Witness Name: Dr Elizabeth Evans

Date: 10 April 2024

PEOPLE'S COVID-19 VACCINE INQUIRY

WITNESS STATEMENT OF DR ELIZABETH EVANS, ON BEHALF OF THE UK MEDICAL FREEDOM ALLIANCE (UKMFA)

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I, Dr Elizabeth Evans, co-founder and CEO of the UK Medical Freedom Alliance, Blake House, 18 Blake Street, York, YO1 8QG, will say as follows:

Introduction

- 1. I am Dr Elizabeth Evans, MA (Cantab), MBBS (Hons), DRCOG. I am a retired medical doctor, now practicing complementary medicine as an independent practitioner, with over 15 years' experience of caring for patients and adhering to the fundamental principles of medical ethics. I co-founded the UK Medical Freedom Alliance (UKMFA), an organisation campaigning and lobbying for medical ethics and informed consent, in October 2020.
- 2. I make this statement to the People's COVID-19 Vaccine Inquiry, held in London on 07 May 2024.
- 3. In this statement, I am speaking on behalf of the UKMFA, and the opinions stated are based on our collective medical, scientific and legal training and professional experience. The evidence presented is true to the best of my knowledge and belief.

UKMFA History, Purpose and Aims

- 4. UK Medical Freedom Alliance (<u>www.ukmedfreedom.org</u>) was founded in October 2020 by a group of concerned doctors, healthcare professionals, scientists and lawyers, in response to Government and healthcare COVID-19 policies which undermined fundamental and well-established principles of medical ethics and medical choice (e.g. face mask mandates and COVID-19 testing mandates).
- 5. UKMFA is a recognised and respected grassroots organisation, campaigning for the fundamental principles of medical ethics to be upheld in all circumstances, in accordance with national and international laws, declarations and codes. We have established ourselves as a leading voice on medical ethics in the UK, in the public sphere and the media.

- 6. UKMFA is a Limited Company, co-founded by two medical doctors, Dr Elizabeth Evans and Dr Anna Forbes, along with a team of around 40-50 other healthcare professionals (doctors, nurses, osteopaths, dentists and naturopaths), scientists, lawyers and concerned members of the public.
- 7. The UKMFA team has changed and reduced in number over time. We currently have a core team of 7 directors (listed on our website¹) from different backgrounds and with different responsibilities, aided by a small panel of experts in the fields of science, law and medicine who support our campaign and who provide the UKMFA with advice and analysis of the latest scientific evidence and data when required.
- 8. UKMFA has been run for the last three years largely by volunteers, with minimal expenses claimed by the team. Our funding comes solely from public donations which are around the level required to meet our running costs, including professional fees to our bookkeeper, accountant and website designer.
- 9. We campaign and lobby on issues that threaten the public's right to informed consent, bodily autonomy and medical choice. We contend that ethical medical decision-making can only take place in the context of a personal and confidential doctor-patient relationship, where the doctor's duty of care is primarily to the patient and not to other parties such as the NHS, wider society or "the greater good".
- 10. Over the last three years, we have written over 60 fully referenced, evidence-based Open Letters (published in full on our website) to Government ministers, regulators, decision-makers, medical bodies, institutions, community leaders and individuals. These include many letters relating to COVID-19 vaccine safety and effectiveness, COVID-19 rollout policies, COVID-19 vaccine mandates and ethical issues relating to COVID-19 vaccines, their approval, use and deployment. These letters, and a series of FOI requests, have created a dated, evidence-based and referenced paper trail of accountability. Our first open letter² was sent in November 2020 to the MHRA, JCVI and Government Ministers, urging them not to rush into authorising the use of COVID-19 vaccines due to serious safety and ethical concerns.

- 11. As well as lobbying decision-makers, UKMFA has also published evidence-based, referenced information leaflets, legal template letters and other information (medical, scientific and legal) on our website, to educate and inform the public. These are intended to aid and support the process of giving informed consent for COVID-19 vaccines and other medical interventions and to provide tools to help the public to challenge unethical and unlawful mandates and policies in their workplaces and wider community.
- 12. UKMFA wrote and published submissions to Government Public Consultations, including the consultations on mandatory COVID-19 vaccines for care workers in May 2021³ and mandatory COVID-19 vaccines for NHS and wider care sector workers in October 2021⁴, strongly opposing these unethical policies.
- 13. We collaborate with other UK and International campaign groups on ethical issues and run and participate in related campaigns such as "Time to Pause" in early 2022, which addressed serious safety and ethical concerns around the rollout of COVID-19 vaccines to children. We called for an immediate pause of the children's COVID-19 vaccine rollout, following emerging data showing an unexplained rise in all-cause mortality for 15–19-year-old males since the Pfizer vaccine was rolled out to that age group.
- 14. We contend that it is essential to scrutinise and evaluate all the policies relating to the COVID-19 vaccines that the Government implemented and to carry out a retrospective and full cost-benefit analysis and assessment of any resulting collateral damage. Now is the time to calmly and rationally assess all the arguments and evidence that campaigning groups have tried to present but, due to extreme censorship, have been deliberately kept away from debate in the public and political spheres. For over three years, UKMFA has repeatedly sought to engage with Government Ministers, regulators, policymakers and decision-makers, presenting an evidence-based and rational perspective on unethical and dangerous policies, but have been largely ignored.
- 15. UK Medical Freedom Alliance has been heavily censored, silenced and smeared during the pandemic, following our public opposition to unethical and unscientific Government COVID-19 policies and for challenging the wisdom and ethics of the

- reckless COVID-19 vaccine rollout. This despite all our letters and articles being fully referenced, and that it is now apparent that many of the warnings and concerns we raised have sadly come to pass.
- 16. I was personally targeted and smeared in the July 2021 illegal hacking and publishing of the Health Advisory Recovery Team (HART) private workspace chat (to which I belonged) by a group called Logically AI⁶, who were contracted by the UK Government to "monitor mis/disinformation". HART responded to this incident with this statement⁷ and published a further article in February 2023⁸.
- 17. PayPal suspended both the UK Medical Freedom Alliance account and my (unrelated) private account on the same day (01 September 2022). Neither have been reinstated. The deliberate targeting and de-banking of individuals and organisations who are lawfully campaigning against Government policies is deeply sinister and requires public investigation.
- 18. Following a Subject Access Request to the Cabinet Office, it was revealed that I (as co-founder of UKMFA) have been investigated by the Cabinet Office Rapid Response Media Monitoring Unit. Government monitoring of individuals who have not broken any laws, merely for daring to speak and campaign against their policies and the use of taxpayers' money to do this, is deeply concerning and is a matter of public interest. This cannot be acceptable in a society based on the rule of law and must be investigated properly, with due process.
- 19. UKMFA was also seriously smeared in a BMJ article⁹, using insinuations and unsubstantiated, unreferenced allegations. The authors appeared to seek to undermine the contribution of our organisation to the COVID-19 Public Inquiry, a critical debate of national importance. This was a blatant push to silence legitimate scientific debate and to seek to exclude opposing voices from the Inquiry. Our full rebuttal, in the form of an open letter to the BMJ Editor, was subsequently published in the BMJ¹⁰.

Summary of UKMFA Concerns

- 20. Medical ethics are vitally important and should be non-negotiable in a civilised society. They exist to hold doctors and healthcare professionals accountable for their actions and to protect vulnerable patients from abuse and atrocities, recognising the unavoidable power imbalance in the doctor-patient relationship.
- 21. The time when it is most important to hold firm to ethical principles is in an emergency, when decisions may be driven by panic and fear, and abuse and atrocities are most likely to occur. Yet, over the last three years, under emergency laws around the world, we have seen fundamental, long-standing ethical principles violated or abandoned.
- 22. Medical ethics cannot just be discarded or overlooked in an emergency, for "the greater good". The maxim "First do no harm" must always be upheld and full risk-benefit and cost-benefit analyses must be done for all interventions, for both the individual and wider society.
- 23. The fast-tracking of the COVID-19 vaccine clinical trials was only achieved by undermining or removing fundamental ethical principles and practice during the clinical trials and the administration of medical treatments. These trials were not due to be completed prior to the rollout of the vaccines and will never be completed according to the initial trial protocols. This included the violation of the confidential doctor-patient relationship, informed consent and individual bodily autonomy. The failure to wait for the clinical trials to be completed before authorising a mass rollout and the early vaccination of the control group before the trials ended, eliminating the ability to acquire long-term safety data, was particularly egregious in our opinion.
- 24. There was a failure to properly consider the ethical violations resulting from policies mandating COVID-19 vaccines. In relation to policies that made COVID-19 vaccines a condition of deployment (vaccine mandates), the stated aims of the Government, to reduce so-called "vaccine hesitancy" and maximise the speed of vaccine rollout, implied that the only ethical considerations were to get the vaccines

- out to as many groups and as fast as possible, with no corresponding consideration given as to whether it was ethical to mandate the COVID-19 vaccines as a condition for deployment in the first place.
- 25. The desire of Public Health authorities to maximise "vaccine confidence" and minimise "vaccine hesitancy" appears to have been prioritised over the ethical duty to responsibly establish vaccine safety (short-, medium- and long-term) and effectiveness. This was carried out using coercive messaging and other unethical tools. The UKMFA has always rejected the assertion or belief that every person in the country should be inoculated with a COVID-19 vaccine as soon as possible, regardless of their individual risk v benefit profile or their immune status.
- 26. The widespread use of the term "vaccine hesitancy" or the more pejorative "anti-vaxxer" label is unhelpful and coercive, as it comes with the unspoken assumption that it is a threat that must be eliminated, rather than a genuine concern that should be addressed. These terms ignore the fact that different vaccines carry different risks and benefits for different individuals, just as is the case for all pharmaceuticals. The negative labelling of people as "vaccine hesitant" or "anti-vax" may be harmful and certainly threatens their reputation and right to free speech if they are made to feel that they must not ask questions about medical interventions such as vaccines.
- 27. We will highlight the failure of the MHRA, Public Health officials and Government to act on clear safety signals coming from the MHRA's own Yellow Card passive reporting system data, or to communicate risks clearly to the public as the data became available.
- 28. We will evidence that we repeatedly wrote to policymakers and decision-makers from November 2020 with increasing (and now overwhelming) published, peer-reviewed evidence that COVID-19 vaccines were causing significant harm. We presented evidence of cardiovascular injury such as myocarditis and abnormal clotting conditions, and links to neurological damage, immunological damage and other symptoms and diseases in every system of the body, including death. We have presented more than enough evidence in our open

letters to challenge the hypothesis that COVID-19 vaccines are universally 'safe and effective'.

- 29. In our opinion, the failure of the authorities to institute a rigorous safety surveillance system to closely monitor the expedited COVID-19 vaccine rollout, was grossly negligent. In an open letter dated 23 November 2020¹¹ we urged the MHRA, JCVI and Government to institute such a surveillance system as part of a responsible approach to rolling out a novel technology with only 2 months' worth of safety data from incomplete trials. We suggested that "Any individual who consents to a Covid Vaccine should be made aware of an active surveillance programme (run by MHRA or another body) to monitor short- and long-term side effects. This programme should be made directly accessible to the individual (rather than their GP). They should be given a website address and encouraged to report any side effects or new illnesses that occur in the next five years.". It is most unfortunate that such a policy programme was not actively or consistently instituted.
- 30. It is apparent that UK Vaccine Damage Payment Scheme is completely unfit for purpose in every area ease of access, time for claims to be assessed, the criteria for awards (60% disability or more required to get any compensation) and the completely inadequate amount of money awarded. We contend that there is an immediate need for a complete overhaul and reform of the scheme, to create a humane and ethical system for those injured or killed by a public health measure.

Ethical Concerns relating to the Development and Approval of COVID-19 Vaccines

- 31. We have witnessed the clinical regulatory trials for COVID-19 vaccines being conducted without adhering to the ethical principles of research.
- 32. UKMFA has highlighted the following concerns repeatedly to public officials and regulators.
 - i. Interpretation of results with interim analyses before completion of the trial.

- ii. Crossover of the placebo group mid-trial resulting in losing the control group and therefore the ability to ascertain long-term safety and effectiveness.
- 33. We first raised our concerns in November 2020, before the COVID-19 vaccines were authorised, in our urgent Open Letter to the MHRA, JCVI and the Secretary of State for Health and Social Care, Rt Hon Matt Hancock¹². In this fully referenced, 14-page letter, we detailed serious safety and ethical concerns relating to the proposed COVID-19 vaccine authorisation and rollout.
- 34. We implored the MHRA not to rush into emergency authorisation of the vaccines and the Government not to rush into a rollout of any COVID-19 vaccines. We laid out evidence that this could jeopardise public safety to a degree that was not justified, especially due to the lack of evidence of any existential threat to society from SARS-CoV-2 at that time. We urged them not to go ahead with authorisation or rollout until our concerns were addressed.
- 35. We divided our concerns into the following four sections, providing substantial evidence already in the public domain for each area of concern:
 - i. Over-Estimation of the Public Health Risk from SARS-CoV-2
 - ii. Inadequate Assessment of the Public Health Risk from a COVID-19 Vaccine
 - iii. Medical Freedom and Informed Consent
 - iv. Media Claims and Misinformation
- 36. The evidence we presented in our letter was readily available in the public domain in the Autumn of 2020. We presented findings from the available vaccine trial data and related published literature and considered the situation from ethical and legal standpoints. It is striking how many of the arguments we put forward in our letter have since been confirmed, including:

- The estimate of average population IFR for SARS-CoV-2 at 0.23% (0.05% for <70 years) which is around the same level as seasonal influenza (0.1-0.3%).
- ii. The median age of death with SARS-CoV-2 in the UK being 82.4 years.
- iii. Concerns about the accuracy and representation of the epidemiological data relating to SARS-CoV-2 infections and associated deaths (including criticism of the Ferguson model), which we argued had led to an exaggeration of the severity of the threat to public health from the virus and thus an exaggerated need for a vaccine.
- 37. A summary of the issues we raised, based on evidence we presented and referenced, were:
 - i. Erroneously augmented numbers of both COVID-19 cases and deaths with SARS-CoV-2 had driven Government policies and pronouncements, leading to hysteria and unnecessary fearmongering in the mainstream media. The data were not viewed in the context of other real and ongoing challenges to public health, including mortality and morbidity from other respiratory conditions, heart disease, Alzheimer's, diabetes, cancer and mental health. The data did not indicate large numbers of excess deaths (as would be expected if there were a pandemic of a dangerous deadly virus) to justify expediting a vaccine, by rushing through safety trials, to protect people or suppress its spread. This overestimation of the risk to public health from SARS-CoV-2 and/or COVID-19 should have been considered when making decisions about an urgent rollout of a COVID-19 vaccine.
 - ii. We urged public health officials not to repeat the mistakes of the past. In 2009, the swine flu (H1N1) vaccine was rushed into circulation, even though morbidity and mortality risks of the H1N1 virus were extremely low. The population was assured the vaccine was safe but, in fact, resulted in

over 1000 children and teenagers across Europe, as well as some NHS staff, developing the debilitating and permanent neurological illness, narcolepsy.

- iii. We rejected the idea that every person in the country should be inoculated with a COVID-19 vaccine as soon as possible. In our professional opinion and with the information and data available we considered that this would be a reckless and unnecessary course of action. At the time of writing (November 2020), only a few months' worth of safety data were available and only several tens of thousands of largely healthy people had received a COVID-19 vaccine in clinical trials. We suggested that the safety and long-term effects of a COVID-19 vaccine should be studied meticulously in trial subjects over a minimum of five years, but ideally for an entire generation, as it was using a novel, gene-based technology. This could only be done properly alongside a control group of individuals who had not taken the vaccine.
- iv. We wanted to ensure that, in the haste to roll out a COVID-19 vaccine under emergency measures, all proper procedures were followed, including ensuring due process to uphold the right of the individual to make a fully informed choice regarding vaccination with these products. We pointed out that doctors, nurses and others who may be authorised to vaccinate the public had a duty to facilitate this right under international agreements, conventions, and European and national laws. We raised concerns that recent Parliamentary discussions appeared not to attach proper weight to concerns about potential vaccine risks and the right to informed consent, instead focussing solely on strategies to increase the uptake of vaccines in the general population.
- v. We argued that the morbidity and mortality impact on public health from SARS-CoV-2 must be balanced with the risks and cost of a vaccine rollout. We demonstrated that the mortality and morbidity from SARS-CoV-2 was not an existential threat to society.

- vi. We concluded that "It is a huge responsibility to roll out a vaccine manufactured with novel technology. To do so with the intention that all 60+ million people in the UK should receive the vaccine as soon as possible, without full transparency as to potential risks, may be viewed as irresponsible, potentially even negligent, from a legal standpoint. We urge you to heed the wisdom in the Hippocratic Oath: "First, do no harm". We are confident that the MHRA, JCVI and the DHSC are each aware of their respective duty of care to the UK public and would not wish to take unnecessary risks with our health. We therefore expect that you will take our concerns seriously. Even in circumstances where the Government has declared a national emergency, we trust that you will make the time to thoroughly digest our letter and the numerous references we have provided."
- 38. Despite sending the letter (by post and email) to all the addresses on 23 November 2020, we did not receive a response. On 2 December 2020, the MHRA issued a temporary emergency use authorisation to rollout the Pfizer-BioNTech COVID-19 vaccine, stating in their press release 13 "We have carried out a rigorous scientific assessment of all the available evidence of quality, safety and effectiveness. The public's safety has always been at the forefront of our minds safety is our watchword."

Ethics of UK COVID-19 Vaccine Policies and Rollout

(a) Summary of Fundamental Principles of Medical Ethics

- 39. When considering any medical intervention for an individual, it must be proportionate, necessary and applied under strict ethical principles.
- 40. Medical ethics have underpinned the practice of medicine since Hippocrates (c.400BC) drew up an ethical code of practice, the **Hippocratic Oath**, that gave moral guidance and accountability to doctors when treating their patients. The

- instruction "Primum non nocere", which means "First, do no Harm", is attributed to Hippocrates and remains a basic tenet of medical practice.
- 41. The **Nuremberg Code** (1947), although not legally binding, is a landmark document in medical and research ethics. It was drawn up at the end of the Nuremberg trial of doctors, who had carried out medical experimentation on vulnerable patients under the orders of the Nazi regime. It states that "the voluntary consent of the human subject is absolutely essential...this means that the person involved should have legal capacity to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion" 14.
- 42. The **World Medical Association's Declaration of Helsinki**¹⁵ was first adopted in 1964 and most recently amended in October 2013. It is a statement of ethical principles for physicians undertaking medical research involving human subjects. Both the Nuremberg Code and the more recent Declaration of Helsinki state that experimental treatment must only be carried out with the fully informed consent of the study participant.
- 43. The gold standard model of an ethical doctor-patient relationship is that of patient-centred care, in which the primary duty of care of the doctor is to the patient in front of them, acting in their best interest and considering their physical, emotional and philosophical/spiritual needs and wishes at all times.
- 44. All medical interventions have the potential to cause harm, so doctors are required by law to ensure that they obtain voluntary and fully informed consent, following a discussion of the risks and benefits to that individual and any alternative options. Healthcare professionals are expected to maintain confidentiality and respect the value and dignity of each person, acting as their patient's advocate.
- 45. Informed consent is the cornerstone of good, ethical medical practice and is firmly enshrined in the code of conduct issued by the General Medical Council (GMC) in their "Decision Making and Consent" guidance¹⁶ underpinning Good Medical Practice¹⁷. Similar codes of practice are required by the Nursing and

Midwifery Council (NMC) and the NHS Constitution, as well as being mandated in UK and International Law.

- 46. The **Supreme Court judgement in Montgomery v Lanarkshire (2015)**¹⁸ changed the focus of the law on consent from doctor-focused or paternalistic to patient-focused, prioritising the autonomy of the patient. It tightened the requirements for informed consent, requiring the doctor to take reasonable care to ensure that the patient is aware of any material risks from the treatment that the patient (not the doctor or other experts) is likely to deem significant.
- 47. England and Wales currently operate a system of patient autonomy which gives patients the right to give their consent prior to any medical treatment. For consent to be valid, a healthcare provider must abide by the following legal requirements set out in the **NHS Constitution** (last updated in August 2023)¹⁹ and guidance issued by the NHS (last updated in December 2022)²⁰ stating that:
 - i. The patient should be free to accept or refuse treatment that is offered.
 - ii. The patient should not be given any treatment unless they have given valid consent.
 - iii. The patient should be given information about the test and treatment options available, what they involve and their risks and benefits, to inform their decision.
 - iv. The patient should be involved in planning and making decisions about their health and care with their care provider(s)
 - v. Their decision should be voluntary and must not be influenced by pressure from medical staff, friends, or family. Their decision must be respected.
- 48. Article 3 of the EU Charter of Human Rights "Right to Integrity of the Person"²¹ protects individual bodily autonomy, the fundamental right of each human being to self-determination over what happens to their own body, including what medication is ingested or injected.

- 49. Article 6 of the Universal Declaration on Bioethics and Human Rights (2005)²² states that "any preventive, diagnostic, and therapeutic medical intervention is only to be carried out with the prior, free, and informed consent of the person concerned, based on adequate information".
- 50. In relation to COVID-19 vaccines specifically, the **Parliamentary Assembly of the Council of Europe passed Resolution number 2361 (2021)**²³ on 27 January 2021, in which it was stated that:
 - 1.1 Paragraph 7.3.1 ensure that citizens are informed that [the Covid-19] vaccination is NOT mandatory and that no one is politically, socially, or otherwise pressured to get themselves vaccinated if they do not wish to do so themselves.
 - 1.2 Paragraph 7.3.2 ensure that no one is discriminated against for not having been vaccinated, due to possible health risks or not wanting to be vaccinated.

(b) Ethics of the COVID-19 Vaccine Rollout

- 51. We have witnessed the rollout of the COVID-19 vaccine program being implemented in apparent disregard of established and fundamental principles of ethical medicine, including the basic human rights of informed consent, medical freedom and bodily autonomy.
- 52. We have witnessed the unethical use of mass propaganda and advertising, with the simplistic marketing slogan "safe and effective" repeated ad nauseum by Government and in the media to coerce the public to take these products. Powerful and incessant Government and media messaging persuaded the public that the vaccines would be our only way out and that we should "trust the science".
- 53. Public trust in the medical profession and health authorities has been seriously damaged as evidence of unprecedented levels of vaccine injury mount and the extraordinary claims of 95% or even 100% effectiveness have not been borne out. Indeed, real world data is repeatedly showing negative effectiveness of

the COVID-19 vaccines in a matter of weeks, meaning that you are more likely to catch COVID-19 if you are vaccinated than unvaccinated. The vaccines have not lived up to the incessantly repeated marketing slogan of "safe and effective".

- 54. The use of the term "vaccine hesitancy" has been widely used by Government officials and regulators in a pejorative way. Policies to address "vaccine hesitancy" in fact undermine individual autonomy and the right to freely choose which medical treatments to accept. UKMFA advocates that the public should be provided with unbiased and scientifically verified evidence in order to make informed decisions.
- 55. The widespread Government and media censure of "vaccine hesitancy" has been used as a tool to coerce people into accepting a product that they may not want or need. UKMFA condemns the use of this label and any policies that seek to identify and target individuals who have come to a personal decision not to take a pharmaceutical product, to attempt to change their mind.
- 56. All COVID-19 vaccines authorised and used in the UK are based on completely new genetic technologies that had never previously received full regulatory approval for mass rollout in humans. We cannot comprehend why this strategy was pursued, as opposed to using well-established vaccine technology, when the aim was to produce a safe and effective product in the shortest time possible. This fact should have been clearly shared with the public, before offering and urging them to accept an unlicensed product which was to remain in clinical trials until 2022/2023, and where cohorts of the population were not represented in the initial and ongoing trials, such as children, pregnant women and people with multiple comorbidities.
- 57. The precautionary principle was abandoned, and ethical codes violated in the decision to roll out COVID-19 vaccines to the whole population. The administration of a completely new technology with no long-term safety data, not only to those at most risk from COVID-19 but to those at little or no risk and especially pregnant women and children, goes against all common sense as well as violating well-established medical practice and ethics.

- 58. It was unprecedented that a pharmaceutical product still in the clinical trial phase was administered to children and pregnant women on such a mass scale. That this has been done without full disclosure of the known and unknown risks and with aggressive marketing completely undermined the ability of anyone to give full, voluntary and informed consent and, in our professional opinion, has been extremely reckless. The fact that, in 2024, these products are still being recommended for and injected into pregnant women and children is, in our opinion, unconscionable.
- 59. Doctors have been prevented from acting in their patients' best interest. For example, they were blocked from issuing medical exemptions for patients who decided against having COVID-19 vaccines, even when they had genuine medical contraindications, under threat of losing their careers and livelihoods. Instead, doctors were forced to practise a 'one-size-fits-all' approach to medicine, following protocols and mandates set by distant bureaucrats with no knowledge of or duty of care to the individual patient, which is a dangerous and unethical way to practise medicine. At the heart of the practice of safe and ethical medicine is the doctor-patient relationship, where the patient's unique medical history, his or her individual risk-profile and personal philosophy and wishes should always be the prime concern of the doctor administering a treatment.
- 60. The UKMFA has repeatedly raised these concerns with public officials and regulators. We wrote fully referenced and evidenced medical, legal and ethical Open Letters in 2020-2022 to:
 - i. General Medical Council Chair Dame Clare Marx²⁴ (May 2021) and the Nursing and Midwifery Council²⁵ (March 2021) raising concerns that doctors, nurses and midwives were being asked to practice in violation of their own ethical codes and principles of Good Medical Practice, such as evidence-based practice and informed consent. We described a culture developing in the NHS where health professionals were discouraged from reporting any potential patient safety issues which challenged official Government or NHS policies. We implored the regulatory bodies to investigate unethical practices and all individuals who were enforcing them. We also requested that any doctors resisting such practices should receive

protection from their regulatory body, the General Medical Council (GMC), as we understood that many feared investigation and possible suspension.

- ii. General Medical Council Chair Dame Carrie MacEwen²⁶ (July 2022), detailing grave concerns that the GMC was failing to maintain standards of decision-making and informed consent as determined by its own guidance. Specific concerns related to inadequate provision of care in COVID-19 vaccination centres and the omission of vital information concerning known risks from the COVID-19 vaccines in the consent process being followed. We highlighted key discrepancies between the GMC Guidelines and the experience of patients on the ground.
- iii. Royal College of Obstetrics and Gynaecology, Royal College of Midwives and MHRA CEO Dame June Raine²⁷ (May 2022) raising serious safety and ethical concerns regarding the continued rollout of COVID-19 vaccines to pregnant women.
- iv. Care Quality Commission (CQC) CEO, Ian Trenholm²⁸ (July 2021) raising serious concerns about the Public Health England (PHE) COVID-19 Vaccine Consent Forms being used by doctors and vaccinators, that could result in the failure to obtain legally valid informed consent. We contended that the PHE consent forms did not comply with GMC Guidelines and that healthcare providers were being misled by these inadequate consent forms, putting them at risk of prosecution. Patients were not being informed of all material risks nor reasonable alternatives, nor given sufficient time to consider their choice. We asked for an urgent investigation and appropriate action to be taken by the CQC.

After consulting with the GMC and PHE/UKHSA, the CQC replied to us²⁹ to clarify that the CQC does not regulate PHE. Regarding the PHE consent form, they stated that it was not mandatory for vaccinators to use it, that it was not a stand-alone document and other information sheets were given to patients before vaccination, including links to information about side-effects. Therefore, they argued that the consent form was only one aspect

- of the consent process and that the vaccination process allowed additional dialogue between patient and health provider while obtaining consent.
- v. **GPs and Vaccinators**³⁰ (June 2021) informing them of the importance of adhering to certain legal requirements to ensure that full and informed consent is obtained prior to the administration of COVID-19 vaccines. We listed fourteen points that we believed should be covered and documented in discussions with patients when consenting them for COVID-19 vaccines, as part of the process of obtaining fully informed consent, with specific reference made to the fact that the end of the clinical trials must be awaited before COVID-19 vaccines may confidently be declared safe.
- vi. Care Home Managers re Informed Consent³¹ (December 2020) UKMFA and Rational Global wrote a joint letter designed to help care home managers understand the legal requirement for fully informed consent to be obtained for their residents and employees before administering a COVID-19 vaccine, as we were concerned that vulnerable residents may be subject to unethical coercion or given insufficient information for them or their Lasting Power of Attorney to make an informed decision.
- vii. Chief Medical Officers³², Headteachers³³ and Public Officers³⁴ regarding the safety and ethics of COVID-19 vaccination of children.
- viii. Notice of Legal Obligations and Potential Liabilities pertaining to Misfeasance to MPs, MSPs and MSs³⁵ (November 2021) reminding them of their duties as public office holders and the legal position should they breach those duties, in relation to harms caused by decisions that they made or complied with, pertaining to COVID-19 vaccinations and related mandates including vaccine passports or certification.

(c) COVID-19 Vaccine Mandates

61. We completely opposed the unprecedented and unethical use of legal mandates and threats of mandates to coerce individuals in certain employment

- groups to accept a vaccine they may not have wanted or needed, under threat of losing their jobs and livelihoods.
- 62. A one-size-fits-all approach to medicine is never ethical or safe and is unscientific. All medical interventions come with risks, which may be life-changing or life-ending, therefore an individual must be allowed to weigh up the risks and benefits of any medical treatment based on their own individual circumstances.
- 63. Vaccines are given to healthy people who may be at extremely low-risk or at no risk from the illness and with no guarantee that they will personally benefit. Therefore, vaccination should be completely voluntary, with no threat of sanction for refusing, and the vaccine must have an exceptionally high safety profile in both the short- and long-term.
- 64. Medical ethics is necessarily undermined and destroyed in any system where 'the greater good' is prioritised over individual bodily autonomy and where the sacred doctor-patient relationship is not honoured. Vaccine mandates constituted a profound threat to the ethics of Good Clinical Practice and undermined the dignity, bodily autonomy and medical freedom of every person in this country.
- 65. All government policies must be demonstrably proportionate and ethical. There was no scientific justification to support the implementation of COVID-19 vaccine mandates as a condition of employment (in late 2021 and 2022), as a proportionate response to the (by then) rapidly reducing public health threat of COVID-19, and for an illness that was never life-threatening for most people.
- 66. Section 45E of the Public Health (Control of Disease) Act (1984)³⁶ specifically prohibits the introduction of regulations mandating medical treatments or vaccines.
- 67. UKMFA submitted formal responses to the UK Government Public Consultation on Making COVID-19 Vaccination a Condition of Deployment in Older Adult Care Homes³⁷ and subsequently to the UK Government Public Consultation on Mandatory COVID-19 Vaccines for NHS and wider Care Sector Workers³⁸, which sought views on mandatory vaccines for NHS and all social care employees.

- 68. The first group of workers subject to COVID-19 vaccine mandates were Care Home Workers in England, following a vote in Parliament on 13 July 2021. UKMFA, Lawyers for Liberty and The Workers Union of England published an Open Letter on 20 August 2021³⁹ for employees and potential employees to share with any employers who were proposing to make COVID-19 vaccines a condition of employment. Our letter outlined the legal rights of the employee to informed consent and medical choice, relevant employment law protections afforded to employees, and summarised the legal duties of employers to their employees. We also provided evidence of the potential risks of COVID-19 vaccines and the trial data indicating that the vaccines do not prevent infection or transmission of the virus.
- 69. In response to the proposed COVID-19 vaccine mandate of all NHS and CQC-regulated healthcare workers, we wrote an open letter to all Members of the House of Lords⁴⁰ appealing to them to vote against this unethical, disproportionate and divisive bill, detailing and referencing serious safety, ethical and workforce concerns.
- 70. We argued that it would be grossly disproportionate and unnecessary to override fundamental medical ethics and dismiss tens of thousands of healthcare workers for a disease like COVID-19 that has an infection fatality rate similar to influenza, at a point when we would expect the pandemic to be nearly over, and with most people having either acquired natural immunity or some protection from their vaccinations.
- 71. We concluded that they were being asked to approve an illegal and unethical mandate of an ineffective and unsafe product, for the very people in society who are trained and capable of assessing scientific evidence to make informed health choices. We noted that:

"The NHS is already in crisis. We cannot afford to lose a single highly qualified worker if there is any hope of tackling the enormous waiting lists of patients needing care and the consequent declining health and rising all-cause mortality in our nation. Dismissing staff could bring about the

complete collapse of the NHS and would be an unprecedented, self-inflicted public health disaster."

- 72. In advance of the Parliamentary Debate on 24 January 2022, concerning the discussion of the petition: "Prohibit employers from requiring staff to be vaccinated against COVID-19", we wrote to all Members of Parliament (MPs)⁴¹, asking our supporters to send a copy to their own MP to implore them to thoroughly consider at least three points:
 - COVID-19 vaccines had been shown not to prevent viral infection or transmission so could only ever benefit an individual and not the wider population.
 - ii. Informed consent is paramount in Good Medical Practice.
 - iii. The safety of the COVID-19 vaccines had not been established and there was growing evidence of serious potential side-effects, such as myocarditis, blood clots and death, in official Government reporting systems around the world. Any potential long-term effects of the COVID-19 vaccines on autoimmune diseases, carcinogenesis and fertility were entirely unknown.
- 73. We also provided data indicating that mandating COVID-19 vaccines was not justifiable, even within the healthcare sector.
- 74. Following suggestions that Universities and Higher Education facilities could impose COVID-19 vaccine requirements for students to access education, or penalise unvaccinated students, we wrote to all University Vice Chancellors and Higher Education College Senior Management⁴², appealing to them to refrain from imposing any COVID-19 health-related conditions on students accessing education at their institutions, specifically urging them to strongly resist imposing any requirements for students to accept a COVID-19 vaccine.
- 75. We set out our concerns relating COVID-19 vaccine safety, and the violation of laws and guidelines around informed consent that would result from imposing this

condition on students' access to education, commenting that "It is entirely unprecedented that interventions interfering with bodily integrity and autonomy should be stipulated as conditions to receiving higher education, and excluding students based on such requirements would grossly violate the basic freedoms and human rights, which have been essential components of our Western, liberal democracy."

- 76. We referred to the laws and ethical codes enshrining the right to informed consent for all medical interventions, arguing that informed consent could not be freely given if a medical intervention was a condition of access to education.
- 77. Regrettably, despite our pleas for an ethical and evidence-based policy approach, several medical schools did impose COVID-19 vaccines as a condition for entry and education in 2021-2022, causing immense stress to many students affected.
- 78. In response to reports of unvaccinated people being refused medical treatment or operations by some NHS and private hospitals in 2021 and 2022, we published a template letter "Medical Treatment Refused without COVID-19 Vaccine" with relevant legal and ethical facts referenced, to help individual members of the public to state their case to the medical staff involved and uphold their right to refuse medical treatment without penalty.
- 79. In September 2023, UKMFA teamed up with HART and the Thinking Coalition to send an open letter⁴⁴ to the 319 MPs who voted for COVID-19 vaccine mandates for all care workers in July 2021, by supporting an Amendment to the Health and Social Care Act 2008. We sought to hold them to account for supporting this unethical amendment which forced thousands of care workers out of jobs they loved and needed, to avoid having a medical treatment they did not want or need. We encouraged the public to send this letter to their own MP and request answers to our points.
- 80. We set out the violation of medical ethics in undermining care workers' "fundamental right to informed consent" and detailed the wealth of scientific and medical evidence available at the time that showed the jabs did not stop transmission and were causing unprecedented levels of harm. We stated that the principle of respecting bodily autonomy has been one of the foundations of western

society and that breaching this principle represented a major violation of the social contract and must never happen again.

(d) Policies Recommending COVID-19 Vaccines in Pregnancy

- 81. We have been particularly disturbed that a gold standard of medical ethics and the safe practice of medicine, that no experimental product is given to pregnant women without significant proven benefit to them and until proven safe in healthy adults in the long term, has been violated. The early rollout of novel, gene-based COVID-19 vaccines to pregnant women, before the clinical trials were complete and before they had been rigorously tested for short, medium- and long-term safety in pregnant women and their unborn babies, was egregious.
- 82. Administering these novel COVID-19 vaccines to pregnant women is inconsistent with evidence-based medicine and the ethical, moral and medical responsibility to protect pregnant women and their unborn babies from potential harm. The failure of public health bodies to observe the precautionary principle for this cohort, on the scale we have witnessed, is unthinkable and without precedent.
- 83. In March 2021, we wrote to the Royal College of Midwives (RCM) and Royal College of Obstetrics and Gynaecology (RCOG)⁴⁵, voicing our concerns about misleading advice in an information leaflet and decision aid aimed at pregnant women to help them decide whether to accept COVID-19 vaccination. We referenced evidence relating to COVID-19 vaccine efficacy, risk from COVID-19 disease in pregnancy, and COVID-19 vaccine safety in pregnancy.
- 84. We pointed out that the authorisation of these novel, gene-based products was based on interim data analyses of the ongoing trials in which no pregnant women were included. Administering a COVID-19 vaccine to a pregnant woman should therefore only have been done with extreme caution, fully informed consent and as part of a clinical trial with rigorous monitoring systems in place.

- 85. Following the JCVI updated advice recommending COVID-19 vaccines to all pregnant women in April 2021, we wrote an urgent open letter to Professor Andrew Pollard (JCVI Chair), Professor Wei Shen Lim (JCVI COVID-19 Chair), Dr Mary Ramsay (PHE Head of Immunisation) and Mr Edward Morris (President of RCOG) urging them to immediately retract this advice⁴⁶.
- 86. The JCVI published their advice despite the continued lack of robust safety data in pregnant women, with no available clinical trial results or peer-reviewed evidence regarding pregnancy. Instead, they cited "real world data from the United States" which apparently indicated that no safety concerns were raised in "around 90,000 pregnant women" who were vaccinated.
- 87. The data they relied on was from the V-Safe Covid-19 Vaccine Pregnancy Registry, in which 4478 pregnant women were fully enrolled as of 12th April 2021. The remaining 86,956 pregnant women were merely registered as having self-identified via a smartphone-based tool. No further information regarding any adverse events in this group were published at this point. We could not see how this information could reassure regarding vaccine safety in pregnancy, for the mother or baby, when the period of observations had not even spanned half the length of a single pregnancy.
- 88. In our letter we noted that, by April 2021, several official databases had already captured reports of adverse events from the COVID-19 vaccines in pregnant women, as well as hundreds of thousands of reports of adverse events in the general population. These should have raised the alarm that these products were not as safe as claimed, and therefore should certainly not be authorised for, or recommended to, pregnant women.
- 89. By 15 April 2021, the MHRA had documented a total of 626,087 adverse event reports, including 61 spontaneous abortions and 4 stillbirths. 847 adverse events had a fatal outcome. The WHO database recorded 527,790 adverse events and 3440 deaths as of the 18 April 2021. The US Vaccine Adverse Event Reporting System (VAERS) database had recorded 2602 deaths relating to COVID-19 vaccines as of 8 April 2021; over ten times the average annual number of all

- vaccine-related deaths normally reported to VAERS (under 200 per year) in a period of only 3 months.
- 90. There was already alarming data regarding the serious clotting issues now confirmed to be caused in some people by the AstraZeneca vaccine, resulting in a temporary suspension of the product in a few countries as a precaution. We pointed out that pregnancy is already a prothrombotic state, so any added risk of thrombotic events from COVID-19 vaccines was particularly relevant, not only to the health of the pregnant woman but also to placental development and circulation.
- 91. We noted that, as of 15 April 2021, 778 strokes and thrombolytic events had been reported to the MHRA, 570 events after the AstraZeneca vaccine but also 204 events relating to the Pfizer-BioNTech vaccine, indicating a possible "class effect" from the spike protein. This information is likely to be deemed significant by most people and therefore should have been shared with pregnant women, according to the UK Supreme Court 2015 Montgomery v Lanarkshire Health Board ruling, that patients must be informed of any risks that "any reasonable person in the patient's position would be likely to attach significance to".
- 92. At the beginning of June 2021, UKMFA sent an Open Letter to Scottish Chief Medical, Nursing and Pharmaceutical Officers regarding the COVID-19 vaccine rollout in Scotland^{47,} in response to their recent update on the Scottish COVID-19 Vaccination program sent to Scottish Health Boards and Local Authorities.
- 93. In this letter, we detailed specific safety and ethical concerns about the continued rollout of this program, specifically with regards to pregnant women. We explained that pregnant women and their babies were at risk of unnecessary harm and were being denied factual and comprehensive information, compromising the validity of informed consent. We highlighted the paucity of scientific evidence to support the current policies.
- 94. We also argued that patient information leaflets for pregnant women, from the RCOG, RCM and Public Health Scotland (PHS), failed to highlight the experimental nature of the vaccines or the safety signals that had been observed, which is in violation of the requirements for fully informed consent. We demanded

that factually accurate and comprehensive information, relating to both risks and benefits, must be made available to the public, especially pregnant women, to allow them to make a fully informed decision about COVID-19 vaccination, in line with ethical and lawful practice of medicine and the GMC Code of Conduct.

- 95. In January 2022, UKMFA was extremely disturbed by the increasingly coercive promotion of COVID-19 vaccines to pregnant women by NHS Fertility Centres in Scotland, who introduced an egregious, unscientific and unethical policy barring unvaccinated couples (both partners) from accessing any fertility treatment. We therefore wrote an open letter to the Scottish NHS Fertility Centres⁴⁸, copying in Dr Gregor Smith (Chief Medical Officer for Scotland), Humza Yousaf (Scottish Cabinet Secretary for Health and Social Care) and the Human Fertilisation and Embryology Authority. In this letter we argued that their policy was completely disproportionate, unsupported by scientific evidence and amounted to unlawful discrimination, as well as being unacceptable as it was targeting a particularly vulnerable cohort who were already in distress due to infertility, potentially causing stress and further deterioration of their mental wellbeing.
- 96. We argued that, in the absence of robust scientific evidence specifically demonstrating the safety of COVID-19 vaccines in early pregnancy, it was unethical and irresponsible to offer, let alone mandate, this product to couples whose fertility was already compromised and who were having to resort to fertility treatment. We also raised wider societal implications that this would set a precedent for unethical discrimination based on vaccination status to be implemented in other NHS services. We demanded that this policy be immediately terminated.
- 97. In May 2022, we sent another urgent open letter to Dame June Raine (Chief Executive of the MHRA), Mr Edward Morris (President of the Royal College of Obstetricians & Gynaecologists) and Rebeccah Davies (President of the Royal College of Midwives)⁴⁹. We re-emphasised concerns stated in previous letters and reinforced by emerging data. We argued that continuing to recommend COVID-19 vaccination for pregnant women, whilst ignoring or even denying the significance of growing numbers of serious adverse event reports, was grossly negligent and

- irresponsible and demanded the release of scientifically robust and transparent evidence for the safety and efficacy of COVID-19 vaccines in pregnancy.
- 98. In November 2022, in response to an alarming increase in Scotland's neonatal mortality rates observed in official databases, we wrote to Dr Helen Mactier and Health Improvement Scotland⁵⁰, appealing to them to investigate all possible factors which may have contributed to the increase in neonatal mortality, including the possibility of COVID-19 vaccination having a causative effect. We presented compelling evidence and data to support the hypothesis that COVID-19 vaccination of pregnant women may have caused or contributed to the tragic increase in neonatal deaths.
- 99. In the same month, several UKMFA doctors and I signed an open letter from over 60 doctors to the Royal College of Obstetricians and Gynaecologists, Royal College of Midwives and UK Health Security Agency, calling for an urgent review of the evidence around the safety of COVID-19 vaccine use in pregnancy. We argued that the current official advice "is not grounded in robust data based on ethically conducted research" and evidenced multiple serious safety signals and research data that should prompt an **immediate halt to the rollout to pregnant women**, pending a full, independent safety analysis. We concluded that "we have a collective duty to restore the principles of medical ethics to our practice and to clinical research to protect the most vulnerable groups from harm, and this includes pregnant women and their babies".

(e) Policies Recommending COVID-19 Vaccines for Children and Young Adults

100. The MHRA failed to observe established principles of ethical research and medical practice when they authorised the use of novel products, still under emergency use authorisation and in the absence of any medium or long-term safety data, in children who were at almost zero risk from COVID-19. This ethical failure was compounded by the willingness of the JCVI and Government to actively promote the rollout of these gene-based products to children and young adults, in apparent disregard for potential known and unknown risks.

- 101.UKMFA was very early to raise serious concerns about any future rollout of COVID-19 vaccines to children, detailed in our Open Letter to Child Health Experts/Officers, Nadhim Zahawi, JCVI, and MHRA, sent on 25 February 2021⁵¹. We referenced the current scientific evidence that clearly showed (even then) that the risk v benefit calculation did not support administering experimental COVID-19 vaccines to healthy children.
- 102. We concluded that it would be irresponsible, unethical and unnecessary, to include any children under 18 years in the national COVID-19 vaccine rollout or in any clinical trials. We stated that the end of the current Phase 3 trials in adults must be awaited, as well as several years of safety data to rule out long-term adverse effects on autoimmune diseases, fertility, genetics (on offspring of the vaccinated) or cancers. Sadly, many of our concerns appear to have been realised.
- 103. Following the unbelievable decision by the MHRA in June 2021, to grant regulatory approval for temporary emergency use of the Pfizer-BioNTech COVID-19 vaccine in 12- to 15-year-old children, we wrote directly to Dr June Raine CEO MHRA, Mr Stephen Lightfoot, MHRA Chair, and Professor David Webb MHRA Deputy Chair, copying in the Prime Minister Boris Johnson, First Ministers and several Government Ministers⁵². In our letter, we detailed grave concerns about this emergency authorisation, citing evidence of known and potential harms (including reports of deaths) that may result. We laid out the serious ethical issues raised by this unprecedented decision, which was not based on peer-reviewed science but on interim analysis of the manufacturers' own, incomplete and underpowered clinical trials on children, with no public scrutiny of the raw trial data.
- 104. We again stated and evidenced the fact that COVID-19 vaccines would have virtually no benefit to children themselves but had both known and unknown risks, making it profoundly unethical and indefensible to vaccinate them, especially with an experimental vaccine using novel technology in what appeared to be a misguided attempt to protect adults and achieve herd immunity. As the concept of ending a pandemic by vaccinating the entire population has no historical precedent or basis in science, there was no imperative to vaccinate children.

- 105. We implored the MHRA to exercise caution and immediately reverse their decision, citing multiple datapoints indicating that their decision would have devastating consequences for a significant number of children in the UK and their families, which would be "an unforgiveable act of completely avoidable harm".
- 106. We referenced multiple groups of doctors and experts from around the world, including in the UK, US and Israel, who had already raised serious ethical and safety concerns and called for children to be excluded from any COVID-19 vaccine rollout.
- 107. We presented evidence of the known and unknown risks from COVID-19 vaccines, including significant, life-changing injury and death. Most worryingly, some of the serious reported injuries, such as blood clots and myocarditis, had specifically occurred more frequently in young people and children.
- 108. There were already reports of deaths and injury in children in the US and Canada, where vaccines were being trialled and rolled out to children. Even with rare risks (1:10,000 to 1:100,000), we pointed out that if these vaccines were given to around 10 million UK children, it seemed certain that there would be deaths and serious injuries in a significant number of children who would never have been harmed by COVID-19.
- 109. We argued that a precautionary approach was essential, as children have a lifetime ahead of them and we had no idea of the impact of these novel, gene-based vaccines on their health or fertility in 5-10 years' time. Considering these facts, we challenged whether the review by the MHRA could in any way be described as rigorous, or the conclusion to grant regulatory approval responsible.
- 110. Following the authorisation for children it was proposed that the COVID-19 vaccines be rolled out in schools, which raised serious ethical and medical concerns. UKMFA asserts that schools are not an appropriate place for medical interventions to be carried out for many reasons, including lack of confidentiality, lack of parental support and input, and coercive peer pressure.
- 111. In July 2021, UKMFA wrote an open letter to Headteachers and Teachers⁵³, detailing our grave medical and ethical concerns about any rollout of COVID-19

vaccines to children in schools, setting out the potential legal liability of school leaders in the event of any resulting harm to children whilst in their care. We also raised concerns about vaccine promotion material being provided to schools by external organisations as "educational resources" which did not give the full and balanced information required to make an informed decision.

- 112. As previously stated, every decision to vaccinate an individual should only be taken with fully informed consent, following a comprehensive risk-benefit analysis for that individual. We argued that for children the benefits of COVID-19 vaccines were miniscule or zero and the medium- and long-term risks unknown, therefore legally valid informed consent would be impossible to obtain.
- 113. We were also very concerned about suggestions that Gillick Competence could be employed for older children to give consent to a COVID-19 vaccine against their parents' wishes and without their knowledge. We argued that it was not possible to assume Gillick Competence from the current knowledge of COVID-19 vaccine risks and the climate of coercive social pressure and propaganda surrounding the rollout.
- 114. At the beginning of September 2021, the UKMFA sent an urgent email⁵⁴ to the four UK Chief Medical Officers (CMOs) Professor Whitty, Dr McBride, Dr Smith and Dr Atherton, who had been asked by Rt Hon Sajid Javid (Secretary of State for Health and Social Care) to consider overruling the JCVI decision (the day before) not to recommend a COVID-19 vaccine rollout to healthy children aged 12-15 years. The JCVI had concluded that this was "not in the best medical interest of children" and the Government wanted the CMOs to consider non-medical justifications for rolling out the vaccines to this cohort e.g. educational benefits or benefits to wider society.
- 115. We urged the Chief Medical Officers to consider the high position of trust which had been bestowed on them and their professional duty as doctors to practice ethical medicine and to 'First do no harm', which should override all pressures brought to bear on them politically and from outside vested interests.
- 116. We reminded them that this decision would affect the health and lives of millions of children, with the risk of causing completely avoidable and unnecessary

- iatrogenic harm and deaths. We implored them to take a precautionary approach by rejecting any extension of the vaccine rollout to under-16s.
- 117. Regrettably, the CMOs bowed to political pressure and, after several days of deliberations, on 13 September 2021, approved the universal vaccination of under-16s with one dose of Pfizer-BioNTech COVID-19 vaccine, citing "the additional likely benefits of reducing educational disruption, and the consequent reduction in public health harm from educational disruption, on balance provide sufficient extra advantage in addition to the marginal advantage at an individual level identified by the JCVI to recommend in favour of vaccinating this group"55.
- 118. Following the CMOs' decision to recommend the vaccines to children aged 12-15 years, we sent Freedom of Information Requests to each CMO Prof Chris Whitty (England)⁵⁶, Prof Sir Michael McBride (Northern Ireland)⁵⁷, Dr Frank Atherton (Wales)⁵⁸ and Dr Gregor Smith (Scotland)⁵⁹. We asked for the evidence on which they based their decisions, names of other individuals involved in making the decision, and conflicts of interest of all individuals involved in the decision-making process. We also asked for copies of minutes of meetings relevant to this process. We did not receive a substantive reply from any of the CMOs.
- 119. In February 2022, UKMFA launched a "Time to Pause" campaign⁶⁰, calling for an urgent pause of the Children's COVID-19 vaccine rollout. This followed the release of new data showing an unexplained rise in all-cause mortality for males aged 15-19 years since the Pfizer vaccine was rolled out to this age group. This included ONS data suggesting 2-3 excess deaths per week of teenage boys in the UK correlating with the vaccine rollout and further published data showing that myocarditis is a very significant risk from the vaccines for this cohort. This was also in the context of the emergence of the milder variant Omicron, which the vaccine has poor efficacy for, and the high levels of natural immunity in children estimated at 80-90% at that time.
- 120. As part of our Time to Pause campaign, I co-signed an Open Letter to the JCVI from the Children's Covid Vaccine Advisory Group (CCVAG)⁶¹ and co-signed by over 700 medical professionals, calling for an immediate pause to the COVID-19 vaccine rollout to children, pending a public inquiry.

- 121. In February 2022, UKMFA also published an Open Letter with Notice of Legal Obligations and Potential Liabilities to anyone Advocating or Administering COVID-19 Vaccines to Children⁶², addressed to Public Officers in both their personal and professional capacities. It notified them of their legal duties to any children in their care, in their capacity as a teacher, healthcare professional, public office holder, carer or parent, and the potential legal position should they breach those duties. We encouraged members of the public to distribute this letter as required, to educate and inform all those participating in the COVID-19 vaccine rollout to children.
- 122. In the letter, we argued that administering COVID-19 vaccines to children was not justifiable, presenting evidence on the following points: COVID-19 vaccines do not benefit children; COVID-19 vaccines do not prevent infection or viral transmission; the safety of the COVID-19 vaccines had not been established; informed consent and application of Gillick Competence.
- 123. On 22 February 2022, I participated in a press conference⁶³ organised by Dr Ros Jones, retired Paediatrician and CCVAG Chair, to raise awareness of new and alarming safety signals relating to COVID-19 vaccine safety in children and young people. The expert panel from the Children's Covid Vaccine Advisory Group (CCVAG) included Professor David Livermore, Professor Angus Dalgleish, Dr Ros Jones, Dr Clare Craig and me. We presented new evidence to journalists concerning the unfavourable risk-benefit balance of the Pfizer-BioNTech COVID-19 vaccine for children. The audience also heard from Maxwell Harrison, a vaccine-injured young adult.
- 124. In June 2022, we became aware of a disturbing NHS COVID-19 vaccine advertising campaign that appeared to be aimed directly at children aged five to 11 years. I wrote an article, published in The Daily Sceptic, to highlight our concerns⁶⁴.
- 125. Targeting young children to encourage them to desire a medical product seriously compromises the fundamental principles of medical ethics and undermines the process of full and informed consent. The adverts were sent to parents of children in several primary schools, promoting COVID-19 vaccine popup clinics for primary school-age children. The poster was designed in the style of

a children's party invitation, with cartoon superhero branding, large writing and bright, eye-catching colours and, disturbingly, was addressed directly to children, "Calling All Superhero Kids". The advert was for a medical intervention yet did not include any mention of potential risks associated with the COVID-19 injection, compromising informed consent.

- 126. For the NHS to directly target young children to encourage them to take a novel medical treatment, in such a superficial and coercive way, was completely unethical and abhorrent. To comply with the laws and ethical codes for informed consent, all medical decisions require a full disclosure of risks, benefits and alternatives to treatment, and an individualised risk-benefit analysis, in a sober discussion between a qualified healthcare professional and the patient, or parent/guardian of a child under 16 (the legal age of consent). 'Gillick Competence', where an individual child is deemed intellectually and emotionally mature enough to make a medical decision for themselves, is occasionally used for children under 16 years, although almost never for those under 13 years, and can only be ascertained after full psychological assessment by a trained professional.
- 127. In addition to the laws and professional codes of practice around informed consent, these adverts appeared to breach well established Advertising Standards Agency (ASA) rules relating to advertising to children. ASA Advertising Codes contain strict rules to protect children under 16 years from potentially misleading, harmful or offensive material, because children are less likely than adults to be able to understand or process commercial messages in advertisements and are more susceptible to being subtly manipulated. In general, the younger the child, the more susceptible he or she is. In addition, the Government's own guidance around advertising medicines states "You must not... direct your advertising at children (under-16s)."
- 128. In July 2023, UKMFA and CCVAC sent an open letter⁶⁵ (cosigned by over 120 doctors, scientists and healthcare professionals) to the Chief Executives and Chairmen of all NextCOVE trial participating centres and NHS Trusts, Dame June Raine (MHRA CEO) and the Chairs of all Local Research Ethics Committees. We expressed deep concerns regarding the NextCOVE trial of Moderna booster vaccines being carried out on UK children aged 12-17 years. We argued that this

trial contravened medical ethics laws and codes, including the Declaration of Helsinki, the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Universal Declaration on Bioethics and Human Rights (2005), as there is no benefit to children and a significant risk of serious harm. In addition, known serious side-effects, such as myocarditis, were not mentioned on the trial information leaflet for participants.

Vaccine Safety and the Failure of MHRA Post-marketing Surveillance

- 129. We have witnessed the complete failure of effective post-marketing safety surveillance by the UK Medicines & Healthcare products Agency (MHRA). UKMFA has repeatedly directly raised concerns with them, regarding potential safety signals that should have been investigated.
- 130. We believe that UKMFA was one of the first groups to openly and publicly link the early COVID-19 vaccine rollout in care homes to a spike in deaths in that cohort, in our open letter sent on 7 February 2021 to Matt Hancock, Nadim Zahawi, Boris Johnson, the MHRA and the JCVI⁶⁶. We raised concerns about national and international media reports and epidemiological data which indicated there may be a link between COVID-19 vaccination and a rise in deaths and COVID-19 cases reported in care homes and the elderly. We called for an urgent audit and investigation into all deaths that had occurred in these cohorts since the COVID-19 vaccine rollout began. To date none has been published.
- 131. At the end of October 2021, UKMFA published an urgent open letter to Scottish Health officials raising the alarm about a recent trend in Scottish excess mortality⁶⁷, which was significantly out of range compared to averages from the previous 40 years over the summer / autumn period and was continuing to rise week on week. This did not correlate with deaths involving COVID-19, implying another causative factor.
- 132. We noted that the inflection in the trends towards rising excess mortality occurred in a staggered fashion according to age groups, which appeared to correlate with the age cohort staggered rollout of the COVID-19 vaccines. We asked for an urgent

- investigation into this serious situation and for appropriate action to be taken to mitigate any further excess deaths.
- 133. Following the lack of response to our open letter dated 26 October 2021, we wrote again to the Scottish Government in December 2021⁶⁸, highlighting ongoing and grave concerns about the continuing and rising excess all-cause mortality and to demand reassurance as to the following:
 - That the Scottish Government had acknowledged and considered the implications of the data we had presented pertaining to significant excess all-cause mortality in Scotland.
 - ii. That the Scottish Cabinet had formulated a plan for how to address the crisis of steadily rising excess all-cause mortality across all age groups in Scotland.
 - iii. That the Scottish Government had analysed and reviewed in detail the impact and risk assessment of COVID-19 policies, including restrictions of movement and social interactions (lockdowns), wearing of face coverings and COVID-19 vaccinations.
- 134. In a chain of correspondence between October 2021 and June 2022 between the Scottish Government Health and Social Care Analysis team and UKMFA (published in full on our website in "Further Correspondence" under the Open Letter), Scottish Government statisticians repeatedly assured us that there was no evidence that COVID-19 vaccines were responsible for excess mortality but said that they would continue to closely monitor excess deaths.
- 135. Public Health Scotland pointed us to the Medicines and Healthcare Products Regulatory Agency (MHRA) as bearing responsibility for the monitoring of safety of all vaccines, to ensure their benefits continue to outweigh any risks, so in July 2022, we sent a Freedom of Information (FOI) request to the Dame June Raine, MHRA CEO⁶⁹, asking for documents or minutes of meetings analysing Scottish excess all-cause mortality data, as well as Scottish data regarding ambulance callouts for

cardiac events in young people and their temporal associations with COVID-19 vaccinations. We highlighted the striking temporal association between both all-cause mortality and cardiac morbidity and COVID-19 vaccination in different age groups.

- 136. Following an unsatisfactory response from the MHRA⁷⁰, stating that they did not hold the data requested, there was further correspondence between the MHRA and UKMFA including a new FOI sent on 31 October 2022 to Dame June Raine⁷¹ in which we asked for the COVID-19 vaccine safety data criteria they had set (e.g. number of deaths or injuries reported to Yellow Card) that would trigger either a formal safety study or would prompt a halt to the vaccine rollout.
- 137. Despite repeatedly chasing up the MHRA, there was no response to our second FOI, so we wrote to the Information Commissioner's Office (ICO)⁷² to ask them to investigate.
- 138.In May 2023, the ICO issued their decision notice⁷³ in which they upheld our complaint, ruling that the MHRA had breached section 10(1) of the FOIA by failing to provide a valid response to the request within the statutory time frame of 20 working days. The Commissioner instructed MHRA to provide a substantive response to our FOI request within 35 calendar days, warning them that failure to comply may be dealt with as a contempt of court.
- 139.We received a letter from the MHRA⁷⁴ in June 2023 in which they admitted to holding some of the information requested but claiming an exemption due to the cost involved. They did admit that they had <u>no</u> set criteria to trigger an epidemiological study regarding a safety concern. They also disclosed that they do not ascribe causality to individual reported deaths; do not make decisions on vaccination policy; and wanted us to note that "most people receive vaccinations without having any serious side-effects".
- 140. UKMFA responded to the MHRA by email⁷⁵ requesting an internal review, on the grounds that we had received no documentation relating to any of our questions and challenging their use of the Section 12 FOIA exemption. The result of the internal review, published on 4 August 2023⁷⁶, was to rule that the Section 12

- exemption used to withhold requested data was justified based on the cost involved in locating and making the documents available.
- 141.We were unhappy with the result of the MHRA internal review so, in November 2023, we asked the ICO to investigate our belief that the MHRA had not only failed to respond to our FOI request in any meaningful way, as we had received no supporting documents, but had also failed to reassure us that they were carrying out their assigned task of COVID-19 vaccine safety monitoring in a reliable and responsible manner.⁷⁷
- 142. Frustratingly, on 14 November 2023, the ICO informed us that due to "undue delay" of more than 6 weeks in submitting our complaint following the MHRA internal review notification, they were closing the case and that we would need to submit a new FOI to MHRA⁷⁸.
- 143. In December 2023, with the MHRA's continuing support of recommendations to administer COVID-19 vaccines and boosters to many cohorts including pregnant women, we submitted an FOI⁷⁹ to MHRA CEO, Dame June Raine, requesting disclosure of documents that supported their assurance of safety of the vaccines, specifically relating to carcinogenicity, autoimmunity and genotoxicity. We asked them to provide these within 20 days as required under the FOIA.
- 144. We were disappointed to receive an interim email response from the MHRA FOI team invoking sections 43(2) and 22 of the FOI Act, which extended the deadline for a substantive response until the 19 January 2024. In the final response⁸⁰, the MHRA argued that the scope of our request was too broad and therefore they refused to release any of the supporting documents we had requested.
- 145. We were not satisfied with this response so requested an internal review. However, the internal review⁸¹, received on 7 March 2024, supported the MHRA's actions and decision, on the grounds that "compliance with the request would far exceed 24 working hours." We have now asked the Information Commissioner's Office (ICO) to investigate the failure of the MHRA to meaningfully engage with our FOIs and await their response.

<u>UKMFA Formal Engagement with UK Government Departments, the Devolved</u> <u>Administrations and other Public Bodies</u>

146. All our COVID-19 vaccine-related open letters are published on our website⁸². We have referred to many of them in this Witness Statement already and given detail of the content. Of note regarding formal engagement with the UK Government, the devolved administrations and other public bodies, the main letters are as follows:

(a) Open Letters to UK Government

- 147. Our first 14-page, fully evidenced and referenced Open Letter to the MHRA, JCVI and Secretary of State for Health and Social Care (Rt Hon Matt Hancock) regarding the any authorisation and rollout of COVID-19 vaccines, was sent on 23 November 2020 (before the MHRA issued the Temporary Authorisation of the AZ Vaccine)⁸³. Our letter argued that a rushed rollout of any COVID-19 vaccine would seriously compromise public safety and medical ethics, and also infringe on UK and International Law, and urged them not to authorise or rollout the vaccines at that stage (See also sections 33-38 for more detail).
- 148. Open Letter to Rt Hon Matt Hancock, Rt Hon Nadim Zahawi, Rt Hon Boris Johnson (Prime Minister), the MHRA and the JCVI (07 February 2021), highlighting media reports and epidemiological data indicating a possible link between COVID-19 vaccinations and the rise in deaths and COVID-19 cases reported in care homes and the elderly⁸⁴. We called for an urgent audit and investigation into all deaths that had occurred in these cohorts since the COVID-19 vaccine rollout began. To date none has been published. (Further detail in section 130).
- 149. Open letter to Child Health Experts/Officers, Rt Hon Nadhim Zahawi, JCVI, and MHRA (25 February 2021), referencing the current scientific evidence clearly showing (even then) that the risk v benefit calculation did NOT support administering experimental COVID-19 vaccines to healthy children⁸⁵. (Further detail in sections 101-102).

- 150. Joint open letter with Lawyers for Liberty to the Prime Minister, all the First Ministers, Rt Hon Matt Hancock, Rt Hon Michael Gove, Rt Hon Nadhim Zahawi and other MPs (27 February 2021)⁸⁶, detailing grave legal, ethical, and medical concerns regarding the introduction of vaccine/immunity passports, which would also have significant social, economic, and political implications. We argued that vaccine passports represented a dangerous path which has no place in a democratic and free society, and which would be a profoundly illiberal, undemocratic, and un-British policy.
- 151.We received a reply from Nadhim Zahawi in May 2021⁸⁷, stating that "Our objective is to vaccinate as many people as possible, in line with the advice of the Joint Committee on Vaccination and Immunisation" and that "To increase vaccine uptake, the Government is considering amending the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. This would mean that older adult care home providers could only use those staff who have received the COVID-19 vaccination (or those with a legitimate medical exemption) in line with the Government's guidance".
- 152. Open letter to Helen Whately (Minister of State for Care) (27 January 2021)⁸⁸, challenging an unsubstantiated and misleading claim for COVID-19 vaccine efficacy in a Government publication which stated that "for every 20 care home residents vaccinated, one death is prevented".
- 153. Urgent email to the four UK Chief Medical Officers (06 September 2021)⁸⁹, imploring them not to override the JCVI decision not to recommend rolling out the COVID-19 vaccines to children aged 12-15 years. (Further detail in sections 114-118).
- 154. Following the CMOs' decision to recommend rolling out the COVID-19 vaccines to children, on 22 October 2021 we sent a Letter before Action⁹⁰ to Prof Chris Whitty (UK Government Chief Medical Adviser), Dr Gregor Smith (Chief Medical Officer for Scotland), Dr Frank Atherton (Chief Medical Officer for Wales) and Dr Michael McBride (Chief Medical Officer for Northern Ireland). Our letter addressed them in both their personal capacity and professional capacity as Chief Medical Officers, placing them on notice as to their duties as a public office holder and the legal

position should they breach those duties in reference to any and all harms caused by decisions that they had made or complied with, pertaining to COVID-19 vaccinations and any and all related mandates including vaccine passports or certification.

- 155.In our letter we stated that despite mounting and persistently emerging evidence regarding concerns about the safety of COVID-19 vaccines, including life-threatening adverse events and deaths, they continued to promote them to be administered to the British population and had participated in the recommendations to vaccinate pregnant women and children, despite no validated safety data at that point. We reminded them that, as medical professionals, they are legally obliged to adhere to the principles of Good Medical Practice as set out by the General Medical Council (GMC).
- 156. We summarised specific concerns about the safety of COVID-19 vaccines for their urgent attention and stated that in our opinion "Failure to acknowledge and investigate these grave concerns is nothing but irresponsible and grossly negligent" and that their "failure to give proper consideration to the insufficiencies of the post-marketing surveillance is also grossly negligent". We urged them to stop any further COVID-19 vaccine rollout, pending a full investigation of injuries and deaths reported to date.
- 157. The reply we received from the Scottish CMO's legal team⁹¹ challenged the legal basis of our claim and stated that they would therefore not provide a substantive response to the issues we raised. However, they did reveal that "it is the Scottish Government, not the CMO, who has responsibility for the vaccination programme in Scotland. Accordingly, it is not within the power of the CMO to halt the vaccination programme in Scotland as you request".
- 158. The reply we received from the Welsh Government Health and Social Services representative⁹² confirmed that the CMO is not ultimately responsible for medical advice received by the Welsh Government and no individual is ultimately responsible for this medical advice, as it was based on input from a variety of stakeholders. They stated that the JCVI was not overruled as they are merely an advisory body, and that the devolved nations are ultimately responsible for

decisions on their governmental policy. They declared no conflicts of interest and said that "the Minister for Health and Social Services met with the CMO for Wales to discuss the rationale behind the UK's CMOs' advice. No minutes were taken at this meeting, however the rationale behind the decision to accept of [sic] the advice is explained in the written statement that was issued".

159. In February 2024, in light of the ongoing and highly concerning levels of excess deaths in the UK and Western world, UKMFA teamed up with HART and CCVAC to write a letter to the current Health Secretary, Victoria Atkins⁹³, demanding an urgent investigation into the possible role of the COVID-19 mRNA vaccines in the recorded rise in ill-health, disability and deaths. We also called on them to immediately suspend the COVID-19 Booster programme, pending an immediate review of vaccine safety. The letter was co-signed by over one hundred health professionals and academics.

(b) Open Letters to the Scottish Government

- 160. Urgent open letters to Scottish Health Officials regarding alarming Scottish excess mortality data (29 October 2021)^{94 95}, detailed in sections 131-134.
- 161. Open Letter to Scottish Chief Medical, Nursing and Pharmaceutical Officers regarding the COVID-19 vaccine rollout in Scotland (01 June 2021)⁹⁶, in response to their recent update on the Scottish COVID-19 vaccination program sent to Scottish Health Boards and Local Authorities. We detailed our concerns about the implications of the continued rollout of this program, specifically with regards to pregnant women, and highlighted the paucity of scientific evidence to support current policies and the potential risks of harm, especially to those population cohorts not represented in clinical COVID-19 vaccine trials (more details in sections 92-94).

(c) Open Letters to other Public Bodies

162. Please refer to section numbers 33-38, 60 (i-iii), 83-99, 101-109 and 128 above, for details of relevant letters UKMFA sent to the General Medical Council (GMC),

Nursing and Midwifery Council (NMC), MHRA, JCVI, the Care Quality Commission (CQC) and NHS Fertility Centres, raising ethical and safety concerns about the general COVID-19 vaccine rollout as well as highlighting the risks to specific cohorts such as pregnant women and children.

- 163. On 5 July 2023, UKMFA wrote a joint open letter⁹⁷ with Doctors for Patients UK and HART (and co-signed by nearly 100 doctors and health professionals) to the WHO Director General, Dr Tedros Adhanom Ghebreyesus, Dr Hans Kluge (WHO Regional Director for Europe), Dr Michael Ryan (Executive Director, WHO Health Emergencies Programme) and Dr Jeremy Farrar (WHO Chief Scientist), highlighting the experience of clinicians who are seeing many patients with severe diseases that appear linked to COVID-19 vaccines rather than SARS-CoV2 infection. We also highlighted data indicating that the COVID-19 vaccines appear to have a far higher rate of adverse events than all other vaccines. We called on the WHO to urgently introduce "COVID-19 vaccine-induced side effects and related disorders" as an umbrella term disease state in the International Statistical Classification of Diseases and Related Health Problems (ICD), in order to begin to assess the scale and magnitude of the problem.
- 164. We did not receive a reply from the WHO until 5 months later, on 28 December 2023. In their letter they assured us that the WHO has been monitoring COVID-19 vaccine safety regularly and requested that we raise our concerns and solutions via the ICD-11 proposal mechanism, for stakeholder consideration.

Published UKMFA Reports and Evidence

(a) Public Consultation Submissions

165. UKMFA Submission to UK Government Public Consultation on COVID-19 Status Certification (26 March 2021)⁹⁸. This was a joint submission with Lawyers for Liberty and Workers of England Union. We argued that any policy requiring the public to disclose their COVID-19 status in order to access basic human freedoms of movement and association would be disproportionate and unnecessary,

undermining the right of the individual to freely decide whether or not to accept the offer of a medical treatment. We believed that the introduction of an official government Covid Status Scheme would result in an indirect mandate, allowing pressure to be applied by private companies and other authorities, who would be able to demand a valid Covid Status Certificate as a condition of service provision.

- 166. In the context of all vulnerable groups having been offered COVID-19 vaccines, with the rest of the population able to choose to have one if they wished, we voiced serious concerns that further draconian restrictions and loss of freedoms, entailed by any sort of formal Covid Status Certification, would permanently increase state power over our lives and set a dangerous precedent. We stated that "Covid Status Certification has no place in a democratic and free society and would be a profoundly illiberal, undemocratic, unlawful, and un-British policy. We urge you not to pursue this dangerous path towards totalitarianism."
- 167. In April 2021, UKMFA submitted a formal response to the UK Government Public Consultation on COVID-19 Vaccine Status Certification⁹⁹, detailing our objections on medical, scientific, ethical, legal, human rights, discrimination, social cohesion and economic grounds.
- 168. In May 2021, UKMFA submitted a formal response to the UK Government Public Consultation "Making COVID-19 Vaccines a Condition for Deployment in Older Adult Care Homes" objecting in the strongest terms to such an unethical and unscientific policy.
- 169. In October 2021, UKMFA submitted a formal response to the UK Government Public Consultation "Mandatory COVID-19 Vaccines for NHS and wider Care Sector Workers" 101, which sought views on mandatory vaccines for NHS and all social care employees, setting out our objections to this unscientific and unethical policy.
- 170. In June 2022, UKMFA submitted a formal response¹⁰² to the US FDA's Public Consultation on Extending Pfizer COVID-19 Vaccine EUA to Children under 5 years, for consideration at the VRBPAC meeting on 15th June 2022, which discussed expanding the EUA for the Pfizer COVID-19 vaccine to babies and

children aged 6 months to 5 years of age. We highlighted and evidenced multiple reasons as to why it would be completely reckless and a gross violation of medical ethics to further extend the EUA to the youngest cohort of babies and children.

(b) COVID-19 Inquiry Core Participant Applications

- 171. On 30 March 2022, UKMFA submitted a formal comment on the Public Inquiry Draft Terms of Reference¹⁰³, raising concerns that there were no current Terms of Reference examining whether Government policies had ignored and violated fundamental individual human rights and legal obligations concerning Informed Consent and Bodily Autonomy during the pandemic.
- 172. On 02 December 2022, UKMFA applied to be Core Participants in the COVID-19 Inquiry Module 3 on Healthcare Systems Impact ¹⁰⁴. Regrettably, we were not granted Core Participant status.
- 173. On 30 June 2023, UKMFA applied to be Core Participants in the COVID-19 Inquiry Module 4 on COVID-19 Vaccines and Therapeutics¹⁰⁵. We were asked by Baroness Hallett to submit further evidence¹⁰⁶ but were ultimately refused Core Participant status.
- 174.In November 2023, I received a Rule 9 Request from the UK Covid-19 Inquiry Solicitors, to submit a Witness Statement covering matters set out in the Module 4 Provisional Outline of Scope for UKMFA, provided by the Inquiry Solicitors. I drafted and submitted the requested statement on 20 February 2024. Module 4 has since been postponed¹⁰⁷, with no rescheduled date published at the time of writing.

Lessons to be Learned and UKMFA Recommendations to the Inquiry

(a) Violation of Research Ethics in the Development of New Vaccines

175. The principles of clinical research should follow the guidelines of Good Clinical Practice (GCP). These principles are summarised in the UK policy

framework for health and social care research¹⁰⁸, which has 15 guiding principles. The first principle states that "The safety and well-being of the individual prevail over the interests of science and society." This implies that suspected potential safety issues should be particularly meticulously investigated in the regulatory trials. Regrettably, the principles of the studies into the safety of COVID-19 vaccines diverged very significantly from this acknowledged UK policy framework.

- 176. The original COVID-19 vaccine regulatory trials were not completed as designed, due to premature unblinding and the administration of the study product to the control group, affecting the power of the trial and eliminating the ability to gather medium- and long-term safety data.
- 177. Deviation from the approved trial protocol must never be allowed to happen, especially when developing a brand-new product, based on a novel technology. The decision by Government and regulators to allow the pharmaceutical companies to lose the control group in the regulatory clinical trials, by vaccinating the control participants, was disastrous and in violation of firmly established principles of research ethics. Maintaining the control group until the end of the clinical trials is essential for collecting the data required to establish safety.
- 178. No robust reporting system was set up to reliably capture and analyse potential adverse effects and it appears that any reports of injury and death in the trials were immediately declared to be unrelated to the administration of COVID-19 vaccines, without proper investigation. Participants in a clinical trial are required to immediately report any symptom of ill-health and it is the task of the study analysts to determine any possible association or causative link. When due process of ethical clinical research is followed, a single death of a healthy person would be enough to prompt a thorough and comprehensive investigation.
- 179. The entire approach of rolling out a novel and poorly tested product to the entire population without stringent procedures in place for reporting and capturing potential adverse events can only be described as profoundly unethical, grossly negligent and in stark violation of the basic principles of clinical research. The lack of due academic diligence applies to the study of

- COVID-19 vaccine safety in general but is particularly acute in relation to pregnant women, children and the indication for booster shots.
- 180. The possibility of adverse effects potentiated by repeated vaccination with 'booster' doses, such as autoimmune reactions / diseases, haematological or neurological disorders and carcinogenesis, has not been investigated. Whilst natural immunity to COVID-19 infection provides lasting and robust protection to a variety of variants, it is now clear that vaccine-induced immunity wanes quickly in a matter of months. The official response to this issue was to recommend vaccine boosters, however the effect of repeated doses on health were not studied in any trial and the resulting impact on the function of the immune system is therefore completely unknown.
- 181. Pharmaceutical companies must be incentivised to produce safe vaccines by being held fully accountable, both financially and criminally, for any harms resulting, as is the case for all other products. We have witnessed that it is not prudent for pharmaceutical companies, who stand to make vast sums of money from a new product such as the COVID-19 vaccine, to be allowed to carry out their own research without independent scrutiny of all the raw trial data and to be indemnified by the Government (taxpayer) for any harms arising. This creates an inherently unsafe system for the public, as there is no onus or pressure on the pharmaceutical company to produce a safe product, but simply to produce a product as quickly as possible and in as large quantities as possible, in order to maximise risk-free profit.

(b) Regulators' Duty is to Protect the Public not Enable Industry

182. An essential part of the safe practice of medicine involves adapting and adjusting to new data and safety signals. Medical history is littered with drugs and vaccines that were once considered safe and effective and were subsequently withdrawn from the market, months or years after their use was started, as unforeseen harms were identified. For example, the Swine Flu vaccine Pandemrix was rushed to market in the 2009 pandemic and then withdrawn two years later, after millions of doses had been given, when over a thousand children suffered the serious brain injury narcolepsy, not picked up in the trials.

- 183. In our opinion, the MHRA have failed in their role to properly assess the new COVID-19 vaccines and to take a precautionary approach relating to public safety. They appear to have put protection of the pharmaceutical industry above public safety. They have completely failed in their obligation to assess all evidence rigorously and soberly and to hold industry accountable for proving the safety of their products; instead taking claims of safety on trust and based on incomplete data sets.
- 184. Having knowingly taken a serious risk when authorising the vaccines with sparse and incomplete safety data and before the clinical trials were ended, the MHRA then failed to implement a robust post-marketing surveillance system that could have picked up the many safety issues that have subsequently emerged. They also failed to properly warn the public of the experimental nature of these products and to involve them in an active reporting system of any and all side-effects.
- 185. There should have been a high-profile public campaign to alert people and their doctors to have a low index of suspicion for new symptoms and illnesses that developed in the weeks or months post-vaccine.
- 186. We recommend that in future, an active surveillance system is planned whereby every person vaccinated with a new product should be given both a physical postage-free card and a link to a website run by the MHRA, and encouraged to report ALL new symptoms and illnesses that develop within 5 years post-vaccine.
- 187. It is vital that we maintain the ethical principles that underpin any civilised society and put the safety of children and pregnant women as our top priority and that we never again take such a reckless approach with new products. As all medical interventions carry a risk of harm, we have a professional duty to act with care and proportionality. It was unprecedented that a pharmaceutical product still in the clinical trial phase was recommended and allowed to be administered to children and pregnant women on such a mass scale. Without long-term safety data (on either the mRNA technology or the specific COVID-19 vaccines) the MHRA had

no evidence regarding any potential long-term effects on health or fertility, which would only become apparent over the next five to 10 years.

- 188. The UKMFA is calling for the medical profession, politicians and decision-makers to actively engage with the huge amount of published science and real-world data challenging the hypothesis that COVID-19 vaccines are 'safe and effective' and to listen to a multitude of eminent scientists, doctors and independent journalists laying the facts out for easy independent research and understanding. Science (unlike the dogma of 'The Science') involves constantly testing existing hypotheses and adapting and changing them when the facts change or new information comes to light. All viewpoints must be heard and there is no place for censorship of inconvenient truths.
- 189. UKMFA joins thousands of doctors and scientists around the world in calling for an immediate and complete halt to the COVID-19 mRNA vaccine rollout. In our opinion, it is unconscionable that with overwhelming evidence showing that the COVID-19 vaccines are neither safe nor effective, governments and public health authorities are *still* recommending and allowing the injection of COVID-19 vaccines into anyone, let alone into children and pregnant women.
- 190. Tragically, the vast majority of the medical profession and wider public were deceived by the powerful and incessant Government and media messaging that the vaccines would be our 'only way out' and that we should 'trust the science'. As a society, we now have an opportunity and responsibility to change course, to start to put things right and to hold accountable those people who failed in their duties and responsibilities to protect the public, so that this can never happen again.

(c) Violation of Medical Ethics and Informed Consent for COVID-19 Vaccination

- 191. Informed consent, the well-established, fundamental ethical principle in both medicine and law, has been seriously undermined by:
 - i. A lack of transparency and honesty from Government and Public Health bodies.

- ii. The "one-size-fits-all" approach of the COVID-19 vaccine rollout, which has completely failed to recognise individual variations in risk v benefit calculations.
- iii. Aggressive advertising and promotion of the COVID-19 vaccines by the Government, which has grossly overstated benefits and denied or downplayed the known and unknown risks to individuals.
- 192. Safety of these experimental products, which are still under emergency use authorisation, has not been prioritised and the public are still largely unaware of the serious safety concerns that we have raised since November 2020. All medical interventions are subject to the legal and ethical requirement that informed consent must be obtained, after a full explanation from a clinician who must disclose all material risks, benefits, and alternatives to treatment, including doing nothing. Informed consent is only valid if obtained without coercion or pressure, including any penalty or restriction resulting from a refusal to consent.
- 193. It is arguable that no one gave legally valid informed consent to the COVID-19 vaccines. UKMFA published a COVID-19 vaccine informed consent legal summary¹⁰⁹ and template "gold standard" consent form¹¹⁰ on our website in late 2020, to help the public and medical professionals to understand the information disclosure and process that would be necessary, in our professional opinion, to properly obtain informed consent for these products. We are aware that the standard NHS vaccination process did not cover all this detail.
- 194. Fundamental principles of medical ethics have been seriously undermined by Government policies concerning the COVID-19 vaccine rollout, especially vaccine mandates for Care Workers, also threatened for NHS workers. UKMFA worked hard to advocate for and support healthcare workers in understanding and accessing their legal and ethical rights¹¹¹.
- 195. Mandating COVID-19 vaccines breached ethical codes and the GMC/NMC codes of Good Medical Practice relating to informed consent and bodily

autonomy e.g. COVID-19 vaccine mandates for Social Care Workers. NHS staff are required to uphold the core principles of the NHS and medical ethics, including the right to informed consent. It is inconceivable that it is congruent with GMC and NMC Codes of Practice that care staff were denied the right to decline a medical intervention without coercion, penalty or restriction.

- 196. There must be an undertaking that governments are never again allowed to override individual medical choice or mandate medical treatments or vaccines as a condition of employment, even in an emergency.
- 197. The NHS Constitution has been seriously breached regarding ethical conduct through the policies and practices implemented over the last 3 years. The NHS Constitution for England states that "The NHS belongs to the people. It is there to improve our health and wellbeing, supporting us to keep us mentally and physically well, to get better when we are ill and, when we cannot fully recover, to stay as well as we can to the end of our lives".
- 198. There must be an acknowledgement that there are ethical red lines that should never be crossed, no matter what the circumstances, and policies must reflect this fact. Safeguarding individual rights and needs (including medical exemptions) and considering both physical and mental health requirements are important duties of those providing healthcare.
- 199. The way the COVID-19 vaccine rollout was conducted in the UK and around the world completely failed to adhere to well-established ethical practices, including the widespread use of glib marketing, coercion and even bribes. The fact that unethical psychological and marketing techniques were even used to attempt to influence and persuade our youngest children to take this vaccine, in the form of an NHS Superhero poster campaign, shows how far we strayed as a society from responsible and sober medical practice and from the Hippocratic Oath to "First do no Harm".
- 200. As a society, we have a duty of care to protect the youngest and most vulnerable in our society from predatory marketing campaigns whatever the

product, but particularly for medical treatments and interventions with

acknowledged risks. This must never be allowed to happen again.

201. It must be established beyond doubt that all future pandemic responses

acknowledge that fundamental individual human rights and medical ethics

must be invariably upheld and honoured. It is notable and of grave concern that

there is no current Term of Reference in the Covid-19 Public Inquiry to examine

how fundamental, individual human rights and legal obligations around Informed

Consent and Bodily Autonomy have been ignored and violated during the pandemic

by Government policies.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that

proceedings may be brought against anyone who makes, or causes to be made, a false

statement in a document verified by a statement of truth without an honest belief of its

truth.

Signed: Elizabeth A Evans

Dated: 10/05/24

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files.com/5fa5866942937a4d73918723/60a52808564c54c505f5ceea UKMFA Submission Mandatory Vaccines Care Home Workers.pdf

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- $^{22}\,\underline{\text{https://www.unesco.org/en/legal-affairs/universal-declaration-bioethics-and-human-rights?hub=66535}$
- ²³ https://pace.coe.int/en/files/29004/html
- ²⁴ https://www.ukmedfreedom.org/open-letters/ukmfa-open-letter-to-the-general-medical-council-regarding-the-covid-19-vaccine-rollout
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