News from Congressman

BART STUPAK

MICHIGAN'S 1ST DISTRICT

2348 Rayburn Building
Washington, D.C. 20515

202-225-4735
Fax 202-225-4744

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Contact: Chani Wiggins
(202) 225-4735
Chani.Wiggins@mail.house.gov

Stupak-Smith Introduce Bill to Educate Public/Address Harmful Effects of Acne Drug

WASHINGTON – Reps. Bart Stupak (D-MI) and Chris Smith (R-NJ) introduced bipartisan legislation to regulate and track the use of Accutane and generic versions of the prescription drug that causes severe birth defects and is linked to adverse psychiatric effects, including suicides.

The bill, the **"Accutane Safety and Risk Management Act,"** builds upon and strengthens recent recommendations by a Food and Drug Administration (FDA) Advisory Panel that calls for a mandatory registry for Accutane users, prescribers and dispensers. Accutane, the drug which contains the active ingredient isotretinoin, was first approved in 1982 to treat patients with severe cystic acne, but has been increasingly used and marketed for milder skin conditions.

"Accutane is a powerful drug that can cause serious physical harm and death. With a drug like this on the market, it needs to be carefully tracked and monitored to reduce exposures to the drug's harmful side effects," said Stupak. "Unfortunately, we can't seem to rely on the FDA and the drug's manufacturers to do the right thing and implement such a plan."

An FDA Advisory Panel in February recommended that a mandatory registry be created to better track how the drug is being used and its side effects. The agency is now negotiating with the drug manufacturers on this proposal, but **there is no deadline on implementation. A similar recommendation was made in 2000, with no real action.**

Instead in 2002, the FDA launched the SMART program (System to Manage Accutane Related Teratogenicity), a voluntary registry for female users of the drug.

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"We've seen this before. An FDA panel says we need a mandatory registry for this drug and then we get a toothless voluntary registry instead. This drug is too dangerous for that to happen again this time around and that's why we're introducing this bill," Stupak said.

Accutane and its generics have been found to cause serious birth defects like those caused by the drug Talidomide. FDA has estimated that as many as 2,000 pregnancies each year are exposed to this drug. In fact, an FDA internal memo estimated that as many as 18,000 pregnancy exposures to the drug since 1982, resulting in up to 1,100 drug-related birth defects. The FDA has reported 235 known drug-related suicides, although the agency admits this is probably only between 1 and 10 percent of the actual number of suicides associated with the drug.

The Stupak/Smith bill sets up a mandatory registry like Thalidomide. The bill also includes consumer protections and directs the FDA to approve a program to restrict and manage the prescription of Accutane and its generics within 30 days of enactment or the drug is removed from the market. Among the protections required in the plan is to limit prescriptions to severe recalcitrant nodular acne, the medical condition for which Accutane was approved.

The bill has been endorsed by the March of Dimes. Its cosponsors include the following: Weldon (R-FL), Kilpatrick (D-MI), Wamp (R-TN), DeGette (D-CO), Burton (R-IN), DeLauro (D-CT) and Baca (D-CA).

Attached is a side-by-side summary of the Stupak/Smith bill compared to the FDA Advisory/Drug Manufacturers proposal.

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