

From: Ortlieb, Dave
Sent: Friday, February 15, 2008 3:34 PM
To: 'NIOSH Docket Office (CDC)'
Subject: NIOSH Docket Office

NIOSH Docket Office,
Robert A. Taft Laboratories
4676 Columbia Parkway, MS C-34,
Cincinnati, Ohio 45226.

Re: Docket Number NIOSH-115

Dear Sir/ Madam:

The United Steelworkers International Union Health, Safety and Environment Department is providing comments in response to the public review that NIOSH is conducting of the NIOSH document entitled *Current Intelligence Bulletin (CIB): Interim Guidance on Medical Screening of Workers Potentially Exposed to Engineered Nanoparticles*. A total of 38 individuals and organizations have signed onto and endorsed the comments that are being submitted to NIOSH. Those individuals and organizations are listed below:

- 1) Darryl Alexander, Director, Health and Program, American Federation of Teachers, Washington, D.C.
- 2) Ian Illuminato, Health and Environment Campaigner, Friends of the Earth, U.S., Washington, D.C.
- 3) Beth Burrows, President/Director, The Edmonds Institute, Edmonds, WA
- 4) David Michaels, PhD, MPH, Director, The Project on Scientific Knowledge and Public Policy Research,
The George Washington University, Washington, D.C.
- 5) Kathy Burns, Ph.D., Sciencecorps, Lexington, MA
- 6) Dave Ortlieb, Assistant Director, Health, Safety & Environment Department, United Steelworkers International Union, Nashville, TN
- 7) Bill Kojola, Industrial Hygienist, American Federation of Labor and Congress of Industrial Organizations, Washington, D.C.
- 8) George Kimbrell, Staff Attorney, International Center for Technology Assessment, Washington, D.C.
- 9) Eric Uram, Headwater Consulting, L.L.C., Madison, WI
- 10) David O. Carpenter, M.D., Institute for Health and the Environment, University of Albany, SUNY, Albany, N.Y.
- 11) Romeo F. Quijano, M.D., Professor Department of Pharmacology and Toxicology, College of Medicine, University of the Philippines,
Manila
- 12) Georgia Miller, Nanotechnology Project Coordinator, Friends of the Earth, Australia
- 13) Professor Elihu D. Richter, MD, MPH, Hadassah School of Public Health and Community Medicine, Jerusalem, Israel

- 14) Linda Reinstein, Executive Director & Cofounder, Asbestos Disease Awareness Organization, Karmanos Cancer Institute, Detroit, MI
- 15) Marisa Jacott, Environmental Program, Fronteras Comunes .A.C., Mexico
- 16) Michael R. Harbut, MD, MPH, FCCP, Co-Director, National Center for Vermiculite & Asbestos Related Cancers, Karmanos Cancer Institute, Wayne State University Center for Occupational & Environmental Medicine, Royal Oak, MI
- 17) Judy Braiman, President, Empire State Consumer Project, Rochester, NY
- 18) Erik Jansson, President, Department of Planet Earth, Washington, D.C.
- 19) Carolyn Raffensperger, M.A. ,J.D., Executive Director, Science and Environmental Health Network, Ames, IA
- 20) Laura S Welch, M.D., Medical Director, CPWR-The Center for Construction Research and Training, Silver Spring, MD
- 21) Jennifer Sass, Ph.D., Senior Scientist, Natural Resources Defense Council, Washington, DC
- 22) Michael J. Flynn, Director, Occupational Safety and Health, International Association of Machinists & Aerospace Workers Union, Washington, D.C.
- 23) James Powell, President Nanotechnology Citizen Engagement Organization, NanoCEO, Madison, WI
- 24) James Melius MD, DrPH, Director of Research, Laborers' Health and Safety Fund of North America, Washington, D.C.
- 25) Tom Lent, Policy Director, Healthy Building Network, Berkeley, CA
- 26) Jeanne Rizzo, R.N., Executive Director, Breast Cancer Fund, San Francisco, CA
- 27) Joel Shufro, Executive Director, New York Committee for Occupational Safety and Health, New York, NY
- 28) Adam Tapley, Project Director, Center for the Study of Responsive Law, Washington D.C.
- 29) Suzanne Murphy, Executive Director, Worksafe, Inc., Oakland, CA
- 30) James E. Lockey, MD, MS, Professor, Department of Environmental Health, Division of Occupational and Environmental Medicine, Pulmonary Division, Department of Internal Medicine, University of Cincinnati College of Medicine, Cincinnati, OH
- 31) Denny Dobbin, Chair, Society for Occupational and Environmental Health, McLean, VA
- 32) Georges Cingal, Member of the Executive Board of France Nature Environnement, Pilot of the "Mission Europe & Affaires Internationales", Paris, France
- 33) Dr Louis Patry, MD, FRCP, Director, Occupational and Environmental Health Clinic, McGill University, Montreal, QC Canada
- 34) Ray Scannell , Director of Research & Education , BCTGM International Union, Kensington, MD
- 35) David F. Goldsmith, MSPH, PhD, Associate Research Professor, Department of Environmental & Occupational Health, George Washington University, Washington, D.C.

- 36) Howard M. Kipen, MD, MPH, Professor and Interim Chair, Department of Environmental & Occupational Medicine; Chief, Clinical Research & Occupational, Medicine Division; Acting Associate Director, Environmental & Occupational Health Sciences Institute, UMDNJ-Robert Wood Johnson Medical School, Piscataway, NJ
- 37) Kathy Jo Wetter, Ph.D. Researcher, ETC Group, Ottawa, ON Canada
- 38) Joan Greenbaum & David Kotelchuck, Co-Chairpersons, Health and Safety Committee, Professional Staff Congress of the City University of New York, NY

Thank you for allowing us to submit our comments.

Sincerely,

Steven Markowitz, M.D.
USW Medical Consultant and Professor at Queens College
City University of New York, NY

Dave Ortlieb, Assistant Director
Health, Safety and Environment Department
United Steelworkers International Union
Nashville, TN

Comments on the NIOSH Interim Guidance Document on Medical Screening of Workers Potentially Exposed to Engineered Nanoparticles

The NIOSH Interim Guidance Document describes a standard approach to medical screening that applies to circumstances where health effects are well-established or reasonably anticipated. We understand this paradigm and its utility and limitations. We believe that an alternative approach needs to be considered.

In the absence of human evidence concerning the health effects of engineered nanoparticles, is there a role for medical screening of workers as part of a larger program of health surveillance? Indeed, can such medical screening contribute to the development of an evidence base about the toxicity (or lack thereof) of nanosized materials? Is there sufficient concern raised by the a) toxicity studies of nanoparticles demonstrated to date; b) plausibility of potential toxicity based on the physical properties and biological activity of nanomaterials; c) current knowledge about the human toxicity of ambient ultrafine particles; d) uncertainty about the effectiveness of protective technologies in preventing worker exposure, and e) rapid and promising rise of the nanomaterials industries to justify close monitoring of worker populations at present? The answer to all of these questions is yes.

According to a common paradigm, decision-making about medical screening must await epidemiologic studies, which point to specific risks, after which medical screening might be offered to permit early detection of associated medical conditions.

We suggest using a different paradigm to understand the utility and need for medical screening in the nanotechnology industries now. It is in line with the precautionary principle as applied to secondary prevention. We propose instituting broad-based medical screening of nanotechnologies workers at the present time, in part as a safety net against potential toxicity, and in part as a tool to identify, sooner rather than later, health conditions caused by exposure to nanomaterials.

We recommend that NIOSH should adopt the following activities as part of a proactive strategy to understand and prevent human illness associated the nanomaterials:

- I. Develop and Recommend a Basic Medical Screening Protocol for the Nanoparticles Industries**
- II. Implement an ongoing Nanoparticles Toxicity Review Group**
- III. Develop a National Nanotechnology Health Surveillance Program**

Part I: Basic Medical Screening Protocol for the Nanoparticles Industry

NIOSH should recommend, and industry should implement, a basic medical screening protocol for workers with potential exposure to nanosized materials. This protocol should include, at a minimum, routinely available, non-invasive tests that serve as indices of major organ function, i.e. – medical examination and history, pulmonary function tests, chest x-ray, and blood chemistries and cell count, urinalysis, and possibly others. These tests are not especially sensitive, sophisticated, or targeted, but they are widely available, inexpensive, widely accepted and present minimal risk. They will serve as a safety net to permit detection of some of the risks that might accompany exposure to nanosized materials until more specific screening protocols can be developed.

An example of the utility of this protocol and its timeliness is useful. In 1974, Creech and Johnson documented 3 cases of liver angiosarcoma at a vinyl chloride plant in Louisville Kentucky, causing widespread concern about this common monomer and related materials in the plastics industry. Later in 1974, Drs. Lilis, Selikoff, and colleagues at Mount Sinai School of Medicine conducted a survey of vinyl chloride workers at a Goodyear plant in Niagara Falls, using the core protocol cited above. They found widespread liver dysfunction, pulmonary function abnormalities, and neurologic symptoms, demonstrating that the health risks of vinyl chloride were not limited to the few who would develop a rare cancer but affected the many who at that time routinely suffered gross over-exposure to vinyl chloride. If the protocol that we recommend today

had been in place prior to 1973, vinyl chloride-associated health problems would have been documented earlier, perhaps even limiting the carcinogenic impact of vinyl chloride.

Part 2: Implement a Nanoparticles Toxicity Review Group

NIOSH should develop and institute an ongoing Nanoparticles Toxicity Review Group. Among other functions, this review group would monitor the evolving research knowledge about toxicity of nanosized materials and recommend modifications to the initial medical screening protocol suggested above. Given the rapid development of this field, this review process would need to be constant and would require resources. Involving partners from labor, industry, NGOs and academia would facilitate coming to timely agreement about the significance of new research findings and also their rapid translation into actions to promote worker protection, include medical screening. This group should officially review relevant published studies and the currently recommended medical protocol once or twice per year and issue a statement about the need for adaptation of the medical screening protocol. This review group could also guide the development of research strategies, monitor studies of exposure assessment and protective technologies, and perform additional useful functions.

Part 3: Develop a National Nanotechnology Health Surveillance Program

NIOSH should transform its concept of a nanotechnology exposure registry and undertake a full-scale National Nanotechnology Health Surveillance Program. Such a program would enroll large numbers of workers from a variety of industries using nanosized materials to ensure study power to detect rare conditions. Program size is also critical to ensure proper monitoring of these new materials that are enormously heterogeneous in size, structure, chemical composition, biological activity, applications, and exposure opportunities. Prospective longitudinal surveillance with timely aggregation and analysis of resultant data is important to permit rapid detection of health conditions “as they develop.” Such a program would generate and use a common screening protocol; collect and distill the medical data generated by application of this protocol; provide a standardized and timely assessment of symptoms and physician-diagnosed medical conditions; serve as a framework and structure for integrating hypothesis-driven epidemiological and clinical studies; and serve as a vehicle for studies of exposure and efficacy of protective technologies. This program could, if properly designed, also serve a purpose similar to that of syndromic surveillance in the worlds of infectious diseases and, more recently, chemical, biological, and radiation weapon use, providing health data in real time to facilitate immediate analysis and feedback to those charged with investigation and follow-up of potential outbreaks. Industry should fund such a health surveillance program as a straightforward cost of research, development and applications of nanosized materials. The cost would be a small fraction of the current investment in this area, in which there is expected to be a \$1 trillion dollar (US) global market involving 2 million workers within the next 7 years.

It is essential that the proposed health surveillance program address all workers in the life cycle of nanoparticles. The history of occupational safety and health has typically

emphasized understanding the risk in the production phase of a material, without giving equal emphasis to the risk to workers who use or dispose these materials, or who work in the research and development phase, when exposures are often less controlled. To avoid repeating this history, all parts of this strategy should ensure that the potential exposures and health impacts on end-users, waste handlers, and research personnel be specifically included.

The Context for Action

Our recommendations are intended to encourage NIOSH to fulfill its mandated function, as assigned to the Department of Health and Human Services under the Occupational Safety and Health Act of 1970 “to conduct special research, experiments, and demonstrations relating to occupational safety and health as are necessary to explore new problems, including those created by new technology in occupational safety and health.” NIOSH should implement the proposed strategy in order to facilitate the collection of scientific knowledge upon which rational workplace standards can be established.

Our recommendations should also be seen within the broader context of a set of eight fundamental principles upon which adequate oversight of nanotechnology and nanomaterials should be based (1). Assuring the health and safety of nanotechnology workers is one of these key principles.

There are some who may wonder whether there is sufficient evidence of toxicity to warrant these proposals. The issue of “how much evidence is sufficient” to warrant any of a number of actions in the field of occupational and environmental health is, in large part, a social decision. We in labor, public health, and public interest community work to protect workers and the public. It is the law, of course, that the government ensures that employers maintain healthy and safe workplaces. If we err, it should be on the side of caution, rather than in the failure to protect. We should not miss a disease epidemic when it might be detected early and altered.

None of the above-cited recommendations will slow the nanomaterial juggernaut, nor should such concerns trump the duties of those statutorily entrusted with protecting the health and safety of workers and the public. Nor should the recommendations that we make be considered a replacement for the implementation of substantial protective strategies to reduce exposure, for the use the safest possible alternatives, and for the provision of detailed information on the composition and health hazards of materials, as required by OSHA communication standards.

The prominence of the potential application of nanomaterials in the domain of medicine poses a special obligation on the scientific community. We should squarely face the fact that the potential benefits and toxicities of nanomaterials are opposite sides of the same coin. We cannot accept the excitement about the promised benefits of nanomaterials without also accepting the growing concerns about, and the need to take early actions based, on the potential, unwelcome toxicity of these same materials. The

reason is simple. The very qualities of nanosized materials that make them so potentially promising for applications in medicine – their large surface to mass ratio; their size, uniformity, reactivity, and shape; their ability to penetrate or elude membrane or cell barriers; their documented ability to travel along the olfactory nerve or other nerve axons; their attachment to other molecules – these are the very same qualities that may, and in fact probably will, permit undesired biological effects. Nanosized materials that can deliver therapeutic drugs to cells can deliver cellular poisons perhaps as effectively. Nanomaterials that can enter cells or organs more effectively than their larger counterparts can be very useful as probes or as tools of drug delivery but may also be, or bring, agents of unwanted change.

Perhaps the unfettered embrace of the wonders of the revolution of synthetic chemicals in the first half of the 20th century was understandable, though one suspects that even then there were early warning signs that were ignored. Having now, however, witnessed the full and very mixed harvest of that earlier revolution, it would be wrong to endorse this new nano-revolution without simultaneously taking bold, affirmative steps to avoid preventable harm to workers and the public.

(1) *Principles for the Oversight of Nanotechnologies and Nanomaterials*, available at http://www.icta.org/doc/Principles%20for%20the%20Oversight%20of%20Nanotechnologies%20and%20Nanomaterials_finalwJan08sigs.pdf