

ESSURE GROUP LITIGATION

Claim No.: BL-2019-LIV-000003

Claim No.: QB-2020-003824

Claim No.: QB-2021-002000

Claim No.: QB-2022-001081

Claim No.: KB-2023-001940



QB-2020-003824

IN THE HIGH COURT OF JUSTICE

KING'S BENCH DIVISION

Before: The Senior Master

and Master Sullivan

B E T W E E N:

MRS KAREN LOUISE TONGE AND 177 OTHERS

APPLICANTS / CLAIMANTS

- AND -

BAYER PUBLIC LIMITED COMPANY (1)

BAYER PHARMA (AG) (2)

NHS TRUSTS (3)

CARDIFF AND VALE UNIVERSITY HEALTH BOARD (4)

SWANSEA BAY UNIVERSITY HEALTH BOARD (5)

BETSI CADWALADR UNIVERSITY HEALTH BOARD (6)

RESPONDENTS / DEFENDANTS

ORDER

UPON an application for a Group Litigation Order pursuant to CPR 19 having been made by the Applicant Claimants by application dated 28 July 2021

AND UPON hearing Counsel for the Applicants, Leading and Junior Counsel for the First and Second Defendants, Leading Counsel for the Third Defendants, and Counsel for the Fourth to the Sixth Defendants

AND UPON the Senior Master and Master Sullivan having read the written evidence filed with the Court

AND UPON “the NHS Trusts” (Third Defendants) being defined as all the NHS Trusts located in England and one provider of NHS services (Care UK Limited) as are identified on Schedule 3 to each of the Claim Forms issued on 11 March 2019 (BL-2019-LIV-000003), issued on 30 October 2020 (QB-2020-003824), 24 May 2021 (QB-2021-002000) and 31 March 2022 (QB-2022-001081)

AND UPON the parties of the claims brought by the Applicants/Claimants against the NHS Trusts and the Fourth, Fifth and Sixth Defendants under claim numbers QB-2020-003824, QB-2021-002000, and QB-2022-001081 having been stayed

AND UPON the President of the King’s Bench Division having consented to an order being made in the following terms:

IT IS ORDERED that:

A. Scope of the Group Litigation Order

1. This Group Litigation Order (‘GLO’) applies to all Claims (which term includes for these purposes any part of a Claim) brought against the First and Second Defendants which give rise to one or more of the GLO Issues by Claimants who claim that they have suffered injury as a consequence of being surgically implanted with an Essure Device produced by either the First Defendant or the Second Defendant save that it shall not apply to those Claims or part of a Claim in which it is alleged that the Essure Device (a) has migrated and the confirmation test (i) failed or (ii) was not carried out because the Claimant had complained of symptoms in the three-month period following implantation; and/or (b) has perforated the Claimant’s tissue at the time of insertion of the Device and/or (c) has fragmented on removal occurring before the three-month confirmation test.
2. The Claims which are the subject of this Order shall constitute and shall be known as “The Essure Group Litigation”. The parties to these Claims are bound by the orders of the Court made in relation to The Essure Group Litigation.

3. The GLO Issues for the purposes of CPR 19.11(2)(b) are upon agreement set out in Schedule 1 of this Order.

B. Definitions

4. (a) “The Claimants” are those Claimants whose claims are entered onto the Group Register in the manner and under the terms set out in paragraphs 11 to 13 below. Pending the establishment of the Group Register, the Claimants are those Claimants named in Schedule 4.

(b) “The First Defendant” means Bayer plc.

(c) “The Second Defendant” means Bayer Pharma AG.

(d) “The Bayer Defendants” mean both Bayer plc and Bayer Pharma AG.

(e) “The Lead Solicitors” for the Claimants are PGMBM Law Ltd (trading as “Pogust Goodhead”), 70 Mark Lane, London, EC3R 7NQ.

(f) “CPA” means the Consumer Protection Act 1987.

(g) “Directive” means Directive 85/374/EEC.

(h) “the Essure Device” means the permanent contraceptive device known by the trade name Essure.

(i) “Lead Case” means an action which has been fully pleaded and which alone or together with other such actions is intended to dispose, so far as possible, of issues (primarily but not limited to common issues) between the parties to this litigation.

(j) “The Management Court” means the Court managing this litigation, which will be the High Court of Justice, King’s Bench Division in London.

(k) “The Managing Judge” means the judge nominated from time to time by

the president of the King's Bench Division to be responsible for the procedural management of all claims to which this Order applies. Pre-trial applications in this litigation shall be heard, where practicable, by the Managing Judge.

- (l) "The Managing Master" is the Master of the King's Bench Division nominated from time to time by the Senior Master to hear any pre-trial applications in this litigation that are not suitable to be dealt with by the Managing Judge and are released thereto by the Managing Judge.

C. Documentation

5. All documents (including Claim Forms, statements of case, applications and witness statements) filed with the Management Court in respect of a Claim which is subject to this Order shall be marked with the short title of the Claim and shall be marked in the top left-hand corner "ESSURE GROUP LITIGATION".

D. Future claims

6. All future Claims to which this Order applies by virtue of paragraph 1 must be issued out of the Management Court and entered on the Group Register, provided that the Standard Minimum Requirements (as set out at paragraph 23 below) are met.

E. Transfer of Existing Proceedings

7. Any existing Claim to which this Order applies by virtue of paragraph 1 above, and which is proceeding other than in the Management Court, is to be transferred forthwith to the Management Court without further order and entered onto the Group Register, upon service of the Claim Form on the Defendant, provided that the Standard Minimum Requirements are met by each such claim or part a claim (as set out at paragraph 23 below).
8. If any proceedings are brought against the Bayer Defendants (or either of them) and any other defendant(s) in the same claim form, then only that part of the

claim against the Bayer Defendants (or either of them) shall be transferred in accordance with paragraph 7 above. Claims against other defendant(s) in any such proceedings shall be stayed, except that there shall be liberty to apply.

9. On identification of any existing Claims the Lead Solicitors are to send a copy of this Order to each transferring Court. Notices of Transfer in accordance with paragraph 4.1 of Practice Direction 30 are hereby dispensed with.
10. If one or other of the Bayer Defendants is or has been served with a Claim Form falling within paragraph 1 of this Order other than by the Lead Solicitors, then that Defendant shall inform the Lead Solicitors of the name of the Claimant, the Claimant's solicitors (if any) within 28 days of: (a) such service; or (b) of this GLO, whichever is the later.

F. The Group Register

11. A Group Register, on which are to be entered details of the Claims that are subject to this and subsequent orders in this litigation and that comply with the Standard Minimum Requirements as set out in paragraph 23 below, shall be set up and managed by the Lead Solicitors.
12. The Group Register shall be established by no later than 4pm on Friday, **1 September 2023**. It is a condition of being entered on to the Group Register that each Claimant has met the Standard Minimum Requirements set out at paragraph 23 below.
13. The following details shall be recorded in respect of each Claimant who is added to the Group Register:
 - a. the full name of the Claimant (and any Litigation Friend);
 - b. the identity of the Bayer Defendant against whom the Claimant claims;
 - c. the name of any other defendant against whom the claimant is proceeding on the same claim form as the claim against the Bayer Defendants;
 - d. the number of the Claim Form under which the Claimant claims;
 - e. the date of issue and service of the claim form;

- f. the firm of solicitors instructed by the Claimant;
- g. a unique Group Register Reference number;
- h. the date upon which the Claimant's claim was entered onto the Group Register; and
- i. the date of removal of the Claimant's Claim from the Group Register, if it is so removed.

14. The Lead Solicitors shall serve an electronic copy of the Group Register in Excel or similar format on the Defendant within 14 days of its establishment.

15. Solicitors acting for any individual who has issued a claim to which this GLO applies by virtue of paragraph 1 above shall notify the Lead Solicitors within 28 days of the commencement of any such proceedings, providing the information required under paragraph 13 above; and within 28 days of receiving such notification, the Lead Solicitors shall, subject to that claimant's compliance with the standard minimum requirements set out in paragraph 23 below, enter such a claimant on the Group Register.

16. The Lead Solicitors shall review and update the Group Register every 3 months, with the first review taking place 3 months after service of the first iteration of the Group Register. The Lead Solicitors shall serve an electronic copy of the updated Group Register on the Defendants within 14 days of each such update. Further, solicitors acting for any named party in the Essure Group Litigation shall be entitled to an electronic copy of the Group Register in Excel or other agreed format upon request.

17. The Bayer Defendants may give written Notice of Objection to the Lead Solicitors in respect of any Claimant whose Claim has been entered on the Group Register, or as to the accuracy of any other information entered thereon, within 28 days of the service of the version of the Group Register in which the Claimant or information is included for the first time, stating the nature of the objection(s), the ground(s) for it and provide any relevant documentation to support the objection as relevant.

18. The parties concerned with any such objection shall seek to resolve the

objection, but if they are unable to do so within 28 days of the receipt of the Notice of Objection, the Bayer Defendants may apply to the Court for determination of the objection. Such a Notice of Objection shall not affect the individual Claimant's entitlement to remain on the Group Register unless and until the Court directs otherwise.

19. A Claimant's Claim shall remain on the Group Register until such time as she serves a notice of discontinuance or, if required, obtains permission to discontinue, or if the Claim is otherwise disposed of prior to trial, or if the Court orders its removal. In any such event, the Claimant's Claim shall be removed from the Group Register on the expiration of the last day of the three-month period in which the Group Register is being reviewed and updated pursuant to paragraph 16 above during which notice of discontinuance or permission to discontinue is given or the effective date of disposal occurred.
20. For the purposes of CPR 38.2(2)(c), consent to discontinue by any Claimant may be given by the Lead Solicitors on behalf of the other Claimants.
21. The Lead Solicitors shall, as a schedule to the Group Register, maintain a list called the "Discontinued Claims Register" detailing:
 - a. the name of any party discontinuing or the subject of any other form of disposal; and
 - b. the date of the filing of the notice of discontinuance or other form of disposal.
22. The Discontinued Claims Register shall be served alongside the Group Register in the manner set out at paragraphs 14-15 above.

G. Standard Minimum Requirements

23. In any claim to which this GLO applies by virtue of paragraph 1 above, the Standard Minimum Requirements for entry of a claim onto the Group Register are as follows:
 - a. A Claim Form has been issued, on which the individual Claimant is named, and has been served within the validity period allowed by the

CPR. The requirement to serve particulars of claim in a separate document, and any expert medical report, is hereby dispensed with, subject to further order;

- b. The Claimant must have been implanted with the Essure Device;
- c. The Claimant must have either:
 - i. undergone surgery to remove the Essure Device; or
 - ii. been recommended to undergo such surgery and is awaiting such surgery being performed; or
 - iii. been informed by a medical professional that their symptoms are attributable to the Device but advised against and/or opted not to undergo removal surgery for medical reasons.
- d. The Claim raises one or more of the GLO issues; and
- e. The Claimant claims to have suffered loss and damage as a consequence of being implanted with the Essure Device.

H. Schedules of Information

24. All of the Claimants whose claims are listed in Schedule 4 hereto shall serve on the Bayer Defendants by 4pm on 1 December 2023:
- a. a completed Schedule of Information in the form set out in Schedule 2 hereto, such information to be provided to the best of each Claimant's knowledge and belief and signed with a Statement of Truth; and
 - b. such medical records that they hold in respect of each Claimant, by source, and shall use reasonable endeavours to obtain any missing records and provide the same to the Defendant within 42 days of receipt, by source.
25. Any other Claimant who has issued proceedings to which this GLO applies by virtue of paragraph 1 above, and whose claim meets the Standard Minimum Requirements for entry onto the Group Register, and whose claim is subsequently entered on the Group Register, shall serve the documents in paragraph 24(a) and (b) above on the Bayer Defendants within 4 calendar months of such entry.

I. Costs Sharing

26. The following terms are defined in respect of costs:

- a. “QOCS” means qualified one-way costs shifting within the meaning of section II of CPR 44.
- b. “Individual costs” are those costs and disbursements incurred for and/or in respect of any individual Claimant in relation to matters which are particular and personal to each such Claimant, excepting any costs incurred because that claim is under consideration for selection as a lead claim or any costs incurred after that claim is selected as a lead claim.
- c. “Common Costs” are all costs and disbursements of the relevant party other than Individual Costs (and include, for the avoidance of doubt, the categories of common costs stated in CPR r.46.6(2)(i)-(iii)).

27. Save as otherwise ordered or agreed, the liabilities for costs are to be determined in the following manner:

- a. Each Claimant shall be solely liable for, or solely entitled to, the Individual Costs relating to that claim.
- b. The liability of each Claimant for costs, and each Claimant’s entitlement to recover costs, shall be several and not joint.
- c. There shall be quarterly accounting periods for the purposes of calculating Common Costs. The first such quarterly accounting period shall be deemed to have commenced on 30 October 2020 and run to 28 July 2023 and thereafter quarterly accounting periods shall run from the following dates in each year: 29 July, 29 October, 29 January, and 29 April.
- d. The Claimants’ Common Costs shall be apportioned between them by taking the total Common Costs incurred by or on behalf of the Claimants in any quarterly accounting period and dividing that sum by the number of Claimants pursuing claims on the first day of that quarter (the “**Proportionate Share**”).
- e. The Common Costs incurred in any quarterly accounting period by any defendant (including the Bayer Defendants) are to be divided by

the number of the Claimants deemed by subparagraphs 27 (d) and (f) to have been pursuing their claims against that defendant (whether alone or with other defendants) on the first day of the quarterly accounting period.

- f. For the purposes of determining the amount of costs shared between the Claimants in accordance with sub-paragraphs 27(d) and (e) of this Order:
 - i. A Claimant whose claim is entered on the Group Register at any time shall be deemed to have been on the Group Register from the beginning of the first accounting period.
 - ii. A Claimant whose name has been removed from the Group Register in accordance with this Order and/or any rules of Court shall remain subject to the costs sharing provisions of this Order until the last day of the quarterly accounting period in which her name has been removed from the Group Register in accordance with this Order and/or any rules of Court.

28. Unless ordered or agreed otherwise, liabilities for costs between the Claimants and the Defendants are to be determined as follows (subject to QOCS):

- a. The order for payment of Common Costs between the parties shall be determined by the trial judge at the conclusion of the trial of the GLO Issues or Lead Cases, with permission to apply if such a trial does not take place.
- b. Common Costs ordered to be paid shall (in the absence of agreement) be subject to detailed assessment, which shall not take place prior to the conclusion of the trial of the GLO Issues or Lead Cases, with permission to apply if such a trial does not take place.
- c. Common Costs ordered to be paid by the Defendant to the Claimants shall be paid to the Lead Solicitors.

29. Unless ordered or agreed otherwise, in the event that any Claimant discontinues her claim, or compromises her claim on terms which provide for her to pay the Defendant's costs, or her claim is dismissed or struck out

by an order which provides for her to pay the Defendant's costs, then (subject to QOCS):

- a. That Claimant will be liable for any Individual Costs relating to that claim to be assessed if not agreed; and
- b. Any liability she may have for a Proportionate Share of the Common Costs for the period during which she was or was deemed to be a Claimant on the Group Register shall be determined at the trial of the GLO Issues or Lead Cases, with permission to apply if such trial does not take place.

30. Unless ordered or agreed otherwise, in the event that any Claimant compromises her claim on terms which provide for the Defendant to pay to that Claimant her costs, then that Claimant shall be entitled to recover:

- a. The Individual Costs in relation to that claim - to be assessed if not agreed; and
- b. The Proportionate Share of the Common Costs for the period during which she was or was deemed to be a Claimant on the Group Register, such costs to be apportioned upon the basis set out in paragraph 27 (d) and (e) of this Order.

J. Extensions of time

31. The parties may, by prior written agreement, extend the time for directions, in any Order relating to The Essure Group Litigation, by up to 28 days without the need to apply to the Court. Beyond that 28 day period, any agreed extension of time must be submitted to the court by email including a brief explanation of the reasons, confirmation that it will not prejudice any hearing date and with a draft consent order in word format. The court will then consider whether a formal application hearing is necessary.

K. Cut-off date

32. To be entitled to enter on the Group Register, a Claimant whose claim falls within the scope of this GLO must have issued and served a Claim Form by 4 pm on **Friday, 2 February 2024**.

33. The final date on which such claims must be entered onto the Group Register shall be 4 pm on **Friday, 23 February 2024**.

34. These cut-off dates shall be subject to review at the first Case Management Conference, as provided for at paragraph 41 below.

L. Publicity

35. The making of this GLO, and an invitation to prospective Claimants to consider joining this Group Litigation, shall be advertised by the Lead Solicitors in the form set out at Schedule 3 of this Order. The Lead Solicitors shall place appropriate notices on their own website(s), in the Law Society Gazette, and on social media to include but not limited to Facebook. Nothing in this Order is intended to restrict the Lead Solicitors or any other Claimant Firm publicising their involvement in the litigation on any platform in an appropriate form.

36. The costs of such publicity shall be Common Costs and follow the event.

37. The Managing Judge is to arrange for details of this Order to be published on the Courts and Tribunal service website at <https://www.gov.uk/guidance/group-litigation-orders> and in any reports that he or she considers appropriate.

M. Further case management

38. A copy of this Order shall be lodged within 14 days:

- a. With the Senior Master of the King's Bench Division in Room E115 at the Royal Courts of Justice, Strand, London WA2A 2LL and
- b. With the Law Society at 113 Chancery Lane, London WC2A 1PL.

39. A Case Management Conference is to be listed on the first available date after **1 March 2024**, by reference to the court and counsels' availability, before the Managing Judge with a time estimate of 1 day.

40. 28 days before the case management conference listed in accordance with paragraph 40 above, the Claimants and the Bayer Defendants shall file and serve a document confirming the amount of costs that they have incurred thus far and their estimate of the costs that they would each incur up to the conclusion of the trial.

N. Costs of the application for a Group Litigation Order

41. The costs of this application shall be Common Costs, and shall be costs in the cases.

O. Permission to restore

42. The parties have permission to restore.

Dated this 8th September 2023

SCHEDULE 1

LIST OF GLO ISSUES

The matters set out below for the purposes of CPR 19.11 are intended to identify the high level GLO issues to assist the management of the GLO. These issues are likely to require revision and review as the litigation progresses.

1. The correct approach in law to the determination of defect under section 3 of the Consumer Protection Act 1987 (“CPA”).
2. Whether Essure Devices were defective within the meaning of s.3 of the CPA?
3. If so, are the First and/or Second Defendants able to avail themselves of any of the defences set out in section 4 of the CPA?
4. Whether the First and/or Second Defendants were negligent in the distribution of the relevant Essure Devices?
5. At all material times, did the First and/or Second Defendant owe the Claimants a common law duty of care? If so, what was the nature of the duty and was it breached?
6. Whether any claims are statute-barred and, if so, whether limitation should be disapplied in accordance with section 33 of the Limitation Act 1980?
7. Whether any proven loss and damage was caused wholly or partly by any proven defect and/or negligence on the part of the First and/or Second Defendant?

SCHEDULE 2
SCHEDULE OF INFORMATION

1. CLAIMANT'S PERSONAL DETAILS			
1a. Full name of Claimant (including previous names)			
1b. Date of birth (dd/mm/yyyy)		1c. National Insurance number	
1d. Address (including previous address(es)if different at the time of surgery)			
1e. Claim number			
2. PRODUCT DETAILS			
2a. Product Reference / LOT number(s)			
2b. Product Circulation Date			
2c.			

Producer (for the purposes of the CPA)	
2d. Copy of product label(s)	
2e. If 2d. is “no” then, copy of correspondence from treating hospital detailing the product likely used	
2f. Relevant IFU as identified by the Bayer Defendants	
3. RELEVANT MEDICAL HISTORY	
3a. Date(s) of implantation of product	
3b. Hospital at which the index surgery took place and implanting surgeon	
3c. Date of confirmation test (if applicable)	
3d.	

Date(s) of removal of the product or (if product still in situ) date of the decision to remove the product	
3e. Hospital at which the removal surgery took place and removal Surgeon (if applicable)	
3f. Method of removal	
4. CAUSES OF ACTION AND PARAGRAPHS/ SECTION OF THE GENEREIC PARTICULARS OF CLAIM UPON WHICH THE CLAIMANT RELIES	
5. DATE OF KNOWLEDGE AND LIMITATION This section is only to be completed upon receipt of full medical records	
5a. Date of knowledge	
5b. Confirmation of whether the Claimant relies on s.33 of the Limitation Act 1980 and, if so, a summary of the matters relied on in support (by	

reference to the draft general Particulars of Claim)	
6. A PRECIS OF THE CLAIMANT'S RELEVANT MEDICAL HISTORY	
7. SUMMARY OF ALLEGED LOSS AND INJURIES	
Please provide a summary of the alleged loss and injuries sustained by the Claimant as a result of the alleged causative effect of the alleged defect, together with treatment undergone (or scheduled to be undergone) for such injuries and its outcome (if known).	
8. PROVISIONAL CLAIM VALUATION	
<p>Claim valuation inclusive of special damages (please delete as applicable)</p> <p><£25k</p> <p>£25k - £50k</p> <p>£50k-£100k</p> <p>£100k-£250k</p> <p>£250k-£500k</p> <p>£500k-£1m</p> <p>£1m+</p> <p>Heads of loss specific to Claimant (please delete as applicable)</p> <p>Pain, suffering and loss of amenity</p> <p>Past loss of earnings</p> <p>Future loss of earnings</p> <p>Past and future care</p> <p>Private medical expenses</p> <p>Aids and equipment</p> <p>Accommodation</p> <p>Travel expenses</p> <p>DIY/gardening/housework</p> <p>Other non-pecuniary losses</p>	

STATEMENT OF TRUTH

I believe that the facts stated in this document are true. I understand that proceedings for contempt of court may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief in its truth.

SCHEDULE 3

ADVERTISEMENT

THE ESSURE GROUP LITIGATION

The High Court made a Group Litigation Order on [date] in relation to the Essure Group Litigation.

Essure was a permanent contraceptive device. It was marketed as a “non-surgical” alternative to traditional sterilisation methods.

This group action is brought by women claiming that Essure has caused injury, including device migration with associated complications including bladder, bowel and urinary problems; pain, including chronic pain; abnormal bleeding; inability to tolerate the device; device fragmentation during removal; perforation, dyspareunia; psychological issues; surgery to remove the device including associated complications.

The Court appointed Pogust Goodhead (a trading name of PGMBM Law Ltd) of 70 Mark Lane, London EC3R 7NQ as the Lead Solicitors to the group action.

If you believe you have been affected by the Essure device, please contact our dedicated legal team to speak about joining the Essure Group Litigation.

- Visit <https://essureclaimlawyersuk.com//>
- Email essurelitigation@pogustgoodhead.com
- Phone 03330 155 900

It is important that you contact the Lead Solicitors as soon as possible as delay may prejudice your potential claim. The cut-off date for entering new claims on the Essure group register is Friday, 23 February 2024.

This advertisement is published by order of the High Court of Justice.