# Oncologists respond swiftly to FDA safety alerts, study finds

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Within six months of the U.S. Food and Drug Administration's (FDA) move to restrict the label of two immunotherapies, usage of those therapies among oncologists dropped by about 50 percent, according to a new study from researchers in the Abramson Cancer Center at the University of Pennsylvania. The findings come as the world of cancer medicine grapples with the rapid pace of approval for new therapies, particularly as it relates to the FDA's accelerated approval (AA) program. Researchers say these findings offer reassurance that oncologists can be nimble enough to quickly incorporate the latest guidelines into their practices when new safety data comes to light. *JAMA* published the results today.

The FDA's AA program has come under significant scrutiny in recent months. Supporters say it can bring promising drugs into the clinic more quickly, which can benefit millions of patients. Critics say these drugs should not come to market before undergoing randomized phase III clinical trials, which is considered the gold standard in medical and drug development research.

"We felt it was important to evaluate what the data says about this program, and our findings show oncologists are quick to respond to emerging safety data for drugs approved through this process," said the study's senior author Ronac Mamtani, MD, MSCE, an assistant professor of Hematology-Oncology in the Perelman School of Medicine at the University of Pennsylvania.

The study examined usage rates of two immunotherapies approved for first-line use in advanced bladder cancer patients who are not eligible for standard cisplatin-based chemotherapy: the PD-1 inhibitor pembrolizumab and the PD-L1 inhibitor atezolizumab. The FDA approved both therapies in 2017 based on phase II studies. However, data from ongoing phase III studies showed patients had decreased survival when taking these drugs compared to undergoing first-line platinum-based chemotherapy. This led the FDA to restrict the label indications compared to the original approval. The restrictions went into effect in June 2018.

Using a de-identified data set from the Flatiron Health database, which is derived from the health records from more than 280 oncology clinics across the United States, Penn researchers initiated a study to examine the treatments for 1,965 patients with advanced bladder cancer. Between May 2018 and January 2019, the rate of immunotherapy usage among these patients decreased from 51.9 percent to 30.3 percent per 100 patients. The rate of chemotherapy usage increased from 37 percent to 60.6 percent per 100 patients. Rates of PD-L1 testing also increased from 9.3 percent to 21.2 percent per 100 patients.

"Given the rapid expansion of approvals for immunotherapies, understanding how oncologists react to post-approval safety concerns is crucial, and our study suggests uptake of these changing recommendations can occur very quickly," said the study's lead author Ravi B. Parikh, MD, MPP, an instructor in Medical Ethics and Health Policy at the University of Pennsylvania.

Blythe Adamson, Ph.D., senior qualitative scientist at Flatiron Health, is the study's co-lead author and Aaron Cohen, MD, MSCE, associate medical director of Flatiron Health, is the study's co-senior author.

While this study provides reassurances about the agility of oncologists, the researchers caution there are other factors that could be contributing to the trends they observed. They say further study is needed to continue to assess the effect of label changes on clinical practice.

Provided by Perelman School of Medicine at the University of Pennsylvania

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