Assessing COVID-19 Emergency Use Authorizations

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Outline of Presentation

1. The EUA Mechanism
2. COVID-19 EUAs: Drugs, Biologics, Devices
3. Recalibrating the EUA Framework
4. Special Considerations for Vaccines

The EUA Mechanism

Created Amidst Legal Challenges to Anthrax Vaccine

Lowers Regulatory Bar to Market

Broad Legal Shields via PREP Act

COVID-19 EUAs: Drugs and Biologics

Chloroquine phosphate (CQ); Hydroxychloroquine sulfate (HCQ)

Remdesivir

Covid-19 convalescent plasma

Bamlanivimab

COVID-19 EUAs: Medical Devices

In vitro diagnostic tests

- Initial test authorized February 4, 2020
- By March 17-23, 2020; dozen more tests
- Over next two weeks; ten more tests
- By May 1, 2020; over 50 additional tests

PPE: respirators, decontamination systems, face shields, surgical masks

Ventilators and other moderate-to-high risk devices

Recalibrating the EUA Framework

Create a guiding regulatory philosophy

Balance early access with ongoing need for research

More exacting pre-market review

Risk-based framework for device EUAs

Devise and conduct robust post-EUA surveillance

Build and maintain trust

Special Considerations for Vaccines

Require Public Disclosure of Data on Study Endpoints

- Reduction in asymptomatic, mild, moderate, and severe cases
- Reduction in hospitalization and admission to intensive care
- Reduction in death
- How long does vaccine-induced immunity last
- Stratify by risk factors and subpopulations
- Identify number and rate of adverse events

Set Clear Guidelines for Vaccination of Children

Require robust post-market safety and effectiveness review

Thank you

comments welcome

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