

For Immediate Release:
Oct. 8, 2010

Contact:
Dorry Samuels (202) 588-7742

FDA's Decision to Pull Weight-Loss Pill Meridia Commendable, But Took Too Long for Drug's Victims

Statement of Dr. Sidney Wolfe, Director, Public Citizen's Health Research Group

The Food and Drug Administration (FDA) approved Meridia in 1997 despite pre-approval randomized trial evidence of significantly increased blood pressure and heart rate (both risk factors for heart attacks) and despite the opposition of the FDA medical officer who reviewed the drug and the FDA's advisory committee. Our 2002 petition to the FDA to ban the drug was based on this information and a growing number of post-marketing cases of heart attacks with no other explanation in relatively young patients.

Since then, more than 3 million prescriptions have been filled for Meridia, with many patients inevitably having had heart attacks or strokes because of its known toxicity. Even since January of this year (after our December 2009 re-petition to ban the drug), when the European Medicines Agency decided to withdraw the drug from Europe, there have been more than 160,000 prescriptions filled for Meridia in the U.S.

The FDA's decision today to ask pharmaceutical maker Abbott to withdraw the drug is commendable, but dangerously too late for all of the victims of its unacceptable risks. It appears that it was banned only because of the rare concordance about banning a drug between FDA's Office of New Drugs (OND) and FDA's Office of Surveillance and Epidemiology (OSE), as documented in last week's Oct. 4 memo from those two divisions to Center for Drug Evaluation and Research Director Dr. Janet Woodcock.

In both of the other cases in which drugs have recently been taken off the market in Europe - Darvon (propoxyphene) and Avandia (rosiglitazone) - OSE also urged a ban in this country but was "overruled" because of the reckless unwillingness of OND or Dr. Woodcock to ban the drugs. Thus, both of these unacceptably dangerous drugs remain on the market in this country, predictably injuring or killing many people, who, unlike their European counterparts, do not have the government protecting them from drugs with no unique benefits, but significant, unique risks.

To read Dr. Wolfe's earlier testimony on Meridia, go to <http://www.citizen.org/documents/sibutraminetestimony91510.pdf>.

###

Public Citizen is a national, nonprofit consumer advocacy organization based in Washington, D.C. For more information, please visit www.citizen.org.

Joe Newman
Deputy Director of Communications
Public Citizen
1600 20th Street NW
Washington, DC 20009
(202) 588-7703
<http://www.citizen.org>

Check out our blog:
<http://www.citizenvox.org>

Follow us on Twitter:
http://twitter.com/Public_Citizen