Regulating the Pharmaceutical Enterprise: Ongoing Controversy

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Advocates' Perspectives on Drug Regulation are Remarkably Polarized:

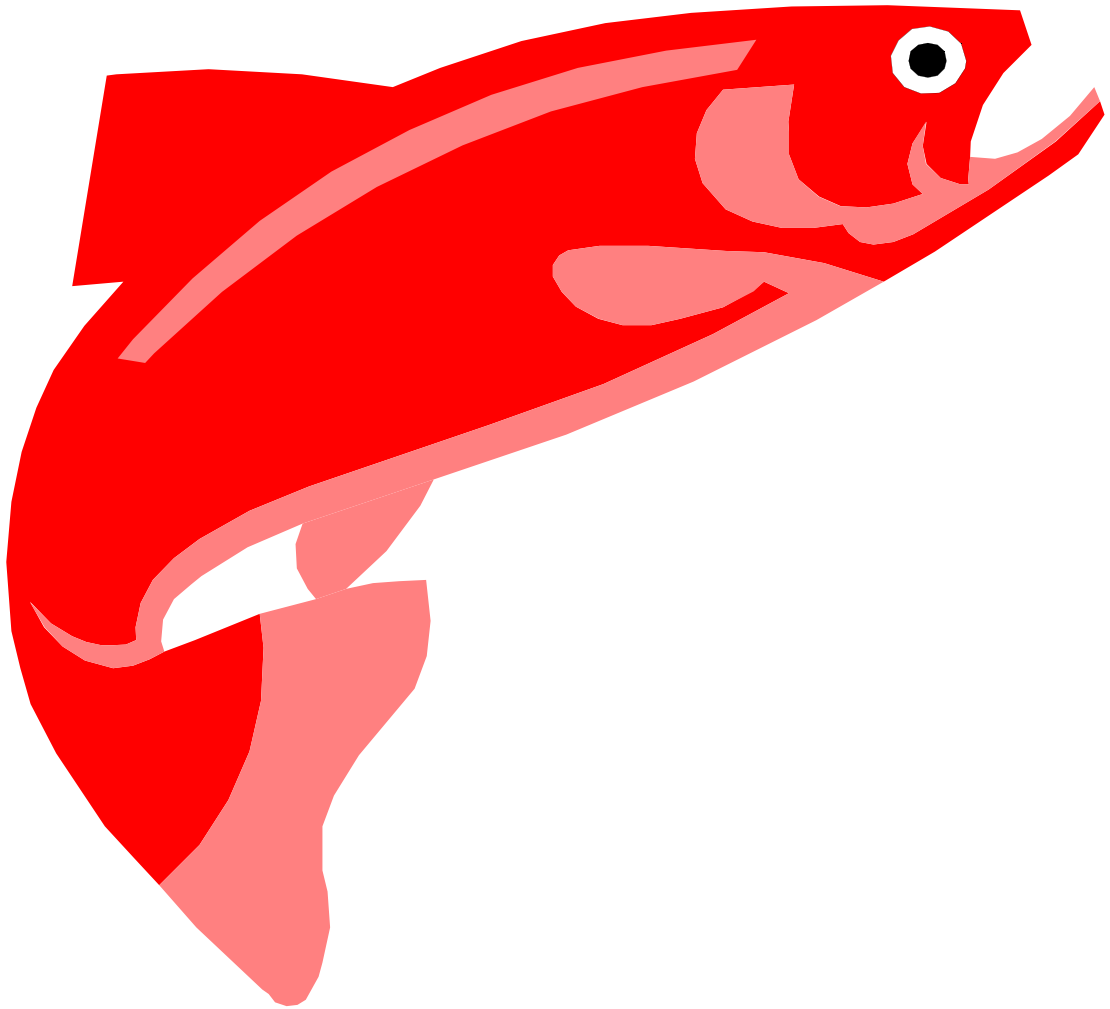
Roadblock	⟷	**Extremely Lax**
Debilitating to Industry		**Threatening**
Consumer		**Safety**
Preventing access to lifesaving therapy		

Public's Desired Outcomes

- Safe drugs
- Available, accessible drugs
- Effective drugs
- Low cost drugs
- (Increasing) Good drug information

Drug Safety

- Impact of PDUFA (User Fees)
- Risk Management
- Role of Medical Errors



Risk Management

- **Broader recognition of risks of drugs**
- **Many alternatives available for some**
- **Some old drugs have become obsolete**

Medical Errors

AARP: 50% of adverse events in hospitalized elderly involve preventable drug side effects

- **Most not dispensing errors**
- **Improper prescribing and monitoring**

Medical Errors

- **Systems approach needed**
- **“Beyond Blame”**
- **Greater Drug Safety = decreased prescribing autonomy**

Globalization of Pharmaceutical Development

- **Emerging consensus among drug regulators worldwide**
- **“International Conference on Harmonisation of Technical Requirements for Pharmaceutical Registration” - ICH 5**
- **10 Years of progressive agreement on the standards**

Globalization

- **Push for harmonisation of standards for emerging technologies**

Cost of Pharmaceuticals - How will this affect drug regulation?

- **Issue of Value**
  - **Cost effectiveness**
  - **Comparative assessments**

Cost of Pharmaceuticals: Generic Drugs

- Ongoing efforts by innovators to thwart generic competition
- Increased legal burden on Agency
- Need for research investment

Cost of Pharmaceuticals: Direct-to-Consumer Advertising

- Always been legally permissible
- Double edged sword
  - Untreated populations
  - Inappropriate usage
- FDA does not have

Drug Pipeline Issues - R & D

- R (drug discovery) capabilities exploding via new technologies
- D (animal & human studies) becoming bottleneck
- Need to reduce cost of

Reducing Development Costs

- Pressure on regulators to streamline investigational stage
- Pressure on regulators to "streamline" marketing requirements
- Society - wants better safety in adequately treated diseases

Incorporating the New Science

- Need adequate scientific expertise at FDA, or access to outside experts
- Major public concern about impact of new technologies must be taken into account
- Unbiased, scientifically-based evaluation helps to introduce new

Incorporating the New Science: Informatics

- The newest science
- Will change our world
- Major impact on drug regulation
- FDA/CDER making significant investments

Legislative Issues: Pediatric Exclusivity

- Part of FDAMA 1997
- Six months additional exclusivity for performance of pediatric studies at FDA request
- Has stimulated intense efforts in children
- No FDA stalling
- Expires 2002

Legislative Issues: PDUFA

- Up for reauthorization in 2002
- FDA Public Meeting - fall
- Lack of consensus on use of fees
- Current level - 50% of premarket review funding
- Some other countries 100% fee based

Policy Matters

- Transparency & FOI
- Conflicts of Interest
- Ethics of Human Experimentation & Human Subject Protection

CONCLUSION: Drug regulation continues to be an area of wide-ranging controversy