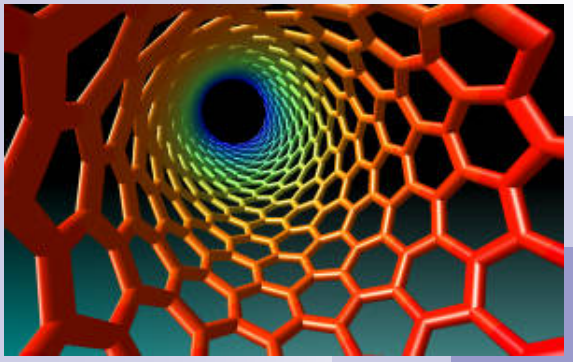


SURVIVING AN EMERGING REGULATORY ENVIRONMENT – PRACTICAL STRATEGIES

Reed D. Rubinstein
Greenberg Traurig LLP
Washington, D.C.

Trends

- Global development and deployment of new technology and products.

- Risk Perception (the “Frankenstein Factor”) is in play.

- Technology Absorption Boundaries (the “Sponge Bob Paradigm”) might be on the horizon.

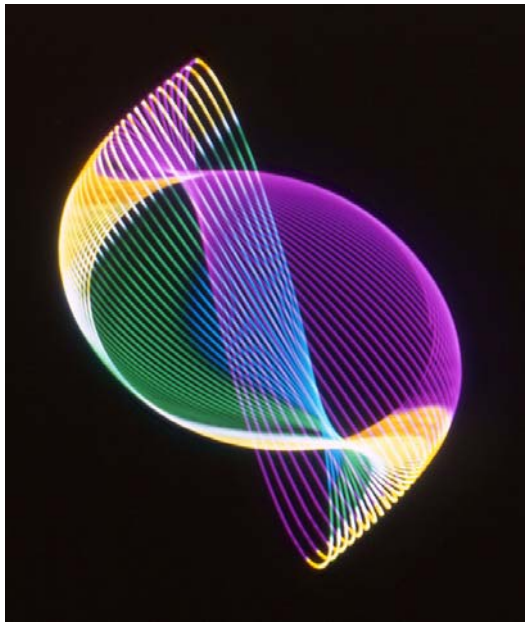
Regulatory Drivers

- Public risk perceptions drive government regulation.

- Elite risk perceptions drive policy choices.

Perceptions matter.

- OSHA standard for TCE exposure: 100 ppm.
- EPA standard for TCE exposure: 5 ppb.
- Scientific rationale: ????



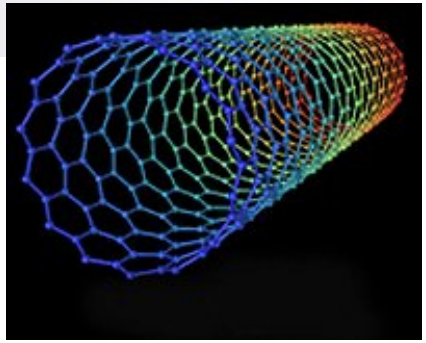
Regulatory Models

- Command and Control.
  - Government regulators command and control firm behavior, controlling “process” and “product.”
  - Assumes bureaucracy is competent to set standards for “product” and equipped to regulate “process.”

- Benchmarking.
  - Government regulators set performance benchmarks for the “product,” while private firms retain discretion over the “process.”
  - Assumes government technologically equipped to set standards for “product.”

- Market regulation.
  - Government does not regulate either process or product.
  - Firm behavior governed by customer response/public perception and by tort liability.

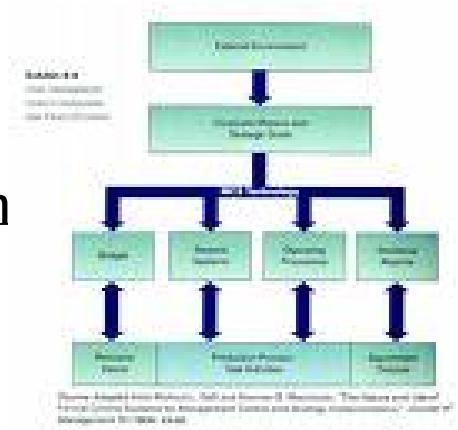
Practical Consequences



- Regulatory models matter.
  - Technological innovation is inversely related to government control.

- In the US, market regulation and benchmarking should predominate for the short term.
  - The general consensus is that nanotechnology will not be specially regulated absent a clear public health threat.
  - The EPA appears to have concluded that engineered nanoproducts are likely subject to TSCA regulation.
  - The FDA apparently believes it has sufficient legal authority and an appropriate regulatory process in place.

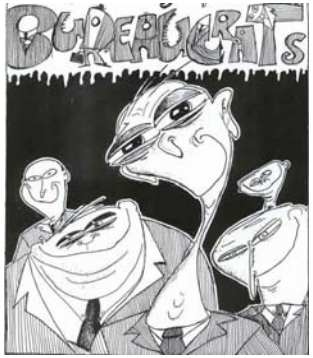
- In the EU, command and control regulation is all but certain.
  - Broad application of the “protective principle,” means trouble for technological innovators.
  - EU approach could cause violations of WTO obligations.
    - ✓The *EC-Measures Affecting the Approval and Marketing of Biotech Products* ruling in February 2006 might be a hint of things to come.
- In China, India, and other developing countries, market regulation is likely to predominate.



Survival Strategies.

- Manage Consumer Perceptions.

- Manage the Regulators.



- Manage the Risk.

Managing Consumer Perceptions

- The key is managing the perceived balance between threat and opportunity.

- "Initial framing" of the issue is determinative (Bt Corn/monarch butterfly debacle).

- Risk judgments depend strongly on "feelings" and not always on science.

Managing the Regulators.

- EPA seems to be developing a “partnership” regulatory model – long term viability depends on the degree of industry initiative.
  - Worker Safety.
  - Consumer Product Risk Assessment.
  - Environmental Fate and Transport.

- Provide the Regulators with Information.

- Promote Responsible “Self-Regulation.”
  - ASTM – Standardize nomenclature.
  - Develop and publish life-cycle “Best Practices” (DuPont/EDF Joint Framework).
  - Test and study.

Managing the Risk.

- Risk-Reward Ratio.
  - Nano-risks complex, uncertain, ambiguous.
  - Nano-return substantial, promising, transformative.

- Anticipate Claims and Unexpected Loss, and Prepare Accordingly.
  - Understand statutory and tort duties.

- Monetize Risk - Insurance.

A Few Words About Insurance.

- Identified Insurability Challenges.
  - Difficult to assess.
  - Global risk.
  - Causation concerns/unjustified risk perceptions.
- Current Position.
  - Nanotechnology risks ARE part of existing (re)insurance covers (per Swiss Re, 2006).
  - No exclusion nor specific nano-cover possible due to current confusion over terminology and distinction criteria.
  - Scope of risk is unknown.
- Future Action.
  - More research.
  - Avoid “strict liability” regime.
  - Define terms.

What Is To Be Done?

- Firm Level.
  - Find and implement Best Practices.
  - Focus on product safety.
  - Insure and inform.

- Industry Level.
  - Aggressively self-regulate.
  - Entertain, inform, and inspire the public.
  - Decisively respond to “fear-mongering.”
  - Act locally AND globally, but focus on meaningful markets.
  - Effective legislative advocacy is key (e.g., liability limits for accidental releases of nanomaterials are currently being reviewed by key members of the Senate Commerce Committee, spearheaded by the chairman of the Senate subcommittee with jurisdiction over consumer affairs, product safety and insurance industry issues).