Central England Law Centre

Legal Action for the Community

97 Walford Road
Birmingham
B11 1NP
tel: 0121 227 6540

Treasury Solicitor's
23 DEC 2015
Received

Government Legal Department
Litigation Group
One Kemble Street
London
WC2B 4TS

By email (Eleanor.Goodfield@ GRO-C
And by post

21 December 2015

Your ref: GRO-B
Ref: GRO-B
Please ask for: Karen Ashton

Dear Sirs

Re: GRO-B Inquest

Please find enclosed a letter sent to the Coroner today together with the reply to the Department of Health's submissions.

Yours faithfully

GRO-C

Central England Law Centre

Central England Law Centre

Legal Action for the Community

97 Walford Road
Birmingham
B11 1NP
tel: 0121 227 6540

Mr Tom Osborne
HM Senior Coroner
Civi Offices
1 Saxon Gate East
Milton Keynes
MK9 3EJ

By email (tom.osborne@ GRO-C and post

21 December 2015

Ref: GRO-B

Dear Sirs

Re: GRO-B

Please find enclosed the further representations submitted on behalf of Mr GRO-B family in reply to those made by the Department of Health.

We also write with reference to your email of 17 December. We note 'Article 2' is included as an item on the agenda for the proposed PIR and as to the scope of any investigation required following Penrose. We had understood that you were intending to make a decision on this issue before the end of December. We would respectfully refer you to the enclosed representations in which we set out our reasons for saying that there is a clear and crystallised issue in dispute between the Department and our client which requires determination before consideration can sensibly be given to the identification of relevant witnesses and documents and the timetable. It is our understanding that the Department does not dispute that the State has a duty of enhanced investigation, but argues that the wider systemic issues have been fully addressed by the Penrose Inquiry. That is the matter in dispute. The determination of this question will have a significant and fundamental impact on the nature and scope of the investigation to be undertaken. This is summarised in the final paragraph of the enclosed representations in the following terms:

> *If the Family are correct the investigation into Mr* GRO-B *death will need to examine wider systemic failures which led to blood products in England & Wales being contaminated (and not simply narrow questions as to how those products came to be provided to Mr* GRO-B *While relevant findings by the Penrose Inquiry can, of course, be*

LEGAL AID LAWYER OF THE YEAR AWARDS WINNER 2015

www.birminghamclc.org.uk
fax: 0121 772 2487

Member of the Law Centres Network
Registered with OISC for Immigration and asylum: N200100510
Registered with Charity Commission: 1087312
VAT registration number: 544 9032 44
Registered in England & Wales as Central England Law Centre Ltd, a company limited by guarantee: 4149673

taken into account, any investigation into, for example, the failure to achieve self-sufficiency or the response of central Government to the growing awareness of the blood contamination problem, is likely to be extensive in scale and requiring a significant number of documents and witnesses (including relevant Ministers and senior civil servants). Ultimately it is difficult to see why the investigation in relation to the provision of contaminated blood in England & Wales would raise less complex issues and require less thorough examination than those conducted into similar events in Scotland, or indeed Canada or Ireland which held public inquiries.

It may be that we have misunderstood the implication of the inclusion of Article 2 and the scope of the investigation post-Penrose in the agenda for the proposed PIR, and we would be grateful for confirmation that we will receive your written decision, with reasons, on the issue in dispute by the end of December. It is likely that both the Department of Health and Mr GRO-B family will want to consider carefully the implications of your determination of this question and that one or both will wish to make further representations to you on the appropriateness, timing and agenda for the proposed PIR. If the matter remains in dispute, it may be that the issue will fall to be settled by the Administrative Court. Clearly this would have implications for the timing of any PIR.

In any event, in relation to the latter we wish to request that the listing is reconsidered. As you are aware Mr Squires has been instructed on behalf of the family since the start of the inquest process. This is a complex matter raising issues of great importance to our client. The instruction of alternative counsel of similar experience at this critical stage would require a considerable amount of duplicate work and it is by no means certain that the family would have the resources to meet these additional costs. We would be extremely grateful if an alternative date for any PIR considering timing, witnesses etc could be explored and fixed for a time after a decision is taken on the engagement of Article 2 and the scope of the investigation required post-Penrose,

Yours faithfully

GRO-C

Central England Law Centre

Cc Eleanor.Goodfield@ GRO-C

BEFORE THE SENIOR CORONER MILTON KEYNES

IN THE MATTERS OF THE INQUEST
INTO THE DEATH OF GRO-B

REPLY ON BEHALF OF
GRO-B FAMILY TO DOH'S SUBMISSIONS

Introduction

1. The Department of Health ("the DOH") has made submissions on the Penrose Inquiry dated 9 October 2015 (references below to "[DOH/§x]" are to paragraphs in the Department's submissions). The DOH's submissions respond to those made on behalf of GRO-B family ("the Family") of 5 August 2015 GRO-B). The following note sets out the issue in dispute following the DOH's submissions and the Family's response to them.

The issue in dispute

2. It is apparent from the DOH and Family's submissions that there is a clear and crystallised issue which requires determination. Other issues are not disputed. It is understood that the DOH does not dispute that (i) the State has a *"duty of enhanced investigation"* (see *R (Humberstone) v LSC* [2011] 1 WLR 1460 §52) pursuant to ECHR Art 2 in relation to Mr GRO-B death, and that (ii) the State therefore has an obligation to ensure that the circumstances of Mr GRO-B death, including any systemic failures that led to him (like thousands of others) being provided with contaminated blood products, is subject to an independent, effective, public and prompt investigation GRO-B. The DOH's position, however, is that *"the wider systemic issues material to Mr* GRO-B *death have been fully addressed by the Penrose Inquiry"* [DOH/§50] (emphasis added). That is the issue in dispute.

3. If the DOH is correct, it has a significant impact on the scope of the investigation now required into Mr GRO-B death. The issue in dispute is as follows: *"has the Penrose Inquiry fully investigated any systemic issues which explain how blood products in England & Wales (which were provided to Mr* GRO-B *in the 1980s) came to be contaminated?"* If so, the only issue that requires investigation in this inquest is the specific circumstances by

which those contaminated blood products came to be provided to Mr GRO-B If the Penrose Inquiry has not fully addressed all relevant systemic issues, there remains an un-discharged obligation on the State to investigate, at least some aspect(s), of the wider circumstances by which blood products in England & Wales came to be contaminated. That will require a very different investigation than the more limited one described above (and raises the question of whether it could be effectively conducted in the course of a single inquest as opposed to a public inquiry akin to Penrose).

4. In summary, the DOH and Family's positions are as follows:

(i) The DOH's position is that all wider systemic issues potentially material to Mr GRO-B death have been investigated by the Penrose Inquiry so that the State's obligation in relation to all those issues has been discharged. Its position is that all significant questions as to why there was a failure to prevent contaminated blood products in England & Wales being provide to haemophiliacs such as Mr GRO-B have been answered, the "*the full facts [have been] brought to light, any culpable and discreditable conduct [has been] exposed and brought to public notice ... [and] lesson learned*" (*R (Amin) v SSHD* 1 AC [2004] 653 §31). In this regard the DOH relies upon *R (Long) v SSD* [2015] EWCA Civ 770 §65 (a case in which there had already been an Army Board of Inquiry and an inquest into the specific soldier's death and which had identified the relevant failures and lessons to be learned). The DOH submits that, as in *Long* §65, in this case there is no "*realistic*" or "*reasonable prospect*" that any "*significant or useful information*" about blood contamination in England & Wales "*could be obtained*", there are no more useful lessons still to be learned and no discreditable conduct that could be brought to public notice by further investigation of systemic issues.

(ii) The Family's position is that that is unsustainable. That is apparent if one examines specific issues that remain un-investigated (see below), but perhaps the starkest indication of why that must be so is provided by a point not addressed by the DOH. As set out in the Family's submissions of 5 August 2015 §§2 & 28, the Penrose Inquiry recorded that the rate of infection of haemophiliacs with HIV during the material time was twice as high in England & Wales as in

Scotland. Or to put it another way, had Mr GRO-B been treated with blood products in Scotland, he was half as likely to have been infected. That must be explained by some failures in the systems, policies and practices in place in England & Wales which did not apply to Scotland. Unsurprisingly an inquiry whose terms of reference expressly related only to Scotland GRO-B §5] did not get to the bottom of that question, and did not conduct an Art 2 compliant investigation to identify who was responsible for any failures that meant the position in England & Wales was so much worse than in Scotland.

Approach of DOH

5. Before turning to issues that require further investigation, the Family addresses a number of general points about the DOH's submissions.

6. Firstly, the DOH has treated the list of potential systemic issues identified by the Family in submissions of 3 March 2014 §11 as being the only ones relevant to Mr GRO-B death. As set out in those submissions, and repeated in the 5 August 2015 submissions, that list is "*non-exhaustive*", and moreover was submitted prior to the Penrose Inquiry reporting.

7. Self-evidently the Family do not have the information or resources of the DOH to determine what was the complete list of potential systemic failures regarding the provision of blood products to haemophiliacs in England & Wales (and which the DOH now concedes required investigation: DOH §4). There is, however, no indication that the DOH has conducted its own review, following the Penrose Inquiry, to determine whether all systemic issues relevant to England & Wales have been fully investigated. If the DOH has conducted such a review, it has given no indication of who conducted it, when they did so, which issues were considered and what was the outcome of the review. The Art 2 obligation to investigate is a pro-active one. State authorities must act "*of their own motion ... they cannot leave it to the initiative of the next-of-kin to lodge a formal complaint or to take responsibility for the conduct of an investigation*" (*Amin* §20(5)). That applies, *a fortiori*, when one is dealing with information that is only in the hands of the DOH. If the DOH has not conducted its own review of relevant systemic issues, that is, itself, a breach of the State's investigative obligation, and it also

means the DOH has no proper basis for submitting that the Penrose Inquiry has discharged the Art 2 obligation.

8. Secondly, the DOH criticises the Family for not indicating *"the witnesses whose evidence would not need to be called ... the categories of documents that have yet to be considered reviewed (sic), or the specific lines of inquiry that would need to be pursued"* (DOH §51 and see further §50-55).

9. That is a surprising submission and reflects the error of law identified above. The DOH appears to consider that it is for the Family to *"take responsibility for the conduct of an investigation"* and to be required to identify witnesses and documents relevant to the formation of Government policy and practices some 30 years ago. It is not clear how it is said they are supposed to obtain that information. If it is necessary at this stage to identify precisely which witnesses and documents will be required, that is plainly information which is within the knowledge of the DOH and which it should be providing (or it should be showing that all potentially relevant witnesses and documents were before the Penrose Inquiry, something it has not done: see further below).

10. Thirdly, the DOH submits that the Family's approach is *"fundamentally flawed"* as it *"purports to address the question of whether the Penrose Inquiry has addressed the wider issues relevant to Mr* GRO-B *death without first identifying what those issues are."*

11. That criticism is not understood [DOH/§7]. It is not disputed by the DOH, as the Family submitted on 3 March 2014, that the overwhelming likelihood is that Mr GRO-B died as a result of his being infected by HIV and Hepatitis C and that he became infected as a result of receiving contaminated blood products provided by the NHS. If that is correct, then any failures in systems, policies, or practices which led to the NHS providing contaminated blood products to Mr GRO-B along with thousands of other haemophiliacs, are plainly *"defects in the system which contributed to the death"*, *"factors which are relevant to the circumstances of the death"* (*R (Middleton) v W Somerset Coroner* [2004] 2 AC 182 §36) and matters which *"might have been expected to avoid"* the risk to life (*R (Medihani) v HM Coroner for Inner South London* [2012] EWHC 1104 §46-7).

Systemic issues not addressed by Penrose Inquiry in ways compatible with Article 2

12. As set out above, it is not the role of the Family, certainly at this stage of the process, to identify every systemic issue that requires investigation in relation to Mr GRO-B death. Nor, without the assistance of the DOH, are they able to do so. The question which currently requires determination is whether the DOH is correct that the Penrose Inquiry has "*fully addressed*" all systemic issues material to Mr GRO-B death, so that the inquest need not examine the wider circumstances in which contaminated blood products came to be provided to haemophiliacs. That that is clearly not the case is apparent by considering three examples: (i) self-sufficiency, (ii) public health and central Government decision-making and (iii) clinical practices.

(i) Self-sufficiency

13. One of the reasons for the lower proportion of Scottish haemophiliacs infected with HIV at the material time as compared to those in England & Wales may be the fact that Scotland was more self-sufficient in blood and blood products (see Penrose Inquiry §3.309). The Family set out the Penrose Inquiry's consideration of self-sufficiency at GRO-B §28-31. The DOH responded at DOH/§34-37.

14. The DOH submits that "*the reasons for the slower progress towards self-sufficiency in England are carefully analysed in the Penrose Report*" (DOH/§35). Insofar as the DOH is contending that the Penrose Inquiry has conducted an Art 2 compliant investigation into the reasons why, in England & Wales, greater levels of self-sufficiency were not achieved by the 1980s, and determined the consequences of that for the levels of HIV and Hepatatis C in NHS blood products in England & Wales, that is an unsustainable submission.

15. The DOH does not identify any findings made by the Penrose Inquiry as to whether anyone was at fault in the failure to achieve greater self-sufficiency, and if so who, what they did wrong, what they should have done differently and what consequences followed from any failures. The DOH does not identify a single witness specifically concerned with the failure to achieve self-sufficiency in England & Wales who was called to give evidence. It is impossible to see how it could be suggested that an Art 2 compliant investigation into potential failings has been conducted when no-one who might have been responsible for the failings was called as a witness and required to

give evidence and explain themselves in public. That is not a criticism of the Penrose Inquiry. It was not a part of its terms of reference to examine why failings occurred in England & Wales. But in those circumstances it is entirely unsurprising that it considered it "*inappropriate to express any view*" of criticisms made of the failures in England & Wales (Penrose Inquiry §21.41) or to explain those failures by comparison of the position in Scotland (ibid).

16. The DOH relies upon the observation by the Penrose Inquiry at §21.35 that self-sufficiency was unlikely to be achieved in England & Wales "*with the level of expenditure granted by Parliament while demand was left to grow without restriction.*" That, however, is not the end of an Art 2 compliant investigation into the failure to achieve self-sufficiency, but the start. It would need to be determined whether that was the only reason for the failure, if so why was insufficient expenditure granted, should increasing demand have been predicted earlier or permitted to grow without restriction? As the Inquiry noted, Scotland was able to remain ahead of England in terms of self-sufficiency due to sufficient facilities and flexibility in production, notwithstanding increases in demand in both countries (§19.72). Furthermore, the Penrose Inquiry also identified the failure to ensure that the Scottish Protein Fractionation Centre ("PFC") could supply plasma products to England. Yet there is no further exploration of why that failure occurred, other than noting in §19.42 that there were issues in supplying plasma from PFC in Scotland due to trade union problems and that the Joint Committee on Blood Products Production in England & Wales "*did not resolve these issues*" (§19.45). That too would require investigation in an Art 2 compliant investigation of the failure in England & Wales to achieve self-sufficiency.

17. It is also telling that a significant portion of the DOH's submissions on self-sufficiency relies upon the "*Archer Inquiry*" as discharging the State's Art 2 obligations [DOH §37]. The Archer Inquiry was a non-statutory inquiry, paid for by donations, with limited resources and no legal powers. It reported in February 2009. The Archer Inquiry found clear evidence of policy failings and errors made in relation to self-sufficiency (describing itself as "*dismayed*" by the "*lethargic progress*" towards self-sufficiency in blood products in England & Wales (p 103), noting that it took 5 years in Ireland but 13 in England & Wales (ibid)). As the Family have submitted on a number of

occasions, however, *"Despite its best efforts … the Archer Inquiry does not come close to satisfying the State's ECHR Art 2 obligations and indeed did not purport to do so"* (see Family's submissions of 8 September 2014 §13 and further at §13-25, as well as submissions of 3 March 2014 at §50). Those submissions have never been answered by the DOH.

(ii) Public health and central decision-making

18. As set out in the Family's submissions of 5 August 2015 [GRO -B §18-22], the Penrose Inquiry did not conduct an Art 2 compatible investigation into potential *"public health"* failures by the DOH[1] or other Government officials and Ministers based in England.

19. A series of potential failures were identified in the Penrose Inquiry such as a lack of a consistent official policy on contaminated products, the failure to establish a body to provide independent scientific advice to Ministers, but did not investigate who was at fault and what should have been done differently (see [GRO -B §21]). There are moreover more general questions as to whether, given the state of scientific knowledge, decision-makers in the DOH should have taken a more *"precautionary"* approach to the provisions of warning to patients or the use of commercial blood products, as some medical experts were advising them to do, rather than waiting for *"conclusive evidence"* that AIDS was transmitted by blood products before acting (Penrose Inquiry §9.108 et seq).

20. The DOH submits that the Penrose Inquiry *"does deal extensively with what may be termed the 'official response' to concerns about blood contamination"* and refers to Penrose Inquiry Report §9.99-9.125 [DOH/§58]. The DOH also submits that at various points in the report, Lord Penrose deals with *"the official view"* or the position expressed by *"DHSS Ministers"* (ibid).

21. If, however, one examines the section of the Penrose Inquiry Report said to *"deal extensively"* with the *"official response"* in London to the emerging evidence of contamination in blood and blood products in the early 1980s, it is plain that the Penrose Inquiry did not conduct, and did not purport to conduct, an Art 2-compliant

[1] References below to potential failures by the *"DOH"* in relation blood contamination should be taken to include failures by predecessors *"the Ministry of Health"* and the *"Department of Health and Social Security"*.

investigation into any failures of central Government policy. The Inquiry Report §9.99-9.125 is simply a description of events in 1983. There is no attempt to determine whether anyone was at fault or to indicate what they should have done differently. No Ministers (such as those referred to in the Penrose Inquiry Report at §9.109) gave evidence. Indeed, as set out in the Family's Submissions of 5 August 2015, no-one at all from the DOH gave evidence. As set out in relation to self-sufficiency, it cannot be suggested that an Art 2 compliant investigation has been conducted when no-one who might have been responsible for failures was questioned or required to explain themselves in public. Indeed, it is very difficult how it could seriously be suggested that an Art 2 compliant investigation could be conducted into what Lord Winston described as the "*worst treatment disaster in the history of the NHS*" without calling any evidence from civil servants within the DOH or any Ministers responsible for the NHS and health policy at the material time.

22. The DOH submissions refer to 5 doctors who were "*English witnesses*" said to have been called by the Penrose Inquiry (Appendix to DOH submissions §7-8). One doctor referred to is Dr Diana Walford, a senior medical civil servant at the DOH at the material time. Contrary to the DOH's submission, however, Dr Walford was not a witness to the Inquiry. She sent a 7 line letter to the Inquiry dated 26 February 2011 (see Inquiry Documents [PEN.010.0079]), having declined a request of 23 December 2010 to provide a statement dealing with a series of issues detailed by the Inquiry (ibid [PEN.019.1279]). Of the other 4 doctors referred to, Dr Perry was a member of the Committee on the Safety of Medicine but only from 1986, some 3 years after the critical period, and neither he nor any of the other doctors identified by the DOH were civil servants or responsible for setting Government policy.

23. Comparisons with the Archer Inquiry are again telling. As set out above, the Archer Inquiry cannot satisfy the State's Art 2 obligations. It is, however, notable that it found clear indications of problems in the Government's response to the warnings about the risks of contaminated blood products. The Archer Report refers at p 50 to the growing public concerns about AIDS in 1983, and then states, laconically, that "*the panic did not extend to Government, nor to all sections of the scientific community whose imperturbability veered in the opposite direction.*" The Government's approach was to await "*conclusive proof*" of the link between AIDS and imported blood products before taking action (p

51-52). The Archer Inquiry observed: *"the danger signals might have indicated some precaution"* (ibid). It continued by noting the tendency of the Government to *"cool discussion"* and that it had *"little sense of urgency in commissioning advice"* (p 51). It set up an expert advisory group on AIDS only in 1985 and with *"individual practitioners being subjected to conflicting advice"* (ibid). As to the Government's decision to continue to use commercial US blood taken before March 1983 when restrictions were imposed on high risk groups (such as those with symptoms of HIV or intravenous drug users), the Inquiry describes it, simply, as *"surprising"* (p 53). In its conclusions the Inquiry stated that it was *"dismayed at the time taken by Government and scientific agencies to become fully alive to the dangers of Hepatitis C and HIV infections"* (p 103).

24. The Penrose Inquiry did not seek to investigate whether there were those kinds of failures by specific Ministers or civil servants in London in setting Government policy at the material time, and if so who should be held responsible. Those matters require consideration and determination if an Art 2 compliant investigation into Mr GRO-B's death is to be conducted.

(iii) Clinical practice

25. As set out in the Family submissions of 5 August 2015, the Penrose Inquiry subjected the individual blood treatment centres in Scotland to close scrutiny [GRO-B §23-25]. It sought, for example, to investigate whether the centres should have adapted their treatment regimes sooner, whether they should have used cryoprecititate in preference to concentrates. As is clear from the Inquiry Report, many of those decisions were made at a local level and there were variations within Scotland. The same questions would require examination in relation to the treatment centres in England & Wales that treated Mr GRO-B They are obviously relevant to the circumstances of his becoming infected with HIV and Hepatitis C, and may suggest systemic failures. The DOH has not replied to those submissions.

Conclusion

26. As set out in the Family's submissions of 5 August 2015, any investigation of Mr GRO-B death would, of course, take the Penrose Inquiry as a starting point and would not need to re-investigate matters determined by Lord Penrose [GRO-B §2 & 4]. It is, however, unsurprising that an inquiry into the provision of contaminated blood

products, and the decision-making which led to it, in Scotland, and which did not hear from relevant witnesses based in England & Wales, would not constitute an Art 2 compliant investigation into the systemic issues applicable to those infected in England & Wales.

27. Mr GRO-B inquest was stayed in 12 September 2014 pending the publication of the Penrose Inquiry report. As the Family stated in their submissions of 8 September 2014, once the report was published it would be possible to determine the scope of the investigation required by Art 2 into Mr GRO-B death, which witnesses would be required and its timescale. That is now possible but it is first necessary to determine whether the Family or the DOH are correct as to whether all wider systemic issues have been fully addressed. If the Family are correct the investigation into Mr GRO-B death will need to examine wider systemic failures which led to blood products in England & Wales being contaminated (and not simply narrow questions as to how those products came to be provided to Mr GRO-B. While relevant findings by the Penrose Inquiry can, of course, be taken into account, any investigation into, for example, the failure to achieve self-sufficiency or the response of central Government to the growing awareness of the blood contamination problem, is likely to be extensive in scale and requiring a significant number of documents and witnesses (including relevant Ministers and senior civil servants). Ultimately it is difficult to see why the investigation in relation to the provision of contaminated blood in England & Wales would raise less complex issues and require less thorough examination than those conducted into similar events in Scotland, or indeed Canada or Ireland which held public inquiries.

Dan Squires
Anita Davies

Matrix Chambers

Karen Ashton
Central England Law Centre

18 December 2015