**IN THE COURT OF PROTECTION** **CASE NO: 12219141**

**IN THE MATTER OF THE MENTAL CAPACITY ACT 2005**

**AND IN THE MATTER OF AD**

**B E T W E E N:**

**AN INTEGRATED CARE BOARD**

**Applicant**

**-and-**

**(1) AD**

**(by his litigation friend, the Official Solicitor)**

**(2) AC**

**Respondents**

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**Written Submissions on behalf of AC at 29 July 2024 (anonymized)**

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*References through to "the Guidance" are to Green Book Chapter 14a in the version pertaining at the time unless otherwise noted.*

## Cast list for reference

### ICB Staff

Ms C – Acting Lead Nurse, COVID Vaccination Programme, The Acute Trust

Ms I, Designated nurse safeguarding adults - The Area Integrated Care Board

Ms B, Social Worker for AD – The Local Authority

Mr Z, Senior Community Learning Disability Nurse – The Mental Health and Learning Disability Trust.

### Care Provider Staff

Ms F – Area Manager

Ms G – Home Manager

Ms H – Team Lead

### GP

GP Practice B

**Sedation and Vaccination History**

- 1st dose attempt (the primary course): AD was sedated but with unsuccessful attempt at vaccination on 12 May 2023 [vaccination report page 880, G56].
- 1st dose (the primary course): AD was sedated and received the primary course of the Covid-19 vaccine (comprising one dose only by this date) at 2pm on 06 Nov 2023 [vaccination report page 889, G65].
- 2nd dose (first booster) attempt: AD was sedated but with unsuccessful attempt at vaccination on ~~11~~ 17 June 2024 [vaccination report page 893, G69]
- 2nd dose (first booster) AD was sedated and vaccinated with the second dose (a first 'booster') on 24 June 2024 [vaccination report page 889, G65].

## A. Introduction

1. The length of these submissions is regrettably necessary, largely to address very serious concerns that are apparent from considering the bundle provided by the ICB, currently nearly 1,500 pages. We summarise these at the outset, that:

    1.1. AD has been unlawfully sedated and vaccinated (sections B to C)

    1.2. Risk assessments are not up to date in supporting any current application. (sections D to F)

    1.3. AD has been discriminated against for the benefit of others and because of his ethnicity (sections G to H)

    1.4. AD has been miscategorised by the parties and the Court as 'clinically extremely vulnerable' (sections I to J)

    1.5. There has been general failure properly to read and to ensure the Guidance is followed (section K)

    1.6. The material change in the 'covid landscape' has been ignored (section L)

    1.7. There is significant new evidence that Trisomy patients are at particular risk from the mRNA covid-19 vaccines (section M)

1.8. There is significant new evidence that the Moderna mRNA covid-19 vaccine presents considerably greater risk than the Pfizer BioNtech product, but which also impacts assessment of the Pfizer BioNtech product (section N)

1.9. Alternative measures and, if insufficient, alternative vaccines should be considered (section O)

1.10. The matter merits consideration for referral to a Tier 3 Judge (section P)

## B. Unlawful administration of sedative and second dose (first 'booster') in June 2024

2. At paragraph 3 of the 05 May Order (authorisation and case management) [page 304, B194] and the 06 Nov 2023 Order [page 348, B238] stated (emphasis added):

> "*It is lawful and in AD's best interests for a booster dose of a Covid-19 vaccination to be given to AD, in accordance with the relevant governmental guidance pertaining at the time, in accordance with the Covid-19 Vaccination Care Plan (as amended and updated by the ICB)*"

3. If the ICB is suggesting that the Court did not intend or expect that any care plan should be in accordance with pertaining Guidance, the ICB should say so.

4. The ICB accepts that any health professional would in any event have to have *regard* to the Guidance. Even if there had not been such explicit reference to the Guidance, it is inconceivable that AD's care plan, or any health professional the administering treatment, would not have been intended to depart from the Guidance without expressly saying so and explaining why. It is inconceivable that they would not have informed the Official Solicitor of the same. It is also disingenuous to suggest otherwise given the recorded rationale/necessity for vaccination stated in the care plans dated 26 April 2023 [page 774, F40] and 14 August 2023 [page 781, F47] (emphasis added):

> *"AD is diagnosed with a Learning Disability and Down's Syndrome. As such government guidance is that he is at increased risk of becoming significantly unwell due to Covid-19 and thus requires additional protection. As such, AD is being offered a Covid-19 vaccine as part of the Government's current*

*vaccination roll-out. It is clinically important that AD receives his vaccination to minimise the risks Covid-19 poses to him."*

and again in the Care Plan dated 31 October 2023 (approved by the subsequent Court Order on 06 November 2023) at [page 801, F67]:

> *"AD is diagnosed with a Moderate Learning Disability and Down's syndrome. As such government guidance is that he is at increased risk of becoming significantly unwell due to Covid-19 and thus requires additional protection. As such, AD is being offered a Covid-19 vaccine as part of the Government's current vaccination roll-out. It is clinically important that AD receives his vaccination to minimise the risks Covid-19 poses to him."*

5. Updated versions of the Guidance were published on 20 February 2024 and again on 18 April 2024. In both versions, AD was no longer in a clinical group recommended for any booster. Hence, vaccination subsequently attempted and finally carried out in June 2024 was unlawful on its administration and in the previous attempt on, as was the administration of sedative medication.

6. Accordingly, the Court must be concerned as to whether an offence of assault was committed on each occasion, that those involved in sedation and attempted or actual vaccination on these occasions knew they were acting without consent or were reckless as to whether they did so having regard.to their responsibility to review and understand changes to the Guidance as well as not to mislead the Court.

7. Of particular concern, Ms C (Acting Lead Nurse, COVID Vaccination Programme, The Acute Trust (BHT), who, per her vaccination report [page 895, G71], administered the vaccine at 1:13pm on 24 June 2024, had at 10:00am showed a clear understanding that AD fell outside the Guidance for a 'booster' dose [page 1292–1293, J273-274]. Despite this, she proceeded to allow sedation by the Care Provider and to administer the injection herself.

**C. Unlawful administration of sedative and attempted first dose on 12 May 2023**

~~8. As noted above, the 05 May 2023 Order was for vaccination in accordance with the care plan [page 348, B238]. Even this attempt was unlawful when the care plan~~

~~provided for vaccination in accordance with the Guidance. The ICB informed the Court that the Guidance provided for primary and booster dose for AD within the Spring programme. However, the Guidance issued on 7 March 2023 explained the end of universal primary and booster offers and provided for booster dose only to those defined as immuno-suppressed. [Green Book Chpt 14a, issued 7 March 2023, internal page 28]. AD was not immuno-suppressed and there was no existing programme for a Spring primary dose for AD.~~

9. ~~This was not noted when the matter was before the Court again 06 Nov 2023 and further Order made. Nor was it noted that t~~ The Order was in further error: AD is not in Table 4, which applies to individuals under 16. He is in Table 3. (see further paragraph 44 below)

**D. Failure to maintain current assessment of risk and benefit**

10. The ICB has failed to maintain up-to-date assessment. The evidence on which AD is estimated to be clinically obese is not clear. It is understood that AD has lost weight since a year ago, perhaps significantly so. AC reports this is since he has been outside more and engaged in more physical activity.

11. The 06 Nov 2023 Order para 5 [page 349, B239] does not explain why interference was necessary and proportionate at that time.

12. With respect, this should be carefully considered and recorded each time this matter is before the Court or otherwise reviewed.

**E. Inadequate assessment of benefit and risks**

13. Ms C (Acting Lead Nurse, COVID Vaccination Programme, The Acute Trust (BHT) has no apparent expertise or knowledge save, of course, what she is instructed from Green Book and government communications and in the course of her training to administer the government programme. Her assertions may, of course, be in line with government public policy statements and communications, but they are no more than repetition of the government position. Her assertions replete within paragraph 20 to 25 as to benefits of vaccination and natural immunity or waning must be recognised for

being are without any or any reliable evidence and her dismissal of harms and Yellow Card reports is without any regard to evidence or proper analysis.

14. It is further concerning that this lead nurse, in her first statement dated 27 April 2023, indicated ignorance of natural immunity suggesting that the existence of any symptoms indicated no immunity [page 698, E330 para 38a]. (It is, of course, the suffering of minor symptoms rather than serious symptoms that may indicate either or both of an effective immune response and a less pathogenic virus. (see further Professor Finn's report paragraph 57 below.)

15. It may be noted that, at June 2024, AD's GP's opinion as to best interests for AD appears solely to rely on the Guidance [page 1289, J270]. The last written opinion from the GP Practice B was in April 2021, when the GP was also followed Guidance at the time in recommending the Astra Zeneca product, a product which was later to be removed from the UK vaccination programme (and later than in a EU countries) having regard to serious adverse effects, most notably myocarditis. It appears clear that medics involved are purely relying on the Guidance as determinative of their opinion even though the Guidance may be slow to respond to emerging and strong evidence.

16. Dr Ben Taylor's expertise in relation to anesthetics are not questioned but he, also, is not qualified and has provided no evidence to support his assertions regarding safety or efficacy of the covid-19 vaccines within his report [page 938, H42].

17. It is said AD would not be able to tolerate medical interventions to treat him if he had Covid-19, yet there is no acknowledgement that the same applies if he suffered adverse effects from the covid-vaccination. The justification cannot be tested unless a comparison is made between absolute risk of requiring treatment for covid against the absolute risk of requiring treatment for adverse effects of the vaccine itself. That comparison has not been done by any of the ICB or Official Solicitor or any expert.

18. Despite broad assertion that the adverse effects are usually minor, the clinical trials of the vaccines reveal effects expected to be suffered by significant percentages of vaccinees that are described as minor but are in fact, at the least, very unpleasant and somewhat beyond a sore arm or feeling tired. There has been no consideration or appreciation of these. These are not symptoms which most people would volunteer for unless they expected some significant benefit in return.

19. With respect, it is insufficient that by the Order of 6 Nov 2023, the Court should only be concerned with 'significant' side effects or adverse reactions [page 350, B240 paragraph 8].

20. Further, and perhaps of keenest importance to AC (and it could well be to AD if he had capacity to understand), this remains an experimental gene therapy treatment where long-term effects are unknown.

21. Given the declared emergency pandemic and concern for extreme vulnerability has passed, those making decisions for AD need to have proper regards for significant risks that may be considerably greater than that posed to AD by covid infection. Analysis of serious adverse events reported in the placebo-controlled, phase III randomized clinical trials of Pfizer and Moderna mRNA COVID-19 vaccines in adults, focusing on the a priority list endorsed by the World Health Organization, shows the rates of serious adverse events of special interest to be 10 per 10,000 (1 in 1,000) for Pfizer and 15 per 10,000 (1 in 666) for Moderna[1]. The Court cannot on AD's behalf can give informed consent by knowing the individual risk/benefit to AD without first assessing the rate of serious adverse events from covid-19 infection to males of AD's age, with adjustment for AD if established to be both appropriate and possible, (see further changed covid landscape below.)

22. Specifically in relation to myocarditis, the rates of occurrence are significant. The Court cannot given informed consent on AD's behalf before recognizing on his behalf that the long term effect of such condition is unclear and study has shown that while most patients may appear to recover from short terms symptoms, most also showed abnormal ECG scans 12 months after initial diagnosis.[2] The Guidance statement that "Onset is within a few days of vaccination and most cases are mild and have recovered without any sequalae" [internal page 12] (i.e. without after effects) may be offered as reassurance but it is clearly not the full picture and is arguably misleading. Such damage could well be life shortening, and hence the condition cannot be dismissed as

[1]Fraiman J, Erviti J, Jones M, Greenland S, Whelan P, Kaplan RM, Doshi P. Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults. Vaccine. 2022 Sep 22;40(40):5798-5805. doi: 10.1016/j.vaccine.2022.08.036. Epub 2022 Aug 31. PMID: 36055877; PMCID: PMC9428332. https://pubmed.ncbi.nlm.nih.gov/36055877/

[2] Cardiovascular Assessment up to One Year After COVID-19 Vaccine–Associated Myocarditis, Yu et al https://www.ahajournals.org/doi/epub/10.1161/CIRCULATIONAHA.123.064772

minor or mild. It cannot be known, without ECG, whether AD had indeed already suffered injury to his heart from the two mRNA vaccines administered to date.

**F. Out of date assessments**

23. The last 'risk assessment' by Mr Z was dated 07 October 2022 [page 765, F31]. It includes various statements raising concern:

23.1. "[AD] has a diagnosis of Down's syndrome, meaning he is considered extremely clinically vulnerable according to national guidance." [page 764, F30]

23.2. "…he will not wear a facemask and has no concept of social distancing" [page 764, F30]

23.3. "there is little evidence on how long a natural immunity will last," [page 765, F31]

23.4. "AD is not able to tolerate lateral flow testing. As such he could be asymptomatic and encounter the public which means he can pass on the virus or conversely a member of the public could be asymptomatic and pass it to AD. It is also not possible to confirm when he has COVID-19." [page 766. F32]

24. The risk assessment is notable, as was the case throughout the government declared emergency, for its focus on covid, and not only with regard to AD but for the supposed risks to others of AD passing on the respiratory virus.

24.1. It is deficient and unlawful in failing to have any regard to the effects on AD of the steps to be taken save, in fairness, to note it considers removing AD from activities would be disproportionate.

24.2. It does not have any regard to the impact on AD of the anti-social behaviours, unnatural to everyone including AD, of 'social distancing' and mask wearing.

24.3. It has no regard whatsoever to the risks of vaccination, nor to its efficacy, and must be proceeding on unquestioning assumption that vaccine is safe and effective.

25. It is now long out of date and out of step with understanding of SARS-Cov-2, as is the last Court-approved Care Plan of 31 Oct 2023 [page 800, F66] and as is the latest Care Plan offered to the Court and dated 28 June 2024 [page 813, F79]. To use the phrase coined by Mr Justice Hayden in re RN (case no. 13905631), the covid landscape has changed. (see below)

**G. Benefit to the community**

26. All parties, except AC, have relied on assumptions regarding efficacy of mask wearing and 'social distancing', none of which are founded on evidence before the Court. Yet this was the reason in 2021 for administering the vaccine.

27. AC need not refer the Court to the lack of such evidence, nor the peer reviewed literature discrediting such assumptions, since neither social distancing nor mask wearing is advised or required by any Guidance and to require AD to adopt such behaviours would, as it is understood is accepted by all, be disproportionate.

28. It would be appropriate, however, for the Court to recognise that it would be contrary to medical ethics and to ECHR principles for treatment to be considered having regard to the benefit to anyone other than the individual concerned. This principle seemed forgotten during the declared pandemic and declared emergency. It is in AD's best interests that this principle should be restated now and for the benefit of all parties. Altruism is not a relevant concern to project onto any person without capacity in absence of solid evidence to know it was their motivation when they previously had capacity.

## H. Ethnicity

29. The Court has not been informed on what basis AD's ethnicity is said to render him clinically extremely vulnerable or indeed at any greater risk from SARS-CoV-2 infection than the general population.

30. References to AD being at risk because of being within any black and asian minority ethnic (BAME) grouping are unsupported by evidence before the Court except so far as reference is made within the Guidance. The evidence underlying the allegation of particular risk from the respiratory disease arising from ethnicity, as opposed to socio-economic factors (low income being associated with poor health) and comorbidities, has not been examined and may well be of poor quality. (see further the evidence of Professor Finn paragraph 37 below)

31. Indeed, the pertaining Guidance (16 April 2021) noted that:

    31.1. "*Current evidence suggests that deprivation and being from black and asian minority ethnic groups results in a higher risk for death from SARS-CoV-2 infection (Williamson et al, 2020), although the factors that contribute to this are not yet clear"* [internal page 4]; and

    31.2. "*As there is an increased risk of hospitalisation in males, those from certain ethnic minority back-grounds, those who are obese or morbidly obese, and those from socio-economically deprived areas, JCVI advises that specific focus should be used to promote and deliver vaccination to these groups.*" [internal page 15]

32. The Guidance published at 17 August 2022 deleted such advice but further explained:

    32.1. "*Early evidence suggested that deprivation and being from black and asian minority ethnic group resulted in a higher risk for death from SARS-CoV-2 infection (Williamson et al, 2020), although the contribution of each of the possible underlying factors to these differences is unclear.*"

33. The Guidance published from 07 March 2023 onwards has contained no reference to ethnicity whatsoever save in relation to pregnant women and efficacy.

34. The early evidence and low take up of vaccinations within such ethnic groups may have affected the identification of priority groups for roll out stages of the vaccination programme, but the Guidance did not state ethnicity to place any individual at particular risk nor suggest they be elevated to consideration as clinically extremely vulnerable.

35. It is not just the ICB which has misinformed the Court (see paragraphs 38 to 50 below). The Official Solicitor also proceeded in her COP Application of 06 June 2022 to report AD as being extremely vulnerable by reason of his ethnicity [page 203, B93 para 8]. The OS is not a health professional and, in any event, the evidence on which that assertion was based has not been disclosed.

36. It should not escape attention that the term BAME was dropped by the government in March 2022, recognizing it was could hardly be a wider category and could skew statistics when looking at particular ethic groups. 'Anything but white' may be as accurate and as unhelpful. No matter if motivation was benign, there has been discrimination against AD by reason of his ethnicity. He has suffered injury and material breach of his Article 8 rights as a result.

## I. Categorisation as clinically vulnerable

37. It is correct that the Guidance categorises those with learning disabilities and Down Syndrome as vulnerable (though not extremely vulnerable). However, it is important to note that even this categoriation is, according to the report of Professor Finn (see further below) based on "poor quality" evidence:

> *8. There is a consensus that patients with Trisomy 21(Down Syndrome) which is the commonest trisomy, are prone to severe COVID-19 although, even now, the quality of the published evidence to support this view is poor. (Ref 2)*
>
> *9. Within the severe learning disability group, evidence regarding the frequency and severity of adverse reactions to vaccination in patients with trisomies, including trisomy 13, were and remain lacking. Accordingly, there was, and remains, no clear evidence upon which to base exceptional (in the sense of advising differently from the rest of the severe learning difficulty risk group) vaccine recommendations for this group.*

## J. Categorisation as clinically extremely vulnerable (CEV)

38. **Mr Y, Deputy Director of Quality care of Study Centre,** was wrong in his Second Witness Statement dated 26 April 2021 when he stated that "the guidance from the NHS is clear that all adults with Down's Syndrome are considered extremely clinically vulnerable to Covid-19." [page 501, para 6]. It did not do so in the Guidance from 16 April 2021 or since.

39. **Mr Z, Senior Community Learning Disability Nurse (Senior CLDN)**, authored a risk assessment on 07 October 2022 which also misleading stated "*AD has a diagnosis of Down's syndrome, meaning he is considered extremely clinically vulnerable according to national guidance.*" [page 765, F31]. The pertaining Guidance was published at 04 September 2022 and this is not the language used. The "clinically extremely vulnerable (CEV)" definition had been abandoned by the Guidance by this date. This failure accurately to quote the definition CEV warns of a lack of detailed attention to the Guidance.

40. Further, AD's risk should never have been assessed by health professionals involved by reference to the CEV definition in the Guidance. This should be read carefully:

    40.1. The 16 April 2021 Guidance [internal page 11] and the 03 September 2021 Guidance [internal page 13] the (emphasis added), under the heading "Clinically extremely vulnerable (group 4) and adults in priority group 6" (emphasis added) noted: "*People who are defined as clinically extremely vulnerable (CEV) are considered to be at high risk of severe illness from COVID-19 (https://www.gov.uk/government/publications/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19#cev).*"

    40.2. The NHS webpage found by the above link states in its introduction (emphasis added):

    "*The success of the COVID-19 vaccination programme has meant that the requirement for shielding and identifying people as clinically extremely vulnerable (CEV) is no longer necessary.*

*Most people who were part of this CEV patient cohort are no longer at substantially greater risk than the general population and are advised to follow the same guidance as everyone else on staying safe and preventing the spread of COVID-19 and other respiratory infections, as well as any further advice received from their healthcare professional.*

*However, there remains a smaller number of people whose weakened immune system means they may be at higher risk of serious illness from COVID-19, despite vaccination."*

40.3. Group 4 (priority groups being identified in Table 2) was "All those 70 years of age and over"; and "Clinically extremely vulnerable individuals (not including those under 16 years of age)".

40.4. Priority group 6 was simply "Adults aged 16 to 65 years in an at-risk group (Table 3)".

40.5. Table 3 was at-risk groups. It was not a table of the clinically extremely vulnerable. Indeed, the Guidance continued [internal page 13] "All patients on the CEV list will also fall into the broader disease categories outlined in table 3".]

41. The Order of 05 May 2023 repeated the errors made by referring to AD as being "categorised" as "clinically extremely vulnerable" and at higher risk of more serious consequences from Covid-19. [page 291, B181 para A].

42. It appears that the repeated reference to AD being "clinically extremely vulnerable" as justification for the need to vaccinate in his best interest has been a material failure of the ICB and OS which has led, without proper scrutiny, to the Court's order for sedation and vaccination.

43. It is noted that the ICB seemed to recognise the difference between vulnerable and extremely vulnerable in their Position Statement for hearing on 28 July 2022 [page 59, A48 para 7] but still they fell into error. (See Section H above re Ethnicity.)

**K. General failure to have proper regard to the Guidance**

44. As note as paragraph 9 above, the Court was in error in referring to AD as falling within Table 4 of the Guidance when reference should always have been to Table 3. This is not a typographical error as it is repeatedly made: see ICB's Position Statement [page 106, A95 para 22]; the Court Order dated 07 September 2023 [page 330, B220 7th bullet point; and page 333, B223 para K]; GN Law's letter of 11 September 2023 to Dr Ben Taylor [page 989, H93 para 8, and at page 990, H94 4th para, wrongly advising "*Table 3 of the Green Book (this is now Table 4 in the most recent version of the Green Book)*"]; in Dr Taylor's report dated 02 October 2023 [page 1005, H109]; Ms C's statement dated 21 October 203 at para 16 [page 721, E353]].

45. Given that reliance on the Guidance is the predominant justification for these proceedings and vaccination, the evidence that those informing the Court and relying upon it are not properly reading it or noting its contents is extremely concerning.

46. **Ms C (Acting Lead Nurse, COVID Vaccination Programme, The Acute Trust** in her first statement dated 27 April 2023 relies on what she has been told about previous evidence given to the Court does not refer only to the Guidance [e.g. page 693, E325 para 7] and shows her misunderstanding of the Guidance, misstating [at page 695, E327 para 20] that

> "*The JCVI continues to recommend Covid-19 vaccination for <u>those who are considered to be at higher clinical risk (previously, this was referred to as "clinically extremely vulnerable")</u> (Green Book, Pg. 22). Higher risk clinical groups for those aged 16 and over are set out in Table 3 of the Green Book at Pg. 25.*" (our emphasis).

47. As already pointed out, the terms are not synonymous and inclusion in a Table 3 category does not equate to being defined as clinically extremely vulnerable. The CEV category was abandoned, not renamed.

48. Mr Z (Senior CLDN for the ICB), in his latest Care Plan dated 28 June 2024 [page 813, F79] refers to Guidance of September 2023, not mentioning the later versions of 2024.

49. References to "extremely clinically vulnerable" [page 844, G20] are out of date and there must be concern that the ICB here, and others who have spent years focused on Covid, appear to maintain an inflexible view of Covid being and remaining a particularly dangerous disease. It may be so for some, but it can no longer generally be viewed in that light.

50. It is also concerning that Mr Z now seeks to move responsibility, stating "The Community Learning Disability Team cannot take responsibility for ongoing monitoring and updates to this care plan. This should be reviewed by the care team responsible for delivery as required." [page 813, F79] If the ICB with all of its resources is unable to have proper regard to the Guidance, it cannot be expected that any contracted care provider should do so.

51. At an RTM on 12 June 2024 for a hearing regarding AD's welfare (separately to the covid-vaccination) it was announced they were going to vaccinate AD the day before, but the sedation was out of stock. AC had not been informed by anyone and, when she questioned why not, she was told she did not need to be told and was asked where in the Court order it said she did. Fortnightly meetings have each been cancelled meeting and AC's emails have not received any or any substantive reply to explain why or to rearrange.

52. It is not clear how it came about that there would be an attempts to administer the vaccine on 11 and then 24 June 2024. It is not clear if someone within the Care Provider, [redacted]) has by him/herself proceeded to determine if and when any dose was to be administered, or if this was a decision taken Ms C or someone else.

53. It should not be necessary to state that inability to follow the Guidance, even by senior nurses of the ICB, should give serious concern about delegating responsibility to administer sedatives medication to AD which could quite easily be negligently overdosed.

54. In all events, a Care Provider's ability to meet a damages claim is uncertain and cover under a policy of insurance must be in doubt if there has been a failure to follow a Court order or pertaining Guidance. It is inappropriate, therefore, that responsibility for vaccination be removed from the ICB.

55. The government's Vaccine Damage Payment Scheme (VDPS) is limited to £120,000, requires proof of 60% disability arising and any payment made is treated as a benefit so that other current social security benefit payments are likely to be removed. All in all, it is wholly inadequate compensation against damage suffered. AC is entitled, therefore, to be assured that any person administering treatment is adequately insured.

## L. The covid landscape has changed

56. With these submissions we have separately provided copies from the case re RN in case no. 13905631:

56.1. Note of Ex Tempore Judgment of Hayden J at Hearing 4 July 2024

56.2. Report of Professor Adam Finn (Anonymised) dated 12 June 2024

56.3. Report of Professor Martin McCaffrey (Anonymised) dated 01 March 2023

57. Those responsible for the carers of AD are not qualified to dispute that which Professor Finn articulated within his statement in RN, which the [different] ICB there accepted when agreeing vaccination was not in RN's best interests, and which the public have long-recognised in any event: the SARS-CoV-2 virus has been everywhere, everyone has had it, and if they were going to get seriously ill they would have done so already:

> *"12. In the context of this case and the time that has elapsed since the question whether RN should be vaccinated arose, it seems relevant to point out significant changes in the drivers of policy recommendations around COVID-19 vaccination with the passage of time. In 2020-21 there was little or no population immunity either from infection or from vaccination, there were large epidemic waves occurring with associated vast health and economic costs and burdens and information on vaccination risks and benefits were still emerging. In particular, down payments were made against COVID-19 vaccine purchase so that the consideration of cost-benefit which applies to all health interventions in normal times were set aside and decisions were framed on risk-benefit considerations alone. It was also unclear at that time to what extent widespread immunisation would prevent virus transmission and thus indirectly protect vulnerable individuals who were less capable of mounting protective immune responses to vaccine or to infections. Policy at that time was framed around trying to protect the most exposed (e.g. health care workers) and the most vulnerable (e.g. the elderly) as fast as possible using the limited vaccine supplies available as they came through.*

*13. By contrast, in 2024, SARS CoV2 infection remains endemic at a relatively low level with much smaller epidemic waves driven in part by emergence of novel virus subvariants. Almost everyone has some degree of specific immunity from vaccination, infection and in most cases, both. It has become clear that the protection provided against infection and diseases by vaccine booster doses are relatively short lived and that widespread immunisation, while it prevents many cases of serious illness, has done little to halt circulation of the virus. Vaccine policy recommendations have thus been adjusted to focus on boosting immunity amongst the most high risk individuals, particularly the very old and those with reduced immune function or increased vulnerability because of underlying medical conditions.*

*14. Many people, including many in risk groups, have now had one or more episodes of infection with SARS CoV2 infection. This both strengthens and broadens any immunity they may previously have acquired from vaccination and illustrates, to some extent, their individual propensity to become seriously ill from this infection (which varies widely between individuals for reasons that are only partly understood, and which are difficult to measure or predict).*

*15. Finally cost-benefit considerations are now beginning to be applied to policy decisions in a more normal way.*

*16. Thus, while COVID-19 vaccination policy continues to play an important role in minimising the health and economic burdens of the SARS CoV2 virus, many aspects of the risk-benefit calculus both at the population and the individual level have changed dramatically."*

58. If the ICB in the current case disputes the above assessment, they should say so now and identify the evidence by which they do so.

59. The Court should also note that among those responsible for AD's care, his mother is no longer alone in her concerns as to benefit of vaccination. At 21 June 2024, AD's social work Claudine Whittaker wrote "*My professional opinion is that I remain unsure of the benefits of DA having the vaccine on a continued basis even after giving consideration to government guidance.*" [page 1288, J269]

**M. <u>New evidence of mRNA covid-vaccine risk particular to Trisomy individuals</u>**

60. In passing, the specific question which Professor Finn's report stated he was asked to address was not a question within the Court-approved letter of instruction to an expert and was irrelevant to the question of whether, in 2024, vaccination was in RN's bests interests.

61. In relation to the evidence in RN, though not apparent from the Hayden J's decision, Professor Finn had advised he considered himself not competent to address Professor McCaffrey's central issue of concern with respect to RN and all individuals with Trisomy conditions. That issue, to quote from an official transcript of that hearing, was identified by Hayden J as follows:

> *"I think that the general framework of the question in focus is twofold. One, do patients with trisomy 13 have a compromised response to oxidative stress, and, two, recognising the basis of the effectiveness of the current Covid vaccine relies on the presumption based on the results of clinical trials, that individuals have the ability normally to process spike protein, as well as to mount an adequate response to the oxidative stress, whether the patient with trisomy 13 can be presumed to have the same response or whether that chromosomal condition is likely to generate a different and less effective response. Now, I do not think that sounds like a cardiology question, but I do not know, so I would like you to"*

62. Thus, the issue is whether RN, having the chromosomal abnormality of Trisomy 13, or AD with Trisomy 21, may have a different response to oxidative stress than those with normal chromosomes and, if so, what might that be, both in terms of safety and in terms effectiveness of the vaccine for RN.

63. AC's solicitor was also solicitor for RN and can inform the Court that the issue was considered so serious that the parties were sent from a hearing on 08 February 2024 to find an expert to challenge Professor McCaffrey's report in a 'hot tubbing' exercise at a later hearing, subsequently listed for 4th and 5th July 2024. In the event, the ICB and ALR failed to produce any expert able to do so. Instead, just 2 weeks before the hearing, relying on Professor Finn's statement and without any comment as to Professor McCaffrey's principle concern, they advised they no longer considered vaccination to be in RN's best interests. The planned examination of Prof McCaffrey's opinion, and chance to examine why during a 5 month search no expert could be found to challenge it, therefore did not occur.

64. In any event, the serious issue raised by Professor McCaffrey remains live. Just as Hayden J considered there was opportunity, and it was appropriate during Winter in February 2024, to pause and investigate it, so that opportunity is available now in respect to AD. This is not an issue that can be left as if it were without merit. Hayden J was unable to consider it so. It was simply that, even without it, Hayden J was satisfied that vaccination was no longer in RN's best interests.

## N. New evidence: Czech Republic record-level data

65. While the Court says it is not in the position to determine questions over the safety and efficacy of the vaccines, that is in practice what is done by always preferring the government approved position in Guidance and when there is unwillingness to consider evidence contrary to the Guidance (on the assumption that the JCVI and MRHA, government appointed bodies, will have taken full and proper account of all such evidence).

66. There is considerable concern that the peer review process has itself been corrupted, as is set out in the peer-reviewed article by Cardiologist Dr Aseem Malhotra titled "*Curing the pan-demic of misinformation on COVID-19 mRNA vaccines through real evidence-based medicine, an article in two parts.*" [3, 4] This article stands as meeting the Court's requirement of credible, peer-reviewed research evidence indicating significant concern for the efficacy and/or safety of the vaccine. It was published on 26 September 2022. It has received worldwide attention but we are unaware of it having been subject to any criticism requiring withdrawal or any correction in response.

67. During the last 4 years, various highly published and renowned scientists have had their papers rejected, stalled or published and then quickly retracted, the only explanation being external pressure upon the journals because the paper was critical of the vaccines in efficacy or safety. It is not proposed to take this case into investigation of that assertion, but the Court can appreciate without need for further evidence that there will be delay between an article being submitted and processed before it is published with the badge of being 'peer reviewed.'

68. Sometimes, however, evidence may be clear enough that peer review is not necessary and may be expected to be delayed or frustrated owing to considerable commercial and political pressure to avoid the conclusions that would arise from it. An example arises now in the case of the Moderna mRNA-1273 COVID-19 vaccine (Spikevax®)), it being announced in December 2022 that

[3] Part 1: https://insulinresistance.org/index.php/jir/article/view/71/221
[4] Part 2: https://insulinresistance.org/index.php/jir/article/view/72/228

> *"Moderna and the UK government have entered a ten-year strategic collaboration to build a messenger ribonucleic acid (mRNA) research, development and manufacturing facility in the country."*[5]

69. The Czech Republic has just released anonymised record-level data for vaccination of over 10 million citizens. This is the first time across the world that such a large amount of patient level data has been released and the first time it has been released with the details of the particular vaccines administered. (The UK government has such data but maintains a refusal to release it.)

70. The Czech data identifies each vaccinee's year of birth, if someone died their date of death, date of vaccination, and brand of covid-19 vaccine. Since different brands of vaccine were used without being prescribed to any particular region or age or category of vaccinee[6] but purely upon what was available – so that all vaccines would be distributed to the same market - it is possible to compare the outcomes between different brands. The importance of this data and this comparison lies in the fact that there are no confounding factors that might explain difference in outcomes.

71. In short, the outcome shown is that death following the Moderna vaccine was more substantially likely than after the Pfizer vaccine and to a "highly statistically significant" extent. In other words, this outcome was not by chance.

72. This does not mean that the Pfizer vaccine was safe. However, the comparison with the Pfizer vaccine that proves that, at the very least, Moderna presents substantially greater risk than another product and so it should be avoided.

73. The analysis is explained by Steve Kirsh in his initial article published on 17 July 2024 (https://kirschsubstack.com/p/breaking-record-level-data-from-czech) and with all points of challenge and debate addressed in subsequent posts. The original data disclosed in response to the freedom of information request to the Czech government is also available via Steve Kirsh's site.

[5] https://www.pharmaceutical-technology.com/news/moderna-uk-mrna-facility/
[6] Steve Kirsh notes there were some particular allocations to those with comorbidities but this does not affect the outome.

74. There is an obvious plausible mechanism for higher rate of adverse effects from the Moderna product in that it uses a dose of 100 micrograms compared to Pfizer using 30 micrograms, though they are essentially the same product and Moderna is currently suing Pfizer Biontech for infringement of its patent on the product. Even the Guidance observes that "*Using a 50 microgram dose of Moderna is expected to have a lower rate of side effects (including myocarditis) than a 100 microgram dose.*" [internal page 15, top paragraph]

75. Further, analysis of the original clinical trials of each product also shows a significantly higher rate of adverse effects with higher dosage, in line with that seen in the Czech data. (Pfizer rejected the higher doses because of their toxicity.) Finally, various reporting systems around the world, such as the UK's Yellow Card and USA's VAERS, also show higher rate of adverse effects with higher dosage, in line with that seen in the Czech data. The Court may, of course, expect expert evidence to be provided in relation to such matters.

Expert evidence

76. Analysis of the Czech data has been conducted separately by others, including Dr Clare Craig, who have come to the same conclusion. Dr Craig has confirmed she would be willing to offer expert evidence to the Court. Although Steve Kirsh has not yet been approached it is anticipated he might also be prepared to assist.

77. In all events, however, AC would object to instruction of a sole expert with any links to manufacturers of vaccine products.

Third Party Disclosure

78. Because there are no confounding circumstances, AC is unaware of any argument to suggest the Czech data is not relevant to the UK. Such an argument would have to reason that the original mRNA covid-19 product trials conducted in the USA and Argentina were irrelevant to authorisation in the UK.

79. However, if objection is raised, then AC would seek an Order from the Court that the MHRA disclose the vaccine data for the UK in similar fashion to that of the Czech

Republic i.e. anonymised and by year of birth. In this way, there can be no reasonable argument that the data would be 'disclosive'.

80. Indeed, it is a matter of public interest that the UK government should be required to disclose this data in any event.

**O. Alternative to mRNA vaccines**

81. There does not appear to have been any consideration of alternative treatment to the novel mRNA gene therapy that remains without long term safety data, without significant short term safety data, which has never been subject to trial in respect of vulnerable persons and which remains under trial.

82. AD would be served well in his general health, in improving his resistance to all respiratory diseases, by continuing to facilitate a healthy diet (such as AC squeezing juice from fresh oranges and cooking lots of vegetables which DA really enjoys when brought on contact days) and ensuring his regular and frequent exercise and time out of the home. This would likely be the most effective preventative treatment that could be prescribed.

83. Finally, AC objects to administration of any covid-19 vaccine as being unnecessary and disproportionate interference with AD's Article 8 rights. However, if the Court is persuaded by evidence before it that vaccination is necessary and proportionate, then any order should note that:

83.1. approved traditional protein-based vaccine products, such as Novavax COVID-19 vaccine (Nuvaxovid®) or HIPRA bivalent Beta/Alpha COVID-19 vaccine (BIMERVAX®), although not in the NHS programme are available and must be considered as preferable alternative to be used instead of any mRNA product;

83.2. the Guidance advises "a booster dose of BIMERVAX® showed non-inferiority or superiority in neutralising antibody against the original, Beta, Delta, and BA.1 strains compared to those seen after Pfizer BioNTech vaccine (Comirnaty®) at 14 days and at some later time points" [internal page 10] i.e. it is more effective as the mRNA products, and certainly not less; and

83.3. if it were necessary for an mRNA product was to be used in circumstances it was not possible to obtain a traditional vaccine product, then the Moderna product must not be used.

**P. Referral to Tier 3 Judge**

84. If a Tier 1 or Tier 2 Judge does not agree with the view taken by Hayden J and the ICB and ALR re RN, it is submitted that an issue of public interest arises that demands the case be referred to a Tier 3 judge for resolution.

85. The Court's best interests decision for AD should be reviewed just as it was for RN. While the Court says that AD's wishes will be foremost, it has overridden his wishes and objection to vaccination on reasons presented as justifications in 2021 during the declared emergency. Since then, all parties agree it is likely AD has had covid at least twice, if not three times, and he has been isolated on the belief he had had it. (While anti-body testing may not have been possible, any idea that AD is unique in the population in not having been exposed to SARS-CoV-2 would be irrational.)

86. In any event, it is apparent that ICB's and care homes are adopting different views as to the covid-19 vaccines and differing interpretations of the Guidance. This itself is a matter of public interest that needs to be addressed.

87. With all respect to Her Honour Judge Brown who has clearly given much consideration to this matter, given that Her Honour did not appear independently to recognise certain issues addressed in these submissions, in particular those regarding mis-categorisation of AD as CEV, and if unlawful sedation and vaccination, in the attempt and in the execution, has occurred while the matter has been under her direction, it is humbly and most respectfully suggested that transfer to a Tier 3 Judge should be considered as a matter of assurance to the public and as being in the public interest.

29 July 2024

Jackson Osborne Solicitors
Ref: SJ/re AD 12219141