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 partner 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 buildup 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,