

18 December 2013

National Nanotechnology Initiative

To Whom It May Concern:

The Nanomedicines Alliance (NMA) is an industry group dedicated to catalyzing the use of nanomedicines for patient benefit. Current members of the NMA include Amgen, BIND Therapeutics, Cerulean, CytImmune, Eli Lilly & Co., Liquidia, Merck Serono, NanoCarrier, Nanoviricides, and Pfizer. The NMA offers its compliments to the NNI and the NSET on the publication of this critical strategic plan document outlining your comprehensive strategy to establish goals and objectives around a national vision to ensure that an unmatched, robust, and productive nanotechnology research and development program continues in the US.

The NMA offers for your consideration the following general observations and comments on the document:

- The engagement of industry and private/public partnerships is defined as critical to success. We suggest that the NNI further define specific agenda items that pertain to each industry in order to facilitate meaningful engagement of industry on the issues most important to specific sectors.
- Related to Goal 2, Objective 1 (helping the business community with useful and reliable information) we ask that the NNI consider how to improve access to information needed by each industry to effectively interact with government R&D programs and agencies. For instance, the nano.gov website could be organized as repository of key resource documents and information, such as guidelines, regulations, meetings, and tools industry representatives could use.
- The four goals and their objectives are characterized as specific and measurable. Yet, generally they lack timelines and specific quantifiable endpoints that would define success. While we appreciate that each government agency may develop more specific and measurable goals, we believe the NNI should offer timeline targets with more specific deliverables, such as number of programs by a date certain, information to be made available by a date certain and by which agency, etc.
- A very important element of industry involvement in nanotechnology is the regulatory environment in which we operate. For nanomedicines, the industry already operates under the longstanding and well-established FDA regulations. For the nanomedicines sector, and other sectors that lack the proactive track record of FDA, early and regular engagement in the process by which new regulations or modifications to existing regulations are developed will be critical. This should be a high priority in the plan.
- Goal 2 and its objectives around technology transfer would be improved by aggressively establishing standards for measurement and defining the techniques/tools/equipment/reference laboratories for each of those measurement standards. Perhaps this could be a Signature Initiative.
- The education objectives captured in Goal 3 and Goal 4 are focused primarily on education institutions and the general public. Additional activities are needed to engage and communicate with the business community that would/could invest and help improve the evolution of nanotechnology and nanotechnology manufacturing.
- There are multiple industry experts who may or may not be involved directly or indirectly in the NNI activities. There is, however, a significant amount of talent that exists in industry executives/scientists who have reached retirement. The NNI and federal agencies could establish a volunteer program akin to youth corps to engage that talent in working with R&D and industry groups to help refine and meet the NNI's goals.

In addition, the NMA specifically offers the following:

- We would welcome membership in the Nanomanufacturing Industry Liaison and Innovation (NILI) Working Group.
- Given NMA's interests and activities in communication and public education/understanding/appreciation for the promise of nanotechnology and the industry's expertise in medical information communications, NMA would welcome membership in the Nanotechnology Public Engagement and Communications (NPEC) Working Group.

Please accept the continued support of the NMA in achieving our shared goals of ensuring the safe and effective adaptation of the promise of nanotechnology to improve the lives of patients and citizens. Our organization remains ready to collaborate and participate in the various initiatives that involve and impact the development of nanomedicines that will benefit patients.

Sincerely,



Henry Havel
Chair of the Nanomedicines Alliance



Frank Malinoski
Vice Chair of the Nanomedicines Alliance