

How to Minimize Litigation Risks of Nanotechnology

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Imagine this scene: You wake up one sunny morning, brush your teeth, apply some moisturizer, put on your tennis clothes and shoes, spray yourself with sunscreen, check your phone for messages, drive your car to the tennis court, pull out your racquet and balls and start to play. You may not know it, but there's a good chance that everything you touched that morning contained engineered nanoscale materials.

Nanoscale materials are between one and one hundred nanometers in size.¹ A nanometer is one-billionth of a meter – roughly one ten-thousandth the diameter of human hair. Engineered nanomaterials are deliberately created, rather than naturally occurring.

Because of their size, nanomaterials have special and distinct properties as compared to their full-scale counterparts. Nanoscale carbon, for example, can be stronger than steel or diamonds and have increased heat resistance and electrical conductivity, which has prompted its use in electronic devices and sporting equipment. Silver nanoparticles have strong anti-microbial properties that have caused them to be incorporated in fabrics, athletic wear, baby bottles, children's toys, toothpaste, food packaging and utensils. Nanosized titanium dioxide and zinc oxide are more transparent than their full-size counterparts, which makes them appealing for use in cosmetics, sunscreens, paints and pigments. According to the Project on Emerging Nanotechnologies, more than 1,000 consumer products include nanomaterials – a number that is certainly under inclusive, because it is based only upon product information available over the Internet.²

As of 2004, nanotechnology product revenue was \$158 billion globally and is expected to reach \$2.6 trillion by 2014.³ In the years ahead, the number of consumer products containing engineered nanomaterials seems destined to increase rapidly. The litigation risk associated with nanomaterials thus has the potential to expand rapidly as well.

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Is Nanotechnology Hazardous to Consumers?

The use of nanomaterials in consumer products has vastly outpaced scientific research into the safety of those materials and whether they are associated with any human health effects. Unlike drugs subject to pre-market approval by the Food and Drug Administration, the vast majority of consumer products containing nanomaterials is currently marketed without any pre-market government review or affirmative demonstration by the manufacturer of the product's safety.

Nanomaterials react differently than their full-scale counterparts. As a result, knowledge about the safety of full-scale elements does not necessarily translate to the nanoscale. Most importantly, the small size of nanomaterials creates concern that nanomaterials will be more easily absorbed by the human body through a variety of exposure pathways. For example, nanoscale materials may more easily penetrate the skin, be inhaled, or ingested. Once inside the body, nanoscale materials may also behave differently than their full-scale counterparts. Some studies have suggested that nanomaterials can more easily be absorbed by the lungs, pass through the stomach wall, penetrate cell walls, accumulate in critical organs, and cross the blood-brain barrier.⁴

Although the results of animal studies cannot necessarily be extrapolated to humans, some animal studies have raised concerns that certain nanomaterials could be associated with health effects. Most notably, several studies have found that carbon nanotubes affect the lungs of exposed mice much like asbestos.⁵ Several animal studies have identified an association in mice between exposure to carbon nanotubes and inflammation and fibrosis of the lungs that may lead to cancer.⁶ In another example, a group of UCLA researchers found an association between nano titanium dioxide exposure and DNA damage and cellular inflammation in mice that could possibly lead to an increased risk of cancer.⁷ One of the studies' authors specifically warned against the use of spray-on sunscreens containing nano titanium dioxide, recommending that consumers use lotions instead, based on concerns about inhalational exposure.⁸ These examples are far from exhaustive, but demonstrate that significant concerns have been raised about nanomaterials that are already in widespread use.

Perhaps the best indicator of the high level of scientific uncertainty surrounding nanotechnology comes from the insurance industry. Beginning in 2008, insurers began specifically excluding liabilities associated with nanotechnology from coverage under insurance policies because of the inability to evaluate the degree of risk.⁹ In fact, the first insurance specifically targeted for nanotechnology has only recently become available.¹⁰

What Tort Litigation Risks Are Associated with Nanotechnology?

Given widespread consumer exposure and the possibility that insurance may not be available, the tort litigation risks associated with nanotechnology merit serious consideration by in-house counsel and risk managers. What are those risks?

Proof of causation is the most significant hurdle that plaintiffs face in mass tort cases. Amassing such proof will likely also be a substantial obstacle for plaintiffs pursuing claims involving nanomaterials. In federal court, for example, the United States Supreme Court's decision in *Daubert v. Merrill Dow Pharmaceuticals Inc.* requires that expert testimony must be relevant and reliable in order to be admissible.¹¹ Although the level of scrutiny varies, particularly at the state court level, courts perform a screening function to keep "junk science" out of the courtroom. Based upon the limited scientific evidence available to date, particularly the lack of significant epidemiological data evaluating the long-term health effects, if any, on humans, it would be extremely difficult for an expert to credibly opine that exposure to a particular nanomaterial caused an individual's disease.

As a result, the initial wave of nanotech tort litigation, when it comes, is most likely to focus on two kinds of claims: (1) medical monitoring; and (2) "no injury" claims for economic harms.

Medical monitoring claims, recognized by more than fifteen states,¹² depend upon proof that an exposure to an allegedly toxic substance caused an increased risk of future disease. In a medical monitoring action, plaintiffs can recover the costs of diagnostic testing that would not be required absent exposure to the alleged toxin. Medical monitoring claims are frequently pursued in circumstances where there is a long latency between an exposure and the manifestation of a disease, like cancer.

Plaintiffs' lawyers find medical monitoring cases attractive for several reasons. Medical monitoring claims are typically brought as class actions. The aggregation of claims in a proposed class increases a company's potential exposure and gives plaintiffs substantial settlement leverage. Because medical monitoring cases focus on groups, they provide an opportunity for plaintiffs to shift the inquiry towards the state of scientific knowledge generally, rather than the very concrete and more complicated question of whether a particular individual's injury was caused by an exposure as opposed to some other cause (e.g., hereditary or lifestyle risk factors).

Medical monitoring class actions can be defeated through careful work that focuses on variation among individual class members and the nature of scientific evidence plaintiffs rely upon to support their claims.¹³ In particular, defendants should educate courts that exposure levels set through risk assessment, whether by government regulators or hired guns, do not set a threshold level of exposure that proves causation. Risk assessment is a process used in the public health field to identify, with a wide margin of safety, a level of a chemical below which there is no appreciable risk to the most sensitive members of the population; it does not identify a threshold level of exposure above which a person is at risk.

Another type of claim likely to be brought against companies that make consumer products containing nanomaterials is colloquially known as a "no injury" class action, because it does not seek to recover for any personal injury. Rather, these "no injury" class actions typically seek a refund based on the allegation that the consumer would not have purchased the product if he had known about the undisclosed allegedly harmful substance in the product. The alleged harm is thus an economic one. Several types of "no injury class actions" have been filed in recent years based upon, for

example, the alleged presence of formaldehyde in baby shampoo and bisphenol-A in baby bottles. These "no injury" class actions are attractive to plaintiffs' lawyers because, they argue, these claims do not require scientific proof of risk or injury. To date, these "no injury" consumer class actions have not been particularly successful, because they ultimately raise many individualized questions about consumer knowledge, and ultimately, whether the substance at issue is in fact harmful (otherwise why would a refund be reasonable based upon the presence of the substance at issue?). The "no injury" class action remains a concern, however, because this is a relatively new type of claim and some state consumer protection statutes provide for treble damages and award attorneys' fees, which substantially increase the potential exposure associated with such claims.

If scientific knowledge evolves to the point where there is sufficient scientific evidence to support a credible claim that a particular nanomaterial causes a health effect, then companies face potential exposure for traditional personal injury product liability claims. These claims are typically brought on an individual basis and may be based on a number of theories, including negligence, strict liability, design defect, manufacturing defect and failure to warn.

These traditional theories could play out in unusual ways in the nanotechnology context. Pre-existing consumer products reformulated or modified to incorporate nanomaterials would come with essentially a built-in design defect claim. With the ready-made comparison between the product before and after nanomaterials were added, plaintiffs would argue that the risk of including nanomaterials outweighed any benefits in product performance. In addition, there is the potential for manufacturing defect claims where raw materials or ingredients containing nanomaterials inadvertently made their way into the supply chain.

In other respects, product liability claims involving nanomaterials would be similar to other product liability claims, where, for example, manufacturers are often forced to defend the adequacy of product warnings based on what was reasonably known at the time of production, rather than with the benefit of hindsight. However, given that the state of scientific knowledge about the impact of nanomaterials, if any, on human health, is likely to accelerate rapidly in coming years, such explanations may prove to be especially challenging in this context.

What Steps Can Companies Take to Minimize Litigation Risk?

Despite this backdrop of scientific uncertainty, there are actions that companies can take to minimize any future liability associated with nanotechnology.

Conduct a product review and supply chain audit to determine whether your products contain nanomaterials. Surprisingly, it's not as easy to answer this question as it might seem. Consumers Union reported in 2008 that four out of five companies that represented that their sunscreen did not contain any nanomaterials were wrong – their products did in fact contain nanomaterials.¹⁴

Common sense dictates that companies cannot take action to mitigate risks that they don't know about. Companies should review their product lines to identify products

that incorporate nanomaterials. This inquiry should not be limited to products that incorporate nanomaterials by design, but should also include any product where nanomaterials could potentially be part of product ingredients or components, either intentionally or inadvertently. Products that create the greatest potential for consumer exposure, through dermal contact, inhalation or ingestion, should be prioritized. Suppliers should be asked directly about whether their products contain nanomaterials and, if so, information about the specific characteristics of those nanomaterials should be obtained.

Where nanomaterials are identified as a result of such an audit, companies should consider:

- whether to require representations that supplies do not contain nanomaterials as part of purchase agreements related to products that are not intended to include nanomaterials;
- whether existing agreements adequately address indemnity for any potential liability generated by nanomaterials;
- whether existing occupational health and safety procedures are adequate to protect workers exposed to nanomaterials;¹⁵
- whether adequate precautions are being taken in disposal of wastes containing nanomaterials; and
- whether existing insurance policies provide adequate coverage or a specialized policy insurance covering nanomaterials should be considered.

Prepare for product labeling; it is coming. Currently, there are no labeling requirements that mandate disclosure of nanomaterials in consumer products. In other words, nanomaterials do not need to be identified as such on the list of product ingredients. Labeling requirements are distinct from mandatory product warnings, such as those that accompany cigarettes or alcohol.

The FDA's Nanotechnology Task Force specifically declined to require disclosure of nanomaterials in all products that FDA regulates, based upon its conclusion that "the current science does not support finding that classes of products with nanoscale materials necessarily present greater safety concerns than classes of products without nanoscale materials."¹⁶ The European Union, by contrast, has reached a different result, requiring that ingredients in cosmetics be designated as "nano" where applicable.¹⁷

Given the realities of the global marketplace, it is not surprising that standards-setting organizations are collaborating to develop voluntary labeling standards for nanomaterials. The American National Standards Institute ("ANSI") recently held a webinar to describe and solicit comments on a draft Technical Specification ("TS") jointly developed by the European Committee for Standardization and the International Organization for Standardization.¹⁸ The draft TS addresses labeling for what it calls "manufactured nano-objects" from both ends of the telescope. It not only requires manufacturers to disclose the presence of nano-objects in their products, but it affirmatively requires them to ask suppliers whether supplies contain nano-objects.¹⁹ This draft TS could be adopted as early as next year and then become an industry standard three years after that.

Companies looking to minimize litigation risks of nanomaterials should monitor these voluntary standard-setting efforts, because any standards ultimately adopted will, as a practical matter, likely serve as a baseline for the standard of care used to evaluate future product liability claims. While disclosure on product labels may not be sufficient to avoid liability if it later turns out that some kind of warning was appropriate, the failure to disclose the presence of nanomaterials despite industry norms could in itself generate liability.

Monitor the evolving regulatory landscape. The federal government is poised to shift the focus of its strategy from voluntary information sharing initiatives that generated minimal industry participation to mandatory disclosure and testing requirements.²⁰ The U.S. Environmental Protection Agency is taking the lead in these efforts.

The EPA recently announced its plans to publish for public comment proposed rules under the Toxic Substances Control Act ("TSCA"). These forthcoming proposed rules would require companies to not only submit "available health and safety data," but also to "require testing for certain nanoscale materials that are already in commerce," including single and multi-walled carbon nanotubes, nano silver, nano titanium dioxide, and nano zinc oxide, among others.²¹ In addition, EPA intends to propose a Significant New Use Rule under Section 8(a) of TSCA that would require companies that intend to manufacture, import or process nanomaterials based on substances listed in the TSCA inventory to provide EPA certain data, including exposure and toxicity data, 90 days before commencing such activity.²² The proposed new TSCA rules are expected to be issued in the fall of 2010.

Compliance with disclosure and testing rules like those envisioned by EPA, though not sufficient to avoid liability, is especially important to minimize future litigation risk. In the hands of a plaintiff's lawyer, any examples of a company providing inaccurate information or improperly withholding data will be characterized as a "cover up" to conceal risks, evidence of intentional wrongdoing, and a basis for awarding punitive damages.

Employees who interact with regulators should be sensitized to the risk of future litigation and the chance that their communications may some day be made public. They should be cautioned against using short-handed descriptions of any studies finding associations between exposure to nanomaterials and health effects or results of overprotective-by-design risk assessments that could later be misconstrued as acknowledgements of a causal link to human disease. The goal is not to be evasive or inaccurate, but to be clear and precise. The same guidance should apply to internal communications, particularly among members of key groups like compliance, regulatory affairs, product safety and risk management.

Consistently stay on top of scientific developments. To the extent that research about potential health effects of nanomaterials is publicly available, companies will likely be deemed to have knowledge of it in future tort litigation, so it makes sense to monitor scientific developments now, when appropriate actions to minimize risk can be taken. The scientific literature should be monitored on an ongoing basis in order to determine whether product disclosures and worker safety measures are adequate. The International Council on Nanotechnology maintains an online database

and Virtual Journal of Nanotechnology, Environment, Health & Safety that collects nanotechnology research articles published in various journals and can be searched by particle type and risk exposure group (e.g., consumers, workers).²³ The National Institute for Occupational Safety and Health ("NIOSH") is developing another online library.²⁴ In addition, if the soon-to-be proposed TSCA reporting and testing rules are ultimately adopted and implemented under an Obama Administration, which is inclined to interpret confidential business information very narrowly, these submissions will likely be publicly available and thus could provide another potential source of health-related information.

Conclusion

Mitigating future litigation risks associated with nanotechnology is not easy given the current evolving scientific and regulatory landscape, but it is by no means impossible. With increased regulatory oversight and voluntary industry labeling likely in the near-term, it is the right time to initiate the careful planning and targeted action that can reduce future litigation exposure to the greatest extent possible.

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² Nano Technology Project, *Consumer Products: An inventory of nanotechnology-based consumer products currently on the Market*, <http://www.nanotechproject.org/inventories/consumer/> (last visited July 16, 2010).

³ Lux Research, Inc., *Framework Report: Sizing Nanotechnology's Value Chain*, (Oct, 1, 2004), https://portal.luxresearchinc.com/research/document_excerpt/2650 (last visited July 16, 2010).

⁴ See generally NIOSH, *Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials*, NIOSH Pub. No. 2009-125, at 13–18 (Mar. 2009), available at <http://www.cdc.gov/niosh/docs/2009-125/> (last visited July 16, 2010).

⁵ *Id.* at 14–17.

⁶ *Id.* at 16–17.

⁷ Benedicte Trouiller et al., *Titanium Dioxide Nanoparticles Induce DNA Damage and Genetic Instability In Vivo in Mice*, *cancer res.* 8784 (Nov. 15, 2009).

⁸ Katie Bird, *Exposure to nano titanium dioxide could up cancer risk, says study* (Nov. 18, 2009), available at <http://www.ap-foodtechnology.com/Formulation/Exposure-to-nano-titanium-dioxide-could-up-cancer-risk-says-study> (last visited July 16, 2010).

⁹ Robert C. Meder, *Risk Management and Nanotechnology: Insurance Concerns About Small Particles*, 7 *Nanotechnology Law & Bus.* 44, 46 (Spring 2010).

¹⁰ *Id.* at 47.

¹¹ 509 U.S. 579 (1993).

¹² See, e.g., Christopher P. Guzelian et. al, *A Quantitative Methodology For Determining The Need For Exposure-Prompted Medical Monitoring*, 79 *IND. L.J.* 57, 58 (2004).

¹³ See, e.g., *Rhodes v. E. I. DuPont de Nemours*, 253 F.R.D. 365 (S.D. W.Va. 2008) (denying class certification based upon conclusion that risk assessment relied upon by

plaintiffs was not common proof of significant exposure to an alleged toxin or an increased risk of disease among members of the proposed class).

¹⁴ Letter from Michael Hansen, PhD, Senior Scientist, Consumers Union to The Honorable Andrew C. von Eschenbach, M.D., Commissioner, U.S. Food and Drug Administration (Oct. 30, 2008), available at http://www.consumersunion.org/pub/core_product_safety/006254.html (last visited July 16, 2010).

¹⁵ See, e.g., NIOSH Pub. No. 2009-125, *supra* note 4.

¹⁶ FDA, *Nanotechnology: A Report of the U.S. Food and Drug Administration Nanotechnology Task Force* (July 27, 2007), available at <http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/Nanotechnology/ucm110856.pdf> (last visited July 16, 2010).

¹⁷ Council of the European Union, European Parliament and Council on Cosmetic Products art. 19 § 1(g), (Nov. 10, 2009) (recast), available at <http://register.consilium.europa.eu/pdf/en/09/st03/st03623.en09.pdf> (last visited July 16, 2010).

¹⁸ ANSI Webinar, *Draft PPT Presentation: ISO/CEN Technical Specification for Labeling Manufactured Nano-Objects and Products Containing Manufactured Nano-Objects* (July 9, 2010) available at http://www.ansi.org/news_publications/print_article.aspx?articleid=2578 (last visited July 16, 2010).

¹⁹ ANSI Webinar PPT Presentation, *supra* note 18.

²⁰ EPA, *Nanoscale Materials Stewardship Program*, <http://www.epa.gov/oppt/nano/stewardship.html> (last visited July 16, 2010).

²¹ *Fact Sheet for Nanotechnology Under the Toxic Substances Control Act*, *supra* note 1, <http://www.epa.gov/oppt/nano/nano-facts.htm> (last visited July 16, 2010).

²² *Id.*

²³ International Council on Nanotechnology, *Virtual Journal of Nanotechnology, Environment, Health & Safety*, <http://icon.rice.edu/virtualJournal.cfm> (last visited July 16, 2010).

²⁴ NIOSH, *The Nanotechnology Information Library (NIL)* (last updated Oct. 19, 2009), <http://www.cdc.gov/niosh/topics/nanotech/NIL.html> (last visited July 16, 2010).