Nanotechnology Law Report

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Comment on: "Regulating Nanoscience: A Proposal and Response to Clarence J. Davies." University of South Carolina professor David Berube recently published "Regulating Nanoscience: A Proposal and Response to Clarence J. Davies," in Nanotechnology Law & Business, Vol. 3, Issue 4 (Dec. 2006). Professor Berube responds to Mr. Davies' 2006 Woodrow Wilson article calling for a comprehensive reexamination of current regulatory regimes relevant to nanotechnology. Professor Berube argues public perception is unlikely to be influenced by regulation, and a comprehensive regulatory scheme "would tend to be self defeating at this juncture." As an alternative, Professor Berube suggests voluntary regulation of nanoproducts, and then "let market mechanisms allocate risk." Professor Berube's "liability [plus] regime would involve the insurance industry and would be enforced by the courts in the form of lawsuits." Professor Berube further suggests "the liability regime advocated here avoids the resolution of the new versus existing materials problem for this determination will be removed from the regulatory hearing and conference process to the courtroom; thus, determinations can be resolved on a case-by-case basis."

While figuring out how and to what extent to regulate nanotechnology is a very complicated issue, abdicating any part of that process to the litigation and/or insurance coverage process is not the answer. First, relying on litigation or even insurance coverage presupposes an alleged loss or injury. Catastrophic punitive damages have been awarded when companies purportedly ignore potential product health risks and take the approach of letting their lawyers and insurance companies sort it out. Second, turning important scientific determinations over to the litigation process is unlikely to produce the results advocated by Professor Berube. Judges and juries are frequently overburdened and are not equipped to analyze complicated scientific questions. Further, even the best scientists sometimes make poor testifying witnesses and may not stand up to cross-examination under the adversarial process. Additionally, there are razor sharp attorneys who can make "white" look "black," and vice versa – regardless of the actual "scientific truth." Simply put, nanotechnology decisions are too important to be determined on a "case-by-case" basis in a forum not designed for this process. Additionally, the old adage that "justice is blind," does not mean two courts will reach the same decision when presented with the same issue. Inconsistency between jurisdictions is frequently lamented in our profession which would be a further hindrance to this nascent industry.

> ***DTF Reply:*** *A highly detailed regulatory regime is not necessary right now (and probably not even possible). Regulatory regimes work better when there is a good understanding of the underlying industry/technology but do not work when the underlying industry/technology is largely unknown. In other words, as a policy matter, the more uncertain (unknown) the future, the more we should rely on litigation (which is backward looking) and the more certain (known) the future, the more we should rely upon regulation. It is a sliding scale, of course, not all of one and none of the other. Drawing the line and shifting it over time is tough. Nonetheless, at this moment in time, less detailed regulations and litigation might be appropriate, but as our knowledge advances, more detailed regulations could be appropriate. Professor Berube is off about labeling not being worthwhile, or at least not worthwhile for a business. For a business, disclosure could result in some limits on liability and/or damages. Also, if Congress felt the need to regulate further, they could be persuaded to mandate labeling. It costs the government little to require labeling and it could allow Congress to pass a law, claim victory, and move on.*

Nanotechnology Liability Protection Plan? In a recent article published by the Washington Legal Foundation, the attorney-author asks: "Is It Time to Consider a Nanotechnology Liability Protection Plan?" In answer to this question, the author advocates the establishment of a Nanotechnology Insurance Fund ("NIF") with two principle purposes: "1) provide an exclusive source of compensation for people such as consumers or workers who claim, and can prove, injury from

nanoparticles and 2) pay for any required environmental cleanup and restoration costs." He also suggests the NIF could be used to fund nano-related EHS research. Finally, he believes this proposal "is a better solution for potential nanotechnology liability problems than years of tedious and expensive litigation followed by large and bankrupting settlements or judgments." *Nanotechnology: Don't Delay Liability Risk Assessments and Solutions*, Washington Legal Foundation, Vol. 21 No. 37 (Dec. 8, 2006).

The author's proposal seems premature. The nanotechnology industry is still in its infancy and no nano-related EHS lawsuits have yet been filed. Moreover, the potential adverse health and environmental effects of nanomaterials are largely undetermined. Top nanotechnology scientists indicate basic research regarding the EHS effects of certain nanoparticles may not be completed until 2012 or later. *See* "Safe handling of nanotechnology," Nature, Volume 444 Number 7117 pp. 243-400 (November 16, 2006). Simply put, while initial scientific research urges caution, it is too early to even remotely suggest the nano-industry will someday find itself in near bankruptcy from EHS litigation.

Further, establishing a NIF would send the wrong message to the public, essentially conceding catastrophic personal injuries and/or environmental problems are a foreseeable likelihood. Why else would manufacturers establish a recovery fund? The larger question will then become why are nanomanufacturers are proceeding to market their products to the public if they believe such a high level of exposure is possible? The establishment of a NIF may also act as an invitation to plaintiffs' attorneys to "find" clients with alleged injuries so they can partake of the fund and recover large contingent fees. If there are no nano-related EHS lawsuits pending before the fund it established, there will be thousands filed shortly thereafter.

Rather than rushing to establish a NIF, each nanomanufacturer should take responsibility for the EHS implications of its own products consistent with existing products liability law and government regulation.

> ***MEH Reply:*** *I agree that a national fund, similar to that of the Superfund that is limping along under CERCLA, is premature, and perhaps even unnecessary. However, the idea of offering nanotechnology insurance, I think, has merit from an environmental protection standpoint. Environmental contamination insurance is now available when purchasing a piece of property that could be contaminated. Similarly, why could not insurance be offered to protect against "nanotechnology contamination?" The goal should be to remediate any nanomaterial contamination, if it happens, as quickly as possible. Admittedly, there are hurdles to overcome before a company may offer such a policy, and even then, it may not be cost effective to do so. However, given the types of insurance policies that are available today, the option of purchasing a policy addressing nanomaterials is not something that should be quickly dismissed.*

Congress to Consider Nano-Liability Limits?
Inside OSHA reports that Senator Mark Pryor (D-AR), who is chairman of the subcommittee overseeing product safety and the insurance industry, is considering the concept of a "nanotechnology liability" cap. While the Senator's office has yet to comment on the report itself, inside sources confirm that the idea is indeed being reviewed.

> ***MEH Reply****: As discussed earlier, final enactment of such limits may be premature given the infancy of the nano-industry. While a liability cap may help develop nano related businesses, it raises questions concerning how lawmakers are treating workplace safety and the message being sent to the public at-large. While Congress should consider as many alternatives as feasible in developing legislation, especially in a new area such as nanotechnology, legislation getting to liability limits and caps should be thoroughly considered before acting upon them.*

AIHA: Nanotechnology a Top 2007 Issue.

The American Industrial Hygiene Assocation has identified nanotechnology safety as one of its members' top concerns for 2007, according to a recent report in Occupational Hazards. AIHA identified nanotechnology as an OSHA concern and characterized the concern this way:

Nanotechnology – The increased use of nanotechnology for consumer products raises concerns that a clearer understanding is needed to

accurately assess the occupational health and safety risks posed by working with this new technology. AIHA supports increased research into the possible hazards involved with nanotechnology.

Moreover, AIHA's 2007 annual AIHce conference will feature a panel on nanotechnology; it will be interesting to see what, if any, recommendations come out of the conference about nanomaterial handling.

Given Berkeley, California's recent decision to regulate occupational and other exposure to nanomaterials through its hazardous materials ordinance, and recent Congressional and other pressures to regulate nanotechnology, it is good to see organizations like AIHA taking a look at nanotechnology regulatory issues. A scientifically-based, rational regulatory approach to nanomaterial safety is welcome; the sooner such an approach is taken, the better. The last thing this industry needs is a highly public "scare" -- such as the German Magic Nano scare last year -- to pique the interest of the trial lawyers.

Orthopedic Implants. Orthopedic implant failure often results from poor bone adhesion and/or infection. Purdue University recently conducted an *in vitro* study to determine whether nanotechnology might be used to reduce both of these risks. Purdue scientists compared the adhesive properties of nanoscale versus microscale samples of ZnO and TiO2 to staph cells and osteoblasts (bone-forming cells). ZnO was chosen because of its antimicrobial properties and TiO2 was selected because it typically forms on titanium implants in the body. The researchers found that – as compared to their microscale counterparts – nanoscale ZnO and TiO2 led to reduced staph cell adhesion and increased osteoblast adhesion. The implication is that staph is less likely to form on titanium medical implants incorporating nanoscale ZnO, while bone adhesion improves at the same time. Obviously, this is only a very preliminary study, but it should be of great interest to manufacturers of orthopedic implants. G. Colon, et al., "Increased osteoblast and decreased staphyloccocus epidermidis functions on nanophase ZnO and TiO2," Journal of Biomedical Materials Research Part A, 2006;78(3):595-604.

For a hypothetical health and safety related scenario using nanotechnology in a similar context see “Preparing for Future Health Litigation: The Application of Products Liability Law to Nanotechnology,” Nanotechnology Law & Business, February 2006, www.nanolabweb.com.

NY Times Article on Berkeley Regulation. On January 14, 2007, the New York Times published an article by Barnaby Feder on Berkeley California's new nano hazardous material handling regulation. The article succinctly summarizes the regulation: "[T]he new regulation . . . requires businesses to annually identify . . . any materials they use or produce with at least one dimension of 100 nanometers or less, no matter how small the quantities. They must also share what they know about how toxic the particles might be and describe procedures for tracking, handling and disposing of them." We have previously posted on Berkeley's ordinance on www.nanolawreport.com. Additionally, our more detailed analysis will be published in the February edition of Nature Nanotechnology, under the working title "The Perils of Pre-emptive Regulation." We use the article to address five specificissues raised by Berkeley's new regulation.

American Public Health Association Adopts Nano-Policy. The American Public Health Association (APHA) recently held its 134th annual meeting in Boston, Massachusetts, at which it adopted policies addressing 22 important public health issues, including nanotechnology. APHA's key policy recommendations are:

- Increase federal funding for nano-related EHS research to $100 million.
- Encourage the voluntary participation by nanomanufacturers in the (i) collection of nano-related safety data and (ii) prevention of human and environmental exposure unless positive information exists showing it is safe.
- Have federal agencies (i) require the collection and submission of workplace and environmental safety data by nanotechnology businesses/manufacturers; (ii) recommend interim risk management measures; and (iii) "assure the education, health and safety of workers, consumers and the general public through promulgation of protective standards and regulations."

Inhalation Research. For us non-scientists, a useful rule of thumb in inhalation toxicology is the finer the substance, the greater the possibility for adverse health effects -- and vice versa. Preliminary

studies indicate this may hold true for nanoparticles which have been shown to have fewer potential adverse health effects when they occur in cluster form (aggregates and/or agglomerates). In the "good news" department, scientists studying aerosol dispersion of nanoparticles have found they tend to cling together when dispersed into the environment. Curious scientists ask logical follow up questions: What happens to these nanoclusters if they somehow make it into the lung? Do they react with the body and end up breaking back down into smaller (and theoretically more toxic) sizes?

A new study by four German researchers makes some in-roads on these questions. M. Maier, et al., "Does lung surfactant promote disaggregation of nanostructured titanium dioxide?," Journal of Occupational and Environmental Medicine, Vol. 48, No. 12 (December 2006).

Maier looked at the theoretical interaction between the primary substance found in lung wall lubricant/fluid -- dipalmitoyl phosphatidylcholine (DPPC) -- and titanium dioxide nanoclusters to determine whether DPPC facilitates their breakdown into smaller sizes. Apparently, it does not. The researchers conducted two tests to reach this conclusion. The first used computer simulation to determine that the DCCP did not have enough energy to break the bonds between individual nanoparticles in the clusters. In the second test, the researchers exposed titanium dioxide nanoclusters to a simulated biological lung fluid containing DPPC. The test results showed no disaggregation in the clusters from exposure to increasing amounts of DPPC, nor did it show any time dependent disaggregation.

The authors "conclude that DPPC only covers [titanium dioxide] aggregates and agglomerates instead of splitting them, i.e., lung surfactant does not promote the disaggregation of [titanium dioxide] agglomerates and aggregates."

Nano-Insurance Underwriting Challenges. Robert Blaunstein recently published an article in Insurance Networking News: "Unfamiliar Exposure: Nanotechnology deals in tiny particles, but its potential risk to insurers is sizable and nearly impossible to calculate." The article begins by noting the "enabling" role the insurance industry often takes with new technologies. Dr. Blaunstein argues this "enabling" function is fulfilled by when insurance companies help businesses manage product risks. In order to play this role in the nanotechnology industry, Dr. Blaunstein argues insurers need to better understand nanotechnology and "have access to accurate data and information that permit a questionable evaluation of the probability and severity of losses." He also advocates government regulation of the use and disposal of harmful nanomaterials.

The article further explains the insurance industry's risk analysis of nanotechnology is lacking because of the: (i) large number of uses of nanomaterials in a "broad array of activities;" (ii) absence of existing data regarding specific risks posed by nanomaterials. Given these uncertainties, Dr. Blaunstein believes insurance coverage for the nano-industry will evolve in three stages:

Early Study Period. The insurance industry is currently in this stage, which is an effort to assess potential risks and insurance exposures. During this period, Dr. Blaunstein believes nanotechnology risks may already be covered by product liability, worker's compensation, professional liability, and general liability insurance policies.

Apprehensive Phase. Serious concerns develop and "insurers and reinsurers begin to look at reducing" coverage. The industry seeks to contain risks through the use of "sub-limits" and "claims made" coverage.

Mature Phase. Insurers understand the risks and potential losses posed by nanotechnology and offer "customized solutions" . . . "at reasonable rates in both the insurance and reinsurance markets."

Dr. Blaunstein closes by urging insurers to embrace an "enabling" role with nanotechnology and to work "with manufacturers, the government, scientists and regulatory agencies to identify and quantify nanotechnology's risks." Additionally, he believes "[s]tandard, affordable coverage will eventually be available. In the meantime, by using claims-made forms and setting appropriate deductibles and limits that are commensurate with unknown risks, insurers can mitigate their potential losses and still participate in this exciting new market."

Dermal Absorption. North Carolina State and Rice University researchers recently published the results of their *in vivo* skin penetration experiments using fullerenes on pig skin. The researchers tested fullerene penetration on stationary skin and skin that was flexed for an hour or an hour and a half. They found the longer the skin was flexed, the greater and

deeper the particle absorption. Additionally, they found greater absorption 24 hours after flexion than that measured eight hours after flexion. N Monteiro-Riviere, et al., Nano Letters, American Chemical Society, January 10, 2007.

It is interesting to compare this to the Cosmetic, Toiletry and Fragrance Association's October 10, 2006 "Nanotechnology White Paper: The Use of Nanotechnology in Personal Care Products," as well as recent efforts by the Pharmos Corporation to develop a dermal drug delivery nano-emulsion.

Canary in a Coal Mine? In support of a proposal for a dramatic increase in federal funding for nano-related EHS research, a top nanoscientist was recently quoted as saying: "Workers are society's canaries-in-the-coal mines when it comes to the environmental, health and safety effects of new materials -- and nanoscale materials are no different." Inside OSHA, Vol. 14 No. 2, January 22, 2007.

> ***JCM:*** *Workers are the often first to face exposure to health risks from new technologies, and often also experience exposure at higher rates than the rest of the population. However, the canary concept could be misconstrued as implying nano-companies are indifferent to possible worker exposure and will only take action once the canary gets sick or dies.*

Conference. Nanotechnology Law Report's own John Monica will be speaking about "The Possible Adverse Consequences of Pre-emptive Nanotechnology Regulation" at the two-day conference and workshop, *Regulations for Nanotechnology in Consumer Products*, February 8-9, 2007, Washington Marriott, Washington, D.C. This conference is aimed at those interested in doing more than simply scratching the surface of nanotechnology regulatory concerns.

The conference will include speakers from: Woodrow Wilson International Center for Scholars; International Standards Committee (ISO)TC229; The International Center For Technology Assessment; The Innovation Society; IBM; Nanotechnology Law & Business; Tel Venture Capital, Center For Biological And Environmental Nanotechnology (CBEN) and International Council On Nanotechnology (ICON); NANTERO: Tikvah Therapeutics: Pacific Northwest National Laboratory: Altairnano; LUNA Innovations Inc.; ENVIRON; and DITTUS Communications.

Book Review: "Nanotechnology: Science, Innovation, and Opportunity." *Nanotechnology: Science, Innovation, and Opportunity*, compiled by Lynn E. Foster and published by Prentice Hall, is an excellent introduction into the world of nanotechnology and the possibilities it brings. The book is a collection of 20 chapters written by different authors, all experts in their field, on the major topics concerning nanotechnology. It begins with general discussions on the possibilities of nanotechnology, like thoughts on energy independence by Richard Smalley, for which the Smalley Institute at Rice University is named. It then moves to identifying those involved with research, development, and funding of nanotechnology, such as the role of venture capitalists and university technology transfer. Following that is a series of chapters on specific applications of nanotechnology, such as drug delivery systems and bio-nano-information fusion. Finally, the book concludes with a transcript of the presentation "Infinitesimal Machinery" that Richard Feynman gave, rather prophetically, to the NASA Jet Propulsion Laboratory in 1983.

While *Nanotechnology* focuses on increasingly technical subjects as it progresses, the book is an easy-to-read glimpse into industries that nanotechnology is impacting. Its broad coverage is supplemented by notes and references at the end of each chapter, providing readers an opportunity to delve deeper individual subjects. For anyone looking to learn more about nanotechnology, its applications, and implications, *Nanotechnology*, is an excellent primer, and will hold the attention of both the casual reader and those studying this new technology alike.

Finally, we would be remiss if we did not take this opportunity to introduce our readers to another option for reading about nanotechnology. As an indicator as to how this field is beginning to take off, you can now find *Nanotechnology for Dummies* at your local bookstore. Like other books in the "for Dummies" series, *Nanotechnology for Dummies,* by Richard Booker and Earl Boysen, is designed to be a straight-forward and easy introduction into nanotechnology. While we have not read the book in its entirety, it might provide a quick tutorial on individual topics when needed. And with the inclusion of the occasional one-liners and cartoons, it is also entertaining.

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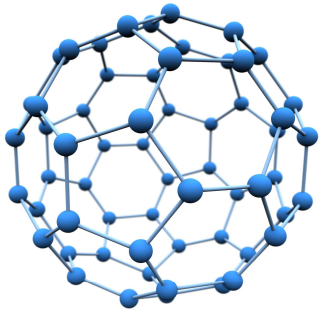

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