

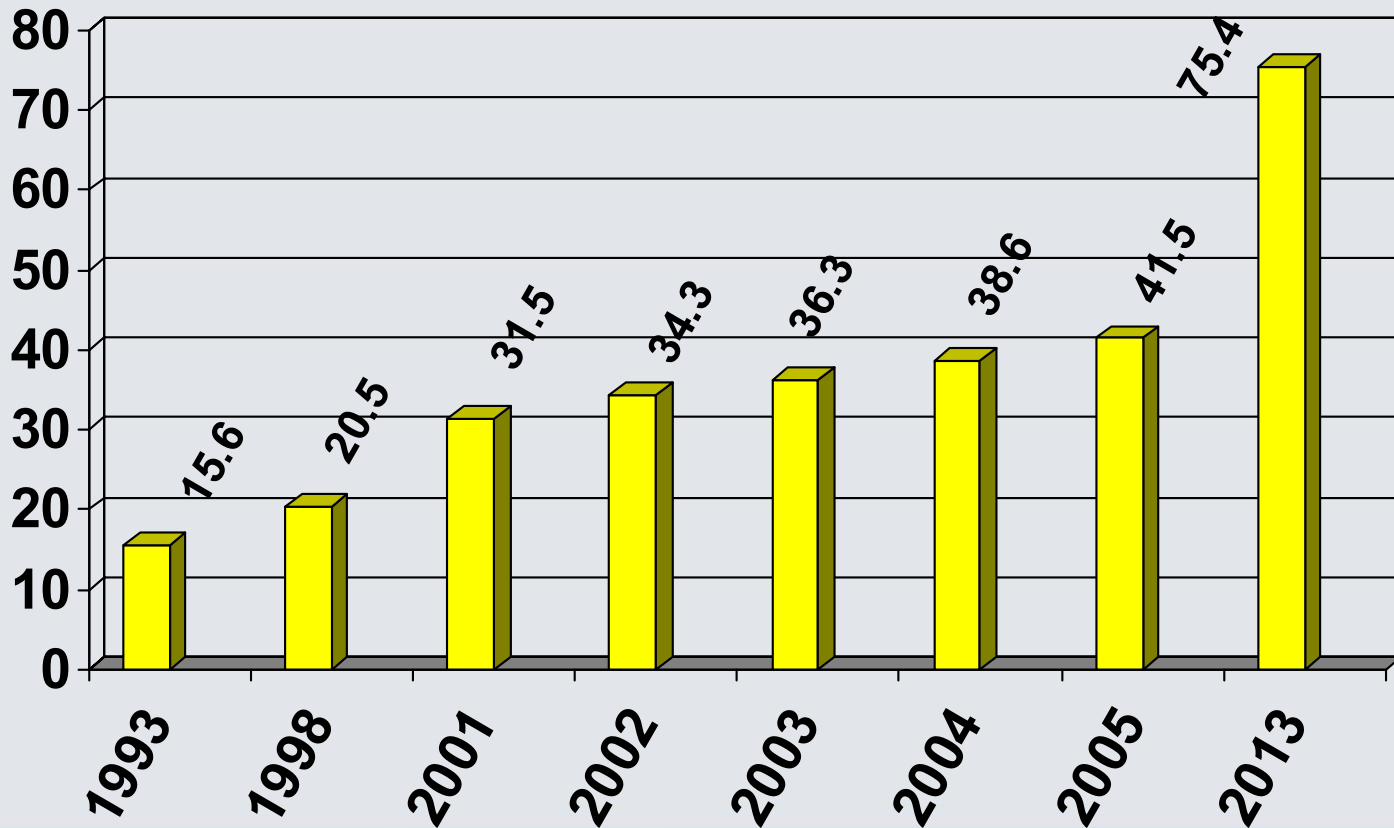
Investigating Fraud & Abuse Violations in Medical Research

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National Health Expenditures on Research

■ Research (billions)



Part I

Players in the Enforcement Community



United States Congress

House Committee on Energy and
Commerce

Senate Committee on Finance

Senate Committee on Health,
Education, Labor, and
Pensions



U.S. Department of Health and Human Services

Office of the Inspector General
("OIG")

National Institutes of Health
("NIH")

Food and Drug Administration
("FDA")



U.S. Department of Justice



Federal Bureau of Investigations
("FBI")

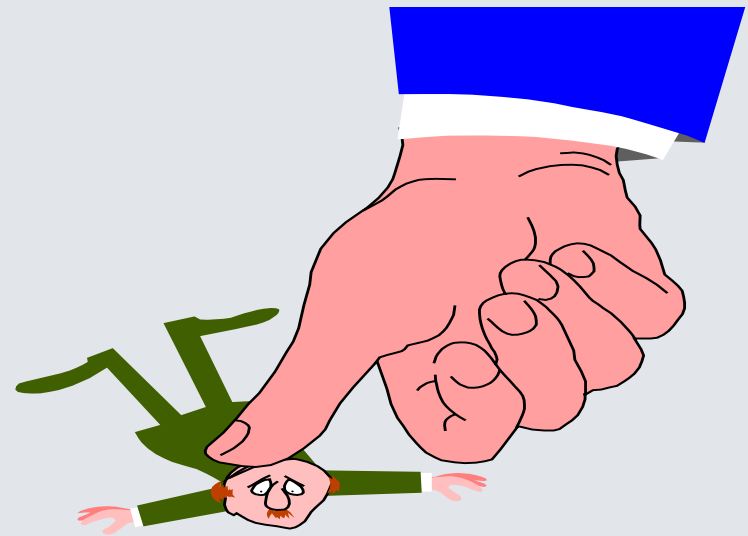
U.S. Attorneys' Offices



Enforcement Issues

Governmental enforcement officials often begin a case through:

- Whistleblower Suits
- Anonymous Calls
- Audits



Part II

Research Misconduct

Research Misconduct

OIG

Authorized to investigate:

- Criminal, Civil, and Administrative Matters

OIG & Office of Management Assessment (“OMA”)

Authorized to investigate:

- Misuse of NIH grant and contract funds
- NIH grantee and contractor conflict of interest

Research Misconduct

Potential Criminal Offenses

- Bribery
- Fraud
- Conflict of Interest
- Misuse of funds, equipment, facilities
- Perjury

Research Misconduct

Dealing with and reporting possible misconduct in
science of PHS awardees governed by 42 C.F.R.
Subpart A

Research Misconduct

Each PHS grantee must:

“establish uniform policies and procedures for investigating and reporting instances of alleged or apparent misconduct involving research training, applications for support of research or research training, or related research activities that are supported with funds made available under the PHS Act.”

42 C.F.R. § 50.101

Research Misconduct

“**Misconduct or Misconduct in Science** means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.”

42 C.F.R. § 50.102

Research Misconduct

Grantees required to submit “Annual Report on Possible Research Misconduct”

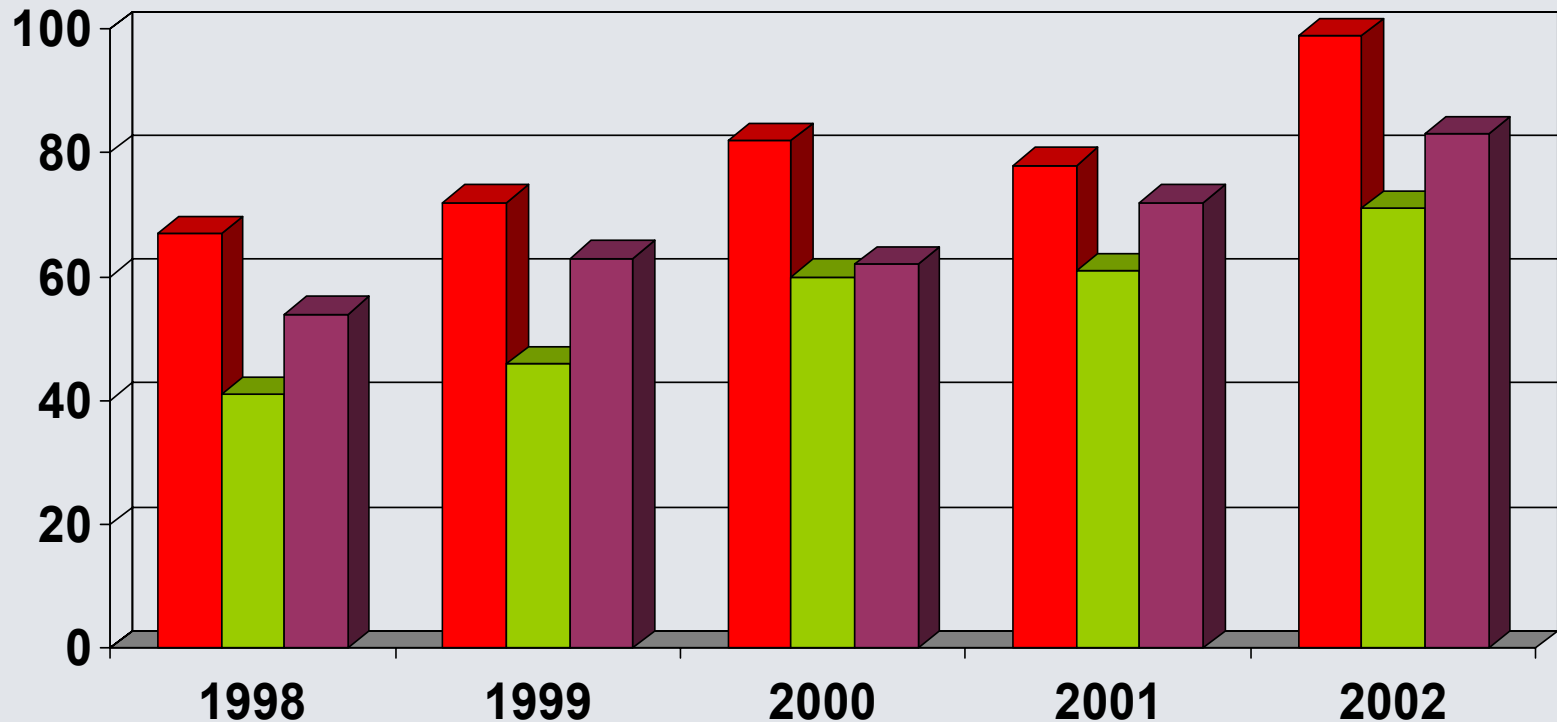
- Indicate whether institution has established administrative policies
- Disclose any alleged misconduct
- Requires **certification** of information provided

Consider Criminal and False Claims Act implications

Institutions Reporting Misconduct

Source: DHHS Office of Research Integrity
"Report on 2002 Institutional Annual Report on Possible Research Misconduct"

■ Reporting Activity ■ New Allegations ■ New Cases Opened

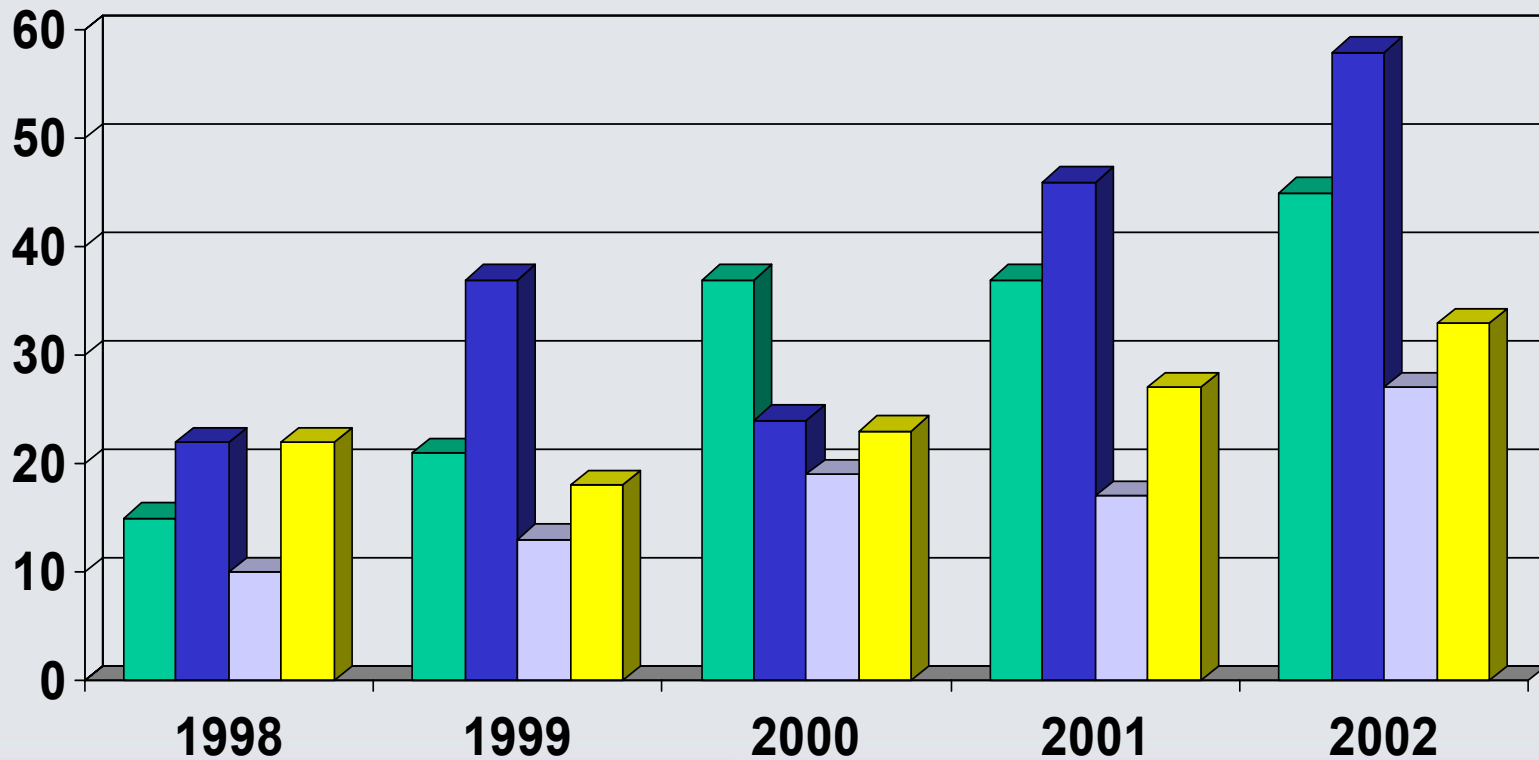


Types of Misconduct

Source: DHHS Office of Research Integrity

“Report on 2002 Institutional Annual Report on Possible Research Misconduct”

Fabrication **Falsification** **Plagiarism** **Other**



OIG Investigation

Depending on issues, OIG will investigate an allegation or refer the matter to OMA

If a criminal matter OIG will notify:

- Local US Attorney
- FBI
- Criminal Division of DOJ

OIG Investigation

In conjunction, NIH may take Administrative Action

- Best interests of government
- Suspend, limit, or terminate Federal funding

OMA Investigation

Generally handles non-criminal allegations

For NIH grantees, OMA has the right to “timely and unrestricted access to any books, documents, papers, or other records or recipients that are pertinent to the awards, in order to make audits, examinations, excerpts, transcripts, and copies of such documents. This right also includes timely and reasonable access to a recipient’s personnel for the purpose of interview and discussion related to such documents.”

45 C.F.R. § 74.53(e)

OMA Investigation

May refer appropriate allegations to:

- OIG (criminal)
- Office of Research Integrity (research misconduct)
- Office for Protection from Research Risks (misconduct involving humans or animals in research)

OMA Investigation

Reporting Process

- **Preliminary Draft Report** – sent to investigated party for comment
- **Final Draft Report** – may incorporate party's comments; sent to NIH Institute, Center or Division Director for review and comment and may be sent to the party
- **Final Advisory Report** – may incorporate additional comments; Sent to selected NIH official with need to know; recommended action within 30 days

Inform OIG if necessary

Part III

On the Horizon: Enforcement Trends



Enforcement Trends

FY 2004 OIG Work Plan

Management & Oversight of Research Grants

Review of NIH awards of noncompeting continuation grants closing out of grants

Issue Date: FY 2004

Grantee Administration of Funds

Review of selected NIH grantees use of grant funds

Issue Date: FY 2005

Enforcement Trends

FY 2004 OIG Work Plan

Monitoring Adverse Events in Clinical Trials

Review of NIH practices to ensure grantees compliance with reporting and monitoring adverse events in clinical trials

Issue Date: FY 2005

Grantee Compliance With Invention Reporting Requirements

Determine grantees compliance with reporting inventions developed under NIH grants or contracts

Issue Date: FY 2005

Enforcement Trends

FY 2004 OIG Work Plan

Royalty Income From Intramural Inventions

Assess NIH's collection of royalty income from new technologies developed by Federal employees in its research laboratories

Issue Date: FY 2005

Recharge Centers

Determine whether colleges and universities have complied with Federal cost principles

Issue Date: FY 2004

Enforcement Trends

FY 2004 OIG Work Plan

University Administrative and Clerical Salaries

Determine whether colleges and universities have appropriately charged administrative and clerical salaries to Federally sponsored grants and cooperative agreements

Issue Date: FY 2004

Disclaimer

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Moreover, slides and presentations provide a general summary of legal and regulatory requirements and do not constitute legal advice