Big Data and the New Regulatory Regime

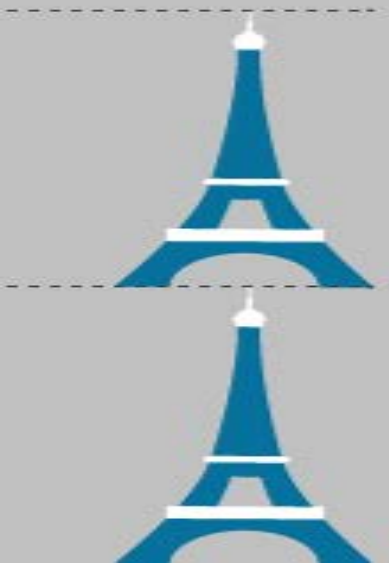
Ryan Abbott, M.D., J.D., M.T.O.M.

Professor of Law and Health Sciences, University of Surrey School of Law

Adjust Assistant Professor, David Geffen School of Medicine at UCLA

EVERYDAY BIG DATA

Big data describes the collection of complex and large data sets such that it's difficult to ***capture, process, store, search and analyze*** *using conventional data base systems. Its uses are shaping the world around us, offering more qualitative* ***insights*** *into our everyday lives.*



EVERY DAY WE CREATE

2,500,000,000,000,000,000

(2.5 QUINTILLION) BYTES OF DATA

This would fill 10 million blu-ray discs, the height of which stacked, would measure the height of 4 Eiffel Towers on top of one another.

Big Data and Drug Regulation

- Data collection
- Data aggregation
- Data analysis
- Appropriate use

Sentinel System

- September 2007: FDAAA required FDA to develop an active surveillance system—25mm individuals by July 2010; 100mm individuals by July 2012
- Contracting and self-regulation vs. notice-and-comment rulemaking.
- Primarily distributed model, common data format, private operation
- Exclusive safety focus
- Today, access to more than 178mm individuals

Inadequate Third Party Participation

- Insurers
  - No benefits from sharing research results
- Academics
  - Slow, not-targeted to regulators, needs translation
- Plaintiffs' attorneys
  - Slow, recovery for damages not preventing injuries, non-transparent

New Incentives for Third Parties

- An administrative bounty proceeding for third parties to submit data on drug safety/efficacy to the FDA modeled after FCA qui tam regime.
- Qui tam litigation used to combat medical and pharmaceutical fraud and abuse under the False Claims Act (FCA)
- Government lacks the resources or ability to adequately combat false claims by itself, so it permits private qui tam actions that enable private individuals ("relators") to enforce the FCA
- Improper payments under Medicare and Medicaid are estimated at a staggering $70 *billion* annually. The federal government gets about $3 billion annually from FCA cases.

Administrative Bounty Proceeding

- Petitioner award for presenting FDA with original data documenting a drug safety/efficacy concern that results in amended product labeling or the withdrawal from market of an approved drug or device.
- An FDA administrative hearing, which would create an adversarial process where one party seeks to maintain drug approval (or labeling) while the other seeks to have the drug withdrawn (or labeling amended).
- The administrative hearing this proposal envisions would be a sophisticated litigation-type process.

Financing

- If a petitioner submission results in the FDA removing a product from the market or amending labeling, the federal government could pay the petitioner a reward based on the government's estimated cost savings over a determined time period.
- If the product's sponsor was negligent in obtaining or maintaining FDA approval, the sponsor could be responsible for paying the petitioner award instead of the government, based on a percentage of a drug's revenue during the period after the manufacturer should have known of the adverse data.
- If the manufacturer knowingly, recklessly, or with gross negligence withheld evidence of a drug safety problem from the FDA, the product sponsor could be responsible for treble damages, half paid to the petitioner and half to the government.

Vioxx

- 29,000 potentially eligible claimants nationwide alleged heart attacks from Vioxx use, and 17,000 alleged strokes.
- The estimated average costs to Medicare of treating a patient for 180 days after a heart attack or stroke are $16,845 and $16,280 respectively.
- This suggests that the total direct costs for patients from Vioxx use were $765 million. About 95 million Americans, or 31% of the population, are covered by government health insurance.
- 31% of $765 million, or $237 million, is the amount the federal government would have to pay as a result of adverse effects from Vioxx during its market life.

Pre-Clinical & Off-Label Use

- Movement toward deregulation of pre-clinical approval and restrictions on pharma speech