Memorandum of Advice

Pfizer & Moderna Covid-19 products are GMOs under UK Law

- Failures to Inform -

Failure of UK Authorities to Inform Citizens

Failure of UK Authorities to Require GMO Disclosure in Product Information

Informed Consent given by All UK Citizens who received the Pfizer/Moderna Covid-19 products Nullified

1. In the United Kingdom ***Genetically Modified Organisms*** are dealt with under the ***Environmental Protection Act*** 1990 and specifically at Part VI.

2. The meaning/definitions for what substances or materials constitute '***genetically modified organisms***' (GMOs) under the Act are contained under Section 106.

3. The GMO definitions under section 106 apply and capture the Covid-19 products of AstraZeneca, Pfizer, and Moderna.

4. For the purposes of this advice we shall concentrate on the LNP-modRNA complexes of Pfizer and Moderna.

GMO Definitions as they apply to Pfizer & Moderna

5. Turning to section 106 and the relevant parts of the definition are found under the following sub-sections:

(2) In this Part the term "organism" means any acellular, unicellular or multicellular entity (in any form) .. the term also includes any article or substance consisting of or including biological matter.

6. The LNP-modRNA complexes satisfy being an entity of ***any*** form, that are acellular.

(3) .. "biological matter" means anything .. which consists of or includes —

(b) genes or other genetic material, in any form, which are so capable [of transferring genetic material: see ss3(a)]

7. The LNP-modRNA complexes contain genetic material (modRNA) where the LNP part of the complexes ***transfers the genetic material*** (modRNA) throughout the human body (bio-distribution) and ***transfers the genetic material*** across/through the cell membrane (transfection) of all cell types in the human body.

(4) For the purposes of this Part an organism is "genetically modified" if any of the genes or other genetic material in the organism—

(a) have been artificially modified, or

(b) are inherited or otherwise derived, through any number of replications, from genes or other genetic material (from any source) which were so modified.

8. Both Pfizer and Moderna have made repeated public statements their Covid-19 products contain *genetically modified* ingredients created from artificially modified nucleosides. For example, filings with the US Securities and Exchange Commission (SEC) include:

Pfizer: 'Our COVID-19 vaccine (BNT162b2) is a nucleoside-modified mRNA formulated in lipid nanoparticles'; and

Moderna: '.. our platform employs chemically-modified uridine nucleotides'

9. Similarly, the Australian Therapeutic Goods Administration (TGA) documents granting provisional approval to the Pfizer and Moderna products specifically recognise that the products contain ***modified* nucleosides**:

> Pfizer AusPAR at page 9:
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> > 'The Pfizer-BioNTech COVID-19 vaccine, BNT162b2 mRNA (tradename Comirnaty), comprises a **nucleoside-modified** messenger RNA (modRNA) encoding the viral spike glycoprotein (S) of SARS-CoV-2. The RNA is encapsulated in lipid nanoparticles (LNPs), which enables entry into host cells'
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> Moderna AusPAR at page 16:
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> > 'The Spikevax COVID-19 mRNA-1273 vaccine contains a **nucleoside-modified** mRNA encoding the viral S protein of SARS-CoV-2 formulated in lipid particles. It forms an mRNA-lipid complex (lipid nanoparticle, LNP)'

(4A) Genes or other genetic material in an organism are "artificially modified" for the purposes of subsection (4) above if they are altered otherwise than by a process which occurs naturally in mating or natural recombination.

10. The modRNA in the Pfizer and Moderna products can only be produced by intensive manufacturing processes involving recombinant technologies, for producing wholly synthetic and artificial nucleoside-modified versions of the messenger RNA component of the SARS-CoV-2 virus. The modRNA *does not and cannot* occur from mating or natural recombination.

11. Further, and in respect of (4)(b) *above*, the modRNA is created from wholly artificial and non-naturally occurring synthetic DNA, which synthetic DNA is created in laboratories using recombinant technologies. Called ***plasmid DNA***, during the

manufacturing process this plasmid DNA is inserted into bacterial E.coli where it self-replicates (replication competent) to produces enormous quantities of the plasmid DNA, which plasmid DNA is later filtered out for being used as templates for the transcription and creation of the modRNA; more details below.

(4B) For the purposes of subsection (4) above—

(a) genes or other genetic material shall be taken to be artificially modified if they are altered using such techniques as may be prescribed for the purposes of this paragraph

(4D) In subsections (4B) and (4C) above "prescribed" means prescribed by regulations made by the Secretary of State

12. For the purposes of subsections 4B and 4D we must turn to the ***Genetically Modified Organisms (Deliberate Release) Regulations*** 2002, and specifically regulation 5:

Techniques of genetic modification

5.—(1) Until the coming into force of the first regulations under section 106(4B)(a) F1 of the Act, genes or other genetic material shall be taken, for the purposes of subsection (4) of that section, to be artificially modified if they are altered using any of the following techniques:

(a) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation.

13. The Pfizer and Moderna products fulfill regulation 5.

14. Both Pfizer and Moderna use recombinant nucleic acid techniques to create wholly synthetic bacterial plasmid DNA (circular DNA molecules) which are then inserted into E.coli (bacteria), where the E.coli is used as a host organism within which the plasmid DNA is capable of continued self-propagation/self-replication, meaning, it is ***replication competent***.

15. The E.coli also replicates (divides and produces another E.coli, which two E.coli in turn replicate, and so on ..) approximately every 20 minutes, enabling the plasmid DNA to further replicate/propagate in new E.coli hosts every 20 minutes. Eventually the vats containing the E.coli reach capacity where minimal to no further E.coli/plasmid DNA replication is possible (saturation).

16. Then, using nucleic acid techniques, various chemicals are added to destroy the E.coli so that they release the plasmid DNA they contain. The E.coli fragments are filtered away. The artificial plasmid DNA is then isolated. Then, using recombinant nucleic acid techniques, various chemicals and nucleic acids are added to the plasmid DNA for the creation (transcription) of the nucleoside-modified RNA (modRNA) using the plasmid DNA as a template. Once the maximum number of copies of the modRNA are created from the plasmid DNA, (the manufacturing vats reach capacities), various chemicals are added (DNase) to break-up and fragment (truncate) the plasmid DNA. The fragmented DNA is now called *linearised* DNA. The linearised (truncated) DNA is then filtered out and away from the modRNA. The isolated and remaining modRNA concentrate solution is then sent to be added to the LNPs to create the LNP-modRNA complexes.

17. To this point both the Pfizer and Moderna Covid-19 products fulfill the section 106 meaning for being properly deemed and described as containing '***genetically modified organisms****',* or GMOs, as the main ingredient.

GMO Damage to Humans

18. The following sub-sections of section 107 of the Act deal with the meaning of '***damage to the environment***' as a consequence of genetically modified organisms that have been ***released*** or escaped from a person's control, where 'a person' here also refers to a company.

> **(2) The "environment" includes land, air and water and living organisms supported by any of those media.**

19. Sub-section (2) is sufficiently broad to deem human beings under the term 'environment', including their internal bodily environment. This is confirmed by sub-section (4) which reads in part: '(4) ***An organism shall be regarded as present in the environment notwithstanding that it is present in or on any human***'.

> **(3) "Damage to the environment" is caused by the presence in the environment of genetically modified organisms which have (or of a single such organism which has) escaped or been released from a person's control and are (or is) capable of causing harm to the living organisms supported by the environment**.

20. Sub-section (3) is of critical importance as it deems an '***environment***' to be '***damaged***' when GMOs have been released into an environment and the GMOs are '***capable of causing harm***'.

21. **Note specifically**: the GMO only has to be ***capable*** of harming an environment to be regarded as ***having caused actual damage to the environment*** where again, 'environment' includes the human body.

> **(6) "Harm" means adverse effects as regards the health of humans**

22. In the context of the Pfizer and Moderna products, sub-section (6) is unbound and means ***any*** adverse effect arising from the genetically modified cargo contained in their products, including adverse effects their GMOs are ***capable of causing***, that is,

that their GMOs ***could possibly cause***. If there is a ***real possibility*** that adverse effects are ***capable of being caused***, then that possibility is ***deemed to be actual damage to the environment***. As the LNP-modRNA complexes are specifically designed to deliver (transfect) the cargo of modRNA into all types of human cells, once entry has been gained into cells (transfection), any adverse effects produced, ***or capable of being produced*** as a consequence of the presence of the modRNA, is deemed 'harm' to the individual.

23. The ***presumption of actual harm*** due to a GMO being ***capable of causing harm***, acknowledges the far reaching and difficult to predict adverse effects consequent upon GMOs entering an environment, particularly a human body, particularly as GMO adverse effects can also manifest in later generations (offspring). Where GMOs enter human bodies without the consent of persons affected, ***the legislation correctly assumes such persons to be harmed*** where the impugned GMOs are ***capable*** of adverse effects, thereby ***placing the onus on the person/company responsible*** for the GMOs being so released into human bodies, to show the GMOs are incapable of causing any actual harm. This is a high and proper evidentiary burden and speaks to a deterrent effect in the legislation.

24. At this point mention must be made that adverse effects from the Pfizer product and otherwise observed from the use of the LNP-modRNA ***technology platform*** (used in both of the Pfizer and Moderna products) have already been observed. Additionally, material submitted by Pfizer to the Australian TGA evidences the Spike protein induced by their product ***entering the cell nucleus***, despite medicines regulators saying this cannot happen, being statements by regulators lacking any scientific basis or proof – indeed they are baseless assertions, not scientific statements of fact. Moreover, there is the over 40 years of science of Retroposition showing mRNAs as always in biology ***revers-transcribing with genomic DNA***. Reverse-transcription typically involves a prior step involving entry into the nucleus of the cell by mRNA. The Pfizer modRNA has already been shown to reverse-transcribe with human DNA: Alden et al 2022. That research observed the Pfizer modRNA ***entering the nucleus of human cells***. All of the effects described here are not therapeutic and can only be

described as adverse effects portending of an as yet unknown range of genetic disorders and disease, inclusive of cancers, with many such disorders inconsistent with life. Reverse-transcription of modRNA also involves the very real risk of genomic integration with natural chromosomal DNA, with obvious consequences for offspring, which has already been observed with the LNP-modRNA complexes: Qin et al 2022. Genomic integration with chromosomal DNA also poses very real risks of interruption to normal DNA processes, (up or down regulation or silencing of normal gene functioning), which dysregulation is often a precursor to genetic disease disorders, inclusive of cancers and tumours. Further details on the critical findings and issues referred to in this paragraph are contained in the accompanying ***Brief of Information & Evidence*** we are working with Australian Senators to present to the Australian Federal Police Commissioner, and Australia's Commonwealth Attorney-General in coming days, (provided here *in confidence* until a media embargo is lifted), within which Brief are found further annexures that explain the scientific details as prepared by a Doctor of Molecular and Cellular Biology, and a peer reviewed and published investigation authored by this writer.

25. Returning now to the legislation.

Risk Assessment & Consent Requirements

26. The Act contemplates products being made available to the public that contain GMOs as seen at sub-section (11) of section 107:

> **(11) Genetically modified organisms of any description are "marketed" when products consisting of or including such organisms are placed on the market by being made available to other persons, whether or not for consideration.**

27. *Normally*, products to be marketed in the UK that contain GMOs require first an extensive environmental risk assessment be undertaken and fully documented, which materials are submitted for the purpose of obtaining *a consent* after extensive

review by the Secretary of State for Environment, Food and Rural Affairs, as seen under the sub-sections to sections 108 and 111 respectively (emphasis added):

Risk assessment and notification requirements.

108(1) Subject to subsections (2) and (7) below, **no person shall import or acquire, release or market any genetically modified organisms** unless, before doing that act—

(a) **he has carried out an assessment of any risks there are** (by reference to the nature of the organisms and the manner in which he intends to keep them after their importation or acquisition or, as the case may be, to release or market them) **of damage to the environment being caused as a result of doing that act**; and
(b) in such cases and circumstances as may be prescribed, **he has given the Secretary of State such notice of his intention of doing that act and such information as may be prescribed**.

Consents required by certain persons.

111(1) Subject to subsection (7) below, **no person shall import or acquire, release or market any genetically modified organisms** —

(a) in such cases or circumstances as may be prescribed in relation to that act,

except in pursuance of a consent granted by the Secretary of State and in accordance with any limitations and conditions to which the consent is subject.

28. *However*, both sections 108 and 111 contain similar ***exemption*** provisions in respect of the requirements to carry out a GMO risk assessment and to obtain a consent prior to seeking marketing approval, as follows:

> **108(7) Regulations under this section may provide for exemptions, or for the granting by the Secretary of State, or by the Secretary of State and the Food Standards Agency acting jointly, of exemptions to particular persons or classes of person, from the requirements of subsection (1) or (3) above in such cases or circumstances, and to such extent, as may be prescribed.**
>
> **111(7) Regulations under this section may provide for exemptions, or for the granting by the Secretary of State, or by the Secretary of State and the Food Standards Agency acting jointly, of exemptions to particular persons or classes of person, from—**
>
> > **(a) any requirement under subsection (1) or (2) above to have a consent, or**
> >
> > **(b) any of the requirements to be fulfilled under the regulations by an applicant for a consent,**
>
> **in such cases or circumstances as may be prescribed.**

29. Under the regulations referred to in sub-sections 108(7) and 111(7) we see regulation 15 sets forth the relevant exemptions:

> **Exempt activities**
>
> **15(1) The cases and circumstances prescribed for the purposes of sections 108(7) and 111(7) of the Act in which persons are exempt from the requirements of section 108(1)(a) of the Act (to carry out a risk assessment) and of section 111(1)(a) of the Act (to obtain consent), respectively, insofar**

as they relate to marketing genetically modified organisms, are all cases and circumstances in which:

(e) a genetically modified organism is marketed which is contained in a medicinal product authorised under the Human Medicines Regulations 2012

30. To be clear, both Pfizer and Moderna did make applications for marketing approval under the Human Medicines Regulations 2012:

(a) Pfizer under regulation 174: see MHRA Public Assessment Report, page 5.

(b) Moderna under regulation 50: see MHRA Public Assessment Report (summary), page 6.

31. By Moderna applying under regulation 50 they were required to furnish all information detailed under Schedule 8 of the Human Medicines Regulations 2021. Schedule 8 did not require any information concerning GMOs, nor that packaging or product information be required to disclose any GMO ingredients contained in their product.

32. Moderna was also required under regulation 50J to furnish a copy of the consent granted under the *Genetically Modified Organisms (Deliberate Release) Regulations* 2002 for the release into the environment of the genetically modified organisms ***for research and development purposes***, inclusive of an environmental risk assessment in accordance with the principles set out in Annex II to Directive 2001/18/EC (European Union), *however*, Moderna never undertook research and development of its Covid-19 product within the UK, so no such consent was ever sought nor required to be produced for the purposes of regulation 50J.

33. As consequence of the use of regulation 50 for making application within the UK for marketing consent, and the failure of regulation 50 and 50J to specifically require an

applicant to provide any information concerning GMOs known to be in their product, Moderna avoided any need to declare or address the GMOs contained within the product, despite their LNP-modRNA complexes satisfying the UK legal definitions under Part VI of the *Environmental Protection Act* 1990.

34. Pfizer on the other hand made application under regulation 174 for the supply of their product on 'a temporary basis', being a regulation used in response to the spread of a pathogenic agent 'which may cause harm to human beings', aka SARS-CoV-2.

35. Again, as consequence of Pfizer using regulation 174 for seeking the grant of temporary authorisation to supply its product in UK, and the failure of regulation 174 to specifically require an applicant to provide any information concerning GMOs known to be in their product, Pfizer avoided any need to declare or address the GMOs contained in their product, despite their LNP-modRNA complexes satisfying the UK legal definitions under Part VI of the *Environmental Protection Act* 1990.

36. This advice demonstrates the legislative pathway that enabled Pfizer and Moderna and in turn UK health authorities to avoid addressing the issue of the LNP-modRNA GMOs contained in the Covid-19 products of each of Pfizer and Moderna. However, though neither Pfizer nor Moderna were required to address their GMOs when making applications to supply their products, no UK citizen was informed that the main ingredient contained in the products have always satisfied the UK legal definitions for being properly deemed and called GMOs.

37. This paper will not go on to treat in detail the additional GMO constituents found in both of the Pfizer and Moderna products, being confirmed modDNA contamination, also confirmed to be found as LNP-modDNA complexes, which also satisfy the UK legal definitions under Part VI of the *Environmental Protection Act* 1990 for being properly deemed GMOs.

38. Pharmaceutical DNA contamination has been a long and well known risk arising from failures in the manufacturing process, with academic and regulatory discussion reaching back several decades. But those identified risks spoke to what is called 'naked DNA', or free floating exogenous DNA and its adverse effects upon humans.

39. However the synthetic DNA involved in the Pfizer and Moderna contamination is 'a different animal' entirely, and never featured in earlier treatises and peer reviewed literature speaking to potential and known damage caused by DNA contamination, because in this instance of the Pfizer and Moderna products yes, ***some*** of the synthetic DNA is *naked* DNA able to be eliminated in the blood when identified by human the immune system, where *naked* DNA otherwise has no ability to cross cell membranes and enter cells, which factor commends it to those experts who have written naked DNA only poses a real threat when contamination levels are extremely high.

40. But the synthetic DNA contamination identified (and independently confirmed) in the Pfizer and Moderna products is also significantly bounded and encapsulated in the protective LNPs, creating LNP-modDNA complexes, which LNPs protect the modDNA from being detected in the blood, (so therefore it is not being cleared by immune systems); and further, the LNPs are specifically designed for delivering the modDNA through cell membranes and into cells (transfection), thereby ensuring high bio-distribution throughout human bodies to all organ types, and high transfection efficiency for delivery of the modDNA into the cells of all organs including the heart, liver, spleen, brain, Central Nervous System, bone marrow, testes, ovaries, and possibly unborn children. The several decades of earlier discussion never spoke to this level of actual and efficient contamination, therefore all regulatory guidance on acceptable levels of DNA contamination are hopelessly outdated and set too low in the face of this much more efficient and modified form of synthetic DNA contamination.

41. In a few words, this form of synthetic LNP-modDNA contamination is never acceptable, particularly when found to exceed stated (old) EMA limits by as much as

18-70 fold. Such levels of contamination and the known adverse effects of genetic disorders and possible/probable genomic integration, and the adverse consequences flowing from same, designate any products discovered to contain such contamination poisons and illegal substances. Hopefully UK lawyers can further look into the offences attaching to the supply of products known to be contaminated, where such contamination has known adverse effects including death, where knowledge of such contamination can be shown at the time of seeking market authorisation or temporary authorisation, or when knowledge of that contamination is brought to the attention of Pfizer and Moderna subsequently, yet both companies fail to respond or act.

42. **Note:** Testing for DNA contamination has been required of manufacturers and regulators alike for decades, involving less than 1 hour at a cost of less than $10.

43. To this end please find accompanying the ***Brief of Information & Evidence*** soon to be presented to Australia's Commonwealth Attorney-General and the Australian Federal Police Commissioner, which further details all relevant aspects of this synthetic DNA contamination, which Brief could serve as a useful template for informing one or more of the following officials: the UK Director of Public Prosecutions (Max Hill KC); Attorney General (Victoria Prentis); the Commissioner of Police of the Metropolis (Sir Mark Rowley).

44. That Brief has annexed the expert report by Angela Jeanes PhD, Cellular and Molecular Biology, which report was settled after consultation with two further PhDs with relevant experience (Cellular Biology and Genomics). Being a report prepared for judicial proceedings (civil) it necessarily responds to questions and answers whether the LNP-modRNA and LNP-modDNA contaminate, from a scientific point of view, fit the Australian legal definitions for being properly deemed GMOs. Dr Jeanes was able to answer easily in the affirmative. The Australian GMO legal definitions are almost identical to those under Part VI of the UK legislation. Once UK and/or European PhDs with similar qualifications are asked the same questions as put to Dr Jeanes and confirm with the same answers, then much needs to be asked, I submit,

of UK health authorities who have kept the true name and nature of the contents injected into millions of UK citizens a secret .. a secret that vitiates all ideas of any UK citizen having provided their Informed Consent.

45. To this end attention should be given to paragraphs 68 through 74 in the accompanying ***Brief of Information & Evidence***, which address the breaches and failures to observe ***non-derogable*** Human Rights contained under several treaties and conventions the United Kingdom is also a signatory and party to, on behalf of all UK citizens. To put it mildly, UK authorities were required to observe and protect those Human Rights but appear to have failed the citizens of the United Kingdom.

46. And then there is the subject of the adverse effects from these GMOs, particularly the more lethal synthetic DNA .. a frightful reality that must be acknowledged at the highest levels and dealt with medically, immediately, and as best we can.

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