



## BETTER EMPOWERMENT NOW TO ENHANCE FRAMEWORK AND IMPROVE TREATMENTS (BENEFIT) ACT

While much progress has been made on incorporating patient experience data in the drug approval process through FDA implementation of previous legislative efforts, some significant gaps remain. One such gap is the lack of any requirement in law today that the FDA include, as part of its benefit-risk framework, any patient experience or patient-focused drug development (PFDD) data. This means that the agency's signature tool for evaluating benefit-risk does not have to include 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.

To address this gap, Senators Roger Wicker (R-MS) and Amy Klobuchar (D-MN) introduced the Better Empowerment Now to Enhance Framework and Improve Treatments or the BENEFIT Act (S. 1052) which passed in the Senate in August of 2017.

This legislation would 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 benefit-risk assessment. This action would send an important signal to all stakeholders that patient experience and PFDD data will be fully incorporated into the agency's review process and would encourage such entities to develop scientifically rigorous and meaningful tools and data.

The BENEFIT Act would also enhance an important transparency and accountability provision from the 21<sup>st</sup> Century Cures Act by requiring the FDA to say how such patient experience and PFDD data was considered within the benefit-risk 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. **PPMD is now working with Congressional champions to reintroduce in the Senate and introduce a companion bill in the House.**