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THE GEORGE WASHINGTON UNIVERSITY
LAW SCHOOL

Nanotechnology Governance

A Hard Law—Soft Law Amalgam

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Governance

- More than just regulation
  - ➢Nature of the problems--Change moving faster than government can move
  - ➢Limitations on government resources
  - ➢Demands by publics to be more involved
  - ➢Behavior being driven more than ever by reputation and social media

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Integrated Governance

- Innovative Governance Models for Emerging Technologies
- An integrated approach to governance
- Hard Law
  - Government regulation
  - Liability

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Integrated Governance

- Soft Law
  - Gov’t technical Assistance
  - International standards
  - Codes of Conduct
  - Supply chain requirements
- Public engagement

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Integrated Governance

- Integrated governance relies on internal economics (reputation, consumer demands, investor pressure, risk management strategies, etc) and values to drive desired behavior rather than just regulation

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Nanotechnology

- Late 2000s
- Explosion of new products and concerns
- Lots of uncertainties about health and environmental impacts, and how to manage risk
- Some NGOs call for a moratorium

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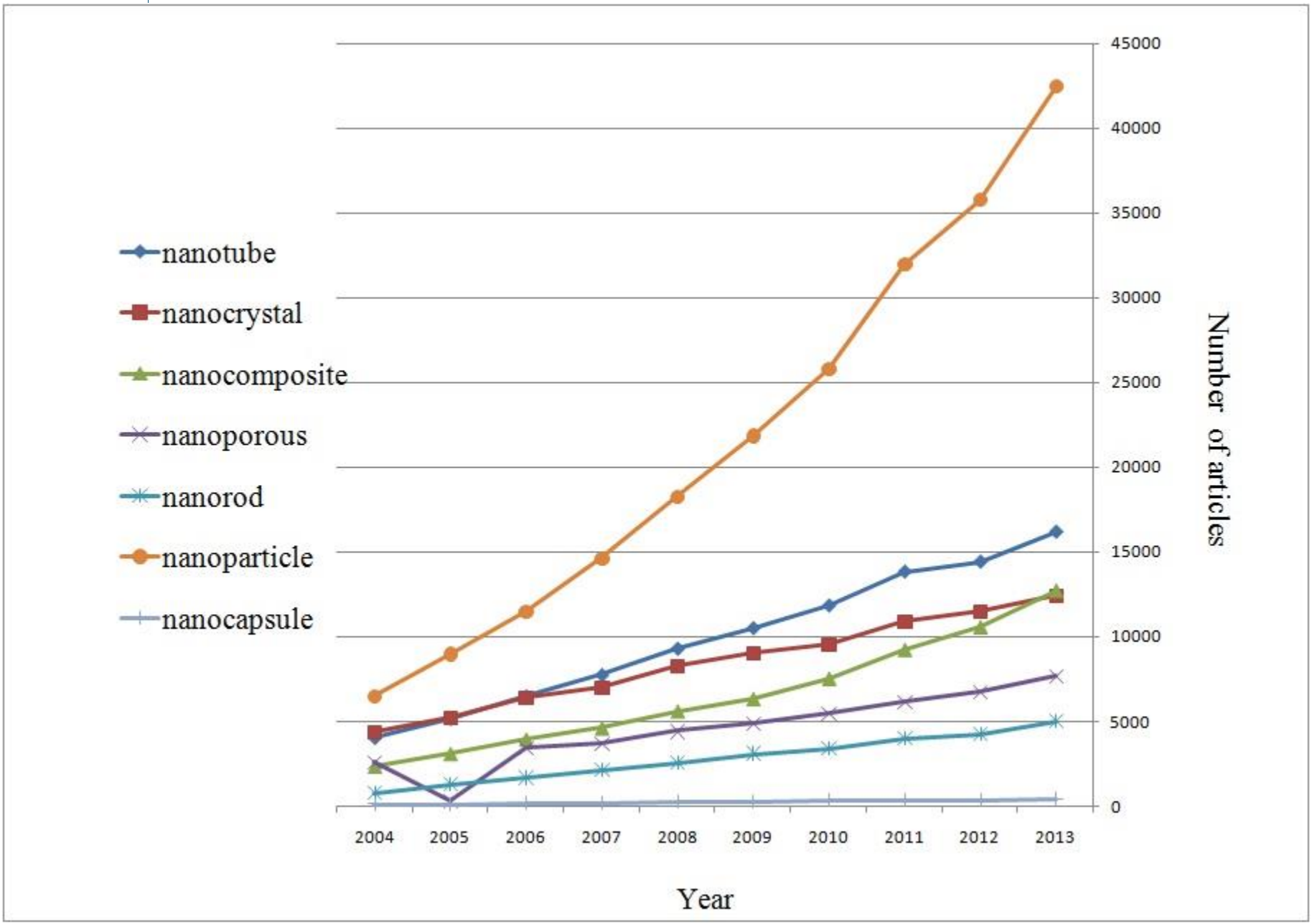
Growth in products

- Woodrow Wilson Center
  - 2005 54
  - 2009 1015
  - 2014 1814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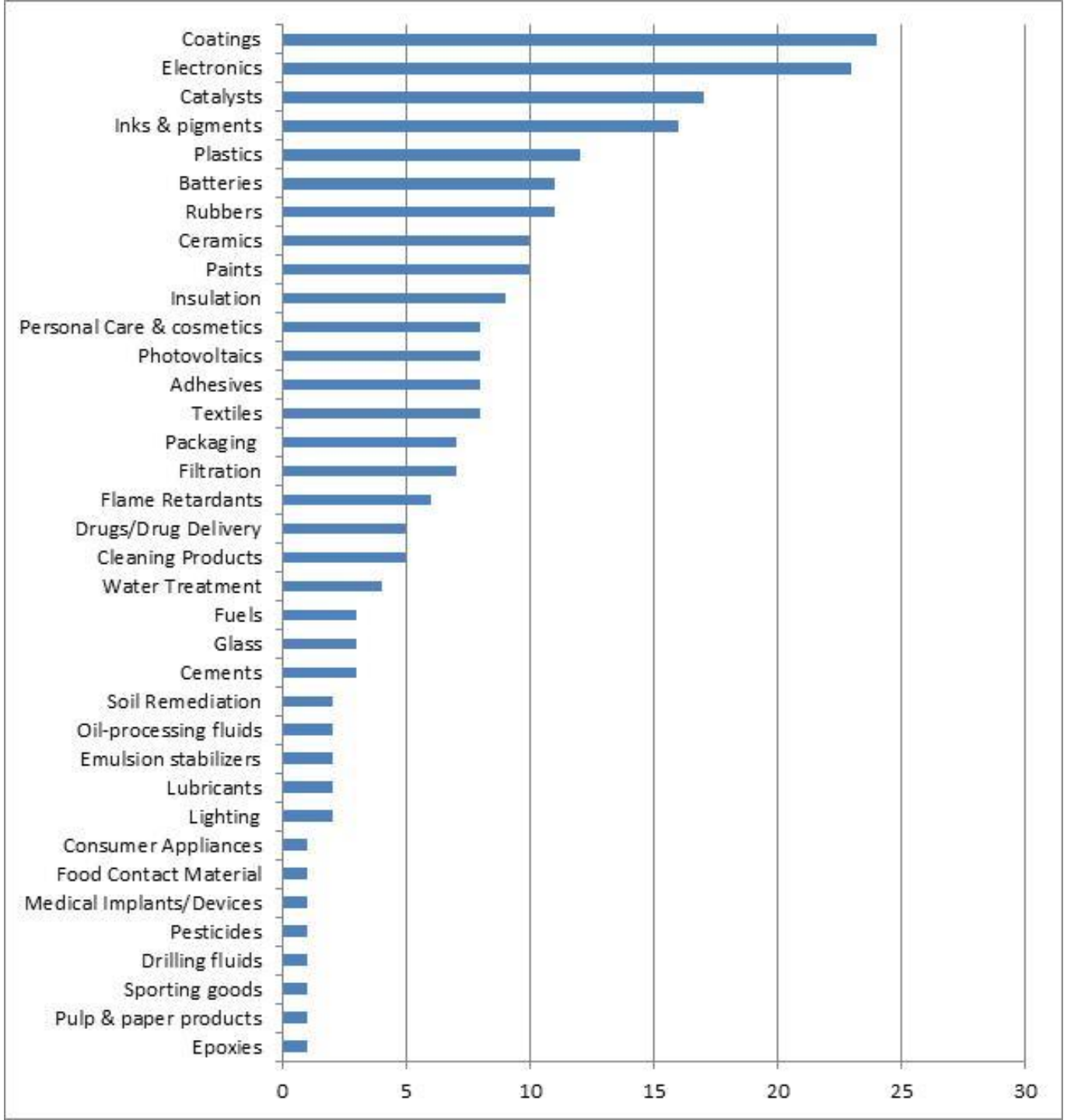
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Personal Care & cosmetics
Photovoltaics
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Textiles
Packaging
Filtration
Flame Retardants
Drugs/Drug Delivery
Cleaning Products
Water Treatment
Fuels
Glass
Cements
Soil Remediation
Oil-processing fluids
Emulsion stabilizers
Lubricants
Lighting
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Food Contact Material
Medical Implants/Devices
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Drilling fluids
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Health Concerns Remain

- No major problem has emerged but….
- NIOSH 2015—information still lacking
  - Occupational—inhalation the greatest risk
  - No nanospecific OSHA regulations
- OECD–"There is still much to learn before our understanding of the safe use of manufactured nanomaterials is sufficient"

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Gov't Regulation

- Maturing but limited
  - EPA TSCA
    - New chemical substance notices (160 since 2005)
    - Some regulatory requirements such as personal protection and limiting environmental releases
    - Proposed 8(a) rule—one time notification and information requirements for nanoscale materials already in commerce

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Gov't Regulation

- FIFRA
  - Approvals for nanosilver pesticide products
  - Litigation related to these approvals
- FDA
  - Guidance documents including safety of nanomaterials in cosmetics, food substances, and in food for animals

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Gov't Regulation

- CPSC-Proposed Center for Consumer Product Applications and Safety Implications of Nanotechnology
- France, Belgium, Denmark—annual inventories
- REACH
  - Quantity threshold relatively high but once in subject to normal REACH requirements

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Gov't Regulation

- July 2, 2015 Executive Memorandum requiring reexamination of agency roles in managing the risks related to biotechnology
- Framing Nano Report in 2009 called for an adaptive regulatory process--"[N]anoregulation must be regarded as a dynamic affair which must adapt to the evolution of scientific knowledge and applications and public attitude. A continuous updating must be part of the governance of nanotechnology."

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Gov't Assistance

- NIOSH—Nanotechnology Research Center
- Massachusetts Office of Technical Assistance and Technology—"Considerations for Safe Development" of nanotechnology
- ACGIH—American Conference of Government Industrial Hygienists
  - Nanotechnology: Environmental Implications and Solutions

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International Standards

- ISO
- 2005--TC 229
- ISO/TR 12885 Health and Safety Practices in occupational Settings
- 2011 Guidelines for Evaluating Nano Risks (based on DuPont—EDF Framework)

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Codes of Conduct

- DuPont—EDF (2007) Plan, do, check model somewhat like ISO 14001 that includes a lifecycle review and risk evaluation
- Fairly widely adopted within the industry

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Codes of Conduct

- Other Codes—Responsible NanoCode—UK; GoodNanoGuide—Int'l Council on Nanotechnology; Responsible Care

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Supply Chain and Procurement

- Green Supply Chain Management is rapidly growing
- Nanomaterials are beginning to be scrutinized through GSCM systems
- Likely to expand, especially as it relates to nanomaterials and food

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Public Engagement

- EU nanotechnology Code of Conduct—nanotechnology research activities "should allow the participation in decision-making processes of all stakeholders involved in or concerned by N&N research activities."
- 2012 article in Journal of Business Ethics—"significant negative attitudes within industry towards 'extended peer review'"

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The Role of Soft Law

"reconsideration [of regulatory design] must take the form of incorporating advances in corporate self-regulation, associational regulation, and standards into the regulatory system and thinking creatively about how public policies can be used to reinforce incentives or compensate for their absence." Marc Eisner, Governing the Environment

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Liability

- The potential for product liability remains a significant force for precaution
- Codes are creating a standard of care for managing nanotechnologies and becoming important in establishing companies are exercising due care

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Concluding Observations

- Hard law is playing a somewhat larger role in nanotechnology but it is developing slowly and with few signs of acceleration
- Soft law plays a major role in managing nanotechnology risks

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Concluding Observations

- Technical assistance programs, codes of conduct and other mechanisms appear to be establishing a normative framework for how nanotechnology should be researched and utilized—An industry ethical standard
- These mechanisms also appear to be creating an industry standard of care that likely has an impact on tort liability and insurability

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Concluding Observations

- Lack of progress on public engagement and awareness leaves a relatively high risk if an incident were to occur
- Integrated governance seems to have become a reality for nanotechnology. Whether this governance structure is sufficient to protect against risk is still an open question.