FDA Response

The FDA stands firmly behind the safety and effectiveness of the mRNA COVID-19 vaccines, which are fully supported by the available scientific data. Staying up to date on vaccination is the best way to reduce the risks of death and serious illness or hospitalization from COVID-19.

To date, the systems in place to monitor the safety of the COVID-19 vaccines authorized or approved for use in the U.S. have identified several health problems potentially associated with vaccination. These include, myocarditis and pericarditis following the Pfizer-BioNTech, Moderna, and Novavax COVID-19 vaccines. The chance of having this occur is very low. As soon as the FDA became aware of the risks of myocarditis and pericarditis and determined that there was reasonable evidence of a causal association with the mRNA COVID-19 vaccines, a Warning was included in the Fact Sheets. As additional post-marketing data accrue over time, the FDA continues to evaluate the data and assess the robustness and the quality of the data to determine whether updates to the labeling are warranted. Over time, based on the data that have accrued, the Warning in the Fact Sheets has been updated to strengthen it and to include language to convey information about risk factors (i.e., risk information based on age and sex). This information remains posted on the FDA website in the current Fact Sheets and in package inserts for these vaccines. Additionally, both FDA and CDC have provided updates on ongoing studies at public meetings.

Additional Background:

The FDA requires vaccination providers to report cases of myocarditis and pericarditis to the Vaccine Adverse Event Reporting System (VAERS). The Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers) for both mRNA vaccines include information on post-authorization experience, including information in the Warning section pertaining to respective risks that have been identified. The Fact Sheets for Recipients and Caregivers have also been revised to include information about safety obtained from post-authorization safety surveillance. These resources are available on the FDA's website here.

The FDA's decisions about the classification of an adverse event from spontaneous reports are typically based on one or more of the following factors: seriousness of the event, number of reports, or strength of causal relationship to the drug/vaccine. Decisions on whether there is some basis to believe there is a causal relationship are a matter of medical and scientific judgment and are based on factors such as: the frequency of reporting, biological plausibility, the timing of the event relative to the time of vaccination, and whether the adverse event is known to be caused by related vaccines. When safety signals have been detected, the FDA has been transparent, and will continue to do so.