FDA labeling restriction quickly reflected in oncology practice

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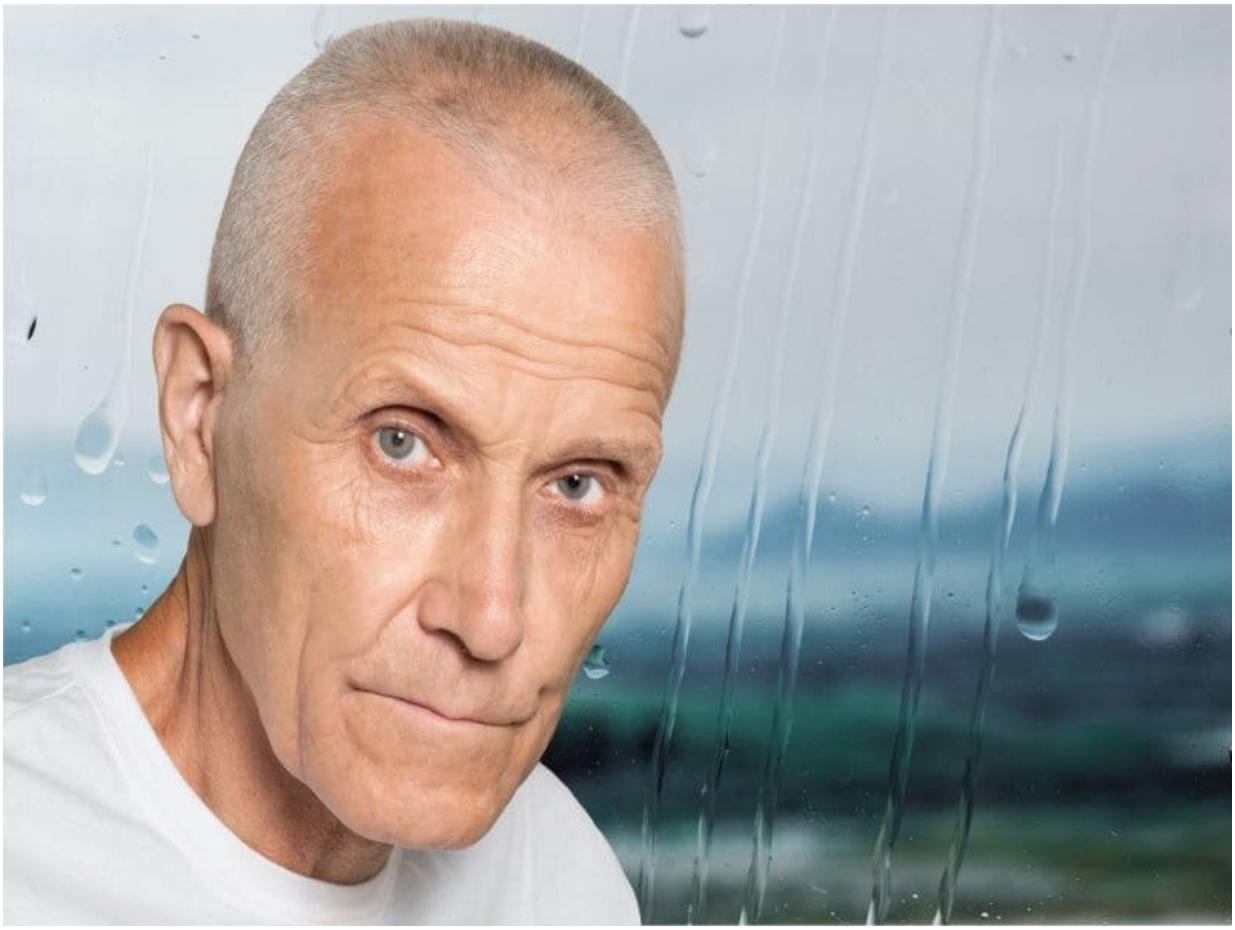

(HealthDay)—The June 2018 U.S. Food and Drug Administration label

restriction on first-line immunotherapy for advanced bladder cancer was associated with a decrease in immunotherapy use and an increase in chemotherapy use, according to a research letter published in the Sept. 24 issue of the *Journal of the American Medical Association*.

Ravi B. Parikh, M.D., from the Abramson Cancer Center at the University of Pennsylvania in Philadelphia, and colleagues used data from the Flatiron Health database to identify 1,965 patients diagnosed with advanced bladder cancer between Jan. 1, 2016, and Jan. 31, 2019, who were treated with at least one line of systemic therapy. Comparisons in utilization rates (first-line immunotherapies, cisplatin- or carboplatin-based chemotherapy) were made before and after the FDA's June 1, 2018, decision to limit the indication for the two antiprogrammed cell death protein/programmed death-ligand 1 (PD-L1) immunotherapies (pembrolizumab and atezolizumab) to cisplatin-ineligible patients with PD-L1-positive tumors.

The researchers found that the FDA label change was associated with reversals in immunotherapy and chemotherapy trends and increased PD-L1 testing. The unadjusted rate of immunotherapy use decreased from 51.9 to 30.3 per 100 patients from May 2018 through January 2019, while rates of chemotherapy use increased from 37.0 to 60.6 and PD-L1 testing increased from 9.3 to 21.2 per 100 patients. After adjusting for patient and practice factors, the FDA label change was associated with a 37.4 percent decrease in immunotherapy use, a 34.4 percent increase in chemotherapy use, and a 12.7 percent increase in PD-L1 testing.

"This study suggests that the FDA label changes were associated with changes in practice, even when the decision was based on emerging trial data," the authors write. "The effect of the FDA label change on clinical outcomes requires further study."

Several authors disclosed financial ties to pharmaceutical companies,

including Roche, which manufactures atezolizumab.

More information: Abstract/Full Text (subscription or payment may be required)