Analysis&Perspective

NANOPRODUCTS

An ominous cloud of uncertainty has settled over nanomaterials because of the potential for health risks, say attorneys Charles H. Moellenberg Jr. and Robin L. Juni. The authors offer practical guidance to risk managers and products counsel on how to manage the uncertain risks of nanoproducts, noting that "Good planning today can prevent or mitigate significant, future litigation risk."

A Practical Guide to Reduce Product Liability Risk for Nanotechnology

By Charles H. Moellenberg Jr. and Robin L. Juni

Nanotechnology presents exponential growth opportunities for innovative products, but also an ominous cloud of uncertainty over potential health risks. Despite good intentions, product manufacturers' research, simulations, and testing in the laboratory are unlikely to discover, let alone quantify, all risks that will arise during a nanoproduct's lifetime of use, misuse and eventual disposal.

A recent article explained the many potential tort theories lying in wait for nanoproducts.[1] Yet the threat of liability from unknown or unknowable hazards should not, and will not, stop the introduction of nanoproducts and nanomaterials into the marketplace.

This article aims to provide practical guidance to risk managers and products counsel on how to manage the uncertain risks of nanoproducts. Prudent risk managers and products liability counsel should identify and address the foreseeable risks and plan for the unforeseeable and unknown risks that nanomaterials may present. Good planning today can prevent or mitigate significant, future litigation risk.

Health Risks of Nanomaterials

Based on limited research to date, nanomaterials are theorized to have human health risks. These include: (1) Increased Mobility—because of their minute size, nanomaterials may be more easily taken up by the body and transported across biological membranes; (2) Increased Reactivity—because of the increased surface area, more biological tissues may interact with nanomaterials; and (3) Increased Persistence—again, because of size, some fate and transport mechanisms that might otherwise remove toxins may operate less effectively against nanomaterials.[2] These mechanisms are hypothetical at this time, but appear to have some facial plausibility. In any event, nanomaterials are likely to come onto the market with substantial unknown risks that science cannot resolve in the short term, in part because there might be a long latency period between exposure to a nanomaterial and the onset of any disease.

Potential Product Liability Claims

Products-related claims fall into several well-known categories: (1) defective manufacture; (2) defective design; (3) failure to provide adequate warnings or in-

[1] Ronald C. Wernette, "The Dawn of the Age of Nanotorts," Toxics Law Reporter, Vol. 24, No. 31 (Jan. 15, 2009).

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The views expressed in this article are the authors' alone and do not necessarily reflect the views of their law firm or its clients.

[2] *See* Gunter Oberdorster, Eva Oberdorster & Jan Oberdorster, *Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles*, 113 Envtl. Health Perspectives 823 (July 2005).

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structions; (4) breach of express warranty; (5) breach of an implied warranty; (6) negligent or fraudulent misrepresentation arising typically from advertising; (7) negligent or fraudulent concealment; and (8) negligence in marketing or distributing the product. Underlying many of these types of claims is the question of whether the manufacturer or distributor sufficiently tested the product to ensure safe design and quality control. Europe and California at least seem to be gravitating toward acceptance of the "precautionary principle," requiring a product to be tested and proven to be safe before it is sold. Other foundational questions involve the risks from the foreseeable uses and misuses of the nanoproducts.

Insurance Portfolio

As with any new business venture, one way to protect the ability to innovate is by ensuring adequate insurance coverage. While insurers will likely introduce policies tailored to nanotechnology risk in the near future, liability based on nanoproducts may already be covered by many commercial general liability policies, unless it is specifically excluded.[3] Insurance coverage counsel should review existing insurance assets for coverage potential before new policies are considered.

Processes and Procedures

Nanotechnology is venturing into new product frontiers. Accepted applications of scientific principles, let alone long field experience with those applications, do not exist. Given that nanoproducts are premised on advanced science and engineering, both the marketplace as well as juries are likely to expect the best use of science and technology to investigate and mitigate potential health risks, too.

At this time, it is easier to articulate the questions that should be asked and the procedures that are prudent to follow than to identify the potential health risks. In today's uncertain environment, adequate, well-documented processes and procedures are of central importance.

1. *Research, Development, and Testing*

- Does R&D include adequate consideration of health and safety for workers in factories? Installers? Customers and likely users?
- Were procedures in place to identify all likely health and safety concerns, and were health concerns identified, tested, addressed and answered?
- Was the feasibility of alternative designs considered and investigated in terms of health and safety?
- Was the consideration of health and safety, along with any testing, adequately documented? Are the final documents preserved for future reference?
- Are dissenting or questioning employees' memoranda and email communications addressed, answered, and retained?
- Have persons with experience and expertise in human factors considered the uses and misuses of the product? And the potential risks from those uses and misuses?
- Have reasonable efforts been made to design out the foreseeable risks from the product uses and misuses? Were these efforts documented adequately and the documents, whether emails, videos, or computer simulations, retained?
- Have the design engineers considered whether any guards or safety devices can remove or reduce the foreseeable risks?
- Has the product been adequately tested for uses and misuses in the laboratory? In the field? With all ages of persons who might use or misuse the product? With persons with various disabilities, sensitivities, or allergies? At the extreme end of the spectrum for anticipated use or exposure?
- Have the foreseeable risks been tested by reasonable toxicological exposure and effect models?

2. *Compliance With Regulations and Industry Guidelines*

Ordinary products enter a marketplace already populated with regulations, industry standards, and customary practices. Not so with the nascent field of nanotechnology, where scientists and regulators are in the early stages of gathering information.

- Given the rapidly evolving legal environment, has a thorough search been done to find the universe worldwide of applicable regulations, rulemaking in progress, and emerging industry standards?
- Is the product subject to regulation under the Toxic Substance Control Act, 15 U.S.C. §§ 2601-2692, or Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136. If so, does it comply with those regulations?
- Has a thorough search been done to find prior claims and lawsuits?
- Have federal and state administrative agency dockets and databases been checked for consumer complaints about similar products? Have worker compensation records been investigated?
- Have hospital and injury-reporting databases be searched for complaints of injuries from similar products?
- Is there a trade association that collects information on health and safety claims and complaints?
- To what extent can regulations and standards be drafted to limit liability? To set reasonable, feasible practices for testing, manufacturing, marketing, design, and disposal?
- Are there procedures to monitor future regulatory proposals and changes, and to monitor data of injuries and complaints in the future?

3. *Manufacturing and Quality Control*

The development of novel nanoproducts will require the engineering of new manufacturing processes as well. Those new processes will also need to be fully tested and periodically checked to ensure that safe products reach the market. A manufacturing defect will lead to almost certain liability. To minimize that risk, several issues should be considered.

- Do manufacturing practices meet industry standards?
- Are adequate controls over materials, suppliers, and contractors in place and enforced through contracts, inspection, testing, and audits?

[3] One insurer, Continental Western Group, has announced its intention to add such an exclusion to its policies. ("Insurer Announces Plan to Deny Nano-Coverage," Greenwire, 9/26/08).

- Are there adequate quality control tests in place before the product is shipped?
- Are those quality control tests recorded and retained?
- Do the manufacturing and quality control tests meet best practices in the industry?
- How should an expected failure or defect rate for a product be determined?
- What is the expected failure or defect rate? How does it compare to the industry? Is it technically and economically feasible to reduce that rate? Are quality control tests procedures and schedules properly designed to detect manufacturing defects at that error rate?

4. *Adequate Warnings and Instructions*

Generally speaking, a product may be found to be defective because of inadequate instructions or warnings when reasonable warnings or instructions would have avoided or reduced the risks of harm from the product's foreseeable use or misuse. A manufacturer or seller generally need not warn about small or inconsequential risks that a reasonable person would not deem material to his or her decision to use the product, or about obvious and generally known risks. Rather, warnings are expected for all inherent risks that reasonably foreseeable product users would deem significant in deciding whether and how to use the product. Manufacturers face additional risks based on their duty, as some courts hold, to research all "reasonably foreseeable or scientifically discoverable" risks before putting a product on the market.[4] But crafting warnings and instructions for nanomaterials is especially difficult because of the many unknown factors, ranging from unknown, long-term health risks to the lack of field experience with the uses and misuses of the product.[5]

Faced with this level of uncertainty, companies with nanotechnology-based products in development may pursue several courses of action to protect themselves from a litigation claim of inadequate warnings and instructions:

- Have outside experts in warnings and human factors been consulted?[6]
- Have products been tested with their likely users to discover likely uses, misuses, and risks?
- Do warnings and instructions acknowledge and explain that many risks are currently uncertain, unknown, and unknowable because the products are new technology?
- Have warnings and instructions been compared against those of competitors? The literature? Industry and regulatory guidelines?
- Are the warnings and instructions as prominently displayed as feasible and presented in a way that requires to the extent possible the user to read them?
- Are the warnings and instructions available in a form that will reach those who use the product other than the initial purchaser?
- Has the need for user training been considered and addressed appropriately?
- Have procedures been established to receive and evaluate returned products and customer complaints for potential risks? Are those returns and complaints reported in writing? Retained? Sent to those with responsibility for design, manufacture and warnings?
- Have procedures been established to regularly review the literature, industry reports, and health and injury databases to ascertain product risks?

5. *Advertising, Marketing and Promotion of Product*

Advertising and marketing will be particularly important to inform customers of new nanoproducts and their uses and limitations. Advertising and promotional materials will be significant educational tools. To prevent liability, educational messages must be accurate and measured.

- Is a process in place to require legal and safety review of advertising, marketing and promotional materials before they are used?
- Do the advertisements and marketing materials avoid any affirmative representation of health and safety?
- Are any claims of health and safety supported by testing? Experience? Scientific literature? Expert advice?
- Are only safe uses and safe users of the product shown in the advertising?
- Do the advertising and marketing statements comply with applicable industry and regulatory standards?

6. *Express Warranties*

Lacking long-term field experience with new nanoproducts and technologies, the data to support express warranties of performance will likely come from research and development tests. Yet, field performance may depart from laboratory testing for unexpected reasons, such as divergent uses or misuses.

- Are the express warranties, if any, strictly limited to proven product performance and characteristics?
- Again, is there a process in place to require legal and safety review?
- Are express warranties of health and safety avoided?
- Are procedures in place to collect, monitor, and analyze express warranty claims? To modify express warranties as necessary based on field experience?

7. *Implied Warranties*

For the same reasons that express warranties should be carefully scrutinized for new nanoproducts, implied warranties should also be scrupulously limited.

- Are the limitations of implied warranties, damages and remedies drafted as broadly as permitted by law?
- Are the limitations drafted to acknowledge the unknown and unknowable risks and uncertainty accompanying the sale and use of new technology?

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[4] *See, e.g., Wood v. Phillips Petroleum Co.*, 119 S.W.3d 870, 873 (Tex. App. 2003) (citations omitted).

[5] The learned intermediary rule may provide additional protection for manufacturers of pharmaceutical drugs and medical devices using nanomaterials.

[6] Independent experts outside the company are likely to have more credibility in litigation and lend credence to the reasonableness of the company's efforts to anticipate and warn against risks. Outside experts may also bring wider experience and expertise than are available within the company. Their use may also be a safeguard against the imposition of punitive damages.

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8. *Packaging, Distribution, and Transport*

Liability can arise from methods of packaging, distribution, and transport. Again, the unique size and characteristics of nanomaterials may raise unusual concerns for packaging, distribution, and transport. Special handling instructions and new hazard symbols may be needed.

- Is there any unusual risk associated with the way in which the product is packaged or shipped? Is some kind of protective packaging needed?
- Does the packaging contain appropriate warnings and instructions to prevent or mitigate product damage, as well as health and safety risks likely to be encountered in shipment?
- Is any special training needed to ensure safe product handling during shipment and distribution?
- Have environmental risks from spills and leaks been considered and adequately contained?
- When will risk of loss or injury pass from the manufacturer?
- Have questions of indemnity from others for their careless shipment and distribution been considered and addressed? Documented?
- Have all industry and regulatory guidelines been met for safe transportation and handling?
- Again, are procedures in place to learn from and adapt to field experience?

9. *Maintenance and Repair*

Brand new nanoproducts with never-before-seen properties and characteristics will require the education and training of those who maintain and repair those products. The health risks to those persons must also be evaluated and prevented.

- Have explicit instructions for recommended inspection, maintenance and repair been given?
- Are all warranties limited in the event of failure to adhere to those recommendations?
- Are trained personnel in place in the field to provide approved inspection, maintenance, and repair? Or must products be returned to the manufacturer for replacement and repair?
- Are warranties limited in the event that untrained or unapproved persons attempt to maintain or repair the product?
- Does testing suggest any anticipated product life? If so, do the instructions explain that anticipated product life? Are the warranties appropriately limited?

10. *Disposal of Product*

The novel characteristics of nanoproducts, such as their persistence and ability to migrate through incredibly minute spaces, may present unique issues for their safe disposal.

- As a product manufacturer or seller, have you met your legal responsibilities to consider, address and instruct on methods of safe disposal of the product?
- Have environmental risks been considered and tested?
- Will disposal implicate any environmental law or regulation?
- What health and safety risks are anticipated in the transport of product waste for disposal?
- What procedures will be used to monitor field experience after disposal of nanoproducts?

11. *Control and Retention of Documents*

Because new nanotechnology products will inevitably raise many questions, concerns regarding unknown risks, doubts about the adequacy of testing models and laboratory simulations, and speculation from skeptics, thoughtful document control and retention will be essential.

- Are memoranda and e-mails carefully worded?
- Are risks fairly described and studies appropriately documented?
- Is speculation and hyperbole avoided?
- Are concerns, questions, arguments and dissents about product performance, health, and safety considered, addressed, and answered with documentation?
- Are document retention policies reasonably drafted and consistently implemented?[7]

12. *Crisis Management*

Given the uncertain risks of nanotechnology and the high visibility of nanoproducts among government regulators and the media, a notable nanoproduct failure can be anticipated to lead to intense media inquiry and legislative and regulatory hearings. The time to prepare for such an eventuality is now when there is time for thoughtful planning rather than when confronting the instantaneous reactions demanded by a crisis.

- Is a global plan in place to handle rapidly and effectively public, media, agency, or legislative questions and investigations over product health and safety? A product recall? A product crisis?
- Is there a protocol for notifying all potentially applicable insurance carriers of a potential liability?
- Has insurance coverage counsel reviewed the claimed liability in order to tailor notice to insurers and avoid inadvertently triggering coverage exclusions?

Conclusion

The unknown and unknowable risks from new nanomaterials should not diminish the exciting prospects offered by innovative nanoproducts. Prudent planning can recognize and temper those risks, allowing the advance of science and technology to benefit consumers and to reward product designers, manufacturers and marketers.

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[7] *See* Robin L. Juni, J.C. McElveen & Nathan C. Doty, *Document Retention Issues in Environmental Law*, in *Environmental Law Practice Guide: State and Federal Law* (Matthew Bender & Co. 2005).