INFECTED BLOOD INQUIRY

ADDENDUM SUBMISSIONS REGARDING "MULL" DISCLOSURE DOCUMENTS

(arising from legal proceedings against pharmaceutical companies)

On behalf of Leigh Day Core Participants

1. In accordance with the determination of the Chair dated 10 November 2023, Leigh Day has reviewed the additional disclosure with the prefix, "MULL", these documents having been provided to the Inquiry by US attorneys and arising from legal proceedings in the 1990s in the US against pharmaceutical companies.

2. We do not consider it necessary or proportionate to comment in detail on this disclosure. By these submissions, however, the Core Participants and clients of Leigh Day intend to assist the Inquiry by making two overarching points and highlighting some particularly pertinent documents for the Inquiry's consideration.

3. First, the totality of the MULL disclosure supports the evidence that has emerged very strongly before the Inquiry that knowledge of the risk of hepatitis, including NANB hepatitis, and thus the risks to patients from blood and blood products, was known by pharmaceutical companies from, by the latest, the late 1970s (supporting our final submissions at pp164-165). That risk emerged very clearly to pharmaceutical companies throughout the 1980s and yet they persisted in aggressively marketing these products for sale and, crucially, the communication of these risks to patients was woefully poor (please see our final submissions at pp309-313). In particular, we note:

    a. MULL0001171_001. A document entitled, "Cutter/Miles binder for expert", summarising evidence which demonstrates multiple reports of hepatitis

transmission from the 1960s through to 1980s. This included a report of a death of a 9-year-old boy from acute viral hepatitis (p8).

b. MULL0000554. The affidavit of Donald Pinkston Francis, who held various positions at the CDC, sets out his "*firm conclusion that the reason why this medical catastrophe occurred with literally no warning to hemophiliacs was because plasma fractionators (manufacturers) of antihemophilic factor ('AHF' or 'Factor VIII') including Armour, Alpha, Cutter and Baxter, allowed their Factor VIII blood product to become contaminated with other viruses as well as HIV from the mid-1970s until 1985, when they began heat-treating AHF products.*" His position is premised on the manufacturers' knowledge of risk of hepatitis B, NANB and HIV at the relevant points in time.

c. MULL0000105. Deposition of Dr David Aronson, which demonstrates that it was known in the 1960s and 70s that users of blood and blood-derived products were frequently being infected with hepatitis.

d. Similarly, MULL0004896, inter-office correspondence of Hyland/Travenol Laboratories dated 14 June 1979 demonstrates a clear understanding that its product, Hemofil, was infected with hepatitis B and, crucially, NANB hepatitis. Indeed, this document refers to a PDC-approved study to remove hepatitis infectivity as early as 1977. It refers to the similar efforts of Behringwerke and Immuno. Knowledge of the risk of blood products in terms of hepatitis was plainly at the top of the commercial agenda for pharmaceutical companies by the late 1970s. This document, and others, demonstrates that the pharmaceutical industry weighed the potential profit increases from the production of such a hepatitis-free product very heavily, yet these risks were not communicated clearly to patients.

e. MULL0000233. This Expert Witness Review for Armour and Revlon Healthcare Group demonstrates the extent of scientific knowledge from the 1970s regarding hepatitis infectivity of blood products.

f. This is echoed in MULL0000031, a deposition summary and parts of the deposition of Michael Rodell, former Vice President of Armour, who accepted that there was a significant risk of hepatitis B and NANB from 1972-1982 with use of factor products.

4. Secondly, the disclosure further substantiates that the pharmaceutical industry wielded huge global influence, including over government, yet showed a flagrant disregard for ethics, patient care and wellbeing. The imperative for safe blood products was overridden by profit and commercial concerns; something that is particularly egregious given the industry's main function is (or should be) to cure and prevent human disease and alleviate symptoms. In particular, we note:

   a. MULL0001055_002. A deposition of Thomas C. Drees, President of Alpha from 1978-1983. Mr Drees had told a newspaper that the only possible reason for his dismissal from Alpha was that an executive of their largest company, Green Cross Corporation of Osaka had told him in 1981 and 1983 words to the effect of *"you are too concerned with the safety of the products"*. This comment had arisen during a discussion about hepatitis testing with Dr Naito, who was the chairman of Green Cross at the time.
   b. MULL0000027. An affidavit of J. Garrot Allen, which offers illuminating evidence as to the "conspiring" of the blood industry to avoid using the HB-core antibody test, and the unduly close relationship between the industry and the FDA (which is also demonstrated by a number of documents below). His damning view was that there was no real regulation and that the industry had instead become self-regulating.
   c. MULL0007770. A memo referring to a meeting held with the FDA, led by Dr Harry Meyer, and all producers of coagulation products to discuss the use/production/license of non-viral inactivated products, which demonstrates a wholesale industry resistance to the FDA's proposal that such manufacturers

should confirm by letter that they would no longer produce or distribute non-heat-treated product (which was still possible within licences at that time). We also note the record in the memo that Dr Meyer "*did not want any attention paid to the fact that the FDA had allowed this situation to continue for so long, and he would like the issue quietly solved without alerting the Congress, the medical community, and the public. Implicit in the discussion was the concern that the FDA felt that this action was long overdue".*

d. MULL0001253_027. Inter-office correspondence at Armour dated 11 June 1985 appears to advise "*moving*" non-HTLV-III tested blood products "*as quickly as possible".*

e. MULL0000531 and MULL0000532, two depositions of prison inmates, contain shocking evidence regarding the abject failures around the safety of blood collection systems in prisons into the 1980s.

f. MULL0000805_003. Bayer's objections in the US Blood litigation cases. *"Bayer admits that some lots allegedly infused by Mr [X (in litigation)] contained some plasma collected in 1982, in full compliance with all applicable regulations and prior to any informal request to cease such collection from plasmapheresis centers located in jails and/or prisons".* There is the same response in relation to collections in 1983.

g. MULL0000026. A summary of the deposition of Dr Steven Ojala notes the "*reckless practice*" of Cutter's approval of a donor centre for a pooled product within a community where the proportion of high-risk donors should have been known. Despite Mr Ojala claiming to have little knowledge about donor demographics he provided evidence that demonstrated a preference for paid donations: "*we have more extensive screening in the paid segment than they do in the volunteer segment*". Mr Ojala's deposition also revealed that claims made by Cutter regarding the safety of their products (by virtue of the location of their

own plasma centres)[1] was perhaps purposefully ambiguous, as these claims did not disclose the fact that plasma was also being procured from other agencies such as the Irwin Memorial Blood Bank of the San Francisco Medical Society.

h. MULL0005758. An internal Cutter memo dated 27 January 1984 contains a number of recommendations in relation to *"AIDS preparedness"* and includes a rejection of a recommendation to "*publish a Miles Health and Safety Bulletin devoted to AIDS plus periodic updates highlighting new developments"* because there *"should not be a great deal of publicity given to this subject; if something is mentioned, make it no big deal."*

i. MULL0000468.[2] A table of needlepoints documenting a timeline of events pertaining to Jack Ryan, former President of Cutter Biological, highlights a series of issues of note, for example, reference is made to a multi-company public relations proposal dated 13 August 1984 involving: "*convincing haemophiliacs there is more danger from not infusing than from getting AIDS*". A memorandum dated 11 May 1983 is also referred to in which it is stated that Cutter should not advise France about the heat-treated Koate product "*because they may stop buying the regular*". This document appears to show that Mr Ryan did not understand the ethical considerations surrounding the continued sale of non-heated blood products while there was still a demand from the Japanese government and amongst haemophiliac patients.

j. MULL0002907. A Department of Health & Human Services memorandum dated 21 July 1983 demonstrates that even as late as 1983 guidance in relation to informed patient consent to treatment was not being given. Within the memorandum it is stated that *"the risk of transmitting AIDS to an individual hemophiliac from a specific lot of Factor VIII is very, very small if it exists. Therefore, disposition of Factor VIII from a pool which contains plasma collected from a donor who may have acquired immunodeficiency syndrome should be*

[1] See MULL0005518, in relation to location of centres.

[2] In general, we invite the Inquiry to review this document.

considered as a discrete incident". We submit that any discussion regarding the balancing of potential risks (in this case, of *"acquiring AIDS"*) and benefits (*"from life-threatening or disabling hemorrhage"*) necessitated a concomitant discussion about informed patient consent to treatment options. These discussions do not appear to have taken place within the context of this memorandum, nor within any of the "MULL" disclosure that we have seen.

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