Safety of morning sickness drug questioned

By SHERRY KAHAN

The drug called Bendectin, which millions of American women have taken to control morning sickness, may cause birth defects.

U.S. Rep. William Brodhead wants to see it investigated by the U.S. Food and Drug Administration, and until that happens he thinks physicians should stop prescribing it.

J. Douglas Peters, attorney with the Detroit firm, Charfoos, Christensen, Gilbert and Archer, believes it may be another thalidomide, but not as powerful. Thalidomide was banned by the FDA in the 1960s because it caused serious birth defects. Peters' law firm is handling 18 suits charging that children have been born with defects after their mothers used Benedictin.

He stated that the children involved have limb defects such as missing hands, forearms, feet and legs. Some have missing or incomplete sternums. Others have heart defects or brain damage.

Dr. Alan Done of Wayne State University's faculty has testified before the FDA that he believes the drug is a low-grade teretogen. That word is defined as a substance causing birth defects.

Southfield attorney Sanford Steiner of the Detroit firm, Ripple, Chambers and Steiner, has filed a suit in Wayne County Circuit Court asking $10-million damages in the case of a child reportedly born with deformed feet and hands.

Bendectin, manufactured by Merrell National Laboratory of Cincinnati, is prescribed in the first three months of pregnancy when the fetus is most vulnerable.

Brodhead, Detroit Democrat whose district also includes Redford Township and parts of Southfield and Farmington, said the drug was approved by the FDA before the thalidomide controversy led to changed standards.

"There is reason to suspect it," he said in an interview. "The drug was approved many years ago. If they applied the new drug standards to it, I don't think Bendectin would be on the market because of the suspicion about it."

BRODHEAD SAID he became interested in the drug after reading an article in the Washington Post.

A staff investigation convinced him there was a problem, he said, so he wrote to the FDA. He said he received an answer pointing out that the drug is "marketed as safe and effective with FDA approval."

The letter added that Bendectin "was found to be 78 percent effective in the firm's (Merrell's) efficacy study involving 1,599 patients. A followup of all these patients revealed a 1.2 percent fetal malformation, which is not an unusual incidence even for a non-drug-exposed sample."

The Post estimated some 30 million women have taken the drug since 1956.

Brodhead sent copies of the information gathered by his staff to a House committee which oversees the FDA. He also wrote House members about the drug.

As a result of pressure from Congress and individuals already concerned about Bendectin, an advisory committee to the FDA held hearings in September. The committee upheld the drug, but claimed that research did not exclude the possibility that it is weak teratogen.

Following the hearing the FDA said it would recommend that information be included in the package telling of possible effects and risks of Bendectine. Doctors would be advised to prescribe the drug only for significant nausea and vomiting.

Congressional members continued to prod the FDA by calling for a hearing on its handling of the case before the Subcommittee on Oversight and Investigation of the House Interstate and Foreign Commerce Committee. This committee oversees the FDA.

The hearing was scheduled for November but cancelled because the national election left the committee chairman a lame duck. However, Rep. Don Edwards, D-California, whose granddaughter was born with birth defects after her mother took Benedectin, hopes to reinstate the plans.

DR. DONE, who is adjunct professor of pharmacology and pediatrics at WSU and director of clinical pharmacology at Children's Hospital in Detroit, has researched the drug. He testified before the September FDA hearing, according to press reports, that he believes the information Merrell provided for the FDA was a misrepresentation. He has declined comment on the situation because he is scheduled to give court testimony in the coming year in Bendectin cases.

After Brodhead read the Washington Post article, his staff began gathering information from medical schools, the Library of Congress and the FDA.

"The more material we got, the more I felt there was a real question here, despite the fact that the material was not conclusive," he said. "Our information filled a cardboard box. We made three copies of all of it and sent one copy to the committee of the House in charge of overseeing the FDA. We sent another set to the FDA, and we kept a set. I began to write to colleagues in the House about it.

"What caught me about Bendectin is that it is a drug that women don't have to take. Morning sickness is unpleasant but rarely life-threatening. A powerful drug is being prescribed for a condition which can be dealt with in other ways. The best scientific minds tell pregnant women not to take any drugs. But Bendectin is taken in the early weeks, which is the time when the fetus is most threatened."

Brodhead maintained that it is inappropriate that Bendectin has been so widely prescribed. He also is angry at what he calls "the inactivity of the FDA."

He said: "It is the FDA's job to look after health," adding that it should have taken action once it had in its files 86 letters from people claiming their child had been born with birth defects after the mother took Bendectin.

He called the situation a breakdown on how doctors were doing their job and how the FDA was doing its work.

"The FDA is slow-moving," he maintained. "It is tough on new drugs coming on the market, and I think it should be. But it is much too easy on existing drugs.

There are two things that must be done, he claimed. Doctors must stop prescribing it. The FDA must investigate it. It must educate doctors on possible damages and it must give a very clear warning. If it proves to be the cause of birth defects, it should be removed from the market.

J. DOUGLAS PETERS was one of those who appeared at the September FDA hearing. He believes Bendectin is a low-grade teratogen. "It has been over-promoted by the drug company and prescribed for women who didn't need it," he said.