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The Coming Intersection of Nanotechnology and Synthetic Biology With Insurance

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The explosive use of nanotechnology and synthetic biology (synbi) in everything from everyday household products, such as deodorants and air fresheners, to applications in medicine, energy, and waste management, has resulted in an evolving series of issues. Should government oversight be increased? What sort of research is really necessary to understand the risks? and How can we ensure that technology that has obvious potential benefit does not become a threat to our biosecurity?

A new and different, but less recognized, issue also is arising. That is the extent to which insurance will cover (or already may be covering) the risks posed by products that include nanomaterials and synbio applications.[1] The typical commercial general liability policy contains an initial insuring agreement that broadly affords coverage for an insured's liability arising from bodily injury or property damage. Therefore, absent a nanotech- or synbio-specific exclusion, such a policy arguably would provide coverage for damages arising from, for example, products incorporating either nanotech or synbio applications. However, at least one insurer already has addressed the issue—last fall, Continental Western Insurance Group issued what was reported to be one of the first nanotech-specific commercial insurance policy exclusions in the United States.[2] While we are not aware that any insurer has yet announced a similar exclusion for synbio applications, it would not be particularly surprising if this occurred, given some of the similar risk characteristics between many nanotech and synbio applications.

This article explores this potential insurance challenge in greater detail.

I. The Continental Western Announcement and Exclusion

In a flash across the life sciences and nanotechnology media in late 2008, it was announced that a carrier was taking a step with potentially major implications for the developing nanotechnology industry—it was notifying its policyholders of a specific exclusion for ''nanotubes or nanotechnology.'' Specifically, in apparent recognition that products with nanotech applications potentially would be covered under the broad coverage afforded for property damage and bodily injury under many liability insurance policies, Continental Western introduced a policy endorsement to exclude:

> bodily injury, property damage and personal and advertising injury related to the exposure of [*sic*] nanotubes or nanotechnology *in any form*. This includes the use of, consumption of, ingestion of, inhalation of, absorption of, contact with, existence of, presence of, proliferation of, discharge of, dispersal of, seepage of, migration of, release of, escape of, or exposure to nanotubes or nanotechnology. (Emphasis added.)

[1] *See e.g.*, NANOTECHNOLOGY THE PLASTICS OF THE 21ST CENTURY, Carpenter & Co., 2006; M. Rakhlin, ''Regulating Nanotechnology: A Private-Public Insurance Solution,'' 2008 DUKE L. & TECH. REV. 2 (Rakhlin).

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[2] Pat Rizzuto, ''Insurance Group Excludes From Coverage Nanotubes, Nanotechnology as of Nov. 15,'' 2 LIFE SCI. LAW & IND. REP. 794, 9/26/08.

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The exclusion extended specifically to the storage, handling, transportation, or disposal of nanotubes or nanotechnology, and any ''structures, manufacturing processes or products'' containing nanotubes or nanotechnology.

Nanotubes were defined as ''hollow cylinders of carbon atoms or carbon fibers or any type or form of nanotechnology'' that contain remarkable strength and electrical properties used in any products, goods, or materials. ''Nanotechnology'' was defined as engineering at a molecular or atomic level.

The exclusion reportedly was prompted by concerns over health risks and simply the unknown risks of a new technology that, perhaps like asbestos, could be quite injurious. Indeed, these concerns have been openly discussed in the insurance industry for some time.[3]

While the fate of this particular exclusion is unknown, and it has yet to be widely adopted across the insurance industry, it is not difficult to see its challenges. Engineering at a ''molecular or atomic level'' is clearly something that can be envisioned in such a range of products as to render the exclusion overbroad—in fact, while the exclusion by its very name and use of terminology appears to be targeted only at nanotech-specific applications, it could be argued that the broad definition of ''nanotechnology'' also brings many, if not all, synbio applications within its scope. Second, many businesses could face difficulties in that they often might not know whether a particular component part meets the nanotechnology definitional test or, indeed, might be entirely unaware that certain components contain nanotech or synbio applications. Finally, it is unclear whether the scope of the exclusion is truly commensurate with the risks realistically present.

II. The Current Exclusion Environment

Setting aside a nanotech-specific or synbio-specific exclusion, two exclusions in the typical commercial general liability (CGL) policy provide guidance on the direction in which insurance issues may develop in the nanotech and synbio areas—exclusions related to asbestos and pollution.

A. Pollution

The typical CGL policy[4] excludes coverage for certain damage arising from ''pollutants.'' Pollutants are broadly defined as:

> ''Any solid, liquid, gaseous or thermal irritant(s) or contaminant(s).''

The exclusion broadly states that the policy does not apply to bodily injury, property damage, advertising injury, or personal injury arising out of the actual, alleged, or threatened discharge, dispersal, seepage, or escape of pollutants. This includes pollutants that were transported, handled, stored, disposed of, processed, or treated as waste by or for any insured party. The exclusion applies whether the pollution was accidental, expected, gradual, intended, preventable, or sudden.

One can envision a variety of situations where this exclusion might be alleged to apply in the nanotech and synbio environment. For example, to the extent that products that are made using either of the technologies are (or become) ''irritants'' or ''contaminants'' coverage arguably could be excluded. This should, in turn, provide nanotech and synbio product manufacturers with incentive to rigorously test such products to ascertain (and mitigate) the likelihood of this occurring from their development, use, or disposal. To the extent such testing is undertaken, and the related risks mitigated, insurers should become more comfortable with the risk, or lack thereof, posed by such products, and the manufacturers should be armed with the research to support a position that these products were not irritants or contaminants in the first instance.

B. Asbestos

Beyond the exclusion for pollution, the asbestos exclusion also may become a model for insurers targeting synbio and nanotech products. Asbestos represents a substance with beneficial qualities—for example, for insulation—that after widespread use was found to have extremely dangerous properties.

While the time between discovery of the harmful effects of asbestos and the change to using nontoxic insulation materials and more protective asbestos mining techniques undoubtedly was too long and its history tortured, the insurance result was a focus on an exclusion surrounding a particularly harmful substance, rather than all insulating material, and a limitation of even the asbestos exclusion to only its negative properties. Thus a typical asbestos exclusion might address bodily injury, property damage, and personal injury ''arising out of the actual, alleged or threatened contaminations, pathogenic, toxic or other hazardous properties of asbestos.'' This exclusion typically would exclude the expenses associated with requirements to respond to or assess the affects of asbestos or any related damages or expenses.

As applied to the nanotechnology or synthetic biology field, a similar approach could be followed. Substances developed through the application of nanotech or synbio technologies with discovered pathogenicity or toxic properties may well become subject to targeted policy exclusions. This would be as opposed to painting with an overbroad brush, as is seemingly done by the Continental Western exclusion discussed previously, where all risk associated with nanotubes or nanotechnology, regardless of pathogenicity, simply is excluded.

C. Recommended Solution for Nanotech and Synbio Risks

The risks of various nanotech materials and synbio products have been discussed for some time. Nanoparticles or genetically engineered molecules, bacteria, or viruses easily can be envisioned in certain circumstances to pose risks to human and animal health, as well as the environment. The insurance industry itself has carefully approached such risks.[5]

To address these risks, one academic has suggested a ''Private-Public solution.''[6] Under such an approach, modeled after the program for nuclear accident insurance and the Price-Andersen Act,[7] an insurance pool would be created with mandatory insurance required

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[3] *See* articles referenced at http://www.swissre.com/pws/about%20us/knowledge_expertise/top%20topics/nanotechnology.html.

[4] The CGL policy is the most common policy under which products-liability coverage is provided in the United States.

[5] *See e.g.*, Annabelle Hett, NANOTECHNOLOGY: SMALL MATTER, MANY UNKNOWNS (2004).

[6] Rablin, *supra,* n. 1.

[7] 28 U.S.C. §§ 2210 *et seq*.

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for those involved in nanotechnology research and development and nanomaterial manufacturers. This concept arises out of a core assumption that nanomaterials are likely to create health and environmental risks and ostensibly could create incentives to ''prove their initiatives are safe enough to be insurable.''

As the author points out, however, such a system has multiple challenges. It does not address how to screen all the potential risks, focuses on after-the-fact compensation, may chill start-up activity, and requires a determination of how to address developments that are occurring globally. These factors alone make it suspect. In addition, it would not address a major problem related to the length of time between invention or proof-of-concept and discovery of toxic effects. There is a further challenge in addressing all of the entities in the United States that already make use of either nanomaterials or particulates (*e.g.*, in perfumes), any number of which simply may not be aware of it by virtue of their use of materials assembled in a number of steps.

The proposal also fails to consider the vast array of products that already take advantage of nanotubes and similar technology (*e.g.*, tennis rackets, bike frames) or likely soon will do (*e.g.*, speakers, printable integrated speakers, conductive clothes, transparent electrodes)[8]

Additional issues exist in the synbio realm. As is the case with nanotech, a requirement for ''pre-emptive'' insurance, on a broad ''every product'' basis, will neither accurately assess the risks—none of which seem yet to have developed, except for known pathologies—nor will likely even address all of the potential participants. Instead, a U.S.-based proposal seems more likely simply to provide a disincentive to development in the United States and be a trap for the unwary.

III. An Alternative For Exploration

Rather than an ''all or nothing'' approach to insuring nanotech and synbio risks, a more nuanced approach would appear more appropriate.

There is no regulatory scheme (at the national level) specifically directed toward nanotech or synbio products. While state and local laws are beginning to address the potential issues raised—exposure, pathways, modes of entry into animals and humans, and toxicity—they are focused on disclosure and, in some cases, permitting. Assuming adequate product testing is occurring, and absent any known toxicity, there seems little reason for insurance to create more stringent requirements than are imposed on other products that have been consumer-tested and shown not to pose excessive risk.

Although the statutory framework is not in place, the approach taken by the National Institutes of Health in its *Guidelines for Involving Recombinant DNA Molecules*, and its proposed amendment,[9] appears a much more thoughtful approach. Under the guidelines, which by virtue of the proposed amendment would be extended to synbio activity, varying categories of activity would require different levels of review based upon perceived risk. Thus, research involving nonreplicating synthetic nucleic acids would be exempt from review while high-risk basic and clinical studies would be subject to review. The level of review required would be based on identified risk—to the lab, the worker, the public, and the environment.

Insurance coverage could follow a similar path. Products and processes that make use of nonreplicating synbio constructs should be treated as any other inert industrial product and not singled out. Nanotech products should be treated in the same fashion.

Furthermore, where there are known risks from existing products, and an attempt is made to create new products or like products that have substantial portions of those risk elements within them (*e.g.* duplication of asbestos fibers or anthrax or significant portions thereof) then the same coverage rules should apply. Thus, known pathogenic elements—as they or variants are created—should be publicly identified, discussed, and addressed in statutory and regulatory schemes and in insurance exclusions.

More clarity also is needed with respect to the application of existing exclusions in this area. Labeling something as an ''irritant'' or ''contaminant'' is not sufficiently specific to provide clear guidance to either insurers or insureds. Consider the difference between an adverse reaction to an approved medication when it results from a synbio or nanotech product infiltrating an unintended area, or doing so with unintended consequences, thereby triggering a disease. Should the insurance coverage be the same, or radically different, simply because the medication included a synbio or nanotech product?

IV. Conclusion

The worlds of nanotech, synbio, and insurance likely already are intersecting, even if the various players do not yet realize it. Insurers likely already are providing coverage for manufacturers of any number of products that include nanotech and synbio materials, including things such as air fresheners, clothing, and perfumes. With the likely coming explosion of new technologies involving nanotech and synbio materials, the extent to which insurers are potentially on the risk for these products will grow exponentially in the near future. This creates not only a world of peril, but a world of opportunity both for insurers and insureds.

On the insurer side, those who seek to find and understand the exposure to nanotech and synbio in their portfolios of insureds will be best positioned to make rational judgments regarding the level and scope of coverage they will extend for such products, and to be able to price the coverage commensurate with the potential risk (or narrowly exclude only those products with known pathogenicity).

For insureds and potential insureds, investing the time to help their insurance company underwriters fully understand the applications and uses of nanotech and synbio and, particularly, the risk assessments and precautions that have gone into the decision to use these technologies, will pay dividends in ensuring that the maximum level of coverage is available if and when it is ever needed. Furthermore, by developing a common understanding of the uses of these technologies, such up front communication will help avoid coverage disputes by allowing the development of policy wording that more appropriately defines what both parties to the insurance transaction intend to cover before a loss occurs.

[8] ''Nanotube Electrodes,'' MIT Technology Review, March/April 2009.

[9] ''Proposed Actions under the NIH Guidelines for Research Involving Recombinant DNA Molecules,'' NIH, 74 Fed. Reg. 9411 (March 4, 2009).

While some in academia have jumped to the conclusion that insurance simply is not available to support the development of nanotech and/or synbio applications, we do not believe that is the case. The fact of the matter is that existing CGL policies probably already cover many products including these technologies. Therefore, while some of these academics have advocated for a government-backed mechanism to provide such coverage, this may be unnecessary and, if utilized only in the United States, may lead to competitive disadvantages for U.S.-based companies.

The more useful avenue would seem to be education of insurers regarding the risks they already are covering. Once insurers are able to more carefully evaluate these risks, and other risks they may be asked to cover in the future, it will be possible to clarify existing coverage ambiguities and, if necessary, develop products specifically to cover risks that the standard CGL policy cannot cover.

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