Dispatch: FDA Panel: Avandia Should Stay, But With Strings Attached

By ACSH Staff — July 15, 2010

After hearing mixed evidence that Avandia may increase patient's risk of heart attack, an FDA advisory panel voted yesterday to keep the diabetes drug on the market [1] but with new warning labels. Twelve of the 33 panelists voted to ban the drug altogether, 10 recommended its continued marketing with both restrictions on sales and additional warning labels, seven voted for its continued marketing with more warning labels, and three suggested it remain on the market as is. The FDA will give its final ruling in the next couple of months.

“I think it was a very mature, sophisticated, and science-based decision on the part of the advisory panel because it would have been so much easier to simply say ‘take it off the market,’” said ACSH’s Dr. Elizabeth Whelan.

ACSH’s Dr. Gilbert Ross remarked on the diversity of headlines used to cover this story. For instance, The New York Times [2] headline is “F.D.A. Panel Votes to Restrict Avandia” while the Washington Post [3] alert said, “FDA panel: Diabetes drug should stay on market,” and Reuters [1] headlined, “U.S. advisers say keep Glaxo diabetes drug on market.” “Depending on the news source, the outcome for GlaxoSmithKline is either half full or half empty — but I’m afraid, GlaxoSmithKline, that the bottle is three-quarters empty,” says Dr. Ross. “As a clinician, I would have a really hard time justifying prescribing Avandia for fear of patient safety and litigation. No matter what it does to blood sugar, the data indicating an increased risk of serious adverse effects has to be paid attention to. If a patient has done well with the drug or refuses other options, then that’s when I would prescribe it.”

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[1] http://news.yahoo.com/s/nm/20100714/hl_nm/us_glaxo_avandia;_ylt=AvEvjaSTGJQh4eoxqNRZBZXVJRIF;_ylu=X3oDMTJsbW1xYmp2BGFzc2V0A25tLzIwMTAwNzE0L3VzX2dsYXhvX2F2YW5kaWEEcG9zAzgEc2VjA3luX2FydGljbGVfc3VtbWFyeV9saXN0BHNsawN1c2FkdmlzZXJzc2E-