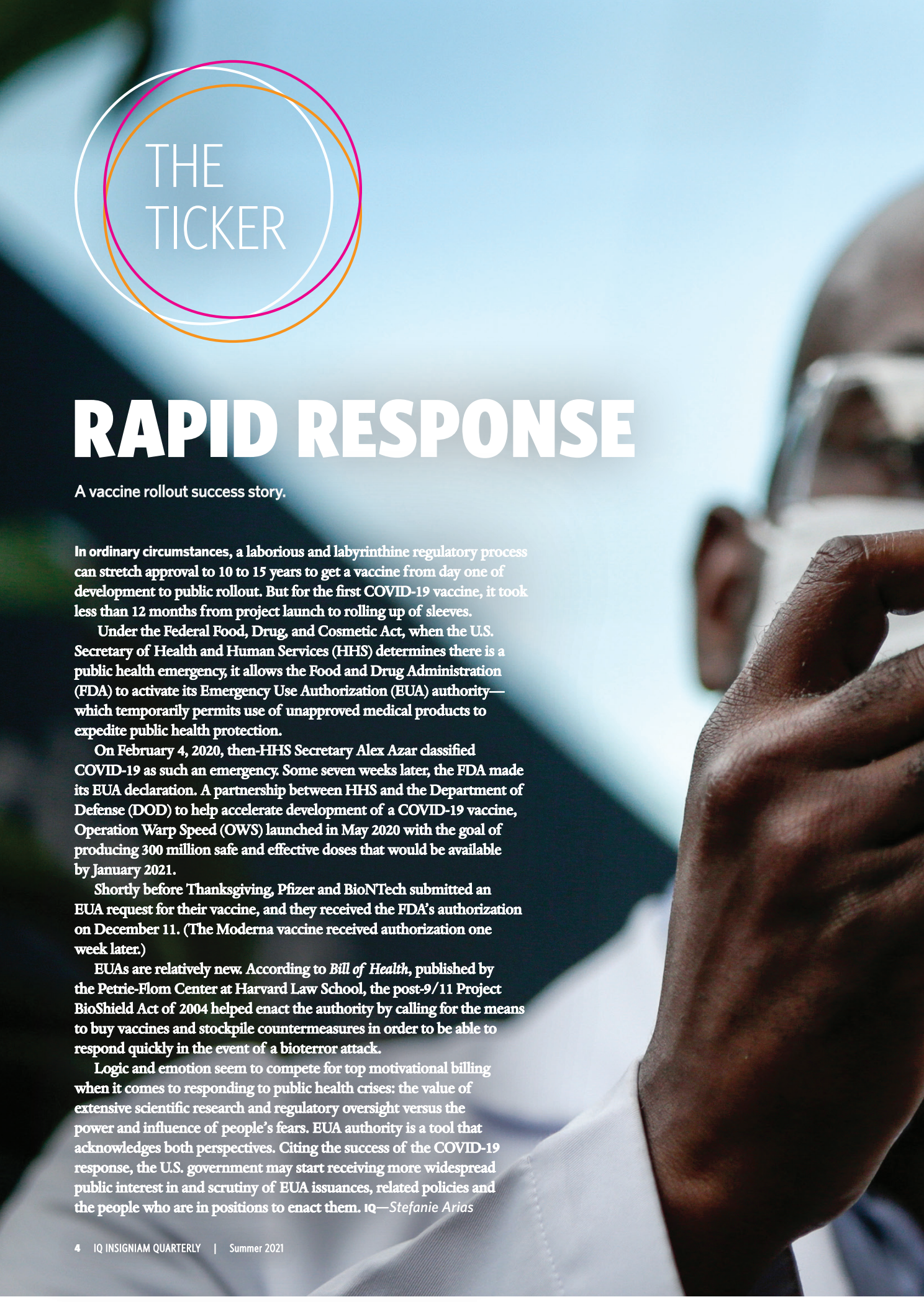

THE TICKER

RAPID RESPONSE

A vaccine rollout success story.

In ordinary circumstances, a laborious and labyrinthine regulatory process can stretch approval to 10 to 15 years to get a vaccine from day one of development to public rollout. But for the first COVID-19 vaccine, it took less than 12 months from project launch to rolling up of sleeves.

Under the Federal Food, Drug, and Cosmetic Act, when the U.S. Secretary of Health and Human Services (HHS) determines there is a public health emergency, it allows the Food and Drug Administration (FDA) to activate its Emergency Use Authorization (EUA) authority—which temporarily permits use of unapproved medical products to expedite public health protection.

On February 4, 2020, then-HHS Secretary Alex Azar classified COVID-19 as such an emergency. Some seven weeks later, the FDA made its EUA declaration. A partnership between HHS and the Department of Defense (DOD) to help accelerate development of a COVID-19 vaccine, Operation Warp Speed (OWS) launched in May 2020 with the goal of producing 300 million safe and effective doses that would be available by January 2021.

Shortly before Thanksgiving, Pfizer and BioNTech submitted an EUA request for their vaccine, and they received the FDA's authorization on December 11. (The Moderna vaccine received authorization one week later.)

EUAs are relatively new. According to *Bill of Health*, published by the Petrie-Flom Center at Harvard Law School, the post-9/11 Project BioShield Act of 2004 helped enact the authority by calling for the means to buy vaccines and stockpile countermeasures in order to be able to respond quickly in the event of a bioterror attack.

Logic and emotion seem to compete for top motivational billing when it comes to responding to public health crises: the value of extensive scientific research and regulatory oversight versus the power and influence of people's fears. EUA authority is a tool that acknowledges both perspectives. Citing the success of the COVID-19 response, the U.S. government may start receiving more widespread public interest in and scrutiny of EUA issuances, related policies and the people who are in positions to enact them. IQ—*Stefanie Arias*

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300M

Initial production goal of safe, effective doses of the COVID-19 vaccine that would be available some eight months after launch of OWS.