

Re: USA Today Exposes Conflicts of Interest in FDA Drug Approvals

Source: <http://sci.tech-archive.net/Archive/sci.med.diseases.lyme/2004-06/0598.html>

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Date: 06/14/04

Date: Mon, 14 Jun 2004 11:01:48 -0400

READ THIS WEISMAN.....

THAT LOOKS LIKE PROOF,THE FDA IS A FRAUD

"hickwithverylitlelyme" <hickwithverylitlelyme@somewhere.net> wrote in message news:0kgzc.749\$Hp2.544@fe39.usenetserver.com...

> *TELL US ITS NOT ALL ABOUT MONEY.....*

>

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> *FDA Advisers Tied to Industry*

> *By Dennis Cauchon, USA TODAY*

>

> *More than half of the experts hired to advise the government on the safety*

> *and effectiveness of medicine have financial relationships with the*

> *pharmaceutical companies that will be helped or hurt by their decisions, a*

> *USA TODAY study found.*

>

> *These experts are hired to advise the Food and Drug Administration on which*

> *medicines should be approved for sale, what the warning labels should say*

> *and how studies of drugs should be designed.*

>

> *The experts are supposed to be independent, but USA TODAY found that 54% of*

> *the time, they have a direct financial interest in the drug or topic they*

> *are asked to evaluate. These conflicts include helping a pharmaceutical*

> *company develop a medicine, then serving on an FDA advisory committee that judges the drug.*

>

> *The conflicts typically include stock ownership, consulting fees or research*

> *grants.*

>

> *Federal law generally prohibits the FDA from using experts with financial*

> *conflicts of interest, but the FDA has waived the restriction more than*

> *800*

> *times since 1998.*

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- > *These pharmaceutical experts, about 300 on 18 advisory committees, make*
- > *decisions that affect the health of millions of Americans and billions of*
- > *dollars in drugs sales. With few exceptions, the FDA follows the*
- > *committees'*
- > *advice.*
- >
- > *The FDA reveals when financial conflicts exist, but it has kept details*
- > *secret since 1992, so it is not possible to determine the amount of money*
- > *or*
- > *the drug company involved.*
- >
- > *A USA TODAY analysis of financial conflicts at 159 FDA advisory committee*
- > *meetings from Jan. 1, 1998, through last June 30 found:*
- >
- > *At 92% of the meetings, at least one member had a financial conflict of*
- > *interest.*
- >
- > *At 55% of meetings, half or more of the FDA advisers had conflicts of*
- > *interest.*
- >
- > *Conflicts were most frequent at the 57 meetings when broader issues were*
- > *discussed: 92% of members had conflicts.*
- >
- > *At the 102 meetings dealing with the fate of a specific drug, 33% of the*
- > *experts had a financial conflict.*
- >
- > *"The best experts for the FDA are often the best experts to consult with*
- > *industry," says FDA senior associate commissioner Linda Suydam, who is in*
- > *charge of waiving conflict-of-interest restrictions.*
- >
- > *But Larry Sasich of Public Citizen , an advocacy group, says, "The*
- > *industry*
- > *has more influence on the process than people realize."*
- >
- > *Number of drug experts available is limited*
- >
- > *By Dennis Cauchon, USA TODAY*
- >
- > *In October, pharmaceutical giant Johnson & Johnson sent a team of*
- > *executives*
- > *to a Holiday Inn ballroom in Silver Spring, Md.*
- >
- > *Their job: persuade the Food and Drug Administration's panel of*
- > *independent*
- > *experts that an expensive antibiotic, Levaquin, should be the first drug*
- > *approved to treat penicillin-resistant pneumonia.*
- >
- > *For Johnson & Johnson executives, the FDA's Anti-Infective Drug Advisory*
- > *Committee included some familiar faces. At least two of the experts were*
- > *paid consultants to the drug company and had worked on the very same*

- > *medicine that they were being asked to evaluate for approval in an important*
- > *new market.*
- >
- > *The expert panel's "consumer representative," whose assignment is to defend*
- > *consumers' interests, had the most extensive financial relationship with*
- > *Johnson & Johnson. Keith Rodvold, a pharmacy professor at the University of*
- > *Illinois–Chicago, serves on a company anti–infective drug advisory board,*
- > *according to Johnson & Johnson spokesman Marc Monseau. Rodvold advised the*
- > *company on how to design and analyze the clinical trials that got the drug*
- > *approved. In 1999, he designed a study to measure how Levaquin is absorbed*
- > *in the lungs. The company also uses him regularly as an consultant on a*
- > *variety of issues, Monseau says.*
- >
- > *Rodvold declined to discuss his relationship with Johnson & Johnson and his*
- > *work on Levaquin. The company declined to say how much Rodvold had been paid*
- > *during the five years he has consulted for it.*
- >
- > *The case of Levaquin reveals how deeply pharmaceutical industry money and*
- > *influence penetrates the drug approval process. FDA advisory committees*
- > *consist almost entirely of pharmaceutical industry consultants and*
- > *researchers. Even consumers' and patients' representatives on the committees*
- > *often receive drug company money.*
- >
- > *At least one committee member had a financial stake in the topic under*
- > *review at 146 of 159 FDA advisory committee meetings, according to a USA*
- > *TODAY study of advisory committee meetings held from Jan. 1, 1998, through*
- > *June 30, 2000. At 88 of those meetings, at least half the advisory committee*
- > *members had financial interests in the topic being evaluated.*
- >
- > *Powerful panels*
- >
- > *Eighteen FDA advisory committees play a crucial role in nearly every major*
- > *decision on drug regulation. They help decide what drugs should be approved*
- > *and how the pharmaceutical industry should be regulated. In recent years,*
- > *the FDA has followed every advisory committee recommendation to approve or*
- > *reject a medicine – except once, FDA spokeswoman Susan Cruzan says. (The FDA*
- > *approved the flu drug Relenza in July 1999 despite an advisory committee*
- > *voting 13–4 against approval.)*
- >
- > *Investors follow advisory committees closely. A committee vote can add or*
- > *subtract hundreds of millions of dollars from a drug company's stock market*

- > value.
- >
- > *The FDA is required by law to screen all committee members for financial*
- > *conflicts. The law says members have conflicts when committee action could*
- > *have the "direct and predictable effect" of causing the member a financial*
- > *gain or loss. The federal agency is forbidden from using experts with*
- > *financial conflicts unless a waiver is granted, usually on the grounds*
- that
- > *the experts' value outweighs the seriousness of the conflict. The FDA*
- grants
- > *these waivers routinely.*
- >
- > *In the period analyzed by USA TODAY, the FDA granted 803*
- > *conflict-of-interest waivers. Seventy-one other times, members had*
- financial
- > *conflicts that were voluntarily disclosed but did not require a waiver. In*
- > *the 746 other member appearances on the committees, there was no conflict*
- of
- > *interest.*
- >
- > *The FDA says granting waivers lets it tap the nation's leading*
- researchers,
- > *most of whom do work for the pharmaceutical industry.*
- >
- > *"The system is designed to bring together the best scientific experts we*
- can
- > *find," says FDA associate commissioner Linda Suydam, who approves waivers.*
- >
- > *She says conflict-of-interest waivers go through as many as eight levels*
- of
- > *review before they are granted. But Larry Sasich, a pharmacist who works*
- for
- > *the Ralph Nader-founded Public Citizen's Health Research Group, says, "It*
- is
- > *outrageous that the pharmaceutical industry's influence is so great that*
- > *even some consumer representatives are on drug companies' payrolls."*
- >
- > *Sasich says it might sometimes make sense to let experts with financial*
- > *conflicts participate, but "it should be rare and that person should not*
- be
- > *allowed to vote."*
- >
- > *Financial conflicts were most common when committees considered broader*
- > *issues, such as warnings labels for pregnant women or how cancer studies*
- > *should be designed. At the 57 meetings on regulatory policy, committee*
- > *members had conflicts 91% of the time.*
- >
- > *At the 102 meetings involving specific drugs, 33% of committee members had*
- a
- > *direct financial stake in the outcome.*
- >

- > *It is impossible to determine how advisory committee decisions might have*
- > *been influenced by the financial relationships its members have. The FDA*
- > *stopped making details of financial conflicts public in 1992, after*
- > *controversies about whether the financial interests of committee members*
had
- > *biased decisions on breast implants, Prozac and a drug to treat*
Alzheimer's
- > *disease. The FDA says it stopped releasing details on conflicts because of*
- > *concerns about violating the privacy rights of committee members, not*
- > *because of the controversies.*
- >
- > *Types of conflicts*
- >
- > *Financial conflicts include stock ownership, consulting fees, research*
- > *grants, a spouse's employment and payments for speeches and travel. The*
- > *conflict could be a tie to the company whose drug is under consideration*
or
- > *to a company that sells a competing drug.*
- >
- > *Many financial conflicts are considered too small to require disclosure or*
a
- > *waiver and were not counted in USA TODAY's study. For example, a committee*
- > *member can be paid up to \$50,000 a year by a drug company without any*
- > *financial conflict being disclosed if the work was on a topic other than*
- > *what the committee is evaluating, according to FDA guidelines. Committee*
- > *members also can own up to \$5,000 in stock in the company appearing before*
the committee.
- >
- > *Advisory committees include many of the nation's leading researchers. The*
- > *pay is not high considering the stature of many members: about \$400 a day*
- > *for meetings, plus travel expenses, and nothing for work done outside a*
- > *meeting. However, the assignments are prestigious, and committee members,*
- > *whose terms last four years, are in heavy demand as industry consultants.*
- >
- > *Conflicts are most common on the committees that consider heart drugs.*
- > *Forty-eight percent of experts had financial conflicts when considering*
the
- > *worthiness of specific heart medicines.*
- >
- > *"The greater degree of expertise, the greater the potential for*
conflicts,"
- > *says Milton Packer, chairman of the Cardiovascular and Renal Drugs*
Advisory
- > *Committee.*
- >
- > *Packer is a good example. He is a leading figure in cardiovascular*
research
- > *and has helped pioneer the development of drugs to treat congestive heart*
- > *failure. Last year, he led an effort by 150 leading cardiac researchers to*
- > *establish consensus guidelines on how to treat congestive heart failure,*
- > *which is suffered by 5 million Americans.*

- >
- > *But his work with pharmaceutical companies creates many financial conflicts.*
- > *The FDA granted him a waiver that allowed him to participate in a meeting*
- > *May 2 on the drug Refludan, which treats clotting. (Packer says he doesn't*
- > *recall what the conflict was.) And Packer did not participate in a meeting*
- > *May 1 on the heart drug Altace because of a financial conflict. (He declines*
- > *to say what the conflict was.)*
- >
- > *Packer says consolidation in the pharmaceutical industry has increased the*
- > *potential for conflicts because there are fewer companies and nearly all*
- > *have heart drugs.*
- >
- > *Financial conflicts are so common that eight of 10 members who evaluated the*
- > *drug Aggrastat, made by Merck, had conflicts of interest.*
- >
- > *Packer says he doesn't believe that financial conflicts distort the*
- > *recommendations of advisory committees: " There are so many checks and*
- > *balances, it would be almost impossible for a single individual to steer the*
- > *committee."*
- >
- > *At the meeting on October 20, 1999, on Levaquin, the chairman of the*
- > *committee and one other member stepped aside because of financial*
- > *conflicts.*
- >
- > *Of the 10 members remaining, four had received conflict-of-interest*
- > *waivers*
- > *from the FDA.*
- >
- > *In addition to Rodvold, New Jersey physician Carl Norden had consulted for*
- > *Johnson & Johnson in 1997 on the design of Levaquin studies for illnesses*
- > *other than the treatment of penicillin-resistant pneumonia, the company*
- > *said.*
- >
- > *Johnson & Johnson says having its consultants on the advisory committee*
- > *didn't create bias.*
- >
- > *"We don't believe (advisory panel members) would let a consulting*
- > *arrangement compromise their reputation and stature in the medical*
- > *community," says Monseau, the Johnson & Johnson spokesman.*
- >
- > *The advisory committee voted unanimously to recommend that Levaquin, an*
- > *\$8-per-pill antibiotic, be approved for treatment of penicillin-resistant*
- > *pneumonia. The FDA ratified the decision in February. Levaquin has been on*
- > *the market since 1997, but the FDA's action allows Johnson & Johnson to*
- > *market the medicine as the first antibiotic approved for the more than 25%*
- > *of pneumonia cases that are resistant to penicillin.*
- >

> *Industry influence on advisory committees will increase later this year.*

As

> *required by a law approved in 1997, the FDA will add official industry*

> *representatives to the committees. The industry officials will participate*

> *in deliberations, but they will not be allowed to vote.*

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