FDA Reconsiders Accelerated Approvals

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The Food and Drug Administration (FDA) created its accelerated approval program to enable more rapid approval of therapies for serious conditions. Rather than waiting for enough deaths to determine whether there's a survival advantage, medications may be approved based on surrogate endpoints, such as tumor shrinkage. But therapies granted accelerated approval are still required to undergo further testing to confirm that they do in fact offer clinical benefits.

In April, an FDA advisory committee reviewed accelerated approvals of six indications for checkpoint inhibitor drugs that have not shown the expected clinical benefits in confirmatory trials. The panel voted to continue approval of Tecentriq (atezolizumab) plus Abraxane (nab-paclitaxel) for triple-negative breast cancer and two drugs, Tecentriq and Keytruda (pembrolizumab), for advanced bladder cancer. The panel unanimously favored maintaining approval of Keytruda alone but narrowly voted to rescind approval of Opdivo (nivolumab) monotherapy for liver cancer. Finally, they voted against maintaining approval of Keytruda monotherapy for stomach cancer.

The experts recommended continued approval of therapies with no good alternatives, while rescinding approval if the treatment landscape has changed and better options are now available. Doctors are still allowed to prescribe available medications "off label" for unapproved indications, but insurers may not cover them.
