INFLUENCING REGULATORY SCIENCE

CSPI Conference on Rejuvenating Public Sector Science

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TOPICS

• FDA as a scientific regulatory agency
• Movement of decision making away from scientists
• Impediments to public health mission
  - Rulemaking barriers
  - Budget cuts
• A timely example
• Thoughts on improvements
Two Images

1) Greedy, malevolent, polluting industry executives, bribing & blackmailing legislators and public officials

2) Regulated entities rationally protecting their interests
   - Former regulators and legislators
   - Access to political executives
   - Resources to challenge science
   [Tobacco, global warming]
Poster Child for Political Meddling

- EPA 1981-83 Anne Gorsuch, Administrator
- Her background
  - Hearing officer, state cosmetology board
  - Corporate communications lawyer
- Took office announcing that EPA was too restrictive on business
- Actions:
  - Cut EPA budget 1/5
  - Scaled back Clean Air & Clean Water Act implementation
  - Dramatically cut cases filed against polluters
  - Reduced R&D
  - Hired senior EPA executives from regulated industries
  - Approved widespread spraying of restricted pesticides
  - Planned to deploy ships to burn toxic waste off the coast of DE
- Forced to resign over Superfund controversy
Fast Facts About FDA

- Science-Based Regulatory Agency
- Organized by Product Area
- 18 Locations, 40 buildings in Washington Area
- 207 Field Offices Around U.S.
  - 13 Field Laboratories
- 10,000 Employees
- Physicians, Pharmacologists, Toxicologists, Microbiologists, and Other Scientific Professionals
- $ 2.2 Billion Annual Budget (FY 2008)
Scope of FDA’S Mission

- Food
- Drugs
- Vaccines/Blood
- Dietary Supplements
- Animal Foods & Drugs
- Toxicological Research
- Biotechnology
- Medical Devices/ Radiological Products
- Cosmetics
FDA
3 Principal Regulatory Pathways

1) New product approval

2) Enforcement
Enforcement Declining

Since 2000:

• 54% decline in warning letters from inspection violations

• 2/3 decline in enforcement cases against false and misleading drug ads

• 80% decline in enforcement of vaccine and biologics manufacturing
FDA Food Scientist and Inspector Staff Declines

CFSAN FTEs

ORA FTEs and Investigators

FDA Food Scientist and Inspector Staff Declines
FDA Staffing

Food and Drug Administration
Full Time Permanent (FTP) Positions / Full Time Equivalents (FTEs)

* Prior to 1980, FDA counted each federal employee as a Full Time Permanent (FTP) position.
** Listed are program level FTP or FTEs only. User Fees, Revolving Fund for Certification and Other Services, Advances & Reimbursable, and Parklawn Computer Center FTP or FTEs are NOT included in the FDA S&E column.
*** Source: DHHS/FDA Justification of Estimates for Appropriations Committees
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Fiscal Year

FTE

5,000

6,000

7,000

8,000

9,000

10,000

11,000
FDA

3 Principal Regulatory Pathways

1) New product approval

2) Enforcement

3) Rulemaking
Rulemaking
A Tortuous (and Tortured) Process

- Agency identifies solution to public health problem
- Science collected to justify regulatory solution
- Seeks approval to draft rules of parent department
- Drafts Notice of Proposed Rulemaking
  - Scientific justification
  - Data Quality Act
  - Cost-benefit analysis
  - Environmental Impact
  - Unfunded mandates
  - Legal justification
  - Federalism E.O.
  - Paperwork Reduction
  - Reg Flex Act
  - SBREFA
A Tortuous (and Tortured) Process (continued)

• Receives comment on NPRM
• Considers and develops responses to comments
• Seeks approval to draft final rule
• Drafts final rule
  - Scientific justification - Legal justification
  - Data Quality Act - Federalism E.O.
  - Cost-benefit analysis - Paperwork Reduction
  - Environmental Impact - Reg Flex Act
  - Unfunded mandates - SBREFA
Clears final rule through Dept.
Clears final rule through OMB
• Dept/OMB clear rule through White House
Timeline
(Many access points)

- Year one – regulatory solution to public health problem identified
- Year 2 – Proposed regulation submitted for review
  - 120 days HHS
  - 90 days OMB
  - Published with 120 day comment period
  - 180 days -- comments considered
- Year 3 – Final regulation submitted for review
  - 120/90/120/180 Repeated
- Year 4 – Final regulation published
- Year 5 – Effective date
Procedural Steps in Rulemaking

- 1906 – 1981 – Delegated authority
- 1980 – OIRA created
- 1981 – Reservation of authority by HHS
- 1980s – 1990s -- paperwork reduction, Federalism, effects on tribes, Regulatory Impact Analysis, Semi-Annual Agenda, EO 12866, small business effects
- 2001 – Data Quality Act
- 2005 – Guidance review
OMB Review of Rulemaking

- Rulemaking prospects on OMB “list”
- Criteria – “Significant” regulations
  - $100M in economic costs
  - “Novel policy issues” aka “We want to see it”
- Thus, much scientific decision making delegated to non scientists
- Example – Nailbiting and thumbsucking OTC drug monograph
The Practical Meaning

- A GS-12 can stop virtually any agency’s rulemaking
- Disputes are decided in OMB’s favor
- Rules are routinely held up for indeterminate periods of times – “black hole”
- Agencies are deterred from solving problems by the sheer task of promulgating rules
- While OMB often describes its reviews as “advice,” it is also “hazardous to ignore.”
- Public health problems don’t get solved for years
The Produce Example

• A timely topic
• Food safety much in the public eye
• Scientific knowledge has advanced greatly in recent years re: combatting foodborne illness
• Yet no regulations by Administration
Background

• CDC estimates that, in the U.S., foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths annually

• Estimated economic cost of foodborne illness is in the range of $10-83 billion annually
Foodborne Disease Outbreaks

FDA Outbreaks 1990-2004

Year

Outbreaks
Fresh Produce Safety
The Problem

- Produce is:
  - vulnerable to contamination because its grown in a natural environment
  - subject to bacterial contamination through packing and handling procedures
  - increasingly attractive to consumers raw, and thus not decontaminated through cooking
  - implicated more and more to serious disease outbreaks
Recent Outbreaks

- Part of an increasing trend

- 1995  3 – *E. coli* O157:H7  105 cases
- 1996  2 – *E. coli* O157:H7  68 cases
- 1997  1 – *Cyclospora*  12 cases
- 1998  2 – *E. coli* O157:H7  6 cases
- 1999  6 – *E. coli* O157:H7  86 cases
- 2002  2 – *E. coli* O157:H7  53 cases
- 2003  3 – *E. coli* O157:H7  60 cases
- 2004  2 – *Cyclospora*  95 cases
  1 – *Salmonella*  79 cases
  1 – *E. coli* O157:H7  6 cases
- 2005  1 – *E. coli* O157:H7  34 cases
- 2006  3 – *E. coli* O157:H7  356 cases
- 2008  *Salmonella* (tomatoes)  1000+
The Fog of War

• In an emergency, you don’t know what you don’t know

• Spinach – 2006
  – E Coli 0157:H7
  – 205 cases, many hospitalizations, 3 deaths
  – Severe bloody diarrhea, cramps
    • HUS – Red blood cells destroyed, kidney failure, death

• Weeks of investigation to find source

• What to Say at the Beginning?
Only Possible Message

- “Don’t eat spinach”
- Weeks later, 3 California farms implicated
- Nationwide spinach crop wrecked
- $100M in economic costs
- What Other Message Could There Be?
Fresh Produce Safety
Why Federal Action Needed

- Despite significant voluntary efforts, steady increase in illness related to fresh produce
- Fresh produce shipped interstate and even globally
- Outbreaks often occur in different states/nations than the location where the implicated produce is grown
- Problem begs for a nationwide solution
- Result -- Denied
A System Out of Kilter

- Many access points for influence by regulated entities
- Weak Congressional support
- Structural impediments (time, procedural requirements, data accuracy, levels of review)
- Ever higher burden on proof
- Increase in de novo decisionmaking
- Non-scientists ruling on scientific decisions
- Diminished credibility of scientists
- Reduced morale
  - “Why Bother?”
How to Fix

• Let science drive decisions
• Let scientists manage decisions
• Congressional/public support for scientists
• Reduce political appointees at the agency level
• Support whistleblowers
• Leadership by President/cabinet officers
• Streamline rulemaking
  - Limit OMB review to major rules