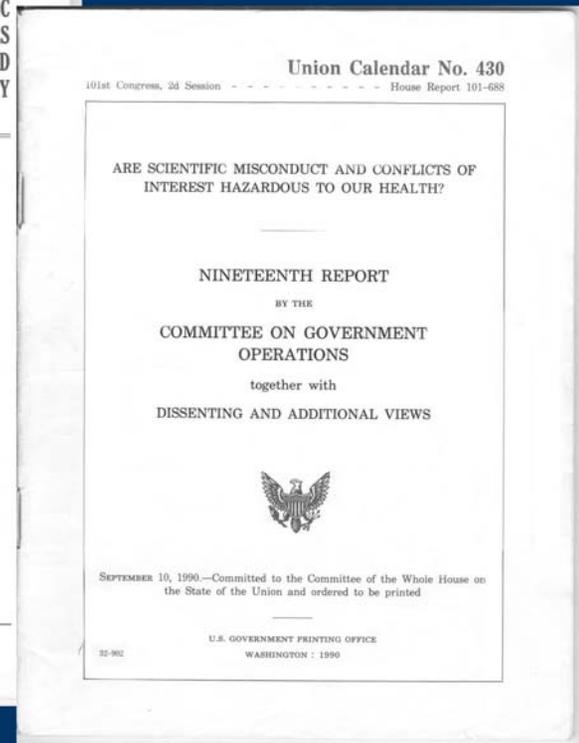
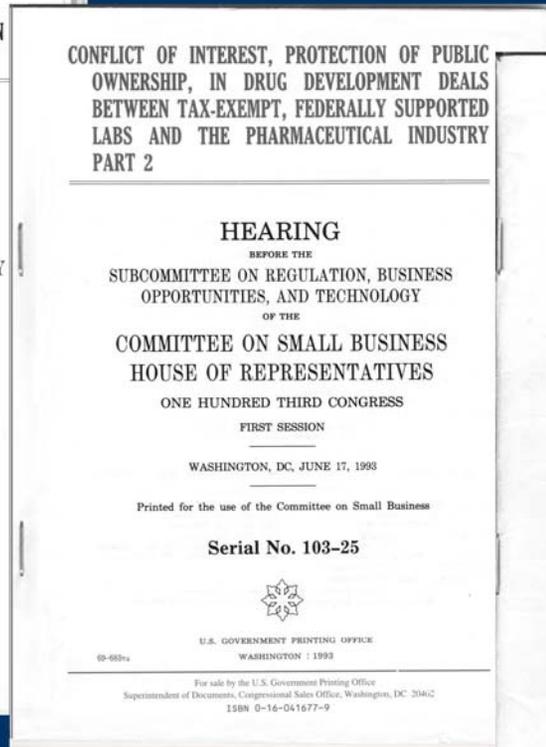
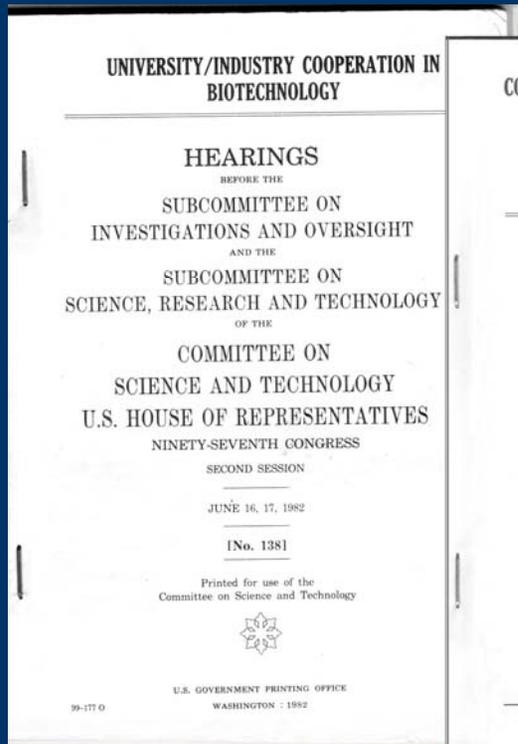


CORRUPTED SCIENCE

Documents & Reports on COI



This section lists some of the most influential reports, guidelines, and rulemakings issued in recent years by federal agencies and professional societies on conflicts of interest and scientific integrity.



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AAU Report

In 2001, the Association of American Universities issued a report on conflict of interest in the universities, stating that

“Research universities are concerned about financial conflict of interest because it strikes to the heart of the integrity of the institution and the public’s confidence in that integrity.” *

* Association of American Universities, Task Force on Research Accountability. *Report on Individual and Institutional Conflict of Interest*, October 2001.



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FDA requires financial disclosure by researchers

On September 22, 1994, the FDA issued a rule that requires scientists to disclose any financial interest they have in the outcome of research they conduct on drugs submitted for agency approval. *

* Department of Health and Human Services, Food and Drug Administration. Financial Disclosure by Clinical Investigators; Proposed Rule. Federal Register 59 (183):46708-48719 (September 22, 1994).



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COI Guidelines for DHHS and NSF

On July 11, 1995 Department of Health and Human Services and the National Science Foundation issued near identical guidelines for the management of conflict of interest of grantees. The purpose of the guidelines was to “ensure that the design, conduct, or reporting of research funded under PHS [Public Health Service] grants, cooperative agreements or contracts will not be biased by any conflicting financial interest of those investigators responsible for the research.”

* Department of Health and Human Services, Public Health Service. Objectivity in Research. *Federal Register* 60 (132):35810-35819 (July 11, 1995).

FDA Rules on Financial Disclosure by Clinical Investigators

“On February 2, 1998, FDA published a final rule requiring anyone who submits a marketing application of any drug, biological product or device to submit certain information concerning the compensation to, and financial interests of, any clinical investigator conducting clinical studies covered by the rule. This requirement, which became effective on February 2, 1999, applies to any clinical study submitted in a marketing application that the applicant or FDA relies on to establish that the product is effective, and any study in which a single investigator makes a significant contribution to the demonstration of safety. This final rule requires applicants to certify to the absence of certain financial interests of clinical investigators or to disclose those financial interests.” (p. 72171)

* DHHS, Food and Drug Administration. Financial Disclosure by Clinical Investigators. *Federal Register* 63 21:5233-5254 (February 2, 1998). Amended Fed. Reg. 63 (251):72171-72181 (Dec. 31, 1998).

1998 GAO Study of Bayh-Dole Act

The U.S. General Accounting Office reported to congressional committees on the implementation of the Bayh-Dole Act (1980).

“Although there is no database or study showing the impact specifically attributable to the act, a fiscal year 1996 report from a survey conducted by the Association of University Technology Managers indicates that inventions from all funding sources, including federal agencies, are increasing in their importance to universities. In fiscal year 1996, the number of inventions disclosed by universities increased by 9.3 percent for the year, and licensing income—which totaled \$365.2 million—increased by 22.1 percent.”

* U.S. General Accounting Office. *Technology Transfer: Administration of the Bayh-Dole Act by Research Universities*. GAO/RCED-98-126, May 1998.

Ethics Reform Act of 1989

Congress enacted the Ethics Reform Act of 1989 (PL 101-94), which contained a new conflict of interest provision in 18 U.S.C. 208. Under the new section 208(b)(3) a special government employee may participate in an advisory committee under the Federal Advisory Committee Act (FACA) despite a potential conflict of interest if the official responsible for the employee's appointment, after reviewing the employee's disclosure statements, determines that the need for the employee's services outweighs the potential conflict of interest created by the employee's financial interest.

FDA Guidance on COI for Advisory Committee Members

February 2000: FDA Guidance on Conflict of Interest for Advisory Committee Members, Consultants and Experts.

“If special Government employees (SGEs) have a financial conflict of interest in a particular matter within the meaning of 18 U.S.C. 208, they must be excluded from participating in advisory committee meetings or other assignments pertaining to that matter unless a waiver from exclusion is granted. There are four types of waivers that may be granted to an SGE at FDA: not so substantial financial interest; need for such an advisor; remote or inconsequential interests; if the member’s participation is necessary to afford the committee essential expertise.” *

* www.fda.gov/oc/advisory/conflictinterest/guidance.html



CORRUPTED SCIENCE

Draft Research Interim Guidance Document on Conflict of Interest & Human Subjects (2001)

“...there is currently no uniform, comprehensive approach to consideration of potential financial conflict of interest in human research.” *

* Office of Human Research Protection. Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider when Dealing with Issues of Financial Interests and Human Subject Protection. January 10, 2001.

COI Report of the Association of American Medical Colleges

On Financial Conflicts of Interest in Clinical Research:

“Disclosure to the IRB [Institutional Review Board] of record, to research subjects, and in all publications should be required whenever the institution holds a financial interest... that is or could reasonably appear to be in conflict with a proposed human subjects research project under the terms of these policy recommendations, and the conflict has not been eliminated through recusal or otherwise.”

* 2002: Task Force on Financial Conflicts of Interest in Clinical Research, Association of American Medical Colleges (AAMC). Protecting Subjects, Preserving Trust, Promoting Progress: Principles and Recommendations for Oversight of an Institution’s Financial Interest in Human Subjects Research, p.14 (October 2002). www.aamc.org/members/coitf/2002coireport.pdf

GAO Study of DHHS COI

“We are recommending that HHS [Health and Human Services] undertake efforts to highlight and communicate best practices for institutions to identify and manage investigator and institutional financial conflicts of interest. We are also recommending that HHS develop specific guidance or regulations to address institutional financial conflicts of interest.”
(GAO, p. 5).*

* General Accounting Office. HHS Direction Needed to Address Financial Conflicts of Interest. November 2001. GAO-02-89.

2003 DHHS Draft Guidance Document on COI and Human Subjects

In March 2003, Department of Health and Human Services Secretary Tommy Thompson issued a second draft guidance document that dealt with conflicts of interest in research involving human subjects. The 2001 interim guidance document stated that a conflict that cannot be eliminated should be disclosed in the human subject consent document. In contrast, the 2003 draft guidance document merely recommended that investigators consider including financial disclosures in the consent document. While DHHS acknowledges that “some financial interests in research may potentially or actually affect the rights and welfare of subjects” the agency leaves to individual institutions the sole responsibility to decide how to protect these subjects.

* DHHS, Office of Public Health & Science. Draft: Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection. *Federal Register* 68(61):15456-15460 (March 31, 2003).

GAO Study of University COI (2003)

“Of the 171 universities that responded to the GAO survey, 148 (87 percent) reported that all of their federally funded research is covered by financial conflict of interest policies that are consistent with either NIH’s or NSF’s standards. However, 17 universities reported that they do not extend either agency’s requirements to cover research grants from other federal agencies.” (GAO Highlights)

“Unless federal agencies uniformly require that universities implement financial conflict of interest policies, the government cannot properly safeguard against conflicts of interest that might bias federally funded research.” (4) *

* General Accounting Office. *University Research: Most federal agencies need to better protect against financial conflicts of interest*. Washington, DC: USGPO, November 2003. GAO-04-31.

NIH Amends its COI Rules: 2004

NIH revised its regulations governing scientific peer review of research grant applications and its conflict of interest requirements.

The new rule sets criteria for COI in the application or proposal process and sets a financial threshold at \$10,000/yr up from \$5,000/yr.

* DHHS, NIH. Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects. Fed. Reg. 69 (2): 272-278 (January 5, 2004).

Financial Relationships in Human Subjects Research

On March 12, 2004, the secretary of the Department of Health and Human Services issued a final guidance document on points to consider in determining whether specific financial interests in research affect the rights and welfare of human subjects.

DHHS recommends that IRBs, institutions, and investigators consider whether specific financial relationships create financial interests in research studies that may adversely affect the rights and welfare of subjects. *

* DHHS. Financial relationships and interests in research involving human subjects: Guidance for human subject protection. *Federal Register* 69(92):26393-26397 (May 12, 2004).

NIH Revised COI Rules for Senior Employees

August 25, 2005, the National Institutes of Health revised its Feb. 3, 2005 standards of ethical conduct for NIH senior employees. It prohibits outside consulting by NIH staff with “substantially affected organizations” (SAO) such as drug, biotech and medical device manufacturing companies. NIH requires divestiture of all holdings in SAOs in excess of \$15,000 per company (\$50,000 aggregate); it loosened restrictions on receiving monetary awards from outside sources; prior approval must be received for many non-prohibited activities.*

* Department of Health and Human Services (HHS). Supplemental Standards of Ethical Conduct and Financial Disclosure Requirements for Employees of the Department of Health and Human Services. *Federal Register* 70 (168):51559-51574 (Aug. 31, 2005).