Witness Name: Jason Jonathan Evans

Statement No: WITN1210008

Exhibits: WITN1210009-036

Dated: February 2020

INFECTED BL	OOD INQUIRY	
EXHIBIT WI	TN1210032	



www.Factor8Scandal.uk

Dear x,

Thank you for your e-mail of 28 November about concerns that Nicola Blackwood misled Parliament during the Backbench debate on Infected Blood payment scheme reforms on 24 November 2016 in the House of Commons.

I do not believe that Nicola Blackwood misled Parliament.

Blood (including blood plasma) can be a vector for human viruses, and can result in blood products manufactured from such plasma also being infective. The aim behind viral inactivation is to remove or destroy such viruses - using heat, chemicals, radiation, or a combination of these - and so to make blood products safe for human use.

As knowledge of hepatitis C began to emerge in the 1970s and early 1980s there were no tests available to screen blood donations and no means of inactivating the virus in blood or blood products.

Ensuring the safety of the supply of blood and its components has always been, and remains, a priority. Blood is a precious commodity, and it is important that the active element in a blood product (for example Factor VIII) is not compromised by the introduction of any new treatment to inactivate viruses. New tests must be properly evaluated in terms of efficacy and the wider safety of the process. In addition, it can be difficult to establish with certainty that a given inactivation process has been successful in reducing any risks from as yet unidentified viruses. Before introducing heat treatment, it was critical that a full assessment and validation of the new process was carried out.

By 1985, a screening test for HIV was available and heat treated plasma products which inactivated viruses had been developed. Earlier heat-treated Factor VIII concentrates were found to transmit non-A and non-B (NANB) Hepatitis (now recognised as hepatitis C) even after heat treatment, and it was not until December 1984 that commercial heat-treated factor VIII became available in any reasonable quantity.

In January 1985 moves were already being put into place to introduce heat-treatment to Bio Products Laboratory (BPL) produced blood and blood products in England. The first of these were in production by April 1985 and by July all Factor VIII produced in England had been heat treated. A fully validated test for hepatitis C was introduced in 1991.

I am aware of the YouTube clip that shows Professor Tuddenham discussing the simple practice of pasteurisation. Although using chemical stabilisers to pasteurise albumin for 10 hours at 60°C was regarded as successful in inactivating the hepatitis virus, it was widely understood that this approach could not simply be replicated for coagulation factors such as Factor VIII. The coagulation factors are more easily destroyed or damaged by heat. Finding chemical stabilisers capable of protecting factor concentrates against heat sufficient to inactivate viruses was not straightforward.

Since 1998, a centrally funded synthetic (recombinant) clotting factor for the treatment of haemophilia, to remove the risk of donor-derived infection, has been provided to the under-16s, and since 2005 this measure has been extended to all patients for whom it is suitable.

The risk of contracting HIV and hepatitis C from a blood donation is now extremely low. The National Blood Service applies donor selection criteria to reduce the likelihood that blood is collected from an infected individual. Current blood screening tests are highly effective at

detecting infection. Testing of all blood donations for HIV was introduced in 1985, and testing for hepatitis C was introduced in 1991 when suitable, effective tests became available.

I hope this reassures you that the government acted lawfully and appropriately to introduce heat treated products at a time that was safe and understood by professional clinicians at the time. We know there were some who felt that government should have acted sooner despite no data available on long term effects of these treatments. I hope this response also reassures you that there was never any attempt on the part of Nicola Blackwood to mislead the House and, where no error in what she said exists, no formal apology is required

Best wishes

Jeremy

Rt Hon Jeremy Hunt MP

Member of Parliament for South West Surrey



www.Factor8Scandal.uk



www.Factor8Scandal.uk

Dear X,

Thank you for your e-mail of 28 November about concerns that Nicola Blackwood misled Parliament during the Backbench debate on Infected Blood payment scheme reforms on 24 November 2016 in the House of Commons.

I do not believe that Nicola Blackwood misled Parliament. I am aware of concerns about whether Nicola intentionally misled Parliament when she stated that the action and introduction of heat-treated clotting-factor products in England took place 'as soon as possible'. However, we still believe this to be the case and the Department stands by Nicola's statement.

Blood (including blood plasma) can be a vector for human viruses, and can result in blood products manufactured from such plasma also being infective. The aim behind viral inactivation is to remove or destroy such viruses - using heat, chemicals, radiation, or a combination of these - and so to make blood products safe for human use.

As knowledge of hepatitis C began to emerge in the 1970s and early 1980s there were no tests available to screen blood donations and no means of inactivating the virus in blood or blood products.

Ensuring the safety of the supply of blood and its components has always been, and remains, a priority. Blood is a precious commodity, and it is important that the active element in a blood product (for example Factor VIII) is not compromised by the introduction of any new treatment to inactivate viruses. New tests must be properly evaluated in terms of efficacy and the wider safety of the process. In addition, it can be difficult to establish with certainty that a given inactivation process has been successful in reducing any risks from as yet unidentified viruses. Before introducing heat treatment, it was critical that a full assessment and validation of the new process was carried out.

By 1985, a screening test for HIV was available and heat treated plasma products which inactivated viruses had been developed. Earlier heat-treated Factor VIII concentrates were found to transmit non-A and non-B (NANB) Hepatitis (now recognised as hepatitis C) even after heat treatment, and it was not until December 1984 that commercial heat-treated factor VIII became available in any reasonable quantity.

In January 1985 moves steps were already being put into place taken to introduce heat-treatment to Bio Products Laboratory (BPL) produced blood and blood products in England. The first of these were in production by April 1985 and by July all Factor VIII produced in England had been heat treated. A fully validated test for hepatitis C was introduced in 1991.

I am aware of the YouTube clip that shows Professor Tuddenham discussing the simple practice we are aware of claims about the use of pasteurisation. Although using chemical stabilisers to pasteurise albumin for 10 hours at 60°C was regarded as successful in inactivating the hepatitis virus, it was widely understood that this approach could not simply be replicated for coagulation factors such as Factor VIII. The coagulation factors are more easily destroyed or damaged by heat. Finding chemical stabilisers capable of protecting factor concentrates against heat sufficient to inactivate viruses was not straightforward.

Since 1998, a centrally funded synthetic (recombinant) clotting factor for the treatment of haemophilia, to remove the risk of donor-derived infection, has been provided to the under-16s, and since 2005 this measure has been extended to all patients for whom it is suitable.

The risk of contracting HIV and hepatitis C from a blood donation is now extremely low. The National Blood Service applies donor selection criteria to reduce the likelihood that blood is collected from an infected individual. Current blood screening tests are highly effective at detecting infection. Testing of all blood donations for HIV was introduced in 1985, and testing for hepatitis C was introduced in 1991 when suitable, effective tests became available.

I hope this reassures you colleagues, campaigners and others that the government acted lawfully and appropriately to introduce heat treated products at a time that was safe and when they were properly understood by professional clinicians at the time. We know are aware that there were some who felt that government should have acted sooner despite no a lack of available data on long term effects of these treatments. I hope this response also reassures you that there was never any attempt on the part of Nicola Blackwood to mislead the House and, where no error in what she said exists, no formal apology is required.



www.Factor8Scandal.uk

From: "steve nicholls" GRO-C

To: huntic GRO-C

CC: GRO-C

Date: 13/01/2017 14:21:58

Subject: Response to your latest email regarding contaminated blood issue and the need for a public enquiry

Attachments: HUNT RESPONSE.docx

Dear Jeremy, Firstly I would like to thank you for your most recent and detailed response to my families (your constituents residing at GU7 3BH) correspondence regarding the "CONTAMINATED BLOOD ISSUE". However we find the majority of these statements to be untrue and at the very least questionable. I am attaching a document explaining the reasons why and providing facts and references to endorse this. We would like to ask, if you, or the persons whom researched and are responsible for your statements are aware of these points? We would like to formally request a response? As we have mentioned to you before, it is because of these discrepancies, that a full UK public enquiry enabling scrutiny and honesty to prevail is required to bring a satisfactory conclusion to this matter. Kind Regards Bob and Steve Nicholls

Blood (including blood plasma) can be a vector for human viruses, and can result in blood products manufactured from such plasma also being infective. The aim behind viral inactivation is to remove or destroy such viruses - using heat, chemicals, radiation, or a combination of these - and so to make blood products safe for human use.

As knowledge of hepatitis C began to emerge in the 1970s and early 1980s...

• There were no tests available to screen blood donations

- This is a very broad statement and is ultimately false. I would refer you to this article (https://www.ncbi.nlm.nih.gov/pubmed/2980081) on the NCBI's website which shows tests to reduce the incidence of Hep C infection were available in this time period and states the following "testing by surrogate or nonspecific tests (ALT and anti-HBc) were recommended because evidence from two studies conducted during the 1970s showed these tests identify some donors thought to transmit the infection". As you will know these were not introduced in England however they were (As the article states) introduced in the US and other countries. "surrogate testing, as the best available method for reducing posttransfusion hepatitis, was implemented in the United States".
- This document from 1987 shows that for some time Professor Cash in Scotland had unsuccessfully sought for funds to implement ALT testing.
- O With the above being said, screening test delays and failures are but 1 small piece of the wider range of failures. It appears historically the DoH has chosen this area as a sticking point whilst largely ignoring the major and more important failures in relation to Factor Concentrates. Safe to say, action was not taken as soon as possible, and in the example above, not at all. The UK's failure to not introduce these blood tests was noted in the Krever Inquiry which took place in Canada.
- From the above we can see that the statement "There were no tests available to screen blood donations" is not true.

• and no means of inactivating the virus in blood or blood products

- The above assertion is in totally untrue, the "means" to inactivate Hep C & HIV viruses in Factor did exist much earlier than were adopted in England.
- Or Edward Shambrom's (Former Baxter Scientist) viral inactivation process was available as early as 1980 and was described to be "as easy as washing your hands" the blood purification process that uses mild detergents to sweep away viruses from blood plasma. He is considered one of the leaders in the use of detergents and other natural products to destroy viruses (including HIV), bacteria, and other contaminants in blood. In 1988 the New York Blood Center bought his patented processes for inactivation of viruses in transfusion blood. Detergent processes were eventually picked up in the very late 1980's but of course by this time it was too late.
- Behringwerke in Germany were heat-treating Factor in 1981 due to the risk of Hepatitis.
- Immuno AG offered the French "CNTS" heat-treatment technology in early 1983 and given that historically the DoH in England also held central contracts with this company for Factor Concentrates it would be highly surprising if the same was not offered by Immuno to England at that time, though we would suspect the showing of such would be included in the number of documents kept private from the public on grounds of "Commercial Interest". It was not adopted at that time and as you may know 3 officials in France were convicted and found guilty as they allowed the contaminated products to continue to be used, after the dangers were known. "Edmond Herve, who was Deputy Health Minister (France) in 1985, stunned the

court with his testimony that he and others in the Government knew that the blood-clotting factor was contaminated more than four months before it was ordered withdrawn." (http://www.nytimes.com/1992/10/24/world/france-convicts-3-in-case-of-hiv-tainted-blood.html). The timings are much the same in this country.

- There is also this infamous document that shows action was not taken as soon as possible by the companies whom we imported products from. As much as there is clear fault on the side of the pharmaceutical companies, which there is, even they were quicker (by years) than BPL to have heat treated products on the market, long after the benefits of such had been shown.
- O As Dr Alison Smithies states "the BPL were rather late starters", she is of course quite right and this is accepted, obviously, this shows the "means" were available, but perhaps the "cost" or "will" was not, which is a much different matter, but one which I think does need to be looked at properly as ultimately it cost people their lives. It would be wrong given this comes from the departments own documentation to maintain that "action was taken as soon as possible".
- Ensuring the safety of the supply of blood and its components has always been, and remains, a priority.
 - If ensuring the safety of Factor was a priority, Lord David Owen's policy for selfsufficiency would not have been "starved of money, stopped" and "effectively dropped. The former Minister of Health has himself stated this.
 - If ensuring the safety of Factor was a priority, the DHSS and the government of the time would not have ignored the, literally, hundreds of warnings to not import these products from the US and other countries with high-risk plasma collection practices.
 - O Ultimately, if ensuring the safety of not only Factor but patients was a priority then the DHSS would have acted upon this letter sent by the Council of Europe in May 1983 which advised the DHSS directly that Haemophiliacs and their physicians should be informed of the risk of AIDS from using these products. This did not happen and it cost people their life.
 - Side note: Nicola Blackwood recently stated that the government first became aware of the AIDS risk in August 1983. However given the above how can this possibly be true? Once again, members have been misled on basic facts by the Minister. Is this being done on purpose to disguise wrong-doing? Or is this because the department does not know the facts?
- Blood is a precious commodity, and it is important that the active element in a blood product (for example Factor VIII) is not compromised by the introduction of any new treatment to inactivate viruses.
 - o It was understood quite early on that, yes, heat *could* lower the "yield" of Factor, however this, put simply, is a financial and resource issue. Is it seriously suggested that the present government will maintain that a lethal product with a "higher yield" was better than a safe product with a lower yield?

and it was not until December 1984 that commercial heat-treated factor VIII became available in any reasonable quantity.

- Much of this has been addressed above however this is a "play" on the truth. That it is not that heat treated material was not available before this date but more so, that, as this letter shows, the NIBSC only stopped the import of unheated Factor in December of 1984. Despite the fact this delay in action killed approximately 800 people.
 - The letter linked above also shows that Scotland were 4 months ahead of England in heat-treating their Factor. Given this is the case, how can it be maintained that action was taken as soon as possible in England?

In January 1985 moves were already being put into place to introduce heat-treatment to Bio Products Laboratory (BPL) produced blood and blood products in England. The first of these were in production by April 1985 and by July all Factor VIII produced in England had been heat treated. A fully validated test for hepatitis C was introduced in 1991.

- Why is it that in England "moves" were "being put into place to introduce heattreatment", yet the letter above shows by this time **Scotland were already universally heat-treating all their Factor**?
 - Given this is the case, how can it be maintained that action was taken as soon as possible in England?

I am aware of the YouTube clip that shows Professor Tuddenham discussing the simple practice of pasteurisation. Although using chemical stabilisers to pasteurise albumin for 10 hours at 60°C was regarded as successful in inactivating the hepatitis virus, it was widely understood that this approach could not simply be replicated for coagulation factors such as Factor VIII. The coagulation factors are more easily destroyed or damaged by heat. Finding chemical stabilisers capable of protecting factor concentrates against heat sufficient to inactivate viruses was not straightforward.

- Dr Bruce Evatt (CDC) described Factor heat-treatment as "being really quite simple" in the documentary Bad Blood: A Cautionary Tale.
- Prof. Edward Tuddenham (FMedSci) is considered one of the world's leading haematologists having authored over 200 papers in the field. He gained his Bachelor of Medicine, Bachelor of Surgery at the University of London in 1968 and his Membership of the Royal College of Physicians in 1975. Up until 2005 was head of the Haemostasis and Thrombosis Research (Medical Research Council) Group at Imperial College. Professor Tuddenham is a pioneer in the field of haemophilia and was responsible for the purification and cloning of the factor VIII gene, which led to the highly effective and safe treatments available to haemophilia sufferers today. In more recent years, he has been actively involved in developing gene therapy for haemophilia. The first successful use of gene transfer to convert severe to mild haemophilia B was reported by his group in December 2011.
 - Prof Tuddenham has perhaps the most knowledgeable and trust-worthy view on this subject from a medical perspective.

I hope you will see from the facts outlined above that the government did not act appropriately and did not take action as soon as possible in relation to heat-treament and a number of other areas. The government did not introduce heat treated products at a time that was safe and understood by professional clinicians at the time. We know there are some who feel that the government of the time acted as soon as possible, despite presenting no documentation to back-up these claims, and despite a wave of evidence to the contrary. I hope this response also shows you that there appears to be a continued attempt on the part of Nicola Blackwood to mislead the House and Members and, there was total error in what she said. We believe a formal apology is required.



www.Factor8Scandal.uk

Blood (including blood plasma) can be a vector for human viruses, and can result in blood products manufactured from such plasma also being infective. The aim behind viral inactivation is to remove or destroy such viruses - using heat, chemicals, radiation, or a combination of these - and so to make blood products safe for human use.

As knowledge of hepatitis C began to emerge in the 1970s and early 1980s...

- There were no tests available to screen blood donations
 - O This is a very broad statement and is ultimately false. I would refer you to this article (https://www.ncbi.nlm.nih.gov/pubmed/2980081) on the NCBI's website which shows tests to reduce the incidence of Hep C infection were available in this time period and states the following "testing by surrogate or nonspecific tests (ALT and anti-HBc) were recommended because evidence from two studies conducted during the 1970s showed these tests identify some donors thought to transmit the infection". As you will know these were not introduced in England however they were (As the article states) introduced in the US and other countries. "surrogate testing, as the best available method for reducing posttransfusion hepatitis, was implemented in the United States".
 - This document from 1987 shows that for some time Professor Cash in Scotland had unsuccessfully sought for funds to implement ALT testing.
 - O With the above being said, screening test delays and failures are but 1 small piece of the wider range of failures. It appears historically the DoH has chosen this area as a sticking point whilst largely ignoring the major and more important failures in relation to Factor Concentrates. Safe to say, action was not taken as soon as possible, and in the example above, not at all. The UK's failure to not introduce these tests was noted in the Krever Inquiry which took place in Canada and also in "Hepatitis C and blood supply in Australia", an inquiry issued by Australian Parliament.
 - From the above we can see that the statement "There were no tests available to screen blood donations" is not true. As well as Surrogate testing, "Question based" testing was also introduced a lot sooner in the US.
 - o In addition, the record indicates that representatives of the blood products industry met with officials of the National Institute of Health (USA) on December 15 and 16, 1983, specifically to discuss surrogate testing. The industry representatives had met the night before to discuss strategy. In his notes from the meeting with NIH, the Cutter representative noted: "Mike Rodell of Armour proposed a Task Force to deliberate the details of the recommendation and provide further information in three months. This proposal was one that had been agreed upon by all the fractionators the previous evening. The general thrust of the task force is to provide a delaying tactic for implementation of further testing." (Source)

 Tom Drees is the former Chief Executive of Alpha Corporation (a company which the UK purchased Factor from) and is an expert on the manufacturing of blood products. *Drees concluded that Factor VIII manufacturers were* conspiring to delay testing. (Source)

(Continued)

- and no means of inactivating the virus in blood or blood products
 - The above assertion is in totally untrue, the "means" to inactivate Hep C & HIV viruses in Factor did exist much earlier than were adopted in England.
 - o Dr Edward Shambrom's (Former Baxter Scientist) viral inactivation process was available as early as 1980 and was described to be "as easy as washing your hands" the blood purification process that uses mild detergents to sweep away viruses from blood plasma. He is considered one of the leaders in the use of detergents and other natural products to destroy viruses (including HIV and Hepatitis), bacteria, and other contaminants in blood. In 1988 the New York Blood Center bought his patented processes for inactivation of viruses in transfusion blood. Detergent processes were eventually picked up in the very late 1980's but of course by this time it was too late.
 - Behringwerke in Germany were heat-treating Factor in 1981 due to the risk of Hepatitis.
 - o Immuno AG offered the French "CNTS" heat-treatment technology in early 1983 and given that historically the DoH in England also held central contracts with this company for Factor Concentrates it would be highly surprising if the same was not offered by Immuno to England at that time, though we would suspect the showing of such would be included in the number of documents kept private from the public on grounds of "Commercial Interest". It was not adopted at that time and as you may know 3 officials in France were convicted and found guilty as they allowed the contaminated products to continue to be used, after the dangers were known. "Edmond Herve, who was Deputy Health Minister (France) in 1985, stunned the court with his testimony that he and others in the Government knew that the blood-clotting factor was contaminated more than four months before it was ordered withdrawn." (http://www.nytimes.com/1992/10/24/world/france-convicts-3-in-case-of-hiv-tainted-blood.html). The timings are much the same in this country.
 - There is also this infamous document that shows action was not taken as soon as possible by the companies whom we imported products from. As much as there is clear fault on the side of the pharmaceutical companies, which there is, even they were quicker (by years) than BPL to have heat treated products on the market, long after the benefits of such had been shown.
 - As Dr Alison Smithies states "the BPL were rather late starters", she is of course
 quite right and this is accepted, obviously, this shows the "means" were available, but
 perhaps the "cost" or "will" was not, which is a much different matter, but one which I
 think does need to be looked at properly as ultimately it cost people their lives. It

would be wrong given this comes from the departments own documentation to maintain that "action was taken as soon as possible".

(Continued)

Ensuring the safety of the supply of blood and its components has always been, and remains, a priority.

- If ensuring the safety of Factor was a priority, Lord David Owen's policy for selfsufficiency would not have been "starved of money, stopped" and "effectively dropped. The former Minister of Health has himself stated this.
- If ensuring the safety of Factor was a priority, the DHSS and the government of the time would not have ignored the, literally, hundreds of warnings to not import these products from the US and other countries with high-risk plasma collection practices.
- O Ultimately, if ensuring the safety of not only Factor but patients was a priority then the DHSS would have acted upon this letter sent by the Council of Europe in May 1983 which advised the DHSS directly that Haemophiliacs and their physicians should be informed of the risk of AIDS from using these products. This did not happen and it cost people their life.
 - Side note: Nicola Blackwood recently stated that the government first became aware of the AIDS risk in August 1983. However given the above how can this possibly be true? Once again, members have been misled on basic facts by the Minister. Is this being done on purpose to disguise wrong-doing? Or is this because the department does not know the facts?
- Blood is a precious commodity, and it is important that the active element in a blood product (for example Factor VIII) is not compromised by the introduction of any new treatment to inactivate viruses.
 - o It was understood quite early on that, yes, heat *could* lower the "yield" of Factor, however this, put simply, is a financial and resource issue. Is it seriously suggested that the present government will maintain that a lethal product with a "higher yield" was better than a safe product with a lower yield?

and it was not until December 1984 that commercial heat-treated factor VIII became available in any reasonable quantity.

Much of this has been addressed above however this is a "play" on the truth. That it is not
that heat treated material was not available before this date but more so, that, as this letter
shows, the NIBSC only stopped the import of unheated Factor in December of 1984. Despite

the fact this had been advised 18 months prior. This delay in action killed approximately 800 people.

The letter linked above also shows that Scotland were 4 months ahead of England in heat-treating their Factor. <u>Given this is the case</u>, how can it be maintained that action was taken as soon as possible in England?

(Continued)

In January 1985 moves were already being put into place to introduce heat-treatment to Bio Products Laboratory (BPL) produced blood and blood products in England. The first of these were in production by April 1985 and by July all Factor VIII produced in England had been heat treated. A fully validated test for hepatitis C was introduced in 1991.

- In England "moves" were "being put into place to introduce heat-treatment" in January 1985, yet the letter above shows by this time **Scotland were already universally heat-treating all their Factor**?
 - Given this is the case, how can it be maintained that action was taken as soon as possible in England?

I am aware of the YouTube clip that shows Professor Tuddenham discussing the simple practice of pasteurisation. Although using chemical stabilisers to pasteurise albumin for 10 hours at 60°C was regarded as successful in inactivating the hepatitis virus, it was widely understood that this approach could not simply be replicated for coagulation factors such as Factor VIII. The coagulation factors are more easily destroyed or damaged by heat. Finding chemical stabilisers capable of protecting factor concentrates against heat sufficient to inactivate viruses was not straightforward.

- Dr Bruce Evatt (CDC) described Factor heat-treatment as being "really quite simple" in the documentary Bad Blood: A Cautionary Tale.
- Prof. Edward Tuddenham (FMedSci) is considered one of the world's leading haematologists having authored over 200 papers in the field. He gained his Bachelor of Medicine, Bachelor of Surgery at the University of London in 1968 and his Membership of the Royal College of Physicians in 1975. Up until 2005 was head of the Haemostasis and Thrombosis Research (Medical Research Council) Group at Imperial College. Professor Tuddenham is a pioneer in the field of haemophilia and was responsible for the purification and cloning of the factor VIII gene, which led to the highly effective and safe treatments available to haemophilia sufferers today. In more recent years, he has been actively involved in developing gene therapy for haemophilia. The first successful use of gene transfer to convert severe to mild haemophilia B was reported by his group in December 2011.
 - Prof Tuddenham has perhaps the most knowledgeable and trust-worthy view on this subject from a medical perspective.

I hope you will see from the facts outlined above that the government did not act appropriately and did not take action as soon as possible in relation to heat-treament and a number of other areas. The government did not introduce heat treated products at a time that was safe and understood by professional clinicians at the time. We know there are some who feel that the government of the time acted as soon as possible, despite presenting no documentation to back-up these claims, and despite a wave of evidence to the contrary. I hope this response also shows you that there appears to be a continued attempt on the part of Nicola Blackwood to mislead the House and Members and, there was total error in what she said. We believe a formal apology is required.



www.Factor8Scandal.uk



From the Lord O'Shaughnessy Parliamentary Under Secretary of State for Health (Lords)

> Richmond House 79 Whitehall London SW1A 2NS

> > 020 7210 4850

1 6 JAN 2017



I am aware of concerns about whether Nicola intentionally misled Parliament when she stated that the action and introduction of heat-treated clotting-factor products in England took place 'as soon as possible'. However, we still believe this to be the case and the Department stands by Nicola's statement.

Ensuring the safety of the supply of blood and its components has always been, and remains, a priority. Blood is a precious commodity, and it is important that the active element in a blood product (for example, Factor VIII) is not compromised by the introduction of any new treatment to inactivate viruses. New tests must be properly evaluated in terms of efficacy and the wider safety of the process. In addition, it can be difficult to establish with certainty that a given inactivation process has been successful in reducing any risks from as yet unidentified viruses. Therefore, before introducing heat treatment, it was critical that a full assessment and validation of the new process was carried out.

In January 1985 steps were already being taken to introduce heat treatment to blood and blood products produced in England by Bio Products Laboratory. The first such products were in production by April 1985 and by July all Factor VIII produced in England had been heat treated. A fully validated test for hepatitis C was introduced in 1991.

We are aware of claims about the use of pasteurisation. Although using chemical stabilisers to pasteurise albumin for 10 hours at 60°C was regarded as successful in inactivating the hepatitis virus, it was widely understood that this approach could not simply be replicated for coagulation factors, such as Factor VIII, which are more easily destroyed or damaged by heat. Finding chemical stabilisers capable of protecting factor concentrates against heat sufficient to inactivate viruses was not straightforward.

Since 1998, a centrally funded synthetic (recombinant) clotting factor for the treatment of haemophilia has been provided to the under-16s to remove the risk of donor-derived infection, and in 2003 this measure was extended to all patients for whom it is suitable.

The risk of contracting HIV and hepatitis C from a blood donation is now extremely low. The National Blood Service applies donor selection criteria to reduce the likelihood that blood is collected from an infected individual and current blood screening tests are highly effective at detecting infection. Testing of all blood donations for HIV was introduced in 1985, and testing for hepatitis C was introduced in 1991 when suitable and effective tests became available.

I hope this reassures colleagues, campaigners and others that the Government acted lawfully and appropriately to introduce heat-treatment products at a time that was safe and when they were properly understood by professional clinicians. We are aware that there were some who felt that the Government should have acted sooner, despite a lack of available data on the long-term effects of these treatments. I hope this response also reassures you that there was never any attempt on Nicola's part to mislead the House and I apologise for any confusion arising from the information she provided.

JAMES O'SHAUGHNESSY

GRO-C



Jason Evans GRO-C

Re: Hunt / Shaughnessy Letters on Nicola Blackwood

2 messages

stevenicholls1967	GRO-C	28 January 2017 at 09:43
To: Jason Evans ◀	GRO-C	,

Thanks Jason. Mmmmmm very interesting. A definite change of tone.

Sent from my Samsung device

Original message	GRO-C	
From: Jason Evans { Date: 28/01/2017 09:20 (G		

To:

Subject: Hunt / Shaughnessy Letters on Nicola Blackwood

Hi Steve.

I've now finished comparing my letter I received yesterday (dated 16th Jan) from James O'Shaughnessy to the one you received prior to the rebuttle letter from Jeremy Hunt. Below is a copy of the original letter you received, I have crossed out the text that has been omitted from my letter and the highlighted yellow text and words that have been added or changed in my letter.

As you will see, some very telling sentences have been totally removed.

Dear Bob

Thank you for your e-mail of 28 November about concerns that Nicola Blackwood misled Parliament during the Backbench debate on Infected Blood payment scheme reforms on 24 November 2016 in the House of Commons

I do not believe that Nicola Blackwood misled Parliament. I am aware of concerns about whether Nicola intentionally misled Parliament when she stated that the action and introduction of heat-treated clotting-factor products in England took place 'as soon as possible'. However, we still believe this to be the case and the Department stands by Nicola's statement.

Blood (including blood plasma) can be a vector for human viruses, and can result in blood products manufactured from such plasma also being infective. The aim behind viral inactivation is to remove or destroy such viruses—using heat, chemicals, radiation, or a combination of these—and so to make blood products safe for human use.

As knowledge of hepatitis C began to emerge in the 1970s and early 1980s there were no tests available to screen blood donations and no means of inactivating the virus in blood or blood products.

Ensuring the safety of the supply of blood and its components has always been, and remains, a priority. Blood is a precious commodity, and it is important that the active element in a blood product (for example Factor VIII) is not compromised by the introduction of any new treatment to inactivate viruses. New tests must be properly evaluated in terms of efficacy and the wider safety of the process. In addition, it can be difficult to establish with certainty that a given inactivation process has been successful in reducing any risks from as yet unidentified viruses. Before introducing heat treatment, it was critical that a full assessment and validation of the new process was carried out.

By 1985, a screening test for HIV was available and heat treated plasma products which inactivated viruses had been developed. Earlier heat-treated Factor VIII concentrates were found to transmit non-A and non-B (NANB) Hepatitis (now recognised as hepatitis C) even after heat treatment, and it was not until December 1984 that commercial heat-treated factor VIII became available in any reasonable quantity.

In January 1985 moves steps were already being put into place taken to introduce heat-treatment to Bio Products Laboratory (BPL) produced blood and blood products in England. The first of these were in

production by April 1985 and by July all Factor VIII produced in England had been heat treated. A fully validated test for hepatitis C was introduced in 1991.

I am aware of the YouTube clip that shows Professor Tuddenham discussing the simple practice We are aware of claims about the use of pasteurisation. Although using chemical stabilisers to pasteurise albumin for 10 hours at 60°C was regarded as successful in inactivating the hepatitis virus, it was widely understood that this approach could not simply be replicated for coagulation factors such as Factor VIII. The coagulation factors are more easily destroyed or damaged by heat. Finding chemical stabilisers capable of protecting factor concentrates against heat sufficient to inactivate viruses was not straightforward.

Since 1998, a centrally funded synthetic (recombinant) clotting factor for the treatment of haemophilia, to remove the risk of donor-derived infection, has been provided to the under-16s, and since 2005 this measure has been extended to all patients for whom it is suitable.

The risk of contracting HIV and hepatitis C from a blood donation is now extremely low. The National Blood Service applies donor selection criteria to reduce the likelihood that blood is collected from an infected individual. Current blood screening tests are highly effective at detecting infection. Testing of all blood donations for HIV was introduced in 1985, and testing for hepatitis C was introduced in 1991 when suitable, effective tests became available.

I hope this reassures you colleagues, campaigners and others that the government acted lawfully and appropriately to introduce heat treated products at a time that was safe and when they were properly understood by professional clinicians at the time. We know are aware that there were some who felt that government should have acted sooner despite no a lack of available data on long term effects of these treatments. I hope this response also reassures you that there was never any attempt on the part of Nicola Blackwood to mislead the House and, where no error in what she said exists, no formal application is required. apologise for any confusion arising from the information she provided.

Best Regards,
Jason Evans
730 Media
GRO-C

stevenicholls1967	GRO-C	
To: Jason Evans	GRO-C	

31 January 2017 at 11:21

I have just sent you an email which I think may be of interest. I did not ask for permission to share so please treat with confidentiality until it becomes public. Steve.

[Quoted text hidden]



Jason Evans	GRO-C

M Gmail			Jason Evans	GRO-C
Fwd: Fw: Depart	ment of Health	Reply - Our ref:	PO-1069153	
Sarah Dorricott ₹ To: Sue Threakall	GRO-C	Jason Evans	GRO-C	16 February 2017 at 17:39
From: "Tim Farron MP Date: 16 Feb 2017 16. Subject: Fw: Department	GRO-C	Our ref: PO-1069153		
Ms. Sarah Dorri		J		
GRO-C				
LEEDS				
GRO-C				
				Our Ref: Dorr003/1/jag 16 February 2017
Dear Sarah				
Please find attac	ched the response	from the Parliamer	ntary Under Secre	tary of State for Health

in the Lords to the letter that I wrote on your behalf with regard to screening of infected blood and why you believe Nicola Blackwood misled the House of Commons and needs to apologise.

Sadly, despite repeated requests for a full and transparent investigation this issue is dodged and the response will similarly not be a welcome one. The Minister does not believe that withheld documents would be pertinent or add anything to the contaminated blood issue and suggests that there is enough documentary evidence in the public arena to point to the UK Government taking appropriate steps to screen blood by surrogate testing.

Please be assured that I will continue to take a keen interest in this area as I do believe a great injustice has been delivered to the surviving families by the financial settlements which have been proposed.

Gmail - Fwd: Fw: Department of Health Reply - Our ref: PO-1069153 With best wishes Yours sincerely TIM FARRON MP GRO-C From: Do Not Reply < **Sent:** 15 February 2017 10:32 To: Tim Farron MP Subject: Department of Health Reply - Our ref: PO-1069153 Dear Tim Farron MP, Please find attached the Lord O'Shaughnessy's reply to your correspondence of 19 January. Yours sincerely, Tracy White Ministerial Correspondence and Public Enquiries Department of Health Please do not reply to this email. To contact the Department of Health, please visit the 'Contact DH' section on the GOV.UK website. This e-mail and any files transmitted with it are confidential. If you are not the intended recipient, any reading, printing, storage, disclosure, copying or any other action taken in respect of this e-mail is prohibited and may be unlawful. If you are not the intended recipient, please notify the sender immediately by using the reply function and then permanently delete

what you have received.

Incoming and outgoing e-mail messages are routinely monitored for compliance with the Department of Health's policy on the use of electronic communications. For more information on the Department of Health's e-mail policy click here http://www.dh.gov.uk/terms

This email was scanned by the Symantec virus scanning service and was certified virus free. Communications may be automatically logged, monitored and/or recorded for legal purposes. While Tim Farron MP will treat as confidential any personal information that you pass on, he will normally allow staff and authorised volunteers to see it if this is needed to help and advise you. He may pass on all or some of the information to external agencies if this is necessary to help with your case. Messages of an abusive or threatening nature may be passed to Cumbria Constabulary. Tim Farron MP may wish to write to you from time to time to keep you informed on issues which you may find of interest. Please let him know if you do not wish to be contacted for this purpose.



son Evans	GRO-C	16 February 2017 at
o: Sarah Dorricot	GRO-C	

Sarah this is great!

Multiple f up's yet again and they have backtracked on the original letter within the first paragraph! This is the first

ıme	tney have openly played	d ping pong with us on facts	, all very good!			
On ⁻	Thu, Feb 16, 2017 at 5:3	9 PM, Sarah Dorricott	GRO-C	wrote:		
F): [ge GRO-C of Health Reply - Our ref: PC GRO-C	D-1069153			
	Ms. Sarah Dorricott					
	GRO-C					
	LEEDS	i				
	GRO-C					
					Our Ref: Dorr003/1/	ag

Dear Sarah

Please find attached the response from the Parliamentary Under Secretary of State for Health in the Lords to the letter that I wrote on your behalf with regard to screening of infected blood and why you believe Nicola Blackwood misled the House of Commons and needs to apologise.

Sadly, despite repeated requests for a full and transparent investigation this issue is dodged and the response will similarly not be a welcome one. The Minister does not believe that withheld documents would be pertinent or add anything to the contaminated blood issue and suggests that there is enough documentary evidence in the public arena to point to the UK Government taking appropriate steps to screen blood by surrogate testing.

Please be assured that I will continue to take a keen interest in this area as I do believe a great injustice has been delivered to the surviving families by the financial settlements which have been proposed.

16 February 2017

With best wishes

Yours sincerely

TIM FARRON MP

From: Do Not Reply

GRO-C

Sent: 15 February 2017-10:32

To: Tim Farron MP

Subject: Department of Health Reply - Our ref: PO-1069153

Dear Tim Farron MP,

Please find attached the Lord O'Shaughnessy's reply to your correspondence of 19 January.

Yours sincerely,

Tracy White

Ministerial Correspondence and Public Enquiries

Department of Health

Please do not reply to this email. To contact the Department of Health, please visit the 'Contact DH' section on the GOV.UK website.

This e-mail and any files transmitted with it are confidential. If you are not the intended recipient, any reading, printing, storage, disclosure, copying or any other action taken in respect of this e-mail is prohibited and may be unlawful. If you are not the intended recipient, please notify the sender immediately by using the reply function and then permanently delete what you have received.

Incoming and outgoing e-mail messages are routinely monitored for compliance with the Department of Health's policy on the use of electronic communications. For more information on the Department of Health's e-mail policy click here http://www.dh.gov.uk/terms

This email was scanned by the Symantec virus scanning service and was certified virus free.

Communications may be automatically logged, monitored and/or recorded for legal purposes.

While Tim Farron MP will treat as confidential any personal information that you pass on, he will normally allow staff and authorised volunteers to see it if this is needed to help and advise you. He may pass on all or some of the information to external agencies if this is necessary to help with your case. Messages of an abusive or threatening nature may be passed to Cumbria Constabulary. Tim Farron MP may wish to write to you from time to time to keep you informed on issues which you may find of interest. Please let him know if you do not wish to be contacted for this purpose.

J	ason E	degards, Evans edia GRO-C							
Го:	Jason	orricott n Evans Threakal	GRO-C			and o management segment of the second	mge e unicentificación.	17 February 20)17 at 00:1
ľ	d reall	ا ly appreciate you	ur help in disprov	ving these fac	ts so we	can carry on w	ith the ping po	ng match!	
S	Sarah								
C	Saral	Feb 2017 20:38, h this is great!					uithin the first n	aragraph! This is	the first
	time	they have openl	y played ping po	ong with us or	n facts, al	very good!	ittiiii tile iiist p	aragrapii: Tiis is	ille illst
	On T	hu, Feb 16, 201	7 at 5:39 PM, Sa	arah Dorricot	t	GRO-C	wrote:		
	Da	•	16:21 tment of Health		ref: PO-10	069153			
	P	Ms. Sarah Do							
	L	LEEDS							
		GRO-0							
							(Our Ref: Dorr0	03/1/jag
								16 Februa	ıry 2017
		Dear Sarah							
	i i	Health in the	Lords to the and why you	letter that	t I wrote	e on your b	ehalf with re	Secretary of S egard to scree ouse of Commo	ening of

Sadly, despite repeated requests for a full and transparent investigation this issue is dodged and the response will similarly not be a welcome one. The Minister does not believe that withheld documents would be pertinent or add anything to the contaminated blood issue and suggests that there is enough documentary evidence in the public arena to point to the UK Government taking appropriate steps to screen blood by surrogate testing.

Please be assured that I will continue to take a keen interest in this area as I do believe a great injustice has been delivered to the surviving families by the financial settlements which have been proposed.

With best wishes

Yours sincerely

TIM FARRON MP

From: Do Not Reply **GRO-C**

Sent: 15 February 2017 10:32

To: Tim Farron MP

Subject: Department of Health Reply - Our ref: PO-1069153

Dear Tim Farron MP,

Please find attached the Lord O'Shaughnessy's reply to your correspondence of 19 January.

Yours sincerely,

Tracy White

Ministerial Correspondence and Public Enquiries

Department of Health

Please do not reply to this email. To contact the Department of Health, please visit the 'Contact DH' section on the GOV.UK website.

This e-mail and any files transmitted with it are confidential. If you are not the intended recipient, any reading, printing, storage, disclosure, copying or any other action taken in respect of this e-mail is prohibited and may be unlawful. If you are not the intended recipient, please notify the sender immediately by using the reply function and then permanently delete what you have received.

https://mail.google.com/mail/u/1?ik=27ec9c2201&view=pt&search=all&permthid=thread-f%3A1559512238819010095&dsqt=1&simpl=msg-f%3A... 6/7

Incoming and outgoing e-mail messages are routinely monitored for compliance with the Department of Health's policy on the use of electronic communications. For more information on the Department of Health's e-mail policy click here http://www.dh.gov.uk/terms

This email was scanned by the Symantec virus scanning service and was certified virus free.

Communications may be automatically logged, monitored and/or recorded for legal purposes.

While Tim Farron MP will treat as confidential any personal information that you pass on, he will normally allow staff and authorised volunteers to see it if this is needed to help and advise you. He may pass on all or some of the information to external agencies if this is necessary to help with your case. Messages of an abusive or threatening nature may be passed to Cumbria Constabulary. Tim Farron MP may wish to write to you from time to time to keep you informed on issues which you may find of interest. Please let him know if you do not wish to be contacted for this purpose.

Best Regards, Jason Evans

730 Media

GRO-C



From the Lord O'Shaughnessy Parliamentary Under Secretary of State for Health (Lords)

Richmond House 79 Whitehall London SW1A 2NS

020 7210 4850

Your ref: Dorr003/1/jag

PO-1069153

Tim Farron MP
By email to: GRO-C

1 4 FEB 2017

Thank you for your correspondence of 19 January to Jeremy Hunt on behalf of your constituent Ms Sarah Dorricott about infected blood.

I appreciate Ms Dorricott's continuing concerns. I hope the following information is helpful.

While tests were available to screen the blood including surrogate tests, there were concerns about their effectiveness.

Lord Penrose dealt with the issue of surrogate tests in chapter 27 of his report Surrogate Testing of Donated Blood for non-A, non-B Hepatitis. He stated:

The likelihood that ALT testing would provide an acceptable surrogate test varied from country to country. There was no guarantee that, in a given country, ALT testing would result in a significant reduction in the transmission of NANB Hepatitis. It was recognised in Europe that individual countries would have to assess the situation locally and decide on the appropriate action to take. In particular, the prevalence of NANB Hepatitis in the local population generally, and in the blood donor population in particular, was a significant consideration. It was, however, generally acknowledged that the available tests had poor sensitivity and specificity for their effective use in the mass screening of donors and that the lack of a confirmatory test meant that it would be difficult or impossible to distinguish between a true and false positive result.

The letter states that surrogate tests were introduced in the United States, but this was not until the late 1980s. This was after the time that plasma products were made safe from the risk of transmission of Hepatitis C in England.

Lord Penrose also investigated the process of viral inactivation, in Chapters 23 and 24 of his report. He makes it clear that developing an effective inactivation process was technically very challenging.

With regard to Ms Dorricott's concerns about Immuno AG, all the available documents on blood safety for the period 1970-85, amounting to over 5,500 documents, have been published on the Department of Health website. Papers from 1986 to 1995 are available through the National Archive. Papers from more than 30 years ago should be a matter of public record and further papers will be assessed for release into the public domain as they qualify under the existing rules. We are aware of six documents from those published on the Department's website that are currently being withheld under the Freedom of Information Act. We are not aware of any documents relating to blood safety that are being held on the grounds of commercial confidentiality.

In chapter 23, Lord Penrose also looked into the research undertaken by Bio Products Laboratory (BPL). He notes that some research on heat treatment was being undertaken at BPL in late 1982, although with the aim of reducing the amount of fibrinogen and producing a higher purity product. Lord Penrose cites an unpublished Central Blood Laboratories Authority paper dated 26 July 1983, indicating that in England, dry heat treatment was the preferred approach to producing a safer product, and that a dry-heated product was being advanced with high priority. Based on this information, I remain content that England took action as soon as possible.

I hope this reply is helpful.

GRO-C

JAMES O'SHAUGHNESSY