

a drug which I do not have to mention here. He then goes on to discuss what he calls hard teratogens, those exemplified by these four classes, and soft teratogens. He classifies the antiobesity drugs, the amphetamines, as soft, and points out the difficulties in ascertainment, when you have a low-level of frequency. Dr. Nora has expounded in much greater details, I will not repeat this, his opinions about the teratogens and the antiobesity drugs, but it is worthwhile to point out that one needs a minimum number of 18 cases of congenital heart disease per 1,000 exposed fetuses to be able to distinguish that from background—

Mr. GORDON. That is anatomical?

Dr. YAFFE. Yes; and that leads me to the last point, which I would like to emphasize, of Dr. Goldman's, and that is possibility of a functional effect, that is, effect upon the central nervous system. Although we do not have any human evidence, we do know that dexamphetamines administration can produce an effect on brain function, even though there is no congenital malformation.

I bring to your attention the fact that these drugs are used to minimize weight gain, and during pregnancy this is not a proper use of the drugs, the indications are not proper.

Dr. Prout mentioned that the limited evidence about the efficacy in the first place, but I do not even have to get into that, because I think weight gain during pregnancy is a physiological effect, something that really does not need treatment, unless it is perhaps extremely excessive.

I think obstetricians have changed their thinking from 10, 20, 30 years ago, when women were ordered not to gain very much weight, and now there is a more generous weight allowance during pregnancy, so that the state of nutrition of the fetus will not be compromised.

Mr. GORDON. There are a number of days when a woman can be pregnant without even knowing it, are there not?

Dr. YAFFE. Absolutely.

Now, that is my interpretation of Dr. Goldman's remarks.

Now, if I may, I would like to move into the other area, the other role, which I have been asked to testify by the d-amphetamine and related central nervous system stimulants in children. The substance of my testimony is contained in the article which Senator Nelson mentioned in the introductory remarks. This article appeared in *Pediatrics* in February 1973, which was written while I was chairman of the Committee on Drugs of the American Academy of Pediatrics.

Here again, I would like to give you some paraphrasing of this article, and underscore certain points which are contained in it.

I might say at the outset that we were prompted to prepare this commentary as an educational resource for pediatricians, who are members of the Academy of Pediatricians.

We were prompted to develop this commentary for two reasons, one, the rescheduling of several of these compounds into schedule II in 1972, which has been mentioned by Dr. Prout, and, second, that in our neighboring country, Canada, the use of amphetamines for the treatment of obesity was prohibited.

We did have representation on the Committee on Drugs from the Health Protection Branch in Canada and in some way, the Canadians