Research reveals widespread use of ineffective COVID-19 treatments after FDA deauthorized their use

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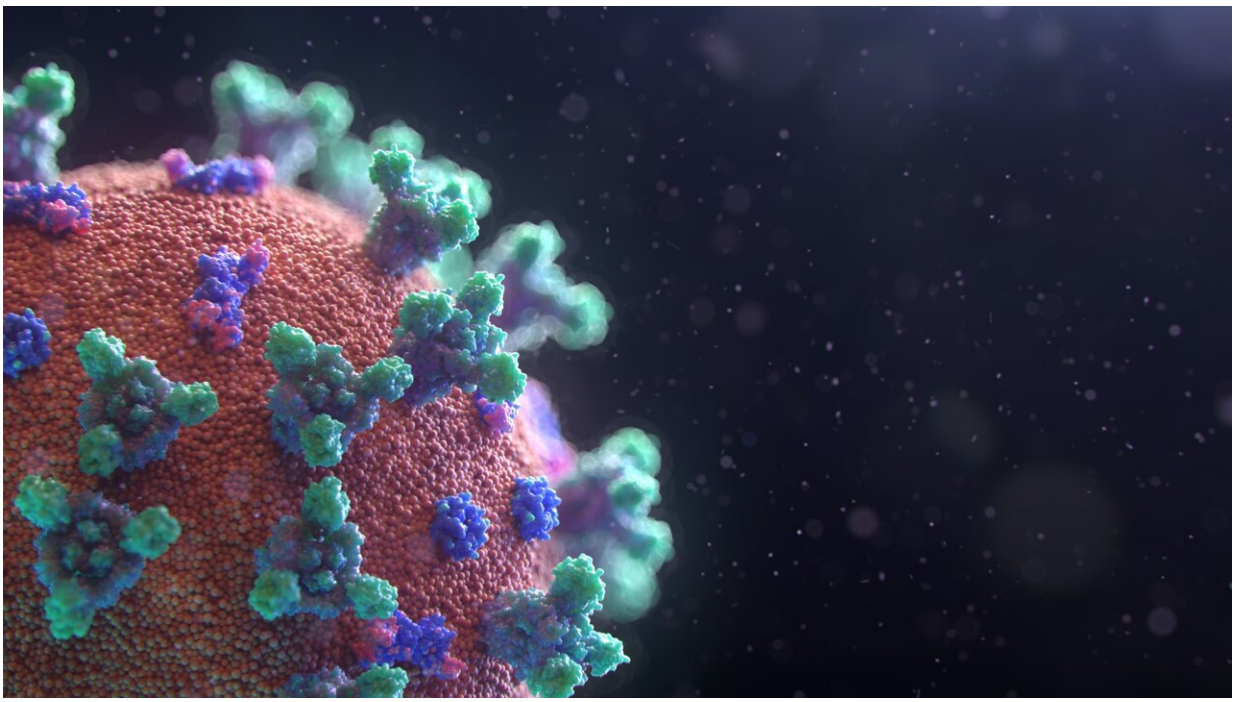

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Monoclonal antibodies are laboratory-designed treatments tailor-made to fight specific infections. In early 2021, the U.S. Food & Drug Administration issued emergency use authorization for two monoclonal antibodies (bamlanivimab/etesevimab and casirivimab/imdevimab) for

the treatment of mild to moderate COVID-19 in high-risk, non-hospitalized patients. However, these treatments were shown not to work against the omicron variant of COVID-19, which emerged in the United States in December 2021 and was responsible for a record-breaking COVID-19 surge in the winter of 2021–22. As a result of the monoclonal antibodies' reduced efficacy against the variant, the FDA deauthorized their use in early January 2022.

In a paper published in *JAMA Network Open*, physician-scientists at Beth Israel Deaconess Medical Center (BIDMC) assessed the use of these two monoclonal antibodies for patients with COVID-19 before and after FDA deauthorization. The team observed that though overall use of the two monoclonal antibodies declined gradually following deauthorization, a large number of doses were administered to patients well into 2022. Altogether, over 158,000 doses of monoclonal antibodies were administered, providing little to no benefit to patients and potentially contributing millions of dollars in costs. Whether the FDA will take regulatory action against those violating guidance remains unknown at this time.

"Continued use of these treatments represents low value care and may reflect conflicting state government guidance or a lack of hospital awareness of deauthorization," said lead author Timothy Anderson, MD, MAS, Lead for Improving Value in Healthcare at Center for Healthcare Delivery Science at BIDMC and assistant professor of medicine at Harvard Medical School. "Though the FDA clearly stated these treatments were no longer authorized for use, the FDA did not fully revoke their emergency use authorizations based on the possibility that they may work to treat future COVID-19 variants. This could have led to confusion and misinterpretation."

Anderson and colleagues examined mandatory public reporting by hospitals to the U.S. Department of Health and Human Services from

October 2021 to June 2022. They observed that in early 2022, hospitals administered more than 158,000 doses of the deauthorized monoclonal antibody treatments bamlanivimab/etesevimab and casirivimab/imdevimab. The researchers also saw wide variability by state in the treatments' use following deauthorization.

While use of the ineffective medications steadily declined after deauthorization, the proportion of COVID-19 cases for which the unauthorized treatments were used did not peak until late March. Moreover, usage following deauthorization varied widely by state, with Florida and New York accounting for 24% and 20% of monoclonal antibody use in 2022 respectively. Eleven states administered more than half of their remaining supply after deauthorization, while 14 states used less than 10% of their remaining supply.

"We believe these findings are quite surprising and indicate a need for the FDA to investigate the continued use of treatments found to not be effective for COVID-19," said senior author Jennifer Stevens, MD, director of the Center for Healthcare Delivery Science at BIDMC and associate professor of medicine at Harvard Medical School. "Efforts to improve transparency, equity and value in the COVID-19 response should include public facility-level reporting for all COVID-19 therapies. We hope that our findings will lead to greater attention and more diligent regulation by health care providers and government agencies to prohibit the use of unauthorized treatments."

More information: Administration of Anti–SARS-CoV-2 Monoclonal Antibodies After US Food and Drug Administration Deauthorization, *JAMA Network Open* (2022). DOI: 10.1001/jamanetworkopen.2022.28997

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