Witness Name: Dr Shanida Nataraja
Statement No.: WITN7663001
Exhibits: Nil
Dated: 28 February 2023

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR SHANIDA NATARAJA

I provide this statement in response to a request under Rule 9(1) and (2) of the Inquiry Rules 2006 dated 14 February 2023.

I, Dr Shanida Nataraja, will say as follows: -

Section 1: Introduction

1. Please set out your name, address, date of birth and any professional qualifications relevant to the work you undertook for the Department of Health.

Name: Shanida Helena Nataraja
Address: GRO-C
Date of birth: GRO-C 1973
PhD, Neuroscience, University College London (UCL)
BSc (First Class Honours), Human Sciences & Neuroscience, UCL

2. Please outline your employment history including the various roles and responsibilities that you have held throughout your career, as well as the dates.

Mar 2001 - Aug 2005

Medical Writer/Senior Medical Writer

Dianthus Medical Limited

Projects included content development for the following:

- Clinical study reports/protocols
- Investigator brochures
- Manuscripts for publication in peer-reviewed journals
- Online disease information for MD Consult
- Training materials

Aug 2005 - Aug 2007

Senior Medical Writer

Discovery London

Projects included content development for the following:

- Scientific symposia
- Patient/nurse information booklets
- Manuscripts for publication in peer-reviewed journals
- Online patient support programmes
- Training materials
- Advisory board meetings

Aug 2007 - Dec 2008

Scientific Director

Discovery London

Responsibilities included the following:

- High-science input to new business activities and pitch attendance
- Coaching and mentoring medical writing teams on new therapy areas
- Senior medical writing support and review of all materials produced on new accounts to ensure high quality deliverable

- Provision of medical writing training to all medical writers to ensure high standards are maintained across the agency, and in line with the agreed personal development goals for each medical writer
- Trouble-shooting with regards to medical writing activities on existing and new accounts
- Ensuring alignment of all writers with in-house medical writing processes
- Close collaboration with Editorial Department and Managing Director to ensure implementation and refinement of in-house quality control processes

Jan 2009 - May 2010
Senior Scientific Director
Medicus International

Responsibilities included the following:

- Head of Scientific Direction department, with line managing responsibility for all scientific directors and associate scientific directors
- High-science input to new business activities and pitch attendance
- In-house medical writing training programme to ensure high standards are maintained across the agency, and in line with the agreed personal development goals for each medical writer
- Coaching and mentoring client service teams on new therapy areas and products
- Writing support and review of all materials produced on new and existing accounts to ensure high quality deliverable
- Trouble-shooting with regards to medical writing activities on existing and new accounts

Jun 2010 - Apr 2013
Editorial and Scientific Director
AXON

Responsibilities included the following:

- Strategic, scientific and editorial input into new and existing accounts as needed
- High-science input to new business activities/pitch attendance
- Implementation of in-house medical writing training programme to ensure high standards are maintained across the agency
- Writing support and review of materials produced on new and existing accounts as needed

May 2013 - Feb 2022

Director, Real-World Evidence, Value & Access

AXON

Responsibilities included oversight over a team of over 25 consultants on a wide range of real-world mandates, including:

- Real-world data generation and analysis, from targeted & systematic literature reviews, communication support for real-world studies, development of study protocols, study reports, and publications, and development of process guidance of the assessment of, and implementation, of health economic and outcomes research
- Real-world value communication, from designing value narratives and messaging, inputting into global value dossiers, developing & implementing analytical and publication plans for real-world research, and symposia and meet-the-expert sessions at industry congresses
- Real-world market access, from market access strategy, landscape analyses, Payor research, disease awareness campaigns, patient advocacy and global healthcare policy

Mar 2022 - Present

Senior Director, Real-World Practice

AXON

In addition to the responsibilities listed for my previous role at AXON, my current responsibilities as Practice Lead include:

- Establishing a long-term sustainable growth plan for AXON, and for the Real-World practice
- Developing, tracking and communicating the Real-World business plan, including talent acquisition, new business, and marketing
- Managing any business-critical issues with, or that impacts, the clients of the Real-World practice

3. Please set out your membership, past or present, of any other committees, associations, parties, societies or groups relevant to the Inquiry's Terms of Reference, including the dates of your membership and the nature of your involvement.

2001–2016 (don't remember exactly when I let my membership lapse): Member of the European Medical Writers' Association (EMWA)

2019–current: Member of the International Society for Pharmacoeconomic and Outcomes Research (ISPOR)

4. Please confirm whether you have provided evidence to, or have been involved in, any other inquiries, investigations or criminal or civil litigation in relation to human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products. Please provide details of your involvement and copies of any statements or reports which you provided

I can confirm that I have not provided evidence to, or have been involved in, any other inquiries, investigations or criminal or civil litigation in relation to human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products.

Section 2: Work for the Department of Health

5. On 7 June 2004 an agreement was signed by Dr Adam Jacobs, on behalf of Dianthus Medical Ltd, and Mr Richard Gutowski, on behalf of the Department of Health, for Dianthus Medical Ltd to "provide the services of one or more of its medical writers to the Department of Health to improve the quality of referencing in a report of hepatitis C and blood transfusions" [WITN5292057].

Please answer the following questions:

a. How did you come to be appointed to undertake the work? What was your experience that was relevant to the work to be undertaken?

If, in the above question, 'you' refers to the company, Dianthus Medical Ltd, I have no recollection of the circumstances under which Dianthus Medical Ltd was appointed to take on this work with the Department of Health. As a junior medical writer at the time, to the best of my recollection, my responsibilities would not have included direct contact with client prior to contracting, or involvement in discussions with client related to the scope or budget for a specific project. Dr Jacobs, as the owner of Dianthus Medical Ltd, was solely responsible for all new business activities. I have no recollection of being told how Dianthus Medical Ltd, or Dr Jacobs specifically, was contacted by the Department of Health or appointed to undertake the work.

If, in the above question, 'you' refers to myself as an individual, I was appointed to undertake the work by Dr Jacobs, as owner of Dianthus Medical Ltd. The scope of the work as defined in WITN5292057 highlights that a key skill needed to execute the project was an ability to appropriately reference a body of text. Having reviewed and developed academic research papers in the past, and attended relevant medical writing training at EMWA, to the best of my recollection, at the time, I had an understanding of what constituted an appropriate reference, and the statements within the report that required a supporting reference. I also had the ability to critically review source documents, extract key messages and synthesize evidence, and edit existing text and create new content when required.

At the time, to the best of my recollection, I didn't have any specific experience in the subject matter (i.e. infectious diseases or the contamination of blood products), or with working with the Department of Health.

b. Prior to the signing of this agreement, what was discussed, and with whom, about the task that was to be completed?

I have no recollection of the circumstances under which Dianthus Medical Ltd was appointed to take on this work with the Department of Health. As a junior medical writer, to the best of my recollection, my responsibilities would not have included direct contact with client prior to contracting, or involvement in discussions related to the scope or budget for a specific project.

c. Was a written "brief" or instructions provided to you prior to commencing the work about what amendments were to be made to the report?

I have no recollection of the way in which I was briefed to work on the project, or the content or nature of that brief, given this project occurred 19 years ago, and I have no record of communications from the relevant time period.

d. What was your understanding of the task that was required to be completed by Dianthus Medical Ltd?

To the best of my recollection, the brief was to improve the quality of referencing in the report, both sourcing references when none had been cited, and checking cited references to ensure they were appropriate. In the materials that have been shared with me by this inquiry, I note that to obtain a proportion of the references, I was required to attend a Department of Health office. Although I do not recollect any specific information related to these onsite visits, I understand that the aim of these visits was to review documents related to the subject at hand to find appropriate references and, if possible, provide a more complete chronology of what was known by the Department of Health and when in relation to the issue of self-sufficiency and the contamination of blood products.

6. When you were engaged by Dr Jacobs for the work under the agreement, noted above, what were you asked to do?
a. Were you supplied with the list of things that were thought by the Department of Health to be required before the report could be made "more widely available" (please see DHSC0020720_081 which suggests that the Department considered it needed an executive summary and additional references)? To what extent does this list accord with your instructions prior to commencing the work on the report? (see also WITN5292016 at paras 4.39 – 4.42).

I have no recollection of any specifics relating to this project, including the instructions I received prior to commencing the work, given it occurred 19 years ago. Therefore I cannot confirm if I was aware of the list of things that were thought by the Department of Heath to be required prior to commencing the work. However, to the best of my recollection, of the three items listed in DHSC0020720_081, I would have been aware of the need to improve the quality of the referencing and the need to develop an executive summary, but I am unlikely to have been aware of the suggestion to ask key contributors to the original report to review the revised report after these amends were made to confirm factual accuracy. The 2004 report (WITN7485007) also contains a list of abbreviations, and amends were made to the

supplementary table detailing the chronology of events described in the report. I assume therefore that these too were requested in the instructions given to me by Dr Jacobs.

7. Were you asked to "redraft the Report in a more robust form" (see DHSC5336358)?If so, what was your understanding of what that meant?

I do not know whether the term 'robust' was used when the Department of Health briefed Dr Adam Jacobs, and I have no recollection of whether the term 'robust' was used when the brief was relayed to me by Dr Adam Jacobs. Given the information provided in WITN5292057 on the need for the quality of the referencing of the report to be improved, and with the many years of medical writing experience I have gained since, I can only assume that, if used, the term 'robust' would have referred to the need for references to be provided for the content of the report, and the need for gaps in the chronology of events to be filled wherever possible, thereby making the findings of the report more robust.

8. Please consider WITN7485005 ("the 2002 draft report"). Was this the report that you were provided with, as the report on which work was required? If not, please provide a copy of the original report you were asked to work on if you have it.

I cannot confirm whether WITN7485005 ("the 2002 draft report") is an exact copy of the report that Dianthus Medical Ltd was provided with. I do not have access to any of the documentation relating to this project, and haven't had so since leaving Dianthus Medical in 2005.

9. During the project that you undertook, were you given any additional instructions of what you were tasked to do? If so please set out who gave those instructions, what they were and when the instructions were given. If there are any documents setting out instructions, please provide them.

I have no recollection of receiving any additional instructions relating to this task. As stated, I do not have access to any documentation relating to this project.

10.Please set out how you went about the task of redrafting / amending the report.

I have no recollection of the exact steps that I took when undertaking the task of improving the quality of the referencing in the report. Given the information provided in the context of this

inquiry, and with the many years of medical writing experience I have gained since, I can only assume that the content of the report would have been reviewed systematically, checking any references cited and flagging any missing references. Gaps in referencing would have then been filled, either through the systematic review of the documentation that was made available to me by the Department of Health, or where appropriate, research of the scientific literature. Once the full reference set had been identified, a check would have been done against these references, to ensure they supported the content and that no changes to the content were needed to be made in light of the content of the references. Amends to the report will have likely been made as a result of finding additional relevant references to support the existing content. As a final step, an executive summary would have been developed in line with the revised content, the table detailing the chronology of events at the end of the document would have been updated with additional milestones identified through the search of source documentation, and an abbreviation list created to define all abbreviations used in the text.

11. It is understood that the work on the report was undertaken with Dr Jacobs. Please explain:

a. What the division of tasks was between you and Dr Jacobs;

I have no recollection of how the tasks were divided by Dr Jacobs and myself, given the project was 19 years ago. However, given Dr Jacobs was the owner of Dianthus Medical and had many years of experience in medical writing at the time, and I had only just started on my career as a medical writer, to the best of my recollection, all of my work would have been checked thoroughly by Dr Jacobs, and amended as needed, prior to sending the final written deliverable to client.

b. Whether there were any disagreements between you and Dr Jacobs about amendments that should be made to the report;

To the best of my recollection, there were no disagreements between Dr Adam Jacobs and myself relating to this project.

c. Who had ultimate responsibility for the writing of the report.

It is my understanding, on reviewing the materials provided to me as part of this inquiry, that the original report was drafted by an individual at the Department of Health. To the best of my recollection, we were commissioned to appropriately reference the original report, filling in

gaps as possible, so the report could be finalized by the Department of Health. As a result of this exercise, some content changes were made. As the owner of the Dianthus Medical Ltd, and given my junior position at the time, to the best of my recollection, Dr Jacobs would have checked all work generated by me before sending a written deliverable to client. Through this senior review, and sign-off, he effectively takes responsibility for the client deliverable. However, as described in the materials shared with me as part of this inquiry, having generated the original 2002 report, the revised 2004 report was then reviewed and approved by one or more individual at the Department of Health before it was published. In my opinion, the ultimate responsibility for the writing of the report rested with the Department of Health. Dianthus Medical Ltd provided editorial support, but given we did not originate the 2002 report, and were not listed as authors on the final report, the Department of Health was responsible for the writing and publishing of this report.

12.When undertaking the task, did you attend at the Department of Health to examine files? If so:

a. **Which files did you consider?**

b. **Why did you consider it necessary to consider files?**

c. **Who provided the files and/or told you which files were available?**

DHSC0200135 may be of assistance – please see the reference on p.2 of this document which states that "colleagues who were present at that time recall seeing the consultants working on documents from the cupboard where the files were held".

I have a vague recollection of attending a Department of Health premises, which may have been located by the river; however, I do not remember any specifics relating to these visits nor the exact number of times I visited the offices nor whether Dr Jacobs accompanied me for any of the visits. To the best of my recollection, during my visit or visits, I was directed to the location in that office building where files relating to the subject at hand were stored. (a) I have no recollection of selecting specific files to review, but assume that I reviewed all files that were made available to me. In the materials provided to me as part of this inquiry, I note that many of the relevant documents were not available at the time of my review, and therefore again I assume that I reviewed all of the surviving documentation. The original 2002 report, and the revised 2004 report, both state that the evidence reviewed was incomplete and sometimes contradictory. (b) Given I have no recollection of selecting specific files to review, I assume that I reviewed all files that were made available to me at the time. I also have no

recollection of who provided the files and/or told me which files were available, who I met or spoke with while in the office premises, or how long the task took me.

13.When undertaking the task, did you interview or have any discussions with anybody about the contents of the report? If so, please set out who you spoke to and what you were told.

I don't remember interviewing or having any discussions with anybody about the contents of the report, either when present in the Department of Health offices or otherwise.

14.It is understood that by September 2004, you had produced a first draft of the re-worked report (DHSC5349579 at p.1, which asserts that "the consultant has now produced a first draft of the report, which concludes that the Department acted reasonably at the time in terms of known infectivity of blood"). Is WITN7485007 the first draft of your report produced in September 2004 ("the 2004 draft report")? If not, please provide, if you are able to, a copy of the report you submitted in September 2004.

I cannot confirm whether WITN7485007 ("the 2004 draft report") is an exact copy of the first draft of the report that Dianthus Medical Ltd provided to the Department of Health. I do not have access to any of the documentation relating to this project, and haven't had so since leaving Dianthus Medical in 2005. On reviewing the documents provided to me by this inquiry, it is worth noting that the 2004 report (WITN7485007) does not conclude "that the Department acted reasonably at the time in terms of known infectivity of blood", as stated in DHSC5349579. The 2004 report states that there was evidence to suggest that in the 1970s and 1980s, the Department of Health was actively pursuing the policy of self-sufficiency and that, at the time, the long-term sequalae of NANBH were not known, and the advantages of Factor VIII concentrates for patients with haemophilia outweighed the risks. This conclusion is given in the context of an introductory statement stating that the evidence reviewed as part of the report was incomplete and at sometimes contradictory.

15.**Please consider WITN7485005 (the 2002 draft report), WITN7485007 (the 2004 draft report) and paragraph 3.25 onwards of WITN7485001. Please explain how the changes to the 2002 draft report came to be made, specifically:**

a. **Who made the changes to the relevant paragraphs of the Report?**

I have no recollection of making the specific changes highlighted, but assume that these changes were made by either myself or Dr Jacobs.

b. Why those changes were made?

Given I have no recollection of making the specific changes highlighted, I cannot provide details about why those changes were made. However, on reviewing the materials provided to me in the context of this inquiry, I note that, many of the statements that have been added are referenced to specified sources cited in the reference list at the end of the document. They therefore reflect a fact or opinion expressed in that source reference. It is worthy of note that the original report (WITN7485005; the 2002 draft report) doesn't include a reference list, although some references to specific documents are made in the text. WITN7485007 (the 2004 draft report) cites 158 references. Changes to the content of the report would be expected as a result of this expanded evidence base, and validating the content of the original report against this evidence base.

c. What evidence was relied upon to make the changes?

As stated, I have no recollection of making the specific changes highlighted. As also stated above, WITN7485007 (the 2004 draft report) cites 158 references, many of which were not cited in the original report. Changes to the content of the report would be expected as a result of this expanded evidence base, and validating the content of the report against this evidence base.

d. Whether the changes represented your view of the documents or whether you were requested to make any of the changes? If you were requested to make changes, please set out who made that request, when the request was made and what was said

I have no recollection of making the specific changes highlighted, or of receiving any specific requests to make specific changes. To the best of my recollection, if I did make any of the listed changes, which I cannot confirm, this would have represented my interpretation of the evidence available to me at the time of writing.

Section 3: Other

I would like to reinforce that I have very limited recollection of the project referred to in this document. The project occurred 19 years ago, and I have been involved in the development & review of hundreds of written deliverables since. My review of the materials provided to me in the context of this inquiry has triggered vague and non-specific memories relating to the project, but my recall of specific details remains limited. It is also worth noting that, at the time of working on the report, I was a junior medical writer, in my first medical writing job since leaving academia. I was not involved in any type of new business activity, rarely had direct contact with clients, and was largely focused on content development. In some of my responses, I have used the experience I have gained since 2004 to provide some assumptions around how the task would have been completed; however, this information should be interpreted in the context of the fact I have limited recollection of specifics relating to this project.

Statement of Truth

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

Signed GRO-C

Dated 28/02/23