




Leadership  
And Corporate Accountability

## Lecture 14



## DISCLAIMERS

- ◎ 1. My personal opinions
  - ◎ 2. Not official policy of Department of Justice.
  - ◎ 3. A complaint or indictment is an allegation, and the defendant has a presumption of innocence and right to put government to its proof.
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## THE RESEARCH FRAUD PROBLEM

### ◎ It's not new

- Sigmund Freud fabricated case studies
- Isaac Newton altered records of lunar and solar sightings to fit his theories
- Pasteur made false statements about the first public trial of his anthrax vaccine
- Gregor Mendel's plant-breeding results are too good to be true

## WHAT IS RESEARCH FRAUD

### ◎ Intentional

- Scientific/research misconduct
  - ◎ Fabricating or falsifying data
  - ◎ Plagiarism
  - ◎ Overstating, misreporting results
  - ◎ Misrepresenting credentials


## WHAT IS RESEARCH FRAUD(2)

### ◎ FRAUD ON IRB

- Failure to submit and obtain approval
- Failure to identify changes
- Failure to comply with study protocol
- Failure to comply with subject disclosures and protections



## EXAMPLES OF RESEARCH FRAUD-BIOCRYST'S BCX-34


- ◎ 1994 study - University of Alabama-Birmingham - psoriasis, lymphoma treatment
  - ◎ “It wasn’t a school overly burdened with strictures or rules and regulations.” (UAB Director of gene therapy program)
  - ◎ False records, false reports, inflated improvement rates
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## BIOCRYST'S BCX-34

- ◎ 1994-False reports to FDA
- ◎ False statements for company press release
- ◎ 1995 FDA investigation
- ◎ 2000 trial – Dr. Harry Snyder and Study coordinator Renee Peugeot-convicted
- ◎ 2000 sentencing/appeal
- ◎ 2002 appeal denied
- ◎ 2004-Snyder 34 months, Peugeot 28 months




## EXAMPLES OF RESEARCH FRAUD-3/17/05

- ◎ Dr. Eric Poehlman, U. of Vermont Professor of Medicine
  - ◎ Fabricated research data in “Longitudinal Menopause Study” and “Longitudinal Study of Aging”
  - ◎ False grant applications and papers
  - ◎ Guilty plea to 1001, related to NIH grant
  - ◎ Permanent exclusion from all federal health programs
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EXAMPLES OF RESEARCH FRAUD/SAFETY ISSUE-University  
of Pennsylvania - 2/05

- ◎ Jesse Gelsinger - gene therapy research participant - died from research role
  - ◎ Prof. James Wilson - barred until 2010 from research on humans
  - ◎ Research team failed to halt study on learning of serious toxicities, and failed to disclose risks to participants
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## EXAMPLES OF RESEARCH FRAUD

- University of South Florida - testing of drug for fetal lung development on pregnant women
- Multiple amniocenteses
- Failure to disclose alternative approved drug
- Private civil action, no prosecution

## EXAMPLES OF ALLEGED FRAUD


- © BioCryst Pharmaceuticals/University of Alabama-Birmingham- RN Renee Peugeot and Harry Snyder, Ph.D.-false reporting of results of lymphoma study- nurse and scientist convicted- 291 F. 3d 1291 (11<sup>th</sup> Cir. 2002)
- © Pat Palmer, University of Iowa-fabricated interviews with autism families, her degrees, and her publications 69 F.R. 7488
- © Lajuane Woodward - U. of Md.- fabricated interview records for teen HIV prevention program 68 F.R. 67450

## HOW EXTENSIVE IS RESEARCH FRAUD?

- ◎ Some studies suggest- 40% of researchers are aware of misconduct but have not reported it. (Nicholas Steneck, U. of Michigan)
- ◎ Office of Research Integrity (ORI) handles HHS research-receives 150-200 reports/year
- ◎ NSF-100 misconduct complaints/year
- ◎ How many clinical trials have same issues?
- ◎ FDA Clinical Investigator Inspections/IRB Inspections




## FOCUS IN CLINICAL RESEARCH ENFORCEMENT

- ◎ MAKING INSTITUTIONS AND SPONSORS RESPONSIBLE FOR THEIR CONDUCT
  - ◎ MAKING INDIVIDUAL RESEARCHERS ACCOUNTABLE FOR THEIR ACTS
  - ◎ EMPOWERING PATIENTS, SUBJECTS, AND COMMUNITIES
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## RESPONSIBLE INSTITUTION

- ◎ Sponsor
  - ◎ Institutional review board (“IRB”)
  - ◎ Contract research organization
  - ◎ Site management organization
  - ◎ University
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## INDIVIDUALS

- ◎ INVESTIGATOR
  - ◎ CLINICAL COORDINATOR
  - ◎ IRB MEMBER
  - ◎ TREATING PHYSICIAN
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