# Donations tie drug firms and nonprofits - Many patient groups reveal few, if any, details on relationships with pharmaceutical donors.

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The American Diabetes Association, a leading patient health group, privately enlisted an Eli Lilly & Co. executive to chart its growth strategy and write its slogan.

The National Alliance on Mental Illness, an outspoken patient advocate, lobbies for treatment programs that also benefit its drug-company donors.

The National Gaucher Foundation, a supporter of people suffering from a horrific rare disease, gets nearly all its revenue from one drugmaker, Genzyme Corp.

Although patients seldom know it, many patient groups and drug companies maintain close, multimillion-dollar relationships while disclosing limited or no details about the ties.

At a time when people are making more of their own health-care decisions, such coziness raises questions about the impartiality of groups that patients trust for unbiased information. It also poses a challenge for groups trying to hold patients' trust and still raise money to serve them.

An Inquirer examination of six groups, each a leading advocate for patients in a disease area, found that the groups rarely disclose such ties when commenting or lobbying about donors' drugs. They also tend to be slower to publicize treatment problems than breakthroughs. And few openly questioned drug prices.

At the same time, the groups perform an important function by providing services unavailable elsewhere, such as patient education and help in obtaining medications or affording insurance.

They also try to police themselves. For example, each declares it does not endorse or reject products. All formally require that industry grants be "unrestricted," meaning that there are no strings attached. One of them, Children & Adults with Attention Deficit/Hyperactivity Disorder, or CHADD, formally caps pharmaceutical donations.

Combined, the six received at least $29 million from drug companies last year, according to tax returns and annual reports. The amount ranged from 2 percent to 7 percent of revenue at the Arthritis Foundation, to 89 percent to 91 percent at the much smaller National Gaucher Foundation.

Some health-care experts, although applauding the groups' work, are calling for greater disclosure. And many patients expressed surprise at the ties.

"I don't think that would make a difference as far as taking a drug," said Gloria Antonucci, 65, leader of a Montgomery County pain-support group that relies on Arthritis Foundation advice. "But I think it would make me, maybe, 250 percent more skeptical about what the group is saying."

Jerome Kassirer, a Tufts University and Yale University medical school professor and author of On the Take: How Medicine's Complicity With Big Business Can Endanger Your Health, said better disclosure would guard against abuse.

"These organizations are susceptible to industry influence because they have trouble raising money themselves," Kassirer said.

But not all nonprofits are alike, said Marc Boutin, executive vice president of the National Health Council, a standard-setting coalition funded by nonprofits and drug companies. He said leading nonprofits with "fire walls" against donor influence were worlds apart from questionable organizations.

"We are controlled by volunteers who are living with a condition and the drugs they take, and I guarantee these people would not be influenced by a donor," Boutin said.

Matter of credibility

For drug companies, patient groups carry credibility that the industry sometimes lacks to target patients and "opinion leaders" who drive prescriptions, and hence, sales. Nonprofits also help patients stay on the medicine and push insurers to pay for it.

"Does it help us? Sure," said Matthew Emmens, Wayne-based chief executive officer of Shire PLC, the No. 1 ADHD drugmaker and a major donor to CHADD.

"In the industry, we feel we're doing a pretty good thing while making money, which is even better," said Norm Smith, president of Langhorne-based Viewpoint Consulting Inc. and veteran marketer for Merck & Co. Inc., Johnson & Johnson and others.

The donations are sometimes portrayed by the companies and nonprofits as "giving back" to patients. But the funding usually comes from the companies' marketing or sales divisions, not charity offices, company and nonprofit officials said. Grants often rise with promotional spending as a drug hits the market and fall when sales ebb.

Donations from Merck and Pfizer Inc. to the Arthritis Foundation more than doubled, to at least $1.65 million combined, in 2000 as they launched Vioxx and Celebrex. The donations fell below $375,000 by 2004, when safety fears had flattened sales, foundation reports show.

Merck explicitly wove the foundation into sales strategies. A 2001 internal memo, disclosed in product-liability trials, shows that Merck sought to use the foundation's pain-management program to "demonstrate additional benefits" of its products.

Foundation president John Klippel said he was unaware of Merck's plan. But he dismissed it as an example of mutual interests in treatment, not profits. "We envision that as an educational program," he said. "Their marketing folks envision it as marketing."

When interests diverge, however, groups must be ready to face donor pressure. Michael J. Fitzpatrick, president of the National Alliance on Mental Illness, or NAMI, said one donor recently demanded that, in return for funding a TV public-service announcement, the ad include the company's direct contact information. Fitzpatrick said NAMI refused.

The industry also benefits in Washington and state capitals, where nonprofits lobby for issues such as expanded Medicaid drug coverage or treatment programs. That can boost sales.

All six groups are active lobbyists. NAMI, for example, urges and helps states and localities to create special one-on-one "assertive" treatment programs, which include making patients take their medicine.

It acknowledged that drug-company donors may benefit but insisted that's not the goal. "Nobody from the pharmaceutical industry tells us what to do," NAMI president Fitzpatrick said.

Unusual corporate gift

In 2000-2001, the American Diabetes Association did not disclose an unusual gift from Lilly: a lent executive, Emerson "Randy" Hall Jr., who moved into its Alexandria, Va., headquarters and coached it on growth strategies, all paid by Lilly.

Vaneeda Bennett, the ADA vice president for development, denied that the gift compromised the group but conceded that it might look bad. "We always walk a fine line on showing favoritism to one company or another. I would imagine other corporate donors would look askance at it," Bennett said, adding that, if it were offered again, "we'd ask for money."

Hall, a Philadelphia native now retired and living in Princeton, said he never tried to influence the group and merely helped it market itself, including writing its slogan, "Cure. Care. Commitment." He estimated that his work, including diabetes patient research he subsequently shared with Lilly, would have cost "hundreds of thousands" from a contractor.

Asked why it did not cite Hall on its tax returns or annual report, ADA spokeswoman Diane Tuncer said: "There is not a requirement to do so."

Nonprofit experts laud such executive "loans," as long as groups disclose them and limit their authority.

Another group, NAMI, did not disclose that Lilly marketing manager Gerald Radke briefly ran its entire operation. Radke began in 1999 as a Lilly-paid "management consultant," then left Lilly and served as NAMI's paid "interim executive director" until mid-2001. The group acknowledged this only after being shown Radke's resume listing the job.

NAMI's president, Fitzpatrick, said he did not know why his predecessors did not disclose Radke's work. He said using Radke "was a reasonable move to try to increase capacity."

"But there is a perception issue," he said. "So that makes it, in hindsight, a difficult choice."

Radke, of Harrisburg, declined to comment. After NAMI, he ran the Pennsylvania Office of Mental Health and Substance Abuse, and now serves in the state Health Department.

Indianapolis-based Lilly, which donated at least $2.5 million to the ADA and $3 million to NAMI between 2003 and 2005, called its executive loans mutually beneficial. "The primary goal is to assist that organization in developing a needed capacity or function, but it also often serves to assist in the career development of the employee," a Lilly spokesman, Edward G. Sagebiel, said.

Avoiding favoritism

Drug marketers battle hardest over safety and effectiveness, and nonprofits say they strive to avoid favoring one product over another. The six appeared to be cautious on safety scares and rarely took the lead sounding drug-safety alerts, even as they highlighted news of drug breakthroughs and approvals they say members demand, their materials show.

"We don't position ourselves as a watchdog," said Bennett of the ADA.

The ADA, which received 5 percent to 10 percent of its revenue last year from drug companies, reported little initially in 2004 about suspected diabetes risks from antidepressants. Instead, Tuncer, its spokeswoman, said it convened an expert conference - funded by drug companies - and ended up echoing the concerns.

The Arthritis Foundation, which received 2 percent to 7 percent from drug companies, said little in 2000 about early studies raising questions about Vioxx. But when follow-up studies confirmed the concerns in 2001 and 2002, the group highlighted the problems and called for more safety research. A year later, Merck cut off all donations.

Patrick Davish, a Merck spokesman, denied any link between the donation cutoff and criticism, calling it just a "change in funding priorities."

Klippel, the group's president, said he doubted there was a link but said it would not matter anyway. "It's not to say they've not been unhappy with us from time to time," he said. "But it would not influence me."

The ADHD group, while calling itself a science-based information clearinghouse, has not published some critical information about ADHD drugs, including an FDA warning last September about suicide risk from Strattera, made by one of its biggest donors, Lilly.

Its chief executive, E. Clarke Ross, said the group's professional advisory board took time to review all information before posting it. Although the group is an outspoken proponent of ADHD drugs, he said, it has strict fire walls against corporate influence. Indeed, it was alone among the six in publishing an easy-to-find figure on pharmaceutical donations: 22 percent last year, or $1.01 million.

"We have a number of conflict-of-interest practices that meet industry standards," he said.

NAMI, like most groups, lists only FDA-confirmed side effects and typically refers people with any questions to the drugmaker.

One outspoken NAMI critic, David Oaks of the support group MindFreedom, described the group as an independent but willing pawn of industry.

"We're not saying there is some conspiracy in a skyscraper by a pharmaceutical executive rubbing his hands together," Oaks said. "It's that the entire paradigm is owned by the drug companies, and that the hazards of the drugs, like brain damage, are not discussed."

NAMI's Fitzpatrick defended its information, but acknowledged that groups were facing demands for fuller drug information. "I think we should be much more like Consumer Reports. We should have transparency on both side effects and benefits," he said.

Close ties on orphan drugs

Ties between drug marketers and patient groups appear closest on so-called orphan diseases, which involve relatively few patients, experts and drugmakers. Financial disclosures by two groups show they used most of the deductible donations to pay the medical bills and insurance premiums of patients using donors' products. That, in effect, spreads around costs while leaving pharmaceutical prices unchanged.

The National Organization for Rare Disorders, a Connecticut-based coalition that tries to spur development of orphan drugs, got $10.5 million - 68 percent of its revenue - from drug companies last year. It helps pay patients' premiums and bills, administers companies' free-drug programs and helps recruit patients for their clinical trials.

Founder Abbey S. Meyers said that donors did not shape her group's positions and noted that the industry needed the groups as much as they needed it: "I criticize them [donors] all the time. It has never come back to hurt us."

The Gaucher group, according to tax returns, received $1.77 million of its $2 million in revenue last year from Boston-based Genzyme, and spent $1.69 million on medical bills and insurance premiums of patients taking Genzyme's enzyme therapy Cerezyme, which cost insurers as much as $350,000 a year.

In contrast, the foundation took nothing from Actelion Pharmaceuticals US Inc., of San Francisco, maker of a second-line treatment, Zavesca, to be used when Cerezyme doesn't work. Actelion said the foundation rejected its no-strings grants and gave little or only critical Zavesca information.

"I don't want to say anything nefarious is going on. But it doesn't pass scrutiny," said Actelion's president, Shal Jacobovitz. He portrayed the foundation "almost as a commercial arm" of Genzyme.

Ronda P. Buyers, executive director, denied that the group is biased toward Genzyme. "We're two different organizations. We do get its money, which allows us to do what we do," she said.

Another company, Shire Human Genetic Therapies, formerly Transkaryotic Therapies Inc., which is developing an alternative to Cerezyme, also called the foundation unusually close with Genzyme, even though it had accepted Shire's small donations.

Genzyme "is aggressive, and it's all part of their marketing plan to have a dominant position," said Matt Cabrey, a Shire spokesman in Wayne.

David Meeker, president of Genzyme's lysosomal business unit, said Genzyme had no control over the foundation. He acknowledged that the group was so important for Cerezyme marketing that if it didn't exist, Genzyme would have looked for another.

"This is how we built our business," said Meeker, whose company took in $932 million last year from Cerezyme, high for an orphan drug. "It's also building a community where patients can get the help they need. It's the ultimate win-win."

Buyers, who did not respond to repeated follow-up calls after an initial interview, said:

"We cannot make them bring the price down. They do make a lot. But without the drug, there would be all these people who would be in such horrible positions. More people would die."

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**Caption:** PHOTO AND CHART
Emerson Hall Jr., an executive on loan from Lilly, advised one nonprofit. CHART Donations and the Marketing of Drugs: A Case Study (SOURCES: IMS Health; Arthritis Foundation annual reports; news reports; JOHN TIERNO / Inquirer Staff Artist) Pharmaceutical Donations to Patient Groups (SOURCES: IRS tax returns; annual reports; group officials; The Philadelphia Inquirer)
**Memo:** PHARMACEUTICALS' QUIET DONATIONS

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