STATEMENT FOR THE RECORD
Representative Andrew R. Garbarino
Committee on Energy and Commerce – Member Day Hearing
December 12, 2025

Chairman Guthrie, Ranking Member Pallone, and Members of the Committee, thank you for the opportunity to submit this statement for the record and for convening this Member Day hearing. I appreciate the Committee's continued commitment to addressing issues that directly affect the health and well-being of the American people.

I would like to highlight a bill of mine and urge my colleagues to join me in advocating for the brave men and women who ran toward danger and aided in the aftermath of the September 11th terrorist attacks by supporting the *9/11 Responder and Survivor Health Funding Correction Act of 2025*.

While our nation remembers the 2,997 lives lost on September 11, 2001, those of us in New York also remember the assurances that the air around Ground Zero was safe. Tragically, that assurance proved false. In the years since the attacks, tens of thousands of first responders, law enforcement officers, and relief workers have fallen ill or died as a result of their service in the rescue and recovery effort.

Congress responded by passing the James Zadroga 9/11 Health and Compensation Act, establishing the World Trade Center Health Program (WTCHP) and reopening the September 11th Victim Compensation Fund. In 2015 and again in 2019, with strong bipartisan support, Congress expanded funding and extended program authorizations to ensure that those who were injured, and the families of those who paid the ultimate price, would receive the care and compensation they deserve.

Today, the WTCHP provides medical treatment and monitoring to more than 137,000 first responders and survivors, representing every state and all but one congressional district. Since its inception, the program has operated without any reports of fraud, an extraordinary record that reflects both its integrity and its necessity.

However, despite Congress extending the WTCHP through 2090, rising medical costs and increasing cancer rates among the 9/11 population have created an impending funding shortfall. Without congressional action, the program will soon be forced to announce that responders and survivors with 9/11-related illnesses will no longer be able to apply for enrollment. Shortly after, the program would be required to bar new enrollees and implement additional cuts to services. If Congress fails to act, the very individuals who risked their lives for our nation will lose access to the care they urgently need.

The *9/11 Responder and Survivor Health Funding Correction Act of 2025* addresses this shortfall and ensures that the WTCHP remains fully funded for years to come. The bill also includes several technical updates to improve program efficiency and strengthen care for eligible first responders and survivors.

For these reasons, I respectfully call on my colleagues to support this legislation and reaffirm our nation's commitment to those who served heroically on September 11th and in the months that followed.

I look forward to working with the Committee to ensure that Americans continue to have reliable access to the healthcare they need. The stakes for patients could not be higher, and this Committee's leadership is crucial to achieving a durable solution.

I also write today to highlight an urgent and preventable threat to the availability of levothyroxine, a daily lifesaving medication used to treat thyroid disorders. More than 19 million Americans rely on this medicine, one of the most prescribed drugs in the United States, and uninterrupted access is essential for patient stability and long-term health.

A narrow but consequential inconsistency in federal law now jeopardizes the continued domestic production of levothyroxine. The issue stems from the unique regulatory history of the drug. For decades, levothyroxine was marketed without formal FDA approval. When the FDA required manufacturers to submit applications in the late 1990s, the earliest products were approved under new drug applications (NDAs), even though these applications relied entirely on literature and data the agency had long accepted and offered no patent protections or market exclusivity. Later, the FDA determined that all subsequent levothyroxine applications must be submitted as abbreviated new drug applications (ANDAs), consistent with generic drugs, using the same underlying body of scientific evidence. This historical administrative distinction, unrelated to innovation, pricing, or product complexity, now has major implications under the redesigned Medicare Part D benefit.

Under the new Medicare Part D Manufacturer Discount Program, manufacturers of drugs approved under NDAs must pay significant mandatory rebates for their products to remain covered under Part D. Generics approved under ANDAs are exempt. However, because the earliest levothyroxine products were approved as NDAs, even though they function as generics, they are now swept into the rebate program.

As a result, a family-owned manufacturer in my Long Island district that supplies approximately 40% of the U.S. levothyroxine market faces rebate obligations that have increased by nearly 200 percent. No domestic manufacturer can sustain this burden indefinitely. If these companies are forced to cease production, the United States would lose its largest remaining domestic source of a critical medicine relied on by millions.

This outcome is not hypothetical. It is imminent unless Congress acts. Losing domestic production would increase dependence on foreign suppliers, including facilities that have faced recalls and quality-control issues. It would also heighten the risk of nationwide shortages for a narrow-therapeutic-index medication, where even minor variations can destabilize patient health, and trigger a mass switching event that would affect millions of Americans and pose serious risks to patient safety.

This is not a partisan matter. It is a patient safety issue, a supply chain stability issue, and a national resilience issue caused by a bureaucratic inconsistency Congress never intended.

To address this, I introduced the *Ensuring Access to Essential Drugs Act*, a bipartisan, narrowly tailored bill that exempts from the Medicare Part D Manufacturer Discount Program any drug that has already received a "narrow exception" under the Medicaid Drug Rebate Program. For years, CMS has used this Medicaid exception to treat certain NDA products, including levothyroxine, as generics when the regulatory classification does not reflect their real-world status. The *Ensuring Access to Essential Drugs Act* simply aligns Medicare policy with longstanding Medicaid practice.

This targeted fix will protect access to a widely used, essential chronic medication, prevent avoidable drug shortages, support American manufacturing jobs, strengthen domestic pharmaceutical supply-chain security, and ensure consistent treatment of equivalent products across federal programs.

Members across the political spectrum have emphasized the importance of stable domestic production of essential medicines. This bill is a straightforward, bipartisan opportunity to uphold that commitment.