Proposed FDA Conflict-of-Interest Guidelines Get Lukewarm Reception

By Joel B. Finkelstein

The U.S. Food and Drug Administration has shed new light on the process of vetting advisory committee members, but several experts said that recently proposed financial guidelines do not go far enough to weed out conflicts of interest.

The FDA has come under increasing pressure from Congress to implement stricter oversight of regulated products throughout the approval process. Among several currently pending proposals is legislation that would require that the agency publish the conflict-of-interest information for its advisors at least 30 days before committee meetings, under most circumstances.

The FDA’s proposed guidelines leapfrog those congressional efforts by establishing a financial cutoff, said Bill Vaughan, a senior policy analyst for Consumers Union, publisher of Consumer Reports.

According to the draft document, which is open for public comment through May 21, FDA staff will take several steps to determine what monetary ties potential recruits have to companies that may come before an advisory panel. Those with more than $50,000 in financial interests won’t be allowed to participate without a waiver issued by the agency itself. Those with financial interests that fall below that cutoff can still participate on the panel but won’t get to vote, though this restriction could also be waived at the agency’s discretion.

Roger Pielke Jr., Ph.D., director of the Center for Science and Technology Policy Research at the University of Colorado in Boulder said the guidelines are helpful. “They allow some sunshine on the process. But I guess there are still some dark corners that need illuminations.”

For example, why choose $50,000 as the threshold, Pielke and other experts asked. According to the FDA, $50,000 was chosen as a level they can live with. They say it
effectively strikes a balance between the amounts of financial interests that are commonly seen in the research community and the agency’s ability to recruit committee members with relevant expertise.

“The difficulty the agency faces in trying to hire members to serve on FDA advisory committees is that the world’s experts, who are engaged in cutting-edge bench science, clinical research, and independent consulting work, are the very same individuals that are sought after by regulated industry,” FDA staff wrote in an e-mail.

It would make more sense to base the threshold on whether the financial interest would influence an individual’s decision making, said Sheldon Krimsky, Ph.D., currently a visiting scholar at Columbia University in New York City.

“Fifty thousand dollars seems awfully high to me. I think it would seem high to most of the American public,” he said. For years the cutoff was set at $10,000 and only more recently raised to $20,000.

“They don’t want to be embarrassed again by a USA Today story that says that they issued a waiver 50% of the time. If they raise the minimum level, then maybe they don’t have to do that as much. That’s the way it appears to me,” he said.

There’s also the law of unintended consequences. Having a published threshold opens up the possibility of gaming the system. For example, companies could structure their payments to researchers so that the scientists can still sit on an FDA panel, Pielke said.

“In the future you will see a lot of people who have financial interests of $49,999,” he said.

**Breaking the Cycle**

The only appropriate threshold for conflict of interest is zero, said Merrill Goozner, director of the integrity in science project at the Center for Science in the Public Interest in Washington, D.C.

With 125 U.S. medical schools, the agency should be able to find people with the expertise they need who don’t have financial conflicts, he said. And if the agency needs someone with special expertise who does have a financial interest in the company, that person can always be brought in to testify before the advisory panel, he said.

Consumer Reports’ Vaughan agreed. “If you have someone with a conflict of interest, bring them in but don’t have them sitting and schmoozing with the members of the panel.”

Finding scientists who are not involved with drug companies may not be easy for the FDA, but somebody has to break the cycle of rewarding physicians on advisory committees, Krimsky said.

“What you are doing in the current situation is reinforcing people with conflict of interest, giving them the prestige of operating on federal advisory committees. Not only that, but it actually raises their pay from drug companies. If I’m a physician I’m worth more to a drug company if I’m on a federal advisory committee,” he said.

Experts also point out that financial interests are only one kind of conflict, but the FDA guidelines don’t address any others. Scientists are just as likely to be affiliated with an advocacy or political group that has a position on certain drugs or classes of drugs, Pielke said.

“There is no such thing as the pure philosopher king sitting out there with no competing interests,” he said.

Instead, the agency should work to make sure that advisory committees are balanced and representative of the range of prevailing views, he said.

“What we need to do is not to try to get rid of [conflicts of interest] or pretend that they don’t exist but to develop a process that allows us to manage the reality that researchers have financial incentives,” he said.

**A Step Forward**

It’s not clear at this point whether the guidelines will, in fact, change much about the way that the FDA determines who is eligible for advisory committee membership. FDA staff are considering including case-specific examples in the final rules to illuminate how the process will be applied. However, what seems more clear is that the guidelines may be less about reforming internal practices and more about changing the public’s perceptions about the agency, Krimsky said.

And the agency’s staff seem to acknowledge that is part of their motives. “FDA is committed to making the advisory committee process more rigorous and transparent so that the public has confidence in the integrity of the recommendations made by its advisory committees,” said Randall Lutter, Ph.D., FDA’s acting deputy commissioner for policy.

The changes may also be aimed at changing the views on Capitol Hill. However, it is unlikely to divert the attention of agency critics such as Sen. Chuck Grassley (R-IA) who, as a member of the Finance Committee, has been pursuing an investigation into questionable drug approvals.

“Sen. Grassley believes that any work to make positive changes at the FDA is good, but he remains concerned that it’s being done piecemeal. There are so many problems that he believes there needs to be a thoughtful, systematic, long-term plan to the reform,” a Grassley spokesperson said.

That thought meshes with what those in the advocacy community would like to see, including better public disclosure of potential conflicts of interest and the addition of FDA staff whose sole task is to vet committee candidates.

“It’s a great step forward and it’s much better than the congressional proposals,” Vaughan said. “Now let’s build on it.”