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)

Time Horizon

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:
  - "[R]egulation cannot work in a globalized world unless it is global in scope. Nonetheless, national-level regulation must come first. Effective regulation almost never starts at an international level …." *Foreign Policy*, Mar/Apr 2002.
- But developing national regulations first may:
  - Delay international regime
  - Promote race-to-bottom inefficiencies
  - Entrench positions (GMOs)

Preliminary Comments

- Choice
  - Singe 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

- Joint Meeting of OECD Chemicals Group and Management Committee in Nov. 2004, June 2005, Sep. 2005, and Dec. 2005
  - 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)
  - WHO Framework Convention on Tobacco Control (2003)
- 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