Patterson Belknap Webb & Tyler LLP

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FDA Releases COVID-19 Vaccine Guidance for Industry

On June 30, 2020 the U.S. Food and Drug Administration's Center for Biologics Evaluation and Research released its first "Guidance for Industry" document for the development and licensure of COVID-19 vaccines. The full text of the Guidance is available here. While the procedures and recommendations set forth in the Guidance are nonbinding and subject to change, the document nevertheless provides interested stakeholders with a comprehensive overview of FDA's current thinking on what benchmarks will need to be met before a COVID-19 vaccine is approved for widespread use.

To that end, the Guidance sets forth specific considerations related to the formulation, manufacturing, and testing of potential vaccine candidates, including requirements related to both pre-clinical and post-clinical studies in laboratory, animal, and human population settings. However, recognizing the importance of getting a safe and effective vaccine to market quickly, the Guidance also contains specific provisions allowing certain study phases to be conducted in parallel (as opposed to serially, as would be common in ordinary vaccine development) and incremental approvals to be granted based on data from prior studies.

Similarly, acknowledging the disparate impact of COVID-19 on certain populations, the limitations of traditional vaccine development programs (which tend to focus on healthy adults in the first instance), and the need for a vaccine to be widely available upon launch, the Guidance also encourages that vaccine developers design studies from the outset to be broadly inclusive to "ensure that vaccines are safe and effective for everyone in the indicated populations." This includes recommendations that developers include people "most affected by COVID-19, specifically racial and ethnic minorities," "elderly individuals and individuals with medical comorbidities," and even pregnant women and children in studies.

That said, the Guidance does not depart from traditional best practices in vaccine development insofar as recommending that "later phase trials, including efficacy trials, should be randomized, double-blinded and placebo controlled" wherever ethically appropriate, and that study participants continue to be followed over time. And while the Guidance contemplates that several vaccines may be provisionally approved pursuant to FDA's power to issue Emergency Use Authorization on a case-by-case basis, it also indicates that further approval eventually will still be required, along with the possibility of mandatory postmarketing safety studies.

Notably, citing the exigency of the pending COVID-19 crisis and the power vested in it by the Secretary of Health and Human Services's January 31, 2020 declaration of a public health emergency, FDA released this guidance without first opening it to public comment, which would otherwise be required. As a result, the Guidance makes clear that it remains subject to comment, and will be revised and replaced within 60 days after the public health emergency subsides.

While this Guidance in no way represents FDA's last word on the requirements that any COVID-19 vaccine must meet before it can be made available in the United States, it does provide vaccine developers with a comprehensive roadmap of the approval process they will face in the coming months as the race to bring a safe and effective vaccine to market continues.

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