

This legislation reauthorizes the pediatric exclusivity provision provided for in the Food and Drug Administration Modernization Act of 1997, which expires at the end of this calendar year. This legislation reauthorizes the provision through fiscal year 2007.

The bill directs the Secretary of HHS to create an annual list of approved drugs for which: (1) There is an approved or pending new drug application and (2) additional pediatric safety and effectiveness studies are needed. It further instructs the Secretary to award contracts to entities that have the appropriate experience for conducting clinical trials of such drugs.

The legislation also amends the Federal Food, Drug, and Cosmetic Act to: (1) Eliminate the user fee waiver for pediatric supplements to a human drug application; (2) provide priority status for pediatric supplements; (3) include neonates within the definition of pediatric studies; (4) provide for dissemination of pediatric supplement information; and (5) set forth requirements for the additional six-month exclusivity period for new or already-marketed pediatric drugs. Additionally, it amends title IV of the Public Health Service Act to direct the Secretary to establish the Foundation for Pediatric Research to support research on drugs lacking exclusivity for which pediatric studies are needed.

Finally, the bill directs the Secretary to: (1) Establish an Office of Pediatric Therapeutics within the Office of the Commissioner of Food and Drugs, which shall coordinate all FDA pediatric activities; and (2) contract with the Institute of Medicine to review federal regulations, reports, and support for research involving children, with particular attention to issues of compensation, informed consent, and risk/benefits assessments in terms of research versus therapeutic treatment.

Mr. Speaker, the pediatric exclusivity provision that was established in the FDA Modernization Act of 1997 has been overwhelmingly successful in generating clinical studies for the pediatric population in its 5 years of existence. According to the FDA, in the 6 years prior to the enactment of this provision, there were a total of six studies on the pediatric population at the request of the FDA, the 4 years since enactment have seen 197 requests to conduct more than 400 studies.

These studies are an invaluable tool in determining the safety and efficacy of newly approved drugs on the pediatric population. With the large number of drugs being approved each year, it is imperative that we have a working knowledge of the effects these medicines will have on our children's health and well-being. This bill will advance this purpose, and for that I urge my colleagues to support its adoption.

ALAN JACKSON MEMORIALIZES
THOSE LOST

HON. MAC COLLINS

OF GEORGIA

IN THE HOUSE OF REPRESENTATIVES

Friday, November 16, 2001

Mr. COLLINS. Mr. Speaker, on September 11th, 2001 our nation suffered a cataclysmic

attack of unprecedented proportion. More than 6,000 Americans lost their lives in less than 1 hour's time.

In the two months following that tragic day, our citizens have struggled for ways to accept and deal with such a horrific loss. We have held candlelight vigils, all night prayer groups, talked of memorials and rebuilding. We have launched a major military campaign to seek justice for those victims.

But one young man, whose name is known to many of this body and many of the American people, has found a way to genuinely memorialize those victims and that day in song.

Alan Jackson was born in Newnan, Georgia in 1958. Since that time he has grown into one of the nation's most loved Country Music stars. Some have called him the conscience of Nashville for his actions and the type of music he makes.

On November 7th at the Country Music Awards, Alan sang a song he wrote, which more than any other that I have heard, expressed the wide range of emotions experienced on September 11, 2001. I would like to read those lyrics to you now.

WHERE WERE YOU (WHEN THE WORLD STOPPED
TURNING)

(By Alan Jackson)

Where were you when the world stop turning
on that September day
Were you in the yard with your wife and
children

Or working on some stage in L.A.
Did you stand there in shock at the sight of
that black smoke
Rising against that blue sky
Did you shout out in anger, in fear for your
neighbor

Or did you just sit down and cry
Did you weep for the children who lost their
dear loved ones

And pray for the ones who don't know
Did you rejoice for the people who walked
from the rubble
And sob for the ones left below
Did you burst out in pride for the red, white
and blue

And the heroes who died just doin' what they
do

Did you look up to heaven for some kind of
answer

And look at yourself and what really mat-
ters

I'm just a singer of simple songs
I'm not a real political man
I watch CNN but I'm not sure I could
Tell you the difference in Iraq and Iran
But I know Jesus and I talk to God
And I remember this from when I was young
Faith, hope and love are some good things
He gave us
And the greatest is love

Where were you when the world stop turning
on that September day

Teaching a class full of innocent children
Or driving down some cold interstate
Did you feel guilty 'cause you're a survivor
In a crowded room did you feel alone
Did you call up your mother and tell her you
loved her

Did you dust off that bible at home
Did you open your eyes, hope it never hap-
pened

And you close your eyes and not go to sleep
Did you notice the sunset the first time in
ages

Or speak to some stranger on the street

Did you lay down at night and think of to-
morrow

Go out and buy you a gun
Did you turn off that violent old movie
you're watchin'
And turn on "I Love Lucy" reruns

Did you go to a church and hold hands with
some strangers

Stand in line and give your own blood
Did you just stay home and cling tight to
your family

Thank God you had somebody to love

I would like to take this opportunity to commend and congratulate my former constituent, a great American who has used his gifts as a songwriter and performer to lift the American spirit in this great pursuit for justice. Alan Jackson has crafted a thoughtful memorial to the victims of September 11th and serves as an example of how all Americans can help heal our nation from the wounds we suffered on that tragic day. Thank you Alan, for helping us to remember those we lost and for helping to keep their memory alive.

HONORING DR. THADDEUS
SZEWCZYK FOR HIS 50 YEARS OF
DEDICATED WORK TO THE
CAUSE OF RETROLENTAL
FIBROPLASIA

HON. JERRY F. COSTELLO

OF ILLINOIS

IN THE HOUSE OF REPRESENTATIVES

Friday, November 16, 2001

Mr. COSTELLO. Mr. Speaker, I rise today to ask my colleagues to join me in honoring Dr. Thaddeus Szewczyk of Belleville, Illinois who 50 years ago discovered the cause of retrolental fibroplasia.

During the 1930's, retrolental fibroplasia, a disease causing permanent, total blindness, affected premature babies placed in incubators in hospital nurseries. This disease became rampant in industrialized countries during the 1940's and 1950's, causing blindness in thousands of children. Twenty percent of all newly born premature babies were affected and doctors feared that within a few years, most premature babies born in the United States would be blind. Then, in December, 1951, Dr. Szewczyk, working at Christian Welfare Hospital in East St. Louis, Illinois, suggested that misuse of oxygen was the cause of retrolental fibroplasia and careful control of oxygen might control this disease. His findings were published in prestigious medical journals, including The American Journal of Ophthalmology. Because of the massive increase in incubator usage, this discovery prevented a tidal wave of blindness in baby-boomer babies.

Dr. Szewczyk has had a distinguished career and as a result, has received several awards and honors. In 1976, he received the International Leslie-Dana Gold Medal from the St. Louis Society for the Blind. In addition, the National Polish-American organization recognized him for this brilliant, medical discovery. Furthermore, the Illinois House of Representatives recently passed a resolution honoring Dr. Szewczyk for 50 years of dedication and hard work on retrolental fibroplasia.

Dr. Szewczyk was the first of four children born to Stanley and Genevieve Szewczyk. He