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NanoSafety
Consortium for
Carbon
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INTERTOX

Credentials – John Monica

porterwright

George Washington
J.D. with Honors '91

Northwestern
B.A. '87

Member
DC, VA,
MD, and
OH Bars.

A Nanotechnology Legal Framework in **Nanotechnology Environmental Health and Safety**, (Elsevier 2009)

Nanotechnology Law, (West 2009)

Considerations for Implementation of Manufactured Nanomaterial Policy and Governance in **Nanomaterials Risks and Benefits**, NATO Science for Peace and Security Series C: Environmental Security, (Springer 2008)

"Examples of Recent EPA Regulation of Nanoscale Materials Under the Toxic Substances Control Act," Nanotechnology Law & Business, Oct. 2009

"A Nano-Mesothelioma False Alarm," Nanotechnology Law & Business, Oct. 2008

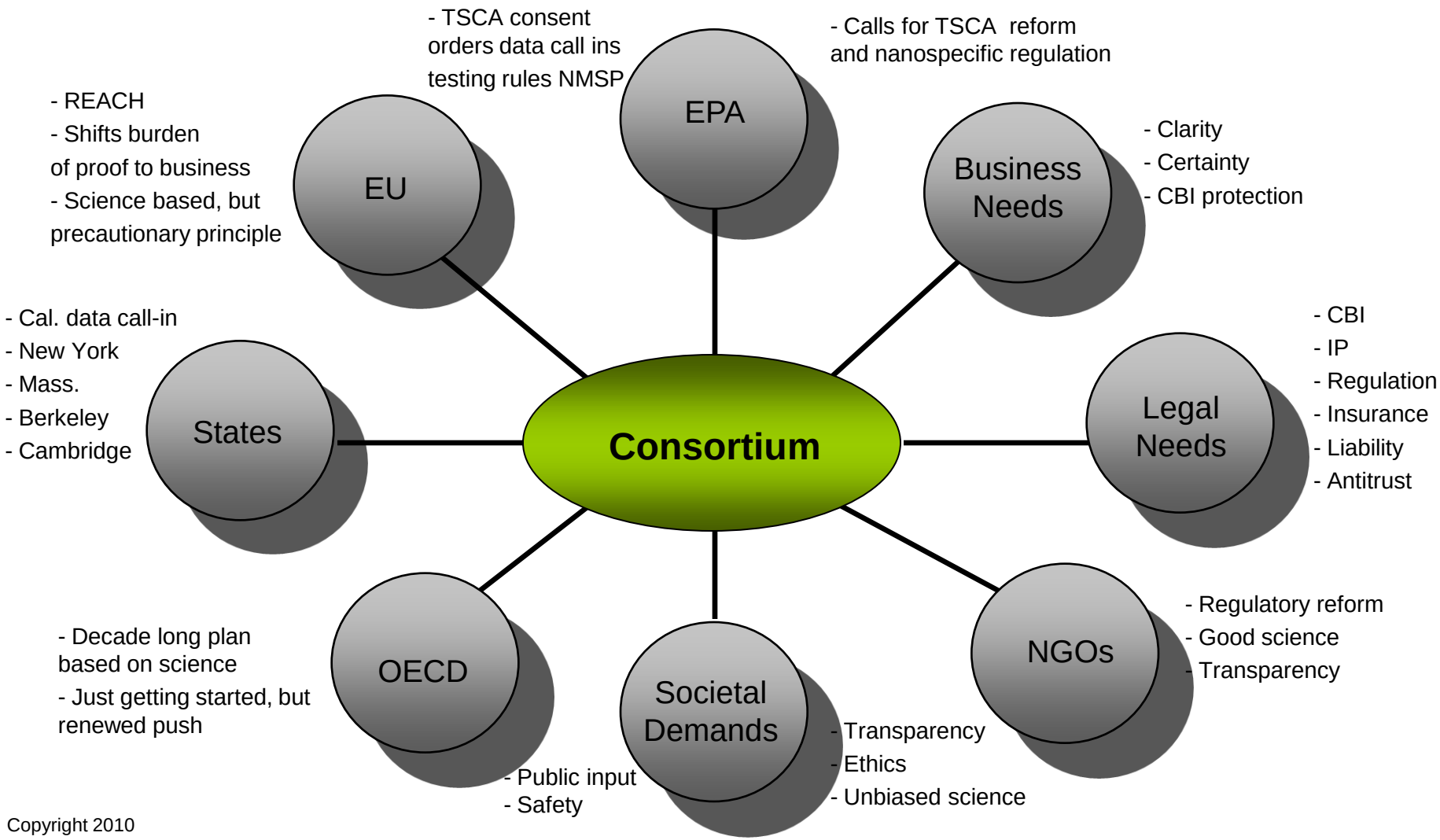
"FDA Labeling of Cosmetics Containing Nanoscale Materials," Nanotechnology Law & Business, Feb. 2008

"Ramping up the EPA's Nanoscale Materials Stewardship Program," Small Times Magazine, Vol. 7, No. 5, Sept./Oct. 2007

"Preparing for Future Health Litigation: The Application of Products Liability Law to Nanotechnology," Nanotechnology Law & Business, Feb. 2006

http://tinyurl.com/jmcredentials

Regulatory Environment



Initial Members

Angstron Materials
Applied Sciences
Continental Carbon Nanotechnologies
Cheap Tubes
Eikos
Nano-C
NanoLab
Nanoshel
Pyrograf Products
SouthWest NanoTechnologies
Unidym
XG Sciences

Current Advisory Board

Vince Castranova -- National Institute for Occupational Safety and Health

Steffi Friedrichs -- Nanotechnology Industries Association

Chuck Geraci --National Institute for Occupational Safety and Health

Bettye Maddux, Ph.D. -- University of Oregon

Jeffrey Morse -- University of Massachusetts, Amherst

Günter Oberdörster -- University of Rochester

Mark Tuominen --University of Massachusetts, Amherst

Developing Bottlenecks

Regulatory Bottleneck
(EPA)

Commercialization Bottleneck
(Customers and public)

Contention: Given their small size and unique properties, carbon nanomaterials may pose unacceptable environmental, health, and safety risks because they can theoretically enter the environment and biological matricies in novel ways and cause extensive damage once there.

Less artfully . . . carbon nanomaterials may be the next “asbestos.”

Persistent drip of studies lacking a common reference point or consistency of approach.

Typical TSCA CNT Consent Order

II.SUMMARY OF TERMS OF THE ORDER

The Consent Order for this PMN substance requires the Company to:

(1) Deliver to EPA a 1 gram sample of the PMN substance along with a copy of MSDS;

(2) Submit to EPA the results of a 90-day inhalation toxicity study in rats with a post exposure observation period of up to 3 months, including bronchoalveolar lavage fluid ("BALF") analysis (OPPTS 870.3465 or OECD 413) at least 14 weeks before either (a) manufacturing or importing a total of [ ] kg of the PMN substance, or (b) [ ] years [ ] months after commencing non-exempt commercial manufacture of the PMN substance, whichever comes first. The production/time limit shall be calculated from a date 2 years after signing this Consent Order by the Company,

(3) Within 6 months of commencing non-exempt commercial manufacture of the PMN substance, submit certain material characterization data;

(4) Use gloves impervious to nanoscale particles and chemical protective clothing;

(5) Use a NIOSH–approved full-face respirator with an N -100 cartridge while exposed by inhalation in the work area;

(6) Use the PMN substance only as a [ ];

(7) distribute the PMN substance only to a person who agrees to follow the same restrictions (except the testing requirements); and

(8) maintain certain records.

Basic Concept

Be proactive and address the issue head-on while there is still time.

Create a consortium of companies to conduct joint *in vivo* toxicity testing of a representative set of carbon nanomaterials in order to satisfy EPA regulatory requirements and also to alleviate developing commercialization bottlenecks. Testing will also be coordinated with interested foreign regulatory bodies as appropriate.

The consortium will consist of manufacturers, suppliers, distributors, and industrial users of carbon nanomaterials. The consortium shall be open to all businesses for which carbon nanomaterials constitute a material part of the business plans.

The consortium will be assisted by NIST, NIOSH, select universities, pertinent chemical and nanotechnology associations, and interested non-governmental organizations.

Why Consortium?

Control own fate.	Potential government/public funding got testing and publication.
Enhanced credibility and transparency.	Shared administrative costs, expertise, and experiences.
Being part of a group of leaders in the field.	Minimize potential of rogue test findings.
Comprehensive approach to global regulatory needs.	NIST – Best and most credible material characterization experts.
Enhanced dialogue with EPA and other regulatory bodies.	NIOSH – Best and most credible inhalation experts.
Public dissemination of project and results.	Ability to conduct testing on a representative suite of materials.
Antitrust and other legal protections.	Support of universities, associations, and NGOs.

Benefits

Ensuring compliance with all pertinent federal and state laws.

Benefits

Ensuring that research will satisfy Toxic Substances Control Act regulatory and legal requirements.

Benefits

Consortium can be used for additional testing if regulatory and commercialization needs change.

Consortium can be used to address
TSCA Section 4 Testing Rules
TSCA Section 8 Data Collection Rules

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CINCINNATI
CLEVELAND
COLUMBUS
DAYTON
NAPLES
WASHINGTON, DC

March 26, 2010

Mr. James Alwood
Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Room 4133J, Mail Code 7405M
Washington, DC 20460

Dear Jim:

I wanted to let you know about a new group of nanotechnology companies that Porter Wright and Intertox has pulled together to focus on potential environmental, health, and safety issues related to the commercialization of carbon nanomaterials. Our group has named itself the NanoSafety Consortium for Carbon (NCC), and you can learn more about what we are doing on our website -- **www.nanosafetyconsortium.com**.

While NCC has a very broad focus, our initial objective is to reach out to EPA to pursue the potential development of a mutually agreeable testing regime for a suite of representative carbon nanomaterials to fulfill the toxicity testing requirements of any TSCA consent order applicable to our members' existing carbon nanomaterials.

As part of any overall representative testing regime, we would also like to develop a mutually agreeable approach which allows a reasonable range of modification to members' products without requiring renewed comprehensive toxicity testing.

Additionally, at the appropriate juncture, we would like to provide your office with our perspective on the scope of any data-call-ins or testing rules which might be issued for carbon nanomaterials under Sections 4 or 8 of TSCA.

We know that these are very difficult and complicated issues, but we believe they are important for NCC to pursue in a unified fashion in order to address public health and safety issues and, at the same time, provide a predictable path for the responsible development of our members' products. Our hope is that EPA will agree to work with NCC to achieve towards these goals.

If you are available, I would like to set up a meeting with you to discuss the consortium in person. Please let me know a convenient date and time for a meeting at or near your office.

Finally, for your consideration, NCC is comprised of the following initial participants: Angstron Materials, Inc.; Applied Sciences, Inc.; CheapTubes; Continental Carbon Nanotechnologies, Inc.; Eikos, Nano-C; NanoLab; Nanoshel; Pyrograf Products; SouthWest NanoTechnologies; Unidym; and XG Sciences. Additionally, the following individuals have agreed to serve on NCC's Advisory Board: Chuck Geraci (NIOSH); Vince Castranova (NIOSH);

ML-41484

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MAY 5 2010

Mr. John C. Monica, Jr.
Porter Wright
1919 Pennsylvania Ave NW
Suite 500
Washington, DC 20006-3434

Dear John:

I received your letter dated March 26, 2010 regarding the NanoSafety Consortium for Carbon (NCC). EPA has successfully worked with numerous other industry groups in the past to address mutual environmental health and safety testing issues that affect a consortium of companies. The advisory board you have formed to address scientific issues may prove to be especially beneficial regarding testing of nanoscale materials.

EPA looks forward to working with NCC on the issues you have identified in your letter. EPA agrees that addressing these issues will be difficult and complex to work through. As you and I have discussed, TSCA section 5(e) consent orders for carbon nanotubes specifically encourage consortia of companies to develop alternative testing for a representative set of carbon nanotubes. The consent orders also state that EPA would consider accepting the results of such testing in lieu of triggered testing in this order. We welcome the chance to work with NCC on using this same approach with its members.

I will be in touch with you to discuss how NCC can develop and bring forward concrete proposals.

Sincerely,

James Alwood

James Alwood

NanoSafety Consortium
FOR CARBON

DRAFT

To: James Alwood, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency

From: John C. Monica, Jr.

Date: June 4, 2010

Re: Basic Product Descriptions for Potential Inclusion in Theoretical Nanocarbon Testing Regime (Draft)

Product	Description
MWCNT	35-50nm in diameter; aspect ratios of 100/1-200/1
	50-150nm in diameter; aspect ratio of 100/1
	140-240nm in diameter; aspect ratio of 15/1
	400-600nm in diameter; aspect ratio of 13/1
	15-30nm in diameter; 1-20 microns in length
	4-12nm in diameter; 3-30 microns in length
	6-9nm in diameter; 1 micron in length
DWCNT	1.5 to 4 nm diameter (range of aspect ratios)
	4nm in diameter; 1-5 microns in length
SWCNT	0.7 to 3 nm diameter (range of aspect ratios)
	1-15nm in diameter; 10 microns in length
	2nm in diameter; 3-30 microns in length
	1.01nm in diameter; aspect ratio of 1000/1

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Product	Description
	.8-1.2nm in diameter; 100-1000nm in length
	1nm in diameter; several microns in length
CNT Hybrids	(Proprietary blends of CNT and non-tubular carbon structures such as carbon black).
Tailored Fullerene Nanotubes	(application specific grades)
Carbon nanofiber	Stacked hats; 10 - 200nm in diameter; 50-100 microns in length
C60 fullerenes	
C70 fullerenes	
Nanographene platelets	Flakes/sheets; 0.5nm - 100nm thick

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Questions?

www.nanosafetyconsortium.com