



Investigative Media Reports

THE NEW YORK TIMES NATIONAL MONDAY, DECEMBER 6, 2004

F.D.A., Strong Ties to the Drug Industry and Less Monitoring

From Page Al

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Stealth Merger: Drug Companies and Government Medical Research

Some of the National Institutes of Health's top scientists are also collecting paychecks and stock options from biomedical firms. VOL. CLIII ... No. 52,869

THURSDAY, JUNE 3, 2004

New York State Official Sues Drug Maker Over Test Data

Glaxo Challenged in the Use of Paxil for Children

By GARDINER HARRIS

in a novel claim testing the way that the \$400 billion worldwide pharmaceutical industry is regulated, the New York State attorney general, Eliot Spitzer, sued the British-based drug glant GlaxoSmithKline yesterwith Paxil, we believe, is a powerful one that shows that GSK was making selective disclosures and was not giving doctors the entirety of the

GlaxoSmithKline officials issued a





LA Times Investigation of Drug Company Influence at National Institutes of Health (NIH)*

- NIH allows over 94% of its top-paid employees to keep their consulting income hidden due to a ruling redefining the disclosure law.
- Director of the NIH's arthritis institute, S. Katz, was a paid consultant to Schering A.G. when their drug, Fludara, led to the death of 42 yr. old nurse in Institute's lupus-related study. Patient was not informed of COI.
- Deputy director of laboratory at National Institute of Allergy and Infectious Diseases, R. Germain, received \$1.4 million in outside consulting.
- NIH recusal policy runs on "honor system." Diabetes researcher, signed recusal and then participated in a series of decisions aiding a drug company to which he consulted. NIH researchers "routinely" sign confidentiality agreements with drug companies.
- Current NIH Director Zerhouni told Congress in 2002 that NIH had 274 ongoing R&D agreements with industry.

^{*} David Willman. Stealth Merger: Drug Companies and Government Medical Research. <u>Los Angeles Times</u>, December 7,





Medical schools sign contracts to keep drug tests confidential

- Academic institutions receive millions of dollars annually to run drug trials, according to New York Times report.*
- Companies refused to supply unpublished data showing the potential risks of pediatric antidepressants even to the studies' researchers.
- A study of Paxil with positive results in depressed children was published; a study showing it to be ineffective was not.
- The Private testing industry in the form of Contract Research
 Organizations (CROs) now coordinates many studies, taking over the
 role of medical schools.
- Pfizer, paid \$80,000 to Univ. of Texas Medical Center at Galveston which tested their drug Zoloft on children;
- Pfizer paid Galveston's Dr. Wagner \$20,500 during a trial showing Zoloft only 10% more effective than a placebo to claim it "effectively treated depression" in adolescents.*

^{*} Barry Meier. Contracts Keep Drug Research Out of Reach. New York Times, November 29, 2004, A1, A 16.





Drug companies pay doctors to prescribe their drugs

- New York Times in June 2004 reported that doctors received unsolicited checks for \$10,000 from Schering-Plough to prescribe their hepatitis drug.
- Pfizer in June 2004 agreed to plead guilty to illegally marketing the pain drug, Nuerontin, and paid \$430 million in penalties.
- AstraZeneca (\$355 million in fines in 2003) and TAP Pharmaceuticals (\$875 million in fines in 2001) pleaded guilty to fraud in pushing doctors to bill the government for drugs the companies supplied at no cost.
- Six specialists claim Schering-Plough paid "consulting fees" to doctors to maintain their loyalty to the company's products.
- Drug companies spending on marketing is double their research budgets.*

^{*} Gardiner Harris. "As Doctor Writes Prescription, Drug Company Writes a Check. New York Times, June 27, 2004, A1, A 19.





Doctors Paid to Recruit Patients for Drug Tests

Findings of a ten month investigation of contracts and thousands of other confidential documents by *New York Times* (1990-1998):

- SmithKline Beecham PLC, paid \$1,610 (1995) to doctors for each patient they signed up to test a new drug to shrink prostrate.
- A patient without any symptoms the drug could help was enrolled by his doctor who did not disclose his financial interest. Patient developed a test-drug related heart problem requiring a pacemaker.
- Companies forbid doctors to disclose contract terms; including coauthorship of ghost-written, academic articles related to study.
- Top patient recruiters can earn \$500,000 to \$1 million/year.*

* Kurt Eichenwald and Gina Kolata. Drug Trials Hide Conflicts for Doctors. New York Times, May 16, 1999, A1, A 28.





Food and Drug Administration (FDA) Shift in Emphasis

- Since 1992 FDA has cut funding for laboratories and independent drug safety experts to focus on drug approval.
- In 1992, the industry promised to give FDA \$200 million in FY2003 if the agency "spent a specified level of money on new drug approvals."
- FDA cannot get drug makers to do safety tests once a drug is approved.
- FDA Center for Drug Evaluation and Research, which oversees drug reviews and safety, receives 50% of its budget from drug industry user fees; 31 percent of its budget was supplied by drugmakers in 1998; none in 1992.
- The consequences of "rapid review": approval of drugs like Vioxx, has been implicated in 1000's of cases of heart failure.

* Gardner Harris. At F.D.A., Strong Ties and Less Monitoring. *New York Times*, December 6, 2004, A1, A 20.





Rx for Scandal

Boston Globe investigative journalist Peter G. Gosselin broke a story involving an ophthalmologist with a Harvard appointment who tested drugs his company produced that had not been approved for human experimental use. "Tseng secretly administered an unsanctioned drug to one group of patients. He tested his dry eye drug on a hundred more than authorized. And he helped start Spectra [Pharmaceutical Services, Inc] to make the drug.*

^{*} Peter G. Gosselin. Flawed study helps doctors profit on drug. *The Boston Globe*, October 19, 1988, A1. Peter G. Gosselin. The system failed in drug research probe. *The Boston Globe*: Science-Health-Technology, December 5, 1988, p. 4.





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High Stakes on Campus

"Science for \$ale" a series by Trish Wilson and Steve Riley of the Raleigh, N.C. *News and Observer* (March 27-April 3, 1994) explored the new commercialism in academia in these stories:

- "Spinning ideas into gold,"
- · "The doctor and his implants,"
- "Minding their own business",
- · "High stakes on campus," and
- "Corporate dollars pay for perks at cancer center."

"Universities are selling discoveries for millions of dollars, but the big money on campus raises questions. Do university scientists still serve the public good or are they pursuing financial gain?" *

* Wilson and Riley. Raleigh News and Observer, Reprint edition, March 27, 1994, p. 1.





In a two-part series titled "Fat's overlap" and "Obesity: Fat pills, fat profits," Kitta McPherson and Edward R. Silverman of the New Jersey *Star-Ledger* wrote that "many of the experts who decide you need to shed pounds work for the industry that profits from their declarations." *

^{*} Kitta McPherson and Edward R. Silverman. *Star Ledger Special*. Obesity: Fat pills, fat profits, Feb. 16, 1997, p. 1. Fat's overlap. Feb. 17, 1997, p. 1.







Self-Dealing Scientists

The Spotlight team of the *Boston Globe* prepared a 3-part series on public research and private profit that discusses how physicians and scientists are milking public funds for private interests. *

^{*} Mitchel Zuckoff, Alice Dembner and Matt Carroll. Self-Dealing Scientists. *The Boston Globe*, April 5-7, 1998.





Money + Science

The *Nation* published an article by David Shenk titled "Money + Science = Ethics Problems on Campus."

The article focused on the Betty Dong case and Knoll Pharmaceuticals in the context of other trends in the rise of academic commerce. * Betty Dong is a professor of clinical pharmacy at the University of California at San Francisco who was threatened by her corporate sponsor with legal action if she published the results of her comparative efficacy study of several thyroid drugs.*

* David Shenk. The Nation, March 22, 1999.





Industry-University Ties

Under the general heading "Medical Research: Can We Trust it?" in *The Hartford Current* (April 9-11, 2000) Mathew Kaufman and Andrew Julian published the following investigative reports on the impact of corporate money on the culture of academic science:

- 1) Surge in corporate cash taints integrity of academic science (4/9/00);
- 2) King of sex: Urologist feels flush with success (4/9/00)
- 3) Bad hair makes you sad (4/9/00)
- 4) Pushing a diet drug (4/10/00)
- 5) Industry cash: A potent habit (4/11/00) *

^{*} Duff Wilson and David Heath. Uninformed Consent. Seattle Times, March 11-15, 2001.



Drug Companies Profit from Publicly-funded Research

Under the headline "Medicine Merchants" Jeff Gerth and Sheryl Gay Stolberg of *The New York Times* in April 2000 investigated how the pharmaceutical industry is subsidized by the public funding of drug development research.*

* Jeff Gerth and Sheryl Gay Stolberg. Drug companies profit from research supported by taxpayers. *The New York Times*: Science/Health Section, April 23, 2000.



Conflict of Interest at the Hutch

In a five part series published between March 11-15, 2001, journalists Duff Wilson and David Heath of the *Seattle Times* investigated the prestigious Fred Hutchinson Cancer Research Center ("the Hutch") in a series entitled "Uninformed Consent."

In their story, "The Blood-Cancer Experiment," the journalists wrote of 20 people who died in a blood cancer experiment and who had never been told that some of the Hutch's doctors had financial interests in the drugs being tested in the experiment, *or* that there were safer and more effective alternative treatments.

* Duff Wilson and David Heath. Uninformed Consent. Seattle Times, March 11-15, 2001.







Physicians and Drug Companies

Shannon Brownlee examines the conflicting interests of physician-scientists and their effect on the publication of results:

"When industry has penetrated every level of medicine from the lab bench to the FDA advisory panels, from the pages of the medical journals to your doctor's prescription pad, how are physicians to make decisions about treating their patients?" *

* Shannon Brownlee. Doctors without borders. Washington Monthly, April 2004.