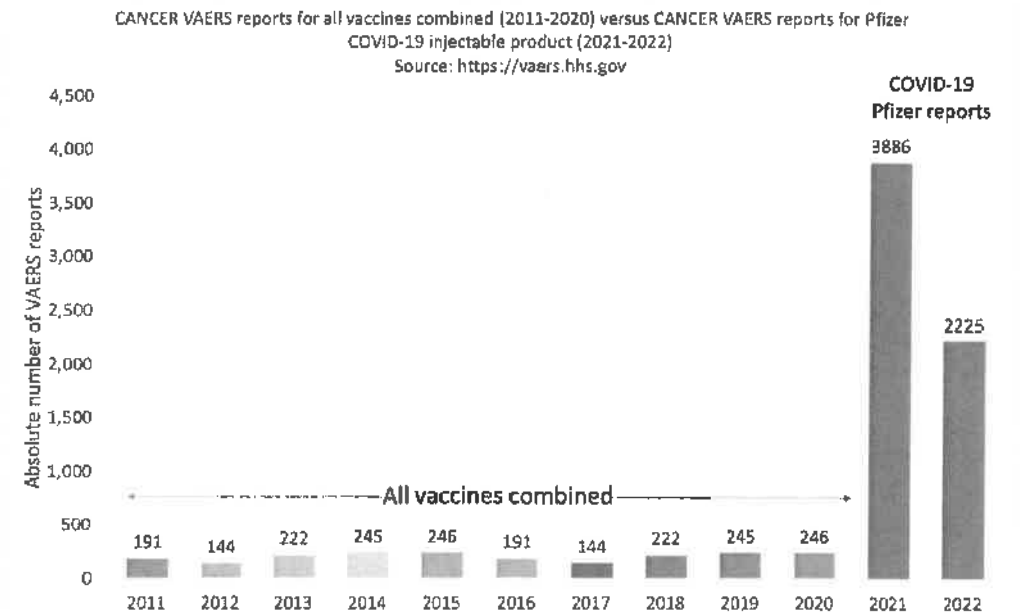
66.4. VAERS reports of Creutzfeldt-Jakob Disease ("CJD"), a serious brain disease, have skyrocketed 2,900% for the Pfizer COVID-19 vaccine compared to all vaccines combined from 2011-2020. CJD is a rare, degenerative, and fatal brain disorder that affects about one in every one million people worldwide.

66.5. This is extremely concerning as the number of reports far exceeds the background reporting rate for CJD is the U.S. The National Institutes of Health (NIH) website states that the average number of reports of CJD, per year, per million individuals in the United States is 1. Thus, if we consider that about 270,000,000 people have been injected at least once with one of the COVID-19 injectable products, then we would expect 270 people in the U.S. to report CJD as a background number of cases. The combined number of reports of CJD in the VAERS domestic data set is 16. Thus if we consider an underreporting factor of 31, (as estimated by Dr Rose and co-investigators), then we are already at 226 individuals above background. That's more than 2.1 times more cases already originating only from VAERS domestic data. These findings are cause for alarm and further investigation is needed.



66.6. VAERS reports show a 1,754% increase in cancer cases related to the Pfizer vaccine compared to all vaccines combined from 2011-2020. Rare cancers such as Acute Lymphocytic Leukaemia and male breast cancers are also being reported in older individuals. Data is still being updated for 2022.



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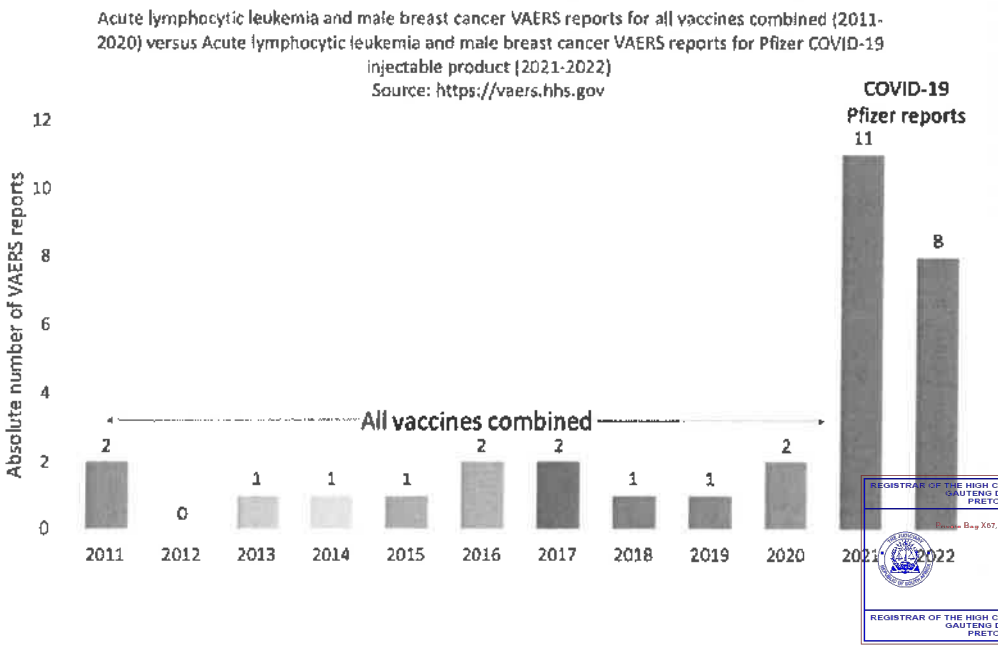
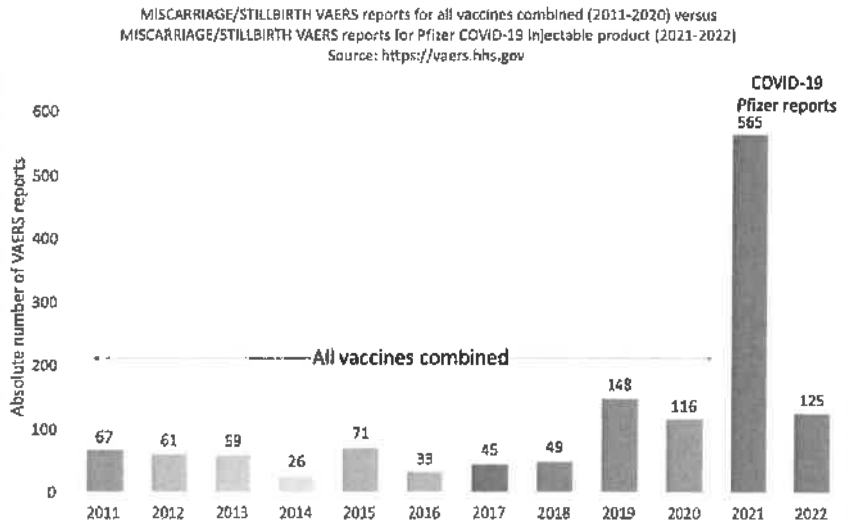


66.7. VAERS reports show a 737% increase in serious pregnancy-related issues (spontaneous abortion, miscarriages, stillbirths) when comparing the mean number of reports for all vaccines from 2011-2020 to a single product (Pfizer) in 2021 and 2022. Reports are still being updated for 2022.



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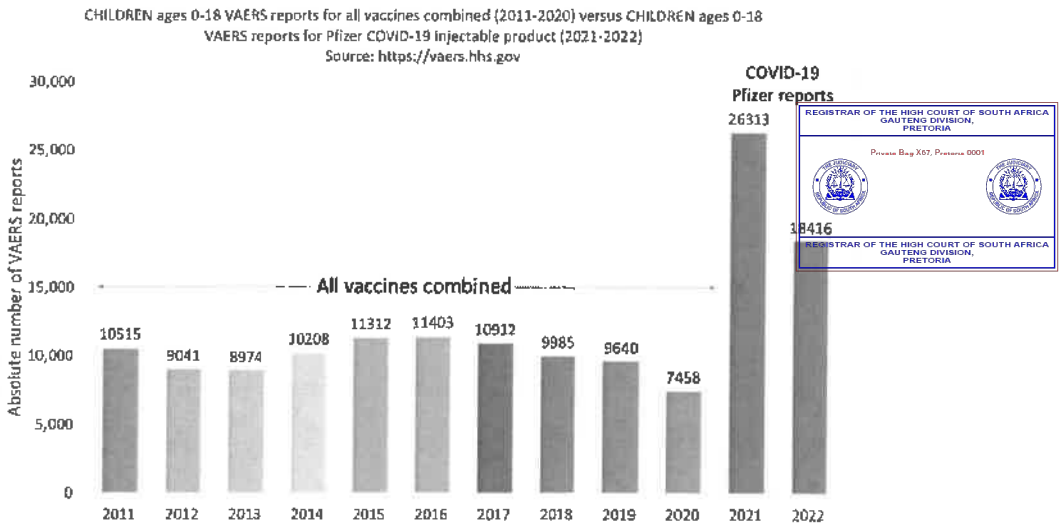
66.8. VAERS reports show 165% increase in adverse events in children after receiving Pfizer vaccine in 2021 compared to all vaccines combined from 2011-2020. This may continue to rise as children have not been vaccinated for as long as adults. This data is based on reports since the CDC Emergency Use Authorization of the vaccine in children.



67. Dr Rose's analysis of VAERS is weighty in its own terms. However, as the learned Judge will realise upon a further perusal of the papers, her findings tie up with (i) the dangers associated with mRNA vaccine technologies as set out by Dr Kyriakopoulos, and, more disturbingly with Pfizer's own listed adverse events of special interest ("AESI") expounded upon later in these papers. An AESI refers to a specific type of adverse event or side effect potentially associated with a medical product or treatment that is closely monitored by regulatory agencies and medical communities due to its potential severity or uniqueness. AESIs are typically selected based on current scientific knowledge and understanding of the medical product or treatment, and they may be considered high-priority or red flag events that warrant prompt investigation and reporting. Examples of AESIs include serious

adverse events such as death, life-threatening conditions, hospitalization, or disability, as well as events that are unexpected or may indicate a safety risk associated with a medical product or treatment.

68. Pfizer's list of Adverse Events of Special interest (which is detailed later in this affidavit) include all the issues catalogued and referenced above by Dr Rose.

THE PFIZER BIONTECH COLLABORATION, AND WHY PFIZER'S INTENTIONS, CLINICAL TRIALS, AND DATA SHOULD BE HANDLED WITH CAUTION.

69. Against the backdrop of the Covid-19 pandemic, and on or around March 17 2020, a collaboration agreement was entered into between Pfizer (an American multinational pharmaceutical and biotechnology corporation) and BioNTech (a German biotechnology company that develops and manufactures active immunotherapies for patient-specific approaches to the treatment of diseases) ("the agreement"). That agreement is annexed in full as "**HE14**".

70. The preamble to the agreement explains the reason for the collaboration between these two companies: Pfizer and BioNTech wished to engage in "*expedited*" collaborative research and development to identify and develop vaccine candidates to aid in combatting the Covid-19 pandemic. They wished to "*seek expedited regulatory approval for [the vaccines], and launch [the vaccines worldwide, excepting China] as quickly as reasonably possible*."

71. BioNTech was the owner or controller of the necessary patents, patent applications, technology, know-how, scientific and technical information and other

proprietary rights and information relating to the identification, research and development of the necessary vaccines. As for Pfizer, the agreement makes plain that its contribution was its "*expertise in development and commercialization of pharmaceutical and biopharmaceutical products*".

72. It is important for the Court to note the singularly commercial tone of the agreement, and to bear the associated consequences in mind when considering the remaining data presented in these papers.

73. The agreement was to produce vaccines as quickly as possible, and to use Pfizer's commercialization expertise to market it throughout the world with haste.

74. There is no indication anywhere in the agreement that this haste in development, commercialization and distribution was to be subject to rigorous safety checks of the vaccine. There is a rationale for this, and the purely commercial, profit-driven nature of the agreement is unsurprising. Pfizer is, after all, an ordinary commercial entity like any other.

75. It is perhaps for this reason that the pharmaceutical industry is amongst the most highly fined industries in the word (for unethical and unlawful conduct): Between 2009 and 2014, the industry in the United States alone received fines totalling $13bn for criminal behaviour that included hiding data on harms and adverse events associated with its products, and manipulation of clinical trial data results. As proof of this, I annex as "**HE15**" a peer-reviewed journal article titled "*Restoring the pharmaceutical industry's reputation*".

76. The aforementioned fact is of contextual import because it adds credence and credibility to the applicant's allegations in this case. In particular, the applicant contends that Pfizer's data on the Covid-19 vaccines is inaccurate.

77. Given that the pharmaceutical manufacturers have no duties of their own to produce safe medical products, the only safety checks and balances come from global regulatory authorities (in the case of South Africa, SAHPRA). Those regulatory authorities require safety and efficacy data before they will approve new medicines (such as the vaccines in question in these papers). That is the only reason that companies like Pfizer conduct clinical safety and efficacy trials.

78. When it came to the marketing of Comirnaty, the authorities (including SAHPRA), in apparent collaboration with Pfizer, encouraged the public to "*trust the science*". Trust is, however, based on transparency.

79. I have reason to believe that the behaviour of Pfizer has been anything but transparent. Pfizer has successfully negotiated deals with several major governments, globally (including the South African Government) that (i) force governments to keep the agreements confidential, and that (ii) indemnify them (Pfizer) against any financial liability in the event of vaccine-related harm.

79.1. I ask the Court to note that India, the world's largest democracy, refused to conclude the agreement, and to grant Pfizer indemnity for any harms that may be caused by its vaccines. It did not trust Pfizer's data and sought to conduct its own domestic trials on the product. Rather than undertake a local safety and immunogenicity study, Pfizer walked away from the Indian market.

79.2. If Pfizer was confident in the integrity of its trial data, and the safety and efficacy of its product, why would it have shied away from India's request to conduct its own product trials?

79.3. The fact that Pfizer abandoned the Indian market, together with the fact of the confidentiality and indemnity bonds it has forced other Governments to sign, creates serious suspicion about the integrity of Pfizer's intentions, trial work, and subsequent data. I annex as **"HE16"** and **"HE17"** respectively two articles from Reuters verifying these facts.

80. These facts are, however, not the only reasons to exercise caution when assessing the integrity of Pfizer's claims pertaining to its Covid-19 vaccines.

80.1. Dr Aseem Malhotra, whose affidavit and *curriculum vitae* are annexed above, is a British cardiologist and science writer. He is a Fellow of the Royal College of Physicians (FRCP) and a member of the British Medical Association. He is also a Fellow of the Royal Society for Public Health (FRSPH) and a Fellow of the Faculty of Public Health (FFPH). Dr Malhotra has also been an honorary consultant cardiologist at Croydon University Hospital, London. In his published, peer-reviewed article (annexed as **"HE18"**) titled "*Curing the pandemic of misinformation on COVID-19 mRNA vaccines through real evidence-based medicine - Part 2*" which I request the Court to accept as his expert opinion, he explains the following:

80.1.1. There is a long-documented history (both through studies and lawsuits) of the strategies in which drug companies hide, ignore or misrepresent evidence about new drugs. Distortion of medical literature and misrepresentation of data by companies keen to expand the marketplace for their product, may result in overprescribing with predictable consequences of millions of patients suffering from avoidable adverse reactions.

80.1.2. In an international survey of respondents from higher education institutions, 14% admitted to knowing a colleague who fabricated, falsified and modified data, and 34% of scientists report questionable research practices that included selective reporting of clinical outcomes in published research and concealing conflicts of interest. This information comes from an official UK parliament enquiry and can be accessed at the web address in the attached footnote[1].

80.1.3. Pfizer has yet to share all the raw data from its pivotal clinical trials for its vaccines. The raw data from clinical trials comprises thousands of pages that have yet to be released for independent scrutiny. This information is sourced from an article published in the British Medical Journal titled "*We must have raw data, now*". The article is annexed as "**HE19**".

1 https://researchbriefings.files.parliament.uk/documents/POSTPN-0544/POST-PN-0544.pdf.

80.1.4. This lack of transparency is important because what it means is that global approval of the vaccines has not been granted based complete data sets from Pfizer.

80.1.5. A major risk factor for failure to protect the public from the harms of data manipulation is the lack of independence of the global regulators. For example, the FDA's Centre for Drug Evaluation Research (CDER) receives 65% of its funding from the pharmaceutical industry (mainly in the form of user fees). For example, as part of the approval process for its COVID-19 vaccine, Pfizer made a wire transfer to the FDA of $2 875 842 in May 2021. FDA approval for Pfizer's COVID-19 injection duly followed in August 2021 despite recent evidence emerging that the original randomized control trial data suggested a greater risk of serious adverse events from the vaccine than from hospitalisation because of COVID-19.

81. One of the many questions that arise in these papers is this: could Pfizer manipulate data, or present misleading data, or sabotage the conduct of its trials in order to mislead regulatory authorities to secure regulatory approval to protect their own financial vested interests? Unfortunately, the evidence presented in these papers suggests as much.

82. Because of the seriousness of the accusations levelled against Pfizer, and the seriousness of the consequences thereof, Pfizer's domestic offices have of course been cited in these papers.

83. Furthermore, a copy of these papers has also been couriered to the Pfizer head office in New York in the United States.

84. I will return to Pfizer's trials and the data that emanated from those trials later in these papers. For now, though, I want to take the Court through an explanation of the type of vaccine that was developed as a result of this collaborative agreement, namely an mRNA (messenger ribonucleic acid) vaccine, and the facts and concerns associated with this technology.

PFIZER'S COMIRNATY VACCINE'S mRNA TECHNOLOGIES – THE FACTS, AND THE DANGERS

85. The information below is a summary of Dr Anthony M Kyriakopoulos' evidence (contained in his affidavit already annexed above). He is an expert in mRNA technology. It is his expert opinion that the mRNA technology was used (prematurely) as a weapon against infectious diseases, and especially against the SARS-CoV-2 pandemic.

86. The product was rushed to market with grossly inadequate evaluation of either safety or effectiveness. The public was told that this product was "safe" even

though mRNA technology had never before been successfully tested for efficacy and safety in tackling infectious diseases.

87. The result is that an unsafe, inadequately tested product is being administered to the global population.

88. Peer reviewed papers in recent months are showing links between the mRNA technology and conditions such as autoimmune diseases, aggressive deadly cancers, severe inflammatory conditions, prion diseases (contagious untreatable diseases resulting in the gradual decline of brain function leading to personality changes and death), myocarditis, blot clotting, impaired fertility, miscarriages and spontaneous abortions. In the paragraphs that follow, I set out a summary of Dr Kyriakopoulos' reasoning.

88.1. The Pfizer vaccines are synthetic mRNA "gene vaccines". mRNA stands for "messenger RNA". It is a molecule that acts as a blueprint for making proteins.

88.2. Proteins perform many essential functions in the body. mRNA is made by copying a section of DNA, which is the genetic material that contains the instructions for making all the proteins in the body. This process is called transcription.

88.3. The mRNA molecule then leaves the cell's nucleus and travels to the ribosome, which is the cellular structure responsible for making proteins.

88.4. At the ribosome, the mRNA serves as a template for making the relevant protein. Another type of RNA called transfer RNA brings the building blocks of proteins (amino acids) to the ribosome, and the ribosome links these amino acids together in the sequence specified by the mRNA to create a chain of amino acids, which folds into a functioning protein.

88.5. In this way, the cellular mRNA acts as a go-between, transmitting the instructions stored in DNA to the ribosome to produce proteins.

88.6. Pfizer's mRNA "gene vaccines" make use of the above process providing instructions (in the form of synthetic viral mRNA) for the ribosomes to make a synthesized version of the virus SARS-CoV-2's spike protein.

88.7. The theory is that once the SARS-CoV-2 spike protein is produced from the synthetic viral mRNAs in "gene vaccines", the immune system will recognize it as foreign, and mount an immune response, ultimately enabling it to kill the virus by attacking the spike protein of the virus.

88.8. In this way, the Pfizer "gene vaccines" are unlike traditional vaccines. Traditional vaccines contain attenuated (inactivated or weakened) viruses or pieces of viruses, in order to trigger immune responses, whereas Pfizer's novel mRNA "gene vaccines" use the body's protein synthesis production as a mechanism to produce a viral protein in order to trigger an immune response.

88.9. The mRNA in the vaccine is encased in a lipid nanoparticle, which helps it enter cells and be translated into the viral spike protein. After this, the immune system creates antibodies against the spike protein. That is in turn supposed to provide protection against COVID-19 if the person is exposed to the virus in the future.

88.10. In summary, mRNA "vaccines" are supposed to work by using the synthetic mRNA to instruct or "hijack" the cells in the human organism to make a version of the virus's spike protein, thus meant to trigger an immune response that can provide protection against COVID-19.

88.11. Moreover, the mRNAs in the "gene vaccines" are equipped with robust synthetic caps that protect the viral mRNA from breakdown, thereby leading to endurance of the mRNA inside the cell for an unnatural and unwanted duration. This can lead, as Dr. Kyriakopoulos has published in peer-reviewed journals, to cancer, autoimmunity and aging defects.

88.12. Dr. Kyriakopoulos accepts in his affidavit that mRNA technology was, and still is, a promising therapeutical intervention against cancer and genetic disorders. But, he points out that it is crucial to understand that prior to Covid-19, mRNAs had never been successfully trialed as a weapon against infectious diseases such as Covid-19.

88.13. Due to the lack of adequate testing of this technology's efficacy and safety in targeting infectious diseases, the reality is that much remains unknown, and what is known creates serious doubt as to its

effectiveness at preventing disease or death, and more importantly, its safety.

88.14. Even when the mRNA technology has been used (prior to the Covid-19 pandemic) for cancer treatment, there were severe detected side effects in related clinical trials, prompting more safety related clinical research prior to use. For example, Bell's palsy, a form of acute facial paralysis, was also indicated as a serious side-effect of mRNA technology.

88.15. Unsurprisingly, it has also been widely reported as a serious side effect due to the Pfizer "gene vaccines" against covid-19.

88.16. Marketing these vaccines as "safe" and "effective" under the circumstances, was (and still remains), in Dr Kyriakopoulos' expert opinion, a gross misrepresentation that has jeopardized public health and has caused severe disease and death.

88.17. In the following paragraphs I detail some of the real risks associated with the mRNA technology to buttress the view that these viral "gene vaccines" have, to date, not been found to be "safe". The reality is that there are still too many unknowns about how this technology operates in the human body, particularly in the context of expressing a highly toxic spike protein, to qualify this "gene vaccine" as "safe".

88.18. While the science is complex, the immune response to these injections can be described in relatively simple terms, and it is quite distinct from

the immune response to a natural infection with SARS-CoV-2 in many ways.

88.19. The mRNA gene "vaccine" is injected into the deltoid muscle. The injection contains a large number of mRNA molecules coding for a modified form of the Covid-19 virus' spike protein ("the spike protein"), normally produced by the virus. These mRNA molecules are packaged into lipid nanoparticles ("LNP"). These LNPs serve several roles: to protect the mRNA from breakdown, to facilitate its uptake into the cell and to facilitate its release into the cell's cytoplasm. The LNPs also act as adjuvants to further provoke an immune response, and to promote rapid synthesis of the spike protein within the cell, according to the mRNA code.

88.20. Essentially, these nanoparticles also hijack human host cell machinery to get it to synthesize the spike protein, and present it on the surface of the cells, provoking an immune cellular response.

88.21. It is important to understand the differences between the spike protein in the Covid-19 virus, and the spike protein in the Pfizer "vaccines". The virus (and attendant spike protein) enters cells mainly via a specific type of receptor called the ACE2 receptor.

88.22. Those receptors are present only in certain cell types, which means that the virus and attendant spike protein can only enter certain cells, and not others.

88.23. The vaccine is different. The LNP enables the mRNA molecules to enter all cells throughout the human body, where spike protein will then be synthesized. The net effect is that the vaccine results in a greater biodistribution (distribution throughout the human body) of the spike protein than does the virus.

88.24. Notably, the injected nanoparticles are rapidly taken up by immune cells that would not normally be infected by the virus because they have no ACE2 receptors. What could logically result theoretically is an autoimmune response, in which the immune system attacks and removes its own immune cells, because they are displaying a toxic foreign protein on their surface.

88.25. Before the advent of the use of mRNA "gene vaccines" against COVID-19, Dr Kyriakopoulos had contributed to prognose and analyze the causation of autoimmunity by the mRNAs in "gene vaccines".

88.26. Later publications proved his initial medical prognosis and reinforced that mRNAs in "gene vaccines" cause elevation of autoimmune antibodies, which in turn increase the risk of severe autoimmune diseases.

88.27. Enhancing the toxicity even more, the mRNA sequence coding for the spike protein itself is also very different from the sequence present in the RNA of the original SARS CoV-2 virus.

88.28. Most notably, it has been "humanized" by inserting special sequences on both ends that disguise its viral origins. This results in a stealth entry mechanism, that does not provoke the normal immediate response to viral mRNA, which normally serves as an early warning system.

88.29. The developers felt this was necessary because otherwise the mRNA would be destroyed before it ever got a chance to make the spike protein. This "humanization" causes the mRNA to be extremely resistant to breakdown. While most mRNA molecules only survive for a few hours after they are produced, the mRNA in these injections has been shown to still be present in the draining lymph nodes two months after vaccination.

88.30. Following injection of the nanoparticles into the deltoid muscle, the muscle cells rapidly take up the particles and begin producing spike protein at a high rate, which is then displayed on their surface shortly thereafter.

88.31. Circulating immune cells respond to the alarm signals released by the muscle cells by swarming into the arm muscle. They too cannot stop themselves from taking up the nanoparticles and also synthesizing spike protein. They rapidly begin migrating into the lymph system, congregating initially in the lymph nodes under the arm, to begin the process of informing antibody-producing immune cells of the imminent danger.

88.32. Swollen lymph nodes under the arms are normally a signal for breast cancer, but this phenomenon is now often observed following vaccination with the Pfizer vaccines, showing clearly that much of the action is taking place in these lymph nodes.

88.33. The limited animal tracer studies that have been done on the biodistribution of mRNA vaccine nanoparticles injected into muscle have shown that, while the bulk of the product remains localized to the injection site, a substantial amount of the mRNA ends up in the draining lymph nodes, and detectable amounts also show up in multiple organs throughout the body.

88.34. Among organs, the highest concentration is consistently found in the spleen, with the liver and ovaries not far behind, and detectable, although low levels have been found in mouse brains.

88.35. In immunology, the term antigen refers to a foreign molecule (usually a protein) whose presence in the body provokes an immune response, and antibodies are the proteins that are produced by the immune cells (through interactions between B-cells and T-cells) in response to the foreign antigen.

88.36. With subsequent exposures to that same antigen, the antibodies bind to the antigen and interfere with its uptake by cells, thus thwarting an infection with a virus such as SARS-CoV-2.

88.37. Research has shown that immune cells in the spleen release exosomes (small lipid particles) containing the antigen into the external space, and the antibody-producing cells (B-cells and T-cells) take up those exosomes as a central and essential activity during antibody induction.

88.38. In *vitro* experiments with the "gene vaccine" mRNA nanoparticles coding for the spike protein have shown that exposed cells release exosomes containing the spike protein, along with certain microRNAs that alter protein expression in recipient cells.

88.39. Furthermore, this same study showed that microglia (immune cells in the brain) can take up those exosomes and react by inducing an inflammatory response (inflammation in the brain, which can lead to neurological damage).

88.40. In the same experiment, two specific microRNAs were found: miR-148a and miR-590. These microRNAs can weaken the body's response to a signal called the type-1 interferon response, which helps the immune system fight cancer and infections. When immune cells absorb exosomes with these microRNAs, their ability to respond to type-1 interferons is reduced.

88.41. A predicted result is increased risk to cancer and infection by any pathogen. Indeed, there is a strong signal in the Vaccine Adverse Event Reporting System (VAERS), maintained by the United States CDC, for

conditions such as Bell's palsy and shingles in association with the COVID vaccines.

88.42. Many medical practitioners have reported alarming increases in cancer among their patient's following vaccination. Particularly noteworthy is cancer that was in remission resurfacing in an aggressive form. The VAERS database also shows significantly more reports linking cancer to the COVID vaccines than to all other vaccines, particularly breast cancer. This is what Dr Kyriakopoulos predicted in his recent publication even before the cancer reports emerged.

88.43. A likely pathway by which exosomes released by immune cells in the spleen could be taken up by microglia in the brain is via major nerves in the trunk.

88.44. Exosomes are known to be able to migrate along nerve fibers as a transport system to reach distant places. The released exosomes would travel along the splanchnic nerve to a nerve center called a ganglion, whence they can continue along the vagus nerve to reach not only the brain, but also the heart, lungs, liver and gut.

88.45. VAERS contains a huge repository of vaccine adverse events related to the Pfizer vaccines. These events far outnumber events reported for other vaccines over the same time period, and many of the symptoms are typical symptoms of inflammation in the vagus nerve and other

nerves, particularly in the face, such as the auditory nerve, the optic nerve, the trigeminal nerve and the facial nerve.

88.46. The exosomes can also reach, via these nerve conduits, major centers in the brain stem controlling basic life functions such as heart rhythm and heart rate, blood pressure, consciousness, and breathing. Disturbances in these centers, leading to an intense inflammatory response and subsequent nerve damage, can have life-threatening consequences.

88.47. A recent peer reviewed paper published by the late Professor Luc Montagnier (Nobel prize winner for his work on the HIV virus) and colleagues discussed 26 cases, mostly in Europe, of severe Creutzfeldt Jakob Disease (CJD, essentially human MADCOW disease) associated with COVID-19 vaccination.

88.48. In all cases involving the Pfizer "gene vaccine", symptoms first appeared within one month of the second "vaccine". Progression towards paralysis was very rapid, and many of these patients died within three months of the onset of symptoms. All except one of the original 26 are now dead. This is very alarming, as CJD is very rare, with only 1 out of a million people previously diagnosed with it.

88.49. This rare, but severe adverse reaction to the mRNA vaccine is likely due to the fact that the spike protein has prion-like properties.

88.50. A prion is a type of protein that can cause certain diseases in the brain and nervous system. Unlike most pathogens, such as viruses and

bacteria, prions are not composed of DNA or RNA, and they do not replicate by dividing or making copies of themselves. Instead, they cause disease by changing the shape of normal proteins in the body into abnormal, infectious forms.

88.51. Prion diseases are a group of neurological disorders that are caused by prions. They are characterized by a gradual decline in brain function, leading to memory loss, personality changes, and eventually death. Some well-known prion diseases include Creutzfeldt-Jakob disease, Kuru, and variant Creutzfeldt-Jakob disease (vCJD), which is associated with consumption of infected beef in the United Kingdom. Prion diseases are rare, but they are of great concern because they can spread from person to person, and there is currently no cure or effective treatment for these diseases.

88.52. CJD is a prion disease, caused by misfolding of the prion protein, a protein which normally has multiple important roles in neurons but which turns rogue when it misfolds into a toxic structure that precipitates out as a plaque. Dr Kyriakopoulos surmises that the spike protein, given its prion-like properties, acts as a seed to crystallize the prion protein into its misfolded form.

88.53. There are several papers in the literature that have identified certain sequences within the spike protein that are characteristic of prion-like proteins. This property, combined with its ability to reach the brain via exosomes released from immune cells in the spleen, can likely explain

many of the neurological symptoms that people are experiencing in response to these vaccines. Of course, the spike protein produced by the virus could cause similar problems, but an important distinction is that the virus is mostly confined to the lungs in patients with a healthy immune response, whereas the vaccine immediately breaches both the lung- and vascular barriers such as the blood-brain barrier.

88.54. Furthermore, the association of mRNA-spike protein injections with multiple deadly cancers was highlighted in Dr Kyriakopoulos' recent publication.

88.55. The potential molecular reasons for severe autoimmunity due to increased levels of p53 have been recently published in a paper where Dr Kyriakopoulos was first author. That paper unravels the complex reasons why the p53 levels are elevated due to the spike protein.

88.56. The elevated levels of p53 will cause prion and prion related disease since they boost the production of prion proteins within the organism. In many ways, p53 is a protein that is critical for preventing the development of cancer. It acts as a tumor suppressor by regulating the cell cycle and promoting cell death (apoptosis) in cells that are damaged or have the potential to become cancerous. P53 also plays a role in the immune system by regulating the function of immune cells and promoting the activation of the type-1 interferon response, which helps the immune system fight infections and cancer.

88.57. However, increased levels of p53 have been linked to autoimmunity, which is when the immune system mistakenly attacks and damages the body's own tissues. This can occur because p53 can disrupt the normal balance of immune cells, causing them to become overactive and attack the body's own tissues. In addition, high levels of p53 can suppress the type-2 interferon response, which normally helps to control and limit the immune response, leading to further immune system overactivity and autoimmunity.

88.58. Thus, the delicate balance between p53 and other immune regulatory proteins is important for maintaining a healthy immune response and avoiding autoimmunity. This homeostatic balance unfortunately is disrupted in the gene mRNA vaccinated sufferers that develop autoimmune diseases like multiple sclerosis and polyneuropathies.

88.59. A much more common adverse reaction to the vaccine is myocarditis (inflammation in the heart), which is especially affecting young male athletes, but also affects the rest of population, and unfortunately it can result in sudden death.

88.60. Because young people rarely suffer from severe disease when they are exposed to COVID-19, any risk from the vaccine quickly offsets any putative benefits for them. The mechanism leading to this in many ways parallels the mechanism causing neurological symptoms. Exosomes containing the spike protein can easily breach the vascular barrier in the heart via nerve fiber pathways.

88.61. The spike protein has been shown to cause an inflammatory response in the heart, likely related in part to its ability to bind to ACE2 receptors, which are prevalent in heart muscle cells.

88.62. Athletes in particular are known to have significantly more ACE2 receptors in their hearts than those who don't exercise vigorously. Mechanistically, inflammation causes the release of inflammatory cytokines. These cytokines trigger the release of reactive oxygen species (ROS), which damage the heart muscle cells.

88.63. The subsequent infiltration of fibroblasts leads to the production of scar tissue replacing certain portions of the heart muscle, thereby weakening heart function and predisposing to arrhythmias.

88.64. The presence of preexisting myocarditis due to the vaccine can be very dangerous in the context of an adrenalin rush, because the inflamed heart is less able to react appropriately to the excess load induced by the adrenalin response. This can lead to arrhythmias and cardiac arrest, which is often fatal, particularly if emergency assistance to restart the heart is not immediately available.

88.65. There are now several peer-reviewed case studies and epidemiological studies linking fatal myocarditis to the "gene vaccines", and also showing that the risk is much greater from the "gene vaccines" than it is from the disease itself.

88.66. The COVID "gene vaccines" may have serious side effects on platelets, causing severe blood clotting problems. Most of the reports in VAERS show a strong link between the COVID "gene vaccines" and blood clots, including a dangerous condition where a blood clot moves to the lungs (pulmonary embolism). This may be because the "gene vaccine" triggers the body to produce antibodies that attack platelets, leading to clumping and formation of clots. This could happen because the antibodies target the spike protein in the virus, which is similar to proteins found in platelets.

88.67. There may also be a risk of other autoimmune diseases because the spike protein is similar to other proteins in the body that are associated with autoimmune diseases.

88.68. Further, the expression of the spike protein post "gene vaccination" in the testes and ovaries could result in an autoimmune attack against these tissues, leading to impaired fertility. There is a strong signal in VAERS for miscarriages and disrupted menstrual cycles associated with these "gene vaccines".

88.69. One major class of antibodies are the immunoglobulin G (IgG) antibodies. Within that class, researchers have identified three major subclasses categorized as IgG1, IgG2 and IgG4. IgG2 is especially important as it is known to be very effective in stopping the virus from infecting cells. IgG4, on the other hand, is recognized as an anti-

inflammatory antibody that binds to the antigen but does not prevent infection.

88.70. Furthermore, it interferes with the binding of the productive antibodies like IgG2. In studies it has been observed that IgG4 made up only 0.04% of the total IgG pool following the second vaccine, but the percentage of IgG4 after the booster shot rose to nearly 20% on average. This was a complete surprise to the researchers, and it suggests that the vaccines are leading the immune system towards a state of anergy (absence of the normal immune response) possibly due to immune exhaustion.

88.71. Disturbingly, high levels of IgG4 are linked to many autoimmune diseases. On top of this a recent publication describing a rare case of IgG4 related nephritis relapse post the mRNA "gene vaccination" presents a forthcoming great worldwide risk for kidney failure patients receiving the "gene vaccination".

88.72. In a series of autopsy studies in 25 individuals who died unexpectedly from myocarditis, the major prevailing histopathological finding was death due to arrhythmia and heart failure. The cause of these deaths was clarified by the authors of this clinical investigation as a severe complication following the mRNA-spike protein expressing injections.

88.73. In relevance to the mRNA-spike protein expressing injection-produced myocarditis study, it has been found that in all (16 out of 16) patients who received the mRNA and developed myocarditis, the full-length spike

protein persisted in a concentration of 33.9 ± 22.4 pg/mL in their plasma post their second mRNA injection.

88.74. In a recent sudden death incident in a 22-year-old Korean patient who suffered from myocarditis 5 days after the first mRNA-spike protein shot, and died 7 days later, the main histopathological finding from the autopsy performed was extensive band necrosis in the atria and ventricles of the heart. As the authors conclude, "the primary cause of death was determined to be myocarditis, causally-associated with the BNT162b2 vaccine".

89. In summary, Dr Kyriakopoulos states that his expert opinion is that that the mRNA genetic biologics, mistakenly called "vaccines," are producing severe illnesses in a vast section of the population, and, most importantly, cancer, autoimmunity, neurodegeneration and death. They are neither safe nor effective, and therefore it does not make sense to continue to encourage the general population to get repeated boosters.

90. It is his further opinion that the mRNA technology should be reconsidered and, in many ways, can be described as a complete failure in the fight against COVID-19. He recommends that authorities should acknowledge this fact and stop the manufacture and sales of this harmful biologic agent.

91. I now return to the Pfizer trials. In the following section, I take the Court through the conduct of the Covid-19 vaccine trials, the data that emanated therefrom, and the concerns around both the trial conduct and the data.

THE PFIZER TRIALS: THEIR DESIGN, CONDUCT, AND DATA

92. On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act, the Secretary of the Department of Health and Human Services in the United States (HHS), determined that there was a public health emergency that had a significant potential to affect national security, or the health and security of United States citizens living abroad, and that involved the virus that caused the Coronavirus Disease 2019 (Covid-19).

93. On the basis of such determination, the Secretary of HHS, on March 27 2020, declared that circumstances existed justifying the authorization of *emergency use* of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act.

94. It was under this Act that Pfizer and BioNTech, who were collaborating in vaccine development, would ultimately seek Emergency Use Authorisation (EUA) in the US for their mRNA vaccines, followed later by boosters, and further Covid-related vaccine products.

95. Pfizer's press release dated 18 November 2020, and annexed as "**HE20**" explains that the clinical trial for the Pfizer BioNTech BNT162b2 mRNA Covid-19 Vaccine

(the Comirnaty vaccine), began in April 2020 and ended on November 18, 2020 (a period of six months).

96. The vaccine's initial 2-month safety and efficacy data was collected during this time period. At the data cut-off date of October 9 2020, a total of 37,706 participants had a median of at least 2 months of safety data available after the second dose, and they contributed to the main safety data set.

The two-month trial data

97. It was on the basis of Pfizer's 2-month data that the Comirnaty vaccine was given Emergency Use Authorization by the FDA in the US on December 11 2020.

98. Pfizer published its 2-month safety data two weeks later, on 31 December 2020, in the New England Journal of Medicine in an article annexed as "**HE21**", and titled "*Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine*".

99. At face value, in the 2-month report, the efficacy findings (as set out by the authors) looked compelling, and the safety findings looked reasonable. The following emerges from the safety and efficacy claims in the 2-month report:

99.1. In terms of safety, the vaccine was considered to have a mild-to-moderate safety profile, with the most common adverse events being pain at the injection site, fatigue and headache.

99.2. The majority of local and systemic reactions were reported by younger participants, but the frequency of severe systemic events was regarded as low and the frequency of serious adverse events was also regarded as low.

99.3. The majority of documented adverse events were mild to moderate and resolved within 1-2 days. No significant safety concerns were identified during the trial, and the vaccine was granted Emergency Use Authorization by the FDA on December 11, 2020.

99.4. In terms of efficacy, the study observed 36,523 participants who had not previously had Covid-19. 8 Cases of Covid-19, with onset at least 7 days after the second dose, were observed among vaccine recipients; and 162 among placebo recipients. This corresponded to a vaccine efficacy calculation, or relative risk reduction (RRR), of 95.0%.

100. The problem is that the published summary of safety and efficacy profiles does not bear scrutiny. The authors did not publish any calculation of absolute risk reduction (ARR), as required in terms of an FDA publication "Communicating Risks and Benefits: An Evidence-Based User's Guide". On page 60 of this Guide, in paragraph 2, the FDA advises "*Provide absolute risks, not just relative risks. Patients are unduly influenced when risk information is presented using a relative risk approach; this can result in suboptimal decisions. Thus, an absolute risk format should be used.*"

101. The authors also did not publish any information about "effectiveness" as opposed to "efficacy". Thorough, independent analysis of the information in the 2-month report raises concerns.

102. A serious issue of concern relates to the conveniently and selectively chosen study population itself, and the blanket vaccine efficacy and safety claims made in the published summary of the trial data.

103. In trials that test for efficacy, it is only possible to make efficacy claims for the population demographics and other circumstances that applied in the trial. For example if you're trialing medicine X, and you test it in adults in the trial, you cannot then claim efficacy or safety for children. The reasons are self-evident. I attach as "**HE22**" the affidavit of Dr Stephen Schmidt, whose expertise is in the conduct of clinical trials.

104. The 2-month report claims that the vaccine has a general 95% efficacy and a "favourable" safety profile. But these claims are misleading. The reason is that the vaccine was not trialed on all the target population demographics. The vaccine was only trialed in healthy individuals over age 16, and those with stable disease. This fact appears from page 49 of the trial protocol (annexed as "**HE23**") which states as follows:

> *"Type of Participant and Disease Characteristics:*
>
> *[...]*
>
> *3. Healthy participants who are determined by medical history, physical examination (if required), and clinical judgment of the investigator to be eligible for inclusion in the study.*

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Note: Healthy participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, can be included. [...]"

105. That means that the efficacy finding of 95% and the alleged "favourable" safety profile only held true for the population demographic on which the vaccine was tested (being healthy individuals over the age of 16). That is what Pfizer should have said in its report - but instead it presented the efficacy finding as being effective, generally, in the population.

106. The problem is that vulnerable portions of the population (individuals over 75 years of age and pregnant/lactating women, for example) were either entirely excluded, or substantially excluded, from the trial.

107. That, in turn, means, that the efficacy and safety findings could not, and should not, have been considered to apply to them – but they were.

108. The result was that Comirnaty, once approved, was marketed and administered to some of the most vulnerable people in society even though there was no efficacy or safety data for those people. Four examples will suffice (though many more can be found):

108.1. First, adolescents below the age of 16 years were excluded from the initial trial. Adolescents between 12 and 15 years of age were only included after the 2-month data had been collected. Notwithstanding this exclusion, the Pfizer 2-month data made a blanket claim of 95% efficacy and a favourable safety profile, which leads one to believe that the

vaccine's safety and efficacy on adolescents is supported by Pfizer's data – but it wasn't.

108.2. Second, and perhaps most alarmingly, pregnant women and women who were breastfeeding, were excluded from the trial. This appears from the protocol at page 42, where the following is stated:

> *"5.2. Exclusion Criteria*
>
> *[...]*
>
> *11. Women who are pregnant or breastfeeding."*

108.3. Notwithstanding this exclusion, the Pfizer 2-month data makes a blanket claim of 95% efficacy and a favourable safety profile, which leads one to believe that the vaccine's safety and efficacy on pregnant women is supported by Pfizer's data – but, again, it was not.

108.4. In fact, Pfizer and BioNTech acknowledge in official documentation that the effect of the vaccine on pregnant woman and unborn babies is wholly unknown.

108.5. I have been provided with an official informed consent for Pfizer's trial (presently underway) of study vaccines to fight the parent SARS-CoV2 virus, the alpha strain, the delta strain and the omicron strain. The informed consent document is annexed as "**HE24**". In clause 1.8.2 of that document, the following is stated:

"It is not yet known whether the use of the study vaccines (which includes the Comirnaty product) in a parent could be harmful to an unborn baby or an infant."

108.6. It is important to note that an informed consent document contains a lay explanation of the totality of all available trial safety data of the drug in the question (Comirnaty). The implication, therefore, of the above statement is that there is no viable trial safety data on the effect of Comirnaty on pregnancy and unborn babies.

108.7. Third, this Court may take judicial notice of the fact that 85% of the people most at risk from Covid-19 were those over the age of 75 years[2], and it was to that age group that the vaccine was most aggressively marketed. The trial should therefore have had proportional numbers of trial participants who were aged over 75 years. But that wasn't the case.

108.8. Instead, those of age 75 and above only represented 4.3% of trial subjects. That figure comes from the fact sheet for healthcare providers administering Covid-19 Pfizer vaccines (annexed as "**HE25**"), where the following is stated:

"Clinical studies of Pfizer-BioNTech COVID-19 Vaccine include participants 65 years of age and older who received the primary series and their data contributes to the overall assessment of safety and efficacy [...] Of the total number of Pfizer-BioNTech COVID-19 Vaccine recipients [...] 4.3% (n=860) were 75 years of age and older.

[2] Source: https://wonder.cdc.gov/bridged-race-v2019.html.

108.9. Notwithstanding this substantial exclusion, the Pfizer 2-month data makes a blanket claim of 95% efficacy and a favourable safety profile, which leads one to believe that the vaccine's safety and efficacy on the aged population over 75 years is supported by Pfizer's data – but, again, it wasn't.

108.10. Fourth, the vaccine was also not tested in those who were sick with underlying health conditions, despite the fact that those individuals were most at risk from Covid-19. That demographic was completely excluded (a full list of exclusion appears on pages 42 and 43 of the protocol).

108.10.1. Their exclusion from the trial is astounding given that 95% of people who have died from Covid-19 have had at least 1 co-morbidity.

108.10.2. In fact, the average is four co-morbidities[3].

108.10.3. Again, the vaccine was not tested for safety or efficacy in these demographics, but was nevertheless marketed aggressively to them, and duly administered.

109. A further serious issue of concern is that the 95% efficacy appears to be overstated. The reasons follow:

[3] Source: https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.html.

109.1. Firstly, the 2-month report explains that, in the trial, the vaccine group of trial participants were compared to a group of trial participants that received a saline placebo:

> ***"Trial Procedures***
>
> *With the use of an interactive Web-based system, participants in the trial were randomly assigned in a 1:1 ratio to receive 30 µg of BNT162b2 (0.3 ml volume per dose) or saline placebo. Participants received two injections, 21 days apart, of either BNT162b2 or placebo, delivered in the deltoid muscle."*

109.2. This is a flaw in the trial design. Again, Dr Schmidt can attest to this. In order to obtain a true efficacy profile, the trial should have compared the vaccine intervention to, at the very least, other interventions against Covid-19 and/or natural immunity.

109.3. Not only is that the only way to design a trial to test true efficacy – but it is also necessary for the maintenance of equipoise. But, as set out in the Pfizer trial protocol, patients who had been treated with medicines intended to prevent infection, and those with previous exposure to Covid-19 (and who therefore had natural immunity) were excluded. As evidence of this, see page 41 of the trial protocol which reads as follows:

> ***"5.2. Exclusion Criteria***
>
> *Participants are excluded from the study if any of the following criteria apply:*

69

[...]

4. Receipt of medications intended to prevent COVID-19.

5. Previous clinical (based on COVID-19 symptoms/signs alone, if a SARS-CoV-2 NAAT result was not available) or microbiological (based on COVID-19 symptoms/signs and a positive SARS-CoV-2 NAAT result) diagnosis of COVID-19.

109.4. Secondly, the protocol sets out that the primary end point (a primary end point is the main outcome or measure that the trial is designed to evaluate) was preventing the occurrence of confirmed Covid-19 cases 7 days post dose 2 of the vaccine. In lay terms, what that means is that they gave the trial subjects injections on day 1 of the trial, then again 21 days later, and only screened for Covid-19 seven days after the second dose.

109.5. So, the trial participants were only screened for Covid-19 four weeks after receiving their first injection. That is a serious problem for efficacy because what it means is that any trial subjects who presented with Covid-19 in the four-week period following their first injection were not included in the trial data. Why not?

109.6. It is a known fact that vaccines cause temporary immune suppression for a few weeks following the injection, making subjects more vulnerable to illness and disease (including Covid-19) during that period.

109.7. Not including those who presented with Covid during the relevant four-week time frame had the effect of artificially inflating the efficacy figures.

109.8. Next, an examination of the end points as defined in the protocol makes plain that, whereas the study was designed to test whether the vaccine protects recipients from contracting Covid-19; it was not designed to test whether the vaccine:

109.8.1. protects others from transmission of Covid-19,

109.8.2. protects recipients from hospitalization for Covid-19, or

109.8.3. protects recipients from death by Covid-19.

109.9. The above omissions are significant because, as will be demonstrated later in these papers:

109.9.1. the South Africa Government claimed repeatedly that the Comirnaty vaccine protected against transmission and hospitalization. These were inaccuracies given that these aspects had not been tested in the Pfizer trial; and

109.9.2. scrutiny of the trial data finds that Comirnaty was **not effective** at preventing disease or death in the vaccinated study group:

109.9.2.1. 300% more participants in the vaccinated study group suffered health problems by 1 month than in the unvaccinated placebo study group;

109.9.2.2. 75% more participants in the vaccinated study group suffered severe health problems by 1 month than in the unvaccinated placebo study group;

109.9.2.3.10% more participants in the vaccinated study group suffered serious health problems by 6 months than in the unvaccinated placebo study group; and

109.9.2.4.20 vaccinated participants died by 6 months, as opposed to 14 unvaccinated placebo participants.

110. As stated above, the EUA for Comirnaty (based on the two-month data discussed above) was given in the US in December 2020, and the rollout in the United Stated commenced in the second half of December 2020.

111. Immediately following the rollout, post-authorization research was commissioned by Pfizer to assess how the vaccine performed in the general population and, specifically, to monitor any safety concerns or adverse events that may have not presented in the two-month data.

112. The post-authorization surveillance data highlighted some significant safety signals (as early as they were), and it is to that which I now turn.

Data from post-authorization surveillance conducted for two and a half months after December 2020 EUA and rollout to the public.

113. The early post-authorization surveillance considered data from the date of the rollout in US (mid-December 2020) to 28 February 2021.

114. The purported reason for collecting the data was so that the FDA could track the real-world performance of the Pfizer BioNTech BNT162b2 mRNA Covid-19 Vaccine (Pfizer's "COMIRNATY" vaccine), including its adverse events, and use that data to reach conclusions and make rational decisions about whether to continue with the vaccine rollout.

115. Instead of making this data public, the FDA subjected it to confidentiality clauses, and did not disclose it.

116. Transparency advocate groups in the United States sued the FDA to gain access to the data upon which Comirnaty was granted its EUA. They won the case, but the FDA wanted the Federal Judge to allow the agency fifty-five years to release the data. That was not allowed by the Judge - but it begs this question: Why would the FDA – who is responsible for oversight of products like Comirnaty – go to these lengths to keep the data away from the public. What were they trying to hide?

117. The lawyer acting on behalf of the plaintiff in the case aptly summarized the situation as follows:

> *"[T]he government also sought to delay full release of the data it relied upon to license this product until almost every American alive today is dead. That form of governance is destructive to liberty and antithetical to the openness required in a democratic society."*

118. The post-authorization surveillance data, now released in part under Court order, appears in a document titled "*Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) [i.e. Comirnaty] received through 28-Feb-2021*".

119. The document was drafted by a company called Worldwide Safety, and is annexed as "**HE26**". It provides an integrated analysis of the cumulative post-authorization safety data including US and foreign post-authorization adverse event reports received through 28 February 2021.

120. The report shows concerning safety signals. It commences by noting that there were a large number of adverse events reported. It notes inter alia that:

> *"Due to the large numbers of spontaneous adverse event reports received for the product, the [marketing authorization holder] has prioritized the processing of serious cases, in order to meet expedited regulatory reporting timelines and ensure these reports are available for signal detection and evaluation activity."*

121. It proceeds to set out information about the adverse events reported. The relevant section appears in paragraph 3.1 of the document, on page 6, titled "*Safety Database*".

122. Although the document does not say how many doses of Comirnaty had been administered (that information has been redacted) by the time the data was collected, the following is recorded in the document:

> *"Cumulatively, through 28 February 2021, there was a total of 42,086 case reports (25,379 medically confirmed and 16,707 non-medically confirmed) containing 158,893 events Most cases (34,762) were received from United States (13,739), United Kingdom (13,404) Italy (2,578), Germany (1913), France (1506), Portugal (866) and Spain (756); the remaining 7,324 were distributed among 56 other countries."*

123. Table 1 of the same document is titled "*General Overview: Characteristics of All Cases Received During the Reporting Interval*". The relevant portion of the table showing the case outcomes of the 42,086 reports is reproduced below for ease of reference:

Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	Not recovered at the time of report	11361
	Fatal	1223
	Unknown	9400

124. It is not known how many individuals were vaccinated (this information has been redacted) so it is impossible to assess what percentage of vaccinated individuals suffered various adverse events – but what is clear is that significant numbers of adverse events were being reported globally.

125. In this respect, it is important to note that the data collection was passive: vaccinated individuals were not actively contacted and followed up with. As the reporting was voluntary, there is a strong likelihood of a significant under-reporting factor.

126. Of the 42,086 case reports of adverse events following the vaccines, 1223 people were dead within 2½ months of the roll-out, 11361 were not recovered at the time of the reports, and 9400 had unknown outcomes, any number of which may have died or suffered other serious adverse outcomes. Those figures are not insignificant by any measure.

127. The death figure, as well as the unrecovered and unknown figures, are particularly alarming. Historically the FDA, or drug manufacturers themselves, have pulled drugs off the market in circumstances where fewer serious adverse effects had been reported, or where as few as 4 deaths (let alone 1223 as in this case) had been associated with the medicine in question. This raises the question why Pfizer's Comirnaty vaccines are still being marketed as "*safe and effective*" despite such alarming safety signals.

128. Examples of previous drug withdrawals, and the comparatively low numbers of adverse event reports that resulted in those withdrawals follow below:

128.1. In August 2001, drug maker Bayer pulled its popular cholesterol-lowering medication off the market. According to the Food and Drug Administration, Bayer Pharmaceuticals voluntarily withdrew Baycol, known generically as Cerivastatin, as a result of the 31 patients deaths associated with the drug over the last four years. In support of this, I annex as "**HE27**" an article in the BMJ titled "*Bayer decides to withdraw cholesterol lowering drug*".

128.2. A drug called Brombenac was retracted in 1998. This pain killer was effective in relieving pain, but it caused 4 deaths, 8 liver transplants, and 12 cases of severe liver damage in the year it was on the market.

128.3. A drug called Bextra was withdrawn in 2005 for lack of effectiveness and because it caused adverse heart effects including death, heart attacks, and strokes, as well as an increased risk for serious skin reactions, such as epidermal necrolysis, erythema multiforme, and Stevens-Johnson syndrome.

128.4. Vioxx, a drug for arthritis, infamously heightened the risks for heart attack and stroke, and was tied to nearly 28,000 heart attacks in the US population between 1999 and 2003. Researchers reported that the drug resulted in an estimated four heart attacks per 1,000 patients who took it. Its manufacturer, Merck, voluntarily pulled it from the market in 2004. In total, this drug was given to more than 20 million people.

128.5. Accutane, a drug for acne, was recalled in 2009 due to its increased risk of birth defects, miscarriage, and premature deaths among pregnant women who used it, as well as suicidal ideation and inflammatory bowel disease.

128.6. Seldane, an antihistamine was recalled in 1998 due to fatal heart problems.

128.7. Rezulin, an antidiabetic and anti-inflammatory drug was pulled from the market in 2000 because it was associated with 90 cases of liver failure and at least 63 deaths. It also resulted in 35,000 lawsuits against its maker, Parke-Davis/Warner Lambert (now Pfizer).

128.8. Raptiva, a drug used to treat psoriasis, was recalled from the market when it was found to cause progressive multifocal leukoencephalopathy—a rare and lethal disease that results in inflammation and damage of the white matter of the brain.

129. The severe events reported in the Comirnaty 2½ month post-authorization data included:

> *"General disorders and administration site conditions (51,335 AEs), Nervous system disorders (25,957), Musculoskeletal and connective tissue disorders (17,283), Gastrointestinal disorders (14,096), Skin and subcutaneous tissue disorders (8,476), Respiratory, thoracic and mediastinal disorders (8,848), Infections and infestations (4,610) […]."*

130. Of further and particular concern, given that the Comirnaty vaccine had not been tested on pregnant women, were the adverse events reported in pregnant women in the 2½ month post-authorization data.

131. Two hundred and seventy four cases of adverse events were reported in pregnant women, with issues that included spontaneous abortions (23 of them), outcome pending (5 of them), premature birth with neonatal death, and normal outcome (1 each), and no outcome was provided for 238 pregnancies.

132. What that means, statistically, is startling. If no outcome was provided for 238 pregnancies, that means they only collected data for 32 pregnancies. Of those 32 pregnancies that had data, 31 of them had either an abortion or foetal death. That equates to 97% of pregnant women in the available data set having an abortion or foetal death.

133. These concerns notwithstanding, the report claimed that a review of the available data confirmed a favorable benefit/risk balance for Pfizer's "COMIRNATY" vaccine, but that further pharmacovigilance was required and would be conducted.

134. That conclusion appears to be a whitewash – especially considering the absence of any effectiveness data, as well as the death statistics, the pregnancy statistics, and the likely under-reporting factor I highlighted above, which do not appear to have been considered in the report.

135. To re-cap, at the time of the publishing of the two-month trial data in December 2020, no further data was available, and the next available data that was gathered and analysed was presented in the 2½ month post-authorisation paper detailed above.

136. In total, that's four and a half months of data. Already at that stage, serious concerns were apparent, or should have been apparent to anyone who looked, and these should have raised red flags for regulators including SAHPRA.

137. The picture of Pfizer's inaccurate data, and concerns about adverse side effects truly begins to rear its head in the six-month data. It is to that data that I will turn shortly, but before I do, there is one crucial piece of information requiring ventilation. That information appears in the section immediately following.

The unblinding, the cross-over and destruction of any long-term efficacy and safety datasets resulting in an invalidated trial

138. In any phase three clinical randomised controlled trial (RCT), which is what the Pfizer trial purported to be, there must be an inoculated group of trial subjects and an equivalent placebo group. Those groups must subsist until the end of the trial. It is the long-term comparison of the efficacy and safety profiles between the vaccinated trial arm and the placebo trial arm which allows for a proper assessment as to whether or not the product (in this case, Comirnaty) has acceptable efficacy and safety profiles.

139. Without this data it is impossible to assess long term efficacy or safety. Again, Dr Schmidt can attest to this.

140. Usually, vaccine trials are run for a period of ten to fifteen years. This time, because of the exigencies of the situation, the trial period was severely truncated to three years, due to terminate sometime in 2023. The vaccine arm and placebo arm should have been maintained until the culmination of the trial in order to secure decent efficacy and safety data sets.

141. But Pfizer crippled the comparative data collection process, thereby invalidating their trial. Below, I describe how they did this:

141.1. After only 2 months, the trial groups were unblinded. "Unblinding" is a term used in the context of clinical trials to refer to the process of revealing the group assignment of a participant in a study – in other words, telling trial subjects whether they were part of the vaccine arm, or the placebo arm of the study.

141.2. Following the unblinding, those in the placebo group were offered the vaccine. This information appears in Pfizer's 6-month report (published in the New England Medical Journal under the title "*Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months*") and annexed as "**HE28**". At pg. 1762, the following appears:

> *"Starting in December 2020, after BNT162b2 became available under emergency or conditional use authorizations, participants 16 years of age or older who became eligible for Covid-19 vaccination according to national or local recommendations were given the option to learn their trial assignment. Those who had been randomly assigned to receive placebo were offered BNT162b2. After unblinding of the group assignments, participants were followed in an open-label trial period."*

142. 88.8% of the trial subjects in the placebo group elected to take the vaccine and crossed over. This appears from an official FDA document titled "BLA Clinical Review Memorandum"[4].

[4] https://www.fda.gov/media/152256/download.

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143. On page 37 of that document, the following is stated:

> *"During the open-label follow-up period, most participants originally randomized to the placebo group for Doses 1 and 2 of study vaccine received BNT162b2 as Doses 3 and 4 (88.8% and 72.4%, respectively) of study vaccine."*

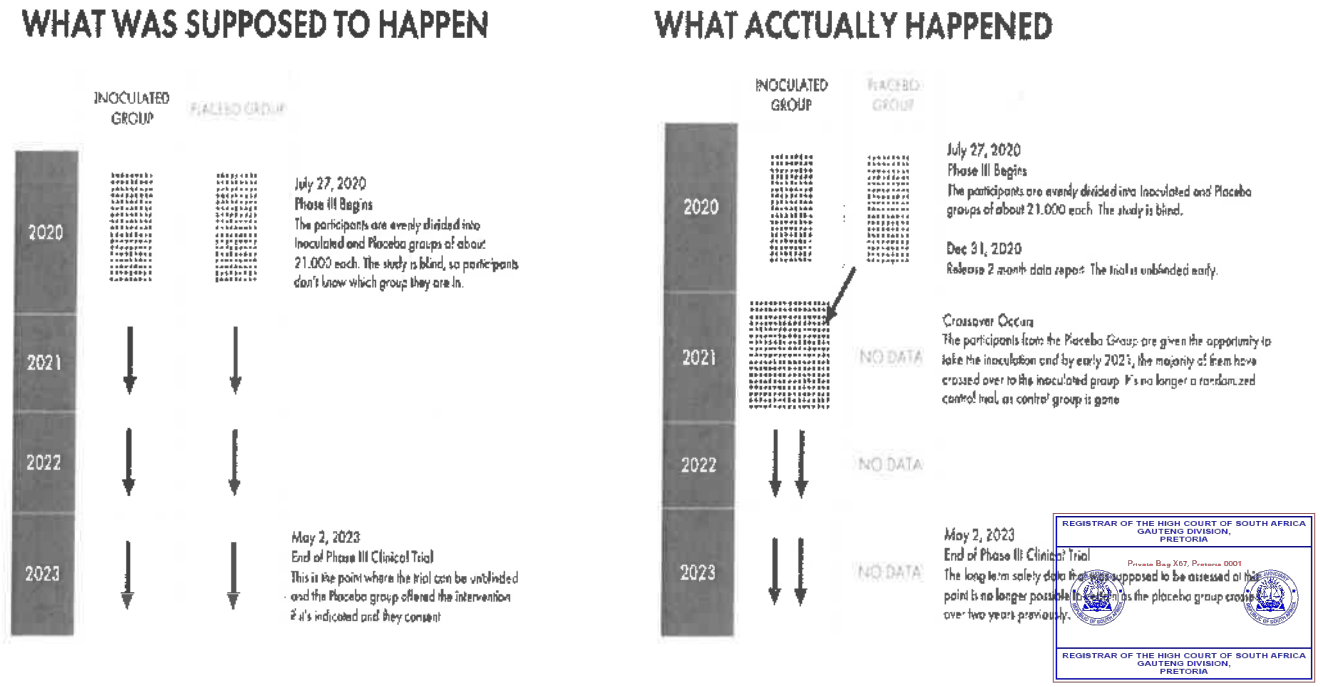
144. An 88.8% crossover is a calamity. It effectively annihilates any prosect of collecting reliable long-term efficacy and safety data about the vaccines.

145. The applicant calls on Pfizer to explain how comparative efficacy and safety data is going to be collected under these circumstances.

146. The applicant also calls on SAHPRA to explain how it concluded that they vaccine was safe given that long-term safety data collection processes had been destroyed.

147. In the event that no such answer is forthcoming, the applicant will ask this Court to conclude that no long-term efficacy or safety data for these vaccines will be available at any juncture.

148. For the convenience of the Court, I highlight below in graphic format (with thanks to Deanna McLeod, and the Canadian Covid Care Alliance) how the trial was supposed to be conducted for the purposes of the collection of long-term efficacy and safety data versus what actually happened:



Pfizer's 6-month trial data

149. I turn now to deal with the six-month trial data. Before I canvass the data, it is important to note that in my opinion, and in the opinion of Dr Schmidt, the 6-month report should never have been published.

150. Any data it cites, and any and all conclusions it purports to draw are invalidated by the 2-month cross-over detailed above.

151. However, for the purposes of analysis only, I will work with the data and conclusions as presented by Pfizer.

152. The six-month trial data has already been annexed above. It was published in the New England Journal of Medicine on 4 November 2021. It must; however, be read together with its supplementary appendix, which is annexed as "**HE29**".

153. The conclusions that the authors draw from the Pfizer six-month data is that the vaccine had a "*favorable*" safety profile, and a 91.3% efficacy profile (down from 95% in the 2-month data).

154. However, an evaluation of the raw data presented paints a concerning safety picture and torpedoes the efficacy claim. Not only that, but it unmasks clear inaccurate data which must be viewed with the utmost seriousness.

155. I begin with the safety issues raised in the six-month report.

156. On page 11 of the supplementary index, a table of deaths occurring in the trial is reported. The table is reproduced below for ease of reference.

Reported Cause of Death[a]	BNT162b2 (N=21,926) n	Placebo (N=21,921) n
Deaths	15	14
Acute respiratory failure	0	1
Aortic rupture	0	1
Arteriosclerosis	2	0
Biliary cancer metastatic	0	1
COVID-19	0	2
COVID-19 pneumonia	1	0
Cardiac arrest	4	1
Cardiac failure congestive	1	0
Cardiorespiratory arrest	1	1
Chronic obstructive pulmonary disease	1	0
Death	0	1
Dementia	0	1
Emphysematous cholecystitis	1	0
Hemorrhagic stroke	0	1
Hypertensive heart disease	1	0
Lung cancer metastatic	1	0
Metastases to liver	0	1
Missing	0	1
Multiple organ dysfunction syndrome	0	2
Myocardial infarction	0	2
Overdose	0	1
Pneumonia	0	2
Sepsis	1	0
Septic shock	1	0
Shigella sepsis	1	0
Unevaluable event	1	0

Table S4 | Causes of Death from Dose 1 to Unblinding (Safety Population, ≥16 Years Old). a. Multiple causes of death could be reported for each participant. There were no deaths among 12–15-year-old participants.

157. The table reports that there were 15 deaths in the vaccine arm, and 14 deaths in the placebo arm. On the face of it, there is little problem with those figures. They appear to be balanced which presents no problem.

158. Because 15 and 14 are so close numerically, it appears that the assumption can be made that the vaccines were not causing more harm than good – and that there was no cause for further investigation. But the facts below expose this table as containing inaccurate data.

158.1. First, by the date of Pfizer's six-month report, there were in fact 20 deaths in those who had received the vaccine – not 15. This appears from the article to which the appendix is attached. There it states:

> *"During the blinded, placebo-controlled period, 15 participants in the BNT162b2 group and 14 in the placebo group died; during the open-label period, 3 participants in the BNT162b2 group and 2 in the original placebo group who received BNT162b2 after unblinding died."*

158.2. It is important to understand the above statement. In the trial, the participants were randomly assigned in a 1:1 ratio to receive two 30-µg intramuscular injections, 21 days apart, of the vaccine or saline placebo. However, starting in December 2020, after the vaccine became available under EUA, participants 16 years of age or older who became eligible for Covid-19 vaccination according to national or local recommendations were given the option to learn their trial assignment.

158.3. Those who had been randomly assigned to receive placebo were offered the vaccine. After unblinding of the group assignments, participants were followed in an open-label trial period. I have set this out above already.

158.4. The point of relevance here is that it appears that the death figures in the table above only report deaths prior to placebo participants having been offered the vaccine but exclude the additional deaths that followed vaccination of the unblinded placebo arm.

158.5. At the time of the report, they knew of 20 vaccinated deaths but in the table they only reported on 15. That means that, if the table presented were accurate, it would have record 20 deaths in the vaccine arm and 14 deaths in the placebo arm. Those figures would have been statistically significant, warranting further investigation and would have alerted regulatory authorities to a possible serious safety signal.

158.6. The question that arises, once again, is why did Pfizer not provide this data in the article instead of putting it into the easily accessible table?

158.7. But there are further flaws. After stating in the article that 20 people in total died after having received the vaccine, the article proceeds to state:

> *"None of these deaths were considered to be related to BNT162b2 by the investigators."*

158.8. But that, too, is unmasked as inaccurate when cross-referenced with the table. The last line item on the table states that the cause of death in at

least one instance was an "unevaluable event". That means that the cause of death is unknown. How can the authors state, on the one hand, in the article that "*none of the deaths were considered to be related to the BNT162b2 vaccine*" while simultaneously conceding that at least one death had an unknown cause?

158.9. Furthermore, the authors give no details as to how they established that there was no causal link between the deaths and the vaccines. Autopsies, together with detailed review of medical records, would have been the objective mechanism by which to determine causality, but there is no indication anywhere in Pfizer's report that autopsies or reviews of medical records were conducted.

158.10. Another bizarre item in the table is line item 11, which states that a "*cause of death*" is "*death*". That makes no sense. What was the actual cause of that death? Was it also unknown?

158.11. There is another problem. When physicians catalogue "causes of death", the cause of death must be reported by referencing the immediate cause of death, and not underlying health conditions.

158.12. As a medical practitioner, I am qualified to write a death certificate, and I have direct knowledge of how those certificates are written and the contents of those certificates.

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158.13. On death certificates, in terms of the diagnosis, the physician will list the immediate cause of death, and then separately list any underlying causes that may have contributed to the death. The point is that the underlying health conditions are not causes of death, so they cannot be listed as such. I also annex as "**HE30**" a document titled "*cause of death certification*" which was published by the statistician general in South Africa.

158.14. Based on international standards, it sets out guidelines for how deaths are to be reported and explains clearly that the "*immediate cause of death is the final disease, injury or complication directly causing the death*".

158.15. Underlying health conditions, referred to in the guide as "*an underlying cause of death*" is "*the disease or injury that started the sequence of events leading directly to death*". In this respect too, table 4 on page 11 of the supplementary index is misleading. The table lists a number of "*underlying conditions*" as "*causes of death*". Examples of this are arteriosclerosis, cardiac failure congestive, chronic obstructive pulmonary disease, dementia, and hypertensive heart disease. Serious vaccine adverse events may well have been the final disease, injury or complication directly causing the death in any or all of these cases – but these would not have been noted or investigated because the underlying cause was reported instead of the immediate cause of death.

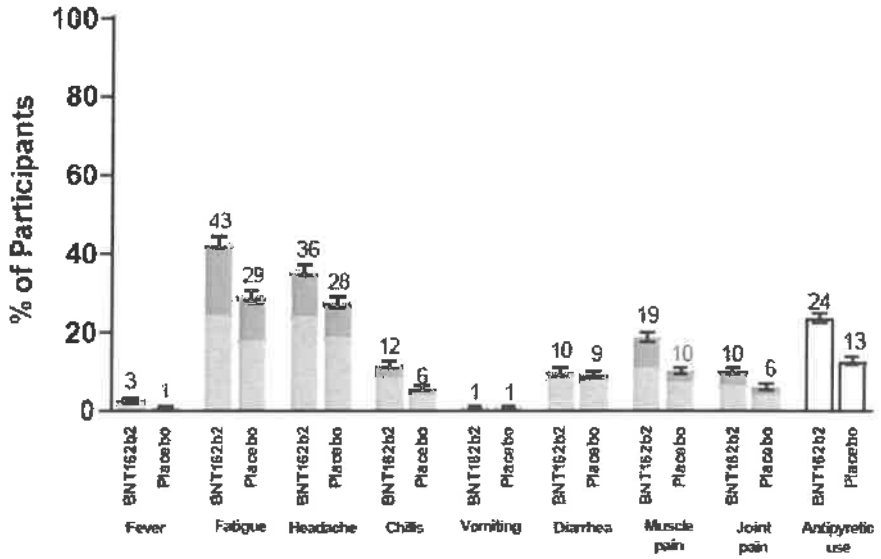
159. I now move onto the efficacy claims made, and the problems with those claims.

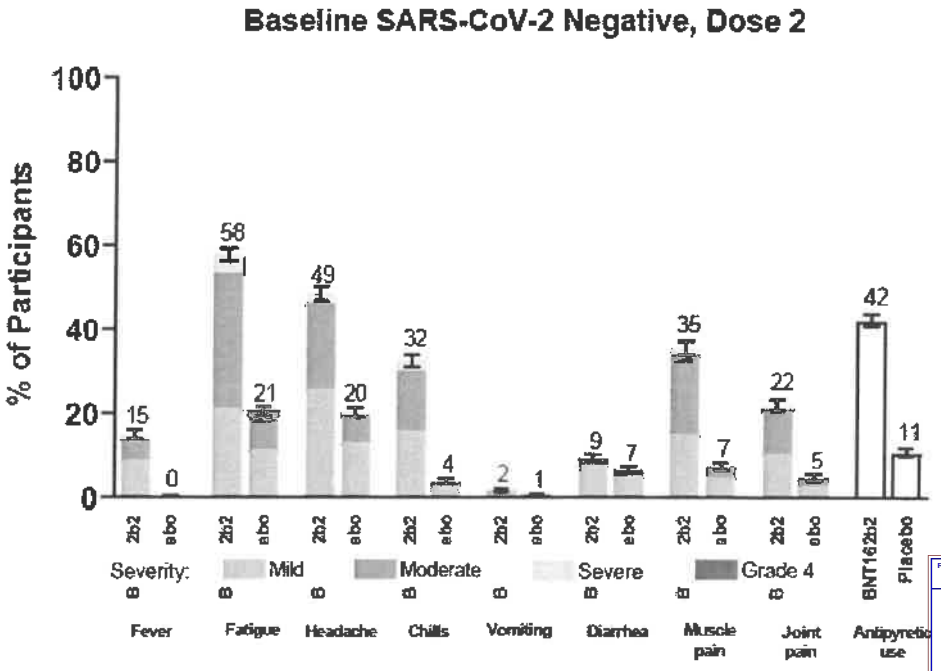
160. The six-month report claims an efficacy "against Covid" of 91.3% (down from the 95% efficacy claim in the two-month report). Any rational person would interpret this to mean that, not only would they have a 91.3% chance of being protected from contracting Covid-19 – but that they would be spared the symptoms of Covid-19.

161. The problem for Pfizer is that the data in the supplementary appendix places the efficacy claim in doubt because it shows that the trial subjects in the vaccine arm were getting more Covid-like symptoms (even through their PCR tests were negative or were not tested) than those in the placebo group.

162. This data emerges from two tables in the supplementary appendix to the six-month report. Those tables appear on page 17 and they are reproduced below for the Court's ease of reference:

Baseline SARS-CoV-2 Negative, Dose 1





163. What these graphs demonstrate is that many more people in the vaccine arm than in the placebo arm became ill with Covid-like symptoms. The situation becomes worse after dose two with many of the Covid-like symptoms becoming more severe in the vaccinated arm than in the placebo arm. For example, the second graph shows that after dose 2 of the vaccine:

163.1. 15% of participants in the vaccine group had fever compared to 0% in the placebo arm.

163.2. 58% of participants in the vaccine group had fatigue compared to 21% in the placebo arm.

163.3. 49% of participants in the vaccine group had headaches compared to 20% in the placebo arm.

163.4. 32% of participants in the vaccine group had chills compared to 4% in the placebo arm.

163.5. 2% of participants in the vaccine group had vomiting compared to 1% in the placebo arm.

163.6. 9% of participants in the vaccine group had diarrhea compared to 7% in the placebo arm.

163.7. 35% of participants in the vaccine group had muscle pain compared to 7% in the placebo arm.

163.8. 22% of participants in the vaccine group had joint pain compared to 5% in the placebo arm.

164. What is also significant is that the adverse events classified as "severe" (represented in the graph as orange), are worse in the vaccinated arm after the second dose as compared with the first dose.

165. The same trends (albeit less severe) can be seen in the first graph which tracks the same datapoints 7 days after dose 1. That means that in every single metric measuring Covid-like symptoms, participants in the vaccine arm got more sick, and had more symptoms than those in the placebo arm. How can one say a vaccine has high efficacy in preventing Covid if participants are getting more

sick with Covid-19 like symptoms in the treatment arm than they are in the placebo arm?

166. Despite there being more cases of symptomatic Covid-19 (defined as cases with symptoms plus a positive PCR test) in the placebo arm after the first and second doses, the rates of Covid-like symptoms are dramatically higher in the vaccine arm than the placebo arm after each injection, meaning that the vaccine was negatively effective at preventing Covid-like morbidity, the very thing the vaccines were ostensibly supposed to prevent.

167. The efficacy profile also appears to have been inflated. Pfizer took the results from their adult trial, which started in July 2020, and then added the results from the 12-15 year old trial despite the fact that the adolescent trial started four months later. The following is stated in the six-month report:

> *"Between October 15, 2020, and January 12, 2021, a total of 2306 participants 12 to 15 years of age underwent screening, and 2264 underwent randomization at 29 U.S. sites. Of these participants, 2260 received at least one dose of BNT162b2 (1131 participants) or placebo (1129), and 99% (1124 in the BNT162b2 group and 1117 in the placebo group) received the second dose. […] [Data] for this cohort are included in the analyses of vaccine efficacy in the overall."*

168. It is well known that the efficacy of the vaccines wanes over time. Pfizer itself concedes as much in their six-month report:

> *"From its peak after the second dose, observed vaccine efficacy declined. From 7 days to less than 2 months after the second dose, vaccine efficacy was 96.2% (95% CI, 93.3 to 98.1); from 2 months to less than 4 months after the second dose, vaccine efficacy was 90.1% (95% CI, 86.6 to 92.9); and from 4 months after the second dose to the data cutoff date, vaccine efficacy was 83.7% (95% CI, 74.7 to 89.9) […]*

Efficacy peaked at 96.2% during the interval from 7 days to less than 2 months after the second dose and declined gradually to 83.7% from 4 months after the second dose to the data cutoff date — an average decline of approximately 6% every 2 months."

169. That means that adding children in at a later stage gave a false boost to the efficacy numbers – this is especially so due to children having stronger immune systems than adults, and therefore being less susceptible to Covid-19.

170. The efficacy for these two demographics should have been reported separately, not presented as one combined result. Without this boost, the Pfizer 6-month reported efficacy would probably have been lower.

THE SOUTH AFRICAN GOVERNMENT'S AUTHORISATION OF THE COMIRNATY VACCINES AND THE "SAFE AND EFFECTIVE" NARRATIVE.

171. SAHPRA registered Pfizer's vaccine/s as follows:

171.1. On 16 March 2021, SAHPRA approved Pfizer's "COMIRNATY" vaccine under section 21 of the Medicines and Related Substances Act 101 of the 1965 ("the MARS Act").

171.2. Section 21 registrations are a special restricted authorisation category, meaning that the relevant product does not yet have full regulatory approval.

171.3. The relevant SAHPRA press release is annexed as "**HE31**".

171.4. On 8 December 2021, SAHPRA approved the use of a third (booster) dose of the Pfizer's "COMIRNATY" vaccine in individuals aged 18 years and older, as well as a third (booster) dose in individuals aged 12 years and older who were severely immunocompromised.

171.5. It is not clear from the relevant SAHPRA press release, annexed as "**HE32**", whether the registration was under section 15 or section 21 of the MARS Act – but for the purposes of this application, I assume that the registration was under section 21.

171.6. On 25 January 2022, Pfizer's "COMIRNATY" vaccine was approved under section 15 of the MARS Act, and thereby given full regulatory approval.

171.7. The relevant SAHPRA press release is annexed as "**HE33**". In terms of section 15(3)(a)(iii), SAHPRA can grant section 15 approvals (which are full regulatory approvals) for medications, including vaccines when it is satisfied that the medications are "*safe, efficacious, and of good quality […]*", In so doing, it is empowered by section 15(3)(a) to pursue any investigation or enquiry that it deems necessary in order to satisfy itself of the requirements listed in section 15(13)(i)-(iii).

171.8. Considering what I have detailed in these papers, it is doubtful that SAHPRA could have pursued adequate investigation of Pfizer's data. I am advised that all of this will be answered when the rule 53 record is provided by SAHPRA.

171.9. On 15 November 2022, SAHPRA then registered two new Pfizer vaccines: First, Pfizer's Ready To Use (RTU) adult vaccine, and its Dilute To Use (DTU) paediatric vaccine.

171.10. Both of these vaccines have also been registered in terms of Section 15 of the MARS Act. The relevant SAHPRA announcement is annexed as "**HE34**".

171.11. No data has been publicly released about these vaccines or their trials, so it is impossible to do the forensic work on those vaccines that has been done in these papers on Comirnaty.

171.12. However, those vaccines use the same problematic mRNA technology, and were also manufactured by Pfizer/BioNTech.

172. Section 2A of the MARS Act sets out the objectives of SAHPRA. They are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines in the public interest. SAHPRA does this, according to section 2B, by evaluating applications for medicines transparently, fairly and ensuring that evidence of existing and new adverse events, interactions, information with regard to post-authorization surveillance and vigilance is being monitored, analysed and acted upon.

173. It is at this stage unknown precisely what data SAHPRA had before it when it made the decisions to grant full section 15 authorisations to the various Pfizer vaccines.

174. What is known, however, is that at the time of the section 15 approvals, which occurred on 25 January 2022 and 15 November 2022, both Pfizer's two-month report (published on 31 December 2020), and its six-month report (published on 4 November 2021), were already publicly available.

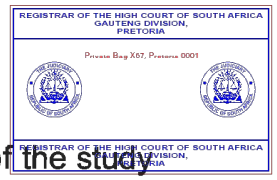
175. SAHPRA must have had these two reports at the very least. How and why SAHPRA granted full authorisation to these products when, at a bare minimum it knew (or ought reasonably to have known) the following from the data, are questions that we call for it to answer in this case:

175.1. That global safety signals from a reliable adverse event reporting system, VAERS, was showing alarming rates of serious, life-threatening adverse events and deaths that were potentially linked to the vaccine.

175.2. That Pfizer's six-month safety data had markers of serious inaccuracies, as detailed above.

175.3. That the unblinding and cross-over of trial participants from the placebo arm to the vaccine arm torpedoed the collection of any long-term safety data of adverse events, thereby invalidating the study, and which further meant that unless they performed their own investigation as had been proposed by the Government of India, SAHPRA would not be able to effectively assess the long-term safety of the vaccines.

175.4. That the vaccine was being authorized for the most vulnerable populations (pregnant and lactating women, immunocompromised individuals with known or suspected immunodeficiency, people receiving cytotoxic agents or systemic corticosteroids, and people with other serious underlying health conditions), as well as individuals with a previous diagnosis of Covid-19, even though the vaccine's efficacy and safety had not been tested in any of those population demographics in the trial.



175.5. That the data showed that trial subjects in the vaccine arm of the study were presenting more frequent, and more severe Covid-like symptoms than those in the placebo arm.

175.6. That the vaccine had not been tested against natural immunity, and that neither its efficacy nor effectiveness compared to natural immunity were known.

176. But that is not the only criticism to be levelled against SAHPRA. Section 15 of the Medicines and Related Substances Act requires SAHPRA to satisfy itself, prior to registration, that the relevant vaccines were safe and efficacious.

177. SAHPRA did not conduct any independent trials on Pfizer's vaccine products (Comirnaty, DTU and RTU). What this means is that what SAHPRA had before it was data, and data analysis done by Pfizer.

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178. The registration was done based on Pfizer's data without any external checks and balances, or verification.

179. I have set out above that Pfizer was contractually bound (in its agreement with BioNTech) to "commercialize" Comirnaty and other Covid-19 vaccine products. SAHPRA's sole reliance on the very party responsible for commercialization of these vaccines creates a significant conflict of interest, rendering the registration of the Comirnaty vaccines, the RTU vaccines, and the DTU vaccines vulnerable to attack on the basis of irrationality, either under the prescripts of or PAJA or legality. In the circumstances, SAHPRA could not have exercised its powers under the Act rationally.

180. SAHPRA's conduct is not the only conduct worthy of scrutiny. The Government has consistently (and continues to) run campaigns that the vaccines, including all of the Pfizer vaccines "*prevent transmission*" and are "*safe" and "effective*".

181. Astonishingly, Government also encourage pregnant women to take the vaccine despite Pfizer and BioNTech's admission (detailed above) that "*it is not yet known whether the use of [Comirnaty] in a parent could be harmful to an unborn baby […]*".

182. The above narrative has been so widely publicised that the Court can take judicial notice of it.

183. To the extent that the respondents deny this, and the Court does not take judicial notice of these facts, the applicant will present further screenshots of statements made to that effect. For now, however, I annex as "**HE35**" sources

from the South Africa Government's official website (https://www.gov.za/coronavirus/faqs/vaccine) which quotations are valid and remain on the website as of the date on which this affidavit was deposed to:

183.1. First, the Government explains that the reason to get vaccinated is that the vaccine protects others – meaning it stops transmission. They say:

> *"Two key reasons to get vaccinated are to protect ourselves and to protect those around us. Because not everyone can be vaccinated – including very young babies, those who are seriously ill or have certain allergies – they depend on others being vaccinated to ensure they are also safe from vaccine-preventable diseases."*

183.2. Second, the government assures the public that the vaccines are safe and effective:

> *"The vaccine is both safe and highly effective to prevent severe COVID-19 disease and death."*

183.3. Thirdly, and most surprisingly considering that the novel Pfizer BioNTech COVID-19 vaccines are known to contain viral genetic material (mRNA) in lipid nanoparticles, the Government explains that:

> *"However, because vaccines contain only killed or weakened forms of germs like viruses or bacteria, ..."*

184. Fourth, the NICD[5] maintains its position that vaccination is safe in pregnant women. On its website it says:

> *The Vaccine Ministerial Advisory Committee (VMAC) continues to monitor the safety and effectiveness of COVID-19 vaccination during pregnancy and lactation for all vaccines included in, or considered for inclusion, in the national vaccine rollout. Although the risk is small, pregnant and postnatal women are at increased risk of severe COVID-19 disease compared to their non-pregnant counterparts. They are also at increased risk of preterm birth, and possibly other adverse obstetric outcomes. As a result of the growing body of safety evidence that supports the use of COVID-19 vaccines in pregnant women, the VMAC has recently updated its recommendations regarding administration of COVID-19 vaccines during pregnancy.*
>
> *Current recommendations are as follows (updated recommendations are shown in bold):*
>
> 1. *COVID-19 vaccination should be offered to women who are eligible to be vaccinated during any stage of pregnancy, and during lactation. As previously recommended, both the Comirnaty® (Pfizer) vaccine or the Janssen® (J&J) vaccine can be offered. Everyone 18 years and older is now eligible to be vaccinated, and women 18 years and older should therefore be offered vaccination during any stage of pregnancy, and during breastfeeding.*
> 2. *Consideration should be given to providing vaccination to pregnant and breastfeeding women during routine antenatal and postnatal visits. Where this is not possible, health care workers should encourage pregnant and breastfeeding women to access vaccination at a nearby vaccination site.*
> 3. *Health care workers are encouraged to discuss the benefits and possible risks of COVID-19 vaccination with their patients. These discussions should include the increased risk, albeit small, of severe disease in pregnant women when compared to non-pregnant women, reassurance about the growing evidence supporting the safety of vaccines in pregnant and breastfeeding women, the strong immune response following vaccination and the benefits of immune transfer to the baby, and ongoing safety monitoring of vaccine use in pregnancy. Furthermore, that there are no known risks associated with other non-live vaccines given routinely to pregnant women.*

[5] https://www.nicd.ac.za/vaccination-of-pregnant-and-breastfeeding-women-august-update/

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4. *COVID-19 vaccination is strongly encouraged for non-pregnant women contemplating pregnancy.*

185. I also annex collectively as "**HE36**" screenshots from Government's official Twitter account stating that the vaccines are "*safe and effective*"[6]. This narrative continues to this day.

186. I have already cast significant doubt on both the safety and effectiveness by examining Pfizer's data, but there is more data available to demonstrate that the vaccines do not stop transmission, and that they are neither effective nor safe. Conclusive statements about safety, or more accurately stated the magnitude of risk, could not be made at this stage.

187. I now commence by dealing with the evidence pertaining to the claim that the vaccines stop transmission, and I then progress to setting out the additional evidence supporting the applicant's contention that the vaccines are neither safe nor effective.

It is not true that the vaccines stop transmission.

188. Pfizer executives admitted in the European Parliament that Comirnaty had not been tested prior to authorisation to evaluate whether it stopped transmission of the SARS-CoV-2 virus.

[6] (https://twitter.com/governmentza/status/1397840068799352834?lang=en)
https://twitter.com/governmentza/status/1532972921953652737
https://twitter.com/healthza?lang=en

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189. It is, however, not necessary to rely on that admission, because the fact that the ability of the vaccine to prevent transmission was never intended to be part of the Pfizer trial, appears from its protocol already annexed above,

190. The Pfizer trial protocol sets out the objectives of the trial. Nowhere in the trial protocol is assessing the effect of the vaccine on transmission listed as a trial objective. The short title of the study states:

> *"**Short Title**: A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals."*

191. Testing for the vaccine's effect on transmission is not mentioned in the short title.

192. To the extent that further confirmation is required; the objectives of the Pfizer trial appear in detail from the table at pages 10 – 14 of the Pfizer trial protocol, and they show conclusively that the trial objectives were limited to testing for safety, tolerability, efficacy and immunogenicity.

193. It is manifest from the protocol that the effect of the vaccine on transmission of Covid-19 was not part of the trial.

194. It is further manifest from the aforementioned 2-month and 6-month studies published in the New England Journal of Medicine that the effect of the vaccine on transmission of Covid-19 was not measured.

102.

195. The protocol, as well as these published studies, must have been available to SAHPRA, the Ministerial Advisory Committee of Covid-19, and the Government. It is inexplicable that the Government told the South African public that the vaccines stopped transmission, and that getting vaccinated would "*protect others*" when the documentary evidence did not prove that.

196. Many South Africans, even those who were vaccine hesitant, were convinced to take the vaccination under this ruse, and even to vaccinate their children.

197. Even more inexplicable is the fact that the Government has not retracted its statements on transmission to date, leaving many in the public misinformed about the vaccine and transmission.

It is not true that Comirnaty was proven "effective". Effectiveness was never tested. It is also not true that the vaccines are "safe".

198. I have already annexed evidence above to the effect that the Government's consistent stance is that the vaccines, including Comirnaty, were "*effective*".

199. The government at no stage attempted to inform the public regarding the definition of "*effectiveness*". That definitional lacuna left open the possibility for errors and shifting benchmarks – which is exactly what happened.

200. When the public were told that the vaccines were effective, they believed that meant that the vaccine was effective in real-world circumstances at preventing

infection, transmission, severe disease, hospitalisation and death from COVID-19. That, at least, was the original claim made by government authorities.

201. When the Pfizer mRNA vaccines were awarded EUA by FDA, it was widely publicised that the new mRNA technology was 95% effective at prevention of transmission of the SARS-CoV-2 virus. This claim was made on the basis of a single Pfizer trial, dated 31 December 2020, in which the authors claimed "95% efficacy" (not "95% effectiveness").

202. The crucial differences between the meanings of the words "efficacy" and "effectiveness" are set out below.

203. The subsequent 6-month data report of Pfizer, dated 15 September 2021, found a gradual decline in vaccine efficacy, at that stage claimed to be 91.3%. Whether the efficacy was 95% or 91.3%, real-world data simply does not support the claim of effectiveness.

203.1. South Africa's first wave of Covid cases peaked on 19 July 2020 at 210.10 Covid cases per million people.

203.2. South Africa's second wave of Covid cases peaked on 11 January 2021 with 317.93 cases per million people.

203.3. South Africa then commenced its national vaccination rollout in February 2021. If government's claims that vaccines were effective at stopping infection and transmission were correct, one would have expected the

reported cases in the Covid waves that followed to decrease. But that is not what happened. The reported cases in fact increased after the vaccination rollout.

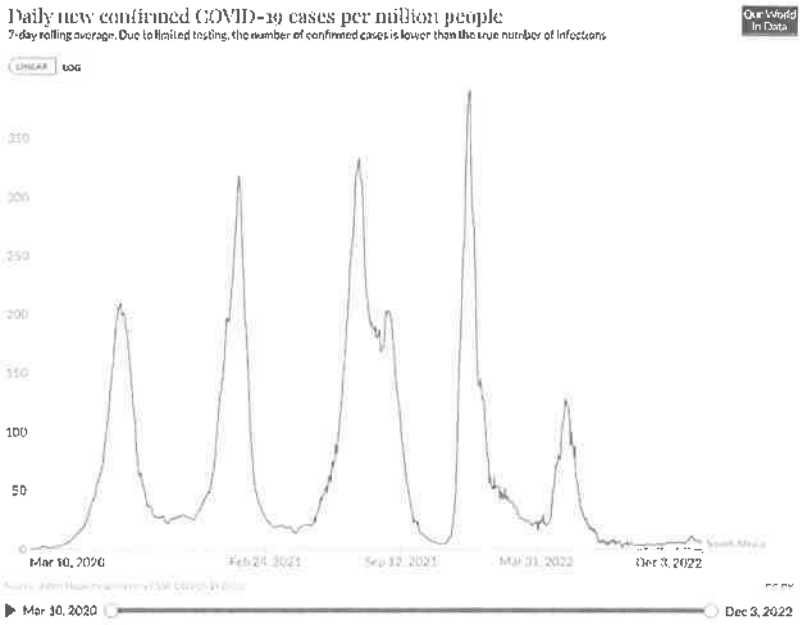
203.4. The third Covid case wave peaked on 7 July 2021, 5 months after the rollout of the vaccinations had commenced with 330.02 cases reported per million people.

203.5. Similarly, the fourth Covid case wave peaked on 17 December 2021 with 391.31 cases per million people.

204. The above data was sourced from the Our World in Data website ("**OWD**"). Their raw data on confirmed cases and deaths for all countries is sourced from the COVID-19 Data Repository of the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University. It represents official government data from the relevant country (in this case obtained from the South African Department of Health).

205. The above data is graphically represented below, and the red line shows the date of the commencement of the vaccination rollout[7]:

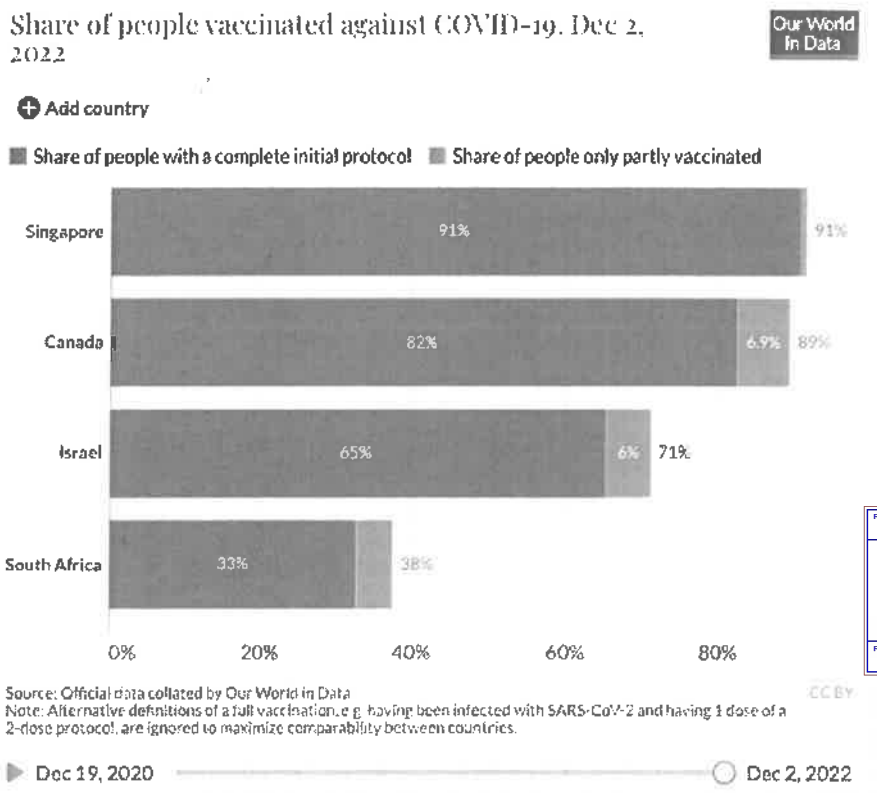
[7] Source: https://ourworldindata.org/covid-cases.



206. I accept that the above data is hampered by the relatively low percentage of vaccinated South Africans, so I turn now to assess the data (also from OWD) from a random cross-section of countries that have higher percentages of their populations vaccinated.

207. As of December 2022, Israel had 71% of their population vaccinated, Canada had 89% of their population vaccinated, and Singapore had 91% of their population vaccinated[8].

[8] Source: https://ourworldindata.org/covid-vaccinations.



208. Similarly to South Africa, the Covid cases in the respective waves in these countries also reflect increasing case reports post-vaccination instead of decreasing case reports. This also flies in the face of the assertion that the vaccines were effective at preventing infection and transmission.

208.1. Singapore rolled out their vaccination program in January 2021. The data shows that there was little effect for 11 months, after which Singapore began experiencing spikes in case reports.

208.2. Israel and Canada both began rolling out their vaccination programs in December 2020, after which both countries reported more Covid cases

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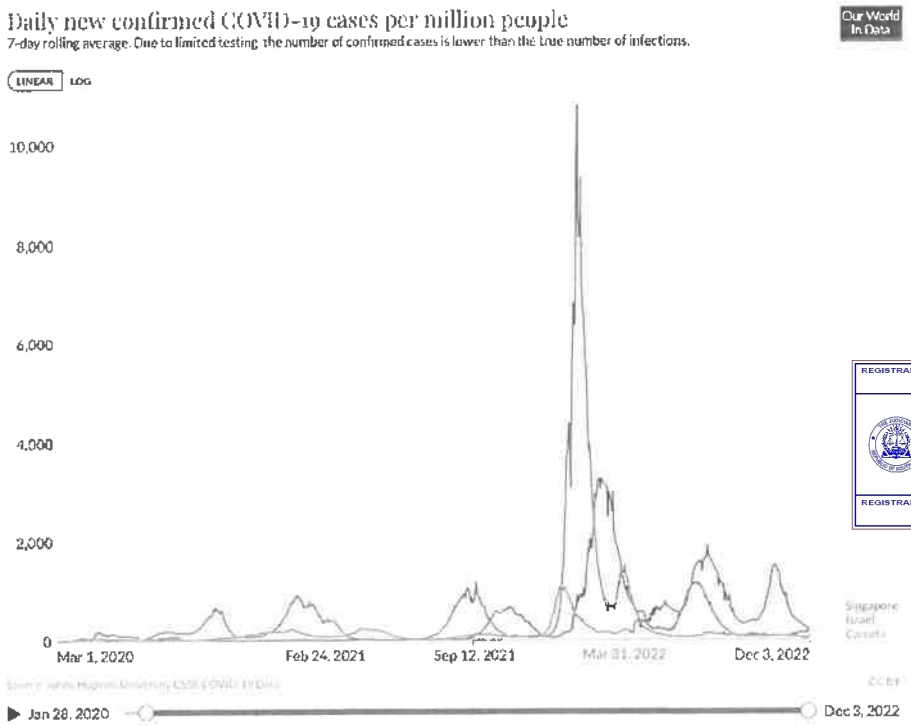
in the waves following vaccination than they had reported in the waves preceding vaccination.



209. Global authorities realized that the data was not showing that vaccines were effective at preventing infection or transmission. Having realized this, they shifted the "effectiveness" benchmark. At this juncture, they largely abandoned the claim that the vaccines prevented infection or transmission, and shifted to stating that they prevent "severe illness and death".

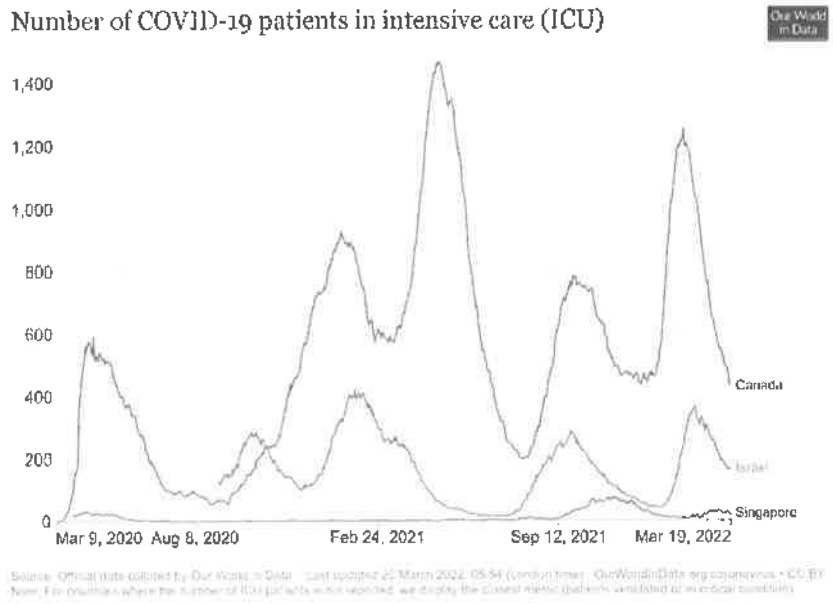
210. But the data doesn't support that either.

211. If it were true that the vaccines prevented severe illness or death in those who contracted Covid, one would expect to see real-world factual data in highly vaccinated countries such as Singapore, Canada and Israel reflecting

diminishing trends of both ICU admissions and deaths. But that is not what the data demonstrates. Here again, the data as represented in the graph below in fact shows the opposite[9]:

211.1. Singapore, which commenced its vaccination program in January 2021 saw no effect for around eight months, after which it saw spikes in Covid-related ICU admissions.

211.2. Likewise, Israel and Canada who began their vaccination programs in December 2020, saw an increase in Covid-19 related ICU admissions.



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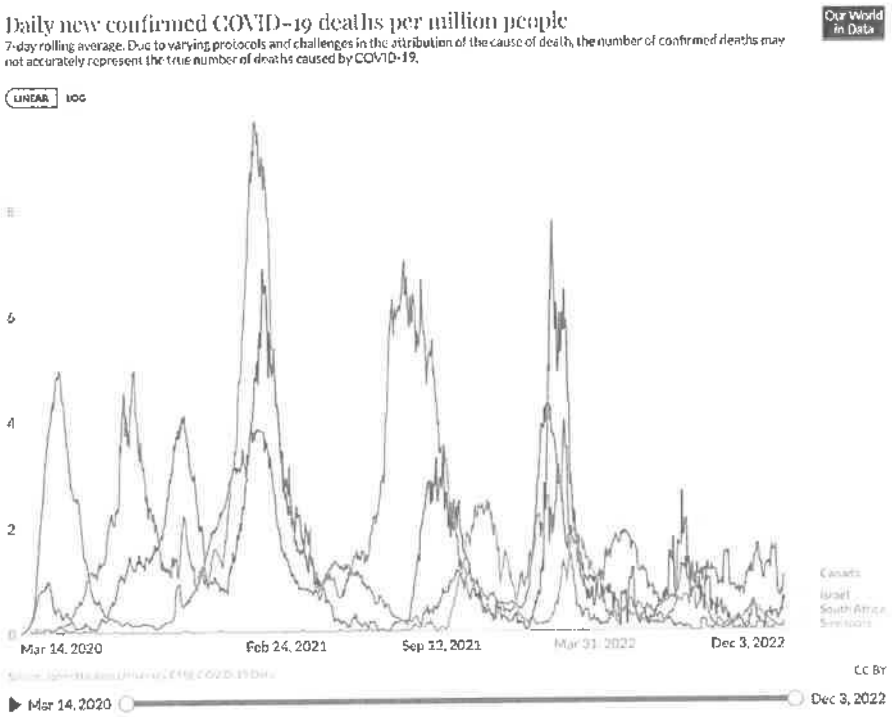
212. The same trend can be seen in Covid-19 related deaths:

212.1. The data from Singapore shows no benefit for the first 8 months, followed by an escalating trend of increasing deaths.

212.2. The data from Canada and Israel shows a transient diminishing trend for the first 11 months or so, followed by an escalating trend of increasing deaths.

212.3. In contrast, the data from South Africa, which has the lowest proportion of vaccinated individuals, does show a diminishing trend of deaths over time. This diminishing trend in South Africa is most probably the result of natural immunity that has been acquired by the 62% of the South African population who remain unvaccinated.



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213. In conclusion, the real-world data contradicts the narrative of the global authorities, and the South African Government, that the vaccines prevent severe illness and death. My introduction of real-world data has been dismissed in other legal proceedings by Professors Salim Abdool Karim and Glenda Grey solely on the basis that it is not data contained in peer-reviewed journals, and is therefore neither reliable nor credible. That argument is farcical.

214. BioNTech, in its SEC (Securities and Exchange Commission) filing already annexed above, itself relies on real-world data to measure effectiveness. This is demonstrated by the extracted quotes copied below:

> *"The global distribution of BNT162b2 has also generated a vast array of real-world vaccine effectiveness data in diverse populations. Vaccine effectiveness following the primary two doses demonstrated protection against symptomatic infections, asymptomatic infections, severe infections, hospitalizations and deaths in real world vaccine effectiveness trials, mirroring the high efficacy and confirming the safety observed in our Phase 3 clinical trial.[…]*
>
> *"Real world data confirms that vaccine effectiveness decreases over time as the interval after the second dose increases, while vaccine effectiveness against hospitalization continues to be high. Waning vaccine effectiveness observed in the real-world setting coincided with the global spread of the Delta variant. Real world evidence also shows that high vaccine effectiveness is restored with a third dose booster, both against severe disease, as well as confirmed infection, including infections caused by the Delta variant. […]"*

215. I note that the BioNTech SEC filing makes the claim that the real-world data demonstrates vaccine effectiveness. I do not know on what source data they base that conclusion because they do not disclose it, but I deny that those

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conclusions are correct based on the real-world data that I have reproduced above. Pfizer is cited in this application. I invite them to produce the real-world data that their manufacturing partner, BioNTech, say supports the claim that the vaccines are effective.

216. In any event, the point is simply that real-world data is credible. If it was not, BioNTech would not themselves reference it in effectiveness assessments.

217. There is further real-world evidence that, in my respectful opinion, demonstrates that the Pfizer vaccines are neither safe nor effective. This data comes from official data published by the Government in the United Kingdom – specifically, data published by The Office for National Statistics ("ONS")[10]. The Pfizer vaccines were the most widely used of all registered vaccines in the United Kingdom.

218. The graph below shows the number of deaths caused by Covid-19 in England from August 2021 to December 2021. Green bars show deaths among people who were unvaccinated, red bars show the cumulative Covid deaths among the vaccinated, and yellow and mauve bars show deaths among people who received one or two doses of the vaccine. It shows clearly that, in every month, there were significantly more Covid-19 deaths amongst the vaccinated than there were amongst the unvaccinated (compare primarily the green and red bars). That is clear evidence that the vaccinations are not effective at either

10 Source site: https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/deathsregisteredweeklyinenglandandwalesprovisional/weekending9december2022.

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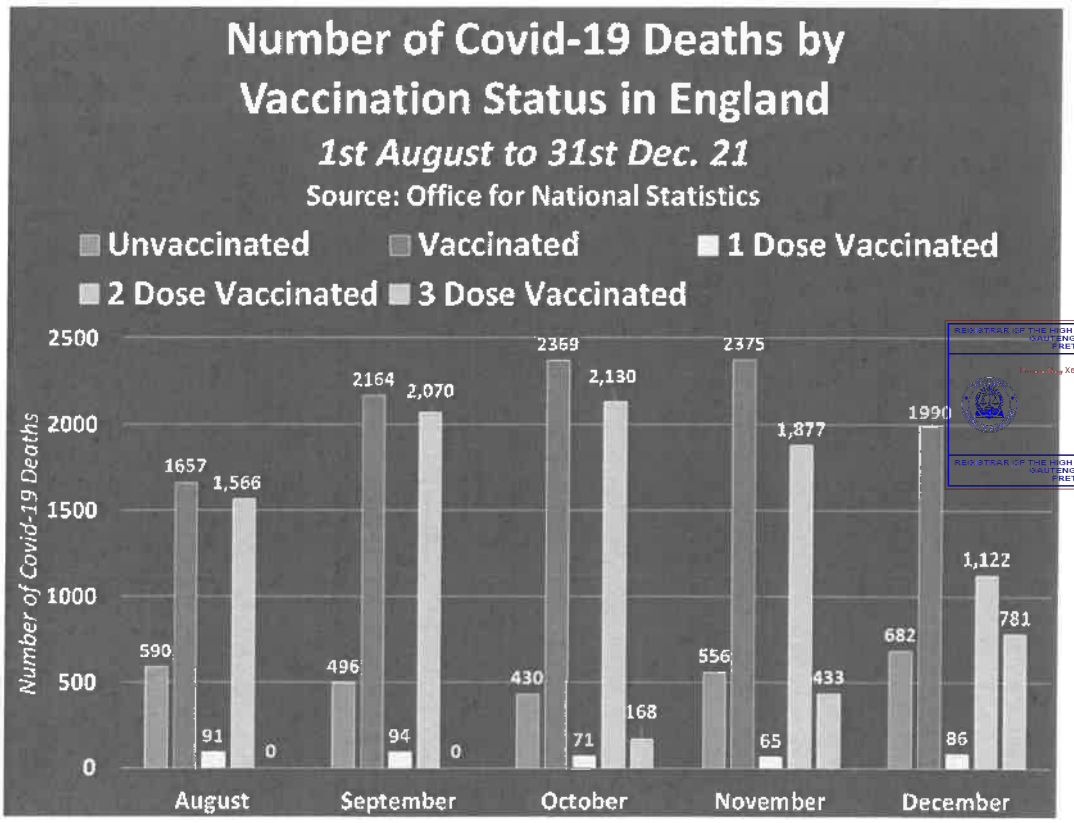
preventing the contraction of Covid, hospitalisation from Covid, or death from Covid.



219. The trend in the above table continues into the period 1 Jan 2022 to 31 May 2022. But the later data shows another interesting trend: The Covid-19 death statistics in the unvaccinated decline steadily over the five month period, possibly reflecting the acquisition of herd immunity in the unvaccinated.

220. The relevant graph appears below:

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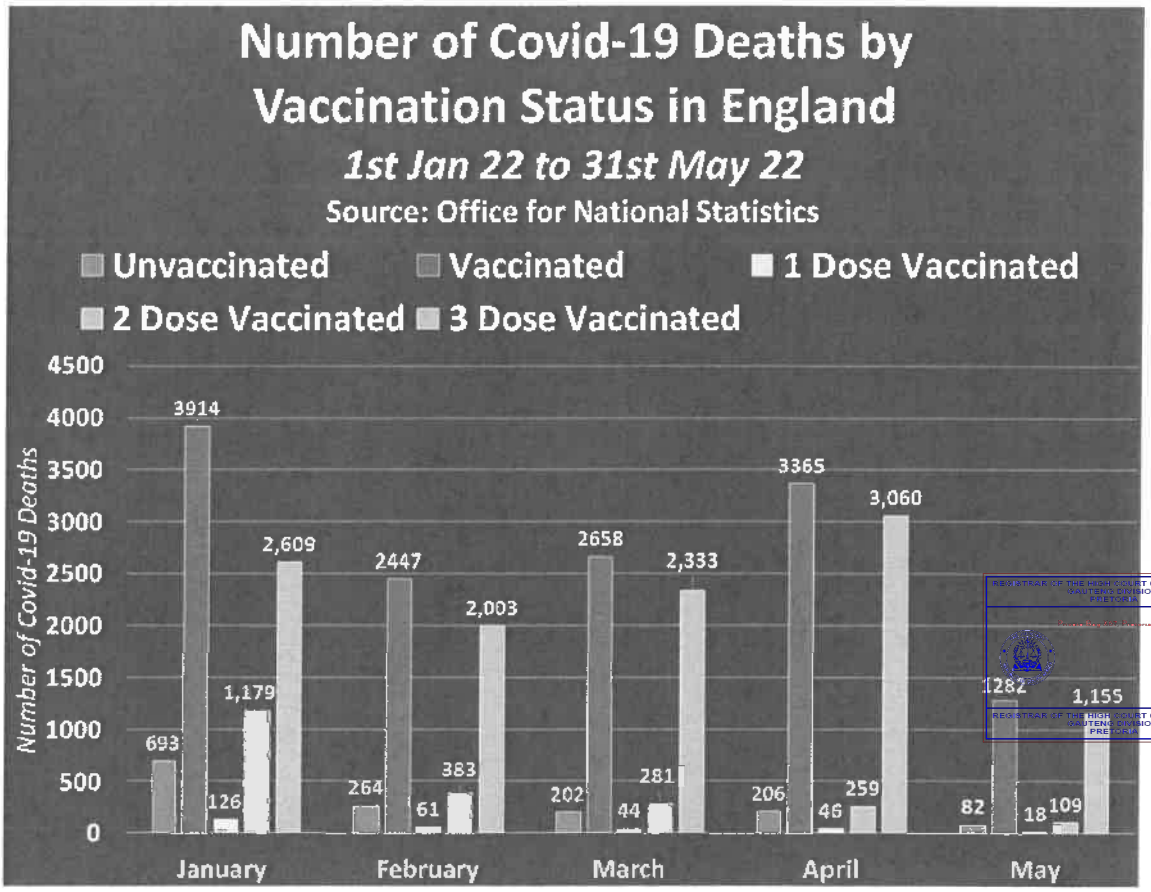


221. Of course, the number of deaths in the vaccinated and unvaccinated arms must be calculated as a percentage of the relative percentages of the UK population that are both vaccinated and unvaccinated. Both Our World in Data (referenced and sourced above) and the United Kingdom's Health Security Agency (UKHSA) provide figures of 20% unvaccinated, and 80% vaccinated in the UK. Having a population of 56 million, that means that approximately 11 200 000 individuals are unvaccinated, and approximately 44 800 000 individuals are vaccinated in the UK.

222. If one looks at the individual months on the source data (referenced and sourced above), the trend is clear: individuals in the vaccinated arm have a higher percentage probability of death.

223. I have done these calculations in multiple months and have observed the same trends but, in order to not overburden the court, I use only one month as an example. I have chosen May 2022 (the last month reflected in the abovementioned dataset).

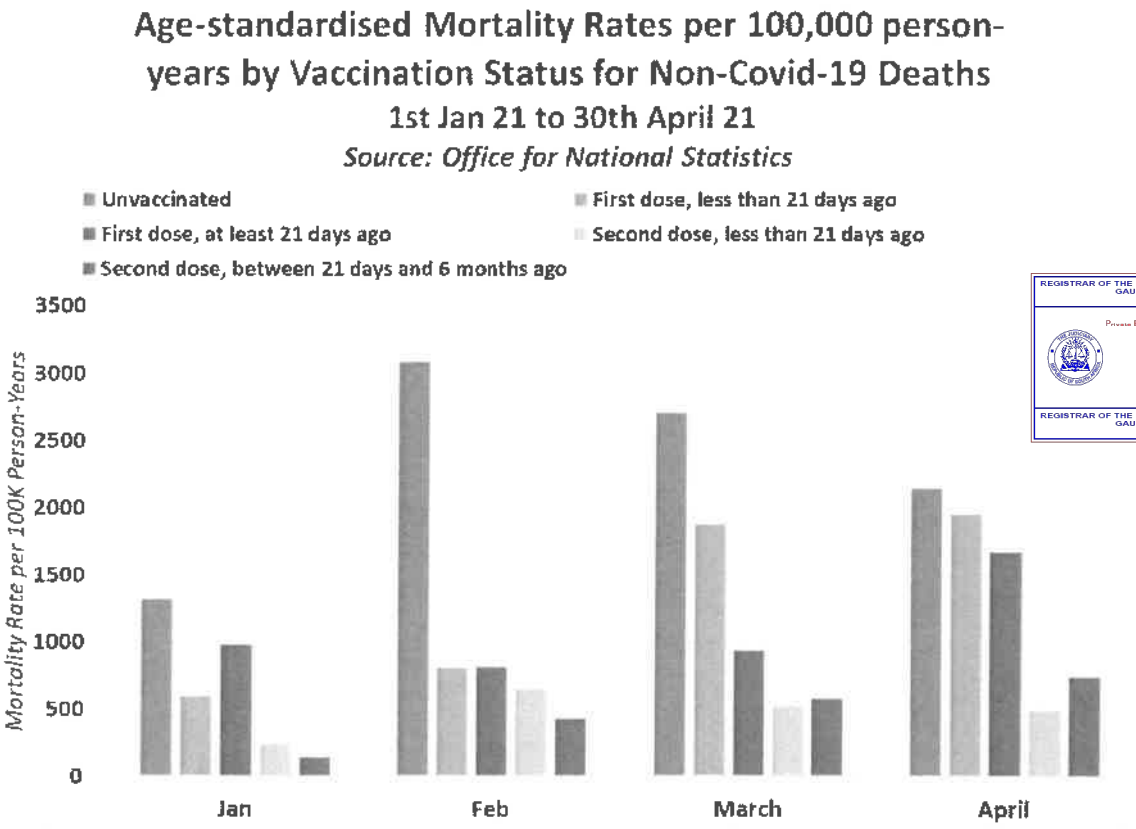
223.1. In May 2022, 82 people died out of the 11 200 000 unvaccinated individuals. That works out to a percentage of 0,00073%. Conversely, 1282 people died out of the 44 800 000 vaccinated individuals.

223.2. That works out to a percentage of 0,0029%. What that means is that, in May 2022, the vaccinated had a 4x greater chance of dying of Covid-19 than did the unvaccinated. That trend tracks through most months of available data. That is a deadly blow to vaccine effectiveness arguments.

224. Further an analysis of official ONS data reveals that, even in non Covid-related deaths, deaths were increasing in the vaccinated to the extent that they surpassed the deaths in the unvaccinated.

225. Approximately five months after each dose of the Covid-19 vaccine was administered, the non Covid-related mortality rates among the vaccinated rose significantly compared to the unvaccinated in each age group. The following charts were created using data extracted from table 1 of the Office for National Statistics dataset on 'Deaths by vaccination status (Jan 2021 to May 2022).

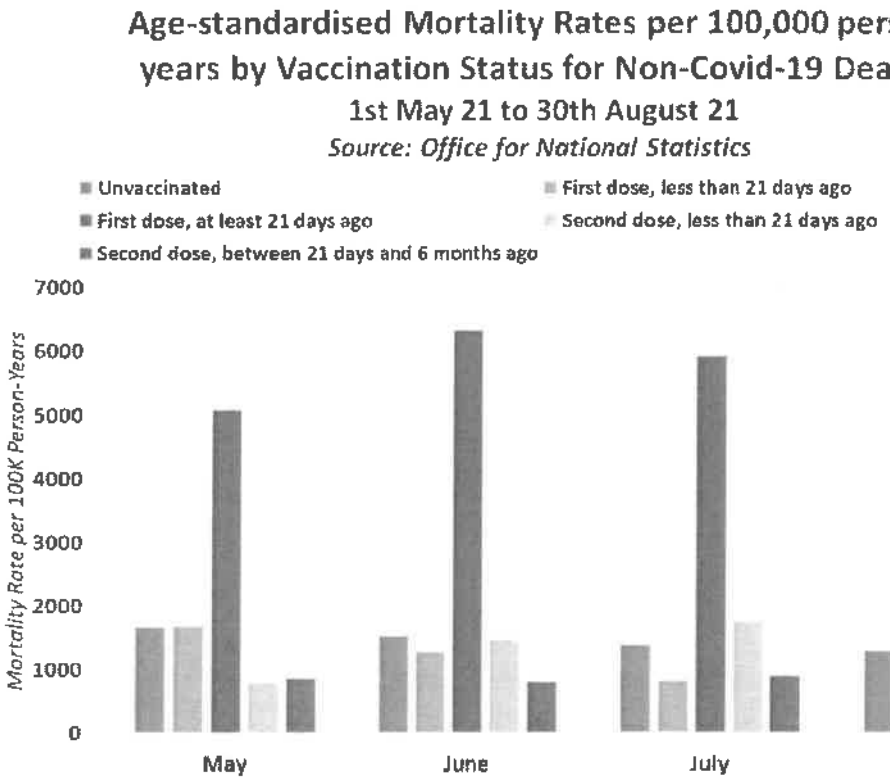
226. The first chart shows the age-standardised non Covid-related mortality rates by vaccination status between 1 January 2021 and 30 April 2021.



227. At face value the above bar chart appears to show that non Covid-related mortality rates were initially highest among the unvaccinated. However, were the brown, red, yellow and purple bars to be stacked on top of one another, to indicate total deaths in vaccinated individuals, the picture changes.

228. By the end of April 2021, five months after the first Covid-19 injection was administered in the UK, things became, and remained, manifestly worse for the vaccinated,.

229. The below chart shows the age-standardised non Covid-related mortality rates for the next four months: 1 May 2021 to 31 August 2021. They reveal that the mortality rate among the vaccinated began to escalate significantly, while revealing a some gradual decrease in mortality rate among the unvaccinated.

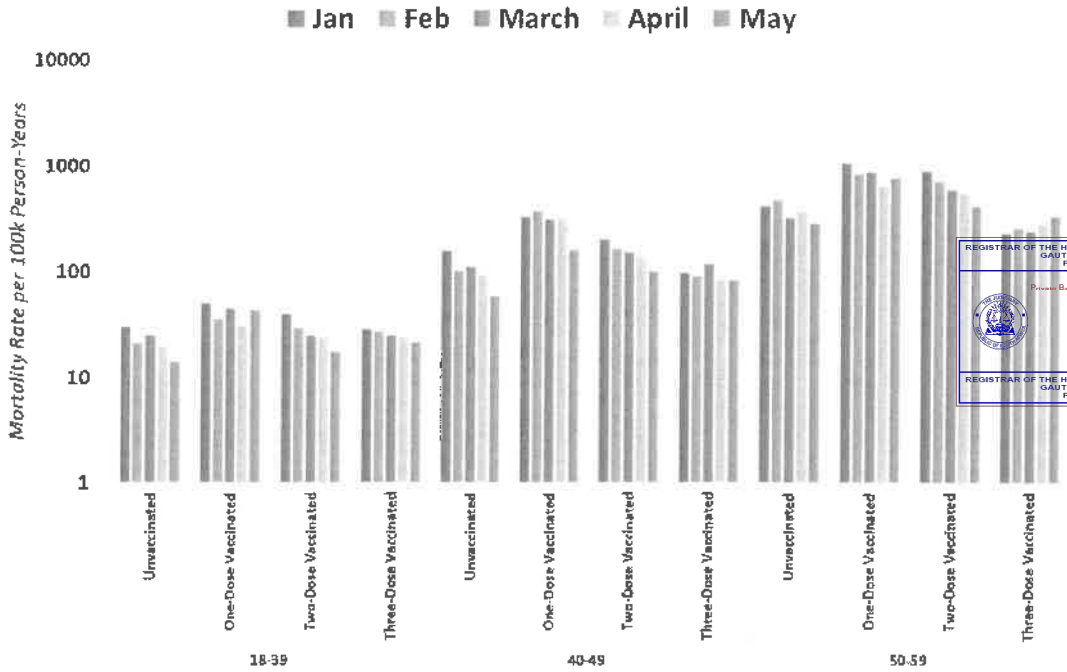


230. Unfortunately, a follow-up report published by the ONS on 6 July 2022, proves that things did not improve for the vaccinated population. By the end of May 2022, mortality rates for Non-Covid-19 deaths were lower among the unvaccinated than among the vaccinated in every age group between 18 and 90+ years in England.

Monthly Age-Standardised Mortality Rates by Vaccination Status by Age Group for Non-Covid-19 Deaths in England

January to May 2022

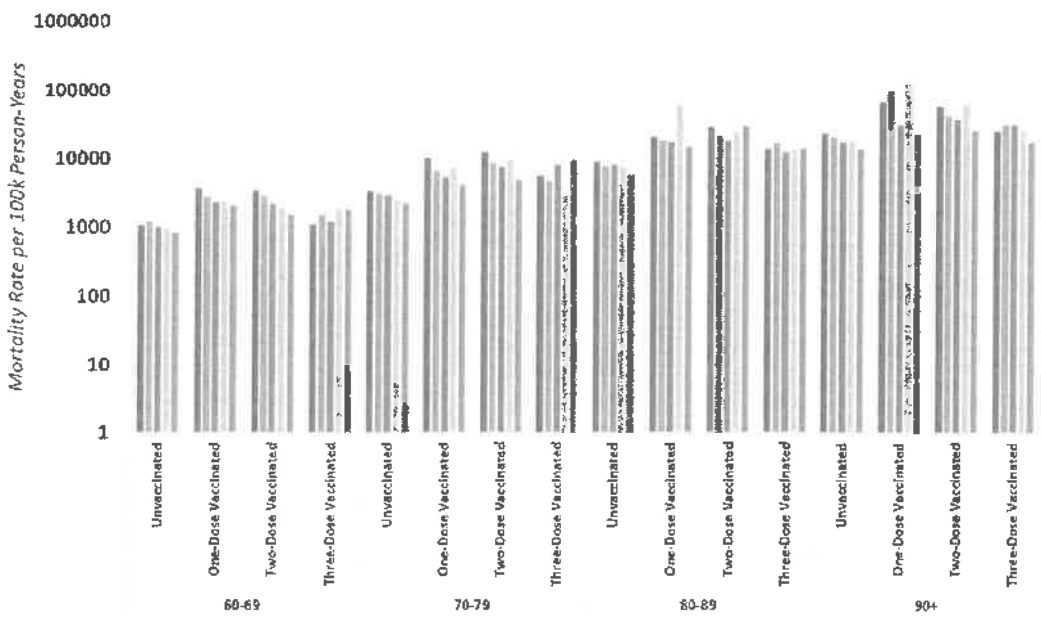
Source: (UK Gov.) Office for National Statistics



Monthly Age-Standardised Mortality Rates by Vaccination Status by Age Group for Non-Covid-19 Deaths in England

January to May 2022

Source: (UK Gov.) Office for National Statistics



231. The above data offers compelling evidence that the Pfizer vaccines are neither effective nor safe .

232. Furthermore, data from a UK Health Security Agency (UKHSA) presentation to the UK Parliament's Joint Committee on Vaccine and Immunization on 25 October 2022 is important.

232.1. The data contains a table titled "*Table 3: NNV (number needed to vaccinate) for prevention of hospitalization [...]*". The table shows the number of people that need to be vaccinated, in different age groups, in order to keep one person out of hospital for Covid-19. The table, reproduced below for ease of reference, shows that:

232.1.1. In age cohorts 5 – 11, 34200 people need to be vaccinated in order to keep one person out of hospital;

232.1.2. In age cohorts 12 – 15, 31400 people need to be vaccinated in order to keep one person out of hospital;

232.1.3. In age cohorts 16 – 19, 11200 people need to be vaccinated in order to keep one person out of hospital;

232.1.4. In age cohorts, 20 -29, 13300 people need to be vaccinated in order to keep one person out of hospital;

232.1.5. In age cohorts 30 – 39, 9900 people need to be vaccinated in order to keep one person out of hospital.

232.1.6. In age cohorts 40 – 49, 10000 people need to be vaccinated in order to keep one person out of hospital.

232.1.7. In age cohorts 50 – 59, 3000 people need to be vaccinated in order to keep one person out of hospital.

232.1.8. In age cohorts 60 – 69, 1200 people need to be vaccinated to keep one person out of hospital.

232.1.9. In age cohorts 70+, 300 people need to be vaccinated to keep one person out of hospital.

Table 3: NNV for prevention of hospitalisation for different programmes

	Programme			
Age	Primary	Booster (2+1)	Autumn 2022 boost	Spring 2023 boost
5 to 11	34200			
12 to 15	31400			
16 to 19	11200	76000	73500	
20 to 29	13300	17600	40900	
30 to 39	9900	15300	35900	
40 to 49	10000	9600	20600	
50 to 59	3000	3000	8000	
60 to 69	1200	1000	3600	
70+	300	500	800	
In a risk group	Primary	Booster (2+1)	Autumn 2022 boost	Spring 2023 boost
20 to 29	2400	3400	7500	7500
30 to 39	1600	3100	7800	7800
40 to 49	2200	2500	6000	6000
50 to 59	800	1200	3100	3100
No risk group	Primary	Booster (2+1)	Autumn 2022 boost	Spring 2023 boost
20 to 29	19900	33900	168200	
30 to 39	21700	53800	210400	
40 to 49	21700	44900	92500	
50 to 59	10900	15800	43600	

233. The same trend, albeit worse, is apparent for the prevention of severe hospitalisation. The relevant graph is reproduced below:

Table 4: NNV for prevention of severe hospitalisation for different programmes

	Programme			
Age	Primary	Booster (2+1)	Autumn 2022 boost	Spring 2023 boost
5 to 11	112200			
12 to 15	162600			
16 to 19	106500	193500	185100	
20 to 29	166200	418100	275200	
30 to 39	87600	188500	217300	
40 to 49	53700	40600	175900	
50 to 59	18700	16200	48300	
60 to 69	5700	9200	27300	
70+	2500	10400	7500	
In a risk group	Primary	Booster (2+1)	Autumn 2022 boost	Spring 2023 boost
20 to 29	11400	43500	59500	
30 to 39	10700	28600	40500	
40 to 49	9400	10600	49800	
50 to 59	5600	6100	18600	
No risk group	Primary	Booster (2+1)	Autumn 2022 boost	Spring 2023 boost
20 to 29	no cases	no cases	706500	
30 to 39	318400	no cases	no cases	
40 to 49	186800	190400	932500	
50 to 59	51600	107000	256400	

234. On the face of it, these numbers are concerning because they are so high, but the real impact, and the risk/benefit ratios, become more apparent when these numbers are compared to the numbers of serious adverse events of special interest (serious AESIs) published in the peer-reviewed journal "Vaccine", and annexed as "**HE37**".

235. The relevant article, which is titled "*Serious adverse events of special interest following mRNA Covid-19 vaccination in randomized trials in adults*", finds that in the Pfizer trial, the excess risk of serious AESIs in vaccinated participants vs placebo participants was 10.1 per 10,000.

236. This means that vaccinating 10,000 individuals resulted in about 10 individuals suffering serious adverse events. Serious adverse events are defined as medical events that result in death, life-threatening conditions, permanent disability or hospitalization. Comparison to the above NNV table, finds that vaccination of 10,000 individuals, to keep one out of hospital with severe Covid-19, occurs at the cost of far higher numbers of serious adverse events (death, life-threatening conditions, permanent disability or hospitalization). I ask rhetorically, is that a vaccine with a favorable safety profile or risk/benefit ratio?

237. Furthermore, the article itself, without comparison to data from any other source, concludes as follows under the heading "harm benefit considerations":

> *"In the Pfizer trial, the excess risk of serious AESIs (10.1 per 10,000) was higher than the risk reduction for COVID-19 hospitalization relative to the placebo group (2.3 per 10,000 participants)."*

238. In lay terms, what that means is that for every 2.3 individuals that are kept out of hospital due to vaccination, that same vaccination gives 10.1 people serious adverse events, which include death, life-threatening conditions, permanent disability and/or hospitalization.

239. There is, however, another reason that the Government's claims of 95%, alternatively 91.3% effectiveness of the Pfizer vaccines was inaccurate and needed to be retracted. That reason is this: not even Pfizer claimed 95% effectiveness in their official data and reports. What they claimed was 95%, alternatively 91.3%, efficacy.

240. "Effectiveness" and "efficacy" are two different scientific terms with two wholly different definitions, and the distinction is important in terms of conveying accurate information to the South African public. What the South African government appears to have done is rely on inaccurate data on the efficacy as effectiveness, which ultimately convinced more people to take the vaccine.

241. I explain the difference between "effectiveness" and "efficacy" immediately below with reference to an article annexed as "**HE38**", titled *"What is the difference between efficacy and effectiveness?"* and published by the Global Alliance for Vaccines and Immunity ("GAVI").

241.1. Efficacy is defined in the GAVI article in the following terms:

> *"Efficacy is the degree to which a vaccine prevents disease, and possibly also transmission, under ideal and controlled circumstances – comparing a vaccinated group with a placebo group."*

241.2. Effectiveness is defined in the GAVI article in the following terms:

> *"Effectiveness meanwhile refers to how well [the vaccine] performs in the real world."*

241.3. The article proceeds to explain that efficacy measured in trials does not always translate into effectiveness. The reality is that efficacy measurements can significantly overestimate a vaccine's impact in practice. This is because, in clinical trials, the trial participants are often healthy without underling health conditions.

241.4. I have already demonstrated that that was exactly the case in the Pfizer trial. When a vaccine is then given to the population, factors, such as the medication people are taking, underlying chronic illnesses, age, and how the vaccine is stored and administered under everyday conditions, can reduce how effective the vaccine is at preventing disease. This is why the difference between "efficacy" and "effectiveness" is so important. If trial-measured "efficacy" is reported as "effectiveness" – as it was by the South African Government – then the population is being led to believe that the vaccine has a high effectiveness when, in reality, the effectiveness was not tested in the trial.

242. In support of the GAVI article, I annex as "**HE39**" another article titled "*A Primer on Effectiveness and Efficacy Trials*". It is an important, comprehensive and well-referenced article and I humbly request this Honourable Court to read in in full.

243. That article draws the same distinctions as the GAVI article between efficacy and effectiveness. The article commences with the following introduction:

> *"Although efficacy and effectiveness studies are both important when evaluating interventions, they serve distinct purposes and have different study designs. Unfortunately, the distinction between these two types of trials is often poorly understood. In this primer, we highlight several differences between these two types of trials including study design, patient populations, intervention design, data analysis, and result reporting."*

244. The article first explains the difference between "efficacy" and "effectiveness" in the context of the study design. It explains that randomized control trials – such as the Pfizer trial are ideally suited for efficacy studies – not effectiveness studies, and that effectiveness studies are designed to examine interventions under circumstances that more closely resemble real-word conditions:

> *"Efficacy studies investigate the benefits and harms of an intervention under highly controlled conditions. Although this has multiple methodologic advantages and creates high internal validity, it requires substantial deviations from clinical practice, including restrictions on the patient sample, control of the provider skill set and limitations on provider actions, and elimination of multimodal treatments. A placebo controlled randomized controlled trial (RCT) design is ideal for efficacy evaluation because it minimizes bias through multiple mechanisms, such as standardization of the intervention and double blinding. RCTs generally eliminate issues of access (intervention is provided free), provider recommendation, and patient acceptance and adherence.*
>
> *Effectiveness studies (also known as pragmatic studies) examine interventions under circumstances that more closely approach real-world practice, with more heterogeneous patient populations, less-standardized treatment protocols, and delivery in routine clinical settings. Effectiveness studies may also use a RCT design; however, the intervention is more often compared with usual care, rather than placebo. Minimal restrictions are placed on the provider actions in modifying dose, the dosing regimen, or co-therapy, allowing tailored therapy for each subject. Although effectiveness studies sacrifice some internal validity, they have higher external validity than efficacy studies."*

245. The article proceeds to explain the difference between "efficacy" and "effectiveness" studies in the trial population. Efficacy trials have high exclusion rates. They often exclude people that are unlikely to respond to the intervention such as people with co-morbidities.

246. Again, I have already demonstrated above that this is exactly what occurred in the Pfizer trial.

247. Effectiveness trials, on the other hand, have high rates in inclusivity, including more individuals with co-morbidities, more elderly individuals, or more patients in vulnerable groupings within the population. This means that effectiveness trials give more reliable data about the real-world performance of any medical intervention – including (as in this case) vaccines.

248. Bearing in mind the difference between "efficacy" and effectiveness", I proceed now to evaluate whether the Pfizer trial was designed to test "efficacy" or "effectiveness" of Comirnaty.

249. My analysis refers to the Pfizer trial protocol already annexed above and concludes that it was a trial designed to test efficacy, and not effectiveness.

250. My conclusions rest on the following extracts from the Pfizer trial protocol:

250.1. First, the title of the protocol indicates that the study tests for "efficacy":

> *"A phase 1/2/3, placebo-controlled, randomized, observer-blind, dose-finding study to evaluate the safety, tolerability, immunogenicity, and efficacy of SARS-CoV-2 RNA vaccine candidates against covid-19 in healthy individuals."*

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250.2. Second, the study rationale on page 9 of the Pfizer protocol states that the study was intended to investigate the safety, immunogenicity, and efficacy of the vaccine candidates.

250.3. Third, under table headed "Objectives, Estimands and Endpoints for phase 1" commencing on page 10 of the Pfizer protocol, the objectives are stated as testing for "efficacy". There are no objectives listed to test for "effectiveness".

250.4. Fourth, under the heading "study design" on page 36 of the Pfizer trial protocol, the overall design is described as testing for, amongst other criteria, efficacy. Again, there is no mention of effectiveness.

250.5. Fifth, under the heading "study population" commencing on page 40 of the Pfizer trial protocol, numerous exclusions spanning three pages are listed. The trial was heavily controlled, and only healthy individuals were enrolled. This accords with the definition for "efficacy studies" in the aforementioned article and does not accord with the definition of an "effectiveness study".

250.6. Sixth, clause 8.1 of the protocol is headed "Efficacy and/or Immunogenicity Assessments", again indicating that the Pfizer study was an efficacy study.

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250.7. Seventh, Pfizer's two-month data report clearly show "vaccine efficacy" of 95%. The relevant portion of the table is reproduced below for convenience (the highlighting is my own), but the full original table appears on page 2613.

Table 3. Vaccine Efficacy Overall and by Subgroup in Participants without Evidence of Infection before 7 Days after Dose 2.

Efficacy End-Point Subgroup	BNT162b2 (N=18,198)		Placebo (N=18,325)		Vaccine Efficacy, % (95% CI)†
	No. of Cases	Surveillance Time (No. at Risk)*	No. of Cases	Surveillance Time (No. at Risk)*	
Overall	8	2.214 (17,411)	162	2.222 (17,511)	95.0 (90.0–97.9)

250.8. It is important to pause here and assess the table above in the context of the representations made by our Government about effectiveness. What the table shows is the following:

250.8.1. 36 523 (18 198 in the vaccine arm + 18 325 in the placebo arm were part of the study) participants were injected in the trial. That is a significant number of trial participants.

250.8.2. But the 95% efficacy statistic was not calculated with reference to all 36 523 trial participants. It was calculated with reference to 170 trial participants. The 95% efficacy is calculated as follows: the number of Covid cases in the vaccine arm (8) was subtracted from the number of Covid cases in the placebo arm (162) equaling 154. 154 was then divided by 162, and multiplied by 100 to reach the 95% efficacy statistic. So, the reality is that our government made the claim of "95% effectiveness" based on "efficacy" data from 170 of the 36 523 trial participants.

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250.8.3. It is not possible from the data to get a proper effectiveness statistic. That is because, as explained above, that would require data from a much broader patient cohort, including patients with underlying health conditions, patients in vulnerable groups, and patients on medication over a much longer duration. But one can get some indication of effectiveness by dividing the number of participants that the vaccine prevented from getting Covid (154) by the number of participants given the vaccine (18 198). That gives a result of 0.84%, which is known as the "absolute risk reduction" (ARR). The authors of this report failed to comply with the requirement of the FDA (see paragraph 63 above) to provide absolute risk reduction, not just relative risk reduction.

250.8.4. That perfectly highlights the problem with relying on efficacy studies and erroneous effectiveness studies. It is simply wrong.

251. The conclusion that can be drawn from the above is a simple one: the Pfizer trial was not intended to, nor did it, test for effectiveness. It tested for efficacy. The Government's claim that the Pfizer vaccine is 95, alternatively 91.3% effective is a not accurate. It is correct to say that the Pfizer vaccine had an efficacy of 95% at 2 months and 91.3% at 6 months. Effectiveness of the vaccine was never tested in the trial. One has found no data released by Pfizer to date capable of lending itself to effectiveness calculations.

252. It is not clear how the Government misinterpreted the objective of the Pfizer trial to this extent. It is crystal clear from a perusal of the trial protocol that the Pfizer trial did not test for effectiveness – but that it only tested for efficacy. How and why, under the circumstances, the thirty-three person-strong team (including the esteemed Glenda Gray, Claudina Loots, Harry Moultrie, Tom Moultrie, Emile Stipp, Debbie Bradshaw, Rob Dorrington, Shabir Madhi, Lucille Blumberg, Cheryl Cohen, Wolfgang Preiser, James McIntyre, Ian Sanne, Moherndran Archary, Dean Gopalan, Angelique Coetzee, Eftyhia Vardas, Francesca Conradie, Francois Venter, Helen Rees, Jacqui Miot, Lynn Morris, Silingene Ngcobo, Nombulelo Magula, Prakash Jeena, Lufuno Mathivha, Shabir Banoo, Shaheen Mehtar, Simon Nemutandani, Sitembiso Velaphi and Wendy Stevens) advised government that is was appropriate to tell the public that a vaccine that had <u>not</u> been tested for effectiveness was, in fact, 95%, alternatively 91.3% effective is unclear. The is astonishing.

253. We call on the government respondents in this application to account for the apparent errors.

254. The Government ought to retract the statement the Pfizer vaccines are 95%, alternatively 91.3% effective, and instead explain to the public that the vaccines were only tested for efficacy. To the extent that they do not retract this statement every official who made the statement about "effectiveness" is likely guilty of an offence under the MARS Act.

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255. There is another document in which BioNTech admits that both the safety and efficacy of Comirnaty is, at the very least, still in question. That appears from their official filing to the United States of America's Securities Exchange Commission ("**SEC**") dated 24 April 2022, and annexed as "**HE40**". In that filing, the following is stated:

> *"We may not be able to demonstrate sufficient efficacy or safety of our COVID-19 vaccine and/or variant-specific formulations to obtain permanent regulatory approval in the United States, the United Kingdom, the European Union, or other countries where it has been authorized for emergency use or granted conditional marketing approval.*
>
> *Our COVID-19 vaccine has been granted full U.S. FDA approval for individuals 16 years and older, emergency or limited use authorization in a number of countries and approval for use in certain other countries. Our COVID-19 vaccine has not yet been approved by regulatory authorities in many of such countries. We and Pfizer intend to continue to observe our COVID-19 vaccine and other variants of a COVID-19 vaccine candidate in global clinical trials. It is possible that subsequent data from these clinical trials may not be as favorable as data we submitted to regulatory authorities to support our applications for emergency use authorization, marketing or conditional marketing approval or that concerns with the safety of our COVID-19 vaccine will arise from the widespread use of our COVID-19 vaccine outside of clinical trials. Our COVID-19 vaccine may not receive approval outside of the emergency use setting in the countries where it is not currently approved, which could adversely affect our business prospects.*

256. The above is an outright admission by BioNTech that the global monitoring of the vaccine may disprove both the safety and efficacy profiles previously presented by Pfizer.

257. In circumstances where BioNTech itself admits that there is insufficient data to adequately assess the safety and efficacy of the vaccine as it is rolled out to the public, and that global data collection may change the safety and efficacy

profiles, then on what basis has the South African government assured the public that Comirnaty is "safe and effective"?

REPORTS FROM LOCAL DOCTORS SEEING ADVERSE EFFECTS OF THE PFIZER VACCINE PROCDUCTS

258. Across the country, doctors are seeing and reporting adverse events (the same as, or similar to those highlighted by Dr Jessica Rose in her VAERS statistical analysis).

259. These adverse events, as catalogued below, have manifested in otherwise healthy patients with strong temporal associations between the dates on which they received their vaccines, and the dates on which their symptoms began to manifest.

260. In medical terms, a "*temporal association*" refers to a relationship between two events or conditions that occur in a specific order in time. For example, a temporal association between a headache and an onset of nausea could indicate a certain type of headache or a certain cause of the headache.

261. A temporal association is used as a diagnostic tool, as well as a means of understanding the progression of a disease or condition. It is a way to detect patterns and link causes and effects in medical conditions.

262. I have included details from two such doctors for the benefit of the court: Dr Anton Janse Van Rensburg and Dr Maré Olivier.

263. The majority of the vaccine injuries detailed below are listed in the post-authorisation adverse event report, already annexed above commissioned by Pfizer as actual reported adverse events, and/or as "*adverse events of special interest*" (AESIs) potentially related to Pfizer's "COMIRNATY" vaccine.

264. These conditions include – but are not limited to - motor-neurone disease, heart attacks, blood clotting disorders, and neuropathy.

265. The fact that these AESIs coincide with post-vaccination events now presenting in South African patients such as those catalogued below, does not of itself establish causation – but does establish correlation. This correlation, together with consistency, specificity, temporality, plausibility and analogy (Bradford Hill criteria for causation), strongly suggests causation, or proves causation on the balance of probability, between administration of Pfizer's "COMIRNATY" vaccine and the relevant conditions. These were factors that were considered in reaching the diagnoses referred to below.

Dr Maré Olivier

266. Dr Maré Olivier, whose supporting affidavit is annexed as "**HE41**" has provided examples of six vaccine injured patients. Her supporting affidavit contains the rationale for her diagnoses and the Court may refer to that affidavit to the extent that it requires supplementation of the below summary. I now summarize those patients below:

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266.1. The first patient was a previously healthy, fit 57-year-old. Prior to his death, he had been Dr Oliver's patient for the past fifteen years, and she can attest to the fact of his health (prior to the Covid-19 vaccine) as well as his clean family medical history. It was a difficult journey watching this patient's deterioration after his Pfizer vaccine on 7 September 2021 to his ultimate and untimely death on 24 January 2023. This patient suffered enormous pain, physical degeneration, and a loss of dignity as he slowly died. This notwithstanding, he photographically documented his journey and gave me permission to share those photographs in legal proceedings (even after his death) if ever asked to do so.

266.2. This patient's first and only Pfizer injection was on 7 July 2021. He began presenting with symptoms a mere four days later. By 11 July 2021, he was presenting with pain in his right eye and temporal area. He saw a neurologist in November 2021, and she requested an MRI, the results of which came back as "normal". She made the diagnosis of Bell's Palsy (unilateral facial paralysis/paresis) and trigeminal neuralgia. She prescribed pain medication to manage the trigeminal neuralgia.

266.3. I pause here to note that facial paralysis/paresis and trigeminal neuralgia are listed as adverse events of special interest in the Pfizer post-authorization report, and were reported as actual adverse events of vaccination within the initial 2½ month data collection period.

266.4. Dr Olivier saw the patient for the first time after his MRI, in February 2022. By this stage he told her that the pain tablets were not working

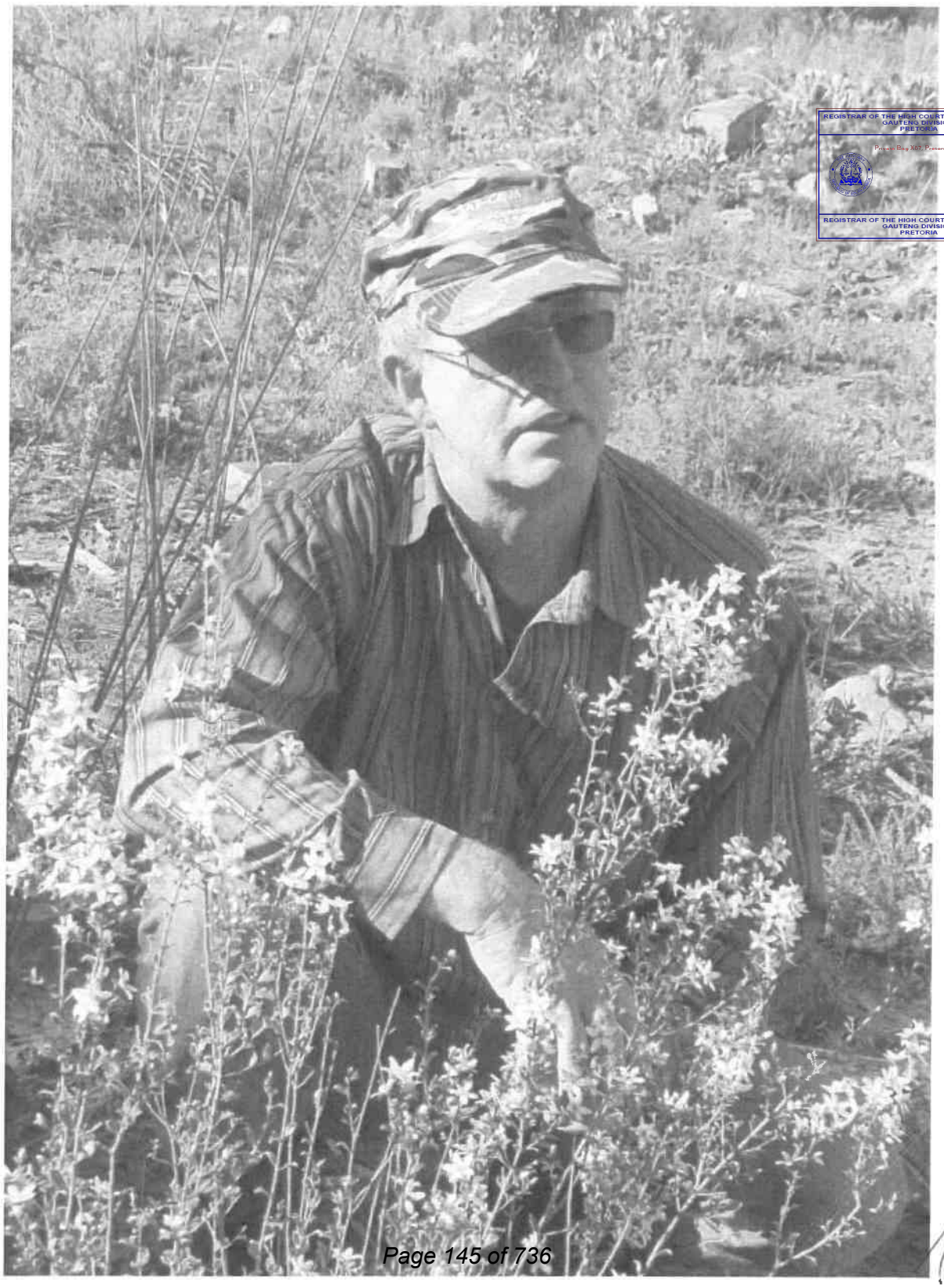
adequately, and that his symptoms were worsening. At that point, he had spent in excess of ZAR 160 000 trying to find out what was wrong with him, and to procure effective treatment – but had failed.

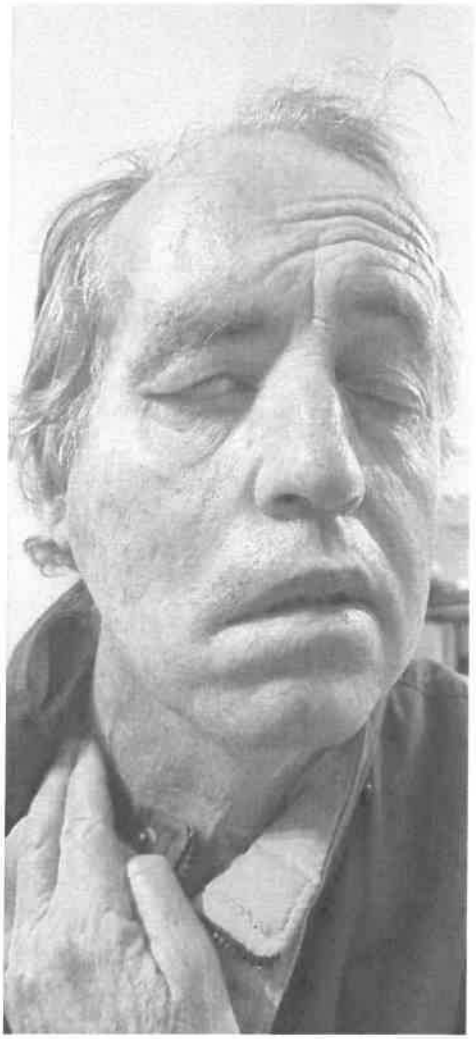
266.5. Dr Olivier saw him again in the beginning of August 2022. By this time, he had severe wasting, and he presented with a palpable hard mass in his right external ear canal. The hard mass obstructed his entire ear canal which, in turn, prevented a physical examination. Dr Olivier sent the patient for a CT scan which showed a mass in his parotid gland, spreading to different cranial nerves and facial muscles responsible for chewing. He then underwent a biopsy at Tygerberg hospital, and he was diagnosed with basaloid carcinoma of the parotid gland. Basaloid carcinoma is a type of cancer that affects the parotid gland, which is one of the major salivary glands located in the cheek near the jaw. It is a rare form of cancer that is often aggressive and may spread to other parts of the body.

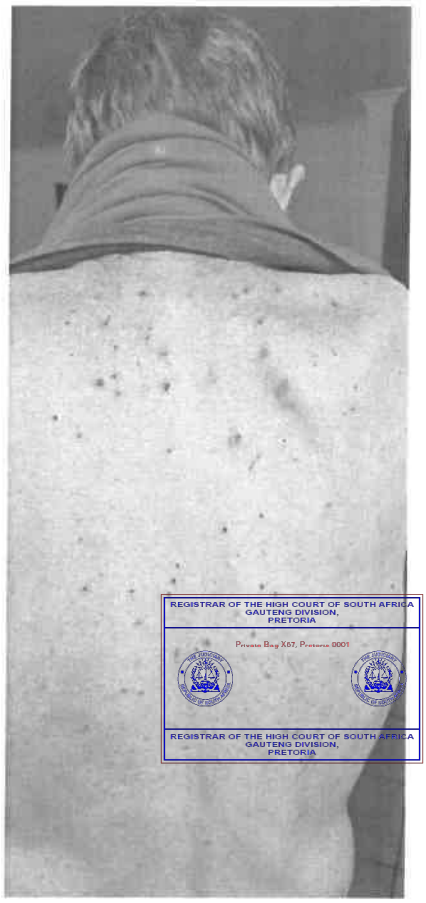
266.6. He died from this cancer on 24 January 2023.

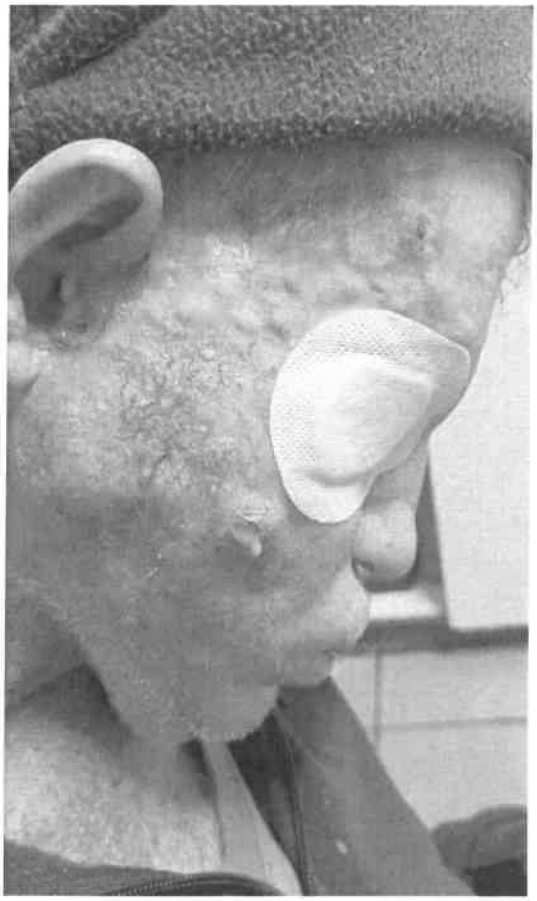
266.7. The sudden and unexplained onset of this patient's condition, together with its rapid progression, and the close temporal association to the vaccine led Dr Olivier to conclude that this patient was probably injured by the Pfizer vaccine. The facts that facial paralysis/paresis and trigeminal neuralgia are listed in the Pfizer 2½ month post-authorization adverse events report (see above), as well as the fact that longer term

VAERS data show a huge increase in cancer cases related to the Pfizer/BioNTech vaccine (see paragraph 42.6 above), were further factors that she considered in reaching her conclusion. Photographs of this patient until the month of his death appear immediately below.









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266.8. A second otherwise healthy patient had two doses of the Pfizer vaccine. Two weeks after her second vaccine, she presented with a thrombosis (formation of a blood clot inside a blood vessel, which obstructs and may cut off the flow of blood in the vessel) on the left forearm with increased D-dimers.

266.9. It is important to understand what raised D-dimer levels mean. A D-dimer is a blood test that measures the level of a protein fragment that is produced when a blood clot breaks down. Elevated levels of D-dimers may indicate the presence of a clot or an increased tendency for clotting, which can be due to a variety of underlying medical conditions, such as deep vein thrombosis, pulmonary embolism, or stroke.

266.10. By 17 September 2021, she had developed acute pulmonary tuberculosis ("**TB**"). At this juncture, her wasting was severe. She was admitted to hospital, where she subsequently died on 1 January 2022. For similar reasons to those set out above, Dr Olivier diagnosed this patient as probably having been injured by the Pfizer vaccine.

266.11. A third otherwise healthy patient received two doses of the Pfizer vaccine. A year later (in July 2022), she was diagnosed with aggressive colon cancer (despite her previous health and no family history of this disease). The cancer spread rapidly, killing her on 5 August 2022. For similar reasons to those set out above, Dr Olivier diagnosed this patient as probably having been injured by the Pfizer vaccine.

266.12. A fourth otherwise healthy patient received two doses of the Pfizer vaccine. On 30 November 2021, just after her second dose of the Pfizer vaccine, she had a mammogram which returned normal results.

266.13. However, by March 2022 (a mere 4 months later), she had presented with a lump in her breast and had another mammogram which subsequently confirmed the presence of a carcinoma. On 11 April 2022, a biopsy confirmed the presence of breast cancer.

266.14. The patient is currently receiving chemotherapy. For similar reasons to those set out above, Dr Olivier diagnosed this patient as probably having been injured by the Pfizer vaccine.

266.15. A fifth otherwise healthy patient received two doses of the Pfizer vaccine. One month after her second Pfizer vaccine, the patient consulted with Dr Olivier at her practice. She presented with a change in her stools and blood when defecating. She screened her for cancer. Both her CEA (carcinoembryonic antigen) and D-Dimer counts were found to be elevated. Because of this, Dr Olivier referred her for a colonoscopy, which subsequently confirmed colon cancer. While she was in hospital for treatment of the cancer, the patient also suffered a heart attack. This patient had no family history of colon cancer, and there were no medical markers present for the development of this disease. The patient is stable at present, and on treatment for her cancer. For similar reasons to those set out above, Dr Olivier diagnosed this patient as probably having been injured by the Pfizer vaccine.

266.16. A sixth otherwise healthy patient was a 15-year-old adolescent. He received one dose of the Pfizer vaccine. Within three months, he was presenting with severe abdominal pains. Within nine months after his Pfizer injection, he was diagnosed with macroscopic haemorrhagic cystitis (visible presence of red blood cells in the urine).

266.17. Haemorrhagic cystitis is a condition in which the bladder becomes inflamed and experiences bleeding. The important factor here was that the test she conducted showed a negative culture for infectious organisms.

266.18. Haemorrhagic cystitis with a negative culture refers to a situation where there is visible blood in the urine, but no bacterial or fungal growth is present in a urine culture. This suggests that the cause of the bladder inflammation and bleeding is not due to an infection, but rather due to other factors such as chemotherapy, radiation therapy, or an underlying medical condition or inflammation. The problem was, of course, that this young child had no such underlying causes that could have resulted in his condition.

266.19. Over and above this, haemorrhagic cystitis is uncommon in healthy men – and particularly uncommon in healthy adolescents. For similar reasons to those set out above, Dr Olivier diagnosed this patient as probably having been injured by the Pfizer vaccine.

Dr Anton Janse Van Rensburg

267. Dr Anton Janse Van Rensburg, whose supporting affidavit is annexed as "**HE42**" has provided examples of six vaccine injured patients. His supporting affidavit contains the rationale for his diagnoses and the Court may refer to that affidavit to extent that it requires supplementation of the below summary.

268. I summarize five of those patients below. In the clinical scientific process of reaching his diagnoses, Dr Janse Van Rensburg had regard to the Pfizer 2½ month post-authorization adverse events report (see above), as well as to the longer term VAERS data (see above) and the Bradford Hill criteria (see above). In brief:

268.1. One otherwise healthy patient received two doses of the Pfizer vaccine. Within 20 days of the administration of the second Pfizer vaccine, the patient was experiencing stiffness in his hands.

268.2. By December 2021, the patient started losing sensation in his left leg. This was followed by a progressive loss of motor function in both legs, and he was ultimately diagnosed in March 2022 with motor neurone disease by a neurologist. He was referred to Dr Janse Van Rensburg for palliative care and management of his condition. It is a medical certainty that this condition will eventually kill the patient, following a long period of muscular degeneration and horrendous suffering. Dr Janse Van

Rensburg diagnosed this patient as probably having been injured by the Pfizer vaccine.

268.3. A further otherwise healthy patient received one dose of the Pfizer vaccine. Within three days of having received the vaccine, the patient presented with vertigo, severe ear pain, diarrhoea, and vomiting. Her symptoms persisted, untreated by doctors who refused to consider vaccine injury, until she saw Dr Janse van Rensburg in October 2022.

268.4. In April 2022 she developed severe tinnitus due to suspected vestibulocochlear neuropathy. Dr Janse Van Rensburg diagnosed the patient as probably having been injured by the Pfizer vaccine.

268.5. A third otherwise healthy patient had received two doses of the Pfizer vaccine. Within two weeks of receiving the second dose of the Pfizer vaccine, the patient presented with signs of olfactory and trigeminal neuropathy.

268.6. In lay terms, he presented with severe nervous problems related to smell and facial sensory perception. His symptoms include severe fragrance hypersensitivity, unbearable facial pain (described by those who suffer from it as suicidally painful), burning skin and a skin rash. Dr Janse Van Rensburg diagnosed this patient as probably having been injured by the Pfizer vaccine.

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268.7. A fourth patient received one dose of the Pfizer vaccine. Within five days of having received the Pfizer vaccine, the patient developed obstructive jaundice.

268.8. Obstructive jaundice is a specific type of jaundice, where symptoms develop due to a narrowed or blocked bile duct or pancreatic duct, preventing the normal drainage of bile from the bloodstream into the intestines. It may be severe or even fatal. He also developed hyper-coagulability, which is a high clotting risk, with clot formation, and reported developing abscesses in multiple sites of his body. His pre-existing Parkinson's symptoms also worsened. Dr Janse Van Rensburg diagnosed this patient as probably having been injured by the vaccine.

268.9. A fifth otherwise healthy patient received two doses of the Pfizer vaccine. Within 24 hours after the first dose of the vaccine, the patient had an acute anaphylactic reaction, which is a severe, deadly allergic reaction. She was given injectable and oral cortisone by a general practitioner to manage the attack. Had it not been for that intervention, the patient would likely have died. Dr Janse Van Rensburg diagnosed this patient as probably having been injured by the vaccine.

A SUMMARY OF THE GROUNDS OF REVIEW

269. It is against the facts set out above, that I summarise the provisions of law relied upon by the applicant for purposes of this application. These are:

269.1. Section 6(2)(a) of PAJA;

269.2. Section 6(2)(b) of PAJA;

269.3. Section 6(2)(c) of PAJA;

269.4. Section 6(2)(d) of PAJA;

269.5. Section 6(2)(e)(i) of PAJA;

269.6. Section 6(2)(e)(ii) of PAJA;

269.7. Section 6(2)(e)(iii) of PAJA;

269.8. Section 6(2)(e)(vi) of PAJA;

269.9. Section 6(2)(f) of PAJA;

269.10. Section 6(2)(h) of PAJA;

269.11. Section 6(2)(i) of PAJA.

270. In the alternative to the above provisions of law, the applicant also relies on the principle of legality as a basis for the review. As demonstrated in this affidavit, the impugned decisions are clearly irrational.

271. The rights implicated in this case include the rights protected in the following constitutional provisions:

271.1. section 10 of the Constitution;

271.2. section 11 of the Constitution;

271.3. section 12 of the Constitution; and

271.4. section 33.

272. As is evident from what I have stated in this affidavit, the rights infringed by the impugned decisions are not only those of the applicant and its members, but those of the broader public as well.

CONCLUSION

REGISTRAR OF THE HIGH COURT OF SOUTH AFRICA
GAUTENG DIVISION,
PRETORIA
Private Bag X67, Pretoria 0001
REGISTRAR OF THE HIGH COURT OF SOUTH AFRICA
GAUTENG DIVISION,
PRETORIA

273. The applicant humbly requests the Court to grant the relief sought in the notice of motion in the interests of the health of the South African public.

WHEREFORE on behalf of the applicant, I pray for an order in terms of the notice of application to which this affidavit is attached.

HERMAN JACOBUS EDELING

The deponent has acknowledged that he knows and understands the contents of this affidavit, which was signed and sworn before me at PRETORIA on this the 22 day of MARCH 2023, the regulations contained in Government Notice No. R1258 of 21 July 1972, as amended, and Government Notice No. R1648 of 19 August 1977, as amended, having been complied with.

COMMISSIONER OF OATHS

Name:

Address:

Position:

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