

We will be most happy to answer any questions or comments that you may have on Torecan or any other of our drugs.

Sincerely,

CRAIG D. BURRELL, M.D.,
Director Medical Services.

GEIGY PHARMACEUTICALS,
Yonkers, N.Y., November 27, 1962.

DEAR DOCTOR: The November 17, 1962 issue of the British Medical Journal carried a letter to the editor concerning a woman who had taken Preludin®, brand of phenmetrazine hydrochloride and who had been delivered of two children with severe congenital defects of the left diaphragm. Although this internal defect bears no relation to phocomelia, the authors reviewed the patient's history of drug therapy during early pregnancy, and reported that she had taken Preludin between the fourth and twelfth weeks of pregnancy.

We enclose a reproduction of the full publication. Apparently, the history of drug ingestion "on the advice of a friend" was obtained in retrospect years after the event. There is also no information concerning the nature of two earlier miscarriages in the same patient.

The recurrence of congenital defects in repeated pregnancies of the same woman is well recognized. Butler and Claireaux (*Lancet*, March 31, 1962, pp. 659-663, "Congenital Diaphragmatic Hernia as a Cause of Perinatal Mortality") described this phenomenon and cite inherited factors and several common complications of pregnancy as possibly etiologic. Their description of pathologic findings closely parallels that reported in the British Medical Journal, and includes an instance of two infants with diaphragmatic hernia born to the same mother eight years apart.

It is estimated that there have been over ten million patient months of therapy with Preludin in the United States. Approximately 85% of these patients were females, and about 5 to 10% of them had obtained their prescriptions from obstetricians. We estimate that about 500,000 pregnant women received Preludin in the United States. There has been no evidence of a change in incidence of fatal diaphragmatic hernia as compared to the pre-Preludin era and we know of no other reports suggesting any type of congenital problems in relation to Preludin.

Accordingly, we believe that the position of Preludin in the treatment of obesity has not been altered by the recent publication in England.

In general, we can understand the view expressed in some medical circles that no drug should be employed during early pregnancy unless the physician feels there is a clear need for it. However, we see no reason why Preludin differs from literally hundreds of other commonly used drugs in this respect.

Only the physician can evaluate the dangers of obesity to the health of each individual patient, and match this with the therapeutic measures he deems advisable.

Sincerely yours,

HART E. VAN RIPER, M.D.,
Medical Director.

G. D. SEARLE & Co.,
Chicago, Ill., August 7, 1962.

IMPORTANT—DRUG CAUTION

DEAR DOCTOR: We are addressing this letter to you in keeping with our policy of bringing to you all of the pertinent facts concerning our products and as a response to recent publicity dealing with the occurrence of thrombo-embolic phenomena coincident with women receiving Enovid.

Since its introduction there have been reported to us as of this date 28 cases of thrombo-embolic disease in the more than one million users of Enovid in the United States. Among these were 10 cases of pulmonary embolism, 5 of which were fatal. In addition, there are press reports of 4 cases, including 1 death from the United Kingdom.

In some of these one or more of the usually accepted inciting causes of thrombophlebitis were evident; in some they were not.

Reports to the manufacturer do not reflect the accurate incidence of reactions and the available statistics are not adequate to determine whether or not there is a causal relationship, but caution requires consideration of this possibility.