



Ensure Patient Perspectives Are Included in FDA Benefit-Risk Assessments: Cosponsor the S. 373/H.R. 4472, the Better Empowerment Now to Enhance Framework and Improve Treatments (BENEFIT) Act

Overview

Congress and the Food and Drug Administration (FDA) have made considerable progress in driving forward policies and procedures to ensure the patient perspective is considered by FDA reviewers evaluating candidate drugs and other medical products. As a result of numerous provisions of both the Prescription Drug User Fee Act (PDUFA) of 2012, (FDASIA) and the 21st Century Cures Act in 2016, the FDA now has programs and policies in place to evaluate the benefits and risks of potential therapies and to gather and assess patient perspectives.

But while much progress has been made, some significant gaps remain. One such gap is the lack of any requirement in law today that the FDA include patient experience or patient-focused drug development (PFDD) data as a part of its risk-benefit framework. This means that the agency's signature tool for evaluating risk-benefit does not have to data from the patient perspective that could be critical to informing the agency's evaluation and, ultimately, decision on whether or not to approve a product.

The BENEFIT Act

To address this gap, Senators Roger Wicker (R-MS) and Amy Klobuchar (D-MN) and Representatives Doris Matsui (CA-6) and Brad Wenstrup (OH-2) have introduced S.373/H.R. 4472, the Better Empowerment Now to Enhance Framework and Improve Treatments (BENEFIT) Act. This legislation will amend the Food, Drug and Cosmetic Act (FDCA) to ensure that patient experience, PFDD and related data – including information developed by a product sponsor or a third party such as a patient advocacy organization or academic institution – be considered as part of the risk-benefit assessment. This action will send an important signal to all stakeholders that patient experience and PFDD data will be fully incorporated into the agency's review process and will encourage such entities to develop scientifically rigorous and meaningful tools and data.

The BENEFIT Act will also enhance an important transparency and accountability provision included in the 21st Century Cures Act by requiring the FDA to share how such patient experience and PFDD data was considered within the risk-benefit assessment for any approved therapies. This will provide additional learnings to all stakeholders, particularly patients, and help further refine and develop such tools going forward.

Conclusion

The nascent field of patient engagement in drug development continues to flourish thanks to a continued interest and focus by Congress. The BENEFIT Act will continue this evolution by filling a sizeable gap by ensuring such data is fully considered as part of the FDA's risk-benefit assessment for any new products. **Advance patient engagement by cosponsoring the BENEFIT Act today.**

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House: To cosponsor H.R. 4472, contact Rep. Matsui's office:

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