The Scottish Parliament

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Dear Professor Ludlum

Thank you for your time at our recent meeting – I appreciate you have a very busy schedule. I found the meeting very helpful. There are a number of questions arising from it which I hope you can help me with.

At our meeting you talked of how patients were pressing for home treatment with Factor VIII instead of cryoprecipitate. From all the documents I can find and our meeting it's clear that patients were not informed of the documented risks of using Factor VIII, the Council of Europe recommendation (no 8), or offered a choice of continuing on cryoprecipitate or other alternatives. I'm still finding it difficult to understand why, when the statistical risks of cryoprecipitate in adults as well as children, are lower than Factor VIII, that only children were treated with cryoprecipitate only. You did suggest that resources and infrastructure would have made it difficult to produce significant quantities of cryoprecipitate and that in any case it has since been shown that infection rates of blood borne viruses have been the same as Factor VIII. I wonder if you could point me in the direction of the documentation that would demonstrate that?

I've taken the opportunity to read your academic papers – thanks for the ones you provided – and wonder if you can help me with the following:

In your letter to The Lancet in May 1983 you describe 23 patients with severe haemophilia and in the article "Abnormalities in circulating lymphocyte subsets in an AIDS free population" of June 1984, 37 Haemophilia A patients, 10 Haemophilia B patients. Can you tell me how many of these patients received the presumed infective batch of Factor VIII?

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I'm a bit confused about the process of identifying the infected batch. As far as I'm aware, no virus has ever been isolated from any of these batches. You suggested this was due to the lack of sensitivity of the tests available. Does this include tests that became available in the early 1990s? I would be extremely concerned if tests to detect the HIV virus were not sensitive enough at a time when blood products were heated and screened and deemed to be safe. When did the tests become sensitive enough and has the suspected batch been subject to these tests?

On the subject of heat treatment, you said that trials of heated Factor VIII began on the presumption that Hepatitis Non A Non B was in every blood product and that the elimination of HTLVIII didn't figure initially. However SNBTS papers frequently refer to heat treatment being concerned with the elimination of the "AIDS virus" which was identified and cultured late 1983/early 1984. And in autumn 1984 SNBTS regarded as apparent that HIV might be heat sensitive. Do you know the process of reaching that conclusion and what mechanisms/trials were used to identify this?

Can you also tell me how much commercial Factor VIII was administered from early 1983 onwards? Of the patients who received commercial Factor VIII, how many became HIV positive?

I'm also a bit confused about your statements about the implications of positive antibody results in haemophiliacs in 1984. You suggested that in the academic world it wasn't clear what a positive antibody result meant – it may have suggested protection from AIDS. Yet you expressed your shock and horror when you discovered in late 1984 that some of your patients were antibody positive. From the literature internationally I have been able to obtain it seems clear to me that such a result and the clear emergence and association of HIV, AIDS and blood products would have meant that there must have been a very charged climate of fear at that time about AIDS and the risks from Factor VIII particularly.

With reference to trials of heat treated products, I'd be grateful for more detailed information about these: when they began, rationale, number of patients involved, how their efficacy as a treatment and the elimination of viruses was determined.

I wonder if you've had further thought about the recording of the infected batch in patient treatment records. You thought that its recording in long form, unusually, may have been done retrospectively when it was cited as the infected batch. Have you had a chance to check that out?

It would be helpful if you could give me an idea of what risks of infection with blood borne viruses, per virus, were generally believed to be the case year on

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year from 1980 onwards. I note for example it was generally accepted 1983 onwards that "non A-non B" would be very prevalent in all blood products. Can you quantify the perceived risks for each virus, both in terms of prevalence in the blood supply and risk of transmission to patients?

Finally, I wonder if you could expand a bit on your concerns, first raised in 1983, about the lack of arrangements in place for compensating patients, both in relation to your organisational concerns and what you feared patients would have had to be compensated for?

Thank you very much for your co-operation and help with these matters.

Yours sincerely

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