

The damage from Ike, and the even more catastrophic Hurricane Harvey, could have been reduced significantly by the proposed coastal barrier that we call the Ike Dike. After years and years of pushing for this vital barrier system, I am proud that it is included in WRDA 2022.

While this bill does not reflect all the priorities we might prefer, I urge my colleagues to vote in favor of this bill. I, too, add my order of thanks to both sides. This has been a great task, a great staff we have.

Mr. DEFAZIO. Mr. Speaker, I reserve the balance of my time.

Mr. GRAVES of Missouri. Mr. Speaker, I yield 1 minute to the gentleman from California (Mr. LAMALFA).

Mr. LAMALFA. Mr. Speaker, I thank my colleague for yielding.

Tonight, I join my colleagues in support of this year's Water Resources Development Act. While it may not be readily apparent, the threat of storm damage and floods remains front and center, despite the prolonged drought across the Western United States.

In the wake of wildfires, mudslides will bring vegetation down from mountainsides into our public waterways. With fewer but more intense storms seen this year, the risk of flash floods has increased.

Now, as with many bipartisan bills, there are policies and provisions that I believe are missing from this measure. That work is not done. I will continue to push for more control over project construction to be given to local water agencies; more up-front inclusion of Tribes so we can avoid ruining their cultural and burial sites, literally crushing skulls while working on levees—this is about basic respect; and for the Army Corps and EPA to work with our constituents, rather than against them, such as penalties for when farmers plow their fields or change crops.

Indeed, we need to keep this conversation going, but I appreciate the legislation and the direction we are going.

Mr. DEFAZIO. Mr. Speaker, I reserve the balance of my time.

Mr. GRAVES of Missouri. Mr. Speaker, I yield myself the balance of my time.

Mr. Speaker, H.R. 7776, or WRDA 2022, is a very good bipartisan piece of legislation that will improve flood control infrastructure. It is going to improve ports, harbors, and inland waterways all across the country.

This bill provides the support and the investment in our country's water infrastructure needed to keep our supply chain moving and boost the competitiveness of the American economy.

When it comes right down to it, this bill is a projects bill that was pulled together based off requests from Members from all across the country in the House on both sides of the aisle, and there isn't a single line in this bill that cannot be attributed to an individual Member request.

I again thank my colleagues and the members of the committee for coming

together to develop this bipartisan legislation. Again, I thank the chairman for his work.

Mr. Speaker, I urge support of this important piece of legislation, and I yield back the balance of my time.

Mr. DEFAZIO. Mr. Speaker, I yield myself the balance of my time.

Most of what we do here would not be possible without the hard work of staff, so I would like to take a moment specifically to thank the staff of the Subcommittee on Water Resources and Environment that took the lead in developing WRDA 2022 and ensuring that Members' priorities and national priorities were included: Ryan Seiger, the staff director of the subcommittee, who worked to enact more of WRDA than any other staffer on Capitol Hill; Alexa Williams; Logan Ferree; Michael Bauman. On the minority side: Ryan Hambleton, the minority staff director; Leslie Parker; Tim Petty; and Melissa Beaumont. Without them and their work, we would not be here today.

Paul Sass has already been thanked a number of times, but I congratulate him on his 20 years on the Hill and wish him well in his next endeavor.

Mr. Speaker, I urge support, and I yield back the balance of my time.

Ms. JOHNSON of Texas. Madam Speaker, nearly 80 percent of our traded goods rely on American ports, harbors, and inland waterways to reach consumers.

Therefore, it is incumbent upon us to support our waterways and ecosystems, improve our defenses against floods and extreme weather, and create good-paying jobs along the way—and that's what the Water Resources Development Act of 2022 (WRDA) will do.

Specifically, this bill authorizes the construction of 16 new projects and 72 feasibility studies approved by the Corps of Engineers and expedites the completion of 15 ongoing investigations. The bill also includes a water resource initiative that is very important to my constituents and the many residents of North Texas.

The White Rock Lake is a 1,015-acre city lake located outside of Dallas. The lake is one of the most heavily-used parks in the Dallas Parks system. It is home to the Dallas Arboretum, the White Rock Lake Museum, the Bath House Cultural Center, a large boat ramp and fishing pier, over nine miles of hiking and biking trails, a dog park, a picnic area, and pavilions. White Rock Lake has experienced an accumulation of sediment since it was last dredged in 1998, reducing the overall capacity of the lake, with reductions in both its water quality and recreational use. And with the pandemic increasing the already heavy usage rate of the lake, the need to dredge it has never been more urgent.

The goals of the White Rock Lake dredging project included in the WRDA are to remove sediment from the shoreline to improve maintenance, improve water quality to minimize negative impacts to aquatic habitat and other environmentally sensitive areas, and restore the depth of the lake to enhance watersport recreation.

The bill also authorizes \$19.2 billion in funding to restore and protect Texas' coastline. The project is one of the largest in the history

of the Corps of Engineers and includes improvements that reduce risks to public health and the economy, restore critical ecosystems, advance coastal resiliency, and help prepare the state for future damaging weather events.

I want to commend Chairman DEFAZIO and Subcommittee Chairwoman NAPOLITANO for their perseverance in developing this bipartisan bill and getting it to the House floor for a vote.

I strongly support the passage of the Water Resources Development Act of 2022 and encourage my colleagues to pass a bill that is essential to America's economic competitiveness and helps improve the quality of our waterways for all our constituents.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Missouri (Mr. GRAVES) that the House suspend the rules and pass the bill, H.R. 7776, as amended.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the yeas have it.

Mr. ROY. Mr. Speaker, on that I demand the yeas and nays.

The SPEAKER pro tempore. Pursuant to section 3(s) of House Resolution 8, the yeas and nays are ordered.

Pursuant to clause 8 of rule XX, further proceedings on this motion are postponed.

#### AUTHORIZING USE OF CAPITOL GROUNDS FOR GREATER WASHINGTON SOAP BOX DERBY

Mr. DEFAZIO. Mr. Speaker, I move to suspend the rules and agree to the concurrent resolution (H. Con. Res. 88) authorizing the use of the Capitol Grounds for the Greater Washington Soap Box Derby.

The Clerk read the title of the concurrent resolution.

The text of the concurrent resolution is as follows:

#### H. CON. RES. 88

*Resolved by the House of Representatives (the Senate concurring),*

#### SECTION 1. USE OF CAPITOL GROUNDS FOR SOAP BOX DERBY RACES.

(a) IN GENERAL.—The Greater Washington Soap Box Derby Association (in this resolution referred to as the “sponsor”) shall be permitted to sponsor a public event, soap box derby races (in this resolution referred to as the “event”), on the Capitol Grounds.

(b) DATE OF EVENT.—The event shall be held on June 18, 2022, or on such other date as the Speaker of the House of Representatives and the Committee on Rules and Administration of the Senate jointly designate.

#### SEC. 2. TERMS AND CONDITIONS.

(a) IN GENERAL.—Under conditions to be prescribed by the Architect of the Capitol and the Capitol Police Board, the event shall be—

(1) free of admission charge and open to the public; and

(2) arranged not to interfere with the needs of Congress.

(b) EXPENSES AND LIABILITIES.—The sponsor shall assume full responsibility for all expenses and liabilities incident to all activities associated with the event.

#### SEC. 3. EVENT PREPARATIONS.

Subject to the approval of the Architect of the Capitol, the sponsor is authorized to

erect upon the Capitol Grounds such stage, sound amplification devices, and other related structures and equipment as may be required for the event.

#### SEC. 4. ADDITIONAL ARRANGEMENTS.

The Architect of the Capitol and the Capitol Police Board are authorized to make such additional arrangements as may be required to carry out the event.

#### SEC. 5. ENFORCEMENT OF RESTRICTIONS.

The Capitol Police Board shall provide for enforcement of the restrictions contained in section 5104(c) of title 40, United States Code, concerning sales, advertisements, displays, and solicitations on the Capitol Grounds, as well as other restrictions applicable to the Capitol Grounds, with respect to the event.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Oregon (Mr. DEFAZIO) and the gentleman from Missouri (Mr. GRAVES) each will control 20 minutes.

The Chair recognizes the gentleman from Oregon (Mr. DEFAZIO).

#### GENERAL LEAVE

Mr. DEFAZIO. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material on H. Con. Res. 88.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Oregon?

There was no objection.

Mr. DEFAZIO. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, today, we are again considering legislation, H. Con. Res. 88, to authorize the use of the Capitol Grounds for the Greater Washington Soap Box Derby. I thank Majority Leader HOYER for introducing this resolution on behalf of the Washington regional delegation.

The Greater Washington Soap Box Derby is an annual competitive event that encourages boys and girls, ages 9 through 16, to construct and race their own soap box vehicles.

On Capitol Hill, the event has become a great tradition in the Washington, D.C., metropolitan area over the last quarter of a century. It provides a terrific opportunity for children to appreciate the workmanship necessary to build the vehicles and enjoy the thrill of competition.

The Greater Washington Soap Box Derby organizers will work with the Architect of the Capitol and the Capitol Police to ensure appropriate rules and regulations are in place and the event remains free to the public and safe for all those involved.

Mr. Speaker, I support this legislation and urge my colleagues to join me. I reserve the balance of my time.

Mr. GRAVES of Missouri. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, this resolution, as has been pointed out, authorizes the use of the Capitol Grounds for the annual Greater Washington Soap Box Derby on June 18, 2022.

This is a time-honored tradition. With the exception of World War II, it has run every year since 1934 and pro-

vides children in the greater Washington area an opportunity to build knowledge and character through fair and honest competition.

This is one of the many regional competitions across the country to qualify children to compete in the All-American Soap Box Derby. This is a program I participated in some 40-odd years ago. It is a good program, and I fully endorse it.

Mr. Speaker, I urge support of the legislation, and I reserve the balance of my time.

Mr. DEFAZIO. Mr. Speaker, I yield 1 minute to the gentleman from Maryland (Mr. HOYER), the majority leader and sponsor of this legislation.

Mr. HOYER. Mr. Speaker, I thank the chair and the ranking member for bringing this bill to the floor.

I am honored to bring this resolution to the floor every year. It authorizes an event, as you have been told, that I am proud to support every year. This will be the first time it has been held since 2019 because of the pandemic.

That event is the Greater Washington Soap Box Derby, one of my favorite events of the year. The Soap Box Derby brings families together from across the greater Washington metropolitan area, encouraging kids and their adult family members or community members to compete in a fun and educational race.

This is my 29th year sponsoring the Soap Box Derby resolution. I don't know whether that is a record on the Soap Box Derby, but in any event, this is the Greater Washington Soap Box Derby's 79th year.

The race will be held on June 18, and you will see soap box racers from ages 8 to 17 compete in three divisions: stock, super stock, and masters. The winner from each division, Mr. Speaker, will have a chance to compete at the national All-American Soap Box Derby, which is held each year in Akron, Ohio.

Much of the fun, however, takes place even before the race begins. Participants spend weeks, perhaps months, building and testing their racers at home, a wonderful bonding experience for kids, parents, grandparents, and other family members and those engaged in mentorship in their communities.

Soap box derbies have been called the greatest amateur racing event in the world. They have become a staple of the American experience and an important piece of Americana. They teach sportsmanship, engineering, manufacturing, and leadership.

Oftentimes, racers are sponsored by local civic groups, service organizations, and police or fire departments, with members coming out to cheer on their hometown participants.

Mr. Speaker, I am proud to sponsor this resolution today that will authorize the use of the Grounds of the U.S. Capitol for this year's Soap Box Derby.

I thank my cosponsors, members of the region's congressional delegation:

Representatives DON BEYER, DAVID TRONE, GERRY CONNOLLY, ANTHONY BROWN, JENNIFER WEXTON, and JAMIE RASKIN.

I am also proud that several Greater Washington Soap Box Derby champions have come from Maryland's Fifth District, my district, in recent years, including the winners from 2007, 2008, 2009, 2012, 2013, 2014, and 2018. So my guys do pretty well in this race, and some of them are gals, by the way.

Our racers even won a national championship in 2007 and 2008. I am excited to see how the Fifth District racers do this year, and I am looking forward to seeing their colorful and creative soap box designs.

I thank the organizers of the Greater Washington Soap Box Derby, as well as Chairman DEFAZIO and the Committee on Transportation and Infrastructure, for their support. I hope every Member, as they have in the past, will join in supporting this resolution. I invite them to join me in cheering on the Greater Washington Soap Box Derby on June 18.

Mr. GRAVES of Missouri. Mr. Speaker, this resolution authorizes the use of the Capitol Grounds for a longstanding tradition for the children of the greater Washington, D.C., area.

Once in a while, we do some fun stuff here on the floor, and this is one of those things. I urge support of the legislation, and I yield back the balance of my time.

Mr. DEFAZIO. Mr. Speaker, I yield myself the balance of my time.

Again, I thank the majority leader for bringing this legislation. I misspoke earlier. I thought it had only been a quarter of a century. It has been 29 years.

That is extraordinary, and this is a wonderful event for youth. It does bring a little something to Capitol Hill other than the day-to-day business, which can sometimes be suffocating.

I urge my colleagues to support this legislation unanimously, and I yield back the balance of my time.

Ms. JACKSON LEE. Mr. Speaker, I rise in strong support of H. Con. Res. 88, "authorizing the use of Capitol grounds for the Greater Washington Soap Box Derby."

This bill calls for support to hold the traditional Soap Box Derby association's free, public event on the Capitol grounds.

The Soap Box Derby international nonprofit organization, whose mission is to "build knowledge and character, and to create meaningful experiences through collaboration and fair and honest competition," prides itself for allowing the race to take place on the most powerful hill in the world, Capitol Hill.

For 88 years, this event has been an opportunity in which the community comes out to support our youth. Annually, our youth get the opportunity to participate in the international nonprofit's biggest event.

Participants who compete range from ages 9–16 years old and come from the Greater Washington, D.C. Metropolitan Area. They could potentially have the honor of representing D.C. in the National Soap Box Derby competition.

This completely sponsored soap box derby event will be free of charge for the public and has a flexible date that will ensure it does not interfere with the needs of Congress.

In Texas, anytime we can celebrate our youth and their accomplishments, while also bringing the community together, it is an opportunity fellowship and relationships through friendly competition.

Mr. Speaker, I urge my colleagues to join me in supporting H. Con. Res. 88, to host the traditional, Greater Washington Soap Box Derby on our nation's Capitol grounds, an event that will bring the community together for a wonderful celebration.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Oregon (Mr. DEFAZIO) that the House suspend the rules and agree to the concurrent resolution, H. Con. Res 88.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the concurrent resolution was agreed to.

A motion to reconsider was laid on the table.

□ 1815

## FOOD AND DRUG AMENDMENTS OF 2022

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 7667) to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 7667

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

### SECTION 1. SHORT TITLE.

This Act may be cited as the “Food and Drug Amendments of 2022”.

### SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

- Sec. 1. Short title.
- Sec. 2. Table of contents.

#### TITLE I—FEES RELATING TO DRUGS

- Sec. 101. Short title; finding.
- Sec. 102. Definitions.
- Sec. 103. Authority to assess and use drug fees.
- Sec. 104. Reauthorization; reporting requirements.
- Sec. 105. Sunset dates.
- Sec. 106. Effective date.
- Sec. 107. Savings clause.

#### TITLE II—FEES RELATING TO DEVICES

- Sec. 201. Short title; finding.
- Sec. 202. Definitions.
- Sec. 203. Authority to assess and use device fees.
- Sec. 204. Reauthorization; reporting requirements.
- Sec. 205. Conformity assessment pilot program.
- Sec. 206. Reauthorization of third-party review program.
- Sec. 207. Sunset dates.
- Sec. 208. Effective date.
- Sec. 209. Savings clause.

#### TITLE III—FEES RELATING TO GENERIC DRUGS

- Sec. 301. Short title; finding.
- Sec. 302. Authority to assess and use human generic drug fees.
- Sec. 303. Reauthorization; reporting requirements.
- Sec. 304. Sunset dates.
- Sec. 305. Effective date.
- Sec. 306. Savings clause.

#### TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

- Sec. 401. Short title; finding.
- Sec. 402. Definitions.
- Sec. 403. Authority to assess and use biosimilar fees.
- Sec. 404. Reauthorization; reporting requirements.
- Sec. 405. Sunset dates.
- Sec. 406. Effective date.
- Sec. 407. Savings clause.

#### TITLE V—IMPROVING DIVERSITY IN CLINICAL STUDIES

- Sec. 501. Diversity action plans for clinical studies.
- Sec. 502. Evaluation of the need for FDA authority to mandate postapproval studies or postmarket surveillance due to insufficient demographic subgroup data.
- Sec. 503. Public workshops to enhance clinical study diversity.
- Sec. 504. Annual summary report on progress to increase diversity in clinical studies.
- Sec. 505. Public meeting on clinical study flexibilities initiated in response to COVID-19 pandemic.
- Sec. 506. Decentralized clinical studies.

#### TITLE VI—GENERIC DRUG COMPETITION

- Sec. 601. Increasing transparency in generic drug applications.
- Sec. 602. Enhancing access to affordable medicines.

#### TITLE VII—RESEARCH, DEVELOPMENT, AND SUPPLY CHAIN IMPROVEMENTS

##### Subtitle A—In General

- Sec. 701. Animal testing alternatives.
- Sec. 702. Emerging technology program.
- Sec. 703. Improving the treatment of rare diseases and conditions.
- Sec. 704. Antifungal research and development.
- Sec. 705. Advancing qualified infectious disease product innovation.
- Sec. 706. National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing.
- Sec. 707. Advanced manufacturing technologies designation pilot program.
- Sec. 708. Public workshop on cell therapies.
- Sec. 709. Reauthorization of best pharmaceuticals for children.
- Sec. 710. Reauthorization for humanitarian device exemption and demonstration grants for improving pediatric availability.
- Sec. 711. Reauthorization of provision related to exclusivity of certain drugs containing single enantiomers.
- Sec. 712. Reauthorization of the critical path public-private partnership program.
- Sec. 713. Reauthorization of orphan drug grants.
- Sec. 714. Research into pediatric uses of drugs; additional authorities of Food and Drug Administration regarding molecularly targeted cancer drugs.

##### Subtitle B—Inspections

- Sec. 721. Factory inspection.
- Sec. 722. Uses of certain evidence.

- Sec. 723. Improving FDA inspections.
- Sec. 724. GAO report on inspections of foreign establishments manufacturing drugs.
- Sec. 725. Unannounced foreign facility inspections pilot program.
- Sec. 726. Reauthorization of inspection program.
- Sec. 727. Enhancing intra-agency coordination and public health assessment with regard to compliance activities.
- Sec. 728. Reporting of mutual recognition agreements for inspections and review activities.
- Sec. 729. Enhancing transparency of drug facility inspection timelines.

#### TITLE VIII—TRANSPARENCY, PROGRAM INTEGRITY, AND REGULATORY IMPROVEMENTS

- Sec. 801. Prompt reports of marketing status by holders of approved applications for biological products.
- Sec. 802. Encouraging blood donation.
- Sec. 803. Regulation of certain products as drugs.
- Sec. 804. Postapproval studies and program integrity for accelerated approval drugs.
- Sec. 805. Facilitating the use of real world evidence.
- Sec. 806. Dual Submission for Certain Devices.
- Sec. 807. Medical Devices Advisory Committee meetings.
- Sec. 808. Ensuring cybersecurity of medical devices.
- Sec. 809. Public docket on proposed changes to third-party vendors.
- Sec. 810. Facilitating exchange of product information prior to approval.
- Sec. 811. Bans of devices for one or more intended uses.
- Sec. 812. Clarifying application of exclusive approval, certification, or licensure for drugs designated for rare diseases or conditions.
- Sec. 813. GAO report on third-party review.
- Sec. 814. Reporting on pending generic drug applications and priority review applications.
- Sec. 815. FDA Workforce Improvements.

#### TITLE IX—MISCELLANEOUS

- Sec. 901. Determination of budgetary effects.
- Sec. 902. Medicaid Improvement Fund.

#### TITLE I—FEES RELATING TO DRUGS

##### SEC. 101. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the “Prescription Drug User Fee Amendments of 2022”.

(b) FINDING.—The Congress finds that the fees authorized by the amendments made by this title will be dedicated toward expediting the drug development process and the process for the review of human drug applications, including postmarket drug safety activities, as set forth in the goals identified for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

##### SEC. 102. DEFINITIONS.

(a) HUMAN DRUG APPLICATION.—Section 735(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1)) is amended by striking “an allergenic extract product, or” and inserting “does not include an application with respect to an allergenic extract