COMMENTS OF CAROLYN NUNLEY CAIRNS MPH,
to the NATIONAL RESEARCH COUNCIL COMMITTEE FOR REVIEW OF THE FEDERAL STRATEGY TO ADDRESS ENVIRONMENTAL, HEALTH, AND SAFETY RESEARCH NEEDS FOR ENGINEERED NANOSCALE MATERIALS

May 5, 2008

Thank you for the opportunity to share my views today on this federal strategy for research on the environmental health and safety of nanomaterials. As Program Leader for Product Safety at Consumers Union,[1] I have been investigating the rapid influx of nanomaterials in consumer products for quite some time.

Particularly in the wake of disastrous decisions to formulate products with chemicals like lead and asbestos, consumers expect government to fund a well-planned public research strategy that will ensure toxicity and biological fate are well-studied before new substances are widely dispersed in commerce. However, the current pace of nanomaterial commercialization and the priorities outlined in this report do not give us confidence that the lessons of the past are being heeded.

The document resembles a laundry list of ad hoc projects that some agencies have shoehorned into relevance for environmental health and safety. It is not a strategy that will accelerate the research needed to prevent our toxic past from repeating itself in nanoform. The document fails to articulate how the disparate projects outlined will be pulled together to glean meaningful conclusions that participating agencies can use to protect the public from dangers inherent in commercializing nanomaterials. I hope the committee's review and our discussion today will help convince the NNI to take a more effective approach to this critical research.

---

[1] Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health, and personal finance; and to initiate and cooperate with individual and group efforts to maintain and enhance the quality of life for consumers. Consumers Union's income is solely derived from the sale of *Consumer Reports*, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, *Consumer Reports* and *Consumer Reports Online* (with approximately 5 million paid circulation) regularly carry articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions which affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

My comments today emphasize three basic deficiencies that must be addressed in order for this strategy to be successful:

- a lack of clear goals and structure focused on protecting public health;
- misaligned priorities, and
- a lack of specificity in critical areas.

Clarify Goals and Objectives for Public Health

The plan lacks the most critical element of a successful strategic plan: clearly articulated goals and objectives. The goal of the strategy seems divided between protecting public health from nanomaterials themselves, on the one hand, and developing health-related nano-enabled products, on the other. Public health protection is clearly losing out to commercial development. For example, on page 46 it says that the research should "*expand the horizons of nanotechnology-based applications,*" and that "*gaps identified in research that supports regulatory decision-making should not be addressed at the cost of broad-based fundamental research – to do so would ultimately undercut the US nanotechnology initiative as a whole.*" Putting commercial interests ahead of public health is the kind of thinking that put lead paint in children's nurseries and toys, asbestos in schools, and other serious chemical hazards into our environment. It does not belong in a national research strategy for environmental health and safety.

The current list of funded projects also reflects a confused mission and misleads the public about our government's true commitment to science in the public interest. For example, nearly all of the 100 projects under Priority 2 - Nanomaterials and Human Health, are designed primarily to develop nanomaterials for drugs and diagnostics, not investigate health risks. I count just 22 of these projects that have some relevance to understanding adverse biological impacts of otherwise untested nanomaterials.

This kind of mission creep and confusion is particularly disturbing given that so much of the budget for the NNI is already supporting work aimed at developing commercial applications. We simply can't afford to lose half of even a paltry 10% of the NNI budget to projects that don't effectively advance our understanding of nanomaterial risks.

We strongly urge this committee to recommend that the plan's goals, and research agenda be revised to focus exclusively on characterizing risks associated with commercially important nanomaterials.

Re-align Priorities with the Goals of Risk Prevention

Priorities in the plan currently reflect a casual approach that is designed more to investigate interesting phenomena rather than to accelerate scientific findings that can be directly applied to characterize and manage risk.

We recommend reversing the priorities. Instead of starting from a scattershot effort to identify toxic endpoints and working backwards to assess exposures to substances found to be harmful, we suggest starting with what's knowable about how nanomaterials are or will be used, and developing metrologies and toxicity assays that focus on related exposures and exposure-intensive applications. Most project descriptions do not even specify which classes of materials will be studied. Only five of the projects seem directly focused on workers and factors affecting workplace exposure and none examine consumer exposures. In fact, under the Human and Environmental Exposure Assessment, only one of the two funded projects is focused on a specific product category - photovoltaics –in which nanomaterials are typically in the solid-state, unlikely to directly expose consumers. While we strongly support life cycle work even for solid-state applications, a much more urgent need exists to understand the risks associated with ingredients in cosmetics, food additives or personal care products, which are ingested, inhaled or applied directly to the skin. Research characterizing exposure to and toxicity of nano-silver (which doesn't appear to be covered in any funded projects), carbon nanotubes, and nano-scale titanium and zinc oxides should be given a high priority. Like the OECD research strategy,[2] and a plan recently published by the International Council on Nanotechnology (ICON),[3] the US strategy should aim to develop a standard data set for commercially important materials.

Specify Funding, Authorities and Outcomes

Besides a lack of goals, the current plan also lacks any specificity with respect to how research will be coordinated, how gaps will be filled, and how findings will be translated into effective action to characterize, prevent and manage risks. While some of the shortcomings mentioned here are recognized in the strategy, no details are given about how the gaps will be filled or priorities changed.

Despite the participation of the main regulatory bodies (OSHA, FDA, EPA and CPSC), it is striking how little of the research is contributed by these agencies, despite the fact that

---

[2] Nanotechnologies at the OECD, paper presented at the Sixth Session of the Intergovernmental Forum on Chemical Safety, 15-19 September, 2008.

[3] International Council on Nanotechnology, Towards Predicting Nano-bio-interactions: An International Assessment of Nanotechnology Environment Health and Safety Research Needs, May 1, 2008.

so many nanomaterials fall under their jurisdiction. It's also unclear how authorities for implementing the plan will be distributed and how, for example, FDA and EPA will share the coordinating functions for risk management methods. Further, some of these agencies have their own research strategies that, as indicated on page 47, may reflect different priorities from those outlined in this document. It's unclear what purpose this document then serves if the participating agencies are focused on disparate priorities.

The plan also gives no indication of how the considerable authorities that do exist within these agencies to gather information about nanomaterial use and risk will be leveraged to guide planned research. Efficiencies could be gained by agencies such as the EPA contributing information from new chemical petitions under TSCA section 5, substantial risk reports under 8(e) and information submitted for approvals under FIFRA. FDA could contribute adverse event reports submitted on nano-enabled cosmetics; and CPSC could submit injury and incident data from nano-engineered products like rechargeable lithium-ion batteries. Without a closer link to regulatory objectives, it's hard to see how they will be served by this plan.

In sum, we find this strategy to be woefully inadequate. We appreciate the opportunity to share our views and hope they will help bring about the changes needed to create a strategy that serves the urgent public interest in characterizing the risks associated with commercialized nanomaterials. I look forward to the discussion and to answering any questions.