Re. The Penrose Inquiry –The Late Mr Victor Tamburrine
Reaction to letters from Thompsons' solicitors

Dear Mrs Lovell,

The reports of the inspection by the Medicines Inspectorate on the status of the Plasma Fractionation Centre in Edinburgh in October 1981 and May/June 1988 concluded that a number of deficiencies regarding the buildings and facilities (1981) and GMP-related issues (1988) were found. In addition the inspectors defined matters of concern like insufficient storage areas and lack of standard operating procedures (SOP's).
When interpreting these findings it should be taken into account that in the 1980's pharmaceutical companies, including plasma fractionation centres, were in the process of implementing Good Manufacturing Practices (GMP). This process takes considerable time in particular when the construction of buildings and facilities for manufacturing occurred before the requirements of GMP were defined. As a consequence, when GMP became required by the regulatory authorities changes in the lay-out of buildings, new equipment and training of staff were necessary which took time. When the inspection reports of 1981 and 1988 are compared it appears that a number of such changes and improvements had taken place in Edinburgh.

The question that Thompsons' solicitors want the Inquiry to consider is "whether there is any potential link between the documented unsatisfactory state of affairs at Liberton in the 1980's and the possible infection of Mr Tamburrini with hepatitis C as a result of the transfusion in September 1984". Although this is not specified I assume that the term transfusion is used here for the administration of SPPS. Given that I do not have sufficiently detailed knowledge of the practices of SNBTS at the time, I am unable to completely and absolutely discount the proposition that Mr Tamburrini somehow was treated with unsafe SPPS. However, when the question would be asked "Is that proposition (the causal link between the state of affairs at Liberton in 1980 and the hepatitis C infection) likely?" my answer would be that it is highly unlikely.

The likelihood of mislabelling of products and mixing heated and non-heated products is difficult to judge. It requires an insight in the labelling procedure(s) being used in 1984. But more important, even when such mixing would have occurred and led to an infectious product, one would expect that other recipients of this batch of SPPS would have developed hepatitis C. I have not seen data showing that in 1984 or afterwards recipients of SPPS manufactured and distributed by SNBTS developed hepatitis C. In my report to the Penrose Inquiry (December 2010) I provided information from the international scientific literature showing that there has never been a report of hepatitis C transmission through albumin solution.

With regard to another question from Thompsons' solicitors, namely batches being contaminated by staff movement during virucidal efficiency trials, my answer is that such trials are normally done in separate facilities outside the manufacturing rooms. I expect that when the plasma fractionation centre in Liberton executed virucidal efficiency trials a separate or dedicated room was used. Furthermore such trials were not performed until the late 1980's because the origin of the hepatitis C virus was not known earlier. A model virus for HCV, which could have been used for spiking experiments to demonstrate the virucidal

efficiency of the pasteurisation step in the manufacturing van SPPS, was unknown. Therefore this proposition can be left aside.

Contamination of batches due to the re-use of pH-probes while using (virus) spiked samples can be excluded for the same reason (i.e. virucidal efficiency of hepatitis C was not determined until the late 1980's). In addition measurements (such as the pH) of spiked, viral contaminated samples are normally done outside the manufacturing facility and contamination of batches cannot occur because the samples are discarded...

With kind regards,

W.G. van Aken MD, PhD.
(Em.) Professor of Medicine

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