EUA of Vaccines

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U.S. Candidates – October 2021

- mRNA
  - BNT162b2 (Pfizer-BioNTech) – EUA granted Dec 11, 2020
    - Licensure for individuals 16 years of age and up granted to COMIRNATY on August 23, 2021
  - mRNA-1273 (Moderna) – EUA granted Dec 18, 2020

- Non-Replicating Viral Vector
  - Ad26.COV2.S (Janssen) – EUA granted Feb 27, 2021
  - ChAdOx1 (Astra Zeneca-Oxford)

- Protein Subunit
  - NVX-CoV2373 (Novavax)
  - MRT5500 (Sanofi-Translate Bio)

Biologics License Application (BLA)

- Biologics are licensed under section 351 of the Public Health Service Act
- Product must be safe, pure, potent
- FDA considers evidence from adequate and well-controlled clinical trials

Emergency Use Authorization (EUA)

- Put in place after 9/11 to ensure that potentially lifesaving medical products could be available to people in medical need when there is not an approved and available alternative

- The standard used is that the product “may be effective” and its “known and potential benefits outweigh the known and potential risks”

EUA for a COVID-19 Vaccine

- FDA based authorization on clear and compelling efficacy in large well-designed phase 3 clinical trials
- Careful evaluation of quality, safety, efficacy
- Public advisory committee meeting
- Enhanced post-deployment surveillance

EUA in Public Health Emergencies

- Adaptability
  - Can appropriately apply to different product classes
- Flexibility
  - Can adapt to the specific nature of the threat
- Agility
  - Changes can be made rapidly as data emerge


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