July 16, 2018

The Honorable Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: American Patients First, Drug Pricing Blueprint

Dear Secretary Azar:

The Cystic Fibrosis Foundation is a national organization dedicated to curing cystic fibrosis (CF) and providing all people with the disease the opportunity to lead full, productive lives by funding research and drug development, promoting individualized treatment, and ensuring access to high-quality, specialized care.

CF is a chronic, life-threatening disease that requires a complex daily treatment regimen, including multiple daily medications and regular visits to a multidisciplinary care team at an accredited care center. This approach has resulted in drastically improved outcomes: Today, people with CF are living into their 30s, 40s, and beyond, compared to just a few decades ago when children with the disease rarely lived long enough to attend elementary school.

Living with CF is expensive. Families must bear the cost of premiums, deductibles and copays for medication, medical equipment, visits to the clinic, and hospitalizations. The cost of care can be hard to predict, and we have heard from parents that they can’t reasonably budget for how much it might take to care for their child. While nearly all people with CF have insurance, too many individuals report skipping a medication or a meal due to the cost of the disease. We also hear from public and private payers with concerns about the budget impact of CF care.

Access and affordability are essential to building on the progress we’ve made in both treatment development and care delivery. A subset of our community is currently eligible for genetically-targeted medications that address the underlying cause of disease, and innovative therapies are on the horizon that would extend the benefits of disease-modifying treatment to more than 90 percent of people with cystic fibrosis. With so much at stake we are resolute: Cost must not prevent people with CF and other pre-existing conditions from accessing life-saving medicines.

We welcome your efforts to address this critical issue through the drug pricing blueprint, American Patients First, and appreciate the opportunity to comment on behalf of people with CF. As the
Administration moves forward with defining these proposals in greater detail, we urge that collaboration with patients and health care professionals continue to be of the highest priority.

Our comments focus on proposals within the broader plan which most directly impact people with CF:

- Strategies to increase competition
- Reforming the rebate system and encouraging discounts
- Formulary standards and protected classes in Medicare Part D
- Transparency about prices, rebates, and cost-sharing
- Changes in the Medicare Part B program
- Alternative payment models for prescription drugs
- Adequate, affordable and available coverage for prescription drugs

**Encouraging competition in the marketplace is worthwhile, but it is a long-term goal with uncertain impact on prices.** The CF Foundation is significantly supporting the development of a wide range of innovative drugs in the hopes that patients will have multiple treatment options and price competition can be realized. However, development of these drugs is a complex matter, and accomplishing competition in the marketplace is a long-term goal.

While many CF-specific drugs do not yet have generics or biosimilars available, we support proposals to eliminate delays in the introduction of these products to the market. These include efforts to prevent the abuse of Risk Evaluation and Mitigation Strategies (REMS) to block generic competition and polices to improve the availability and competitiveness of biosimilars.

**Reforms to payment structures must be designed to avoid merely shifting costs from one part of the system to another without reducing costs to patients directly.** The Department of Health and Human Services (HHS) has signaled its strong interest in reforming rebates, which it sees as an obstacle to price reductions, a means for pharmacy benefit managers to profit, and a burden to patients because cost-sharing is calculated before application of rebates. Instead, HHS favors discounts, as opposed to rebates, that could benefit patients through lower cost-sharing and the system through reduced expenditures.

We see advantages to the use of discounts in the prescription drug system but do not see a clear path in the blueprint to accomplish this goal. We look forward to learning more from the Department about its plan to secure drug pricing discounts that will improve affordability for patients and the system.

**Restrictive formularies that assume interchangeability of drugs in Medicare Part D classes could put CF patients at risk of not receiving clinically appropriate treatment.** We understand the desire to enhance Medicare Part D negotiation for prescription drugs. If such negotiation reduces the prices paid, accompanying reductions in patient cost-sharing and potential improvements in program sustainability may also be realized. To accomplish the aim of greater negotiation, the blueprint recommends elimination of the protected classes in Medicare Part D, which currently require coverage of all or substantially all drugs in protected classes, and changes in formulary standards to a single drug per class in Part D.

Some people with CF are candidates for double lung transplants, and those who do receive transplants benefit from the protections afforded to immunosuppressive drugs through Part D. We support retaining the protected drug classes, as individuals with an array of complex, severe medical needs – including CF, cancer, HIV/AIDS, transplant patients, and individuals with mental illness – have benefitted
from streamlined access to these important drug classes since the design and implementation of Medicare Part D.

However, the more significant issue for people with CF is the formulary treatment of the disease-modifying CF drugs. Because of the special needs of people with CF for genetically targeted therapies – needs that are shared by many other patients receiving benefits from targeted or personalized therapies – strict formularies and aggressive formulary management tools, including a one drug per class minimum, have the potential to block access to clinically appropriate drugs. These drugs are targeted according to genetic mutation, and proper targeting of these drugs in clinical practice requires that all be included on formularies. These drugs are not interchangeable for people with CF, and that means restrictive formularies that assume interchangeability of drugs in a class will put CF patients at risk of not receiving proper treatment.

We support the concept of increased transparency related to drug prices, discounts, and rebates; however, we strongly urge you not to place the onus of responsible purchasing on patients when the actual leverage in purchasing decisions resides with third party payers. In our current health care system, patients have very little purchasing power, and individuals who have few or no existing treatment alternatives, like people with cystic fibrosis, have no choice but to pay whatever cost-sharing is required for their medications.

The proposed transparency initiatives include direction to the Centers for Medicare & Medicaid Services (CMS) to improve the usefulness of its drug pricing dashboard and provide patients more information on cost-sharing; improve explanation of benefit documents to share information on prices and price increases; and eliminate pharmacy gag clauses. We recommend these policies be refined to reflect the design of health insurance and the role that patients play as purchasers of care.

For example, we understand the value in prohibiting pharmacy gag clauses so that pharmacists could explain to patients that the direct purchase of a drug would be less expensive than using insurance. However, for people with CF, it is likely more economical to use insurance and incur the cost-sharing because it would count towards their deductible or meeting a cost-sharing maximum. This information may not be immediately apparent to the patient and serves to illustrate how educating patients at the pharmacy counter without considering the individual’s plan benefit structure could hinder affordability.

Analyses show that moving Medicare Part B drugs to Part D would result in most – but not all – beneficiaries incurring more substantial cost-sharing responsibilities for Part B drugs reimbursed through Part D than they would if those same drugs were reimbursed through Part B. This directly contrasts with the blueprint’s goal to reduce out-of-pocket spending for patients. Even if the B to D shift is likely to benefit the Medicare program and contribute to long-term stability, the shift should not occur until the impact of this proposal on beneficiaries has been fully assessed. Important issues such as which drugs will be moved from B to D, how and when the decisions about those drugs will be made, and what standards for coverage and cost-sharing responsibilities apply to drugs moved from B to D remain unclear in the proposal.

Many individuals with CF who are Medicare beneficiaries qualify for this coverage due to the receipt of Social Security Disability benefits. People with CF who are enrolled in Medicare currently face obstacles to obtaining quality CF care as the result of coverage limitations or exclusions for critical medical equipment, as well as cost-sharing associated with prescription drugs and medical services, including
inpatient stays and routine visits. People with CF dependent on SSDI benefits cannot routinely afford out-of-pocket costs associated with Part D drug coverage nor the costs associated with purchasing Medigap coverage.

Should Part B drugs be moved to Part D, we recommend at a minimum that such a reform be paired with an out-of-pocket maximum for patients. This would support the Administration’s goals of lowering out-of-pocket costs for patients and leveraging negotiation opportunities for Part D.

We offer similar cautions about the Competitive Acquisition Program. Although we see potential advantages to a competitive system for acquisition of Part B physician-administered drugs, there are many open questions about how such a program will be designed and how it will serve patients.

**Strategies to establish value-based purchasing of prescription drugs should be tested but must adequately reflect the impact of medicines on patient quality of life.** We encourage continued discussion about value-based purchasing and how such models should be implemented, but we have consistently expressed caution about the efforts to date to establish the value of CF medications, as current value assessments have not fully incorporated input from patients and clinical experts and do not recognize the value of preventing disease progression in people with CF.

**In light of serious access barriers to prescription drugs faced by people with CF and many other people with serious and life-threatening illnesses, we urge greater attention be paid to improving prescription drug coverage in addition to lowering drug pricing.** Almost all people with CF have insurance coverage, and their coverage comes from the widest possible range of insurance options – Medicare, Medicaid, CHIP, employer-sponsored insurance, and Affordable Care Act insurance coverage. Still, people with CF increasingly find their insurance inadequate to ensure reliable, affordable access to prescription drugs. They must often patch together payment for care that includes multiple forms of insurance coverage, their own resources, family resources, and patient assistance from a wide range of sources.

In the blueprint, the Department has stated a commitment to lowering out-of-pocket prescription costs for patients. We support this goal but note that out-of-pocket expenses are only one part of the cost burden faced by many patients, especially those with chronic and costly conditions. The most direct approach to protecting patients is to ensure access to adequate, affordable, and comprehensive health insurance.

That is why, on behalf of people with CF and other chronic conditions, we oppose the Administration’s proposed rule on short-term, limited-duration insurance plans and final rule on association health plans (AHPs). Short-term plans and AHPs, in addition to other shortcomings, are unlikely to include adequate prescription drug coverage for people with virtually any prescription drug needs. These plans not only fail to meet the needs of people with chronic health care conditions, but they also undermine the small group and individual market, which are more likely to offer plans with adequate prescription drug coverage.

As you pursue the goal of lowering prescription drug spending, a goal we applaud, we urge you to simultaneously ensure that the other health needs of people with chronic conditions will also be met through strong benefit standards for third party payers.
We appreciate the opportunity to comment on the drug pricing blueprint. As you noted in your message accompanying the plan “too often, [this system] has not put American patients first. We have access to the greatest medicines in the world, but access is meaningless without affordability.” We agree with your concern about affordability and hope that this document marks the beginning of a discussion with patients and health professionals about reforms that will lead to patient-centered design of prescription drug benefits.

Sincerely,

Preston W. Campbell, III, MD
President and Chief Executive Officer