

APPENDIX XII

G. D. SEARLE & Co.,
Chicago, Ill., January 30, 1963.

AF 13-505.

NDA 10-976 (Enovid).

Enovid medication and increased blood clotting.

On January 25, 1962 an article on Enovid medication and coagulation changes along with Drs. O. Egeberg and P. A. Owren Medical Paper on "Oral Contraception and Blood Coagulability," Brit. Med. Journal, January 26, 1963, page 220 and 221, was addressed to Dr. Frances O. Kelsey by Faye Marley, a Science Service Medical Writer, Washington, D.C.

There are some deficiencies in this Science Service medical writer's summary, that should be corrected before it is released to the press, etc.

First of all—it is not the first time (The report in Brit. Med. Journal—see above) that it has been shown that Enovid medication changes blood coagulation factors towards hypercoagulability. Similar and other changes have been already known to certain investigators and published in the Proceedings of a conference: "Thromboembolic Phenomena in Women," page 154 through 157, copyright 1962, G. D. Searle & Co., Chicago, Illinois. The fact is only that the knowledge of these changes in the coagulation factors has not found its way into the American or World Medical literature nor has the existence of those findings been emphasized in the press releases, therefore they have remained unknown to most of the medical circles and public.

Secondly, in September 1962 nine cases (not six) of deaths were discussed at the meeting in Chicago and the reported number of deaths is now increased over 31, as presented in the letter to physicians by G. D. Searle & Co. of December 26, 1962.

Finally the statement made by Dr. Lee D. VanAntwerp, Searle's Assistant Medical Director is untrue (if only Faye Marley is quoting him correctly) that American scientists have not been able to find a relationship between Enovid medication and changes in the blood coagulation factors. Those changes towards hypercoagulability have been published in the above mentioned proceedings of the conference and should be known to Dr. VanAntwerp.

I recommend that these facts should be made known to the Science Services for appropriate corrections of their review on "Enovid and changes in blood coagulation system."

Further since Dr. Owren is internationally known as an expert on coagulation, I believe he should be invited to serve in our panel, which is going to evaluate the Enovid medication and coagulation changes.

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