



## MESSAGE FROM THE VICE CHAIR: FRANK MALINOSKI



I am honored to be elected as the Vice Chair of the Nanomedicines Alliance and to partner with Dr. Havel in guiding this important industry group. The Alliance plays a critical role in educating and communicating with pharmaceutical, regulatory, medical, and lay communities, and with the strong leadership of our organization we will continue to advance the field of nanomedicines.

Biography of Frank Malinoski, MD, PhD, Chief Medical Officer, Liquidia Technologies, Vice Chair, Nanomedicines Alliance

I received my BA from Colby College, my PhD from Rutgers University and the College of Medicine and Dentistry of NJ, and my medical degree from Albany Medical College. I served on active duty in the US Army for 7 years where I trained in clinical and regulatory affairs developing vaccines and small molecules for infectious disease threats faced by our troops. I started my career in the pharmaceutical industry at Lederle-Praxis (now part of Pfizer) developing vaccines for children, followed by work at Nabi in clinical and medical affairs for vaccines and immunotherapy, then Wyeth in a global medical affairs role, then MedImmune (now part of AstraZeneca). Currently, I serve as Chief Medical Officer Liquidia Technologies, a nanotechnology platform company in Research Triangle Park in NC that has been recognized for its innovative approach to nanomedicines. I have been fortunate to also work with a number of government agencies and NGOs in evaluating solutions for global medical problems and assisting the neediest populations.

## REGULATORY AND LEGISLATIVE DEVELOPMENTS

### **Proposed NIOSH Survey on Nanomaterial Risk Management Practices**

The National Institute for Occupational Safety and Health (NIOSH) has announced a proposed survey to evaluate the use of NIOSH guidelines and risk mitigation practices for safe handling of nanomaterials in the workplace. Comments on the survey are due by September 15.

<http://www.regulations.gov/#!docketDetail;D=CDC-2013-0010>

### **EU Nanomedicines Award**

The European Technology Platform for Nanomedicine (ETPN) has launched the Nanomedicines Award, intended to award international projects that provide “innovative solutions” and “new tools” for revolutionizing the medical field. The Review Board intends to evaluate proposals for both a Concept/Preclinical Award and a Clinical Award. The call for proposals ends September 7, 2013. Winners will be chosen in November.

<http://nanomedicine-award.com/>

*For further information, or if you have any questions about the Nanomedicines Alliance, please contact the Nanomedicines Alliance Secretariat at 1-202-230-5653.*

### Report on National Nanotechnology Initiative Workshop Released

The National Nanotechnology Initiative (NNI) has released a report on a workshop held on Portland, Oregon in May 2012. The NNI is a federal initiative established in 2000 to coordinate nanotechnology research and development. The report includes the workshop's recommendations on commercialization, collaboration, policy, support for regional, state, and local initiatives, and "roadmapping." The report also recommends next steps for nanotechnology.  
[http://www.nano.gov/sites/default/files/pub\\_resource/nni\\_rsl\\_2012\\_rpt\\_0.pdf](http://www.nano.gov/sites/default/files/pub_resource/nni_rsl_2012_rpt_0.pdf)

### European Commission Research Strategy for Nanosafety

The Finnish Institute of Health and the European Nanosafety Cluster have produced a strategy for nanomaterial safety research for the European Commission. The report is entitled "Nanosafety in Europe 2015-2025: Towards Safe and Sustainable Nanomaterials and Nanotechnology Innovations." The report addresses the regulatory framework, environmental health, international collaboration, and the communication of research to key stakeholders beyond the research community. Research is strongly needed in nanomaterial identification and classification, exposure and transformation, effects on human health and the environment, and tools for predictive risk assessment. The strategic goal of this research is to develop a "nano tool box" for exposure and risk assessment.  
[http://www.tti.fi/en/publications/Electronic\\_publications/Nano\\_safety\\_in\\_europe\\_2015-2025/Documents/nanosafety\\_2015-2025.pdf](http://www.tti.fi/en/publications/Electronic_publications/Nano_safety_in_europe_2015-2025/Documents/nanosafety_2015-2025.pdf)

### Austrian Nanotechnology Action Plan Progress Report

The Austrian government recently publicized a progress report on the implementation of its Nanotechnology Action Plan formed in 2010. The progress report was developed at the end of 2012 and has only now been made available for public review. Austria's Nano Information Portal is available [here](#) in German. The Austrian government will be reassessing the position of nanotechnology in 2015.  
[http://nanoinformation.at/uploads/media/Umsetzungsbericht\\_2012\\_EN.PDF](http://nanoinformation.at/uploads/media/Umsetzungsbericht_2012_EN.PDF)

### European Commission Opens Public Consultation on REACH Annexes on Nanomaterials

The European Commission has released a public consultation on modifications to the REACH Annexes on Nanomaterials. The consultation aims to "provide clearer REACH requirements for nanomaterials to ensure that industry demonstrates safe use." The Commission hopes to propose revisions in 2013 accompanied by an Impact Assessment. Comments are requested by September 13.  
[http://ec.europa.eu/environment/consultations/nanomaterials\\_2013\\_en.htm](http://ec.europa.eu/environment/consultations/nanomaterials_2013_en.htm)

### Triennial Review of the National Nanotechnology Initiative

The National Research Council has published a review of the National Nanotechnology Initiative (NNI) called for by 21st Century Nanotechnology Research and Development Act of 2003. This report assesses the progress of the NNI through technology transfer, mitigating the risks of nanotechnology, developing a nanotechnology workforce, and more. The report names five areas for improvement and gives several recommendations, such as posting data sets online to demonstrate success, working groups addressing specific goals and objectives, and strategic plans for initiative teams.  
[http://www.nap.edu/catalog.php?record\\_id=18271&utm\\_medium=email&utm\\_source=National%20Academies&utm\\_campaign=05132013WhatsNews&utm\\_content=Web&utm\\_term=#toc](http://www.nap.edu/catalog.php?record_id=18271&utm_medium=email&utm_source=National%20Academies&utm_campaign=05132013WhatsNews&utm_content=Web&utm_term=#toc)

### FDA recently co-authored articles about nanomaterials:

**Continuing to strengthen FDA's science approach to emerging technologies.** Nanomedicine: Nanotechnology, Biology, and Medicine, July 2013, Vol. 9, Issue 5, pp. 594-599. Rachael Anatol, Steven Bauer, Suzanne Epstein, Ross Filice, Kristina Lauritsen, Mark H. Lee, Elizabeth Mansfield, Michelle McMurry-Heath, Joseph Milone, Carlos Peña, Steven Pollack, Issam Zineh.  
[http://www.nanomedjournal.com/article/S1549-9634\(13\)00177-9/abstract?elsca1=etoc&elsca2=email&elsca3=1549-9634\\_201307\\_9\\_5&elsca4=internal\\_family\\_medicine](http://www.nanomedjournal.com/article/S1549-9634(13)00177-9/abstract?elsca1=etoc&elsca2=email&elsca3=1549-9634_201307_9_5&elsca4=internal_family_medicine)

**CDER Risk Assessment Exercise to Evaluate Potential Risks from the Use of Nanomaterials in Drug Products.** AAPs Journal, July 2013, Vol. 15, Issue 3, pp. 623-628. Celia N. Cruz, Katherine M. Tyner, Lydia Velazquez, Kenneth C. Hyams, Abigail Jacobs, Arthur B. Shaw, Wenlei Jiang, Robert Lionberger, Peter Hinderling, Yoon Kong, Paul C. Brown, Tapash Ghosh, Caroline Strasinger, Sandra Suarez-Sharp, Don Henry, Maat Van Uitert, Nakissa Sadrieh, Elaine Morefield.  
[http://link.springer.com/article/10.1208/s12248-013-9466-6?wt\\_mc=alerts.TOCjournals.12248](http://link.springer.com/article/10.1208/s12248-013-9466-6?wt_mc=alerts.TOCjournals.12248)

## REVIEWS AND OTHER PUBLICATIONS OF INTEREST

### **Magnetic field triggered drug release from polymersomes for cancer therapeutics.**

Journal of Controlled Release, June 2013, Vol. 169, Issue 3, pp. 165-170. Hugo Oliveiraa, Encarnación Pérez-Andrés, Julie Thevenota, Olivier Sandrea, Eurne Berrac, Sébastien Lecommandouxa.  
<http://www.sciencedirect.com/science/article/pii/S0168365913000308>

### **Can bioadhesive nanoparticles allow for more effective particle uptake from the small intestine?**

Journal of Controlled Release, June 2013, J. Reineke, D.Y. Cho, Y.L. Dingle, P. Cheifetz, B. Laulich, D. Lavin, S. Furtado, E. Mathiowitz.  
<http://www.sciencedirect.com/science/article/pii/S0168365913003544>

### **Nanoparticle toxicity by the gastrointestinal route: evidence and knowledge gaps.**

International Journal of Biomedical Nanoscience and Nanotechnology, 2013, Vol. 3, No. 1/2, pp. 163-210. Ingrid L. Bergin, Frank A. Witzmann.  
<http://www.inderscience.com/info/inarticle.php?artid=54515>

### **Using shape effects to target antibody-coated nanoparticles to lung and brain endothelium.**

PNAS, June 2013, Vol. 110 No.

26, pp. 10753-10758. Poornima Kolhara, Aaron C. Anselmo, Vivek Gupta, Kapil Pant, Balabhaskar Prabhakarandian, Erkki Ruoslahti, and Samir Mitragotria.

<http://www.pnas.org/content/110/26/10753>

### **Three-Dimensional Nanolithography Using Light Scattering from Colloidal Particles.**

ACS Nano, June 2013, Xu A. Zhang, Jonathan Elek, and Chih-Hao Chang.

<http://pubs.acs.org/doi/abs/10.1021/nn402637a>

### **Solution-based circuits enable rapid and multiplexed pathogen detection.**

Nature Communications, June 2013, Vol. 4, Brian Lam, Jagotamoy Das, Richard D. Holmes, Ludovic Live, Andrew Sage, Edward H. Sargent, Shana O. Kelley.

<http://www.nature.com/ncomms/2013/130612/ncomms3001/full/ncomms3001.html>

### **Nanoparticles Do Not Penetrate Human Skin—A Theoretical Perspective.**

Springer AAPS Journal Pharmaceutical Research, August 2013, Vol. 30, Issue 8, pp. 1943-1946. Adam C. Watkinson, Annette L. Bunge, Jonathan Hadgraft, Majella E. Lane.

[http://link.springer.com/article/10.1007/s11095-013-1073-9?wt\\_mc=alerts.TOCjournals.11095](http://link.springer.com/article/10.1007/s11095-013-1073-9?wt_mc=alerts.TOCjournals.11095)

## CONFERENCES AND WORKSHOPS

### **Cancer Nanotechnology, July 14-19, 2013, West Dover, VT, USA**

Materials synthesis  
Characterization  
Biocompatibility

<http://www.grc.org/programs.aspx?year=2013&program=cancnano>

### **NanoGagliato, July 25-30, 2013, Gagliato, Italy**

Nanomedicine  
Nanobionics  
Theranostics  
Transport Oncophysics

<http://www.nanoqagliato.org/>

### **ICANM 2013: Advanced and Nanomaterials Conference, August 12-14, 2013, Quebec, Canada**

Nanomedicines  
Nanobiotechnology  
Nanotoxicology

<http://www.iaemm.com/ICANM2013/>

### **NanoForum, September 18-20, 2013, Rome Italy**

Nanomedicines  
Nanotoxicology

<http://www.nanoforum.it/convegno/conference>

### **Pharmaceutical Nanotechnology Congregation 2013, October 15-16, 2013, London, UK**

Manufacturing  
Applications  
Regulatory Considerations  
Nanotechnology in Healthcare

<http://www.etp-nanomedicine.eu/public/news-events/events/pharmaceutical-nanotechnology-congregation-2013>

### **Nanocon 2013, October 16-18, 2013, Brno, Czech Republic**

Bionanotechnology  
Antibacterial materials  
Molecular analysis  
Anti-tumor therapy

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Targeted drug transport  
Tissue engineering  
Nano-implants  
<http://www.nanocon.eu/en/>

**6th International Symposium on Nanotechnology, Occupational and Environmental Health, October 28-31, 2013, Nagoya, Japan**

Nanomaterial processing and characterization  
Health effects and toxicity  
ADME  
Environmental toxicity  
Risk assessment and management  
<http://square.umin.ac.jp/nanoeh6/index.html>

**Carbon-Based Nano-Materials and Devices, November 3-8, 2013, Hualien, Taiwan**

Synthesis of carbon-based nanomaterials  
Characterization and processing of carbon-based nanomaterials  
Devices and Applications of carbon-based nanomaterials

Multiscale modeling and computation  
<http://www.engconfintl.org/13ap.html>

**2013 AAPS Annual Meeting Short Course #2: Quality Control of Nano Particulate Drugs: Manufacturing, Characterization, and Regulatory Considerations, November 10, 2013, San Antonio, Texas, USA**

Manufacturing Methods  
Regulatory Perspectives  
Physical/Chemical Stability  
Standards Development  
<http://www.nxtbook.com/nxtbooks/aaps/annualmeeting2013/preprogram/#/114>

**NanoBIG: Nanotechnology in Healthcare, December 5-6, 2013, San Diego, CA**

Nanocomposites  
Medical devices  
Preventive healthcare applications  
<http://www.tcbi.org/files/brochures/nanoBIGSanDiegoInformation.pdf>

## REFERENCE SECTION

### Nanobio- and Nanomedicine Companies

Listed alphabetically:  
[http://www.nanowerk.com/nanotechnology/nanomaterial/nanobiomedicine\\_a.php](http://www.nanowerk.com/nanotechnology/nanomaterial/nanobiomedicine_a.php)

### 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/home0>

Nanomedicine:  
<http://www.futuremedicine.com/page/about.jsp>

Nature Nanotechnology:  
[http://www.nature.com/nnano/focus/highlights/index.html?WT.mc\\_id=NM1110CT01](http://www.nature.com/nnano/focus/highlights/index.html?WT.mc_id=NM1110CT01)

## CONTACT

For further information, or if you have any questions about the Nanomedicines Alliance, please contact the Nanomedicines Alliance Secretariat at 1-202-230-5653 or [info@nanomedicines-alliance.org](mailto:info@nanomedicines-alliance.org).

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