

FDA Report Language

Cancer Immunotherapy and Combination Treatments.— The Committee commends the FDA for its continued efforts to accelerate the review and approval of cell and gene therapies for cancer, which have provided hope for many patients when more traditional treatments have failed. Research suggests that therapies that combine cellular products and other cancer drugs may prove more effective for some patients, including those who do not benefit from single-drug treatments. These combination treatments increase the complexity of trial design, especially regarding treatment sequencing and the number of treatment arms per trial. Therefore, the Committee urges the FDA to work with and provide guidance to industry and the broader research community on how to standardize clinical trial designs for cellular therapy treatments combined with other cancer therapies. This will allow sponsors to streamline trial designs, while still ensuring adequate safety and maximizing efficacy for patients.