EXTENSIONS OF REMARKS

ADDING ZIKA VIRUS TO THE FDA PRIORITY REVIEW VOUCHER PROGRAM ACT

SPEECH OF

HON. FRANK PALLONE, JR.

OF NEW JERSEY

IN THE HOUSE OF REPRESENTATIVES

Tuesday, April 12, 2016

Mr. PALLONE. Mr. Speaker, I rise today in opposition to S. 2512, which would add Zika to the list of qualified tropical diseases under the Food and Drug Administration's Tropical Disease Priority Review Voucher Program. While I know that we would all agree that there is desperate need for a treatment for Zika, I do not believe that this legislation offers the solution that will help us to achieve that goal. Further, I am disappointed that this legislation has not had the benefit of any legislative action in our Committee where Members could discuss in greater detail the need for reforms to the currently flawed priority review voucher program.

In 2007, Congress established the Tropical Disease Priority Review Voucher Program at FDA to incentivize treatments for neglected tropical diseases for which there was no market incentives to develop. Sponsors that develop a treatment for a qualified tropical disease are awarded a priority review voucher and have the option of retaining this voucher for a shortened review of another product in their development pipeline, or can sell the voucher to another company to use. Since enactment, three vouchers have been awarded under this program, two of which sold for $67 million and $125 million respectively. The value of the vouchers to sponsors has led to the development of the priority review voucher as a financial incentive in other areas, such as rare pediatric diseases.

However, this program is not without flaws. Use of priority review vouchers is not limited to additional tropical disease products, meaning that companies can use this voucher for a review in six months of any product of its choosing. This can result in new drug applications receiving priority review that would not otherwise qualify if they do not treat a serious disease or condition, or offer a significant improvement in safety or effectiveness. In practice, this allows companies to ''purchase'' services from the agency at the expense of other important public health work, undermining FDA's mission and the morale of the agency's review staff. It also creates additional workload for the FDA by requiring a shortened review of applications for treatments that will be used in millions of patients and diverting review staff from other work. Finally, the additional priority review voucher fee associated with use of the voucher has not been effective in covering the full cost of the expedited review.

In addition to effects on FDA, the current tropical disease priority review voucher program contains two additional flaws—eligibility for this program is not limited to novel therapies, nor are sponsors required to make the qualifying therapy available or accessible for those who are most in need. Two of the three priority review vouchers awarded under this program were awarded to therapies that were already in use in other countries prior to the program's establishment. Thus a voucher was awarded to sponsors without any new investment in tropical disease treatments. Similarly, patients and other organizations still struggle to access two of the three therapies awarded a priority review voucher either due to affordability or lack of availability. An award such as a priority review voucher should only be given to companies who are committed to making their therapy available to patients in disease-endemic countries for which the program is intended to help.

As we consider the bill before us today, it is important to note that FDA has the authority to add Zika to the tropical diseases program administratively if there is no significant market in developed nations for that disease and the disease disproportionately affects poor and marginalized populations. I will submit a letter from FDA noting that it is ''extremely unlikely that the Zika virus meets the criteria set out in the statute'' as there is a significant market for medical products for Zika virus currently. According to the agency, expanding the program to include Zika, which would be ineligible, would weaken the effectiveness of the priority review program and would create an undue burden on FDA.

Mr. Speaker, it is for all of these reasons that I am opposing S. 2512 today. It is clear there are significant issues with the tropical disease priority review voucher program that should have been discussed and considered as a part of the Committee process. Unfortunately, we were not afforded that opportunity. If the goal of the House is to address the Zika crisis, we should not be expanding a flawed program that will provide incentives for which there is no need. Instead Congress should be working together, including with the Administration, to fully fund a comprehensive response to Zika. I submit the following letter:

DEPARTMENT OF HEALTH & HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION,

Silver Spring, MD, February 29, 2016.

DEAR MEMBER: Thank you for your letter of February 05, 2016, urging the Food and Drug Administration (FDA or the Agency) to add Zika virus to the list of qualified tropical diseases under the Tropical Disease Priority Review Voucher (PRV) Program by issuing an order, as authorized by the Adding Ebola to the FDA Priority Review Program Act [PL 113–233].

FDA is actively working on many fronts to help mitigate the Zika virus outbreak. The Agency's primary areas of activity include:

(1) protecting the safety of the nation's blood supply and ensuring the safety of cell and tissue products;

(2) facilitating the development and availability of blood donor screening and medical diagnostic tests for identification of the presence of, or prior exposure to, Zika virus;

(3) supporting the development of investigational vaccines and therapeutics;

(4) reviewing proposals for the use of innovative strategies to help suppress the population of virus-carrying mosquitoes;

(5) protecting the public from fraudulent products that claim to prevent, diagnose, treat, or cure Zika virus disease.

Specific activities include issuing guidance to blood collection centers on safeguards to prevent transfusion transmission of Zika virus in areas of the U.S. and its territories with active mosquito borne transmission (currently Puerto Rico, U.S. Virgin Islands, American Samoa and Marshall Islands), and in unaffected areas where the virus might be introduced by persons returning from affected areas. FDA is also developing guidance that will address appropriate donor screening for human cells, tissues, and cellular and tissue-based products: concerns in this area have been highlighted by reported possible sexual transmission of the Zika virus. FDA is reaching out to potential commercial product manufacturers to encourage them to develop and submit applications for emergency use of diagnostic tests for the Zika virus. In addition, FDA is actively engaged with the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Biomedical Advanced Research and Development Authority (BARDA), the National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC) to advance the development of diagnostic tests, vaccines, therapeutics, and donor screening and pathogen-reduction technologies for blood products to help mitigate this outbreak. These efforts have already realized a major success. On February 26, 2016, under its Emergency Use Authorization (EUA) authority, FDA authorized the use of a Zika virus diagnostic test—developed by CDC—for the qualitative detection of Zika virus-specific immunoglobulin M (IgM) antibodies by qualified laboratories. This diagnostic test can help expand domestic readiness for Zika virus by enabling the identification of patients recently infected with Zika virus in support of response efforts.

As you are aware, under section 524 of the Federal Food, Drug, and Cosmetic Act, the Secretary of Health and Human Services is authorized to add infectious diseases to the list of tropical diseases that would qualify the developer of a licensed or approved product to prevent or treat an identified tropical disease to receive a PRV under FDA's Tropical Disease PRV Program, if: (1) there is no significant market in developed nations for that disease; and (2) the disease disproportionately affects poor and marginalized populations. This authority is delegated to FDA.

FDA has provided a process for requesting that additional diseases be added to the PRV list through the submission of a request to a special docket set up to facilitate the consideration of such requests, accompanied by information to document that the disease meets the statutory criteria required to be added to the PRV list. While FDA has not received a request to add the Zika virus to the PRV list via the docket, the Agency does not want to foreclose anyone from following that process and will evaluate any submissions that are made with respect to the Zika virus. FDA wants to make it clear, however, that—based on the information currently available to FDA—it is extremely unlikely that the Zika virus meets the criteria set out in the

statute. While it appears likely that the Zika virus disproportionately affects poor and marginalized populations, it also appears that there is a significant market for the Zika virus medical products in developed nations, which would render the Zika virus ineligible for addition to the PRV list under the statute at this time.

FDA agrees that we need to do all that we can to facilitate the development of and access to medical products as quickly as possible to respond to the Zika virus outbreak. We fully believe that the incentives currently available for the Zika product development—such as funding for research and development, and clinical trial costs from government and non-governmental organizations—as well as extensive HHS technical assistance for product developers, are sufficient to help bring Zika products to market. FDA is fully prepared to use its authorities to the fullest extent appropriate—including proven mechanisms to speed the availability of medical products for serious diseases—to help facilitate the development and availability of products with the potential to mitigate this outbreak as quickly as the science will allow. However, expanding the PRV program by adding diseases or conditions that do not meet the criteria for inclusion is unnecessary, weakens the effectiveness of the PRV program, and creates an undue burden on FDA that can ultimately harm public health.

As you are aware, the Administration has asked Congress for approximately $1.9 billion in emergency funding to enhance our ongoing efforts to prepare for and respond to the Zika virus, both domestically and internationally. Approving this funding request, which includes support for medical product development and procurement, is essential for sustaining HHS's effort to effectively incentivize the development and availability of medical products for the Zika virus.

Thank you, again, for contacting us concerning this matter. If you have any questions or concerns, please do not hesitate to contact me. The same letter has been sent to your cosigners.

Sincerely,

DAYLE CRISTINZIO,
Acting Associate Commissioner for Legislation.

NO RATE REGULATION OF BROADBAND INTERNET ACCESS ACT

SPEECH OF

HON. KATHY CASTOR

OF FLORIDA

IN THE HOUSE OF REPRESENTATIVES

Friday, April 15, 2016

The House in Committee of the Whole House on the state of the Union had under consideration of the bill (H.R. 2666) to prohibit the Federal Communications Commission from regulating the rates charged for broadband Internet access service:

Ms. CASTOR of Florida. Mr. Chair, I rise today in opposition to H.R. 2666, the No Rate Regulation Act. Many small businesses and many of my neighbors in the Tampa Bay area have experienced loss of internet, TV and phone services. I want to ensure that my neighbors and businesses are protected—I am fighting for them to receive the services they paid for. The No Rate Regulation Act aims to dismantle the open internet and take the ''cop off the beat'' by hamstringing the FCC's ability to protect the consumer. Because of these concerns on behalf of my neighbors and small businesses, today I will vote against this bill.

This is timely legislation for all the wrong reasons. On April 1 of this year, Frontier Communications assumed Verizon's TV, internet and land-line phone services in the Tampa Bay area. Since the transition, small businesses and individual consumers in Florida have experienced loss of internet, TV and phone services. Consumers are paying for services they are not receiving. Even now, customers are reporting waiting for Frontier's technicians that are ''no shows''. Frontier appears to be unable to provide the necessary services to my neighbors, at the present time.

I am here today to ensure all customers are protected. I have been fighting to protect the consumer and for robust public interest reviews. On February 2nd I stated in my letter to the FCC regarding the proposed Bright House Networks/Time Warner Cable/Charter merger that it is appropriate for the FCC to investigate that ''best practices'' are present on behalf consumers.

The awesome power of the internet should be used to build up our community and grow opportunity for our children. I am proud that last year Tampa was selected as one of only 27 communities nationwide to participate in ConnectHOME, which promotes locally tailored solutions to help bridge the gap in digital access for working-class households by addressing the barriers they have to high-speed broadband.

We should be dedicated to significant community boosts in access to digital opportunities for our students. We should be working with all agencies to develop the types of skills needed to secure today's higher paying jobs for all our kids. Instead of inviting a promising tomorrow, Republicans have chosen to focus on a bad bill with no future today.

On the House floor Republicans have offered the No Rate Regulation Act. If passed it could undermine key provisions in the FCC's Open Internet order and harm the Commission's ability to protect consumers. This bill simply fails to define a clear definition and experts assert that the bill could result in unintended consequences. The No Rate Regulation Act is overly broad and extends far beyond the goals of codifying the FCC's forbearance from applying provisions of the Communications Act related to tariffs, rate approval, or other forms of utility regulation. The FCC should not be stymied in their participation of mergers and acquisitions like the Bright House/TWC/Charter proposal. For example, I have said that BHN's Connect2Compete Program should be maintained, but as written, this legislation could undermine the FCC's ability to encourage customer service agreements that protect the most vulnerable.

We have seen the Comcast Universal merger approval include the supply of an affordable internet program called the Internet Essentials. These stipulations are important and should be maintained in other deals moving forward.

Mr. Chair, today I will vote against this Republican bill that could undermine key provisions in the FCC's Open Internet Order and harm the FCC's ability to protect consumers. We should not be undermining the FCC. This legislation could exacerbate already negative consequences for my neighbors in the Tampa Bay area. I will continue work to protect consumers and neighbors in my community and vote no on the No Rate Regulation Act.

COMMENDING BETSY FLEMING FOR HER SERVICE AS PRESIDENT OF CONVERSE COLLEGE

HON. TREY GOWDY

OF SOUTH CAROLINA

IN THE HOUSE OF REPRESENTATIVES

Monday, April 18, 2016

Mr. GOWDY. Mr. Speaker, today I commend President Betsy Fleming of Converse College for her service to higher education and her remarkable impact on South Carolina.

After growing up in Spartanburg, President Fleming left in 1984 to embark on her journey to become a renowned art-historian. Throughout her career, she held curatorial positions at several prominent museums across the United States as well as overseas in London. Prior to being named President of Converse College in 2005, Fleming served as the executive director of the Gibbes Museum of Art in Charleston, South Carolina.

Under President Fleming's eleven years of leadership, Converse College experienced incredible transformation. During her tenure, Converse reduced its tuition by 43 percent and celebrated its largest undergraduate enrollment in over 25 years, becoming a national leader in affordability and value. Furthermore, Converse gained full NCAA Division II membership in eleven sports programs and raised more than $76 million in support.

In addition to her impact on the Converse College community, President Fleming's service extends above and beyond her commitment in Spartanburg. An Aspen Institute Liberty Fellow, President Fleming serves on the Council of Presidents for the Association of Governing Boards (AGB), the Council of Independent Colleges (CIC) Steering Committee in the Future of Higher Education, and on the Board of Directors for both the Federal Reserve Bank of Richmond, Charlotte Branch and Blue Cross Blue Shield of South Carolina.

President Fleming's impact on students, staff, and faculty will always be remembered, and her legacy will transform the future of Converse College. I thank President Fleming for her extraordinary service and congratulate her on her retirement. We look forward to the next chapter of her remarkable life as she continues to serve our community, state and country.

IN MEMORY OF RACHEL HOUSTON

HON. SCOTT GARRETT

OF NEW JERSEY

IN THE HOUSE OF REPRESENTATIVES

Monday, April 18, 2016

Mr. GARRETT. Mr. Speaker, I stand today to remember and honor the life, faith, and service of Rachel Margaret Houston. A former legislative assistant in my office, Rachel passed away on April 10, 2016, at the far-too-young age of 32.

Those of us who had the honor to know Rachel knew her kind heart, deep faith, and compassion for others. Friends and former coworkers remembered her as a ''wonderful'' and ''lovely person,'' and a ''soft, sweet spirit,'' with a ''bright smile, kind words, and warm heart.'' Rachel was that rare person who could reach out to someone new and make him or her feel welcomed, supported, and encouraged. Her kindness left a mark on all who