FDA lax on conflicts of interest

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THE FOOD and Drug Administration has done far too little to avoid conflicts of interest among those who serve on its scientific panels and advisory boards. The latest example came last Monday, when the agency appointed to a tobacco advisory committee two scientists who have financial ties to companies that sell smoking cessation products.

One of the scientists, Jack Henningfield, makes most of his income from a consulting company that has GlaxoSmithKline, which makes Nicorette gum, as a client, according to a Wall Street Journal report. The other, Neil L. Benowitz, formerly worked as a consultant for GlaxoSmithKline and still consults for Pfizer, which makes the quit-smoking drug Chantix.

It could be worse. The pair of scientists could have financial ties to cigarette makers - which would violate federal law since the two will vote on recommendations for how to regulate the tobacco industry. But no matter how honorable the individuals involved, there’s a clear danger when those who decide whether menthol cigarettes should be banned and whether smokeless tobacco products are safe also stand to profit from the sale of products that help people quit smoking.

It's encouraging that the FDA asked the scientists to disclose their financial ties to the drug companies. The reason for their appointment is the same scientific expertise they also offer to the pharmaceutical industry. But the agency must justify why the nine voting members of the committee could not be selected from the many scientists who do not have such ties.

If the two scientists are indeed the best that can serve the committee, they should not be allowed to vote on whether particular tobacco products can come to market unless they agree not to receive profits related to smoking-cessation aids. In addition, the FDA, which promised to screen all panel members for conflicts of interest before each meeting, should make the criteria and results of those screenings public while the panel meets and before any of its recommendations become national policy.
ALG Calls On Administration to Dismiss Science Panel Members With Conflicts

FDA Scientific Advisory Panel Rife with Conflict

FAIRFAX, Va., March 31 /PRNewswire-USNewswire/ -- Americans for Limited Government (ALG) President Bill Wilson today released the following statement regarding what Wilson termed are "blatant conflicts of interest on one of the Food and Drug Administration's key outside panels."

"An important panel set up by the FDA has a near majority of its voting members getting paid by special interests who have billions of dollars riding on the outcome of the committee's ultimate decision. This is ludicrous.

"The Obama administration continues its rhetoric about a balanced, objective approach to science - an approach that sets aside agendas and emphasizes science - but we keep finding that special interests trump scientific findings.

"On this advisory panel, ironically called the Tobacco Products Scientific Advisory Committee, the heavy influence of big pharmaceutical companies is overwhelming. Pharmaceutical companies stand to make huge profits if the committee takes certain actions like banning menthol.

"We strongly recommend that the Obama Administration reconsider the make up of this committee, dismiss the members or require them to abstain from issues affecting their own financial interests."

- Jack Henningfield a voting member of the committee is a consultant to GlaxoSmithKline the maker of Nicorette gum who would stand to benefit financially from further restrictions on tobacco products

- Neal L. Benowitz was Pfizer consultant which makes the drug Chantix that aids people who want to quit smoking. Benowitz has also worked for GlaxoSmithKline and Nabi Pharmaceuticals

- Dorothy Hatsukami received grant support from Nabi Pharmaceuticals to study their nicotine vaccine

The head TPSAC, Jonathan Samet, also received grants from GlaxoSmithKline and the organization he headed was funded by two different pharmaceutical companies.
The law establishing the committee specifically states that the "membership of the advisory committee to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee;" and that the committee "contain appropriate provisions to assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's independent judgment."

ALG is not alone in having concerns about the financial conflicts of interest on the TPSAC panel. A recent report by the financial giant UBS cited unease by noted Professor Michael Siegel that the panel "is loaded with people who have a very strong pharmaceutical industry ties. Four of the panelists, actually, are either funded by pharmaceutical companies or actual consultants for pharmaceutical companies that manufacture smoking cessation products."

Just today, two major anti-smoking researchers called for the head of the committee to step down due to conflicts.

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FDA denied Philip Morris USA request to remove tobacco-panel members over conflicts
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RICHMOND, Va. (AP) - Cigarette maker Philip Morris USA says the Food and Drug Administration denied its request to remove four members of its tobacco-products advisory panel that the company said had conflicts of interest.

Altria Group Inc., Philip Morris' parent company, said in its quarterly report filed Thursday that the nation's largest tobacco company objected to four voting members of the committee. The company said the members had financial and other conflicts, including having served as paid experts for plaintiffs in litigation against tobacco companies.

Philip Morris USA's targets included the committee's chairman, Dr. Jonathan Samet, director of the University of Southern California's Institute for Global Health and former director of the Institute for Global Tobacco Control at Johns Hopkins University.

The members have "disqualifying conflicts and biases arising from their active and zealous participation" in lawsuits "designed to destroy the tobacco industry," Denise Keane, executive vice president and general counsel for Altria, said in a letter to the FDA dated March 22.

The FDA denied the request to remove the members of the committee, but said it would continue to screen members for potential conflicts of interest on topics the committee would be considering.

FDA spokesman Kathleen Quinn said the agency followed existing law and procedure to recruit the best scientific experts and to ensure that the committee has a "balanced composition of expertise to handle the many complex tobacco related issues it will face."

The committee, which met for the first time last month, is tasked with advising the agency on a range of issues, including menthol cigarettes and dissolvable tobacco. Seven members are health professionals, one represents state governments and one the general public. It also includes three nonvoting members representing the tobacco industry.

The FDA won the authority in June to regulate tobacco including banning certain products, limiting allowable nicotine and blocking labels such "low tar" and "light" meant to convey that certain products are less harmful.
The law doesn't let the FDA ban nicotine or tobacco, just regulate what goes into tobacco products, require the ingredients be publicized and limit how tobacco is marketed, especially to young people.

Altria and Philip Morris USA, which makes the top-selling Marlboro brand, supported the law that created the panel.

But its chief rivals -- No. 2 Reynolds American Inc., parent company of R.J. Reynolds, and No. 3 Lorillard, both based in North Carolina -- opposed the law saying it would lock in Altria's share of the market because its size gives it more resources to comply with regulations and limits on marketing under the law.
The Rest of the Story: Tobacco News Analysis and Commentary

Tuesday, March 02, 2010

Four Members of FDA Tobacco Products Scientific Advisory Committee Have Received Pharmaceutical Money; Influence of Industry on FDA Grows

Pfizer and Nabi Pharmaceuticals Also Given a Seat at the Table

Yesterday, I reported that the FDA has appointed GlaxoSmithKline to sit on its Tobacco Products Scientific Advisory Committee, by virtue of its appointment of a Glaxo consultant and expert witness to the panel.

Today, I report that the influence of the pharmaceutical industry on FDA policy will be even greater than I suggested yesterday, because three additional members of the Committee have also received pharmaceutical money.

First, the chair of the Committee - Dr. Jonathan Samet - has received grant support from GlaxoSmithKline. In addition, the organization that he directed - the Institute for Global Tobacco Control - is funded by GlaxoSmithKline and Pfizer.

Second, an additional panel member - Dr. Dorothy Hatsukami - has received grant support from a pharmaceutical company to study the nicotine vaccine for use in smoking cessation.

Third, an additional panel member - Dr. Neal Benowitz - co-authored a study on the use of Chantix in smoking cessation which was funded by Pfizer and has also served as a Pfizer consultant. In particular, Dr. Benowitz served as a Pfizer consultant on how to develop a scientific base to support the use of Chantix in smoking cessation. Benowitz has also consulted for GlaxoSmithKline and Nabi Pharmaceuticals.

The Rest of the Story

The FDA Tobacco Products Scientific Advisory Panel is a virtual smorgasbord of tobacco and pharmaceutical financial interests. This is hardly what I imagine President Obama had in mind when in his inaugural address he called for "science to be restored to its rightful place."

The FDA has now given a seat on the panel to GlaxoSmithKline, Pfizer, and Nabi Pharmaceuticals, alongside the tobacco companies, through their paid consultants or grantees.

There is no way this panel can objectively consider tobacco product regulation and policy - based purely on the science - in the midst of such a potpourri of pharmaceutical
The conflicts of interest of two of the panel members were highlighted in an article in today's *Wall Street Journal*.

Given that the FDA has already been under siege for complaints about the undue influence of politics over science, due to the influence of industry, it is unclear why the Agency would want to compound the problem by crafting a highly conflicted panel to advise it on tobacco issues. There is enough bias in this field to begin with; we don't need to add to it by appointing a panel with numerous members who have severe, personal financial conflicts of interest.

The rest of the story is that by virtue of its appointment of numerous members with financial conflicts of interest with Big Pharma, the FDA Tobacco Products Scientific Advisory Committee has now become a literal extension of pharmaceutical company financial interests. These companies have been given the gift of a seat at the table (actually, four seats).

This means that 7 of the 12 seats on the panel are now industry seats:

- Big Tobacco: 3
- Big Pharma: 4
- Total Industry Seats: 7

The tobacco and pharmaceutical industries must be laughing all the way to the bank. There's nothing like sitting on the panel of the Agency that regulates your products or makes decisions about the regulation of the products of your chief competitors.

*posted by Michael Siegel @ 2:11 PM*

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