Witness Name: Cunningham, Paul
Statement No.: WITN3531001
Exhibits: WITN3531002 - 007
Dated:

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PAUL CUNNINGHAM

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 13 August 2019.

I, Paul Cunningham, will say as follows: -

Section 1. Introduction

1. My name is Paul Cunningham. My date of birth is GRO-C 1968 and my address is known to the Inquiry. I am a journalist and author, and am currently Political Correspondent for RTÉ. Previously, I was editor of a weekly television political programme, 'The Week In Politics' (2015 - 2018); Europe Correspondent, based in Brussels (2011 - 2014); and Environment Correspondent (2001 - 2010).

2. I intend to speak about my experience of reporting on Irish people with haemophilia, and their infection with HIV and/or Hepatitis C through contaminated blood products.

3. I did the majority of this reporting between 1997 and 2003. I reported on the Lindsay Tribunal (hereafter, the Tribunal). I was named 'ESB National Radio Journalist of the Year' in 2001 for that coverage. This is an annual media award given in Ireland.

4. I was the reporter on the documentary entitled 'Bad Blood', which has been viewed by the investigators. The documentary explores the practices of US-based pharmaceutical companies that exported blood products to Ireland in the 1980s. The programme was an independent production by Andec Productions for RTÉ. It won an Irish Film and Television Award in 2002 in the News and Current Affairs category.

5. I also co-wrote a book with Rosemary Daly on the impact of contaminated blood products called 'A Case of Bad Blood' published by Poolbeg Press in 2003. Rosemary was the Administrator of the Irish Haemophilia Society.

6. It has been approximately fifteen years since the making of the film and the writing of the book. I no longer have complete notes and documentary records of my work. The information contained in this statement is the most accurate information that I can provide.

7. The exhibits to this statement are précised in a table that follows this statement. This table was created by the investigators using documents that I gave them when we met in Dublin.

Section 2. Reporting on infected blood

8. I began reporting on people with haemophilia who received infected blood products in about 1997. At the time, I was a journalist at RTÉ.

9. There was a demand by Irish people with haemophilia to be given a voice, as they had withdrawn from the 1997 Finlay Inquiry which

focussed on the infection of women with Hepatitis C following injections with Anti-D.

10. When the Lindsay Tribunal was set up in 1999, I became RTÉ's reporter on the tribunal and related issues. I held this position until the Tribunal's final report in 2002. I attended every day of the Tribunal.

11. I became very interested in cross-referencing the evidence given to the Tribunal with evidence from outside it.

12. As the Tribunal went on, I noticed that many international witnesses testified, especially from the US, but only about the global state of knowledge pertaining to HIV and hepatitis C. There was not, however, much investigation into the practices of the US pharmaceutical companies because the Tribunal deemed this to be outside of its terms of reference.

13. The Tribunal chose not to delve into the conduct of American pharmaceutical companies. The journalist in me felt that this was a fundamental piece of the puzzle that was not being addressed. From an ethical point of view, it was not problematic for us to investigate issues that the Tribunal had elected not to explore.

Section 3: The making of 'Bad Blood'

14. Noel Curran, who previously worked at RTÉ Current Affairs but was an Executive Producer with the independent TV company Andec Productions, approached me with the idea to make a documentary that covered the origins of contaminated blood products in Ireland by investigating the US pharmaceutical world. We saw the film as plugging a gap that the Tribunal was likely to leave.

15. Noel also approached Fiona Gough who had worked on the BBC Radio 4's 'Face the Facts', Granada Television's 'World in Action' and RTÉ's prime time programmes . It was the three of us who made 'Bad Blood'.

16. We began the reporting process by interviewing people in Ireland who were infected through or affected by contaminated blood. We made contact with a range of people. It was important for us to interview a cross-section of people from different age groups and regions of Ireland.

17. One of the most important aspects of our work was investigating the plasma collection processes of US-based pharmaceutical companies as this was where most coagulation products came from. We wanted to dig deeper into plasma collection, as well as what staff members knew about the infectivity rates of the blood that they were collecting and selling. We also wanted to look into what was or was not done when plasma companies became aware of product that was infected.

18. After some investigation, we decided to visit three locations in the US: Angola Prison in Louisiana, Los Angeles' Skid Row, and San Francisco. We chose these locations because each of them represented a different facet of the involvement of US pharmaceutical companies in the contaminated blood scandal.

19. We chose Angola because of its reputation of housing a "blood factory" prison. Skid Row was chosen because of the many accounts of people with drug dependency donating blood and plasma. We chose San Francisco because it was alleged that gay men were targeted as blood donors because many of them carried the Hepatitis B antigen (HBAg).

20. Probably unsurprisingly, none of the pharmaceutical companies were amenable to participating in the film despite numerous requests from us.

The American system of paid donors

21. During our research in the US, we were told repeatedly that blood banks had a huge commercial incentive to bleed as many people, as many times as possible.

22. We collected many adverts publicised by blood banks encouraging donations. While I no longer have copies of these adverts, some of them featured in the film. The investigators have taken two stills from the film that show these adverts. See Exhibit **WITN3531002**.

23. Particularly notable is the first of the two adverts. It is a notice stuck up on a wall dated August 1975 stating that "$10 will be paid on the 2nd donation of the week". I no longer have a copy of this advert that we sourced from World in Action.

24. The US blood donation system in place at the time was one of mass donations incentivised by small payments for each donation. The most regular donors were often people desperate for small amounts of money. These people included people with drug dependency problems and homeless people.

25. 'Bad Blood' documents a 1975 statement by Dr Jack O'Riordan, Director of the Irish Blood Transfusion Service (hereafter, the 'Irish BTS') at the time. He noted "there are dangers inherent in the type of person who comes forward as a donor". He mentioned that "drug addicts come forward and these people in some cases have passed certain diseases from one to another... such as hepatitis (a form of jaundice), and obviously these wouldn't be suited to a blood transfusion service's needs".

26. Despite these concerns, the Irish BTS began importing and distributing US blood products, made in part using paid donors. Our investigations at the time of the film revealed that this was because there were insufficient donors and funds available to make local blood product manufacturing a viable option.

27. Notwithstanding this, people with haemophilia, some of whom I interviewed for the film, were told by clinicians in the US that the plasma used to make the blood products was donated by "medical students and civic minded people".

Donations from intravenous drug users

28. We interviewed for the film many individuals who understood the blood donor system that operated in the 1980s on Skid Row, Los Angeles. Many of those interviewed still lived on Skid Row when we interviewed them.

29. One of the people we interviewed for the film told us that "the people I'd shoot dope with; they'd all already be high when they were donating plasma". She recalls that the donors knew that the blood bank staff could see "the fresh needle marks but they were getting what they wanted. They wanted the blood".

30. She continued: "almost all the people I shot dope with have either died from AIDS or are dying from AIDS. I'm not surprised at all that blood donations turned out to be positive because of the people I knew and know are dying from AIDS".

31. Another former donor we interviewed knows now that she is HIV positive. She said on camera that prior to being diagnosed, she would "donate, rest, get up, go buy me a fix".

32. She told us that she would "shoot up in the same spot they took the plasma from so there were no marks. Or I'd do it in my neck and wear collars to hide the marks. If they knew that you used drugs, they would refuse the plasma".

33. That said, she told us that it was up to the donor to answer the pre-donation questionnaire. She said that donors would regularly conceal their habits and that "they didn't ask questions one on one - it was always on paper". The implication is that it was easier to omit or obfuscate information or to lie when questions were answered in written form.

Blood donations from prisoners bled in prison

34. As I mentioned, an important aspect of the film was investigating the prisons from which donations were obtained. We interviewed former inmates of US prisons. Some of these inmates agreed to be interviewed on camera and many of these interviews feature in the film.

35. We interviewed some former inmates of Angola Prison about the plasma plant that was set up on the prison's premises.

36. The plant was FDA approved and had safeguards in place regarding donations.

37. One former inmate at Angola told us that despite the rules in place at the plasma plant, "there were ways around them".

38. He told us that inmates with hepatitis frequently sold blood, as did intravenous drug users. In his words, "You didn't have to hide it [if you were an IV drug user]. Nobody cared... You wanna sell it? You got it? We'll buy it. Bottom line".

39. The former-inmate told us that "a lot of time, there were people working in the plasma unit who were drug abusers, giving plasma".

40. Procedures were often not adhered to. For example, plasma collected from one person may be deliberately recorded as coming from a different individual.

41. When asked about HIV and AIDS, the former-inmate interviewed on film told us that drug users and homosexual donors "continued to give it [blood donations]" after the HIV outbreak was publicised. This was echoed by other former-inmates.

42. Through our work on prison plasma centres, we came into contact with people who provided us with documentation related to this area of investigation.

43. I remember a document from 1982 that stated that plasma from prisons had no higher level of Hepatitis infectivity than blood of other origins. I am no longer in possession of this document.

Targeting of gay men as blood donors

44. As I said previously, one of the issues that we investigated was the deliberate encouragement of gay men to donate blood and/or plasma by US pharmaceutical companies.

45. Charles Kozak, an American lawyer we interviewed for the film, told us that "homosexuals had built up a resistance to Hepatitis because of their sexual practices". The "drug companies" therefore recruited gay men as donors as Hepatitis B antibodies in their blood was desirable.

46. We contacted Donald Francis, a former employee of the Centers for Disease Control and Prevention of the United States (hereafter, the

'CDC'), the leading national public health institute. In this capacity, he advised pharmaceutical companies and tracked the development of diseases.

47. We met with Mr Francis in 2001. We had in our possession at this meeting, a deposition of his that he had made prior to our meeting (Exhibit **WITN3531003**). As I understand it, the deposition was a supplemental expert report that is now a public court document in America.

48. The handwritten annotations on the copy attached to this statement are my notes and comments. The video testimony that we took of Mr Francis for the film closely mirrors the deposition.

49. He explained that "since 1996", he learned that Cutter, Baxter and Alpha "collected plasma from urban homosexual men for Hepatitis B immunoglobulin (HBIG) production; used that same plasma in the manufacture of Factor VIII and IX concentrates prescribed for hemophilia; and continued to market this dangerous product after it was well-established that the source plasma presented the worst possible risk of AIDS to haemophiliacs".

50. I saw this process as a perfect design for infecting haemophiliacs with HIV.

51. In Donald Francis's words, "the same conduct that made urban homosexual men valuable plasma donors caused multiple other diseases that made this population inappropriate donors for any other blood or plasma product".

52. We found some newspaper and magazine adverts that evidence the deliberate targeting of homosexual donors. Examples of these were annexed to Donald Francis's deposition. The investigators have

attached a still from the film that evidences these adverts (Exhibit **WITN3531004**). I no longer have a copy of these adverts.

53. We had in our possession at the time of making the film a number of internal memoranda, particularly from Cutter. The memoranda evidence that blood containing Hepatitis B antigen was used first for extraction of HBIg and then for blood products for haemophiliacs.

54. One FDA memorandum (dated 20 August 1982) referred to in Donald Francis's deposition noted, after a meeting with Cutter representative Mr Moore, that "under usual circumstances, these units [of plasma taken from a predominantly male homosexual plasma collection point] ... would have been pooled with other units collected for use in Hepatitis B immunoglobulin (HBIG)."

55. He continued: "The cryoprecipitate would have been removed and pooled with cryoprecipitates obtained from ordinary plasma pools...". I do not have a copy of this document in my possession, but its contents is covered in paragraph 13 of the deposition of Dr. Francis.

56. One Cutter memorandum dated 30 August 1982 (Exhibit **WITN3531005**) notes that "until recently Cutter's anti-HBs plasma (all collected from centers dealing predominantly with homosexuals) has been used in the manufacture of coagulation products".

57. We also obtained a letter (Exhibit **WITN3531006**) authored by Hyland Vice President, Michael Rodell, to the FDA dated 15 September 1982 in which he stated that Hyland "...is not engaged in any recruitment programs targeting the homosexual community for plasma that may be used in the production of Antihaeophilic Factor (Human)".

58. On 9 December 1982, however, Mr Rodell wrote to the National Haemophilia Foundation regarding HBIg production (see Exhibit WITN3531007). He stated that "we no longer allow this plasma to enter

those pools leading to AHF [Antihaemophilic Human Factor] manufacture".

59. As Donald Francis concluded, "the only reasonable conclusion is that defendants Cutter, Baxter and Alpha used the high-risk plasma to make Factor concentrates until July 1982".

60. Donald Francis in his deposition stated that "this document indicates that Baxter did mix high risk Hepatitis B plasma into the Factor concentrate pools, until several months before the December 9 1982 letter."

61. He also noted that a meeting was held in July 1982 at the CDC. The meeting was attended by representatives from Cutter and Hyland. Dr Francis stated that "[they] never disclosed to the CDC, at the July 27 1982 meeting, nor at any time during my employment at the CDC, that they used HBIG plasma donated by urban homosexual men for the manufacture of Factor VIII and IX used by haemophiliacs".

62. Donald Francis also told us in an interview that is recorded in 'Bad Blood' that "if the companies had done what we [the CDC] had recommended, and indeed kept the material collected from high risk donors out of the market forever, we would have saved probably half of the haemophiliacs".

63. Moreover, he stated that "plasma taken from homosexual men should never have been used for any purpose other than the production of HBIG or Hepatitis B Vaccine. The use of such plasma in the manufacture of Factor VIII and IX concentrates for hemophiliacs was unconscionable, particularly after the summer of 1981 when the epidemic of fatal immunosuppressive disease in this population became public knowledge".

64. This information did not go before the Lindsay Tribunal given that it did not examine US pharmaceutical companies.

Internal documents of pharmaceutical companies regarding blood products

65. At the time of making the film, we had in our possession a number of internal documents from various pharmaceutical companies. Unfortunately, I no longer have copies of these documents.

66. These documents evidenced that by February 1983, the Food and Drug Administration (the 'FDA') had received assurances from pharmaceutical firms that prison plasma would no longer be used in haemophilia blood products.

67. Despite these assurances, Highland continued using plasma from prisons in the manufacture of these products for a further eight months.

68. An internal memorandum from Armour revealed that senior executives in the company had serious concerns about the safety of all heat-treated products. Despite these concerns, a decision was taken not to tell the FDA about these doubts.

69. These concerns were based in part on findings by Dr Alfred Prince, who had conducted tests on Armour's Factor VIII. He concluded that despite being heat treated, virus remained present in the product.

70. Dr Peter Foster informed us that Armour prevented Dr Prince's publication of these findings and continued to distribute its products in Ireland, the UK and more widely.

71. By February 1986, Dr Foster was so concerned about Armour's heat-treated products that he decided to raise his doubts publicly at the UK's major conference on AIDS.

72. He had colleagues whose patients had tested positive for HIV after treatment and whom had tested negative before. He told us that "by the time [he] blew the whistle, [he] knew of two definite cases, and two or three suspect cases. [He] decided that the time had come to make this knowledge public".

73. Dr Foster also told us that "manufacturers of the product got together to make a petition to stop [him] from saying [he] was worried".

74. Later in 1986, Dr Prince's findings regarding Armour's heat-treated product finally made it to print in the Lancet medical journal.

75. Four months afterwards, Armour recalled its product.

76. This narrative was aired at the Lindsay Tribunal when Dr Prince and Dr Foster gave evidence. It is his view that fault lies with Armour for blocking him from publishing his findings.

Reactions to the film

77. After the film was aired, I was relieved that the response from the haemophilia community was positive. I felt that we had given a voice to hundreds of people with haemophilia who had for years felt like the silenced "small guys" against large corporations. For four or five years after the release of the film, I was contacted numerous times by members of this community, many of whom thanked us for publicising this story.

78. The release of 'Bad Blood' led to a question being asked in the Irish Parliament about why the state had not held the American pharmaceutical companies responsible for their actions. Following the debate an opposition pressure, the government decided to appoint a senior barrister to assess the capacity of the Irish state to litigate against the US drug firms.

79. The film also sparked interest in the possibility of a second tribunal. Paul Gardiner SC wrote an opinion piece on the merits of legal action against the pharmaceutical companies. Ultimately, it was decided not to initiate proceedings.

Other issues

80. At the time of filming, I was very much on top of the facts. I was careful to be as fair and as accurate as I could be at all times, not least because I was alive to the risk that the pharmaceutical companies may institute legal action against us. This did not happen.

81. During our research for the film, we contacted both plasma collection companies and concentrate manufacturers. Neither would comment or be interviewed.

82. I stand by every claim that we made in the film.

83. Personally, I think it is a huge disappointment that US drug firms were not taken to court by the Irish state. Given that so many people died as a direct result of contaminated blood products, it was clearly in the public interest that such companies should be made to defend their actions. This is particularly acute given the multitude of serious concerns raised by the media and through documents that have come to light via litigation.

Statement of Truth

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

Signed GRO-C

Dated Sat 31 Oct 2020

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