

authority to establish the clinical superiority pathway, Congress enacted the FDA Reauthorization Act of 2017 (P.L. 115–52), which clarified FDA has such authority, and expressly enumerated the three ways a sponsor could demonstrate clinical superiority for the “same” drug for the same use. Specifically, the subsequent product must demonstrate a “significant therapeutic advantage” relative to the previously approved drug “in terms of greater efficacy, greater safety, or by providing a major contribution to patient care.”

Congress intended for this standard to be rigorous, particularly for “major contribution to patient care” (which is only considered when neither greater safety nor greater effectiveness has been shown), to ensure it is reserved for truly transformative advancements in treating the underlying rare disorder Congress did not specifically define “major contribution to patient care,” intentionally allowing FDA to exercise its judgment with the understanding that this threshold would remain high. In fact, FDA’s orphan drug regulation itself describes “major contribution to patient care” as a “narrow category” to be used in “unusual cases.” In the unique circumstance when FDA applies “major contribution to patient care” to allow a follow-on product to break the exclusivity of a previously approved orphan drug, the subsequent drug must fundamentally elevate the standard of care for the rare disease or condition by providing a significant measurable clinical benefit relative to the previously approved drug. Without maintaining a rigorous threshold, the incentive underpinning the Orphan Drug Act risks being diluted and diminished, threatening the progress made in rare disease drug development and undermining future innovation.

As a co-chair of the Rare Disease Congressional Caucus, I am committed to ensuring that FDA’s authority to evaluate whether a follow-on treatment provides a “major contribution to patient care” is exercised judiciously, in a manner that does not diminish the value of orphan exclusive approval. This incentive is fundamental to driving new investments into rare disease research and development, leading to new treatment options and ensuring that patients with significant unmet medical needs continue to see meaningful innovation. With 95 percent of the more than 10,000 rare disorders lacking an FDA-approved therapy, FDA must be especially diligent in protecting the exclusivity period for innovators that took the initial substantial risk to bring a first-ever FDA-approved therapy to a rare disease community.

The intent of Congress is clear— orphan drug exclusivity must be preserved as a powerful incentive for rare disease drug development, and the criteria for demonstrating clinical superiority must not diminish that value. The Orphan Drug Act has provided tremendous benefits for patients with rare diseases, and its continued success depends on the preservation of strong exclusivity incentives for innovator therapies. Congress expects FDA to apply the clinical superiority framework as originally intended, maintaining the high standard required to protect the value of orphan exclusivity, especially for those orphan drugs that were the first FDA-approved therapy for a rare disease or condition. The success of the Orphan Drug Act and the continued development of rare disease therapies depends on the integrity of orphan exclusive approval. I

urge FDA to remain steadfast in maintaining an appropriately high bar in its application of “major contribution to patient care” of the clinical superiority threshold. As we look to Rare Disease Day 2025, recognized on February 28th, the mission of the Orphan Drug Act remains as important as ever. I urge my fellow members to work with me and with FDA to keep these incentives strong in order to get new treatments and cures to rare disease patients in need.

HONORING MR. CURTIS PORTER’S CAREER OF PUBLIC SERVICE

HON. EUGENE SIMON VINDMAN

OF VIRGINIA

IN THE HOUSE OF REPRESENTATIVES

Tuesday, February 18, 2025

Mr. VINDMAN. Mr. Speaker, I rise today to honor Mr. Curtis O. Porter, for his leadership and countless contributions serving our children, youth, and families across the Nation.

Mr. Porter began his professional career as the Special Program Coordinator for the 31st Judicial District Court Service Unit in Manassas, Virginia. His innovative work diverting over 100 runaway and homeless youth from secure detention to volunteer host home families earned him the Meritorious Award in Juvenile Justice Probation in 1984.

Mr. Porter’s dedication to at-risk youth led him to serve as the Senior Assistant Director of Volunteer Emergency Families for Children (VEFC), where he seemed crucial funding and expanded the program’s reach. His exemplary work caught the attention of Governor L. Douglas Wilder, who appointed him to several state boards, including the State Criminal Justice Services Board and the Virginia Juvenile Justice and Delinquency Advisory Committee.

In 1995, Mr. Porter transitioned to federal service, joining the U.S. Department of Health and Human Services. Over the next 29 years, he served in various high-level positions, including Acting Associate Commissioner and Acting Deputy Associate Commissioner of the Family and Youth Services Bureau. His leadership was instrumental in overseeing critical national programs addressing runaway and homeless youth, adolescent pregnancy prevention, domestic violence prevention, and mentoring children of prisoners.

Mr. Porter’s commitment to public service extended beyond our borders when he represented the Department of Health and Human Services on a trip to New Orleans with First Lady Laura Bush, supporting the city’s recovery efforts after Hurricane Katrina. Throughout his career, Mr. Porter has been recognized with numerous awards, including the Department of Health and Human Services Secretary’s Award for the Mentoring Children of Prisoners Program and the Administration for Children and Families Assistant Secretary’s Award for Exemplary Leadership.

As Curtis O. Porter retired from federal service on December 31, 2024, I want to commend him for his exceptional service and enduring impact on the Commonwealth of Virginia and our Nation. His unwavering dedication to improving the lives of children, youth, and families serves as an inspiration to us all.

Mr. Speaker, I ask my colleagues to join me in honoring Curtis O. Porter for his remarkable 43-year career in public service and to wish him well in his well-deserved retirement.

RECOGNIZING THE LIFE OF ROSA COOK

HON. MIKE ROGERS

OF ALABAMA

IN THE HOUSE OF REPRESENTATIVES

Tuesday, February 18, 2025

Mr. ROGERS of Alabama. Mr. Speaker, I ask for the House’s attention today to recognize the life of the oldest living Alabama citizen, Rosa Cook. Rosa passed away on February 8, 2025 at the age of 112 years old. Rosa was born in Coosa County, Alabama on May 24, 1912, to Lewis McKinney and Georgeanna Ingram. She lost her mother at eight years old and was raised by her older brothers and sisters. She was married for 24 years to the late K.C. Cook, who died at a young age of a massive heart attack in 1965. She and K.C. were blessed with three children. Rosa moved to Sylacauga, Alabama, to live with her daughter Ruth.

Rosa was a member of the Rising Star Baptist Church where she sang in the choir until she became disabled. She also was active in the Faithful Worker’s Missionary Society Club, the Rising Star Senior Choir and Recreational Golden Keys.

Rosa’s life was celebrated on February 13, 2025.

Mr. Speaker, please join me in recognizing the life of Rosa Cook.

INTRODUCTION OF THE ACTI- VATING NATIONAL PARKS IN CITIES ACT

HON. ELEANOR HOLMES NORTON

OF THE DISTRICT OF COLUMBIA

IN THE HOUSE OF REPRESENTATIVES

Tuesday, February 18, 2025

Ms. NORTON. Mr. Speaker, today, I introduce the Activating National Parks in Cities Act, which would expand the mission of the National Park Service (NPS) to include active use of National Park System units in urban areas. This bill would address the unique needs of NPS neighborhood parks.

NPS’s primary mission is to preserve spaces for the enjoyment of future generations. This noble mission was crafted for the purpose of wilderness preservation, allowing nature to remain untouched by time. However, this mission is ill-suited for the unique needs of NPS neighborhood parks. In addition to grand national parks, NPS also owns neighborhood parks in urban areas. For example, more than 20 percent of land in the District of Columbia consists of parkland, and NPS owns nearly 90 percent of it, over two-thirds of which consists of neighborhood parks, smaller than one acre. These parks could benefit from activation.

A report issued in 2023 by George Washington University’s Sumner M. Redstone Global Center for Prevention and Wellness examined strategies to create a more equitable and activated park system in D.C. As the report notes, NPS parks in D.C. “do not meet the needs of people who both live near and experience the park system as a part of their daily lives.”

This bill would expand the mission of NPS to include the promotion of active use of its parks in urban areas. Active use prioritizes