UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

CHAIRMAN ELLIOT F. KAYE

March 30, 2015

The Honorable Pete Olson
United States House of Representatives
312 Cannon House Office Building
Washington, DC 20515

Dear Congressman Olson:

Thank you for your letter regarding the U.S. Consumer Product Safety Commission's (CPSC) Fiscal Year 2016 Performance Budget Request to Congress and our proposal for funding a consumer product nanotechnology research center. I greatly appreciate your interest in the CPSC and your familiarity with the topic of nanotechnology. Indeed, nanotechnology is an exciting field that appears to hold great promise for U.S. manufacturers and has the potential to become an even far greater economic boon for many sectors of the U.S. economy.

As the agency charged with protecting consumers from unreasonable risks of injuries from consumer products, CPSC knows that exciting scientific breakthroughs, such as nanotechnology, can also present challenges in anticipating and addressing newly-presented potential risks to consumers. This knowledge keeps us keenly aware of the need to address known hazards while at the same time endeavoring to prepare for the next potential emerging hazard. We believe that our Performance Budget Request allows us to accomplish these goals, particularly regarding nanotechnology and in a cost-effective manner.

As your letter notes, our request to create a nanocenter, based on a successful model used by the National Science Foundation (NSF) and the Environmental Protection Agency (EPA) to study and characterize human exposures to nanomaterials from consumer products is a significant project and one we take very seriously, which is why CPSC has been studying the issue since 2003. Currently, CPSC co-chairs the

Nanotechnology Environmental and Health Implications (NEHI) working group within the National Nanotechnology Initiative (NNI), which focuses on environmental, health, and safety implications of nanomaterials. CPSC staff also served on the advisory board for the Rice University-based International Council on Nanotechnology (ICON), which was supported by funding from the National Science Foundation. Serving on ICON's advisory board presented an excellent opportunity for CPSC staff to be engaged in, and develop a greater understanding of, cost effective approaches for addressing the critical issues surrounding the applications and implications of nanotechnology. The ICON facilitated the staff's exchange of information with scientists and stakeholders participating in various ICON projects, and at the same time allowed staff to observe ICON's focus on promoting effective nanotechnology stewardship through hazard assessment, research and risk communication.

Since 2011, CPSC has spent less than $10 million researching the implications of nanomaterials in consumer products, which is less than .0015% of what the federal government has committed to studying the potential environmental, health, and safety (EHS) impacts of this technology. Although $22 billion has been allocated to nanotechnology research and development overall, the CPSC's relatively small expenditures has been the only dedicated examination of the technology in consumer products to this point. This work has provided for foundational research that has allowed us to understand some of the initial consumer applications of nanotechnology and the breadth of the type of products employing nanotechnology. In addition, it has made us aware of concerns that have been raised within the scientific community regarding possible health risks associated with exposure to certain nanomaterials and the pressing need for the development of robust test methods and exposure assessments needed to measure nanomaterial exposure from consumer products.

Simply put, our work has identified significant data gaps regarding exposure to nanomaterials from consumer products that CPSC must address to assist with the responsible development and commercialization of nanotechnology. Although almost $1 billion has already been spent examining certain types of EHS risks, CPSC is the only agency specifically responsible for studying the issue of exposure to nanomaterials from consumer products. If, for example, a consumer product containing nanomaterials was alleged to have resulted in an illness or injury, CPSC's current funding levels do not allow for the development of robust test methodologies to answer questions regarding how exposure to that consumer product could be measured or how any potential identified risks can be addressed.

Your letter asks about the metrics of success for CPSC's proposed nanotechnology centers. CPSC staff undertook this exact thought process before presenting its proposal to the Commission. Consistent with the President's Council of Advisors on Science and Technology (PCAST) guidance in the most recent Report to the President and Congress on the NNI, CPSC's proposal outlines broad goals for a center rather than a strict formula of requirements. As suggested by PCAST, this flexibility is intended to "allow for ideas to 'bubble up' from investigators and allow researchers to pivot from one project to another should an unexpected, promising discovery be made."[1] At the same time, there must be specific criteria to determine the success of such an important project, and I am pleased to share with you the four categories of success criteria that are the foundation of the request:

- First, the center will need to develop robust test methods to determine and characterize human exposure to nanomaterials from consumer products. During the past few years, the CPSC has executed a number of interagency agreements with the EPA, the Food and Drug Administration (FDA), the National Institute for Occupational Safety and Health (NIOSH), the National Institute of Standards and Technology (NIST), NSF, and academic institutions, including Virginia Tech, Rutgers University, Duke University, and Harvard University's School of Public Health. Although this work has resulted in useful reports and manuscripts for publication in peer-reviewed scientific journals, the work has also made clear that to develop robust test methods successfully, there must be a center dedicated specifically to this work, rather than focused on all manner of nanomaterials generally.
- Second, the center will work to characterize and understand consumer use of products containing nanomaterials. This will help identify factors affecting the release of the materials and exposure patterns, as well as identifying unique exposure factors for vulnerable populations (*e.g.*, children, seniors).
- Third, the center will provide support to manufacturers, especially small businesses, with approaches to testing their products for the release of, and potential exposure to nanomaterials. This work will facilitate creating guidance on best practices for implementing safety assessments into

[1] *Report to the President and Congress on the Fifth Assessment of the National Nanotechnology Initiative,* Executive Office of the President, President's Council of Advisors on Science and Technology, October 2014, pg. 57, at: https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_fifth_nni_review_oct2014_final.pdf

future research and development, as well as allow manufacturers and other stakeholders to engage in test method validation.

- Fourth, the center will close data gaps identified in the 2011 NNI EHS research strategy, including developing exposure classifications for nanomaterials and processes, developing comprehensive predictive models for exposures to a broad range of engineered nanomaterials, and characterizing individual exposures. This work will lead to studies that examine emissions and human contact during normal use, after wear and tear have degraded a product, as well as during repeated exposures.

Unquestionably, these are ambitious goals and your letter requests more detail on how the size of the budget request for this major undertaking was derived. I am pleased to provide that information. Based on our decade-long work within the NNI, CPSC staff examined the types of centers that other health and safety agencies created and from there, crafted a list of needs for our agency to be able to successfully create a center focused on consumer products. Based on this research, we believe that the $5 million request is appropriate because this level of funding would provide for:

- The use of an existing brick and mortar facility at a university that already possesses the equipment and technology to examine these materials based on previous work with nanotechnology. (Adopting the proven model of NSF and EPA, this approach would prevent CPSC from unnecessarily acquiring laboratory equipment used solely to develop a test method and then having no need for the equipment once the test method is developed);
- Staffing of approximately:
  - 12 Senior scientists
  - 15 Technicians
  - 10 Post-Doctoral students
  - 10 Graduate students.

To be clear, our needs analysis was validated against existing nanotechnology research centers, and included guidance from NSF, based on their experience in creating and managing similar centers.

Your letter also raises the question of how this work will support, and not unnecessarily hinder, the bright future of nanotechnology. This concerns CPSC as well, and underscores the need for this center. All walks of industry prefer clarity over

uncertainty, as uncertainty often slows commercialization. This center would aim to provide manufacturers with information on voluntary standards and recommended testing approaches. In addition, we would seek to invite manufacturers to use the equipment in the center to test their products and provide instruction to manufacturers on the best methods available for quantifying release and exposure of nanomaterials. In other words, the center will be a resource for manufacturers and distributors of nano-enabled products and will develop approaches to providing information on the safe use of this technology in consumer products, thereby supporting commercialization efforts.

Finally, no other federal agency evaluates consumer product implications or nanomaterial exposure from the products under CPSC's jurisdiction. For example, EPA and NSF are making sizable investments addressing the exposure implications from nanomaterials released into the environment and ecosystem impacts to non-human receptors. NIOSH has an extensive research portfolio that addresses worker exposures, but does not address exposures to consumers, especially young children. If CPSC does not do the proposed work, another federal agency is not planning to fill the gap. Failure to undertake this work more robustly in the near future would be a disservice to all interested parties, especially the American consumer.

Thank you again for your letter and for your continued support of the Commission and its mission to safeguard consumers. Should you or your staff have any questions, please do not hesitate to contact me, or Jason K. Levine, Director of the Office of Legislative Affairs, by telephone at (301) 504-7853, or by e-mail at JLevine@cpsc.gov.

Sincerely,

Elliot F. Kaye