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Blog Post

COVID-19 and Possible Silver Bullets: Update on Vaccine Development

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By Robert E. Slavkin

As the world continues to grapple with the COVID-19 pandemic that has taken the lives of over 250,000 Americans, and worldwide over 1 million people, this year, an effective vaccine has emerged as our silver bullet – a way for the nation, and the world, to fight back and, in time, begin to return to some semblance of normalcy. There is some encouraging news on that front, as there are two promising separate clinical trials that have produced potentially viable vaccine candidates in the pipeline for potential emergency approval by the US Food and Drug Administration (FDA), with others possibly coming soon as well.

Clinical Trials – The Latest

Pfizer, and its partner, BioNTech, a German biotech company, announced that the data from phase three of its clinical trial shows their developed vaccine to have an effective rate of approximately 95 percent. For a vaccine to earn FDA approval, generally, a minimum threshold of 50 percent effectiveness is generally sought. By way of comparison, an annual flu vaccine is 40-60 percent effective, and a dual dose of a Measles vaccine is 97 percent effective. The numbers reported by Pfizer, therefore, are encouraging. Pfizer plans to submit an application to the FDA for emergency use authorization (EUA) on November 20, 2020.

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Separately, Moderna, an American biotechnology company based in Cambridge, MA, announced this week that early data from its phase three trial shows an efficacy rate of 94.5 percent, also encouraging and significantly above the FDA baseline for consideration for approval.

Both vaccines were developed using a new technology called messenger RNA, or mRNA. Because it is a new method of vaccine development, there may be questions raised by both the FDA and the CDC regarding safety.

What's Next – The EUA Approval Process

Normally a vaccine's development and approval takes years. To have a potentially viable vaccine available in less than a year's time is unprecedented. In this case, the Vaccines and Related Biological Products Advisory Committee, a group of independent advisors to the FDA comprised of independent experts and a consumer representative, will be the first to review an EUA application. This committee may have additional follow-up questions, including possible concerns about the mRNA process. If the committee ultimately votes to approve the vaccine, then the FDA considers whether to accept the committee's guidance.

Then, the Advisory Committee on Immunization Practices, an advisory committee for the CDC, will make recommendations as to which groups would be initially eligible to receive the vaccine, with the CDC's priority likely going first to front line health professionals, then to the elderly and immunosuppressed, and then to the general public.

Challenges Ahead

Keep in mind that the process that is outlined above is if all reviews go smoothly. Once the vaccine is approved, the manufacturers have to make the doses in large quantities, so the best-case scenario is that a vaccine is available to the general public in the spring of 2021, at the earliest. Another concern is

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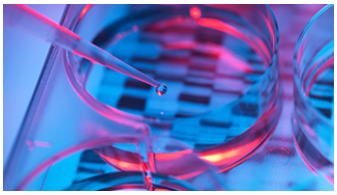

that at least one of the promising vaccines must be stored at a temperature of nearly -100 degrees Fahrenheit, presenting a significant logistical challenge for providers. While the vaccine trial results present promising news for all of us, the challenges ahead, both in regulatory approval and in the logistical hurdles of delivering the vaccine to patients' arms worldwide, present the next set of challenges to overcome. We will keep you apprised of developments as they roll out.
