

Witness Name: The Rt Hon Lord David Owen CH FRCP

Statement No: WITN0663001

Dated: 6 August 2020

## INFECTED BLOOD INQUIRY

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### SUPPLEMENTARY WRITTEN STATEMENT OF THE RT HON LORD DAVID OWEN

I, The Rt Hon Lord David Owen CH FRCP, will say as follows:-

1. I have tried to bring to the attention of the Secretary of State for Health and Social Care that convalescent purified hyperimmune coronavirus Covid-19 immunoglobulin could save lives and yet the Government, it appears, has for some time not been ready to order its manufacture.
2. One of their reasons appears still to be CJD and any NvCJD in blood. An initial caution was justified. But now that incidence of NvCJD is becoming very small, what evidence is there that British patients are at risk over fractionating post Covid-19 British blood plasma? Should we continue to import plasma from overseas with all the associated risks? It seems to me that this Inquiry cannot ignore the questions that the treatments for Covid-19 have raised. France was recorded in 2005 as the second highest incidence of vCJD to the UK in the world. What are the most up to date international comparisons? Is the risk of using plasma that has been purchased from the donor a higher risk for the recipient than British plasma freely donated?
3. Since the beginning of March, I have been waiting for the Government to announce that they would order the manufacture of Covid-19 Hyperimmune Immunoglobulin from convalescent plasma by the Cohn fractionation process. The product would be used in its intravenous form to give immediate passive immunity to treat seriously ill patients with Covid-19 and to give in its intramuscular form to frontline health workers, care home staff and residents, the BAME community, the

immunocompromised and all other vulnerable groups to be used in a prophylactic manner.

4. From the experience of using other viral immunoglobulins, in this latter form, passive immunity can last for several months or more. During the Second World War, Edwin J Cohn, an American Harvard University Scientist, was asked to develop a process that would separate albumin from human plasma to be used to treat soldiers suffering from shock and burns. The process that he developed was not only successful in separating albumin but a whole range of plasma proteins including immunoglobulin. The Cohn fractionation process is still used today in plasma fractionation facilities around the world. The one of most importance for today's coronavirus Covid-19 pandemic is called specific hyperimmune immunoglobulin. It is called specific because plasma is collected from blood donors that have recovered from a specific viral infection, examples being Hepatitis, Measles, Varicella-Zoster, Rabies etc. The plasma, known as convalescent plasma, is high in antibody (hyperimmune) to the viral infection from which they have recovered. Specific immunoglobulins have been manufactured from convalescent plasma for more than 50 years and this very safe and efficacious product has saved thousands of lives
  
5. I recognize that Covid-19 has a complicated immune response and we are still learning about that response. I recognize too the double-blind trial underway, whereby a transfusion is given to patients with Covid-19 infections has value. But this is *not* the same as fractionating post-Covid blood plasma. From the end of March, the US Department of Health and Human Services announced that they, in cooperation with the FDA, were approving the use of convalescent plasma for direct infusion into patients suffering with Covid-19. This would continue until their plasma fractionators had enough convalescent plasma to pool and manufacture the specific Covid-19 hyperimmune immunoglobulin to treat patients. One plasma fractionator, Grifols, was given an upfront payment of \$14.5 million to make the product. The French fractionator is working with the alliance of plasma fractionators from around the world. Studies of the use of

convalescent plasma and hyperimmune immunoglobulin in previous SARS outbreaks have been reported as reducing the case fatality rate.

6. Until a vaccine is ready - and this could be a long way off - there are tens of thousands of people that have recovered from Covid-19 across countries in Europe and who are ready to donate their blood plasma. If all plasma fractionators are prepared to manufacture the specific Covid-19 hyperimmune immunoglobulin now then not only could Covid-19 infected patients be injected and not transfused but the "at risk groups" could be given prophylactic passive immunity. With stocks of the product it could save us from a potential second wave. I simply cannot understand why our UK Government is not moving ahead now to manufacture this product to save lives.

Statement of Truth

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

Signed: ..... GRO-C .....

Dated: ..... 6.8.20 .....