way to demonstrate that a drug is a teratogen is through passionate litigation rather than through dispassionate investigation.

The idea has been fostered that one need only to demonstrate the possibility that a given agent could have caused a malformation in an individual. But as I have said, and I believe that most teratologists would agree, under the right conditions almost any drug can be teratogenic.

However, the question we are addressing here is whether or not amphetamines cause birth defects to the extent that they represent a significant health hazard.

From our retrospective data and the peripheral evidence from experimental studies of mechanisms of action in animal models, I would give a qualified yes to the question.

There have been a number of other retrospective studies published by other investigators of teratogenic effects attributed to amphetamines and related sympathomimetic drugs, such as phenmetrazine.

Levin found a significant increase in biliary atresia following maternal exposure to amphetamines, and we have some confirmation of this in our study.

Matera and coworkers reported an infant with exencephaly, which is one of the prominent malformations we found in our mouse studies, so here again animal studies offered supportive but not conclusive evidence.

Nelson and Forfar in a retrospective study of 1,369 patients found an excess of infants with maternal exposure to appetite suppressants among those with abnormalities.

Lenz found a case of diaphragmatic hernia and Powell and Johnston, two cases, following maternal phenmetrazine administration.

Moss found limb anomalies in the infant of a mother who had taken phenmetrazine.

It should be noted that all of these studies are retrospective and some are merely case reports, but they contribute to a sizable volume of evidence which supports the possibility that these drugs are teratogenic, despite the fact that the definitive prospective study has not been performed.

If appetite suppressants, which is just a polite term for "uppers", had a useful function in the medical armamentarium, one could not accept the present retrospective data as sufficient evidence to abrogate the use of these drugs.

We are currently trying to resolve the problem of conflicting retrospective data regarding birth defects and the "Pill" and various progestogens and estrogens through a prospective study.

The point is: The world needs the "Pill" or some agent that can perform its function equally well.

I am frankly unable to identify a similar need for amphetamines and related drugs.

Mr. Chairman, the references to my prepared statement follow.

Senator NELSON. Are you saying you find no need for amphetamines at all?

Dr. NORA. I am not finding it the way the world needs the "Pill."

I think there is no great need for appetite suppressants, but the type of need we have is for some medications that are for very specific indications, such as narcolepsy and hyperkinesis.