REGULATORY REACTION TIMELINE OF COVID-19

JANUARY

Dec 31

A pneumonia of unknown cause detected in Wuhan, China is first reported to the World Health Organization.

Jan 17

CDC provides guidance for COVID-19 testing. Patients are tested if they have traveled to China or come into contact with someone with COVID-19.

CDC starts screening travelers at San Francisco (SFO), New York (JFK), and Los Angeles (LAX) airports.

Nancy Messonnier, Director of the CDC, says, "Based on the information that CDC has today, we believe the current risk from this virus to the general public is low. For a family sitting around the dinner table tonight this is not something that they generally need to worry about."

Jan 21

CDC Director Messonnier says, "Right now, testing for this virus must take place at CDC, but in the coming weeks, we anticipate sharing these tests with domestic and international partners through the agency's International Reagent Resource."

The CDC confirms first case of COVID-19 in the United States in Washington.

400 confirmed cases are known world-wide.

FEBRUARY

Feb 4

In two weeks, the number of COVID-19 cases increases to over 20,000 worldwide.

The Secretary of the Department of Health and Human Services (HHS) declares a state of emergency.

The FDA grants an EUA to CDC's COVID-19 testing kit, two weeks after initial testing.

Feb 5

The CDC ships their COVID-19 testing kit to 200 labs across the United States.

Feb 7

The first batch of test kits for COVID-19 from the CDC are recieved by more than fifty state and local public-health labs.

Feb 8

The public labs began reporting problems with the CDC test kit to the agency.

Feb 10

The CDC notifies the FDA about the problems in the test kits.

Feb 11

The FDA formally designates the virus as Coronavirus Disease 2019 or COVID-19.

Feb 12

The CDC announces that they have discovered problems with their testing kit.

Feb 16

The CDC responds to a request by the organizers of the Seattle Flu Study to shift focus to COVID-19 testing, telling them to check with the FDA. The FDA will later deny approval because the lab isn't certified under under regulations established by the Centers for Medicare & Medicaid Services, which could take months to process.

Feb 21

CDC Director Nancy Messonnier tell reporters that the problems with the test kits were still not resolved, "We are working with the FDA, who have oversight over us, under the EUA, on redoing some of the kits..."

Feb 23

The CDC becomes aware that a woman in Northern California might be the first community transmission case of COVID-19. Hospital administrators claim that the patient was not tested because she did not meet the "strict criteria" established on January 17.

Feb 24

Scott Becker, the CEO of the Association of Public Health Laboratories (APHL), and president, Grace Kubin, send a letter to the FDA asking for the FDA to grant their members, which include the largest state health labs, to create a laboratory developed test (LDT) for COVID-19.

Feb 25

Although they lack the needed permis-sions, Dr. Chu and her colleagues working at the Seattle Flu Study begin testing people for COVID-19. They get immediate positive results.

Just 12 labs outside of the CDC, in just five states, have the ability to test for the virus.

Feb 26

The first community spread case of COVID-19 is confirmed by CDC in Washing-ton State.

The FDA Commissioner responds to APHL's letter and tells them to apply for an EUA.

Feb 28

Alex Greninger at the University of Washington Medical Center and dozens of other clinical microbiologists write a letter to Congress complaining that the EUA process was slowing down the ability of their labs to deploy coronavirus tests.

Feb 29

The FDA issues an EUA for New York State Department of Public Health's (CDC) New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel.

Later in the day, the FDA releases new guidance on diagnostics, allowing for widespread testing through an Emergency Use Authorization.

The CDC and Washington State report the first COVID-19 death.

MARCH

Mar 2

The Seattle Flu Study's institutional review board at the University of Washington determines that it would be unethical for the researchers not to test and report the results in a public health emergency.

Mar 4

CDC releases updated COVID-19 guidance for testing, which is expanded to include a wider group of symptomatic patients.

Mar 5

LabCorp makes the 2019 Novel Coronavi-rus (COVID-19) NAA test available, five days days after the company filed paperwork with the FDA.

Mar 7

The FDA releases an updated EUA template for CLIA certification.

Mar 12

The FDA releases an updated EUA template for test kits.

The FDA grants Roche an EUA for their cobas SARS-CoV-2 test.

Mar 13

FDA issues EUA for Thermo Fisher's TaqPath COVID-19 Combo Kit.

Mar 16

The FDA updates a policy originally issued on Feb. 29 on diagnostic testing for coronavirus (COVID-19) in order to achieve more rapid testing capacity in the U.S.

The FDA also issues EUA for Hologic's Panther Fusion SARS-CoV-2 test and LabCorp's RT-PCR Test. LabCorp had applied approximately five days earlier.

Mar 17

The FDA issues an EUA for Quest Diagnos-tics' RT-PCR test, four days after the company filed paperwork.

The FDA also issues an EUA for Quidel Corporation's Lyra SARS-CoV-2 Assay, six days after the company filed paperwork.

Mar 18

FDA issues an EUA for Abbott's RealTime SARS-CoV-2.

Mar 19

FEMA takes over coordination of COVID-19 response.

FDA issues an EUA for Simplexa COVID-19 Direct assay.

The FDA also issues an EUA for ePlex SARS-CoV-2 Test.

Mar 20

The FDA grants an EUA to Cepheid's Xpert Xpress SARS-CoV-2 test.

The FDA issues an EUA to Primerdesign Ltd COVID-19 genesig Real-Time PCR assay. The application seems to have been made earlier that day.

Key

CDC - *The Centers for Disease Control and Prevention (CDC) is a national public institute that focuses on infectious disease response. Its parent agency is Department of Health and Human Services (HHS).*

CLIA - *The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulates all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease..*

EUA - *An Emergency Use Authorization (EUA) is a the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives.*

FDA - *The Food and Drug Administration (FDA) is a federal responsible for regulating food, medications, and medical devices. The FDA Commissioner reports directly to the Secretary of Health and Human Services (HHS).*

Seattle Flu Study - *In late 2019, the Seattle Flu Study begins with the aim to better detect, monitor, and control flu outbreaks. Researchers on this project are among the first to discover COVID-19 cases in the United States.*

Sources

Food and Drug Administration, The Centers for Disease Control and Prevention, World Health Organization, Federal Emergency Management Agency

For full list of sources, visit www.growthopportunity.org

Compiled by Will Rinehart, Senior Research Fellow at the Center for Growth and Opportunity at Utah State University

The Center for Growth and Opportunity at Utah State University