INFECTED BLOOD INQUIRY

NOTE ON
LATE DISCLOSURE
PERTAINING TO THE PHARMACEUTICAL INDUSTRY

Introduction

1. This note seeks to supplement the observations made by the Saunders Law CPs in their primary submission of December 2022. We make these additional observations after receiving and perusing further disclosures related to the pharmaceutical industry, since the time of our submission. This brief updated note remains faithful to the essential arguments we've previously made but adds nuance, in light of the disclosures that we have now considered.

2. The Saunders Law CPs have long highlighted the key role of the pharmaceutical industry ("pharma") in this investigation and expressed "*disappointment*" at the relative paucity of material at the substantive hearings.[1] Pharma were the chief purveyors of blood and blood products to vulnerable people living with haemophilia. The industry was a transnational ecosystem, dominated largely by American multinational companies. They relied hugely on donors

[1] [SUBS0000060], 'Written submissions of Saunders Law', [6/8].

from US metropolitan centres[2] and most of the products used in the UK were US-imported. The unifying feature of this system was its seeming pervasiveness, as the dominant, if not sole option for blood and blood products to be consumed by those living with haemophilia.

3. In our primary submissions, we argued that the UK failed to put in place, proper apparatus or institutional arrangements regulating the activities of pharmaceutical companies to ensure the safety of commercially produced Factor VIII.[3] Implicit in the duty to ensure a proper system, was a positive obligation to regulate the conduct of non-state actors such as pharmaceutical companies. We argued that that it formed part of the core obligation of the UK to have provided public health information messaging about the enhanced risks associated with commercial, U.S. products. In addition, we submitted there was no rigorous comparative analysis between continued use of commercial Factor VIII and its alternatives that were capable of mitigating risks (e.g. cryoprecipitate).

Legal framework

[2] Robert James, 'Geographic Location of Commercial Plasma Donation Clinics in the United States, 1980 – 1995', Am J Public Health. 2004 July; 94(7): 1224–1229. doi: 10.2105/ajph.94.7.1224.

[3] [SUBS0000060], 'Written submissions of Saunders Law', [96/211].

4. The Saunders Law CPs maintain there is an arguable breach of the systems duty under Article 2 of the ECHR. In the 1970's and 80's, the regulatory system that delivered blood and blood products to end-users such as people living with haemophilia, was so defective that it was not fit for purpose – and led to the worst treatment disaster in UK history. Article 2 of the ECHR is the appropriate framework for discussion of these issues, because of the near existential nature of the matters under investigation, even if the members of the Saunders Law CP cohort are not themselves CPs by way of bereavement.

5. The UK Supreme Court (UKSC) in R. *(on the application of Maguire) v HM Senior Coroner for Blackpool and Fylde* [2023] UKSC 20[4], notes that the European Court of Human Rights has rarely found deficiencies in states' regulatory frameworks; and that it was only in very exceptional circumstances that the state's substantive responsibility under Article 2 was engaged in respect of providers' acts and omissions. Individual lapses were not to be confused with a deficiency in the system. The Saunders CPs will not repeat its discussion of the law in the primary submissions. We commend our discussion on accountability for the Chair's consideration, which is predicated on a systems breach under Article 2 of the ECHR.

[4] R. *(on the application of Maguire) v HM Senior Coroner for Blackpool and Fylde* [2023] UKSC 20.

6. It bears saying in this updated note, that Article 2 of the ECHR further imposes a positive obligation to protect life in certain circumstances. This positive duty is fulfilled by: a) having in place legislative frameworks; and b) taking preventative *operational measures* to protect an individual, placing a duty upon the State to take appropriate steps to safeguard the lives of those within their care where they *knew,* or *ought to have known* of the *existence* of a *real and immediate risk* to lives. The scope of the operational duty should also be considered, when assessing the events under investigation.

7. The UKSC in *Maguire*[5] reinforces the point that the operational duty is not one to take steps in the abstract but to take steps to avert a specific risk to life. A risk was *"real and immediate"* if it were a substantial or significant risk and not remote or fanciful. To be "*immediate*" the risk need not be imminent, but "*present and continuing.*"

Discussion

8. The disclosure that we have reviewed will likely be helpful to the Inquiry, as the material was obtained largely from court proceedings in the USA. We highlight the following, not as an exhaustive

[5] R. *(on the application of Maguire) v HM Senior Coroner for Blackpool and Fylde* [2023] UKSC 20.

exercise, but to reinforce and add nuance to some points we have made before:

i) Longstanding evidence of serious potential harm

9. The transcript of testimony of Dr Shohachi Wada in *re: [GRO-A] et al. vs. Armour Pharmaceutical et al*[6] illustrates longstanding knowledge of potential harm in pharma practices and how there was almost an institutionalised acceptance of lower standards of care or harm towards haemophilia patients being treated with blood and blood products.

> [Page 21 to 22]
> 'Q*: Doctor, in the period 1970 to '72, were you aware of the fact that the plasma that was being used to manufacture Factor IX… at Cutter carried a risk of transmitting hepatitis virus?*
> *A: Yes, I was aware.'*
>
> [Pages 23 to 24]
> *'Q. So my understanding, then, would be, Dr. Wada, that as an employee of Cutter at that time working with plasma, you understood that there were risks associated with the plasma and that there were reports in particular of patients developing hepatitis in association with Konyne and on occasion, deaths occurring? A: Yes. However, I was understanding that was a very rare*

[6] [MULL0000004_001], 'Transcript of Testimony of Dr Shohachi Wada in re: [GRO-A] et al. vs. Armour Pharmaceutical et al.', [21 – 24].

occasion.

Q: Okay. Doctor, again sticking with the 1970 to '72 time frame --- understanding, as I do, that you were a research scientist, were you aware of the fact that there were reports in the medical literature, in medical journals -- of cases of hepatitis occurring in association with Konyne?

A: Yes.

Q: Did you know that?

A: Yes.'

ii) The system and culture of donor selection and screening were endemically flawed.

10. In the transcript of testimony of Charles Griffin, in [*GRO-A], personally and as surviving guardians of [GRO-A]. deceased v Armour Pharmaceutical Corp.*[7]; Charles Griffin, a phlebotomist at Armour Muncie Plasma Centre from 1983 – 1987, gave evidence in respect of poor donor screening policies at the centre, inappropriate relationships between donors and the centre's staff, and other poor employee behaviour, such as drug use while at work.

[Pages 10 to 11]

[7] [MULL0000006_001], 'Transcript of testimony of Charles Griffin, in [GRO-A], personally and as surviving guardians of [GRO-A]. deceased v Armour Pharmaceutical Corp.; February 1997', [10 – 11].

'Q: Were the employees and management given any bonuses or perks based on production?

A: Yes, we were.

[…] Q. All right. Could you describe for the Jury the nature of your personal relationship with the donors from '83 say through '85?

A. Well, there was dating, drug use. We played softball together. We would meet at bars for drinks, play pool.'

11. In addition, in the *Affidavit of J. Garrot Allen in re: John Doe vs. Cutter Biological et al.* [8] we learnt that 'the "*paid for*" sector had no incentive to use the HB Core Test because many of their donor centres were in slum areas. Their donors were traditional high-risk donors for hepatitis. Many were also homosexual. They feared having to replace these donors.

iii) There was an institutional incentive to export to Europe.

12. In the summary of deposition of Thomas Drees (*Doe v. Cutter*, Case No. 90-687-CIV-ORL-3A20)[9] , the former CEO of Alpha – and an expert of manufacturing blood products, gave evidence

[8] MULL0000027_003, 'Affidavit of J. Garrot Allen in re: John Doe vs. Cutter Biological et al.', [4].

[9] MULL0000211, 'Summary of Deposition off Thomas Drees (Doe v. Cutter, Case No. 90-687-CIV-ORL-3A20)', [7].

which asserted that exporting to Europe was more profitable. This explains why there always seemed to be an abundance of supply for US commercial products in the UK. In addition, there would have been massive incentive to pass off products in the UK, on the promise of greater profits.

iv) Inflection period in assessing system failure, portending catastrophe in late 1982.

13. The deposition Summary of Thomas Drees *([GRO-A] vs. Cutter, et. al.*; Case No. 88-693-CIV-T-17(A)[10] explains as follows: –

> [Page 2]
>
> *'In Drees' opinion, in November/December 1982 there was sufficient information available within the industry to justify including a warning about AIDS in the factor product package. When Drees left Alpha in November of 1983, he was not aware of any manufacturer of Factor 8 who included a warning in their package inserts nor was there any effort made by any of the manufactures to educate their sales forces to warn of the risk of AIDS, nor were any "Dear Doctor" letters sent to any of the hemophilia treaters. What they were doing instead (at least at Alpha) was attempting to screen out infected donors and working*

[10] [MULL0000215], 'Deposition Summary of Thomas Drees ([GRO-A] vs. Cutter, et. al.; Case No. 88-693-CIV-T-17(A)))', [2 – 3].

to try to develop heat treated Factor 8, although Drees admits they should have taken that next step of warning the patient.'

[Page 3]

'Once again, he said that he found out in early November of 1982 that this new disease AIDS or as he calls it the HIV virus (although it was not known to be a virus then) could be transmitted through factor 8 products. He communicated this fact to Alpha's management committee in writing and to the National Hemophilia Foundation, but that was not in writing. Once again, Alpha's reaction to this was to concentrate on donor screening and heat treatment and they did not emphasize warnings at that time.'

14. This inflection period may also be discerned from the point of view of the regulator, in the deposition of Bruce Evatt, Vol 3 (MDL-986; In *Re: Factor VIII or IX Concentrate Blood Products Litigation*; Case No. 93 C 7452; In the United States District Court Northern District of Illinois Eastern Division).[11] Bruce Evatt, who was employed by CDC (Centres for Disease Control and Prevention) in the Hematologic Diseases Branch within the HIV/AIDS division, gave evidence about awareness of the risk of

[11] [MULL0000225], 'Deposition of Bruce Evatt, Vol 3 (MDL-986; In Re: Factor VIII or IX Concentrate Blood Products Litigation; Case No. 93 C 7452; In the United States District Court Northern District of Illinois Eastern Division)', [10 – 22].

the spread of AIDS in blood and blood products.

> [Page 10]
>
> *'Q. Now, you indicated I think yesterday and the day before that -- that, if I understand correctly, that you felt in 1982 that there was a risk of AIDS being transmitted during -- by blood and blood products; is that correct? […] THE WITNESS: In 1982 my division certainly did feel that there was a risk of -- of AIDS being transmitted in – in blood and blood products and it was most likely a viral agent.'*

> [Page 22]
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> *'THE WITNESS: Our position [in January 1983] was that it was -- our position was at the time that there was a -- a -- we thought that it was a -- we felt that the spread of AIDS through blood and blood products was a -- the data that we had indicated that that was a – a probable hypothesis to be working on and that it was -- it should -- a strong enough hypothesis at that point in time that – that measures should be taken to -- to screen high-risk donors out of the donor pool.'*

v) *Pharma refusal to adopt reasonable steps to mitigate the fact of clear and present risk in commercial factor VIII.*

15. Pharmaceutical companies' refusal to take steps to mitigate the clear risk, is highlighted in the following evidence:

a) In the Summary of Trial Testimony of *Michael Rodell ([GRO-A] v. Armour Pharmaceutical Co.*, No. 89-1705-CIV-T-23B; United States District Court M.D. Fla.)[12], transcript from infected blood product litigation and Armour Pharmaceutical in the USA, it shows that as of January 1983, Armour had not concluded that there was a potential risk of AIDS transmission via concentrate. The considered opinion was that Armour had no obligation to issue an AIDS warning with its concentrate until it was proven that a hemophiliac had been infected with the AIDS virus from Armour's product.

b) The Letter from Robert E. Barden, Cutter Biological, to David C. Elliott, Jackson Plasma Center, re: FDA decision on AIDS and its effect on marketing and the selling of any Factor VIII or Factor IX product states:[13]

"Marketing will not be able to sell <u>any</u> Factor VIII or Factor IX if we do not institute our questions along with

[12] [MULL0000454], 'Summary of Trial Testimony of Michael Rodell ([GRO-A] v. Armour Pharmaceutical Co., No. 89-1705-CIV-T-23B; United States District Court M.D. Fla.) Transcript from infected blood product litigation and Armour Pharmaceutical in the USA', [6].

[13] [MULL0000837_022], 'Letter from Robert E. Barden, Cutter Biological, to David C. Elliott, Jackson Plasma Center, re: FDA decision on AIDS and its effect on marketing and the selling of any Factor VIII or Factor IX product', [1].

the other fractionators. Obviously, pressure from the competition and the FDA have pushed us into this decision. Despite the lack of much evidence, it does appear that AIDS in caused by an infectious agent... Marketing has been pushing its IGIV for use with AIDS patients and it is being used at an ever expanding rate. Resign yourself to the inevitable; AIDS is with us to stay."

c) A letter, from Michael B. Rodell, to Elaine C. Esber, regarding heat-treatment of Antihemophilic Factor (Human) Lots – being a letter from Armour to a doctor – stated:

"it is not our intention to routinely subject lots of nonheated product to heat-treated, either in part or in whole, once they have been released to finished goods." [14]

Further, an Armour memo, shows that a switch to cryoprecipitate was feasible:

[Pages 3 – 4]

"The NHF and other groups have recommended decreased utilization of clotting factor concentrates by substituting individual units of cryoprecipitate AHF and fresh frozen plasma for Factor VIII and Factor IX deficiencies

[14] MULL0004240, 'Letter, from Michael B. Rodell, to Elaine C. Esber, re: heat-treatment of Antihemophilic Factor (Human) Lots', [1].

respectively. From a logistic standpoint, this change is feasible. In fact, if all frozen plasma currently used to prepare AHF concentrates were diverted to cryo production, the amount of available AHF would double due to higher yields in cryo." [15]

vi) Calculation of balance of risk without any patient involvement

16. It appears that by early to mid-1983, there was an institutional awareness of risk from commercial concentrates. This is poignantly illustrated by a 'Questions and Answers about AIDS' Memorandum dated 8 February 1983 from Cutter to all Plasma Centre Owners and Regional Managers, which stated:

"Q. What product is affected by AIDS?

A. Right now, it is believed that Factor VIII and Factor IX, Koate[R] *and Konyne*[R]*, can pass AIDS on to the recipient."* [16]

17. Moreover, not only was there an awareness, but also an ongoing analysis of whether continued use outweighed the harm from them that was by then, readily apparent. Unsurprisingly, it was in pharma's interest to off-load as much contaminated products as

[15] [MULL0004243], 'Memorandum, from Michael B. Rodell, to Mr William C. Weathersby, re: Federal Interagency Technical Committee Meeting on AIDS', [3 – 4].

[16] [MULL0000841_015], 'Memorandum from Robert Barden, Cutter, to All Plasma Center Managers, re: Screening of donors, cases of haemophiliacs having contracted AIDS, and regulatory framework', [1].

they could, to maximise profit taking. There does not appear to be much consideration of the perspective of those living with haemophilia, in weighing such risk. The nature of the considerations, appear to be brusquely captured in this summary of evidential points:

> "j. *August 2023, 1983 Letter from Deputy Commissioner of Food and Drugs stating that the Blood Product Advisory Committee's request that a balance be struck between the risk of contaminated product to recipients against "the need for an uninterrupted supply of AHF."*[17]

Conclusion

18. The pharmaceutical industry, as a non-state actor, played an outsized role in the matters under investigation in this Inquiry. As the dominant – or even rapacious – purveyor of blood and blood products in the UK, the industry succeeded in passing contaminated products to vulnerable people living with haemophilia, showing a disregard for human life, which had a devastating personal impact for those infected and affected. This was made possible by a UK state system that failed at multiple levels to ensure there were adequate protections in place for those who were the end-users of pharma products. As such, the UK was in dereliction of its duty to

[17] MULL0000647_017, 'Summary of Evidential Points', [1].

protect the life and health of those adversely affected by the actions of the pharmaceutical industry during the 1970's and 1980's.

19. All findings of accountability, or any apologies or statements of acceptance of responsibility regarding the UK, should particularly recognise the outsized role of the pharmaceutical industry as described in the foregoing paragraph. Such acknowledgement is important because most of the individual pharma companies that were directly involved in these matters no longer exist. There does not appear to be any robust umbrella organisation of the industry that has had a watching brief in this Inquiry – and that could take any semblance of moral responsibility. Additionally, unlike in the US and elsewhere, there has been no juridical process – that is, neither criminal case nor civil suits – that have managed to bring any pharma company to book in the UK. It is therefore critically important that the role of the pharma industry in defining the State's Article 2 and other human rights obligations, is clearly spelt out in all findings of accountability.

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