Nanotechnology Law Report

PORTER WRIGHT MORRIS & ARTHUR LLP
1919 Pennsylvania Avenue, NW, Suite 500
Washington, D.C., 20006
(202) 778-3050

Texas In Vivo Study Said to Indicate No Immediate Adverse Heath Effects From Carbon Nanotubes in Bloodstream. The on-line edition of the Proceedings of the National Academy of Sciences appears prepared to publish findings from recent in vivo animal research into the possible health effects of deliberately injected SWCNTs. Scientists at Rice University and the University of Texas are said to have found that carbon nanotubes are filtered from the bloodstream by the liver just over one hour after injection. The scientists are also said to have sampled tissue from various locations in the test animals and apparently found SWCNT deposits in the liver, and trace amounts in the kidney -- both of which were expected. Preliminary reports tout the study as supporting the conclusion that there are no immediate adverse health effects from SWCNTs injected into the bloodstream.

Nanotech Helping to Clean Water. Given all the recent news about possible environmental regulation of nanotechnology, the potential benefits of these new discoveries sometimes gets lost in the shuffle. However, Rice University reported on November 16, 2006 that nanotechnology research shows promise in removing arsenic from drinking water. Recent experiments conducted by the Center for Biological and Environmental Technology at Rice University resulted in arsenic removal from drinking water through the use of nano-sized rust particles. The experiments are significant in that arsenic removal technology, as it currently exists, is both expensive and complicated because it uses high pressure pumps and needs electricity. Researchers at Rice discovered that "nanorust," iron oxide particles, could be removed from water in the presence of a weak magnetic field. In some instances, small, handheld magnets were enough to create the necessary magnetic force. Researchers previously thought that given the size of the nanorust, only large electromagnets would remove the particles from water. Iron oxide binds to arsenic extremely well, and such binding does not appear to impact the magnetic properties of the nanorust. This technology shows promise for areas of the world that do not have reliable electricity or funding, such as Southeast Asia, and who need to remove high levels of naturally occurring arsenic from their water supplies. This discovery may make it possible to decontaminate drinking water on a household scale without the use of electricity.

Altairnano Provides EHS Example. At the International Conference on Nanotechnology Occupational and Environmental Health and Safety in Cincinnati, Ohio, Altairnano President and CEO -- Alan Gotcher -- and Health Safety and Environment Facilitator -- Tabitha Maher -- both gave presentations regarding Altairnano's environmental, health, and safety (EHS) efforts centered around the company's use of nanomaterials. Altairnano is an 80 employee company with facilities in Reno, Nevada, and Anderson, Indiana. The company uses conglomerates of sphere-shaped metal oxide nanoparticles in the production of its products aimed a four (4) markets: power systems; pigments; drug campaigns; and performance materials.
Gotcher made a convincing business case for the early implementation of EHS programs by smaller, start-up nanotechnology companies in order to attract and maintain the best talent, address public perceptions regarding nanotechnology, prepare for possible product liability lawsuits, and to act before possible regulation hinders market entry of products. Gotcher indicated that in an effort to be highly proactive on nano-related EHS issues, Altairnano hired a full-time industrial hygienist approximately 18 months ago as its 31st employee, and budgets over $500,000 per year on EHS efforts. The company also opened its facilities to NIOSH for extensive ambient nanoparticle measurements, and used the resulting data to help structure its EHS efforts. Gotcher advocated proactive, open, and honest communication with employees, third-parties, and the public about the various known and unknown risks surrounding Altairnano's use of nanomaterials. Maher provided insight regarding Altairnano's EHS efforts that even start-up nanotechnology companies should consider implementing when faced with limited initial budgets. To this end, she explained the

company's extensive use of fume hoods, protective clothing, HEPA respirators, employee training, and workplace cleanliness efforts to reduce possible worker exposure. Maher drove home the point that every nanocompany can make at least some EHS-related efforts and should do so as early as possible as part of a good business model. Gotcher and Maher also indicated that Altairnano had recently embarked upon its own animal toxicity studies to supplement its EHS efforts. Remarkably, all of these steps have been undertaken even though the company has yet to post a profit. Altairnano has a modest section on its website regarding its EHS efforts.

Existing Respirator Materials Prove Effective For Certain Nanoparticles. At the International Conference on Nanotechnology Occupational and Environmental Health and Safety in Cincinnati, Ohio, Daniel Japuntich, Division Scientist at 3M, presented "Filtration and Respirators: Current Knowledge." Japuntich shared 3M's research findings indicating HEPA respirator materials are effective in filtering nanoparticles down to three nanometers in size. The 3M research found nanoparticles act as solids, "obey the laws of physics," and fit nicely within existing filtration models. Thus, Japuntich concluded existing NIOSH respirator standards under 42 CFR 84 should be sufficient for many nanorelated uses. Japuntich noted the efficacy of filter materials must be evaluated in the context of a complete workplace respirator program including hazard measurement and assessment, face-piece choice, face fit testing, and worker training programs. Another conference presentation by Michele Ostraat, a Research Engineer at DuPont, discussed similar findings by the Nanoparticle Occupational Safety and Health Consortium. Ostraat spoke regarding the Consortium's recent aerosol chamber research studies on a variety of respirator material using six different types of nanoparticles. Ostraat posed that, while existing respirator material proved effective for nanomaterials, filter efficacy for nano-aerosols decreases as exposure time increases in certain instances. The Consortium intends to publish several papers in 2007 setting forth its research findings in detail. Ostraat also explained the Consortium's parallel goals of making consistent nano-aerosols for research purposes (which it has already accomplished), and creating a reliable, inexpensive, portable, nanoparticle measuring device (which it hopes to unveil by mid-2007).

UPDATE: Berkeley City Council to Consider Nanotechnology Regulation. On December 5, 2006 the Berkeley, California City Council began considering two municipal code amendments directly addressing manufactured nanoparticles. As reported here earlier, the ordinance will amend two portions of the Berkeley Municipal Code, sections 15.12.040 and 15.12.050, to include reporting requirements for manufactured nanoparticles. Those required to report are all "facilities" who produce or use manufactured nanoparticles. The amendments call for written disclosure of "the current toxicology of the materials reported, to the extent known, and how the facility will safely handle, monitor, contain, dispose, track inventory, prevent releases, and mitigate such materials." The amendment further defines nanoparticles subject to disclosure as those "with one axis less than 100 nanometers in length." If passed, after the required subsequent readings by Council and a vote, this will be the first known regulation aimed specifically at manufactured nanoparticles by a local government.

Consumer Survey: U.S. Consumers Willing To Use Nanotechnology, But Have Reservations. Rice University's Center for Biological and Environmental Nanotechnology, together with researchers from University College London and the London Business School, released the results of a major consumer research study that sought to measure public perceptions of the risks & benefits of nanotechnology. As reported in PhysOrg:

The largest and most comprehensive survey of public perceptions of nanotechnology products finds that U.S. consumers are willing to use specific nano-containing products – even if there are health and safety risks – when the potential benefits are high. The study also finds that U.S. consumers rate nanotechnology as less risky than everyday technologies like herbicides, chemical disinfectants, handguns and food preservatives.

The study also found that American consumers did take nanotechnology's possible health risks into consideration when evaluating whether they would purchase products containing nanotechnology:

One survey polled consumers about how likely they would be to use four specific, nano-containing products: a drug, skin lotion, automobile tires and refrigerator gas coolant. This is the first large-scale

study to experimentally gauge the public's reaction to specific, nano-containing products, and [Professor Steven] Currall said the use of scenarios about plausible, specific products yielded results that challenge the assumption that the public focuses narrowly on risk.

"It was clear that people were thinking about more than risk," he said. "The average consumer is pretty shrewd when it comes to balancing risks against benefits, and we found that the greater the potential benefits, the more risks people are willing to tolerate."

Their findings were published in the December edition of Nature Nanotechnology.

Standardization: ASTM Releases "Terminology for Nanotechnology." For those of you who have been paying close attention to nanotechnology issues, be they regulatory or otherwise, you have probably noticed that there does not seem to be any one standard for nanotechnology terms, including "nanotechnology." While various organizations and agencies, such as the United States Environmental Protection Agency, American Bar Association, and Rice University, among others, have all provided somewhat similar definitions for "nanotechnology" and related terms, ASTM International (formerly the American Society for Testing and Materials) recently released its Standard for nanotechnology related terms. ASTM, International, by its own description is, "one of the largest voluntary standards development organizations in the world-a trusted source for technical standards for materials, products, systems, and services. Known for their high technical quality and market relevancy, ASTM International standards have an important role in the information infrastructure that guides design, manufacturing and trade in the global economy." ASTM International develops many of the standard testing methods and procedures for scientific processes, and they have now created standard definitions for nanotechnology. Standard E 2456-06 is a collection of definitions and terminology that should help to alleviate some of the confusion inherent in many organizations using slightly different definitions for nanotechnology related terms. Terms addressed by the Standard include: “nano,” “nanoparticle,” “nanotechnology,” and “nanoscale.” This release by ASTM International is important because that organization is heavily relied upon for developing and maintaining many of the world's scientific standards and procedures. The fact that they have now developed, what we hope to be, standardized definitions in the nanotechnology arena, helps to alleviate any confusion surrounding what is properly within the field of nanotechnology, and what is not. This, in turn, frees up those working in the field to turn their attention to the substantive issues at hand. While not binding on any organization or agency, the Standard reflects an attempt by several scientific organizations, including the American Institute of Chemical Engineers, NSF, International, the National Institute of Advanced Industrial Science and Technology, the Institute of Electrical and Electronics Engineers, the American Society of Mechanical Engineers, and the Semiconductor Equipment and Materials International to reach a consensus concerning the scope of nanotechnology.

UPDATE: Nanoparticles Used as a Topical Drug Delivery Device. As a follow up to our November 14, 2006 article, Pharmos Corporation recently announced the completion of another first round of testing of a topical cream used as a drug delivery device for an anti-inflammatory drug. Again, the tests were successful. See "Pharmos completes Phase 1 study of topical Diclofenac NanoEmulsion cream," Law & Health Week via NewsRx.com, December 16, 2006. It is interesting to compare what Pharmos is doing with its Diclofenac NanoEmulsion to the Cosmetic, Toiletry and Fragrance Association's October 10, 2006 "Nanotechnology White Paper: The Use of Nanotechnology in Personal Care Products," (maintaining scientific evidence confirms a lack of dermal absorption of nanoparticles).

Carbon Nanotubes Can "Swim.”
Researchers at the Georgia Institute of Technology (Georgia Tech) have discovered that multiwalled carbon nanotubes will remain suspended in water for a month or longer when combined with other organic materials. The January issue of the journal Environmental Science & Technology , will fully report the findings by Assistant Professor Jaehong Kim, Professor Joseph Hughes, researcher John Fortner, and graduate student Hoon Hyung. However, the initial conclusion from the experiments is that multiwalled carbon nanotubes are easily dispersed throughout the environment due to their extended suspension in river water. The nanotubes interacted with the organic material found in water from the Suwannee River, and as a result, remained suspended in the water. As reported by Georgia Tech, "Carbon nanotubes, which can be single- or multiwalled, are cylindrical carbon structures with novel properties that make them potentially useful in

a wide variety of applications including electronics, composites, optics and pharmaceuticals. This, of course, adds to the body of science regulators are looking to as they try to develop sound policy for governing nanotechnology.

Geckos use nanotechnology? A gecko's amazing ability to cling to walls and ceilings is an ability that scientists have studied for decades. Recent research suggests that the gecko's abilities owe to 200 nm adhesive hairs on the gecko's feet. While the traditional definition of nanotechnology requires that the material be smaller than 100 nm, we are willing to make an exception for the gecko. Nanowerk reports that researchers at the Max-Planck Institute for Metals Research in Germany have leveraged this research to create new adhesive materials:

Copying the biological adhesive mechanism, the Max-Planck scientists used the insights gained from their years of research to develop a material with a biomimetic structure that exhibits excellent adhesive qualities. The special surface structure of the material allows it to stick to smooth walls without any adhesives. Potential applications range from reusable adhesive tape to shoe soles for climbing robots and are therefore of considerable relevance to technology.

The Nanowerk article is unclear as to whether the new material actually employs nanoscale fibers. This actually raises an intriguing question about nanotechnology regulation; if we accept that 100 nm is the largest "nanomaterial," then presumably gecko feet and other "almost" nanoscale materials are not subject to the regulation. However, it is uncertain whether the alleged human health hazards associated with nanomaterials sharply diminish once the particle exceeds 100 nm in length along any one axis.

Department of Defense is Watching "Nanomaterials." The United States Department of Defense's Materials of Evolving Regulatory Interest Team (MERIT) recently announced that it added "nanomaterials" to its emerging contaminants watch list. The DoD defines "emerging contaminants" as those chemicals and materials with a "perceived or real threat to human health or environment," an "evolving regulatory interest," and "either no peer reviewed health standard or an evolving standard." In addition, an emerging contaminant may have "insufficient human health data/science," or "new detection limits," or "new exposure pathways." The watch list however, is different from the emerging contaminants action list. The watch list includes those materials that DoD believes have a "probable mission or budget impact." DoD then monitors events surrounding the listed material while conducting "rough impact analysis." Other materials found on the watch list include: tungsten and its alloys, lead, beryllium, dichlorobenzenes, and dioxins, among others. "DoD places materials on the Watch List when they are identified through the scanning phase as potentially affecting one or more DoD business areas. While the exact nature and magnitude of the potential impacts are unknown, the Department has identified these materials as having a potential to affect DoD functions. As a result, DoD is conducting Phase I assessments for each of these materials."

The difference between the watch list and action list is that under the watch list the DoD monitors developments concerning the listed material while expending minimal resources. If the material is upgraded to the action list, DoD has determined that the material is likely to impact the department, and it performs detailed analysis on the material while possibly expending "significant" resources on understanding the material. Other activities performed once a material is upgraded to the action list include undertaking risk management actions and pollution prevention efforts by DoD. This listing of nanomaterials, without more information, is interesting for a number of reasons. First, the DoD's watch and action lists are selective in nature. There are only eighteen materials on these lists in total, so the addition of nanomaterials is significant. We therefore see this action as a step towards regulation of nanotechnology by DoD's recognition of nanomaterials as potentially impacting department operations and the environment. Second, it is hard to know what DoD will be watching by posting "nanomaterials" on its watch list. Given the different types and functions of nanomaterials and nanoparticles, a blanket listing is vague at best. However, because the DoD elected to list nanomaterials at all is proof that federal agencies are increasing their focus on nanotechnology in general. While this listing does not cause any regulatory actions to be taken by DoD, an upgrade to the action list could certainly mean a significant change in course as to how one of the country's largest agencies addresses nanotechnology

NIOSH Guidance for Nanotechnology Employers. As the impact of nanotechnology grows, more companies are considering the utilization of nanotech products and processes in the workplace. Questions regarding nanotechnology's effect on the American worker, however, come side-by-side with these business decisions. As reported in Occupational Hazards, The National Institute for Occupational Safety and Health (NIOSH) may issue guidance for employers facing these problems. Doug Trout, Associate Director for Science for the Division of Surveillance, Hazard Evaluations and Field Studies discussed this issue at the International Conference on Nanotechnology Occupational and Environmental Health and Safety. According to the article, NIOSH will recommend that all nanotechnology employers implement an occupational health surveillance program designed to help employers evaluate the risks and necessary protections resulting from nanotechnology's use. The necessity for such guidance is apparent, considering "the growth of nanotechnology in the workplace, the unique physical and chemical properties of nanomaterials and early evidence suggesting that 'nanoparticles may have toxic effects greater than larger-size particles and at lower doses.'" For those unaccustomed to the field of occupational health, the article explains that an occupational health surveillance program includes hazard surveillance and/or medical surveillance. These two components are designed to identify and monitor workplace hazards and occupational health problems. The first step in any health surveillance program is a needs assessment. NIOSH intends to provide a needs assessment framework for employers, including recommendations for the evaluation of various risk factors. We know, however, that the needs assessment will contain a hazard assessment and an exposure assessment. The article quotes Trout as stating "The purpose of this needs assessment in an occupational setting is to determine – by performing hazard and exposure assessments – whether a health risk due to occupational exposure [to nanomaterials] exists in the workplace." As most employers already realize, the research on the risks and effects of nanotechnology is still evolving. Trout is quoted as acknowledging that "information may not be available to make a well-informed determination of risk." For that reason, "periodic reassessment" will be of vital importance in the workplace. Even NIOSH cannot yet provide definitive answers. Experts agree, however, that exposure to nanomaterials might pose health risks to employees. If issued, the NIOSH guidance may provide relief to employers struggling to understand the dangers of nanotechnology and how to avoid them.

Congressional Leaders Urge Nanotech Safety Research. According to a December 21, 2006 press release, both outgoing House Science Committee Chairman Sherwood Boehlert (R-NY) and incoming Chairman Bart Gordon (D-NT) urged the Bush administration "to establish a research agenda with clear priorities to ensure a greater understanding of the potential environmental, health, and safety risks associated with nanotechnology." We suspect that in 2007, the new Congress may well push a nanotechnology safety initiative. Nanotechnology safety issues are increasingly being publicly discussed, especially given Berkeley's new regulations and NIOSH's continued interest in occupational nanotechnology safety. Andrew Maynard's proposal, discussed in Nature in connection with the National Nanotechnology Initiative, so far looks to be the most comprehensive public proposal -- the press release expressly references it. We reported on Maynard's proposal twice in November 2006

Contacts: John C. Monica, Jr., (202) 778-3050, jmonica@porterwright.com; Michael E. Heintz, (614) 227-2100, mheintz@porterwright.com; Patrick T. Lewis, (216) 443-2513, Plewis@porterwright.com.