Senator NELSON. Are there any neurological symptoms that you can think of that the user of the drugs should be notified about and which do not now appear in the package insert, for example, in the contraindications and side effects?

Dr. CLARK. I really could not answer that accurately, Senator Nelson. I have not reviewed those package inserts in the last year or so. I am not certain.

Senator NELSON. Have you listed here all the neurologic symptoms that would occur to you that ought to alert a user to consult a physician, or are there others?

Dr. CLARK. I should think that under section 7 on page 10, I listed the important symptomotology which should excite suspicion.

Senator NELSON. You do not think of others that would be of significance?

Dr. CLARK. No, sir.

Senator NELSON. I think all the witnesses who have testified, on questioning, have all regretted the lack of adequate reporting systems to give us sufficient data on a large statistical basis. Do you have any suggestions as to what the answer to that is?

Dr. CLARK. Well, I am afraid that my suggestions might not be very well received, Senator Nelson, because they all cost money.

Senator NELSON. Well, what would be the suggestion if you had the money?

Dr. CLARK. You see, studies of this sort require a large staff of highly trained people. It is getting pretty hard to staff an organization with such people. In my own institution, which is very generously supported by the State, I have a keen interest in this problem, but I have a department to run; I have to teach medical students, and I have to take care of epileptics, and I have to do a lot of things. Just the time of sufficiently trained people is very short.

You ask how one would do it. I should think that one should begin by forming a registry of cases, just in this small area of my own interest, the strokes. One should begin, in sizable population areas, mandatory registration of all strokes known to occur in women who are in the childbearing age group for a few years. Then we can at least identify the cases.

Moving on from that, we would run into a very expensive, although very productive study, because this has to be analyzed very carefully. I think one of the complaints that can be justifiably raised about many of these studies is that you find yourself on the horns of a sort of dilemma.

If you study your cases intensively, you can study only a very few. If you start working with a large enough group of cases or a large enough population base so that your figures become reliable, you find yourself moving farther and farther from the patients. And anyone who has been an active clinician for years knows that there is no substitute for a very close contact and a fairly close personal relationship with patients before the facts come out. They do not come out in a nice, mail-order questionnaire, or something of that sort. You just have to spend a good deal of time with these women before you really get all the information that is pertinent to the problem.

This takes many trained people and many, many hours.