December 4, 2020

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

Re: HHS-OS-2020-0012, Securing Updated and Necessary Statutory Evaluations Timely

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

Dear Secretary Azar:

On behalf of the Cystic Fibrosis Foundation, I write in response to the HHS proposed rule, Securing Updated and Necessary Statutory Evaluations Timely (SUNSET). If finalized, this proposed rule would require review of all agency regulations on a ten-year basis with failure to review existing regulations resulting in expiration of a given rule.

We are deeply concerned that the proposed rule could negatively impact predictability, transparency, and public engagement essential to the regulatory process, and have particularly damaging effects on the drug development process. We therefore urge HHS to rescind this proposal.

Background on Cystic Fibrosis and the CF Foundation
The Cystic Fibrosis Foundation is a national organization actively engaged in the research and development of new therapies for cystic fibrosis (CF) – a rare, life-threatening genetic disease that affects more than 30,000 people in the United States. When the CF Foundation was formed in 1955, no CF-specific drugs existed. However, by raising and directing funds needed to fuel drug development programs, the CF Foundation has encouraged pharmaceutical companies to invest in research for this rare disease. Today, there are 14 therapeutic products available in the United States to treat people with cystic fibrosis, four of which treat the underlying cause of the disease.

Additionally, because care for cystic fibrosis is complex and multi-faceted, specialized care is critical for those living with CF. Progress in standards of care for patients with CF would not have been possible without the CF care model and the nationwide network of more than 130 specialized care centers. These centers leverage the expertise of dedicated health care professionals to provide the best disease management and care for people CF.

Thanks to advances in treatment options and the use of evidence-based care, people with CF as a whole are leading longer, more productive lives. 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.
The SUNSET Rule Will Negatively Impact Regulatory Predictability
If finalized, the proposed 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 Fails to Recognize the Strain on Resources to Carry Out Reviews
Importantly, the SUNSET rule fails 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 finalized, this rule may result in the delay or disruption of core FDA activities to the detriment of patients across the nation.

The SUNSET Rule Will Reduce Transparency and Public Engagement in the Regulatory Process
The proposal 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 proposal, HHS acknowledges 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 will likely result in significant regulatory gaps as each rule often builds upon previous regulations, and therefore will 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 proposed rule how regulations issued jointly by these Departments will be treated.

Once again, we urge HHS to rescind this proposal as it will decrease predictability, transparency, and public engagement critical to the regulatory process. Thank you 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