

Neutral Citation Number: [2022] EWHC 1996 (Admin).

Case No: CO/3001/2021

# IN THE HIGH COURT OF JUSTICE **QUEEN'S BENCH DIVISION** ADMINISTRATIVE COURT

Royal Courts of Justice Strand, London, WC2A 2LL

<u>I</u>	Date: 21st July 2022
Before:	
MR JUSTICE POOLE	
Between:	
The Queen (on the application of AB, a child by her Mother and Litigation Friend, EF)	<u>Claimant</u>
- and -	
Secretary of State for Health and Social Care	<u>Defendant</u>
The Joint Committee for Vaccination and Immunisatio	n <u>Interested Party</u>

Francis Hoar (instructed by Jackson Osborne Solicitors) for the Claimant Ewan West and Ruth Keating (instructed by the Government Legal Department) for the **Defendant** 

The Interested Party not appearing and not represented

Hearing dates: 21st July 2022

# **JUDGMENT**

This judgment was given in public. The judge has approved this version of the judgment for publication but the anonymity of the child Claimant and members of her family, including her litigation friend, must be strictly preserved. All persons, including representatives of the media, must ensure that this condition is strictly complied with. Failure to do so will be a contempt of court.

#### **Mr Justice Poole:**

1. This is a renewed oral application for permission to review the decision of the Defendant Secretary of State for Health and Social Care to offer Covid-19 vaccination to all 12 to 15 year old children ("the decision"). The judicial review claim is now brought solely through the First Claimant, a 13 year old girl who proceeds by her mother and Litigation Friend. The decision was made on 13 September 2021 and communicated by the Defendant on twitter and by a press release. The claim was issued on 1 September 2021. The route to the hearing before me is a little complex but I need only set out those parts of the history of these proceedings necessary to understand how the issue before this court has come to be framed.

## **Procedural History**

- 2. The claim as issued on 1 September 2021 applied for judicial review of a number of decisions related to the offer of Covid-19 vaccination to children and young people. On 2 September 2021 Eady J made an anonymity order and gave directions. On 17 September 2021 Swift J directed that the application for interim relief and permission to apply for judicial review should be considered at a hearing on 28 September. On 24 September 2021, the Claimants amended their Statement of Facts and Grounds (SFG). On 28 September 2021 at an oral hearing Jay J refused permission to review four of the decisions that had been challenged and adjourned permission to review two further decisions. On 20 October 2021 on paper, Jay J refused permission to apply to review those two decisions making costs orders to be assessed. On 22 October 2021, the Claimants applied for reconsideration of the refusal of permission at an oral hearing. That is the hearing that has now come before this court. This hearing has been delayed in part because of a disclosure application. On 13 January 2022 Swift J refused the Claimants' application for disclosure awarding costs against them. On 20 January 2022, the Claimants re-amended the SFG. On 8 February 2022 Swift J gave permission to amend the claim (dependent on permission being given) also permitting the Defendant and Interested Party to file and serve amended Summary Grounds of Defence in response (SGD). On 5 July 2022, the Claimants re-re-amended the SFG to indicate issues which were no longer pursued.
- 3. The claim is now pursued only by the First Claimant and only in respect of one decision the decision of 13 September 2021.

#### The Decision

4. In his tweet of 13 September 2021 the Defendant wrote, "I have accepted the unanimous recommendation from the Chief Medical Officers to offer vaccination to those aged 12 to 15. This will protect young people from catching Covid-19, reduce transmission in schools and help keep pupils in the classroom." The press release confirmed the Defendant's reliance on the recommendation which had been made in advice by the Chief Medical Officers (CMOs) of England, Northern Ireland, Scotland, and Wales to the Defendant dated 13 September 2021 headed, "Universal vaccination of children and young people aged 12 to 15 years against Covid-19." The CMOs also produced

appendices analysing evidence that they had considered, including a paper on the impact on school absences. Their advice referred to advice to the Defendant from the Joint Committee on Vaccination and Immunisation (JCVI), the Interested Party, said in the CMOs' advice to have been given on 2 September 2021 but in fact dated 3 September 2021.

- 5. The JCVI is an independent Departmental Expert Committee and a statutory body, a Standing Advisory Committee, established under the NHS (Standing Advisory Committees) Order 1981 (SI 1981/597). That order specified that the Committee is constituted for the purpose of advising the Secretary of State on "[t]he provision of vaccination and immunisation services being facilities for the prevention of illness". Its membership comprises experts in vaccinology, immunology, epidemiology, paediatric infectious disease, virology, infectious respiratory disease, adult infectious disease, public health, general practice, mathematical modelling, health economics and operational delivery of vaccination programmes.
- 6. The JCVI had advised on 3 September 2021,

"Overall, the committee is of the opinion that the benefits from vaccination are marginally greater than the potential known harms (tables 1 to 4) but acknowledges that there is considerable uncertainty regarding the magnitude of the potential harms. The margin of benefit, based primarily on a health perspective, is considered too small to support advice on a universal programme of vaccination of otherwise healthy 12 to 15-year-old children at this time. As longer-term data on potential adverse reactions accrue, greater certainty may allow for a reconsideration of the benefits and harms. Such data may not be available for several months.

"JCVI has considered commentary from stakeholders on the benefits of vaccination on the operation of schools and the educational impact of the pandemic on children and young people. JCVI is constituted with expertise to allow consideration of the health benefits and risks of vaccination and it is not within its remit to incorporate in-depth considerations on wider societal impacts, including educational benefits. The government may wish to seek further views on the wider societal and educational impacts from the chief medical officers of the 4 nations, with representation from JCVI in these subsequent discussions. There is considerable uncertainty regarding the impact of vaccination in children and young people on peer-to-peer transmission and transmission in the wider (highly vaccinated) population. Estimates from modelling vary substantially, and the committee is of the view that any impact on transmission may be relatively small, given the lower effectiveness of the vaccine against infection with the Delta variant."

- 7. The CMO for England acts as the UK government's principal medical adviser, and the professional head of all directors of public health in local government and the medical profession in government. The CMO provides public health and clinical advice to ministers in the Department of Health and Social Care (DHSC) and across government. It is an independent position at Permanent Secretary level. The other CMO's advise the Northern Ireland Executive, and the Scottish and Welsh Governments respectively.
- 8. In their advice to the Defendant of 13 September 2021, the CMOs say that at the Defendant's request, as recommended by the JCVI, the CMOs considered the matter of offering vaccination for 12 to 15 year olds from a "broader perspective". They list the bodies whose presidents, chairs and representatives had provided information – they included a number of royal medical colleges, the Faculty of Public Health and the Association of Directors of Public Health. They say that they examined data from the Office of National Statistics and published data on the impact of Covid-19 on education. They refer to the Medicines and Healthcare products Regulatory Agency (MRHA) which had determined that two vaccine products were safe and effective to use for children and young people over the age of 12. They note that the MRHA's decision was similar to the regulatory approvals given for the same age groups in multiple other jurisdictions. The CMOs said that the UK had benefited from having data from the USA, Canada and Israel which had already offered vaccines to children and young people aged 12 to 15. The CMOs had engaged in discussions with the JCVI after 3 September 2021 and the provision of their recommendation.
- 9. In their advice the CMOs expressly considered that there were risks and benefits from the use of any vaccine, The MRHA, JCVI, and international regulators had taken the view that for 12 to 15 year olds there was an advantage in being vaccinated against Covid-19 but that the absolute advantage was small or marginal. However, the CMOs also considered the impact of vaccination being offered to that age group as against no vaccination being offered, on their education, in particular the impact in areas of relative deprivation, on their mental health, and on the education system more widely, including the consequences for public health of local school closures and disruption of education. They concluded,
  - "Overall ... the view of the UK CMOs is that the additional likely benefits of reducing educational disruption, and the consequent reduction in public health harm from educational disruption, on balance provide sufficient extra advantage in addition to the marginal advantage at an individual level identified by the JCVI to recommend in favour of vaccinating this group. They therefore recommend on public health grounds that ministers extend the offer of universal vaccination with a first dose of Pfizer-BioNTech COVID-19 vaccine to all children and young people aged 12 to 15 not already covered by existing JCVI advice."
- 10. The Defendant Secretary of State's decision was to offer the vaccine to all 12 to 15 year olds (irrespective of whether they had any particular vulnerabilities) not to make vaccination compulsory. As it happens AB has not had the vaccine. It has been questioned during the proceedings whether the First Claimant has sufficient interest to

bring this claim but that point was not taken by the Defendant at the hearing before me and I proceed on the basis that she has standing to bring the claim in its now, more focused form.

### **Grounds**

- 11. The only ground now pursued in the claim is that in making the decision the Defendant acted irrationally and/or interfered disproportionately with the First Claimant's rights to life and bodily autonomy protected by Arts 2 and 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms (EHCR). Previously argued grounds, including a failure to make adequate inquiry prior to making the decision have been withdrawn. In short the First Claimant now contends that the decision was irrational in that the Defendant and his advisers failed to take into account relevant considerations, took into account irrelevant considerations or gave them manifestly disproportionate weight, and came to conclusions unavailable to any reasonable decision-maker. In particular,
  - i) The JCVI's advice that there was a marginal benefit from vaccination for healthy children was irrational because the evidence showed barely any risk from Covid-19 to those children and the risk of harm to those children from vaccination would be disproportionate. The re-re-amended SFG states, "there was no evidentially sound basis on which the Secretary of State, in making the impugned decision, could rationally and/or reasonably have determined that the benefit to children of authorising and/or offering the Vaccine to children in the relevant age-group outweighed the potential risk, alternatively, ... there is no sound evidence that can reasonably be relied upon that their benefit outweighs their risk."
  - ii) The CMOs' advice to the Defendant was irrational because they failed to model or quantify school absences due to the vaccination programme itself or due to the side-effects of vaccines;
  - iii) The Defendant acted further irrationally in accepting the advice of the CMOs when (a) the JCVI had not advised "mass vaccination" for this age group and the Defendant did not ask the JCVI to consider the CMOs' advice; and (b) the CMOs' advice was predicated on social grounds not medical grounds.
- 12. The First Claimant also contends in her skeleton argument, but not in the re-reamended SFG that the decision-making process was unlawful in that it was the JCVI, not the CMOs which was statutorily responsible for giving advice to the Defendant in this matter.
- 13. The First Claimant also contends that the decision was a disproportionate interference with her rights under Arts 2 and 8 of the ECHR "and, by extension [those of] all other children in her respective age-group), in view of the unreasonable exposure of children to an unreasonable risk."
- 14. The substantive remedies sought are a mandatory order that the Defendant advises that the vaccines are not offered to the relevant age group, a declaration under s.4 of the

Human Rights Act 1998 that the Defendant has violated Art 8 of the EHCR, and a declaration that the impugned decision is unlawful.

#### **Evidence**

15. I have been provided with witness evidence on behalf of the Defendant from Professor Whitty, CMO for England, Professor Lim, Chair of the JCVI on Covid-19, Dame June Raine, Chief Executive of the MHRA, Keith Willett, Senior Responsible Officer/ National Director for the COVID-19 Vaccine Deployment Programme at NHS England and NHS Improvement, Antonia Williams, Director of COVID-19 Vaccine Deployment in the Department of Health and Social Care, responsible for advising Ministers on policy issues relating to the deployment of COVID-19 vaccines, Lucy Vickers, Head of Profession for Statistics and Deputy Director for Statistics and Data Science at the Department of Health and Social Care, and Paul Allen, Deputy Director, COVID-19 and Health Protection Analysis in the Department of Health and Social Care. For the First Claimant I have received statements from her mother, her solicitor, Dr Clare Craig, a trained diagnostic pathologist who has specialised in cancer diagnosis but who has carried out "independent and autonomous research" in the area of Covid-19, Dr Peter McCullough, an expert in cardiovascular disease from Dallas, Texas, USA, and reports from Dr Rosalind Ranson, Executive Medical Director, Department of Health and Social Care, Isle of Man. Dr Ranson's evidence was directed to other challenges which are not now for my consideration.

## **Submissions**

- 16. I have received lengthy written submissions from the parties. The First Claimant emphasises alleged deficiencies in the evidence relied upon when advice and recommendations were given to the Defendant. These render the decision irrational. The three key failings identified in Mr Hoar's oral submissions were:
  - i) The absence of data available to the JCVI to justify its advice that vaccination could reduce the incidence of PIMS-TS (an inflammatory condition associated with Covid-19). On 19 July 2021, the JCVI had issued advice in which it noted that it was not known how Covid-19 vaccination might influence the occurrence or severity of PIMS-TS and that the available data were insufficient to advise on Covid-19 vaccination for the prevention of PIMS-TS. The First Claimant says that nothing had changed by 3 September 2021.
  - ii) There was "irrational reliance" by the JCVI on hospitalisation data within the so-called Warwick model. In particular the model assumed a rate of natural immunisation of 26% within the population whereas more recent evidence was that amongst schoolchildren infection rates were at about 50%.
  - iii) The Warwick model did not take into account school absences due to the implementation of an immunisation programme for 12-15 year olds or side-effects of the vaccine. It was irrational of the CMOs to take into account a model

quantifying school absences without vaccination, whilst not having evidence quantifying school absences due to vaccination.

- 17. The First Claimant further submitted that the fact that the decision concerns the safety of children and that it threatens their "fundamental rights" should give rise to intensive scrutiny of the decision by the court. Further, in the circumstances, "much more limited deference should thus be accorded to a decision maker where fundamental rights are at stake."
- 18. The First Claimant submits that it was irrational to defer the final advice on vaccination to the CMOs the JCVI should not have delegated its advisory functions in that way.
- 19. The First Claimant submits that the protection of a person's private life by Art 8 of the ECHR includes the physical and moral integrity of the person and encompasses protection against "compulsory or unwanted treatments". Although the vaccines are not mandated "they have been strenuously promoted, advertised and encouraged in a persistent national governmental campaign." Informed consent to treatment must be obtained before treatment is given *Montgomery v Lanarkshire Health Board* [2015] UKSC 11.
- 20. The Defendant submits, in short, that the most the First Claimant can do is show that there may be differences of opinion about the recommendations and the decision. There is no "knock-out blow" of the kind needed to show that the decision was unlawful due to irrationality. Given that the vaccination programme was not mandatory the First Claimant has failed to identify any breach of Convention rights. The JCVI gave its advice about vaccination but recognised that the advice needed to be considered within a broader picture. They did not delegate their responsibility with regard to medical advice about the risks and benefits of vaccination provision.

#### **Discussion and Conclusion**

- 21. The test I must apply is that I should refuse permission to apply for judicial review of the decision unless satisfied that there is an arguable ground for judicial review which has a realistic prospect of success.
- 22. The decision under challenge was a judgment by the Defendant who relied entirely on the recommendation of the CMOs of 13 September 2021. In turn, the CMOs had made their recommendation having accepted the advice of the MHRA and the JCVI about the efficacy and safety of the two Covid-19 vaccines under consideration for the 12 to 15 year age group, and the marginal advantage that vaccination would afford children and young people within that group. The CMOs stated in their recommendation to the Defendant Secretary of State that they had not "revisited" the advice of the JCVI or the MHRA. In making the decision the Defendant was obliged to consider relevant matters including the efficacy and safety of the vaccines for the relevant age group, the foreseeable impact of widespread uptake of the vaccine by 12 to 15 years olds, and the consequences of not offering the vaccine to them. Based on that assessment the Defendant had to make a judgment of what was in the public interest and, specifically, the interests of the children and young people concerned.
- 23. This court will not intervene as if it were for the court to substitute its own judgment for that of the Defendant. It is "forbidden territory" for the court to evaluate the

substantial merits of a decision of the kind made in this case, see for example *R* (*Plan B Earth*) *v Sec of State for Transport* [2020] EWCA Civ 214 at [273]. This is even more obviously so when, as here, the judgment is based on sophisticated medical, scientific or other specialist analysis. The question is not whether the court considers the analysis and the judgment to be correct, but whether the decision was one which the Defendant was lawfully entitled to make.

- 24. The medical professionals, scientists and other experts who contributed to the MHRA authorisation and the JCVI advice had considered and analysed a great deal of evidence. Due to the recency of Covid-19 and the fast development of new vaccines to counter it, the MHRA, the JCVI, international regulators and the CMOs had to base their advice and recommendations without the benefit of the sort of data that might have been available had the virus been in the community for decades or the vaccines years in development. The MHRA authorised the use of the vaccine for children and young persons without the benefit of the usual comprehensive studies. The long term effects of the vaccine had not been observed because the vaccines were so new. The circumstances in which these bodies had to operate were fast-moving and it was known that further data would become available in the future. The advice on which the decision was based was largely predictive – it was about the future consequences of alternative strategies in circumstances where the future was difficult to predict with confidence. Not so long after the decision being challenged was made, a new variant, Omicron, caused a surge in Covid-19 cases. It was not known on 13 September 2021 exactly what lay ahead. The context in which this judgment was made by the Defendant is important to any consideration of its lawfulness.
- 25. The circumstances in which advice was given, including the constant inflow of evidence, and the limitations of some of that evidence, were recognised by the JCVI and the CMOs. The First Claimant sought, nevertheless, to identify three fundamental flaws that, she maintained, rendered the decision unlawful.
- 26. First, complaint is made that the JCVI said in July 2021 that it would not recommend mass vaccination of under 18's unless more safety data was available, but that by the time of its advice of 3 September 2021 no further safety data had become available. Professor Lim contradicts that assertion. He states that at a meeting of the JCVI on 1 September 2021 they considered a safety report from the MHRA. Indeed, work in analysing new information was almost constant. The advice of 19 July 2021 which had identified a lack of data concerning the effectiveness of a vaccine in reducing incidence of PIMS-TS was based on data available as of 1 July 2021. Professor Lim's evidence shows that a great deal of further evidence had been provided to the JCVI since then. Not all of the evidence could be published much of it was confidential. However, it is very clear that the JCVI was in receipt of further evidence and entitled to take that into account when giving its advice on 3 September 2021, including its analysis of the likely effect of vaccination on reducing incidence of PIMS-TS.
- 27. Second, the First Claimant criticises reliance on the so-called Warwick model of hospitalisation when other evidence as to natural immunity was at odds with its assumptions. The model assumed 26% of the population had had Covid-19. Other evidence, referred to by Professor Lim in his statement for example, is that 50% of schoolchildren had had Covid-19. However, when written-up the model had express caveats about uncertainty. The CMOs advice, *Impact on school absence from COVID-19*, provided on the same day as its recommendations, 13 September 2021, sets out a

number of important caveats concerning the modelling of school absences, including "significant uncertainty" about the epidemiology scenarios, incomplete data, and "simplifications". The modelling was adopted as a tool – one of a number to allow the CMOs to consider the effects of vaccination as against no vaccination for 12 to 15 year olds. They clearly took into account the modelling "warts and all".

28. Third, the Warwick model did not quantify school absences due to the delivery of the vaccination programme and vaccine side-effects. The CMOs therefore quantified school absences without vaccination but not school absences following vaccination. Again, this is apparent from the CMOs advice and its paper on the impact on school absence. The Warwick model was not the sole evidence relied upon, as Professor Whitty's statement shows. The write-up of the Warwick model by the CMOs expressly includes a caveat about school absence:

There may also be some educational costs of vaccination: a small amount of school time is likely to be lost as a result of children attending vaccination sessions and some may have side effects of the vaccine that may lead to school absences which are not factored in here.

That caveat does not discredit the usefulness of the modelling, it merely indicates that the caveat has to be taken into account. Since it is stated as a caveat by the CMOs it must be concluded that they did take it into account.

- 29. The First Claimant also submits that the CMOs could not legitimately make a recommendation on the basis of a broader picture that included the consequences of the offer of vaccination, or no offer of vaccination, to the age group, including the consequences for education. In effect it is said that they were not qualified to do so. However, as experts in public health they were very well placed to consider the broader picture, including the medical evidence and, as they said, the public health consequences of the disruption to education which formed part of the basis for their recommendation. It is not arguable that they exceeded their function when making their recommendation to the Defendant Secretary of State. Nor did the JCVI delegate to the CMOs its own statutory duties. The JCVI's advice was given in compliance with its duty but some matters were outwith its function what it described as the broader picture.
- 30. The impugned decision was based on expert advice and recommendations. In this case that advice and those recommendations came from conspicuously well-qualified and experienced bodies of experts. With respect to those who have given written evidence on behalf of the First Claimant, it matters little that there are witnesses and experts who take a different view of the evidence that was available at the time of the decision or who would have made a different recommendation. Unless the First Claimant can point to a clear error undermining the rationality of the advice and recommendations given after expert scientific and medical analysis, rendering the decisions unlawful, then the court will not interfere. Beatson LJ in *R* (on the application of Mott) v Environment Agency [2004] 1 W.L.R. 4338 (at [69]) held that, "[in] principle, the court should afford a decision-maker an enhanced margin of appreciation in cases involving scientific, technical and predictive assessments". The court may scrutinise an expert assessment

for obvious error or logical flaw, but it will not seek to substitute its own analysis of technical, medical and scientific assessments, particularly those of a predictive nature and, in this case, in a fast-moving and developing field of knowledge, for those of esteemed bodies of expertise. It is not for the court to weigh the risks and benefits of offering a vaccine to the 12 to 15 year olds. Nor is it for the court to decide whether one expert's opinion should be preferred to another's. It would be astonishing if there was not a range of opinion about the subject matter of the CMOs' recommendation and the Defendant's decision. This is not a merits review. The First Claimant may take a point of interpretation of evidence here, or argue an inconsistency there, but she has failed to identify any flaw in the expert analysis on which the decision was based that could possibly be said to render the decision irrational. On the contrary, the decision was based on high-level analysis by experienced experts with access to all the most recent data and opinion.

- 31. Whilst an announcement of a decision of this importance by tweet and in a press release will not do justice to the sophisticated expert advice, that advice and its basis is set out in the recommendations of the CMOs and the JCVI to which I have referred. Those written advices are themselves summaries of voluminous evidence and analysis. The evidence makes it very clear that the Defendant relied on the analysis and assessments of experts which did take into account the relevant matters, did not omit consideration of relevant matters and which resulted in a decision which was very clearly one which could reasonably have been made in the circumstances at the time. The case that the decision was unlawful by reason of irrationality or *Wednesbury* unreasonableness is unarguable and has no realistic prospect of success.
- 32. The JCVI had recommended input from the CMOs and the role of the CMO for England was to advise the Defendant. That he did so in conjunction with the three other CMOs added weight and consistency to the approach across the four nations. There is no merit in the First Claimant's contention that it was impermissible for the Defendant to rely on the recommendations of the CMOs rather than the JCVI. In any event the JCVI had invited the Defendant to seek advice of the broader picture from the CMOs and were kept in discussions pending the CMOs recommendation on 13 September 2021.
- 33. The human rights ground adds nothing in this case because it is based on the same premise as the irrationality ground, namely that there was no evidence, or none that could reasonably be relied upon, to justify an interference with the Convention rights of the First Claimant and other children and young people. There was ample justification for the decision to offer the vaccine to 12 to 15 year olds and the decision was lawful. Furthermore, the decision was to offer vaccination not to compel vaccination. Those children or young people who were Gillick competent could decide for themselves whether to be vaccinated. The parents or guardians of those who were not competent to make the decision for themselves could choose or refuse vaccination on their behalf. There is no complaint about the inadequacy of the information provided to enable such decisions to be made. It is a mischaracterisation of the decision to say that it constitutes an interference with Art 2 or Art 8 rights when it leaves individuals or those responsible for them to make a free choice whether to have the treatment on offer.
- 34. Reference was made during written submissions to the best interests of children. It appears to me that it cannot be argued that the decision was inconsistent with seeking to promote and safeguard the best interests of children. The welfare of children is not

to be narrowly considered by reference only to clinical benefit. It is necessary to consider all the circumstances and to assess a child's or children's welfare in the widest sense – *Wyatt v Portsmouth NHS* [2005] EWCA Civ 1181 at [87] to [88]. The multifactorial assessment of efficacy, risks and benefits, taking into account the broad picture, which was carried out by the advisory bodies in this case was exactly the sort of analysis that would be expected to determine the best interests of the children in the relevant age group.

35. In my judgment there is no arguable ground for judicial review which has a realistic prospect of success and permission to apply for judicial review is refused.