

Those suffering with psoriasis are also at an increased risk for numerous other serious, chronic and life-threatening conditions such as heart disease, diabetes and mental health conditions. These co-morbidities inflict a significant economic and social burden on society in addition to the individuals with psoriasis. This legislation would direct the Secretary of Health and Human Services to convene a summit of researchers, public health professionals, patient advocacy organizations, academic institutions, and Federal and State policymakers on the current research, treatment, education, and quality-of-life activities conducted or supported by the Federal Government with respect to psoriasis and psoriatic arthritis, including psoriasis and psoriatic arthritis related co-morbidities. A comprehensive report from this summit would provide a roadmap for future activities necessary to address current gaps and better our chances of finding a cure. Lastly, the bill would require a study and report by the Institute of Medicine to address health insurance and prescription drug coverage as they relate to medications and treatments for psoriasis and psoriatic arthritis. We must ensure that these patients receive the best regimen and most appropriate care for their disease.

In closing, I would like to commend the National Psoriasis Foundation for their more than four decades of leadership and work to improve quality of life for people with psoriasis and psoriatic arthritis. I would also like to extend great thanks to my constituents, John and Vivian Latella, who have shared their personal stories of the difficulties of living with psoriasis. For them, and for the millions of Americans suffering from this disease, I urge my colleagues to join me in cosponsoring the Psoriasis and Psoriatic Arthritis Research, Cure, and Care Act.

#### PAXIL

Mr. GRASSLEY. Madam President, for the last few years, I have been looking at how drug companies try and influence medical care in America. Companies can do this by, for example, creating studies favorable to their drugs, by hiring doctors to promote their products, and in some cases even intimidating critics of their drugs.

Today, I would like to talk about a different tactic by drug companies hiding data. I don't mean that they actually hide the data. But they make these numbers so difficult to find that they might as well be invisible.

Last February, I asked GlaxoSmithKline to turn over a couple of reports on Paxil, a drug used to treat depression. These reports were written by Dr. Joseph Glenmullen, a professor of psychiatry at Harvard.

Based on the review of documents uncovered in litigation, Dr. Glenmullen concluded that GlaxoSmithKline knew for almost two decades that Paxil is as-

sociated with an increased risk of suicide. He submitted these reports as an expert witness in several lawsuits now pending around the country.

So what did GlaxoSmithKline do with these reports? Well, the company tried to hide them. They went to the judge and asked to have Dr. Glenmullen's report and all the confirming documents placed under seal—that means that no member of the public could see them. In fact, Glaxo has been doing everything possible to ensure that this information remains under court seal.

It seems to me that GlaxoSmithKline tried to hide these reports because they seem to demonstrate what the company knew—that Paxil was associated with an increased risk of suicide based on the company's own studies. In fact, Dr. Glenmullen argues that GlaxoSmithKline knew this when they submitted the New Drug Application to the Food and Drug Administration back in 1989.

Essentially, it looks like GlaxoSmithKline bamboozled the FDA.

How did GlaxoSmithKline get away with this? Easy, they just moved around numbers in their studies to make it look like Paxil was safe. Here is how Dr. Glenmullen says they did it. GlaxoSmithKline ran several studies comparing people on Paxil against people on a placebo, in other words, a sugar pill.

If a patient attempted suicide before a study began—let me emphasize this: Before the study began—that person was automatically put into the placebo group. That means the company was comparing Paxil users against patients who were already prone to suicide. So when you compared the placebo numbers to the Paxil numbers, it looked like Paxil was the same as the placebo.

But, when Dr. Glenmullen re-analyzed the data, he found that Paxil WAS associated with a risk for suicide. And it looks like this is what GlaxoSmithKline was trying to hide from the American public.

Thankfully, a judge in Kansas made one of Dr. Glenmullen's reports public.

Finally, I would like to address GlaxoSmithKline's responses to my questions about whether it hid data on Paxil. I am unhappy to say that Glaxo's answers were a little more than word games. I don't wish to use the word "lie" but let me say this: their answers were less than candid.

Let me give you one example. In a letter to GlaxoSmithKline, I asked them when they learned that Paxil was associated with suicide risk. They wrote back that they "detected no signal of any possible association between Paxil and suicidality in adult patients until late February 2006 . . ."

So GSK claims to a U.S. Senator they knew nothing about suicidality in adults until February 2006. But in the United Kingdom, government investigators found that the company had the data back in 1998.

Two weeks after I received the letter from GSK, England's Medicines and

Healthcare products Regulatory Agency released a report on Paxil.

The report concluded that data from GlaxoSmithKline's own clinical trials confirmed that patients under 18 had a higher risk of suicidal behavior. This report involved 4 years of investigation by this agency which is England's counterpart to our FDA. It was the largest most thorough report in the history of that agency.

According to the Medicines and Healthcare products Regulatory Agency, the only reason that criminal charges were not filed in the UK is because "the legislation in force at the time was not sufficiently strong enough . . ." So the company didn't get off because it didn't do anything wrong. It got off because the laws in UK did not address such situations.

Today, I am asking the FDA to take a look at the same information that was examined in the UK. And I am asking the FDA if we need to change any laws here in the United States.

We cannot live in a nation where drug companies are less than candid, hide information and attempt to mislead the FDA and the public. These companies are selling drugs that we put in our bodies, not sneakers. When they manipulate or withhold data to hide or minimize findings about safety and/or efficacy, they put patient safety at risk. And with drugs like Paxil, the risks are too great.

The CEO of GlaxoSmithKline, Jean-Pierre Garnier, is resigning. I hope that the company's new leadership will do right by the public and be more open about side effects of their products.

What happened with Paxil, as well as, in my investigations involving the painkiller Vioxx and the antibiotic Ketek are only a few examples of why it is important that bad actors be held accountable when they withhold data, submit questionable or fraudulent data, or attempt to mislead the FDA, the medical community, and the public.

That is why I am also working on legislation that would require that companies certify to the FDA that they gave the FDA complete and accurate data related to the safety and efficacy of their products and that the information is not false or misleading. If a company knowingly violates those certifications, it could be subject to civil and possibly criminal penalties.

#### NEUROFIBROMATOSIS AWARENESS

Mr. COBURN. Madam President, I rise today to highlight the difficulties caused by neurofibromatosis, NF, the work currently being done by the Federal Government to address this difficult disease, and the importance of awareness about NF.

NF is a genetic disorder of the nervous system, which causes tumors to form on the nerves anywhere in the body at any time. NF is a progressive disorder and is one of the most common genetic disorders in the United

States. An estimated 100,000 Americans have a neurofibromatosis disorder. About half of those affected with NF have a prior family history of the disease.

NF has two distinct forms, NF1 and NF2. NF1 is the more common version, occurring in 1 of nearly every 4,000 individuals in the U.S. It has varying manifestations and degrees of severity resulting from a mutation of the NF1 gene. Symptoms include common skin abnormalities and are often evident at birth or shortly afterwards. NF1 can cause learning disorders, bone deformities, and may even be associated with cancer. NF2 is a much more rare condition, resulting from a mutation of the NF2 gene, that is most frequently associated with hearing loss and visual impairment.

The National Institutes of Health, NIH, supports critical research to fight NF, investing approximately \$13 million a year. At NIH, the \$1.5 billion National Institute of Neurological Disorders and Stroke, NINDS, supports research and clinical trials to understand normal and abnormal development of the brain and nervous system to improve our understanding of the disease and our ability to prevent, treat, and ultimately cure the NF disorders. Researchers have been able to locate the exact NF1 gene, which they found normally works as a "molecular brake" to keep cells from overmultiplying, and the NF2 gene, which they found normally helps suppress tumors. It is the mutations of these genes that cause the difficulties associated with NF. According to NINDS:

Understanding the molecular pathways and mechanisms that govern these key proteins and their activities will offer scientists exciting opportunities to design drugs that could replace the missing proteins in people who have neurofibromatosis and return their cell production to normal.

NINDS is currently researching how NF1 can also cause abnormal fetal development that can cause learning disabilities and cognitive deficits for children. NINDS also supports research aimed at developing improved methods of diagnosing NF and identifying factors that cause the wide variations of symptoms and severity of the disorders.

As a practicing physician, I am encouraged that NINDS is performing research to help doctors equip parents for their child's education by pinpointing associations between brain abnormalities and specific cognitive disabilities. This will help parents to develop and implement early intervention programs.

Having treated patients with NF, I know firsthand the pain and suffering associated with the disease and the difficulties it can cause for parents. The ongoing Federal research activities though NIH are critical toward fighting NF. I also applaud the tremendous efforts of private foundations and the thousands of NF volunteers and advocates across the country. It is my sin-

cere hope that public-private partnerships will continue to provide medical breakthroughs that can prevent, treat, and cure NF and other painful diseases.

#### ADDITIONAL STATEMENTS

##### HONORING JACKLYN H. LUCAS

• Mr. BURR. Madam President, I wish to honor the life of Jacklyn Harrell Lucas. Mr. Lucas was born in Plymouth, NC, to Louis Harold and Margaret Lucas on February 24, 1928. He was in the eighth grade at Edwards Military Institute when the Japanese bombed Pearl Harbor. Lucas felt an obligation to serve the country and refused to let age get in his way.

Ten months after Pearl Harbor, Jack Lucas joined the Marine Corps Reserve at the age of 14. He listed his age as 17 and joined without his mother's consent. Lucas soon reported to Parris Island for basic training, where he qualified as a sharpshooter.

He was assigned to a machine gun crew and moved to Pearl Harbor at the end of 1943 where he was promoted to PVT first class. A year later, Lucas and his unit had not been deployed, so Lucas decided to deploy himself. He stowed away on the USS *Duel*, which was carrying the 5th Marine Division to battle in the Pacific.

A month into the journey he came out of hiding. Despite being reported as AWOL a month earlier and having been reduced in rank, PVT Jack Lucas was assigned to the 5th Marine Division. He was assigned to a rifle team and longed to get into the fight.

On February 19, 1945, Lucas finally got his wish as he and 30,000 other marines stormed the beaches of Iwo Jima. On the second day of the invasion, Lucas was pinned down with three members of his rifle team when two grenades landed in their foxhole.

His Medal of Honor citation describes best what happened next. Private Lucas "unhesitatingly hurled himself over his comrades upon one grenade and pulled the other one under him, absorbing the whole blasting force of the explosions in his own body in order to shield his companions from the concussion and murderous flying fragments." He saved the lives of his fellow marines by an act that would almost surely result in death, but Lucas survived.

Seven months and twenty-one surgeries later, Lucas was medically discharged from the Marine Corps. He left the service with over 200 pieces of shrapnel in his body. A month later he was awarded the Medal of Honor. Private Lucas was only 17 years old. He was one of 27 marines given the medal for their heroic actions at Iwo Jima. Eight-two marines were awarded the Medal of Honor during World War II, and almost a third received the medal for their heroism during this historic battle. Lucas is the youngest person ever to receive this Nation's highest military honor.

This Nation lost one of its best on June 5, when Jacklyn Harrell Lucas succumbed to cancer. He is survived by his wife Ruby C. Clark Lucas; 4 sons—William, Jimmy, Louis, and Kelly; a daughter, Peggy; 3 stepdaughters, Joan, Debbie, and Melinda; a brother, Louis; 15 grandchildren; and 16 great-grandchildren.

Madam President, the determination, patriotism, and selflessness of Jack Lucas should be admired by all. He was a fine North Carolinian and a great American.●

##### HONORING HORACE P. AXTELL

• Mr. CRAPO. Madam President, I am pleased to recognize an extraordinary honor bestowed upon Horace P. Axtell, elder of the Nimiipu, more commonly known as the Nez Perce Tribe. Horace is a 2008 recipient of the National Endowment for the Arts, NEA, National Heritage Fellowship, an annual fellowship that honors American folk artists for contributions to American culture. The highest federal honor in the folk and traditional arts, only 10 NEA National Heritage Fellowships are awarded every year.

Horace is a Nez Perce tribal historian, storyteller, singer and drum maker. In fact, he is a spiritual leader of the Seven-Drum religion, a traditional religion of the tribes of the plateau region that requires practitioners to memorize songs and accompany them on handmade drums. He still builds these drums in the traditional way, curing hides and stretching them over wooden frames. Spending his youth listening to stories of the tribal elders, some of whom survived the 1877 war against the Nez Perce by the United States, Horace is now a respected elder himself and a pipe carrier for his tribe, a position of great honor. He is the author of a memoir, the first one printed in over half a century by a Nez Perce elder. He has received numerous awards including the President's Medallion from the University of Idaho, an honorary doctorate from Lewis-Clark State College and the Washington State Historical Society Peace and Friendship Award.

It is an honor for me to publicly recognize the remarkable achievements of Horace P. Axtell.●

##### 300TH ANNIVERSARY OF RIDGEFIELD, CONNECTICUT

• Mr. DODD. Madam President, today I recognize a significant milestone for one of the towns in my home State of Connecticut. This year, the town of Ridgefield is celebrating the 300th anniversary of its founding.

Ridgefield's heritage dates back to the founding of this country and the American Revolution. A small militia force led by Generals David Wooster and Benedict Arnold faced off here against a larger British force at the Battle of Ridgefield on April 27, 1777. Whether it's the graves of the soldiers