

### **FDA Report Language**

*Cancer Immunotherapy Clinical Trials.*— The Committee commends the FDA for its recent efforts to accelerate the review and approval of immune-oncology therapies that safely and meaningfully improve the lives of patients with cancer. With thousands of immuno-oncology clinical trials currently under way or in development, understanding how to make comparisons across studies and identify the highest priority treatments is becoming increasingly important, especially when evaluating early clinical data. The Committee understands that early endpoints commonly used to evaluate standard cancer treatments may not always be appropriate for predicting overall survival outcomes from cancer immunotherapy treatments. Therefore, the Committee urges the FDA to work with the research community and pharmaceutical industry to develop surrogate endpoints for cancer immunotherapy treatments that can be standardized and recognized by the entire drug development community as avenues toward regulatory approval.