FAX
Charge 16-62118

Copy: P. DeHart
B. Dyos (FAX Cutter UK Stoke Court)
J. P. Fallise (FAX Bayer Wuppertal)
E. Greene
J. Pennington
M. Sternberg
J. Wood (FAX Troponwerke)

October 13, 1987

Ref: JB 87-655

To: Marie Tatt
Cutter UK Stoke Court

From: R. H. Rousell
Cutter Berkeley

Subject: Konyne-HT Licensing in the United Kingdom

Both Dr. Greene and I have been instructed by Dr. Sternberg to discuss the above subject with you and provide the necessary guidance and support.

In your telefax you indicate that the major stumbling block is "some long-term evidence of safety in clinical use with special reference to the transmission of infectious viruses." The only absolute data we have on this is the in vitro work performed by McDougal et al at the CDC published in J Clin Invest 76, 875-7, 1985. In addition to that, we can at any time prepare a detailed account from our adverse reaction files indicating the total use of Konyne-HT over any given period, coupled with the number and nature of spontaneously reported adverse reactions during that period.

The third possibility is, of course, to set up a prospective study. This would be similar to that proposed for Koate-HS in which we would follow-up, seldom-or-never previously treated patients with blood or blood products, over a six-to-twelve month period after receiving Konyne-HT. You seem to suggest that Professor Temperley might be prepared to collaborate. If you wish Dr. Fallise and I could draft a protocol which either or both of us, depending upon other commitments could present to Professor Temperley and solicit his cooperation/participation.

You will probably wish to discuss this internally at Cutter UK. Please let us have your comments once you have done so. Unfortunately, it does not appear as though I will be visiting Europe again this year, and no visit is planned for early 1988, so that we will need to discuss the matter by FAX, letter, and telephone. I think the same applies to Eli Greene.

Please let me have your comments as soon as possible.

Kind regards.

GRO-C

Ralph H. Rousell, M.D., M.Sc.
Director International Clinical Research

RHR:jb