“TECHNIQUES AGENCIES USE TO MANAGE UNCERTAINTY”

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Basic Elliott/Tyler analysis

- “Techniques intended to minimize errors”
- “Techniques intended to reduce costs of errors that occur”
  - Including severability clauses to manage uncertainty of judicial review
Minimizing Errors

• Timing
  • Sometimes wait until science has “settled down” (drawbacks)
  • Proactively advance science so it quickly “settles down” (agency sponsored research)
Advancing science through private sector

- Mandate testing by private sector (e.g. pre-market approval by FDA, EPA)
  - Including on limited human populations with informed consent
Carrots for private sector (1)
Carrots for private sector (2)
Ex post cost reduction

- Retrospective review/adaptive management/Bayesian updating
- Benefit of systematic learning
- Challenges
  - More data, but may need to build in systems for data collection
  - Selection of rules (other than large cost, obvious changes)
Precautionary principle/maximin

- Minimizing errors or reducing cost of errors?
- Risk vs. risk (large health/safety costs on both sides)
The “regulator’s dilemma” (H.G. Eichler of EMA)
Maximizing use of *existing* data

• “Big data to knowledge”
  • Data siloes and legal barriers to aggregating data
  • De-biasing data
Two FDA case studies

- Off-label use
- Clinical trial data
Off-Label Use

• For 3 leading drugs in each of 15 leading drug classes, off-label > 21% of prescriptions (Stafford 2008)
  • Especially true for cancer, kids, rare diseases
• Uncertainty about whether uses work (such that benefits exceed risks)
• Information in EMRs
• Many laws that impede aggregation of information
Sharing Clinical Trial Data
MAXIMIZING BENEFITS, MINIMIZING RISK

Recommendation at a Glance: When to Share Data

Rationale for Responsible Sharing of Clinical Trial Data

Clinical trials play a crucial role in advancing medical innovation and represent a significant investment from all involved — including trial participants, sponsors, and researchers. Data are generated throughout the clinical trial lifecycle, but results are often not published in a timely manner, and many data are not shared beyond the original investigators.

Data sharing could advance scientific discovery and improve clinical care by maximizing knowledge gained from data collected in trials, stimulating new ideas for research, and avoiding unnecessarily duplicative trials; however, to reduce potential harms, policies are needed to protect the privacy and consent of participants, the validity of analyses, the investment of funders and sponsors, and the academic recognition of investigators.
A word on severability clauses . . .

- Agree that judicial review is important uncertainty
- “Stochastic and destructive”
- *Chevron*-style deference to agency severability clauses → good idea
Question (1)

• Why have step 1/\textit{de novo} review on whether “remainder” would be A&C

• \textit{MD/DC/DE Broadcasters Association} (Judge Douglas Ginsburg)
  • Option A by itself (broad outreach) seemed quite consistent with agency’s purpose of minority access
  • Hardly “thin rationality”
Question (2)

• Even with *Chevron*, would agencies use severability clauses?
• “*Target on one’s back*”