Congressional conflicts about FDA conflicts-of-interest slow drug research

By ACSH Staff — July 12, 2011

As Congress sets to work on a five-year FDA reauthorization bill, Republicans are proposing to ease recent conflict-of-interest rules they believe are depriving the agency of needed pharmaceutical expertise. The rules determine who can take part in FDA advisory panels, which counsel the FDA on the benefits and risks of new drugs under consideration. Currently, experts with even a tenuous association with the pharmaceutical industry are prohibited from serving on these panels, but the policy has proven problematic: not only are such experts barred from giving their opinions and advice to the FDA, but the drug approval process is also slowed. As long-time Director of the FDA’s Center for Drug Evaluation and Research (CDER) Dr. Janet Woodcock observed, sometimes it is only after an exhaustive process of finding experts in a given field that their industry ties are discovered and the search must begin anew.

Republicans and the FDA itself are not alone in decrying these arbitrary prohibitions. ACSH’s Dr. Josh Bloom’s feelings are rather clear on this matter. These hypocrites in congress spend half the day taking money from lobbyists and employing their friends and families, he says, but when some renowned expert who owns maybe one share of Pfizer wants to serve on a panel, they subject him or her to an absurd level of scrutiny. They pretty much want to know what your allowance was when you were six.

ACSH has long believed [1] that these particular conflict-of-interest rules discourage drug innovation, since so many setbacks can arise during the approval process. Barring experts because of such ties is really an amazing waste of resources, says ACSH’s Dr. Gilbert Ross. On the other hand, the rules are perfectly OK with allowing the opinions of experts whose careers depend on a certain perception of drug risks and benefits as long as they haven’t taken actual money from industry. It’s a completely counterproductive policy and should indeed be scrapped.

The reauthorization bill is a must-pass measure that will be addressed within the next year.