Fall 2009

SPECIAL LEGISLATIVE UPDATE
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Nanotechnology Law Report

Legal Issues Surrounding Nanotechnology & General Nanotechnology News & Events

PUBLISHED BY
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INSIDE THIS ISSUE

EPA Considering New Approach to Nanoscale Materials Under TSCA

Inside EPA's September article "EPA Developing Strict Approaches for Overseeing Nanomaterials" summarizes recent comments by EPA's Assistant Administrator for Office of Prevention, Pesticides and Toxic Substances at a conference sponsored by the London School of Economics, the Environmental Law Institute, and the Woodrow Wilson International Center for Scholars' Project on Emerging Nanotechnologies.

The Assistant Administrator apparently questioned EPA's past "distinct molecular identity" approach to determining whether nanoscale materials are considered new chemical substances requiring premanufacturing notice and approval under the Toxic Substances Control Act (TSCA). Regular readers may recall that this approach examines nanoscale materials on a case-by-case basis to determine whether they have a separate and unique molecular identity from those chemical substances already on EPA's TSCA inventory of existing chemical substances. If the molecular identity is unique, then it is considered a New Chemical Substance requiring TSCA premanufacturing registration and approval. This approach was first formalized in a 2008 EPA document, which you can find at http://epa.gov/oppt/nano/nmsp-inventorypaper.pdf.

Regarding EPA's current approach, the Assistant Administrator stated, "I cannot say what the outcome of that review will be, but I can tell you that we will be taking a fresh look at this issue and at the basis and reasoning for the decision made by the EPA last year."

Our prediction: Substantial revisions to the existing approach will take place in 2010.

EPA May Issue Mandatory Data Collection Rule for Nanoscale Materials Under TSCA

Eight months after EPA's interim report on initial industry participation in its Nanoscale Materials Stewardship Program, EPA's Toxic Substances Control Act (TSCA) Interagency Testing Committee (ITC) recently published a report in the Federal Register mentioning that EPA may issue a new mandatory data collection rule for nanoscale materials under TSCA Section 8(a):

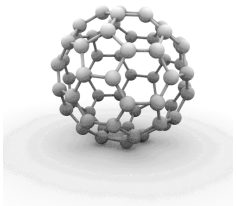
"EPA intends to develop a proposed TSCA section 8(a) rule to obtain information on the production, uses, and exposures of existing nanoscale materials. EPA has indicated that it will ensure that the chemicals where there is ITC interest as described in this unit are either included in

that action or are otherwise new chemical substances subject to premanufacture notifications (PMN) reporting under TSCA. EPA also intends to develop a proposed TSCA section 4 rule to develop needed environmental, health, and safety data."

Among other things, TSCA section 8(a) allows EPA to issue a rule requiring the mandatory submission of data regarding:

(A) The common or trade name, the chemical identity, and the molecular structure of each chemical substance or mixture for which such a report is required; (B) the categories or proposed categories of use of each such substance or mixture; (C) the total amount of each such substance and mixture manufactured or processed, reasonable estimates of the total amount to be manufactured or processed, the amount manufactured or processed for each of its categories of use, and reasonable estimates of the amount to be manufactured or processed for each of its categories of use or proposed categories of use; (D) a description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance or mixture; (E) all existing data concerning the environmental and health effects of such substance or mixture; (F) the number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substance or mixture in their places of employment and the duration of such exposure; and (G) . . . the manner or method of its disposal, and in any subsequent report on such substance or mixture, any change in such manner or method.

Some of the specific nanoscale materials prompting the TSCA ITC's interest appear to be: fullerenes; titanium oxide nanowires and nanoparticles; nano zinc oxide; nanosilver; nanoscale silica; nanoscale quartz; nanoscale cerium oxide; nanoscale indium tin oxide; dendrimers; single-walled carbon nanotubes; multi-walled carbon nanotubes; carbon nanofibers; Se and Cd quantum dots; nanoceramic particles; and nanoclays.



EPA Takes Aim at Antimicrobial Products Under FIFRA

The EPA has taken recent enforcement actions against two manufacturers allegedly making unsubstantiated antimicrobial claims for their products – much like occurred in the IOGEAR nanosilver computer keyboard/mice episode in 2008. Although these products did not purport to use nanoscale materials, the alleged claims for these products are similar to those made by manufacturers for certain nano-based antimicrobial products. Thus, our readers may be interested in EPA's actions.

The EPA issued a press release in October stating that the parent company of North Face faces up to $1,000,000 in fines for allegedly making unsubstantiated health-related claims for almost 70 of its shoe products using AgION™ silver ion technology. The EPA press release states:

> "At issue were more than 70 styles of footwear that incorporated an AgION silver treated footbed. The company sold the products making unsubstantiated claims that the footwear would prevent disease-causing bacteria. Specifically…North Face made the following public health claims about the footwear on-line and on product packaging: • 'AgION antimicrobial silver agent inhibits the growth of disease-causing bacteria' • 'Prevents bacterial and fungal growth' • 'Continuous release of antimicrobial agents'"

The fines are being sought by EPA under the Federal Insecticide Fungicide and Rodenticide Act which prohibits unsubstantiated public health claims regarding unregistered pesticides.

From AgION's website: "AgION technology operates at the surface of a product through the controlled release of silver ions which attack microbes and inhibit their growth in three different ways. We offer a variety of silver-based technologies to suit various manufacturing and product requirements."

In another press release, EPA also publicized a complaint it filed "against Peoria, Ariz.-based Granite Marketing, Inc. for the alleged sale and distribution of an unregistered pesticide in violation of the Federal Insecticide, Fungicide and Rodenticide Act…for offering for sale the unregistered antimicrobial pesticide known as Titania Antibacterial System."

There are often developments in the nano legal world that do not fit into our traditional nanolawreport format, yet might be of interest to some of our readers.
You can now find these short postings and other musings on twitter.com/nanolaw.

EPA Unveils New Principles for Chemical Management Reform

Health care and financial regulatory reform efforts by the Obama administration have been getting the majority of recent media and public attention. At the same time, reform and updating of the Toxic Substances Control Act (TSCA) has been hovering in the background.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During a September speech to the Commonwealth Club of San Francisco, EPA Administrator Lisa Jackson announced the administration's "Essential Principles for Reform of Chemicals Management Legislation:"

- First, we need to review all chemicals against safety standards that are based solely on considerations of risk – not economics or other factors – and we must set these standards at levels that are protective of human health and the environment.
- Second, safety standards cannot be applied without adequate information, and responsibility for providing that information should rest on industry. Manufacturers must develop and submit the hazard, use, and exposure data demonstrating that new and existing chemicals are safe. If industry doesn't provide the information, EPA should have the tools to quickly and efficiently require testing, without the delays and procedural obstacles currently in place.
- Third, both EPA and industry must include special consideration for exposures and effects on groups with higher vulnerabilities – particularly children. Children ingest chemicals at a higher ratio to their body weight than adults, and are more susceptible to long-term damage and developmental problems. Our new principles offer them much stronger protections.
- Fourth, when chemicals fall short of the safety standard, EPA must have clear authority to take action. We need flexibility to consider a range of factors – but must also have the ability to move quickly. In all cases, EPA and chemical producers must act on priority chemicals in a timely manner, with firm deadlines to maintain accountability. This will not only assure prompt protection of health and the environment, but provide business with the certainly that it needs for planning and investment.
- Fifth, we must encourage innovation in green chemistry, and support research, education, recognition, and other strategies that will lead us down the road to safer and more sustainable chemicals and processes. All of this must happen with the utmost transparency and concern for the public's right to know.
- Finally, we need to make sure that EPA's safety assessments are properly resourced, with industry contributing its fair share of the costs of implementing new requirements.

It has been expected for some time that new legislation to update TSCA will be introduced by Senators Frank Lautenberg and Barbara Boxer, and Representatives Henry Waxman and Bobby Rush before the end of the 111th Congress. We will keep an eye out for when the legislation is introduced and report on its course through Congress.

EPA Report on the Use of Nanoscale TiO_2 in Water and Sunscreens

EPA's Office of Research and Development recently released a draft case study on the use of nanoscale TiO_2 in water and sunscreens: "Nanomaterial Case Studies: Nanoscale Titanium Dioxide in Water Treatment and in Topical Sunscreen" FR 74,146 at 38188 (July 31, 2009). The draft report is divided into five chapters: Introduction; Life Cycle Stages; Fate and Transport; Exposure - Dose Characterization; and Characterization of Effects.

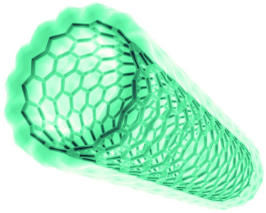
The report is formidable in length, scope, and detail. For those looking for some quick highlights, the report provides a great series of summaries of the existing nano TiO_2 environmental, health, and safety literature. For example:

- **Table 4-4** presents an overview of approximately 25 existing nanoTiO_2 skin absorption/penetration studies dating back to 1997;
- **Table 5-3** provides a summary of nano-TiO_2 ecological effects; and
- **Tables 5-4 through 5-6** summarize health effects of nano-TiO_2 particles in mammalian animal models via dermal, oral, and respiratory exposure routes.

EPA notes that the "document is not intended to serve as

a basis for risk management decision in the near term on these specific uses of nano-TiO_2." Rather, its focus is on developing necessary data for "future assessment efforts." Specifically, the "document is a starting point to determine what is known and what needs to be known about selected nanomaterials as part of a process to identify and prioritize research to inform future assessments of the potential ecological and health implications of these materials." You can find the case study at http://www.epa.gov/fedrgstr/EPA-RESEARCH/2009/July/Day-31/r18386.htm.

EPA Withdraws Carbon Nanotube SNURs



In August, the EPA withdrew two significant new use final rules for carbon nanotubes after having received a notice of intent to submit adverse comments. The text of the notice follows:

"SUMMARY: EPA is withdrawing two significant new use rules (SNURs) promulgated under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for chemical substances which were the subject of premanufacture notices (PMNs), i.e., multi-walled carbon nanotubes (PMN P-08-177) and single-walled carbon nanotubes (PMN P-08-328). These chemical substances are subject to TSCA section 5(e) consent orders issued by EPA. EPA published the SNURs using direct final rulemaking procedures. EPA received a notice of intent to submit adverse comments on these rules. Therefore, the Agency is withdrawing these SNURs, as required under the expedited SNUR rulemaking process. EPA also intends to publish in the Federal Register, under separate notice and comment rulemaking procedures, proposed SNURS for these two chemical substances.

In the Federal Register of June 24, 2009 (74 FR 29982), EPA issued several direct final SNURs, including SNURs for the two chemical substances that are the subject of this withdrawal. These direct final rules were issued pursuant to the procedures in 40 CFR part 721, subpart D. In accordance with 40 CFR 721.160(c)(3)(ii), EPA is withdrawing the rules issued for multi-walled carbon nanotubes (PMN P-08-177) and single-walled carbon nanotubes (PMN P-08-328) because the Agency received a notice of intent to submit adverse comments. EPA intends to propose SNURs for these two chemical substances via notice and comment rulemaking in a future Federal Register document."

Press Release: New Contributing Editor for InterNano

Porter Wright attorney John Monica has been selected as a new Contributing Editor for Environmental, Health, and Safety (EHS) and Regulation for InterNano, a full-service resource provider for the nanomanufacturing community (see www.internano.org). InterNano is a project of the National Nanomanufacturing Network, funded by the NSF Center for Hierarchical Manufacturing and supported by the University of Massachusetts Amherst Libraries.

As a Contributing Editor, Mr. Monica is charged with informing InterNano readers of the latest EHS and regulatory developments in the world of nanotechnology. Relying on top experts across the country, Mr. Monica will deliver articles, commentary, and reviews on cutting-edge nanomanufacturing EHS and regulatory issues.

"I'm very happy to be working with NNN and InterNano," stated Mr. Monica. "There's a lot happening in this area, and InterNano provides a nice complement to Porter Wright's traditional focus on nano-related legal problems. Nanomanufacturing is where the rubber meets the road," he continued.

"Mr. Monica's dedication to this topical area is a welcome addition to the original content that we provide through InterNano," said Jeff Morse, Managing Director of the National Nanomanufacturing Network. "We are looking forward to further developing this category of our information services."

Mr. Monica, a partner in Porter Wright's Washington, D.C. office, chairs the firm's nationally recognized, multidisciplinary Nanotechnology Practice Group. He has been recognized by Nanotechnology Law & Business peer-reviewed journal as one of the "Top Ten Experts" in EHS issues related to engineered nanomaterials and authored the comprehensive legal text, Nanotechnology Law (West 2009).

InterNano (http://www.internano.org) supports the information needs of the nanomanufacturing community by bringing together resources about the advances in applications, devices, metrology, and materials that will facilitate the commercial development and/or marketable application of nanotechnology. InterNano both aggregates existing resources related to nanomanufacturing and creates original commentary on those resources, including news highlights, review and feature articles, and topical assessments of the current state of practice in nanomanufacturing.

Virginia CLE presentation: "Insurance, Nanotechnology, and Risk"

Porter Wright presented its approved Virginia CLE presentation "Insurance, Nanotechnology, and Risk" in mid-September to a nationally recognized intellectual property law firm based in D.C. The presentation covered issues related to the alleged environmental, health, and safety (EHS) risks accompanying certain nanoscale materials from the perspective of both the insured and insurer. Particular emphasis was placed on (i) insurer approaches to EHS risk and uncertainty, (ii) the first commercial insurance exclusion for nanotechnology in the US, (iii) industry reaction to certain recent adverse EHS studies concerning carbon nanotubes, and (iv) three initial steps nano-related businesses should consider when dealing with these issues. The core of the PowerPoint was also presented at the Nanotechnology Health and Safety Forum in Seattle in June 2009 and at the National Nanotechnology Initiative's October 2009 workshop on "Nanomaterials and the Environment & Instrumentation." We anticipate additional presentations in D.C. and Virginia over the upcoming months. Please let us know if you have any interest in attending one of the future sessions, and we will try to hook you up for some free CLE credit.

Nanoparticles and Deaths in the People's Republic

By now, most of our readers will have read either "Exposure to Nanoparticles is Related to Pleural Effusion, Pulmonary Fibrosis, and Granuloma" by Yuguo Song, Xue Li, and Xuqin Du, recently published in the European Respiratory Journal, or any of the many news articles based on it. For anyone who has not read the article, a brief synopsis is in order:

From January 2007 to April 2008, seven female patients were admitted to Chaoyang Hospital in Beijing. All seven worked in the same department of a printing plant and all seven were suffering from the same symptom - shortness of breath, pleural effusion and pericardial effusion, and were treated with antibiotics and surgery and placed on oxygen to assist their breathing. Five of the women stabilized; two, ages 29 and 19, died of respiratory failure. Further investigations revealed purported accumulations of nanoparticles, which were also allegedly found in the workplace, in their lungs.

The authors reached the following conclusion:

> "...it is the nano materials containing nano-sized particles that appear to produce the toxicities seen in the exposed workers. Therefore, we have more evidence to show that the nano particles contained in the polyacrylate emulsion had possibly caused the disease. There is an indication from this report that shows the possible dangerous nature of nano particles. Nano particles can penetrate the membrane of pulmonary epithelial cells and lodge in the cytoplasm and caryoplasm, as well as aggregate around the membrane of red blood cells and exert toxicity. Patients may develop clinically serious conditions associated with damaged respiratory function including a progressive pulmonary fibrosis that is resistant to several methods of treatment."

Many critics of nanotechnology and nanoindustry may use this study as a basis for calls to end the use of nanoparticles in manufacturing processes or to call for the shutdown of nanoindustries altogether. That is unlikely to happen. Too much time, money and effort have been invested for a shutdown to become a reality. The genie has left the bottle and is not returning.

Further, as the authors state throughout their article, the women's workplace contributed as much, if not more, to

the women's illnesses as the purported nanoparticles did:

"A survey of the patients' workplace was conducted. It measures about 70 square meters...has one door, no windows, and one machine used to air spray materials, heat and dry boards. This machine has three atomizing spray nozzles, and one gas exhauster (a ventilation unit) that broke 5 months before the occurrence of the disease.

Accumulated dust particles were found at the intake of the gas exhauster. During the five months preceding illness the door of the workspace was kept closed due to cold outdoor temperatures. The workers...had no knowledge of industrial hygiene and possible toxicity from the materials they worked with. The only personal protective equipment (PPE) used on an occasional basis were cotton gauze masks. According to the patients, there were often flocculi produced during air spraying, which caused itching on their faces and arms. It is estimated that the airflow or turnover rates of indoor air would be very slow, or quiescent due to the lack of windows and the closed door."

In their conclusions, the authors note that "...more studies on the possible mechanisms, diagnosis, treatment and prevention of the nano material related disease are needed."

"...these cases arouse concerns that long term exposure to some nanoparticles without protective measures may be related to serious damage to human beings...Effective protective methods appear to be important in terms of protecting exposed workers from illness caused by nano particles."

Such future studies as the authors call for may be used as the basis for regulation in China to prevent tragedies such as the deaths of the two young women in this study. Undoubtedly, had the business concerned employed even the most basic workplace safety measures, the tragedy would have been prevented.

Soil Association Cites China Deaths in Renewed Call for Moratorium on Nanotechnology Commercialization

In early September, the Guardian newspaper in the U.K. printed a letter from the Soil Association criticizing the paper's nanotechnology supplement. The letter cites the Song study from China (see analysis above) as evidence supporting its call for a moratorium on nanoscale materials along with "nano-free" standards, which we have previously covered. Key statements from the letter follow:

"Seven women working in a factory [in China] where nanoparticles were used in paint fell ill with serious lung disease and two died. Researchers...found nanoparticles deep in the lungs of the women...A chemical in the paint, the patients' lung tissue and the liquid surrounding the lungs were all found to contain nanoparticles."

"There should be an immediate freeze on the commercial release of nanomaterials until there is a sound body of scientific research into all the health impacts."

The letter does not attempt to explain any of the severe criticism the Song article has received by most mainstream scientists, and is a good example of questionable science put to a reactionary use.

Sweating the Small Stuff

In September, Reuters news service carried an article by Richard A. Liroff, "Nanomaterials: Why Your Company Should Sweat the Small Stuff," primarily aimed at management executives at companies contemplating using nanomaterials in their products or manufacturing processes.

Noting that nanomaterials present "the potential to yield extraordinary health, environmental, and other global social benefits," Liroff also notes, as with asbestos, the potential for nanomaterials to have "novel toxicity risks." He further points out that regulatory agencies in Canada, California, and the EU are basically at the beginning stages of issuing regulations. Although EPA is also noted for having initiated "a handful of regulatory actions," since most of these actions featured voluntary compliance rather than mandatory, he deems

its success rate as "poor."

Mr. Liroff points out that corporate management will

> "need to exercise especially demanding due diligence to make sure you're not taking on liabilities that you and your shareholders will come to regret."

With that in mind, Mr. Liroff poses several questions, largely focusing on suppliers of nanomaterials, that management should keep in mind while performing their due diligence and long term planning, including planning for a "worst case" scenario.

It is important that management and shareholders ask questions and heed warnings

> "about the unknown and under-researched hazards of nanomaterials...If these misgivings go unheeded, that would be tragic on multiple counts. Not only because the potential benefits from the burgeoning forms of nanotechnologies will founder and be lost on the shoals of public mistrust and rejection, but also because companies and their shareholders will see corporate financial values vaporize in the face of closed markets and possible litigation."

Liroff raised the specter of asbestos in his article and it is important to learn from what happened - and is still happening in that arena, since litigation over the effects of asbestosis is still being filed decades after asbestos was used in factories and consumer products - to avoid exposure to possible litigation and loss of shareholder investment.

You can now find nanolawreport on Linkedin under "John Monica," as well as our new "Nano EHS Forum." Please feel free to link in or to join our new discussion group.

Nanotechnology Legislation in the 111th Congress: Part I -- The House of Representatives

This fall seems like a good moment to review nanotechnology legislation that has been introduced so far in the 111th Congress. In Part I we will examine legislation introduced in the House of Representatives, and in Part II we will examine legislation introduced in the Senate.

HR 554, the "**National Nanotechnology Initiatives Amendments Act of 2009**," was introduced by Rep. Bart Gordon (Dem - TN - 6th Dist) on 01/15/2009 and was passed by the House under suspension of the rules on 02/11/2009. Received in the Senate on 02/12/2009, it was referred to the Senate Committee on Commerce, Science and Transportation; it has not been reported out of committee and no hearings are currently scheduled.

Major amendments to the 21st Century Nanotechnology Research and Development Act (P.L. 108-153 15 USC 7501 et seq) include:

Requiring the National Nanotechnology Coordination Office to "develop and maintain a database accessible by the public of projects funded under the Environmental, Health, and Safety, the Education and Societal Dimensions, and the Nanomanufacturing program component areas, or any successor program component areas, including a description of each project, its source of funding by agency, and its funding history."

Requiring the designation of an Associate Director of the Office of Science and Technology Policy as the Coordinator for Societal Dimensions of Nanotechnology. The Coordinator would be tasked with insuring that ethical, legal, environmental and other social concerns with nanotechnology are considered. The Coordinator would also be responsible for convening a panel to develop a research plan for the environmental, health and safety program areas; the plan would be updated annually.

Requiring the Director of the National Science Foundation (NSF) to provide grants to establish Nanotechnology Education Partnerships. Nanobusinesses would be part of these partnerships which would be designed to help prepare secondary school students to pursue college courses in nanotechnology.

Providing for the establishment of "Industry Liaison Groups" for all industrial sectors that would benefit from nanotechnology applications.

Requiring the National Nanotechnology Coordination Office to sponsor public meetings to (1) solicit views on the relevance and value of nanomanufacturing research; (2) receive recommendations on ways to strengthen research supported by the nanomanufacturing program; and (3) receive recommendations on improving nanomanufacturing facilities.

HR 820, the "**Nanotechnology Advancement and New Opportunities Act**," was introduced by Rep. Michael Honda (Dem – CA – 15th Dist) on 02/03/2009 and was referred to the House Committees on Science and Technology, Energy and Commerce, Ways and Means, and Homeland Security. No hearings have been held by any of these committees on this bill and no hearings are currently scheduled. It has not been reported out of any of the committees.

The bill would require the Secretary of Commerce to establish a "Nanomanufacturing Investment Partnership," contingent upon the private sector raising $100 million within two years after the bill's enactment. The Partnership would provide funds, via direct investment, loans or loan guarantees or other unspecified mechanisms, to nanocompanies for pre-commercial research and development that would not be funded by either the private sector or under the 21st Century Nanotechnology Research and Development Act.

The Secretary of Commerce would also be directed to establish an Advisory Board to assist in determining which nanocompanies would receive funding. The Advisory Board would be made up of two groups: (1) representatives of those investors who had provided more than $10 million to the Nanomanufacturing Investment Partnership (in short, the stakeholders) and (2) Presidential appointees drawn from government agencies, industry, and academia. This second group would control 60% of the votes on the Advisory Board and thus would be the ones deciding where the money goes. This would seem to be a flaw in the bill; as we have seen in the recent past and may see again under future administrations, it is possible to politicize government agencies and, as currently written, this section of the bill opens up that possibility here. It is possible that the bill may be amended in one of the committees before it is reported out or an amendment may be adopted during floor debates.

The tax code would also be amended by creating tax credits to encourage the purchase of stock in qualified nanotechnology developers (as defined by the bill). Tax credits would also be available to cover up to 50% of the cost of nanotechnology education and training courses and programs.

The Secretary of Commerce would be directed to establish the "Nanotechnology Start Up Advisory Council" with membership drawn from industry, marketing, venture capitalist firms, attorneys, and nanotechnology researchers. The Council's duty would be to review the business plans of nanotech start up companies, to ensure that they are truly viable.

Other sections of the bill would establish competitive grants to encourage the application of nanotechnologies to solving environmental problems, renewable energy sources, health-related uses, and homeland security programs.

The Secretary of Energy would be directed, six months following enactment, to deliver to Congress a report containing a plan to increase interaction on nanotech issues between scientists and engineers at DOE's national laboratories and informal science education communities with the goal of developing exhibitions for school age children and the general public.

HR 2769, the "**Commercializing Small Business Research and Development Act**" introduced by Rep. Bobby Bright (Dem – AL -2nd Dist) on 06/09/2009, is not primarily a nanotechnology focused bill. Rather, its aim is to amend the Small Business Act. Section 4 of the bill, however, is titled "Nanotechnology related research topics" and amends two substantive [rovisions of the SBIR/SBA as follows:

> SEC. 4. NANOTECHNOLOGY-RELATED RESEARCH TOPICS.
>
> SBIR- Sections 9(g)(3) and 9(o)(3) as amended, are further amended--
>
> by adding at the end the following: (F) the national nanotechnology strategic plan required under section 2(c)(4) of the 21st Century Nanotechnology Research and Development Act (15 U.S.C. 7501(c)(4)) and in subsequent reports issued by the National Science and Technology Council Committee on Technology, focusing on areas of nanotechnology identified in such plan.

HR 2965, the "**Enhancing Small Business Research and Innovation Act of 2009**," was introduced by Rep. Jason Altmire (Dem –PA – 4th Dist) on 06/19/2009. The bill would have amended and extended the Small Business Act sections on the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, which include nano-based businesses. HR 2965 was assigned to the House Committees on Small Business and Science and Technology. Both Committees reported the bill with amendments (H. Rept. 111-190 Pt. 1 and H. Rept. 111-190 Pt. 2).

Amended during floor debates, HR 2965 was passed by

the House on a vote of 386-41 on 07/08/2009. On 07/09/2009, HR 2965 was received in the Senate, where it was called up for debate on 07/11/2009. The Senate amended HR 2965 by an amendment in the nature of a substitute. This means that the Senate voted to remove the language of the bill following the enacting clause and substituted the language of S. 1233, the Senate version of the bill. The amended bill was then passed by unanimous consent. The amended bill does have a section (Sec. 206) that briefly treats nanotechnology:

SEC. 206. NANOTECHNOLOGY INITIATIVE.

(a) In General- Section 9 of the Small Business Act (15 U.S.C. 638), as amended by this Act, is amended by adding at the end the following:

(ff) Nanotechnology Initiative- Each Federal agency participating in the SBIR or STTR program shall encourage the submission of applications for support of nanotechnology related projects to such program.'

(b) Sunset- Effective October 1, 2014, subsection (ff) of the Small Business Act, as added by subsection (a) of this section, is repealed.

The bill was then returned to the calendar.

The House at some time will have to vote again on the amended HR 2695. If the House votes to pass the bill as amended by the Senate, it will be sent on to President Obama for his signature. If the House fails to pass the bill, it will not become law. There is the possibility that the House could further amend the bill and, if it insists on its amendment, a Conference Committee will be formed to come up with a compromise bill that both chambers could accept. Considering the popularity of these two programs, the bill in some form is likely to be passed.

Nanotech Legislation in the 111th Congress: Part II – The Senate

S. 596, the "**Nanotechnology Innovation and Prize Competition Act of 2009**," was introduced by Senator Ron Wyden (Dem-OR) on 03/16/2009. The bill directs the Secretary of Commerce to establish a program to award prizes for achievement in one or more applications of nanotechnology (environmental, development of alternative energy sources and fuels, health, and development of consumer products). A board would be established to administer the prizes.

The bill was referred to the Senate Committee on Commerce, Science and Transportation; to date, no hearings have been held and none are scheduled in the near future. The bill remains in committee.

S. 1233, the "**SBIR/STTR Reauthorization Act of 2009**," was introduced by Senator Mary Landrieu (Dem - LA) on 06/10/2009 and was referred to the Senate Committee on Small Business and Entrepreneurship, which reported it out of committee with an amendment in the nature of a substitute on 07/02/2009. For a further discussion of S. 1233, please see the discussion of HR 2965 in Part I above.

S. 1482, the "**National Nanotechnology Initiative Amendments Act of 2009**," was introduced by Senator John Kerry (Dem - MA) on 07/21/2009 and was referred to the Senate Committee on Commerce, Science and Transportation. No hearings have been held and none are scheduled. S. 1482 would reauthorize and amend the 21st Century Nanotechnology Research and Development Act. Significant amendments to the 21st Century Nanotechnology Research and Development Act include:

Sponsorship by the National Nanotechnology Program (NNP) of Nanotechnology Education and workforce development programs;

Support by the NNP of the development of standardized reference materials, instruments, and computational tools;

Participation in national and international organizations developing commercialization and regulatory guidelines and standards; and

Coordination of research to determine what health, safety and environmental risks nanoparticles and nanomaterials may pose.

The Director of the National Nanotechnology Coordination Office would be charged with developing and maintaining a publicly accessible and keyword searchable database of projects funded by the Nanoscale Science, Engineering and Technology subcommittee of the National Science and Technology Council. This is somewhat similar to the database proposed in HR 554, which was discussed in Part I above.

As with HR 820, an associate Director of the Office of Science and Technology Policy would be designated as the Coordinator for Societal Dimensions of Nanotechnology. The Coordinator's duties would include ensuring that a

research plan is developed, updated annually, implemented and responsive to the recommendations of the sub panel mentioned above. The Coordinator, within sixty days of S. 1482's enactment date, would be required to convene a panel to create a research plan for the environmental, health and safety program. This plan would include a description of how the NNP would ensure the development of the standards and standardized reference materials also referred to above.

The Director of the National Nanotechnology Coordination Office, no later than six months following enactment, would convene national discussions to encourage both stakeholders and non-stakeholders to express their concerns and priorities regarding nanoproducts, research and development and regulatory policy affecting nanotechnology. The Director would be required to submit a report summarizing these discussions to the Congressional committees that have oversight responsibilities in this area, namely the Senate Committee on Commerce, Science and Transportation and the House Committee on Science and Technology.

SA (Senate Amendment) 1472 was part of a bloc of amendments offered by Senator Carl Levin (Dem-MI) to amend **S. 1390, "The National Defense Authorization Act of 2010**," and amended the reporting requirements for the Defense Nanotechnology Research and Development Program. The complete text of the amendment is below:

> AMENDMENT NO. 1472
>
> (Purpose: To modify the reporting requirement for the defense nanotechnology research and development program)
>
> At the end of subtitle D of title II, add the following:
>
> SEC. 252. MODIFICATION OF REPORTING REQUIREMENT FOR DEFENSE NANOTECHNOLOGY RESEARCH AND DEVELOPMENT PROGRAM.
>
> Section 246 of the Bob Stump National Defense Authorization Act for Fiscal Year 2003 (Public Law 107-314; 10 U.S.C. 2358 note) is amended by striking subsection (e) and inserting the following new subsection (e):
>
> (e) Reports.--The Under Secretary of Defense for Acquisition, Technology, and Logistics shall submit to the National Science and Technology Council information on the program that covers the information described in paragraphs (1) through (5) of section 2(d) of the 21st Century Nanotechnology Research and Development Act (15 U.S.C. 7501(d)) to be included in the annual report submitted by the Council under that section.

S. 1390 was amended during the course of debate in the Senate from June 14 until June 23, 2009. The Senate then voted to amend H.R. 2647, the House version of "The National Defense Authorization Act of 2010, by striking all the language on H.R. 2647 after the enacting clause and substituting the language of S. 1390 as amended. As discussed above, this was an amendment in the nature of a substitute.

After the Senate insisted on its amendment and the House had formally disagreed with the amendment, a Conference Committee was created and members selected by both the House and Senate. The Conference Report, H. Rept. 111-288 was delivered by the Conference Committee on Oct. 7, 2009 and adopted by the House the next day, following a short debate. The Senate voted to adopt the language of the Conference Report on Oct. 22, 2009. The bill was signed by President Obama on Oct. 29, 2009 and it became law as P.L. 111-84.

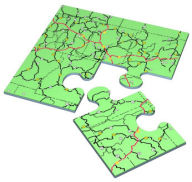
The language of SA 1472 remained unchanged in both the Conference Report and P.L. 111-84. It can be found as section 242 of Title ii, "Research, Development, Test and Evaluation."

As with the majority of the House bills, the Senate bills remain in committee. Considering the focus of Congress on health care reform, financial regulatory reform, and various appropriations bills that need to be passed, when and if these bills are reported out and voted on is unknown. We will continue to track these bills and others affecting nanotechnology that may be introduced in the future.

The NNCO would be required to "develop and maintain a database accessible by the public of projects funded under the Environmental, Health, and Safety, the Education and Societal Dimensions, and the Nanomanufacturing program component areas…including a description of each project…and its source of funding."

HR 554 National Nanotechnology Initiatives Amendments Act of 2009

Mapping Nano



In August, the Woodrow Wilson International Center for Scholars' Project on Emerging Nanotechnologies (PEN) released an updated version of its Nano Metro Map which depicts the U.S. metro areas with the largest concentrations of nano-based activity.

California and the New England - New York regions dominate, with the Research Triangle area of the Carolinas and Texas closely following. The map also shows the presence in all the continental states of at least one research facility, nanoindustry, etc. Nanotechnology has spread from the California and New England regions to become a truly national presence. You can find the map at: http://www.nanotechproject.org/inventories/map.

Flight of the Nanobees

A recent article by Neelesh R. Soman and other researchers at the Washington University School of Medicine in St. Louis and published online by the Journal of Clinical Investigation describes and discusses what the authors refer to as

> "a new paradigm for targeted delivery . . . of problematic classes of cell-penetrating peptides to kill cancer cells both in vitro and in vivo."

The article describes how the researchers created targeted nanostructures to deliver melittin, a toxin found in bees and usually transmitted to humans and other creatures via the stinger, leading to the nanostructures being dubbed "nanobees" in the university's press release.

As experiments with mice demonstrated, the nanobees had a dramatic effect on breast cancer cells, slowing growth by up to 25%, and on melanoma tumors, decreasing their size by up to 88%. Nanobees that never reached their targets accumulated in the spleen and liver, then passed harmlessly out of the body.

While the nanobees may be effective in treating cancer, the usual adverse side effects of chemotherapy or radiation therapy were not observed:

> "...we observe a dramatic lack of toxicity with melittin-loaded nanoparticles in our mouse studies in terms of changes in serum electrolytes, serum enzymes, or body weights even after repeated injections (total 7) at doses 4 times the LD of free melittin."

As the authors note:

> "Perfluorocarbon nanoparticles thus represent the first in a class of unique lipid-based delivery vehicles for melittin and other cytolytic peptides with broad spectrum and multimodal antivascular and antitumor actions that could be exploited for anticancer therapy."

Fruit Flies And Carbon Nanotubes

Environmental Science And Technology recently published an online article, "Differential Toxicity of Carbon Nanotubes in Drosophila: Larval Dietary Uptake is Benign, but Adult Exposure Causes Locomotor Impairment and Mortality," by Xinyuan Liu and a team of scientists from the Chemistry, Engineering, Ecology and Evolutionary Biology Departments and the Institute for Molecular and Nanoscale Innovation of Brown University. That article examined reactions to exposure to carbon nanotubes (cnts) in the larval and adult stages of the common fruit fly.

The experiments showed that fruit fly larvae, exposed to cnts since the time of their hatching could absorb and sequester the cnts in their bodily tissues with no evident toxic side effects, even at concentrations of cnts that were four times greater than what they would have encountered in a "normal" environment.

Adult fruit flies, on the other hand, were not so fortunate when exposed to powdered forms of nanoparticles, with effects ranging from a loss of the ability to climb out of a test tube, due to the nanoparticles adhering to the fruit flies' feet, to death. At lower levels of concentration and exposure, nanoparticles were found to be transmitted to unexposed adult flies via fly-to-fly contact and grooming behaviors.

Noting that flies have acted as disease vectors throughout human history, the authors observed that

> "In the environment, such transport and redeposition may bring nanoparticles into contract with humans or environmental receptors that would not otherwise be exposed."

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