CYSTIC FIBROSIS FOUNDATION®

December 15, 2021

Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal

Submitted electronically at http://www.regulations.gov

Dear Secretary Becerra:

Thank you for the opportunity to comment on this proposed rule to withdraw or repeal the final rule entitled, *Securing Updated and Necessary Statutory Evaluations Timely (SUNSET rule)*.

The Cystic Fibrosis Foundation submitted comments in December 2020 expressing our grave concerns with the proposed SUNSET rule and urged the Department of Health and Human Services (HHS) to immediate withdraw it. The rule, which was subsequently finalized in January 2021, would negatively impact predictability, transparency, and public engagement that are essential to the regulatory process, and have particularly damaging effects on the drug development process.

Background on Cystic Fibrosis and the Cystic Fibrosis Foundation

The CF Foundation is a national organization dedicated to curing cystic fibrosis (CF). We invest in research and development of new CF therapies, advocate for access to care for people with CF, and fund and accredit a network of specialized CF care centers.

Cystic fibrosis is a life-threatening genetic disease that affects more than 30,000 children and adults in the United States. Through careful, aggressive, and continuously improving disease management, the average life expectancy for people with cystic fibrosis has risen steadily over the last few decades. In addition to advances in care, recently approved genetically-targeted drugs that address the underlying cause of CF are available for patients with specific genetic profiles and have contributed to the increases in life expectancy. This milestone reflects over 50 years of hard work to improve CF treatments, develop evidence-based standards of care, and encourage adherence to a lifetime of chronic care. However, despite immense progress in recent decades, there is still critical work to be done to ensure that all those living with the disease have access to effective therapies and, ultimately, a cure.

We appreciate that HHS has reconsidered the comments submitted on the original proposal and strongly support the current rulemaking to repeal the final SUNSET rule. We provide the following comments on this rulemaking:

The SUNSET Rule Would Negatively Impact Regulatory Predictability

If implemented, the SUNSET rule would undermine regulatory predictability for many regulated entities. This may be particularly harmful in the drug development space, where new therapeutic products can

sometimes take decades to bring through the development and review process. The research and development process by nature is lengthy and expensive, and drug sponsors rely on a predictable regulatory environment to plan their development programs. An environment in which Food and Drug Administration (FDA) regulations or other HHS regulations may be capriciously withdrawn may hamper progress on much needed therapies in the drug development pipeline for those with unmet medical needs, including patients with CF.

The SUNSET Rule Failed to Recognize the Strain on Resources to Carry Out Reviews

Importantly, the SUNSET rule failed to recognize the substantial resources required for the regulatory reviews and assessments necessitated by this proposal which could derail other critical work done by agencies. For example, the FDA's most critical resource is its staff. Diverting staff time to routine review of existing rules will significantly hamper the FDA's ability to advance regulatory science, engage with sponsors to support product development, communicate standards to stakeholders on new therapeutic areas like gene editing, and conduct timely reviews of new drug applications. If implemented, this rule may result in the delay or disruption of core FDA activities to the detriment of patients across the nation.

The SUNSET Rule Would Reduce Transparency and Public Engagement in the Regulatory Process

As the Department states in the withdrawal proposal, this rule fails to provide measures to ensure public transparency and adequate review processes for each regulation. Due to the high volume of regulations that HHS and its agencies would need to review, we are deeply concerned that some regulations may not be reviewed before the deadline, resulting in the automatic and arbitrary rescission of key rules. In the final rule, the previous administration acknowledged that 1,044 rules would need to be reviewed within the first year. Additionally, many agency guidance documents are based on regulation that could be revoked or become expired under the SUNSET rule. This process would likely result in significant regulatory gaps as each rule often builds upon previous regulations, and therefore likely leave key stakeholders unsure of proper procedures and parameters related to their work.

Finally, from a regulatory review perspective, HHS does not have full regulatory control over some policies required to go through this process. Many policies impacting health coverage and patient protections under the Affordable Care Act have been jointly issued by HHS and agencies such as the Internal Revenue Service, Department of Labor, and Department of Treasury. It is unclear from this rule how regulations issued jointly by these Departments would be treated.

Once again, we are pleased that HHS rescinds this rule prior to implementation as it would decrease predictability, transparency, and public engagement critical to the regulatory process. Thank you again for the opportunity to comment on this proposal and your consideration for people with cystic fibrosis.

Sincerely,

Mary B. Dwight
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Senior Vice President of Policy & Advocacy
Cystic Fibrosis Foundation