**More Drugs Added to FDA Watch List**

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June 20, 2014

* [Testosterone Products to Get Venous Blood Clot Warning](http://www.medscape.com/viewarticle/827120)
* [FDA Issues Warning About Lymphoma Drug Brentuximab](http://www.medscape.com/viewarticle/756886)
* [Antidepressants Linked to Glaucoma in Elderly](http://www.medscape.com/viewarticle/739335)

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The US Food and Drug Administration (FDA) has placed testosterone products, most antidepressants, and the cancer drug brentuximab vedotin (*Adcetris*, Seattle Genetics) on its latest quarterly list of medications to monitor because of potential, unconfirmed health risks, the agency announced June 16.

The FDA said it would scrutinize testosterone products because it had received reports suggesting the possibility of abuse, misuse, or dependence. The products are indicated for men with low testosterone levels associated with another medical condition.

In terms of negative publicity, testosterone has had a bad week. Yesterday, in an unrelated announcement, the FDA said that it was [requiring manufacturers](http://www.medscape.com/viewarticle/827120) to add a general label warning about the risk for venous blood clots. The current label mentions this risk for testosterone users who experience polycythemia, an abnormal increase in red blood cells that sometimes stems from this therapy. However, the agency said yesterday it had received reports of venous blood clots in patients who did not have polycythemia.

Meanwhile, the agency continues to study whether or not testosterone increases the risk for stroke and heart attack.

All antidepressants other than monoamine oxidase inhibitors made the agency watch list because of signals of angle-closure glaucoma. Some research has [linked antidepressants](http://www.medscape.com/viewarticle/739335) to glaucoma in elderly patients.

The FDA will monitor brentuximab vedotin, approved in 2011 to treat Hodgkin's lymphoma and systemic anaplastic large cell lymphoma, for evidence it may lead to hepatotoxicity. In 2012, the FDA ordered a boxed warning for the drug about the risk for progressive multifocal leukoencephalopathy, a rare but serious brain infection.

The decision to place all these drugs on the watch list was based on reports of possible safety issues received by the FDA Adverse Event Reporting System (FAERS) database in the first 3 months of 2014.

An appearance on the list does not mean the FDA has determined that the drug indeed poses the health risk reported through FAERS. However, the agency will investigate if there is a causal link. If such as link is established, the agency then would consider a regulatory response, which can include gathering more information to better describe the risk, revising the drug's label, or requiring a risk evaluation and mitigation strategy.

The FDA also stresses that it is not suggesting that clinicians should stop prescribing drugs on its watch list or that patients should stop taking them.

**Table. Potential Signals of Serious Risks/New Safety Information Identified by FAERS, January to March 2014**

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| --- | --- | --- |
| **Product Name: Active Ingredient (Trade) or Product Class** | **Potential Signal of a Serious Risk/New Safety Information** | **Additional Information (as of May 1, 2014)** |
| Brentuximab vedotin (Adcetris) | Hepatotoxicity | FDA is continuing to evaluate this issue to determine the need for any regulatory action |
| Testosterone products | Potential for drug abuse, misuse, or dependence | FDA is continuing to evaluate these issues to determine the need for any regulatory action |
| Antidepressant drugs (except monoamine oxidase inhibitors) | Angle-closure glaucoma | FDA is continuing to evaluate this issue to determine whether the current labeling for antidepressant products includes accurate information about the risk for glaucoma |

*Source: FDA*

More information on FAERS and its quarterly watch list is available on the FDA [Web site](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm398223.htm).