MANAGING NANOPHOBIA

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NANOTECH PRODUCTS

There are 1,000+ manufacturer-identified nanotechnology-based consumer products currently on the market.

Nanotech Applied: Consumer Products

Already Contain:

- Personal watercraft
- Fabric softener
- “Anti-odor” socks
- Toothpaste
- Air purifiers
- Refrigerators
- Insulation
- Fishing Lures

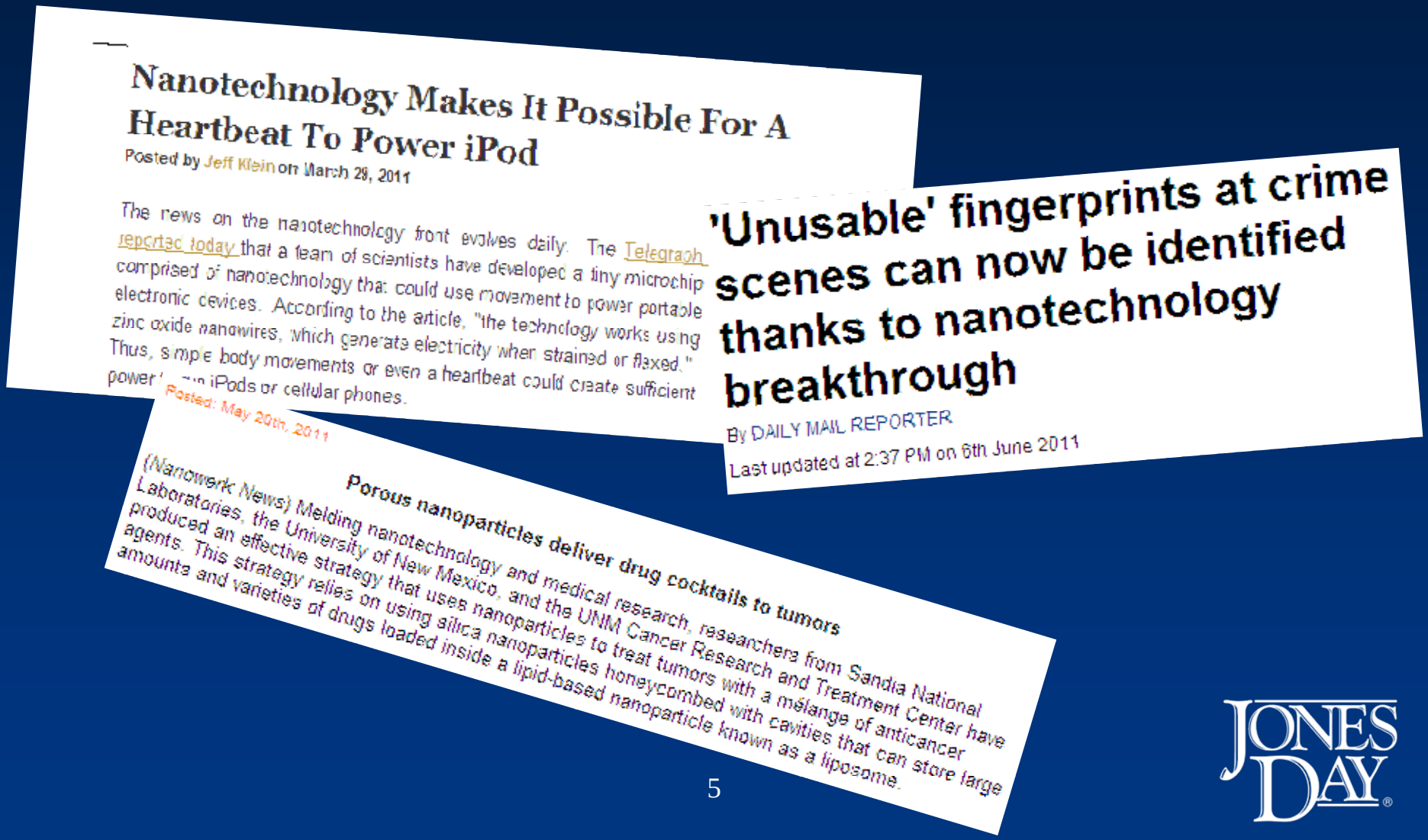
May Contain in the Future:

- Food storage containers
- Vitamins
- Plush toys
- Paint
- Bedding
- Towels
- Cleaners and degreasers
- Baby carriage and strollers

Current Industrial and Commercial Applications

- Drinking water filtration
- Wastewater treatment
- Food processing
- Circuit Boards
- Computer Chips
- Concrete
- Steel
- Glass
- Pigments
- Catalysts

Exploring New Frontiers



Nanotechnology Makes It Possible For A Heartbeat To Power iPod

Posted by Jeff Klein on March 29, 2011

The news on the nanotechnology front evolves daily. The Telegraph reportac today that a team of scientists have developed a tiny microchip comprised of nanotechnology that could use movement to power portable electronic devices. According to the article, "the technology works using zinc oxide nanowires, which generate electricity when strained or flexed." Thus, simple body movements or even a heartbeat could create sufficient power [illegible] iPods or cellular phones.

'Unusable' fingerprints at crime scenes can now be identified thanks to nanotechnology breakthrough

By DAILY MAIL REPORTER

Last updated at 2:37 PM on 6th June 2011

Posted: May 20th, 2011

Porous nanoparticles deliver drug cocktails to tumors

(Nanowerk News) Melding nanotechnology and medical research, researchers from Sandia National Laboratories, the University of New Mexico, and the UNM Cancer Research and Treatment Center have produced an effective strategy that uses nanoparticles to treat tumors with a mélange of anticancer agents. This strategy relies on using silica nanoparticles honeycombed with cavities that can store large amounts and varieties of drugs loaded inside a lipid-based nanoparticle known as a liposome.

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POTENTIAL RISKS

Few companies have comprehensively evaluated the risks that nanomaterials may present.

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Risk Management

Hazard Assessment

Must consider data from human epidemiological and clinical studies, experimental animal and in vitro studies, in silico studies. Increased research in recent years, yet data remains sparse.

Hazard Assessment

- Nanoscale materials often behave quite differently than the larger sized version.
- Nanoparticles are able to penetrate cells and cross the blood-brain barrier causing damage in ways the larger version of the chemical cannot.

Hazard Assessment

- Studies find nanomaterials (carbon tubes and titanium dioxide) carcinogenic in animals (respiratory uptake).
- German authorities determine studies are insufficient to find causal link, but say the information "[s]hould be taken seriously." (April 2010)

Research Unknowns: Environment and Human Health

- Hazard identification incomplete
- No reliable measurement technology to detect nanomaterials in different media.
- Difficulty isolating and studying effect of single nanomaterial.
- Dose-response curves for various nanomaterials undetermined.

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U.S. Government Sponsored Research

National Nanotechnology Initiative (NNI):

- The U.S. NNI coordinates multiagency efforts in nanotech science and will allocate $2.1 billion to 15 agencies in 2012.

Identified research needs:

- Understand processes and factors that determine exposure to nanomaterials.
- Identify population groups exposed to engineered nanomaterials
- Characterize individual exposures to nanomaterials.
- Conduct health surveillance of exposed populations

E.U. Government Sponsored Research

European Commission:

- The European Commission funds nanoparticles health and environmental impact projects and budgeted $2.6 billion for reserch and development in 2012.

Research areas include:

- Engineered Nanoparticle Impact on Aquatic Environments: Structure, Activity and Toxicology
- Risk Assessment of Engineered Nanoparticles
- Nanomaterials-related environmental pollution and health hazards throughout their life-cycle

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Japanese Government Sponsored Research

- Japan's Nanotechnology Research Institute is the core of diverse nanotechnology activities in the National Institute of Advanced Industrial Science and Technology.
- Government funded Japanese research is mostly focused upon developing future-generation computer chips.

Singaporean Government Sponsored Research

- Singapore's Agency for Science, Technology and Research collaborates with the Biomedical Research Council and its research institutes and consortia to develop nanotechnology drug and gene delivery, biosensors and biodevices, and pharmaceutical synthesis and nanobiotechnology.

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Managing Risk in an Absence of Data

- How do we properly manage risk without hazard identification, reliable measurement technologies and exposure data?

Caution: Expect the Unexpected

- "The first lesson learned is to expect the unexpected when you are dealing with technology, particularly one that has the potential of being life-threatening and ecologically disastrous."

Dick Thornburgh (commenting on 30th anniversary of Three Mile Island)

INTERSECTION OF LAW AND NANOTECHNOLOGY

Regulators are just beginning …

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Law in the Nanoproduct Lifecycle

- Intellectual property: patent, trademark, licensing
- Regulatory approvals and reporting requirements
- Workplace safety: OSHA, NIOSH
- Product and consumer liability
- Environmental discharges and disposal
- International regulation

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Legal Report Card

- No lawsuits.
- No reports to FDA of adverse events.
- Few proposals for specific laws and regulations.
- Emerging guidance and regulations.

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Executive Office of the President

- The White House issued a memo outlining policy principles concerning regulation of nanotechnology and materials. (June 2011)
- "Federal agencies should avoid making scientifically unfounded generalizations that categorically judge all applications of nanotechnology as intrinsically benign or harmful."

EPA: Toxic Substances Control Act (TSCA)

- Premanufacture Notification.
- Significant New Use Rules.
- Test Rules.
- Burden on EPA to show that a chemical is unsafe; different from REACH and FIFRA.
- Requires EPA to choose least burdensome regulatory action to mitigate risks.

TSCA §5 : Premanufacture Review

Premanufacture Review (TSCA §5)

- Chemicals are subject to premanufacture review if they are “new.”
- Chemicals are “new” if they are not on U.S. EPA’s TSCA Inventory.
- Many nanomaterials are just smaller versions of chemicals already on the Inventory.

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TSCA §5 : Premanufacture Review

- Recognizing that the smaller size may change the properties of a substance, U.S. EPA has determined that some nano-versions of existing chemicals are in fact "new."
- EPA classifies nanomaterials under TSCA based on their "molecular identities" rather than particle size or physical properties.

TSCA §5 : Significant New Use Rules ("SNURs")

- Significant New Use Rules under TSCA § 5(a) bind other entities (*e.g.*, manufacturers) to the same terms and conditions for that chemical.
- Because of subtle differences in nanostructures, manufacturers face uncertainty regarding whether they are subject to a SNUR.

EPA TSCA 2011 Agenda

- "A TSCA section 4(a) test rule may be needed to determine the health effects of multiwall carbon nanotubes."
- Propose TSCA § 8(a) rules to obtain information on the production volumes, methods of manufacture, uses, and exposures of nanoscale materials already in commerce.

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EPA TSCA 2011 Agenda

- New SNUR would require persons who intend to manufacture, import, or process new nanoscale materials based on chemical substances listed on the TSCA Inventory to submit a Significant New Use Notice (SNUN) to U.S. EPA at least 90 days before commencing the activity.

EPA: Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

- Regulates pesticides, including antimicrobials.
- EPA has expressed intent to regulate any products that release silver for antimicrobial purposes as pesticides.
- Nanosilver is used in numerous commercial products, including food storage containers, clothing, toys and electronics.

EPA: Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

- EPA wants to re-interpret FIFRA to obtain more information regarding what nanoscale material is present in a registered pesticide product and its potential.
- The EPA submitted one interpretation in June 2010 to OMB and issued a pre-publication notice of the first interpretation and an alternative in June 2011.

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EPA: Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

- Proposed § 6(a)(2) interpretation: the deliberate presence of an intentionally produced nanoscale material in a pesticide product would be reportable.
- Proposed § 3(c)(2)(B) interpretation: Use a data call-in (DCI) to force a pesticide registrant to identify nanomaterials in its products.

FDA Regulation

- Relatively unaggressive: “[N]ot apparent [nano] would have more inherent risk.”
- Stringent regulations for nanotechnology in medicine and medical technology.
- No active regulations for nanotechnologies used in cosmetics, food and dietary supplements. FDA maintains a voluntary disclosure list.

FDA: June 2011 Draft Guidance on Nanotechnology

- Contains no regulatory definition.
- Does not categorically judge nanomaterials or application of nanotechnology.
- Evaluations of safety, effectiveness or public health impact of nanotechnology should be based on property and behavior of the nanomaterial.

NIOSH and OSHA

- NIOSH and OSHA agreed to investigate and characterize the potential hazards of nanomaterials.
- In 2010 NIOSH proposed a recommended exposure limit of 7 micrograms per cubic meter of air for carbon **nano-tubes and nanofibers**.
- NIOSH expects to finalize in 2011.

NIOSH Recommendations

- Continuous sampling.
- Identify jobs where workers handle particles in bulk.
- Education.
- Provide hand washing facilities.
- Use light colored clothes and gloves to make dark nanotubes more visible.
- Engineering controls.
- PPE.

State and Local

- California has begun call-in of information from manufacturers of carbon nanotubes regarding, among other issues, analytical test methods and fate & transport.

- Cambridge, MA officials are developing “best practices” and providing “consumer-friendly” information on nanomaterials.

European Union: REACH

- Covers substances made or imported into the EU in quantities greater than one ton.

- Manufacturer/importer must provide relevant studies; argue for application to tests on other chemicals; or contend that test waiver criteria is satisfied.

Member State Regulation

- Netherlands: *Guidance on Working Safely with Nanomaterials and Nanoproducts* (May 2011)

- Step-by-step instructions for identifying and mitigating risks arising from engineered nanomaterials

LITIGATION: BACK-END REGULATION

Broad legal duties to design safe products, to test and to warn

Nanophobia Sources

- Perception of risk is driven by fear of the unknown and perceived absence of control.

- Fear leads to demand for medical monitoring without injury.

Risk Perception

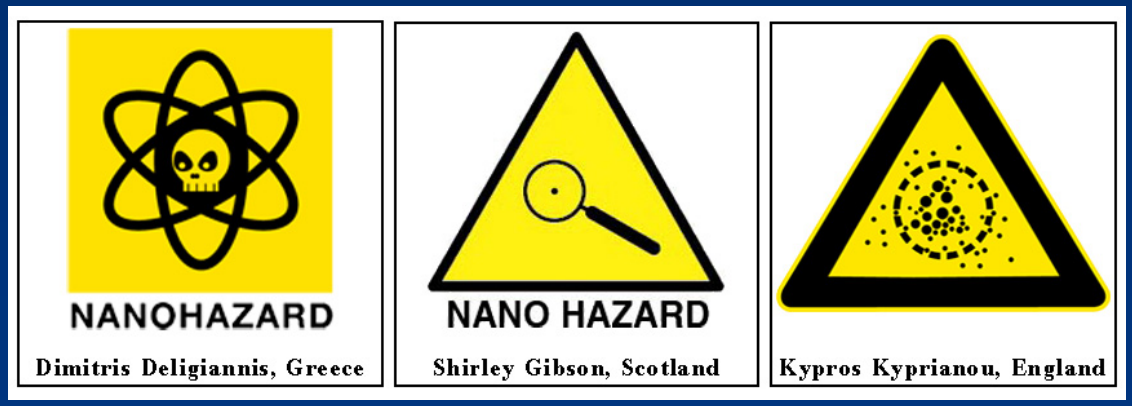
- Complex causation lends itself to “junk science” and *a priori* reasoning.

- Evolution in scientific knowledge creates risk of second-guessing foreseeability, reasonableness, and failure to test and disclose.

Advocacy Groups

- **ETC Group hosted a competition in 2007 to design a nanohazard symbol.**

Competition Winners:



PREPARE FOR CHANGE

Prudent risk managers and counsel should identify and address the foreseeable risks that nanomaterials may present.

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Insurance Portfolio

- Evaluate current policy for insurance coverage.
  - Many general liability policies may cover nanoproduct liability.
- Products coverage for BI and PD.
- Watch for new exclusions.
  - Recall coverage.
  - Environmental pollution exclusion.

Stay Informed

- Develop procedures to monitor developments.
- Conduct literature search on risks.
- Look to trade association guidance.

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Stay Informed

- Identify and follow relevant proposed rules.
- Know how any prior claims or lawsuits were handled.
- Check federal and state administrative dockets and hospital/injury-reporting databases for relevant consumer complaints.

Document Retention

- Carefully word memoranda and emails.
- Fairly describe risks and appropriately document any applicable studies.
- Avoid speculation and hyperbole.

Document Retention

- Appropriately address and document responses to any concerns, questions and dissents about product performance, environmental risk, or health & safety.
- Draft reasonable document retention policies and consistently implement them.

Be Part of the Discussion

- Help design reasonable design and testing standards.
- Submit comments if appropriate.
- Help design industry standards and guidelines.

Be Part of the Discussion

- Research issues and funding.
- Use PR and multiple media sources.

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PREVENTING LITIGATION

Good planning today can prevent or mitigate significant future litigation risks.

Reduce Work-related Exposure

- **Elimination**: Avoid using substance or process that causes exposure.
- **Substitution**: Change the material or process to one with lower risk.
- **Process Enclosure**: contain the activity or process that releases nanomaterials.

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Reduce Work-related Exposure

- **Engineering Control**: industrial ventilation.
- **Procedural Control**: reduce number of potentially exposed workers, or time spent on process.
- **Personal Protective Equipment**

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Research, Development and Testing

- Identify, test and address health and safety concerns.
- Consider alternative design feasibility.
- “Design out” foreseeable product risks.
- Test product for uses and misuses.

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Manufacturing and Quality Control

- Meet or exceed best manufacturing or quality control practices in the industry.

- Implement controls over materials, suppliers and contractors and enforce through contracts, inspections, testing and audits.

Manufacturing and Quality Control

- Conduct and record pre-shipping quality control tests. Appropriately set failure/defect rates.

- Design QC procedures/schedules to detect manufacturing defects at intended error rate.

Adequate Warnings and Instructions

- Consult experts in warnings and human factors.

- Test products with likely users to identify uses, misuses and risks. User training may be required.

Adequate Warnings and Instructions

- Warnings and instructions should acknowledge and explain that many risks are currently uncertain, unknown and unknowable because the products involve new technology.

- Warnings and instructions should be compared against those of competitors, literature, industry standards and regulatory guidelines.

Adequate Warnings and Instructions

- Warnings should extend beyond the original purchaser, if appropriate and feasible.
- Procedures should be established to receive and evaluate consumer complaints related to potential risks.

Express and Implied Warranties

- Express warranties, if any, should be limited to proven product performance and characteristics.
- Avoid express warranties regarding health or safety.
- Express warranties and representations can arise from advertising and sales promises.

Express and Implied Warranties

- Draft limitations of implied warranties, damages and remedies as broadly as permitted by law.
- Draft limitations to acknowledge unknown and unknowable risks, as well as uncertainty related to new technology.
- Develop procedures to analyze claims of warranty breach, and to modify warranties as appropriate.

Packaging, Distribution and Transport

- Evaluate for unusual risks associated with packaging or shipment and whether protective packaging may be needed.
- Packaging should contain appropriate warnings and instructions to prevent or mitigate product damage, as well as to address health or safety risks that might be encountered in shipment.

Packaging, Distribution and Transport

- Meet industry standards and regulatory guidelines regarding safe transport.
- Address environmental risks from spills and leaks.

Packaging, Distribution and Transport

- Appropriate indemnities from handlers and distributors.
- Analyze when risk of loss or injury passes to consumer.

Maintenance and Repair

- Explicit instructions for recommended inspection, maintenance and repair should be provided.
- If testing suggests any anticipated product life or expected shelf life, product instructions and warranties should be limited accordingly.

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Maintenance and Repair

- Warranties should be limited if instructions are not followed.
- Evaluate whether field personnel should provide inspection and repair, or whether the product will be returned to the manufacturer.

Preventing Litigation: Product Disposal

- Evaluate whether environmental risks have been tested and modeled, and to what degree that is possible.
- Evaluate whether disposal will implicate any environmental law or regulation.

Product Disposal

- Evaluate health and safety risks in transport of product waste for disposal.
- Instruct product users in safe disposal methods.
- Consider procedures to monitor field experience after product disposal. Will studies (either short- or long-term) be conducted?

Summary

- Compliance with regulations and industry standards, including agency reporting.
- Monitor competitors' products and scientific literature.
- Quality control and field experience.

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Crisis Management

- Design a plan to handle public, media, agency or legislative questions and investigations regarding product health and safety, recall or other crisis.
- Identify and train spokespersons.

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Crisis Management

- Implement protocol to notify all potentially applicable insurance carriers of a potential liability.
- Have insurance coverage counsel review potentially claimed liability in order to tailor notice to insurers and avoid inadvertently triggering coverage exclusions.

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Questions??

- Moellenberg and Juni, “A Practical Guide to Product Liability Risk for Nanotechnology,” BNA Toxics Law Reporter, March 5, 2009

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Resources

- National Nanotechnology Institute
  - http://nano.gov/publications-resources
- NIOSH: Nanoparticle Information Library
  - http://nanoparticlelibrary.net/index.asp

Resources

- NCI: Nanotechnology Characterization Laboratory
  - http://ncl.cancer.gov/
- NIST: Standard Reference Materials
  - http://www.nist.gov/srm/

Resources

- National Nanotechnology Coordination Office
  - http://www.nsti.org/outreach/NNCO/
- National Toxicology Program: Nanotechnology Safety Initiative
  - http://www.niehs.nih.gov/news/media/questions/sya-nano.cfm

Resources

- EPA White Paper: Nanotechnology Environmental Health Implications
  - http://www.epa.gov/osa/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf
- FDA Nanotechnology Task Force Report
  - http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/NanotechnologyTaskForceReport2007/default.htm

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Resources

- National Science and Technology Council, subcommittee on Nanoscale Science, Engineering and technology and its Nanotechnology Environmental health implications
  - http://www.nano.gov/NNI_EHS_Research_Strategy.pdf

Resources

- DuPont and Environmental Defense Fund: Nano Risk Framework June 2007
  - http://www.nanoriskframework.com/page.cfm?tagID=1095
- Woodrow Wilson International Center: Project on Emerging Nanotechnologies
  - http://www.nanotechproject.org/

Resources

- European Union: Publications
  - http://cordis.europa.eu/nanotechnology/src/publication_events.htm
- Royal Society and Royal Academy
  - http://royalsociety.org/

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