



The Honorable Cathy McMorris Rodgers  
Chair  
House Energy and Commerce Committee  
2188 Rayburn House Office Building  
Washington, DC 20515

The Honorable Frank Pallone  
Ranking Member  
House Energy and Commerce Committee  
2107 Rayburn House Office Building  
Washington, DC 20515

The Honorable Morgan Griffith  
Chair  
Subcommittee on Oversight and Investigations  
House Energy and Commerce Committee  
2202 Rayburn House Office Building  
Washington, DC 20515

The Honorable Kathy Castor  
Ranking Member  
Subcommittee on Oversight and Investigations  
House Energy and Commerce Committee  
2052 Rayburn House Office Building  
Washington, DC 20515

**House Energy and Commerce Committee Subcommittee on Oversight and Investigations  
Hearing: “Antimicrobial Resistance: Examining an Emerging Public Health Threat”  
April 28, 2023**

**Statement for Record**

The mission of the Cystic Fibrosis Foundation is to cure cystic fibrosis and to provide all people with CF the opportunity to lead long, fulfilling lives by funding research and drug development and advancing high-quality, specialized care. Since our founding in 1955, the CF Foundation has worked alongside the cystic fibrosis community to effectively transform a genetic disease in a single generation—making CF one of the best stories in medicine today.

**Cystic Fibrosis and Proneness to Infections**

Despite significant progress in treating CF, infections remain a serious threat to the nearly 40,000 Americans who live with cystic fibrosis. The faulty gene that causes CF affects how salt and water moves in the lungs. This salt imbalance results in thick, sticky mucus that builds up in the lungs, allowing microbes to thrive and multiply. When the body’s defense system attacks the microbes, the lungs become inflamed. This inflammation spurs the creation of more mucus, which then blocks the airways, and allows more microbes to grow. As a result, chronic lung infections are a hallmark of life with CF. Recurrent infections can cause progressive, irreversible damage in the lungs, increased and lengthened hospitalizations, and worsening lung disease that may require lung transplants or lead to death. To keep infections in check, people with CF take antimicrobials as part of their daily treatment routine. Commonly, when people with CF experience lung exacerbations, they will also receive a “tune up”—typically, a 2-4 week course of intravenous (IV) antibiotics administered during a hospitalization or at home. This regular but medically necessary use of antimicrobials provides a window into the risks of persistent antimicrobial use and the potential effects of antimicrobial-resistant organisms.

**Cystic Fibrosis as a Microcosm of the AMR Threat to Patients: Two Case Studies**

In 2019, more than 40% of people with CF cultured for *Pseudomonas aeruginosa* (*P. aeruginosa*), a major cause of lung infections. Once established in the airways, *P. aeruginosa* is very difficult to eradicate and can lead to rapid decline in lung function, advanced lung disease, and early mortality.

Nearly 20% of individuals with a *P. aeruginosa* infection in 2019 were found to have a multi drug-resistant strain, limiting the already small arsenal of antibiotics capable of treating their infection. One adult man living with CF in Kentucky has a strain of *P. aeruginosa* resistant to almost every known antibiotic approved to treat the infection. In 2017, out of options, he was put on a new IV medication that shut down his body, culminating in liver damage. He continues using this antibiotic to this day, despite the damage it does to his body—because without it, he wouldn't be able to address the multi-drug resistant *P. aeruginosa*, which is ultimately more dangerous due to the difficulty of eradicating it once it colonizes the airways.

Of the various bacteria that cause lung infections in CF, the *Burkholderia cepacia* complex (*B.cepacia*) has been most commonly associated with shortened life span. In 2019, about 3% of people with CF were infected with *B.cepacia*. A young woman living with CF in California dealt with a persistent case of *B.cepacia* that, at its worst, led to frequent hospitalizations and exacerbations that required vest treatments every 3 to 4 hours just to breath. In 2018, while dealing with her infection, she caught a virus that led to 12 days in the hospital; in 2019 it was recommended that she receive a double lung transplant because of the deterioration of her lungs, the swiftness of which was a direct cause of *B.cepacia*.

Importantly, though people living with CF are particularly prone to these pathogens, they are not simply a CF problem. Multi-drug resistant *P. aeruginosa* caused an estimated 32,600 infections amongst hospitalized patients and 2,700 estimated deaths in the United States in 2017<sup>1</sup>. *B.cepacia* is one of the most commonly reported contaminants of nonsterile pharmaceutical products and was involved in 34% of nonsterile product recalls between 2004 and 2011<sup>2</sup>; just this year, the FDA advised drug manufacturers that *B.cepacia* continues to pose a risk of hazardous contamination<sup>3</sup>.

### **Reinvigorating the Antimicrobial Ecosystem**

The emergence of drug-resistant pathogens and shortage of effective antimicrobials is a top public health concern. For people with CF, it is often a matter of life or death. In 2018, recognizing the significant threat antimicrobial resistance poses to the CF community, the CF Foundation dedicated \$100 million through 2024 to our Infection Research Initiative as part of a sweeping effort to advance infection research. To date, the Foundation already has committed more than \$135 million to the initiative, surpassing our initiative investment nearly two years ahead of schedule. Though we reached this initial investment milestone, we are continuing to fund any science that we believe holds promise.

However, research investment alone will not solve the challenges of antibiotic development. Products in the antimicrobial pipeline need to be supported by a robust array of incentives to combat the low market, but high societal value of these goods. Due to the current nature of the antimicrobial marketplace, the development of novel antimicrobials cannot occur without creating concerns about inappropriate use of these critical products; payment methods that de-link sales volume from revenue can help. Congress must invest in solutions to ensure access to antimicrobials that work both now and in the future by reforming market incentives for antimicrobials.

The PASTEUR Act has the potential to spur vital investment into new antimicrobials by addressing the economic disincentives that have long been associated with antimicrobial development. By providing companies with a more predictable ROI that aligns with antimicrobial stewardship and allows clinicians on the front lines to make prescribing decisions based on what's best for their patients, the PASTEUR Act could be a transformative solution to this crisis.

CF is a rare disease, but in the case of AMR, people with CF face challenges today that are risks to the larger population tomorrow. While no single proposal will solve all the issues, today's hearing is an important step. Collectively, we must continue to create targeted economic solutions and bring desperately needed antimicrobials into the hands of those who need them most.