Full FDA approval of Pfizer vaccine is milestone in pandemic fight

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Full FDA approval of the Pfizer-BioNTech coronavirus vaccine for those age 16 and older is a milestone in our long battle against COVID-19, one that holds the promise of finally ending this pandemic by removing any doubt about this vaccine’s safety and effectiveness.

Although the three widely available vaccines for COVID-19 have been shown safe and highly effective through intense study and research, the FDA’s announcement Monday should instill confidence in those who, until now, have been wary of the emergency use designation given to these vaccines. The message could not be more clear: This vaccine is safe and highly effective in preventing severe illness, hospitalization and death due to COVID-19.

With full FDA approval and licensing, AMA policy supports the use of vaccine mandates by public and private sector employers and other organizations for the populations recommended to receive the vaccine by the Advisory Committee on Immunization Practices.

Approximately 100 million Americans already enjoy the protection conveyed by this vaccine, which will now be branded and marketed as Comirnaty. The FDA’s action confirms what we already knew about its safety and efficacy, while providing additional assurance that the manufacturing process, protocols and facilities used to produce it meet strict quality standards.

Full FDA approval and licensing of Comirnaty is a welcome culmination of months of intense scrutiny and data evaluation comprising a review process that has earned our trust. No corners have been cut nor any other action taken outside the parameters of a thorough licensing review process, with a six-month follow-up period of a clinical trial that enrolled 44,000 people.

The FDA’s priority review and positive licensing decision of Comirnaty reinforces the overwhelming science that physicians and the medical community see in its safety and effectiveness and its ability to protect us against severe illness and death from COVID-19. After all, physicians and other health
care professionals were among the very first to receive COVID-19 vaccinations, and since then have strongly urged others to take the same action as our best shot to end the pandemic.

If you remain unvaccinated, the time to act is now. The delta variant of COVID-19 continues to inflict severe illness and death upon many Americans, mostly unvaccinated populations, because of its high transmissibility and virulence. We can expect additional mutations until vaccinations help end the spread of this virus. Vaccination can save your life and the lives of those you love.

Science has given use the means to bring COVID-19 to its knees. It is up to each of us to take advantage of the most important tools yet offered to us—vaccination—in the best interests of ourselves, our communities and our nation.