INTER-OFFICE CORRESPONDENCE

TO A. B. Bessler **CONFIDENTIAL FOR COUNSEL ONLY**	FROM Dr. Fred Feldman
	CO. Armour Pharmaceutical Co.
	CITY Kankakee, IL
THIS IS IN REPLY TO YOUR LETTER DATED	DATE February 19, 1985
SUBJECT PLASMA FRACTIONS RESEARCH PROGRAMS ON HEPATITIS SAFETY	

In Dr. Landaburu's memorandum to Dr. Smith of December 13, 1984, which you recently sent me, Dr. Landaburu proposes additional research and evaluation of further, more rigorous virus inactivation processes to promote hepatitis safety in plasma fractions. I am in strong agreement that additional efforts in this area are needed. It appears likely that our current HT Factor VIII process does not inactivate Hepatitis B and probably only inactivates one in a series of Non-A, Non-B Hepatitis viruses. It is clear from reports of clinical experience with Travenol's heat treated Factor VIII and from the limited experience with Armour's HT Factor VIII in the U.K. that Non-A, Non-B Hepatitis still continues to be a major problem with these products. Although there are variants on these treatments currently among our competitors (for example, Cutter heat treats at higher temperatures and longer times than we do, that is, at 68° C. for 72 hours instead of our 60° C. 30 hour treatment; and Alpha utilizes what they call a "wet" process), there is no indication that any of these is safer than the other. It should be further noted that even though Alpha calls theirs a "wet" process, there is no indication that their process is a liquid pasteurization treatment similar to the Behringwerke procedure. As near as I know, the Alpha process still utilizes dry powder and heats it. However, to the best of my understanding, they flood their dry cake with some type of organic solvent (possibly Freon) during their heat treatment process. The combination of liquid organic with dry powder they term "wet heating."

Dr. Landaburu makes comments concerning experience with a number of virus inactivation processes which I have heard referred to, but have seen no data on at all. Specifically, Dr. Landaburu refers to a "super heating" protocol with Factor VIII in the dry form and indicates that this process will render Factor VIII safe, although involving 10% loss of activity. I am unfamiliar with any of this data. I understand that R&D has developed a super heating protocol for Factor IX, but am unaware what chimpanzee studies backed that up to indicate its improved safety vs. the data available concerning our 60° C. 30 hour processing. That data would be worth reviewing. I further have seen no data involving either the application of Dr. Purcell's procedure or the protocol which

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Dr. Landaburu is attempting to patent involving chloroform. If there is animal data indicating improved viral inactivation and improved product safety, I have not seen that either. That data would also be worthwhile reviewing.

I could not agree more that our strategy in this area needs review, not only with regard to our currently marketed products, but also with regard to the potential safety of our VIII:C product.

GRO-C

FF/cd
cc: J. T. O'Brien
M. B. Rodell
J. A. Sedor

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