

# Comparing Medicine Regulation

## The Vioxx Crisis and its Effects in the UK and the US

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# Developing an argument

- How did the regulatory systems in the US and the UK deal with a crisis in drug safety?
- Vioxx becomes a landmark case of regulatory failure resulting in changes to the regulation system
- The case makes visible the inadequacies of the principles on which the existing system rests

# Paper plan

1. Medicine regulation in the UK and the US
2. Failings within the existing regulation regimes
3. Some theoretical perspectives: The contours of a regulatory reform

# Medicine Regulation in the US

- Less pressure on drug pricing
- Kefauver investigation
- FDA as the trusted 'protector of public health'
- FDA under Congressional scrutiny
- Adversarial policy climate

# Medicine Regulation in the UK

Post-thalidomide:

- CSD: Need for an independent approval process
- Ensuring public health rather than industry interests?
- Approval based on 'pure' science

Medicine regulation through medical-professional and health-policy networks

# Failings in Medicine Regulation

- Does the Vioxx scandal show an industry bias within the system?
- Erosion of trust in industry and regulators
- Issues of funding
- Inefficient post-marketing surveillance
- Medicine users remain marginalized in the current system of governance

# Some Theoretical Perspectives: The Contours of a Reform

- Issues of inclusion/exclusion and 'Public Interest'
- Establishing 'Partnerships'
- Expert system versus democratic inclusion
- Re-articulation of the managerial myth

# Some Theoretical Perspectives

- “we need to sit down with the regulators and academia and scientists etc. and develop a system which we can all support and has this wonderful integrity”  
(industry respondent 3 2006)

# Some Theoretical Perspectives

- “Our response was to wait and see and allow the data to emerge, have sensible conversations with regulators. Begin to manage this thing as a partnership... And I think the regulators were pretty cheesed up about the fact that the first time they found out that Vioxx was going to be withdrawn, and of course therefore undermining the whole approval process, data assessment, risk assessment, was through the media” (Industry respondent 5 2006)

# Conclusions

- Vioxx as a disruptive event revealing shortcomings within the regulating system
- While Vioxx did result in policy re-evaluation and some regulatory reform, the effects in terms of interest inclusion and securing public health are probably ambiguous