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# NANOTECHNOLOGY: INSURANCE AND RISK MANAGEMENT IMPLICATIONS

We are in the initial stages of a scientific revolution. Nanotechnology is the understanding and control of matter at dimensions between 1 and 100 nanometers. At the nanoscale (a size tens of thousands of times smaller than the width of a human hair), common bulk elements and compounds exhibit unique properties that can be exploited by industry. In fact, the rate at which products are becoming nanoenabled is quickly increasing. The Project on Emerging Nanotechnologies (PEN) at the Woodrow Wilson International Center for Scholars currently lists over 1,000 nanoenabled consumer products, including coatings, computers, clothing, cosmetics, sports equipment, and medical devices.

"Nanotechnology" is actually a misnomer because, at this time, it is not primarily a stand-alone technology. Rather, it is an enabling technology primarily used to improve existing products or provide a foundation for new iterations of old products. It is the potential use in a wide array of industries that makes it so intriguing and promising. Among the many terms used in relation to nanotechnology, the most important is probably "**engineered** nanoparticle," because it implies an intent to understand, create, and utilize the unique properties matter exhibits at the nanoscale. This creates a critical distinction between the nanorevolution that is underway and historical examples of nanoscale serendipity, such as the use of gold in glassmaking to create a red hue or the use of carbon black in the tire industry to color and reinforce tires.

Nanotechnology will have a significant impact on the economy. It is anticipated that sales of nanoenabled products will reach $1.0 trillion by 2015. Still, nanotechnology's rosy future is tempered by the fact that there remains a great deal of uncertainty as to the potential toxicological effects of many of the nanoparticles in use.

Given the existence of unknown risks, many insurers are closely scrutinizing nanotechnology. However, the identification, quantification, and assessment of potential risk should be a cooperative effort among all interested parties, not just insurers. The time is right for an enhanced model of risk assessment and management to emerge, one that depends on the joint efforts of industry stakeholders and insurance companies. A cooperative effort to build a risk profile should be taken particularly seriously by all stakeholders at this early stage because insurability, especially for young or thinly capitalized companies, can mean the difference between survival and failure.

This article examines what is currently known about the risks posed by nanotech-

nology and the fundamentals of a flexible, cooperative risk management model to address them.

### The Current State of Risk Knowledge

Nanotechnology is a victim of its own success in some ways and, to date, its uses have progressed faster and further than toxicological studies. As a result, little is presently known about the general effects of any type of bodily injury exposure arising from most nanoparticles, whether from dermal contact, inhalation, or ingestion. Similarly, environmental impacts are not fully understood. Given the nature of toxicology research, future studies will more than likely demonstrate adverse effects or hazards associated with at least some nanoparticles. The ability to assess these is one key issue. Another is whether health and environmental effects occur from exposure and, if so, the exposure pathways involved.

Some exposure pathways are predictable. The manufacturing process for nanoparticles may lead to exposure in the absence of voluntary or mandatory (i.e., regulatory backed) workplace safety protocols. Other pathways may not be so obvious and may lead to a more passive type of exposure, such as ingestion of nanoparticles that have made their way into the water supply, atmosphere, or food chain.

Perhaps the most notable example of the potential risks of nanotechnology is revealed in a 2008 study on multiwalled carbon nanotubes. Carbon nanotubes vary in design, use, and mode of manufacture, and can be single walled or multiwalled in configuration. Generally, carbon-based nanotubes have tremendous potential and can be used to make structural materials lighter and stronger, such as composite materials in aircraft and in sports equipment. However, this study reported that, when injected into the abdomen of hybrid mice, they can precipate an inflammatory response, an effect resembling that seen caused by asbestos fibers. They may also contribute to the formation of cancerous tumors in mice but not rats.[1]

Before sounding the panic alarm, it is important to understand what information these studies are providing, given the experimental design. Clearly, more research is needed to determine whether the exposure pathways utilized in the studies are relevant. Although the two studies above utilized unlikely exposure pathways (i.e., injection in the abdominal cavity), the broader point is that other exposure routes exist, and the continued use of nanotubes definitely raises concerns about insurable risk.

Ultimately, the point is to determine whether the enunciated risk associated with exposure is actual and has applicability to the real world. In other words, how does one build a well-founded risk profile? The answer to this question is important to insurers and nanotechnology stakeholders alike, and involves a delicate balance of toxicology, risk management principles, and the law.

### Toxicology

Both insurers and insureds should work together to understand the potential pitfalls relating to nanomaterials. Each holds a different piece of the risk profile puzzle, and cooperation is one way to prevent an unnecessary bottleneck in an otherwise dynamic field. From a toxicological per-

[1] See Poland, C.A., et al. "Carbon Nanotubes Introduced into the Abdominal Cavity of Mice Show Asbestos-like Pathogenicity in a Pilot Study," *Nature Nanotechnology* 3 (2008): 423–428; Takagi, A., et al. "Induction of Mesothelioma in p53+/- Mouse by Intraperitoneal Application of Multiwall Carbon Nanotube," *The Journal of Toxicological Sciences* 33, no. 1 (2008): 105–116; Muller, A., et al. "Absense of Carcinogenic Response to Multiwall Carbon Nanotubes in a 2-Year Bioassay in the Peritoneal Cavity of the Rat," *Toxicological Sciences* 110, no. 2 (2009): 442–448.

spective, the types of activities and information at the heart of a reasonable risk analysis would include the following.

**Keep up with current toxicological information based on good science.** Many nanotechnology stakeholders and insurers do not have the resources to actively study the toxicological effects of nanoparticles. Staying abreast of developments and sharing them with each other is key. It is well worth developing partnerships with toxicological experts to stay informed especially when, as in the case of smaller stakeholders, they cannot perform toxicological assessments or keep current through their own efforts.

**Build a science and applications overview of the nanoparticles or products that enables a common, transparent, and accurate data exchange between insurers and insureds.** This includes not only identifying the types of particles but also explaining how they are used. For example, working with composites with embedded nanoparticles may prove safer than working with free particles in a manufacturing capacity, but anticipated use by consumers should be part of the calculus as well. An end user who cuts, sands, or otherwise creates dust that contains nanoparticles may alter the risk profile of the manufacturer. Stakeholders introducing nano-enabled products into the stream of commerce should be able to present an accurate picture of anticipated uses and abuses to their insurers. Additionally, the depth and breadth of distribution will be important, as will amounts of nanoparticles used, which relates to potential dose in downstream exposure.

**Explain current efforts and available methodologies to safeguard the health and safety of workers, consumers, and middlemen.** The current National Institute for Occupational Safety and Health (NIOSH) document, called "Approaches to Safe Nanotechnology," is an excellent start for industry as it recommends best practices for occupational safety and health. However, this document may not completely account for the risk associated from other potential exposures for businesses that use nanotechnology.

**Examine the completeness of material safety data sheets (MSDS) or disclosure of components by the manufacturer's suppliers.** Some suppliers located in foreign countries may not have detailed information about the materials; the recent troubles with goods manufactured in China underscores this point.

**Acknowledge the lag in regulatory responses to risk associated with nanotechnological risk.** Although governmental agencies have been following developments in the nanotechnology field, most of them have not promulgated specific rules and regulations relating to nanotechnology.

**Understand potential environmental risk by analyzing the product or particle from "cradle to grave."** This should include any relevant information about the long-term impact of disposal of manufacturing waste as well as the product itself. Such a life cycle analysis is often the best and most comprehensive analysis.

### Risk Management

The business of risk management is equal parts science and art, requiring not only solid facts on which to form an opinion, but also a well-tuned feel for identifying, analyzing, and treating presently known risk, then tweaking the risk pool over time as more information becomes available.

Even though most policies have standard coverage limitations and generic exclusions that can arguably be used by insurers to exclude coverage for many types of claims arising from the use of nanotechnology in products, nanotechnology still presents some level of potential exposure under standard policies. Until insurers act

to define the risk and deal with it effectively, coverage litigation will likely be commonplace. Consequently, from an insurer's perspective, risk is magnified because not only does it have to deal with the relatively unknown risk presented by nanotechnology, but it also has to determine how this amorphous sphere of nanorisk fits within the confines of existing policy language. Truth be told, this indeterminate state is really not so much a risk issue as it is an exposure issue, because in the absence of exclusions or clear caselaw, insurers are often considered, at least by the insureds, to be providing *de facto* coverage for new technologies.

This is not only an insurance industry problem. Nanotechnology stakeholders should be very concerned because, without appropriate risk definition and established methods and standards to appropriately control potential exposures, many insurers may choose not to insure certain businesses or risks or may compensate by charging sizable extra premiums for the unknown exposure. To illustrate these points further, we can examine the two most likely types of insurance to be implicated in nano related risk: workers compensation and general liability.

**Workers Compensation Insurance.** Employee injury resulting from exposure to nanoparticles at the workplace will be primarily channeled to workers compensation insurance since it compensates employees for loss of wages and medical expenses due to work-related injury or exposure. Compensability is typically determined on a state-by-state basis, and statutory levels of compensation will vary depending on the locally established benefit levels for lost wages and medical expenses.

Given the unknown toxicology of nanoparticles, there is a possibility that deleterious effects may not present themselves immediately after exposure. A time lag between sickness and exposure always creates challenges in terms of establishing which employer and corresponding insurer is responsible for benefits. In very general terms, compensability is frequently assigned to the employer and insurer of record at the time of the last workplace exposure to the sickness-causing agent. For example, if a worker becomes ill as a result of exposure to carbon nanotubes while working at a job that does not involve the use of carbon nanotubes, compensation benefits will become the responsibility of the business and insurer where the now-ill worker was last exposed to carbon nanotubes.

The process of determining the responsible employer and insurer involves establishing an exposure fact line/chronology. Thus, businesses and their insurers should carefully document (and independently verify) the hazardous or benign nature of nanoparticles involved in their operations to protect against erroneous assignment of responsibility for exposure. Additionally, even though states maintain records as to the insurers of record for each employer, businesses and insurers should maintain their own records in perpetuity in case they need evidence of their past insurance or noninsurance.

Because workers compensation benefits are statutorily mandated and are generally an employee's sole remedy for employment-related injury or sickness, this coverage is subject to a high degree of regulation. This regulatory oversight has at least two main consequences. First, it ensures the availability of coverage. Second, it leaves little room for insurers to implement broad-based exclusions. Although the rapid deployment of nanotechnology into all corners of industry is creating occupational exposures that are not completely understood at this time, insurers will have a difficult time avoiding exposure by de-

ciding not to voluntarily write workers compensation policies. In such a case, the exposure will simply shift to the involuntary state-mandated workers compensation pools in which all workers compensation insurers are required to participate. Thus, it is in the best interest of the nano users, insurers, and regulators to work cooperatively to study and profile potential nanoparticle occupational exposure and safety methods for mitigating the same.

Moreover, payment for work-related injuries does not stop with workers compensation—it just happens to be the path of least resistance because it is statutorily mandated. It is just one source of recovery among many, and there is still the potential that a person suffering ill effects from nanoparticle exposure could seek recovery from third parties on the theory that that party, and not the employer, is ultimately responsible for the injurious exposure. This type of lawsuit can be initiated directly by injured workers or by the injured workers' employer and/or its workers compensation insurer by way of subrogation. Thus, the door is still open to establish liability against responsible third parties that are in turn protected by general liability insurance.

**Commercial General and Products Liability Insurance.** Unlike workers compensation insurance, commercial general liability insurance is not statutorily mandated coverage. Even though it is maintained by most businesses, coverage forms and the application of coverage vary greatly by policy, insurer, and industry. Most businesses purchase relatively all-inclusive commercial general liability (CGL) policies that cover liability arising from premises, operations, completed operations, products, and independent contractor liability hazards. However, some manufacturers of particularly hazardous products find it necessary to purchase products liability insurance on a stand-alone form from the specialty insurance marketplace. While variations exist, there are some standards which are followed as to structure and generic scope of protection for CGL policies. Furthermore, many insurers use standard forms developed by Insurance Services Office, Inc. (ISO), or other service organizations, but may deviate on a case-by-case basis from such forms and tailor their policies to specific risks/risk pools.

Liability insurance can be arranged so that coverage is triggered on an occurrence or claims-made basis. Occurrence-based coverage is more prevalent for those business with traditional (and reasonably well-understood exposures). However, there is a strong likelihood of a greatly increased use of claims-made coverage forms for nanotechnology businesses given the unknown risks and emerging understanding of exposure. The reason has to do with an insured's reporting requirements under each type of policy. In a claims-made policy, coverage is incumbent on a claim being made and (usually) reported to the insurer during the period of the policy (or any tail period), no matter when the act occurred (unless there is an endorsed retroactive date that dictates otherwise). Under an occurrence policy, coverage is effective if the injury occurred during the period of the policy, regardless of when the claim is made or reported.

From an insurer's perspective, a claims-made policy offers greater control and finality as to claims. It puts the burden of reporting on the insured within a set period of time and effectively closes the door to future claims that materialize after policy or extended discovery tail expiration. Although this may seem overly zealous at first blush, bear in mind that the insured is generally the first party to know of any problems that may require coverage. Of course, the tension for an insured is whether all potential claims should be reported prior to

the expiration of the policy or extended discovery period. Prudence may dictate that anything and everything should be reported so that coverage is available. However, a potential downside to reporting too many potential claims is the prospect of becoming uninsurable. Reporting of claims under a claims-made policy involves decisions that are best hashed out within the company by risk managers, general counsel, and outside counsel, if necessary.

In addition to reporting provisions, most liability forms carry exclusions for injury arising out of pollution hazards. The pollution exclusion in the standard ISO CGL form (CG 00 01 10 01) is predominantly premises hazard based and applies to the "…actual, alleged or threatened discharge, disposal, seepage, migration, release or escape of pollutants." A separate "total pollution exclusion" (CG 21 55 09 99) is often added and is more expansive in nature in that it also applies to products liability. While these exclusions do not specifically refer to nanoparticles, the definition of "excluded pollutants" is broad based and includes:

> …any solid, liquid, gaseous or thermal irritant or contaminant, including smoke, vapor, soot, fumes, acids, alkalis, chemicals and waste. Waste includes materials to be recycled, reconditioned or reclaimed.

The interpretation of pollution exclusions and whether nanotechnology is swept up in its broad language will be a matter for the courts, but at this time, there is nothing on the face of the exclusion that indicates it does not apply to nanomaterials.

Aggregation of limits should be of interest to nonstakeholders and their insurers, especially in light of the oft-cited (but so far unfounded) comparison to asbestos. Many standard liability policies and excess umbrella /excess liability policies are now subject to general annual aggregate limits for liability arising out of premises and operations. Additionally, liability arising out of products and completed operations are also subject to annual aggregate limits. Further, most policies now include provisions to avoid stacking of limits over multiple policy terms to cover liability for injury that manifests itself over time. Excess liability insurance will provide additional limit protection with terms and conditions that typically follow form with the primary general liability policy.

In light of the foregoing, the question for insurers and insureds alike is "What can nanotechnology stakeholders and their insurers do to create more certainty?" This is the million (billion? trillion?) dollar question for several reasons. First, the absence of well-grounded, scientifically based, easily understood risk profiles may encourage uniform treatment of all participants in the industry, causing insurers to underwrite to a worst-case standard by either excluding coverage, charging high premiums, or reducing available coverage limits. For companies with limited financial means, a lack of insurance could be a death knell and would be a chilling effect on an otherwise promising industry.

Nanotechnology is probably not capable of a one-size-fits-all type of insurance approach, a fact that all parties should recognize. Therefore, a good risk profile will help appropriately tailor coverage and include up-to-date toxicological information and specific information relating to potential insurability.

Accurate science will be the key to understanding the risk presented by a particular business, which will allow insurers to make case-by-case determinations of insurability. Insurers, for their own benefit, may want to build business-specific profiles by compiling information about:

- The types of nanoparticles used by insureds as well as their sources

- Known and potential hazards of the particles from cradle to grave or cradle to cradle (if recyclable)
- The state of science regarding the nanoparticles used
- Potential environmental effects, if known
- Steps being taken to address environmental and worker health and safety issues
- Steps being taken to inform consumers about known and/or potential hazards (i.e., through labeling or MSDS)

This type of behavior by insurers should encourage corresponding behavior by stakeholders, such as the development of individualized risk management practices. Because nanotechnology is nascent, stakeholders are going to have to assume costs that are not present in other, more developed industries. Creating sound risk management practices is expected to be one of those costs. The return on the cost is that nanotechnology is so unique that wholesale exclusions of coverage will probably be impractical. Instead, the world of nanotechnology insurance will arguably be populated by negotiated and tailored policies, particularly in the case of insureds with large resources and negotiating power.

Insurance will probably *not* devolve into an industry offering a different policy for each nanoparticle, which would be unwieldy. But what *may* (and probably should) happen is that different particles will be grouped according to the risk they present. Policies can then be created for different risk points, which will allow for some negotiation of terms. Therefore, when deciding on policy language (or even whether to underwrite the risk) insurers should take into account the insured's behavior in building a risk profile and managing health and safety issues. Stakeholders will be on the frontlines and will be in the best place to work with insurers to deal with risk in an efficient manner.

Although the primary focus in nanotechnology will be risk monitoring and management, other important variables within the control of insurers include:

- Staying abreast of toxicological data
- Reviewing existing policy language to determine whether coverage may arguably exist for nanotechnology-related claims and decide whether the current price accurately reflects the underlying risk
- Reinsuring to spread the risk
- Determining whether the state of knowledge within the industry is sufficient to allow some risks to be covered by way of endorsement while others can be excluded
- Utilizing claims-made policies which require greater diligence by insureds (The net benefit is twofold—it provides an additional reason for stakeholders to care about toxicology, which will benefit the nanotechnology industry as a whole, and it will also remove some of the burden placed on insurers arising from occurrence coverage triggers.)

Insurers should, at a minimum, include these factors in their core decision chains when attempting to come to terms with the challenges of nanotechnology. Moreover, combining forces with their customers and accurately profiling nanotechnological risk to create targeted insurance solutions will place insurers in a solid position to provide cost-effective insurance while avoiding unnecessary risk and litigation costs.

### The Law

The law is a variable that neither insurers nor insureds can control, but a proper risk profile should always be undertaken with an understanding of legal issues relating to coverage and exposure. Familiarity with the law is important because, as stated previously, there is some indication that litigation about harm allegedly caused by exposure

to nanoscale particles may become prevalent. A comparison to asbestos is difficult to avoid, and the economic impact of that generation of lawsuits cannot be overstated. Actuarial estimates indicate that the overall economic cost of asbestos litigation is likely to exceed $200 billion, of which an estimated $75 billion may be insured.

The dearth of toxicological data should spur insurers and insureds to greater cooperation aimed at avoiding the morass associated with years of asbestos litigation. Treatment of risk at an early stage, although not without cost, can be a smart financial strategy in the long run. Nondisclosure agreements with insurers may be one way to allay concerns about disclosing or discussing proprietary information.

From a legal perspective the prospect of litigation is especially troubling and, make no mistake, there will be lawsuits alleging bodily injury and environmental harm relating to nanotechnology. The plaintiffs' bar is closely monitoring developments relating to nanotechnology, and past history indicates that once a suitable plaintiff is located, along with an expert whose testimony will seemingly pass the *Daubert* test or analogous state law thresholds, the first lawsuits will be filed. A cooperative effort to immunize the industry as much as possible could also include voluntary adoption of best practices to: minimize workplace exposure during manufacture; increase product labeling and the potential use of warnings directed to end users post-sale; and promote proper methods for environmentally safe disposal—three of the most important phases in a cradle-to-grave risk management approach to a nanoparticle's lifecycle.

Even in the absence of regulations mandating best practices, taking steps to minimize exposure, while not without cost, should be considered. Insurance companies can drive behavior in this regard by adjusting premiums based on preventative steps to minimize exposure. When compared to the billions of dollars incurred in asbestos litigation, the cost of prevention may be relatively modest.

## Conclusion

Although nanotechnology promises to yield significant socioeconomic gains, little is known about the potential risks in this nascent field. The uncertainty will diminish as research increases and experience grows. In the meantime, insurers and insureds should work together to develop useful risk profiles that facilitate the management of the risks and underwriting of insurance for those risks, and insurers should examine their policies to determine how best to tailor them in light of the current unknowns.

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