

# INTRODUCING THE FDA DEEMING AUTHORITY CLARIFICATION ACT OF 2015

**HON. TOM COLE**

OF OKLAHOMA

IN THE HOUSE OF REPRESENTATIVES

*Tuesday, April 28, 2015*

Mr. COLE. Mr. Speaker, today I rise to introduce legislation, the FDA Deeming Authority Clarification Act of 2015, to make a technical change to the Family Smoking Prevention and Tobacco Control Act (FSPTCA). The Family Smoking Prevention and Tobacco Control Act provides the framework for the Food and Drug Administration (FDA) to regulate tobacco products and products with nicotine derived from tobacco.

Under the FSPTCA, the FDA was provided immediate regulatory authority over cigarettes, smokeless tobacco, and roll-your-own tobacco. Further, the FSPTCA allows FDA to regulate other tobacco products through a regulatory process.

The issue that my legislation seeks to remedy relates to a specific date—the predicate/grandfather date of February 15, 2007. The FSPTCA specifies that any cigarette, smokeless tobacco or roll-your-own tobacco product that was in the market before February 15, 2007 is grandfathered and can stay on the market without manufacturers submitting applications to FDA approval, but FDA is still able to regulate these products.

Manufacturers making changes to grandfathered tobacco products or introducing new tobacco products after this date are required to file an application with the FDA.

Further, a manufacturer is able to file a more abbreviated substantial equivalence application if the manufacturer can demonstrate that the modified or new tobacco product is substantially equivalent to a tobacco product that was on the market before this grandfather date. For this reason, this date is doubly important because it serves as both the grandfather date and the predicate date.

The FSPTCA further lays out that any products that came to market between February 15, 2007 and the date of enactment (June 22, 2009), or during the following 21 months (before March 22, 2011) were permitted to stay on the market, but the manufacturer was required to file a substantial equivalence (SE) for those products before the end of this transition period.

Finally, no product may be brought to market after this transition period without authorization from FDA.

Questions may be raised as to why the so-called predicate/grandfather date of February 15, 2007 was picked in the Act. If you look at the legislative history, February 15, 2007 was the date the Act was introduced in the 110th Congress. There was no other specific reason for the date chosen in the Act. Moreover, the 2007 date reflects the predicate/grandfather date for those immediately regulated products—not for products that FDA could choose to regulate at a later time.

On April 25, 2014, FDA released its proposed deeming regulation, which would grant authority for the agency to regulate cigars, vapor products and other products with nicotine derived from tobacco.

However, in the proposed rule, the agency stated it would maintain the February 15, 2007

as the predicate/grandfather date for newly deemed products even though the FDA has the regulatory discretion to choose a different date. Notably, the FDA provided for a two-year transition period, similar to the 21-month transition period contained in the Act.

The FDA claims that it lacks the legal authority to change the February 15, 2007 date even though it has used regulatory authority to make a number of decisions that were not spelled out in the initial Act. The agency should apply that same authority to altering the predicate/grandfather date for newly deemed tobacco products, while maintaining this important transition period.

Should the agency choose not to alter the date, the February 15, 2007 predicate/grandfather date will make it costly and create significant barriers for the industry and the FDA to bring innovative new products that may significantly reduce the harms associated with tobacco to market, and could force the withdrawal of many products that have come to market since February 2007.

The end result will be that newly deemed tobacco products would be treated much more harshly than immediately regulated products. Specifically, the “look back” period for cigarettes, smokeless tobacco and roll-your-own tobacco products was two years (June 2009 to February 2007) while the period for newly deemed products would be eight years (June 2015 to February 2007) if FDA meets its June 2015 target to publish a final deeming rule, and perhaps longer if FDA does not publish its final rule in time.

It makes no sense that immediately regulated products—which Congress decided were most in need of FDA regulation—get such an advantage over later regulated products.

In addition, applying the February 2007 predicate/grandfather date to newly deemed products or failure to provide for a transition period will immediately and dramatically add to FDA’s enormous backlog of SE applications, which stands at thousands to date.

Even though the FDA already has this authority, the legislation I introduce today will underscore that FDA should choose a new grandfather/predicate date each time the agency deems new tobacco products. Specifically, the bill would make the grandfather/predicate date for newly deemed tobacco products the effective date of the final rule and mimic the 21-month transition period provided for cigarettes, smokeless tobacco and roll-your-own tobacco.

Accordingly, on the crucial issue of path to market, later regulated products would be treated no better and no worse than immediately regulated products.

## CELEBRATING THE 36TH ANNIVERSARY OF THE TAIWAN RELATIONS ACT

**HON. J. RANDY FORBES**

OF VIRGINIA

IN THE HOUSE OF REPRESENTATIVES

*Tuesday, April 28, 2015*

Mr. FORBES. Mr. Speaker, I rise to commemorate and celebrate the 36th anniversary of the passing of the Taiwan Relations Act, the landmark piece of legislation that provides the legal basis for our bilateral relations with Taiwan, our close economic and security part-

ner and friend with which we share so many principles and values.

Our relationship with the Republic of China dates back decades, but it is as important today as ever. Taiwan stands today as a symbol of what countries can accomplish when they commit themselves to democracy, free enterprise, the rule of law, and respect for human rights. The Taiwan Relations Act, accordingly, stands as a symbol of the United States’ unwavering support for those values and its commitment to protect and uphold them wherever they take root.

The Taiwan Relations Act is also more than a symbol, however. It is a binding resolution that we in Washington will “consider any effort to determine the future of Taiwan by other than peaceful means, including by boycotts or embargoes, a threat to the peace and security of the Western Pacific area and of grave concern to the United States.”

Today, the peace and security of that critical region is being undermined by a military build-up on the mainland and increasingly aggressive behavior in its littoral waters. In this strategic environment it is critically important that we reaffirm our support to countries that share our values and behave with respect to their neighbors and the norms of international behavior.

## INTRODUCTION OF THE UNITED STATES COMMISSION ON AN OPEN SOCIETY WITH SECURITY ACT OF 2015

**HON. ELEANOR HOLMES NORTON**

OF THE DISTRICT OF COLUMBIA

IN THE HOUSE OF REPRESENTATIVES

*Tuesday, April 28, 2015*

Ms. NORTON. Mr. Speaker, as the nation’s capital brings thousands of Americans to Washington, D.C. this tourist season despite recent security incidents, I rise to reintroduce the United States Commission on an Open Society with Security Act of 2015. The bill is as timely now as when I first began working on it. I saw the first signs of the closing of parts of our open society after the Oklahoma City bombing, whose 20th anniversary we commemorated this year. I saw it again after 9/11. This bill grows even more urgent as the country is ensnared in wars that threaten our security, causing an increasing variety of security measures to proliferate throughout the country without due diligence and deep thinking about the effects on common freedoms and ordinary public access, and often without guidance from the government or bona fide security experts. Take the example of some ordinary government buildings. Security in some federal buildings bars tourists here for Cherry Blossom season from even getting in to use the restroom or enjoy the cafeterias. The security for some federal buildings has for too long been unduly influenced by non-security experts, who happen to work for an agency but do not have the expertise to take into account actual threats.

Another example is the District of Columbia’s only public heliport, which the Transportation Security Administration (TSA) and Federal Aviation Administration (FAA) shut down following the September 11, 2001, terrorist attacks, without explanation or means to appeal the decision. Just days after the 9/11 attacks,

however, helicopter service was restored in New York City, the major target of the attacks. Yet, even 12 years after the attacks, TSA and FAA and particularly the Secret Service still will not permit commercial helicopters to fly to D.C., unlike all other cities in the United States.

The bill I reintroduce today would begin a systematic investigation that fully takes into account the importance of maintaining our democratic traditions while responding adequately to the real and substantial threat that terrorism poses. To accomplish its difficult mission, the bill authorizes a 21-member commission, with the president designating nine members and the House and Senate each designating six members, to investigate the balance that should be required between openness and security. The commission would be composed not only of military and security experts, but, for the first time at the same table, also experts from such fields as business, architecture, technology, law, city planning, art, engineering, philosophy, history, sociology, and psychology. To date, questions of security most often have been left almost exclusively to security and military experts. They are indispensable participants, but these experts should not alone resolve all the new and unprecedented issues raised by terrorism in an open society. In order to strike the security/access balance required by our democratic traditions, a diverse group of experts needs to be at the same table.

For years, parts of our open society have gradually been closed down because of terrorism and the fear of terrorism, on an often ad hoc basis. Some federal buildings such as the U.S. Capitol have been able to deal with security issues, and continue their openness to the public. Others, like the new Department of Transportation headquarters, remain mostly inaccessible to the public. These examples, drawn from the nation's capital, are replicated in public buildings throughout the United States.

After 9/11, Americans expected additional and increased security adequate to protect citizens against the frightening threat of terrorism. However, in our country, people also expect their government to be committed and smart enough to undertake this awesome new responsibility without depriving them of their personal liberty. These times will long be remembered for the rise of terrorism in the world and in this country and for the unprecedented challenges it has brought. Nevertheless, we must provide ever-higher levels of security for our residents and public spaces while maintaining a free and open democratic society. What we have experienced since Oklahoma City and 9/11 is no ordinary threat that we expect to be over in a matter of years. The end point could be generations from now. The indeterminate nature of the threat adds to the necessity of putting aside ad hoc approaches to security developed in isolation from the goal of maintaining an open society.

When we have faced unprecedented and perplexing issues in the past, we have had the good sense to investigate them deeply before moving to resolve them. Examples include the National Commission on Terrorist Attacks Upon the United States (also known as the 9/11 Commission), the Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction (also known as the Silberman-Robb Commission),

and the Kerner Commission, which investigated the riots that swept American cities in the 1960s and 1970s. In the aftermath of the 2013 Navy Yard shooting, I wrote to the President of the United States requesting the establishment of an independent panel to investigate issues raised by that tragedy and to evaluate how to secure federal employees who work in facilities like the Navy Yard that are a part of a residential or business community. However, this bill seeks a commission that would act not in the wake of a tragedy but before a crisis and before erosion of basic freedoms takes hold and becomes entrenched. Because global terrorism is likely to be long lasting, we cannot afford to allow the proliferation of security measures that neither require nor are subject to civilian oversight or an analysis of alternatives and repercussions on freedom and commerce.

With no vehicles for leadership on issues of security and openness, we have been left to muddle through, using blunt 19th-century approaches, such as crude blockades, unsightly barriers around beautiful monuments, and other signals that our society is closing down, all without appropriate exploration of possible alternatives. The threat of terrorism to an open society is too serious to be left to ad hoc problem-solving. Such approaches are often as inadequate as they are menacing.

We can do better, but only if we recognize and come to grips with the complexities associated with maintaining a society of free and open access in a world characterized by unprecedented terrorism. The place to begin is with a high-level commission of experts from a broad array of disciplines to help chart the new course that will be required to protect our people and our precious democratic institutions and traditions.

#### HONORING LIEUTENANT COLONEL RAY SCHAAF

#### HON. JOHN R. CARTER

OF TEXAS

IN THE HOUSE OF REPRESENTATIVES

*Tuesday, April 28, 2015*

Mr. CARTER of Texas. Mr. Speaker, I rise today to honor Lieutenant Colonel Ray Schaaf, U.S. Army, Retired of Round Rock, Texas as he celebrates his 90th birthday on April 24, 2015. Even with nearly a century of living behind him, he remains a vibrant part of his growing central Texas community.

Born in Colorado, LTC Schaaf entered the Army in June 1943. After rigorous training, he arrived in England the following year where he bravely flew combat missions with the 381st Bomb Wing over Europe. His post-war military career saw this brave aviator serve in Korea, China, Greenland, and numerous bases in the U.S. LTC Schaaf retired in 1970 and made his home in the Lone Star State.

Following his retirement, the warrior became an artist. A skilled handyman, LTC Schaaf makes jewelry and restores saddles. He's an avid painter and is especially adept in the centuries-old craft of knife making. This determination to live life to its fullest is a reminder to us all to make the most of every day.

Family remains at the center of his life. LTC Schaaf married his beloved Marge. They brought four children into the world and were united through feast and famine. Now a proud

grandfather of nine, great-grandfather of fourteen, and great-great-grandfather of one, he has the pleasure of watching his beautiful family grow and prosper.

All should marvel at the extraordinary times LTC Schaaf has witnessed. In his nine decades of living, he defended freedom on foreign shores, watched a humble midwesterner take mankind's first steps on another world, and marveled at technological advances beyond any of his dreams. He saw how America has been defined by extraordinary men and women who fought for a country brave enough to confront its past imperfections and hopeful enough to embrace a better tomorrow.

LTC Ray Schaaf's patriotism, citizenship, and commitment to service reflect the very best values of both the Greatest Generation and Central Texas. Let April 24 continue to be a celebration of one of our nation's heroes who devoted his life to keeping us free and making America a beacon of hope in the world. Along with his friends, family, and loved ones, I wish him both a happy 90th birthday and all the best in the years ahead.

#### RECOGNIZING BUCKS COUNTY CHILDREN AND YOUTH SOCIAL SERVICES AGENCY

#### HON. MICHAEL G. FITZPATRICK

OF PENNSYLVANIA

IN THE HOUSE OF REPRESENTATIVES

*Tuesday, April 28, 2015*

Mr. FITZPATRICK. Mr. Speaker, for 50 years, the Bucks County Children and Youth Social Services Agency has been protecting the children of Bucks County.

Through investigating reports of child abuse and neglect, providing for the temporary care of children not able to remain with their own families and working to develop community-wide social service programs that empower kids and their families, Children and Youth has played a vital role in our community for decades—a fact we celebrate this anniversary.

As a former County Commissioner, I've had the opportunity to work side-by-side with the committed staff and leaders that make this agency the success it is. Their work has promoted safer, healthier communities and played a part in strengthening the lives of thousands of children.

Our children are our greatest resource. And, through the dedicated efforts of Bucks County Children and Youth Social Services, Bucks County's future is brighter.

#### TRIBUTE TO MR. DONALD S. POWERS

#### HON. TODD ROKITA

OF INDIANA

IN THE HOUSE OF REPRESENTATIVES

*Tuesday, April 28, 2015*

Mr. ROKITA. Mr. Speaker, I rise today to honor a notable Hoosier, Mr. Donald S. Powers, who passed away on April 21, 2015. I would like to express my gratitude for his community service and economic development in my hometown of Munster, Indiana. Most important to me, he was a friend and mentor who was always ready to provide sound guidance. He was among my very first supporters