

Top Ten Takeways

Nano-Liability: Litigation and Nanotechnology

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Brian Davis recently delivered a presentation on the regulation of nanotechnology at a conference hosted by the Materials Research Society. He described how the still burgeoning field of nanotechnology holds both tremendous promise and possible risks. The market for products that incorporate nanotechnology is growing quickly, but so is the perception that those products may pose a threat to human and environmental health. There has been little litigation so far, but companies can take a number of measures now to protect themselves in the future.

The Promise and Risks of Nanotechnology

1. **Nanotechnology is increasingly popular.** Nanotechnology, defined as the manipulation of materials that are less than 100 nanometers (nm) in any one dimension, is now employed in more than one thousand consumer products. Nanoparticles can make materials stronger, give cosmetics more sheen and make fabrics resistant to bacteria, among myriad other uses. It has been predicted that nanotechnology will play a role in \$1 trillion worth of products by 2015.
2. **Yet there are risks associated with nanotechnology.** Nanoparticles are so small that they may infiltrate human tissue or escape into the natural environment in ways that bigger particles cannot. Nanoparticles also have large surface areas and are therefore more chemically reactive. Concerns over such risks have led to the creation of a new field: nanotoxicology. Peer-reviewed research in nanotoxicology has grown nearly 600% since the year 2000.
3. **Nanoparticle related deaths were reported in August 2009.** Two women in China who had been exposed to nanoparticles while working in a factory without using respirators died of pleural effusion within two years of their last exposure to the particles. An investigation revealed that the nanoparticles to which they had been exposed had entered their lung tissue.

Regulation of Nanotechnology

4. **Countries are assessing risks, but not yet enacting major legislation.** Most regulatory agencies in the United States feel that products that employ nanotechnology can be regulated under existing statutes. The same is true in the European Union, Australia, Canada, Japan, China, Korea and Taiwan. However, many of these nations have begun to collect data in order to more fully assess the threat nanotechnology may pose to the environment. Regulations that address nanotechnology specifically may soon appear in these nations.
5. **The Environmental Protection Agency (“EPA”) has demonstrated an intent to regulate nanotechnology within the U.S.** Twice in the last two years, the EPA has taken enforcement actions against companies that have advertised the antimicrobial properties of unregistered consumer products containing nanosilver. The EPA believes that such

advertising claims are a violation of the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”), which requires anyone making antimicrobial claims about a product to first register that product as a pesticide. The EPA has also used its authority under the Toxic Substances Control Act (“TSCA”) to regulate the use of other nanomaterials, such as carbon nanotubes.

Protecting Against Future Litigation

6. **A nano-disaster may not be an insurable risk.** It is increasingly well known that nanoparticles may be hazardous. However, many insurance companies are concerned about the limited information regarding the health and environmental risks of nanotechnology. At least one insurance company has added a nanotechnology exclusion to its Commercial General Liability Policies, removing coverage for injuries related to the presence of or exposure to nanotechnology.
7. **Litigation may be on the horizon.** There have been no reported product liability cases involving nanotechnology. However, history has shown that the simultaneous rise in revenues and risk awareness within an industry makes litigation more likely. Past examples include asbestos, tobacco and nutritional supplements. Lessons learned from product liability cases in other industries are applicable to the nanotechnology industry.
8. **Producers of nanotechnology must understand the potential risks.** In limited cases, ignorance of a product’s risks may serve as a defense. In *Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal. 3d. 987 (1991), the court held that manufacturers may be shielded from liability if a hazard is not “scientifically knowable” at the time the product is produced. However, manufacturers that rush a product to market without sufficiently testing for the product’s risk may later be held liable for putting the public at an “unknown risk of injury.” See, e.g., *Hawkinson v. A.H. Robins Co., Inc.*, 595 F. Supp. 1290 (D. Colo. 1984).
9. **Producers should also apprise the public of risks.** Compliance with federally mandated warnings may shield a corporation from punitive damages in the event of a product liability suit. Yet compliance alone may not be enough; even in cases where a manufacturer has complied with federal regulations regarding warnings, juries have found the warnings to be inadequate and have awarded damages to an injured plaintiff.
10. **Manufacturers of nanoparticles can mitigate risk.** The hazards of nanotechnology are unknown and possibly unknowable. Manufacturers should invest the time and effort needed to assess risks, and they should warn the public of any foreseeable risks and comply with all applicable regulations. Manufacturers should also stay tuned – this is a rapidly changing field, with new technologies and new regulations always on the horizon.