



REGULATORY AND LEGISLATIVE DEVELOPMENTS

European Commission Provides €488 Million for Nanotechnology Research

The EC has announced €7 billion to fund innovative research, €488 million of which will be allocated to nanotechnology research. Created under the EU's Seventh Framework Programme for Research (FP7), this funding package is at the centerpiece of a EU innovation strategy, the Innovation Union. The EC hopes to provide better support to bridge the research and market, and will fund activities such as demonstrating the commercial potential of new technologies.

Innovation Union homepage: http://ec.europa.eu/research/innovation-union/index_en.cfm

Nanotechnology Advancement New Opportunities Act (H.R. 2749) Introduced in the US House of Representatives

On 1 August 2011, Representative Mike Honda (D-CA) introduced the Nanotechnology Advancement New Opportunities Act (H.R. 2749). The bill intends to “promote the development and responsible stewardship of nanotechnology in the US” and addresses safety concerns regarding nanotechnology. It has been referred to the Committee on Science, Space, and Technology, and the Committees on Energy and Commerce, Ways and Means, and Homeland Security.

See text of bill at <http://www.opencongress.org/bill/112-h2749/show>

Hearings on Nanotechnology in US Congress

Both the US House of Representatives and Senate have held hearings on nanotechnology since the spring. Most recently, the Senate Commerce, Science, and Transportation Committee held a hearing titled “National Nanotechnology Investment: Manufacturing, Commercialization & Job Creation” on 14 July 2011. The hearing examined federal research initiatives, barriers to commercialization, possible health and safety risks, and possible steps for Congress to improve the return on nanotechnology investments.

Senate Committee on Commerce, Science, and Transportation homepage:

<http://commerce.senate.gov/public/index.cfm?p=ScienceandSpace>

National Nanotechnology Initiative Issues Four EHS Workshop Reports

The National Nanotechnology Initiative has released reports resulting from four EHS workshops focusing on the following areas, respectively:

1. Nanomaterials and Human Health & Instrumentation, Metrology, and Analytics
2. Nanomaterials and the Environment & Instrumentation, Metrology, and Analytics
3. Human and Environmental Exposure Assessment
4. Risk Management Methods and Ethical, Legal, and Societal Implications of Nanotechnology

See full press release at <http://www.nano.gov/node/648>

FDA Issues Draft “Identifying CDER’s Science and Research Needs Report”

This report identifies the current regulatory science needs that will guide CDER’s strategic planning of internal research initiatives and contributions to the development of agency regulatory science efforts. Topics highlighted include the following:

- Access to post-market data sources
- Risk management and management strategies to reinforce the safe use of drugs
- Effectiveness and impact of regulatory communications
- Product quality attributes, manufacturing processes, product performance
- Predictive models of safety and efficacy in humans
- Clinical trial design and analysis
- Individualization of patient treatment

Comments are due 26 September 2011.

See full report here: <http://www.fda.gov/Drugs/ScienceResearch/ucm264327.htm>

FDA Issues Draft Guidance “510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device”

This draft guidance clarifies when changes to a previous cleared 510(k) device require a new premarket submission. These include specific kinds of labeling changes, changes to the technology used in the device, changes in performance specifications, manufacturing changes, and changes in the materials used in the manufacture of the device. The draft guidance includes a special section on considerations for medical devices utilizing nanotechnology.

The draft guidance can be found here:

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM265349.pdf>

European Commission Plans to Issue Regulatory Definition of Nanomaterials

The EC has announced that it plans to adopt a regulatory definition of nanomaterials during the summer. The definition will be a nonbinding recommendation that can be used in member states and regulatory bodies. The EC intends to craft a flexible definition that can be applied across different sectors and regulatory contexts.

Netherlands Issues Paper “Risks Associated with Nanomaterials”

The Dutch delegation at the meeting of the Environmental Council of the EU presented a paper analyzing the potential hazards of nanomaterials for workers and consumers. The paper identifies the lack of a standard definition of nanomaterials as one of the key issues, and outlines three recommendations for the EC: 1) issue a broadly applicable definition of nanomaterials, 2) ensure traceability and a speedy response if a specific nanomaterial happens to be found hazardous, and 3) develop a risk assessment and management system for nanomaterials and products that utilize nanotechnology.

The paper can be found here:

<http://register.consilium.europa.eu/pdf/en/11/st11/st11626.en11.pdf>

EU Publishes Final Recast of the Directive on the Restriction of Hazardous Substances

The Directive calls for the substitution of hazardous substances by more “environmentally friendly alternatives.” In particular, the Directive states that hazardous

substances include “any substances of very small size or with a very small internal or surface structure (nanomaterials) which may be hazardous due to properties relating to their size or structure.”

The text is available at : [http://eur-](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0088:0110:EN:PDF)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0088:0110:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0088:0110:EN:PDF)

ObservatoryNANO issues 2011 Report on Developments in Nanotechnologies Regulation & Standards

The ObservatoryNANO project, funded under FP7 by EC until 1 April 2012, has published its 2011 report on “Developments in Nanotechnologies Regulation & Standards.” The report focuses on regulatory developments and standardization activities in the EU and certain third countries. The developments discussed in the report includes draft definitions of nanomaterials, review of applying chemical legislation to nanomaterials, identification of nanomaterials, and ISO standards.

The report can be found here:

http://www.observatorynano.eu/project/filesystem/files/DevelopmentsInNanotechnologiesRegulationandStandards_2011.pdf

REVIEWS AND OTHER PUBLICATIONS OF INTEREST

1. **Nanotoxicology and Nanoparticle Safety in Biomedical Designs.** International Journal of Nanomedicine, May 2011, Vol. 6, pp. 1117-1127. Ai J, Biazar E, Jafarpour M, Montazeri M, Majidi A, Aminifard S, Zafari M, Akbari HR, Rad HG
<http://www.dovepress.com/nanotoxicology-and-nanoparticle-safety-in-biomedical-designs-peer-reviewed-article-IJN>
2. **The Problem of Regulating Sophisticated Materials.** Nature Materials, August 2011, Vol. 10, No. 8, pp. 554-557. Andrew Maynard, Diana Bowman, and Graeme Hodge.
http://www.nature.com/nmat/journal/v10/n8/full/nmat3085.html?WT.ec_id=NMAT-201108
3. **How Stealthy are PEG-PLA Nanoparticles? An NIR *In Vivo* Study Combined with Detailed Size Measurements.** Pharmaceutical Research, Vol. 28, No. 8. Andreas Schädlich, Cornelia Rose, Judith Kuntsche, Henrike Caysa, Thomas Mueller, Achim Göpferich and Karsten Mäder.
<https://springerlink3.metapress.com/content/j9419512g7358wu3/resource-secured/?target=fulltext.html&sid=g2wnvw45wygi25qwdrxbox45&sh=www.springerlink.com>
4. **Experimental Validation of Atomic Force Microscopy-based Cell Elasticity Measurements.** Nanotechnology, 26 August 2011, Vol. 22, No. 34. Andrew R Harris and G T Charras. <http://iopscience.iop.org/0957-4484/22/34/345102>

5. **Bio-Synthesis of Gold Nanoparticles by Human Epithelial Cells, *in vivo*.** Nanotechnology, September 2011, Vol. 22, No. 35. E Larios-Rodriguez, C Rangel-Ayon, S J Castillo, G Zavala, and R Herrera-Urbina. <http://iopscience.iop.org/0957-4484/22/35/355601>
6. **Reengineering Translational Science: The Time is Right.** Science Translational Medicine, 6 July 2-011, Vol. 3, No. 90, pp. 90. Francis S. Collins. <http://stm.sciencemag.org/content/3/90/90cm17.abstract>

CONFERENCES AND WORKSHOPS

Biological Responses to Nanoscale Particles

September 11-15, 2011, Essen, Germany

- Organised by Priority Programme (SPP1313) of Deutsche Forschungsgemeinschaft (DFG) and University of Duisburg-Essen (UDE)
- Topics include interactions of nanoscale particles with biomolecules and membranes, mechanisms of cellular uptake and intercellular trafficking, biological impacts of nanoscale particles, synthesis and characterisation of nano particles, in-vivo and in-vitro imaging and diagnostic techniques, biodegradation of nanoscale particles, life cycle analysis and risk assessment

http://www.spp1313.de/website/program/general/programm_82/en/en_programm_univer_1.php

NANOCON 2011

September 21-23, 2011, Brno, Czech Republic

- Two sessions on biotechnology, nanomaterials in medicine, and health, safety and environmental challenges

<http://www.nanocon.cz/>

Nanoscale Bioceramics in Healthcare and High Performance Ceramics

October 12-13, 2011, Stoke-on-Trent, Staffordshire, UK

- Hosted by Institute of Nanotechnology and CERAM
- Focus on application of bioactive glass and ceramics to orthopaedics, regenerative medicine, dentistry, biosensing, controlled drug release, high performance coatings, and functionalized biomaterials.

<http://www.nano.org.uk/events/ion-events>

NanoDDS 2011

October 15-16, 2011, Salt Lake City, UT

- Advanced nanomaterials
- Theranostics
- Drug delivery
- Translational nanomedicine

<http://www.nanoinstitute.utah.edu/portal/site/nanoinstitute/menuitem.bd784eb820e465c65b2c5b69c1e916b9/?vgnnextoid=f5295a86d2a96210VgnVCM1000001c9e619bRCRD>

NanoMedicine – 2011

November 3 – 5, 2011, Shenzhen, China

- Breaking Research of Nanomedicines
- Versatile Nanotech and Nanomaterials in Biomedicine
- Nanodevices and Diagnostic
- Nanomedicine Targeting Major Diseases
- Regenerative Nanomedicine
- Culturing Public Environment for Healthy Growth

<http://www.bitconferences.com/NanoMedicine2011/>

IEEE International Conference on Nano/Molecular Medicine and Engineering

November 9-12, 2011, Jeju, South Korea

- Nano and molecular technologies in medical diagnosis and therapy
- Nanotechnology in drug delivery
- Biomedical imaging
- Nano and molecular technologies in medical diagnosis and therapy
- Nano-technology in drug delivery
- Biochips and Bio-MEMS
- Biomechatronics
- Biological interface
- Cell at the nanoscale
- Frontiers in nanobiotechnology

BioNanoTox and Applications International Research Conference

November 10-14, 2011, Mobile, AL

- Multidisciplinary focus on biology, nanotechnology, and toxicology
- Joint research between nanomaterials and biological systems

<http://sites.google.com/site/bntconference/>

International Conference on Biomedical Engineering

December 10-12, 2011, Manipal Karnataka, India

- Medical applications of nanotechnology one of focus areas

<http://uic.manipal.edu/icbme/#contact>

Nano Health

January 15-16, 2012, Egypt, Cairo

- To address the future of nanotechnology, as well as potential risks and regulatory issues
- New frontiers in drug delivery and therapeutics
- New frontiers in imaging and diagnosis
- Nanotechnology and the developing world
- Roadmapping new technologies
- Novel medical materials and products

<http://www.clocate.com/conference/Nano-Health-2012/13170>

IEEE International Conference on Nano/Micro Engineered and Molecular Systems

March 5-8, 2012, Kyoto, Japan

- Nanophotonics
- Nanomaterials

- Carbon nanotube based devices and systems
- Nanoscale robotics, assembly, and automation
- Molecular sensors, actuators, and systems
- Integration of MEMS/NEMS with molecular sensors/actuators
- Microfluidics and nanofluidics
- Micro and nano heat transfer
- Nanobiology, nano-bio-informatics, nanomedicine
- Micro and nano fabrication
- Micro/nano sensors and actuators
- Micro/nanoelectromechanical systems

http://www.ieee-nems.org/2012/general_info/introduction/

77th Prague Meetings on Macromolecules: Polymers in Medicine

July 8-12, 2012, Prague, Czech Republic

- Polymers for Nanomedicine
- Stimuli responsive polymers
- Polymers for Advanced Drug Delivery
- Polymers for Biomedical Applications
- Biomaterials for Tissue Engineering

<http://www.imc.cas.cz/sympo/pmm2012/>

REFERENCE SECTION

Nano Organizations

- National Center for Toxicological Research (NCTR): <http://www.fda.gov/AboutFDA/CentersOffices/NCTR/default.htm>
- National Nanotechnology Initiative (NNI): <http://www.nano.gov/>
- Nano Science and Technology Consortium (NSTC): <http://www.nstc.in/>
- Nano Science and Technology Institute (NSTI): <http://www.nsti.org/>
- The Nanotechnology Institute (NTI): <http://nanotechinstitute.org/>

Nano Journals

- American Chemical Society -- Nano Letters: <http://pubs.acs.org/journal/nalefd>
- Institute of Physics – Nanotechnology: <http://iopscience.iop.org/0957-4484/>
- Journal of Nanoscience and Nanotechnology: <http://www.aspbs.com/jnn/>
- NanoTrends - A Journal of Nanotechnology and its Applications: <http://www.nstc.in/journal/default.aspx>
- BCC Research -- Nanotechnology Reports: <http://www.bccresearch.com/index/category/code/nanotechnology>
- Nanomedicine: Nanotechnology, Biology, and Medicine: <http://www.nanomedjournal.com/home>
- Nanomedicine: <http://www.futuremedicine.com/page/about.jsp>

CONTACT

For further information, or if you have any questions about the Nanomedicines Alliance, please contact the Nanomedicines Alliance Secretariat at 1-202-230-5607 or info@nanomedicines-alliance.org

This newsletter is provided as a public service and resource to the scientific and regulatory community interested in nanomedicines. The mention of any organizations, conferences or other events in this newsletter IS FOR INFORMATIONAL PURPOSES ONLY and does not represent an endorsement by the Nanomedicines Alliance or any of its members.