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Drugs and demagogues

By Thomas P. Stossel | April 17, 2007

IN 427 BC, the Athenians recaptured the town of Mytilene from the Spartans. The historian Thucydides described the intense debate that followed over the fate of Mytilene's citizens, who had collaborated with the enemy. Cleon, whom Thucydides characterized as a violent demagogue, argued for killing them all; Diodotus, who did business with the Mytilenians, recommended mercy.

In siding with Diodotus, Thucydides noted how some people invoke financial conflicts of interest to discredit worthy opponents: "If a man gives the best possible advice but under the slightest suspicion of being influenced by his own private profit, we are so embittered by the idea that we do not allow the state to receive the certain benefit of his good advice." In this case, the state did not benefit, and Cleon prevailed.

Recently the Food and Drug Administration furthered this venerable tradition, when it proposed to keep anyone with a financial interest of \$50,000 or greater in a field of medical technology from taking part in an FDA advisory panel in that same field. But why?

The answer is not that financial conflicts of interest provably influence FDA panel recommendations. A study of advisory panel decisions published in *The Journal of the American Medical Association* found that advisers' financial relationships had no effect on their approval recommendations. Nor are experts who lack financial conflicts more "objective" than conflicted ones -- as if otherwise "objective" advisers could be bought off for \$51,000 but not \$49,000.

Furthermore, medical experts who consult for private companies have the most research agency grant funds. They are the most knowledgeable, inventive, and productive scholars -- which is why corporations want to work with them. Meanwhile, some groups selected for their independence can make terrible recommendations. After having to retract its assertion that certain baby car seats were unsafe, *Consumer Reports* magazine recently changed its policy of consulting only with experts without commercial ties. The second-best experts do not produce the best results.

The FDA's stated goal for its new policy is "reassuring the public that advice is not tainted." In other words, it is a public-relations exercise. Cleon's descendants in the press and in Congress have praised it.

"So many lives have been lost as a result of the failure of the FDA to review drugs properly," said Representative Maurice Hinchey, Democrat of New York.

In reality, medical care has improved enormously over the years, thanks to FDA-approved drugs and devices, whose benefits far outweigh their risks. The public wants access to such products. Moreover, as recently documented in *The New England Journal of Medicine*, most patients in cancer treatment trials had no concern if their physicians had financial relationships with the companies sponsoring the trials.

I have been doing research for 35 years. I have not participated in FDA panels, but I do have some corporate relationships that could exclude me under the proposed rules. When people ask me if I may be subtly biased by such connections, I respond that I am totally biased -- but in a variety of ways.

Getting general acceptance for even the most rigorous research results requires passionate advocacy. In addition to financial gain, medical researchers can be biased by the desire for fame, promotions, patient referrals, research grants, and recognition by influential peers.

Any cuddly feelings an FDA reviewer may have for a company are balanced by the need to sustain credibility with peers -- something a company still will never enjoy. Yet, business-phobic critics persist in acting as though corporate connections are the only serious conflicts of interest in medicine.

The FDA proposal is a vain political effort to placate the medical journal editors, ethicists, and bureaucrats who enforce conflict-of-interest regulations. They vilify drug and device companies and bully entrepreneurial physicians and scientists. In doing so, they inhibit medical progress. A total ban on corporate consulting by researchers at the National Institutes of Health has disaffected them and deprived companies of expert advice.

Similar rules at universities prohibit faculty from obtaining research sponsorship from companies in which they have equity ownership. These rules have discouraged venture capitalists from investing in start-up companies based on the technology of academic inventors. Among the founders of the for-profit biotechnology industry in the 1970s and 1980s are scores of prominent researchers, including Nobel Prize winners -- people who may be excluded from FDA reviews under the proposed rules.

Conflict-of-interest demagogues have been appealing to envy and impugning others' motives for 2,500 years of recorded history. When Cleon tarred Diodotus as a liar for hire, 1,000 Mytilenians died. The proposed FDA regulations, if enacted, will be far more lethal.

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