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The Secretary's Advisory Committee on Infant Mortality Meeting
1-25-2021

Objectives

Discuss FDA efforts to collect data in COVID-19 therapeutics and vaccines in pregnant people and children

Disclaimer

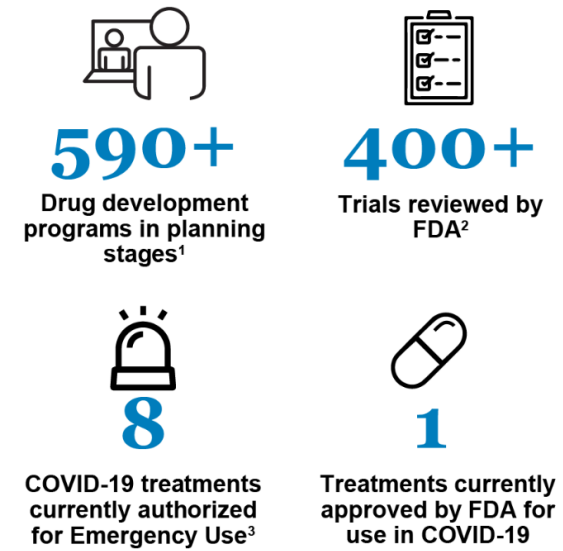
- I do not have any financial disclosures to report
- This presentation represents the views of the speaker, and not the official position of the FDA

FDA's Pregnancy Related Activities

- Committed to advancing research in pregnant and lactating people
  - Data necessary to inform labeling
  - FDA-NICHD Workshop on COVID-19 and pregnancy (9-2020)
  - Recent guidance publications
- Participant in Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)
  - Required under the 21st Century Cures Act of 2016
  - Objectives: Identify and address gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women
  - Prepared a report and recommendations to the Secretary of the Department of Health and Human Services (completed 9-2018 and 10-2020)

FDA Coronavirus Treatment Acceleration Program

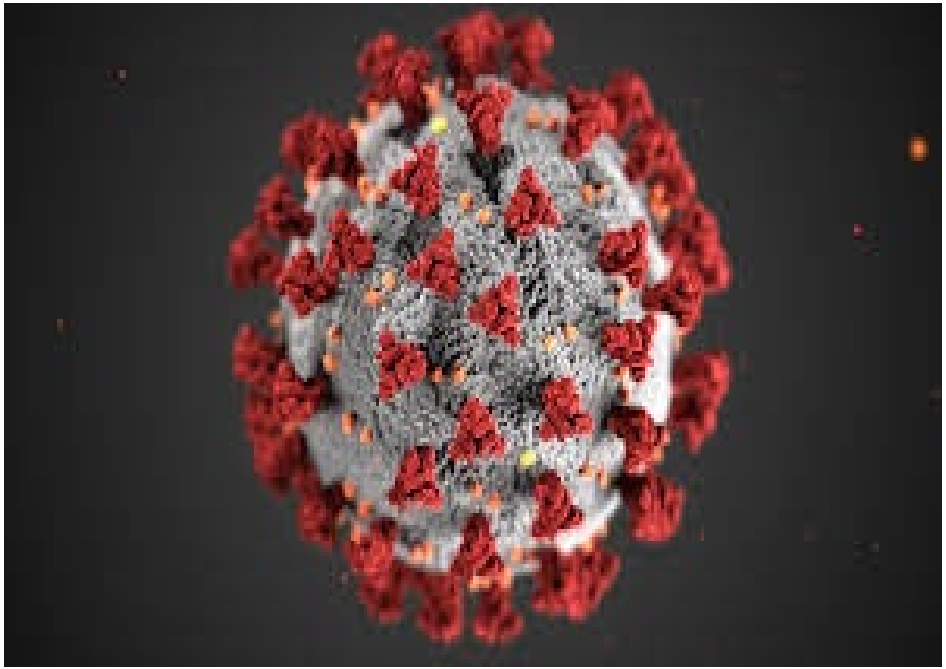
- Immediate triage of requests from developers and scientists seeking to develop or evaluate new drug and biologic therapies
  - Identify appropriate FDA staff
  - FDA will generally respond within a day
- Provide ultra-rapid, interactive input on most development plans--within 24 hours of submission, in some cases
- Complete review of single patient expanded access requests around-the-clock – and generally within 3 hours.
- Work closely with applicants and other regulatory agencies to expedite quality assessments for products to treat COVID-19 patients
  - Transfer manufacturing to alternative or new sites to avoid supply disruption



Data as of 12-31-2020

[1] Active Pre-INDs (excluding vaccines)
[2] safe to proceed INDs (excluding vaccines)
[3] includes 1 EUA authorizing both medical devices and drug for emergency use

COVID-19: FDA Response



- FDA has provided rapid and wide-ranging response to COVID-19
- Advancing development of vaccines, therapies, diagnostics tests, medical devices
- Monitor human and animal food supply
- Swift actions against fraudulent COVID-19 products
- Participating in Operation Warp Speed: HHS Agency partnership to accelerate development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics

COVID-19: FDA Guidances

- FDA has published 70 guidances since March 2020 related to COVID-19
- Selected Guidances:
  - COVID-19: Developing Drugs and Biological Products for Treatment or Prevention – Guidance for Industry
  - Development and Licensure of Vaccines to Prevent COVID-19
  - Investigational COVID-19 Convalescent Plasma – Guidance for Industry
  - FDA Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Public Health Emergency

Available at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders

COVID-19: Developing Drugs and Biological Products for Treatment or Prevention

- Final Guidance published May 11, 2020
- FDA encourages the enrollment of pregnant and lactating individuals in the phase 3 (efficacy) clinical trials if appropriate
- Children should not be categorically excluded from clinical trials of investigational COVID-19 products in which there is a prospect for direct benefit

COVID-19: Vaccine Guidance

- Final Guidance published June, 2020
- FDA recommends the early conduct of developmental and reproductive toxicology (DART) studies to allow pregnant women to enroll in clinical trials
- Important to plan for pediatric assessment of safety and effectiveness

COVID-19: FDA Sentinel Study

- Master protocol includes various cohorts, to address regulatory questions
- Safety of therapeutics used in pregnancy and pediatrics
- International collaboration related to pregnancy with other regulatory agencies (International Coalition of Medicines Regulatory Authorities (ICMRA))

VIRTUAL

Scientific and Ethical Considerations for the Inclusion of Pregnant Women in Clinical Trials; Public Meeting

FEBRUARY 2 - 3, 2021

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- Meeting Information

Date: February 2 - 3, 2021

Time: 12:00 PM - 3:00 PM ET

Thank You