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19 March 2013

Via Federal Rulemaking Portal

NIOSH Docket Office
Robert A. Taft Laboratories
MS-C34 4676 Columbia Parkway
Cincinnati, OH 45226

**Re: CDC-2013-0001 NIOSH-134-B Protecting the Nanotechnology Workforce:
NIOSH Nanotechnology Research and Guidance Strategic Plan 2013-2016**

Dear Madam or Sir:

We submit these comments on the NIOSH draft strategic plan “Protecting the Nanotechnology Workforce: NIOSH Nanotechnology Research and Guidance Strategic Plan 2013-2016”¹ on behalf of the Nanomedicines Alliance², a consortium of pharmaceutical and biotechnology companies that develop nanomedicines. Current members of the Alliance include Amgen, BIND Biosciences, Cerulean Pharma Inc., CytImmune, Eli Lilly, Liquidia, NanoCarrier, NanoViricides, Pfizer, and Roche. The mission of the Nanomedicines Alliance is to promote and facilitate the scientific advancement, regulatory approval and public appreciation of nanotechnology-based medicines worldwide for the diagnosis, treatment and prevention of disease. The scope of the Nanomedicines Alliance includes nanomaterials and nanotechnologies involved in the discovery, research, development, testing, manufacturing, marketing and disposal of pharmaceuticals, biologics and medical devices, including imaging and diagnostics.

We recognize that the NIOSH strategic plan intends to advance the understanding of risks involved in unintended workplace exposures of engineered nanomaterials to develop appropriate management practices that can be implemented throughout the lifecycle of engineered nanomaterials. We note the draft plan outlines that “the challenges are to determine whether the nature of intentionally produced (engineered) nanostructured materials and devices presents new occupational safety and health risks.”³ In this context, **we would find clarification on the scope of the strategic plan helpful.** For example, unlike some other types of nanomaterials, nanomedicines are designed specifically for introduction to the human body. Nanomedicines, like all new drugs, are subject to extensive and rigorous toxicology and safety testing throughout the drug development process. These toxicology and

¹ CDC-2013-0001 NIOSH-134-B Protecting the Nanotechnology Workforce: NIOSH Nanotechnology Research and Guidance Strategic Plan 2013-2016 <http://www.regulations.gov/#!home:tab=search>

² <http://www.nanomedicines-alliance.org/>

³ CDC-2013-0001 NIOSH-134-B Protecting the Nanotechnology Workforce: NIOSH Nanotechnology Research and Guidance Strategic Plan 2013-2016, p.4.

safety studies are regulated and reviewed by regulatory agencies worldwide prior to administration to humans and for use as therapeutic agents in patients.⁴ Additionally, nanomedicines are most often suspended in aqueous liquids, thus limiting exposures to workers as opposed to airborne nanomaterials. An explanation that the plan refers to unintended exposures to nanomaterials rather than intended exposures would be beneficial and clarify the scope of the plan.

We also question the underlying assumption in the plan that all manufacturing processes for creating engineered nanomaterials are essentially identical. The Alliance welcomes the agency's intention to collect data, but we would advise caution and clarity in the related communications to prevent any misperceptions that all engineered nanomaterials are subject to the guidelines that may emerge from the NIOSH studies.

Thank you for this opportunity to provide comments. Please do not hesitate to contact us with any questions.

Sincerely,



Mary Devlin Capizzi
Nanomedicines Alliance Secretariat

⁴ For example, Redbook 2000: IV. A Introduction: Guidelines for Toxicity Studies (<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/Redbook/ucm078311.htm>); Guidance for Industry: M3 Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals, 1997 (http://ocw.jhsph.edu/courses/drugdevelopment/PDFs/FDA_Guidance_on_NonClinical_Safety_Studeis.pdf); European Medicines Agency: Non-clinical: Toxicology (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000397.jsp&mid=WC0b01ac058002956f). References are included for illustration purposes and are not comprehensive in nature.