FDA: Pradaxa is as safe as Coumadin

By ACSH Staff — November 6, 2012

Recent safety concerns among Pradaxa users, their families and some doctors, has caused the Food and Drug Administration to issue a safety review [1] on Friday stating that the risk of serious bleeding in Pradaxa patients is no higher than that among patients taking the older and widely used standard blood thinner warfarin (Coumadin).

The drug’s manufacturer, Germany-based Boehringer Ingelheim, maintained that the drug has no higher bleeding risk than the older drug. However, an apparent spike in reported bleeding events following initiation of Pradaxa therapy prompted the agency to start looking into the matter last December. After analysis of insurance claims and administrative data, the FDA stated, "The results indicate that the observed bleeding rates associated with new use of Pradaxa do not appear to be higher than the bleeding rates associated with new use of warfarin.

Pradaxa, which was approved by the FDA in October 2010, has become a blockbuster drug. Warfarin requires careful monitoring of a patient’s diet and drug regimen, and frequent blood tests to ensure that it is working at exactly the level needed to prevent clots, but not so much as to provoke bleeding. Pradaxa requires no such monitoring and, compared with warfarin, appeared to be better at preventing strokes. The problem however, lies in the fact that unlike warfarin, Pradaxa currently has no antidote to reverse the blood-thinning effects if serious bleeding occurs. Warfarin can be deadly too, but at least doctors have a means of reversing it, by giving a patient vitamin K.

There are trade-offs and risks, says ACSH’s Dr. Gilbert Ross. People need to be adequately informed of the risks, this is something that needs to be discussed between a doctor and patient. The key is discussion and informed consent.