

FDA Staff Travels on Drug Industry Dollars

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Groups tied to FDA-regulated industry paying for agency officials' trips.

Washington - Through an apparent loophole in agency rules the Food and Drug Administration has allowed its employees to receive more than \$1.3 million in sponsored travel since 1999 from groups closely tied to pharmaceutical and medical device companies.

FDA policy bars employees from taking trips paid for by the drug, medical device and other companies the agency regulates or by their trade groups. But the Center for Public Integrity has found nonprofit associations that draw their members, their boards and even some of their funding from medical and pharmaceutical-related companies paying for the travel of hundreds of FDA employees.

The sponsor of the most trips was the Drug Information Association, which footed the bill for more than 600 trips taken by FDA employees. The nonprofit group made up of pharmaceutical and medical device employees, academics and government regulators boasts 13 members on its board of directors who work or have worked for the industry or its consulting groups.

The FDA has come under heavy criticism since Vioxx and other widely prescribed drugs were recalled for safety reasons. Members of Congress and government watchdog groups have charged that the regulatory agency is too close to the industry it oversees to impartially and effectively police the roughly 10,000 drugs on the market.

At the behest of Congress, the Inspector General of the Department of Health and Human Services has investigated ties between the industry and the agencies that oversee it. Many of the top sponsors have membership or financial ties to medical and pharmaceutical-related companies. Nonprofit groups and universities with such ties paid for roughly a third of the more than 3,600 trips taken by agency officials, suggesting that the industry is indirectly subsidizing the travel taken by employees of the FDA.

The Center for Public Integrity analyzed all of the FDA's available reports of privately sponsored trips taken by agency officials between October 1999 and September 2005 that cost more than \$250. The traveler ranks included many division and department directors.

The Center identified 10 officials who took more than 25 trips each, often serving as speakers at the events they attended. Two of those officials are also members of the agency's new Drug Safety Oversight Board. Adobe Acrobat PDF After the recall pileup of Vioxx and other potentially dangerous medications, the safety board was established last year to independently monitor approved drugs. Seventeen of the board's 29 members have taken more than a combined 160 privately sponsored trips, at a total cost of more than \$220,000.

Substantial Corporate Ties

More than a quarter of all of the trips reported were sponsored by five groups with ties to the pharmaceutical, biologic and medical device industries: the Drug Information Association, the American Association of Pharmaceutical Scientists, the Parenteral Drug Association, the International Society for Pharmaceutical Engineering, and the Regulatory Affairs Professionals Society. They were responsible for close to 1,000 excursions, spending more than \$1.3 million to fly and host agency employees. Eleven drug safety board members were among the travelers sponsored by those groups. They took 55 trips costing approximately \$75,000.

These groups do not describe themselves as trade associations. Instead, they promote themselves as scientific associations of individuals, apparently thereby skirting FDA travel sponsorship prohibitions.

Each of the five groups boasts board members with ties to medical and pharmaceutical-related firms, including current and former employees, contract workers and consultants. Many of the groups' members have similar connections.

For example, Nikki Mehringer, an Eli Lilly quality control manager, was PDA's treasurer in 2000. She also testified before Congress that year on the subject of drug importation, promoting the industry argument that drugs from other countries might not be safe.

All of the organizations appear to draw at least some funding from corporations and individuals with business before the FDA:

- The American Association of Pharmaceutical Scientists' "Loyal Supporters" brochure lists Pfizer, Eli Lilly, Sanofi-Aventis and GlaxoSmithKline among companies funding some of its programs and events.
- Amgen and Bristol-Myers Squibb were among the sponsors of the Regulatory Affairs Professionals Society annual conference in 2005. RAPS promoted the expected attendance of "more than 1,000 regulatory affairs professionals from around the globe - including the decision makers, senior- and mid-level executives you want to reach."
- The International Society for Pharmaceutical Engineering's 25th anniversary gala last year listed sponsors that included AstraZeneca and Wyeth.
- The Parenteral Drug Association is offering exhibit and sponsor opportunities for its upcoming annual meeting in April; exhibitors signed up so far include subsidiaries of pharmaceutical manufacturers Dupont, Eisai, and Baxter.
- DIA, which has a policy prohibiting corporate sponsorship of programs and events, allows exhibits by companies such as AstraZeneca and Bristol-Myers Squibb at its meetings and conferences.

Independent consulting firm the Weinberg Group frequently assists companies with applications before the FDA. It boasts employees tied to the top travel sponsor, DIA, including DIA's last former president. At last year's DIA annual meeting, a Weinberg Group employee delivered one of its many tutorials; the topic: "FDA Enforcement: What You Need to Know to Avoid or Respond to the FDA."

Theresa Musser, president of DIA and executive director of Rigel Pharmaceuticals, defended the presentation. "When you're looking at a neutral forum, the bias would be if we didn't allow that to go on," she said.

Research Universities in the Mix

Universities and multilateral organizations were also among the major trip sponsors. One of the largest patrons was the University of Rhode Island, which spent \$275,000 underwriting the travel of FDA employees, some of whom were entertained at annual conferences sponsored by the school's College of Pharmacy that were held at Chesapeake Bay and Hilton Head, S.C., resorts.

URI's College of Pharmacy itself has strong ties to the drug industry. The school has adjunct professors hailing from just about every major drug company, including Schering-Plough, Novartis, Hoffman-La Roche and Pfizer. The university is currently conducting clinical trials for vaccines with drug giants GlaxoSmithKline and Merck.

Michael Simeone, the pharmacy school's director of continuing education, acknowledged that the school's close relationship with the industry could appear to be a conflict of interest.

"There's definitely going to be some interaction whenever you have an exchange of ideas," Simeone said. By footing the bill for the FDA to educate members of the industry, "we're helping stretch the limited resources that the FDA has - I don't know if that's proper."

Two other universities with ties to the pharmaceutical industry together sponsored more than 100 trips costing roughly \$98,000. The University of Texas conducts clinical trials for drug companies, including AstraZeneca and TAP Pharmaceuticals, while the University of Wisconsin is a major research center that has conducted clinical trials for Pfizer, GlaxoSmithKline and other companies.

Consumer and government watchdogs worry that trips sponsored by those with financial ties to regulated companies provide opportunities for pharmaceutical, medical device and other related industries to set the agenda for the FDA.

"There is no countervailing perspective," said Dr. Peter Lurie, deputy director of Public Citizen's Health Research Group, which monitors the FDA and the health industry. "They mostly become schmooze-fests for people from industry."

"We strongly think it's a problem," said Bill Vaughan, senior health policy analyst with Consumers Union. "It contributes to the revolving door."

Travelers Move on to Industry Jobs

Several former FDA officials now work for the industry they policed. Some are involved with groups that formerly funded their travel; the Center identified 20 former FDA officials who took trips sponsored by one of the five associations that went on to work for medical and pharmaceutical-related companies.

Charles Hoiberg, former deputy director of the FDA's Office of New Drug Chemistry, now works for Pfizer. Hoiberg is a board member of the International Society for Pharmaceutical Engineering, a group that paid more than \$15,000 for his travel to Milan, Tokyo, Singapore, Zurich and Dublin while he was with the FDA.

Hoiberg declined to comment on his connection to ISPE, but said that he received no money from any of the organizations that sponsored his travel. Travelers are repaid indirectly - the FDA receives funds from the sponsoring organization and passes on the travel reimbursement to the FDA staffer.

Ajaz Hussain, former deputy director of the FDA's Office of Pharmaceutical Science, took more than 35 privately sponsored trips costing more than \$68,000 before leaving the agency last fall to work for Sandoz, a manufacturer of generic drugs owned by pharmaceutical giant Novartis.

"You utilize the resources you have," Hussain said, citing the limitations in the FDA's travel budget as a reason for accepting outside sponsored travel. "You have to fulfill your responsibility of realizing the agency's public health objective."

Potential for a Hand in Shaping Policy

While many of the meetings held by groups such as DIA involve discussions of highly technical topics, sometimes important policy considerations are in play as well.

At DIA's 2002 annual meeting in Chicago, a panel on amendments to the Declaration of Helsinki, the world's main statement of ethics regarding medical research, included both director for medical policy at the FDA's drug unit Robert Temple and Bert Spilker, then-senior vice president for scientific and regulatory affairs of the Pharmaceutical Researchers and Manufacturers of America - the drug industry's main trade lobby.

The panel addressed amendments that would limit the use of placebos in clinical trials and require that patients have access to treatments after a trial ended. Industry has opposed those changes and the FDA has backed the industry position. In a 2004 letter Adobe Acrobat PDF addressed to Dr. David Lepam, who oversees clinical regulation at the FDA, the watchdog group Public Citizen charged that the ultimate goal of Temple and the FDA was the "undermining" of the declaration.

Temple said that he opposed giving the Declaration of Helsinki the force of law because "you don't want to be relying on anybody who's not sending you drafts."

He also denied that his policy decisions and those of the agency had been influenced because of the trips he took. "I don't pay attention [to who pays]," Temple said. "We don't get any more money or more attention if somebody else pays."

In 2004, Congress examined the National Institutes of Health ethics programs after news reports documented that NIH and FDA employees engaged in outside consulting work. The Inspector General of the Department of Health and Human Services - of which the FDA is a part - reviewed similar conflicts at the agency. But references to some top officials were noticeably absent.

Daniel Troy, the FDA's former chief counsel, is mentioned only once among the reports. During his tenure, Troy attracted many critics who accused him of creating or modifying policies favorable to the same pharmaceutical companies he once represented. And in September 2005, Legal Times reported that between August 2001 and November 2004 he met dozens of times with industry representatives and gave almost 80 speeches.

According to the records, Troy disclosed only one of those trips as having been sponsored by a third party. On Feb. 21, 2002, he traveled to New York to address the DIA on the subject "Marketing of Pharmaceuticals: How to be Aggressive and in Compliance." The DIA billed it as Troy's "first public speech" in his new position. When questioned, he said that he did not specifically recall the trip or being reimbursed for it, something he said his assistant would have handled.

"I basically took the position that if I was traveling on the government's time, I should use the government's money," Troy said.

Dr. Sidney Wolfe, director of Public Citizen's Health Research Group, was critical of the FDA's reliance on travel sponsorship by DIA and other nonprofits.

"It sounds like they're violating the spirit of the law, if not the letter of the law," Wolfe said.

Tighter Budgets, Looser Restrictions

The organizations sponsoring travel have grown quite a bit in the past few decades. For example, DIA's Web site says that it had only 300 members in 1979, compared with 27,000 in 2001.

Asked about the activities of such groups during his 1977 to 1979 tenure as FDA commissioner, Donald Kennedy said that he doesn't "remember that there were these types of associations."

Gerald Meyer, a former FDA associate commissioner for management and operations, said that the agency allowed travel paid by trade associations until the late 1970s, but "there was a perception that it was a cozy relationship."

Meyer, whose office oversaw conflict of interest questions, said that although he believes that lavish accommodations posing an actual problem was a rare event, "we made a decision. If someone needed to attend something, we'd pay for it ourselves."

The rules were further toughened in 1988, after several FDA employees were caught taking payoffs, expensive trips and pricey meals from generic drug companies. As a result, outside groups were barred from sponsoring travel. But the tide turned in 1992, when Congress passed the Prescription Drug User Fee Act, which billed drug companies to fund the drug approval process. DIA was again permitted to sponsor travel around that time.

Restrictions on travel sponsorship by several other groups were also relaxed after passage of the PDUFA legislation. Sherry Keramidas, executive director of the Regulatory Affairs Professionals Society, said that sometime around 1995, the FDA first made "some requests" that they support travel to critical meetings. But lack of funds has left the regulatory agency's officials dependent on organizations whose members have significant business interests before it.

Alan Andersen, who was associate director of the Office of Device Evaluation when he left the agency in 1993, said the travel policy changed "because of budget constraints." Andersen said that the roughly \$1 million supplement to the agency's annual travel expenditure of \$28 million is "significant."

"It's a 5 percent increase in what you're able to do," he said.

Susan Ellenberg, a former director of FDA's Office of Biostatistics and Epidemiology, said she could not have attended conferences without private groups' support. "Our budget is very limited," she said.

Sharon Smith Holston, who oversaw FDA's conflict of interest questions after Meyer, accounted for the decision by characterizing DIA's role as educational. Ellenberg, Meyer and other former FDA employees agreed and referred to DIA not as a trade association, but as a professional association.

"The public doesn't gain anything from not having anyone at these presentations," Meyer said.

All current and former FDA officials interviewed for the Center's report defended FDA's oversight of travel sponsorship.

"We have very tight travel restrictions," said Stephen Wilson, a deputy director with the agency's drug unit. "It's not like we're going off to Hawaii."

Ellenberg agreed with Wilson, adding that FDA officials "police it very tightly."

FDA's policy manual states that "if an employee's participation warrants the expenditure of official time, it also warrants the expenditure of [government] travel funds." However, according to Meyer, funds aren't always available.

"Getting money for that kind of thing is not in the cards," Meyer told the Center. "That's the right answer, no question - have FDA pay for all their travel."

A Neutral, Educational Role

Many of the private organizations sponsoring FDA employees' trips defend the practice, saying that they help provide a forum for learning about policies.

"To get all those parties into discussions will lead to greater productivity," said Robert Best, president of the International Society for Pharmaceutical Engineering.

Representatives of several organizations said they saw no conflict of interest in sponsoring the travel, and most stressed their groups' neutrality.

"We have absolutely no bearing and no influence on what [the industry is] saying," said Matthew Clark, director of marketing services for the Parenteral Drug Association.

Other organizations also stressed their independence from the industry, noting that most of their funding comes from individual membership dues and program activities. Stacey May, the public affairs director of the American Association of Pharmaceutical Scientists, said that her group does not lobby.

"We really view ourselves as a scientific organization. We support science only," May said, citing the association's written policy.

ISPE's Best said that while his group's funding comes from individuals, "probably the vast majority" of those dues were underwritten by the members' employers. Musser of DIA said she believes its dues and program fees are paid in part by both members and their employers, but that she did not know the details.

RAPS executive director Keramidas told the Center that who pays a member's dues has no bearing on the group itself.

"Many of our members work for corporations and they may be paying their dues. It's not as if corporations are driving our agenda," she said.

Victoria Kreha contributed to this report.