Health Care Compliance Association
Research Compliance Conference
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Chicago, Illinois
Presenters

- Rory Jaffe, M.D. MBA
  - Executive Director — Medical Services
  - University of California

- John E. Steiner, Jr., J.D.
  - Chief Compliance Officer
  - UK HealthCare / University of Kentucky
Agenda

I. Introduction
II. Regulatory Trends
III. Medical Science and Ethics
IV. Future Roles and Responsibilities
V. Questions and Answers
Disclaimers

- Those who have knowledge, don’t predict. Those who predict, don’t have knowledge. — Lao Tzu
- Prediction is very difficult, especially if it’s about the future. — Nils Bohr
Our co-presenter

THE GIFTS OF MISS CLEO

SUNDAY,
SEPTEMBER 16
9PM ET
ON IN DEMAND
PAY-PER-VIEW

GET A FREE 7 MINUTE TAROT READING
California dreaming

- “In 2004, the University of California’s president, Robert Dynes, signed a deal with Governor Arnold Schwarzenegger that froze state public funding of the university’s system, began tuition and fee hikes, and committed the university to seek billions of dollars a year in additional private-sector funding.”
Kentucky Unbridled Spirit

- Legislative mandate 2020
- University of Kentucky to be one of the Top 20 public research organizations in the country by 2020
II. Regulatory Trends

- Follow the money
- Support clinical translational science
Federal support R&D

http://grants.nih.gov/grants/award/awardtr.htm*
US health care research funding $B 2005

http://www.kff.org/insurance/snapshot/chcm030807oth.cfm
September 2000 NCD dealt primarily with drug trials

July 2007 CMS Decision Memorandum

October 2007 CMS Final CRP
Government Expectations

- Comply with 2000 and 2007 CRP NCDs
- Get engaged with clinical translational science
Conflicts of Interest

- Quality of Research
- Funding affects conclusions
  - Relationship between Funding Source and Conclusion among Nutrition-Related Scientific Articles
    - Industry funded: 0% negative conclusions
    - Other: 37% negative
Changes in NIH

- NIH Roadmap for Medical Research
  - New Pathways to Discovery
  - Research Teams of the Future
  - Re-engineering the Clinical Research Enterprise

- Clinical and Translational Science Awards (CTSAs)
III. Medical Science and Ethics
Recent NEJM articles
Recent NEJM articles

- Advanced life support for out-of-hospital respiratory distress
- Randomized comparison of strategies for reducing treatment in mild persistent asthma
- Mutations in VANGL1 associated with neural-tube defects
- The egg trade — making sense of the market for human oocytes
- NSAID trials and the choice of comparators — questions of public health importance
Advanced life support for out-of-hospital respiratory distress

- Non-consent (or proxy consent) research
- Some current major issues require this
  - ACLS
  - ICU studies
  - Rapid response teams
  - Alzheimer’s
Randomized comparison of strategies

- Randomized comparison of strategies for reducing treatment in mild persistent asthma
- Evidence-based medicine
  - More post-approval studies
  - Larger populations
  - May not have company backing
    - Who funds these?
Mutations in VANGL1 associated with neural-tube defects

- We can now discriminate on the basis of genetic risk
  - What legal protections?
- Human material and privacy—at a primitive state
  - HIPAA pretty much ignores DNA
  - 45CFR164.512(f)(2)(ii): law enforcement purposes: identification and location – cannot disclose any information related to DNA or DNA analysis, dental records, or typing, samples or analysis of body fluids or tissue [except ABO Rh type].
The egg trade — making sense of the market for human oocytes

- How can we conclude that providing eggs for reproduction is less exploitative or dangerous than providing them for research?
- **TIME**: You have been very candid about your mistakes: that your team accepted eggs from two of its own members, and also paid volunteers for eggs. How big an ethical lapse is this?
- **Hwang Woo Suk**: They donated their eggs voluntarily without any coercion and their direct expenses were paid.
“In the United States, the long tradition of leaving to the pharmaceutical industry the task of evaluating the efficacy and safety of its products has permitted manufacturers to make study-design choices that largely determine the shape of the answers eventually provided by the trials. The identification, design, and prioritization of large phase 4 drug trials of potential public health importance represent a major medical, social, and scientific effort that currently lacks a champion in the United States.”
Informed Consent

- Adequacy of Consent
- Vulnerable Populations
Freedom Trial

- Multi-center (approx. 60 centers)
- Percutaneous Coronary Intervention (PCI) vs. Coronary Artery Bypass Graft surgery (CABG)
  - Have to randomize patients between PCI and CABG
- Difficult to consent patients because it is a high risk trial
- Consenting issues:
  - Have to be honest with patient
  - Have to inform patient that you may do PCIs every day, but patient may be randomized into a CABG
Premium Trial

- UK one of top 5 enrollment in the country
- Patent Foramen Opening
  - Does a large PFO correlate with migraines?
- Randomized, double-blinded study
- Protocol:
  - Either close the PFO or do not close the PFO
  - Patient doesn’t know for one year whether the PFO is closed
  - Prevents shunting of O₂ to the brain.
IV. Future
Roles & Responsibilities

- Principal Investigators (PIs)
  - Understanding of personal obligations
  - How do you reach your PIs?
- Fiscal Compliance
  - Where do you place your internal controls?
  - Coordinators
    - Greater responsibility
    - Greater workloads
- Infrastructure Needs
  - Training
  - Oversight
  - Environmental
  - IT security issues
Questions?