II.

I will first consider plaintiffs' APA claims against the FDA[3] and DOD. In plaintiffs' view, those entities acted unlawfully—the FDA by approving the vaccines, and the DOD by mandating their use. Before turning to those claims, though, it is helpful to cover some relevant background.

The parties do not agree on all the facts, but neither side requested an evidentiary hearing. Regardless, many of the pertinent facts are essentially undisputed.

Pfizer developed a COVID-19 vaccine, for which the FDA issued an Emergency Use Authorization ("EUA"). This allowed Pfizer to distribute the vaccine starting in December 2020. ECF No. 1-6 at 2-3. An EUA is not a full FDA license. It instead represents the FDA's conclusion that a product may be effective against a disease in a public health emergency where there is no "adequate, approved, and available alternative." *See generally* 21 U.S.C. § 360bbb-3(a)-(c). EUA drugs must include labeling and package inserts telling patients "of the option to accept or refuse administration of the product." *Id.* § 360bbb-3(e)(1)(A)(ii)(III).

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[3] The plaintiffs also include a claim against the Secretary of the Department of Health and Human Services. ECF No. 3-2 at 14; *see also* ECF No. 1. But it is unclear why HHS is an appropriate party. The FDA is part of HHS, but an order against HHS is not necessary to effect the relief plaintiffs seek against the FDA.