Marking the End of an Era: The COVID-19 Vaccine Market Goes Commercial

Healthcare Business Today

February 13, 2023 | Publications

Richard H. Hughes, IV, Strategic Advisor with EBG Advisors and Member of the Firm at Epstein Becker Green, and **William (Will) Walters,** Associate at Epstein Becker Green, co-authored an article in *Healthcare Business Today,* titled "Marking the End of an Era: The COVID-19 Vaccine Market Goes Commercial."

Following is an excerpt:

The federal government has acted as the sole purchaser of all COVID-19 vaccines since the vaccines received Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) in 2020, supplanting the existing system of vaccine coverage and finance to assure access for every American. That role is ending, the Biden Administration is terminating the Public Health Emergency in May, and COVID-19 vaccines will inevitably transition to a traditional public-private marketplace or "commercial market" beginning with the 2023-2024 respiratory season.

As recently indicated, commercialization could begin as early as this summer, with the timing being driven by factors that include the federal government's existing supply of vaccines and the demand for those vaccines as the 2022-2023 respiratory season subsides, as well as increasing political disinterest and opposition to additional vaccine purchase.

U.S. COVID-19 Vaccine Supply and Demand

Today, the market predominantly consists of bivalent vaccines, which protect against both the original SARS-CoV-2 strain and the omicron variant and were authorized August 31, 2022 by the U.S. Food & Drug Administration (FDA). The FDA no longer authorizes

People

Richard H. Hughes IV
Strategic Advisor
Life Sciences
202-861-1893
RHHughes@ebglaw.com

Focus Areas

Services

Pharmacy & Drug Pricing

the monovalent mRNA COVID-19 vaccines as booster doses for individuals 12 years of age and older. The federal government's supply will therefore depend upon its supply of the more recently developed and purchased bivalent COVID-19 vaccines. The federal government list price procured more than 170 million bivalent booster doses for the 2022-2023 respiratory season.

COVID-19 vaccine demand has declined significantly over the course of the pandemic. While over 200 million Americans completed the initial two-dose series of the monovalent vaccine, less than 50 million have received the bivalent booster vaccine. Consequently, approximately 120 million publicly purchased bivalent booster doses remain unused. The original monovalent vaccines remain FDA-authorized for administration as a primary series for individuals 6 months of age and older through age 11. The government's remaining supply of monovalent vaccine product is less clear than that of bivalent.

Despite a particularly severe season of respiratory disease and the emergence of new variants of concern, political resistance is likely to suppress further government purchase. The Biden Administration's decision to reallocate existing funds for bivalent booster purchase drew political pushback last year. This is likely to dissuade the administration from seeking additional bulk purchase with the exception of supporting the CDC's limited purchase of doses through the Section 317 and Vaccines for Children (VFC) programs. Congress has not shown a willingness to replenish funding for COVID-19 vaccines and that is unlikely to change.

The government's role as the sole, monopsony purchaser of COVID-19 vaccines, therefore, has likely ended. The current government supply of bivalent boosters is unlikely to be depleted prior to the 2023-2024 respiratory season. Purchase of the next iteration of the COVID-19 vaccine as the season begins is most likely to occur through traditional routine vaccine purchase channels, both public and private.