ACSH responds to criticism of Blue Ribbon Panel's Report on Phthalates

By ACSH Staff — September 21, 1999

The American Council on Science and Health (ACSH) is disappointed, but not surprised, by activists continued attempts to discredit a panel of well-respected, nationally and internationally recognized scientific and medical professionals, headed by the former U.S. Surgeon General Dr. C. Everett Koop. Once again, there has been an attempt to shift attention from sound science to misrepresentations and half-truths.

It should be obvious that when attempting to reach a scientifically valid conclusion on the issue of phthalate safety, much weight must be given to those studies most relevant to human health, while less credence is given to weaker and less relevant studies. Panelists with specific expertise in reproductive toxicology, as well experience and knowledge of DEHP and reproductive/developmental endpoints of concern in relationship to human health, were on the ACSH Blue-Ribbon panel. As we have previously pointed out, while the panel specifically noted that toxicity for several endpoints was found in animal studies, it evaluated the weight of the scientific evidence by considering the dose level, route of exposure, metabolism, and species differences. These factors, among others, were instrumental in the Panel’s deliberations, discussions, and conclusions related to the interpretation and meaning of animal studies as to the possibility of extrapolation to humans.

ACSH is dedicated to helping Americans distinguish between real and hypothetical health risks and in doing so reiterates the blue-ribbon panel’s conclusion that the phthalates in vinyl medical devices and toys are not harmful to children or adults.

Below is clarification of the thorough and scientific review by Dr. Koop and the panel members, in response to the recent criticism by the activist group, Health Care Without Harm (HCWH):

- The goal of the ACSH blue-ribbon panel was to focus on quality studies relevant to the route of exposure for humans with higher than average DEHP exposures (i.e., IV administration), thus the section on reproductive and developmental toxicity did not review and discuss every study or publication.
- The blue-ribbon panel reviewed, but did not place particular emphasis on, the Poon, Gray, and Arcadi studies because these studies focused on an oral route of exposure and were not relevant to medical devices because IV or parenteral administration is the critical route of exposure for medical devices.
- The Li et al study is an In Vitro study and as such is not particularly useful for risk assessment or safety assessment purposes. In Vivo studies, which may possibly be extrapolated to human risk, do not show decrements in reproductive function at the low DEHP exposures used in the Li study, but do inform us about effect levels in whole animals.
The levels at which adverse effects were seen were considered by the blue-ribbon panel in the course of their evaluation of DEHP and human risk.

- HCWH attempts to dismiss the merits of citing the Kurata study in marmosets. However, its argument that these adult animals could not provide insight into the effects of DEHP on testicular development was shortsighted and shallow. In fact, Kurata used juvenile marmosets that were 12-15-months-old, to specifically capture the timeframe of their sexual maturation, the most sensitive period for putative DEHP effects.

HCWH also claims that the study was only a 'short term' exposure of 13 weeks. The 13-week exposure used in the Kurata study was adequate to evaluate a potential for adverse effects on testes development and structure.

HCWH fails to understand the standard reporting practices for histological data in peer-reviewed scientific publications. HCWH seems to believe that the Kurata study was not valid because it did not include pictures of the microscopic sections. What HCWH failed to note was that Kurata found no structural differences between the treated and control animal tissue at the level of light or electron microscopic examination and thus, the journal did not print the pictures. Standard practice in a publication would be to only show examples of differences.

Finally, the standard approach in toxicology for evaluating testicular effects is to measure organ weight and to perform histopathologic examinations, usually with light microscopy. If effects are seen then an electron microscopy is conducted. The electron microscopy is considered to be the most thorough assessment. But when you compare Poon, Arcadi and Gray to the Kurata study, you find that the former three merely did the first exam but failed to do the more thorough procedure, while Kurata started with the most thorough procedure available and still found no effects from DEHP.

- Responding to the statement that "Koop et al., fail to cite readily available studies which demonstrate that the developing male reproductive system is vulnerable...," the ACSH panel placed the greatest amount of emphasis on studies using the IV route of exposure and did not summarily ignore other studies; they simply focused their attention on the route of exposure most relevant to higher-than-average-exposed humans.

ACSH stands firmly behind the conclusions drawn from the weight of the scientific evidence by Dr. Koop and his distinguished colleagues. As Dr. Koop has said, "Consumers can be confident that vinyl medical devices and toys are safe."