Dispatch: FDA Advisory Panel Says Qnexa Is Too Risky

By ACSH Staff — July 16, 2010

An FDA advisory panel surprised observers Thursday by voting 10-to-6 to reject Vivus Inc.’s anti-obesity drug Qnexa, citing concerns of adverse side effects and unknown safety risks associated with its long-term use. The panel’s rejection is not final, and the FDA will make a decision on the drug’s market approval in a few months.

Qnexa is a combination of two older drugs: phentermine, an amphetamine-type drug that suppresses appetite, and topiramate, an anticonvulsant drug sold by Johnson & Johnson as Topamax. “Both phentermine and topiramate have been used for many years,” says ACSH's Dr. Gilbert Ross. “Though combination therapies may pose different side effects, I think the panel is being overly cautious considering the severity of the obesity epidemic.”

Dr. Ross suggests that instead of rejecting the drug, the FDA require Vivus Inc. to conduct a phase 4 post-market study, which would provide more robust evidence about its safety. “Data on thousands of patients who have been using the drug for over one year can be screened for toxicity signals, which would give further evidence about any risks of taking the drug.” He adds, “Hopefully the FDA will take that approach rather than send the drug back to the clinical trial route.”