The Coming Regulation of Nanotechnology: Transnational Models

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Overview

I. Threshold Assumption:
   I. Regulation is inevitable and law will play an integral role in its development, direction, and application.

II. Questions:
   I. Transnational vs. National Regulatory Frameworks
   II. Lessons of Transnational Legal Regulation of Technologies
Regulation is Coming
Regulatory Inevitability

- Legal Regulation is inevitable
  - Permissive (In place—evolving)
    - Seeding technologies, Funding Rationality
      - Government funding decisions, IP protections
      - Consortia
  - Prophylactic (Inevitable—anticipatory)
    - Approvals, Bans, Mandates
      - Stem Cells, New Drug Apps, WTO
Transnational Regulation?
Portfolio of Potential Nanotechnology Risks

- Workplace
  - Direct exposures to workers and product users
- Environmental
  - Exposures (air, water, soil)
- Socioeconomic and/or ethical risks of nanotechnology
  - Agriculture, Labor, Manufactures
- Malfunction or unintended effects of advanced nanodevices and nanosystems, including those produced by molecular nanomanufacturing
  - Grey or Green goo
- Offensive military applications of nanotechnology
- Potential Threats to Civil Rights
  - Privacy
- Malevolent use of nanotechnology (e.g., terrorism)
Is Regulation of Nanotech Risks Premature?

• Most nanotechnology risks largely hypothetical and uncertain
  – Yet recent emphasis on precaution counsels against waiting for harms to occur
    • e.g., EU, The Precautionary Principle in the 20th Century: Late Lessons from Early Warnings

• Even if regulation of nanotechnology premature, discussion of possible regulatory models is not
Anticipatory Regulation

**Pros:**
- Prevent genie from getting out of bottle
- Be prepared to act when problem emerges (c.f., Dolly)
- Allow public a role in shaping technology & its regulation prior to implementation
- Create stable and predictable regulatory framework for industry
- Assure public that adequate regulatory oversight in place

**Cons:**
- Difficult to design regulations when nature of technology uncertain
- Unnecessary regulation will impede innovation & drive technology underground
- Hard to back down from unduly stringent reqts in initial regulations
- Difficult to get adequate resources & participation in developing appropriate regulations when potential problems not a priority
Potential Arguments for Transnational Regulation

• Cross-border effects
  – Marketing, Sales, Manufacturing
  – Nanoparticle/device hazards

• Harmonization of Rules
  – Strategic Efficiencies
  – Reduction of ex ante trade barriers

• Minimum Standards
  – “Race to the bottom,” “risk havens”

• Normalized Competition
  – “Arms” Race
National vs. Int’l Regulation: Which Comes First?

• Francis Fukuyama:

• But developing national regulations first may:
  – Delay international regime
  – Promote race-to-bottom inefficiencies
  – Entrench positions (GMOs)
Preliminary Comments

• Choice
  – Single dedicated forum (promoting tradeoffs and rationality)– vs. Experimentation and national choice (“let a 1000 flowers bloom”)

• Nanotechnology Itself
  – Meaningful to discuss nanotechnology as monolithic or consistent

• Adaptability for rapidly developing technology

• Liability approaches potential alternative/supplement to regulatory approach
Potential Models for Transnational Regulation
Existing Multinational Initiatives on Nanotechnology

  • Responsible and co-coordinated response to threats and benefits
  • Identification of threats—harmonization of responses
  • Rob Visser, Director of OECD’s EHS division: “Countries have a choice today, which is whether they want to do this nationally or internationally.”

• International Dialog on Responsible Research and Development of Nanotechnology (June 2004)
  – discussed establishing an international organization to promote and encourage responsible nanotechnology development
List of Models Being Studied

• International Environmental Agreements
  – **Stockholm Convention on POPs**; Stratospheric Ozone Treaty
• Non-Proliferation Arms Control Treaties
  – **Biological Weapons Convention**; Chemical Weapons Treaty; NPT
• International Bans/Social-Ethical Treaties
  – UN Cloning Ban
• Codes of Conduct
  – Asilomar; **Pathogen/Biotech research**; Responsible Care; Foresight Guidelines
• Framework Conventions
  – UNFCCC; Framework Convention on Tobacco Control
• Existing International Law Principles
  – Precautionary Principle; International Criminal Law; Transboundary Harms
• Joint Development Agreements
  – Outer Space Treaty; Law of the Sea Convention
• Control of Technology Trade via Intellectual Property and Licensing
  – WTO, Regional Agreements, TRIPS; DMCA
• Information Controls and Oversight
  – Export Controls; National Science Advisory Board for Biosecurity
• Non-governmental
  – Workplace conditions, environmental standards, humanitarian responses.
International Agreements on Environmental Pollutants

• Agreements very difficult to negotiate; tend to succeed only for pollutants with clearly-established global health consequences
  – e.g., Stockholm Treaty on Persistent Organic Pollutants (“dirty dozen”)
  – e.g., Montreal Protocol on Substances to Deplete the Ozone Layer
  – c.f., UNEP & proposed mercury convention

• Treaties tend to ban small number of bad actors (accepted by industry) rather than develop acceptable limits for larger number of agents that will remain in commerce

• These characteristics do not align with what we know about nanotechnology risks at this time
Non-Proliferation Treaties

• Three major treaties:
  – Nuclear Non-Proliferation Treaty (NPT) -- 1968
  – Biological Weapons Convention (BWC) -- 1972
  – Chemical Weapons Convention (CWC) – 1993

• All three treaties have provided important benefits, but share some key obstacles:
  – Non-signatories
  – Non-compliance
  – Verification
  – Limited application to non-state actors

• Reactive rather than Anticipatory
Non-Proliferation Treaties: Some Relevant Observations

• Two-tier structure creates ongoing tensions between nations that already had weapons and those that do not at time treaty adopted (NPT)
  – argues for establishing treaty before any nation develops weapons

• Technology transfer and assistance provisions for peaceful uses of technology are a strong inducement for participation by developing nations

• Creation of specific enforcement and oversight agency very beneficial (NPT, CWC v. BWC)

• Verification provisions critical but controversial
Non-Proliferation Treaties: The Dual-Use Problem

- Growing potential for the same materials, equipment and techniques relevant for nuclear, chemical and biological weapons to have non-military applications
  - e.g., biotechnology
- BWC relies on “general purpose criterion”
  - prohibitions depend on intended use rather than nature of technology
- High sensitivity of national governments and industry to protecting proprietary value of non-weapons technology
- Treaties have had difficult time adapting to and overseeing rapid scientific/technological advances
Non-Proliferation Treaties: Lessons for Nanotechnology

- Nuclear, chemical and biological weapons are clear “bad actors”; nanotechnology applications may not be so clear
- “Dual-use” technologies difficult to regulate using arms control agreements
- Intrusive verification provisions likely to be necessary but highly controversial
- Technology exchange mechanism important inducement for participation
Global Ethics Treaties: The UN Cloning Ban

• Less than 30 of the U.N.’s 192 nations have banned human reproductive cloning
• In 2001, the U.N. General Assembly established an Ad Hoc Committee to draft an international convention prohibiting the reproductive cloning of human beings
• The Human Cloning ban deadlocked in the U.N. in December 2003 due to disagreement
• Deadlocked again at Oct. 2004 meeting
• U.N. Legal Committee voted 71 to 35 with 43 abstentions to ban all forms of human cloning, but in a non-binding instrument
• UN General Assembly will now take up proposal
Global Cloning Ban: Issues of Disagreement

• Major disagreement over scope of the prohibition: reproductive cloning only or all human cloning (including therapeutic cloning)
  – “widening the scope of the potential convention to include issues for which no consensus existed could threaten the entire exercise, leaving the international community without a coordinated legal response.” UN Ad Hoc Committee Report (2002)

• Also disagreement on whether it should be a permanent ban or a limited-duration moratorium

• Disagreement on penalties/sanctions
  – Some countries have argued that it should be prerogative of each nation on whether or not to impose sanctions
Proposed Human Cloning Ban: Lessons for Nanotechnology

• Even when strong international consensus on urgency and opposition to specific technology, negotiating international prohibition may be complicated by attempts to include related applications lacking such clear consensus.

• A complete prohibition on nanotech is undesired as some acceptable uses will likely be outlawed; need more nuanced and hence complicated and controversial convention for nanotech.

• Permanent ban vs. limited duration moratorium.

• How to keep convention current with rapidly progressing technology?
Recent Examples of Codes of Conduct

- Asilomar Conference/NIH Guidelines on Recombinant DNA
- U.S. chemical industry, Responsible Care program (6 different codes of conduct)
- New legal scholarship on role of “norms” in social ordering
- Foresight Institute Guidelines for molecular nanotechnology
- 2005 Annual Meeting of the BWC States Parties will focus on the “content, promulgation, and adoption of codes of conduct for scientists”
Problems with Codes of Conduct

- Rarely provide clear guidance for resolving complicated/controversial cases
- Usually open to multiple interpretations
- Often perceived as “public relations” gimmicks to avoid real regulation
- Many codes unenforceable against practitioners who fail to comply
- Hard to back down from requirements that subsequently appear overly stringent
Framework Conventions

• Recent examples of nations adopting a “framework convention” on an issue of common concern
  – UN Framework Convention on Climate Change (1992)
  – UN Convention on Biological Diversity (1992)
• Establishes general commitment and process to address issue on an ongoing basis at international level
• Incremental change as substantive requirements are added in subsequent protocols
  – e.g., Kyoto Protocol (1997)
International Law Principles: The Precautionary Principle

• Incorporated into more than twenty international environmental treaties
  – Included in 1992 Maastricht amendments to European Treaty
  – Incorporated into national laws of many countries (e.g., most EU nations, Australia, Canada)
• Several activist groups and scholars have called for a moratorium on research in nanotechnology based on the precautionary principle
• Problematic
  – No standard definition and no standard approach
• No version of the PP answers key questions:
  – What level of risk is acceptable?
  – What early indications of potential hazard needed to trigger precaution?
• Arbitrary
  – Stewart Commission (UK) recommended restrictions on use of cell phones even though it concluded no risk
  – Netherlands banned Kellogg's Corn Flakes
  – France banned “Red Bull” caffeinated drink
  – Denmark banned Ocean Spray Cranberry drinks
  – Zambia rejected U.S. food aid to help starving population because of presence of GM corn
Conclusions
Feasibility of International Nanotechnology Agreement

• International agreements difficult to negotiate
  – Often need immediate and serious threat
    • WTO?
      – Benefits of Cooperation made clear by abuse

• Enforcement of treaties difficult and controversial

• Dual-use technologies incompatible with traditional international agreements on arms control proliferation and environmental pollutants?

• Some non-compliance and non-signatories likely
  – Tolerability? Havens?
Lessons from Case Studies for International Agreement

• Need to balance burdens on beneficial uses vs. restrictions on harmful uses
• Defining scope of technology to be regulated critical
• Include technology sharing inducements
• Need to involve industry
• Consider non-state actors
• Managing information as important as controlling material and equipment
• Any agreement must have built-in flexibility to evolve
Some Possible Interim and Second-Best Solutions

• Less formal approaches for the shorter term
  – Benefit and information sharing
  – “Civil-society-based monitoring” and expertise
    • BioWeapons Prevention Project (bans)
    • Australia Group (export controls)
    • IPCC (climate change expertise)
  – Industry Participation
    • Joint Codes of Conduct
      – Expertise
    • CBMs
      – Public Information and Education

• Intellectual property and trade
  – Permissive
Overall Conclusions

- Creative approaches will be needed to address risks of nanotechnology at the international level
- Existing models provide valuable lessons; but nanotechnology will likely require unique approaches
- It is essential to develop regulatory and risk management approaches prospectively before technologies impose harms
- “Law” will be an important player in shaping and directing these decisions
Upcoming Conference

www.law.asu.edu/forbiddingscience

Forbidding Science?
Should research be restricted? How far is too far?

Should some pathogen and toxin experiments be prohibited?
How do we prevent the misuse of nanotechnology?
What are the ethical concerns with cognitive enhancement?

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