

FDA advisory panels: Expertise vs. conflict of interest

By ACSH Staff — September 11, 2014



How do you ensure that the FDA advisory panels crucial to the drug

approval process have the right members?

ACSH advisor Dr. David Shlaes, the former head of infectious disease research at Wyeth, addresses these issues especially as they relate to antibiotic panels in his recent thought-provoking entry entitled *Conflict of Interest vs. Competent Advice*.

Dr. Shlaes discusses a [study](#) ^[1] just published in *The Milbank Quarterly* a journal that focuses on population and health policy. Some of the findings of this study are both surprising and counterintuitive. But, since we are still smack in the middle of an antibiotic crisis, this issue is especially important.

The Milbank study analysed the voting patterns of about 400 advisory committee members who voted 16,000 times between the years 1997 and 2011, examining the effect of conflict of the panel members and how they voted. Some of the findings are fascinating.

In particular, the study found that 13 percent of panel members revealed some type of financial relationship with companies that had drugs being reviewed by the panels. Dr. Shlaes notes, These [panel] members could be divided into two classes; one class had multiple financial relationships with multiple companies while the second had an exclusive relationship with the company in question.

The voting patterns in the two groups were very different. For example, all panel members, both with and without stated conflicts, voted to approve what they were evaluating 52 percent of the time. But upon further analyses, some very interesting trends emerged.

For example, there was a very profound difference in the voting pattern in panel members who reported a financial relationship with a single company than for panel members who had multiple conflicts with different companies. While the members with multiple conflicts voted the same as members without any conflicts, members with financial ties to only one company voted 84(!) percent of the time to approve the products from that company.

Dr. Shlaes, who has been intimately involved with the FDA's antibiotic policies and practices for many years says, The take-home lesson to me is that experts are actually experts. Those that are in demand by multiple companies for help in analyzing or developing their products are more likely to be the kind of experts the FDA is seeking and less likely to let their financial and other relationships with sponsors get in the way of their expertise.

ACSH's Dr. Josh Bloom comments, I guess we are simply looking at human behavior involving incentives that people will ultimately do what benefits them when they are incentivized to do so. This is the entire premise of *Freakonomics* a brilliant 2005 bestseller that should be on everyone's must-read list. Authors Steven Levitt and Stephen Dubner examine human behavior as a function of incentives in a wide variety of very diverse subjects. You won't believe some of them.

But this particular issue is especially important, since it speaks directly to the question of how to get the *appropriate* experts on the antibiotics FDA panel something that has not necessarily been done because of the FDA's fixation on conflict rather than expertise.

You can read Dr. Shlaes' entire commentary [here](#) [2].

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[1] <http://www.milbank.org/publications/the-milbank-quarterly/current-issue/article/3986/revisiting-financial-conflicts-of-interest-in-fda-advisory-committees>

[2] <http://antibiotics-theperfectstorm.blogspot.com/2014/09/conflict-of-interest-vs-competent-advice.html>