Witness Name: Professor Hugh Tunstall-Pedoe

Statement No.: WITN0700001

Dated: 17th July 2019

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF HUGH TUNSTALL-PEDOE

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 7 May 2019.

I, Hugh Tunstall-Pedoe, will say as follows: -

Section 1. Introduction

1. My name is Professor Hugh Tunstall-Pedoe MA, MD, FRCP, FRCPE, FFPH, FESC and my date of birth is GRO-C 1939. In my late 70's I am largely retired, although still researching, attached to the University of Dundee. I have spent much of my career in epidemiological research, the study of prevention and risk in heart disease, as well as in teaching epidemiology and latterly medical ethics. I intend to comment on my lifetime experience of working in the medical profession, and as a blood donor. In particular, my early limited experience of treating haemophiliac patients, the problems caused by advances in treatment, and the ethical and societal issues of responsibility when things go wrong, both on an individual basis, and through systematic errors affecting whole groups of patients, and who tells what to whom.

2. I trained as a doctor at Cambridge University and Guy's Hospital London, qualified in 1964 and occupied junior posts in several London teaching hospitals with an interest in cardiology and general medicine. I started epidemiological research in 1969 and obtained a senior lectureship in epidemiology and an honorary consultancy at St Mary's Hospital Medical School in 1974 working on

a study of prevention of coronary heart disease. I was appointed professor and director of a new research unit for studying the scale, causes and prevention of heart disease in Scotland at Dundee University in 1981, continuing this work through my so-called retirement in 2005 until the present day. I worked with medical inpatients before coming to Scotland, and with cardiac outpatients throughout my career. My specialist qualifications were in epidemiology and cardiology.

3. Apart from my MA and MD, I am a Fellow of the Royal Colleges of Physicians of London and of Edinburgh, a Fellow of the Faculty of Public Health, and a Foundation Fellow of the European Society of Cardiology. I chaired the Dundee Cardiopulmonary Resuscitation Committee for many years and was a founding member of the European Resuscitation Council and a member of the United Kingdom Resuscitation Council. I developed two widely used cardiovascular risk scores in 1991 and 2007, and participated in a third, beside making contributions to aviation cardiology. I sat on a research medical ethics committee for 8 years in the 1990s, and coordinated medical ethics teaching for medical students for some years in Dundee around the time of my retirement.

4. Much of my research from 1969 was collaborative through the World Health Organization. I have many scores of medical publications listed on PUBMED CENTRAL, mainly scientific papers, but have also authored chapters of books and books (see appendix for a sample). I have had some humorous articles published in the *BMJ* and *Lancet* along with many serious ones. I was 'Rapporteur' to the World Health Organization MONICA Project (Multinational MONItoring of Trends and Determinants in CArdiovacular Disease) from 1980 until 2003. I was primarily responsible for writing the protocol and was lead author of some of the major publications in the *Lancet* and *Circulation*, and wrote half, and also edited the final monograph. The study involved 38 populations in 21 countries. I have been on several steering committees of international studies and remain so. In the early 2000s I was a member of the subcommittee on cardiovascular disease of the Committee on Medical Aspects of Air Pollution in London where an argument, relevant here, prompted my resignation (see later).

5. I have not given evidence or been involved in any other inquiries, investigations, criminal or civil litigation in relation to HIV/HCV infections in blood and blood products, nor do I have any commercial, financial, or other interest in any of the products or issues under discussion in this Inquiry. Nor was I directly or indirectly

involved in who said what to whom when the blood contamination and subsequent morbidity and mortality were recognised.

6. The options for anonymity and redactions have been explained to me. I have elected not to be anonymous.

7. The dates throughout my statement should be treated as approximate to the best of my knowledge and are often based on deductions from other life events.

Section 2. My Experience Within the Medical Profession of Blood Transfusion as a Treatment

8. My experience of blood transfusion as a student and junior doctor was limited and I was not usually the person who ordered it. In the 1960s medical inpatients were tested for syphilis without their knowledge, and I assume that all blood donors would have been also (the idea of informed consent and counselling for these things came later). There was a horror story about using someone with latent malaria as a donor (with a fatal result). The main concerns then were what was then called serum hepatitis (hepatitis B virus) and incompatible blood transfusion through failure of blood grouping or clerical error. Hepatitis C (HCV) and Human Immunodeficiency Virus (HIV) were only recognised many years later.

9. Blood transfusion was considered, rather uncritically, a good thing when I was a medical student. When doing obstetrics two patients for hysterectomy were cross-matched with blood before surgery and I was sent up from the operating theatre to the ward to start a post-operative transfusion on one. I set it up on the wrong patient (but with their blood) and the surgical opinion was that it was a good thing anyway, no harm done. The decision - whether or not to transfuse - had been borderline in both cases and I guess it would not have been done now. I did not have direct experience of major trauma at that time, but some medical patients were brought in for routine 'topping up' (see later).

10. My first house-job on qualifying was a three-week locum on a world- famous cardio-thoracic surgery unit. One post-operative patient had acute bleeding from a peptic ulcer in the middle of the night and I transfused him with multiple pints of blood through drips going into both legs before he could be operated on for it (successfully in the short-term) in daylight. In this process I emptied the hospital blood bank of all the blood of his group (mostly not cross-matched for him). I

was congratulated for my vigorous action, although it meant a scheduled cardio-pulmonary bypass operation on someone else had to be postponed.

11. In 1968-69 I was registrar on a medical firm that did general medicine and cardiology, but one physician in a rotation was a haematologist. Patients were admitted for blood transfusion; the decision having been made already. They tended to be people with leukaemia. The transfusion would have been authorized by somebody more senior than myself. I did not see haemophiliacs then.

12. At that time (paragraphs 9,10,11) I do not think that the long-term consequences of transfusion came into consideration for obstetricians, cardio-thoracic surgeons, and haematologists treating leukaemia. For them it was the short-term that was dominant. You have to be alive to suffer delayed consequences, as happens now to people surviving acute complications of long-term disease.

13. Worries about the long-term (apart from serum hepatitis) came after I had stopped working with hospital medical inpatients.

14. In 1969 I joined the MRC Social Medicine Unit in London to do an epidemiological survey of heart disease. The excitement soon after (1970) was over a book by Richard Titmuss, 'The Gift Relationship', which claimed that unpaid blood donors in Britain were virtuous, healthy, public-spirited people, not usually carrying disease, and that was the opposite of the USA where paid donors were often destitute, criminals, or drug addicts and at high risk of transmissible disease such as serum hepatitis (hepatitis B virus).

15. People who are carriers of serum hepatitis (hepatitis B virus) were a problem not only for blood donors, but became a subject of discussion later concerning doctors, other health workers, and the recruitment of medical students in medical school. The proportion of carriers varies with the country of origin of those concerned, quite apart from any subsequent lifestyle practices. A similar problem arose with being HIV positive as a potential threat to patients under care.

Section 3. Experience of Treating Haemophiliac Patients

16. As a medical student and junior doctor at Guy's Hospital from 1961 to 1967 I was on general medical firms which admitted a small number of haemophiliac patients who were having bleeding crises.

17. They had recurrent crises and were well known to the staff as chronic recurrent patients. The few I came across were illiterate having been unable to attend school regularly because of their vulnerability. They were disabled, having been crippled by bleeds into joints which left them with contractures – bent, seized-up joints. Life expectancy was limited and life frequently very painful. So untreated or poorly treated haemophilia was an appalling lifelong situation to be in, revolutionised later by the treatment that, however, introduced new threats.

18. In 1965 I admitted such a patient in crisis as a house-physician and administered the then recommended treatment – two pints of fresh-frozen plasma (it was before the days of concentrated factors). The curmudgeonly old consultant (general) physician came around on his ward round and asked me what I was doing. When I told him, he said 'Stop it at once, you will kill him!' He had been brought up in the days when blood transfusion (which saved thousands of lives in maternity and in World War II) was more dangerous. We all knew he was wrong! The nursing sister pulled the curtains round and made as if to put the patient on a bed-pan, making sure he got the rest of his second pint before the drip was taken down.

19. Concentrated Factor VIII arrived after I stopped inpatient medical work by which time haemophiliacs would have been treated by haematology consultants and not general physicians. I do not know the exact dates. It meant pooling material from many different donors, multiplying the cross-infection risk many times compared with a single blood transfusion. It transformed haemophilia from being such a crippling and painful condition, but at a cost that became apparent later.

Section 4. Experience of Giving Blood

20. Nobody knew about Hepatitis-C or HIV when I first gave blood, the worries were syphilis which was tested for, and serum hepatitis (now known as Hepatitis B). In 1958 I gave blood as a student in Cambridge but I have no memory of what questions I was asked. In 1964 as an exchange student in Chicago I volunteered to donate a pint of blood for one of my patients who needed to find twelve donors to have major surgery. I was refused because on routine questioning I admitted to having recently been in contact with a patient with jaundice. I got the impression that blood donation from doctors exposed to many sick patients was rather discouraged, and did not give blood again for some years. Although I joined an emergency panel of donors at St Mary's 1974 – 1981 I was never called

on. Dundee Ninewells Hospital where I worked next had a blood donor centre and I gave blood as frequently as I was allowed to from 1981 to recently, although interrupted by visits to possible malarious areas, when I was laid off.

21. In my lifelong blood donor career, I succeeded in donating some 90 pints. Immediately after the '9-11' Twin-Towers atrocity in New York, I felt moved to go and give blood in Ninewells Hospital Dundee where I worked, but I knew, paradoxically, that I would have been refused in the USA. All British potential donors were thought to be dangerous elsewhere, because they were potentially transmitting BSE outside Britain, leading to variant CJD, a major scare at the time, subsequently thought to be exaggerated.

22. HIV arrived on the scene in the 1980s and Hepatitis-C some time later. As a blood donor I was subjected to more and more questions on the form I completed before giving blood each time. There were questions about injecting drugs, having sex with someone of the same sex, visiting certain countries within the last n years (malaria), visiting foreign countries for sex, and having sex at all when visiting Africa. I remember pointing out that some of us went on safari in Africa with our spouses in a monogamous relationship and would answer 'yes' to the last question. I recently read that a history of brucellosis (undulant fever) was a lifelong contraindication to being a blood donor. I remembered an outbreak in my boarding school in the country from infected milk when I was very young, and being ill with it, in the 1940s, but I was never asked about it, and subsequently gave blood over nearly sixty years.

23. Before I eventually stopped giving blood (I was refused because of my aging blood count) it was rumoured that the authorities were going easier on gay (homosexual) people giving blood, the latter had complained of discrimination. By then there were tests for HIV, although they were not positive if recently acquired. I got the impression that the nurses and technicians in the donor area seemed to be worried by particular younger donors, who they thought had a flippant attitude, were sometimes giving blood for a bet, and potentially dishonest in the way they answered their questionnaire. I had no idea whether these worries were justified, but the staff obviously felt happier with mature regular donors. The service needed to recruit young donors to replace the older ones. It was difficult to quantify how much the disapproval of the older generation of young people's sometimes disorganized, chaotic, and experimental lifestyles went with actual increased risk.

Section 5: Other Issues

24. When the scandal broke I was amazed that, given the Titmuss' book of 1970 that the NHS had gone to the USA for supply of blood products, rather than sourcing them within the British blood transfusion service.

25. If I was conducting the Inquiry I would like to know the following:

    a. Who made the decision to get blood products from the USA? What advice were they given at that time by specialists in Britain – were there dubious commercial claims or any funny business? Why was the Titmuss book ignored? Why were blood products not developed for the NHS using British blood donations?
    b. Was the British experience the same, better, or worse than in other countries? Did any country avoid infusing contaminated blood products? Are there any exemplary models?
    c. Was the reaction time to the discovery that blood products were contaminated similar or different to elsewhere? Was systematic testing unduly delayed? Was there a cover-up and who was responsible?
    d. Those affected are asking for compensation. What about the American suppliers of these products? Is there any liability there? Have they been sued?
    e. What was the risk to those treated? Publicity has been given to those who became ill or died but what was that in relation to the number treated?

26. I would also like to raise some more general ethical and philosophical points:

    a. Given that medical technology has the ability to keep more and more people alive and well in the face of previously disabling or fatal conditions, an increasing proportion of deaths or serious illnesses will be caused by failures of one sort or another that will be blamed on the NHS with compensation lawyers involved. Popular coverage assumes 100% responsibility on the NHS and none on the hazardous underlying condition. Is that view sustainable in the long-term? One can even imagine a dystopian world where all deaths can be blamed on medical failures, although there must be a distinction between known hazards and unknown ones.
    b. A historical perspective: In 1964, when I qualified, I could obtain *lifetime* malpractice insurance from the Medical Defence Union for 50 guineas. I knew that it was a bargain – it would have been the best investment I ever

made - but I did not have fifty guineas. Some years later I read a discussion on medical litigation in which an opinion was expressed that, because NHS patients had free treatment, they were not under contract with the NHS doctors treating them, and therefore had no right to claim financial compensation if things went wrong! Times have changed. Medical compensation is now a major area of litigation, and costs the NHS a substantial percentage of its funding. For doctors the threat of malpractice claims can be a determinant of their chosen speciality, obstetrics being a particular example.

c. An American vice-president was ridiculed for classifying potential information as known-known, known-unknown, unknown-known and unknown-unknown, but this was reasonable nonetheless. HIV and hepatitis-c were unknown for years but the risk of transmitting an unknown factor by pooled concentrates might have been anticipated: known-unknown.

d. Media coverage has included hard-luck stories from women who became ill after blood transfusion of one or two pints in obstetric cases in Britain. These would have been of blood from individual British volunteer donors – a completely different situation from using imported pooled concentrate from the USA. These women were indeed very unfortunate, but were at very much lower risk, when they were transfused, given the routines then involved in Britain to screen, and reject potential donors.

e. **Who tells what to whom**. When I was a medical student the approach to what you told patients was paternalistic, imparting the minimum, withholding bad news, using euphemisms, and fostering optimism. Patients had blood tests for syphilis without any explanation. The word 'cancer' was interpreted as a death sentence: patients were told they had an ulcer. There was a great deal of wriggle room short of outright dishonesty, although this undoubtedly occurred. The culture has changed: partly because doctors, for the most part, are no longer as patronising and arrogant; the public is far more knowledgeable and has multiple other sources of information; patients no longer simply have things done to them uncomprehendingly - they need to understand and collaborate with their treatment; and they are now looked after by different medical teams who need a consistent story - the truth is easier to sustain than conflicting fairy-stories, easily rumbled.

f. When the HIV/AIDS story broke in the 1980s it was easily transmissible but almost untreatable and the diagnosis a likely sentence of early death. Department of Health lawyers insisted that nobody should be tested for it

without prior written informed consent and proper counselling. This exercised me with my former experiences, and my concerns of its spread, as a public health problem. The above stipulation turned out to be rather impractical, and testing became routine in obstetrics, and in blood transfusion, where, although I was told I would be tested, I was not counselled of the consequences of a positive test. Reports of who gets tested over the recent decades suggested that, on the one hand written informed consent and counselling are not practised in many cases where tests are done, but conversely that many who ought to be tested are not, possibly because informed consent and counselling would be too tedious and inhibiting for the doctor involved. (A case history used in medical ethics teaching some years ago featured a demented patient who, a judge had ruled, could not be tested for AIDS because he could not give informed consent). This situation is now much less dramatic, as HIV/AIDS is treatable, is better treated early, and no longer a death sentence, or as much of a stigma as it was, so testing is less threatening than formerly, although the public health and ethical problems remain.

g. **Safe or unsafe?** Infected blood is part of the story about risk and how it is seen and handled. Statements for public consumption (for example about vaccination) state that it is safe, the alternative being unsafe - the unknown and in-between rarely figures. Most things are considered safe until the opposite is proven. The degree of proof demanded is often related to the vested interests of those involved. My assessment on the evidence of air pollution causing heart disease in the early 2000s was that it was very suggestive but inadequate to be conclusive until more work was done. The Secretary of the Committee, a civil servant, said the Treasury wanted a categorical statement that I/ we believed it was definitely causal, and would not do anything otherwise. I told him that as a scientist, for me it was the burden of evidence, and not belief, but if evidence was suggestive that something was harmful we should adopt the precautionary principle. I was strongly pressurized and resigned, telling some other members what had happened. But the covering letter to the report many months later quoted the precautionary principle, so I felt vindicated. Since then further evidence of causation has accrued.

h. Had the lack of evidence on safety been taken seriously; along with the memories of the Titmuss book from 1970s; also the idea of 'known unknown'; and the precautionary principle..... I suspect Factor VIII concentrate would

not have been sourced from the USA. I hope those involved from the other side of the Atlantic will give evidence to this inquiry. One wonders whether there were independent quality control checks on the suppliers' safety and product testing, or whether their claims were accepted uncritically. The infected blood story is featured as a British national NHS scandal, but the problem must have been international and what happened elsewhere is relevant.

Statement of Truth

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

Signed GRO-C

Dated 17th July 2019.

Appendix : **Hugh TUNSTALL-PEDOE Publications (extracted sample)**

url https://www.ncbi.nlm.nih.gov/pubmed/term=Tunstall-Pedoe+H

215 results from above but excludes others under Pedoe HDT and Pedoe H and contributions to books and unattributed anonymous editorials

1. Twenty-year predictors of peripheral arterial disease compared with coronary heart disease in the Scottish Heart Health Extended Cohort (SHHEC). *J Am Heart Assoc* 2017 Sep 18 doi:10.1161/JAHA 117 005967 (multi-author study, lead author)

2. Prime mover or fellow traveller: 25 hydroxyvitamin D's seasonal variation, cardiovascular disease and death in the Scottish Heart Health Extended Cohort (SHHEC). *Int J Epidemiol* 2015 : 44(5)285: 1602-12 (multi-author study, lead author)

3. Starting statins for primary prevention of cardiovascular disease. *Heart* 2013 Nov, 99(21): 1547-8. (invited editorial).

4. The decline in coronary heart disease: did it fall or was it pushed? *BMJ* 2012 Jan 25:344 d7809. (invited editorial).

5. Adding social deprivation and family history to cardiovascular risk assessment: the ASSIGN score from the Scottish Heart Health Extended Cohort (SHHEC). *Heart* 2007 Feb, 93(2): 172-6. (first-authored by my statistical collaborator).

6. *MONICA Monograph and Multimedia Sourcebook: World's largest study of heart disease, stroke, risk factors and population trends 1979-2002.* (ed). Geneva, Switzerland: World Health Organisation; 2003 ISBN 92 4 15623 4 (69 contributors, HTP editor, designer and coordinator).

7. What was preventing coronary heart disease prevention and why its time is now come. Chapter one in *Effective Secondary Prevention and Cardiac Rehabilitation*. Aesculapius Medical Press 2002. ISBN-10: 1903044227. (proceedings of conference).

7. Do not resuscitate decisions. Resuscitation should not be part of every death. *BMJ* 2001 Jan 13:322 (7278): 102-3. (letter)

8. Estimation of contribution of changes in coronary care to improving survival, event rates and coronary heart disease mortality across the WHO MONICA Project populations. *Lancet* 2000 Feb 26:355 (9205) 675-87. (lead author of collaborative report)