whether such drug is effective in use

or not such drug is safe for use and

full reports of investigations which have been made

21 USC §325 (Approval of new Drugs)
18 USC §355 (Approval of new Drugs)
't full reports of investigations which have been made
to show whether or not such drug is safe for use and
whether such drug is effective in use'
Problems with "safe" and "effective"

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- Drugs are never "safe"
- How safe? How effective?
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Who decides on our risks?

- Not legislators
- Regulators? FDA? EMA?
- The Supreme Court(s)
- International Bodies?
- Experts?
Decisions on risks are important enough to be decided by parliament (i.e. these decisions can't be delegated)

- Scientific evidence often far from clear
- Cost-Benefit-Analysis does not include fundamental rights / non-economic values
- Experts have no legitimacy to decide on "residual risks"

Parliament can't take decisions on risk because
Parliament can't take decisions on risk because
- Live is complex
- Not enough data/knowledge
- Innovative markets move (too) fast
- Tough decisions, no compromise possible
- Regulation is not feasible (constitutional bars, frustration of private efforts, ...)

What to do? The Idea of Co-Regulation...
- Industry/Consumers negotiate regulation, together or with regulators
- Rules are more accepted, more flexible, provide better results, are effective, are efficient
- Formal Legitimacy of Regulator replaced by "Substantive" Legitimacy of people affected
How to encourage Co-Regulation?
- Co-Regulation can't be imposed...
- Legal Incentives (declare as standard, less liability, change burden of proof, promise regulatory restraint, punish non-cooperating parties...)