Witness Name: Dr Henrietta Hughes
Statement No.: WITN7328004
Exhibits: WITN7328005 – WITN7328026
Dated:

INFECTED BLOOD INQUIRY

SECOND WRITTEN STATEMENT OF DR HENRIETTA HUGHES

I provide this statement in response to a request under Rule 9(1) and (2) of the Inquiry Rules 2006 dated 29 February 2024.

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

Background

1. I set out the scope and powers of the Patient Safety Commissioner in my First Witness Statement dated 18 October 2022.

2. It is important to repeat, in the context of the points I make below, that the remit of my role is limited to medicines and medical devices and therefore does not currently include blood or blood products. However, I consider an important part of my role is in outreach to inform and ensure cross-organisational learning and sharing across those parts of the system that otherwise do not fall within the statutory function of the post.

3. At the time of my First Witness Statement, my role and my Office were very much in their infancy given that I only took up my post on 12 September 2022. Since

then, I have been listening hard to the voices of patients and their representatives, and I have developed the role and my Office significantly. In terms of an overview of what I have achieved in the role:

a. My 100 Day Report was published in February 2023 on the Patients Association website, as the Patient Safety Commissioner's website was still in development at the time [**WITN7328005**]. This covered my first three months in post and what I heard from my patient engagement, as well as engagement with bodies within the healthcare system such as regulators, healthcare providers and senior leaders.
b. Working with patient groups and professionals, I developed a letter for patients to bring to their GP to help discuss the next steps in their care, which I published in Spring 2023 [**WITN7328006**].
c. In line with my statutory obligations under the Medicines and Medical Devices Act 2021 (the 'Act'), I published the PSC's first Annual Report in July 2023 [**WITN7328007**], covering a more detailed list of my work from the start of my appointment through to the end of the financial year in March 2023. It is my intention to publish the second PSC Annual Report in July 2024, covering the financial year 23/24.
d. I have made three sets of recommendations using my powers under the Act: one set to the Health Secretary on 20 October 2023 in relation to Martha's Rule; one set to NHS England concerning the use of teratogens on 2 November 2023 and one set to the government more broadly on redress on 7 February 2024:

- On Martha's Rule, my recommendations relate to how we can successfully implement Martha's Rule across the NHS in England [**WITN7328008**]. I discuss this work in more detail below.
- My recommendation to NHS England concerns the use of teratogens. This recommendation follows from extensive work in year 1 of my term on the medicine valproate – a known potent teratogen. Valproate was examined as part of the IMMDS Review and was also included within the scope of my work on redress. Despite much focus on improving the safe prescribing and dispensing of valproate and other such teratogens, patients continued to raise serious concerns with me. As a result, I recommended that a National Quality Improvement Programme was introduced, starting with the safe use of valproate. A positive response to this recommendation from Professor Sir Stephen Powis, the National Medical Director for NHS England, was received on 30 January 2024, and is published on the PSC website [**WITN7328009**].
- I published the Hughes Report into options for redress for those harmed by valproate and pelvic mesh on 7 February 2024 [**WITN7328010**], which made 10 recommendations to government, covering both financial and non-financial redress for those harmed. The Report represented the delivery of a significant project which had started in June 2023. Given the limits on my resource, I was provided with additional resource for this project by the Department in the form of Dr Sonia Macleod, who was appointed as an expert

advisor, and two additional civil servants for the duration of the project. As of March 2023, I am awaiting a substantive response to this set of recommendations.

4. In addition, I published the first strategy for the Patient Safety Commissioner in January 2024, reflecting on what I thought should be my priorities after 16 months in the role hearing and engaging with patients. In developing the strategy, we spoke to our key stakeholders to ensure alignment with their strategies and vision for the healthcare system.

5. The updated PSC strategy has three core strands, with three ambitions within each [**WITN7328011**].

6. The first core strand is to drive the alignment of the healthcare system to deliver a just and learning safety culture. Without a just and learning culture in the system, across frontline staff, managers, and patients, we cannot achieve safety.

7. This is a central plank of the PSC strategy and underpins the vast majority of our activity.

8. It is underneath this plank that sits a specific strategic ambition I cited in my evidence to the Health and Social Care Select: “We will call for a Safety Management System for the healthcare sector to reduce patient harm to as low as reasonably possible” [**WITN7328012**].

9. I think it is important to note that I am clear that the ambitions of the strategy will only be delivered through collaboration with others. The current size of my team

and budget means that I am necessarily limited in the resource that I can dedicate to projects. I continue to advocate for additional resourcing, as set out in the PSC's July 2023 Annual Report (exhibited at paragraph 2c above) at pages 18 and 19.

10. However, even with additional resource, I firmly believe that it is only by working with and through others in the complex healthcare landscape that we can deliver sustainable change. This is a point I will return to in the course of this statement.

Safety Management Systems

Ambitions and Objectives

11. I think a good starting point for the definition of a Safety Management System ("SMS") is that of the Health Services Safety Investigations Body ("HSSIB") in their report on SMSs that I reference and exhibit at paragraph 15, namely that "(a)n SMS is a proactive and integrated approach to managing safety. It sets out the necessary organisational structures and accountabilities and will continuously be improved. It requires safety management to be integrated into an organisation's day-to-day activities."

12. The reason that a call for a SMS is one of my key ambitions for the strategy is because it would represent a significant culture shift for the healthcare system. As the HSSIB definition cited above makes clear, an SMS means that safety is seen as the responsibility of everyone including senior leaders in NHS provider organisations, arm's length bodies and departmental officials.

13. I know that calls for a safety management system prompts comparisons between healthcare and high safety industries such as civil aviation, construction, and chemical engineering. However, we must also acknowledge that these industries, and their safety management systems, operate in a very different context to that of healthcare. I note that I share this view with the one Dr Benneyworth expresses in her statement [**WITN7689001**].

14. This proactive approach to safety contrasts with what happens too often in the healthcare system now, namely that we look back once something has gone wrong. We need to be looking forward and introducing an SMS to reduce the risk of future avoidable harm.

15. In this regard, I welcome the recommendations HSSIB made in their report on SMSs that I referred to at paragraph 11 above [**WITN7328013**] and am pleased that NHS England has set up a safety management system co-ordination group.

16. I also welcome the roll-out of Patient Safety Incident Response Framework ("PSIRF") by NHS England as part of the steps towards establishing an SMS across the NHS. PSIRF represents a welcome shift from an investigation framework to the required proactive, and data-driven approach, to incident response which prioritises the compassionate engagement and involvement of those affected by patient safety incidents.

17. However, the history of the NHS is littered with good initiatives that succumb to tick-box implementation. There are two elements to successful implementation – (i) the process and (ii) the deeper cultural changes that are needed for effective and sustainable change. Too often, the NHS falls down on the second of these.

18. This is why I wanted our strategy to have a strong focus on cultural improvements. To truly move the dial on patient safety and successfully implement a SMS, we need to ensure all this work is focussed on delivering on the core strand from our strategy referenced earlier, namely the creation and maintenance of a just and learning culture within the NHS, founded on restorative culture and practice. Local examples of success, notably Mersey Care NHS Foundation Trust, show that these cultural changes are possible [**WITN7328014**].

19. Improvements to the culture surrounding patient and staff voices when speaking up about patient safety and care is needed across the entirety of the healthcare system. This includes government departments, arms-length bodies ("ALBs"), regulatory bodies, commissioners, and other health organisations.

20. What is needed by all these bodies is a change in mindset to prioritise listening carefully to what people say, before, during and after their treatment, ensuring that treatment is tailored to the individual's needs and that feedback leads to learning and improvement. As Mr Bragg said to the Inquiry, "we need to make sure that anybody who has a concern in the NHS, they feel they can express it" [**INQY1000266**] (page 172).

21. One of the best ways to address this is for patients and families to be asked proactively about their views; for organisations to have systems in place to escalate concerns; and for these concerns to be acted upon proactively, without needing to make a complaint, which is why I am so passionate about the successful implementation of Martha's Rule.

22. The introduction of Martha's Rule is part of the set of recommendations that I made to the Secretary of State in October 2023 [**WITN7328015**], following a series of policy sprints (meetings to rapidly analyse important health policy questions) with stakeholders from across the health system. These are:

    a. We must implement a structured approach to obtain information relating to a patient's condition directly from patients and their families at least on a daily basis. In the first instance this will cover all in-patients in acute and specialist Trusts.
    b. All staff in those Trusts must have 24/7 access to a rapid review from a critical care outreach team who they can contact should they have concerns about a patient.
    c. All patients, their families, carers and advocates must also have access to the same 24/7 rapid review from a critical care outreach team which they can contact via mechanisms advertised around the hospital and more widely if they are worried about the patient's condition. This is Martha's Rule.

23. Each of these elements are based on listening to patients, families and staff and providing identifiable and non-adversarial routes of escalation of concerns. They draw heavily upon the Worry and Concern pilots led by NHS England, and the experience of trusts with 'Call4Concern', first introduced by Mandy Odell at Royal Berkshire NHS Foundation Trust [**WITN7328016**].

24. I was delighted that NHS England announced the first phase of the implementation of Martha's Rule in February 2024 [**WITN7328017**]. As part of this announcement, the Secretary of State appointed me Chair of the stakeholder oversight group, jointly with NHS England and the Department of Health and

Social Care [**WITN7328018**]. I see my role on this group as being about providing joined-up, visible leadership to the system to ensure a receptive culture and regulatory environment is in place for the successful roll-out of Martha's Rule.

25. Another crucial element in encouraging this just and learning culture is leadership intent. This involves leaders prioritising regular walkabouts and meetings where they proactively listen to patients, families, and staff. There then needs to be regular opportunities for the Board to triangulate the information gleaned from these activities with other indicators of the safety culture, from incidents teams, Patient Safety Partners, Freedom to Speak Up Guardians, staff network chairs etc. to identify hotspots (good and bad) of culture in their organisation.

26. To foster the right leadership behaviours, we also need to remove the unhelpful division between quality and safety, and people and culture that exist at both local and national healthcare bodies. Instead, we need to bring together all aspects of culture together - so that links between staffing, training, patient safety, and patient experience can be understood and addressed by leaders.

<u>Mr Bragg's proposals and Dr Benneyworth's statement</u>

27. I firstly want to pay tribute to Mr Bragg for all his work in this space on behalf of those infected and affected by blood products, but also on behalf of patients more generally. I share his sentiments that the NHS has a long way to go with respect to the culture of learning and openness.

28. As a general point, I think it is always important to consider the limited bandwidth of the healthcare system to respond to recommendations – and that in many

areas recommendations from previous inquiries remain unimplemented. This is why I am so supportive of the work the HSSIB is leading, looking at how recommendations are made to the healthcare system and moving towards an agreed set of principles that national organisations and office holders (such as the Patient Safety Commissioner) with the power to make safety recommendations can sign up to.

29. From my point of view, before any significant new recommendations are made in this area, I think two things, at a minimum, need to happen.

30. The first is a detailed examination of the current patient safety landscape – including the existing duties on organisations and individuals and the roles and responsibilities of the existing patient safety bodies (at both a local and national level). There is too often a rush to create new bodies and duties without giving serious thought to whether they duplicate (or even worse, contradict) what already exists.

31. To support this, my Office and I would like to work to produce a detailed gap analysis of the current landscape. This would involve taking a step back to look at existing systems, structures, and processes to identify who does what, and with what authority and implications. I think that this work should also have a patient-facing element in the sense of helping to explain to patients who does what and how they might be able to help them.

32. This work would help support what I think is one of the missing elements in the current system, which is about ensuring that work is done to reduce gaps and duplications whilst ensuring systems and current regulations allow proportionate

escalation of different risks in a way that is visible to the relevant organisations. This requires those involved at the existing bodies having the requisite knowledge of what each body does, and the consent and direction to work together to address issues of patient safety before there is a problem, in a collective and consistent way.

33. In this area of increased reporting, for example, to which Mr Bragg's recommendation [**INQY1000266**] relates, I understand that there is ongoing work by the Department of Health and Social Care on death certification reform and medical examiners, [**WITN7328019**] – which sits alongside the already well-established coronial system. There is also already the statutory duty of candour, [**WITN7328020**] and the Learn From Patient Safety Events ("LFPSE") service, [**WITN7328021**]. Any recommendation along the lines of Mr Bragg would need to sit and work alongside this existing system.

34. In addition, the suggestion of the creation of a new national body alludes back to the National Patient Safety Agency ("NPSA") – created in 2001 and whose patient safety functions were moved into NHS England in 2012 [**WITN7328022**]. As Dr Benneyworth notes, it would be important to understand the impact of a national patient safety agency before recommending its re-creation.

35. My concern with moving back to this model is that, once again, patient safety at a national level may be seen as the preserve of highly specialised 'experts', in a separate part of the system, in contrast to high reliability organisations in other sectors with SMSs, where safety is seen as the responsibility of everyone from the CEO downwards. To this end I wrote to the NHS England CEO, Amanda

Pritchard, on 7 March 2024 calling for patient safety to be included in the NHS England planning guidance [**WITN7328023**].

36. Overall, the patient safety landscape has arguably become too cluttered and is too confusing from the point of view of patients, something I referred to at paragraph 2.3 of my first statement [**WITN7328001**] and is discussed in more detail at Appendix 2 of the First Do No Harm Report exhibited to that statement. Reorganisations also inherently present short-term inefficiencies and delay.

37. Whatever the solution, it must show an understanding and support of the need to bridge the gap between these large and distinct organisations and the patient voice, and is something I will be continuing to work towards.

38. The second is, as again Dr Benneyworth's statement refers, work and research that is required to understand what data is currently being collected, what data is being shared and aggregated, and where we can improve. Data collection for different agencies can present an administrative burden to provider organisations where management time could be better spent on delivering improvements in patient outcomes. There is a particular need for real-time data when it comes to patient safety, and I think there is considerable work still to do to improve this area. Data collection, in and of itself, is unlikely to lead to the change we all want for patients.

<u>Further priorities for improving the collective response to threats to health</u>

39. I am particularly interested in the role of Boards, particularly Non-Executive Directors ("NEDs"), in patient safety which is why I included this area as another one of my strategic aims.

40. Recommendation 6 of the Leadership for a Collaborative and Inclusive Future report [**WITN7328024**], called for the establishment of an expanded, specialist non-executive talent and appointments team. In particular, the authors rightly noted that "despite the pivotal governance role of boards, the selection and development of NEDs is currently too localised and arbitrary to assure the right balance of skills, experience and background around the table."

41. The need for trust boards, both executives and NEDs, to have training in patient safety was made crystal clear by the shocking Lucy Letby case. NEDs are the second line of defence when it comes to patient safety, having a crucial, independent role, to play when patients and staff are not listened to. We must ensure that they know how to discharge their responsibility properly.

42. In February 2024 the NHS Leadership Competency Framework ("LCF") [**WITN7328025**] was published for all board members of NHS providers, ICBs and NHS England's Board as a direct result of the Kark Review of the fit and proper persons test, [**WITN7328026**]. The LCF provides a consistent competency and skills benchmark against which board members will individually self-assess as part of the annual 'fitness' attestation. The framework was intended as a guide to support ongoing development at the highest levels.

43. In light of the framework, I considered my role in leading the organisation's approach to improving quality, from immediate safety responses to creating a proactive and improvement-focused culture.

44. In addition, Recommendation 2 from the Kark Review was "a central database of directors should be created holding relevant information about qualifications and history." As recommended, this information would include their "history of training and development undertaken". This recommendation was made in the context of the review emphasising the importance of Board and director development. It has not been progressed.

45. Such a database would provide a valuable evidence base to identify gaps and develop solutions including making it far easier to form networks of leaders (supported by membership organisations such as NHS Providers) which provide support, information, and training. With the current fragmentation of information, it is not possible to identify all NEDs of NHS bodies to assess their learning needs or provide useful information or guidance. This makes it very hard to address the problem of NEDs of NHS Trusts and Foundation Trusts not receiving training on patient safety, for example.

46. Finally with regards board members comes the issue of their regulation. Better regulation would achieve three things. First, it would clearly set the expected standards of performance in the role. Second, it would help recruiters ensure that individuals appointed have the right skills, knowledge, and experience to meet those expected standards. Third, it would support better discussions on how people are expected to meet and maintain those standards.

47. This process would open much-needed discussions around the necessary training requirements around issues such as patient safety. Only when these steps are in place, can we start to inject the required level of accountability and professionalism into the managerial structures that would support the design and delivery of safer healthcare.

Statement of Truth

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

Signed GRO-C

Dated 3 April 2024

Exhibit Table

Date	Description	Exhibit Number
February 2023	Patient Safety Commissioner - 100 Days Report	WITN7328005
31 May 2023	Mesh Patients Resource for GPs	WITN7328006
July 2023	Patient Safety Commissioner Annual Report 2022-23	WITN7328007
20 October 2023	Letter from Dr Henrietta Hughes to The Rt Hon Steve Barclay MP	WITN7328008
30 January 2024	Letter from Professor Sir Stephen Powis to Dr Henrietta Hughes	WITN7328009
7 February 2024	The Hughes Report	WITN7328010

Undated	Patient Safety Commissioner - Strategy	WITN7328011
January 2024	Written evidence submitted by the Patient Safety Commissioner	WITN7328012
18 October 2023	Investigation report: Safety management systems - an introduction for healthcare	WITN7328013
7 March 2024	The Mersey Care Just and Learning Culture	WITN7328014
20 October 2023	Letter from Dr Henrietta Hughes to The Rt Hon Steve Barclay MP	WITN7328015
29 January 2019	Patient and relative activated critical care outreach: a 7-year service review	WITN7328016
Undated	Martha's Rule	WITN7328017
21 February 2024	Martha's Rule update - Statement	WITN7328018
14 December 2023	An overview of the death certification reforms	WITN7328019
5 October 2020	Duty of candour guidance	WITN7328020
Undated	Learn from patient safety events (LFPSE) service	WITN7328021
3 November 2010	After the abolition of the National Patient Safety Agency	WITN7328022
7 March 2024	Letter from Dr Henrietta Hughes to Amanda Pritchard	WITN7328023
8 June 2022	Leadership for a collaborative and inclusive future	WITN7328024
28 February 2024	Leadership competency framework for board members	WITN7328025
November 2018	Kark Review on the fit and proper persons test	WITN7328026