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## They lie – They Cheat – They Kill – Then They Coverup

### Despite Vow, Drug Makers Still Withhold Data

NYTimes May 31, 2005 By [ALEX BERENSON](#)

When the drug industry came under fire last summer for failing to disclose poor results from studies of antidepressants, major drug makers promised to provide more information about their research on new medicines. But nearly a year later, crucial facts about many clinical trials remain hidden, scientists independent of the companies say.

Within the drug industry, companies are sharply divided about how much information to reveal, both about new studies and completed studies for drugs already being sold. The split is unusual in the industry, where companies generally take similar stands on regulatory issues.

Eli Lilly and some other companies have posted hundreds of trial results on the Web and pledged to disclose all results for all drugs they sell. But other drug makers, including [Merck](#) and [Pfizer](#), release less information and are reluctant to add more, citing competitive pressures.

As a result, doctors and patients lack critical information about important drugs, academic researchers say, and the companies can hide negative trial results by refusing to publish studies, or by cherry-picking and highlighting the most favorable data from studies they do publish.

"There are a lot of public statements from drug companies saying that they support the registration of clinical trials or the dissemination of trial results, but the devil is in the details," said Dr. Deborah Zarin, director of [clinicaltrials.gov](#), a Web site financed by the National Institutes of Health that tracks many studies.

Journal editors and academic scientists have pressed big drug makers to release more information about their studies for years. But the calls for more disclosure grew stronger after reports last year that several companies had failed to publish studies that showed their antidepressants worked no better than placebos.

In August, [GlaxoSmithKline](#) agreed to pay \$2.5 million to settle a suit by Eliot Spitzer, the New York attorney general, alleging that Glaxo had hidden results from trials showing that its antidepressant Paxil might increase suicidal thoughts in children and teenagers. At a House hearing in September, Republican and Democratic lawmakers excoriated executives from several top companies, including Pfizer and [Wyeth](#), for hiding study results. In response, many companies promised to do better.



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At the same time, Merck and Pfizer have been criticized for failing to disclose until this year clinical trial results that indicated that cox-2 painkillers like Vioxx might be dangerous to the heart.

Drug makers test their medicines in thousands of trials each year, and federal laws require the disclosure of all trials and trial results to the F.D.A. While too complex for many patients to understand, the trial results are useful to doctors and academic scientists, who use them to compare drugs and look for clues to possible side effects. But companies are not required to disclose trial results to scientists or the public.

Some scientists and lawmakers say new rules are needed, and a bill that would require the companies to provide more data was introduced in the Senate in February. So far no hearings have been scheduled on the legislation. The bill's prospects are uncertain, said a co-sponsor, Senator Christopher J. Dodd, Democrat of Connecticut.

The drug makers have been criticized both for failing to provide advance notice of clinical trials before they begin and for refusing to publish completed trial results for medicines that are already being sold.

The two issues are related, because companies cannot easily hide the results of trials that have been disclosed in advance, said Dr. Alan Breier, chief medical officer of Lilly, the company that has gone furthest in disclosing results.

"You're registering a trial - at some point, the results have got to show up," Dr. Breier said. He added that disclosing trial results was important both to give doctors and patients as much information as possible and to improve the industry's reputation, which has been damaged by several recent withdrawals of high-profile drugs.

"Fundamentally, what we're doing is in the interest of patients, and I think that that is the winning model, for academia, for industry and for the future," he said.

In September, Pharmaceutical Research and Manufacturers of America, an industry lobbying group known as PhRMA, said it would create a site for companies to post the results of completed trials. Then, under pressure from the editors of medical journals, the major drug companies in January agreed to expand the number of trials registered on [clinicaltrials.gov](http://clinicaltrials.gov), the N.I.H. site, which was originally created so patients with life-threatening diseases could find out about clinical trials.

But Merck, Pfizer and GlaxoSmithKline, three of the six largest drug companies, have met the letter but not the spirit of that agreement, Dr. Zarin said.

The three companies have filed only vague descriptions of many studies, often failing even to name the drugs under investigation, Dr. Zarin said. For example, Merck describes one trial as a "one-year study of an investigational drug in obese patients."



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Drug names are crucial, because the [clinicaltrials.gov](http://clinicaltrials.gov) registry is designed in part to prevent companies from conducting several trials of a drug, then publicizing the trials with positive results while hiding the negative ones. If the descriptions do not include drug names, it is hard to tell how many times a drug has been studied.

"If you're a systematic reviewer trying to understand all the results for a particular drug, you might never know," Dr. Zarin said. "You don't know whether you're seeing the one positive result and not the four negative results - you don't have context."

Pfizer, Merck and GlaxoSmithKline say that they disclose their largest trials, which determine whether a drug will be approved. Though they would not discuss their policies in detail, executives and press representatives at the companies said generally that disclosing too much information about early-stage trials might reveal business or scientific secrets.

Rick Koenig, a spokesman for Glaxo, said the company understood the concerns about disclosure and planned to add more information to [clinicaltrials.gov](http://clinicaltrials.gov). He declined to be more specific, saying Glaxo and other companies were discussing the issue with regulators and medical journal editors.

In contrast, Lilly has registered all but its smallest trials at [clinicaltrials.gov](http://clinicaltrials.gov). Dr. Breier of Lilly said the company believed that it could protect its intellectual property and still increase the amount of information it released.

Lilly has also posted the results of many completed studies to [clinicalstudyresults.org](http://clinicalstudyresults.org), the Web site created last September by PhRMA. That site now contains some information on nearly 80 drugs that are already on the market. Both Lilly and Glaxo have posted detailed summaries of hundreds of studies.

Pfizer, on the other hand, has posted only a few, and Merck has posted none.

All the companies were meeting the group's guidelines for the site, said Dr. Alan Goldhammer, associate vice president for regulatory affairs at PhRMA. The lobbying group requires only that its members post a notice that a trial has been completed and a link to a published study or a summary of an unpublished study, he said. Studies completed before October 2002 are exempt from the requirements, and PhRMA has not set penalties for companies that do not comply.

"We're seeing pretty regular posting on a weekly basis, and as best we can assess right now, things are on track for meeting the goal we and our members set for ourselves," Dr. Goldhammer said.

The continued gaps in disclosure have caused some lawmakers to call for new federal laws. The bill introduced in February by Mr. Dodd and Senator Charles E. Grassley, Republican of Iowa, would convert [clinicaltrials.gov](http://clinicaltrials.gov) into a national registry for both new trials and



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results and impose civil penalties of up to \$10,000 a day for companies that hide trial data. But Mr. Dodd said that the chances the bill would pass in this Congress were even at best.

"I haven't had that pat on the back saying, 'This is a great idea, let's get going on this as fast as we can,' " Mr. Dodd said.

Dr. David Fassler, a psychiatry professor at the University of Vermont and a longtime proponent of more disclosure, said that trial reporting had improved in the last two years. But he said that a central federally run site, as opposed to the current mix of government and industry efforts, was the only long-term solution.

## Legal Drug Dealers - They Kill -They Lie - They Cheat – They Hide

### Hiding the Data on Drug Trials

**NYTimes June 1, 2005**

Any Americans gullible enough to believe that the drug industry can be trusted to report fully on what clinical trials it is sponsoring or what results were found must be sorely disappointed by recent developments. A government survey determined that three of the largest drug companies have effectively reneged on their pledges to list trials in a federal database. [A report in yesterday's Times](#) by Alex Berenson reveals that this intransigence also extends to a voluntary industry database. It looks as if demands from researchers and the medical profession for full access to clinical trial data will continue to be frustrated.

Companies already provide the data to the Food and Drug Administration, which is required to keep much of it confidential. A public listing of trials is important to prevent drug makers from hiding results that reflect badly on their drugs while publishing only results that make their drugs look good. By law, the companies are supposed to register important trials with a government Web site. Most manufacturers are complying, but the three big obfuscators - Merck, GlaxoSmithKline and Pfizer - are often getting around the requirement by not naming the drugs they are testing, instead using phrases like "an investigational drug." Merck was the worst offender, failing to provide a drug's name some 90 percent of the time. Glaxo withheld a name 53 percent of the time, and Pfizer 36 percent of the time.

Merck and Pfizer are also the most prominent withholders of trial results from the industry's voluntary database. As Mr. Berenson reported, Pfizer has posted only a few results of clinical trials, and Merck has posted none. That meager contribution appears to satisfy the weak guidelines set by the industry, but it offers a sorry contrast with the record of Eli Lilly. Lilly appears to have been quite scrupulous in listing its current trials with the government site and has posted the results of hundreds of completed clinical trials on the industry site. Surely if one big company can make its trials transparent, other drug makers can do the same.

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A coalition of medical editors has just stiffened its announcement that leading journals will soon refuse to publish the results of any clinical trial that has not complied with tough international standards for transparency. That should apply useful pressure to recalcitrant companies. But the best hammer would be federal legislation to compel all companies to provide critical information when a trial is begun and full results when a trial is completed, with stiff penalties for noncompliance.