

# USA Today Exposes Conflicts of Interest in FDA Drug Approvals

[USA TODAY](#) analyzed financial conflicts of interest on the 18 expert advisory committees established by the Food and Drug Administration's Center for Drug Evaluation and Research. These committees vote on whether new drugs should be approved and what regulations should govern the drug approval process. The newspaper created a database of financial conflicts disclosed at all 159 advisory committee meetings from Jan. 1, 1998, through June 30, 2000. About 250 members appeared 1,620 times during those meetings.

As required by law, FDA advisory committees disclose when members have a financial interest in the subject of the meeting. Financial interest is defined in FDA regulations "as the potential for gain or loss as a result of government action on a particular matter."

## 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.**

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 a 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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