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CONGRESSWOMAN SHEILA JACKSON LEE OF TEXAS

COMMITTEE ON THE JUDICIARY
MARKUP HEARING STATEMENT ON:

H.R. 5374, THE "SHOP SAFE ACT";
H.R. 2883, THE "STOP STALLING ACCESS TO AFFORDABLE MEDICATIONS";
H.R. 2891, THE "PRESERVE ACCESS TO AFFORDABLE GENERICS AND BIOSIMILARS ACT";
H.R. 2873, THE "AFFORDABLE PRESCRIPTIONS FOR PATIENTS THROUGH PROMOTING COMPETITION ACT OF 2021";
H.R. 2884, THE "AFFORDABLE PRESCRIPTIONS FOR PATIENTS THROUGH IMPROVEMENTS TO PATENT LITIGATION ACT";
H.R. 3617, THE "MORE ACT OF 2021";
H.R. 2116, THE "CROWN ACT OF 2021";
H.R. 187, "FOR THE RELIEF OF VICTORIA GALINDO LOPEZ.";
H.R. 680, "FOR THE RELIEF OF ARPITA KURDEKAR, GIRISH KURDEKAR, AND VANDANA KURDEKAR.";
H.R. 681, "FOR THE RELIEF OF REBECCA TRIMBLE.";
H.R. 739, "FOR THE RELIEF OF MEDIAN EL-MOUSTRAH.";
H.R. 785, "FOR THE RELIEF OF MARIA ISABEL BUESO BARRERA, ALBERTO BUESO MENDOZA, AND KARLA MARIA BARRERA DE BUESO."

SEPTEMBER 29, 2021
2141 RAYBURN

- Thank you, Chairman Nadler and Ranking Member Jordan, for convening this important markup hearing on
    - **H.R. 5374**, the "Stopping Harmful Offers on Platforms by Screening Against Fakes in E-commerce Act" or the "SHOP SAFE Act";
    - **H.R. 2883**, the "Stop Stalling Access to Affordable Medications";
    - **H.R. 2891**, the "Preserve Access to Affordable Generics and Biosimilars Act";
    - **H.R. 2873**, the "Affordable Prescriptions for Patients Through Promoting Competition Act of 2021";
    - **H.R. 2884**, the "Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act";
    - **H.R. 3617**, the "Marijuana Opportunity Reinvestment and Expungement Act of 2021" or the "MORE Act of 2021";
    - **H.R. 2116**, the "Creating a Respectful and Open World for Natural Hair Act of 2021" or the "CROWN Act of 2021";
    - **H.R. 187**, "For the relief of Victoria Galindo Lopez.";
    - **H.R. 680**, "For the relief of Arpita Kurdekar, Girish Kurdekar, and Vandana Kurdekar.";
    - **H.R. 681**, "For the relief of Rebecca Trimble.";
    - **H.R. 739**, "For the relief of Median El-Moustrah.";
    - **H.R. 785**, "For the relief of Maria Isabel Bueso Barrera, Alberto Bueso Mendoza, and Karla Maria Barrera De Bueso."

H.R. 5374, the "Stopping Harmful Offers on Platforms by Screening Against Fakes in E-commerce Act" or the "SHOP SAFE Act"

- I strongly support H.R. 5374, the "Stopping Harmful Offers on Platforms by Screening Against Fakes in E-commerce Act" or the "SHOP SAFE Act, "which will protect consumers by making platforms appropriately responsible for harmful counterfeits sold through their websites by others and encouraging them to go on the offensive in the fight against fakes.

- Specifically, the SHOP SAFE Act will:
    - Establish trademark liability for online marketplace platforms when a third-party sells a counterfeit product that poses a risk to consumer health or safety and that platform does not follow certain best practices;

- Incentivize online platforms to establish best practices such as vetting sellers to ensure their legitimacy, removing counterfeit listings, and removing sellers who repeatedly sell counterfeits; and

- Call for online marketplaces to take steps necessary to prevent the continued sale of counterfeits by the third-party seller or face contributory liability for their actions.

- According to the U.S. Census Bureau, Americans spent $791.7 billion on e-commerce in 2020, up over 30% from 2019.

- As more consumers opt to shop online, they are increasingly vulnerable to the rising number of counterfeit goods sold on e-commerce platforms.

- The COVID-19 pandemic has also exacerbated this potential harm as the amount of time consumers spend online and the types of high-risk counterfeits available on these platforms have risen.

- According to a report from Incopro, 26% of American consumers have accidentally bought at least one counterfeit product in the past year, and 52% of U.S. consumers have lost trust in a brand after buying a fake good online.

- The sale of fake items has been a problem for retailers for some time, especially during the holiday season.

- Online marketplaces like Amazon, eBay and Etsy have often been the subject of scrutiny for counterfeit goods sold on their sites.

- Amazon in particular has been the subject of recent scrutiny.
  - A major Wall Street Journal investigation recently revealed that Amazon has listed "thousands of banned, unsafe, or mislabeled products," from dangerous children's products to electronics with fake certifications.

  - The Verge reported that even Amazon's listings for its own line of goods are "getting hijacked by impostor sellers."

- CNBC found that Amazon has shipped expired foods—including baby formula—to customers, pointing to an inability to monitor something as basic as an expiration date.

- Because of the proliferation of counterfeits and Amazon's unwillingness to help it fight them, neither Birkenstock nor Nike will sell on Amazon anymore.

- The SHOP SAFE Act reduces the availability of harmful counterfeit products online by incentivizing platforms to engage in best practices for vetting sellers and goods, addressing repeat counterfeiter sellers, and ensuring consumers have access to relevant information at the time of purchase.

- As American consumers increasingly turn to the Internet to shop, counterfeiters have kept pace, and we must address this rising trend in online sales of unsafe counterfeit products.

Prescription Drug Prices Legislation

- According to the U.S. Department of Health and Human Services, Americans spend more on prescription drugs than residents of any other developed country.

- Because branded drug manufacturers have so much to lose from the entry of a generic competitor, they are highly incentivized to engage in anticompetitive conduct to block or delay generic entry of generic drugs, which harms American consumers through higher drug prices and worse healthcare outcomes.

- Several anticompetitive tactics by both branded and generic drug manufacturers contribute to delayed generic entry.

- These tactics are addressed by this package of bills, and include:

    - (1) pay-for-delay settlements, which occur when a branded drug company pays its potential generic competitor to abandon a patent challenge and delay entering the market with a lower-cost generic product.

        - **This is addressed by H.R. 2891, the "Preserve Access to Affordable Generics and Biosimilars Act"**

    - (2) citizen petition abuse, which occurs when a branded drug company abuses the U.S. Food and Drug Administration's citizen petition process to delay generic approval by raising sham scientific or legal issues that the agency must respond to before approving a generic drug.
        - **This is addressed by H.R. 2883, the "Stop Stalling Access to Affordable Medications"**

    - (3) product hopping, which occurs when a branded drug company seeks to extend its market exclusivity on a drug for which its patent is about to expire by switching doctors and patients from the old version to a new version, which may not offer any improvements in effectiveness or safety.
        - **This is addressed by H.R. 2873, the "Affordable Prescriptions for Patients Through Promoting Competition Act of 2021"**

    - (4) patent thicketing, when drug manufacturers prolong their exclusive rights to market a drug by filing numerous patent claims to extend the exclusivity of the underlying drug beyond its ordinary course of exclusivity.
        - **This is addressed by H.R. 2873, H.R. 2884, the "Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act"**

- Forcing a delay in the entry of a generic drug can be worth millions of dollars for pharmaceutical companies.

- For example, the Hepatitis C drug, Sovaldi, reached $7.9 billion in sales in the United States in 2014, which is a means that the issuing company stands to gain $658 million in sales by delaying a generic brand by a single month.

- These delays can be the difference between life and death for some consumers, as patients skip doses, take less than the prescribed

amount of medicine, or fail to refill their prescriptions due to prohibitive costs.

- According to a 2016 study by the National Center for Health Statistics, on average, 28 percent of pre-Medicare-age adults say they aren't adhering to their prescriptions as written because of the high cost of the medications.

- Texas has one of the highest rates of noncompliance, with 36% of adults aged 19-64 reporting that they do not take their medications as prescribed by their doctor.

- And since that study was released, costs have kept rising:
    - The annual price of the Lantus SoloStar insulin pen, commonly used to treat both conditions, went from $2,907 in 2012 to $4,703 in 2017 — a 62 percent increase.
    - The annual price of Benicar, a drug commonly prescribed to such patients, went from $1,643 in 2012 to $3,509 in 2017 — a 114 percent increase.

- According to an AARP study, in Texas, the average annual cost of prescription drug treatment increased 26.3% between 2015 and 2019, while the annual income for Texas residents only increased 15.7%.

- We must reign in the rampant anticompetitive behavior of pharmaceutical companies, or else watch as the citizens of this country grow sicker, weaker, and poorer each year.

- We have tried decades of allowing pharmaceutical companies to self-regulate in this area, Mr. Michael Kades, the Director of Markets and Competition Policy at the Washington Center for Equitable Growth states before this Committee last Congress: in the absence of a strong deterrent, "many companies will see antitrust liability simply as a cost of doing business."

- This package of bills is intended to reduce the anticompetitive behavior of the pharmaceutical industry, and will lead to a healthier and richer nation.

H.R. 2883, the "Stop Stalling Access to Affordable Medications"

- I strongly support H.R. 2883, the "Stop Stalling Access to Affordable Medications Act," which will prohibit the submission of sham citizen petitions to prevent or delay the approval of a generic or biosimilar drug product.

- The FDA's citizen petition procedures concerned citizens with an opportunity to solicit changes to agency regulations regarding health and safety policy.

- While this important process has given individuals the opportunity to raise a variety of necessary health and safety issues, certain branded manufacturers have manipulated the process to stifle generic competition.

- For example, some branded manufacturers have responded to applications for drug approval by generic competitors by filing citizen petitions that question the safety, efficacy, and bioequivalence standards for approving generic drugs.
- The FDA must review and respond to each citizen petition it receives, which has resulted in manufactured delays in the approval of generics.

- The FTC has stated that abuse of this system allows some drug companies to "unlawfully maintain a monopoly by delaying generic entry" into the marketplace.

- This commonsense bill addresses this issue by providing that an entity that submits a sham citizen petition to the FDA shall be liable for damages under antitrust laws.

H.R. 2891, the "Preserve Access to Affordable Generics and Biosimilars Act"

- I strongly support H.R. 2891, the "Preserve Access to Affordable Generics and Biosimilars Act," which will establish that certain pay-for-delay agreements are presumptively anticompetitive and would authorize the FTC to initiate an enforcement proceeding against parties to such an agreement involving the sale of a drug or biological product.

- Pay-for-delay agreements are financial agreements in patent litigation between brand-name and generic pharmaceutical companies that take the form of a patent litigation settlement agreement in which the branded drug firm pays its potential generic competitor to abandon a patent challenge and delay entering the market with a lower-cost generic product.

- According to an FTC study, pay-for-delay agreements are estimated to cost American consumers $3.5 billion per year—$35 billion over the decade from 2010 to 2020.

- Under our current antitrust framework, a generic competitor may seek entry prior to expiration of the patents on a brand-name drug by declaring that its product does not infringe the relevant patents or that the relevant patents are invalid.

- However, given the costs and potential uncertainty of patent litigation, brand-name and generic pharmaceutical companies often settle their patent litigation before a final court decision.

- Due to the significant loss of market share and profits that branded manufacturers experience upon entry of generic competitors, brand-name drug companies have entered into pay-for-delay agreements in which the branded manufacturer commits to pay the generic manufacturer a fee to delay the marketing of its generic version of the drug for a specified period of time.

- While the FTC has filed a number of successful lawsuits to stop these deals, which culminated in the Supreme Court 2013 landmark decision in *FTC v. Actavis* where it held that these settlements are subject to antitrust scrutiny, lawsuits challenging pay-for-delay agreements continue to take up a large amount of time and resources at taxpayer expense.

- In order to save our citizens money, free up the FTC to address other issues, and increase the availability of generics in the marketplace, this bill establishes a presumption of anticompetitive behavior if a settlement agreement provides anything of value to a generic manufacturer and the agreement includes a limitation on research,

development, manufacturing, marketing, or sales of a product for any period of time.

H.R. 2873, the "Affordable Prescriptions for Patients Through Promoting Competition Act of 2021"

- I strongly support H.R. 2873, the "Affordable Prescriptions for Patients Through Promoting Competition Act of 2021," which would make prescription drugs more affordable for patients and increase competition in the prescription drug market by strengthening the FTC's ability to bring and win cases against drug companies that engage in product hopping.

- Product hopping occurs when a branded drug company seeks to extend its market exclusivity on a drug for which its patent is about to expire by switching doctors and patients from the old version to a new version, which may not offer any improvements in effectiveness or safety.

- Product hopping threatens to undermine the generic-promoting goals of our antitrust laws through a switch to a reformulation for which a generic cannot be automatically substituted.

- This bill is necessary to help end the harmful practice of product hopping and to improve the FTC's ability to bring and win cases against companies that use product hopping to block generic or biosimilar competitors from entering the market.

- Litigation under existing law is extremely resource-intensive in terms of time and money, and even when the FTC is ultimately successful, litigation can take too long to provide timely relief to companies and consumers – sometimes taking a decade to fully resolve, as was the case in the *FTC v. Actavis* case.

- This legislation is a necessary addition under our antitrust laws, in order to curb the blight of product hopping and get needed medicine to our citizens.

H.R. 2884, the "Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act"

- I strongly support H.R. 2884, the "Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act," which will amend the process for resolving patent infringement claims for biological products by limiting the number of certain patents that a biological product manufacturer can assert in an infringement action.

- Patent thicketing occurs when a brand-name drug manufacturer prolongs its exclusive rights to market a drug by filing numerous patent claims to extend the exclusivity of the underlying drug.

- The process through which patent thicketing occurs has been described by Forbes as the biggest driver of rising drug costs.

- In response to companies engaging in patent litigation that must address dozens of patents, H.R. 2884 amends our antitrust laws to limit parties to asserting a maximum of 20 patents in litigation.

- The limit to 20 patents will force companies to identify and focus on their best patents and arguments, which will streamline the litigation process.

- Additionally, this bill will limit the categories of patents that can be asserted to ones that allow brand-name manufacturers to exploit the exclusivity of the patent system, such as asserting later-filed method of manufacturing claims that the reference product sponsor does not itself use or that are not particularly relevant to the biologic, or later-filed claims to the subject biologic that do not incorporate significant changes.

H.R. 2116, the "Creating a Respectful and Open World for Natural Hair Act of 2021" or the "CROWN Act of 2021"

- I strongly support H.R. 2116, the "Creating a Respectful and Open World for Natural Hair Act of 2021" or the "CROWN Act of 2021," which explicitly prohibits discrimination on the basis of hair texture or hairstyles commonly associated with a particular race or national origin in areas of the law where discrimination on the basis of race or national origin is already prohibited.

- This issue is intimately important to me, because just last year, in Houston Texas, Barbers Hill High School student DeAndre Arnold was suspended for his natural locs.

- Arnold, who was a senior at the school, had locs for years and it was part of his identity and culture.

- Arnold's family is from Trinidad, and the men in his family often grow their locs to below their waist.

- However, his school routinely inspected his hair for potentially violating a hair length school policy, ultimately suspending him for violations.

- Arnold wasn't allowed to return to school or attend his graduation ceremony unless he cut his hair.

- I am thankful that Arnold was able to take this decision to court, where it was determined that he could return to school without fear of reprisal, but our society should not force our students to undergo litigation just to obtain an education.

- In another case from my home state, Kerion Washington, 17, was denied a job at Six Flags because his natural hair violated their "grooming" policy.

- Kerion had been growing out his hair for the last three years and it now sits shoulder-length on his head.

- And it is not just Texas; discrimination based on natural hair is seen throughout our country:
    - In 2017, a Banana Republic employee was told by a manager that she was violating the company's dress code because her box braids were too "urban" and "unkempt."
    - In 2018 2018, Andrew Johnson, a New Jersey high school student, was forced by a white referee to either have his dreadlocks cut or forfeit a wrestling match, leading him to have his hair cut in public by an athletic trainer immediately before the match.

- Also in 2018, an 11-year-old Black girl in Louisiana was asked to leave class at a private Roman Catholic school near New Orleans because her braided hair extensions violated the school's policies.

- People of color, especially Black people, have long felt pressure to alter their natural hair to conform to what society has deemed "acceptable."

- The CROWN Act would end the demeaning practice of forcing conformity onto people of color, and make it illegal for employers and educators to deny an individual employment or educational opportunities due to the length, texture or style of their hair.

- To be frank, it is a tragedy that we need federal legislation to end these discriminatory practices and give people of color the dignity that is their inherent right.

- I urge my colleagues to support this bill so that men and women of color no longer feel that they cannot or should not enter certain spaces because they wish to wear the hair that they are born with.

Private Bills

- I strongly support these private bills, which will allow the named individuals to be eligible for an immigrant visa or status as a lawful permanent resident.

- Each of these individuals present a compelling case for relief, and the denial thereof would result in extreme hardship and injustice.

H.R. 187, "For the relief of Victoria Galindo Lopez."

- Victoria Galindo Lopez entered the United States in 1988 and has left only twice since then.

- Her daughter has been the victim of sexual abuse perpetuated by her father, during the times when Victoria was working nights to support her family.

- At only 11 years of age, her daughter made her first suicide attempt.

- The abuse inflicted upon her daughter did not come to light under her 16th suicide attempt at the age of 17.

- Immediately, Victoria acted to protect her daughter and other children, filing criminal charges against her husband and filing for divorce.

- Her husband has since been deported, and if Victoria is not granted protection by this committee, then her family will lose the primary caretaker and breadwinner.

H.R. 680, "For the relief of Arpita Kurdekar, Girish Kurdekar, and Vandana Kurdekar."

- Arpita Kurdekar arrived in the United States in 2014 on a student visa, in pursuit of a master's degree in civil ingineering.

- In 2016, she was struck by a tree limb and instantly paralyzed.

- Arpita has continued to maintain her student visa and is currently pursuing a Ph.D. in structural engineering at the University of Connecticut.

- Her parents arrived shortly thereafter to act as caregivers, and remain in lawful status.

- However, all three of the family members lack options to remain in the United States permanently.

- If the family returns to their home country of India, where access to the specialized treatment and accommodations that are necessary to sustain Arpita's quality of life is both limited and costly, they will undoubtedly experience excessive hardship.

H.R. 681, "For the relief of Rebecca Trimble."

- Rebecca Trimble was born in Tecate, Mexico in late August 1989. Her biological mother was 13 years old when Rebecca was born.

- Rebecca has had no contact with her biological mother since her birth, and she is currently unaware of her whereabouts.

- The only parents Rebecca has ever known are George Ernest Wilson and Pamela Taylor (Wilson), both U.S. citizens.

- Rebecca's adoptive parents were told by hospital staff that they only needed a birth certificate listing them as Rebecca's parents to legitimize the adoption.

- They received what they believed to be a valid Mexican birth certificate, and three days after Rebecca's birth, her adoptive parents brought her to the United States.

- After settling in at their home in Salem, Oregon, Rebecca's parents presented her birth certificate to the Social Security Administration and received a social security number in her name.

- Unaware that her birth was not formally registered in Mexico, or that she had not been lawfully adopted, Rebecca grew up believing she was a U.S. citizen.

- In 2012, upon applying for a REAL ID driver's license, she discovered that she was not a U.S. citizen because her adoption was not legal. She later learned that because she had voted in a federal election—without any knowledge that she was not, in fact, a citizen—she was denied a green card and was informed that she was subject to deportation.

H.R. 739, "For the relief of Median El-Moustrah."

- Median El-Moustrah was born in Lebanon and has lived in the United States for nearly 30 years.

- In 1993, he was granted conditional permanent residence based on his marriage to a U.S. citizen.
- Shortly after obtaining such status, the couple began having marital problems, separated, and divorced.

- Median's petition to remove the conditions on his permanent residence was denied and he was placed in removal proceedings.

- He has worked cooperated with ICE ever since.

- However, Median suffers from chronic liver disease due to Hepatitis B, as well numerous other conditions that require regular medical attention, medication, and monitoring, including esophageal tears, hypertension, hyperglycemia, and Type 2 diabetes.

- Medical experts confirm that Median should not fly due to his conditions.

- The Chief of Gastroenterology at the Lebanese American University confirms that a liver transplant is not available in Lebanon, and that Median's life would be in jeopardy if he is removed to Lebanon.

H.R. 785, "For the relief of Maria Isabel Bueso Barrera, Alberto Bueso Mendoza, and Karla Maria Barrera De Bueso."

- In 2004, the Bueso family arrived in the United States from Guatemala on B-2 visitor visas for Maria Isabel to participate in a clinical trial. Maria Isabel has a rare genetic disorder, mucopolysaccharidosis type VI (MPS VI), a life-threatening condition that causes dwarfism, blindness, hearing impairment, spinal cord compression, and bone abnormalities.

- the Buesos have remained in the United States so that Maria Isabel can continue receiving a treatment for the disorder, participating in a clinical trial that was ultimately approved by the Federal Drug Administration, and it.

- The Pan-American Health Organization and Maria Isabel's doctors confirm that the treatment is not available in Guatemala and if Maria Isabel is required to return there, she will likely die within weeks.