

characterize, and laboratory analysis of the finished product is insufficient to ensure its safety and efficacy.

The pharmaceutical drug production process is easily replicated and a “generic” drug product is virtually identical to the original innovative product, so generic drug manufacturers are permitted to reference the original testing data submitted by the innovator companies when the original drug is submitted to the FDA for approval. With biologics, the manufacturing process is unique to each biologic and is not generally disclosed as part of the published patent. A biosimilar manufacturer would have to have intimate knowledge of these proprietary processes in order to “duplicate” the biologic product, and even then it is extremely difficult—no two living cell lines are identical, so no two biologics manufacturing processes have identical starting materials or proceed in the same way.

It's also important to note that because biologics are produced with cells from living organisms, many of them can cause an immune reaction which is normally benign and does not affect safety. However, some of these reactions can negate the effectiveness of the biologic or even cause side effects that are more dangerous. Most of these reactions can only be observed through clinical trials with real patients.

Any expedited regulatory pathway for biosimilars must account for all these factors and I'm proud to join with Congressman JAY INSLEE and the Ranking Member of the Energy and Commerce Committee, Rep. JOE BARTON, to introduce the Pathway for Biologics Act. Our bill builds on the significant progress the Senate, led by Senators KENNEDY and ENZI, already made during the last Congress, as well as the significant level of consensus we have heard on our Committee about this issue. The Pathway for Biologics Act will establish a new statutory pathway for biosimilars guided by three principles:

1. Legislation to facilitate the development of biosimilars should promote competition and lower prices, but patient safety, efficacy and sound science must be paramount.

2. We must preserve incentives for innovation and ensure that patients will continue to benefit from the ground-breaking treatments biotechnology alone can bring.

3. We must strive to protect the rights of all parties and resolve disputes over patents in a timely and efficient manner that does not delay market entry and provides certainty to all parties.

The regulatory pathway set forth in the Pathway for Biologics Act embodies each of these principles and sets forth a sensible, scientifically sound process for approval of biosimilars. The legislation allows for input from all interested parties and provides FDA appropriate flexibility to protect patient health by requesting analytical, animal and clinical studies to demonstrate the safety, purity and potency of a biosimilar. The FDA will be empowered to require the tests and data it deems necessary, but the results of clinical testing for immunogenicity will always be required as part of this data unless the FDA has published final guidance documents advising that such a determination is feasible in the current state of science absent clinical data and explaining the data that will be required to support such a determination. Since biologics are derived from human and animal products,

immune reactions are a major concern for any new biologic product and are now impossible to detect without actual human testing.

Our legislation also addresses the important issue of interchangeability of biosimilars for the reference product. Some legislative proposals would allow the FDA to permit pharmacists and insurers to substitute a biosimilar for a physician's prescription for an innovator biologic product even when they cannot be demonstrated to be identical in their composition or effectiveness. Interchangeability of generic pharmaceuticals for brand name drugs is entirely appropriate since traditional generic drugs are chemically identical to the reference product. However, if the state of science is such that a complex molecule cannot be fully characterized and a precursor biologic cannot be adequately compared to a proposed biosimilar, then the biosimilar should not be fully substitutable for the precursor product without a physician's direction. The Pathway for Biologics Act makes it clear that the FDA cannot make a determination that a biosimilar is interchangeable with a reference product until it has published final guidance documents advising that it is feasible in the current state of scientific knowledge to make such determinations with respect to the relevant product class and explaining the data that will be required to support such a determination. This requirement is consistent with the recommendations of the Chief Scientist of the FDA.

An essential element of any new regulatory scheme for the biotech industry is a careful balancing of incentives for innovation and opportunities for new entry by competitors. To preserve incentives for innovation, the Pathway for Biologics Act provides 12 years of data exclusivity for new biologic products, which ensures that biosimilar applications that rely on the safety and efficacy record of existing biologic products will not be permitted to enter the market for 12 years following the approval of the innovator product. The 12-year exclusivity period is meant to preserve existing protections biotech companies receive from patents. The Congressional Budget Office has found that the effective patent life for pharmaceuticals is about 11.5 years, so a data exclusivity period of 12 years is consistent with that finding. Data exclusivity is necessary to provide additional protections and incentives for biologics because biosimilars—unlike generic drugs—will not be chemically identical to the reference product and will be less likely to infringe the patents of the innovator.

The legislation also includes incentives for additional indications and pediatric testing. New indications are critical for biologics and are often more significant than the indications for which approval was granted. Incentives for continued testing on new indications must be included to promote access to new treatments and cures, and this bill provides an additional two years exclusivity for new indications. I also believe it's important to provide incentives similar to those given traditional pharmaceuticals under the Best Pharmaceuticals for Children Act to biologics, so the legislation provides an additional six months of data exclusivity for testing for use in pediatric groups.

In order to protect the rights of all parties and ensure that all patent disputes involving a biosimilar are resolved before the expiration of the data exclusivity period, the Pathway for Biosimilars Act establishes a simple, streamlined patent resolution process. This process

would take place within a short window of time—roughly 6–8 months after the biosimilar application has been filed with the FDA. It will help ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large. The legislation also preserves the ability of third-party patent holders such as universities and medical centers to defend their patents.

Once a biosimilar application is accepted by the FDA, the agency will publish a notice identifying the reference product and a designated agent for the biosimilar applicant. After an exchange of information to identify the relevant patents at issue, the applicant can decide to challenge any patent's validity or applicability. All information exchanged as part of this procedure must be maintained in strict confidence and used solely for the purpose of identifying patents relevant to the biosimilar product. The patent owner will then have two months to decide whether to enforce the patent. If the patent owner's case is successful in court, the final approval of the application will be deferred until the patent expires.

Madam Speaker, I believe the Pathway for Biosimilars Act sets forth a straightforward, scientifically based process for expedited approval of new biologics based on innovative products already on the market. This new biosimilars approval pathway will promote competition and lower prices, but also ensure that patients are given safe and effective treatments that have been subjected to thorough scrutiny and testing by the FDA. The Pathway for Biosimilars Act will also protect the rights of patent holders and preserve incentives for innovation in the biotechnology sector to develop the next generation of life-saving, life-changing therapies.

I strongly urge my colleagues to support the Pathway for Biosimilars Act.

---

#### TRIBUTE TO HARRISBURG JUNIOR BULLDOGS

**HON. JOHN SHIMKUS**

OF ILLINOIS

IN THE HOUSE OF REPRESENTATIVES

*Tuesday, March 17, 2009*

Mr. SHIMKUS. Madam Speaker, I rise today to pay tribute to a championship team from Harrisburg, Illinois.

On February 18, the Harrisburg Junior Bulldogs beat previously-undefeated Carlyle 52–43 to clinch the 2009 Southern Illinois Junior High School Athletic Association Class L state championship. Finishing with a record of 26–1, the Junior Bulldogs gave Harrisburg Middle School its first state championship in boys basketball.

Facing a strong, talented opponent, the Junior Bulldogs stayed cool under pressure, held off a late rally and then came from behind to seal the win. This year's team exemplifies teamwork. As Coach Kevin Dowdy told the local newspaper, “Everyone had their part.”

I want to congratulate Coach Dowdy and his assistant coach, Marcus Questelle, on their fine work with this group of student athletes. I also want to extend my congratulations to the members of the 2008–2009 Harrisburg Junior Bulldogs state championship boys basketball team: Tyler Smithpeters, Capel Henshaw,

Ryne Roper, Brian Berkel, Caleb Bailey, Justin Younger, Cody Hall, Isaac Ingram, Caleb Bartok, Gabe Oglesby, Phillip West, Brandon Pate and Chris Wilsey.

This outstanding group of young men represented themselves, their school, families and community in a first-rate fashion. It is my privilege to congratulate them on a job well done.

INTRODUCTION OF THE PRESERVATION OF ANTIBIOTICS FOR MEDICAL TREATMENT ACT

**HON. LOUISE McINTOSH SLAUGHTER**

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

*Tuesday, March 17, 2009*

Ms. SLAUGHTER. Madam Speaker, I rise today to reintroduce legislation that is critically important in preventing our current stock of antibiotics from becoming obsolete. As a mother, grandmother, and microbiologist, I cannot stress the urgency of this problem enough.

Two million Americans acquire bacterial infections during their hospital stay every year, and 70 percent of their infections will be resistant to the drugs commonly used to treat them. As a result, every day thirty-eight patients in our hospitals will die of those infections.

Sadly, children and infants are particularly susceptible to infections caused by antibiotic resistant bacteria. For example, Salmonella causes 1.4 million illnesses every year. Over one-third of all diagnoses occur in children under the age of 10. Infants under the age of one are 10 times more likely than the general population to acquire a Salmonella infection. In 1995, 19 percent of Salmonella strains were found to be multi-drug resistant. That means that our children are left to undergo multiple treatments for otherwise simple infections because we have allowed traditional treatments to become ineffective.

And the cost to our already strained health care system is astronomical. In fact, resistant bacterial infections increase health care costs by \$4 billion to \$5 billion each year.

Currently, seven classes of antibiotics certified by the Food and Drug Administration (FDA) as "highly" or "critically" important in human medicine are used in agriculture as animal feed additives. Among them are penicillin, tetracyclines, macrolides, lincosamides, streptogramins, aminoglycosides, and sulfonamides. These classes of antibiotics are among the most critically important in our arsenal of defense against potentially fatal human diseases.

Penicillins, for example, are used to treat infections ranging from strep throat to meningitis. Macrolides and Sulfonamides are used to prevent secondary infections in patients with AIDS and to treat pneumonia in HIV-infected patients. Tetracyclines are used to treat people potentially exposed to anthrax.

Despite their importance in human medicine, these drugs are added to animal feed as growth promotants and for routine disease prevention. Approximately 70 percent of antibiotics and related drugs produced in the U.S. are given to cattle, pigs, and chicken to promote growth and to compensate for crowded, unsanitary, stressful conditions. The nontherapeutic use of antibiotics in poultry skyrocketed

from 2 million pounds in 1985 to 10.5 million pounds in the late 1990s.

This kind of habitual, nontherapeutic use of antibiotics has been conclusively linked to a growing number of incidents of antimicrobial-resistant infections in humans, and may be contaminating ground water with resistant bacteria in rural areas. In fact, a National Academy of Sciences report states that, "a decrease in antimicrobial use in human medicine alone will have little effect on the current situation. Substantial efforts must be made to decrease inappropriate overuse in animals and agriculture as well."

Resistant bacteria can be transferred from animals to humans in several ways. Antibiotic resistant bacteria can be found in the meat and poultry that we purchase in the grocery store. In fact, a New England Journal of Medicine study conducted in Washington, DC found that 20 percent of the meat sampled was contaminated with Salmonella and 84 percent of those bacteria were resistant to antibiotics used in human medicine and animal agriculture. Bacteria can also be transferred from animals to humans via workers in the livestock industry who handle animals, feed, and manure. Farmers may then transfer the bacteria on to their family. A third method is via the environment. Nearly 2 trillion pounds of manure generated in the U.S. annually contaminate our groundwater, surface water, and soil. Because this manure contains resistant bacteria, the resistant bacteria can then be passed on to humans that come in contact with the water sources or soil.

And the problem has been well documented.

A 2002 analysis of more than 500 scientific articles and published in the journal *Clinical Infectious Diseases* found that "many lines of evidence link antimicrobial resistant human infections to foodborne pathogens of animal origin."

The Institute of Medicine's 2003 report on *Microbial Threats to Health* concluded "Clearly, a decrease in the inappropriate use of antimicrobials in human medicine alone is not enough. Substantial efforts must be made to decrease inappropriate overuse in animals and agriculture as well."

As the impact of MRSA continues to unfold, there is little doubt that antibiotic resistant diseases are a growing public health menace demanding a high priority response. Despite increased attention to the issue, the response has been inadequate. Part of the problem has been the FDA's failure to adequately address the effect of the misuse of animal antibiotics on the efficacy of human drugs.

Although the FDA could withdraw its approval for these antibiotics, its record of reviewing currently approved drugs under existing procedures indicates that it would take nearly a century to get these medically important antibiotics out of the feed given to food producing animals. In October 2000, for example, the FDA began consideration of a proposal to withdraw its approval for the therapeutic use of fluoroquinolones in poultry. The review, and eventual withdrawal of approval, took five years to complete. Under its regulations, the FDA must review each class of antibiotics separately.

The legislation I am reintroducing today, the Preservation of Antibiotics for Medical Treatment Act, would phase out the use of the seven classes of medically significant anti-

biotics that are currently approved for nontherapeutic use in animal agriculture. Make no mistake, this bill would in no way infringe upon the use of these drugs to treat a sick animal. It simply proscribes their nontherapeutic use.

Madam Speaker, when we go to the grocery store to pick up dinner, we should be able to buy our food without worrying that eating it will expose our family to potentially deadly bacteria that will no longer respond to our medical treatments. Unless we act now, we will unwittingly be permitting animals to serve as incubators for resistant bacteria.

It is time for Congress to stand with scientists, the World Health Organization, the American Medical Association, and the National Academy of Sciences and do something to address the spread of resistant bacteria. We cannot afford for our medicines to become obsolete.

I urge my colleagues to support the Preservation of Antibiotics for Medical Treatment Act to protect the integrity of our antibiotics and the health of American families.

TRIBUTE TO TRINITY EPISCOPAL CHURCH

**HON. JOHN SHIMKUS**

OF ILLINOIS

IN THE HOUSE OF REPRESENTATIVES

*Tuesday, March 17, 2009*

Mr. SHIMKUS. Madam Speaker, I rise today to pay tribute to an important community institution in Mt. Vernon, Illinois.

In February, Trinity Episcopal Church celebrated its 100th anniversary. Since the first service was held at 1100 Harrison Street in Mt. Vernon on January 3, 1909, thousands of people have visited Trinity Episcopal to worship with their neighbors. Generations of families in Mt. Vernon and Jefferson County have been welcomed into the congregation.

Today, Trinity Episcopal is an important part of the spiritual fabric of the community and serves as a good neighbor to families in need throughout the area. Through a century of the congregation's generosity, many have found a helping hand, warm embrace, and comfort in times of despair.

I want to congratulate Father Gene Tucker of Trinity Episcopal, all members of the congregation, and the extended Trinity Episcopal family on 100 years of service and thank them for the important role they play in our community.

RECOGNIZING AND COMMENDING THE NATIONAL AERONAUTICS AND SPACE ADMINISTRATION (NASA), THE JET PROPULSION LABORATORY (JPL), AND CORNELL UNIVERSITY FOR THE SUCCESS OF THE MARS EXPLORATION ROVERS, SPIRIT AND OPPORTUNITY, ON THE 5TH ANNIVERSARY OF THE ROVERS' SUCCESSFUL LANDING

**HON. KEN CALVERT**

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

*Tuesday, March 17, 2009*

Mr. CALVERT. Madam Speaker, just over 5 years ago, two engineering marvels—the Mars