Worst Pills, Best Pills News
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FROM THE EDITOR Michael Carome, M.D. • Director, Health Research Group

Our Current Views on the First Two FDA-Authorized COVID-19 Vaccines

On Dec. 11, 2020, the Food and Drug Administration (FDA) granted an emergency use authorization (EUA) for the COVID-19 vaccine developed by Pfizer and BioNTech for individuals aged 16 and older. One week later, the agency granted an EUA for a COVID-19 vaccine developed by Moderna and the National Institutes of Health (NIH) for adults aged 18 and older. Soon thereafter, we began receiving inquiries from our readers asking for our opinion about these vaccines.

Given the calamitous number of COVID-19 cases, hospitalizations and deaths and based on our review

of the interim safety and effectiveness data regarding the Pfizer-BioNTech and Moderna-NIH vaccines that were made public in December, we concluded that the benefits of both vaccines outweigh their risks. We therefore agreed with the agency's decisions to grant EUAs for these vaccines.

Both the Pfizer-BioNTech and the Moderna-NIH COVID-19 vaccines — each administered in two doses separated by three and four weeks, respectively — were tested in large, well-designed, placebo-controlled clinical trials. The trial for the former vaccine enrolled approximately 44,000 subjects and for the latter about 30,400 subjects, with half of the subjects in each trial receiving the active vaccine and the other half a placebo. These trials are ongoing and will follow subjects for up to two years.

Both vaccines were found to be remarkably effective in preventing COVID-19: 95% for the Pfizer-BioNTech vaccine and 94% for the Moderna-NIH vaccine, levels that far exceeded the FDA's threshold of 50% effectiveness for a COVID-19 vaccine to qualify for an EUA. Importantly, the effectiveness of the vaccines was similar across age groups, genders, and racial and ethnic groups. Both vaccines also appear to be highly effective in preventing severe COVID-19.

From a safety perspective, both vaccines caused generally short-term adverse effects, such as pain, redness and swelling at the injection site and fatigue, headaches, muscle and joint pains, fever, and chills. Adverse effects were more common after the second vaccine dose. There have been rare cases of a severe allergic reaction known as anaphylaxis reported in recipients of the Pfizer-BioNTech vaccine. Further long-term safety data needs to be collected, but we concluded that the available safety data was sufficient to justify emergency use of these vaccines.

Although there remain important unanswered questions — such as how long the effectiveness of the vaccines lasts and whether they cause yet unidentified rare serious adverse effects — we encourage readers eligible to receive these vaccines under the EUAs to get vaccinated when they become available. Importantly, until we know more about the effectiveness of these vaccines, vaccinated individuals should continue to wear face masks and follow social-distancing guidelines to contain the pandemic.