BNA, INC.

TOXICS LAW REPORTER

BNA Employee-Owned Since 1947

NANOPARTICLES

TOXIC TORTS

Companies commercializing nanotechnology should evaluate ways to safeguard against a potential tide of future ''nanotorts,'' say attorneys James W. Mizgala and Michael L. Lisak in this BNA Insight. The authors assess a manufacturer's duty to warn of potential dangers posed by nanomaterials, and discuss several ''potentially powerful'' defenses against failure-to-warn claims that could aid nanomaterial defendants facing failure to warn claims.

Nanotechnology Manufacturers' Duty to Warn and Potential Affirmative Defenses

BY JAMES W. MIZGALA AND MICHAEL L. LISAK

Nanotechnology is fast becoming a commonplace feature in our lives.[1] From tennis rackets to pharmaceuticals to food to clothing, manufacturers are increasingly relying upon the unique physical and chemical properties of nanomaterials to improve their products.[2] This proliferation has not gone unnoticed.

James W. Mizgala is a partner, and Michael L. Lisak is counsel, at Sidley Austin LLP in Chicago. The authors practice extensively in the areas of product liability and toxic torts, and are members of the firm's Nanotechnology Practice. Mizgala and Lisak can be reached at JMizgala@Sidley.com and MLisak@Sidley.com, respectively.

[1] Nanotechnology, although often referred to as involving materials measuring less than 100 nanometers (''nm'') in at least one external dimension (or having internal structures in the nanoscale), is new enough that even definitions of fundamental terms such as ''nanotechnology'' and ''nanomaterial'' remain unsettled. For example, EPA's Office of Pesticide Programs uses a ''working definition'' of a ''nanoscale material'': ''An ingredient that contains particles that have been intentionally produced to have at least one dimension that measures between approximately 1 and 100 nanometers.'' Presentation on Nanotechnology and Pesticides by William Jordan, Senior Policy Advisor to EPA's Office of Pesticides Programs (April 29, 2010). Additionally, the International Organization for Standardization (''ISO'') is in the process of publishing initial international consensus definitions in ISO 8004-1 (in press).

[2] Over 1,000 nanotechnology-enabled products have been made available to consumers around the world, according to the Project on Emerging Nanotechnologies (PEN). http://www.nanotechproject.org/process/assets/files/8277/cpi.pdf

 ISSN 0887-7394

Fueled, in part, by a 2008 rodent study (the ''Poland Study'') that suggested that carbon nanotubes may cause mesothelioma—the same form of cancer caused by asbestos,[3] lay media, consumer groups, regulatory entities and government agencies have voiced concerns regarding the safety of nanotechnology.[4] Although the methodology of the Poland Study has been questioned, as has whether its results can be fairly extrapolated to humans,[5] its conclusions raised the specter of substantial products liability exposure for companies that manufacture and use nanomaterials,[6] particularly as asbestos has generated (and continues to generate) decades of costly litigation that influences much of modern mass tort law. Accordingly, companies commercializing nanotechnology should be evaluating ways to safeguard against a potential tide of future ''nanotorts.''

For example, nanomaterial manufacturers, that sell their products to intermediary companies and not directly to the ultimate end-user or consumer, may be able to limit their liability exposure by anticipating three different affirmative defenses that could shift the duty to warn to a ''downstream'' intermediary company. The following discussion will first assess a manufacturer's duty to warn of potential dangers posed by nanomaterials, and then analyze three defenses related to that duty, including the bulk supplier doctrine, the learned intermediary doctrine, and the sophisticated user doctrine. Although this article focuses on traditional product liability concepts such as the duty to warn, companies should not lose sight of risk management and product stewardship strategies aimed at the early identification, evaluation and mitigation of risks associated with design, selection and performance of their materials and products.[7] Such preventive strategies are likely the first line of product liability defense.

Duty to Warn

Future plaintiffs will almost certainly argue that manufacturers of nanomaterials knew, or should have known, of the potential risks of their products, triggering a duty to warn adequately unsuspecting end-users of those risks. Broadly speaking, manufacturers of a product may be liable for defects if they failed to use reasonable care in warning end-users of risks that the end-users are unlikely to appreciate on their own.[8] Manufacturers may also be exposed to liability when the foreseeable risks of harm caused by the product could have been reduced or avoided through reasonable warnings, such that the product was not reasonably safe without the warnings.[9] The question in both cases is whether the manufacturer adequately discharged any alleged duty to warn.

What a future jury may find as an adequate warning is particularly challenging to predict within the nanotechnology context given that ''nanotechnology'' encompasses scores of different materials used in a myriad of different products. For instance, a piece of sports equipment incorporating nanoparticles will likely raise very different liability issues than a medical device that potentially introduces nanoparticles into a patient's organs and/or bloodstream. Thus, manufacturers will not be able to rely on a blanket warning for all products containing nanomaterials. Instead, they will be required to implement more individualized approaches, taking into account the specific product and end user, the extent and nature of any potential exposure to nanomaterials, and the risks associated with such exposures.[10]

---

[3] C. Poland, et al., *Carbon Nanotubes Introduced Into the Abdominal Cavity of Mice Show Asbestos-Like Pathology In a Pilot Study*, NATURE NANOTECHNOLOGY, May 20, 2008.

[4] *See, e.g.*, http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/NanotechnologyTaskForce/default.htm (describing emerging FDA approach to regulation of nanotechnology in the United States); European Commission, *Towards a Strategic Nanotechnology Action Plan 2010-2015*, http://ec.europa.eu/research/consultations/snap/consultation_en.htm (same for European Union). U.S. EPA has already taken regulatory actions regarding carbon nanotubes pursuant to the Toxic Substances Control Act (75 Fed. Reg. 56880 (Sept. 17, 2010)), as has California, and the EU has included specific provisions regarding nanomaterials in the Cosmetics Directive as ''recast'' in 2009.

[5] *See, e.g.*, A. Kane et al., *The Asbestos Analogy Revisited*, NATURE NANOTECHNOLOGY, Vol. 3, 378-379 (July 2008); John C. Monica, Jr., *A Nano-Mesothelioma False Alarm*, 5 NANOTECHNOLOGY L. & BUS. 319 (2008).

[6] Kenneth Chang, *In Study, Researchers Find Nanotubes May Pose Health Risks Similar to Asbestos*, N.Y. TIMES, May 21, 2008.

[7] See, e.g., the *Nano Risk Framework* (2009) created jointly by DuPont and the Environmental Defense Fund, which can be found at www.nanoriskframework.org. This document sets out a product stewardship approach for identifying and managing the risks associated with manufacturing and using manufactured nanomaterials. The International Organization for Standardization (''ISO'') will soon publish an enhanced version of that document which will be called ISO TR 13121 *Nanotechnologies – Nanomaterials Risk Evaluation*. ISO has also published a report on occupational safety and nanomaterials: ISO/TR 12885 (2008) *Nanotechnologies – Health and Safety Practices In Occupational Settings Relevant To Nanotechnologies*, as has the National Institute of Occupational Health and Safety. *Approaches To Safe Nanotechnology: Managing Health and Safety Concerns Associated With Engineered Nanomaterials* (NIOSH, March 2009).

[8] RESTATEMENT OF TORTS (SECOND) § 388 (1965).

[9] RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(c) (1998). The common law duty to warn downstream users of risks finds statutory counterparts in a number of areas, from the warning labels on drugs to the information contained in Material Safety Data Sheets for materials used in occupational settings. The EU's comprehensive chemical regulatory regime, REACH, establishes extensive inter-company communications requirements that are reverberating throughout the global supply chain. Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 396, 30.12.2006, p. 1 (as amended).

[10] Evaluating potential exposures to nanomaterials can itself be a complex task, which in turn creates significant challenges in determining *whether* and when to warn, and what to warn about. For example, certain types of nanomaterials, such as certain nanoparticles, might rapidly ''agglomerate'' into larger particles that are several hundred nanometers in diameter. Therefore, the end product might contain very low percentages, or perhaps even no, discrete nanoparticles. This is among the many scenarios that create challenges when attempting to arrive at a definition of ''nanomaterial.'' For example, a scientific arm of the European Commission has suggested that a ''nanomaterial'' should include any material less than 500 nm in diameter that also contains at least 0.15% particles that are less than 100 nm (by particle count). *Scientific Basis for the Definition of the Term ''Nanomaterial,''* European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (July 6, 2010). This proposal has been criticized as being impractical and inconsistent with the work of other relevant bodies.

  TXLR ISSN 0887-7394

Fashioning adequate warnings may also prove complicated, because basic research is in a constant state of flux and is being performed by a variety of non-traditional entities, such as consumer protection organizations. Given the concerns being raised about the uncertain safety of nanotechnology, a manufacturer's duty to test the toxicological properties, as well as the potential short and long-term safety risks, of its nanoproducts will likely be an important issue in later defending the adequacy of that same manufacturer's warnings. Moreover, a manufacturer's efforts in testing its product's risks will be measured not only against the ''state of the art,'' but also against its efforts in promoting the utility of its product. In this scenario, there exists a very real potential for the development and commercialization of nanotechnology ''outrunning'' the knowledge of any risks associated with that technology, leaving manufacturers to navigate in the absence of complete information.

A manufacturer's duty to test the toxicological properties of its nanoproducts will likely be an important issue in later defending the adequacy of warnings.

As the ''state of the art'' of nanotechnology evolves over time, so does our understanding of its corresponding risks and benefits. Non-governmental actors, such as consumer and public interest organizations, are taking a more active role in seeking to define nanotechnology's ''state of the art'' by conducting and supporting their own research. Thus, manufacturers must stay abreast of the latest research and regulatory requirements in order to ensure that their warnings are adequate. Manufacturers who also perform and/or fund state-of-the-art research will be better able to eventually defend the adequacy of their warnings.

Unlike asbestos, the concern about nanotechnology's potential risks has been aired publicly from the outset. Manufacturers' ability to later argue that they either did not know, or could not have known, about the potential risks of nanomaterials may thus be constrained, despite the present uncertainty about both the technology's potential risks and the applicable regulatory requirements. In later defending the adequacy of their warnings, manufacturers that document efforts to stay current with the state-of-the-art concerning nanotechnology's risks and benefits are more likely to succeed.[11] These issues must inform manufacturers' duty to warn (as well as their overall risk management/product stewardship strategies).

Potential Defenses

Company A manufactures a nanomaterial and sells it in bulk to Company B, which uses the material in producing a widget that is then sold to the public. Can Company A be held liable if the widget injures one of Company B's purchasers and the nanomaterial is alleged to have been a cause of the injury? Defendants faced with such liability claims may turn to several related affirmative defenses designed to insulate component manufacturers from liability where their product passes through the hands of intermediaries before reaching the public. These defenses include the bulk supplier, the learned intermediary, and the sophisticated user doctrines. These defenses may relieve manufacturers of any obligation to warn the ultimate consumer of their product in cases where the manufacturers relied on a knowledgeable intermediary to warn the end user.[12] This common-sense approach is recognized, with some variation, in almost all jurisdictions.[13] At the core of each doctrine is the essential question of what warning a manufacturer should reasonably make, and to whom it should be given.

Bulk Supplier Doctrine

The bulk supplier doctrine allows a supplier of raw materials to satisfy its duty to warn where the supplier has reasonably relied on an intermediary to transmit warnings to the end user.[14] It protects a manufacturer of a raw material from liability by shifting the duty to warn to an intermediary.[15] It applies in instances where the manufacturer delivers its product, in bulk,[16] to a second company, that may use those raw materials in a variety of ways before packaging the end product for sale.[17] In such cases, because the manufacturer of the raw material often has no knowledge or control over how the intermediary has incorporated and/or transformed the original material, the intermediary is better positioned to assess the risks posed by the product it ultimately places on the market. Courts may thus hold that the intermediary should have provided warnings and thereby relieve the original manufacturer of its duty to warn eventual downstream users.[18]

Whether it was reasonable for the manufacturer to rely on the intermediary to provide warnings can turn on a number of factors. Courts may consider whether the end product was dangerous, the purpose for which it is used, the reliability of the intermediary, the magnitude of the risk involved, and the burden that would be

[11] Such internal documentation must be accomplished in such as fashion that minimizes the litigation risk in potentially creating ''notice'' of a safety concern.

[12] *In re TMJ Implants Prods. Liab. Litig.*, 872 F. Supp. 1019, 1029 (D. Minn. 1995).

[13] *See Meridia Prods. Liab. Litig. v. Abbott Laboratories,* 447 F.3d 861 (6th Cir. 2006) (45 out of 50 states apply learned intermediary doctrine); *In re Silicone Gel Breast Implants Prods. Liab. Litig.*, 996 F. Supp. 1110, 1113 (N.D. Ala. 1997) (bulk supplier and sophisticated user doctrines apply in all states where issue has been presented).

[14] *Genereux v. Am. Beryllia Corp.,* 577 F.3d 350, 373-74 (1st Cir. 2009); *see also* AM. JUR. PRODS. LIAB. § 1198 (1997).

[15] *Taylor v. Am. Chemistry Council,* 576 F.3d 16, 25 (1st Cir. 2009).

[16] Bulk sales are typically those where products are ''delivered in tank trucks, box cars, or large industrial drums, and stored in bulk by the intermediary, who generally repackages or reformulates the bulk product.'' *Hoffman v. Houghton Chemical Corp.,* 751 N.E.2d 848, 856 (Mass. 2001). Another common characteristic of products sold in bulk is that they have ''multitudinous commercial uses,'' such as a chemical used in the manufacture of several different products. *Id.*

[17] *Genereux*, 577 F.3d at 373-74; *Port Auth. of New York and New Jersey v. Arcadian Corp.*, 189 F.3d 305, 316-317 (3d Cir. 1999).

[18] *Genereux*, 577 F.3d at 373-74.

imposed on the manufacturer by requiring that it directly warn all end-users.[19] Therefore, manufacturers of raw materials should be prepared to show, among other things, that it would be impracticable for them to communicate warnings to individual end users of whom they had limited knowledge.

There are, however, limitations to the applicability of the bulk supplier doctrine. It cannot be invoked when the manufacturer of the raw material voluntarily assists the intermediary in crafting warnings for the end user.[20] If, for instance, the manufacturer willingly chooses to review and comment on labels the intermediary intends to place on the end product, it may still be exposed to liability if those labels are later held to be inadequate.[21] Raw material manufacturers should thus adequately inform intermediaries of any potential risks associated with the materials they are providing, but allow the intermediary to draft and manage the specific warnings and packaging instructions associated with the intermediary's products.

Learned Intermediary Doctrine

The learned intermediary doctrine is often at issue in cases where plaintiffs allege a drug or medical device has injured them. This defense protects manufacturers from liability where the intermediary is ''learned''—for instance, a physician—so long as the intermediary has been adequately warned of the product's risks.[22] In other words, an adequate warning to the physician has the same legal effect as if it were provided directly to the patient.[23] As with the bulk supplier doctrine, numerous courts have recognized that it makes sense to shift the duty to warn to the intermediary physician who not only directly interacts with the patient, but also because it is the physician who makes the prescription and is better positioned to assess the benefits and risks of the product for each particular patient.[24] A manufacturer can warn an intermediary physician in a number of ways, including placing a formal description of the drug in the Physician's Desk Reference and the FDA-approved package insert.[25] Learned intermediaries can also receive pertinent information through materials beyond that which the manufacturer disseminates, such as published literature.

[19] *Id.; but see Taylor,* 576 F.3d at 26 (noting that some jurisdictions do not require the manufacturer to show reasonable reliance).

[20] *Lakeman v. Otis Elevator Co.*, 930 F.2d 1547, 1551 (11th Cir. 1991).

[21] *Id.*

[22] *Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013, 1016-17 (8th Cir. 2004); *Porterfield v.Ethicon,* 183 F.3d 464, 468 (5th Cir. 1999); *but see McNeil v. Wyeth,* 462 F.3d 364, 368 (5th Cir. 2006) (manufacturer may be held liable where warning to physician is inadequate or misleading).

[23] *In re Prempro Prods. Liab. Litig.*, 514 F.3d 825, 830 (8th Cir. 2008).

[24] *See, e.g., Vanderwerf v. SmithKline Beecham Corp.,* 603 F.3d 842, 844 n. 2 (10th Cir. 2010); *Dietz v. SmithKline Beecham Corp.,* 598 F.3d 812, 815-16 (11th Cir. 2010); *Talley v. Danek Medical, Inc.,* 179 F.3d 154, 162-63 (4th Cir. 1999).

[25] *Anderson v. McNeilab, Inc.*, 831 F.2d 92, 93 (5th Cir. 1987); *Martin v. Hacker,* 83 N.Y.2d 1, 9 (1993); *but see Meridia Prods. Liab. Litig.,* 447 F.3d at 868 (in some jurisdictions, learned intermediary doctrine may not apply to drugs marketed directly to consumers, such as over-the-counter medications).

The FDA has provided no guidance to nanomaterial manufacturers on whether and how to include any information about nanomaterials on labels.

Just what these warnings for prescription medications and medical devices containing nanomaterials ought to look like very much remains an open question. The regulatory framework for medical devices and drugs incorporating nanotechnology is in flux. Currently, the FDA does not regulate products using nanotechnology or containing nanomaterials any differently than other products. Under the current regime, the FDA has provided no guidance to nanomaterial manufacturers or pharmaceutical/medical device companies on whether and how to include any information about nanomaterials on labels. However, legislation that would alter this status quo is currently pending in the Senate.

Under the proposed Nanotechnology Safety Act of 2010, the FDA would be required to investigate FDA-regulated products using nanomaterials to assess ''the potential toxicology of such materials, the effects of such materials on biological systems, and interaction of such materials with biological systems.''[26] The FDA has also formed a Nanotechnology Task Force charged with determining whether nanotechnology-specific regulation is needed.[27] The Task Force reached a preliminary conclusion in 2007 that the FDA's existing regulatory oversight was generally effective for products that required pre-market approval, such as drugs or medical devices, but that additional regulation may be needed for products not subject to pre-market approval, such as food or cosmetics.[28] As the regulatory framework inevitably shifts, industry needs to be at the table to ensure that any future regulations, including labeling requirements, are grounded in sound science. Nanomaterial manufacturers should engage in and maintain their own databases of toxicology studies, clinical trials, and adverse event reports, as well as staying current with the applicable scientific literature to ensure that unreliable science is excluded from the data set used to formulate regulations.

Courts have applied the learned intermediary doctrine even where the drug is still in clinical trial or under investigation by the FDA.[29] This is particularly relevant to manufacturers of nano-products, many of which are currently at an experimental stage. Manufacturers may be required to provide greater warnings to the physician in such cases, but so long as they have

[26] Nanotechnology Safety Act of 2010, S. 2942, 111th Congress § 2.

[27] *See* http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/NanotechnologyTaskForce/ default.htm.

[28] *See* http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/NanotechnologyTaskForceReport 2007/default.htm.

[29] *See, e.g., Reeves v. AcroMed Corp.,* 44 F.3d 300 (5th Cir. 1995); *Tracy v. Merrell Dow Pharmaceuticals, Inc.,* 58 Ohio St. 3d 147, 151 (1991).

  TXLR ISSN 0887-7394

done so, they may be shielded by the learned intermediary doctrine.[30]

Within the nanotechnology context, it is important to emphasize that the learned intermediary doctrine only protects companies that *directly* manufacture drugs or medical devices.[31] It does not insulate a company that sells a nanomaterial to a second company which uses it as a component within its own medical device or prescription medication. In that example, only the second company would be absolved from directly warning the end-user of the product's potential risks. The first company could, however, avail itself of the bulk supplier defense, if it has provided adequate warnings or information to the second company. Similarly, several courts have ruled that the learned intermediary doctrine does not protect manufacturers that market directly to consumers through advertising, on the theory that such advertisements represent a direct communication between manufacturer and end user in which warnings can and should be conveyed.[32] Finally, West Virginia has expressly rejected this doctrine.[33]

Sophisticated User Doctrine

The sophisticated user doctrine obviates the need for warning where the intermediary or end-user possesses knowledge ''equal'' to that of the manufacturer.[34] In such cases, a warning from the manufacturer would be superfluous and would have little deterrent effect.[35] The manufacturer is therefore excused from its common law duty to warn.

Just how courts measure ''knowledge equal to the manufacturer'' varies from jurisdiction to jurisdiction. Some courts apply an objective ''knew or should have known'' test.[36] In those jurisdictions, a defendant's showing that the level of expertise in question is common in the intermediary or end user's field will be sufficient to shift the duty to warn. Other jurisdictions employ a subjective test, and ask whether the intermediary or end user actually possessed the requisite knowledge.[37] In assessing the level of sophistication, courts may review the intermediary manufacturer's manuals and procedures for handling nanotechnology, its policies and internal memoranda, and warnings provided by bulk suppliers. An intermediary which customarily handles nanomaterials and has developed internal policies for their use might qualify as a sophisticated user.

Conclusion

Plaintiffs' lawyers eager for the next mass tort litigation are more than likely to eventually turn their sights on nanotechnology and nanomaterials. However, because nanomaterials are typically a component part of another product, nanomaterial manufacturers frequently do not sell directly to the end-user or consumer, but rather pass their products through an intermediary who processes, reformulates and/or repackages the nano-product for the market. This significant variation from the typical products liability lawsuit could provide nanomaterial manufacturers with potentially powerful additional defenses against failure-to-warn claims. Nanomaterial manufacturers acting now, through comprehensive risk management strategies including the consideration of how they communicate the potential risks of their products to intermediaries, will best limit future product liability exposure.

---

[30] *Id.*

[31] *White v. Weiner,* 386 Pa. Super. 111, 124-26 (1989).

[32] *See, e.g., Perez v. Wyeth Lab., Inc.,* 734 A.2d 1245, 1256 (N.J. 1999) (noting that ''consumer-directed advertising of pharmaceuticals . . . belies each of the premises on which the learned intermediary doctrine rests'' but nonetheless holding that ''when prescription drugs are marketed and labeled in accordance with FDA specifications, the pharmaceutical manufacturers should not have to confront state tort liability premised on theories of design defect or warning inadequacy.'').

[33] *Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 907-14 (W.Va. 2007); *see also Rimbert v. Eli Lilly & Co.*, 577 F. Supp. 2d 1174 (D.N.M. 2008) (predicting that the Supreme Court of New Mexico would not, in 2008, adopt the learned-intermediary doctrine).

[34] *Taylor v. Airco, Inc.*, 503 F. Supp. 2d 432, 444 (D. Mass. 2007); *see also* AM. JUR. PRODS. LIAB. § 1195 (1997).

[35] *Taylor v. Am. Chemistry Council,* 576 F.3d 16, 24-25 (1st Cir. 2009).

[36] *Carrel v. Nat'l Cord & Braid Co.,* 447 Mass. 431, 112 (2006).

[37] *Martinez v. Dixie Carriers, Inc.,* 529 F.2d 457 (5th Cir. 1976).