

**NIH Advisory Committee to the Director**

# **Overview of COVID-19 and the Research Response**

**Anthony S. Fauci, M.D.**

**Director**

**National Institute of Allergy and  
Infectious Diseases**

**National Institutes of Health**

**June 11, 2020**



# Science

January 3, 2020

## **Novel Human Virus? Pneumonia Cases Linked to Seafood Market in China Stir Concern**

By Dennis Normile

# The Washington Post

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January 9, 2020

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## **Washington Post: China Identifies New Strain of Coronavirus as Source of Pneumonia Outbreak**

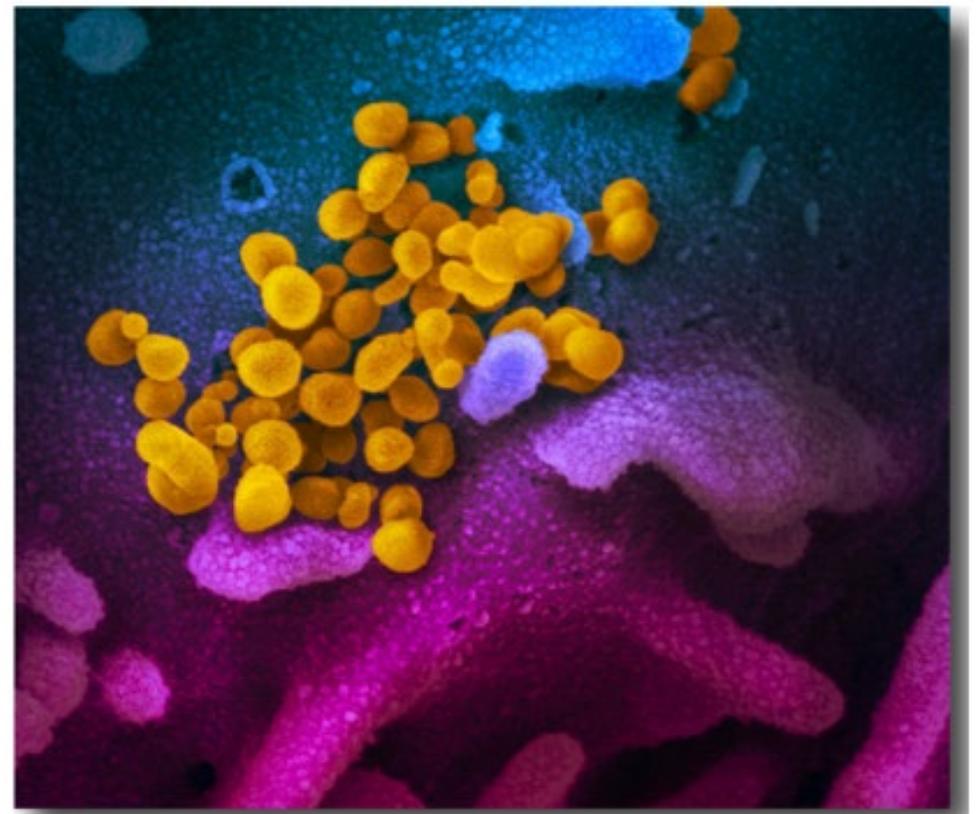
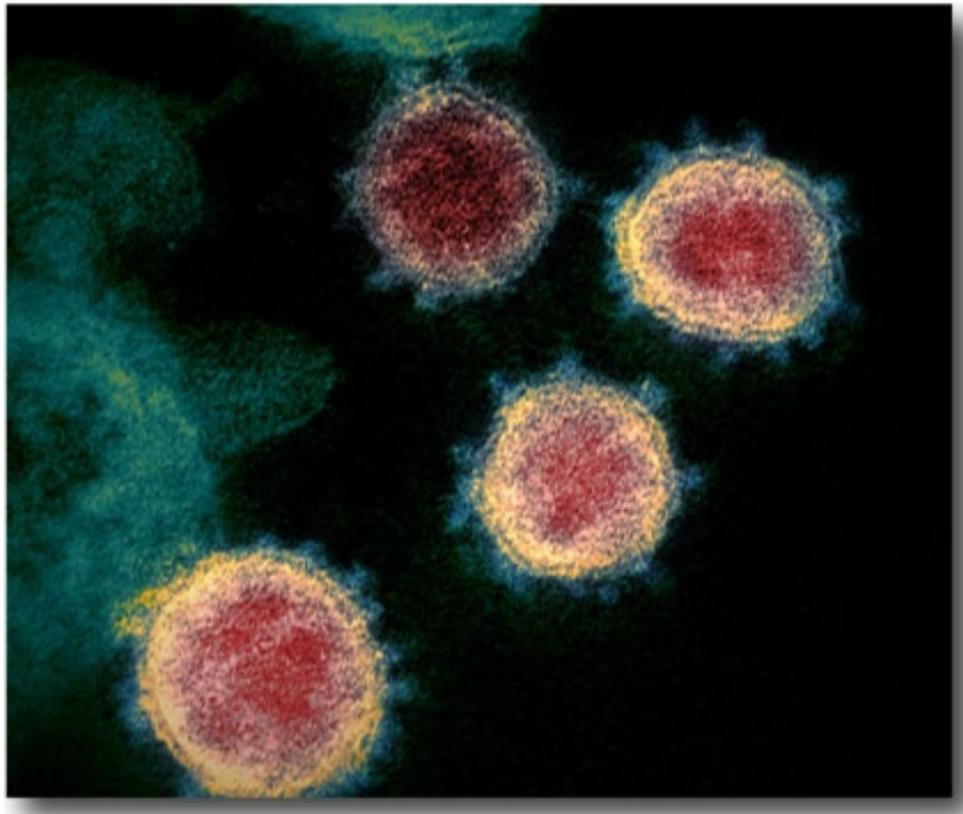
**Health officials run thermal scans on passengers arriving from Wuhan, China, at Bangkok's Suvarnabhumi Airport on Wednesday.**

By Gerry Shih and Lena H. Sun

# Coronavirus Disease 2019 (COVID-19) (December 2019 – Present)

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- **COVID-19** is caused by the novel coronavirus **SARS-CoV-2**



# The Washington Post

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January 17, 2020

## Travelers at 3 U.S. Airports to Be Screened for New, Potentially Deadly Chinese Virus

January 21, 2020

## U.S. Screenings for the Coronavirus Expanded to Airports in Atlanta and Chicago





Centers for Disease Control and Prevention

**Press Release**

January 21, 2020

# **First Travel-related Case of 2019 Novel Coronavirus Detected in United States**



Centers for Disease Control and Prevention

**Press Release**

February 26, 2020

# **CDC Confirms Possible Instance of Community Spread of COVID-19 in U.S.**

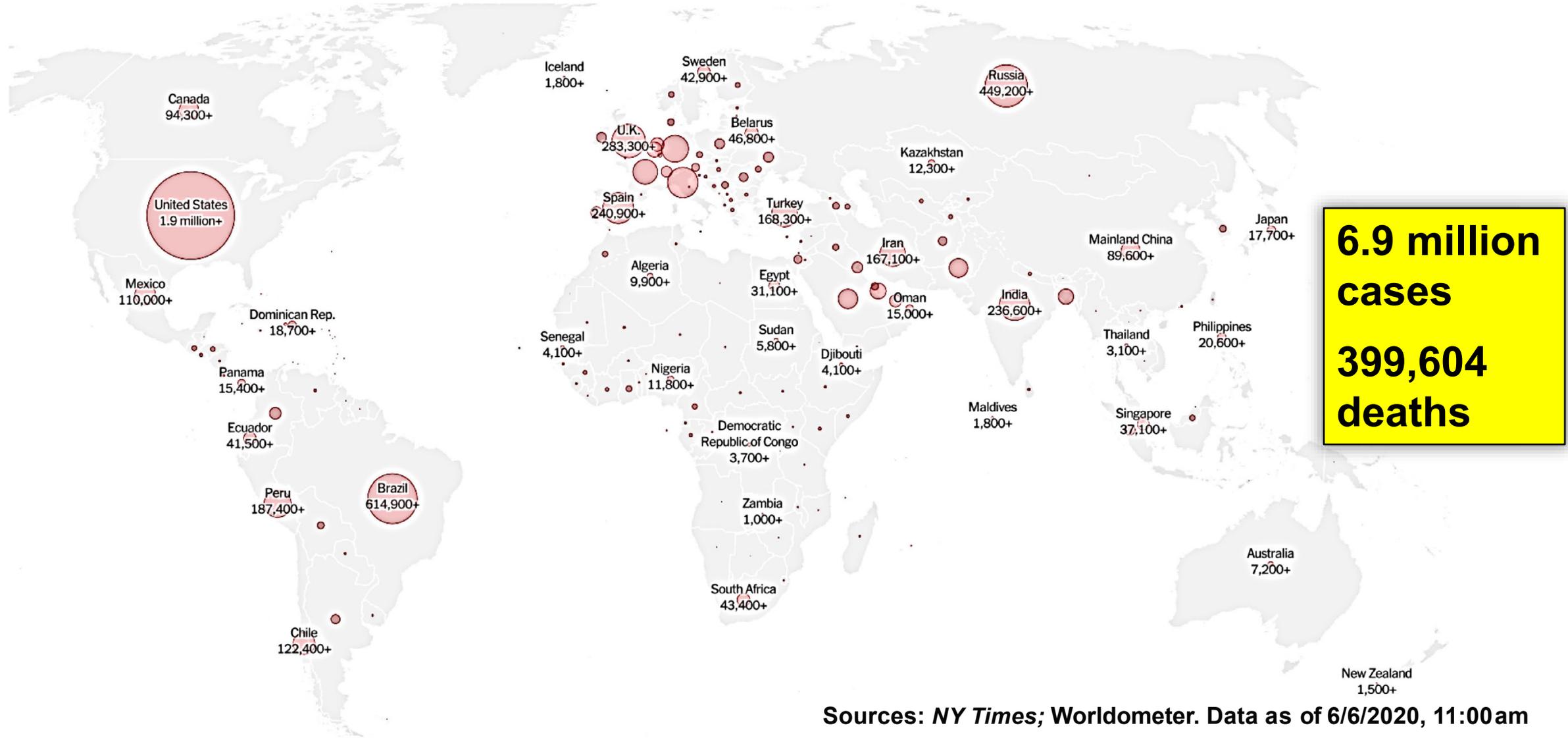
The Centers for Disease Control and Prevention (CDC) has confirmed an infection with the virus that causes COVID-19 in California in a person who reportedly did not have relevant travel history or exposure to another known patient with COVID-19.

# March 3: President Trump Visits NIH Vaccine Research Center

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# COVID-19 Globally: 6.9 Million Cases 213 Countries and Territories



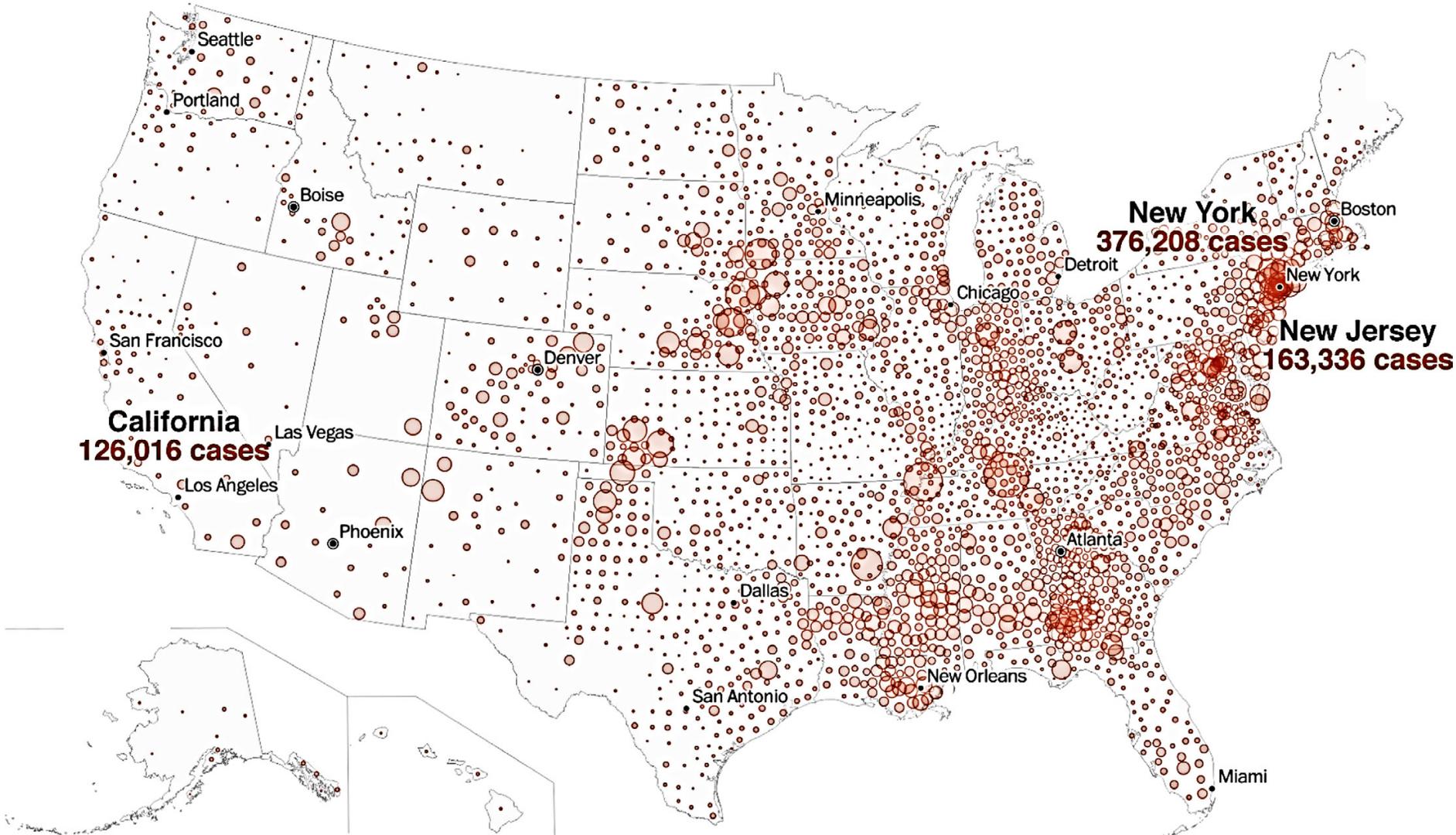
Sources: *NY Times*; Worldometer. Data as of 6/6/2020, 11:00 am

March 22, 2020

# **New York to Shut Down As It Becomes Next Virus Hot Spot**



# Reported COVID-19 Cases and Deaths the United States

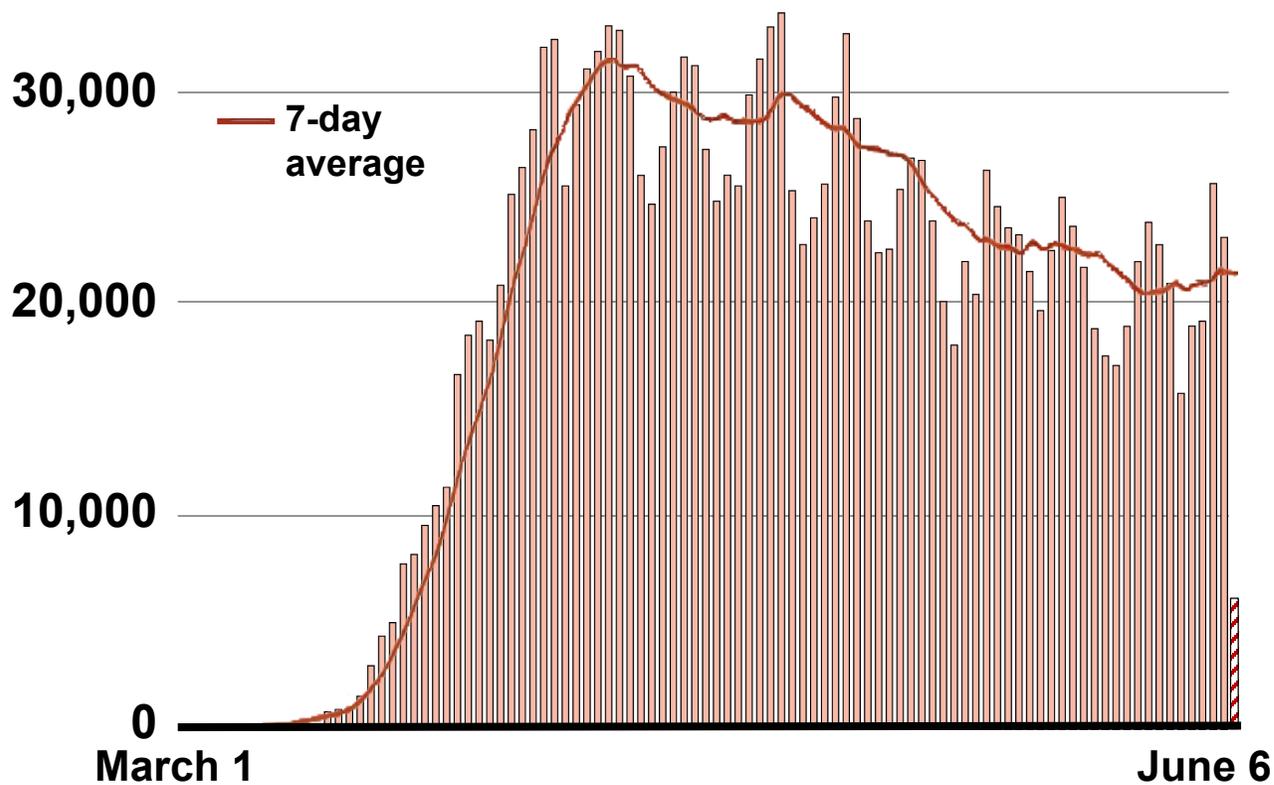


Reported cases:  
**1,971,399**

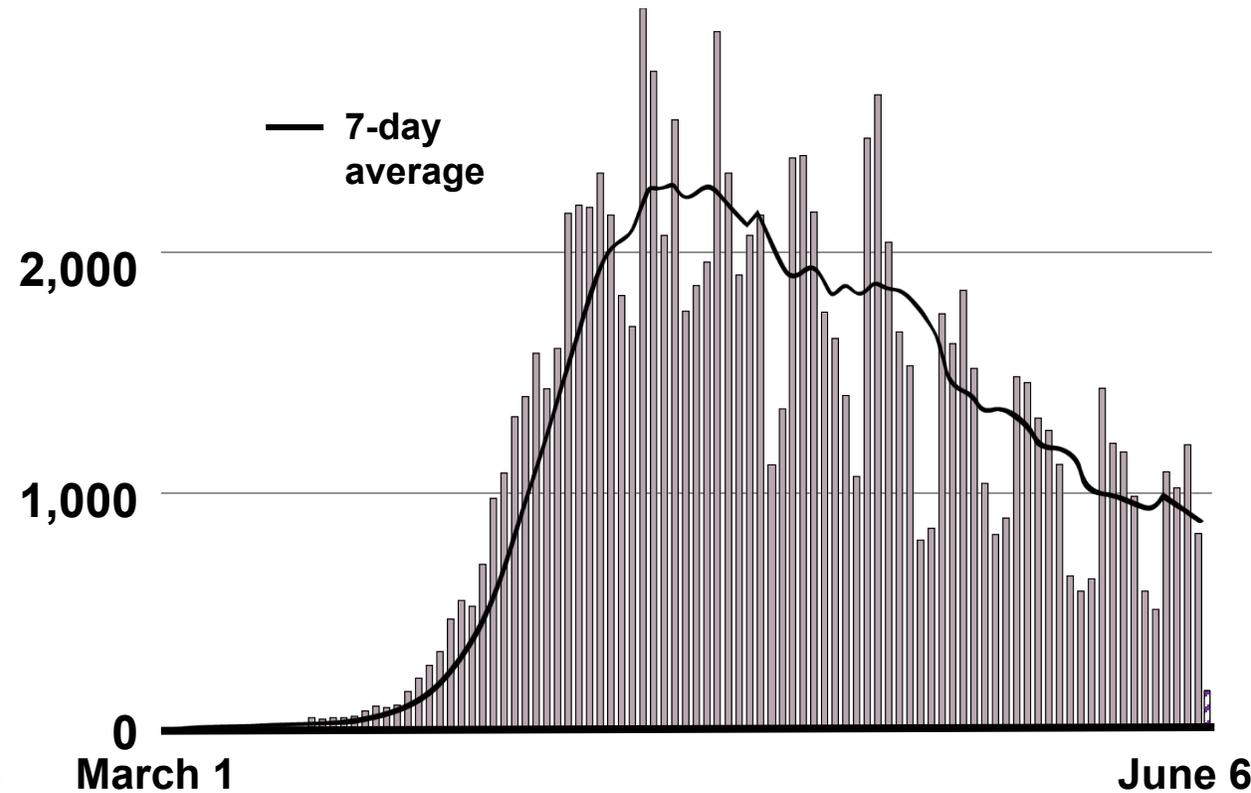
Reported deaths:  
**111,491**

# Reported COVID-19 Cases and Deaths in the United States

## Reported cases per day



## Reported deaths per day



# COVID-19 Clinical Presentation

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■ Fever	83-99%
■ Cough	59-82
■ Fatigue	44-70
■ Anorexia	40-84
■ Shortness of breath	31-40
■ Myalgias	11-35

## Other non-specific symptoms reported

- Sore throat, nasal congestion, headache, diarrhea, nausea, vomiting. Loss of smell/taste preceding the onset of respiratory symptoms.

# COVID-19: Wide Spectrum of Disease

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**Asymptomatic Illness**

No symptoms

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**Mild Illness**

Uncomplicated upper respiratory tract infection

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**Moderate Disease**

Pneumonia without the need for supplemental oxygen

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**Severe Pneumonia**

Pneumonia plus one of the following: respiratory rate > 30 breaths/min; severe respiratory distress; or SpO<sub>2</sub> < 90% on room air

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**Critical Illness**

ARDS, sepsis, septic shock, multiple organ dysfunction/failure

**Prevalence of  
Asymptomatic  
SARS-CoV-2  
Infection  
A Narrative Review**

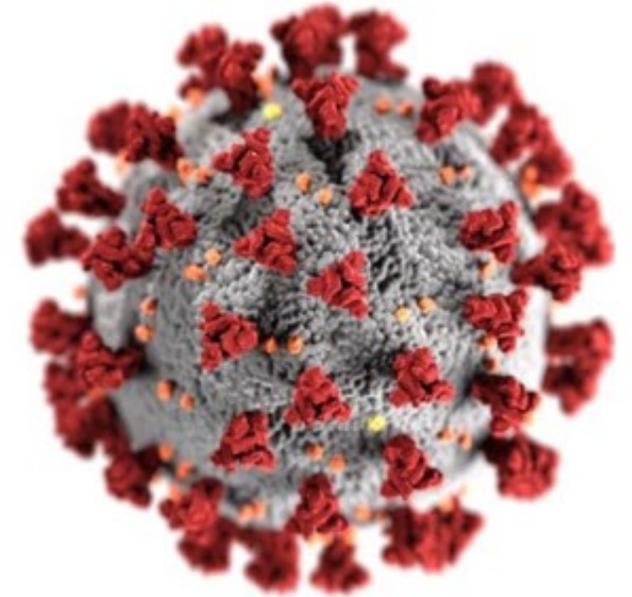
DP Oran and EJ Topol

- Data from 16 cohorts, total n= 45,000+
- Asymptomatic persons account for 40-45% of SARS-CoV-2 infections

# Groups at Higher Risk for Severe COVID-19 Illness

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- Age >65 years
- People in nursing homes or long-term care facilities
- Asthma
- Chronic kidney disease
- Chronic lung disease
- Diabetes
- Hemoglobin disorders
- Immunocompromised
- Liver disease
- Serious heart disease
- Obesity (BMI  $\geq$ 40)



**JAMA**

The Journal of the American Medical Association

May 11, 2020

**Viewpoint**

# **COVID-19 and Racial/Ethnic Disparities**

M.W. Hooper, A.M. Nápoles, and E.J. Pérez-Stable.

*"The most pervasive disparities are observed among African American and Latino individuals, and where data exist, American Indian, Alaska Native, and Pacific Islander populations."*

# **COVID-19 Research Response**

# NIH COVID-19 Supplemental Funding

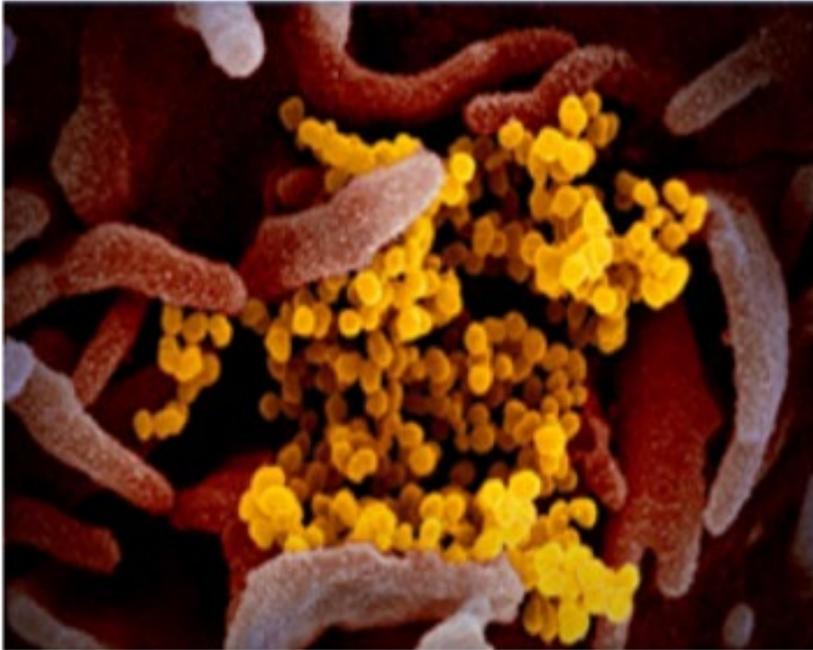
*(\$s in millions and are available until 9/30/2024)*

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<b><u>NIAID</u></b>	Basic research, pathogenesis, animal models, epidemiology, diagnostics, vaccines, therapeutics	\$1,532
<b><u>Other Institutes</u></b>		\$2,055
<b><u>NHLBI</u></b>	Therapeutics and longitudinal studies	103
<b><u>NIEHS</u></b>	Worker safety	10
<b><u>NIBIB</u></b>	Point-of-care and other rapid testing	560
<b><u>NLM</u></b>	Research resources	10
<b><u>NCATS</u></b>	Drug screening	36
<b><u>NIH-OD</u></b>	Point-of-care and other rapid testing	1,030
<b><u>NCI</u></b>	Serological testing and associated technologies	306
<b>Total</b>		<b>\$3,587</b>

# NIAID STRATEGIC PLAN FOR COVID-19 RESEARCH

APRIL 10, 2020



- **Improve fundamental knowledge of SARS-CoV-2 and COVID-19 disease**
- **Develop diagnostics and assays**
- **Characterize and test therapeutics**
- **Develop safe and effective vaccines**

# Viral Isolates and Reagents Made Available to the Research Community

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b | e | i RESOURCES

SUPPORTING INFECTIOUS DISEASE RESEARCH



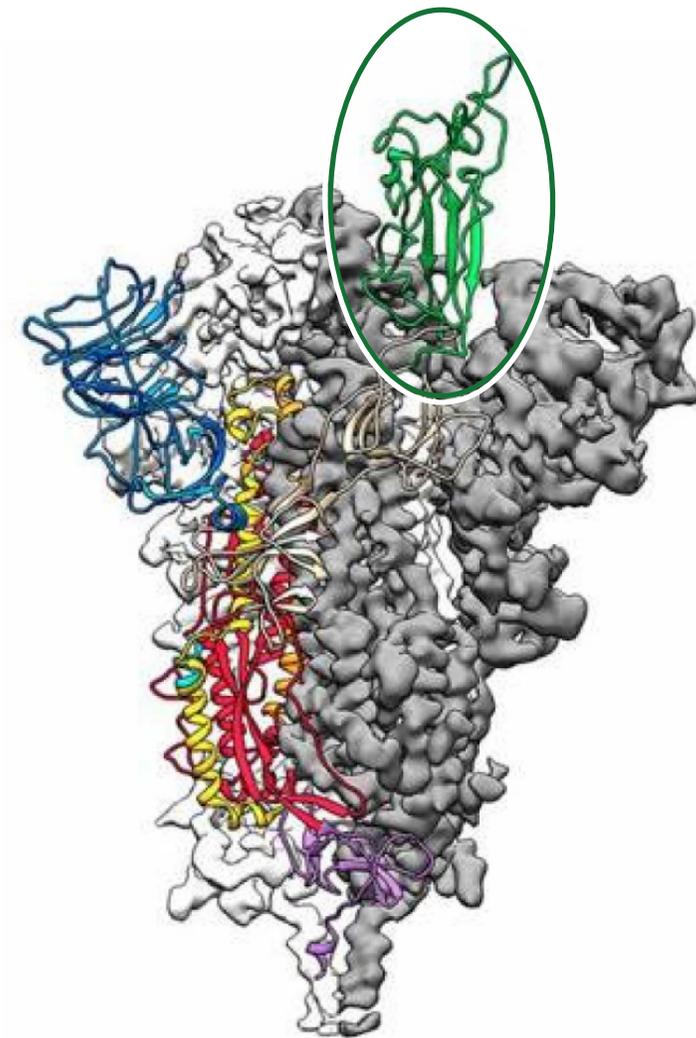
World Reference Center for Emerging  
Viruses and Arboviruses

The University of Texas Medical Branch



# **Cryo-EM Structure of the 2019-nCoV Spike in the Prefusion of Conformation**

D Wrapp, N Wang, KS Corbett, JA Goldsmith, C-L Hsieh, O Abiona, BS Graham, JS McLellan



Viral membrane

Atomic-level structure of SARS-CoV-2 spike protein. Receptor binding domain is colored green and circled.



# **Functional Assessment of Cell Entry and Receptor Usage for SARS-CoV-2 and Other Lineage B Betacoronaviruses**

M Letko, A Marzi, and V Munster

Uncovering coronavirus entry

- **Human ACE2 is the receptor for SARS-CoV-2**

# **Respiratory Disease in Rhesus Macaques Inoculated with SARS-CoV-2**

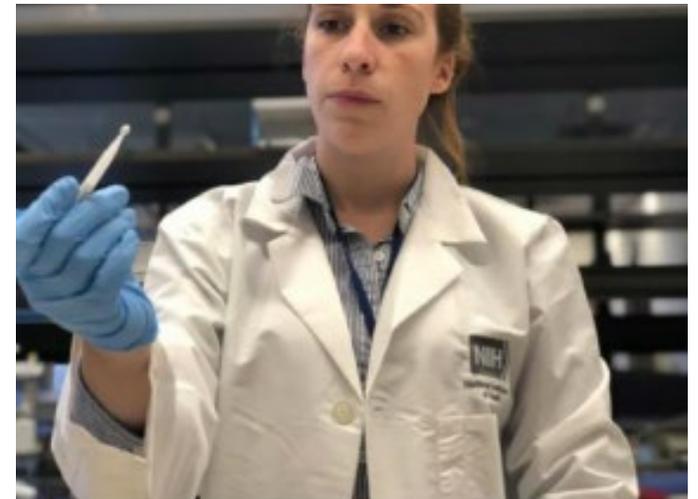
- **Rhesus macaque model recapitulates moderate disease observed in the majority of human COVID-19 cases**



News Release

# **NIH Begins Study to Quantify Undetected Cases of Coronavirus Infection**

*Serological study will provide  
insights into which  
communities and populations  
are most affected by COVID-19*





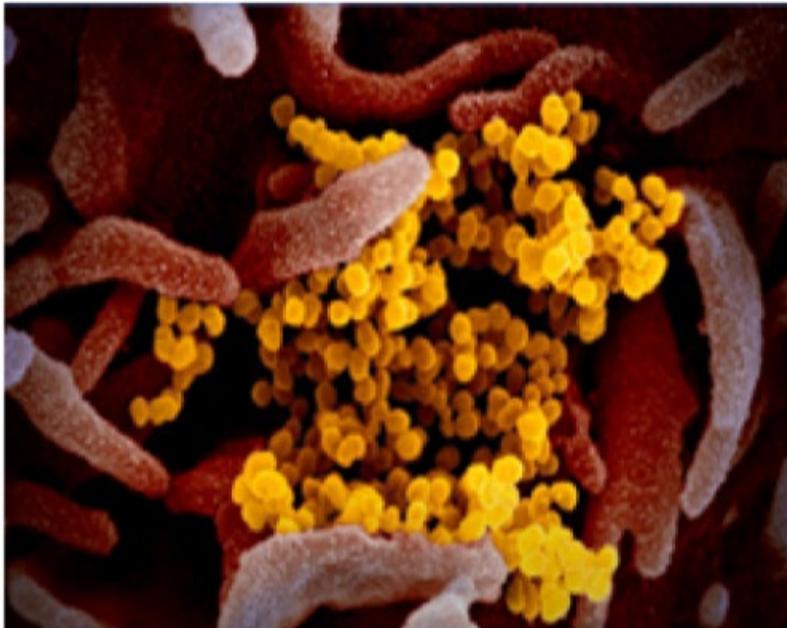
## News Release

# Study to Determine Incidence of Novel Coronavirus Infection in U.S. Children Begins

- HEROS study aims to enroll 6,000 people/2,000 families
- Study goals are to determine
  - The incidence of SARS-CoV-2 in children
  - Whether asthma or allergies affect the incidence of infection
  - The percentage of infected children who develop COVID-19

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News Release

June 4, 2020

# **Coronavirus (COVID-19) Update: FDA Publicly Shares Antibody Test Performance Data From Kits as Part of Validation Study**

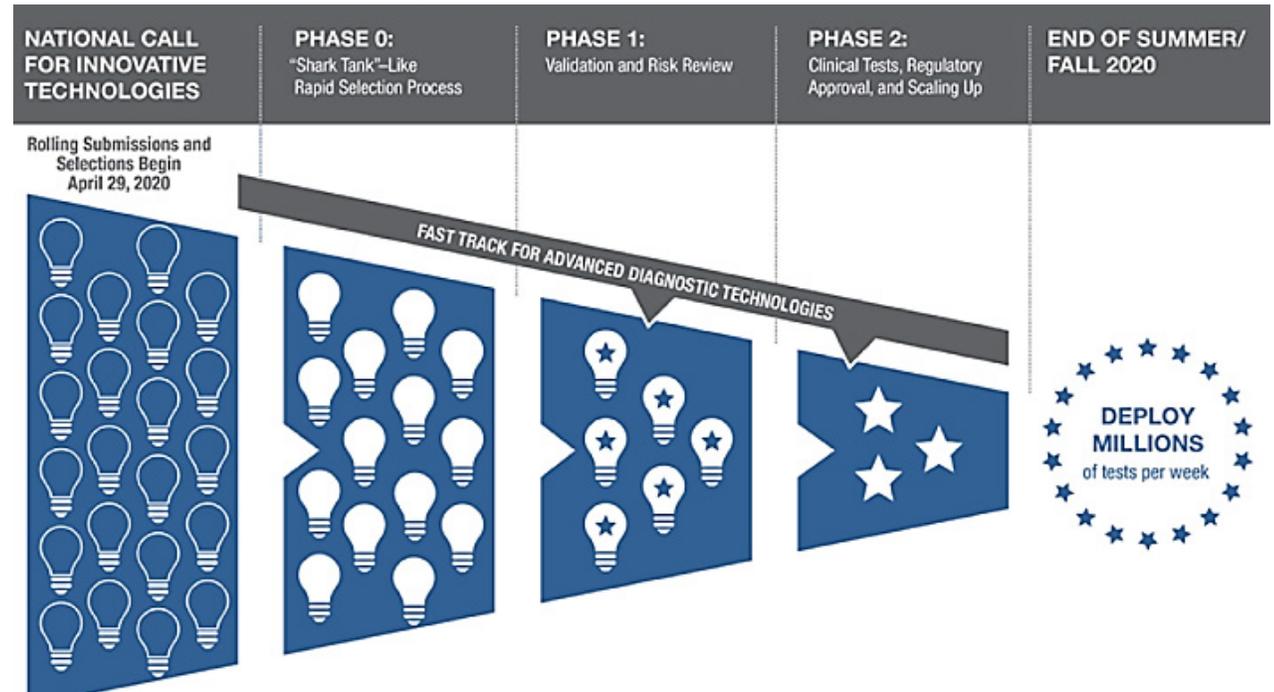
- **Validation study is headed by NCI, with collaboration of NIAID, CDC and BARDA**
- **Includes tests already available as well as those not yet on the mark**



News Release

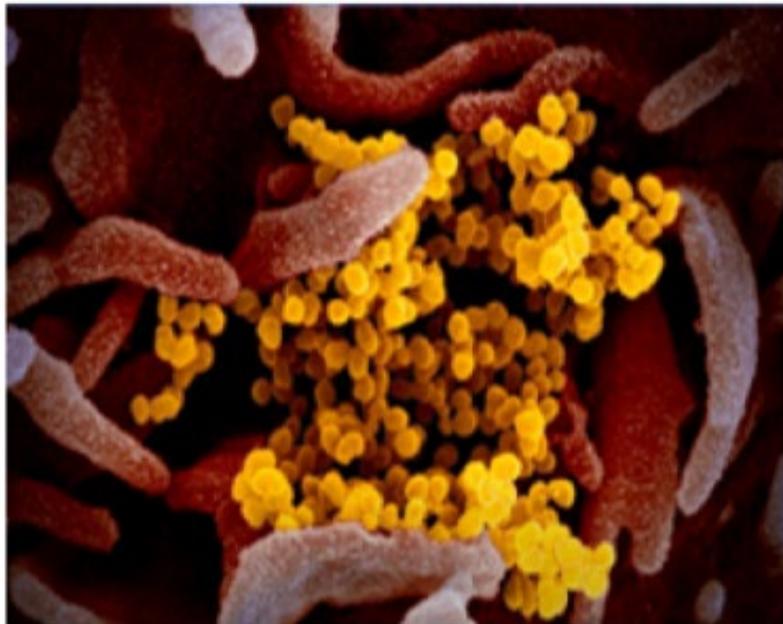
# NIH Mobilizes National Innovation Initiative for COVID-19 Diagnostics

- NIH Rapid Acceleration of Diagnostics (RADx) Initiative for COVID-19
- Award up to \$500 million to support development of COVID-19 diagnostics



# NIAID STRATEGIC PLAN FOR COVID-19 RESEARCH

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# Investigational Therapeutics for COVID-19

- Remdesivir
- Other broad-spectrum antivirals
- Convalescent plasma/hyperimmune immunoglobulin
- Repurposed drugs, e.g. hydroxychloroquine, lopinavir/ritonavir
- Host modifiers/immune-based therapies
- Anti-SARS-CoV-2 monoclonal antibodies
- Others





The  
New England  
Journal of Medicine

Established in 1812 as THE NEW ENGLAND JOURNAL OF MEDICINE AND SURGERY

published online May 22, 2020

# **Remdesivir for the Treatment of Covid-19 — Preliminary Report**

**JH Beigel, HC Lane et al. for the ACTT-1 Study Group Members**

- **Patients who received remdesivir had a 32% faster time to recovery than those who received placebo ( $p < 0.001$ )**
- **Results also suggested a survival benefit**
- **N=1,063 patients from 10 countries in U.S., Europe, Asia**



News Release

# NIH Clinical Trial Testing Antiviral Remdesivir Plus Anti-Inflammatory Drug Baricitinib for COVID-19 Begins

*“ACTT-2 will examine if adding an anti-inflammatory agent to the remdesivir regimen can provide additional benefit for patients, including improving mortality outcomes.”*

**-Anthony S. Fauci, MD**



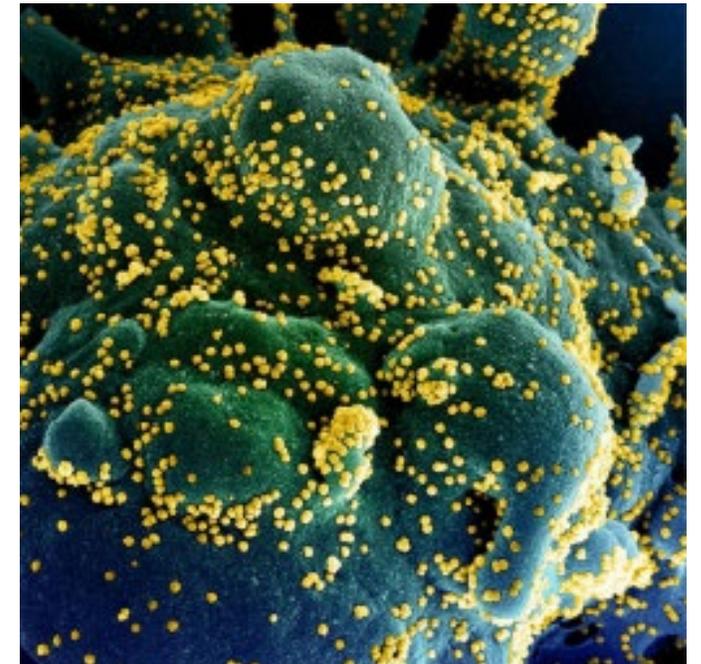


News Release

# Expert U.S. Panel Develops NIH Treatment Guidelines for COVID-19

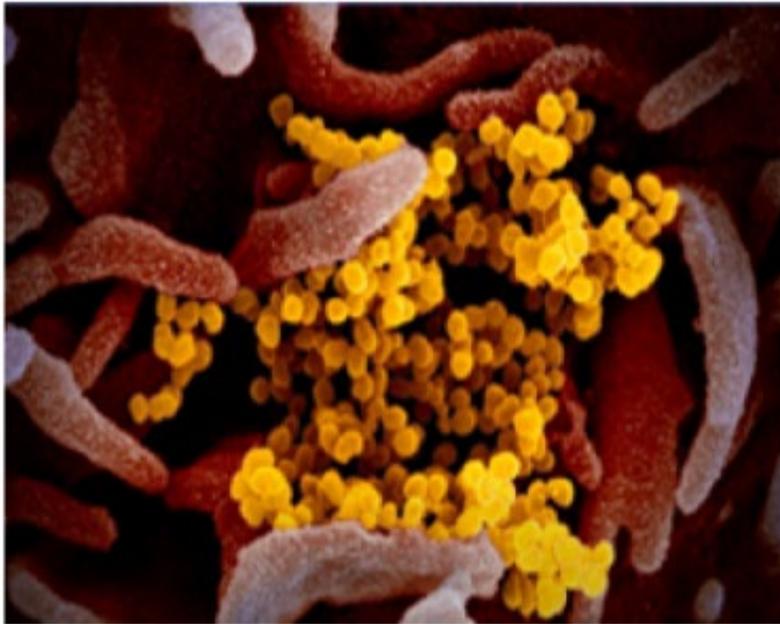
*"Living document" expected to be  
updated often as new clinical data  
accrue*

■ [Covid19treatmentguidelines.nih.gov](https://www.covid19treatmentguidelines.nih.gov)



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# BARDA-Supported COVID-19 Vaccine Candidates

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**mRNA**



**Replication Incompetent Adenovirus (ChAdOx1)**



**Replication Incompetent Adenovirus (Ad26)**



**Adjuvanted protein subunit**



**Replication-competent Vesicular Stomatitis Vector (VSV)**

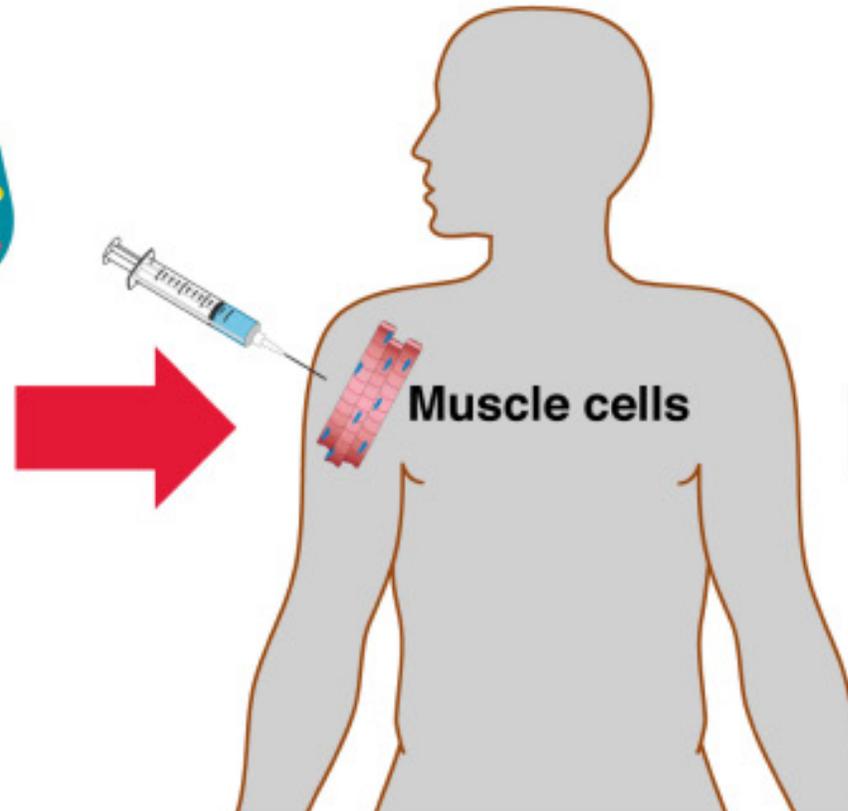
# **mRNA Vaccine Approach**

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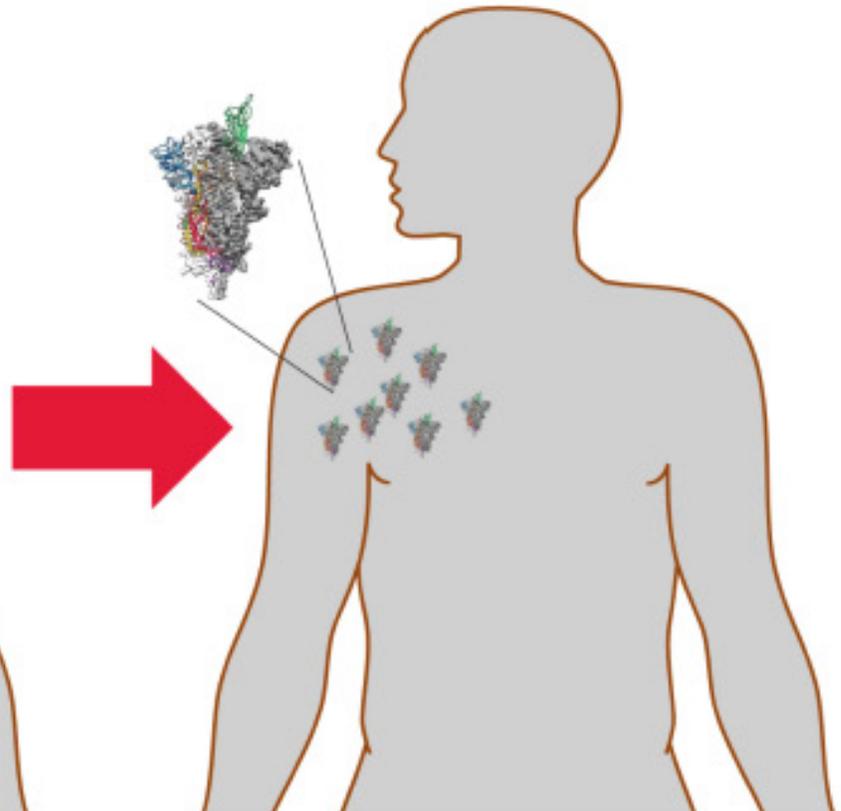
**mRNA for spike protein of coronavirus**



**Inject into muscle cells**



**Muscle cells read the mRNA and make spike protein**





News Release

# **NIH Clinical Trial of Investigational Vaccine for COVID-19 Begins**

## *Study Enrolling Seattle-Based Healthy Adult Volunteers*

- **Trial of vaccine candidate mRNA-1273 will enroll 45 healthy adult volunteers ages 18 to 55 years over approximately 6 weeks**



Photo: AP

# The New York Times

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May 18, 2020

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## **Moderna Coronavirus Vaccine Trial Shows Promising Early Results**

**Data from 8 healthy volunteers: vaccine safe and provoked a strong immune response. It is on an accelerated timetable to begin larger human trials soon.**



Health and Human Services  
Press Release  
May 15, 2020

# **Trump Administration Announces Framework and Leadership for 'Operation Warp Speed'**

- **National program to accelerate development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics**
- **Public-private partnership between HHS (CDC, FDA, NIH, BARDA), DoD, other federal agencies, and private firms**
- **Chief Scientific Advisor: Moncef Slaoui, PhD**
- **Chief Operating Officer: General Gustave F. Perna**

Published online May 11, 2020

# Science

## **A Strategic Approach to COVID-19 Vaccine R&D**

L Corey, JR Mascola, AS Fauci & FS Collins

- **Unprecedented collaboration and resources will be required to research and develop safe and effective vaccines for COVID-19 that can be manufactured and delivered in the scale of billions of doses to people globally.**

# **April 17: NIH Launches Public-Private Partnership to Speed COVID-19 Vaccine and Treatment Options**

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**■ The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership will:**

- Standardize and share preclinical evaluation methods in an open forum**
- Prioritize and accelerate clinical evaluation of therapeutic candidates with near-term potential**
- Maximize clinical trial capacity and effectiveness**
- Advance vaccine development**

# Briefing President Trump on the COVID-19 (Coronavirus) Outbreak

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# May 5: White House Briefing of Vice President Pence on COVID-19 Vaccines

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# January 29: White House Coronavirus Task Force Announced

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**Chair: VP Mike Pence**

**Response Coordinator: Deborah Birx**

- Jerome Adams
- Alex Azar
- Stephen Biegun
- Robert Blair
- Ben Carson
- Francis Collins
- Ken Cuccinelli
- Kelvin Droegemeier
- Thomas Engels
- Anthony Fauci
- Joe Grogan
- Stephen Hahn
- Derek Kan
- Larry Kudlow
- Chris Liddell
- Steven Mnuchin
- Robert O'Brien
- Sonny Perdue
- Matthew Pottinger
- Robert Redfield
- Gene Scalia
- Joel Szabat



- Seema Verma
- Robert Wilkie