

FY23 SITC FDA Appropriations Language

Topic: Effectiveness of Cellular Therapies

The Committee commends the FDA for its continued efforts to approve cellular therapy drugs to treat cancer, which provide personalized living medicine for patients when traditional treatments have failed. In many cases, the drug's mechanism of action is not fully understood, so numerous tests must be performed to determine its effectiveness, or potency. These tests help establish that each patient receives the correct drug. To date, however, establishing standardized methods to determine the effectiveness of these therapies has been challenging. Therefore, the Committee urges the FDA to work with industry and the research community more broadly to continue enhancing its guidance and regulations concerning standardization of potency testing requirements for cellular therapies. This will expedite the advancement of novel cellular therapies and accelerate delivery of medicines to patients with complex and unmet medical need.