STATEMENT OF DR. EDMOND KASSOUF, PRIVATE PHYSICIAN, CRANFORD, N.J.

Dr. KASSOUF. My name is Edmond Kassouf, and I practice medicine in Cranford, N.J. My interest in the pill developed by chance and not by career.

Senator MCINTYRE. Doctor, in order to enable everybody to hear, perhaps you could pull that microphone a little closer and talk right into it.

Dr. KASSOUF. In September 1961 I telephoned the G. D. Searle Co., concerning a case of deep phlebitis in a healthy woman on a high pill dosage. They assured me there was no evidence to implicate the pill.

I will center my discussion primarily on pill information given to the physician and patient or that not given to them. It is now generally agreed major pill clotting reactions occur on the order of one major clotting reaction in 2,000 pill users per year. Pill deaths are estimated to occur on the order of one death per 25,000 pill users per year to one death per 67,000 pill users per year.

As a frame of reference, deaths due to Chloromycetin are spoken of as being in the range of pill deaths. These ranges clearly place the recognition of a pattern between the pill and these reactions beyond the daily experience of the physician. It is meaningless when a physician says he has used the pill widely and has seen no adverse effect. The reverse is not necessarily true and that, in fact, is how it all began. Since the attack rates are such, it is apparent the physician becomes totally dependent on others in the evaluation of safety.

It is worthwhile to touch upon these surveys, special committee reports, and company statements. In 1961 and 1962, private and public questions of safety arose. In the summer of 1962, British press reports of possible pill clotting disorders caused a stir in the United States On August 7, 1962, a "Dear Dr.——caution" letter was issued by G. D. Searle & Co. On September 10,1962, G.D. Searle & Co., sponsored the first major conference on pill safety.

The conference concluded the available evidence did not reveal a pill clotting risk. In September 1963 Dr. Irwin Winter of G. D. Searle & Co., replied to Senator Humphrey's subcommittee in regard to a number of complaints I had set forth. Part of his reply stated:

It is difficult to reach any other conclusion but that Enovid is not only one of the most intensively investigated drugs available, but is also one of the safest.

He continued by stating:

Enovid shows real promise in delaying the abrupt onset of aging in women at menopause and in the prevention of arteriosclerosis.

In 1966, the first FDA report chaired by Dr. Hellman declared the pill not unsafe for human use. On September 30, 1968, Dr. Victor Drill and David Calhoun, representatives of G. D. Searle & Co., wrote the lead article in the Journal of the American Medical Association. They concluded that U.S. data does not demonstrate a clotting risk.

There is another body of opinion, however. The British in 1967, 1968, and 1969 released reports confirming a morbidity and death risk in Great Britain due to the pill. In September 1969 the second FDA report, chaired by Dr. Hellman, was released. It confirmed the British conclusion. Finally, in October 1969, an editorial in Lancet concluded