

IN THE FAMILY COURT

NEUTRAL CITATION No: [2018] EWFC 56

**Before His Honour Judge Clifford Bellamy
sitting as a Deputy Judge of the High Court**

**Re B (A Child: Immunisation)
(Judgment handed down on 22 August 2018)**

Dan Foster, counsel for the mother

Miriam Yafai, counsel for the father

Muctar Johal, solicitor for the child

This judgment was delivered in private. The judge has given leave for it to be reported on the strict understanding that (irrespective of what is contained in the judgment) in any report no person other than the advocates and any other persons identified by name in the judgment itself may be identified by name and that, in particular, the anonymity of the child, the adult members of her family and their location must be strictly preserved.

JUDGE BELLAMY:

1. B is a 5-year-old girl. She is an only child. Her parents separated in 2015. Since their separation disagreements have arisen concerning B's care. In 2017 the mother issued an application seeking a child arrangements order to determine the living and contact arrangements for B, a specific issue order concerning nursery provision for B and a specific issue order to permit the mother to arrange for B to be immunised. Only the last issue remains contested. This judgment deals with that issue.

Background

2. The issue is properly categorised as an issue of preventative health care rather than medical treatment. In the UK the vaccination of children is not compulsory. The vaccination of very young children, though strongly recommended, is a decision which the State entrusts to parents to determine as part of their parental responsibility. Such a decision would not be brought to court if the parents were agreed that the vaccination should not be given.
3. When B's parents were living together B had all of the immunisations recommended for a child of her age. The recommendations are set out in *The routine immunisation schedule* ('the schedule') which is to be found in the *Green Book: Immunisation against Infectious Diseases* ('the Green Book') published by Public Health England. Both parents consented to those immunisations taking place.
4. At her present age, the schedule recommends that B should now have three further vaccinations: a single dose of the combined diphtheria/tetanus/whooping cough/polio immunisation, by injection; a single dose of the combined measles/mumps/rubella immunisation ('MMR'), by injection; and a single dose of influenza vaccine by nasal spray. The first two are overdue. The third should be given at the beginning of the influenza season (September/October).
5. The court granted permission to the parties jointly to instruct a medical expert witness, Dr David Elliman. Dr Elliman has assisted the court by providing both written and oral evidence. Both parents have filed written statements. Neither has given oral evidence. B has been joined as a party to these proceedings and an officer of Cafcass appointed as her Children's Guardian ('the guardian'). The mother's position, supported by the guardian, is that the outstanding immunisations should take place. The father objects.

Dr David Elliman

6. Dr David Elliman has devoted a large part of his career to the study of immunology. His curriculum vitae is very impressive. From 1989 to 2003 he held the post of Consultant in

Community Child Health in Wandsworth and District Immunisation Coordinator. For many years he was a member of the British Paediatric Association (now the Royal College of Paediatrics and Child Health) Standing Committee on Immunisation. He has written a large number of articles on immunisation in childhood. He is one of the editors of the *Manual of Childhood Infections* first published in 1995 and now in its fourth edition. He is the co-author of *Childhood Immunisation. The Facts*, a guide for parents. He currently works half time for Great Ormond Street Hospital from where he is seconded to Public Health England. He does not have an immunisation role for Public Health England. However, he is also an honorary consultant with Whittington Health and North Central London NHS Trusts where he provides clinical advice and teaching in relation to immunisation. Dr Elliman is exceptionally well qualified to provide the court with an expert opinion in this case.

B's medical history

7. Dr Elliman has reviewed B's GP records. B was born at term. She had a normal birthweight. No neonatal problems were recorded. Her 6-week physical examination is recorded as normal. She has had a number of minor illnesses, a minor head injury and injuries to her left elbow. Dr Elliman is satisfied that there is nothing in B's medical history that contraindicates the appropriateness of her having the vaccinations proposed.

The viruses and infections and their incidence

8. The detail which follows concerning the nature of the viruses and infections against which immunisation is sought for B and the incidence of those viruses and infections in the general population, is taken from Dr Elliman's report.

Diphtheria

9. Diphtheria is a highly contagious and potentially fatal infection. The infection is spread by respiratory droplets from an infected person, but can also be passed on by contact with the germ. The infected person may not have any symptoms. Amongst the effects is the production of a membrane across the back of the throat, which can lead to suffocation if not treated. The toxin can also cause paralysis of the muscles of the limbs or of the heart. This can result in breathing problems and heart failure.

Incidence

10. Prior to the introduction of the vaccine, between 2,500 and 3,000 children died each year from diphtheria in England and Wales. Between 2000 and 2015, there were four deaths due to diphtheria and 16 cases of classical diphtheria. Two of the deaths occurred in unimmunised children, one of whom had not been abroad. In England in 2016 and 2017,

there has been one further case of classical diphtheria and no deaths. In this context, 'classical diphtheria' refers to the form of the disease in which a grey membrane forms across the throat impeding breathing.

Tetanus

11. Tetanus is a serious but rare condition caused by bacteria getting into a wound. The wound itself may be of a minor nature, barely noticed and not requiring medical treatment. The organism multiplies in the wound and produces the toxin. The toxin causes the muscles to go into spasm with the most minor of stimuli.

Incidence

12. Between 2000 and 2015 there were 110 cases of tetanus and nine deaths from tetanus in England and Wales. In England there were 9 cases and no deaths to the end of 2017.

Whooping cough

13. Whooping cough is a highly contagious bacterial infection of the lungs and airways. The typical illness begins with what can appear to be a cold. A cough develops, which may occur in bouts accompanied by vomiting. The whole illness often lasts for a matter of months and can be very debilitating, at whatever age it occurs. The disease may be complicated by weight loss due to vomiting, chest infection and brain damage due to lack of oxygen. Complications and death are most likely in young children, particularly in those less than six months old.

Incidence

14. The incidence of whooping cough follows a cyclical pattern with peaks every four years. In the 1940s, prior to the introduction of the vaccine, in most years there were over 100,000 cases notified and, in some years, over 160,000. Each year there were, on average, over 900 deaths, although this was falling. Since the introduction of the vaccine, the number of reported cases has fallen as have the numbers of deaths.

Polio

15. Polio is caused by a virus of which there are three strains (1, 2 & 3). Most people who are infected by the virus do not develop the disease. However, in industrialised countries about 1 in 1000 children and 1 in 75 adults who are infected go on to develop the disease. The disease may take the form of paralysis of the muscles. This can be severe enough to require mechanical support with ventilation. Some patients die, others may recover but with a residual paralysis and others recover totally. Some survivors develop 'post-polio syndrome' some decades after they had polio. There are a variety of symptoms, but it can

be very like chronic fatigue syndrome. The only effective remedy is prevention by prior vaccination.

Incidence

16. Wild polio virus types 2 and 3 have been eradicated. Wild polio infections due to type 1 still occur in Pakistan and Afghanistan.

Measles

17. Measles is caused by a virus that is spread by respiratory droplets. It is highly infectious. It is predominantly a disease of childhood and results in rash, temperature and malaise. Complications are common – otitis media (7-9%), pneumonia (1-6%), convulsions (one in 200), and encephalitis (one in 1000). Between one in 1000 and one in 5000 people who develop measles will die from it. Before the introduction of immunisation against measles, almost all children would have had the disease by their tenth birthday and 100 people would die from measles each year.

Incidence

18. Following the introduction of vaccines, the number of deaths due to measles has fallen. Since 1992, when there was one death, there has been a single death in each of 2006, 2008, 2013 and 2016. The deaths in 2006 and 2008 were in adolescents on immunosuppressive drugs. In 2013 a young adult with asthma died in Wales from measles and in 2016, a ten-month-old baby died from the complications of measles. Most years there is one or more deaths due to the late effects of measles. There was an upsurge in cases in predominantly unimmunised people, in 2006/13. This appeared to have subsided, but there has been a recent increase with 440 confirmed cases this year up to May 9. This compares with 267 cases in the whole of 2017 and 531 cases in 2016. Most cases are linked to importations from Europe.

Mumps

19. Mumps is a contagious viral infection that is spread by respiratory droplets. Some infected people have no symptoms whereas others have swelling of the parotid glands (one of the pairs of salivary glands, situated at the angle of the jaw on each side). Complications include meningitis (the commonest form of viral meningitis before the vaccine was introduced), inflammation of the pancreas and permanent (usually one sided) hearing loss.

Incidence

20. Prior to the introduction of the MMR vaccine there were up to five deaths a year and most children would have had the disease by the time they reached ten years old. Since

the introduction of the MMR vaccine, the incidence of mumps has decreased, though there have been marked fluctuations with a considerable increase in 2004/5. A large number of cases were adolescents or young adults who had not had two doses of the MMR vaccine. In 2017 there were 1840 confirmed cases.

Rubella

21. Rubella (also known as German measles) is caused by a virus that is spread by respiratory droplets. Many people may be infected without ever being aware of it. In most people who have symptomatic disease it takes the form of a rash and little else. However, if a susceptible woman in early pregnancy is infected with rubella, the unborn baby may become infected and this infection can severely damage the baby. This damage can affect the ears, eyes, heart and almost any other part of the body.

Incidence

22. The number of confirmed cases of rubella in 2012 and 2013 were 65 and 12 respectively. In 2017, this had fallen to 4. In recent years there have usually been one or two cases each year of babies damaged by maternal rubella. There were none in 2016 and 2017.

Influenza

23. Influenza-like illness is caused by a number of different viruses including influenza virus A, B, C and D. Influenza virus C is of little importance and influenza virus D does not infect humans. The A and B strains often change in their composition year on year. Every so often the circulating virus undergoes a major change and pandemics occur. Including that of 1918/19, there have been four pandemics in the last 100 years. Infection is by respiratory droplets and is easily spread. The disease usually takes the form of a fever, with chills, muscular aches and pains, headache and general malaise. There may be other symptoms of an upper respiratory tract infection. One of the main dangers is the development of a bacterial infection, eg pneumonia.

Incidence

24. The disease is worse at either extreme of age and in those with underlying medical problems. The actual burden of influenza disease varies year on year, even in non-pandemic years. It has been estimated that between 2000/1 and 2007/8, 176 (95% C.I. +/-5) per 100,000 otherwise healthy children aged 6 months to 4 years and 10 (95% C.I.+/-0.8) per 100,000 aged 5 to 14 years were admitted to hospital each year with influenza. As important, young children are a major source of infection for the rest of the population, including vulnerable adults and the elderly, such as their grandparents. They have been referred to as “super-spreaders”.

The vaccines proposed for B

25. Dr Elliman describes the vaccines which the schedule proposes that B should have and their efficacy.

Diphtheria and tetanus vaccines

26. These are produced by taking the toxin produced by the germs and chemically treating them so that they can no longer cause disease, but the immune system is tricked into thinking it is the toxin and producing a protective immune response. These vaccines were produced before randomised controlled trials were widespread and relied on the observation that the vaccines produced high levels of antibodies. The introduction of the vaccines was followed by falls in the incidence of the diseases. To maintain immunity throughout life, a total of five doses of each vaccine is necessary.
27. Both vaccines have been in use around the world for many decades and have a very good safety record. Local reactions, such as redness and tenderness at the site of the injection are common, as is a mild rise in temperature. More serious side effects are extremely uncommon. WHO describes diphtheria vaccine as “one of the safest vaccines available” and states that “severe reactions are rare”. Tetanus vaccine, likewise, has an excellent safety record. WHO states that it is “considered very safe” and while “mild local reactions are common”, “more serious reactions are rare”.

Pertussis vaccine

28. The pertussis vaccines now in use in the UK and most industrialised countries are known as *acellular* pertussis vaccines (aP). Those used in the UK are prepared from three or five components of the pertussis germ. These are much more highly purified than the previously used whole cell vaccines. Because pertussis is more difficult to diagnose than many other diseases, it is difficult to estimate the efficacy of the vaccines accurately. A recent review of the literature concluded that the efficacy of the vaccine against severe disease was 84-85% and against mild disease was 71-78%. The protection does wear off, as is the case following the disease, and one or more boosters are needed.
29. The old whooping cough vaccine gave rise to significant side effects, although it was never proven that it caused any lasting harm. The current acellular vaccines cause fewer side effects. Adding the new acellular vaccines to combinations of diphtheria and tetanus vaccines does not appear to give rise to any increase in reactions.

Inactivated polio vaccine (IPV)

30. The vaccines in current use in the UK, and most well-resourced countries, contain the three wild viruses that have been inactivated. Prior to the introduction of inactivated

(Salk) vaccine, a large trial in the 1950s demonstrated an efficacy of 80-90% against paralytic polio and 60-70% against any form of polio. Experience in Canada recorded an efficacy of 96% for the inactivated vaccine. The currently used enhanced IPV has even greater efficacy.

31. Adverse reactions apart from local reactions are very uncommon. As the vaccines are inactivated, they cannot cause the disease.

Diphtheria/tetanus/acellular pertussis/inactivated polio vaccine - the combined vaccines

32. Dr Elliman makes the point that it is not appropriate to assume that a combined vaccine will act in a way that just takes on the properties of the separate vaccine. There have been examples where this has been shown to be untrue. However, these do appear to be exceptions to the general pattern which is that combined vaccines tend to work just as well as separate vaccines and do not cause greater side effects. The evidence is that their safety and effectiveness profile is no different from when the vaccines are given separately.

Measles, Mumps and Rubella vaccine (MMR)

33. The MMR is the only vaccine available on the NHS to protect against the constituent diseases. The individual vaccines are not available separately on the NHS. MMR consists of the wild viruses that have been toned down (*attenuated*), but not killed.
34. In 2012 a systematic review for the Cochrane Collaboration concluded that a single dose of MMR vaccination “was at least 95% effective in preventing clinical measles” and using the vaccine containing the mumps vaccine virus used in the UK, was between 69% and 81% effective against clinical mumps. They found no studies showing how effective the combined vaccine was against rubella. There is evidence that the protection against mumps falls with time. A slightly more up to date review found the effectiveness of the MMR vaccine to be about 99% against rubella. The effectiveness of two doses of MMR against measles was 97% and against mumps was 88%.
35. The main side effect of the vaccine is the development of a mild form of one or more of the illnesses. One in ten develops mild measles at 7-10 days after the vaccine and one in fifty develops mild mumps. Mild rubella is less common and often unnoticed. Between 1 in 1000 and 1 in 2000 children receiving their first dose of vaccine in the second year of life will have a febrile convulsion – this is about a tenth of the risk from the disease. About 1 in 30,000 children develop a temporary lowering of platelets making them more likely to bleed. This is about a tenth to twentieth the risk from the diseases and is usually milder than the non-vaccine related condition. The Cochrane review (mentioned above)

reported that “Exposure to the MMR vaccine was unlikely to be associated with autism, asthma, leukaemia, hay fever, type 1 diabetes, gait disturbance, Crohn's disease, demyelinating diseases, bacterial or viral infections”. The review stated that mumps meningitis has been reported with vaccines containing particular strains of mumps virus. These were used in UK, but withdrawn in 1992. There is no good evidence that this left any permanent harm.

Influenza

36. There are two forms of influenza vaccine – a live attenuated vaccine and many forms of inactivated vaccine, containing all or parts of the virus. The live vaccine is the variety recommended for children of B's age. It contains four strains of virus and is administered nasally.
37. Preschool children are much more likely to suffer the complications of influenza, thus requiring hospital admission. There is also a substantial reservoir of disease from which spread occurs to other members of the population. Pre-school have been called ‘super-spreaders’. It has been shown that immunising primary school children not only reduces the incidence of infection in the recipients, but it also reduces the incidence of influenza in the local general population. For these reasons, the Joint Committee on Vaccine and Immunisation has recommended that all children between 2 and 16 years old inclusive should ultimately receive the live attenuated inactivated vaccine (LAIV). This vaccine was chosen because it seemed to be the most effective in children.
38. In England in 2015/16, the effectiveness of LAIV in reducing the frequency of hospital admission in two to six-year olds was about 55%. Data from the 2016/17 season showed that the LAIV used in 2-17 year old children and young people had an effectiveness against influenza disease of approximately 66% against all circulating influenza viruses.
39. Data from the 2015/16 season in England confirmed that, when the vaccine was given to all primary school children in an area, there was indeed a reduction in many measures of influenza in the local adult population, although most of this did not reach statistical significance because of the small numbers involved.
40. The vaccines can cause minor local reactions in the nose after the LAIV nasal spray and at the site of injection of the inactivated vaccines. The vaccines can also cause fever and malaise. No major side effects have been associated with LAIV.
41. Having set out the landscape I now turn to consider the father's objections.

The father's objections

42. Though he has no relevant medical or scientific training or expertise, the father has clearly undertaken an immense amount of research. He has exhibited to his statements more than 300 pages of material comprising, for the most part, academic articles and statistical information. He says,

‘I appreciate that there is a lot of conflicting information with regards to the safety and necessity of vaccines, and it is difficult to discern what is factual and what is speculation, but I believe we would err to not take into account all of the information available. It is especially difficult to conduct meaningful research against a child having vaccinations as the majority of studies exist behind a pay wall. I have therefore conducted my research by obtaining information from individuals who are facing similar issues, and who believe that the current policy of making children obtain vaccinations is purely based on policy, not on the basis of whether it will benefit their health.’

I have no reason to believe that the father's objections are not reflective of genuine and sincerely held beliefs. The mother does not accept that to be the case. As I have not heard oral evidence from the father I am not able to reach a firm conclusion on that point.

43. Dr Elliman accepts that most peer reviewed studies in medicine, and in many other fields, are published in academic journals to which one has to subscribe, though he notes that an increasing number of journals are providing free access to some articles and even, in some cases, to all articles they publish. It is, though, his opinion that conducting research by obtaining information from individuals “facing similar issues” is likely to lead to bias and is no replacement for examination of the original research.

44. The father's key points appear to be that:

(i) The need for further vaccinations for B has not been established. B has never been tested to see if she is immune to any of the viruses she is being vaccinated against either before or after vaccinations have taken place. In the father's opinion it is quite possible that B's immunisation status is such that there is no need for her to have further vaccinations.

(ii) The proposed vaccinations would put B's health at greater risk than is necessary. The father is concerned that vaccinations continue to be administered as a precaution despite the associated risks. He is also concerned about the fact that the ingredients in the vaccines include a number of artificial products, chemicals, human and animal DNA, live viruses, aluminium based adjuvants and many other known toxic ingredients. The father does not consent

to B being injected with any toxic substance. Parent Information Leaflets available online list a range of potential adverse consequences from vaccines.

- (iii) Certain vaccines have in the past been withdrawn from use because of adverse reactions even though those vaccines had been tested and considered to be 'safe' at the time they were put into general use. It is not possible to have absolute confidence in the safety of vaccinations routinely administered to children.
- (iv) It is frequently said that the benefits of vaccination outweigh the risks. The father submits that this statement needs to be used with care. The benefits of vaccination programs are being misrepresented. The pharmaceutical industry has a clear financial interest in promoting the vaccines it produces. B is a child who is fit and healthy with no medical conditions to be concerned about. This reduces her risk of contracting any of the diseases referred to. Further, as Dr Elliman acknowledges, there is no reason to believe that B is at particular risk from any of the vaccine-preventable diseases or their complications.
- (v) The science involved in immunology is not settled and much of what the public is told about vaccinations comes from policy-driven assumptions. Although vaccinations may have had some impact on reducing the prevalence of disease they are not the only factor in reducing illnesses and susceptibility to illness.
- (vi) The Green Book states that 'if one parent agrees to immunisations but the other disagrees, the immunisations should not be carried out unless both parents agree or there is a specific court approval that the immunisations are in the best interest of the child'. This clearly shows that preference is given automatically to the parent who does not consent. So far as concerns B, 'best interest' must be that which is determined to be the safest option for her and which puts her least at risk.

45. The father has considered the expert evidence of Dr Elliman. His position remains unchanged.

Dr Elliman's response to the father's concerns

46. *Point (i)*: Dr Elliman does not accept the father's proposition that some children may develop immunity without taking the full course of vaccine. It would be unusual for someone to have immunity against a particular disease without being vaccinated against that disease. Dr Elliman found it difficult to conceive that this was a realistic possibility.

47. Dr Elliman also does not accept that children should routinely be screened before being given a second dose of the same vaccine. In his report he says that,
- ‘It has been suggested that as some people may develop immunity without completing a full course of vaccine, it ought to be routine to measure immunity part way through a course to see if they need to have all the doses of a vaccine. There are a number of problems with this. It would be an immense undertaking to take blood samples from a very large number of children, would be more unpleasant for the children (a blood test is more traumatic than an intramuscular injection) and there is often not a good correlation between routinely measured antibodies and protection. In view of this and the fact that having ‘extra’ doses causes no significant harm, it is not an officially recommended practice anywhere.’
48. Dr Elliman also makes the point that screening is not reliable. In the past it had been common to test for rubella during pregnancy but it came to be recognised that the test was not reliable and so it was stopped.
49. There is evidence to suggest that over time the effectiveness of a vaccine wears off and a booster is required. With respect to mumps, in particular, there is a lot of doubt about how long immunity lasts. 10% of those who contract measles have had the MMR vaccine. This is why a second dose is recommended.
50. *Point (ii)*: Dr Elliman does not accept that the proposed vaccinations would put B’s health at greater risk than is necessary. It is clear from B’s GP records that she is a healthy child. That reduces the risk of her developing serious side effects.
51. The vaccines which it is proposed B should have contain neomycin (the MMR vaccine); aluminium phosphate, formaldehyde, neomycin, polymyxin B, phenoxyethanol and aluminium hydroxide (the combined diphtheria/tetanus/whooping cough/polio vaccine) and egg protein (ovalbumin) and porcine gelatin (influenza vaccine). Three of these are live attenuated vaccines and the fourth (the combined diphtheria/tetanus/whooping cough/polio vaccine) is inactivated. Although there has been anxiety about the inclusion in vaccines of, for example, aluminium (a recent paper has suggested that levels of aluminium are set too high) no published study has provided evidence of harm. The amount of formaldehyde in vaccines is less than that which occurs naturally in the body. The levels of neomycin, polymyxin B and phenoxyethanol used in vaccines are much too small to give rise to a risk of harm.
52. Dr Elliman does not share the father’s view that these factors give rise to a level of risk that cannot be justified and which should be avoided. Vaccines are always trialled before they go into general use. Such trials enable the nature and frequency of side effects to be ascertained. Adverse events must be reported to the Medicines and Healthcare Products

Regulatory Agency. Such reports are a signal that there may be a problem. Carefully structured research would need to take place before making a decision as to whether a suspected side effect of a vaccine is indeed related or whether it is simply coincidental.

53. With respect to the father's general point concerning the toxicity of vaccines, Dr Elliman noted that there are substances which are widely acknowledged to be beneficial in small doses, such as vitamin D, but which when taken in large quantities are poisonous. Vaccines do not contain toxins at a level that could be poisonous.

54. *Point (iii)*: Dr Elliman accepts that some vaccines have been withdrawn from use because of concerns relating to risk. For example, he says that

‘Guillaine-Barre Syndrome, a neurological condition, was associated, in adults, with the inactivated pandemic ‘flu vaccine used in USA in 1976. It has not been reliably associated with other ‘flu vaccines. There was an increased risk of narcolepsy and cataplexy in children after the administration of one brand of inactivated vaccine, used during the pandemic in 2009. This vaccine is no longer in use. Another inactivated vaccine has been shown to increase the risk of febrile convulsions in children under five years old. It is no longer recommended for young children. No such problems have been reported after LAIV.’

55. It could be said that the fact that some vaccines have been withdrawn from use because of concerns relating to risk is an indication that the systems in place for the continuous monitoring of efficacy and safety of vaccines is effective.

56. I note in passing that the Green Book is available online. It is regularly updated. It is possible to sign up to receive vaccine updates. So far in 2018 eight vaccine updates have been published. The website provides updating safety information.

57. *Point (iv)*: Dr Elliman did not accept the father's contention that vaccines should not be used because there is no absolute certainty that a vaccine will not give rise to side effects. It is a matter of balancing risk. The risks to health of not having a particular vaccine and developing the disease are greater than the risk of suffering a serious adverse reaction to the vaccine. The father's contention requires the proof of a negative. Dr Elliman made the point that it is impossible to prove a scientific negative.

58. Dr Elliman also does not accept the father's submission that the introduction and use of vaccines are motivated by financial gain more than by scientifically proven efficacy. He says that,

‘The major considerations when deciding whether to introduce a vaccine, apart from whether a vaccine exists, are the vaccine's efficacy (how well it protects), safety and cost; and the disease's frequency and severity. It is the balance of these factors that will form the basis of the decision.’

In the UK, whether a vaccine should be part of the national immunisation programme is decided by the Department of Health based on advice from the Joint Committee on Vaccination and Immunisation (JCVI), an independent Departmental Expert Committee and a statutory body, consisting of a variety of experts and at least one lay member. To reach its decision, the JCVI will review all the existing evidence, including how safe and effective the vaccine is likely to be, how much it costs and whether it can be delivered safely and to all who want it. They will also consider the frequency and severity of the disease and whether there are any groups within the population who are more or less at risk of catching the disease or suffering its complications. Much of this evidence will be from trials for which the funding will have come from a variety of sources – government, health service and vaccine manufacturers being the most common. The trials will be examined to see whether there may be any sources of bias, whether unintentional or intentional. The source of funding will be noted (it is a requirement for this to be provided), but this of itself will not influence decisions. Any evidence will be read, carefully, and conclusions not accepted where the evidence doesn't support them. It has been noted on a number of occasions that sometimes the conclusions are more favourable to a drug or vaccine than the evidence would show and that this is commoner when funding has been by the manufacturer of the product than a government related source. However, the fact that this is apparent shows the value of ensuring all studies describe their methods and results in full and that the reader reads the whole account of how the evidence was collected and analysed, not just the summary.'

59. *Point (v)*: Dr Elliman agrees that there are many factors that are important in reducing illness and susceptibility to illness including sanitation, nutrition and reducing overcrowding and underlying illness. However, he makes the point that repeated studies comparing unimmunised and immunised groups of children, who are otherwise similar, have shown that unimmunised children are more likely to be infected with organism(s) targeted by the vaccine and suffer the effects of the infection.
60. *Point (vi)*: The father's proposition appears to be that if two parents are unable to agree whether their child should have a particular vaccination, the status quo should be preserved and the views of the objecting parent should hold sway. I do not accept that proposition. It is wrong in law. In *Re Z* [1996] 1 FLR 191 at p. 217, Sir Thomas Bingham MR analysed the function of the court in the following passage:

'I understood the mother's counsel to advance two reasons why discretion could only be properly exercised to the effect contended for. The first was that the court should never override the decision of a devoted and responsible parent such as this mother was found to be. I would for my part accept without reservation that the decision of a devoted and responsible parent should be treated with respect. It should certainly not be disregarded or lightly set aside. But the role of the court is to exercise an independent and objective judgment. If that judgment is in accord with that of the devoted and responsible parent, well and good. If it is not, then it is the duty of the court, after giving due weight to the view of the devoted and responsible parent, to give effect to its own judgment. That is what it is there for. Its judgment may of course

be wrong. So may that of the parent. But once the jurisdiction of the court is invoked its clear duty is to reach and express the best judgment it can.’

61. Although that analysis was formulated in a wardship case, it has been held that it equally defines the function of the court deciding an application for a specific issue order advanced by one parent and resisted by another, each holding parental responsibility in relation to the child (see *Re B (A Child)* [2003] EWCA Civ 1148 per Thorpe LJ at §20).

Why vaccinate?

62. Given the concerns expressed by the father and the acknowledgment by Dr Elliman that no vaccination is 100% risk-free, the question arises: why vaccinate? Dr Elliman says that the answer is to be found in a risk/benefit analysis which needs to be undertaken not in a generalised way but in a specific way in respect of each and every vaccine which is considered for general use. He explains this approach in some detail. He says that,

‘Vaccines are given to people for two reasons. The prime reason is to protect them from getting the disease and suffering its effects. This applies to most vaccines and for some is the sole reason. An example of this latter is tetanus vaccine. As the source of infection is not another human being, even if everyone else were immunised, the chances of catching tetanus would still be the same as if no one were immunised. What is important is the immunisation status of the individual.

On the other hand, with most vaccines, if the uptake of the vaccine is high enough transmission of the disease is interrupted. This is known as ‘herd’ or ‘community’ immunity and means people who are susceptible are protected because most of the rest of the population are immune and so cannot pass on the disease. The uptake necessary to achieve this depends on the disease and other factors. For measles and whooping cough, it is estimated to be 92-95%; for rubella it is 85-87% and for diphtheria 80-85%. As a generalisation there needs to be a higher coverage in school children, as opposed to preschool children, and higher in secondary than primary school children. This is because older children are mixing with larger numbers of people and are therefore more exposed.’

63. A Bulletin published by the World Health Organisation in 2008 began by making the point that, ‘Vaccination has greatly reduced the burden of infectious diseases. Only clean water...performs better.’

The law

64. The question I have to determine relates to the upbringing of a child. Section 1(1) of the Children Act 1989 therefore requires that B’s welfare must be the court’s paramount consideration. In determining what is in B’s best interests the court must have regard to the factors set out in the welfare checklist in s.1(3). Section 1(2) sets out the general principle that any delay in determining the questions before the court is likely to prejudice B’s welfare, a significant factor in this case in that had the parents agreed that B should

have all of the vaccinations recommended by Public Health England she would have had them some months ago.

65. Section 1(5) requires that the court shall not make any order unless it considers making an order is better for B than making no order at all. In this case, given that the parents' views are polarised, I am in no doubt that it is appropriate that the court should make the decision for them.
66. As I noted earlier, decisions relating to the vaccination of children are a function of a parent's parental responsibility. For the court to determine the issue because the parents are unable to make that decision for themselves is an interference with their right to respect for their private and family life. Article 8 of the European Convention is therefore engaged. Interference with that right is only permissible if it is,

'in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.' (Article 8(2)).

That requires that in determining this question any order the court makes must be proportionate and in B's best welfare interests.

Previous decisions concerning immunisation

67. Although it is only rarely that the court is called upon to determine whether a child should have the vaccinations recommended by the schedule, over the last fifteen years there have been five published decisions in which the court has had to consider this issue.
68. The first reported decision is that of Sumner J in *Re C and F (Children)* [2003] EWHC 1376 (Fam) in June 2003. There were two applications before him relating to two girls, one aged 4 and the other aged 10. The applications were not connected. They were heard together because they raised the same issue and had other points in common. In both cases the fathers wished their daughters to receive immunisation appropriate to their age. The mothers opposed the applications. There was, therefore, a dispute between the parents involving the welfare of their children. The judge made the point that,

'5. In all such cases, under s.1 of the Children Act 1989, the court has to determine whether immunisation is in each of the girls' best interests as their welfare is the court's paramount consideration. If it is in their best interests, the court has next to consider whether there are good reasons why that declaration should not be made...
6. If there are no reasons and it is in the child's best interests, I am asked by the fathers to make a declaration and give directions.'
69. The judge was assisted by expert evidence. He heard from three doctors, one instructed on behalf of the fathers, one instructed on behalf of the mothers and one instructed by

Cafcass Legal. The judge was highly critical of the expert instructed on behalf of the mothers. He said that he was

'58. ...compelled to the reluctant conclusion that in this case Dr Donegan has allowed her deeply held feelings on the subject of immunisation to over rule the duty she owes to the court. She has the capacity to see that when it is pointed out and to accept it. Her views are genuine in the sense that she has now convinced herself. But on the objective approach I have been unable to accept her conclusions where they differ without independent corroboration.'

70. The judge was therefore left with the opinions of two experts, broadly in agreement with each other, whose evidence he accepted. He ordered that both children should receive most of the vaccinations proposed by the fathers. The mothers appealed. The appeal was unsuccessful.

71. One matter that has been a particular subject of public concern in the relatively recent past is the safety and the potential side effects of the MMR triple vaccine. It is appropriate to set out Sumner J's conclusions on this vaccine in full. He said:

'194. I am satisfied that I should accept Professor Kroll's conclusions. He relies also on the fact that over 20 million doses of MMR have been delivered in the United States alone. It is used in Canada, Australia and over 30 European countries. He is unaware of any country where the doses are given separately. He considers that if there were real problems they would have emerged.

195. I accept his argument that there are dangers in giving injections one by one over a period of time. The reason is that the child is exposed to the unvaccinated illnesses in the meantime.

196. On the evidence before me the benefits of having the 3 vaccinations at one time outweigh any risks there may be. A child's immunity is not overloaded by receiving 3 vaccinations in one. It is daily exposed to a vast array of potential infections. The risk is I am satisfied as Professor Kroll said rather the reverse, namely that the effectiveness of the vaccinations may be reduced. On the evidence I see no advantage and much disadvantage in staging the administration of the 3 vaccines over a period of time.

197. His conclusions, supported by Dr Conway with which I concur are –

"1. Measles, mumps and rubella are serious infections, each of which carry an appreciable risk of dangerous complications in healthy individuals. Vaccination is the only practical way to prevent an individual from contracting infection, and all the evidence is that it is effective and has a very low level of side effects, which are generally mild and transient.

2. Despite the formal impossibility of proving a negative, the accumulating and substantial body of evidence shows no link between MMR vaccination and autism.

3. There is no evidence to support the suggestion that combining measles, mumps and rubella vaccines in a single injection is harmful, or that giving the components separately is safer. On the contrary, the delivery of the vaccine components in stages increases the risk of an unprotected child contracting one or other of the infections it is intended to prevent.

4. With due consideration for established contraindications to vaccination in an individual case, it is otherwise in every child's interest to be protected against measles, mumps and rubella with the MMR vaccine."

72. Next in time is the decision of Theis J in *LCC v A, B, C & D (Minors by their Children's Guardian) K,S* [2011] EWHC 4033 (Fam). This case concerned an application by a local authority to invoke the inherent jurisdiction seeking declarations regarding the immunisation of children in its care. The local authority's application was opposed by the birth parents but supported by the Children's Guardian.
73. As in the case of *Re C and F (Children)* [2003] EWHC 1376 (Fam), the judge was assisted by expert evidence, in this case by a single expert, a Consultant Paediatrician, whose evidence she accepted.
74. Once again it was the MMR triple vaccine that gave rise to particular concern on the part of the parents. In setting out her conclusions at §17 of her judgment, Theis J came to the following conclusions concerning the MMR vaccine:

‘(3) As set out in Dr Ward's report the MMR vaccine protects children against "illnesses that have serious complications which is why it is important that children are vaccinated against them": (i) Measles causes a range of symptoms that can include ear infection, bronchitis, convulsions (fits) and brain damage. Measles can be fatal. (ii) Mumps used to be the main cause of viral meningitis in children. It also causes temporary deafness, miscarriage, inflammation of the pancreas and causes pain and swelling of the testicles in men. (iii) Rubella can lead to painful joints, blood disorders and encephalitis. It damages unborn babies and may cause miscarriage if women catch the disease while pregnant. Babies born with congenital rubella syndrome may have some degree of deafness, blindness and damage to their heart or brain".

(4) There is no competent body of professional opinion that supports a link between the MMR vaccine and autism. In particular Dr Wakefield's research has been discredited.

(5) Article 24 of the United Nations Convention on the Rights of the Child 1989, although not enjoying the force of law, stipulates: "1. States Parties recognise the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services. 2. States Parties shall pursue full implementation of this right and, in particular, shall take appropriate measures... (f) To develop preventative health care".

(6) The side effects of the vaccination are rare.

(7) The views of the parents should be carefully considered and retain considerable importance to the balancing exercise. Nevertheless they should be weighed in the light of an almost complete failure by the parents to co-operate with health professionals and a neglect of the children's health. In respect of the link between autism and the MMR, they rely on discredited research...

(10) The abovementioned vaccinations are in the welfare interests of the children and are a necessary and justifiable interference with Article 8(2) in order to protect their health.’

75. The third published decision, also a decision of Theis J, is that of *F v F* [2013] EWHC 2683 (Fam). In this case a father applied to the court for an order that his daughters, aged 15 and 11, should receive the MMR vaccination. The mother objected. The children were old enough to express their wishes and feelings. They, too, objected. No expert evidence was relied upon. As in the other two cases to which I have referred, concerns related to the safety of this vaccine and in particular to the risk of side effects.
76. Theis J concluded that both children should receive the MMR vaccination. I highlight two of the reasons the judge gave for arriving at her decision. At §22, she said,
- ‘(4) Obviously in reaching this decision I am aware this is against the girls' wishes, but that it not the only factor. It is of course an important factor, particularly bearing in mind their ages but the court also has to consider their level of understanding of the issues involved and what factors have influenced their views. In this case I do not consider there is a balanced level of understanding by them of the issues involved, the focus has been on the negative aspects in a somewhat unfocussed way.
- (5) The medical advice is for children to receive the vaccine even though it is accepted there are risks of side effects of the vaccine. The health risk of getting any of the diseases the vaccine prevents is clear. They are serious diseases that could have long term health consequences. That has not been a live issue in the case. If the mother had sought permission to call any expert evidence then it may have been necessary to consider any evidence required to respond to that. The recent issues raised by the girls regarding the ingredients of the vaccine have not been balanced with these other considerations.’
77. The fourth decision is *Re M and N (Parental Responsibility: Immunisations)* [2016] EWFC 69, a decision of His Honour Judge Mark Rogers sitting as a Deputy High Court Judge. The case related to two children, M and N, aged 4 and 2 respectively. M had had some vaccinations. N had had none. The father wished the children to be vaccinated. The mother was fundamentally opposed. The judge was assisted by evidence from a single joint medical expert witness. The judge set out a summary of the mother’s objections:
- ‘16. Distilling it down, the mother's case is this; that firstly M was vaccinated but had adverse reactions so that it would be unsafe for him, and by analogy for N, to receive any further or any fundamental vaccinations. Secondly, that the children are healthy. They have no apparent immune compromise, that they will benefit from the protection of the herd, and that the diseases against which they would conceivably be vaccinated are in any event rare and in the unlikely event of contagion can be coped with. Thirdly, as a vegan, she disapproves of animal testing or animal based elements of the vaccines and that view conscientiously held should be respected. Fourthly, that notwithstanding the overwhelming medical consensus she believes that it is flawed and that the people who would agree with her are too afraid to speak out because of the pressure (or corruption arguably) of central government and regulatory agencies.’

78. The judge went on to set out the approach he was required to take in determining the father's application, referring to the provisions of s.1 of the Children Act 1989 and to Article 8 of the European Convention. He then went on to say:

'55. For the purposes of this case and following the guidance set out [in *Re B (A Child)* [2003] EWCA Civ 1148], by which I am bound, it seems to me that the court is therefore an independent arbiter exercising a dispassionate objective judgment. The mere fact that the prominent parent has a strong view is a factor of little or no significant weight. Even if I had found that father was wilful, the court still would have to make an objective welfare-based decision once its jurisdiction was engaged. The impact on a parent, however, is a relevant factor. That is emphasised in both *Re C* and *F & F*. Equally, expert evidence is important. It is perhaps of significance that in *F & F* itself there was no expert evidence, so strong an inference was there that the medical mainstream had identified the best interest test. In this case, however, there is medical evidence which, of course, the mother does not accept, but Dr Mittal was forensically unshaken and in my judgment he is plainly in the mainstream. His view is that vaccination is a general public good. It benefits society at large and crucially each of the individuals within it. In other words, his view accords with the view of Thorpe, LJ, in paragraph 22 to which I have referred.

56. Dr Mittal accepted that no vaccine is risk free or 100 per cent effective, but overwhelmingly the medical mainstream, to which he himself subscribes, is that vaccinations provide a personal and general advantage.'

79. The judge accepted the evidence of the medical expert, Dr Mittal, saying that he preferred 'his assessment of the general public health benefits and reject the alternative views as put forward by the mother as unlikely to be in the mainstream'.
80. The fifth and most recent decision is that of MacDonald J in *London Borough of Barnet v SL* [2017] EWHC 125(Fam). A local authority issued care proceedings in respect of four children. One of those children, SL, was 7 months old and was the subject of an interim care order. The local authority sought permission to arrange for the child to receive the Haemophilus Influenza Type b vaccine and the pneumococcal conjugate. The mother objected.
81. The mother was ordered to file a statement in support of her objections. She did not comply. I assume the basis of the mother's objections to be reflected in her counsel's submissions. These include a reference to a claim by the mother that there had been three previous instances of her older children attending hospital for what she contended were adverse reactions to immunisation. There was no evidence to support that claim.
82. The judge gave permission to the parties jointly to instruct an expert. In light of the expert's evidence (and also, no doubt in light of the lack of any evidence from the mother) the judge granted the declaration sought by the local authority. He reaffirmed the

approach set out in the other authorities to which I have referred. His final paragraph bears repetition. He said,

‘51. Finally, I make clear that the decision of the court is not a judgment on whether immunisation is a good thing or bad thing generally. Like Sumner J and Theis J before me, I emphasise that the court is not saying anything about the merits of vaccination more widely and does not in any way seek to dictate how this issue should be approached in other situations. This judgment is concerned solely with an evaluation of one child's best interests based on the very particular circumstances of this case and on the evidence that is available to the court.’

Discussion

83. The mother (supported by the Children's Guardian) wishes B to have three vaccines: the combined diphtheria/tetanus/pertussis/polio vaccine, the MMR vaccine and the influenza vaccine. The father objects to B having any of those vaccines. As the judge, my role is not to evaluate the reasonableness of the positions taken by each of these parents but to come to my own conclusion on what is in B's best welfare interests.
84. In determining what is in B's best welfare interests the views of the parents should be carefully considered. They retain considerable importance in the balancing exercise. But they are not necessarily determinative. They are simply to be taken into account as part of the overall evaluative exercise.
85. Another important aspect of the evaluative exercise is the expert evidence of Dr Elliman. The views expressed by Dr Elliman appear to be in broad agreement with the evidence of other experts who have given evidence on similar issues in the previous cases to which I have referred. Dr Elliman considers his opinions to be 'mainstream'. I am satisfied they are. In contrast, and for the reasons given by Dr Elliman, I consider the father's views to be biased and unreliable. The fruits of the father's untutored, amateur research are at odds with the expert medical evidence of Dr Elliman. In my judgment, where there is disagreement between the father and Dr Elliman the expert opinions of Dr Elliman are to be preferred.
86. In determining what is in B's best interests I have in mind, of course, all of the factors set out in the welfare checklist in s.1(3) of the Children Act 1989. In this case, one of those factors is of particular importance. Section 1(3)(e) requires the court to consider 'any harm which B has suffered or is at risk of suffering'.
87. With the consent of both parents, B has already received some vaccinations. At the time those vaccinations took place there was nothing in B's known medical history to suggest that having those vaccinations was contra-indicated. There was no reason to believe that

the vaccinations would cause her harm. More importantly, there is no evidence that those vaccinations did in fact cause her harm

88. That being the case, is there anything known about B's health today (i.e. has there been any change in her medical history since the date when the parents agreed to her having the vaccinations she has already had) to suggest that she is at greater risk today than when she was previously vaccinated? The answer, plainly, is 'no'.
89. Is there anything known about these vaccines today that gives rise to a risk that if B took them she would be exposed to a risk which any well-informed and reasonable carer might properly regard as unwise or inappropriate? Again, in my judgment, in light of the expert evidence of Dr Elliman, the answer, plainly, is 'no'.
90. Dr Elliman acknowledges that all vaccinations carry risks. There is a very wide body of research evidence – international and not just British – concerning the risks of individual vaccines and, on the other side of the balance, the risks that arise from contracting the diseases concerned. As a consequence, the known risks of particular vaccines can, with confidence, be balanced against the known risks of not being immunised with those vaccines. Rational, balanced, informed decisions can be made.
91. Research is ongoing. The frontiers of knowledge are being continuously rolled back. The science in this area does not stand still. With respect to any of the vaccines I am concerned with the possibility that in the future new risks may be identified cannot be ruled out. However, decision-making takes place today in the light of what is known today about risks and in the light of what is known today about B.

Conclusions

92. I am satisfied that it is in B's best welfare interests that she should receive the vaccines recommended by *The routine immunisation schedule* for a child of her age. There will be a declaration to that effect and a specific issue order. I invite the parties to prepare a draft for my approval.
93. In making that order, like MacDonal J, I make it clear that my judgment is not a commentary on whether immunisation is a good thing or a bad thing generally. I am not saying anything about the merits of vaccination more widely. I do not in any way seek to dictate how this issue should be approached in other situations. I am concerned only to determine what is in B's best welfare interests.
94. That said, it is, in my judgment, appropriate to make the point that this is now the sixth occasion when the court has had to determine whether a child should be vaccinated in circumstances where a birth parent objects. On each occasion the court has concluded

that the child concerned should receive the recommended vaccine (save that *in Re C and F (Children)* Sumner J decided that the older child, aged 10, should not have the HIB vaccine, because the danger for her had past, or the Pertussis vaccine, because there was no approved vaccine for a child of her age). With respect to the vaccines with which I am concerned, in the absence of new peer-reviewed research evidence indicating significant concern for the efficacy and/or safety of one of those vaccines, it is difficult to see how a challenge based on efficacy or safety would be likely to succeed.