BACKGROUND

February 4: In-Effect Emergency Use Authorization (EUA)
March 31: Coronavirus Treatment Acceleration Program (CTAP) Established
April 17: Accelerating COVID-19 Therapeutic Inteventions and Vaccines Partnerships (ACTIV) Launched
May 11: EUA Guidance Updated
July 8: COVID-19 Prevention Trials Network (COVPN) Launched
July 12: 9% of 41 million COVID-19 tests in the United States (US) were positive
Today: US, which comprises 4% of world population, has 27.9M cases (~25% of global cases)

OBJECTIVE

To investigate the effectiveness of current federal guidance towards accelerating availability and development of COVID-19 testings and therapeutics

METHODOLOGY

1. General Overview of Assessing FDA Authorizations and Clinical Data
   - FDA Authorizations & Clinical Trials

   - Diagnostic Testings
     - Accuracy Parameters (sensitivity, specificity, percentages of false-positive/negative results)

   - Treatments
     - Treatment Types: antivirals, cell & gene therapies, immunomodulators, neutralizing antibodies

2. Examination of FDA Documents for Diagnostic Testings and Treatments

   1. Comprehensive review of FDA guidelines before and after COVID-19
   2. Compile list of authorizations and recalls/withdrawals for COVID-19 developments from FDA Database
   3. Compare clinical data from clinicaltrials.gov with approval rates for diagnostic testing and treatment applications
   4. Assess and compare successful approvals versus unsuccessful approvals

RESULTS: DIAGNOSTIC TESTINGS

- The regulatory structure for the issuance of EUAs aimed to expedite the availability of diagnostics through the use of independent verification.
- This allowed for laboratories to develop and begin diagnostics before the FDA has completed review of the authorized test and its performance data, resulting in a 31.9% revocation rate of EUAs that significantly underperformed industry standards.

RESULTS: TREATMENTS

- Eight COVID-19 treatments are currently authorized for emergency use: five neutralizing antibodies, two immunomodulators, and one antiviral. One treatment is currently FDA approved for COVID-19.

CONCLUSIONS

- Expedited mechanisms have been implemented to approve diagnostic testing and treatments, without a reliable system to accurately and promptly deliver results.
  - Preliminary study results indicate that current federal guidance has failed to produce reliable diagnostic tools and treatments:
    - Inconsistent testing accuracies and high relative percentage of EUA revocations,
    - Extremely low denial rate for proposals through CTAP, given the low yield of treatments authorized.
  - The lack of uniform testing and qualification strategy has been a major setback in terms of holistic pandemic response, and consequently called into question the reliability of subsequent data collection.

WORKS CITED

- Center for Devices and Radiological Health. "Coronavirus Disease 2019 (COVID-19) EUA." U.S. Food and Drug Administration, FDA.
- Center for Drug Evaluation and Research. "Coronavirus Treatment Acceleration Program (CTAP)." U.S. Food and Drug Administration, FDA.