

of Iowa. As a physician, a legislator, and a member of the Rare Disease Congressional Caucus, I have seen firsthand the life-changing impact that medical innovation can have on patients battling rare diseases. Iowa's first congressional district is home to clinical trials for several rare diseases that lack a Food and Drug Administration (FDA)-approved therapy, including Becker muscular dystrophy, Gaucher disease type 3, and limb girdle muscular dystrophy. For these patients, and the millions of Americans suffering from rare diseases, scientific advancements represent more than just medical progress—they offer hope where none previously existed.

That hope would not be possible without the Orphan Drug Act, which has served as the foundation for rare disease drug development for over four decades. The Orphan Drug Act's most critical incentive is orphan drug exclusivity, which is a seven-year period of market exclusivity. This incentive ensures that innovators willing to take the extraordinary risk of developing a first-in-class treatment for a complex condition affecting a small patient population are appropriately rewarded.

For many rare diseases, the first FDA-approved treatment is a lifeline. These therapies often require years of research, billions in investment, and considerable perseverance to bring these medicines to patients. Without a strong and reliable exclusivity framework, these treatments simply would not exist. Congress intended orphan exclusivity to serve as "a marketplace-oriented solution that provide incentives for private enterprise to develop orphan drugs." FDA established regulations that aimed to protect this critical economic incentive while also encouraging continued innovation for a rare disease by allowing a follow-on product that is the same drug for the same use to break orphan exclusivity if it demonstrates greater efficacy, greater safety, or a "major contribution to patient care" relative to the original orphan drug. Congress codified these regulations in 2017.

Congress has long recognized that the "major contribution care" prong of the "clinical superiority" standard is meant to be a high bar. We did not intend for minor modifications such as changes in dosing frequency or formulation to erode the exclusivity protections of the first innovator drug unless such modifications result in a significant clinical benefit in treating the underlying conditions. If we allow marginal improvements rather than true clinical advancements to justify breaking orphan exclusivity, we undermine the very incentive that encourages companies to develop first-in-class therapies in the first place. The FDA has a clear precedent for maintaining a high bar for clinical superiority determinations. If we lower the bar for breaking orphan exclusivity, especially for "major contribution to patient care," we will undermine the future of rare disease drug development.

Lowering the bar will deter investment in first-in-class therapies by reducing the certainty that companies will be able to benefit from the exclusivity protections Congress intended. Lowering the bar will create regulatory uncertainty, leading to litigation, market instability, and hesitation from investors who fund rare disease innovation. Lowering the bar will set a dangerous precedent for copycat products with few modifications, encouraging incremental changes rather than bold scientific advancements. Lowering the bar will hurt pa-

tients most of all, delaying or discouraging the development of a first-ever therapy for the nearly 10,000 rare diseases that still lack an FDA-approved treatment.

As a physician, I know that true medical breakthroughs require bold investment, sustained commitment, and regulatory certainty. As a legislator, I am committed to preserving the integrity of the Orphan Drug Act and ensuring that it continues to drive life-changing treatments for patients. FDA must apply the law a Congress intended and not allow minor modifications to erode exclusivity protections that serve as the foundation for rare disease innovation. Today, I am calling on my fellow members of the Rare Disease Congressional Caucus to stand together to protect the value of the incentives established in the Orphan Drug Act.

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HONORING DARRELL S.  
TREMBLAY

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HON. ROBERT J. WITTMAN

OF VIRGINIA

IN THE HOUSE OF REPRESENTATIVES

*Thursday, May 29, 2025*

Mr. WITTMAN. Mr. Speaker, I rise today to celebrate the retirement of Darrell S. Tremblay.

Darrell S. Tremblay first joined the fire service in February of 1987 as a volunteer fireman in Stafford County, Virginia. From 1991 to 1995, he spent time as a professional fireman in the Naval District Washington Department of Fire and Emergency Services. Darrell graduated from Washington D.C. Fire and Emergency Medical Services Department Recruit Class 315 on August 8, 1995. His first appointment was to Engine 30 before his appointment to Truck 17. On March 30, 2005, Darrell Tremblay was appointed to the Marine Division within Special Operations.

During his time on the Fire Boat, Darrell was promoted to Marine Operator, Assistant Marine Pilot, and then to Marine Pilot, also earning his 200-ton masters license as a Merchant Mariner from the United States Coast Guard. Serving the citizens and visitors of the district from the water was Darrell's passion. His time spent working on the Fire Boat included maintaining the department's fireboat fleet, training with municipalities around the region to hone his skill set, and performing countless rescue operations.

In the 20 years served on the Fire Boat, Darrell has earned commendations to include a Class II Unit Citation for Valor, Armed Forces Expeditionary Ribbon, the Coast Guard Meritorious Team Commendation, and many others. After 30 years in the DCFD, and a commendable service record, Darrell Tremblay is retiring on July 12, 2025.

Mr. Speaker, I ask that you join me in recognizing Darrell S. Tremblay for his service to the Nation. I am proud to join him in celebrating this remarkable achievement. May the Lord bless him as he embarks on his next challenge, and I look forward to seeing his continued success in the future.

RECOGNIZING PATRICIA ANN MILLER FOR HER SERVICE AS SURVIVING SPOUSE LIAISON

HON. CHRIS PAPPAS

OF NEW HAMPSHIRE

IN THE HOUSE OF REPRESENTATIVES

*Thursday, May 29, 2025*

Mr. PAPPAS. Mr. Speaker, I rise today in recognition of Patricia Ann Miller's outstanding service as a Surviving Spouse Liaison at the Military Officers Association of America. Pat has approached her work as a liaison with immense passion and commitment, exemplifying the virtues of service to her community and Nation.

Pat has continuously shown the highest standard of care to veterans' surviving spouses, advocating for legislation that supports them, helping them access healthcare benefits, and reaching out on a routine basis to encourage them in their daily life. Pat has represented the MOAA on numerous occasions and spearheaded events to honor surviving spouses. In one case, Pat established a memorial fund that donated to family charities identified by each surviving spouse in memory of their loved one.

Pat showcases exceptional personal care for the people she helps, immediately contacting newly surviving spouses to support them in their time of grief and inform them of available resources. Every holiday, Pat contacts each surviving spouse personally with well-wishes and comfort.

On behalf of my constituents in New Hampshire's First Congressional District, I thank Pat for her thoughtfulness and dedication to the surviving spouses she has supported. Granite states are grateful that the spouses of our brave veterans may receive attentive care from professionals like Pat, and I wish her only the best in the years to come.

RECOGNIZING FIRST LADY ELIZABETH MOBLEY OF MT. OLIVE MISSIONARY BAPTIST CHURCH

HON. TIMOTHY M. KENNEDY

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

*Thursday, May 29, 2025*

Mr. KENNEDY of New York. Mr. Speaker, I rise today to recognize First Lady Elizabeth Mobley of Mt. Olive Missionary Baptist Church. A woman whose spiritual influence can be seen and heard throughout Western New York through children of all ages and parishioners beyond the walls of church on Sunday.

First Lady Mobley studied at SUNY Fredonia, earning a Master's Degree in Speech Pathology. From there, she began her career in the Buffalo Public School system, identifying the proper communication skills of students by working with educators and families to ensure students' success.

First Lady Mobley is committed to prioritizing the needs of her students and parishioners, serving as the leader of the Senior and Youth Ministry at Mt. Olive Missionary Baptist Church, while remaining an active participant in the choir and Women's Ministry. Bound by love and strengthened by prayer, she credits the work that she does to the unwavering support of her family, Pastor Keith

Mobley, and their four blessed children: only acknowledge her dedicated career as a Church, providing a safe space for all to be  
Tyson, Talia, Tevin, and Troy. Speech Pathologist and her steadfast commit- heard. First Lady Mobley service is a blessing,

Today, as we recognize the incredible serv- ment to children in need, but her dedication to and we look forward to many more years of  
ice of First Lady Elizabeth Mobley, let us not ministry at Mt. Olive Missionary Baptist her inspired leadership.