

Public Comment

Re: NTP's Nanotechnology Working Group

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Physicians Committee for Responsible
Medicine (PCRM)**

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PCRM

The Physicians Committee for Responsible Medicine (PCRM) is a nonprofit organization of physicians, scientists, and laypersons working together for compassionate and effective medical practice, research, and public health.

For both ethical and scientific reasons, we advocate for the replacement of animals in research, product development and testing, and education.

Our Concerns

- **That the types of information that would be collected using current regulatory test schemes may not be useful in assessing the safety of nanoscale materials in humans or in the environment**
- **That many thousands of animals will be subjected to inadequate and inaccurate tests before a more rational approach is adopted for evaluating nanoparticle toxicity**

Purpose of the Nanotechnology Working Group (NWG)

**The NTP has established the
NWG...“to enhance public and
stakeholder input into the NTP
nanotechnology research
program.”**

Interested Stakeholders

The animal protection community is an interested stakeholder in Federal programs that require, recommend, or encourage the use of animals in research or testing

Recommendations on Structure of the NWG

- **Animal protection groups must be included as interested stakeholders in NWG activities**
- **Scientists from animal protection organizations should have one or more representatives appointed to the NWG**

Recommendations on Goals of the NWG

- **Evaluating the toxicities of nanoscale materials is a complex and emerging science that must be better understood before a sound and meaningful regulatory testing paradigm can be developed and imposed**
- **Due to the novel nature of the nanoparticle test materials and their biological effects, both animal and nonanimal tests recommended for evaluation of nanoparticle toxicity by a regulatory agency must be considered as new or revised test methods and therefore must be validated according to the ICCVAM Authorization Act**

Recommendations on Goals of the NWG (con't)

- The NTP nanotechnology research program can provide valuable information on new methods to assess nanoparticle toxicities such as: the mining of existing data (human exposure and hazard data) on nanoparticles to develop predictive databases and computer models for toxicity assessment; the development of *in vitro* and high throughput technologies to develop faster and more predictive methods for evaluating nanoparticle safety to humans and the environment; etc.

Recommendations on Goals of the NWG (con't)

- **The NWG has the opportunity to play an important role in providing advice to the NTP on the types of research and approaches that will be useful in developing nonanimal approaches for assessing nanoparticle toxicity, which we anticipate will provide more predictive and cost-effective data than could be obtained by defaulting automatically to the existing regulatory framework**