

their orbitofrontal cortex of the brain. Is this damage to the brain permanent? Only more research will answer this question.

I do not know why the FDA and Hoffman-LaRoche seem reluctant to look for these answers. The FDA has already determined that the link between Accutane and psychiatric events is strong enough to require a bold warning on the physician label and the packaging label for this drug.

The FDA should also re-examine previous studies submitted on Accutane. A 2001 review of three studies that were not disclosed by the drug company found the drug to cause an excessive serotonergic response and concludes that it should be noted that increased serotonergic function is presumed to be the mechanism of action of a major class of antidepressants or SSRIs, or selective serotonin re-uptake inhibitors. In other words, Accutane acts like antidepressants in the brain so it couldn't possibly cause psychiatric effects.

We all realize the uproar that has been caused by the FDA when they would not allow their own expert to testify that antidepressants used in young people were ineffective and increased suicidality. The British came to the same conclusion, and they banned the use of antidepressants in people under the age of 18.

Just 2 weeks ago, the FDA finally declared that there is an increased risk in suicidality in children who take SSRIs. It has created a firestorm of debate about how safe these drugs are and how they affect kids.

Yesterday's Wall Street Journal had a story about the possible reasons why there is an increase of suicidality of children who take antidepressants. The story says, "One hypothesis is that, in some patients, these drugs have a disinhibiting effect," says one Wayne Goodman, chairman of the FDA panel that examined the issue in young people. "Children are already a bit disinhibited because their brains aren't fully developed." Remember, in 2001, Accutane studies that the FDA reviewed concluded that Accutane was like the antidepressants with its SSRI function.

The FDA must demand a full accounting of how these drugs, both Accutane and antidepressants, affect our children and their developing brains.

There is no excuse for allowing Accutane to be prescribed to hundreds of thousands of kids without, at the very least, continuing to demand answers as to the effect of this drug on the brain.

At the very least, FDA can begin to address the "off label" use of this drug, but yet the FDA estimated in 2002 that 90 percent of the prescriptions were written for "off label," meaning they were not written to treat severe acne unresponsive to other antibiotics.

At the very least, FDA can finally approve a mandatory risk management

plan to track Accutane's side effects and prevent thousands of pregnancy exposures, miscarriages and abortions each year. FDA advisory committees have called for stricter distribution of the drug and a registry of the patients to control the use of this drug. They have called for this twice in the last 4 years. Unfortunately, the FDA has ignored these recommendations, and the same failed policy and system is in place with this drug.

Last week, I and a few of my colleagues shared our concerns with the Secretary of Health and Human Services Tommy Thompson about the lack of action on implementing these advisory committee recommendations.

The birth defects caused by Accutane are similar to those of thalidomide. People of my generation and older remember vividly the thalidomide babies of the 1960s.

Over 1.5 million prescriptions for Accutane and its generics were written in 2003, and clearly, Accutane has the potential to do greater damage, so why do we not have the same controls as we do on thalidomide?

Madam Speaker, my time has expired, and I will insert the rest of my remarks at this point in the RECORD.

It's no secret that I am no fan of the FDA's handling of Accutane or the drug company, HLR's, constant denial that Accutane does not cause depression or affect the brain—we know with this PET Scan their denials are baseless! However, I am appalled at the FDA's inaction on this registry. That's why in June, I joined with colleagues on both sides of the aisle and introduced the Accutane Safety and Risk Management Act (H.R. 4598). The legislation would create a mandatory program to manage the drug, and includes provisions to protect the health of patients and their children. To make sure we do not allow our children and their developing brains to be destroyed.

History suggests that unless there is strong leadership from Congress on this issue, the Advisory recommendations to the FDA will end up collecting dust on a shelf.

I hope my colleagues on both sides of the aisle will join me in cosponsoring this important legislation to send a strong message to the FDA and HLR that we will not accept their inaction any longer.

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Indiana (Mr. BURTON) is recognized for 5 minutes.

(Mr. BURTON of Indiana addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)

#### SUPPRESSING THE COST ESTIMATE

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Ohio (Mr. BROWN) is recognized for 5 minutes.

Mr. BROWN of Ohio. Madam Speaker, November 17 a year or so ago, just three weeks before the Medicare bill

was signed into law, President Bush said this law would cost \$400 billion. That is what he told the American public. That is what he told the Congress. Five months earlier, his actuaries in the center for Medicare/Medicaid services, the Medicare bureau, estimated the President's Medicare bill would cost \$534 billion.

I am not saying that the President lied about this, but it is pretty clear the President's people knew this bill cost \$134 billion more than it really did. Whether the President knew about it, whether his top aides told him, remains a question.

Now, the White House says, though, the bill will cost \$576 billion. It is bad enough that the President and Republicans in Congress advertised one thing to this Congress and to the American people and sold them on another. What is worse is the deliberate nature of this deception and tactics used to achieve it.

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But let us go back and look at this whole Medicare bill and how we ended up where we did, starting from the time the drug industry and the insurance industry met in the Oval Office with President Bush and wrote the bill. Starting with then and following through all the way until Labor Day weekend, 3 weeks ago, where the President announced a 17 percent, a record increase, 17.4 percent in Medicare premiums that seniors will be forced to pay.

First the bill was written with President Bush and Vice President CHENEY sitting down with the drug industry, sitting down with the insurance industry and writing a Medicare privatization bill. You know that it was written by the drug and insurance industry because the drug industry profits go up \$180 billion under this bill, that is \$180 billion with a "b," and you know the insurance industry was part of this because they benefit to the tune of billions of dollars in direct subsidies from seniors through increased premiums and taxpayers in increased dollar subsidies to the insurance industry.

Now, we also know that the passage of this bill was perhaps the most sordid spectacle we have seen in this Chamber of the House of Representatives in decades. The debate started at midnight, the votes started at 3 o'clock in the morning after most of the press had gone home and after most Americans had turned their televisions off. Normally, a vote takes about 20 minutes, but this took 2 hours and 55 minutes. There was arm-twisting on the House floor, when this bill was actually defeated, for the first 2 hours and 45 minutes. The bill was down 216 to 218. We also know that there was a Member of Congress from Michigan, Republican, who the next day told a radio station in Michigan that Republican leaders attempted to bribe him on the House floor with campaign money. We know