Testimony Before FDA's Vaccines and Related Biological Products Advisory Committee

Development, authorization and licensure of vaccines to prevent COVID-19

October 22, 2010

Sidney Wolfe, MD
Health Research Group of Public Citizen

I have no financial conflicts of interest.

Still inadequate new requirements for a vaccine EUA.

The EUA efficacy standard is now a *potentially* 50% or greater significant reduction in COVID-19 in vaccinated compared to placebo cases, *potentially* just as it is for vaccine approval. Similarly, EUA standards for chemistry, manufacturing and controls are now practically the same as those required for approval.

But how much longer, after the current inadequate EUA requirements would be fulfilled, would it take to complete the all-important phase 3 trials and for FDA and your advisory committee to review all the data?

Currently Allowable Serious EUA Vaccine Deficiencies

---Based on incomplete Phase 3 Trials---

- **EUA approval could occur when up to half of the participants in phase 3 trials could have been followed for less than two months after completion of full vaccination regimen (a safety and efficacy problem).**
- **Safety data would include over 3,000 vaccine recipients [out of 15,000 to 30,000 in various trials] followed for serious adverse events (SAEs) and adverse events of special interest for just one month or more after completion of the full vaccination regimen.**
- **Completed phase 1 and 2 data [probably on no more than a few hundred people] would complement the available data from safety follow-up from ongoing Phase 3 studies because it would be of a longer duration than safety data available from incomplete Phase 3 trials at the time of EUA request submission.**

EUA: Benefit and Risks of Using Unfinished Phase 3 Data

Benefit:

Faster availability of vaccine, depending on time to finish Phase 3 studies

Risks:

- **Incomplete safety and efficacy data because large Phase 3 studies have not been finished and reviewed by FDA and your committee.**
- **Recent U.S. polls have found waning public confidence in a COVID-19 vaccine.**

The "logic" of saving time by a faster but riskier data-deficient EUA pathway will surely be outweighed by the loss in public confidence in an incompletely tested, unapproved EUA vaccine, accompanied by decreased willingness to be vaccinated.

Question for Advisory Committee and FDA

- **Based on incomplete Phase 3 trials, will your advisory committee have enough confidence, despite all this missing data, to recommend authorizing—via an EUA—a vaccine for use in tens of millions of people?**
- **The gap between completed Phase 3 trials needed for approval and the current EUA standard allowing half of phase 3 trial participants to be followed for less than two months after completion of full vaccination regimen does not engender confidence.**