Exhibits (MJS01 to MJS34)

Claimant: MJ Sutherland

Document Reference No: NE013712676GB

Exhibit MJS01 The Principles of Public Life in Scotland and Members' Code of Conduct

https://www.nhs.scot/wp-content/uploads/2020/06/Non-Executive-Development-Website-Principles-of-Public-Life-and-Fit-and-Proper-Person.pdf

Duty
You have a duty to uphold the law and act in accordance with the law and the public trust placed in you. You have a duty to act in the interests of the public body of which you are a member and in accordance with the core tasks of that body.

Selflessness
You have a duty to take decisions solely in terms of public interest. You must not act in order to gain financial or other material benefit for yourself, family or friends.

Integrity
You must not place yourself under any financial, or other, obligation to any individual or organisation that might reasonably be thought to influence you in the performance of your duties.

THIS IS THE **Exhibit MJS01** REFERRED TO BY CLAIMANT IN THE STATEMENT OF FACTS (Ref: NE013712676GB).

SIGNED _____ (CLAIMANT) Date: 16th September 2022

Exhibit MJS02 Covid Vaccine Clinical Trials

Pfizer (Main Trial):

Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals

https://clinicaltrials.gov/ct2/show/NCT04368728

ClinicalTrials.gov Identifier: NCT04368728

Recruitment Status : Active, not recruiting
First Posted : April 30, 2020
Last Update Posted : July 1, 2022

Note below table from above link to NCT04368728 - Biological: BNT162b2 in Phase 3

Condition or disease	Intervention/treatment	Phase
SARS-CoV-2 Infection	Biological: BNT162b1	Phase 2
COVID-19	Biological: BNT162b2	Phase 3
	Other: Placebo	
	Biological: BNT162b2SA	

Note estimated Phase 3 study completion date: February 8 2024

Study Design

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	46949 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Triple (Participant, Care Provider, Investigator)
Primary Purpose:	Prevention
Official Title:	A PHASE 1/2/3, PLACEBO-CONTROLLED, RA
	IMMUNOGENICITY, AND EFFICACY OF SARS-
Actual Study Start Date :	April 29, 2020
Estimated Primary Completion Date :	February 8, 2024
Estimated Study Completion Date :	February 8, 2024

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Exhibit MJS02 Covid Vaccine Clinical Trials (continued)

Further confirmation can be found on study (by 7 MD's and/or PhDs) "Serious adverse events of special interest following mRNA vaccination in randomized trials" (J Fraiman, P Doshi et al) downloadable from this link:

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4125239.

Note keywords on that link "Pfizer-BioNTech COVID-19 vaccine **BNT162b2**" and "**NCT04368728**"

Also note Pfizer trial No **NCT04368728** listed on Table 1 of that study matches the number on the link to the clinical trial.

Table 1. Data sources for phase III trials

Trial	Data cutoff date	Journal articles	FDA sources	Health Canada sources
Pfizer trial in ages 16 and above (NCT04368728)	14 Nov 2020 (supported Dec 2020 EUA)	Aggregate data only	**Table 23 in sponsor briefing document**	**Table 55 in sponsor document C4591001 Final Analysis Interim Report Body**
Moderna trial in ages 18 and above (NCT04470427)	25 Nov 2020 (supported Dec 2020 EUA)	Table S11 in publication	Table 27 in sponsor briefing document	**Table 14.3.1.13.3 in sponsor document mRNA-1273-P301 Unblinded Safety Tables Batch 1 (DS2)**

Note: bolded font indicates dataset chosen for analysis; EUA = Emergency Use Authorization

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Exhibit MJS02 Covid Vaccine Clinical Trials (continued)

Further confirmation of clinical trial status of Pfizer vaccine on this study:

BNT162b2 mRNA COVID-19 Vaccine: First Approval (Yvette N. Lamb)
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7938284/

Key clinical trials of BNT162b2 for the prevention of COVID-19 (sponsored by BioNTech)

Vaccine(s)	Phase	Status	Location(s)	Identifier
BNT162b2, BNT162b1, placebo	I/II/III	Active, not recruiting	Multinational	NCT04368728; C4591001; 2020-002641-42
BNT162b2	III	Not yet recruiting	US- and EU-manufactured batches	NCT04713553; C4591017
BNT162b2, BNT162a1, BNT162b1, BNT162c2	I/II	Recruiting	Germany	NCT04380701; BNT162-01; 2020-001038-36; U1111-1249-4220
BNT162b2, placebo	I/II	Active, not recruiting	Japan	NCT04588480
BNT162b2, placebo	II	Recruiting	China	NCT04649021; BNT162-06

Open in a separate window

- Under the section "Ongoing clinical trials" it states that "*The pivotal phase I/II/III trial (which has enrolled participants ≥ 12 years of age)* ***is ongoing***"

Key milestones in the development of the BNT162b2 mRNA COVID-19 vaccine. *WHO* World Heath Organisation

Note: *"Est. Jan 2023" phase 3 completion date has been put back to February 8th 2024 as evidenced.*

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Exhibit MJS02 Covid Vaccine Clinical Trials (continued)

Pfizer (Pregnant Women):

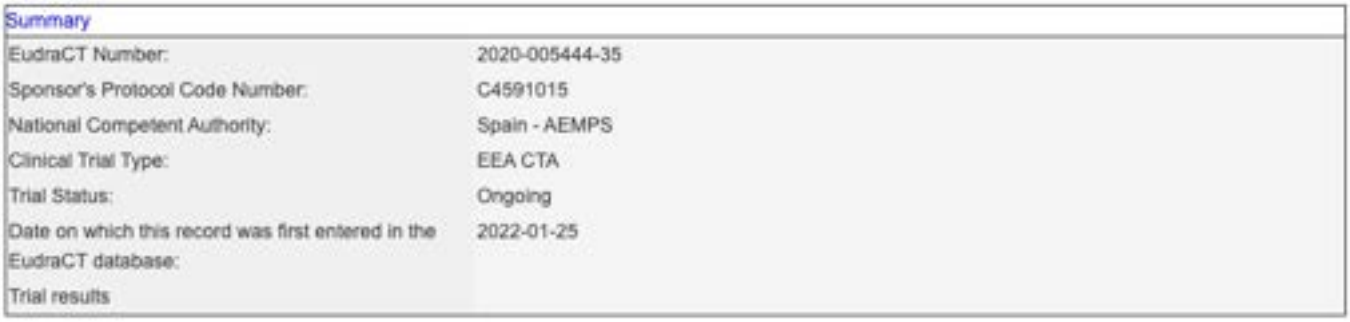
Study to Evaluate the Safety, Tolerability, and Immunogenicity of SARS CoV-2 RNA Vaccine Candidate (BNT162b2) Against COVID-19 in Healthy Pregnant Women 18 Years of Age and Older
https://clinicaltrials.gov/ct2/show/study/NCT04754594

Intervention/treatment	Phase
Biological: BNT162b2	Phase 2
Other: Placebo	Phase 3

Study Design

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	348 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Triple (Participant, Care Provider, Investigator)
Primary Purpose:	Prevention
Official Title:	A PHASE 2/3, PLACEBO-CONTROLLED, RANI
	SARS-COV-2 RNA VACCINE CANDIDATE (BNT
Actual Study Start Date :	February 16, 2021
Estimated Primary Completion Date :	July 26, 2022
Estimated Study Completion Date :	July 26, 2022

Note: as of 16th September 2022, the above link indicates "No Results Posted", and the EU Clinical Trials Register for this trial (EudraCT Number: 2020-005444-35) indicates that the trial status is "Ongoing"
(https://www.clinicaltrialsregister.eu/ctr-search/trial/2020-005444-35/ES).



Summary	
EudraCT Number:	2020-005444-35
Sponsor's Protocol Code Number:	C4591015
National Competent Authority:	Spain - AEMPS
Clinical Trial Type:	EEA CTA
Trial Status:	Ongoing
Date on which this record was first entered in the EudraCT database:	2022-01-25
Trial results	

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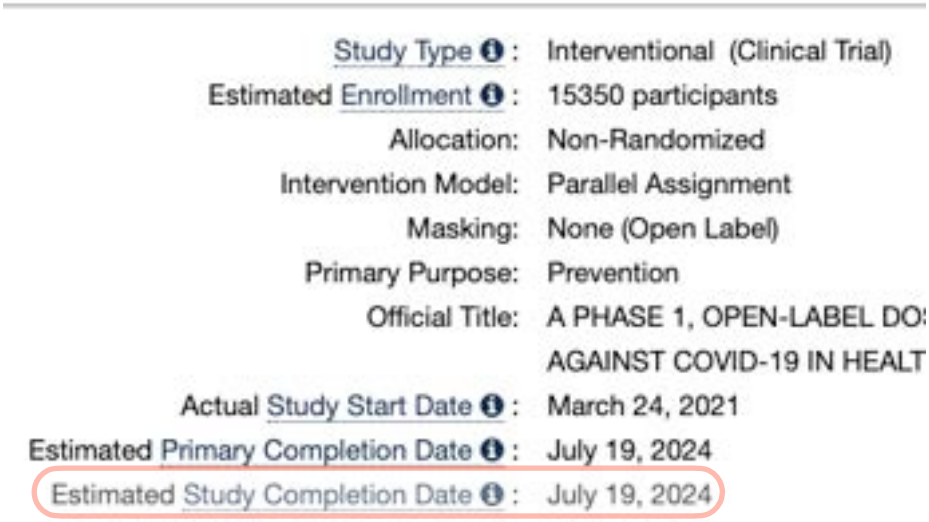
SIGNED _____ (DEPONENT) Date: 16th September 2022

Exhibit MJS02 Covid Vaccine Clinical Trials (continued)

Pfizer (Child Vaccine Study): https://clinicaltrials.gov/ct2/show/NCT04816643

A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, and Immunogenicity of an RNA Vaccine Candidate Against COVID-19 in Healthy Children and Young Adults

Intervention/treatment	Phase
Biological: Biological/Vaccine: BNT162b2 10mcg	Phase 2
Biological: BNT162b2 30mcg	Phase 3
Biological: BNT162b2 30mcg	
Other: Placebo	
Biological: Biological/Vaccine: BNT162b2 3mcg	



Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	15350 participants
Allocation:	Non-Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open Label)
Primary Purpose:	Prevention
Official Title:	A PHASE 1, OPEN-LABEL DO
	AGAINST COVID-19 IN HEALT
Actual Study Start Date :	March 24, 2021
Estimated Primary Completion Date :	July 19, 2024
Estimated Study Completion Date :	July 19, 2024

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Exhibit MJS02 Covid Vaccine Clinical Trials (continued)

AstraZeneca

Phase III Double-blind, Placebo-controlled Study of AZD1222 for the Prevention of COVID-19 in Adults

https://clinicaltrials.gov/ct2/show/NCT04516746?term=AZD1222&draw=2

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	32459 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Intervention Model Description:	Participants are assigned to o
Masking:	Quadruple (Participant, Care F
Masking Description:	Double Blind: two or more par
Primary Purpose:	Treatment
Official Title:	A Phase III Randomized, Doub
Actual Study Start Date :	August 28, 2020
Actual Primary Completion Date :	March 5, 2021
Estimated Study Completion Date :	February 24, 2023

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Exhibit MJS02 Covid Vaccine Clinical Trials (continued)

Moderna

A Study to Evaluate the Immunogenicity and Safety of mRNA Vaccine Boosters for SARS-CoV-2 (COVID-19) Variants

https://clinicaltrials.gov/ct2/show/NCT04927065?term=moderna&cond=COVID-19&draw=4&rank=119

Study Design

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	4658 participants
Allocation:	Non-Randomized
Intervention Model:	Sequential Assignment
Masking:	None (Open Label)
Primary Purpose:	Prevention
Official Title:	A Phase 2/3 Study to Evaluate
Actual Study Start Date :	May 28, 2021
Estimated Primary Completion Date :	March 31, 2023
Estimated Study Completion Date :	March 31, 2023

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Exhibit MJS02 Covid Vaccine Clinical Trials (continued)

https://www.nia.nih.gov/health/what-are-clinical-trials-and-studies

What are the four phases of clinical trials?

Clinical trials advance through four phases to test a treatment, find the appropriate dosage, and look for side effects. If, after the first three phases, researchers find a drug or other intervention to be safe and effective, the FDA approves it for clinical use and continues to monitor its effects.

Clinical trials of drugs are usually described based on their phase. The FDA typically requires Phase I, II, and III trials to be conducted to determine if the drug can be approved for use.

- A **Phase I trial** tests an experimental treatment on a small group of often healthy people (20 to 80) to judge its safety and side effects and to find the correct drug dosage.
- A **Phase II trial** uses more people (100 to 300). While the emphasis in Phase I is on safety, the emphasis in Phase II is on effectiveness. This phase aims to obtain preliminary data on whether the drug works in people who have a certain disease or condition. These trials also continue to study safety, including short-term side effects. This phase can last several years.
- A **Phase III trial** gathers more information about safety and effectiveness, studying different populations and different dosages, using the drug in combination with other drugs. The number of subjects usually ranges from several hundred to about 3,000 people. If the FDA agrees that the trial results are positive, it will approve the experimental drug or device.
- A **Phase IV trial** for drugs or devices takes place after the FDA approves their use. A device or drug's effectiveness and safety are monitored in large, diverse populations. Sometimes, the side effects of a drug may not become clear until more people have taken it over a longer period of time.

*Note: this confirms, in other words, that each vaccine is classed as an **experimental drug** and the **long-term side effects are unknown**.*

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Exhibit MJS03 IS IT A CLINICAL TRIAL OF A MEDICINAL PRODUCT? (MHRA Algorithm)

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/949145/Algorithm_Clean__1_.pdf

Exhibit MJS04 MHRA Conditional Approval for Emergency Use

Conditions of Authorisation for COVID-19 Vaccine Pfizer/BioNTech (Regulation 174)

https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/conditions-of-authorisation-for-pfizerbiontech-covid-19-vaccine

"**Vaccine BNT162b2** – Conditions of authorisation under Regulation 174"

"This authorisation under **Regulation 174** [see below] of the Human Medicine Regulations 2012 (as amended) is subject to a number of conditions attached under **regulation 174A(1)** [see below]…"

"This authorisation **is not a marketing authorisation**"

"Pfizer/BioNTech **ensure that clinical trials are performed** to national regulations and relevant guidelines…"

"Pfizer/BioNtech submit to MHRA GCP inspections to assess the compliance any of the **clinical trials**…"

"Pfizer/BioNTech must:
Submit protocols for the **studies** stated in the BNT162b2 RMP pharmacovigilance plan
Provide the **interim analysis and final clinical study reports for BNT162-01 once available**

————————————————————————

Regulations 174A and 247A: one-year review (Published 5 April 2022)

https://www.gov.uk/government/publications/changes-to-human-medicine-regulations-to-support-the-rollout-of-vaccines-one-year-review/regulations-174a-and-247a-one-year-review

"1. Introduction

The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 were laid in Parliament on 16 October 2020. The amendments made included the addition of regulation174A(R174A) that allows for conditions to be attached to the ***temporary authorisations of an unlicensed medicine, such as a COVID-19 vaccine****"*

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THESE ARE THE **Exhibits MJS03 and MJS04** REFERRED TO BY CLAIMANT IN THE STATEMENT OF FACTS (Ref: NE013712676GB).

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Exhibit MJS05 Unproven Interventions

World Health Organisation *"Emergency use of unproven clinical interventions outside clinical trials: ethical considerations"*

https://apps.who.int/iris/bitstream/handle/10665/352902/9789240041745-eng.pdf?sequence=1

Other terms for unproven intervention: Other terms often used to refer to unproven interventions or subgroups of unproven interventions in both ethics and regulatory documents are:

- *Lack of sufficient evidence*. This first group of terms refers to or implies lack of sufficient evidence for regular use of an intervention and includes the terms "unproven", "**experimental**", "**investigational**", "empirical", "untested", "unvalidated" and "non-validated".
- *Lack of full authorization*. A second group of terms refers to **lack of full authorization** by a relevant regulatory authority for regular use in a health system, such as "unregistered", "**unlicensed**", "unauthorized" and "unapproved"

————————————————————————

THIS IS THE **Exhibit MJS05** REFERRED TO BY CLAIMANT IN THE STATEMENT OF FACTS (Ref: NE013712676GB).

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Exhibit MJS05 Unproven Interventions (continued)

Email to/from the Secretary General of the World Medical Association

From: Mike Sutherland <mikesutherland@hotmail.co.uk>
Date: Tuesday, 12 July 2022 at 17:33
To: WMA WMA <wma@wma.net>
Subject: Unproven Interventions

Dear Sir/Madam,

As you will no doubt be aware, Article 37 of the Declaration of Helsinki deals with "unproven interventions".

Is there a specific official definition for this phrase that you can direct me to?

Is an unproven intervention something which has never had a clinical trial, or does it include a product that is still in ongoing clinical trials and has therefore not completed them?

Any advice you may have, or can direct me to, would be appreciated.

Thank you in advance.

Regards,
Mike

AW: Unproven Interventions

Otmar Kloiber <otmar.kloiber@wma.net>
Fri 15/07/2022 15:41

To: mikesutherland@hotmail.co.uk <mikesutherland@hotmail.co.uk>

Dear Mr. Sutherland,

The article aims to exclude a serial application of compassionate treatments which are neither proven nor are they "known treatments" (=conventionally accepted) thus circumventing the requirements for experimentation set by the Declaration of Helsinki.

This may apply to a treatment that is still under investigation in a trial, when being used not under the protocol of the ongoing trial.

Sincerely,

Dr Otmar Kloiber
Secretary General

World Medical Association, Inc.
13A chemin du Levant
01210 Ferney-Voltaire,
France

ph: +33 450 40 75 75
Fax: +33 450 40 59 37
E-mail: wma@wma.net
WEB: www.wma.net

THIS IS THE **Exhibit MJS05** REFERRED TO BY CLAIMANT IN THE STATEMENT OF FACTS (Ref: NE013712676GB).

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Exhibit MJS06 INVESTIGATIONAL MEDICINAL PRODUCT (IMP)

https://www.noclor.nhs.uk/imp

- *"a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial"* (refer to **MJS03**)
- *"Where there is any uncertainty as to whether the proposed use of a medicinal product within a clinical trial falls within the scope of Directive or not, refer to the MHRA algorithm"* (refer to **MJS04**)

Exhibit MJS07 Experimental

FDA Basics About Clinical Trials

https://www.fda.gov/patients/clinical-trials-what-patients-need-know/basics-about-clinical-trials

What is a placebo and how is it related to clinical trials?

A placebo is a pill, liquid, or powder that has no treatment value. It is often called a sugar pill. **In clinical trials, experimental drugs are often compared with placebos** to evaluate the treatment's effectiveness.

Is there a chance I might get a placebo?

In clinical trials that include placebos, quite often neither patients nor their doctors know **who is receiving the placebo and how is being treated with the experimental drug**. Many cancer clinical trials, as well as trials for other serious and life-threatening conditions, do not include placebo control groups. In these cases, all participants receive the **experimental drug**. Ask the trial coordinator whether there is a chance you may get a **placebo rather than the experimental drug**. Then, talk with your doctor about what is best for you.

Exhibit MJS08 Gene Therapy

BNT162b2 mRNA COVID-19 Vaccine: First Approval

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7938284/

- "Rapid response **genetic platforms** have facilitated rapid vaccine development. **Gene-based vaccines (which include**, among others, **mRNA vaccines** and DNA vaccines) carry **genetic instructions** for the production of an antigen by the cells of the vaccine recipient. For coronavirus vaccines, the target antigen is the surface **spike protein**…"
- On 2 December 2020, BNT162b2 received a **temporary emergency use authorization (EUA) in the United Kingdom** based on a rolling submission which included phase III data from a multinational **clinical trial** (NCT04368728)

Developments in Viral Vector-Based Vaccines https://pubmed.ncbi.nlm.nih.gov/26344749/

"Viral vectors are promising tools for gene therapy and vaccines."

THESE ARE THE **Exhibits MJS06** to **MJS08** REFERRED TO BY CLAIMANT IN THE STATEMENT OF FACTS (Ref: NE013712676GB).

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Exhibit MJS09 Genetic Modification

Australian Academy of Science "What is genetic modification?"

https://www.science.org.au/curious/earth-environment/what-genetic-modification

"It's still a very broad term, as there are many different techniques and technologies used... However, **they all involve adding, deleting, or turning on or off specific gene functions to achieve more desirable characteristics in an organism**." [ie, production of the foreign viral organism spike protein of Sars-CoV-2]

"How can you **change genes**? [...] To **change an organism's genetic makeup**, scientists can identify a specific gene that **produces a particular function or trait in one organism** [eg, production of the foreign viral organism spike protein of Sars-CoV-2], such as resistance to insect pests, then copy and isolate that gene to transfer it into another organism. If successful, that gene will then produce that function or trait in the **modified** animal, plant or microbe."

Genetic Modification: Definition, Advantages & Disadvantages

https://study.com/academy/lesson/genetic-modification-definition-advantages-disadvantages.html

"**Genetic modification** involves making **changes to an organism's genes** to give it **new traits that wouldn't occur in nature**"

"The technology also exists for **genetic modification** in humans, known as **gene therapy**"

Exhibit MJS10 Medicines for Human Use (Clinical Trials) Regulations 2004

https://www.legislation.gov.uk/uksi/2004/1031/2008-05-01/data.pdf

PART 1 Section 2 (Interpretation):

"clinical trial" means any investigation in human subjects, other than a non-interventional trial, intended—

(a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products,
(b) to identify any adverse reactions to one or more such products, or
(c) to study absorption, distribution, metabolism and excretion of one or more such products, with the object of ascertaining the safety or efficacy of those products

Exhibit MJS11 WMA DECLARATION OF HELSINKI – ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

THESE ARE THE **Exhibits MJS09** to **MJS11** REFERRED TO BY CLAIMANT IN THE STATEMENT OF FACTS (Ref: NE013712676GB).

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Exhibit MJS12 Covid-19 vaccination guidance to NHS Boards

https://www.publichealthscotland.scot/media/2932/covid-19-vaccination-guidance-to-nhs-boards-consent-in-care-homes-in-scotland.pdf

Exhibit MJS13 Green Book Chapter 2 Consent

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/994850/PHE_Greenbook_of_immunisation_chapter_2_consent_18_June21.pdf

Exhibit MJS14 The General Medical Council guidance for doctors on decision making and consent (2020)

https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent

Exhibit MJS15 The Ropewalk Chambers (Barristers regulated by the Bar Standards Board) *"Informed Consent: Updated GMC Guidance"*

https://www.ropewalk.co.uk/knowledge-sharing/blog/clinical-negligence/1790/informed-consent-updated-gmc-guidance

Exhibit MJS16 British Medical Association (2019). Consent and refusal by adults with decision-making capacity – A toolkit for doctors

https://www.bma.org.uk/advice-and-support/ethics/seeking-consent/seeking-patient-consent-toolkit

THESE ARE THE **Exhibits MJS12** to **MJS16** REFERRED TO BY CLAIMANT IN THE STATEMENT OF FACTS (Ref: NE013712676GB).

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Exhibit MJS17 Review of FOI 21-159

Dumfries and Galloway NHS Board

Chief Executive's Office
Freedom of Information

Ground Floor North
Mountainhall Treatment Centre
Bankend Road
Dumfries
DG1 4AP
☎ 01387 272752
✉ dg.feedback2@nhs.scot

Ref.: 21-159
Date: 14 June 2021

FREEDOM OF INFORMATION

I have now completed my review of our response to your request under the Freedom of Information (Scotland) Act 2002 (FOISA) for reference 21-159

As stated in our response the Scottish Government provides guidance to all Scottish Health Boards. This guidance is available on their website, with the following as a link to the documents and letters issued:
https://www.gov.scot/collections/coronavirus-covid-19-vaccination/

The COVID Vaccines are approved by the Medicines and Healthcare Regulatory Agency (MHRA) which regulates medicines in the UK and the Joint Committee on Vaccination and Immunisation (JCVI) advises UK health departments on immunisation. Recipients are not taking part in a 'Clinical Trial' as the vaccines have been approved as safe to use by the MHRA and JCVI.

NHS Dumfries and Galloway act in line with JCVI https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation and Scottish Government Guidance.

If you are unhappy with the outcome of this review you have the right to appeal to the Scottish Information Commissioner about our decision within 6 months of receiving this letter.
You can contact the Commissioner at:
The Scottish Information Commissioner
Kinburn Castle
Doubledykes Road
St Andrews
Fife KY16 9DS
E-mail: enquiries@itspublicknowledge.info
Telephone: 01334 464610

Yours sincerely

Jeff Ace
Chief Executive

THIS IS THE **Exhibit MJS17** REFERRED TO BY CLAIMANT IN THE STATEMENT OF FACTS (Ref: NE013712676GB).

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Exhibit MJS18 Coronavirus (COVID-19): vaccination

Collection of information and guidance on the coronavirus (COVID-19) vaccination programme.

https://www.gov.scot/collections/coronavirus-covid-19-vaccination/

Exhibit MJS19 Coronavirus (COVID-19): vaccination guidance for health and social care professionals

https://www.gov.scot/publications/coronavirus-covid-19-vaccination-guidance-for-health-and-social-care-professionals/

Exhibit MJS20 Coronavirus (COVID-19): guidance for use of Pfizer BioNTech vaccine in care homes

https://www.gov.scot/publications/coronavirus-covid-19-guidance-for-use-of-pfizer-biontech-vaccine-in-care-homes/

Exhibit MJS21 Coronavirus (COVID-19): vaccination of children and young people - letter from Chief Medical Officer Directorate

https://www.gov.scot/publications/vaccination-of-children-and-young-people-letter-from-chief-medical-officer-directorate/

THESE ARE THE **Exhibits MJS18** to **MJS21** REFERRED TO BY CLAIMANT IN THE STATEMENT OF FACTS (Ref: NE013712676GB).

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Exhibit MJS22 PCR TESTS

CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel (founding document for all PCR tests worldwide)

https://www.fda.gov/media/134922/download

Page 38

- **Detection of viral RNA may not indicate the presence of infectious virus or that 2019-nCoV is the causative agent for clinical symptoms**. *(3rd bullet point)*
- The performance of this test has not been established for monitoring treatment of 2019-nCoV infection. *(4th bullet point)*
- This test **cannot rule out diseases caused by other bacterial or viral pathogens**. *(6th bullet point)*

ThermoFisher TaqPath COVID−19 CE−IVD RT−PCR Kit (used by NHS Dumfries & Galloway)

https://assets.thermofisher.com/TFS-Assets/LSG/manuals/MAN0019215_TaqPathCOVID-19_CE-IVD_RT-PCR%20Kit_IFU.pdf

- the product is specifically for symptomatic use (*"intended for the **qualitative** detection of nucleic acid from SARS-CoV-2 [..] from **individuals suspected of COVID-19**"*)
- the product cannot be used as the basis for diagnosing someone with Covid-19, as "***clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status***"
- *"**Positive results do not rule out bacterial infection or co-infection with other viruses**."*
- *"**The agent detected may not be the definite cause of disease**."*

THIS IS THE **Exhibit MJS22** REFERRED TO BY CLAIMANT IN THE STATEMENT OF FACTS (Ref: NE013712676GB).

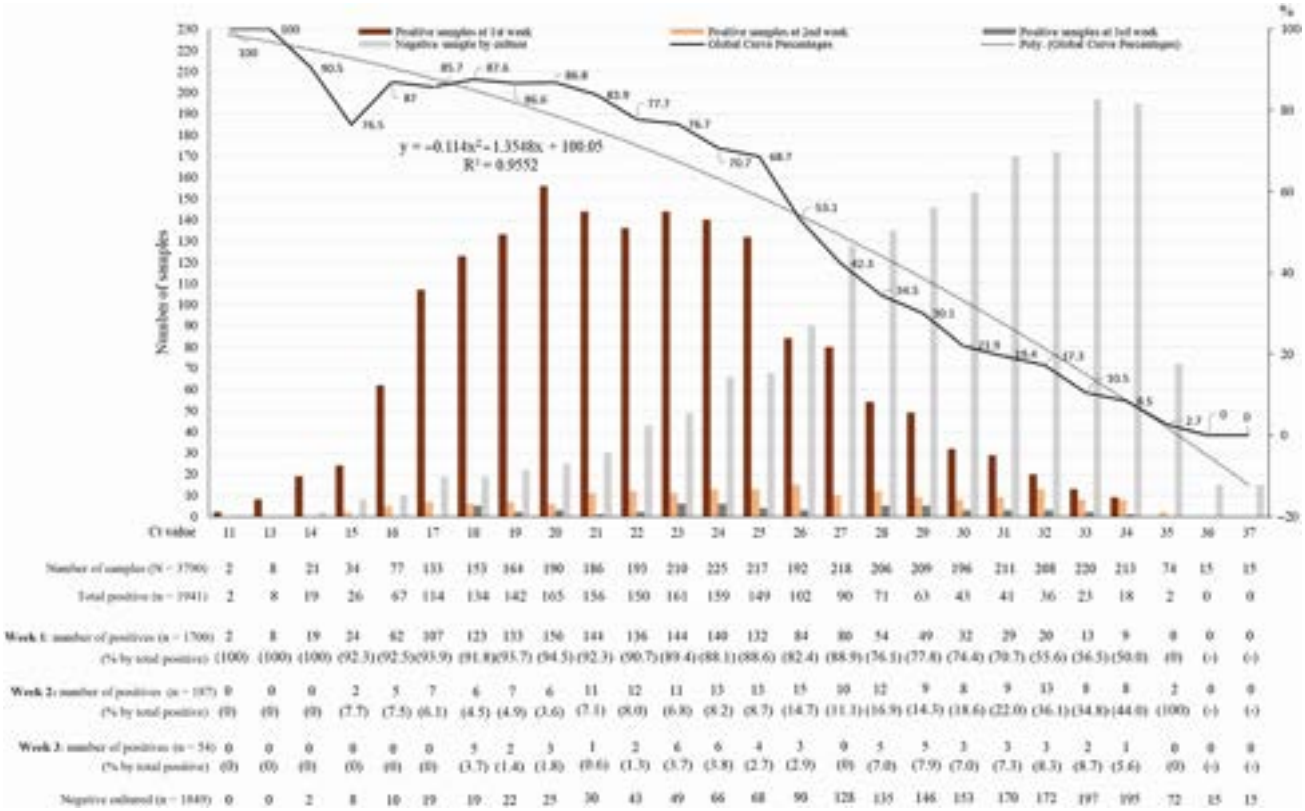
SIGNED _____ (CLAIMANT) Date: 16th September 2022

Exhibit MJS22 PCR TESTS (continued)

Study by Jaafar et al. (used as evidence in Lisbon court case (MJS)) *"Correlation Between 3790 Quantitative Polymerase Chain Reaction–Positives Samples and Positive Cell Cultures, Including 1941 Severe Acute Respiratory Syndrome Coronavirus 2 Isolates" (study*

https://academic.oup.com/cid/article/72/11/e921/5912603?login=false

"It can be observed that at Ct = 25, up to 70% of patients remain positive in culture and that at Ct = 30 this value drops to 20%. ***At Ct = 35, the value we used to report a positive result for PCR, <3% of cultures are positive****. Our Ct value of 35, initially based on the results obtained by RT-PCR on control negative samples in our laboratory and initial results of cultures [8], is validated by the results herein presented and is in correlation with what was proposed in Korea [9] and Taiwan [10]"*



Percentage of positive viral cultures of severe acute respiratory syndrome coronavirus 2 polymerase chain reaction–positive nasopharyngeal samples from coronavirus disease 2019 patients, according to Ct value (plain line). The dashed curve indicates the polynomial regression curve. Abbreviations: Ct, cycle threshold; Poly., polynomial.

The graph shows at 36-37 cycles the percentage of positive cultures is **ZERO**.

In Scotland PCR tests are run at **40 cycles**.

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Exhibit MJS22 PCR TESTS (continued)

"Covid-19 Target: A Specific Target for novel coronavirus detection" *(Khakhki et.el.)*

https://www.sciencedirect.com/science/article/pii/S2452014420301540?via%3Dihub

*"**RdRP, E and N genes are not completely exclusive for COVID-19**."*

———————————————————

"Diagnostic detection of 2019-nCoV by real-time RT-PCR" *(Corman et al)*

https://www.who.int/docs/default-source/coronaviruse/protocol-v2-1.pdf?%20sfvrsn=a9ef618c_2

*"All samples were successfully tested positive by the E gene assay. Detection of these relatively distant members of the SARS-related CoV clade suggests that **all Asian viruses are likely to be detected**."*

———————————————————

Dr Reiner Fuellmich, Corona Investigative Committee (@ 22:45):

https://youtu.be/E3Vc33-QWHI?t=1366

*"**The PCR Test is being used on the basis of false statements; NOT based on scientific facts with respect to infections**. In the meantime, we have learned that these PCR tests....**do NOT give any indication of an infection with any virus**, let alone an infection with Sars-Cov2. Not only are PCR tests expressly **not approved for diagnostic purposes** - as is correctly noted on leaflets coming with these tests, and **as the inventor of the PCR test Kary Mullis has repeatedly emphasised** - instead, they're simply **incapable of diagnosing any disease**. That is, contrary to the assertions of Drosten, Wieler and the WHO, which they have been making since the proclamation of the pandemic, **a positive PCR result does NOT mean that an infection is present**. **If someone tests positive it does not mean they are infected with anything**, let alone with the contagious Sars-Cov2 virus."*

———————————————————

HSE Health Protection Surveillance Centre *"Guidance on the management of weak positive (high Ct value) PCR results in the setting of testing individuals for SARS-CoV-2"*

https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/outbreakmanagementguidance/PCR%20weak%20results%20guidance.pdf

"There are very few reports of viable SARS-CoV-2 virus being retrieved in culture from clinical specimens with a Ct value of >34"

———————————————————

W.H.O. *"Diagnostic testing for SARS-CoV-2 Interim guidance 11 September 2020"*

https://apps.who.int/iris/bitstream/handle/10665/334254/WHO-2019-nCoV-laboratory-2020.6-eng.pdf?sequence=1&isAllowed=y

*Figure 1: Diagnostic flow diagram for the detection of acute SARS-CoV-2 infection in individuals with clinical suspicion for COVID-19 states "**Patient meets the clinical criteria for COVID-19**"*

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Exhibit MJS22 PCR TESTS (continued)

Dr Roger Hodkinson (CEO & Medical Director – MA, MB, FRCPC, FCAP)

http://deessoapbox.com/wordpress/?p=271

"And a word on testing," added Hodkinson. Reminding the committee he was in the business of COVID-19 testing, *"I do want to emphasise that* ***positive test results do not, underlined in neon, mean a clinical infection****. It's simply driving public hysteria and all testing should stop unless you're presenting to hospital with some respiratory problem."*

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Exhibit MJS23 LATERAL FLOW TESTS

Innova SARS-CoV-2 Antigen Rapid [Lateral Flow] Qualitative Test Instructions for Use
https://minhalexander.files.wordpress.com/2020/12/instructions-for-use-innova-sars-cov-2-antigen-test-ifu.pdf

- *"Test is a colloidal gold immunochromatography **intended for** the qualitative detection of nucleocapsid antigens from SARS-CoV-2 in human nasal swabs or throat swabs from **individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms**."* (ie, NOT for asymptomatic use)
- *"Positive results indicate the presence of viral antigens, but **clinical correlation with patient history and other diagnostic information is necessary to determine infection status**"*
- *"**Positive results do not rule out bacterial infection or co-infection with other viruses**"*
- *"**The agent detected may not be the definite cause of disease**."*
- *"Results from SARS-CoV-2 Antigen Rapid Qualitative Test **should be correlated with the clinical history, epidemiological data, and other data available to the clinician** evaluating the patient."*
- *"**The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection and performance may differ in asymptomatic individuals**."*
- *"Specimen stability recommendations are **based upon stability data from influenza testing and performance may be different with SARS-CoV-2**"*

BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test Instructions for Use
https://www.fda.gov/media/140443/download

- *"The BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test **should not be used to diagnose acute SARS-CoV-2 infection**."*
- *"**A positive result may not indicate previous SARS-CoV-2 infection**."*
- *"Results should only be used in conjunction with other clinical and laboratory data."*
- *"**Results** from antibody testing **should not be used to diagnose** or exclude acute **COVID-19 infection or to inform infection status**."*
- *"Positive results must be confirmed with another available method and interpreted in conjunction with the patient's clinical information."*
- *"**Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E**."*
- *"**A positive result may not indicate previous SARS-CoV-2 infection**."*

Healgen Scientific, *a wholly owned subsidiary of Zhejiang Orient Gene Biotech Co.,Ltd,* Coronavirus Ag Rapid Test Cassette (Swab)
https://mms.mckesson.com/resources/product-resources/healgen-covid-19-rapid-cassette-instructions-for-use

- *"The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) **should not be used to diagnose acute SARS-CoV-2 infection**."*
- *"**The sensitivity** of COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) early after infection **is unknown**."*
- *"This test **has not been FDA cleared or approved**."*
- *"**This test** detects the presence of SARS-CoV-2 IgM/IgG in the specimen and **should not be used to diagnose or exclude SARS-CoV-2 infection**."*
- *"**A positive result may not indicate previous SARS-CoV-2 infection**."*
- *"Samples with **positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made**."*

THIS IS THE **Exhibit MJS23** REFERRED TO BY CLAIMANT IN THE STATEMENT OF FACTS (Ref: NE013712676GB).

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Exhibit MJS24 Judgment of the Lisbon Court of Appeal

https://www-dgsi-pt.translate.goog/jtrl.nsf/33182fc732316039802565fa00497eec/79d6ba338dcbe5e28025861f003e7b30?_x_tr_sch=http&_x_tr_sl=pt&_x_tr_tl=en&_x_tr_hl=en-GB

Exhibit MJS25 Austrian court overturns judgment: PCR test not suitable for diagnostics (reference number VGW-103/048/3227/2021-2)

https://presseteam-austria.at/en/Austrian-court-overturns-judgment-that-pcr-test-is-not-suitable-for-diagnostics/

Exhibit MJS26 Weimar District Court, decision of April 8th, 2021, Az .: 9 F 148/21

https://www.covidtruths.co.uk/2021/04/sensational-verdict-from-weimar-no-masks-no-distance-no-more-tests-for-students/

Link to judgment: https://www.covidtruths.co.uk/wp-content/uploads/2021/04/Weimar-District-Court-decision-of-April-8th-2021-Az-9-F-148-2.pdf

Exhibit MJS27 Fraud Advisory Panel document *"Fraud in Scotland"*

https://www.fraudadvisorypanel.org/wp-content/uploads/2020/07/Fraud-in-Scotland-4th-ed-July2020.pdf

Exhibit MJS28 Misfeasance in Public Office

https://www.lawtonslaw.co.uk/resources/misfeasance-in-public-office/

What is misfeasance defined as in the UK?

> *"A form of misconduct, misfeasance in public office occurs when a public official, public servant or public body* ***knowingly and willingly acts in a manner with the realisation that their actions are likely to cause loss or harm to another. The action is legal, but is performed in a way that harms another****."*

https://legal-dictionary.thefreedictionary.com/misfeasance

> *A term used in Tort Law to describe* ***an act that is legal but performed improperly****.*

Exhibit MJS29 Wilful Neglect of Duty by a Public Official

https://www.lawcom.gov.uk/app/uploads/2016/01/misconduct_in_public_office_issues-1.pdf

> *"there is an offence in Scotland of "****wilful neglect of duty by a public official****". This offence is similar to the offence in England and Wales in some, but not all respects:* ***It is a crime at common law for a public official, a person entrusted with an official situation of trust, wilfully to neglect his duty****, even where no question of danger to the public or to any person is involved."*

Exhibit MJS30 Medical Malpractice

https://www.standardsofcare.org/medical-malpractice/

> *"Medical malpractice is a kind of negligence, and there are many reasons why a patient may have been harmed. It may be the result of an* ***error in making a diagnosis****, making a mistake with treatment or medication, failing to diagnose or treat a condition, or many other mistakes,* ***omissions****,* ***incompetence****, or simply not providing good care based on* ***accepted standards of care****."*

THESE ARE THE **Exhibits MJS24** to **MJS30** REFERRED TO BY CLAIMANT IN THE STATEMENT OF FACTS (Ref: NE013712676GB).

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Exhibit MJS31 Child Maltreatment

Child maltreatment - recognition and management: What is it?

https://cks.nice.org.uk/topics/child-maltreatment-recognition-management/background-information/definition/

- *"The National Society for the Prevention of Cruelty to Children (NSPCC) defines child maltreatment as '**all forms of physical and/or emotional ill-treatment**"*
- *"Fabricated or induced illness — the **misrepresentation** of the child/young person as ill by the caregiver by fabricating or inducing symptoms."*

Email to/from N.I.C.E.

From: Mike Sutherland <mikesutherland@hotmail.co.uk>;
Received: Mon Mar 14 2022 06:48:20 GMT+0000 (Greenwich Mean Time)
To: NICE mail <nice@nice.org.uk>;
Subject: [EXTERNAL]:Fabricated or induced illness

CAUTION: This email originated from outside of the organisation. Do not click links or open attachments unless you recognise the sender and know the content is safe.

Hi there,

On the following link on your site https://cks.nice.org.uk/topics/child-maltreatment-recognition-management/background-information/definition/ it mentions this:

Fabricated or induced illness — the misrepresentation of the child/young person as ill by the caregiver by fabricating or inducing symptoms. The motivation is usually to obtain emotional or psychological benefit for the caregiver.

Does it count when the abuser makes out to the child that he is ill (when they are perfectly healthy) but no symptoms are fabricated or induced? If they tell the child that they're ill without the presence of any sort of health issues or without any diagnosis being made?

Thank you.

Regards,
Mike

EH-321859-K1B0F3:Fabricated or induced illness

National Institute for Health and Care Excellence (NICE) <nice@nice.org.uk>
Wed 23/03/2022 12:17
To: Mike Sutherland <mikesutherland@hotmail.co.uk>

Dear Mike,

Thank you for contacting the National Institute for Health and Care Excellence (NICE) regarding the Clinical Knowledge Summary (CKS) on child maltreatment.

CKS are developed by an external company called Clarity and are designed to summarise the evidence on the treatment of specific health conditions, however they do not constitute NICE guidance. We work with the publisher to make the CKS available on our website and, while they may refer to NICE guidance (if there is any that is relevant), they also use many other sources. They are written for health professionals working in primary care (usually GPs) however the guidance is freely available for anyone to access.

I have forwarded your query to Clarity, and they have advised:
"I think that it may be difficult to advise further with this particular question. However, the fabricated or induced illness as a form of maltreatment can involve a range of manipulative behaviours which could potentially include a scenario such as that described by your correspondent."

As the question is very specific, we suggest that you discuss this further with you own local health services.

I am sorry that we are unable to help you further but hope the above is useful.

Kind regards
Katy

THIS IS THE **Exhibit MJS31** REFERRED TO BY CLAIMANT IN THE STATEMENT OF FACTS (Ref: NE013712676GB).

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Exhibit MJS32 Wilkinson, R (on the application of) v Broadmoor Hospital, Responsible Medical Officer & Ors [2001] EWCA Civ 1545 (22 October 2001)

https://mansfield.bailii.org/ew/cases/EWCA/Civ/2001/1545.html

56. *"**The fact that they are performing statutory functions** which may sometimes be susceptible to judicial review **does not relieve them of responsibility** in tort **for wrongful acts**."*

THIS IS THE **Exhibit MJS32** REFERRED TO BY CLAIMANT IN THE STATEMENT OF FACTS (Ref: NE013712676GB).

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Exhibit MJS33 Response to FOI Ref.: 20-500 Point 5 - FALSE STATEMENT

Dumfries and Galloway NHS Board

Chief Executive's Office
Freedom of Information

Ground Floor North
Mountainhall Treatment Centre
Bankend Road
Dumfries
DG1 4AP
☎ 01387 272752
✉ dg.feedback2@nhs.scot

Ref.: 20-500
Date: 6 January 2021

FREEDOM OF INFORMATION (SCOTLAND) 2002

Thank you for your email, dated 19 December, where you requested information through the Freedom of Information (Scotland) Act 2002. Please find below responses to the questions you raised.

1. The "best available clinical advice" (with evidence superior to that on the attached Notice) proving that PCR Tests CAN detect infectious disease, despite all evidence online and evidence contained within the attached Notice (Exhibit A) suggesting otherwise.
   NHS Dumfries and Galloway do not hold this information; therefore this request is refused under section 17 of FOISA. "Clinical advice" is provided at National/UK level by either NHS Scotland or NHS England or by the Scottish or UK Governments

2. The "best available clinical advice" (with evidence superior to that on the attached Notice) proving that lockdowns and restrictions are effective, despite all evidence online and evidence contained within the attached Notice (Exhibit B) suggesting otherwise.
   NHS Dumfries and Galloway do not hold this information; therefore this request is refused under section 17 of FOISA. "Clinical advice" is provided at National/UK level by either NHS Scotland or NHS England or by the Scottish or UK Governments.

3. The "best available clinical advice" (with evidence superior to that on the attached Notice) proving that masks prevent the spread of virus, are not harmful in any way, that cloth masks do NOT increase risk of infection and that they are not detrimental to children (see attached Notice, Exhibit C1) despite all evidence online and evidence contained within the attached Notice (Exhibit C) suggesting otherwise.
   NHS Dumfries and Galloway do not hold this information; therefore this request is refused under section 17 of FOISA. "Clinical advice" is provided at National/UK level by either NHS Scotland or NHS England or by the Scottish or UK Governments.

4. The "best available clinical advice" with evidence proving that:
   i) the Pfizer Covid-19 vaccine will NOT trigger an immune reaction against syncytin-1 (Exhibit D1) potentially resulting in infertility
   ii) the Covid-19 mRNA vaccine will have no impact on fertility despite Pfizer themselves not knowing (Exhibit D2)
   iii) NHS D&G know the long-term side effects of the vaccine, even though no-one else does
   In response to all of the above for Q4 NHS Dumfries and Galloway do not hold this information; therefore this request is refused under section 17 of FOISA. "Clinical advice" is provided at National/UK level by either NHS Scotland or NHS England or by the Scottish or UK Governments. The evidence on a new vaccine or type of medication is taken through the Medicines and Healthcare products Regulatory Authority, who reviews all of the safety information, testing outcomes and other medical evidence associated with the product to make a decision on whether the product is safe to use or not. This evidence is not shared with the Boards, only feedback from the Medicines and Healthcare products Regulatory Authority to confirm if the product has been approved for use or not.

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Exhibit MJS33 Response to FOI Ref.: 20-500 (cont'd) Point 5 - FALSE STATEMENT

5. The full, informed consent NHS D&G will be providing to vaccine recipients as required by law, which should include all of the above and everything within the Notice, and if this is not being given then please provide the reasons why (ie, why NHS D&G would give a vaccine with unknown long-term effects, unknown effects on fertility, that will not stop transmission of or being infected with Covid-19, social-distancing, masks, lockdowns etc, all as per the Notice, without informing people of such)
   The rules on informed consent are decided nationally by the Scottish Government and included published information leaflet for the person before consent to vaccination. NHS Dumfries and Galloway are fully compliant with ensuring that informed consent as required by the Scottish Government is obtained.

6. To stress the point once again: will NHS D&G be informing recipients that there the vaccine's effects on fertility are unknown, with questions being asked about immune reaction against syncytin-1?
   NHS Dumfries and Galloway will use, as will all the other Scottish NHS Boards, the Scottish Government published information to ensure an informed decision can be given.

Under section 20 (1) of the Act, if you are dissatisfied with the way NHS Dumfries and Galloway has dealt with your request, you have a right to request a review of our actions and decisions in relation to your request, and you have a right to appeal to the Scottish Information Commissioner.

A request for review must be made within forty working days from 06 January 2021 and should, in the first instance, be in writing to Jeff Ace, Chief Executive, NHS Dumfries and Galloway, Ground Floor North, Mountainhall Treatment Centre, Bankend Road, Dumfries DG1 4AP or by e-mail to dg.feedback2@nhs.scot. You must provide your name, an address for correspondence, details of your original request and why you want a review.

If our decision is unchanged following review and you remain dissatisfied with this, you have the right to make a formal appeal to the Scottish Information Commissioner. Requests for appeal should be made in writing to the Scottish Information Commissioner, Kinburn Castle, Doubledykes Road, St Andrews, Fife, KY16 9DS, telephone 01334 464610, fax 01334 464611 or email: enquiries@itspublicknowledge.info

Yours sincerely

Freedom of Information Officer

THIS IS THE **Exhibit MJS33** REFERRED TO BY CLAIMANT IN THE STATEMENT OF FACTS (Ref: NE013712676GB).

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Exhibit MJS34 Public Health England FOI Ref 11/10/21/ar/1478

Public Health England

Protecting and improving the nation's health

Public Accountability Unit
Wellington House
133-155 Waterloo Road
London SE1 8UG

www.gov.uk/phe

By email
mikesutherland@hotmail.co.uk

Our ref: 11/10/21/ar/1478

19 October 2021

Dear Mike Sutherland,

Re: Freedom of Information Request

Thank you for your request received on 11 October 2021 addressed to Public Health England (PHE). In accordance with Section 1(1)(a) of the Freedom of Information Act 2000 (the Act), I can confirm that PHE does not hold the information you have specified.

Request

Scientific studies, articles or other data, whether carried out by your organisation or by others, which conclusively proves that a positive PCR test following a positive lateral flow test (neither of which is capable of determining infection status) is sufficient to "confirm" diagnosis of infection with Covid-19. In absence of material evidence for Q1, please provide the basis by which your organisation relies on PCR being capable of confirmation of Covid-19 infection following a positive lateral flow test.

Response

In accordance with Section 1(1)(a) of the Act, I can confirm that PHE does not hold this information, but under Section 16 of the Act we can offer the following advice.

There are no perfect tests for COVID-19. The risk of false positives affects laboratory testing across the world, including in the United Kingdom. No diagnostic test is 100% accurate; false positives and false negatives can occur depending on a number of factors not directly related to test performance.

PCR tests are evaluated for accuracy and reliability prior to being approved for diagnostic use. Once in use, the performance of the test is continually monitored and reviewed for technical quality and performance.

PHE provides guidance, advice and support to laboratories to ensure the highest standards of performance are maintained. PHE is aware of the risk of false positives where prevalence is low in the population being tested and works with laboratories to implement measures to reduce that risk. More information can be found here:

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Exhibit MJS34 Public Health England FOI Ref 11/10/21/ar/1478 (Cont'd)

https://www.gov.uk/government/publications/sars-cov-2-rna-testing-assurance-of-positive-results-during-periods-of-low-prevalence

In June 2020 the Scientific Advisory Group for Emergencies (SAGE) published a briefing paper on the impact of false positives and false negatives in the United Kingdom's COVID-19 reverse transcription polymerase chain reaction (RT-PCR) testing programme.

The briefing paper states that the United Kingdom operational false positive rate is unknown, and an attempt has been made to estimate the likely false-positive rate of national COVID-19 testing programmes by examining data from published external quality assessments (EQAs) for RT-PCR assays for other ribonucleic acid viruses carried out between 2004-2019. Results of 43 EQAs were examined, giving a median false positive rate of 2.3%. The paper can be accessed here: https://www.gov.uk/government/publications/gos-impact-of-false-positives-and-negatives-3-june-2020

If you have any queries regarding the information that has been supplied to you, please refer your query to me in writing in the first instance. If you remain dissatisfied and would like to request an internal review, then please contact us at the address above or by emailing foi@phe.gov.uk.

Please note that you have the right to an independent review by the Information Commissioner's Office if a complaint cannot be resolved through the PHE complaints procedure. The Information Commissioner's Office can be contacted by calling the ICO's helpline on 0303 123 1113, visiting the ICO's website at www.ico.org.uk or writing to the ICO at Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF.

Yours sincerely,

Freedom of Information Team
Public Health England

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THIS IS THE **Exhibit MJS34** REFERRED TO BY CLAIMANT IN THE STATEMENT OF FACTS (Ref: NE013712676GB).

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