Modern Regulation and Nanotechnology Innovation

Timothy F. Malloy
Professor of Law
UCLA Law and Environmental Health
Sustainable Technology Policy Program

March 19, 2009

The Road Ahead

- Framing the Conversation
  - Innovation
  - Industry
  - Regulation
- Elements of Effective Regulation

Innovation

- Forms
  - Market Innovation
  - Social Innovation
- Benefits
  - Economic growth
  - Enhanced quality of life
- Risks
  - Opportunity Costs
  - Environmental and Health Impacts

TSCA Section 2601(b)(3)

"[A]uthority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this chapter to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment."

TSCA Section 2601(b)(3)

"[A]uthority ove ces and
mixtures shou uch a manner
as not to impe unnecessary
economic bar l innovation
while fulfilling e of this
chapter to ass ation and
commerce in stances and
mixtures do r sonable risk of
injury to heal nt."

Walking the Line

- Innovation is an important social goal and value, **but**
- Must be integrated into regulation in a more rigorous manner
  - Existing regulation is often a blunt instrument, giving “innovation” a privileged position.
  - Little evidence is demanded regarding the “drag on innovation” caused by regulation.

The Story of Tetraethyl Lead

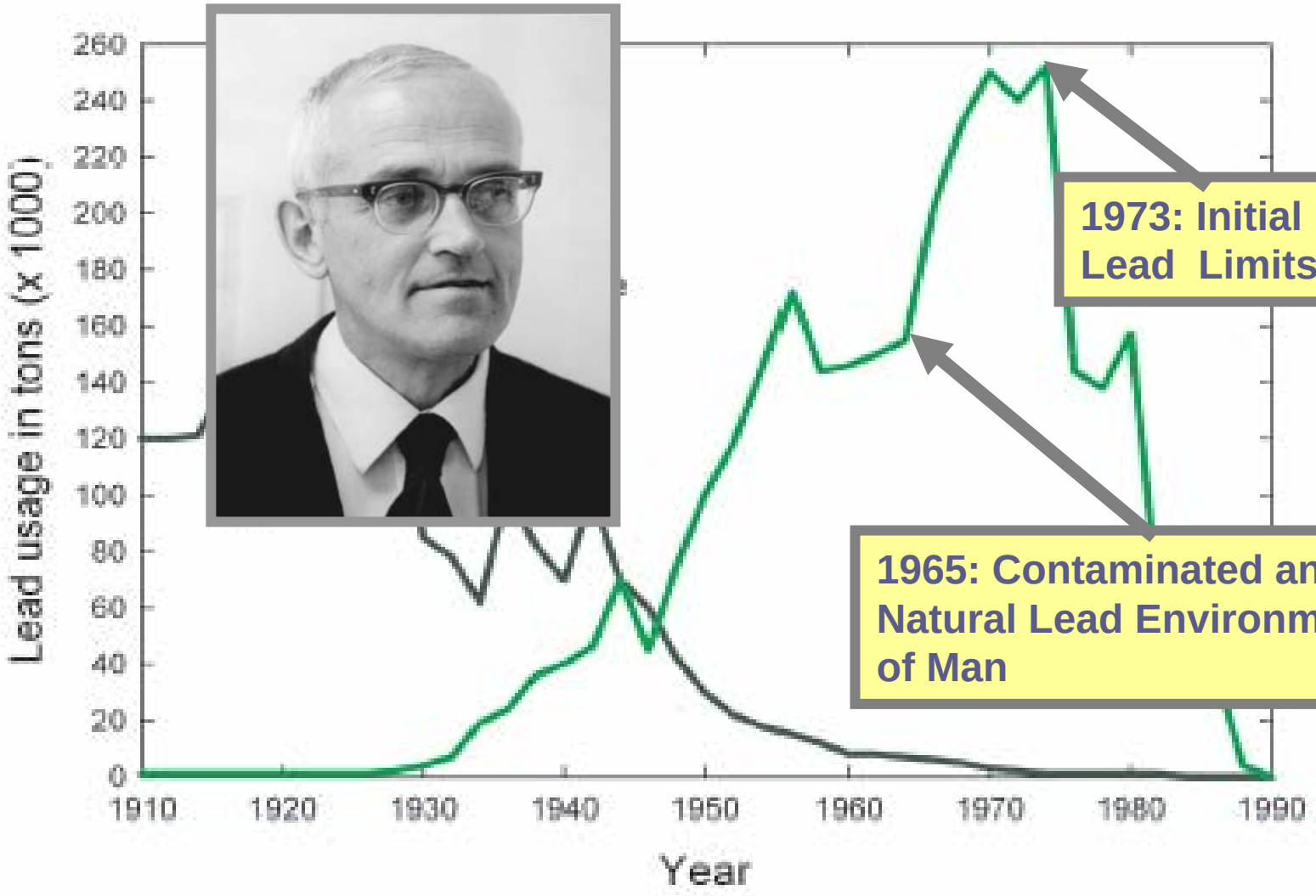
The Story of Tetraethyl Lead

- Expected Outcome
  - Increased power and fuel efficiency
  - No likely health effects

"Your committee begs to report that in their opinion there are at present no good grounds for prohibiting the use of ethyl gasoline, provided that its distribution and use are controlled by proper regulation. . . ."

Report of Committee of Seven Recognized Authorities, 1926

The Story of Tetraethyl Lead



The Story of Tetraethyl Lead

- Expected Outcome
  - Increased power and fuel efficiency
  - No likely health effects
- Unanticipated Outcome
  - Widespread dispersion of lead in environment
  - Increased blood lead levels

Understanding Business

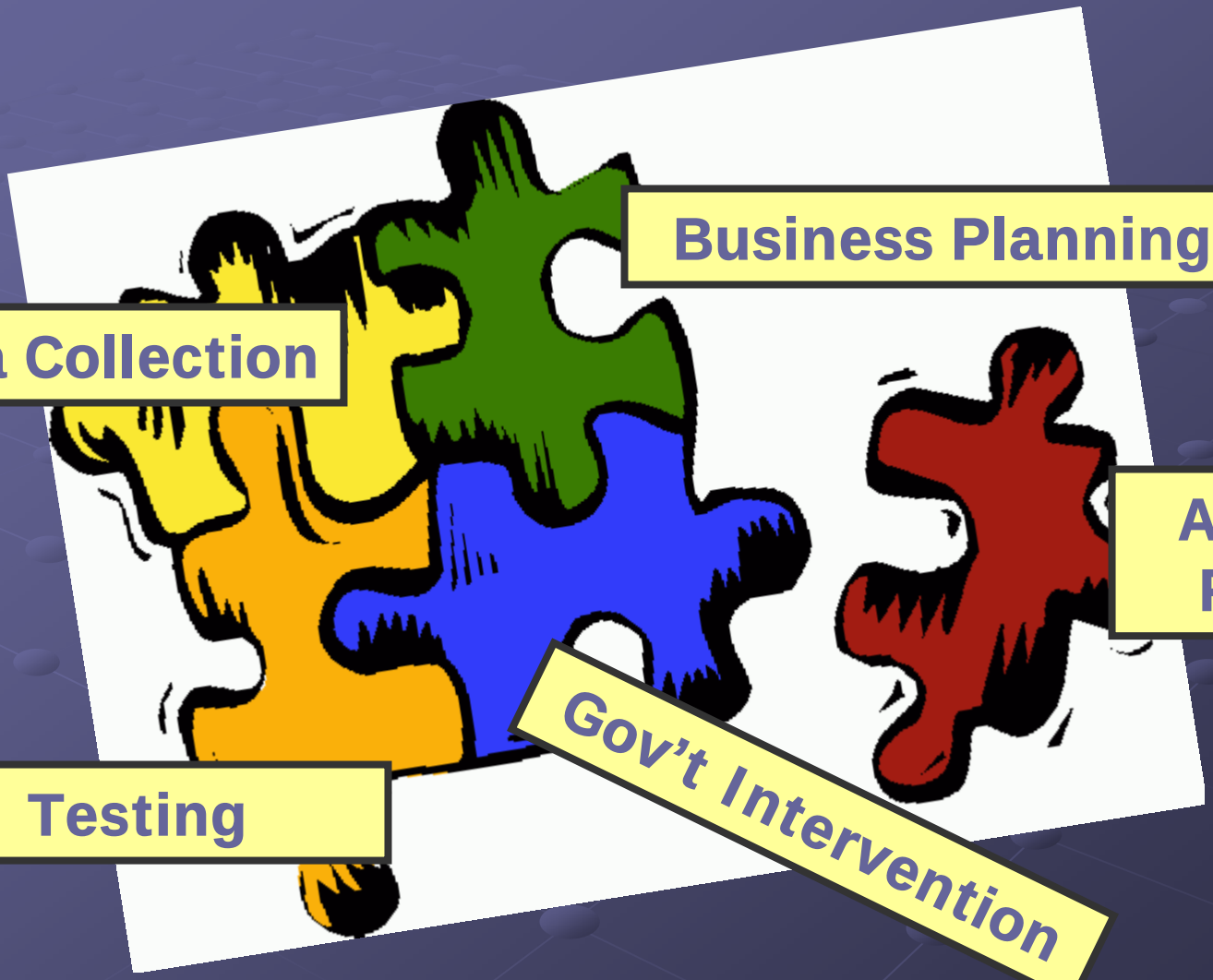
- Start with the proposition that many, perhaps even most, businesses want to do the “right thing” (e.g., incorporate sustainability, worker protection, and public health protection more broadly)

- Yet social science research demonstrates that in the real world of business, such norms will be diluted and difficult to implement.

Types of Norm Slippage

- Calculated Slippage: **Rational Actor in Action**
  - Conflicting Norms
- Routine Slippage: **Coordination Mechanisms**
  - Information Flow
  - Resource Allocation
  - Allocation of Authority
- Cognitive Slippage: **Norm Activation Barriers**
  - Defensive Denial
  - Norm Neutralization

The Regulatory Puzzle



Business Planning

Data Collection

Adequate Funding

Gov't Intervention

Testing

Generate and Disseminate Information

- What
  - Generation/Submission of hazard, distribution, use & exposure data
- Who
  - Chemical producers, intermediaries, and product manufacturers
- Why
  - Manufacturers, intermediate and end-users can make knowing choices and take action
  - Agencies can identify hazards, prioritize resources and take action

Innovation at What Cost?

“EPA officials told us that after EPA screened the chemical or performed a more detailed analysis of it, chemical companies often drop their plans to market a new chemical when the chemical’s niche in the marketplace is uncertain and EPA requests that the company develop and submit test data. According to an EPA official, companies may be uncertain that they will recoup the costs of testing and prefer instead to withdraw their pre-manufacture notice.”

GAO, 2005

Innovation at What Cost?

- Information costs should be allocated to those who benefit from the innovation.
  - Producer and ultimately the end users
- Where information costs are too high, but innovation is socially desirable, government funding is appropriate.
- At present the government and business are funding R&D, but not sufficiently funding safety.

Agency Intervention

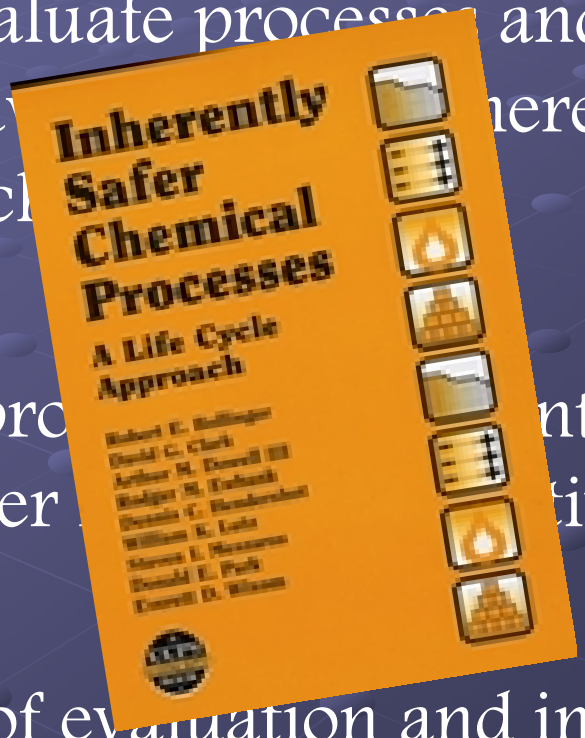
- Review new and existing chemicals, including engineered nanomaterials
- Mandate use of safer feasible alternatives where available
- Otherwise mandate appropriate controls, including consideration of social utility
- Evaluate submitted management plans

Regulatory Tools: Business Responsibility

- Periodically evaluate processes and practices, including the availability of inherently safer processes and chemicals
- Implement approved management plans, including adoption of safer feasible alternatives
- Report results of evaluation and implementation

Regulatory Tools: Business Responsibility

- Periodically evaluate processes and practices, including the a herently safer processes and cl
- Implement appro nt plans, including adoption of safer tives
- Report results of evaluation and implementation



Adequate Funding

"Currently, some members of Congress seek to stop EPA from doing what previous Congresses have mandated it to do, by refusing to give it the funds to act. That is a little like cheering the launch of an airplane bound from New York to Los Angeles while only giving it the gas to reach Chicago, and then decrying the crash as further evidence of pilot ineptitude."

William D. Ruckelshaus, *Stopping the Pendulum*

Adequate Funding

- A sophisticated and modern approach to nano-regulation will require sustainable, substantial funding.
- Neither TSCA nor AB 1879 confront this need.