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Toxic Torts and Environmental Law

- Inside the “NanoRevolution”
- The ABCs of PCBs
- Hydraulic Fracturing Litigation
- And more!

page 42



Fidelity and Surety

page 16

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Inside the
NanoRevolution

By John “Jack” Delany

As litigators, policymakers, and counselors of corporate, industrial, and insurance clients, we need to pay close attention to the potential regulatory implications of nanotechnology.



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A Litigator’s Guide to Health and Environmental Issues

Revolution!

No, it’s not the one happening in the Middle East or in Zuccotti Park or wherever the “occupiers” may be at the moment or during a “tea party.” You may not even know it,

but you are involved in an invisible revolution happening around you and, in some cases, inside of you, at the atomic and sub-atomic levels, that is transforming society. It is the nanorevolution.

Through nanotechnology, the science of manipulating materials on a microscopic scale, humankind now can rearrange atoms to create materials and products that already have and will continue to change the way that we live our lives. Over 1,400 diverse, mass-consumer products contain nanomaterials, from medical, energy, electronic, and computing products to food, cosmetic, construction and building, transportation, military, space, and environmental products. Corporate, financial, scientific, and governmental communities around the world today engage in a fiercely competitive race to reap the economic spoils of this nanorevolution. Presently, a network of federal, state, and local governments monitor, fund, regulate, and control corporate, scientific, and industrial activities in nanotechnology. And although at this juncture,

the legal battles spurred by the nanorevolution have amounted to limited commercial, patent, and regulatory skirmishes, you can surmise that nanotechnology will have legal ramifications in the future that will spur full-blown legal battles. W. Atkinson, *Nanocosm: Nanotechnology and the Big Changes Coming from the Inconceivably Small* (AM-ACOMBooks2003). J. Davies, *Managing the Effects of Nanotechnologies*, Woodrow Wilson Center Forum on Nanotechnology, July 2006. All revolutions have had unintended consequences, despite foresight, good intentions, proper stewardship, and concern for our fellow human beings and for the environment. Some pain has always accompanied scientific gain, and even with our best efforts, we cannot share the rewards and the costs equally at all levels.

As litigators, policy makers, and counselors of corporate, industrial, and insurance clients we need to tune in to the potential legal and regulatory implications of nanotechnology. This article will (1) provide a brief introduction to nano-

technology; (2) explain the U.S. regulatory nanotechnology framework, regulatory response to nanotechnology, and point out key publications about it; (3) describe the scientific and medical state-of-the-art regarding potential health and ecological implications associated with nanotechnology; and (4) attempt to forecast whether nanotechnology has the attributes to morph into a major toxic tort.

Governments, scientists, corporations, activists, researchers, and educational institutions agree that we don't know a lot about the short- and long-term effects that nanomaterials may have on humans, ecological systems, and the environment at this point. Presently, we have not totally defined, developed, adopted, implemented, or enforced adequate risk assessment models to measure these effects.

Despite these facts, the revolution rockets forward. In 2005, \$32 billion of products manufactured with nanomaterials entered the stream of commerce. By 2013, commentators estimate that we will spend \$1 trillion on nanoproducts globally. The nanotechnology industry has grown an average of 13 percent per year since 2005, a surprising growth given the recent global recession and stagnant world economy.

What Is Nanotechnology?

Nanotechnology is the science of manipulating materials on an extremely small scale of less than 100nm. There are nanomaterials on our skin in sunscreen, moisturizers, and makeup, in our food supply in olive oil, on our roads in asphalt and sealant, in our clothing in sports jackets, slacks, and socks, in personal care products such as toothpaste, in diesel fuel, in paints, in home-building products, in sports equipment such as tennis rackets and hockey sticks, in electronics such as the iPhone, in medical devices, in medicine, in food packaging, and even in the water that we may drink as a water purifier.

As with most emergent disciplines, we have not reached consensus on a proper definition; however, the U.S. Environmental Protection Agency (EPA) defines nanotechnology as "the deliberate engineering of particles by certain chemical and/or physical processes to create materials with specific properties different than their macroscale counterparts." The EPA definition

does not include unintentionally produced nanomaterial, nanosized particulate, or materials that occur naturally in the environment, such as viruses, volcanic ash, and sea spray, or nanoparticle by-products of human activity such as diesel exhaust particulates or other friction or airborne combustion by-products. Nanotechnology essentially is material science that converges with other sciences and technologies, namely biology, chemistry, electrical, physics, and engineering, on a micro scale.

How small? Nano means one billionth, and a nanometer is one billionth of a meter, about 1/10,000 the diameter of human hair, 1,000 times smaller than a red blood cell, or about half the size of the diameter of DNA. Nanoscale is the dimensional range of approximately 1 to 100 nanometers. A sheet of paper is about 100,000 nanometers thick; a single, gold atom is about one-third of a nanometer in diameter.

Although nanomaterials exist naturally and human activity unintentionally generates them, nanotechnology research and development began relatively recently. In 1974, the Japanese professor Norio Taniguchi coined the term "nanotechnology." In 1985, Rice University scientists first discovered "buckyballs." A buckyball is a molecule resembling a soccer ball built of carbon. And in 1986 and 1989 respectively, IBM created a tool to capture the image of and manipulate nanomatter and spelled "IBM" with atoms on the surface of a crystal. In 1992, NEC created carbon nanotubes, and the revolution became turbocharged.

Nanotechnology deals with three main types of structures: nanoparticles, nanotubes, and nanoplates. The EPA and other governmental bodies organize nanomaterial into four major groups: (1) carbon-based materials with the carbon taking the form of hollow spheres, ellipsoids, or tubes; buckyballs and nanotubes are carbon based; (2) metal-based materials such as quantum dots, nano gold, nano silver and reactive metal oxides, titanium dioxide and semi-conductor crystals; (3) dendrimers, nano-sized polymers built from branch units; and (4) composites of nanoparticles combined with other nanoparticles or with large materials. Due to their unique properties, even when combined with macromaterials, nanomaterials behave quite differently from their micro or

macro counterparts, which has numerous regulatory consequences and adds uncertainty to predicting and controlling the impact of nanotechnology on the environment and on human health.

The U.S. Government and Nanotechnology

The U.S. government entered the nanorevo-

The EPA has published a multitude of general guidance documents as well as specific documents on certain nanomaterials and their applications.

lution in 1996, and an informal interagency working group of the U.S. National Science and Technology Council (NSTC) began to meet in earnest in 1998 to discuss nanotechnology. In 1999 this interagency working group of the NSTC published a visionary report. M.C. Roco, S. Williams, & P. Alivisato, eds., *Nanotechnology Research Directions: Visions for Nanotechnology in the Next Decade*, (U.S. National Science and Technology Council Committee on Technology Interagency Working Group on Nano Science, Engineering and Technology, Washington D.C. 1999) (also published by Springer, formerly Kluwer, 2000), available at <http://www.wtec.org/loyola/nano/IWGN.Research.Directions/> (last visited Nov. 28, 2011). In 2000, President William J. Clinton launched the National Nanotechnology Initiative (NNI), and in 2003, President George W. Bush signed the 21st Century Nanotechnology Research and Development Act, P.L. 108-153, officially creating the NNI and establishing the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee to carry out the initiative. The subcommittee today consists of representatives of 25 federal agencies and has established four working groups to facilitate and promote safe nanotechnology development: the Global Issues in Nanotechnology (GIN) working group, the



Nanomanufacturing Industry Liaison and Innovative (NILI) working group, the Nanotechnology Environmental and Health Implications (NEHI) working group, and the Nanotechnology Public Engagement and Communications (NPEC) working group.

In October 2011, the NNI presented a comprehensive framework to ensure the safe, effective, and responsible develop-

Remember that individuals involved in research may become potential experts in future litigation.

ment and use of nanotechnology. Nanotechnology Environmental & Health Implications Working Group, Nanoscale Science, Engineering, and Technology Subcommittee, NNI Environmental, Health and Safety Research Strategy (Oct. 2011), <http://www.nano.gov/node/681> (last visited Nov. 29, 2011). This publication guides federal agencies uncovering and producing the scientific information for risk management, regulatory decision making, product use, research planning, and public outreach in the nano world. The federal strategy has prioritized funding research in (1) nanomaterial measurement infrastructure, (2) human-exposure assessment, (3) human health, (4) the environment, (5) risk-assessment and risk-management methods, and (6) informatics and modeling. This publication is the newest guiding light for nanoproducts. If toxic tort litigators ever need to analyze the state-of-the-art related to reasonable corporate conduct in future litigation, this publication along with an EPA White Paper published in 2007 and a 2009 National Institute of Occupational Safety and Health (NIOSH) publication offer good starting points. Science Policy Council, U.S. Env'tl. Prot. Agency, Final Nanotechnology White Paper, EPA/100/B-107-101 (Wash. D.C. Feb. 15, 2007), available at <http://www.epa.gov/osa/nanotech.htm> (last visited Nov. 29, 2011); Nat'l Inst. of Occupational Safety & Health, Ctr. for Disease Control, Approaches to Safe Practices for Nanotech-

nology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials, DHSS/NIOSH Publication No. 2009-125 (Wash. D.C. 2009), available at <http://www.cdc.gov/niosh/docs/2009-125/> (last visited Nov. 29, 2011).

The main U.S. governmental agencies and institutes dealing with the health and ecological impacts of nanotechnology in their respective fields are the U.S. Consumer Product Safety Commission (CPSC); the U.S. Food and Drug Administration (FDA); the U.S. Department of Agriculture (USDA); the U.S. Department of Transportation (USDOT); the EPA; the U.S. Department of Labor Occupational Safety and Health Administration (OSHA); the National Institute of Health (NIH), the Centers for Disease Control and Prevention (CDC), and in particular the CDC NIOSH and the CDC National Institute of Environmental Health Sciences (NIEHS), all under the auspices of the U.S. Department of Health and Human Services (HHS); and the independent U.S. National Science Foundation (NSF). These agencies are responsible for addressing the impact of nanotechnology on mankind and on the environment. The two overall most comprehensive sites to track government nanotechnology developments in the future are the National Nanotechnology Initiative (NNI), <http://www.nano.gov/>, and Gradient, EH & S Nano News, <http://www.ehsnanonews.com/>.

In 2012 the U.S. federal budget allocated \$2.1 billion to the NNI. The 25 federal agencies and institutes that collaborate in the NNI will share those funds. Since 2001, the federal government has devoted \$16.5 billion to the NNI, and Congress has allocated 13 percent of those dollars to federal agencies involved in environmental and health safety. Toxic tort or mass tort and environmental litigators will want to pay close attention to what these institutes and agencies in particular do: the EPA, the OSHA, the NIOSH-CDC, the CPSC, the FDA, the USDA, the NSF, the NIH, and the NIEHS-CDC. Approximately 400,000 people worldwide work directly in the field of nanotechnology today, and nearly half of them work in the United States.

Environmental Protection Agency

The EPA (1) participates in the NNI; (2) funds research through state grants

and Small Business Innovative Research (SBIR) program; (3) engages in international scientific collaboration, standards associations and an intergovernmental cooperative; and (4) evaluates nanomaterial and reviews new chemical submissions on a voluntary pilot program, and reviews nanomaterial registration applications in the Office of Air and Radiation and the Office of Transportation and Air Quality. See National Nanotechnology Initiative, <http://www.nano.gov/>, and U.S. Env'tl. Prot. Agency, Nanotechnology Research, <http://www.epa.gov/nanoscience/>.

The priority recommendations in the 2007 EPA White Paper on Nanotechnology remain constant as of this date. See Final Nanotechnology White Paper, *supra*. Those are to foster or develop (1) pollution prevention, (2) stewardship sustainability, (3) research funding initiatives, (4) risk assessment models, (5) collaboration and leadership, (6) cross-agency work groups; and (7) training and education. Environmental and toxic tort or mass tort litigators should monitor the EPA, specifically, the research that it funds and risk assessment developments.

The EPA has published a multitude of general guidance documents as well as specific documents on certain nanomaterials and their applications. These are the types of documents that we have learned from in the past when we dealt with toxic or mass torts and which became critical to plaintiffs' arguments about the state-of-the-art and the yard stick against which courts and juries should measure corporate conduct. Once the EPA develops a standard, a threshold limit value (TLV), a permissible exposure limit (PEL), or once the American Conference of Industrial Hygienists (ACGIH) or another standards-issuing organization presents a guideline, companies need to understand that they have received notice of a potential health hazard and their conduct concerning that standard or guideline may become an issue in future litigation. Toxic tort litigators and those exposed to potential nanotechnology liabilities should become intimately familiar with the standards organizations, industry groups, and peer-reviewed literature, as well with those of the EPA, NIOSH, the NIH, the NSF, the FDA, and the CPSC. See U.S. Env'tl. Prot. Agency, Nanotechnology

Research, <http://www.epa.gov/nanoscience/> (offering weekly updates, guidance reports, and new research studies).

The EPA also tracks developments on the following topics: nanomaterial types; human exposure, pathways of and routes of exposure; ecological effects; health effects; risk assessment and measuring updates; strategies for pollution management; the fate, transport, and disposal of nanomaterials; and research centers' ongoing work. Remember that individuals involved in research may become potential experts in future litigation.

The EPA has prioritized research and risk assessment in the following areas: (1) chemical identification and characterization; (2) environmental fate; (3) environmental detection and analysis; (4) potential release and human exposure; (5) human health effects assessment; (6) environmental technology applications; and (7) ecological effects. The agency has already issued policy and guidance papers on how existing environmental statutes and regulations may apply to nanomaterials in the future, including papers on the Toxic Substances Control Act; the Federal Insecticide, Fungicide and Rodenticide Act; the Clean Air Act; the Pollution Prevention Act of 1990; the Clean Water Act; the Safe Drinking Water Act; the Comprehensive Environmental Compensation and Liability Act; the Resource Conservation Act; and the Toxic Release Inventory Programs.

The EPA has considered the use of nanomaterials to clean oil spills, contaminated water, and landfills. For instance, Green Earth Technologies (GET) sought approval by the EPA to use nano-emulsion technology for the BP oil-spill remediation.

The EPA is currently developing a significant new-use rule (SNUR) under the Toxic Substances Control Act (TSCA) and other regulations to address potential health and environmental risks from nanoscale materials. The EPA released the first documents on February 19, 2010, and on March 15, 2010. See U.S. Env'tl. Prot. Agency, Control of Nanoscale Materials Under the Toxic Substances Control Act, <http://www.epa.gov/oppt/nano/> (last visited Nov. 29, 2011). For the first time, the agency provided free access to the Consolidated Toxic Substance Control Act (TSCA) chemical substance inventory on its website. *Id.* On June 17, 2011, the EPA proposed a new policy on nanomaterials in

pesticides. Policies Concerning Pesticides Products Containing Nanoscale Materials, 76 Fed. Reg. 35,383 (proposed June 17, 2011) (Docket EPA-HQ-OPP-2010-0197). See also U.S. Env'tl. Prot. Agency, Regulating Pesticides that Use Nanomaterials, <http://www.epa.gov/pesticides/regulating/nanotechnology.html> (last visited Nov. 29, 2011).

Since 2005, the EPA has received and reviewed over 100 new chemical notices under TSCA for nanoscale materials, including carbon nanotubes, and has taken a number of actions to control unlimited exposures to these materials including limiting the use of nanoscale materials, requiring manufacturing workers to use personal protection equipment, such as impervious gloves and NIOSH-approved respirators, limiting environmental releases, requiring testing, and generating health-effect and environmental effect data.

The EPA has decided that many nanoscale materials are "chemical substances" that fall under the TSCA. To ensure that manufacturers produce and use these materials in ways that protect humans and the environment from unreasonable risks, the EPA has taken a comprehensive regulatory approach under the TSCA. This four-pronged approach includes requiring manufacturers to submit premanufacturing notices to the EPA; developing a significant new-use rule, mentioned above; developing an information-gathering rule; and developing a test rule. The applicability of The TSCA to nanomaterials is controversial because many nanomaterials essentially preexist as matter and therefore, are not technically new "materials"; we simply now can observe and manipulate this matter on the nanoscale level. However, it is widely accepted that even though these materials are not new, they behave differently at the atomic and subatomic levels than at the macro level.

NIOSH-CDC

NIOSH has identified 10 critical topic areas to direct the institute's work to address knowledge gaps, to develop strategies for safely handling nanomaterials, and to make nontechnology recommendations for workplaces. Nat'l Inst. of Occupational Safety and Health, Ctr. for Disease Control, Nanotechnology, Ten Critical Topic Areas, <http://www.cdc.gov/niosh/topics/nanotech/critical.html>

(last visited Nov. 29, 2011). Cited above, Approach to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials, reviews what is currently known about nanoparticle toxicity, process emissions, and exposure assessments, engineering controls and personal protective equipment. Nat'l Inst. of Occupational Safety and Health,

As research develops, NIOSH will certainly recommend exposure limits for numerous types of nanomaterials.

DHSS/NIOSH Publication No. 2009-125, *supra*. This document offers guidance on how to handle certain types of nanomaterials based on preliminary studies concerning their potential toxicity and adverse effects on the environment. As research develops, NIOSH will certainly recommend exposure limits for numerous types of nanomaterials. For instance, in April of 2011 NIOSH published a final recommended exposure limit (REL) for titanium oxide.

Currently, in keeping with the agency directive and mission, NIOSH conducts research and assesses the effects of nanotechnology and the applications and implications of nanomaterials in the workplace. Often the first sign of a major toxic tort appears in the workplace because one or more diseases associated with a substance usually first manifest there since workers become exposed to concentrated doses of the substance in a confined environment as happened with mesothelioma and asbestos. The 10 critical topical areas mentioned above that NIOSH has identified as relevant to workplace safety are

- Toxicity and internal dose;
- Risk assessment;
- Epidemiology and surveillance;
- Engineering controls and personal protective equipment measurement methods;
- Exposure assessment;



- Fire and explosion safety;
- Recommendations and guidance;
- Communication and information; and
- Applications.

Nanotechnology, Ten Critical Topic Areas, *supra*.

FDA

The FDA regulates a wide range of products,

Often the first sign of a major toxic tort appears in the workplace because one or more diseases associated with a substance usually first manifest there since workers become exposed to concentrated doses.

including foods, cosmetics, drugs, devices, veterinary products, and tobacco products, many of which presently contain nanomaterials. In June 2011, the FDA published a draft guidance for industry, *Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology*. U.S. Food & Drug Admin., <http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/ucm257926.htm> (last visited Nov. 29, 2011). The FDA continues to accept comments on that document. Further, the FDA has spearheaded research on nanotechnology applications and the safety of using nanomaterials in products. FDA activities include risk characterization, considering risk assessment models, risk communication, nonclinical modeling of nanomaterials in FDA-regulated products, and physical-chemical characterization in FDA-regulated products. U.S. Food & Drug Admin., *FDA Nanotechnology Regulatory Science Research Categories*, <http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/ucm196697.htm> (last visited Nov. 29, 2011). The National Institute of Food and Agriculture (NIFA) met in

December 2011 to review scientific papers on the effects and uses of nanotechnology on agricultural and food products, although as this article went to press the institute had not yet issued a statement or report about the conclusions drawn from the meeting.

At this juncture, regulators still struggle to establish effective safety measures, such as threshold limit values and permissible emission levels for nanomaterials. Many organizations have proposed using an ALARA (as low as reasonably achievable) approach in working with nanomaterials similar to the approach used when working with radioactive materials. Other governmental agencies such as the USDA and OSHA also have laws and regulations in place that they believe pertain to nanomaterials. All these laws and regulations are ripe for administrative challenges in the future.

Health and Environmental Implications

A plethora of medical and scientific articles have raised concerns regarding nanomaterials. They clearly act differently from their macro counterparts in animal and environmental studies. They clearly cause biological responses associated with precursors of certain diseases such as an inflammatory response and have the ability to migrate throughout the body at the cellular level. Whether these biological effects will eventually lead to disease after cumulative exposure remains unknown. Nanoparticles will persist and will travel, but we currently do not fully understand at this point how these qualities will affect humans or the environment. Scientists have just started to explore the health and environmental implications of nanotechnology. A bit of what we know so far is discussed below.

Carbon Nanotubes and Mesothelioma

Some scientists recently expressed concern about the potential causal role of high-aspect ratio nanoparticles (HARN) in lung and pleural pathologies. Similar to asbestos, the structure and length of carbon nanotubes influences whether humans retain the fibers causing inflammatory changes or whether humans expel them. Carbon nanotubes that “exist as compact tangles of nano-

tubes” may pose a greater risk of pleural pathology than the “longer and straighter” nanotubes. Ken Donaldson, *et al.*, *Asbestos, Carbon Nanotubes and the Pleural Mesothelium: A Review of the Hypothesis Regarding the Role of Long Fibre Retention in the Parietal Pleura, Inflammation and Mesothelioma*, *Part Fibre Toxicology* 7: 5 (2010). doi: 10.1186/1743-8977-7-5. Multi-walled carbon nanotubes may have genotoxicity and inflammatory effects on mesothelial cells similar to long amphibole fibers. Several studies have demonstrated that long carbon nanotubes “showed a similar, or greater, propensity to produce inflammation and fibrosis in the peritoneal cavity, to that produced by long asbestos.” C.A. Poland, *et al.*, *Carbon Nanotubes Introduced into the Abdominal Cavity of Mice Show Asbestos-like Pathogenicity in a Pilot Study*, *3 Nature Nanotechnology* 423–428 (May 20, 2008). doi: 10.1038/nnano.2008.11. In particular, a 2011 study found that directly depositing both long and short carbon nanotubes in the pleural cavity “produced asbestos-like length-dependent responses.” F.A. Murphy, *et al.*, *Length-dependent Retention of Carbon Nanotubes in the Pleural Space of Mice Initiates Sustained Inflammation and Progressive Fibrosis on the Parietal Pleura*, *178 American Journal of Pathology* 2587–600 (June 2011).

Silver Nanoparticles and Other Nanometal Oxides

Because nanometals accumulate in the liver and make the liver a potential “target site for nano-particle toxicity,” liver damage might result. Y. Wang, *et al.*, *A Study of the Mechanism of In Vitro Cytotoxicity of Metal Oxide Nanoparticles Using Catfish Primary Hepatocytes and Human HepG2 Cells*, *409 The Science of the Total Environment* 4753–62 (Oct. 15, 2011). But at this point we can’t know with a degree of scientific certainty. Ingestion, inhalation, or absorption of nanometal oxides is known to cause cellular demise as well as damage to cellular and mitochondrial membranes. Y. Wang, *et al.*, *supra*. Again, finding bio responses does not establish disease causation.

Toxicity of silver nanoparticles, found in an increasingly wide range of medical and electronic devices, foods, cosmetics, and fabric due to their antibacterial qualities,

have raised safety concerns. See Troy M. Benn & Paul Westerhoff, *Nanoparticle Silver Released into Water from Commercially Available Sock Fabrics*, 42 *Environmental Science & Technology* 4133–39 (2008). doi:10.1021/es7032718 (discussing silver nanoparticles used in clothing). Drawing from several studies, scientists have concluded that silver nanoparticles “are toxic to mammalian cells derived from the skin, liver, lung, brain, vascular system and reproductive organs.” M. Ahamed *et al.*, *Silver Nanoparticle Applications and Human Health*, 411 *Clinical Chimica Acta* 1841–48 (Dec. 14, 2010). See also P.V. Asharani *et al.*, *Comparison of the Toxicity of Silver, Gold and Platinum Nanoparticles in Developing Zebrafish Embryos*, 5 *Nanotoxicology* 43–54 (Mar. 2011). Silver nanoparticles have also been found to cause pericardial effusions, abnormal cardiac morphology, and circulatory defects in zebrafish embryos. P.V. Asharani, *et al.*, *supra*.

Nanoparticles and Environmental Regulation

The cytotoxicity of nanoparticles and their propensity to bind to other toxic pollutants have demonstrated “higher level consequences for damage to animal health, ecological risk and possible food chain risks.” M.N. Moore, *Do Nanoparticles Present Ecotoxicological Risks for the Health of the Aquatic Environment?*, 32 *Environment International* 967–76 (Dec. 2006). Plant nanotoxicology, a new subdiscipline, seeks to study the toxicity mechanisms of different nanoparticles which, absorbed by plants, enter the food chain. J.K. Dietz & S. Herth, *Plant Nanotoxicology*, 16 *Trends in Plant Science* 592–99 (Sept. 7, 2011). The antibacterial properties of titanium and silver nanoparticles and carbon nanotubes may also have adverse effects on the bacteria used in wastewater treatment systems. N. Musee, *et al.* *The Antibacterial Effects of Engineered Nanomaterials: Implications for Wastewater Treatment Plants*, 13 *Journal of Environmental Monitoring* 1164–83 (2011). See National Nanotechnology Initiative, <http://www.nano.gov/>; Gradient, <http://gradientcorp.com/index.php>; Gradient, EH&S Nano News, <http://www.ehsnanonews.com/>; and Nanowerk, <http://www.nanowerk.com/> (offering other studies about nanoparticles and toxicity).

Will Nanomaterials Become the Bases for Toxic Torts?

Today, about 165,000 employees are exposed to nanomaterials in the workplace. Exposure alone to a substance does not constitute a clinically recognized disease and certainly not a toxic tort. A biological response caused by a substance does not constitute a tort either. Someone needs admissible proof of general and specific causation between a known toxin at the right dosage to an associated recognized disease; if that occurs, someone has a toxic tort. But one National Science Foundation-funded project predicts that companies will need six million nanotechnology workers worldwide by 2020 and locates two million of those jobs in the United States. M.S. Roco, C.A. Merkin, & M.C. Hersam, eds., *Nat'l Science Found.—World Technology Evaluation Center Panel Report on Nanotechnology Research Directions for Societal Needs in 2020: Retrospective and Outlook* (Springer 2010), available at http://www.wtec.org/nano2/Nanotechnology_Research_Directions_to_2020/ (last visited Nov. 29, 2011). In the United States, these two million workers, as well as those who become exposed to nanomaterials through mass production and use, could underpin the core rationale for potential lawsuits in the future if nanotechnology becomes the bases for toxic torts—and that is a big “if.”

In addition to those working directly with nanomaterials, numerous other workers and the public at large are being exposed to nanoparticles on a daily basis; almost 1,400 commercial products have a nanotechnology component. See National Nano Initiative, <http://www.nano.gov/>; Gadiant, EH&S Nano News, <http://www.ehsnanonews.com/>; and Nanotechnology Consumer Products Inventory, *The Project on Emerging Nanotechnologies*, <http://www.nanotechproject.org/inventories/consumer/> (tracking these commercial products at various levels).

We cannot know whether nanotechnology will lead to major mass or toxic torts for at least another decade. Exposure and ecological disposition are relatively minimal at this point, and if we find associations between diseases and nanomaterials, the diseases likely will have latency

periods. In addition, journals and the federal government will not publish the medical and scientific peer-reviewed literature establishing an association between exposure and a disease until years after a disease becomes manifest, if it manifests at all.

However, commonalities exist among major mass or toxic torts and environmental litigation in the past and nanotechnology that we can analyze to determine whether nanotechnology could lead to major litigation in the future. The factors that could create a toxic, nanolitigation storm are (1) ubiquitous exposure; (2) sympathetic plaintiffs; (3) sensational press (4) reactive politicians; (5) product identification capability pointing to a specific product or a specific defendant; (5) biomarker and causation evidence; (6) corporate culpability; (7) state-of-the-art medical and liability; (8) the serious, objective, potentially permanent nature of a potential injury due to nonmaterial exposure compared with potentially subjective transitory injury; (9) deep pockets of recovery; (10) product benefit-cost utility; and (11) warnings and personal choices involved with exposure. In addition, judicial and legislative factors may affect the liability picture, including potential immunities, economic caps, limitations on punitive damages, joint and several liability, the collateral source rule, venue shopping, removal to a federal court, preemption, and the framework that the judiciary uses to manage and adjudicate claims, such as multi-district litigation processes.

Corporate America should work proactively to reduce potential exposure in bringing nanoparticles through nanotechnology to the marketplace. Among strategies to consider are (1) accepting corporate responsibility by progressively, proactively adopting industrial hygiene practices; implementing cautious waste disposal and emission practices; issuing product warnings; fully disclosing any and all scientific research; and proactively managing litigation; (2) lobbying for immunity caps, class action restrictions, and tort reform; (3) undertaking aggressive public relations campaigns disseminating scientific facts to dispel sensationalized claims based on junk science; (4) strategically purchasing insurance, shifting risk, and creating **Nanorevolution**, continued on page 86

Nanorevolution, from page 57
avoidance policies; (5) having corporate structures to insulate liability; and (6) proactively planning ahead so that a company won't need to devise and implement a coordinated defense on the run to confront a nanotechnology-related lawsuit.

Conclusion

The nanodimension has a multitude of unknown risks. Whether those risks will have large costs remains to be seen. With this great power to manipulate atoms, materials, and products comes great responsibility. How corporations conduct themselves in exercising the power to bring

products to the marketplace may become issues if future litigation occurs. Hopefully, 15 years from now, if your client's corporate conduct becomes an issue, you can argue that it has been appropriate because it aligns with the scientific literature on nanoparticles and nanomaterials. 