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In the Spotlight

Swing Vote at the FDA

Congressional obsession with conflicts of interest is denying the FDA access to much needed expertise

David R. Henderson, Charles L. Hooper
Medical Progress Today
August 29, 2008

In Kevin Costner's new comedy *Swing Vote*, the presidential election comes down to a single voter. The premise is absurd. But we don't need to go to the movies to see absurd plots in which big decisions hinge on one voter. The U.S. Congress, via the Food and Drug Administration, has created its own. Except this time, it's a tragedy.

Congress requires the FDA to severely limit independent experts from participating in FDA advisory committees if they have ties to industry. But the FDA has run into an intriguing problem with one particular rare disease, infantile spasm—a devastating form of epilepsy that strikes about 8,500 U.S. infants in the first year of life. When the FDA excluded all those with a "conflict of interest," it ended up with only one available committee member.

In true government fashion, all regulatory progress with Sabril, the new drug to treat infantile spasm, has now ground to a halt until an appropriate committee can be convened. Moreover, according to a study commissioned by the FDA, this problem with convening advisory committees will become more common in the future. Congress's message to patients desperately waiting for new treatments: Too bad.

Here's how this dysfunctional situation came about. The FDA organizes groups of independent experts to review and vote on new drugs before FDA employees make a final decision. Advisory committees give the FDA a thorough assessment of the new drug's strengths and weaknesses and potential therapeutic role, along with a bit of political cover. Who, after all, can fault the FDA for agreeing with a team of independent experts?

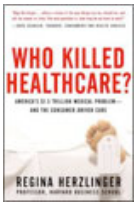
Who are these "independent experts"? They are prominent physicians, researchers, and non-FDA government employees, some of whom have organized clinical trials for new medicines. Recent conflict of interest (COI) rules have turned this real world expertise into a liability because the great majority of clinical trials are sponsored by pharmaceutical and biotech companies.

Here's the Catch-22. While the experts were busy being experts, drug companies were paying them for their services. This bred suspicion that they were "biased" and couldn't be trusted to impartially evaluate new drugs.

Which brings us to the current impasse. In February, Ovation Pharmaceuticals submitted a new drug application to the FDA for Sabril (vigabatrin) to treat, among other things, infantile spasm. Not surprisingly, there are no approved medications for the condition. The FDA tried to convene an advisory committee meeting for early August, but when all those with alleged conflicts of interest were excluded, just one member was left. His name is Gregory Holmes, section chief of neurology at the Dartmouth-Hitchcock Medical Center. Unfortunately, he has served as a principle investigator in clinical trials of epilepsy drugs, and so he, too, might be recused. Now *Swing Vote* becomes *And Then There Were None*.

According to the director of the FDA's Office of New Drugs, John Jenkins, "There are a small number of pediatric epilepsy experts in the country, and they are the experts you go to [to] do a study of a drug. It is likely most of the experts will be conflicted." If the same conflict of interest rules were applied to football, it would be like convening a group of preeminent quarterbacks, but trying to exclude those who have played in the National Football League. Good luck.

Thankfully, the hypothesis that having worked for a drug company makes an expert corrupt can be tested. In fact, this hypothesis *has* been tested—and



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rejected. Moreover, it was rejected by a study done by five researchers, four of whom were employees of the Naderite Public Citizen's Health Research Group.

In 2006, Sidney Wolfe and three of his fellow employees, along with one other author, published an article in the *Journal of the American Medical Association* that draws on 221 meetings of FDA advisory committees, including 76 product-specific meetings that involved yes or no votes on individual drugs.

Their findings? None of the 76 voting outcomes would have changed had voters with conflicts of interest been excluded. The authors also found that those with conflicts were no more likely to vote for "their" company's drug than those without conflicts. Indeed, those with a conflict were actually *more* likely than those without to vote for drugs that would compete with "their" company's product. That didn't stop Wolfe and his co-authors from concluding, "Ideally, all panels of scientific experts advising a federal decision-making body would be free to financial conflicts of interest with the affected companies." Their own findings, though, belie that conclusion.

The problem with the corruption hypothesis is that it is based on only one factor: short-term financial incentives. Sure, these advisors might have a small financial reason to favor a particular drug company or a new medicine. But counterbalancing this potential bias are huge reasons not to be biased, including professional reputation, genuine care for patients, the desire to avoid scrutiny, and adherence to scientific norms. "I think it's a swell drug, just because" won't be persuasive in a room full of other authorities. If experts lose their reputation for independence by voting like paid shills, they become useless to everyone—including pharmaceutical companies.

The FDA can grant COI waivers for outside advisors, but the number of these waivers is limited and declining (thanks, again, to Congress).

If Congress is so interested in removing possible conflicts of interest, it should resign en masse. After all, senators and representatives vote for egregious pork barrel legislation to get reelected, benefiting in myriad ways. Sadly, Congress seems much less concerned about protecting its reputation than the average pharma expert.

In the meantime, Congress should repeal its absurd, and empirically unsupported, FDA conflict of interest rules. As many as 8,500 American babies a year—and, potentially, millions of the rest of us—would benefit.

David R. Henderson *is a research fellow with the Hoover Institution and an economics professor at the Naval Postgraduate School; he was formerly the senior economist for health policy with President Reagan's Council of Economic Advisers.* ***Charles L. Hooper*** *is president of Objective Insights, a company that consults for pharmaceutical and biotech companies, and a visiting fellow with the Hoover Institution. They are co-authors of Making Great Decisions in Business and Life (Chicago Park Press, 2006).*

remarks by Keynote Speaker Douglas Holtz-Eakin, Senior Fellow at the Peterson Institute for International Economics.

IN THE SPOTLIGHT:
Swing Vote at the FDA
by David R. Henderson, Charles L. Hooper
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—Senator Tom Coburn

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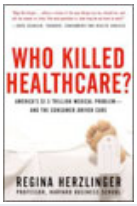

Who Killed Health Care? America's $2 Trillion Medical Problem—And the Consumer-Driven Cure
Regina Herzlinger (McGraw-Hill, June 2007)

THE CURE: HOW CAPITALISM CAN SAVE AMERICAN HEALTH CARE
Dr. David Gratzer (Encounter Books, October 2006)

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