Nanotorts

The Legal Risks of Nanotechnologies

By Ronald C. Wernette and Ryan L. Nilsen

Nanotechnology is truly a portal opening to a new world.

Rita Colwell, National Science Foundation

The more we know about nanomaterials' risks, the more we worry about what we don't know.

Andrew Maynard, Woodrow Wilson Center Project on Emerging Nanotechnologies

Answers to problems give rise to new questions and for each door we open, we find another door closed behind it. Although the atom's existence was first proposed by Leucippus and Democritus in fifth century B.C. pre-Socratic Greece, the doors in chemistry and physics opened relatively slowly. Then, in the early 1980s, the birth of cluster science and the invention of the scanning tunneling microscope opened the door to nanoscience and nanotechnology. The pace of nanoscience discovery has exploded, and each door opens seemingly before the last door has closed. Practitioners need a basic understanding of these hot scientific and business fields—nanoscience and nanotechnology—to effectively assess risks and deal with tort and environmental litigation potentially arising from them in the near and long term.

What Is Nanotechnology and What Makes It Important?

Nanotechnology, hailed as the next industrial revolution, is a multidisciplinary field of applied science concerned with the design, production and control of materials on the molecular level. Nanotechnology is a "general purpose technology," much like the technology underpinning the Internet or electricity. As such, nanotechnology is thought to have broad application in virtually all industrial sectors, and its impact is impossible to predict. Rapid advances in nanoscience—the science and manipulation of chemical and biological structures ranging from 1–100 nanometers—and nanotechnology promise to revolutionize many of the ways we manufacture products, produce energy, increase global food production and diagnose and treat diseases. What the computer science revolution did for manipulating data, the nanoscience revolution will do for manipulating matter.

Most people are understandably baffled because nanoscience involves structures and substances so small that they are essentially invisible, which challenges our ability to conceptualize size. A few definitions are useful. The prefix *nano* means "one billionth." One nanometer is one billionth of a meter. To get a sense of

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the nanoscale, which is that of the molecule and atom, visualize these examples: the head of a pin is one million nanometers in diameter; a human hair's width is 100,000 nanometers; and the width of the smallest objects visible to the human eye is 10,000 nanometers. *Nanomaterials* are molecules or groups of molecules with at least one dimension between one to 100 nanometers.

The full biological and environmental impact of developed nanotechnology, as well as what we will find behind the next door, are unknown.

Nanotechnology is the fabrication of nanomaterials into useful nanoscale devices. As explained by the National Science Foundation, "[o]ne nanometer is a magical point on the dimensional scale. Nanostructures are at the confluence of the smallest of human-made devices and the largest molecules of living things." In other words, nanostructures aren't just smaller than anything ever made before: they are the smallest solid objects it is possible to make. At the nanoscale, a material's physical and chemical properties change. For example, carbon becomes 100 times stronger than steel, aluminum becomes highly explosive, and silver takes on biological properties and becomes a bactericide.

Engineered nanomaterials are created in two ways, top-down and bottom-up, although a hybrid of the two already is—and will continue to be—employed. For "top-down" nanotechnologies, the particle size of existing macro materials is reduced to the nanoscale by photolithographic techniques. With "bottom-up" nanotechnologies, scientists manipulate individual atoms and molecules, like tiny Lego blocks, to build specifically shaped microscopic structures such as tubes, wires, and spheres, and integrate the formed nanostructures into diverse products.

Boon or Bane: Untold Promise and Unknown Risk

Some scientists have suggested that the current pace of technological progress is a real threat to the future of humanity. For example, in "Why the Future Doesn't Need Us," published in the April 2000 issue of *Wired* magazine, Bill Joy, cofounder and chief scientist at Sun Microsystems, identified three major threats to humanity: genetic engineering, robotics and nanotechnology. Even Dr. K. Eric Drexler, one of the chief proponents of nanotechnology, and whose speeches and books are widely regarded as having established the field of molecular nanotechnology, expressed concern at the outset: "There are many people, including myself, who are quite queasy about the consequences of this technology for the future. We are talking about changing so many things that the risk of society handling it poorly through lack of preparation is very large." K. Eric Drexler, "Introduction to Nanotechnology," *Prospects in Nanotechnology: Toward Molecular Manufacturing (Proceedings of the First General Conference on Nanotechnology: Development, Applications and Opportunities)*, edited by Markus Krummenacker and James Lewis (1995) p. 21. While caution in nanotechnology is important, possibly beyond the next door is a breakthrough that may cure cancer or solve global energy problems.

Nanotechnology has quickly moved from science lab to market. Although still in nascent stages, several thousand nanotechnology companies now operate worldwide, and almost 50 percent of Dow Jones Industrial Average companies make or work on nanotech products. In the U.S. alone in 2007, over 12,000 patents were issued containing the prefix *nano*. In 2007, the United Nations estimated that nanotechnology, which accounted for about 0.1 percent of the global manufacturing economy, would grow to $2.6 *trillion* by 2014, representing 15 percent of total global output. A wide variety of nanomaterials are now used in commodities, pharmaceuticals, biomedical products, cosmetics, food products and a variety of other consumer products. In 2008, new nanotechnology consumer products are marketed at a rate of three to four per week, according to the Woodrow Wilson Center Project on Emerging Nanotechnologies, which maintains continuously updated nanomedical device and consumer products databases. *See* http://www.nanotechproject.org.

While the commercialization of nanotechnology is already underway and offers potentially tremendous benefits to society, sufficient information exists to warrant the caution recommended by its pioneers. First, nanoscale substances move more easily through organisms and the ecological system than their regularly sized counterparts. Studies of naturally occurring ultrafine particles suggest that particle size alone can impact toxicity equally, if not more than, chemical composition. *See* NTP Nanotechnology Safety Initiative Fact Sheet, *at* http://ntp.niehs.nih.gov/files/NanoColor06SRCH.pdf. Second, nanoscale materials are not simply miniature versions of their regularly sized counterparts; they exhibit different physical and chemical properties. The characteristics that make nanoscale materials exciting and useful—novel physicochemical properties that differ from their regularly sized counterparts—may increase their biological and environmental risk. In addition to size, factors that may affect nanomaterial risk include: size distribution; shape; agglomeration state; biopersistence, durability and solubility; surface area; surface charge; surface chemistry/coatings; porosity; chemical composition; trace impurities and contaminants; and crystallinity. *See* ASTM Int'l, Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings, E2535-07 (2007). (For good recent discussions of these subjects, *see* Stephen Clough, "Chapter 8: The Potential Ecological Hazard of Nanomaterials," and Chris Mackay and Jane Hamblen, "Chapter 9: Toxicology and Risk Assessment" in *Nanotechnology and the Environment*, Boca Raton, FL: CRC Press, 2008.)

How much risk do nanomaterials pose? No one knows. The full biological and environmental impact of developed nanotechnology, as well as what we will find behind the next door, are unknown. The enabling science and the commercialization of nanotechnology have rapidly outpaced the research about possible health, environmental and safety risks. Nanotoxicity is still a newly emerging scientific discipline. *See*, *e.g.*, Oberdorster, *et al.*, *Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles*, Environmental

Health Perspective 113:823–29, 2005. The first significant textbooks to address the risks associated with exposure to nanomaterials have only recently been published, and they contain only tentative conclusions about the potential toxicological effects and safety of nanostructured materials on human health. *See*, *e.g.*, Nanotoxicology (Y. Zhao and H. Nalwa ed. 2007).

This article describes the current toxicity research and government regulations under development to deal with the perceived risks of nanotechnology, and outlines emerging toxic tort risks associated with nanotechnology.

New Technologies Redux: Leaping Before Looking Again?

We do not think of evolution in living organisms as occurring in a matter of days or weeks, although it does. Every species is changing, in response to its environment and every other species. Perpetual change makes the biosphere so complicated that human actions necessarily have uncertain consequences, and we simply cannot precisely predict the consequences of our actions.

That uncertainty is a powerful argument for caution. Many would argue that man has demonstrated a striking lack of caution in the past. Why? Some argue that emerging technologies always create incentives to overstate benefits and understate risks. As a result, each generation tends to dismiss earlier errors as the result of bad decisions by less capable minds. Recent history is instructive. Although unintentionally, new chemicals and industrial processes that proved beneficial to mankind in the 20th century also polluted the air, water and soil. Tens, if not hundreds, of billions of dollars were spent globally cleaning up chemical runoff and toxic landfills and to mitigate other ecosystem damage, and perhaps even greater human costs were borne as a result of related injury, illness, and death.

Nanoscale devices and nanoparticles are hundreds or thousands of times smaller than human cells. Many can easily enter most cells, and those smaller than 20 nm can migrate out of blood vessels to circulate through the body. They can interact with biomolecules both on and inside cells. With access to virtually the entire body, nanoscale devices offer tremendous opportunity to detect disease or deliver effective therapeutic treatment. Conversely, the nanoparticle features that enhance medical products and treatment delivery might make them potentially toxic substances.

How do manufactured nanostructures behave in living organisms, including humans? The limited research so far indicates that some nanoparticles can bypass the human body's natural defenses that work against large-scaled particle substances. For example, inhaled nanoparticles can move from the lungs into the blood to other organs. Ingested nanoparticles also reach the organs much more readily than large-scaled particles of the same material. It has already been observed that some nanoparticles, when inhaled, may bypass the blood-brain-barrier by entering the nasal passages, traveling along the odor-detecting nerve cells directly to the brain. As for dermal absorption, research to date is unclear about the extent to which some nanoparticles can pass through the skin—the body's largest protective organ—directly into the bloodstream. *See*, *e.g.*, European Commission funded research project "Nanoderm: Quality of Skin as a Barrier to Ultra-fine Particles," 2007, *available at* http://www.uni-leipzig.de/~nanoderm/; and Annabelle Hett, *Nanotechnology: Small Matter, Many Unknowns*, Swiss Reinsurance Company, 2004, *available at* http://www.swissre.com/pws/research%20publications/risk%20and%20expertise/risk%20perception/nanotechnology_small_matter_many_unknowns_pdf_page.html.

Nanotechnology, as an emerging risk to humans, challenges the insurance industry and the tort legal system. Because nanomaterials are *sui generis*, scientists and regulators have been unable to simply draw upon existing toxicological studies, exposure data, or long-term experience to assess nanotechnology risks. The result is a confluence of great uncertainty about potential nanotoxicity or nanopollution, the ubiquity of nanoproducts in the near future, and the possibility of long latent, unforeseen claims. The insurance industry has the task of assuming its business partners' uncertain risks and, with the assistance of capable legal counsel, if possible, of assessing liability exposure. With nanotechnology, uncertainties prevail. As of 2008, neither the probability nor the extent of potential losses are calculable with any degree of confidence.

Nanomaterial Risk Assessment to Date: Many Questions, Few Answers

As Socrates observed, "One thing only I know, and that is that I know nothing." While science is not completely uninformed, current scientific knowledge concerning nanomaterial risk is quantitatively sparse and qualitatively tentative.

The primary criteria to assess the risks of potentially harmful substances—for human health and for the environment—are toxicity, persistence and bioaccumulation. Substances that can cause direct damage to an organism (high toxicity), decay very slowly in the environment (high persistence), and concentrate in fatty tissues or elsewhere (high bioaccumulation) are of special concern. An established, guiding principle in toxicity assessment, including evolving nanotoxicity assessment, is the dose-response maxim first articulated 500 years ago by Phillip von Hohenheim, also referred to as Paracelsus and the father of toxicology: "All things are poison and nothing is without poison; only the dose makes a thing not a poison." *See*, *e.g.*, W.B. Deichmann, *et al.*, *What Is There That Is Not Poison? A Study of the "Third Defense" by Paracelsus*, 58 Arch. of Toxicology 207–213, April 1986. Until a comprehensive theory of the impact of nanoparticles on human health is established, each nanomaterial type/class must be dealt with individually for purposes of hazard assessment. Making scientifically based risk assessments will require understanding the toxic characteristics of, as well as the likely level of human or environmental exposure to, each nanomaterial type/class.

The limited current understanding of potential toxicological and other biologic effects of various nanomaterials suggests caution. For example, the Council of State and Territorial Epidemiologist (CSTE) has urged adoption of the precautionary principle for dealing with nanotechnology because of the current lack of knowledge concerning their effects on human health, safety, and the environment. *See* "Occupational and Environmental Risks of Nanotechnology," Council of State and Territorial Epidemiologists (June 28, 2007). The precautionary principle has also been adopted by some nanomaterial researchers. For example, the U.S. Department

of Energy document "Nanoscale Science Research Centers Approach to Nanomaterials ES&H," Revision 3a—May 2008, states: "Laboratory personnel should treat 'all new compounds, or those of unknown toxicity, as though they could be acutely toxic in the short run and chronically toxic in the long run,'" at http://orise.orau.gov/ihos/Nanotechnology/files/NSRCMay12.pdf.

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Human Toxicity and Health Risk

Nanoparticles can be inhaled, ingested, and perhaps absorbed through the skin. Dose and exposure levels for any particular nanomaterial need examination. Toxicological data required for hazard analyses for most nanoparticles are nonexistent, but the limited number of available, short-term studies suggests that nanoparticles generally are more toxic than their larger counterparts. Additionally, experts agree that existing safety-assessments are inapplicable to nanomaterials because the potential adverse effects and environmental risk from nanoparticles cannot be reliably or validly predicted from the known toxicity of bulk materials. *See*, *e.g.*, Kevin Dreher, *Health and Environmental Impact of Nanotechnology: Toxicological Assessment of Manufactured Nanoparticles*, Toxicological Sciences 2004, 77, 3–5.

Some scientists believe that something can be learned from the study of other small-scale materials, such as mineral fibers, naturally occurring ultrafine particles, and welding fumes, although only inferential conclusions can be drawn because specific nanomaterials have unique properties heretofore unknown. *See*, *e.g.*, Fionna Mowat and Joyce Tsuji, *Primer on Emerging Health and Environmental Issues for Nanomaterials*, 23 Michigan Defense Quarterly 26, October 2006. In sum, neither existing risk assessments for bulk materials nor scientific knowledge concerning other small-scale materials can substitute for nanomaterial-specific research.

Early research suggests that nanoparticles will easily enter the lungs, and they can have harmful effects on the human body in at least two ways—nanoparticle toxicity can directly harm the lung or migrate to other parts of the body via blood circulation and the lymphatic system causing harm elsewhere. The primary, direct toxic effect on the lung is inflammation, which causes tissue damage and other systemic damage. Recent studies involving rats suggest that some carbon nanotubes—currently the most commercially significant nanomaterial—could be as harmful as asbestos if inhaled in sufficient quantities, in part because their shape resembles the shape of asbestos fibers and many nanotubes are highly biopersistent. *See*, *e.g.*, Agnes Kane, *et al.*, *Nanotoxicology: The Asbestos Analogy Revisited*, 3 Nature Nanotechnology 378, July 2008. The nanotech industry is mindful of the potential risks: "Unless we put the safety of consumers and the environment first, nanomaterials could end up being asbestos writ small." Seth Coe-Sullivan, Chief Technology Officer, QD Vision, Watertown, Mass.

Regardless of the uptake route—inhalation, ingestion or dermal absorption—once in the body, distribution of the particles depends on the properties of the specific nanoparticle, such as its composition, size, shape and surface characteristics. Nanomaterial migration in a living body occurs from all uptake routes via the bloodstream to various organs and tissues. Migration is facilitated by the nanomaterial's propensity to enter cells, cross cell membranes and to move along sensory nerves. Further, migration is affected by the degree to which free nanoparticles agglomerate to form particles larger than 100 nm, the size of fine-scaled particles, which may result in exposure somewhat similar to conventional products. However, research concerning the mobility of different types of nanoparticles is incomplete. For example, it is not yet known whether and to what extent certain nanoparticles can pass from a pregnant woman's body via the placenta to an unborn child.

Also unclear is whether nanomaterials will remain in the body for long periods of time, or whether they are excreted by natural cleansing processes. It may depend on whether the nanoparticle is biodegradable or nonbiodegradable. Even if nanoparticles remain in a living body for short duration, are they still damaging? These questions remain unanswered. It is possible that after deposit, nonbiodegradable nanoparticles would accumulate in certain organs like the liver. Other liver diseases suggest that accumulation of even benign substances can impair and damage liver function. Whether certain nanoparticles may have a similar effect is unknown. Nanoparticle accumulation duration, harm triggered, and nanoparticle quantity required to harm the liver have not yet been examined.

Although all the health risks are important, of acute interest is the impact of nanoparticles on the brain. The best protected organ in the human body, the brain's extremely sensitive nerve cells require a precisely defined milieu to function properly. For the most part, the blood-brain-barrier prevents most substances from the blood from entering the brain. Vessels in the brain are lined with special cells that only recognize nutrients and other specific substances, and actively absorb and pass them on to the brain. Nevertheless, research has shown that certain nanoparticles can access the brain despite the blood-brain-barrier. Although the specific route is still unknown, it is undisputed that nanoparticles can enter the brain. Important unanswered questions include:

- What happens when nanoparticles are absorbed by brain tissue?
- Will nanomaterials accumulate in the brain?
- What are the lasting effects of nanoparticle accumulation in the brain?
- Could certain nanoparticles trigger known neurodegenerative diseases, such as Alzheimer's or Parkinson's, thought to be caused by brain chemical disruptions?

As mentioned above, toxicological research focusing on manufactured nanomaterials is very much in its infancy and time and resources have simply been insufficient to ascertain the possible impact of nanomaterial exposure on living organisms and ecosystems. Research to date is inadequate to determine any nanomaterial's reproductive toxicity, immunotoxicity,

developmental toxicity or association with chronic illnesses, such as cancer. Much of the work to date is foundational, to develop research strategies and priorities. *See*, *e.g.*, European Commission, *EU Nanotechnology R&D in the Field of Health and Environmental Impact of Nanoparticles*, January 28, 2008, *available at* ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/final-version.pdf; and JoyceTsuji, *et al.*, *Research Strategies for Safety Evaluation of Nanomaterials, Part IV: Assessment of Nanoparticles*." Toxicology Science 89(1):42, 2006.

In short, in 2008, few scientific assessments of nanomaterial human health and safety risks exist, and existing assessments are inconclusive. But the body of scientific work grows, and some research indicates that it may be possible to "engineer out" unacceptable nanomaterial toxicity levels. *See* Brenda Barry, *The State of the Science—Human Health, Toxicology, and Nanotechnological Risk*, Chapter 4, Nanotechnology: Health and Environmental Risks (2008).

Ecotoxicity and Ecological Hazard

Little definitive knowledge is available on the impact of engineered nanoparticles on the environment. Many manufactured nanoparticles will be new to the environment in type and quantity, constituting a new class of nonbiodegradable pollutants. The long-term behavior of such substances and their effects on the environment are impossible to foresee. Research needs to determine the effect of nanoparticles on species other than humans, how nanomaterials accumulate in the human and animal food chains, and how nanosubstances behave in the air, water and soil. As mentioned above, nanoparticles are extremely mobile because they are super small. Think of dust so fine it can't be seen. Scientists agree that the unique properties of nanomaterials, such as their stability in suspension, also make them much more mobile than their macro-sized counterparts. The smaller the particle, the longer it will remain in suspension in air or water and the more slowly it will settle. Reactivity, persistence and bioaccumulation are all areas of necessary nanomaterials research. Preliminary modeling suggests that quantitative risk assessment is possible, and priorities have been suggested for further research. For good recent discussions of ecotoxicity and ecological hazard, *see* Jo Anne Shatkin, *The State of the Science—Environmental Risks*, Chapter 5, Nanotechnology: Health and Environmental Risks (2008); Martin Scheringer, *Nanoecotoxicology: Environmental Risks of Nanomaterials*, 3 Nature Nanotechnology 322, June 2008; and Rehnata Behra, *et al.*, *Nanoecotoxicology: Nanoparticles at Large*, 3 Nature Nanotechnology 253, May 2008.]

Sources of Nanotechnology Information

Regularly updated databases of major nanotechnology health, environmental, and safety research projects are available at Woodrow Wilson Center Project on Emerging Nanotechnologies, *Inventory of Environment, Health, and Safety Research*, **http://www.nanotechproject.org/inventories/ehs**, and the European Commission site for Nanotechnology, **http://www.cordis.europa.eu/nanotechnology**.

Another excellent information resource is the International Council on Nanotechnology (ICON), established at Rice University. ICON is an international, multistakeholder organization whose mission is to develop and communicate information regarding potential environmental and health risks of nanotechnology. ICON is a technically driven organization; it does not engage in advocacy or commercial activities, and it includes representatives from large and small corporations, government agencies, academic institutions and nongovernmental groups from around the world. In 2005, ICON launched a new database to catalog scientific literature to help researchers and government agencies make up-to-date decisions about nanomaterial safety. The database, available free of charge on the Internet at **http://www.icon.rice.edu/research.cfm**, allows for tailored searches. For example, you can search by "nanoparticle type" or "production method." ICON's database contains credible, evolving information about health and environmental implications of nanomaterials.

U.S. Government Programs and Research

Despite the United States' vigorous regulatory infrastructure, U.S. governmental oversight bodies still have far to go in conducting research and developing regulatory strategies for nanotechnology. *See* Karen Florini, *et al.*, *Nanotechnology: Getting it Right the First Time*, 3 Nanotechnology L. & Bus. 39, Feb./Mar. 2006. As of early 2008, no nanoparticle-specific health, environmental or safety regulation existed anywhere in the world. Regulatory agencies are still in an information-gathering mode, lacking the legal and scientific tools, information and resources to effectively oversee commercial nanotechnological growth in industrial sectors. *See* "Nanotech Regulation: Key Issues" and "International Developments: Spanning the Globe," panel presentations at 1st Annual Conference on Nanotechnology Law, Regulation and Policy (Food and Drug Law Institute, Wash. D.C., Feb. 28–29, 2008).

Much of the initial research conducted by the U.S. Department of Health and Human Services National Toxicology Program, as part of its Nanotechnology Safety Initiative, is not expected to be completed until 2010 or later. And while the array of potential environmental regulatory authorities appears impressive—including the Clean Air Act, the Clean Water Act, the Resources Conservation and Recovery Act and the Toxic Substances Control Act—existing regulations under these statutes are mostly irrelevant to nanomaterials. Adopting new standards will require the Environmental Protection Agency to launch lengthy, data-intensive rulemaking processes that will take years to complete. *See* Linda Breggin, Environmental Law Institute, *Securing the Promise of Nanotechnology: Is U.S. Environmental Law Up to the Job?* (2005), *at* http://www.elistore.org/reports_detail.asp?ID=11116.

The National Nanotechnology Initiative (NNI) is a multi-agency U.S. Government program started in 2001. The NNI coordinates the nanotechnology-related activities of 26 federal agencies, 13 of which have budgets for nanotechnology research and development in 2008. The serious shortfall in nanotechnology risk-assessment information was recently recognized by the U.S. Congress, which found that the NNI program had still not yet put in place a well-designed, adequately funded and effectively executed research program focused on the environmental, health and safety aspects of nanotechnology. *See*, *e.g.*,

House Report 110-682, National Nanotechnology Initiative Amendments Act of 2008, at http://www.congress.gov/cgi-bin/cpquery/R?cp110:FLD010:@1(hr682). That deficiency is addressed in the National Nanotechnology Initiative Amendments Act of 2008, passed by the U.S. House of Representatives in June 2008 and introduced in the U.S. Senate in July 2008. *See* H.R. 5940, at http://www.govtrack.us/congress/bill.xpd?bill=h110-5940, S. 3274, at http://www.govtrack.us/congress/bill.xpd?bill=s110-3274. The legislation aims to increase NNI commitment to environmental, health and safety (EHS) research. It would designate within the White House a Coordinator for Societal Dimensions of Nanotechnology, with responsibility for developing and executing a detailed plan for EHS research, including a timeline for both short- and long-term goals, and which specifies the funding necessary to achieve goals and meet the timeline. The legislation also requires a public database for EHS research projects and White House compliance to recommendations from the NNI's external advisory committee.

Of acute interest is the impact of nanoparticles on the brain.

U.S. Environmental Protection Agency

The U.S. Environmental Protection Agency (EPA), in its *Nanotechnology White Paper* (Feb. 2007), describes the EPA's risk-assessment issues specific to nanotechnology. *Available at* http://es.epa.gov/ncer/nano/publications/whitepaper12022005.pdf. For example, the federal law that regulates chemical substances, including nanoscale chemical substances, is the Toxic Substances Control Act (TSCA). This law provides the EPA with a means to ensure that new and existing chemical substances are manufactured and used in a manner that protects against unreasonable risks to human health and the environment. The TSCA requires manufacturers of new chemical substances—those not on the TSCA Chemical Substances Inventory (http://www.epa.gov/oppt/newchems/pubs/invntory.htm)—to provide specific information to the EPA for review prior to manufacturing chemicals or introducing them into commerce. One important issue of interest to industry and legal practitioners is the EPA's view about whether certain manufactured nanomaterials are considered "new" or "existing" chemical substances under the TSCA, which could have significant regulatory implications. On January 28, 2008, the EPA released *TSCA Inventory Status of Nanoscale Substances—General Approach*, which describes the EPA's current thinking on categorizing nanomaterials. *Available at* http://epa.gov/oppt/nano/index.htm. The EPA can require reporting or development of information to assess existing chemicals already in the marketplace. Additionally, the EPA can take action to ensure that chemicals that pose an unreasonable risk to human health or the environment are effectively controlled, and it is expected that the EPA will use its significant TSCA authority to address potential risks of nanomaterials. *See, e.g.*, Lynn Bergeson and Joseph Plamondon, *TSCA and Engineered Nanoscale Substances*, 4 NANOTECHNOLOGY L. & BUS. 51, Mar. 2007.

To complement and support the EPA's new and existing chemical programs under the TSCA, in early 2008 the agency launched the Nanoscale Materials Stewardship Program (NMSP). *See* http://epa.gov/oppt/nano/stewardship.htm. The NMSP is intended to provide a scientific foundation for regulatory decisions that is stronger than has previously existed by encouraging the development of key scientific information and contributing to improved understanding of risk-management practices for nanoscale chemical substances.

U.S. Food and Drug Administration

The FDA is generally responsible for overseeing the safety and effectiveness of drugs and medical devices for humans and animals, and of biological products for humans. The agency is also responsible for overseeing the safety of foods, food additives, dietary supplements, color additives and cosmetics. Several existing products regulated by the FDA contain nanomaterials. *See* Cindy Strickland, *Nano-Based Drugs and Medical Devices: FDA's Track Record*, 4 NANOTECHNOLOGY L. & BUS. 179, June 2007. Much of the most promising nanoscientific research is focused on nanopharmaceuticals, nanomedical devices, nano-agriculture, and nanofood products. However, most of the laws and regulations under which the FDA operates were written before the advent of nanotechnology. As a result, the FDA is hurriedly taking steps to prepare for the arrival of large numbers of new nanotechnology applications.

The role of the FDA as gatekeeper for the application of nanotechnologies to many products is governed by a basic principle: FDA regulates products, not technology. FDA, for example, does not regulate materials or manufacturing processes, per se, but instead regulates the end products. This principle affects the stage at which the FDA becomes engaged in the regulation of nanotechnology and when, in the process, any regulation takes effect.

The FDA formed an internal FDA Nanotechnology Task Force and a Nano-Technology Interest Group (NTIG) in 2006, recognizing that existing regulatory processes and pathways should be assessed and, where necessary, modified to accommodate nanotechnology. The *Nanotechnology Task Force Report* (July 2007) recommends regulatory approaches intended to enable the continued development of safe and effective FDA-regulated products that use nanoscale materials. *Available at* http://www.fda.gov/nanotechnology/nano_tf.html. In addition, the agency recently held a Public Meeting intended "to gather information that will assist the Agency in implementing the recommendations of the Nanotechnology Task Force Report." *See* FDA Nanotechnology Public Meeting, September 8, 2008, at http://www.fda.gov/nanotechnology2008/.

The Task Force Report did not suggest that any immediate nano-specific regulatory action was necessary, but did recognize that knowledge gaps exists concerning new risks presented by nanomaterials. The Report also recognized that the nature of nanoscale materials permits the development of highly integrated combinations of drugs, biological products, and/or devices, having multiple types of uses, such as combined diagnostic and therapeutic intended uses. As a consequence, the FDA recognized that many anticipated nanomedical products will be difficult to categorize as drugs, devices, or biologics, and many will be considered com-

bination products (*i.e.*, drug-device, drug-biologic, and/or device-biologic). Because combination products involve components that are normally regulated under different types of regulatory authorities, and frequently by different FDA centers, they raise challenging regulatory and review issues. *See*, *e.g.*, Nakissa Sadrieh and Parvaneh Espandiari, *Nanotechnology and the FDA: What Are the Scientific and Regulatory Considerations for Products Containing Nanomaterials?*, 3 NANOTECHNOLOGY L. & BUS. 339, Sept. 2006, and FDA, *FDA and Nanotechnology Products*, *at* http://www.fda.gov/nanotechnology/faqs.html.

It remains to be seen what additional internal process or regulatory action, if any, the FDA will pursue to address nano-specific product and safety issues. This is an evolving area of regulatory law and all drug and medical device attorneys must stay closely attuned.

U.S. Department of Health and Human Services—OSHA/NIOSH

Although information is still scarce, much of the initial focus of U.S. government nanomaterials health and safety research concerns workplace safety. Workers may be exposed to nanomaterials during the manufacturing, end use or disposal or recycling of nanomaterial-containing products, and workplace exposure levels and frequencies are likely to be higher than that seen in the general environment. *See* EPA's *Nanotechnology White Paper* at 43. The National Institute for Occupational Safety and Health (NIOSH) is the federal agency responsible for conducting research and making recommendations to prevent work-related injury and illness. Since 2004, research to assess hazards posed by various types of nanoparticles has been conducted by NIOSH's Nanotechnology Research Center. (For the status of ongoing toxicology research and published results, *see* CDC-NIOSH, *Progress Toward Safe Nanotechnology in the Workplace*, Appendix A (June 2007), *at* http://www.cdc.gov/niosh/docs/2007-123/pdfs/2007-123.pdf, and the updated NIOSH Nanotechnology topic web page at http://www.cdc.gov/niosh/topics/nanotech.)

Workplace exposure risks associated with nanomaterial manufacturing fall under the auspices of the Occupational Safety and Health Act, 29 U.S.C. §651 *et seq.*, and the regulations promulgated under the act. That includes the need to assess and, where necessary, address and mitigate risks. *See* 29 U.S.C. §654 and 29 C.F.R. Part 1910. OSHA requirements directly applicable to the manufacturing, processing, distribution and disposal of nanomaterials include the act's general and special duty clauses, as well as specific regulations dealing with hazardous materials handling, hazard warning communications, including labels and material safety data sheets, engineering controls, administrative controls and personal protective equipment. *See* Paul Sarahan, *Nanotechnology Safety: A Framework for Identifying and Complying with Workplace Safety Requirements*, 5 NANOTECHNOLOGY L. & BUS. 191, Summer 2008.

Maintaining current knowledge of the state of workplace-related nanomaterial safety research is imperative for companies and their attorneys because the act's general duty clause requires that an employer must provide each employee with "a place of employment… free from recognized hazards that are likely to cause death or serious physical harm." 29 U.S.C. §654(a)(1). What is a "recognized" hazard? That language has been held to comprise a standard by which an employer is judged by its own actual knowledge of any workplace hazards, as well as the knowledge of the employer's industry with respect to those hazards. Thus, an employer is required to assess and stay abreast of the general knowledge of any nanomaterial hazards that are likely to cause death or serious physical harm to its employees, and to take action to mitigate those hazards. Given the paucity of nanomaterial hazard scientific research, it is currently difficult for most employers to determine whether nanomaterials in use at their facilities constitute a hazardous substance under OSHA and its regulations. This is an especially important area in which legal counsel with current nanomaterial hazard expertise can provide guidance to clients.

Despite the lack of regulatory guidance, private industry and NGO's have forged ahead in developing risk-reduction frameworks and best practices to protect workers and others. A good example of successful industry-NGO collaboration is the Nano Risk Framework, developed jointly by DuPont Company and Environmental Defense, introduced in June 2007. *Available at* http://www.nanoriskframework.com. A valuable resource for anyone developing strategies to keep nanotechnology-related workplace risks low, to ensure workplace safety and prevent or limit liability, is the ASTM International's "Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings," E2535, published in October 2007. *Available at* http://www.astm.org/Standards/E2535.htm. The E2535 Handling Guide proceeds from the precautionary principle that, because the hazards are still unknown, occupational exposures to unbound nanomaterials "should be minimized to levels that are *as low as is reasonably practicable*" (emphasis added), and provides comprehensive recommendations for a risk assessment and minimization program using standard industrial hygiene principles and applying hazard communication concepts.

Another valuable recent contribution is the British Standards Institution's (BSI) "Guide to Safe Handling and Disposal of Manufactured Nanomaterials," PD 6699-2:2007. *Available at* http://www.bsi-global.com/en/Standards-and-Publications/Industry-Sectors/Nanotechnologies/PD-6699-2/Download-PD6699-2-2007/. The BSI Guide was published in December 2007 and is helpful for anyone currently developing, producing, handling or otherwise working with engineered nanomaterials.

U.S. Department of Health and Human Services—National Toxicology Program

The National Toxicology Program (NTP) is an interagency program whose mission is to evaluate agents of public health concern by developing and applying tools of modern toxicology and molecular biology. The NTP is currently pursuing a broad-based research program to address potential human health hazards associated with the manufacture and use of nanoscale materials. In particular, the goal of the current NTP program is to evaluate the toxicological properties of four major nanoscale material classes representing a cross section of composition, size, surface coatings, and physicochemical properties for nanoscale materials in current production, which use (1) metal oxides in certain cosmetics and sunscreens (nanoscale titanium dioxide and zinc oxide), (2) quantum dots,

(3) carbon fullerenes and (4) single-walled carbon nanotubes. Results of NTP studies are anticipated in the next one to three years. *See* NTP Nanotechnology Safety Initiative Fact Sheet, *available at* http://ntp.niehs.nih.gov/files/NanoColor06SRCH.pdf.

Looking into the Litigation Crystal Ball for Nanotorts

No one knows whether nanotechnology will have harmful consequences or whether it will prove largely a phantom risk. It is not at all clear how the current relative uncertainty regarding toxicity, exposure and other potential liability factors will impact the likelihood of nanotechnology-specific toxic tort litigation—nanotorts—over the next few years. On the one hand, no confirmed cases of harm to humans from any type of manufactured nanoparticles have yet been reported, and there is no firm evidence of any nanoparticle-related signature illness or injury. Compare this to fen-phen, asbestos, silica, benzene or welding fumes.

An August 2008 search of federal and state court opinion databases found no decisions involving nanotort allegations. Likewise, a search of federal and state court dockets available on Westlaw found no pending nanotort actions. The sophisticated plaintiff's bar understands that the current high level of scientific uncertainty creates great legal difficulty meeting the burden of proof of causation—both general and specific—that is now almost universally recognized in both federal and state courts in the context of toxic exposure and other types of toxic tort claims.

On the other hand, experience has shown that new technology breeds new litigation. Tort lawsuits in toxicity and biological areas in particular tend to evolve ahead of the science, or even to fly in the face of it, if sufficient public concern is expressed. One recent example involves the chemical substances known as phthalates. Phthalates are among the most thoroughly studied compounds in the world, and they have been reviewed by multiple regulatory bodies in the U.S. and Europe. Despite extensive scientific review of the chemicals, which found them to be safe in the form commonly used in consumer products, recent concern about developmental toxicity in children has led to a number of recent toxic tort lawsuits and a ban on certain phthalates in children's products until the Consumer Products Safety Commission completes additional review. *See* Consumer Product Safety Improvement Act of 2008, Public Law 110–314, effective August 14, 2008, and the American Chemistry Council's position, *at* http://www.americanchemistry.com/s_acc/sec_news_article.asp?CID=206&DID=7090.

Although only tentative, some early studies suggest that *some* nanoparticles *may* have health and environmental consequences. Experience also teaches that when the public is concerned about *possible* health and safety hazards, trial lawyers are never far behind. Nanotorts, if they emerge, can be expected to cover the full range of tort litigation: product liability, both individual and mass tort/class action; workers' compensation; environmental contamination/cleanup; and property damage.

The limited research to date suggests that any health and safety dangers from nanomaterials are unlikely to be acute, but may become manifest only after a period of years, perhaps even decades. That scenario is potentially frightening and draws comparisons to asbestos and benzene, where the impact of human exposure was not directly evidenced and well-understood until many years later. Nanotechnology industry, insurance professionals, and toxic tort and environmental legal professionals all have the benefit of the asbestos lessons. The question remains how to learn from that past, to ensure that nanotechnology does not follow a similar legal path.

Nanotechnology offers the great promise of innovations that will substantially improve the quality of human life and the natural environment. At the same time, a scientifically sound approach to identification and mitigation of the environmental, health and safety hazards posed by nanomaterials is critical. The legal and regulatory systems will play significant roles. The degree to which the tort system will be involved in that process is unknown, but the stakes are very high. Legal and insurance professionals whose clients are manufacturing, importing, selling, or disposing of nanomaterials—at any stage of the product lifestyle—have a daunting task. They must keep pace with rapid scientific developments about hazards or else fall several steps behind. Nanotechnology is a field where, perhaps more than any other existing area of tort and environmental law, knowledge of contemporaneous scientific

Nanotechnology-related Websites of Interest

- Centers for Disease Control and Prevention/NIOSH: **http://www.cdc.gov/niosh/topics/nanotech**
- Cluster Science, including Nanoclusters and Nanoparticles: **http://www.cluster-science.net**
- Dept. of Health and Human Services National Toxiciology Program: **http://www.ntp.niehs.nih.gov/**
- European Commission Nanotechnology: **http://www.cordis.europa.eu/nanotechnology**
- Richard Feynman, "There's Plenty of Room at the Bottom (An Invitation to Enter a New Field of Physics)," transcript of address at the 1959 annual meeting of the American Physical Society, regarded as the genesis of nanoscience. Available at **http://www.zyvex.com/nanotech/feynman.html**
- International Council on Nanotechnology (ICON), Environmental, Health and Safety database: **http://www.icon.rice.edu/research.cfm**
- NanoBusiness Alliance: **http://www.nanobusiness.org**
- Nano Science and Technology Institute (NSTI): **http://www.nsti.org**
- National Nanotechnology Initiative (NNI): **http://www.nano.gov**
- Safenano (respected U.K. independent resource on nanotech hazard and risk): **http://www.safenano.org/**
- Richard Smalley Institute for Nanoscale Science and Technology at Rice University: **http://www.cnst.rice.edu**
- U.S. Environmental Protection Agency: **http://es.epa.gov/ncer/nano**
- U.S. Food and Drug Administration: **http://www.fda.gov/nanotechnology**
- Woodrow Wilson Center, Project on Emerging Nanotechnologies: **http://www.nanotechproject.org**

developments is required to provide competent legal and risk assessments.

The emergence of nanotechnology-based industries gives paramount importance to the application of sound product liability prevention techniques in the early stages of the new nanotechnology product life-cycles. Of critical importance for both inside and outside counsel are opportunities for the development and execution of well-designed nanotechnology-related *global* programs to identify, quantify, minimize and manage the legal and practical risks in product liability and contractual liability for manufacturers, regardless of tier or entity type. *See*, *e.g.*, Ken Ross, *Establishing an Effective Product Safety Management Program*, For The Defense, January 2003, and www.productliabilityprevention.com.

Interested industry and government stakeholders recognize that neither nano-euphoria nor nano-demonization is beneficial, although some segments of the plaintiff's bar in the United States will undoubtedly attempt to foment some of the latter. No uncontrollable nano-specific risks have yet emerged, but the first doors have just been opened, and continuous, extensive nanomaterial and nanoproduct scientific research is required. Biotoxicological and ecotoxicological data and exposure research will pave the way for science-based regulation, where necessary, and will allow industry, insurance and legal professionals to more accurately assess the potential liability risks of these new technologies.

Through the Next Door

Society and the legal system are confronted with the unanswered question, what effects will nanotechnology products have on human beings and the environment? Nanoparticles have special properties and present the promise of untold benefits to mankind, but resultant risks are still largely unknown and, in all likelihood, will remain unknowable until more doors open. Once again, Socrates' words are apropos: "There is only one good, knowledge, and one evil, ignorance." Attorneys and insurance professionals must stay abreast of their clients' nanotechnology uses, regulatory action, and health and safety research to be prepared to defend against nanotort claims if, and when, they emerge. FD