Response to Lothian Health Board to a request from IBI dated 20th August 2020 for a response to criticisms made by Rachel Gordon-Smith about her father, Randolph Peter Gordon-Smith by Professor Christopher Ludlam.

1. I have been supplied with a partial (incomplete) copy of the letter from the IBI to Lothian Health Board dated 20th August 2020 to which are appended;

   a. First written statement of Rachel Gordon-Smith dated 5th April 2019
   b. First written statement of Justine Gordon-Smith dated 3rd April 2019
   c. Copies of the following appended to the statements
      i. Discharge summary 6th May 1995
      ii. Letter from Prof Hayes to Prof Ludlam dated 12th February 2003
      iii. Clinic letter from Dr Dennis 11 August 2004
      iv. Statement by Mr Gordon-Smith dated 21 February 1994
      v. Letters of 20th, 21st Sept and 4th October 2004 about vCJD
      vi. Request by letter from Dr Cuthbert of 6th Feb 1987 for immune tests
      vii. Letter from Dr Chapman about new hepatitis test and questionnaire
      viii. Letter from Dr Young of 28th July 1992 suggesting hepatitis B vaccine
      ix. Series of documents related to events 2017-2019

2. I was the consultant haematologist who oversaw Mr Gordon-Smith's care during the period from 1980 until 2011. I remember Mr Gordon-Smith and some of his clinical haemophilia difficulties. I believe Mr Gordon-Smith understood the need for his treatment. He took an interest in his condition, was inquisitive and as a result was well informed about his medical situation. I always considered that we had a good and open professional relationship. I was therefore surprised to read the criticisms set out in Rachel Gordon-Smith's statement.

3. Mr Gordon-Smith was born on GRO-C 1940 and died at the age of 78 years in 2018 with liver cancer.

4. Mr Gordon-Smith was diagnosed with moderate haemophilia A with a basal factor VIII level of 9% and thus many of his bleeds were only precipitated by trauma. Following surgery on his knee at some point in the 1990s, for which he received factor VIII therapy, he developed an anti-factor VIII antibody. This had the effect of reducing his basal factor VIII level to that of severe haemophilia with the result that he developed severe spontaneous bleeds.

5. In Rachel Gordon-Smith's witness statement (paragraph 12) she records that Mr Gordon-Smith was infected by hepatitis C genotype 3. This infection occurred as a result of treatment of his haemophilia with plasma products early in his life.

6. My recollection is that when Mr Gordon-Smith attended clinics he only ever came alone. I do not recall meeting his daughters when he was in hospital, or any other member of his family. It appears the criticisms in the statement are based either on what Mr Gordon-Smith may have told his daughters, or what they considered he would have thought. However, it is not entirely clear. No detail is provided about conversations between Mr Gordon-Smith and his daughters, or what the basis was for Mr Gordon-Smith's alleged beliefs.

7. In the letter from the IBI criticisms have been raised in numbered paragraphs by Rachel Gordon-Smith. I provide the following responses to these.

8. **Paragraph 8 of the letter states:-**

8.1 "*At paragraph 6 of her statement, witness W2633 states that her late father, who suffered from haemophilia, knew that if he attended the Royal Infirmary of Edinburgh (RIE) on a busy weekend in the 1970s and 1980s, there was a risk he could receive imported blood products, and consequently he avoided having treatment. Please comment on this.*"

8.2 Response:-

The statement makes the assertion that Mr Gordon-Smith knew if he attended the hospital on a busy weekend there was a risk he would receive imported blood products. It is unclear what is the basis of this perception. Mr Gordon-Smith's treatment will have been guided by his clinical situation at that time and would not have been influenced by the day in the week when he was treated. Mr Gordon-Smith was treated preferentially with NHS products. My recollection is that he only started to receive commercial products after he developed an antibody against factor VIII. As a result of the presence of this antibody he was treated with FEIBA in the 1990s. FEIBA is a commercial blood product for treating patients with inhibitors. At this time the FEIBA would have been safe from HCV (and HIV).

9. Paragraph 9 of the letter states:-

9.1 ***"At paragraph 8, witness W2633 states that it was clear to her father that people at RIE had lied to him about the blood products he received. She states that her father would mention his concerns about the safety of blood products to Professor Ludlam and RIE staff, and they would tell him not to worry as they only used local product (paragraph 10); that her father was not told of the risks of local products, only that they were not imported (paragraph 20); and that he believed the RIE staff may have used cheap imported product (paragraph 14). Please comment on this."***

9.2 Response:-

My recollection of Mr Gordon-Smith was that he took a great deal of interest in his treatment and this is supported by the witness stating 'Dad would always ask lots of questions about products which became available.' It is true as stated in the statement that we would preferentially use 'local product.' He will have been told about hepatitis, and in particular non-A non-B hepatitis. Evidence for this is given in his statement dated 21st February 1994 (WITN2632002) in which he states (page 2) 'I was even issued with a letter, which I still have somewhere on file, to carry around if I left Edinburgh, which invited doctors anywhere in the UK to seek urgent factor VIII supplies from the Edinburgh Centre for me in preference to giving me the products made anywhere else.' This refers to a short, written statement which I gave to all patients in 1980/81 to try and ensure that they would not be treated with commercial products. I explained to all patients when I gave them the statement about the risk of viral infections, and in particular hepatitis viruses, and that I was keen, if possible, for them not to be exposed to commercial blood products.

9.3 In his statement of 21st February 1994 he refers to having a Haemophilia Society booklet on Hepatitis. This may have been the Haemophilia Society booklet which was issued in April 1993 (WITN6932027) which provides a good summary of what was known at this time.

9.4 In addition all relevant patients were given a copy of our locally produced Hepatitis Information sheet (WITN6932028).

9.5 In the mid-1990s Mr Gordon-Smith was reviewed by Prof Hayes and underwent endoscopy and laparoscopic inspection of his liver. He was subsequently started on a

course of interferon therapy (as evidenced in the discharge summary of 6th May 1995). The witness states that 'He was not told of the risks of the local products' (para 20) and that he did not give his consent to treatment. The witness does not provide any evidence for these assertions and in particular was not present at her father's attendances for treatment. Para 14 of the statement states 'He had suspicions that the doctors at RIE had tried to use a product on the cheap or something.' It is not clear what this refers to as no evidence is provided. The choice of treatment was always made on clinical criteria, not cost.

10. Paragraph 10 of the letter states:-

10.1 ***"At paragraph 16, witness W2633 states that her family's concern was that RIE staff may have known that the blood products her father received carried a risk of infection and yet chose to administer them, whereas they should have used an alternative. Please comment on this."***

10.2 Response:-

Mr Gordon-Smith was treated with plasma products on occasions as a child and he will have become infected with hepatitis C at this time. Until the mid-1980s no blood product was safe from hepatitis C although later it became known that the there were higher levels of hepatitis C infection in commercial products than ones manufactured by the NHS. In the first half of his life he had a number of severe bleeds and DDAVP would not have been available or appropriate, and prior to the mid-1980s there was no blood product treatment known to be free from hepatitis. He knew of the risks of hepatitis as set out in the response to para 9 above.

11. Paragraph 11 of the letter states:-

11.1 ***"At paragraph 12, witness W2633 states after he was diagnosed with hepatitis C in late 1993/early 1994, her father wrote to RIE to attempt to identify the occasions on which he may have been infected with hepatitis C, but did not receive a response. Witness W2633 goes on to state that she believes her father could have been informed about his hepatitis C diagnosis sooner than he was (paragraphs 16-17), and that her father was not told about his diagnosis earlier***

***so staff could see how the hepatitis would develop (paragraph 21). Please comment on this.*"**

11.2 Response:-

The statement indicates that 'Dad wrote a letter in February 1994 to the hospital', however this letter has not been provided. Justine Gordon-Smith's statement is accompanied by a statement dated 21st February 1994 (WITN2632002) and apparently written by her father, but it is not clear that this was sent to the hospital. Although this statement in the 'Notes' (page 2 of his statement of 21st February 1994 (WITN2632002)) indicates that he 'had never heard of Hepatitis C, nor even by the name 'non A non B'' this does not accord with what he will have been told at clinics. When the statement (referred to in response to paragraph 9 above) was given in 1980/81 to all patients it would have been explained about the risks of viral infections and in particular hepatitis, as the purpose of trying prevent exposure to commercial concentrates was to reduce the risk of viral infections.

11.3 Although in his statement of 21st February 1994 he sets out his recollection of treatment in August 1979 for a 'serious forearm bleed and some haemarthrosis of r. elbow. HAEMOPHILIA TREATMENT Cryoprecipitate factor VIII relatively impure in Ward 23 R.I.E.' and several further episodes subsequently it is likely that he was infected with hepatitis C prior to 1979 as he had received previously treatment with NHS blood products.

12. Paragraph 12 of the letter states;

12.1 ***"At paragraph 15, witness W2633 states that the information her father was given about his hepatitis C diagnosis was inadequate. She states he was not told of the risk of cancer or deteriorating health, and was not given enough information about the risk of infecting others. Please comment on this."***

12.2 Response:-

Although Ms Gordon-Smith states that 'The information he was given was not adequate' and that he 'was not given enough information about the risk of infecting others' and she indicated that 'He and I didn't really talk about that kind of thing', it is

difficult to understand the basis for these assertions. As indicated above (Paragraph 9 above) Mr Gordon-Smith, at least from 1980, knew about hepatitis.

13. Paragraph 13 of the letter states;

13.1 *"At paragraphs 19-20, witness W2633 states that her father was tested for hepatitis C and other viruses without his knowledge or consent. Please comment on this."*

13.2 Response:-

As indicated previously, my recollection is the witness did not attend the clinics with her father. It is therefore not clear what the basis for this allegation is. At routine clinic visits patients were offered a series of blood tests to monitor their haemophilia, its consequences and its treatment. In the 1980s this would have included viruses known to be transmitted by blood products such as hepatitis B. The benefit of doing so is illustrated in Justine Gordon-Smith's statement (paragraph 21) where she relates that he was offered hepatitis B vaccine because he was found not to be immune and therefore susceptible to this virus (letter from Dr Young to Mr Gordon-Smith of 28th July 1992 (WITN2632008)). Mr Gordon-Smith knew about having hepatitis (non-A non-B hepatitis) as it was our routine practise to tell patients about the routine blood tests we undertook at clinics and to explain the results to them. When a new, and specific test for non-A non-B hepatitis became available we arranged for patients to be tested. We told patients that a new test was becoming available (letter from Dr Chapman to Mr Gordon-Smith dated 20th February 1990, appended to Justine Gordon-Smith's statement (WITN2632006)) and we arranged for the test to be carried out. We were testing for existing and known non-A non-B hepatitis by a new specific test. It is likely that he was tested for anti-HTLVIII, probably from stored blood sample in late 1984 or early 1985 before any recommendations about 'prior counselling' were proposed.

14. Paragraph 14 of the letter states:-

14.1 *"At paragraph 11, witness W2633 states that after haemophilia inpatient care was moved from the RIE to the Western General Hospital, haemophilia patients were treated alongside leukaemia and other blood disorder patients. The*

haemophilia patients complained because of the emotional impact of being treated alongside terminally ill patients. Please comment on this."

14.2 Response:-

Ms Gordon-Smith criticises the arrangements for the inpatient care of patients at the Western General Hospital. In-patient care had previously been provided beside the Haemophilia Centre in Ward 23 of the Royal Infirmary. The Health Board, against my very clear advice, decided to move the care of in-patients to the Western General Hospital; it subsequently became clear that this was an unsuitable arrangement, and the Health Board was forced to reverse its decision.

14.3 The specific criticism of having to share a ward with leukaemic patients has a degree of validity. It was inappropriate to have out-patient acute treatment, review clinics, centre staff and the specialist laboratory at the RIE, and the in-patients (with serious bleeds) at a remote site away from the specialist expertise and laboratory facilities.

15. Paragraphs 15 and 16 of the letter:-

15.1 The events referred to relate to episodes some 6 years after I retired from the NHS.

Statement of Truth

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

Signed GRO-C

Dated 10 February 2022