Witness Name: Professor Sir Ian Kennedy
Statement No.: WITN7007001
Exhibits: none
Dated:

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF SIR IAN KENNEDY

I provide this statement in response to a request under Rule 9 Request of the Inquiry Rules 2006 dated 13 October 2021

I, Sir Ian Kennedy, will say as follows: -

Section 1: Introduction

1. ***Please set out your name, address, date of birth and professional qualifications.***

1. Ian Kennedy, GRO-C
London GRO-C DOB GRO-C 1941. LLB, LLM, LLD, Barrister

2. ***Please set out your employment history including the various roles and responsibilities that you have held throughout your career, as well as the dates.***

2. Assistant Lecturer in law, University College (UCL), 1965-66 Lecturer, UCL, 1967-71
Visiting Professor, Univ of Calif Los Angeles, 1971-72 Lecturer in law, King's College London (KCL), 1974-78
Founder and Director, Centre of Medical Law and Ethics, KCL, 1976-96 Reader in English law, KCL, 1978-83
Professor of Medical Law and Ethics, KCL, 1983-1996 Head and Dean of Law School, KCL, 1986-96
Professor of Health Law, Ethics and Policy, UCL, 1997-2001
Chair, Public Inquiry into the conduct of children's heart surgery at the Bristol Royal Infirmary, 1998-2001
Chair, Healthcare Commission, 2002-2009
Chair, Independent Parliamentary Standards Authority, 2009-2016

3. ***Please provide an outline of any relevant relationships you had, or initiatives you were involved in to ensure that the UK Government, Blood Services, UKHCDO, NHS bodies, medical profession and patients were informed and educated about the risks of vCJD transmission via blood and blood products.***

3. I do not recall having had any relationships, or being involved in

any initiatives, in relation to vCJD transmission.

4. I recall being approached by Sir Michael Rawlins, in the margins of a meeting as I remember, in around 2002. He asked me whether, given my experience with EAGA (the Expert Advisory Group on AIDS), I would be prepared to join a group concerned with possible treatments for vCJD. I responded that, in principle, I would be willing to do so, subject to learning more about the idea. I never heard more about it.

4. ***Could you please confirm whether you have provided any evidence or been involved in any other inquiries, investigations, criminal or civil litigation in relation to variant Creutzfeldt-Jakob Disease (vCJD) infections in blood and blood products. If so, please provide details of your involvement other than the Inquiry mentioned below.***

5. To the best of my knowledge, I have not provided evidence to nor been involved in any inquiries, investigations, criminal or civil litigation in relation to Cruetzfeldt-Jacob Disease infections in blood and blood products.

Section 2: Knowledge of risk

5. ***Please set out your involvement both past and present in relation to the ethics surrounding how emerging diseases should be handled. Please include reference to any research you conducted in this field, any ethical advice you provided in relation to these issues, any relevant committees you were a part of as well as any other involvement or knowledge you had in relation with the handling of emerging diseases, throughout the course of your career.***

6. My involvement in ethics relating to emerging diseases was with HIV/AIDS. I was a member of the Department of Health's Expert Advisory Group on Aids (EAGA) from 1987 to 1994.

7. I have no record of the advice I gave but it would have related to the evolving state of knowledge of HIV/AIDS and responses to it. I gave evidence in the mid/late 90s (I cannot recall when) to the House of Commons' Health Select Committee chaired by Renee Short MP on responses to HIV/AIDS.

6. ***When and in what circumstances did you come to learn about the potential risk of vCJD being transmitted through blood or blood products? Please provide a summary of any discussions you may have had in relation to this and with whom you had these discussions.***

8. I do not recall when I became aware of the potential risks of vCJD being transmitted through blood or blood products.

7. ***Have you been approached by any governmental, scientific or medical organisations in order to provide ethical advice, from 1980 onwards? If so:***

   a. ***Please outline these situations and in what capacity you provided this advice.***

9. I was a member of, or chaired, the following organisations to which I provided ethical advice from 1980 onwards:

- Medicines Commission, DHSS (1984-91)
- General Medical Council (1984-93) (appointed by the Privy Council)

- Working Party on AIDS (1988)
- Working Party on Revision of Professional Guidelines on Ethics (1993-96)
- Expert Advisory Group on AIDS, Department of Health (1987-94)
- Working Party on HIV Infected Health Care Workers (1991-2)
- Committee to Review the Report of the Advisory Group on the Use of Foetuses and Foetal Material for Research, DHSS (1988-89) (see Cmnd 762, July 1989) (Polkinghorne Committee)
- Working Group on Continuing High Risk Behaviour in HIV Positive Individuals, Department of Health (1994-96)
- Chairman, Secretary of State for Health's Advisory Group on Xenotransplantation (1995-6)
- Advisory Group on Complex Commissioning in the NHS, Audit Commission (1996-7)
- Register of Independent Members, Defence Scientific Advisory Council, Ministry of Defence (1997-2005)
- Chairman, Minister of Agriculture's Advisory Group on Quarantine and Rabies (1997-8)

10. I provided advice as a member or as chair of a committee or group. On 2 occasions I acted alone (Reports on Porton Down and for NICE).

b. In what form would you provide ethical advice to such organisations? For example, did you provide formal written reports detailing your advice or did you provide ethical advice on an informal basis.

11. For the most part I provided advice as part of general discussions or in response to specific questions raised in meetings. On occasions I produced a formal written report which was published

(Xenotransplants, Quarantine, Bristol, Porton Down, NICE and Paediatric Cardiac Surgery)

c. Did you provide this ethical advice as part of paid assignments, or was it provided by you on a voluntary basis?

12. I was remunerated for chairing the Bristol Inquiry and for writing the Report for NICE. Otherwise my involvement was on a voluntary basis (I cannot recall if I was remunerated for the Porton Down Report).

8. ***What was the ethical position in relation to the notification of patients who could be at risk for emerging diseases, circa 1996?***

13. My view is that there is rarely, if ever, *"the* ethical position" in relation to any matter at any given time. Instead, there are **judgements** (on which people may legitimately disagree) based upon the application of certain **general ethical principles to facts** as they exist at a certain time. Those judgements may form the basis of **advice** which, in turn, may concretise into **decisions** taken by relevant decision-makers in the form of public **policy.**

14. The starting point of any ethical analysis regarding healthcare (whether in relation to the notification of patients who could be at risk from emerging diseases circa 1996 or otherwise) is the ethical principle of concern for the rights and interests of people/patients. In the vast majority of circumstances this will mean that people are informed of what is contemplated by way of healthcare so that they can decide for themselves what they wish to do. The exceptions having to do with young children or those lacking the necessary mental capacity prove the rule.

15. My general view is that, ordinarily, people/patients should be informed if there is reason to believe that they are at risk as regards emerging diseases. This is the case even if there is nothing that they can do in terms of treatment in response to the information: once informed, they can at least adjust their lives and their relationships with others. This is the judgement I reached as regards HIV/AIDS in the late 1980s when initially there was reluctance by some to obtain consent to testing and thus to inform patients.

16. However, that general position must be balanced against any competing arguments, and in the light of relevant facts or scientific evidence available at the time. The scale on which to carry out this balancing exercise is the need to ensure that as far as possible the patient is not exposed to harm. Ultimately, the question is whether the benefits to the patient of being informed outweigh any harm which could result as a result of being informed.

17. As to any harms associated with being informed, Chapter 4 of the Briefing Paper, "Ethical Considerations", refers to the example of Huntington's chorea/Disease. As the Paper states, the majority of the population at the time (2001) preferred not to be informed as "knowledge of a risk to health of this magnitude could have incalculable implications on life decisions - such as the decision to have children - and would affect life insurance premiums."

18. In the context of the question asked, namely whether patients *could* [my emphasis] be at risk for emerging diseases, the question becomes how great that risk is. If it was not possible to indicate "the magnitude of the risk involved, or whether there is any risk involved" (see the Paper) the balance may be struck in favour of not informing patients.

19. Whilst, therefore, I cannot comment on *"the* ethical position" at the relevant time, I have sought to set out the relevant ethical principles that were (and continue to be) applicable in order to reach a judgement which is/was ethically defensible.

20. It is also important to reaffirm that ethical judgements fall to be reassessed in the light of changes in the facts calling for judgement. If the facts change, so too might the judgement and any subsequent decision or policy.

Section 3: Surveillance studies

9. ***The Inquiry understands that in around July 1996 Patricia Hewitt from the National Blood Association ("NBA") sought ethical advice from you in relation to a retrospective study to examine a possible link between all forms of CJD (including vCJD) and blood transfusions) that became known as the Transfusion Medicine Epidemiological Review ("TMER"). Is this correct? (Please see NHBT0017407)***

21. I have no recollection of the contact with Dr Hewitt but that would appear to be the case, given the contents of Dr Hewitt's letter.

10. ***Please answer the following questions in relation to this:***

    a. ***Please outline your recollection of these events. Were you formally instructed to provide advice in relation to this ethical advice?***

22. Unfortunately (and by way of an important preliminary point), all of my records for this period were disposed of (by shredding) following the sale of the family home in 2012. As a result, I have to rely on my

recollections.

23. I have no recollection of the events described in Dr Hewitt's letter. On the basis that the letter refers to a "conversation" I assume that I was not formally instructed to provide ethical advice: this was not the way in which I interacted with committees. It may be that I was asked for my judgement of the relevant ethical considerations and Dr Hewitt took a note of what I replied, but this is my speculation.

b. What advice, if any, did you provide to Patricia Hewitt with regards to whether patients should be notified that they had received a CJD/vCJD implication blood transfusion?

24. I cannot recall the conversation with Dr Hewitt, and therefore any advice I may have given. That said, I have no reason to doubt that Dr Hewitt's account sought to represent an accurate summary of what we discussed.

c. In what form did you provide this advice to her, for example, was this written advice or did you provide this advice verbally? If it was in writing, could you please provide a copy of it to the Inquiry.

25. As referred to in responses to 10(a) and (b) above, I have no recollection, but on Dr Hewitt's account, it appears that I offered my views in a "conversation" rather than in writing.

d. What was the basis for the advice that you provided?

26. In my answer to question 8, I set out my framework for ethical analysis: I would have applied the relevant ethical principles (described in more detail in my answer to question 8) to the facts and in light of the

scientific evidence available at the time.

27. In the context of vCJD, Dr Hewitt's letter makes clear that, at the time, there was:

i. no scientific evidence that CJD was transmitted by blood transfusion;
ii. no screening or diagnostic test to diagnose infection with CJD; and
iii. no effective intervention which could be offered to those who were infected.

28. In light of those facts, it would appear that I reached a view that the balance lay in favour of not informing patients at that time about the proposed look back exercise because at that point, in 1996, there could be no reason to inform them against something when, at the time and on the facts then known, it did not exist. Others may have struck the balance differently, but they would have to justify the risk of causing harm to people without reason (on the facts as they were).

29. In my judgement, applying the relevant ethical principles, it would have been very likely that patients would have been alarmed when there was, at the relevant time, no ground for alarming them, since, at the relevant time, there was no known causal link between blood transfusion and vCJD.

30. Further, their lives could have been significantly altered unnecessarily (on the facts as known). I had recently been asked to serve on the Association of British Insurers' (ABI) Genetics Committee. I was conscious of the effect on people that even undergoing some test, whatever the outcome, or revealing some information, (eg a family history of a single gene disease such as Huntington's Disease) could have on obtaining life insurance and a mortgage. In that Committee I argued that there should

be a moratorium for at least 5 years on insurance providers asking for such information, a view which was accepted by the ABI.

31. As Dr Hewitt's letter makes plain, the ethical judgement and proposed response would change if the facts on which they were based changed in any material way. Quite separately from the change of circumstances (the "caveats") that she refers to in her letter in relation to the look back, if it were ever established that vCJD could be transmitted through blood transfusions, recipients should have been informed. This is for the reasons that I have set out earlier in my answer to question 8, namely that, whether or not there was a treatment available or whatever the other circumstances, recipients would have a right to know so as to order their lives thereafter. Not to inform them would on that basis be wrong.

32. Though I do not recollect being aware of the involvement of Lothian Ethics Committee nor of the NBA and BPL, the above position is reflected in Annex 2 of the nvCJD Briefing Paper dated January 31 2001. It describes the position taken as "defensible" in the context of the 5 stated premises, but goes on to state that "[i]n the event that one or more of these premises is disproved or modified, the position must be assumed to be invalid (or, at best, unreliable pending urgent review)".

e. Did you consult with any other individuals/experts in order to provide this advice?

33. Though I have no recollection of the event, if (as I suspect) the conversation took place the course of a meeting, others may have commented, particularly as regards the current state of scientific knowledge on which I would have based my advice.

f. Was this a formal request for advice on behalf of the NBA, or did

you provide this advice on an informal basis?

34. I have no recollection of being requested by the NBA to provide advice.

g. Were you remunerated for your work in providing this advice?

35. I was not remunerated for participating in or advising meetings of various committees in the Department of Health and across government.

The Inquiry understands that following the ethical advice you provided to Patricia Hewitt, the TMER study was submitted for ethical approval to the Lothian Local Ethical Research Committee. On this basis, patients would not be notified if they had received CJD implicated blood. (See NHBT0017405_001). The study received ethical approval and proceeded on this basis.

11. ***Were you made aware that your advice would form the ethical basis of the TMER study?***

36. I do not recall being aware of the TMER study. Had Dr Hewitt referred to a proposal to a Local Ethical Research Committee, I would have made it clear that it would be for the Committee to make its own mind up in the light of its own deliberations.

12. ***Were you provided with any updates about the ethical approval of this study on the basis of the advice you had provided?***

37. I do not recall receiving any notification or updates.

13. ***Have you ever been involved with the work of the Lothian Local Ethical***

Research Committee or any other ethical research committee? If so, in what capacity was your involvement?

38. I have never been involved with the work of Lothian Local Ethical Research Committee. I do not recall having been involved in the work of any research ethics committee.

Section 4: Product recalls and notification

Our research indicates that the ethical position approved by the Lothian Ethics Committee which was subsequently adopted in the TMER study (which was not to inform patients that they had received vCJD implicated blood transfusion) was also the approach adopted by the Department of Health, The UK Medical Control Agency, Blood Products Laboratory ("BPL") and the NBA by October 1997, in relation to product recalls and the notification of recipients. (Please see NHBT0001722 and NHBT0004591_003)

14. ***Were you aware of the ethical position these organisations had adopted in relation to not informing patients that they had received vCJD implicated blood/blood products?***

39. I do not recall being aware. As I said in paragraph 6, my involvement related to HIV/AIDS. I do not recall being involved in discussions or policy relating to vCJD.

15. ***Were you contacted by any individuals/organisations, including those mentioned above, in order to provide further ethical advice in relation to product recall of vCJD implicated blood/blood products? If so, please provide a summary of the ethical advice you provided.***

40. I do not recall being contacted by individuals or organisations to provide advice.

16. ***Were you made aware, and if so, did you agree to the extension of your ethical advice to scenarios outside of the TMER study including product recall and blood donation?***

41. As I say at paragraph 36, I do not recall being aware of what is referred to as the TMER study. It is not referred to in Dr Hewitt's letter concerning a look back study. The conversation referred to by Dr Hewitt concerned the ethics of this look back study rather than any broader questions of policy relating to vCJD.

Section 5: Blood donations and notification

The Inquiry understands that Patricia Hewitt from the NBA wrote to you again in April 1999. This was to ask you to reassess the ethical advice you provided previously in light of some new information. (See NHBT0017407). In relation to this, please answer the following questions:

17. ***What advice (if any) did you provide in response to Patricia Hewitt's response? In particular please set out:***

    a. ***The form you provided this advice in (and if written, please provide a copy of it to the Inquiry).***

    b. ***The basis for this advice? Please include whether your ethical position in relation to the notification of patients had changed from any initial advice you may have provided, and if so, why?***

42. I do not recall receiving Dr Hewitt's letter, nor do I recall responding to it. As far as I can recall I was not aware of SACTTI nor of its deliberations. At the relevant time (April/May, 1999) I was involved in chairing the Bristol Public Inquiry. Though I do not recall receiving the letter, I note that as a general practice, if I was not able to respond to requests for advice for whatever reason, I would suggest others who might be able to advise in my stead. I note that the final paragraph of Dr Hewitt's letter invited me to do so if I was unable to help.

18. ***Did you advise Patricia Hewitt on the ethical issues in relation to when a patient who had received vCJD implicated blood/blood products donated blood, and how this should be handled? If so, please detail this advice.***

43. I do not recall advising Dr Hewitt save in the context of what she refers to in her letter of April 15, 1999.

Section 6: General

19. ***Have you provided ethical advice in relation to vCJD on any other occasions? If so, please list when and in what circumstances this advice was provided, and which organisation/s instructed you to provide this advice.***

44. I do not recall having provided ethical advice relating to vCJD.

20. ***Is there any other information in relation to ethics and vCJD that you feel may be relevant to the Inquiry? If so, please provide this.***

45. I have read and endorse the careful analysis in the Report of the Medical Ethics Group.

21. ***In hindsight, do you consider that the advice you gave in the 90's on this issue was the right advice given the circumstances or has your view changed? Please set out your reasons.***

46. It would appear that I only gave advice in 1996. My views as set out in Dr Hewitt's account of our conversation at that time reflect my position at the time and are ethically justifiable, as is the view that any material change in the relevant facts would require re-consideration of how ethically to respond. Dr Hewitt's letter refers, as the first point which served as the basis for the advice, to "the lack of scientific evidence that vCJD is transmitted by blood transfusion". This is crucial. As I stated at paragraphs 17-20, should such evidence become available, recipients should be identified and notified, since at that point their futures would be wholly changed and they would be entitled to know that.

47. According to Dr Hewitt's letter, some of the facts relevant to policy decisions about vCJD had changed by 1999. A policy decision was taken not to allow recipients of blood from people who later developed vCJD to become blood donors themselves. This is important since, as Dr Hewitt mentions, it contemplates a scenario in which such recipients (or at least a number of them) would be informed that they had received blood from someone who later developed vCJD. Quite apart from the relevant ethical questions in 1996 (which may or may not be answered differently in 1999 given the change of facts) there was a fundamental shift in the analysis. It was no longer a question of *whether* recipients should be informed, but instead, given that they (or some of them) will be informed given the policy at the time, *how* should they be informed? The answer to that, of course, is as carefully and sensitively as possible.

48. Unfortunately, it would appear that I was unavailable to advise in

1999 after these important facts changed. Had I been able to, I would have applied the ethical principles I set out earlier to these new facts, and my advice would also have changed. I do not know if Dr Hewitt asked for advice from someone else and, if so, what that advice was.

Section 7: Other issues

Please include any other information which has not been specifically requested above, if it may assist the Inquiry and is relevant to the Terms of Reference.

49. As I have said, I disposed of papers relating to my membership of various organisations including government committees when the family home was sold in 2012. This has meant that in answering the questions posed I have had to rely on my memory of events.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed GRO-C

Dated 15 February 2022