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The Secretary of State for Health and Social Care
C/O The Government Legal Department
102 Petty France
London SW1H 9GL

Date: 05/08/2021

Dear Sir

Proposed claim for Judicial Review
LETTER BEFORE CLAIM PURSUANT TO THE PRE-ACTION PROTOCOL FOR JUDICIAL REVIEW

Challenge to lawfulness of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2021

This is a letter before claim in accordance with the Judicial Review pre action protocol under the Court's Civil Procedure Rules (CPR). We intend principally to set out (a) a clear summary of the facts and the legal basis for the claim and (b) details of the information that our client is seeking and why it is considered relevant.

Proposed claim for judicial review

1. This proposed claim challenges the lawfulness of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2021 ('the 2021 Regulations'), made by the Secretary of State for Health and Social Care, on 22nd July 2021, pursuant to powers delegated to him under s 21 of the Health and Social Care Act 2008 ('the 2008 Act'). The 2021 Regulations prevent any person entering a care home (save relatives and friends of residents and limited other categories) unless they have received two injections of the Janssen, Pfizer/BioNTech, Moderna, and AstraZeneca vaccines ('the Vaccines') for SARS-CoV-2 (also 'the virus') which have received temporary authorisation from the Medicines and Healthcare products Regulatory Agency ('MHRA'), pursuant to reg. 174 of the Human Medicines Regulations 2012 ('the Vaccination Requirement').

The claimant

2. The first proposed claimant is ■■■■, a ■■■■■. The First Claimant's role is non-resident facing. She largely works from home. Since March 2019, the Claimant did not and was not required to visit an operational care home.

3. We also propose to bring proceedings on behalf of a second proposed claimant, namely a front-line care worker of black heritage ■■■■.

The Secretary of State's reference details

4. Please advise.

The details of the claimants' legal advisers

5. Jackson Osborne Solicitors

The details of the matter being challenged

6. The lawfulness of the 2021 Regulations is challenged on the following six grounds:

(1) That they are *ultra vires*, being incompatible with their parent Act and Parliamentary intent in passing it;

(2) That they amount to a disproportionate interference with the right to bodily autonomy of front-line and non-front line care workers, contrary to Article 8 of the (European) Convention for the Protection of Fundamental Rights and Freedoms ('the Convention');

(3) That they amount to a disproportionate interference with Article 8 rights in conjunction with Article 14, by reason of indirect discrimination on the grounds of race and/or sex for front line and non-front line care workers respectively;

(4) That the Vaccination Requirement is irrational (*inter alia* and as enlarged below): in the absence of pre-authorisation testing for their ability to reduce transmission and in circumstances where evidence increasingly shows that the Vaccines do not materially reduce transmission; in view of the irrational inclusion of some classes of person and not others; and through providing for a review within a year rather than a much shorter period, they were irrational;

(5) That they were made in breach of the duty of sufficient inquiry; and

(6) That they were made in breach of the duty to consult.

The details of any Interested Parties

7. We do not consider that there are any interested parties, this challenge relating solely to the lawfulness of secondary legislation.

The issue

Factual background

COVID-19 Vaccinations and Care Homes

8. The Vaccines have not received full marketing authorisation and the marketing authorisation holders are expected to provide additional data on safety and efficacy. It is acknowledged that there is evidence the Vaccines are effective against the severity of infection,[1] which is the only basis on which they were tested.

9. The Delta variant now amounts to almost all new infections in the UK.

[1] The Secretary of State relies on studies from Public Health England, Oxford University and the Siren study. See: Consultation outcome, Making vaccination a condition of deployment in older adult care homes [2]; and Consultation outcome, Making vaccination a condition of deployment in care homes: government response {4.1}. These studies relate to previous variants and the position regarding the Delta variant is less clear.

10. While a recent CDC internal slide presentation suggests that vaccination reduces the risk of death and severe disease ten-fold, it also suggests that fully vaccinated people might spread the Delta variant at the same rate as unvaccinated people.[2] Put another way, vaccination protects residents from death and serious illness, but vaccinated care workers may still become infected with COVID-19 and importantly could still spread it to vaccinated residents. The fact that the double vaccinated Secretary of State for Health tested positive for COVID-19 is an illustration of this. Indeed, the Secretary of State visited Aashana Care Home only four days before the results of his positive PCR test.[3]

11. As of 2 April 2021, 24.3% of registered deaths from COVID-19 in England were care home residents, representing a 19.5% increase in excess deaths.[4] Weekly COVID-19 deaths in care homes peaked at 3,679 on 30 April 2020 and rose again to 2,505 on 29 January 2021. Since 2 April 2021, weekly death rates have ranged between 86 to 10.[5]

12. The Joint Committee on Vaccinations and Immunisation ('JCVI') identified residents and staff of care homes are the top priority group for vaccine rollout.[6] SAGE has advised that an uptake rate of 80% in staff and 90% in residents of a single dose is needed to provide a minimum level of protection against COVID-19 outbreaks.[7] As of 13 June 2021, 95.4% of residents eligible for vaccination and 84.1% of staff in older adult care homes in England received their first vaccination.[8] All regions surpass the 90% threshold for residents and the only region below the 80% threshold for staff is London, at 76.6%. The Secretary of State's position is that only 64.7% of older adult care homes meet the dual threshold due to variation in regions and individual care homes.[9] No data is provided for care homes in general (i.e. other than older adult care homes).

13. While we accept the need for vaccination, particularly of vulnerable and elderly people, it is of note – especially in the context of a mandatory vaccination requirement, that the Vaccines have been authorised well-before the completion of the usual testing protocols.
Reinforcing this concern, the most recent Yellow Card reports for one of the Vaccines (Pfizer) to 7th July 2021 show, out of an estimated 19,700,000 first doses administered:

    (1) 87,789 subject reports;
    (2) 245,395 adverse reactions;
    (3) an average of 2.8 symptoms per subject reporting.

14. Moreover, the mRNA technology used by Pfizer and Moderna, in particular, is novel and has never before been used in human medication. The known risks include thrombotic events, myocarditis and pericarditis; the unknown potential long-term risks (the 'known unknowns') include Antibody Defence Enhancement (ADE), pharmacokinetics and biodistribution of the spike protein, the possible long-term effect on fertility (in the absence

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[2] CNN Article "CDC document warns Delta Variant appears to spread as easily as chickenpox and cause more severe infection" https://edition.cnn.com/2021/07/29/politics/cdc-masks-covid-19-infections/index.html
[3] Daily Mirror Article, dated 17 July 2021 with screen shot of Sajid Javid's Twitter feed.
[4] ONS, Deaths involving COVID-19 in the care sector, England and Wales: deaths registered between week ending 20 March 2020 and week ending 2 April 2021. This is contrary to the 31% figure put forward by the Secretary of State in the Consultation Outcome: Govt Response {2}.
[5] ONS, Care home resident deaths registered in England and Wales, provisional.
[6] DHSC, Independent report: Joint Committee on Vaccination and Immunisation: advice on priority groups for COVID-19 vaccination, 30 December 2020.
[7] DHSC, Press release: Consultation launched on staff COVID-19 vaccines in care homes with older adult residents (14 April 2021).
[8] NHS England, Supplementary information: 15 June 2021 – COVID-19 vaccinations in older adult care homes.
[9] *Consultation outcome: Government Response* {1.1}.

of relevant studies on primates); and there is potential for further unforeseen adverse consequences (the 'unknown unknowns').

15. The principle of the Liberty of Non-vaccination has been established in the UK following amendments to the Vaccination Act 1853 in 1898;[10] and the preservation of free and informed consent to medical treatment is an important principle of domestic and international humanitarian law. On 23 November 2020, the Prime Minister undertook that the United Kingdom would not pursue a policy of mandatory vaccination.[11]

The 2021 Regulations

16. On 22 July 2021, the 2021 Regulations were made via the affirmative procedure. Regulation 5 amends Regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 ('2014 Regulations') as follows:

> *"5. In regulation 12, after paragraph (2), insert—*
>
> *"(3) For the purposes of paragraph (2)(h), a registered person ("A") in respect of a regulated activity specified in paragraph 2 of Schedule 1 (accommodation for persons who require nursing or personal care) in a care home must secure that a person ("B") does not enter the premises used by A unless—*
>
> *B is a service user residing in the premises used by A;*
> *B has provided A with evidence that satisfies A that either:*
> *i. B has been vaccinated with the complete course of doses of an authorised vaccine; or*
> *ii. that for clinical reasons B should not be vaccinated with any authorised vaccine;*
> *it is reasonably necessary for B to provide emergency assistance in the premises used by A;*
> *it is reasonably necessary for B to provide urgent maintenance assistance with respect to the premises used by A;*
> *B is attending the premises used by A in the execution of B's duties as a member of the emergency services;*
> *B is a friend or relative of a service user and that service user is or has been residing in the premises used by A;*
> *B is visiting a service user who is dying;*
> *it is reasonably necessary for B to provide comfort or support to a service user in relation to a service user's bereavement following the death of a friend or relative; or*
> *B is under the age of 18."*
>
> (Emphasis added)

17. The effect is that all staff and contractors, irrespective of whether they have close or even any contact with residents, will be required to be double vaccinated as a condition of deployment in care homes unless they meet one of the exemptions. The amendment will come into force on 11 November 2021 after a 16-week grace period. Regulation 7 of the 2021 Regulations provides for an annual review procedure.

18. The 2021 Regulations were laid before Parliament on 22 June 2021 following a public consultation from 14 April to 26 May 2021. 13,500 responses were submitted through an

[10] Lydia Hayes and Allyson Pollock, 'Mandatory covid-19 vaccination for care home workers' (BMJ, 8 July 2021).
[11] 'UK's Johnson says there will be no compulsory vaccination' (*Reuters,* 23 November 2020).

online survey and meetings were held with stakeholders.[12] Key findings from the consultation include:

(1) 57% of respondents did not support the proposal, including 61% of service users and relatives of service users, and 63% of healthcare providers. 76% of care home providers supported the proposal.

(2) 61% of respondents had concerns on the impact of proposals on the ability to provide a safe service, largely due to staffing shortages. 51% of respondents considered this impact would be severe.

(3) 46% thought groups with protected characteristics would be negatively affected.

(4) 64% of care home managers said they would terminate employment of unvaccinated staff, compared to 18% who would redeploy.[13]

19. An equality impact statement ('the EIS') was published on 16 June 2021 which acknowledges that the policy will have a significant impact on women and ethnic minorities given that they are disproportionately employed as care workers and have higher rates of vaccine hesitancy.[14]

20. The Impact assessment had not been released or undertaken before the new regulations voted on.

21. The House of Lords, Secondary Legislation Scrutiny Committee's 8th Report of Session 2021-22, published 8 July 2021, was highly critical of the proposal and recommended deferring the 2021 Regulations under further information and operational guidance were provided as Parliamentary scrutiny would otherwise be impossible.[15]

22. A statement of impact estimates that 3-12% (17,000-70,000 care workers) will no longer be deployable as a result of the policy, resting on the assumption 87% of staff will have had both doses by the time the 2021 Regulations are in force.[16] This impact statement had not been made available before Parliament when the 2021 Regulations were debated before the House of Commons on 13 July 2021.[17]

The effect of the 2021 Regulations on the Claimants

23. [■■■■] is employed by Barchester Healthcare Ltd as [■■■■■]. She was infected with COVID-19 in beginning of January 2021 and has a degree of natural immunity (last tested in May 2021). She has refused vaccination due to concerns about its safety, the impact on her fertility and her previous history of allergies.

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[12] Consultation Outcome: Govt Response {1.1}-{1.2}.
[13] Ibid {6.5}. Liberty, the British Medical Association, and trade unions were against the proposal, whereas the EHRC backed the proposal subject to certain caveats. 'Liberty responds to reports of mandatory vaccines for care workers' (*Liberty*, 16 June 2021); 'Proposals for compulsory vaccination of care home staff condemned by Unite' (*Unite*, 16 June 2021); 'Care staff more likely to decline jab if threatened by employers, says UNISON survey' (*UNISON*, 24 May 2021); 'Care worker mandatory vaccinations 'incredibly bad idea'' (*GMB*, 15 April 2021); 'Our response to the consultation on making vaccination a condition of deployment in older adult care homes' (*EHRC*, 21 May 2021). A petition to Parliament against the proposal has received 101,580 signatures.
[14] 'Equality Impact Assessment form – Public Sector Equality Duty' (*DHSC*, 16 June 2021).
[15] House of Lords, Secondary Legislation Scrutiny Committee, 8th Report of Session 2021-22.
[16] 'Consultation outcome: Statement of impact – The Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) Regulations 2021' (*DHSC*).
[17] HC Deb 13 July 2021, vol 699, col 270 (Sir Christopher Chope).

24. We also propose to bring this claim on behalf of a front-line careworker of Afro-Caribbean or African origin. Such persons comprise 12% of the adult social care workforce[18] and have a vaccine hesitancy rate of 18% compared to 4% of White adults.[19] ■■■■, we put you on notice of arguments that will be raised on ■■■■ behalf if the Regulations are not withdrawn and we are required to issue proceedings.

Ground One: Ultra Vires

25. Secondary legislation will be invalid if it has an effect or purpose outside the scope of the statutory power pursuant to which it was made, even if approved via the affirmative procedure: *R (Public Law Project) v Lord Chancellor* [2016] AC 1531 (Laws LJ at §§23-23); and the invalidity of secondary legislation extends to where statutory powers are used incompatibility with a different statute: *Apple Fields Ltd v New Zealand Apple and Pear Marketing Board* [1991] 1 AC 344.

26. In *R (VIP Communications Ltd) (In Liquidation) v Secretary of State for the Home Department* [2021] 1 WLR 2839, it was held that in the absence of express words to the contrary, the Secretary of State's powers under s 5(2) Communications Act 2003 did not empower her to direct OFCOM not to carry out its statutory duties under s 8(4), Wireless Telegraphy Act 2006.

27. The need for clear words in the parent Act is underlined, in circumstances such as these where fundamental rights are at stake, by the 'principle of legality', set out in *R. v Secretary of State for the Home Department Ex p. Simms* ([2000] 2 A.C. 115, at 131–132): "...Parliament must squarely confront what it is doing and accept the political cost. Fundamental rights cannot be overridden by general or ambiguous words,"

28. The 2021 Regulations are made pursuant to ss 20 and 161 of the 2008 Act. In isolation, the Vaccine Requirement falls within the scope of those provisions. However, as amended by s 129 of the 2008 Act, the Public Health (Control of Disease) Act 1984 ('1984 Act') provides:

> "***45C Health protection regulations: domestic***
> *The appropriate Minister may by regulations make provision for the purpose of preventing, protecting against, controlling or providing a public health response to the incidence or spread of infection or contamination in England and Wales (whether from risks originating there or elsewhere).*

29. The power in subs (1) may be exercised—

> *in relation to infection or contamination generally or in relation to particular forms of infection or contamination, and so as to make provision of a general nature, to make contingent provision or to make specific provision in response to a particular set of circumstances.*

30. And the following limitation applies to all regulations made under Part IIA of the 1984 Act, added by the 2008 Act.

> ***45E Medical treatment***
> *(1) Regulations under s 45B or 45C may not include provision requiring a person to undergo medical treatment.*

[18] 'The state of the adult social care sector and workforce in England' (*Skills for Care*, October 2020).
[19] 'Coronavirus (COVID-19) latest insights: Vaccines' (*ONS*, 21 July 2021).

(2) " Medical treatment " includes vaccination and other prophylactic treatment."

31. Against this legislative background, the Vaccine Requirement is *ultra vires*, being contrary to the prohibition on mandatory vaccinations in s 45E of the 1984 Act: see *Apple Fields* and *JWCI*. This is so irrespective of the fact that the prohibition in s 45E applies, in particular, to regulations made under ss 45B and 45C.

32. First, the 2021 Regulations fall within the material scope of s 45C of the 1984 Act and should have been made pursuant to the same. Permitting the Defendant to make equivalent regulations to s 45C through alternative provisions so as to bypass the prohibition of mandatory vaccination would render the provision nugatory.

33. Secondly, there are no clear words in the 2008 Act which qualify the scope of s 45E, which itself expresses the clear intention of Parliament to protect: see *Simms*, *EE* and *VIP Communications*.

34. Thirdly, in these circumstances *lex specialis derogat legi generali* applies: a law which governs a specific matter (in this case s 129, which applies a particular statutory code for the imposition, through the 1983 Act, of regulations addressing a public health crisis) overrides, or takes precedence over, a law of general application (s 20, which addresses regulations in the care sector in general terms) (*R (Nealon) v SS for Justice* [2015] EWHC 1565 (Admin) at [32]). See also Moohan v Lord Advocate [2015] AC 901, per Lord Hodge at [62]: 'where two provisions are capable of governing the same situation, a law dealing with a specific subject matter overrides a law which only governs general matters."

35. Fourthly, that the 2008 Act amended the 1984 Act to include s 45E, without qualification, is a strong indicator that Parliament did not intend the powers in the 2008 Act to circumvent the prohibition of mandatory vaccination.

36. Fifthly, a further indicator of Parliamentary intention – and a factor to be taken into account in considering the effect of the inclusion in the Act of a provision protecting individuals from mandatory vaccination – is the fact that Parliament in passing the 2008 Act (and when also adding s 45E to the 1984 Act) can be presumed to have had in mind the 'Liberty of Non-vaccination' that had become a principle over the century since 1898.

37. In the premises, the Secretary of State in making the 2021 Regulations, by purporting to use s 21 of the 2008 Act in response to a public health emergency, has unlawfully evaded the protections against mandatory vaccination for those circumstances set out in another part of the Act; and (further and alternatively) has acted *ultra vires* the parent Act by acting in excess of the powers granted by ss 20 and 161 of the 2008 Act as they must be constructed pursuant to what can be imputed to be Parliament's intention in accordance with other parts of the Act.

Ground Two: Bodily autonomy and Article 8 of the Convention

38. While the submissions below are made in the alternative to those in support of Ground One, they are of relevance to it in view of the protection of fundamental rights (including the right to bodily autonomy) through the interpretive Principle of Legality of fundamental rights.

39. The concept of private life covers the physical integrity and bodily autonomy of the person and involuntary medical intervention (including compulsory vaccination) represents an interference with the right to respect for private life within the meaning of Article 8, ECHR.

40. The right of a person not to consent to medical treatment is a central pillar of international humanitarian law.

41. While applying expressly to medical experimentation, this principle is and was intended to be of general application; and we note that the Vaccines have been given emergency authorisation only and have not been through the testing protocols that would have been required for a full MHRA licence.

42. The Universal Declaration on Bioethics and Human Rights 2005 ('the 2005 Declaration') was a declaration by the International Bioethics Committee) of the United Nations Education, Science and Organisation ('UNESCO') that was declaratory of international humanitarian law. It included the following articles, *Article 5 – Autonomy and individual responsibility and Article 6 - Consent* :

43. By Resolution 2361 (2021) of the Council of Europe ('the CoE'), the CoE urged its 47 members states to ensure that vaccination for the virus was not mandatory, that unvaccinated people should not be discriminated against and that discrimination was prohibited even in the case of existing health risks or if any person chooses not to be vaccinated for any reason.

44. In respect of the above authoritative declarations of international humanitarian law, there is a 'strong presumption' that legislation should be interpreted in a way that is compatible with the United Kingdom's international obligations: *Salomon v Customs and Excise Comrs* [1967] 2 QB 116. The presumption of compatibility applies in relation to international treaty obligations, whether or not they have been incorporated into domestic law.

45. In *Montgomery v Lanarkshire Health Board* ([2015] UKSC 11), the Supreme Court held that a person cannot consent to medication unless the medical practitioner providing the medication or medical procedure informs the patient of all factors necessary to allow her to make a properly informed decision; and that a medical practitioner providing treatment to a patient to which that patient has not consented is liable for any personal injury she may sustain as a result of treatment to which she agrees without having been provided with sufficient information to allow her to consent in a fully informed manner.

46. These tenets of international humanitarian law, and greater, not lesser, recognition by the highest courts of the necessity of securing fully informed consent to medical treatment, are reflective of the statutory protections that Parliament has imposed preventing any form of compulsory treatment for those who have capacity:

    (1) In the repeal of the parts of the Vaccination Act imposing mandatory vaccination in 1898 and the establishment of the Liberty of Non-vaccination; and
    (2) In the limitation on the power of Ministers to impose mandatory vaccination even in regulations aimed at controlling a 'public health emergency' which the Court of Appeal has since found could include restrictions (including the Health Protection (Coronavirus, Restrictions) (England) Regulations 2020) so sweeping that they included the prohibition of public worship, the freedom of association and the ability to associate with one's closest family.[20]

47. If, contrary to our primary case, the 2021 Regulations are not *ultra vires* the parent Act, the continued and active retention of the Liberty of Non-vaccination in primary legislation remains an important consideration in determining the proportionality of reversing it – for the first time in 123 years – in secondary legislation. In those circumstances, the imposition

[20] *R (Dolan) v Secretary of State for Health* [2020] EWCA Civ 1605

of compulsory medical treatment on capacitous individuals cannot be a proportionate interference with fundamental rights in any circumstances, save by express provision in primary legislation, the lawfulness of which cannot be a matter for the courts.

48. Further and alternatively, the imposition of involuntary or compulsory medical treatment in these circumstances is not a proportionate interference with Article 8 rights that could be justified under Article 8(2), which requires that such an interference must (i) be in accordance with the law, (ii) pursue a legitimate aim, and (iii) be necessary in a democratic society in the sense that it answers a pressing social need, the reasons to justify the interference are relevant and sufficient, and it is proportionate to the legitimate aim.

49. The intensity of review is considerable where fundamental rights are at stake: *Pham v Secretary of State for the Home Department* [2015] UKSC; and the margin of appreciation afforded to member states by the European Court of Human Rights ('the Strasbourg Court') does not apply in the domestic context, where courts may apply a stricter standard of review (*Belfast City Council v Miss Behavin' Limited* [2007] UKHL 10 (Baroness Hale at §31).

50. The 2021 Regulations require the putative claimants and almost any other person entering a care home to have had medical treatment. To avoid the loss of their livelihood, they must comply with that requirement irrespective of their personal opinion of the risks and benefits of medication, whether they have religious or philosophical objections to it or any other reasons.

51. In such circumstances: (a) those persons are being coerced into medical treatment; and (b) there is a heightened risk – especially for careworkers on minimal incomes for whom the threat of unemployment is particularly onerous and many of whom will be unlikely to be well-informed as to the potential benefits and risks of the Vaccines – that their consent will not be fully informed and thus will not lawfully be consent (*Montgomery*).

52. We are of course aware of the case of *Vavricka and others v Czech Republic* ([GC], nos.47621/13 (2021)) , where the Strasbourg Court held that compulsory tetanus vaccination of children was lawful. However, there are points of real distinction with the putative claimant's challenge to the 2021 Regulations. In particular, applying the proportionality test:

    (1) The coercion is particularly grave given that those affected are at risk of losing their livelihoods and their ability to work in an entire sector.

    (2) Any coercion to receive medical treatment, but particularly this one, heightens the risk that individuals will receive medical treatment without making themselves aware of the risks and thus incapable of full and lawful consent.

    (3) The above and other points made here are of particular weight in circumstances where the Vaccines are not fully authorised and licensed but fast-tracked by the MHRA through a temporary approval process, they therefore have not been fully tested, there are risks of serious side-effects (up to and including complete disability and death) and the long-term consequences cannot be known, as set out in the introductory section.

    (4) There is a growing body of evidence that the Vaccines do not even reduce the risk of transmission of the virus. We rely, in particular, on the CDC study cited in the introduction and on the statistical evidence from Israel and other countries in which there was no material difference between the proportion of the total population vaccinated and the proportion of the total population infected.

(5) There are less restrictive alternatives available to pursue the legitimate aim of protecting public health, which include (but are not limited to): continuing a voluntary vaccination campaign through encouragement and financial incentives, implementing a testing requirement for *all* persons entering care homes, and requiring use of PPE.[21]

(6) There is no clear evidence that mandatory vaccination regimes are more effective relative than voluntary programs in achieving vaccination uptake.[22]

(7) The Vaccine Requirement will have a serious adverse effect on staff shortages and on undermine a safe service of care.[23]

(8) There has been a considerable reduction in deaths from the virus since the widespread vaccination of residents (emphasising the point that the purpose of these Vaccines is to reduce the severity of symptoms in the recipient, not transmission).

(9) The interference is unnecessary given that the dual threshold outlined by SAGE has already been met - as an average - in all regions except London and in the majority of care homes. It is unclear where the Defendant reached their 64% dual threshold figure. In any event, the figures in the introduction question the necessity of a nationwide policy which applies to *all* care homes and data also suggest that a great many care homes currently under the dual threshold will be very close to the threshold and will likely pass the threshold as rates of voluntary vaccination increase.

(10) The exemptions in reg. 12(3) are arbitrary. There is no medical or rights-based justification for the exemption of friends/families but not care workers. In both cases there is a transmission risk and mandatory vaccination interferes with the Article 8 rights of all concerned.

(11) The Vaccine Requirement is not supported by the majority of care home users responding to the consultation.

(12) The vaccine providers will, in view of the temporary authorisation, be immune from civil liability.

(13) The court's interpretation of Article 8 should be guided by the following external sources: the right to work in Article 6 of the ICESCR and Article 1 of the European Social Charter; the requirement of free and informed consent for medical intervention in Article 5 of the Oviedo Convention 1997; and Resolution 2361 (2021) of the Council of Europe ('the CoE') on Covid-19 vaccines, cited above.

(14) The adequacy of the decision-making process is an important factor in the proportionality assessment. The fact the interference was brought about by way of secondary legislation supports the Claimants' case, given there was limited opportunity for Parliamentary scrutiny. The criticisms of the consultation process

[21] see: *Unite*; *Unison*; *Wilkinson and Savulescu*; *Hayes and Pollock*; *BBC*.
[22] Theodore Lytras and Others, 'Interventions to increase seasonal influenza vaccine coverage in healthcare workers: A systematic review and meta-regression analysis' (PubMed 2016 Mar 3: 671-81).
[23] See: *Consultation Outcome*; *BBC*; *UNISON*.

highlighted by the House of Lords Secondary Legislation Scrutiny Committee should also be taken into account.

(15) In view of the evolving situation regarding variants of the virus, evidence on the effect of vaccination on transmissibility, hospitalisation, death and vaccination rates, provision for annual periodic review in Regulation 7 of the 2021 Regulations is inadequate and adds to severity of the interference by unnecessarily barring the Claimants from re-employment in the sector for, at a minimum, one year.

In respect of [our first client] only (and all non-front-line workers and all contractors), but without prejudice to the force of the submissions above:

(16) It is particularly disproportionate to require double vaccination of persons who have no close or even direct contact with patients.

53. In the premises, the imposition of the Vaccination Requirement is a disproportionate interference with the putative claimants' right to bodily autonomy protected by Article 8 of the Convention and is unlawful.

Ground Three: Article 8 in Conjunction with Article 14 ECHR

54. A violation of Article 14 ECHR arises where, in a case falling within the ambit of a Convention right, there is unjustified discrimination. In *DH and Others v Czech Republic* (no.57325/00, §184,13 November 2007) the Strasbourg Court found that:

> *'[discrimination] may take the form of disproportionately prejudicial effects of a general policy or measure which, though couched in neutral terms, discriminates against a group ... Such a situation may amount to "indirect discrimination", which does not necessarily require a discriminatory intent.'*

55. In such cases there are two questions: (i) does the impugned measure disproportionately adversely affect the relevant group?; and (ii) can the discriminatory effect be justified? (*OA v Secretary of State for Education* [2020] EWHC 276 (Admin), *per* Nicol J at §34).

56. With regard to the latter, the standard test for justification is the same fourfold test as applied in *Bank Mellat*: *R (Tigere) v Secretary of State for Business, Innovation and Skills* [2015] 1 WLR 3820 (Baroness Hale at §33). The standard of review varies according to the circumstances. A light-touch "manifestly without reasonable foundation" standard is used in cases relating to the allocation of scarce public resources: *R (Drexler) v Leicestershire County Council* [2020] EWCA Civ 502 at §§70-71. On the other hand, anxious scrutiny and "*very weighty reasons*" are required in respect of the core statuses of race and sex: *DH* at §176; *Konstantin Markin v Russia* [GC], no.30078/06, §127, 22 March 2012.

57. In this case, a material reason for ■■■■'s decision not to be vaccinated was the Vaccines' unknown effect on female fertility. Our second putative claimant will come from a minority which a considerably lower uptake of the Vaccines which would, as a group and by reason of their protected characteristic, be put at a material disadvantage relative to those without that protected characteristic; and would thus be subject to indirect discrimination, as was recognised in the EIS.

58. The mitigation measures outlined in the EIS rest on the assumption that the Vaccine Requirement will result in more women and minorities being vaccinated and fail to consider

the potential impact of coercion dissuading communities with low levels of trust in public authorities from being vaccinated.[24]

59. Given that the Vaccine Requirement does not implicate questions of resource allocation and the claims concern core statuses, very weighty reasons will be required to justify this disproportionate impact. Subject to this, the analysis regarding proportionality is the same as outlined in respect of the Ground Two, with the added consideration of the direct effect on women of child-bearing age who decide not to be vaccinated because of the known and unknown risks to fertility and the indirect discriminatory effect on individuals of Afro-Carribean and African heritage.

Ground Four: Irrationality

60. A measure will be irrational where it is "*outside the range of reasonable decisions open to the decision-maker*" (*R (Pantellerisco) v Secretary for Work and Pensions* [2020] EWHC 1944 (Admin) (*per* Garnham J at §47)), or the decision and/or impact is not capable of being justified (*R (Johnson v Secretary of State for Work and Pensions* [2020] EWCA Civ 778 (Underhill LJ at §114).

61. The above submissions in relation to proportionality also establish that the Vaccination Requirement is irrational because of (i) the impact of the measure on the Claimants, (ii) its lack of necessity, (iii) the availability of less restrictive and more effective alternatives, (iv) the arbitrariness in singling out care workers in the exemptions, and (v) the inadequacy of the annual review mechanism.

Ground Five: Insufficient Inquiry

62. The relevant principles were outlined in *R (Balajigari) v SSHD* [2019] EWCA Civ 673 by Underhill, Hickinbottom and Singh LJJ at §70:

63. The House of Lords Secondary Legislation Scrutiny Committee's report is relied upon and establishes the following failings which, individually and/or cumulatively, amount to one or more breaches of the duty of sufficient inquiry:

    (1) The failure to consider what percentage of care homes (as opposed to only older adult care homes) met SAGE's dual threshold;

    (2) The failure to consider the impact on staffing shortages that 2021 Regulations would have *in conjunction* with the existing unfilled vacancies in the sector;

    (3) The failure to consider the efficacy of alternatives, such as a testing regime and PPE; and

    (4) The failure to consider whether the policy was justified on a nationwide basis with respect to *all* care homes.

Ground Seven: Consultation

64. The requirements of a fair consultation at public law are that: (i) the consultation is at a time when the decision-maker's thinking is at a formative stage; (ii) it affords adequate information and time to allow a proper and informed response; and (iii) it involves conscientious and open-minded consideration of matters: *R (Moseley) v Haringey LBC*

[24] *WHO* {5}.

[2014] 1 WLR 3947 (Lord Wilson at §25). Public authorities have considerable latitude and "*the test remains whether the process was so unfair as to be unlawful*": *R (Bloomsbury Institute Ltd) v Office for Students* [2020] EWCA Civ 1074 (Bean LJ at §69).

65. In the premises, the purported consultation was a sham and/or unfair due to the technical problem which resulted in seven questions being hidden from respondents in the first week of the consultation. This applied to 6,543 respondents, approximately half of the respondents. While these respondents were emailed, only 958 responses were received.[25] The consultation outcome does not indicate how much time the Defendant gave these respondents to resubmit their answers. If they were given a short period of time, there would be grounds to argue the consultation process was unfair.

The details of the action that the defendant is expected to take

66. Revoke the 2021 Regulations.

ADR proposals

67. Given that this is a challenge to the lawfulness of secondary legislation, it is very unlikely that it could be resolved by ADR.

The details of any information sought

68. This case relies on information that is publicly available. However, if there is information that the Government is aware of that would undermine the justification for the 2021 Regulations, such as:

    (1) the latest data on infections in the vaccinated (including vaccinated care home workers then that is requested);
    (2) SAGE advice supporting the justification for the exemption of families and friends;
    (3) Governmental and or SAGE advice concerning the implication of the vaccinate requirement on ethnic minorities.

    then this is requested.

The details of any documents that are considered relevant and necessary

69. See section 10 above.

The address for reply and service of court documents

70. As at the outset of the address, our address is: as above.

Proposed reply date

71. While the 2021 Regulations do not come into force until November, they have been made and impose continued and unacceptable coercion on all employees of care homes to undergo medical treatment against their will. At least eight weeks is recommended between the first and second vaccinations, which has the effect that any worker who has not had his or her first vaccination by mid-September is at risk of being unable to work –

[25] Consultation Outcome: Govt Response {2}.

and thus of dismissal – because he or she will be unable to enter a care home after 11th November. The Secretary of State will be well aware that this has already led to care home workers being warned of the risk of dismissal if they do not arrange to have both doses of the Vaccine before that date.

72. Consequently, a judicial review of these Regulations will need to be issued as soon as possible in order that the continued coercive effect of their existence is removed.

73. Given the declaration by the Secretary of State that the Regulations are compatible with Convention rights and the EIS, the Secretary of State must be in receipt of legal advice at the highest level that the Regulations do not impose disproportionate interferences with any Convention rights; and he must have been in receipt of legal advice that they were *intra vires* the parent Act. If so, he will be in a position to reply to this pre-action letter without delay. If not, he should not have made the Regulations and should withdraw them without delay.

74. We therefore require a reply to this letter within 14 days.

Please acknowledge receipt of this letter.

Yours faithfully

JACKSON OSBORNE