

Clinton Presidential Center, a place where scholars and all Americans can study the many remarkable achievements of 8 years of the Clinton administration.

As I sat through the dedication ceremonies today, I reflected on the unparalleled economic prosperity that America experienced during President Clinton's tenure. I also could not help thinking about the important matter we would be confronted with on the House floor later in the day, a vote to raise the debt limit for the third time since President Clinton's successor took office. With today's vote, the majority of this House has agreed to a whopping \$800 billion increase in the debt ceiling from its present level of \$7.38 trillion to \$8.18 trillion.

The impending breach of the statutory debt ceiling is the latest warning about the Nation's fiscal health. Our debt has been growing faster than our economy's ability to repay it due in large part to a reckless economic policy over the last 4 years. These policies have undone the hard work it took to balance the budget during the 1990s and have left us awash in a sea of red ink.

At the beginning of the Clinton administration in 1992, the Federal budget deficit was at a historic high of \$290 billion, 10 million Americans were out of work, and the Nation's economic growth rate was the lowest in more than half a century. In response, President Clinton and the congressional Democrats worked together to enact the 1993 Deficit Reduction Plan which passed the House and Senate without a single Republican vote. The balanced budget plan demonstrated that guided by common sense and realism, we could slash the deficit in half while also making important investments in our future including education, health care, science, and technology.

The plan included more than \$500 billion in deficit reduction and cut taxes for 15 million of the hardest pressed Americans as well as small businesses.

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What followed is unarguable: the creation of more than 22 million new jobs and the Nation's lowest unemployment rate in 30 years. The Nation went from the largest budget deficits in history to the largest budget surpluses in history. Four consecutive years of debt reduction also followed, a total of \$453 billion paid down, bringing the public debt down to \$2.9 trillion lower in 2001 than projected in 1993.

When President Clinton left office, we were on track to eliminate the Nation's public debt by 2012, making America debt-free for the first time since Andrew Jackson was President.

Today, we continue the fiscal U-turn that this Congress and administration have steered us into over the last 4 years. Today's vote to increase the debt limit marks yet another unfortunate milestone in our Nation's history where we have the largest deficits we have ever had, \$413 billion, and abso-

lutely no plan in sight to put our fiscal House in order.

For years, members of the Blue Dog Coalition have warned that we were spending money we did not have, that the administration had no economic plan, and that tax cuts alone were not a substitute for an economic plan for our country's future. This Congress continues to reject efforts to budget in the same way that your family and mine does, by paying as you go.

Even as we sought to stave off the day of reckoning, middle-class Americans are paying for our profligacy in the form of rising interest rates. As a result, American consumers are paying more for their mortgages and on their credit cards.

With the retirement of the baby-boom generation beginning in just 4 years, we must rededicate ourselves to ensuring that our children and future generations are not saddled with the enormous responsibility of paying for our economic health and our safety. We owe it to the American people to stop imperiling the Nation's economic future by borrowing money to pay for irresponsible policies.

We all acknowledge that the September 11 attacks and the resulting war on terrorism as well as the war on Iraq have put an additional stress on our economy. But instead of spending political capital to ask all Americans to share in the Nation's sacrifice, the President and the majority today took the easy way out.

Mr. Speaker, the day of reckoning is at hand, and with today's vote we must all acknowledge we have hit rock bottom.

In his farewell address to the Nation from the Oval Office in February, 2003, President Clinton left the American people with three thoughts about our future. His first admonition was that America must maintain its fiscal responsibility. Pointing to record deficits turned into record surpluses and the paying down of our national debt, he urged us to stay on track. "If we choose wisely," he said, "we can pay down the debt, deal with the retirement of the baby-boomers, invest more in our future, and provide tax relief."

Unfortunately, this Congress and this administration have not chosen wisely. The juxtaposition of today's dedication of the Clinton Library and this evening's vote to increase the national debt is a clarion call to return to the sound fiscal policies that were central to the economic boom of the 1990s. We have a duty to the American people to restore sanity and discipline to our Nation's finances.

The SPEAKER pro tempore (Mr. FRANKS of Arizona). Under a previous order of the House, the gentleman from Texas (Mr. PAUL) is recognized for 5 minutes.

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

#### EXCHANGE OF SPECIAL ORDER TIME

The SPEAKER pro tempore. Under a previous order of the House, the gentlewoman from California (Ms. WOOLSEY) is recognized for 5 minutes.

(Ms. WOOLSEY addressed the House. Her remarks will appear hereafter in the Extensions of Remarks.)

#### ORDER OF BUSINESS

Mr. STUPAK. Mr. Speaker, I ask unanimous consent to take my special order at this time.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Michigan?

There was no objection.

#### PUTTING PEOPLE FIRST

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

Mr. STUPAK. Mr. Speaker, it was an honor and a privilege to join with over 100 of my colleagues, Democrats and Republicans, and four U.S. presidents to dedicate the William J. Clinton Library in Little Rock, Arkansas. All of the four presidents spoke eloquently. I was especially moved by the words of former President George W. Bush when he said it not a Democrat or Republican day, but it was a great day for all Americans.

I joined President Clinton in the 1992 election here in Washington to represent northern Michigan to do, as President Clinton challenged us then, to put people first. I have learned and tried to do that each day as a Congressman. I learned this not just from President Clinton but from my own father who was a local elected official in Delta County, Michigan.

I come tonight to put people first, to put our children first as I continue to speak out against the acne drug Accutane. As a legislator, I have called for more restrictions on the distribution and use of this drug, which is known to cause severe birth defects and a form of impulsive behavior and depression in young people taking this drug.

This drug has devastated my family with the loss of our son BJ and more than 250 other families who have lost their young son or daughter across this Nation who have lost them while they were taking Accutane.

As we were flying back from Little Rock, Arkansas, CBS news ran a story tonight, and I quote an FDA safety reviewer, Dr. David Graham, when he spoke to the Senate Finance Committee. Dr. Graham said, "I would argue that the FDA as currently configured is incapable of protecting America against another Vioxx." He told the Senate Finance Committee that "there are at least five other drugs on the market today that should be looked at seriously to see whether

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.)