CANCER SUPPORT COMMUNITY
COMMUNITY IS STRONGER THAN CANCER

March 18, 2022

The Honorable Doris Matsui
United States House of Representatives
2311 Rayburn House Office Building
Washington, DC 20515

The Honorable Brad Wenstrup
United States House of Representatives
2419 Rayburn House Office Building
Washington, DC 20515

Dear Representatives Matsui and Wenstrup,

Thank you for your leadership in sponsoring the BENEFIT Act to address the important issue of patient experience data (PED) in clinical trials. The Cancer Support Community (CSC) has had the privilege of engaging with your legislative staff to discuss the alignment of intent between the BENEFIT Act and Section 204 of the Cures 2.0 Act (Cures 2.0), and to highlight opportunities to close gaps that remain in the process that impede patients and providers from receiving the full benefit of PED as Congress intended. We appreciate the chance to share these concerns with you.

CSC's efforts to raise awareness about PED and psychosocial screening for distress in clinical trials predates the passage of 21st Century Cures and we continue to lead that effort today through our work with Members of Congress, the FDA, patient advocacy organizations, and sponsors as illustrated by our support of Cures 2.0. We led the negotiations with Senator Baldwin during the Food and Drug Administration Reauthorization Act of 2017 (FDARA) to expand the definition of PED in 21st Century Cures to include not only the physical impacts of a condition, therapy, or clinical investigation, but also the psychosocial impacts.

The FDA currently requires clinical trial sponsors to report what (if any) patient experience data is collected during a trial but there is neither an imperative for sponsors to collect and submit PED nor a structure in place ensuring the FDA uniformly considers and meaningfully conveys the information gleaned from PED to patients and providers. Congress, the FDA, sponsors, and patient advocacy organizations laud the importance of PED, but the optionality and variability of its collection and application imposes limitations on its benefit and causes confusion and uncertainty. Unlike Section 204 of Cures 2.0, the BENEFIT Act, as currently drafted, does not include a requirement for sponsors to collect and submit PED or for the FDA to consider it. Establishing standardized metrics or a process to ensure PED is consistently collected, submitted, and considered will achieve Congress' intent to provide patients and providers with meaningful information they can look to when determining treatment options. Furthermore, we are concerned that the BENEFIT Act, if enacted as currently drafted, could unintentionally be mired in the guidance development process which is untimely and messy.

Given the bipartisan leadership on this issue across the committee, we believe there is no better time to ensure the successful and comprehensive use of PED. We encourage you to fully consider incorporating language from Cures 2.0 into your legislation. We believe that by working together, you have the opportunity to elevate PED to a position which will transform and modernize the drug development process and, most importantly, provide tremendous benefit to patients and their families.

Thank you,

Kim Czubaruk

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