

# Conflicts of Interest in Medicine -- Why Studies Are Not All That They Are Cracked Up to Be

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The cornerstone of public trust in medical research is the integrity of academic institutions and the expectation that universities, which rely on public funding, have a responsibility to serve the public good.

Financial conflicts of interest affect millions of American people—those who are subjects of clinical trials testing new drugs and those who are prescribed drugs after their approval. Yet, the leadership paid little attention to the issue until a stream of tragic and unseemly public revelations has shaken public trust in academic research.

In January 2002, the Association of American Medical Colleges (AAMC) approved a report by its task force stating: "Financial conflicts of interest of clinical investigators... [is] the single issue that [ ] poses the greatest threat to maintaining public trust in biomedical research." [The report](#) did not address institutional conflicts of interest which create a culture that collides with the humanist tradition.

Physicians reading [a recent issue of JAMA](#) will be startled to learn that a team of Harvard University professors are advising physicians NOT to prescribe new drugs to their patients because their safety has not been established—despite FDA approval. [Adverse drug reactions](#) they acknowledge, is the leading cause of death in the U.S.

They analyzed the 25-year record of drug label changes (between 1975 to 1999) as they appeared in the Physician's Desk Reference and found that 548 new drugs were approved during that period.

Of these 20% required subsequent black box warnings about life threatening drug reactions, half of these adverse effects were detected within 2 years others took much longer. Sixteen drugs had to be withdrawn from the market because they were lethal.

The [JAMA report](#) provides a basis for evaluating the value and relevance of clinical trial findings for clinical care. It also provides a basis for measuring FDA's performance as gatekeeper in preventing hazardous drugs from reaching the market.

They found that clinical trials are underpowered to detect uncommon, but potentially lethal drug reactions. Their design, biased selection, short duration, and accelerated approval process almost ensures that severe risks go undetected during clinical trials. The JAMA report validates the findings of a Pulitzer Prize winning investigative report in the Los Angeles Times by David Willman.[1]

Willman uncovered evidence demonstrating the adverse consequences of the 1992 Prescription Drug User Fee Act (PDUFA), the law that brought industry money and industry influence to the

FDA. The approval process for new drugs was accelerated and the percentage of drugs approved by the FDA increased from 60% approval at the beginning of the decade to 80% approval by the end of the 1990s.

Willman reported that the FDA was the last to withdraw several drugs that had been banned by European health agencies. There was a concomitant precipitous rise in the approval of lethal drugs: between January 1993 and December 2000, seven deadly drugs were brought to market only to be withdrawn after they had been linked to at least 1,002 deaths.[2] In a follow up article, August 2001, [3] Willman reported that the list of lethal drugs withdrawn since Sept 1997 had jumped to a dozen-9 had been approved after 1993.

None of the drugs were for life-threatening conditions, one was a diet pill, another for heartburn, another an antibiotic that proved more dangerous than existing antibiotics. The approval of these drugs illustrates the collision between corporate interests and the public interest.

Corporate interests revolve around maximizing profits through the marketing of new, expensive drugs, but corporate interests collide with public safety interests. FDA's "expert advisory panels" demonstrate FDA's loss of independence. Most advisory panel members have undisclosed financial ties to the manufacturer whose drugs they recommend for FDA approval.

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**The Alliance for Human Research Protection (AHRP)** is a national network of lay people and professionals dedicated to advancing responsible and ethical medical research practices, to ensure that the human rights, dignity and welfare of human subjects are protected, and to minimize the risks associated with such endeavors.

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### DR. MERCOLA'S COMMENT:

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**This is a fascinating report containing quite a bit of current, comprehensive documentation. However, they only posted the first part of the report, so if you find this information useful I encourage you to go to their site and read the rest.**

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