Neutral Citation Number: [2023] EWHC 1282 (KB)

Case No: F90LV055

**IN THE HIGH COURT OF JUSTICE**
**KING'S BENCH DIVISION**
**LIVERPOOL DISTRICT REGISTRY**

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 26/05/2023

**Before** :

**MRS JUSTICE YIP**

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**Between :**

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| **SARAH JANE WILSON & OTHERS** | **Claimants** |
| **- and -** | |
| **1) BAYER PHARMA AG** | **Defendants** |
| **2) SCHERING HEALTHCARE LIMITED** | |
| **3) AVENTIS PHARMA LIMITED** | |
| **4) SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE** | |

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**Charles Feeny, Jonathan Bertram and Sam Irving** (acting **pro bono** through **Advocate**) for the **Claimants**
**Charles Gibson KC, James Purnell and William Moody** (instructed by **Arnold & Porter**) for the **First and Second Defendants**
**Geraint Webb KC and Lucy McCormick** (instructed by **Arnold & Porter**) for the **Third Defendant**
**Leigh-Ann Mulcahy KC and Robert Dickason** (instructed by **Government Legal Department)** for the **Fourth Defendant**

Hearing dates: 2, 3, 4, 5 May 2023

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# Approved Judgment

This judgment was handed down remotely at 10.30am on 26 May 2023 by circulation to the parties or their representatives by e-mail and by release to the National Archives.

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MRS JUSTICE YIP

**Mrs Justice Yip :**

## Introduction

1. Hormone pregnancy tests ("HPTs") were historically used to confirm whether a woman was pregnant. The method involved prescribing tablets containing synthetic female sex hormones to women reporting amenorrhea. The intention was to induce menstruation in those who were not pregnant and so to confirm pregnancy when bleeding did not result. The allegation underpinning this litigation is that such products could cause damage to a developing foetus, resulting in congenital malformations, miscarriages and stillbirths. Claims are brought by or on behalf of those born with birth defects which they attribute to the use of HPTs and by mothers who suffered miscarriage or stillbirth after taking HPTs.

2. The first and second defendants are sued as the manufacturers and distributers of the drug Primodos. The majority of claims relate to the use of Primodos. A minority are brought against the third defendant and involve another drug, Amenorone Forte. The fourth defendant, the Secretary of State, is included as the party responsible for the regulation of the supply and use of drugs, acting through the Committee on the Safety of Drugs ("CSD") and the Committee on the Safety of Medicines ("CSM"). While the claim against the fourth defendant will plainly give rise to different issues in relation to breach of duty, that is not something I need be concerned with for present purposes. The central issue underlying the applications currently before me is causation.

3. This is not the first time litigation involving HPTs has come before the courts. An action brought on behalf of two infant plaintiffs was discontinued shortly before trial in 1982, after a very substantial quantity of expert evidence had been obtained. The plaintiffs were funded through Legal Aid. The defendants incurred costs in excess of £3.8 million. After exchange of the expert evidence, the plaintiffs' legal advisers concluded (as appears from the transcript of the relevant hearing) that there was no real possibility of establishing a causal association between the plaintiffs' congenital malformations and the drug taken by their mothers (Primodos). Bingham J granted the plaintiffs leave to discontinue "on condition that there be no further proceedings on this present action … without leave of the Court and on such terms as the Court may then impose."

4. One of the infant plaintiffs was Raymond Hyman. He is one of the claimants in this action. Pursuant to the 1982 order of Bingham J, he requires leave to proceed with his claim.

5. Another 101 claimants remain in this action, others having discontinued or having had their claims struck out for non-compliance with case management orders. The defendants maintain that all the claims should be subject to the same requirement to seek leave to proceed, since the cases with which Bingham J was concerned in 1982 were test cases. In the alternative, they apply to strike the claims out as an abuse of process. The defendants contend that the claimants are effectively seeking to relitigate the same causation issue that was the subject of the earlier failed litigation. They say that there have been no material changes in scientific understanding such as would assist the claimants. If anything, the scientific position has hardened against them. The defendants contend that these claims are bound to fail, just as the previous claims did.

Further, they argue that the claims are not viable as the claimants lack funding and representation to progress the litigation.

6. Another claim, referred to as the "Forshaw action" involves a further 69 claimants. Those proceedings have been stayed pending the outcome of the applications with which I am now concerned.

## The original HPT litigation

7. The first and second defendants provided me with a chronology of the original litigation (Schedule 1 to their skeleton argument). The contents were not challenged and I treat it as accurate. I need not set out the entire history.

8. In 1978, the Association for Children Damaged by Hormone Pregnancy Tests ("the Association") was established, with the declared aim of pursuing litigation against manufacturers of HPTs. The first writ in such litigation had been issued in 1977. Mr Hyman's claim was issued on 9 December 1978. The defendants to those claims were the predecessors in title of the current first and second defendants. Between 1977 and 1980, other claims relating to the use of HPTs, including Primodos and Amenorone Forte, were notified and issued. The management of five such actions was considered by the Court of Appeal in June 1980: see *Hudd & others v Schering Chemicals Limited* [1980] E.C.C. 375. The headnote to that report provides a useful summary:

> "The Court, dismissing an appeal by the defendant drug company, held that two actions brought on behalf of children born with physical deformities allegedly as a result of their mothers taking the defendant's drug Primodos while pregnant should proceed as set down for trial, and that three further actions against the same defendant and relating to the same drug but involving different deformities should be stayed pending the outcome of the first two. The Court also refused to split the issue of causation off for trial as a preliminary issue, holding that the questions of causation and of negligence were so intertwined as to require examination in the same proceedings."

9. Mr Hyman's case was one of the two cases which were to proceed. Lord Denning M.R. said this [15]:

> "It seems to me that justice can well be done if the two heart cases are tried first. They have no doubt been selected by the Association and their advisers as being the strongest cases they can bring. If they fail, all the others will fail too. If they succeed, it is true that it does not follow that the others will succeed … But I cannot help thinking that at the trial of the first two cases (the heart cases, as I have called them) the evidence and the findings of the judge will give a good guide as to the outcome of all the remaining actions. It seems to me that the evidence on causation will cover not only the causation of the heart defects, but also the other defects – the hare lip, the limb reduction, and so forth. In considering the teratogenic capability of this drug, it will be necessary for the court to consider the whole range of

> effects it might have in causing the congenital malformations in other cases …"

10. The two cases were listed for trial before Bingham J commencing on 1 July 1982 with evidence to commence in October. The exchange of expert evidence was completed on 22 March 1982. On 19 May 1982, the defendants were alerted that the plaintiffs had been advised that there was no reasonable prospect of success. An application was made to discontinue both claims. That application was heard on 2 July 1982 and resulted in the order to which I have referred. In giving judgment, Bingham J said:

> "The effect of that order is not to shut out the Plaintiffs absolutely. It is open to them to apply in the future in the event of a scientific revolution or a marked change in the circumstances. I should, however, make it clear that for leave to be given on any future occasion a very strong case indeed would have to be made out by the Plaintiffs to show that it was just for the matter to be re-opened, and the Court would have to be satisfied that no unreasonable prejudice to the Defendants would accrue. I think it very unlikely that leave to the Plaintiffs would be given, but I think that it is in all the circumstances just that the door should be kept open to that very limited extent."

11. Thereafter, all other issued claims involving Primodos and Amenorone Forte were discontinued and no other claims were issued. A single claim concerning Amenorone Forte was issued in 1994 but did not proceed.

12. Between 2009 and 2013, Mr Karl Murphy, former chair of the Association, sought to pursue proceedings relating to Primodos. Proceedings were issued by him in 2013 but those proceedings were never served.

**The history of the current litigation**

13. In November 2014, a solicitor Mrs Lisa Lunt, then of Gregory Abrams Davidson, was instructed by the current chair of the Association, Mrs Marie Lyon. Mrs Lunt has provided five statements in the course of this litigation. By operation of a case management order, the claimants do not have permission to rely on the evidence in her fifth statement, although it appears in the bundle and the defendants made reference to aspects of it.

14. In her first statement dated 17 April 2020, Mrs Lunt acknowledged that litigation funding was unlikely to be secured without supportive evidence on causation. Research was being conducted by Professor Neil Vargesson, with whom Mrs Lunt liaised. The government had also been persuaded of the need for a comprehensive review of the evidence relating to HPTs, under the remit of the Commission on Human Medicines ("CHM"). In her first statement, Mrs Lunt explained that, having undertaken research with zebrafish, Professor Vargesson was intending to move onto mammalian studies and that the claimants had decided to await the outcome of that further research, there then being insufficient evidence to progress the claims. In the meantime, the CHM set up an expert working group ("the EWG") which comprised a panel of sixteen experts, drawn from different medical and scientific fields. The EWG published their report in November 2017. I shall return to the findings of the EWG. I note that the Association

did not accept those findings and lobbied for the matter to be brought back to Parliament.

15. In 2018, the establishment of the Independent Medicines and Medical Devices Safety Review chaired by Baroness Cumberlege was announced. That review looked at concerns about three different medical products, namely Primodos, the antiepileptic drug sodium valproate and vaginal surgical mesh. It did not though focus on causation. The Cumberlege report was published in July 2020.

16. In August 2019, letters of notification of claims were sent to the defendants. By then, Mrs Lunt had moved to SPG Law and the claimants had followed her. The letters made it clear that the claimants could not fully particularise their claims at that stage while further investigation was undertaken.

17. These proceedings were issued on 20 December 2019. Mrs Lunt stated that this was done to "preserve the limitation position in respect of those claimants whose limitation was about to expire in early 2020". The claimants applied for an extension of time for service of the Particulars of Claim and supporting documentation. The application also sought permission to proceed on behalf of Mr Hyman ("the Hyman application"). The parties agreed an extension of time for service of the generic Particulars of Claim and a consent order was made on 2 October 2020. The Hyman application was adjourned with liberty to restore it.

18. Generic Particulars of Claim were served on 18 December 2020. The defendants filed acknowledgments of service. The first and second defendants indicated that they intended to contest the court's jurisdiction. In the alternative, they applied to strike out the claim as an abuse of process. Similar applications to strike out were made by the third and fourth defendants. The defendants also required that the Hyman application be restored and contended that all claimants required permission to re-litigate the substance of the claims in light of the history of the earlier litigation.

19. The matter first came before me for a case management conference in April 2021. I decided at that hearing that the defendants' arguments that the claims should not proceed needed to be grasped and directed that the applications should be listed for hearing with a time estimate of four days. In the course of argument, I observed that the heart of what needed to be addressed was whether things had moved on in relation to causation since 1982. I made it clear that I was viewing things from the claimants' position as much as from the defendants. I expressed the view that if (as in 1982) the claimants did not have evidence to establish causation these proceedings would be of no value to anyone and very costly to everybody. On that basis, I said that it was important that both sides put their best case before the court and gave directions for the service of evidence and preparation for the hearing. The hearing of the applications was fixed for June 2022.

20. The claimants' solicitors (by then known as PGMBM) served evidence relating to the Hyman application in July 2021. This comprised the fifth witness statement of Mrs Lunt, with draft Amended Particulars of Claim attached, and material from three experts. The expert material was generic in nature and was not in the form of formal CPR Part 35 reports. The claimants other than Mr Hyman did not apply for permission to proceed. Their firmly stated position was, and remains, that they do not require permission.

21. In late November/early December 2021, the first and second defendants and the fourth defendant served preliminary Part 35 expert reports; the fourth defendant also served notes (without CPR 35 declarations) from two experts who had been members of the EWG. The third defendant did not serve expert evidence, but agreed with and adopted the expert evidence served by the other defendants.

22. Shortly after the service of the defendants' evidence, PGMBM informed the claimants that they could no longer act for them. They then applied to come off the record. That application was heard ex parte by Turner J on 23 March 2022. The material placed before Turner J in support of the solicitors' application to come off the record is privileged and has been withheld from me and from the defendants. The only information I have is contained in a statement from Mrs Lyon, which indicates that PGMBM advised that they could not continue to act because they were unable to find funding in relation to the claimants' potential costs liability. Turner J granted PGMBM's application. His judgment has the citation [2022] EWHC 670 (QB).

23. Some claimants discontinued their claims at the time PGMBM came off the record but 113 claimants remained in the action. A case management conference was due to take place shortly after the hearing before Turner J. I took the view that such a hearing would be unmanageable with so many unrepresented litigants and therefore gave case management directions on paper instead. My order was dated 31 March 2022 and includes my reasons for making it. I was told that the claimants were seeking alternative representation and decided that it was unrealistic to expect that they would be in a position to proceed by June 2022 so adjourned the substantive hearing to a date to be fixed, retaining two days for case management.

24. At the case management hearing in June 2022, Mr Feeny appeared on behalf of the first claimant, Sarah Jane Wilson, on a pro bono basis and without instructing solicitors. All other claimants were unrepresented. They were given the opportunity to be heard but did not seek to make any representations so that Mr Feeny's arguments effectively served them all. I was told that the claimants recognised that realistically this litigation could not proceed without the claimants having funding and representation. I decided that the claimants should be afforded some further time to secure funding and representation but that the time for that could not be extended indefinitely and that there had to be a cut-off point, by which time the claimants would assess the viability of the proceedings and would notify the defendants and the court of the arrangements. In doing so, I said that it was no kindness to the claimants to keep this litigation limping along but not actually progressing. I set 31 October 2022 as the cut-off point, requiring the claimants to serve information about funding and representation by then. I said that if the claimants were in a position to proceed, the applications needed to be heard as quickly as possible. The earliest listing that could be identified was May 2023, a further eleven months away.

25. Further directions given at that time provided the option for the defendants to amend their strike out applications, after the cut-off point, to include lack of viability. I extended the time for the claimants to serve further evidence and gave them permission to file and serve declarations from each expert who had already provided preliminary material confirming that the experts had understood and complied with their duty under CPR Part 35. I shall return to consider the expert material which has been served, including the way in which the claimants' experts responded to this direction.

26. I directed that the claimants could only rely on the fifth statement of Mrs Lunt if they served a statement from her or from another solicitor on record as acting for the claimants, confirming that there were no inconsistencies between what was set out in her statement and the information provided to Turner J, or alternatively if any such inconsistencies were highlighted. No such evidence was served. While it remained open to the claimants to serve other evidence in place of Mrs Lunt's fifth statement, they did not do so.

27. On 21 October 2022, a witness statement from Mrs Lyon was filed and served. Mrs Lyon is not a party to the claim and is aware that, although she claims to have authority to act on behalf of the claimants, she is not entitled to conduct litigation on their behalf. However, as I observed previously, she has approached her role as chair of the Association diligently and has made considerable efforts to assist both the members of the Association and the court. Her statement was adopted by the other remaining claimants and so stands as the only evidence from the claimants as to what has happened since the case management conference.

28. Without waiving privilege, Mrs Lyon explained that further discussions had taken place with counsel, including Leading Counsel. Advice had been given that the Association should be seeking to marshal the expert evidence in support of the claim. She had continued to seek legal advice and made contact with a firm of solicitors, Freeths, who had entered into a retainer with the Association. Freeths have not come onto the record for any claimant. Pro bono advice and assistance was also being provided through Liverpool John Moores University. Mrs Lyon stated that the claimants had been frustrated by a lack of cooperation from their former solicitors. She said that they had refused to hand over their generic file. I note no application was ever made in relation to that. Mrs Lyon also stated that the Association had had contact with "two individuals who have considerable knowledge and experience in relation to litigation funding and established contact with major litigation funders." She said that detailed discussions continued to take place on a confidential basis and that it had been "agreed in principle that any application [for] funding should be made after the expert evidence has been marshalled." She anticipated that would be possible towards the end of 2022. In the circumstances, she concluded that the claimants could not at that stage provide any definitive response to the issues (relating to representation and funding) which they had been ordered to address. No further evidence was served on behalf of the claimants prior to the hearing.

**Representation at this hearing**

29. The claimants were all represented by Counsel, who appeared pro bono. Mr Feeny and Mr Bertram addressed me and I understood Mr Irving to have been engaged in some of the preparation. It remains the case that no solicitors are on record for the claimants.

**Application to admit additional evidence**

30. During the hearing, there were times when Mr Feeny and Mr Bertram's submissions strayed into evidential territory. I was told that there was expert support for the case as now sought to be advanced and that the experts may be prepared to provide reports without a fee. It was also suggested that there was a viable plan to progress the litigation. While that plan might not extend to proceeding to trial, it would allow progress to the close of pleadings and exchange of expert evidence. I questioned why,

if there was such a plan, it had not been evidenced. That would have required an application to rely on evidence served out of time. However, I had declined the defendants' request to treat the order I made in June 2022 as an extension of a previous unless order and to record that it was a final order, leaving open the possibility that the claimants might apply for an extension of time. I said then that I did not intend that the claimants be effectively barred from pursuing their claims simply through running out of time to complete reasonable enquiries. I was surprised that no attempt had been made to offer any evidence beyond that of Mrs Lyon, particularly as her statement acknowledged she was not then able to address the relevant issues.

31. Mr Bertram responded by asking if it was too late to serve further evidence. I recognised that the defendants were bound to object to the introduction of evidence at such a late stage, not merely at the hearing but after they had made their submissions. However, I allowed time for the claimants to consider their position overnight. This resulted in an application to rely on a further statement from Mrs Lyon, which is dated 4 May 2023. I considered that statement without deciding on its admissibility. The evidence contained within it is extremely limited. In my view, it adds nothing of real value for the claimants nor does it prejudice the defendants. It confirms only that Freeths continues to assist the Association in relation to expert evidence and that Liverpool JMU Law Clinic continues to provide pro bono assistance. The funds available to the Association total £61,632.51 plus some additional gift aid yet to be finalised. This comes from annual subscriptions, charitable fundraising and crowdfunding.

**Summary of the history of this litigation and the current position**

32. It is now over eight years since the Association first instructed Mrs Lunt and investigations commenced as to whether it would be possible to mount successful claims notwithstanding what had happened with the previous HPT litigation. It is nearly three-and-a-half years since proceedings were issued. Seventeen months have elapsed since the claimants' former solicitors advised that they could not secure funding and could no longer continue to act. It is fourteen months since they formally came off the record.

33. All the claimants remain without legal representation in relation to the litigation generally. No solicitors have come onto the record as acting for them. The Association has some funds to pay for legal advice and assistance. In the context of this litigation, those funds have to be viewed as extremely limited. They would be exhausted very quickly. The claimants have benefitted from pro bono assistance for the purpose of this hearing. It is very difficult to envisage Counsel acting pro bono at trial and I have no evidence to suggest this is proposed. It may be more likely that Counsel and Liverpool JMU would be willing and able to offer some ongoing pro bono assistance in the interlocutory stages. There is no evidence that there is any realistic prospect of the claimants ever securing representation by solicitors and/or litigation funding. The claimants have provided no evidence of any plan for progressing the litigation in those circumstances. That remains the case even despite taking a very late opportunity to consider whether further evidence might be placed before the court.

## Pleadings

34. During his submissions, Mr Feeny acknowledged that the Generic Particulars of Claim filed in December 2020 were "obviously deficient on causation." At paragraph 148, it was said that the "likely mechanisms of physical injury will be the subject of appropriate expert evidence" before summarising three possible mechanisms. Despite the acknowledged inadequacy, no application has yet been made to amend the Particulars of Claim.

35. Draft Amended Particulars of Claim were attached to Mrs Lunt's fifth statement, with an indication that the claimants intended to apply to amend "in due course". That draft, which was signed by Mr Feeny and two other Counsel, included an amendment to plead a claim for misfeasance in public office against the fourth defendant. It also amended paragraph 148 and included a new paragraph 148A. By these amendments, it was asserted that the claimants now had cogent, supportive expert evidence establishing a causal association between HPTs and birth defects, a plausible mechanism for that causal association and the ability to exclude genetic causes.

36. By way of their skeleton argument for this hearing, the claimants indicated that they no longer sought to amend the Particulars of Claim as set out in the draft attached to Mrs Lunt's statement. Instead, they sought only to amend paragraph 148 of the original Generic Particulars of Claim. A new draft of that paragraph (which had not previously been served) was attached to the skeleton argument.

37. The new draft amended paragraph 148, signed by Mr Feeny, took an unusual form for a pleading. Rather than consisting of a series of positive averments from which the claimants' case on causation can clearly be identified, the draft appears more as written submissions on the scientific material. The new paragraph 148 itself contains 42 paragraphs (presumably intended to be sub-paragraphs) and runs to 15 pages.

38. This draft contains the following positive assertions on causation (references in square brackets are to the numbered sub-paragraphs in the draft):

    i) The birth defects suffered by the claimants were the result of hypoxia-reoxygenation damage in the embryo during organ foundation secondary to failed abortion and uterine contractions initiated by HPTs. [1]

    ii) That causal mechanism is established "in accordance with international guidelines and principles for the evaluation of teratogenicity". [2]

    iii) Epidemiological studies are "consistent with causation by embryonic hypoxia through failed abortion in the context of low progesterone levels." [33]

    iv) The court should conclude, on the balance of probabilities, that HPTs were the cause of birth defects "shown to have had a significantly increased risk from taking of an HPT in the absence of any identifiable genetic cause on testing." [42]

39. Unlike the draft Amended Particulars of Claim attached to Mrs Lunt's statement, this new draft does not positively assert that there is an established causal association between HPTs and birth defects. The closest it comes is in sub-paragraph 2(e), which

sets out one of a number of issues which it is said the claimants "will address" in considering the causal mechanism. The identified issue is:

> "The epidemiological evidence showing a clear association between HPTs and birth defects which in the absence of any other plausible explanation can only be considered causal and which is consistent in its results with the proposed causal mechanism."

40. Mr Feeny explained that having taken the view that the original pleading was deficient, the draft attached to Mrs Lunt's statement was "emergency surgery". He said that draft was not fundamentally inconsistent with the way the claimants now put their case. The only difference was that the word "causal" had been removed in relation to the association demonstrated by the epidemiological evidence. After I asked Mr Feeny for clarification, he confirmed that having seen the defendants' expert evidence, on reflection and after revisiting the claimants' expert evidence, he decided that the allegation that there was an established "causal association" could not be sustained and therefore, in accordance with his professional duty, he took out the word "causal".

41. In fact, the difference between the two versions is much more fundamental than the removal of one word. The new draft takes a completely different form when compared to the earlier one. In the earlier version, the three main issues on causation were identified as:

> "148.1. Whether epidemiological evidence establishes a casual association between HPTs and congenital malformations.
>
> 148.2. If it does, whether a plausible mechanism for the occurrence of such congenital malformations by HPTs can be demonstrated.
>
> 148.3. If so, whether any other possible cause of the relevant congenital malformation can be excluded with confidence."

42. The earlier draft said that the claimants had cogent supportive expert evidence on all three issues. It now appears that the claimants seek to invite the court to infer a causal association without express expert support for that. Further, it seems that the claimants do not yet have expert evidence to exclude any other possible cause with confidence. Instead, paragraph 42 of the new draft states that "in principle", the claimants "are likely to agree to further testing of a more definitive nature." This appears to be acknowledgement that they do not yet have cogent evidence to exclude genetic causes.

43. I do not entirely understand the reference to agreeing to further testing. The 2017 EWG report recommended "full up-to-date genetic clinical evaluation". The Medicines and Healthcare products Regulatory Agency ("MHRA") issued letters which could be given to clinicians to support the request for testing. Mr Hyman and at least some of the other claimants have undergone chromosomal microarray testing. It is not clear from the material before me precisely how many of the current claimants have had such testing nor is it clear whether any genetic cause has been found in any of the cases which remain before the court. It does appear that the microarray testing has not identified a genetic cause in most of the claimants who have had such testing.

44. Mr Hyman was referred to a consultant clinical geneticist, Professor Ruth Newbury-Ecob in 2018. She noted that the Association had suggested he undergo only the microarray test and not genome testing. She explained that did not represent a full diagnostic assessment. Having obtained the results of the microarray testing, which she described as "initial genetic testing", Professor Newbury-Ecob confirmed they were normal but said that this did not rule out a genetic disorder as the cause of Mr Hyman's cardiac problem and that further genetic testing would normally be recommended. It does not appear such further testing has occurred. A similar point was made in 2019 by Dr Frances Elmslie, who was asked to undertake genetic testing of another Claimant (Claire Hazell). Dr Elmslie suggested that the request for microarray testing represented a misinterpretation of the MHRA letters. Dr Elmslie was sufficiently concerned that she emailed the claimants' former solicitors directly. The Association has therefore been on notice since at least 2019 that microarray testing did not amount to a full genetic assessment and that further testing would be required to exclude genetic causes. Mr Hyman received that advice in 2018. In his statement dated 3 December 2021, the first and second defendants' solicitor, Ian Dodds-Smith, highlighted the issues surrounding genetic testing and the advice given by treating clinicians. It is surprising that, nearly three-and-a-half years after the issue of these proceedings, the claimants still have not undergone full genetic testing. This is particularly so in the case of Mr Hyman who bears the burden of satisfying the requirement of Bingham J's order.

**The expert evidence**

45. If this litigation is to proceed, directions will need to be given about the expert evidence required for trial. The expert evidence currently before me is that which the parties have chosen to rely on to deal with the issues relevant to these applications. It is preliminary in nature. There can, of course, be no question at this stage of seeking to determine any dispute between experts.

46. Mr Feeny submitted that if and when directions are given for expert evidence for trial, restrictions ought to be placed on the number of experts the defendants are permitted to rely on for the sake of equality of arms. He suggested that where the defendants' interests aligned, they ought not to be permitted to each rely on experts of their own choosing so outgunning the claimants' experts by three to one but instead should jointly instruct experts. There may be some force in that but that would be a matter for another time and would require careful consideration. At this stage, I am not approaching the expert evidence on the basis that I must weigh the claimants' expert evidence against that presented on the defendants' side. It is therefore of no significance that, taken together, there are currently more experts on the defendants' side. Given the nature of the applications, I have given greater attention to the contents of the claimants' reports than to the defendants'. What I am really interested in at this stage is the case that the claimants are able to put forward. The extent to which their position on causation is now different from that facing the plaintiffs in 1982 is a material consideration for me.

**The claimants' expert evidence**

47. The claimants relied upon the evidence of three experts:

    i) Professor Zeegers, Professor of Complex Genetics and Epidemiology;

    ii) Professor Danielsson, a former professor in Pharmacology and Toxicology;

iii) Dr Reardon, Consultant Clinical Geneticist.

Each of these experts was instructed by Mrs Lunt to provide material to be served for use in these applications. Their initial reports are dated June or July 2021.

48. These reports need to be viewed in context. The grounds for Mr Hyman's application for leave to proceed were set out in the application dated 20 April 2020, drafted by Leading and Junior Counsel (not those presently acting for the claimants). Those grounds were predicated on the basis that determination of the Hyman application required the court to consider whether there has been, in the words of Bingham J, "a scientific revolution or a marked change in the circumstances". It is no longer accepted that this represents the test to be applied on the Hyman application but it is plainly the approach taken by the claimants' former solicitors when instructing the experts. The reports were directed towards consideration of the scientific developments since 1982. No expert evidence has been served dealing more generally with generic causation or with individual causation in the case of Mr Hyman, or any other claimant.

49. The initial reports were served as exhibits to Mrs Lunt's fifth statement. She indicated that the claimants had obtained "substantive reports" from these experts and would, if allowed to proceed, seek permission to serve expert evidence pursuant to CPR Part 35. Privilege was not waived in relation to the expert evidence, beyond that contained in the material attached to the statement. After Mrs Lunt ceased to act for the claimants, consideration was given to the evidential status of the claimants' expert material. This resulted in the direction that the claimants could serve CPR Part 35 declarations from each expert. In that way, the claimants were able to convert the materials from merely being exhibits to a statement they can no longer rely on into expert evidence. It was important to know that the experts understood and had complied with their duty to the court.

50. Professor Zeegers and Dr Reardon added their CPR Part 35 declarations without amending their reports. Professor Danielsson made an important amendment to his report. In the original version, under the heading "Overall conclusion", Professor Danielsson stated:

> "In conclusion, it is my opinion to a reasonable degree of medical and scientific certainty, that observed human teratogenicity after the use of Primodos is causally related to Primodos induced embryonic hypoxia and re-oxygenation damage following an unsuccessful abortion process."

In the version to which he has attached his Part 35 declaration, that paragraph has been removed altogether. This amendment was not highlighted at the time of serving the revised report. The claimants have provided no explanation for the change.

51. The claimants have chosen not to disclose any substantive expert reports, although Mr Feeny confirmed that their former solicitors had provided the reports that they had obtained. In their skeleton argument, the claimants asserted that the proposed amended paragraph 148 was "based upon significant input from relevant experts". During his oral submissions, Mr Feeny acknowledged that, if the expert evidence which the defendants and the court has seen stood alone, it would be "clearly be valid" to say there are deficiencies in it. However, he said that there had been no order for disclosure

of expert evidence yet and that such would normally follow the close of pleadings. He submitted:

> "But the Court can't proceed on the assumption that those deficiencies exist, when the Court has not seen the substantive expert evidence."

Later in his submissions, he suggested that the defendants are "actually seeking to stop the claimants serving supportive expert evidence."

52. I reject these submissions. This litigation has been subject to active case management. There have been two lengthy case management hearings leading up to this substantive hearing. As the transcripts demonstrate, the issues the court was asked to determine at this stage were fully ventilated. The defendants' position has been clearly and consistently set out. I am afraid the same cannot be said of the claimants. The claimants cannot claim to have been left in doubt as to the arguments to be advanced by the defendants or as to the issues they would need to address. The defendants have not stopped them serving supportive expert evidence. The orders I made previously allowed the claimants to serve the evidence they wished to rely on in relation to these applications. The claimants chose to serve some expert evidence and to withhold some. That was a conscious decision. At the June 2022 case management hearing, Mr Feeny confirmed that the claimants did not seek to serve expert evidence going beyond that which had already been served. I made it clear that it was a matter for the claimants to decide what evidence to place before the court bearing in mind the issues to be addressed. It is wholly inappropriate for Counsel to now hint that there is other supportive and relevant evidence without it being disclosed. Even allowing for the difficulties the claimants have faced through the withdrawal of their former solicitors, there has been ample time and opportunity for all parties to prepare for this hearing. I must determine the applications on the basis of the evidence which has been put before me, avoiding speculation as to what might be contained in evidence I have not seen.

## Epidemiology

53. Professor Zeegers' evidence outlines scientific developments in epidemiology since 1982. He refers to the paradigm shift to "Evidence-based Medicine" and the use of "Systematic Review". He then provides two paragraphs on "case-specific developments", referring to six new primary studies since 1982 and what he refers to as an "excellent meta-analysis" on HPTs and birth defects, which was published in 2019. He said he ignored one study because of its poor quality but that the remaining five studies, all published in the 1980s, added statistical power to the previous research. The meta-analysis to which he refers is that conducted by Professor Carl Heneghan *et al.* He described this as being published in a peer-reviewed scientific journal. He said that he did not consider the EWG review as new scientific evidence because it was not published in a peer-reviewed scientific journal. Professor Zeegers concluded that the Heneghan review showed consistent results across all categories of abnormalities "with almost all risk assessments pointing in the direction of harm."

## Teratology

54. Professor Danielsson's report deals with scientific developments in the field of teratology since 1982. He states his belief that there have been very significant

developments in knowledge that failed abortion can result in a spectrum of malformations and in relation to temporary embryonic hypoxia as a teratogen. He proposes that the birth defects seen in those whose mothers took HPTs can be explained by disturbance of the effect of progesterone in "susceptible pregnant women" by the synthetic progestogen Norethisterone (NET) in HPTs. He compares the effects of NET to those of the known abortifacient drugs, mifepristone and misoprostol. The susceptibility to which he refers is having low levels of natural progesterone in early pregnancy. Professor Danielsson concludes that comparison of the pattern of malformations for Primodos with the pattern of malformations for established teratogens "strongly indicate[s] that observed human teratogenicity after use of Primodos is related to a failed abortion process and embryonic hypoxia and re-oxygenation damage."

**Genetics**

55. Dr Reardon confirms that there have been significant developments in clinical genetic practice since 1980. His report contains an interesting historical summary, albeit the details are not directly relevant to the issues to be determined. He suggests that genetic causation of congenital malformations can now be identified in most instances and that new genetic conditions are being identified all the time. The thrust of Dr Reardon's report is that modern genetic testing is much more developed than was the case in 1982.

**The defendants' expert evidence**

56. For the reasons already identified, I have not undertaken the same detailed consideration of the defendants' expert evidence. The first, second and fourth defendants have between them served expert reports from Professor Bracken and Professor van Staa (epidemiology), Professor Tilling (medical statistics), Professor Scialli (teratology) and Professor Friedman (genetics). It suffices for present purposes to note that none of these experts accept that there have been scientific developments which assist the claimants in establishing causation. Specifically, they dispute that the Heneghan meta-analysis supports a causal association between HPTs and birth defects. It is noted that the Heneghan study did not consider cases involving miscarriage or stillbirth. All oppose the claimants' theory on causation and suggest that it does not accord with the current generally accepted science.

57. In addition to the fourth defendant's CPR Part 35 expert evidence, it has provided notes from two expert members of the EWG. Professor Evans (epidemiologist) provides some factual evidence about the work of the EWG. In doing so, he corrects some assertions made by Professor Zeegers. This is not opinion evidence but is a factual account of the approach of the EWG.

58. The note from Dr Wellesley (geneticist) deals with developments in genetics. She was asked to respond to an assertion in the draft Amended Particulars of Claim attached to Mrs Lunt's fifth statement that genetic testing now permits exclusion of genetic causes in the majority of the claims. Dr Wellesley said it was misleading to suggest that genetic testing is able to rule out all genetic causes. The new draft paragraph 148 does not maintain the assertion contained in the last draft and accepts that even the most advanced genetic testing cannot exclude all genetic causes. It seems unlikely that there will be any significant dispute that genetic science has moved on significantly since 1982 but that it is still not possible to exclude all genetic causes. The difficulty the

claimants face is that, although they can say genetic testing has developed significantly, they cannot point to evidence that this has allowed the exclusion of genetic causes for the damage they have sustained. This is particularly so where they have not undergone full genetic assessment.

**Scientific review**

59. A chronology of "post-1982 key events" is attached to the first and second defendants' skeleton argument. It includes brief details of a number of scientific reviews and enquiries undertaken since 1982 here and abroad. No challenge was made to the contents of this chronology. The material to which I refer in the following paragraphs was properly evidenced for the purpose of this hearing. It is dealt with in the defendants' witness evidence, and by way of exhibits. I note in particular the contents of the fourth statement of Preeya Rajani on behalf of the fourth defendant, which makes detailed reference to the reviews undertaken on behalf of the regulatory authorities for the United Kingdom and Europe.

60. In March 2015, the MHRA issued a call for evidence relating to oral HPTs. It appears that this resulted from lobbying by and on behalf of the Association. Individuals and organisations were encouraged to provide any relevant information concerning a possible association between the use of HPTs and adverse effects on pregnancy. The Commission on Human Medicines (CHM) is an advisory non-departmental public body sponsored by the Department of Health and Social Care. Their expert working group (the EWG) was established in October 2015. Professor Evans explains that the brief was to assess whether HPTs led to adverse outcomes of pregnancies. The results of the MHRA call for evidence were provided to the EWG. They also received information from pharmaceutical companies, other organisations and from other countries. Academics and other experts, including Professor Vargesson, made contributions. A literature search was conducted. Thirteen members of the Association presented their personal experiences to the EWG. The EWG's report was published in November 2017.

61. Having reviewed the epidemiological data, the EWG concluded that while the quality of available evidence was very limited, no strong associations were found between the use of HPTs and any single anomaly or pattern of anomalies. They considered that the weak associations observed could have occurred by chance or confounding. Their overall conclusion was:

> "The totality of the available evidence from pharmacology, non-clinical, epidemiological and adverse event reporting data was very limited and did not, on balance, support a causal association between the use of HPTs, such as Primodos, by the mother during early pregnancy and congenital anomalies in the child."

62. The Heneghan meta-analysis was first published in October 2018. As Professor Zeegers places reliance on this study being peer reviewed and contrasts that with the EWG report, some attention was given to the nature of the review during the hearing. The platform on which the study was published does not operate a conventional peer review model. Rather it allows for publication without review. The published item is then open for review, allowing the author to consider revision. The reviews are published alongside the original article. It is apparent that the Heneghan meta-analysis

has been subject to limited review (a total of three reviews). None of the reviewers declared any expertise in epidemiology. Two of three were visiting experts to the EWG. One reviewer (Jesse Olszynko-Gryn) invited the authors to consider the extent to which the association they identified implied a *causal* association. That suggestion was not adopted. In the circumstances, I consider it surprising that Professor Zeegers places reliance on the Heneghan meta-analysis on the ground that it is peer reviewed but expressly disavows the EWG report.

63. The CHM assembled an ad hoc expert group to review the Heneghan meta-analysis. Professor Heneghan was invited to give a presentation to the group. Mrs Lyon also attended and addressed the group. The expert group concluded that the methods used in the meta-analysis were not in line with best practice and that the study could not be considered robust.

64. A review was also conducted by the European Medicines Agency's Committee for Medicinal Products for Human Use ("CHMP"). They published an opinion in April 2019. They noted that members of the Association were involved in the meta-analysis and provided input to the outcome choices and other matters. The CHMP questioned the "independency" of the Heneghan conclusions and whether the analysis was based on independent research. The CHMP concluded that the Heneghan results did not exclude the possibility of an association between HPTs and malformations. However, the results "did not add new information to what is already known". The CHMP concluded that the quality of most of the studies used in the meta-analysis was questionable and that the results could not be considered reliable. The results therefore had no clinical implications and the CHMP did not recommend further regulatory action. That is a matter of some significance. While HPTs are no longer used, their components including NET, are regularly taken for other reasons by women of child-bearing age, who may become pregnant while taking them.

65. I note that the work of Professor Vargesson with zebrafish (published as Brown *et al*.) was also considered by an ad hoc expert group commissioned by the CHM and by the CHMP. The CHMP concluded that this research did not add to current knowledge or give rise to any new concerns.

**The claimants' approach to the expert and scientific material**

66. Rather than focusing on the disclosed expert evidence, Mr Feeny sought to take me to published scientific literature and to invite me to conclude that this demonstrated that the claimants had a meritorious case. A bundle of scientific literature had been provided for the hearing. It included material to which the various experts had referred and the annexes to the EWG report. It was a large bundle, running to 3,550 pages. I had not been invited to read any part of it in advance and had not done so. I was informed that it was unlikely to be referred to and I understood it was being provided simply for completeness. In that way, the material would have been available if any clarification was required in relation to matters arising from the expert evidence or EWG report. I had not anticipated it would be necessary to look at it at all. At trial, experts may be cross-examined about literature necessitating going to the source material. The position is different at this stage. The experts did not give evidence and I am not required to weigh any conflicting opinions.

67. Mr Feeny sought to develop arguments on causation through reference to the scientific literature. He made significant criticisms of the EWG findings. There was a heavy focus on limb reduction defects, contending that was where the evidence was clearest. These arguments were advanced for the first time in oral submissions, albeit references to the material appeared in the draft paragraph 148 attached to the skeleton argument. The defendants were deprived of any proper opportunity to address the points with their experts, contrary to the intent of the case management orders that I had made. In effect, Mr Feeny sought to rely upon the draft pleading and points drawn from the scientific literature as evidence. That was plainly inappropriate. I had given directions for the service of the evidence to be relied upon at this hearing. The hearing was listed for at least four days and it was apparent that this was to allow proper consideration of the available evidence in addition to legal submissions. I had encouraged the parties to put their best case forward.

68. When I questioned his approach, Mr Feeny referred to the circumstances leading up to the hearing, which I took to mean the difficulties the claimants have faced having been left without representation. I accept that it has been difficult for them but I have consistently made allowance for that in the management of the case. I allowed generous extensions of time. I suspect the defendants would say I was overly generous. I did not bar further applications. Had the claimants sought to rely on additional evidence, even at a late stage, I would have considered their application. No such application was made. Counsel for the defendants displayed remarkable restraint in responding to the approach taken on the claimants' side. They did though describe the claimants' submissions as involving "moving goalposts", "smoke and mirrors" and "taking pot shots". I am bound to say that I do not think those are unfair descriptions. It is not appropriate, in my view, to invite a judge to draw conclusions based upon selected extracts of scientific material without any proper expert support for what is being asserted.

69. I made it clear to Mr Feeny that I would approach the applications on the basis of the evidence which had been disclosed pursuant to my case management directions. He confirmed that the claimants' fundamental submission was that the disclosed expert evidence demonstrates that there is merit in the claim and, with some further development, would allow them to establish a case on causation. The defendants disagree. That must be the focus of my consideration.

## The applications

70. Against the background of the history of the previous litigation and the current claim and on the basis of the evidence before me, I turn then to the applications before me.

71. It is appropriate that I consider the Hyman application first. There is no dispute that Mr Hyman cannot proceed with his claim without leave. The claimants' skeleton argument advanced the submission that the Hyman application should await the determination of the other claims. That was a point that had already been argued and determined by me at the hearing in April 2021. My decision was not appealed. There is no reason to revisit it. The defendants suggest that the Hyman application is the prism through which consideration of the claim as a whole should be viewed. They contend that the outcome of the Hyman application directly impacts all claimants. Even if that is wrong, findings I make on the Hyman application will be relevant when I turn to consider the defendants' applications to strike out the other claims.

## The Hyman application

72. Mr Hyman was born with a complex heart defect. He was aged 14 at the time of the hearing before Bingham J. He was represented by Mr Weitzman QC, who explained the difficulty as follows:

> "In order to succeed in their present claims it would be essential for the Plaintiffs to establish as a matter of probability that Primodos, when given to a pregnant woman, materially increases the risk that her offspring will be born with a congenital malformation. The proof of that proposition depends essentially on the evaluation of expert evidence. The expert evidence is concerned with three main areas of enquiry, but the primary field of investigation on which proof of the Plaintiffs' case must ultimately depend is in the discipline of epidemiology ….. There have been many studies published concerned with the relative incidence of congenital malformations, among those exposed to various synthetic or exogenous sex hormones …. Those studies have to be evaluated to assess the reliability of the data incorporated in them …. That evaluation can only be made with the help of expert evidence. Indeed, as your Lordship ruled … the published studies can only ever be received in evidence as part of the material on which the opinions of the expert witnesses are based. This whole area of enquiry has been the subject of reports from a considerable number of expert witnesses, whose reports have been exchanged between the parties.
>
> At the outset of the case the expert evidence available to the Plaintiffs' advisers appeared to indicate that there was a reasonable prospect of establishing as probable the existence of a causal association between Primodos and congenital malformations …. However, as the expert evidence has accumulated we have been driven to the conclusion that the totality of that evidence does not afford any real possibility that we can establish that there is such an association."

73. The judge was provided with further detail of the reasoning which led to that conclusion in an opinion running to 100 pages. That opinion was not disclosed to the defendants at the time or since. It has not been shared with me, although I understand a copy remains available. Having referred to that opinion, Mr Weitzman said:

> "… it is clear that scientists of distinction are not agreed whether or not the mechanisms proposed afford a possible explanation of how Primodos might cause congenital malformations. But we have been driven to the conclusion on the whole of the biomechanical evidence before us, and in the absence of the requisite epidemiological evidence the hypothesised biochemical mechanisms are not capable of establishing that Primodos does cause malformations."

74. The plaintiffs' advisers concluded that there was no real prospect of success in the action and therefore that it should not proceed to trial. However, they sought to discontinue the proceedings rather than the claims being dismissed. The reason given was that the infant plaintiffs would not be barred by limitation for some years. Mr Weitzman said:

> "… we cannot exclude the possibility that within the next few years scientific advances may throw a new light on the problem."

75. The defendants wished to have the claims dismissed. In reply, Mr Weitzman suggested that it was relevant that the defendants would continue to face the possibility that claims could be brought by others who were not party to the present proceedings. I note that the defendants did not submit at the time that others would be caught by the same restriction in bringing proceedings as applied to Mr Hyman.

76. It was on that basis that Bingham J made the order that he did. It is clear from his judgment that he did not envisage the re-opening of the claims so many years later but that does not matter for present purposes. I have already set out what he said about the effect of the requirement for leave to bring any future proceedings.

77. The defendants say that, in light of Bingham J's judgment, I could only grant Mr Hyman leave to proceed if he has demonstrated "a scientific revolution or a marked change in the circumstances" giving rise to "a very strong case indeed" and that it is just for the matter to be re-opened. Although Mr Hyman's application was made on that basis, it is now argued on his behalf that his application for leave is to be considered under CPR r. 38.7. That rule did not exist at the time hence the need for a specific order that a further claim could not be brought without leave. Even if I were considering the application under r. 38.7, I would still need to look at the history and the circumstances in which the original claim was discontinued. I would naturally look at the reasons given for discontinuance and anything said by the judge at the time. In short, my approach would be exactly the same as that envisaged by Bingham J.

78. I do not elevate the words of Bingham J into some sort of formulaic test. They were not intended that way. Indeed it is apparent that Bingham J did not intend to fetter the decision-making of a judge revisiting Mr Hyman's position in the future. It is clear though that what was being contemplated at the time was that scientific developments might lead to a position where Mr Hyman could present a positive case on causation which would, at least, have a real prospect of success. That was particularly so in circumstances where it was envisaged that others would be free to bring claims arising out of the use of HPTs.

79. In his skeleton argument, Mr Feeny submitted that the clear intention was that the plaintiffs then before the court should not be shut out of reconstituting their claims at a later point if others were in the years ahead able to overcome the evidential hurdles that they could not in 1982. Broadly, I consider that to be a fair summary. I would add a qualification. Since Mr Hyman had benefitted from his case being fully investigated and the evidential hurdles had arisen in his case, I do not consider it sufficient for him to merely sit behind others and argue that because they are bringing claims so too should he be permitted to. He must, in my judgment, demonstrate some real change of direct application to his case. He must demonstrate, at the very least, that his claim, which was considered doomed to fail in 1982, now has a real prospect of success. If he cannot

do that, it would plainly be unjust to the defendants to require them to again incur substantial costs in relitigating the same matter again. It would also be of no benefit to Mr Hyman to proceed.

80. Earlier in these proceedings, it was suggested that the previous litigation may have been infected by improper conduct on the part of experts connected to the defendants whose research has since been called into question. That is something that would not have been in the contemplation of the parties or Bingham J in 1982 but which might, if substantiated, amount to a good reason to allow the matter to be reopened. However, that aspect was not pursued and I have seen no evidence that any impropriety affected the outcome of Mr Hyman's previous claim.

81. Given that it is accepted that Mr Hyman bears the burden of establishing that he should be granted leave to proceed, it is striking how little evidence has been presented on his behalf and how little attention was given to his position in the course of the claimants' submissions. It was notable that Mr Feeny's submissions focused to a large extent on limb reduction defects. Mr Feeny recognised that Mr Hyman's case concerns a heart defect but said that the cardiac evidence was more problematic due to a change in categorisation in the statistics since 1982. He said he had focused on the limb reduction cases because that was where the evidence was strongest. This contrasts with the position in the late 1970s when it had been thought that the heart cases, including Mr Hyman's, were the strongest. When pressed, Mr Feeny said that the biggest single change so far as Mr Hyman is concerned is that "there are 101 claimants who wish to bring an action with cogent expert evidence."

82. That is a circular argument. There have always been multiple other claimants who wished to bring an action. Mr Hyman's case was selected as a test case. Mrs Lunt's first statement confirms that there was expert involvement in picking test cases and that a decision had been made to pick a heart case and one where the prescription of Primodos could be dated accurately. The test cases were sponsored by the Association. The processes for group litigation which now exist did not exist at that time but the intention that the cases identified as the strongest by the Association and their advisers should be tried first and would inform the outcome of other cases is clear from the judgment in *Hudd*.

83. It cannot be right that, simply because others now assert they are able to proceed with claims, Mr Hyman should be allowed to present his claim again. That would be to wholly remove the effect of the requirement for leave which was a condition of him being allowed to discontinue in 1982. He must show that things have changed such that history is not going to repeat itself with his claim progressing and substantial costs being incurred without any real prospect of a successful outcome.

84. To succeed on his claim, Mr Hyman would have to show not only that Primodos was capable of causing birth defects but that it did (on the balance of probabilities) cause his heart defect. While the basis of discontinuance in 1982 focused on generic causation, individual causation would have been in issue at trial. I have not seen the evidence that was available to those advising Mr Hyman. I have seen a report from a Dr Navaratnam, who was instructed on behalf of the defendants. He concluded that the cardiac malformation seen in Mr Hyman was most likely to have arisen between the twentieth and twenty-sixth day of gestation. Since Primodos was administered to his mother after that time, it was unlikely to have been the cause. Mr Hyman has presented

no expert evidence to support the contention that his heart defect was (or even could have been) caused by the administration of Primodos. Despite the advice he received in 2018, he either has not had a full genetic assessment or has not presented evidence of such assessment to the court. Mr Hyman, the Association and those advising the claimants, have been well aware throughout these proceedings that the defendants wished to place his case front and centre to test whether the position in relation to causation is now materially different from that existing in 1982. Despite that, he has still not presented anything that could even be regarded as a prima facie case that his heart defect was caused by Primodos.

85. On the issue of generic causation, I am struck by the similarities between the position as presented to Bingham J in 1982 and that presented to me today. Mr Weitzman referred to the many published studies but acknowledged that such studies could only ever be received into evidence as part of the material on which the opinions of experts were based. That remains the case. I would make the same direction today as Bingham J made in the earlier litigation. Mr Feeny's attempt to pick out parts of the scientific literature simply could not plug the gap that must be filled by proper supportive expert evidence.

86. Mr Weitzman explained how it had appeared at the outset that there was a reasonable prospect of establishing a causal association but that as the expert evidence had accumulated it had become clear that there was no real possibility of proving such an association. In recent times, it appeared to the claimants that Professor Heneghan's meta-analysis would provide the key to establishing a causal association. However, it will be recalled that he declined the invitation to express the findings as implying a causal association. The report I have from Professor Zeegers does not offer any clear independent expert opinion that could form a basis for concluding that there is a causal association between the use of HPTs and adverse outcomes. It is of significance that, having reviewed all the expert evidence now available, Mr Feeny decided that he could not properly sustain the allegation he had previously pleaded that there was an established causal association.

87. It is also of note that Professor Danielsson was not prepared to maintain the conclusion that teratogenicity was "causally related" to Primodos induced hypoxia and re-oxygenation damage when asked to provide a Part 35 declaration. Taken at its highest, Professor Danielsson's evidence could provide a biologically plausible mechanism. The defendants are highly critical of this evidence. I have considered the critique offered by Professor Scialli and certainly there are matters that cause me some concern. However, I recognise that Professor Danielsson's report was an initial report and limited in scope. It would be inappropriate for me to adopt any criticisms of him without the expert having an opportunity to respond. As I have already said, there is no question of me seeking to determine any dispute between experts at this stage. I will therefore take Professor Danielsson's evidence at its highest.

88. Again, there is a striking similarity with the position that existed in 1982. Then, as now, there was a scientific dispute on the issue of biological plausibility. Professor Scialli says that Professor Danielsson's theory is not new science. Hypoxia has been proposed as a cause of birth defects since at least the 1960s. Even if there has been some strengthening of the theory, this does not materially advance Mr Hyman's case. He would still be left with the difficulty that a plausible mechanism could, at best, only

provide one element of what is needed to show a causal association. It could not by itself prove causation.

89. The developments in genetics do not assist Mr Hyman. The evidence that he has presented serves only to show that genetic testing has improved since 1982. That comes as no surprise. There is no evidence which purports to exclude genetic causes. In any event, the exclusion of a genetic cause would not significantly improve the prospects of success. The possibility of a genetic explanation does not appear to have been a feature in the decision to discontinue in 1982. Developments in genetics could not help overcome the point raised in Dr Navaratnam's report about the likely timing of the malformation and I have seen no alternative evidence on this issue.

90. Having recognised that he could not sustain the assertion that a causal association between HPTs and birth defects is now clearly established in the epidemiological evidence, Mr Feeny has sought (at a very late stage) to present causation in a wholly different way. He was right, in my judgment, to identify the causation issues in the way that he did in the draft Amended Particulars of Claim attached to Mrs Lunt's statement, as set out above. The evidence available to the claimants did not allow them to make good their case on causation on that basis. Instead, Mr Feeny says that the court is able to infer causation without express expert support for a causal association. The revised pleading is much less clear but concludes:

> "The Claimants' position will be that in respect of a birth defect shown to have had a significantly increased risk from taking of an HPT in the absence of any identifiable genetic cause on testing, the court should conclude on the balance of probabilities that the HPT was the cause."

91. The focus in the new draft upon the proposed mechanism is presumably designed to elevate that factor to greater importance than it has been given thus far. Even if it is assumed that a plausible mechanism can be proved, this cannot overcome the absence of any expert support for a causal association. As a convenient reference point, Ms Mulcahy KC referred to the helpful summary in The Inns of Court College of Advocacy and Royal Statistical Society publication "Statistics and probability for advocates", where it is stated:

> "If a statistically significant relationship is found between an agent and a health outcome, one of the methods subsequently used to determine whether that relationship is indicative of a biologically causal relationship is the Bradford Hill guidelines."

Those guidelines are then set out. Plausibility is just one element within those guidelines. In a case such as this, the court would usually expect experts to engage with the guidelines, or alternatively to offer some other basis for establishing a causal association.

92. In advancing this new case on causation, Mr Feeny referred to *Sienkiewicz v Greif (UK) Ltd; Willmore v Knowsley MBC* [2011] UKSC 10. That case was concerned with causation in cases involving mesothelioma, where the modified test developed in *Fairchild v Glenhaven Funeral Services Ltd* [2003] 1 AC 32 applied. There is no dispute that the *Fairchild* test is not applicable here and that the court is concerned with

the usual "but for" test. However, Mr Feeny relied on obiter observations of Lord Rodger of Earlsferry JSC about the use of epidemiological evidence in cases where causation must be proved on the balance of probabilities (see [163]). Lord Rodger acknowledged the value of epidemiological evidence in such cases and emphasised that epidemiological and statistical evidence may form an important element in proof of causation, but stressed that something more would be required before the court will be able to reach a conclusion on a balance of probability as to what happened in an individual case. He gave the example of where there is a strong epidemiological association between a drug and some condition which could have been caused in some other way and evidence that the claimant developed the condition immediately after taking the drug. Taken together, such evidence may well be enough to conclude, on the balance of probability, that it was the drug that caused the claimant's condition.

93. I note also the observation of Baroness Hale of Richmond JSC at [170], agreeing with Lord Rodger that doubling the risk is not an appropriate test of causation in cases to which the *Fairchild* exception does not apply. She dealt with the position where a disease has known risk factors such that a doctor would sensibly advise a patient to reduce the risks, then said:

> "But if the disease materialises, the existence of a statistically significant association between factor X and disease Y does not prove in the individual case it is more likely than not that factor X caused disease Y."

94. Mr Feeny is right that it is not for an epidemiologist to determine causation. That remains, of course, a matter strictly within the remit of the court. However, the court would require significantly more in the way of expert support before making the leap from a statistically significant association to finding causation proved. Mr Feeny frankly acknowledged that there were problems with the claimants' expert evidence. He answered that by saying there were also serious issues with the defendants' evidence. That does not though help Mr Hyman to demonstrate that he now has a case for which he should be given leave.

95. There has not been a scientific revolution, or anything approaching one. As would be expected, there have been significant developments in all relevant scientific fields in the past 40 years but there is nothing Mr Hyman can identify to demonstrate that he has any real prospect of overcoming the evidential hurdles that prevented his claim from proceeding to trial in 1982. The critical points Mr Feeny relies upon, namely the comparison with the effects of misoprostol and the meta-analysis conducted by Professor Heneghan are not enough to overcome the difficulties on generic causation, regardless of the fact that Mr Hyman has produced no evidence at all to support causation in his individual case.

96. The position in 1982 was that there was conflicting expert evidence on the proposed biomechanical theory but, even if that conflict was resolved in Mr Hyman's favour, there remained insufficient evidence to demonstrate a causal association. That is still the position today. It remains the position despite the considerable time that has elapsed since these proceedings were issued and the extensions of time granted for preparation for this hearing.

97. In those circumstances, it would be wholly inappropriate for Mr Hyman to be allowed to relitigate his claim. The first and second defendants' predecessors incurred very considerable costs in defending the previous litigation. They have not recovered those costs. It would be manifestly unfair to require the defendants to litigate the same issues again when the evidence presented to me suggests that the same outcome is inevitable.

98. I must therefore refuse permission for Mr Hyman's claim to proceed.

**The defendants' applications in relation to the other claimants**

99. The defendants contend that Mr Hyman's original litigation was a test case in de facto group litigation. In those circumstances, they say that all claimants should be subject to the same requirement to obtain leave to proceed as Mr Hyman. In circumstances where I have concluded his claim cannot proceed, the first and second defendants invite me to refuse jurisdiction under CPR Part 11 in respect of the other claims. In the alternative, they invite me to strike out the claims as an abuse of process.

100. At the hearing, the defendants did not strongly press their argument that all claimants should be subject to the requirement to seek leave pursuant to the order of Bingham J. That was not because they concede the point but rather because they say that the abuse of process route leads to the same outcome.

101. Having considered the transcript of the hearing before Bingham J, it appears that it was not in the contemplation of the parties or the judge that the order would bind those who were not party to the proceedings then before the court. A consideration in allowing the plaintiffs to discontinue rather than have their claims dismissed was the fact that others would be free to bring claims in the future. The third and fourth defendants were not parties in the original litigation. Some of the litigants in this action may have intimated or issued claims which awaited the outcome of the first two cases. There is no doubt that those two cases were being pursued as test cases. Then, as now, the Association was closely involved in the litigation. Other claimants, and their families, may have had no awareness of the original proceedings. I am conscious that some, perhaps many, claimants will have been children at the time.

102. In looking at the position of the other claimants as a whole and as against all four defendants, I consider it much more appropriate to address the arguments under the rubric of abuse of process and to approach this as a strike out application. This benefits the claimants in that the burden rests upon the defendants to show that they should not be allowed to proceed rather than it being for them to show that they should be allowed to proceed.

**Abuse of process**

103. The relevant general principles applicable to an application to strike out for abuse of process have recently been summarised in *Município de Mariana v BHP Group (UK) Ltd* [2022] EWCA Civ 951, at [170-178]. I have referred to that summary. I need not repeat it. It is worth restating the important observation that litigants should not be deprived of their claims without scrupulous examination of all the circumstances and unless the abuse has been clearly established. It is only in "clear and obvious" cases that it will be appropriate to strike out proceedings as an abuse of process so as to prevent a claimant bringing an apparently proper cause of action to trial.

104. The question of whether an abuse of process exists is a matter on which a judgment must be made. That does not involve the exercise of a discretion. It does though require the court to weigh the overall balance of justice. In *Johnson v Gore Wood* [2000] UKHL 65; [2002] 2 AC 1, Lord Bingham said that it was not possible to "formulate any hard and fast rule to determine whether, on given facts, abuse is to be found or not." Attempts to relitigate issues which were raised, or which could and should have been raised, in previous proceedings may amount to an abuse of process, even if not strictly res judicata. What is required is:

> "a broad merits-based judgment which takes account of the public and private interests involved and also takes account of all the facts of the case, focusing attention on the crucial question whether, in all the circumstances, a party is misusing or abusing the process of the court by seeking to raise before it the issue which could have been raised before."

105. In the *Município de Mariana* case, the Court of Appeal said:

> "A finding of abuse of process does not lead automatically to a striking out of the claim. The court then retains a discretion as to the appropriate response, which must always be proportionate".

At first blush, that might appear contradictory to what was said in *Tinkler v Ferguson* [2021] EWCA Civ 18 (at [32] and [35]) in which the Court of Appeal, having referred to *Hunter v Chief Constable of the West Midlands Police* [1982] AC 529, said that where an abuse is found the court has a "duty, not a discretion, to prevent it". However, the court in *Tinkler* proceeded on the basis that it would only be in rare cases that litigation which had not previously been decided between the same parties or their privies would amount to an abuse of process. It was acknowledged that it is a serious thing to strike out a claim and the power must be used with care. If there is a difference between the approach adopted in *Municipio de Mariana* and that in *Tinkler*, it is probably only in whether the assessment involves a two-stage approach in which proportionality comes into the second (discretionary) stage or a broad assessment in which proportionality forms part of the considerations.

106. All the authorities make it clear that striking out is not to be undertaken lightly. It is only in a "clear and obvious" case that striking out will be appropriate. If there is an alternative way of dealing with the concerns, it will not be in the interests of justice to take the draconian step of striking out. It is really only in those cases where the court is driven to the conclusion that there is no option but to strike out that such a course will be taken. That view has informed my case management approach. I have sought to ensure that the claimants have had sufficient time to attempt to put their case in order and to demonstrate that the position now is materially different from that which existed in 1982. In considering the defendants' applications, I proceed on the basis that even if abuse of process is identified, the court retains a discretion not to strike out if it would be disproportionate to do so. In short, I remind myself that striking out is a remedy of last resort and that I should at all times consider whether there is a less draconian option available.

107. The grounds set out in the defendants' applications as amended are essentially two-fold:

    i) It is an abuse of process to re-litigate issues which were dealt with in the previous litigation, which was discontinued after great expense had been incurred.

    ii) The litigation is not viable in the absence of funding and representation.

    Those grounds were expanded upon in the witness statements that accompanied the applications. Further, they were subject to discussion and clarification during the case management hearings.

108. Although put in slightly different ways by each defendant, the arguments can be seen as crystalising around three areas:

    i) This is an attempt to re-run the previous failed litigation. Mr Hyman's case was a test case. His claim failed on generic causation after significant costs had been incurred. Nothing has materially changed. Just as he cannot be permitted to proceed, the other claimants should not be permitted to proceed with their claims.

    ii) The claims are speculative and bound to fail. The claims were issued in the hope that something would turn up. That has not happened. Even now, the claimants have not been able to plead a proper case on causation or to put forward proper expert support. There is no real prospect of the claimants proving causation.

    iii) The claims are not viable. The claimants are without funding or representation to proceed to trial. That remains the case even after they have been given generous extensions of time and there is no realistic prospect that the position will change.

109. These factors plainly overlap. Making a broad merits-based assessment requires me to look at all the circumstances, including the history of the previous and the current litigation. If the defendants are right that the claims have no real prospect of success, that clearly feeds into the viability of the claim and the chances of securing funding and representation.

110. It is not suggested that I should approach the position of any defendant differently from any other. Although the third and fourth defendants were not parties to the original claims, the issues that are relevant to the current applications are common to all. There are some additional arguments that may be advanced in relation to any claims involving miscarriage and stillbirth since such outcomes formed no part of the Heneghan meta-analysis relied upon by the claimants. However, I address the arguments on the basis of the entire cohort of claimants and without seeking to categorise the individual claims. In doing so, I place no weight on the fact that some claimants may face additional hurdles but rather take the high point of the claims as represented in their submissions.

111. I also make it clear that, although some arguments were advanced about the conduct of the litigation on the claimants' side, I am not approaching the applications on the basis

that there has been misconduct which might in itself justify the claim being struck out. It is fair to say that the claimants' case has shifted repeatedly. The defendants have been faced with a very late change in the way the causation case is put. Matters that were not in evidence were advanced during submissions. I view all this as being related to the merits and to the lack of representation in the conduct of the litigation rather than a separate issue.

112. Mr Feeny contended that it should be acknowledged that the defendants' position on breach of duty was exceptionally weak. Indeed, he suggested that the defendants may admit breach of duty. He suggested that was a good reason why the claimants should be permitted to proceed to the next stage at least. Their prospects would improve if the defences admitted breach. There is no basis upon which I can anticipate the defendants will take that course. When Mr Hyman's case was before Bingham J, he noted that breach of duty was in issue. The Court of Appeal in *Hudd* refused to split the issue of causation off because negligence and causation were closely related. The focus has been on causation because that was the hurdle which could not be overcome in 1982 and remains the fundamental hurdle upon which the defendants say the claim is bound to fail.

113. It was argued on behalf of the claimants that I should not consider the merits of the claim at this stage because there was no summary judgment application before the court. In his submissions on behalf of the claimants, Mr Bertram suggested that this represented an important jurisdictional distinction and that had the claimants known they were facing arguments based upon the lack of a real prospect of success they may have filed different evidence.

114. I am afraid I cannot accept that. It was made very clear at the case management hearings that this hearing would examine the merits of the claim in the context of both the Hyman application and the abuse of process argument. I encouraged the claimants to put their best case forward. The defendants could have made applications for summary judgment at any stage. There was no need for them to do so in circumstances where the strike out applications provided an appropriate vehicle to examine the merits of the claim in the broader context. The defendants do not rely on the lack of a real prospect of success in isolation. They contend that the merits are to be viewed against the background of the previous litigation and in assessing the viability of this litigation.

115. The defendants relied upon *Nomura International Plc v Granada Group Ltd* [2007] EWHC 642 (Comm), in which Cooke J suggested that it was an abuse of process to issue a claim to stop a limitation defence even though the claimant was in no position to properly formulate its claim. It was submitted that Mrs Lunt's evidence showed that was exactly what had happened here. The claimants were, as in *Nomura*, hoping that "something may turn up". I do not find *Nomura* particularly helpful on the facts of this case. The claimants here did set out their claim in a rudimentary way, albeit they acknowledge that the Generic Particulars of Claim do not adequately set out a full case on causation. It is not uncommon for a claim for personal injury to be issued to protect against limitation at a stage when expert evidence is being refined to address complex causation issues. In itself, I would not regard that as something that falls within the *Nomura* category of abuse.

116. Of greater relevance are the cases of *AB & others v John Wyeth & Brother Ltd (No. 5)* [1997] PIQR P385 and *Herbert George Snell & others v Robert Young & Co* [2002]

EWCA Civ 1644. Both concerned group litigation in which the claims were struck out for lack of viability. In *AB v Wyeth*, the Court of Appeal found that the court was entitled to make an assessment of the viability of the claims and to take a broad view of the difficulties facing the claimants. The judge was entitled to have regard to the fact that legal aid had been withdrawn and, in the absence of realistic proposals for representation and prosecution of the actions, to think that litigation of such complexity could not be brought to trial. The Court of Appeal said that litigation of that nature could not be conducted without the assistance of experienced counsel and solicitors and that it was unrealistic to expect them to act pro bono. Experts could not be expected to appear for nothing. Once the judge had concluded that there was no prospect whatever of the case being brought to trial, let alone to a successful outcome, he had no alternative but to strike the action out. It was his duty "not to prolong the agony." It was noted that the judge had adjourned on several occasions to enable the claimants to put their case in order. A similar approach was taken in the organophosphate litigation (*Snell*).

117. In the end, each case must be determined on its own merits, applying established principles and taking account of all relevant circumstances. The following features are of particular significance:

i) HPTs have been the subject of previous litigation. That litigation almost proceeded to trial. Substantial costs were incurred. The plaintiffs had the benefit of public funding, which was only withdrawn late into the claim when their advisers concluded that there was no real prospect of success at trial. The defendants incurred costs of £3.8 million defending the action. Those costs have not been recovered.

ii) The previous litigation failed because generic causation could not be established. The plaintiffs had obtained supportive expert evidence to allow the claims to proceed as far as they did but in the end it was recognised that they could not prove a causal association.

iii) Mr Hyman's case was a test case. He has sought to relitigate. He required leave to do so. On his application for leave, he was challenged to demonstrate that the position had materially changed since 1982. He was unable to do so. The evidence served on his application was limited. It did not establish a prima facie case on causation. When analysed, the position with regard to generic causation is strikingly similar to that outlined to the court in 1982.

iv) These proceedings were issued nearly three-and-a-half years ago. The claimants are still not in a position to properly plead their case on causation or to provide evidence to demonstrate that their claims have a real prospect of success.

v) The claimants have faced the considerable disappointment of their solicitors withdrawing. They have been provided with time to regroup. It is now over a year since their former solicitors came off the record. They have not been able to secure alternative representation, other than by counsel on a pro bono basis. That arrangement does not cover the conduct of the litigation. Each claimant would therefore have to proceed as a litigant in person. The claimants are not to be penalised for that. Generally, the court will do what it can to assist and to level the playing field. All other things being equal, the court would need to manage the litigation in a way that allows the unrepresented claimants to

participate. I do not determine these applications on the basis of unmanageability, still less because it may be inconvenient for the defendants and/or the court to deal with so many unrepresented litigants. However, in reality it would be extremely hard for the claimants to pursue litigation of this sort without solicitors being on the record. That was acknowledged on their behalf at the hearing in June 2022. Although the claimants were able to secure pro bono representation for the hearing, the evidence for this important hearing was lacking and preparatory steps such as applying to amend the Particulars of Claim and serving appropriate evidence in support had not been taken.

vi) The claimants have only limited funding through the funds of the Association, charitable fundraising and crowdfunding. There is no evidence that they are likely to secure the funds necessary to progress their claim.

vii) The claimants have not presented any realistic plan for this claim. They acknowledge that they cannot show they that can proceed to trial. However, they say (and I would agree) that claimants will often face restrictions on their funding arrangements so that they cannot guarantee that they will be in a position to proceed after the close of proceedings and exchange of evidence. They invite the court to allow the claim to progress to close of pleadings but have not shown how this will benefit them. It is hinted that if I determine that they can proceed that may improve how the prospects of success are viewed and so assist with funding and representation. That is to put things backwards. I must make an assessment of the prospects of this claim succeeding. I cannot work on the assumption that if I allow the claim to proceed then the prospects will improve. There is no evidence to support the conclusion that there is a realistic prospect of the claimants securing funding and representation.

viii) There is also no evidence about how the experts would be instructed and funded. It was hinted that the existing experts may be willing to provide reports on a pro bono basis. Mr Bertram acknowledged that the court might have some reservations about such an arrangement. It would be unusual for an expert to be willing to undertake work in a complex case such as this without receiving payment. I do not say this could never be appropriate but, as Mr Bertram recognised, it might raise questions as to the true independence of the experts. In any event, there is no evidence that the experts have offered to work on a pro bono basis. There is also no explanation as to why the claimants will be in a better position to serve evidence supporting a causal association further down the line than they were for this hearing when they knew the merits were to be examined.

ix) Fundamentally, the claimants have not shown that the claim is meritorious. They have not shown that there has been a material improvement in the chances of establishing generic causation since the earlier litigation was discontinued.

x) Indeed, the defendants argue that the position has hardened against the claimants. They point to the thorough review conducted by the EWG, following the call for evidence and the conclusions of the regulatory authorities. The defendants' experts agree with those conclusions. The claimants' experts have not so far engaged with them. The court would undoubtedly have to take

account of the EWG review. This is a factor which further tips the balance in the defendants' favour.

118. The claimants argue that striking the claims out on the grounds of lack of viability would be contrary to their right under Article 6 of the Convention for the Protection of Human Rights and Fundamental Freedoms ("ECHR") to a fair hearing to determine their civil rights. They contend that they should not be denied access to justice through lack of means. That proposition is certainly true but it does not mean that the claimants have an unfettered right to bring their claims. As Lord Bingham said in *Johnson*, the starting point is that:

> "Litigants are not without scrupulous examination of all the circumstances to be denied the right to bring a genuine subject of litigation before the court."

However, as the cases cited above make clear, there will be instances where it is appropriate to stop claimants proceeding to limit abusive and duplicative litigation. The claimants' lack of means to pursue the litigation is only one aspect of the viability argument and cannot be viewed in isolation.

119. The plaintiffs in the original litigation had funding to pursue their claims through Legal Aid. I note that Mrs Lunt suggested in her second statement that the claimants believe that there was a profound inequality of resources in the original litigation, with the defendants having three times the number of experts as the claimants. Although I have not seen the 100-page opinion explaining the conclusion that there was no real prospect of success at trial, I have no sense from the transcript of the hearing before Bingham J that the difficulties stemmed from an inequality of arms. Likewise, the lack of viability of this litigation cannot be viewed as resulting simply from an imbalance in the financial resources of the parties. The difficulties in securing funding and representation cannot be divorced from the merits of the claim and from the history of the failed previous action.

120. Further, the fact that the claimants genuinely perceive that justice was not done in the earlier litigation and that they seek to correct that through this litigation does not mean that this litigation is not an abuse of process. To quote Lord Diplock in *Hunter*, the court is concerned with:

> "…the inherent power which any court of justice must possess to prevent misuse of its procedure in a way which, although not inconsistent with the literal application of its procedural rules, would nevertheless be manifestly unfair to a party to the litigation before it or would otherwise bring the administration of justice into disrepute among right-thinking people."

121. The fact is that the original litigation involving Mr Hyman failed because generic causation could not be established. The defendants in that action incurred very substantial costs which they did not recover. A significant share of the court's resources were also deployed at that time. In those circumstances, it is incumbent on the claimants to explain what has changed since last time and to demonstrate that the litigation is viable in the sense that they are able to proceed and have a real prospect of success. It

is otherwise manifestly unfair to require the defendants to litigate the same issue again, incurring substantial costs which they will probably not recover.

122. I have observed previously and do so again that it is no kindness to the claimants to permit litigation in which they face insurmountable difficulties and where there is no realistic prospect of the case being brought to trial, still less to a successful outcome, to limp on. In my judgment, this claim has been limping on since the exchange of the preliminary experts and the withdrawal of the claimants' solicitors. The claimants have been provided with time to seek funding and representation and the opportunity to provide evidence that they now have a real prospect of success where none existed in 1982. They have not been able to do so, not through want of effort but because the claims fundamentally lack merit.

123. In those circumstances, I consider that it is an abuse of process for this litigation to be pursued. Having allowed a significant amount of time for the claimants to endeavour to make progress and to present evidence of a viable claim, I do not believe that there is now any option but to strike out the claim as a whole. The alternative plan proposed by the claimants is really not a plan at all. Even at this stage, the claimants have still not been able to put forward a properly pleaded case on causation. I do not see that further time will assist. Standing back as I must and looking at all the circumstances, I conclude that this is one of the rare cases where it is clear and obvious that the claims must be struck out. Having reached that conclusion, I ask myself whether there are any other factors that would persuade me that I should exercise my residual discretion not to strike out on the basis that it would be disproportionate. In the context of the history, the merits and the lack of viability, I consider that not striking the claims out now would only delay the inevitable while resulting in significant additional costs being incurred. I conclude that striking out is not disproportionate. It is the only option open to me and in those circumstances is the course I am duty-bound to take.

124. I recognise the profound disappointment my judgement will bring for the claimants. They believe, and will no doubt continue to believe, that HPTs were the cause of the birth defects and the loss of the babies which they have suffered. No one has been able to confirm definitively that this belief is wrong. The claimants do not believe justice was done in 1982 and they have fought hard to seek justice since. While it appeared that the tide was changing in the last decade, developments have not been sustained in a direction that allows them to demonstrate any real change from the position when the earlier test cases were discontinued in 1982. I have approached this litigation with sympathy for the claimants. I maintain that approach in taking this decision but I am driven to the conclusion that the only appropriate action is to strike the claims out.

## Conclusion

125. Pursuant to the order of Bingham J made in 1982, Mr Hyman cannot proceed with his claim without the leave of the court. For the reasons set out above, he has not established that leave should be granted. I therefore refuse leave and his claim must be struck out.

126. Although I have not treated the order of Bingham J as applying to the other claimants, the history of the previous litigation provides the context in which I have considered the defendants' application to strike their claims out as an abuse of process. This litigation is an attempt to relitigate the issues that were considered in the earlier

litigation which failed because a causal association could not be established between HPTs and foetal harm. Having carefully considered the material placed before me, I conclude that the position has not materially changed in the claimants' favour. It would be manifestly unfair to the defendants to require them to incur further substantial costs in defending this action. Further, it is not in the interests of the claimants to maintain the litigation in circumstances where there is no viable plan to progress the claims and no real prospect of success. I am driven to the conclusion that the proceedings are an abuse of process and that the only appropriate response is to strike out the claims.

127. It follows that the proceedings as a whole will be struck out.