Witness Name: Cees Smit
Statement No.: WITN6411001
Exhibits: WITN6411002 to
WITN6411010
Dated: January 10, 2023

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF CEES SMIT

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 22 June 2021.

I, Cees Smit, will say as follows:

Section 1: Background and Professional History

1. My name is Cornelis Smit (Cees). My full address is GRO-C GRO-C The Netherlands. My date of birth is GRO-C 1951.

2. My qualifications are as follows:

    a. Bachelor's degree Economics, Free University (VU) Amsterdam - 1976
    b. Honorary doctorate of the College of Deans of the Faculty of Medicine of the University of Amsterdam (UvA) - 2003

3. I have held the following professional and voluntary roles:

    a. 1971 to 1998: Editor of the Magazine 'Faktor' of the Netherlands Haemophilia Society (voluntary)

b. 1978 to present: Member of the 'Haemophilia in the Netherlands' Working Party, a longitudinal study into the medical and societal situation of haemophiliacs in the Netherlands (voluntary/professional) at the Leiden University Medical Centre (LUMC)
c. 1979 to 1981: Journalist at the daily newspaper 'Trouw' for articles on the trade in human blood (professional/voluntary)
d. 1987 to 1998: Coordinator of the Netherlands Haemophilia Society (professional)
e. 1998 to 2001: Policy worker at the Foundation Pandora, a 'not-for-profit' organisation for people with mental disorders (professional)
f. 2001 to 2005: Board member of the Dutch Genetic Alliance (VSOP), Chairman from 2003 - 2005 (voluntary)

Evidence or involvement in inquiries/ investigations/ litigation (HIV, HCV, HBV)

Netherlands - Dutch Ombudsman Investigation, HIV

-

4. I was coordinator of the Netherlands Haemophilia Society (NVHP) between 1987-1998. My role is discussed in more detail below. This role led to my involvement with the Dutch Ombudsman Investigation.

5. On 4 January 1994, the NVHP officially filed a complaint with the National Ombudsman against the Ministry of Health for their policies during 1982-1989. The complaint consisted of five points, focusing on the negligence of the Ministry to organise timely interventions.

6. After extensive investigations, the National Ombudsman concluded that the policy of the Ministry of Health was not adequately sufficient with regard to the the following (**WITN6411002**):

    - At the end of 1984 to the start of 1985, when initiatives had failed to restrict the risk of HIV transmissions by excluding, as much as was possible, the use of non-heat-treated Dutch blood products;

- When no stringent directions were given to Dutch producers (the Dutch Red Cross fractionator CLB and the Regional Red Cross Blood banks), to switch to heat-treated clotting factors for the treatment of haemophilia A;
- At the beginning of 1988 when it was decided to recall a Factor VIII product from Armour that was insufficiently heat-treated. There had been an article in 'The Lancet' on 5 April 1986 (**PRSE0002071**), which had been published by a Dutch group from the Academic Medical Centre (AMC) in Amsterdam, noting a seroconversion on that product and thus actions should have been taken sooner as knowledge was known.

7. The Ombudsman report showed that the government was too late in taking actions and just allowed the experts groups outside the government to develop policy.

8. Immediately, after the publication of the Ombudsman's report in 1995 (**WITN6411002**), the Minister of Health, Professor Els Borst-Eilers, accepted the Ombudsman's conclusions. She also announced that the government would launch a scheme for financial compensation.

9. We had the authority from the Ministry to decide how the compensation should be divided. It was up to the NVHP as to how to spend and distribute the money. We looked at which financial models already existed. It was then decided at a meeting from the Netherlands Hemophilia Society as to how the money should be distributed. One man told his story there and quote:

> 'I am absolutely in favour of the same payment for everyone. The fact that I have no children is because my partner and I decided not to have children because of the aids risk. My feeling is that we cannot make a difference based on people having children or not. We all went through the same difficult times during a long period of uncertainty. Let's stay together once more and go for the same compensation for

everyone' (Quote from 'Surviving hemophilia', Cees Smit, Eburon. 2020)

10. Everyone applauded him in the room and we agreed to give funding to everyone equally. We are all in the same position.

11. All HIV infected haemophiliacs or their relatives had to apply for the settlement of 225,000 Dutch guilders from the Dutch Red Cross. This was a separate entity, which was not part of the Central Laboratory of the Blood Transfusion Services of the Netherlands Red Cross (CLB), and was appointed as a trusted third party. We also had a physician as part of this third party who would enter discussions with those who didn't have strong cases for compensation. As the Haemophilia Society, we wanted to stay out of the family quarrels and didn't want to know who was infected. In the end, 155 people applied and received their settlement in 1996 and 1997.

12. At the end of 1999, the NVHP informed the group that those who had received the compensation from the government, would also receive compensation from the blood product producers. The CLB, Armour and Baxter had created a fund of 5 million Dutch guilders to be divided among the 155 registered HIV infected haemophiliacs. The condition was that they should sign a waiver, but I am not sure if everyone signed that waiver, it was left open. In April, 2000, it was communicated that each applicant should receive 41.350 Dutch guilders from that fund.

13. Perhaps we were too naive to think about long term consequences and long term survivors. We were tired of all the fighting and relieved it was seemingly solved. We had no further discussions about compensation as we thought everyone would die early.

14. With regards to compensation for those who contracted HIV via blood transfusions, the Dutch government did not give any funds or compensation. There was a story of seven babies dying from HIV via blood transfusions. Of

those, two parents of babies asked for compensation, but they were never given any money.

HCV

15. For HCV it would have been reasonable to expect HCV compensation but hard to prove guilt. There were issues of hepatitis from the 1960s and 1970s. There was a risk of hepatitis from haemophilia and people assumed it could potentially be cleared then. We had several conversations with doctors, where they would advise not to drink too much alcohol, so as not to bring on liver issues. We underestimated the long term consequences of HCV and how it would affect people in the future. But for negligence or compensation it was hard to prove. In the 1990s, we sent a letter to the government stating that we thought that they were guilty of these hepatitis transmissions. Due to the statute of limitations, we kept re-sending the letter in order to keep the complaint open.

16. I left the NVHP in 1998. My replacement had a different view, and wanted to project a more positive image of hemophilia along with the board, therefore they did not continue with the campaign for HCV compensation.

Court cases - compensation

17. In the 1990s, I had to deal with two court cases from haemophiliacs against their hospital and the request to the Dutch government for compensation for the whole group. This compensation request was awarded after an extensive search from the National Ombudsman in 1995.

18. The first court case was in 1992 against the Academic Medical Centre in Amsterdam, in the Netherlands, officially it was against the hospital and against my personal hemophilia consultant because they were accusing him of having caused an HIV infection on US hemophilia products. The hemophilia consultant himself felt terrible about this accusation and had

stopped treating his patients and left this to his Junior doctors, such as Marcel Levi who later became the Director of the London University Hospital (UCLH).

19. The court case went on for some years and the judge said that the court was not the place for this dispute and that it was an issue for the government. It was clear then, that the government had a responsibility. After the court judgment, we then went to R. G. Samson (Deputy General Director of MoH) and he suggested an investigation followed by the Ombudsman Inquiry in 1995.

20. In the second case, around 1998, the case was not concluded as the haemophiliac had died, and his family did not want to continue the legal process. The case was against the Red Cross Blood Bank in Groningen due to his HIV infection. The man involved was young and later found out about his illness and became quite ill and decided to sue the blood bank because his parents had not been properly informed. This case was instructed even after haemophiliacs received compensation.

No-fault compensation

21. The Dutch didn't have a 'no fault compensation' system, meaning we could not ask for compensation from the government. Scandinavian countries and New Zealand had 'no fault compensation schemes', and we all felt we should receive compensation. Our compensation came much later in time when we gained a better understanding of what was going on in other countries. When we were initially confronted with the issue of haemophilia and AIDS, the last thing we were thinking about was the legal issues. That came later on, when people realised they had financial hardships, no life insurance, and even housing issues following their infection.

22. More legal issues kept coming up, when someone went to court we had to think what is our opinion about this? We were of the view that this happened

to us all and I personally thought that the plasma industry was guilty because of their use of paid donors. But we had the understanding that blood transfusion services working with voluntary non-remunerated donors wouldn't have known before the summer of 1982. We recognised it would be a complex legal issue ahead.

23. In 1982/1983, however, we were involved in a national AIDS policy, and also in the policy debate about those who were gay and donating blood. The gay community wanted to continue to donate blood, as they perceived they were being discriminated against. As time went on, the Director of public health wanted to close down the gay saunas and dark rooms when they were laying out measures. The gay community didn't agree with the proposals to exclude them from donating, but the NVHP insisted on it. As consensus, a voluntary withdrawal was promoted in 1983 and so on.

Canada

24. In the mid 1990s, there was a criminal investigation by the Canadian Mounted Police into the criminal behaviour of American companies. In particular, they were looking at Armour's heat-treated factor VIII concentrates.

25. The police wanted to understand in more detail, about the transmission with HIV of Armour blood products in the Netherlands. They contacted me following an article from the AMC in Amsterdam, published in 1986 in The Lancet (**PRSE0002071**), where a Dutch haemophiliac was mentioned. I was coordinator of the NVHP at that time.

26. The same time, a lawyer from the United States approached me to ask if I knew the name of the person who had been infected in the Netherlands. The American lawyer was specifically looking for the one person who was contaminated by the Armour products as described in The Lancet article. I wrote a short call about this in the newsletter from the NVHP.

27. Between 1997-2001, the Royal Canadian Mounted Police visited The Netherlands on two occasions to speak with me and others. This included an official hearing at the offices of the Amsterdam Police Headquarters.

28. The Lancet article mentioned that there were two Dutch haemophiliac brothers. One of the brothers read my call and read the Lancet article when he illegally went to his hospital and looked through his own medical files and found a copy of it there. He realised the article was about his brother and his brother then contacted this American lawyer. The brother made a settlement with Armour and signed a waiver preventing him from saying anything about Armour and he is still alive to this day.

29. We never got official feedback from the Royal Canadian Mounted Police as to how their investigation ended.

Japan (and EU)

30. In 1996, I was invited to Japan. Both my visits to Japan made a huge impression on me.

31. The International HIV Conference in Yokohama in 1994, was the first occasion where representatives of the EU Haemophilia community, the US haemophilia activists and Japanese lawyers (representing the then 'silent' Japanese haemophilia community) met. That conference served as an eye-opener for the US activists and the Japanese lawyers.

32. In 1996 I went to Tokyo. But a week before I arrived in Tokyo the pharmaceutical representatives were giving excuses in the press and apologies for HIV infections. Japan was not aware of what was going on; this is further discussed below about the situation in Europe (see paragraph 40).

33. I arrived in Tokyo for a meeting of the Japanese HIV Litigation Support Group. At this time the Green Cross operated in the USA but they had a link

to Japan, similar to the Red Cross in that it was governmental. I went to one of the haemophilia meetings, where there were Japanese lawyers representing the Haemophilia society and notably there was only one haemophiliac present. He was the only Japanese haemophiliac who was publicly open about his HIV infection.

34. One evening in Tokyo, there was a performance in a theatre about the situation of Japanese haemophiliacs with HIV. There were haemophiliacs from the EU and the US together with one HIV+ positive Japanese hemophiliac on stage and there was a screen on the stage separating the other HIV Japanese haemophiliacs from the audience. We (from the EU and the US) told stories about our lives with HIV, to show that we were not weird and that we were normal. It was very poignant as previously the haemophilia community was not accepted in Japan and they could not be open about their infections. The stories were translated for the audience. It was very moving that after the break the screen was taken away and the the face of the other infected Japanese haemophiliac was revealed. After all our stories, they decided to be open about their HIV infections as well and so the screen was taken away. They got a lot of media attention through this theatre event.

35. In 1996, I had extensive contact with the lawyers from the Japanese HIV litigation support group. For the Japanese lawyers, I made an official affidavit about how we handled the HIV situation in The Netherlands, and also an overview of HIV and HCV settlements worldwide.

36. Later in 1996, I was invited to a second meeting, this time in Kobe. Whilst in Japan, I also had a meeting with an American haemophiliac who I met in the hotel. It was Corey Dubin, from the Committee of Ten Thousand (COTT). The Native American spokesperson was campaigning against the National Haemophilia Association and there were also cover-up claims. From our conversation, he learnt about compensation in Europe. Later on, the USA were given compensation, but they were late, in relation to other countries.

USA

37. In 1994, the Committee of Ten Thousand (COTT) representatives who had visited the International AIDS Conference in Yokohama contacted me and on their way back we met in Amsterdam. This was a grassroots HIV group, which started at the end of the 1990s. It was through the COTT that the Japanese lawyers contacted me via their interpreter Masami Kobayashi. She lived in the USA where she had extensive contacts with COTT. Especially in Yokohama the representatives from COTT had spoken with hemophiliacs from Europe and especially Terkel Andersen (Denmark) and Werner Kallins (Germany)

38. I had since then contacts with haemophilia HIV activists from the United States and especially those from COTT. The COTT have used their extensive information in their court cases to fight for settlement. This is demonstrated in 'Blood on their hands' from Eric Weinberg and Donna Shaw (2017).

39. Some ten years after the first HIV-cases, unrest began to grow in the USA about the role several stakeholders in the haemophilia community had played in the early 1980s when the first messages about HIV became known.

40. Terkel Andersen (Denmark) and Werner Kallins (Germany) were also present when we founded the 'European Haemophilia Consortium' which started in 1989, and was officially founded in 1993. During this time, we had quite a lot of knowledge on what was going on in Europe to inform the US and Japanese delegates.

41. We received a lot of information about the situation of HIV+ haemophiliacs in the USA before 1994 and especially to install support systems for HIV+ hemophiliacs, and since 1994 there was more an exchange of information of what went wrong in the plasma industry.

42. I helped with the organisation of the International AIDS conference in 1996 in Amsterdam. During this time, I spoke with people from the American National Haemophilia Foundation (NHF) and invited them. As I was in the organising

committee of the Amsterdam Conference, the American National Haemophilia Foundation Society was invited as the official Hemophilia Society representing the US HIV+ hemophilia community and to participate in one of the sessions on hemophilia and HIV as well as a representative from the World Federation of Hemophilia (WFH).

43. In this special session on haemophilia and HIV, the American haemophilia activists from COTT and lawyers from the pharmaceutical companies were present in the audience. Corey F. Dubin was the most outspoken spokesperson on behalf of COTT (see **WITN6411003)**. We were aware of possible dangers when we were writing articles on hemophilia and HIV in the Netherlands, but we were not afraid of people following us from the companies. But the US activists were very afraid of being followed by people and especially lawyers from the plasma companies in Amsterdam. That was something we were not aware of. So in 1996 in Amsterdam, we realised there were huge conflict of interests between the National Haemophilia Foundation (NHF) from the US, the World Federation of Haemophilia and the pharmaceutical industry.

Section 2: Netherlands Haemophilia Society - Coordinator

Role

44. I was the Coordinator of the Netherlands Haemophilia Society (NVHP) between 1987-1998.

45. By way of background, between 1971 until 1987 all activities for the NVHP were performed by volunteers and with a limited budget, without government funding. At the end of 1982, these volunteers also handled the issues around haemophilia and HIV which were emerging.

46. The NVHP was then dealing with more and more complex issues. We did work with volunteers, among them some haemophiliacs who were infected

with HIV and they could assist with questions. We had a couple of volunteers at every centre to talk to someone. We also had buddy support groups with people who they already knew from the NVHP. We asked for a grant from the government and for support.

47. In 1985, when the first dutch person died due to HIV, the board of the NVHP realised that the emerging issues around HIV (like counselling, education etc.) could not be handled anymore by volunteers and that is why they started looking for money for an office and some professional staff that could support these HIV activities, coupled with the daily activities of a patient group. It took them 2 years to find the funding.

48. At the end of 1987, the board asked me if I was willing to become the first coordinator of the society - I accepted the role. It was a full-time job, where I had a part-time secretary. Gradually we had three or four staff people.

49. As a Coordinator, I performed all duties in coordination with the Board; communicated with all stakeholders and all members of the Netherlands Haemophilia Society and especially all those infected with HIV and their relatives. As all of this received significant media attention, I also dealt with the media (television, radio and newspapers; during that time there was no social media).

50. I also supported the board in all kinds of policy decisions, relations with producers of plasma products, blood banks, the government, haemophilia centres and other patient groups, etc. I had to deal with issues regarding haemophilia in all aspects for members and non-members and not only for HIV but also for HCV.

51. The main task was the HIV issue. We worked on the development of educational materials, newsletters, peer support for people and relatives with haemophilia and HIV and the relations with other AIDS support groups.

52. We were first alerted on the hemophilia and AIDS issue by a newsletter article in one of the Dutch newspapers in July 1982 and not by the Dutch Ministry. At the end of 1982, beginning of 1983 we also had conversations with the gay community about the risks of HIV. In other countries like in the USA, the NHF struggled to speak to the gay community. However, there were a lot of exchanges of information between the haemophilia community and the gay community at the end of 1982. The information was not publicly available, it was only within a certain circle. Soon after, the AIDS information centre was formed.

53. The haemophilia group with HIV, fell outside the so-called original 'sex, drugs and rock 'n roll' risk groups' for HIV. Therefore there was a need to organise the support in a separate way, since there were tensions between the haemophilia group and the other risk groups. There were certain members of the haemophilia community who felt that some members of the other risk groups were responsible for the infection of the haemophiliacs with regard to HIV. For example, we had discussions at the end of 1982, about the withdrawal of homosexual men in active sexual relationships (known as MSM) as blood donors. In that way, my role as coordinator was also a 'go-between' with the other HIV stakeholder groups.

54. In addition, it has to be realised that AIDS was a taboo subject in the 1980s and 1990s and that a lot of haemophiliacs, their parents, relatives and family members were very reluctant to speak about what happened to them. As a coordinator I also became the spokesperson of the NVHP with the media.

55. Therefore, my role as Coordinator was a complex one and also a sensitive one. I had to build trust relationships with members and non-members of the NVHP. It was only in 1991 that we could organise peer-support groups for haemophiliacs with HIV, in a closed setting. Before that it was mostly one to one contacts.

Meetings

56. In my role as Coordinator of the NVHP, I was also the initiator of a meeting of European haemophilia societies in 1989. This meeting led to the official foundation of the European Haemophilia Consortium in 1993. In 1996, we co-organised with Israel the Congress of the World Federation of Haemophilia, at The Hague.

57. I attended nearly every single WFH Conference between 1979-1998. I visited the WFH Congresses in 1988 (Madrid), 1990 (Washington) and 1992 (Dublin). In my opinion, the WFH congresses after Stockholm (1983) were less relevant as a source of information on haemophilia and HIV as the information was mostly biased or already well-known. In addition, compensation issues were discussed more in-depth at meetings of the European Haemophilia societies. The WFH was less helpful and instrumental in these issues as they were too closely linked to industry. With an exception for the activities of the WFH Clearinghouse in Heidelberg, led by Professor Klaus Schimpf, where they collected a lot of information on compensation issues for HIV and HCV.

58. My visits to the USA were far more informative. I visited congresses of the National Haemophilia Foundation (NHF) in 1987 (Omaha), 1988 (Atlanta) and 1989 (Oakbrook/Chicago). These visits were made possible by the Dutch Ministry of Health and were meant to see how the USA haemophilia population with HIV were treated and counselled. They were years ahead of what we experienced in The Netherlands, so that gave a good impression of what obstacles (discrimination issues, insurance problems) and possibilities (educational materials, counseling and peer-support) and how we could develop in the Netherlands. During these congresses, the court cases and compensation issues were not yet addressed. That would happen later in time, especially when the Committee of Ten Thousand started at the beginning of the 1990s. They heavily attacked the National Haemophilia Foundation as well as the pharmaceutical companies for lack of information and action in the early eighties.

Section 3: Netherlands Haemophilia Working Group and Dutch Genetic Alliance

Netherlands Haemophilia Working Group

59. The 'Haemophilia in the Netherlands Working Group' was founded in 1972. It was introduced to organise a postal mail survey to help understand the medical and societal situation of haemophiliacs in The Netherlands. This was a joint initiative from the then informal Netherlands Society of Haemophilia Physicians (NVHB) and the NVHP.
60. The surveys were posted in 1972, 1978, 1985, 1992, 2001 and 2019. Since 1978, I have participated in this Working Group. In 1978, I performed my doctoral thesis in this Working Group on the advantages and disadvantages of home treatment in haemophilia and in renal dialysis. Between 1985 and 1988, I was a professional team member of the Working Group and since 1992 I participated as a patient expert on a voluntary basis. From these surveys, between 1985-1988 we received an accurate estimate of the number of HIV positive haemophiliacs in the Netherlands.

61. As part of my work for the 'Haemophilia in the Netherlands Working Group', I was co-author of the scientific articles that were the result of this research.

62. The main publication of this was an article in the British Medical Journal, published in 1989. In this article, we also mentioned our estimate of the total number of haemophiliacs infected with HIV in the Netherlands, ranging between 130 and 170.

63. Later, with compensation in 1996, 155 people applied for this compensation which in retrospect made our estimate quite accurate.

64. Most importantly to me, as a result of my participation in a second survey in 1978, the late haematologist of the LUMC Jan Veltkamp asked me to present my results of my research on home-treatment at the WFH Congress in Tel

Aviv, in the summer of 1979. After my presentation there, I was invited by Professor Egli from the Bonn Haemophilia Centre to speak in 1980 at an International WFH Congress in Bonn.

65. During both meetings, I observed the many social events sponsored by the blood processing pharma companies as well as the luxurious environment where these meetings were held.

Dutch Genetic Alliance

66. I have been asked about the Dutch Genetic Alliance, however there is no connection with HIV and hepatitis issues.

Section 4: Patient Advocate role

67. In 1971, I started studying in Amsterdam, which was the same year the NVHP was founded. The Society asked for volunteers and I mentioned I could write articles for them, since I was editor of my school magazine. I befriended a journalist, Piet Hagen, GRO-A

68. In 1972, I began writing articles and closely cooperated with Piet during the 1970s. He had several friends who worked for NGOs in developing countries. Some of them asked us about our knowledge about the trade in human blood and vice versa. Piet and I were deeply triggered by these conversations.

69. I regularly went in the seventies with Piet to the Central Laboratory of the Dutch Red Cross, where fractionation for Factor VIII and IX was made nationally. We always had one or two conversations per year about the development of Factor VIII and IX products, and learned there was a shortage of products. There was this constant tension between yield and how many products were made at the end of the day. The rougher the production the lower the yield, this was always explained in our articles.

70. At the end of the seventies, there was a shortage of plasma in the Netherlands. Until then, the Netherlands was rather self-sufficient in Factor VIII/IX. Some Dutch haemophilia centres and regional blood banks were importing products, but this was illegal. This was due to the Dutch law on human blood, which forbade importing blood products made from the plasma of paid donors' (**WITN6411004**). So, one of the American producers went to court in The Netherlands to get an official license to import American products and they won. So, between the end of the seventies, early eighties there were several Dutch hemophilia centers who used American hemophilia products to solve shortages and because of its easier use.

71. In 1977, we wrote articles about the risk of hepatitis on hemophilia products based on interviews with physicians. As part of my doctoral thesis, I worked in 1978/1979 on the second national hemophilia survey with Jan Veltkamp in Leiden. The first survey was carried out in 1978.

72. I studied Economics at that time at the Free University in Amsterdam. Some professors there were enthusiastic about my hemophilia work in Leiden and others were not. Leiden University was happy and they wanted me to go to Tel Aviv for the World Federation Conference in 1979 to present my results (see paragraph 64). In the summer of 1979, I went to Tel Aviv where I was the first member of the Netherlands haemophilia patient community to present.

73. I was struck by the wealth of where the conference took place. I arrived on Saturday at the Hilton Hotel in Tel Aviv. There was a trip to the Dead Sea the next day. We were all put in buses and also went through Jerusalem. I found out that this was paid by the pharmaceutical company. A company representative was there and asked if anything was needed. There were social activities every night. On Thursday, we went to the King David Hotel in Jerusalem, which is one of the most luxurious hotels in the world. There was so much wealth and luxury with 200 participants from all over the world.

74. The Founder of the Federation was present, Frank Schnabel, in addition Thomas O. Hecht was there - he was as he said in a speech a good friend of Frank Schnabel. Alan Tanner from the UK, was also the right hand man of Frank. He was very diplomatic and was never involved in the difficult discussions. But behind closed doors, there was still the fact that he was aware of these important decisions being made, and later he must have known of all the consequences regarding HIV. GRO-A GRO-A Alan would look after meetings.

75. I learnt there about licensing and the Dutch court case which was ongoing. Tramedico, a trader in pharma products in the Netherlands wanted to work with Armour to bring their products on the Dutch market and therefore they started a legal procedure against the Dutch government (see paragraph 70).

76. When I returned to the Netherlands, I discussed this with Piet Hagen, who was my co-editor of the Haemophilia journal and my Professor at Leiden University Jan Veltkamp. My Professor was against the American companies and encouraged us to investigate this further. Piet discussed this with his boss at his newspaper, 'Trouw'. After deliberations with his Chief Editor, we got permission to work a few weeks on the issue of the trade in human blood as well as the import of USA factor products in the Netherlands, where Baxter and Armour wanted to import their products. The article was regarding the amount of imports of products internationally (**WITN6411005**).

77. We wanted to know where the USA got their plasma from. We went to speak to Non Government Organisations (NGOs) in Amsterdam who investigated multinational corporations. They had files of the companies and we went through Baxter, Cutter and Armour files (which became Revlon).

78. We even met with Charles Medaware in London who was a famous activist against multinational corporations in the UK. He couldn't tell us anything relevant to the trade of human blood. All the groups did not seem to know anything about bad blood.

79. In late 1979, a colleague of Piet who was in Nicaragua, told us that he knew there was blood going to the US. We got information that blood was coming to Miami via Cutter and Institut Merieux (France). We then openly asked Merieux “Is your company involved in this?” We didn’t expect a fax back from them, but Merieux confirmed that they were importing from there.

80. We then wrote another article about Nicaragua. We also had a confession from a person, that a prisoner in Nicaragua died as too much plasma was taken from the prisoner. We also found out where the Amercian producers got their plasma from, centres were mostly located on the Mexican border. We learned that they were making use of paid donors with a high risk of hepatitis. So in 1979 we had a full picture. We knew about the companies, but also the brokers who indirectly traded in plasma stocks and sold them to companies. This was all published and in print (**WITN6411006**).

81. Through our investigative work, we found out that Thomas O. Hecht was the largest broker for selling plasma in the world. In 1979, Piet went to Paris to meet Thomas. He explained that NGOs could not fit the demand for plasma and he needed to find a solution. He believed he did a good job and service by providing the blood and plasma; nevertheless, financially benefiting. This was published in the ‘Trouw’ newspaper in 1979 (**WITN6411007**).

82. Piet worked for the next couple of years on his book, named ‘Blood: Gift or Merchandise’. This was published in the summer of 1982. During these years I focused on my studies.

83. In 1981 at the WFH conference in Costa Rica, there were several Dutch physicians who went to Mexico to work on a book on hemophilia home-treatment . They had a working holiday with their secretaries paid by one of the American producers and after Mexico they came to the conference in Costa Rica. We were suspicious of that after Tel Aviv. Piet wanted to visit as he was writing a book. They questioned me, and asked why a journalist was

with me. We were not made to feel comfortable due to Piet being there. We (Piet Hagen and me) felt threatened. During this time other journalists were killed in Nicaragua and in Brazil as they had exposed the human blood trade. We did not feel safe.

84. In July 1982, I read about the first case of AIDS in the USA (**WITN6411008**). One sentence mentioned haemophilia, transmission of blood and blood transfusions. During this time I was on the board of NVHP. I alerted the board about the article. In September we met and wrote a letter to the Central Laboratory of the Blood Transfusion Services (CLB) of the Dutch Red Cross to ask what was going on. We also wrote a letter to NVHB (treating haemophilia physicians) the same month informing them about a possible disease.

85. The CLB had colleagues in the USA and by the end of 1982, they were convinced there was a disease that affected haemophiliacs. On the day after Christmas 1982, we all met. This included the Red Cross, and the Haemophilia society of patients. A week later we had a meeting also with the CLB and the Dutch hemophilia treaters. It was there that we decided we had to inform our members. We chose to be really open with our members.

86. In January 1983, there were cases of aids in haemophilia in the USA. In a letter, we wrote that we were thinking about taking measures, but told members that they should talk about their needs with their haematologists. (**WITN6411009**) Then we wrote a second letter (as there were so many emotions), we explained in more detail about what measures were to be taken and we advised not using American blood products. (**WITN6411010**) We organised an Assembly meeting in May 1983, informing our members what was going on, and we had specialists answering questions. Again we advised against using American products. We had good relations with our members and they had many questions, especially as treatment development in hemophilia was only just beginning. There was a lot of trust between us and the members.

87. My problems started in Stockholm in 1983, as the WFH downplayed the risk of HIV/AIDS. They may have thought they were trying to protect the haemophilia community. At the WFH conference we were told not to accuse the companies, because the companies may stop producing the products for us. At the conference there were sales representatives with the haematologists. There were discussions in advance of the conference. One or two days before the conference, big heads of industry arrived earlier to discuss their stance.

88. I felt very depressed, I knew more information than what was being told at the conference. There were a lot of countries, where they were there for the first time, and you can't help but be a little bit impressed by what's going on and cannot pinpoint discrepancies and politics. I didn't trust the WFH and what they said; as the WFH was financially supported by the industry. The Greek Haemophilia Society decided not to tell anything to their members as they told me at the airport of Copenhagen on our way to Stockholm.

89. The WFH set up an AIDS information centre, which was physically located in Shelby Ditrich's (haematologist) offices in Los Angeles. It was a centre for HIV and hemophilia. This was the only positive result from the Stockholm conference.

90. I missed the conference in 1984 in Brazil, as I was disappointed after Stockholm.

91. In 1989, we organised a European Haemophilia Society Conference in the Netherlands with support of our MoH as the World Federation Haemophilia conferences and organisation was not helpful in supporting European issues. The WFH only informed us about statistics, and nothing practical. We thought it was wise for European Hemophilia Societies to be involved in the discussions about a European Blood Directive as a result of the starting European Cooperation in general. We asked all the EU hemophilia societies for data on HIV and HCV and information on compensation issues and discussed that during this first European hemophilia meeting.

92. For the Congress conference in Mexico in 1992, I didn't go due to my HIV infection (I did not feel well enough) and it was unsafe for me to travel. Another reason was that the NVHP was asked by Bayer to visit the San Francisco Bayer plant for recombinant hemophilia products, which I didn't agree with, as I perceived this as a conflict of interest. Bayer reached out and said we will pay just for you to go straight to San Francisco, but I still said no.

Section 5: Haemophilia treatment in the Netherlands 1970-1991

93. On 20 July 1982, I was alerted to the risks of blood products when I saw an article on it in the Dutch National newspaper, de Volkskrant (**WITN6411008**). In combination with my journalistic investigation in the late 1970s, and our understanding of there being possible viruses; Exhibit **WITN6411008** proved that there was a virus present and it had now been nationally flagged. The NVHP and myself notified our members as we chose to be very open with them.

94. In May 1983, at Copenhagen Airport, I ran into a Greek Haemophilia Society nurse and two other Greek delegates after the WFH conference. We spoke about the knowledge of HIV in blood products. I asked the Greek delegation if they knew about HIV, and they said "Shhhh, we don't know enough". This was the attitude in Greece. The Greek medical staff were patronising and felt they needed to be protective of the haemophilia community and did not want to inform them. Therefore the Greeks seemed to not want to pass on knowledge of risk, similar to the Japanese consulates.

95. Unfortunately, when knowledge of HIV occurred at the 1983 conference, batches of blood were sent out of America and Europe through the producers

and then sent to Asia and people continued to be infected. I had seen a document from 1988 from Thomas Drees, CEO of a major pharmaceutical company, stating that blood was sold; "We now know by their own admission that Green Cross continued to sell non heat treated anti-haemophilic factor until 1988, although they had heat treatment approval in 1985 for their own product and they lied to the patients that it was heat treated."

96. The representative of Japan at the WFH Congress Professor Abe (he was also in Stockholm in 1983) made no mention of the HIV problems to the Japanese Haemophilia patient group, which baffled me. This was so in contrast with how we, in The Netherlands, had discussed this issue with relevant stakeholders at quite an early stage, that was almost unbelievable to me.

97. In terms of the risks of transmission of viruses in imported blood products, in 1979, there were 2 or 3 centres using American products out of 16. Sales representatives had been visiting hospitals and blood banks during this time. There were internal discussions between haematologists and blood banks within a centre on whether to use American products. Some centres and blood banks had previously imported products illegally in 1978-1979, this was before there was an official licence to permit imported blood products (**WITN6411004**). Those who were pro-usage of USA blood products, simply thought we (Piet Hagen and me in our Trouw publications) had a new argument against the industry and they didn't take it too seriously because it was coming from us. Blood Banks and centres still used American blood products.

98. As to the preferred treatment approach in the Netherlands in the beginning of 1983, part of the advice was to speak with your physician. Some stopped prophylactic use and some chose on demand treatment but this was only when you had serious bleeding. This was all general advice. 80% of haemophiliacs who were mild-moderate, and 100% of severe haemophiliacs followed the advice. As there was a lot of awareness through discussions that

were put in papers, we encouraged personal conversations with physicians which led to high compliance.

99. The first Dutch HIV case among MSM was in 1981 and at the beginning of 1985 there were no HIV cases among hemophiliacs. There was no HIV, however some had disturbances of T4 and T8 cells which was an early indicator for HIV. The big shock came in February 1985 when a partner of a haemophiliac, in Groningen University Hospital, had a lung infection and had HIV. The doctors wondered how she got this, similar to homosexual men with HIV. They realised that her partner had haemophilia and she got HIV from him. She died soon after, and her partner died later of HIV. Later we learned form one of the medical staff who was present during her diagnosis that all staff involved had to sign a declaration form that the information of the HIV patient was to be kept a secret. This was uncommon during that time, for medical staff to sign something like this.

100. After this, we informed the haemophilia community via a booklet. We formatted a leaflet with 45 questions, answers and measures to be taken for those with HIV and haemophilia. We reprinted this one year later, with 55 questions in total. These were distributed in haemophilia communities and other relevant communities.

101. In the USA, there was only one centre that used Cryoprecipitate and it had a low incidence of HIV. The centres were used to using commercial products and mostly used concentrate. Baxter and the Red Cross were fighting in the 70s over whether the Red Cross should continue to make concentrates, or allow Baxter to make products. Baxter won, according to Robert and Suzanne Massie in their book 'Yourney' published in 1976. The Massie's were in favour of voluntary blood donations, they did not want to leave it to industry and they favoured the social healthcare system in Europe.

<u>My treatment</u>

102. I have severe haemophilia A and had to use blood products, Factor VIII and cryoprecipitate. In 1982/83 I had to make a decision to continue with treatment or not. I said I wanted to continue with Dutch products when I spoke with my doctors. I had used American products before on holiday. In 1979, in Italy we went on an Italian Haemophlia ski trip from Amsterdam Haemophilia Centre - we put all the blood products in one box, all together and we shared these products. All of it was from the USA. I got HCV from the use of blood products, as I had a genotype connected to these blood products, which thankfully enabled me to clear the virus. In October 1990, I found out I was HIV positive.

Plasma production

103. There were Dutch blood banks and the CLB processing plasma. They started in bottles and later were produced in plastic bags. But in order to open them one had to use a Stanley knife to open the plastic bags. This was obviously dangerous for the staff handling this. Another issue was that it would be stored in the fridge and would be cold, and there was sometimes dampness in the fridge, and the products could have contaminated the atmosphere. So, I learned later that personnel of the US companies got transmitted with HCV viruses already long before the HIV problem occurred. In the factories it used to be an open process. However, now it is a closed process.

104. There was a basis of trust when I visited the CLB in the Netherlands in the 70s/80s. We had a lot of assistance from them and that remained over the years from the Directors of the CLB.

Pool Sizes

105. Early in the 1970s, the CLB of the Dutch Red Cross tried to balance yield and donors. They understood the smaller the pool size the higher the

yield, the higher the pool size, the lesser the yield. But this meant, when you have one contaminated donor and you have small pool sizes, this contaminated the plasma. But when you have bigger pool sizes there is a higher risk of contamination because the products go to more patients. This was known in the mid 1970s as we had a shortage of Factor VIII. The Red Cross always said you have to be very careful, you need experienced people in the factory, you cannot allow blood to be wasted. I do not know exact numbers regarding pool sizes.

106. A document dated 10 May 1996, which I provide as Exhibit **WITN6411004** states that, "It was also part of our national decision making process not to use American concentrates (unheated) and to switch - if possible - to a national product from unpaid donations, whether it was a concentrate (large pool) or cryoprecipitate (small pool). The policy in that period certainly led to a lower incidence of HIV transmissions…"

107. Almost all European Red Cross Societies had fractionation plants and there were Red Crosses in Switzerland, Finland, Belgium and they had regular contact on how to improve. The Swiss Red Cross were a little more advanced on larger concentrates, and had more donors and were closer to the American industry with their pool sizes. In the 1970s there were strong principal visions within the European Red Cross Societies, only voluntary donors could be used. They opposed paid donations due to ethical principles and risk of hepatitis.

Donor selection

108. We had a meeting on 30 January 1983, which was referred to as 'Bloody Sunday'. It was an official meeting with the gay and haemophilia community, blood transfusion services, the Public Health Organisation of Amsterdam and one Inspector from the Ministry of Health. There were all kinds of possible measures discussed as to how to safeguard the gay community, haemophiliacs, sex workers, and drug users. We spoke about

whether there would be exclusion of gay men as blood donors. Our main reasoning for the exclusion of the gay community was because it was one of the measures that could be taken early. We also discussed testing for HIV (but there was no test at that time) and how to safeguard the blood products because we also saw thoughts of viral inactivation during the process popping up, but there was nothing available at that time that we were aware of. We reached a compromise where we asked the gay community to voluntarily withdraw from donating blood, which they mostly obliged.

109. In mid-1983 we encouraged homosexuals against donating blood via leaflets and to voluntarily withdraw from donating blood. The gay community must have listened as we only had a few HIV cases a year after this, so it was reasonably successful.

Heat treatment

110. In 1982 to 1983, the Red Cross had contacts with the New York Blood Centre where they had developed a heat treatment procedure, but Baxter had also developed heat treatment, and the Red Cross were discussing buying the patent. However, the Red Cross were concerned about the yield, which was a very low yield, as they did not have enough blood plasma in the country. The Red Cross wanted to wait to see if the procedures were effective, but the government was too late to give guidance on a quick implementation of the heat treatment process.

111. In early 1985, we had no further infections apart from sero-conversations in the Netherlands. From mid-1985, American products were heat treated.

112. In an article published in 1986 (Letter from Van de Berg et al in The Lancet), it noted that the first generation of Armour heat-treated products

were heated at 40 degrees, whilst other companies heated the products until 68 degrees. The higher the heat treatment, the lower the yield, so Armour made this economic consideration.

113. In 1987, it was the first time I was in the USA in Omaha and I heard of several projects for safer hemophilia products.. There was a discussion of how recombinant products, transgenic animals, or gene therapy instead of products from human blood and plasma. Recombinant products were on the market in the 1990s, sheep Dolly produced Factor IX but there was too much animal rights activism against transgenic animals like sheep Dolly, and gene therapy was still developing.

Statistics

114. In the 1980s, 40% of haemophiliacs were severe (with 15% being HIV positive), 20% were moderate and 40% were mild (for the moderate to mild patients with haemophilia, their HIV statuses were quite unknown as they received lesser treatment).

115. There were 1,600 haemophiliacs in the Netherlands and 155 have received compensation for HIV infection.

116. Regarding HCV, 80% of patients with severe haemophilia were HCV positive. By now, most of them cleared HCV thanks to antivirals. There are 20% of long term survivors of HIV. In the 1990s, during my time as coordinator, I gave out leaflets which talked about the side effects of HCV antivirals and whether patients had the choice to take them. I remember having hard discussions with doctors who thought I was being irresponsible as they thought patients needed to get on treatments immediately. However, the NVHP were aware that patients who were getting treatments at the start had severe side effects. According to some of them, this has left long term damage to their memory, but the doctors have said they will be fine after HCV treatment.

117. There was a lower prevalence in Belgium and the Scandinavian countries. They used domestic blood products that were unpaid. In Belgium, there was a 5% incidence of HIV rate, and Scandinavia had 15%. Seroprevalence in Austria, Spain, Italy. Germany. UK, USA were different because of the large use of US hemophilia products. France was not comparable as there were so many internal issues with the French Blood Transfusion Services, therefore, one cannot compare their prevalence with other countries. France decided to use contaminated pools of plasma, whilst in other countries we did not see this, except for companies who sent products containing contaminated batches to Brazil and Japan.

Section 6: Other matters

Industry

118. I recently returned from a conference in Rome discussing plasma in Europe. Sadly, the issues have stayed the same in the blood industry. There is hidden knowledge and reasons as to why countries who have enough plasma are not getting enough products. The players are still the same, with the same issues and the same problems. There is currently lobbying for paid donations due to shortages of immunoglobulins products in the EU. The industry and pharmaceutical companies are saying there is a shortage of plasma in Europe and for the new EU Blood Directive to have paid blood donors to meet the shortages of immunoglobulin.

119. However, there are four main countries Germany, Austria, Czech Republic and Hungary which have produced the largest amounts of plasma from paid donors. For example, the Czech Republic has been producing 200% of plasma needed, but they have a shortage of immunoglobulin. The countries have been collecting more plasma than is needed in their countries, and instead of using it in the countries of production they sell to other countries for a higher price, mostly to the USA. Europe is currently only 60% self-sufficient for plasma, and is strangely dependent on the USA for plasma.

International Inquiry

120. I recently wrote a letter together with Annemarie de Knecht – van Eekelen to Vox Sanguinis explaining why we are in favour of an international inquiry. Our reasoning is that since the UK has put so much effort into the Infected Blood Inquiry it would be possible to open an international inquiry as the UK has possibly paved the way for such an Inquiry . There is the difficulty for the real causes of the HIV and HCV that it happened in the US and also most of the companies involved have their headquarters there. Also the role of the US Government should be investigated for allowing for decades the existence of the paid plasma donor system. Hemophiliacs and their families all over the world are carrying the burden of this. Our proposal is to have organisations that could lead the international inquiry such as the WHO, the UNAIDS, or alternatively UK Inquiry could be extended. Since it is a recent investigation, where the Inquiry has persons who are experienced and the work is currently ongoing and they have already collected a lot of material with could be combined with Inquiry material from other countries like the ones mentioned before.

121. I have written an article with two Italian haemophiliacs, for the Journal Haemophilia. The three authors are survivors, two have HIV and one has HCV. It is a scientific overview of development of haemophilia and treatment for haemophiliacs. We also wrote our personal history, as part of scientific history. In this article I also made a plea for an international inquiry and this will be published soon.

122. Since, I have been a member of several scientific committees as a patient representative, I have written several books on patient participation in healthcare. In addition to books on haemophilia, aging, nutrition, my most recent book and autobiography is ‘Surviving haemophilia, a road trip through the world of healthcare’. I initially intended to write it from a scientific perspective but I was advised to do it from my own personal perspective and

my history. I wrote it in English to make my experiences around the trade in human blood and HIV issues in different parts of the world accessible for a larger audience.

UK Inquiry

123. It's amazing what's happening in the UK with the Inquiry. There are affected persons, where the children are actually asking questions and challenging authorities, and I have not seen this in other countries. Perhaps, this is because other haemophilia societies are not led by those who have had issues with HIV/ HCV.

124. Hopefully, the big knowledge will come once the Infected Blood Inquiry report is published and that there may be a lot of coverage outside the UK. The haemophilia community is still so close to the pharma community and the haematologists outside the UK. I hope there will be a lot of conversations in the community following the report.

Statement of Truth

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

Signed GRO-C

Dated Hoofddorp (NL), January 10, 2023

TABLE OF EXHIBITS

Exhibit number	Notes/ Description	Date
WITN6411002	The National Ombudsman Report (English)	18/07/1995
WITN6411003	'Closing the circle: A thirty- year retrospective on the AIDS/Blood Epidemic' by Corey Dubin and Donald Francis (English)	Undated Correct, but anyhow after 1996
WITN6411004	Cees Smit Affidavit regarding Professor Abe at the 1983 Stockholm Conference. (English)	10/05/1996
WITN6411005	Newspaper article from 'Trouw' regarding the importation of commercial blood products. (Dutch)	25/08/1979
WITN6411006	Newspaper article from 'Trouw' regarding the plasma supply chain and Nicagargua.	15/09/1979

	(Dutch)	
WITN6411007	Newspaper 'Trouw' article interviewing Thomas O. Hecht by Cees Smit and Piet Hagan. (Dutch)	26/09/1979
WITN6411008	Delpher Kranten- De Volkskrant newspaper article which was the first news article in the Netherlands referring to a viral disease. (Dutch)	20/07/1982
WITN6411009	Nederlandse Vereniging van, NVHP 1st Letter (Dutch)	05/01/1983
WITN6411010	Nederlandse Vereniging van, NVHP 2nd Letter (Dutch)	27/02/1983
PRSE0002071	Article 'Seroconversion to HTLV-III in haemophiliac given heat-treated Factor VIII concentrate', published in The Lancet	05/04/1986