PATIENTS RISING NOW

July 5, 2023

Division of Dockets Management
Food and Drug Administration
5630 Fishers Ln
Rockville, MD 20852

RE: Docket FDA-2023-D-0026 – *Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments Into Endpoints for Regulatory Decision-Making; Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders*

On behalf of Patients Rising Now and patients across the country, we would like to thank you for holding a comment period regarding incorporating patient experience data into regulatory decision-making and medical product development. Input on decisions and rule-making processes that take place at the Federal level should not be narrowly confined. Any Federal action should be made with as much guidance from relevant stakeholders as possible, and that guidance should be given the full consideration it rightly deserves. To that end, we thank you for committing to increasing evaluation of data derived from patient experience.

Formed in 2015, Patients Rising Now has developed a significant following of patients and caregivers and has guided them on their journeys to advocate for themselves and their loved ones to get the care and treatments they need to live a fulfilling life. As a patient advocacy organization, we support reforms and legislation aimed at advancing patient access to affordable, quality healthcare.

For as long as cures and treatments have been discovered, there were two main factors that drove their approval and subsequent use: efficacy and safety. When those two criteria were met, it would not be long before said treatment could make its way to the patients who needed it most. A drug/treatment should absolutely meet those criteria before widespread distribution and these comments are not meant to imply that the importance of those criteria should be revised in Federal decision-making. However, limiting decisions to only those factors does not allow for fully comprehensive information on a treatment. Incorporating patient experience into both Federal decision-making and the body of available information is a logical inclusion. This is especially true considering the fact that efficacy and safety of a treatment are data points derived from patients.

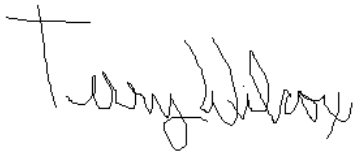
PATIENTS RISING NOW

Patient experience provides insights to all involved parties in drug development, not the least of which being the patients themselves. In the case of a treatment, the biggest indicator of efficacy is whether progression of the disease has stagnated or reversed altogether. This information is invaluable to all stakeholders. But, from the perspective of the patients who would be utilizing this treatment, they are unable to determine what they can expect beyond the currently available data. For this reason, we appreciate that the FDA's guidance memo not only recommends collecting data on how a patient "…feel[s] and/or function[s] in their daily life" but also creating a metric to quantitatively measure this impact.

Gathering data on patient experience during clinical trials is not a new concept. However, as the collection and solicitation of data becomes more commonplace, the processes for collecting this information and what information is collected will undoubtedly change. Seeing as they are the focal point of any study of a new treatment, the patient perspective should be given high consideration with regards to what information to gather. Patients Rising Now strongly recommends further incorporation of the patient voice in any changes or improvements to the patient experience data collection processes.

Patients Rising Now would like to thank you again for holding a comment period on this critical issue. The implementation of this guidance will take some time to finalize and become more widely adopted. However, the willingness of the FDA to both consider this data and solicit it bodes well for the prospect of the consideration of patient experience becoming a permanent facet of treatment development in this country.

Sincerely



Terry Wilcox
Cofounder and CEO