Getting Nanotechnology Right the First Time

Presentation to the National Research Council
Committee to Review the National Nanotechnology Initiative
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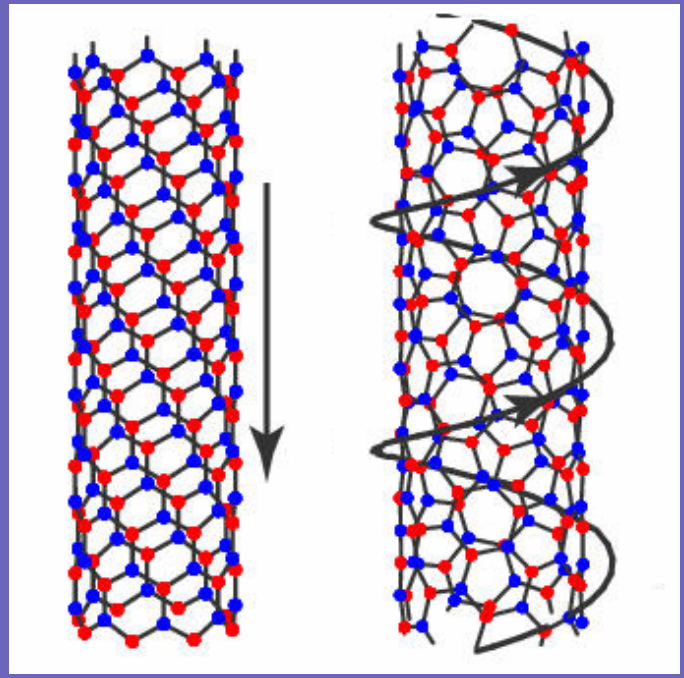
ENVIRONMENTAL DEFENSE
finding the ways that work

Introduction to Environmental Defense

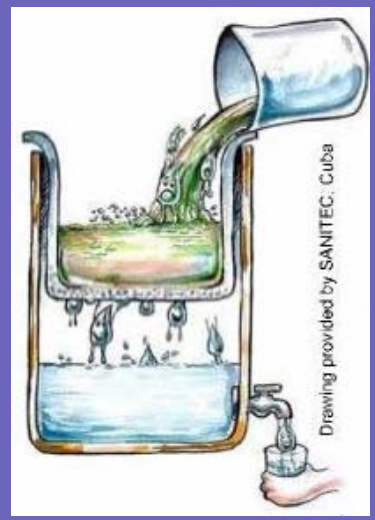
- Founded in 1967
- 250 scientists, economists, attorneys and other professionals in 8 offices
  - *Most PhDs of any environmental advocacy organization*
- Funded by foundations, benefactors and 400,000 members
- Longstanding involvement, expertise in partnership approaches to promote environmental technologies and manage chemical risks
  - *Catalyzed launch of US High Production Volume (HPV) Chemical Challenge program*

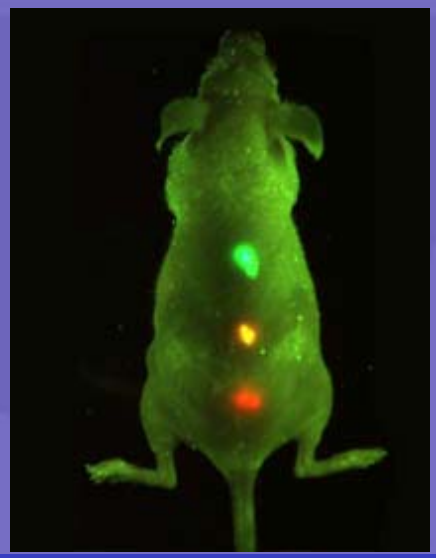
At the nano-scale, materials act differently

Tiny changes make big differences



Novel Properties Will Bring Breakthroughs





…But May Also Bring Unexpected Risks:

Preliminary studies raise concerns

Mobility

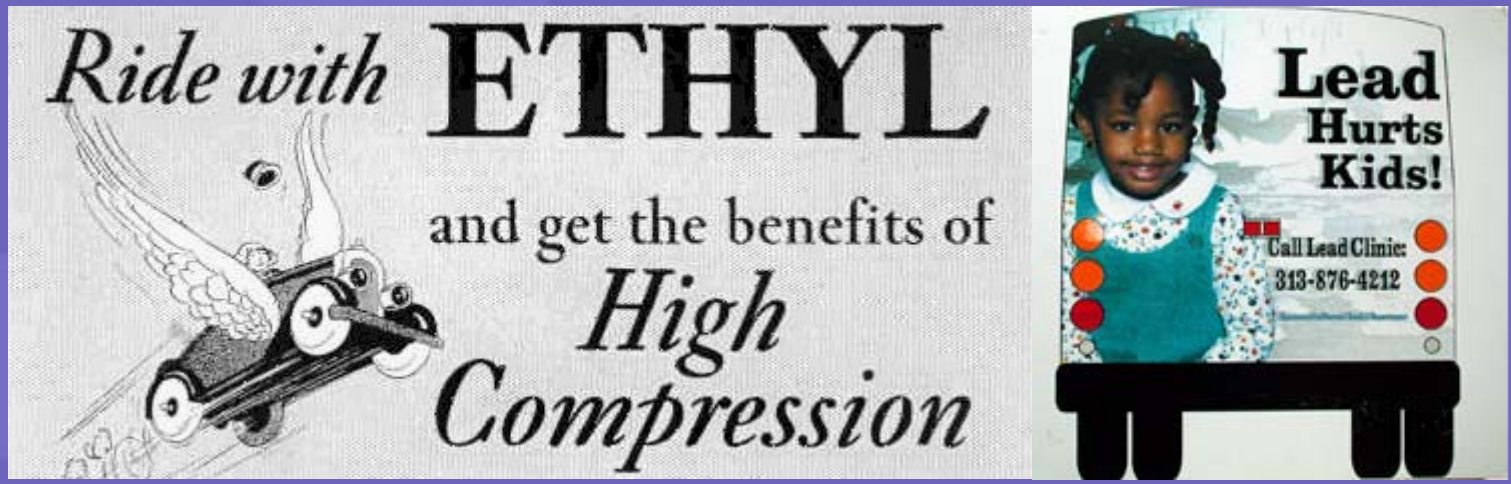
- Through groundwater?
- Bioaccumulation?
- Across blood-brain barrier?
- Across placenta?

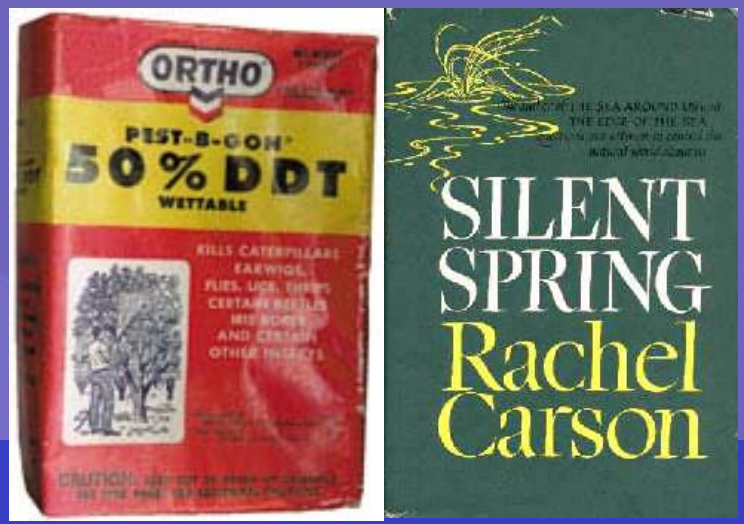
Toxicity

- Aquatic toxicity?
- Cytotoxicity?
- Lung granulomas and fibrosis?
- Brain lipid peroxidation?

…Even to Everyday Products Available Now

Why does this sound familiar?





Questions about nanotoxicity

- What is the fate of nanomaterials over their full lifecycle (production, use, disposal/ release)?
- Will nanoparticles build up over time?
- How will living organisms/systems respond if exposures occur?
- How mobile and persistent are these materials in the environment and organisms?
- Are their transformation (e.g., degradation) products more or less toxic?

Getting it right the first time

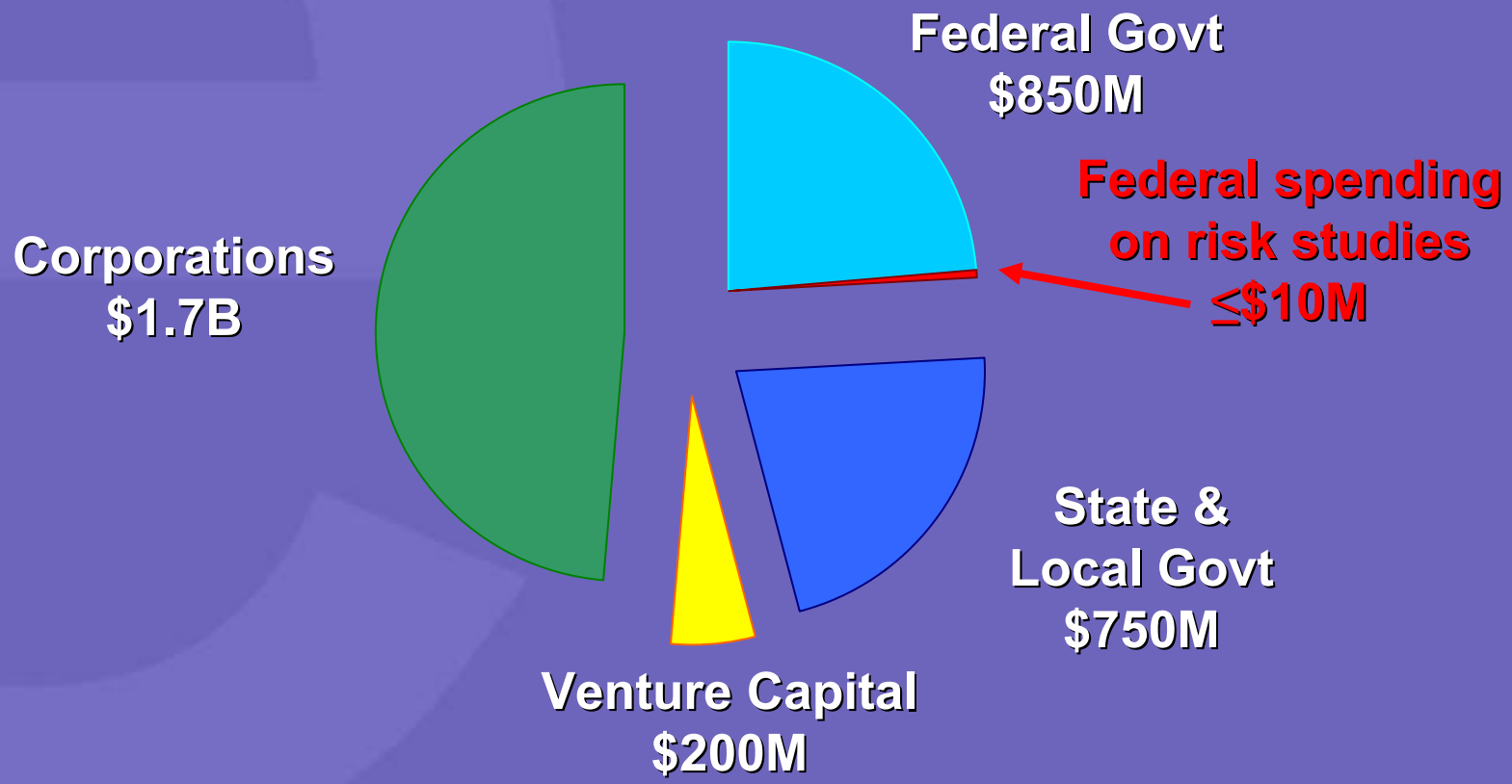
- Possibly transformative technology
- Potential significant downside
- Still at early stage of development

Four Keys to Responsible Nanotechnology Development

- Increase government risk research
- Develop clear government regulatory policies
- Implement proactive risk management standards
- Engage stakeholders in setting agenda

Increase Funding for Risk Studies

Annual U.S. Spending on Nanotech R&D



Total = $3.5B

Is Our Current Regulatory System Up to the Task?

Breadth of applications

- *Consumer products*
- *Personal care/cosmetics*
- *Medical applications*
- *Coatings*
- *Electronics*
- *Catalysts*

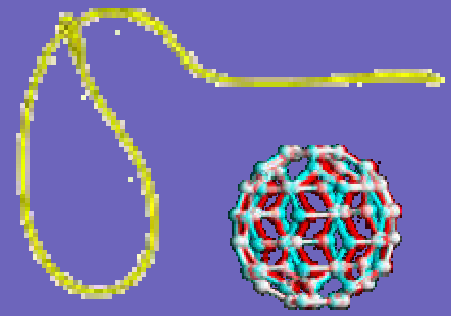
Multitude of federal agencies

- *Occupational Safety and Health Administration (OSHA)*
- *Environmental Protection Agency (EPA)*
- *Food and Drug Administration (FDA)*
- *Consumer Product Safety Commission (CPSC)*

EPA: TSCA Complexities / Limitations

- When are nanomaterials “new” chemicals?
- Existing exemptions (e.g., weight threshold)
- No up-front data requirements for new chemicals
- Significant burden on EPA to require testing
- Poor basis for evaluating risk in absence of data on specific types of nanomaterials
- Nomenclature confusion

Close Regulatory "Nano-Loopholes"



- Many gaps in current regulations create uncertainty
  - *Uncertainty about applicability*
  - *Few requirements for pre-market testing*
  - *Authority to respond to problems largely after-the-fact*
- Clear, protective regulations needed to set level playing field
  - *Clarify, enhance authorities as needed*
  - *Adequate scrutiny before marketing*
  - *Apply use restrictions where necessary*

Proactive Risk Identification & Management

- Acknowledge that nanomaterials are different
  - *Hazards cannot be inferred from bulk materials*
- Commit to up-front research and testing
  - *Sufficient testing to identify risks prior to commercialization*
- Take a responsible approach to managing risks
  - *Risks addressed across the lifecycle*
  - *Protective interim risk management in advance of testing*
  - *Appropriate risk management in response to testing, monitoring*
- Embrace transparency
  - *Public disclosure of all risk-related information*
  - *Labeling, accurate MSDS disclosures*

Responsible Interim Risk Management Approaches

- Interim worker safety steps
  - *Assume toxicity until shown otherwise*
  - *Worker training, industrial hygiene, PPE*
  - *Workplace, worker health monitoring*
  - *Wastes treated as hazardous materials*
- Interim environmental safety steps
  - *Restrict dispersive uses until hazard and exposure/fate data available*
  - *Manufacturers assess and disclose lifecycle risks in advance of commercialization*
  - *Release/environmental monitoring*

What should NSET be doing?

- Ensure more federal research dollars are spent on health & environmental implications of nanotechnology
  - *At least 10-fold increase, to $100 million/yr*
- Oversee assessment of federal agency jurisdictions and regulatory authorities
  - *Identify changes needed to address gaps, uncertainties*
  - *May require enhancing function/authority of NSET*
- Actively engage stakeholders beyond industry, gov't.
  - *Beyond "top-down" public education, risk communication*
  - *Acknowledge value of perspective, relevant expertise*
  - *Involve stakeholders in setting agenda*

What can this Committee do?

- Request detailed figures on what is being spent on risk-related research across the various NNI agencies
  - *Review adequacy relative to the tasks at hand*
- Draw on expertise of the NRC Board on Env'l. Studies and Toxicology and other experts to review ongoing research and research plans
- Identify gaps in existing statutory authorities and regulatory programs
  - *Call for creation of new authorities and programs as needed*
- Facilitate active engagement of stakeholders to help inform and guide the NNI and its research agenda
  - *Incorporate interests and concerns of workers, consumers, health and environmental advocates*