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Evolving Insurance Coverage For Nanotechnology Risks

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Although nanomaterials and nanotechnology are proliferating across traditional manufacturing, medical technology and defense fields, among others, the management of associated risks has lagged behind. Manufacturers and users of nanomaterials must consider how to mitigate and transfer risk. This article focuses on coverage for nanotechnology-related risks under traditional insurance policies and under the one nanotechnology insurance product currently on the market.

Nanotechnology

Defining nanotechnology can be difficult: it is more a process than a line of products. In general, nanotechnology refers to the manipulation of matter at a microscopic scale, usually with at least one dimension of the resulting materials being less than 100 nanometers (a nanometer is a billionth of a meter).[1] Materials manipulated at such a small scale can exhibit properties different from those materials found in nature or created using traditional manufacturing means. For example, nanomaterials in cosmetics can enhance effectiveness and appearance (for example, lifeguards no longer have white noses because the zinc in sunscreen is now nano-engineered); nanomaterials can be incorporated into textiles with antimicrobial effects; and medical treatments could be enhanced by nanotechnology-derived delivery devices that target specific cells and promise increased effectiveness along with fewer side effects.

Claims

To date, nanotechnology-related claims have not given rise to much litigation. A 2014 article from the Journal of Industrial Medicine documented the first known occupational exposure to nanomaterials (nickel) with adverse health consequences, but no litigation appears to have been initiated. See W. Shane Journeay & Rose H. Goldman, Occupational Handling of Nickel Nanoparticles: A Case Report, 57 Am. J. Indus. Med. 1073 (2014). One controversial theory espoused by plaintiffs in a long-running multidistrict litigation regarding hip replacements is that abrasions from metal-on-metal hip-socket replacement joints created nanomaterial cobalt, notwithstanding the fact that were not part of the product design. See In re DePuy Orthopaedics Inc. Pinnacle Implant Prods. Liab. Litig., No. 3:11-MD-2244-K, (E.D. Tex. July 18, 2014). (The verdict is currently on appeal.)

Traditional Insurance

First-party property and third-party liability policies do not refer specifically to nanotechnology,

nanomaterials or similar terms. Liability policies contain a broad grant of coverage — usually for "bodily injury" and "property damage" — and then limit that grant through exclusions. Although one insurer reportedly begun to exclude nanotechnology in 2008, the practice has not become widespread.

Unless the insured's primary business is the production of nanomaterials, a typical insurer might not even ask whether a company's products contain or incorporate nanomaterials. But insurers and other risk-management professionals are certainly aware of nanotechnology risks. Several years ago, reports from Lloyd's of London, Swiss Re, Zurich and other major insurers described nanotechnology-related losses as the "next big thing," akin to the asbestos and environmental wars still being waged. See Lloyd's of London, Lloyd's Emerging Risk Team Report: Nanotechnology Recent Developments, Risks and Opportunities (2007); Swiss Reinsurance Co., Nanotechnology: Small Matter, Many Unknowns (2004); Zurich Financial Services Group, Industry Insight: Insight on Nanotechnology (2009); see also Marsh & McLennan Cos., The Emerging Risks Quandary 10 (example of "future threat"), 18 (example of "transformational innovation") (2016).

Many insurers have taken a "wait and see" attitude toward nanotechnology risks, perhaps because there is little information about the number, type and severity of insured losses that might occur over time. For now, most insurers appear to be content to rely on their existing policy language and respond to claims if and when they occur, using defenses advanced in other contexts. For example, they might invoke pollution exclusions on the ground that nanomaterials are "pollutants" when they are found outside the medium originally placed. Insurers also might take the position that exposure to nanomaterials alone is not an "injury" or "occurrence," when no harmful effects have been discovered or alleged. Consider a claimant who alleges that nanomaterials have migrated from his medical implant to his body and seeks damages for medical monitoring. These issues have split courts in other contexts.

The Lex NanoShield Policy

There is only one nanotechnology-specific policy currently available: the Lexington Insurance Co. "Lex NanoShield" policy, originally released in 2010. We highlight below some of the features that distinguish the NanoShield policy from traditional insurance products.

The NanoShield policy is a "claims made" policy, meaning that it provides coverage only for claims for made against the policyholder during the policy's term. The NanoShield is not a "nanomaterials only" policy. Rather, it is a general liability policy with special features for nanomaterials-related claims. So a policyholder who has historically been insured under an occurrence-based policy might be adopting a more restrictive "claims made" form by changing from a traditional policy to a NanoShield policy.

The NanoShield policy provides both bodily injury and property damage coverages, but it treats those two coverages very differently. The primary changes to traditional coverage are in the property damage coverage. Put simply, the policy excludes liability for property damage caused by the insured's products but then replaces that with a very limited grant of coverage for property damage caused by nanotechnology (and other) products.

The policy defines the insured's products and work as "goods or products, including, but not limited to *nanomaterials* or goods or products that contain *nanomaterials*" or "work or operations involving *nanomaterials* and/or *nanotechnology*." (Italicized words are defined.) The policy then excludes property damage to "*your product* arising out of it or any part of it" and "*your work* arising out of it or any part of it and included in the *products-completed operations hazard*." The policy then channels property damage coverage for *your product/work* — into *new* coverages C-E:

- Coverage C provides product recall expenses. This can be valuable since many general liability policies contain recall exclusions or insurers take the position that recall expenses are not covered because there has been no "property damage" to third-party property. Coverage C also contains numerous exclusions that could seriously reduce the value of this coverage for certain types of policyholders. For example, the policy excludes recall expenses for (1) medical implants; (2) topical or ingestible products if they are not "generally recognized as safe,"[2] have been genetically-modified or are "bio-engineered," and (3) hormone treatment products.

- Coverage D provides "product recall liability coverage" for nanomaterials and other products, subject to important limitations. First, it is subject to the carveouts listed in 1-3 above. Second, coverage is only available in response to a "covered incident," which appears to require a recall or withdrawal of the relevant product from a third party. The coverage includes payments to distributors, purchasers or users of products that are required by contract but does not appear to include tort liability to third parties. Under this policy, such coverage is limited to bodily injury claims.

- Coverage E provides coverage for two types of pollution-related claims: (1) bodily injury or property damage arising out of the insured's products (including products containing nanomaterials); and (2) bodily injury or property damage that can be traced to temporally discrete pollution events reported within a limited time.

Also worth noting are: (1) the recall expenses and liability coverages under Coverages C and D each are limited to $100,000 in the aggregate; this limitation appears in the application for the policy; (2) defense costs are included within the policy's total limits; and (3) all disputes, except as to voidability, are subject to binding arbitration.

In contrast, bodily injury coverage (outside the pollution coverage) is substantially same as that provided by any other current general liability policy. Given what the policy has to say about property damage, this suggests that Lexington is prepared to cover, at least for now, bodily injury claims arising out of nanomaterials just as it would any other claims. That said, several features of the coverage might limit its appeal to potential buyers:

- Products liability coverage for property damage is limited.

- The "replacement" coverages (including recall coverage) appear to have low limits and companies are likely to prefer "occurrence"-based coverage.

- The narrow coverage seems designed to eliminate the possibility of any coverage for latent or long-tail claims.

Given the uncertainty about how the new coverage will apply to nanotechnology liabilities, a company with substantial resources might prefer to rely on its existing general liability coverage and the general rule that ambiguities in insurance policies are construed in favor of coverage. These bedrock principles of insurance policy interpretation can provide powerful leverage in cases involving emerging technologies and related liabilities.

Conclusion

Even though nanotechnology has existed for some time, it is still considered an emerging risk, which means that both the types of losses and liabilities have not been well defined and the insurance available to cover those losses and liabilities is evolving. Historically, as new liabilities have emerged, insurers have initially resisted providing coverage under traditional products that do not exclude them, then have written exclusions into the traditional products, and finally have offered new products designed to cover these risks — or an additional premium. Policyholders employing nanotechnology in their businesses can expect substantial changes in their insurance portfolios as nanotechnology becomes more widespread and claims are asserted.

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[1] Cf. FDA, Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology 5 (June 2014) ("FDA has not established regulatory definitions of 'nanotechnology,' 'nanomaterial,' 'nanoscale,' or other related terms. These terms are commonly used in relation to the engineering (i.e., deliberate manipulation, manufacture or selection) of materials that have at least one dimension in the size range of approximately 1 nanometers (nm) to 100 nm.").

[2] FDA is taking a case-by-case approach to "generally recognized as safe" status but has warned that nanomaterial versions of ingredients are not "generally recognized as safe" simply because their traditional equivalent is. See Covington E-Alert, FDA Issues Final Guidance on the Agency's General Approach to Nanotechnology and the Use of Nanotechnology in Manufacturing of Food Substances and Cosmetic Products (July 1, 2014).