Witness Name: Henrietta Hughes
Statement No.: WITN7328001
Exhibits: WITN7328002-WITN7328003
Dated: 18/10/2022

INFECTED BLOOD INQUIRY

FIRST WRITTEN STATEMENT OF DR HENRIETTA HUGHES

I, Henrietta Sophia Lefanu Seymour Hughes, will say as follows: -

● Contents

Section 1: Introduction

1.1. I am Dr Henrietta Sophia Lefanu Seymour Hughes OBE FRCGP SFFMLM MBBS MA (OXON) DRCOG DFFP. With effect from 12 September 2022 I am the Patient Safety Commissioner for England and I provide this statement in response to a Rule 9 request from the Infected Blood Inquiry ("the Inquiry") dated 7 September 2022. I have provided my address and date of birth to the Inquiry. This statement answers the questions of the Inquiry in the order in which they are asked for ease of reference.

1.2. My professional qualifications and training relevant to the role I discharge are as follows:

- Senior Fellowship of the Faculty of Medical Leadership and Management (2021)
- Cabinet Office National Leadership Centre Course (2020)
- Fellow of the Royal College of General Practitioners (RCGP) (2018)
- NHS Leadership Academy Top Leaders Course (2013)
- NHS London Leadership Academy Aspiring Senior Leaders (2011)
- Responsible Officer Training (2010)
- Membership of the Royal College of General Practitioners (2002)
- Diploma of the Royal College of Obstetricians and Gynaecologists ("RCOG") (1999)
- Diploma of the Faculty of Family Planning, RCOG (1996)
- Member of the Royal College of Obstetricians and Gynaecologists ("MRCOG") Assessment Part 1 (1996)
- Bachelor of Medicine, Bachelor of Surgery (MBBS) Medical College of St Bartholomew's Hospital, University of London (1994)
- Bachelor of Arts (BA) (Class 2:1) Physiological Sciences Christ Church, Oxford University (1990)

1.3 In broad terms, the role of the Patient Safety Commissioner is to be independent of government, act as a champion for patients, lead a drive to improve the safety of medicines and medical devices and improve how the healthcare system, the government and the NHS listen to patients in order to put patients first.

1.4 The role was created in response to the recommendations of the report of the Independent Medicines and Medical Devices Safety Review ("IMMDSR"), also known as the "First Do No Harm" report ("the Report"), which was led by Baroness Cumberlege and published on 8 July 2020. The Report explored issues relating to the use of hormone pregnancy tests, sodium valproate and pelvic mesh and was commissioned because patients did not feel listened to or their concerns acknowledged. I exhibit this report as [WITN7328002] to this statement, and Appendix 2 of that document sets out the recommendation for the Patient Safety Commissioner role and describes the form and function it could take.

1.5 The government published its formal response to the recommendations set out in this document in July 2021 which included the commitment to appoint a Patient Safety Commissioner, with a remit to cover medicines and medical devices. This was legislated for through the Medicines and Medical Devices Act 2021 ("the Act") which makes that provision.

1.6 I set out below details of all memberships, past or present, of any committees, associations, parties, societies or groups that the Inquiry may consider to be relevant as regards both my role and the Terms of Reference, where not already referred to at 1.2 above, along with the dates of my membership:

- Medical Women's Federation, 2022
- Medical Protection Society UK advisory group, 2022

- Non-Executive Director of the South Central Ambulance Service, February to September 2022
- GMC Good Medical Practice advisory forum, 2021 to 2022
- Chair of Childhood First, 2021 to date
- Member of the Health Honours Committee, 2021 to date
- Member of the Society for Assistance of Medical Families, 2021 to date
- Governor of The King's School Canterbury, 2020 to date
- Member of the Health and Care Women Leaders' network guiding group, 2018 to date
- Liveryman of the Society of Apothecaries, 2018 to date
- Member of the British Medical Association, 1994 to date

1.7 I can confirm that prior to providing this statement I have not provided evidence to, or have been involved in, any other inquiries, investigations or criminal or civil litigation in relation to any of HIV, Hepatitis B, Hepatitis C or variant Creutzfeldt-Jakob disease in blood or blood products.

● Section 2: Patient Safety Commissioner Role

2.1 I have been asked to explain the scope and powers of the Patient Safety Commissioner and how I plan to discharge the role.

Scope

2.1.1 The Act sets out the core duties of the Patient Safety Commissioner at S1(2)(a) and (b):

"*The Commissioner's core duties are to—*

(a) promote the safety of patients with regard to the use of medicines and medical devices, and

(b) promote the importance of the views of patients and other members of the public in relation to the safety of medicines and medical devices".

2.1.2 Schedule 1 of the Act provides further provisions about the role and I enclose this [WITN7328003] to this statement. It requires me to carry out a public consultation in order to prepare and publish a set of principles to govern the way in which I will carry out the core duties shown above. I must take reasonable steps to involve patients in the discharge of my core duties. There is particular reference to: ensuring patients are aware of my core duties and how they may communicate with me; and how I must consult with patients (or those groups which appear to me to represent their interests) on matters I propose to consider.

Powers

2.1.3 Schedule 1 part 1(2) of the Act gives me the power to revise the principles referred to in 2.1.1 above, subject to conducting a public

consultation and publishing the revised principles. Schedule 1 part 3 provides that, for the purposes of carrying out the core duties, I may make reports or recommendations to anyone who exercises functions of a public nature in relation to England relating to medicines or medical devices or anyone else who provides services in the course of providing health care relating to medicines or medical devices relating to England.

2.1.4 Where I have made a report or recommendation to someone in the categories referred to above, they must provide a response to that report or recommendation by such deadline as I might reasonably apply. They are also obliged to comply with any reasonable request I make for information in the same way. It is important to note that I may not exercise these powers in relation to individual cases, though I may consider individual cases and draw conclusions from them when considering general issues.

2.1.5 As the Patient Safety Commissioner I need to hear what matters to patients, and to hear the experience of other people in similar circumstances. I understand that there are patients and service users who have safety concerns that are not related to medicines and medical devices, for example waiting lists or practitioner performance. I do not want their views to go unheard and I intend to support them to raise their concerns to the appropriate bodies so that these can be acted upon.

Discharging My Duties

2.1.6 The Report detailed the experiences of patients and their families who had not received the information needed to make an informed choice about their treatment with medicines and medical devices, and suffered

harm. When concerns were raised the healthcare system had not listened or responded in a swift, co-ordinated or compassionate way.

2.1.7 My priorities in discharging my duties are to support and challenge the health system to promote both the safety of patients and the importance of the views of patients in relation to medicines and medical devices. This is to stop harm to patients and their families from medicines and medical devices and for people to listen and act when concerns are raised.

2.1.8 When I gave evidence to the Health and Social Care Committee at a pre-appointment hearing as the preferred candidate for the role on 5 July 2022 ("the Committee Hearing"), I told them that my intention was to work tirelessly to support patients' voices and to ensure that patients' voices, views, experience and expertise are included in all stages, so that we instil the culture of safety from the design to the delivery of healthcare.

2.2 I have been asked to set out the nature of the improvements to patient safety that I hope to achieve during my tenure. My terms of appointment provide for a tenure of three years, from 12 September 2022 to 11 September 2025. At the Committee Hearing I defined success in the role as being when all patients and service users say "This feels really different. I really feel that my views are being taken into account and that I am being given the information that I need" in any situation where they are receiving, or will potentially receive, treatment including medicines or medical devices.

2.3 The patient safety landscape is complex with over a hundred organisations holding some responsibility for patient safety. There are many different channels that patients can turn to. Most problems can and should be fixed at a local level, but where there is a gap in the system and that is not possible

there will be ways for patients to get in touch with me including by contacting me directly. My role is not to investigate or to try to create individual solutions. Instead, it will be to work with the wider system so that when people raise matters they will receive a swift, compassionate, co-ordinated response which prevents future harms occurring.

2.4 At the Committee Hearing I was asked how I will be able to turn the Report recommendations into something that ensures that the organisations or people involved actually follow them in a measurable and effective way. I replied that I recognise that this is a three-year tenure and that three years is quite a short time in which to set the office up, start making changes and start measuring the difference. I expect the first six months to be a period of establishing the role, but intend to publish my first annual report for the first fiscal year focussing on what has been achieved in my first six months.

2.5 I completed a questionnaire in advance of the Committee Hearing in which I set out the steps I intended to take if appointed:

2.5.1 I will set out my vision for the role.

2.5.2 I will develop an overall strategy and an action plan for 2022 to 2025.

2.5.3 I will establish an advisory group so that patients play a central role.

2.5.4 I will consult on and develop a set of principles to govern the way in which my core duties are carried out.

2.5.5 I will explore existing systems by which patients' voices are heard, including vulnerable groups, and work collaboratively to improve these.

2.5.6 I will commission research into the scale of patient safety concerns about medicines and medical devices going unheard.

2.5.7 I will identify immediate concerns regarding medicines and devices and take action to co-create safe and effective systems.

2.5.8 I will develop relationships within and outside the healthcare system, in particular with patient groups affected by all medicines and devices.

2.5.9 I will convene a network of the bodies responsible for the safety of medicines and medical devices to agree ways of working and ensure a high quality, consistent and timely response when patients raise safety concerns.

2.5.10 I will identify and actively promote examples of good practice.

2.5.11 I will identify effective data to monitor the progress of actions.

2.6 It is the impact on people that matters, and I consider this to be the measure of success or not. If the right questions are asked of patients, the public and service users and a measurable difference in their experience is identified, that will be the mark of success in this role. This cultural shift is my long-term strategic ambition.

2.7 I have been asked about the extent of my engagement to date with the Medicines and Healthcare products Regulatory Agency ("MHRA"), as part of the development of relationships within and outside the healthcare system referred to above at paragraph 2.5.8.

2.7.1 I sent an email to Dame June Raine DBE, the Chief Executive of MHRA, on 26 June 2022 after my nomination but before I started as Patient Safety Commissioner in order to introduce myself and arrange a discussion before the Committee Hearing on 5 July 2022.

2.7.2 I received an email in response the same day from Dr Raine inviting me at short notice to the launch event One Agency Live on 27 June 2022 at QEII centre. I attended for part of the morning session and briefly met some of the Executives of MHRA.

2.7.3 Once in post I arranged a one to one call with Dr Raine which took place on 21 September 2022. Dr Raine took me through the work that MHRA is doing to respond to the recommendations in the Report. That engagement will continue. I told Dr Raine that my office is in the set up stage at the moment and that I am in the process of recruiting my team

but that we should explore setting up a memorandum of understanding between my office and MHRA to set out how we will work together.

2.7.4 I visited Leeds Teaching Hospitals NHS Trust for Scan4Safety (a Department of Health and Social Care ("DHSC") initiative that is enabling the delivery of better patient care, improved clinical productivity and supply chain efficiency in the NHS) on 23 September 2022 and Dr Alison Cave, the Chief Safety Officer of MHRA, was also in attendance. I am in the process of arranging a follow up call with Dr Cave.

2.8 The Patient Safety Commissioner role is full time, five days a week. However I do continue to work a small number of hours each week as a GP in my own time in order to maintain frontline experience and engage with patients regularly.

2.9 I have been asked how my work as the Patient Safety Commissioner is to be funded, who I will report to, and about the role's relationship with the NHS and the government. DHSC is the sponsor department of government. Funding comes from the Secretary of State. It has been recognised that it is important that the budget is sufficient to allow me to perform my duties to the full. It is also recognised as being essential that I remain operationally separate from and independent of the DHSC.

2.10 I am required to produce an annual business plan and take reasonable steps to consult before publishing it, and to keep proper accounts each financial year and provide a copy to the Secretary of State. I have an annual budget of £600,000. Budget holder responsibility lies with the Director of NHS Quality, Safety and Investigations who has responsibility for DHSC's relationship with me and my team. I report to Parliament via my annual report and to the Health and Care Select Committee.

2.11 The office of the Patient Safety Commissioner is being set up and recruitment is under way (and in some cases complete) to fill the following roles:

- Chief of Staff;
- Communications and Engagement Lead;
- a business manager role; and
- Diary Manager.

Statement of Truth

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

Signed… GRO-C ……

Dated……18 October 2022……..