

they should remain on the market." He cited the acne drug Accutane.

Why Accutane? Because of the horrendous birth defects, but also because of a recent study by Dr. J. Douglas Bremner. He has demonstrated how Accutane mediates depression, causes impulsive behavior due to changes in the orbito frontal cortex in the front part of the brain. That mediates depression. Depression is found in this part of the brain.

Over the course of our investigation of the Committee on Energy and Commerce research, it has indicated that the current formula of Accutane may be about 240 times greater than what is necessary to be effective. Too much Accutane, a synthetic vitamin A, causes cerebri tumor or a pseudo tumor in some patients. This pseudo tumor is a warning that is found on the packaging, but what does it really mean? It means severe headaches. And while it acts like a tumor in the brain, it cannot be discovered. CAT scans will not show it. There is no evidence of a tumor. So what happens?

As Dr. Bremner showed us here in a study of the orbito frontal cortex, there is a decrease in the metabolism of the brain. This is the baseline of a person before they started Accutane. This is post Accutane, or 4 months on Accutane. Notice the red brain activity in the front part of the brain. Notice very little red after 4 months on Accutane. It neutralizes or decreases the metabolism in this part of the brain.

In this one slide that Dr. Bremner has shared with us, there is a 21 percent decrease in brain metabolism with this patient. This only occurred in Accutane patients. Dr. Bremner did the same thing with other patients on oral antibiotics. And it was not all Accutane patients, just those who complained of severe headaches. Is this excessive dosage found in the current formula of Accutane that is being given to patients, is this the cause in the change that we see?

The medical evidence is clear that Accutane causes changes in the brain, which leads some young people to take their own life through impulsive behavior.

Putting people first. Let us put children first. Let us join with the FDA drug safety reviewer and pull this drug from the market or, at a minimum, severely restrict the use and distribution of Accutane until we have all the answers about this powerful, dangerous drug.

Is a decreased metabolism that we see here, is this reversible? Will the brain repair itself? How much Accutane is safe? What should the real dose be so we do not hurt the developing young brains of our children? Has the FDA done enough to protect our children? Has the FDA seriously looked at this study and similar studies in animal testing, which also demonstrate Accutane harms the brain?

It is time to put our children first. It is time to pull this drug off the market

until all of our questions are seriously answered. Put our children first.

Mr. Speaker, I will submit for the RECORD the CBS news report and also a photocopy of the CAT scan from Dr. Bremner.

INSIDER: FDA CAN'T PROTECT PUBLIC

The American public is "virtually defenseless" if another medication such as Vioxx proves to be unsafe after it is approved for sale, a government drug safety reviewer told a congressional committee Thursday.

"I would argue that the FDA as currently configured is incapable of protecting America against another Vioxx," said David Graham, who warned that the arthritis drug had been linked to an increased risk of heart attack and stroke.

He told the Senate Finance Committee that there were at least five other drugs on the market today that should be looked at seriously to see whether they should remain there. He cited the acne drug Accutane, the weight loss drug Meridia, the anti-cholesterol drug Crestor, the pain reliever Bextra, and the asthma drug Serevent.

Vioxx's maker, Merck & Co. pulled the drug from the market on Sept. 30 after a study indicated the popular painkiller doubled the risk of heart attacks and stroke when taken for longer than 18 months.

Raymond V. Gilimartin, the company president, said in prepared testimony that Merck acted within four days of learning about the risk.

"Given the availability of alternative therapies and the questions raised by the data withdrawing Vioxx was consistent with an ethic that has driven Merck actions and decisions for more than 100 years," he said.

Gilimartin also said the company was surprised by the cardiovascular risk because it differed from past clinical trials. "My wife was a user of Vioxx until the day we withdrew it from the marketplace," he said.

The Food and Drug Administration has defended its actions regarding Vioxx. In a statement issued late Wednesday, the agency cited its "well-documented and long-standing commitment to openness and transparency in its review of marketed drugs."

"What's come to light about Vioxx since Sept. 30 makes people wonder if the FDA has lost its way when it comes to making sure that drugs are safe," said Senate Finance Committee Chairman Charles Grassley, R-Iowa, as the hearing opened.

Grassley suggested that an independent board of drug safety might be needed to ensure the safety of medications after they're approved for the market.

"Consumers should not have to second-guess the safety of what's in their medicine cabinet," he said.

Graham told the committee that research indicated that Vioxx caused up to 160,000 heart attacks and strokes.

"If we were talking about Florida or Pennsylvania, 1 percent of the entire state population would have been affected," he said. "I'm sorry to say Sen. Grassley, but 67 percent of the citizens of Des Moines would be affected and, what's worse—the entire population of every other city in the state of Iowa."

Graham said his research helped to coax the FDA to withdraw a number of drugs including Fen-phen, a weight loss drug, Lotronex, Baycol and Rezulin. "During my career I have recommended the market withdrawal of 12 drugs," he said. "Only two of these remain on the market today."

At the same time, though, he questioned the agency's commitment to removing unsafe drugs from the market, since it would call into question their earlier approval.

Sen. Jeff Bingman, D-New Mexico, said the problem was within the FDA's own culture.

"The culture within the FDA, being one where the pharmaceutical industry, which the FDA is supposed to regulate, is seen by the FDA as its client instead," he said.

He called on President Bush to appoint a new head for the agency. Lester Crawford has been acting commissioner of the agency.

Lester Crawford's statement, sent by e-mail to reporters about 16 hours before the Senate Finance Committee's scheduled hearing on Vioxx, said the FDA initiated and paid for reviews of Vioxx and antidepressants after those drugs had hit the market. "That is evidence the system is working," Crawford said.

"It's not working good for them to have a drug to be out on the market this long * * * and never really announcing that it was causing strokes and heart attacks," John Byrd of Coats, N.C., told CBS Radio News Thursday morning. He's a 47-year-old who had a heart attack last spring and is now suing the maker of Vioxx.

Critics contend the agency ignored risks in both instances, then intimidated its own reviewers when they pointed to safety concerns.

In October, the FDA ordered that all antidepressants carry warnings that they "increase the risk of suicidal thinking and behavior" in children who take them. Vioxx's maker, Merck & Co. pulled the drug from the market on Sept. 30 after a study indicated the popular painkiller doubled the risk of heart attacks and stroke when taken for longer than 18 months.

"I've never had any knowledge that it could cause a heart attack or blood clots or stroke. That's where I find a little shadiness in this recall," said Byrd, a Goodyear employee, who added the Vioxx paperwork only warned that it could upset his stomach.

The FDA's statement disturbed lawyer Andy Birchfield, who is evaluating thousands of potential cases against Merck on behalf of injured patients.

"How can they see that type of problem and look back and say 'We did everything right?'" Birchfield said. "When they're not willing to recognize mistakes, we have no hope for them voluntarily taking measures to correct the situation."

Crawford's statement did not mention Graham by name, but suggested that the reviewer was a maverick who did not follow agency protocol.

Graham was lead author on a research project that studied the records of almost 1.4 million Kaiser Permanente patients, including 40,405 treated with Pfizer's Celebrex and 26,748 treated with Vioxx. The study found that high doses of Vioxx tripled risks of heart attacks and sudden cardiac death.

Vioxx was responsible for an additional 27,785 deaths from heart ailments from 1999 to 2003, Graham concluded.

He has told congressional investigators that, superiors pressured him to soften his conclusions.

Crawford said in his statement that the reviewer voluntarily chose to revise his conclusions, and he did so, in his own words, "without compromising my deeply held convictions."

THE SPEAKER pro tempore. Under a previous order of the House, the gentleman from North Carolina (Mr. JONES) is recognized for 5 minutes.

(Mr. JONES of North Carolina addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)