How to Be Prepared: Preserve Operation Warp Speed's Successes at the FDA

What did the FDA do differently during Operation Warp Speed?

Around-the-clock, **unsustainable** pace. CBER worked around the clock, maximizing the efficiency of already existing processes (such as priority review and rolling review). While admirable of those staff, maintaining such a pace long-term is **unsustainable** and unsafe, meaning CBER needs more resources.

Streamlined clinical trials. The FDA preserved the necessary safety protocols but accelerated approval of human testing and studies in Phases II and III began before Phase I results were complete. This timeline needs to become the norm for products critical to national security.

Frequent communications. During OWS – COVID-19 vaccine applicants had constant contact with FDA staff, were able to arrange ad-hoc meetings as needed, and would receive immediate responses. This atypical, collaborative communication needs to become the norm.

Clearer published guidance. CBER published guidance with greater clarity and incorporated standardized clinical endpoints, thereby enabling easier assessment and comparison of different vaccines. Such guidance needs to become the norm to help reduce compliance burdens.

Why is the Emerging Pathogens Preparedness Program (EPPP) needed?

Q: The FDA's OCET already exists; why do we also need a program within CBER?

A: **CBER's and OCET's functions within FDA are very different:**

- OCET develops FDA policy, providing leadership and guidance to coordinate and prioritize the FDA's work on terrorism, emerging threats, and disasters.
  - OCET was not even involved in OWS because its purpose is not to review vaccine candidates - meaning the lack of such a dedicated team in FDA must be addressed.
- CBER actually reviews biological products - making CBER the appropriate center for such a dedicated team through EPPP.
- OCET would continue to assist with policy, while EPPP in CBER would ensure the FDA had sufficient personnel dedicated to reviewing biological products developed for pandemic preparedness.

Q: Can't CBER's existing team do this work? Do we really need to increase personnel?

A: As noted above, to provide the transparency and communication that were crucial to the successes of OWS, the team had to work **around the clock** – an **unsustainable pace**.

- Currently, CBER has **only two** experts, knowledgeable about Emergency Use Authorizations (EUA).
- CBER needs a dedicated team of people who are experts regarding pandemic preparedness.
- With additional resources, CBER would:
  - have more needed experts already on the team,
  - be more prepared and more sustainably address needs when the next pandemic **does** hit, and
  - be able to more sustainably address the needs of the next crisis.

Q: What value would EPPP add to related work currently underway at FDA?

A:

- EPPP would also allow CBER to have more focus on other priorities **besides** pandemic needs, even during a future pandemic.
- EPPP would increase CBER's capacity, enabling it to streamline existing work and ensure we are prepared for the next threat sooner.