called phocomelia. I think because of the widespread publicity concerning thalidomide, I need not dwell on the lessons learned from the use of this drug in humans.

The thalidomide experience has led to the establishment of four criteria for the detection of a new teratogenic agent in man. The criteria for detection require: (1) an abrupt increase in the incidence of a particular defect or association of defects or syndrome, (2) coincidence of this increase with a known environmental change, for example, widespread use of a new drug, (3) known exposure to the environmental change early in pregnancy at the critical period yielding characteristically defective infants, and (4) absence of other factors common to all pregnancies yielding infants with the characteristic defect. It can be seen that these criteria for detection of new teratogenic agents will be useful only if the teratogen is effective in a majority of exposed fetuses. In this case any of the above mentioned drugs already known to be effective human teratogens would have fulfilled these criteria. I call a teratogen which has the capacity to affect above 30% of exposed fetuses a "hard" teratogen. However, most of the other drugs suspected to play a teratogenic role in man are not of the hard variety but are "soft" teratogens. A soft teratogen has a low level of effectiveness that is, it has the capacity to raise the incidence of a defect by a factor of 2 to 4 times over background level. I believe that the data on the anti-obesity drugs, which Dr. Nora probably will present in greater detail, suggest that these drugs fall into the category of soft teratogens.

The history of the studies suggesting possible teratogenicity of anti-obesity drugs is typical of that of detection of soft teratogens.