

**Actions from Peer Review of the Draft NTP Monograph on Developmental Effects and
Pregnancy Outcomes Associated with Cancer Chemotherapy Use during Pregnancy
October 1-2, 2012**

The NTP Monograph Peer-Review Panel (“the Panel”) was convened on October 1-2, 2012, to peer review the draft NTP Monograph on Developmental Effects and Pregnancy Outcomes Associated with Cancer Chemotherapy Use during Pregnancy (available at <http://ntp.niehs.nih.gov/go/37090>). Summary meeting minutes will be prepared and posted to the NTP website when completed. The Panel reviewed the draft NTP interpretations of the evidence for five main findings and made recommendations regarding each of the findings. The Panel’s recommendations do not necessarily represent the opinion of the NTP. The NTP will consider the Panel’s input in finalizing the NTP Monograph. When completed, the monograph will be published on the NTP website (<http://ntp.niehs.nih.gov/go/evals>).

1. Frequency of congenital malformations by trimester

The Panel unanimously (8 yes, 0 no, 0 abstentions) recommended the following main finding: The evidence in the draft monograph supports NTP’s interpretation that chemotherapy for treatment of cancer in the first trimester represents a higher apparent risk of major malformations than treatment only in the second or third trimesters.

2. Risk of spontaneous fetal death

The Panel unanimously (8 yes, 0 no, 0 abstentions) recommended the following main finding: The evidence in the draft monograph supports the NTP’s interpretation that (1) there is insufficient reported information in human studies that chemotherapy for treatment of cancer in the first trimester affects early spontaneous fetal loss (also called spontaneous abortion, ≤ 22 weeks of gestation), and (2) data reported for the use of chemotherapy for treatment of cancer in the second and/or third trimester suggest an apparent increase of late spontaneous fetal death (also called stillbirth, >22 weeks of gestation).

3. Pregnancy complication associations

The Panel unanimously (8 yes, 0 no, 0 abstentions) recommended the following main finding: The evidence in the draft monograph supports the NTP’s interpretation that (1) chemotherapy for treatment of cancer during pregnancy can result in oligohydramnios or anhydramnios primarily attributable to Trastuzumab, based on available data and (2) chemotherapy for treatment of cancer during pregnancy does not appear to be associated with spontaneous preterm birth.

4. Effects on newborn weight and health

The Panel unanimously (8 yes, 0 no, 0 abstentions) recommended the following main finding: The evidence in the draft monograph supports the NTP’s interpretation that (1) the data on chemotherapy for treatment of cancer during pregnancy are insufficient, but suggestive, of effects on impaired fetal growth and myelosuppression and (2) the evidence is inconclusive that chemotherapy for treatment of cancer during pregnancy that induces cardiotoxicity in treated patients also induces cardiotoxicity in fetuses and neonates exposed to the same agents *in utero*.

5. Effects on offspring growth and development

The Panel unanimously (8 yes, 0 no, 0 abstentions) recommended the following main finding:

Actions on Monograph - continued

The evidence in the draft monograph supports the NTP's interpretation that growth and development of offspring exposed to chemotherapy for treatment of cancer during pregnancy appear normal during infancy and early childhood (<2 years of age); however, it is important to recognize that the data are limited and adverse effects may not be apparent until later in life, e.g., effects on reproductive and other organ function.