significant risk, therefore, I would definitely say that they would not pass such a test.

In fact, while I think the drugs are usable for narcolepsy and hyperkinetic syndrome, I would add then that where narcolepsy is concerned, it may very well be that it would be a struggle to get them by an efficacy criterion, because indeed, as was pointed out, if people who suffer the numerically largest form of narcolepsy, take a nap for 5 or 10 minutes, that is the best treatment of all. So the biggest risk to people with narcolepsy may be the taking of these drugs, so if they just take a nap, and they recognize the problem, as employers must, this usually works quite well, so that there is no reason to take drugs.

As to the question of hyperkinetic children, I think at this moment, there are some children for whom it is efficacious, and the benefits exceed the risks; however, new treatments are coming along, there are other ways to approach it, and I look to the day when regarding the treatment of hyperkinetic children, we would question whether amphetamines is the best way.

My concern about the treatment of hyperkinetic children right now is that many children do not suffer from this very poorly defined syndrome known as minimal brain damage, and I think it is very important for a physician to be quite responsible in diagnosing this illness.

Senator NELSON. Dr. Nora?

Dr. NORA. If I were in this hypothetical position of being able at this moment to accept or reject the use of this drug in the marketplace for antiobesity, I would certainly reject it.

I do not think on the basis of its efficacy or safety, that it is a drug that should be admitted for that purpose.

I would have some more reservations about rejection for some other purposes, but I think that the problem of abuse enters the picture, and I am not sure that I see a great need for the drug in the physician's armatarium.

The only exceptions perhaps are hyperkinesis and narcolepsy.

Senator NELSON. Dr. Prout, do you want to answer that?

Dr. PROUT. I think I have in a sense already answered it. Certainly in my own view, the trivial loss of weight seen with these drugs does not come up to evidence of efficacy. In the future, we will have to deal with the question of what is a reasonable amount of weight loss, for which the drug might be prescribed.

Even if this were a small amount, a half a pound a week, but there was *no risk*, and did not require discontinuation of the drug, or you were able to continue the medication for a lifetime, then we would have a very efficacious drug. So the definition of efficacy and safety is easier perhaps in the drugs we have today. The measure of what would be efficacious and safe in the future, will lead us back to the necessity of making that judgment on the basis of phase IV studies, in addition to phase III-type studies.

Mr. GORDON. The phase IV long term studies?

Dr. PROUT. The long term studies in which evidence of the lack of safety can be amassed over a period of time. Since obesity is a lifetime problem, it is not sufficient to look at their effectiveness in periods of only 8 to 12 weeks.