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FDA's COVID-19 Activities

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Learning Objectives

1

Learn about FDA's regulatory pathways for the approval of products intended for the prevention, diagnosis, and treatment of COVID-19

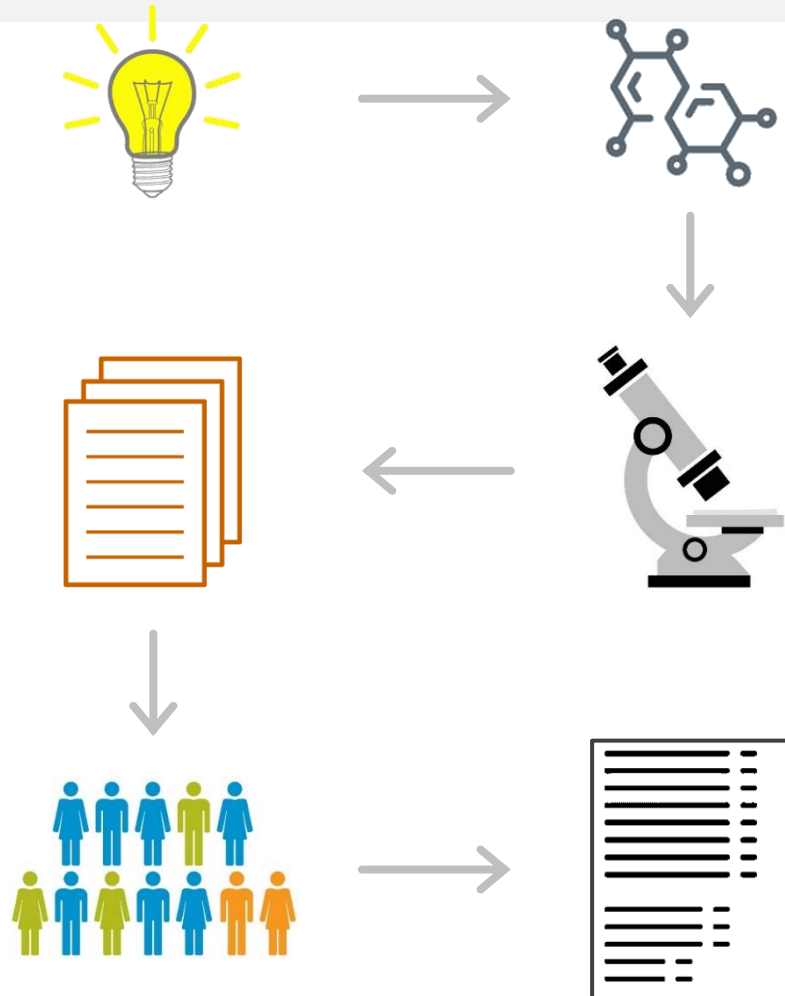
2

Understand actions FDA has taken to assist industry during the COVID-19 pandemic

3

Learn about FDA COVID-19 enforcement

From Idea to Market



- The idea
- The search for compounds
- Preclinical studies
- Submission of IND
- Clinical trials
- Submission of NDA



Diagnostic Tests



Compounded drugs



Vaccines



OTC products



Therapeutics



Convalescent plasma



Ventilators



PPE



Center for Drug Evaluation and Research Response to COVID-19

FDA





Timeline: January 1, 2020 – September 30, 2021



COVID-19 Therapeutic Development:

-  640+ drug development programs in planning stages
-  470+ trials reviewed by FDA
-  11 treatments currently authorized for emergency use
-  1 treatment currently approved by FDA

Regulatory Flexibility: Proactively issued temporary policies to address the pandemic and provide regulatory flexibility on:

-  Certain drugs compounded for hospitalized patients with COVID-19
-  Repackaging or combining Propofol
-  Prescription Drug Marketing Act requirements for distributing prescription drug samples
-  Drug Supply Chain Security Act requirements



Generic Drug Approvals (Abbreviated New Drug Applications):
Approved 1,000+ original and supplemental generic applications for COVID-19 related treatments and supportive therapies



Addressing Fraud:
Took action against sellers of **fraudulent products** for the treatment or prevention of COVID-19, and issued more than **120 warning letters**



Internet Pharmacies:
Issued **17 warning letters** to operators of websites that sell unapproved and misbranded COVID-19 products



Hand Sanitizer:
Published a list with more than **250 listings** of hand sanitizers consumers should not use, including those containing potentially dangerous contaminants



Shortage Mitigation Activities:
Continued outreach to more than **180 manufacturers** relating to manufacturing capacity and supply chain for both COVID-19 and non-COVID-19 treatments



Surveillance and Epidemiology:
Examined and analyzed data across at least **15 data sources**, including **55,000 adverse event reports** to monitor drug safety and medication errors



U.S. Public Health Service Corps Deployment:
Approximately **364 CDER Commissioned Corps officers** fulfilled **623 deployment requests** in support of the COVID-19 mission



Engagement With Stakeholders:
CDER fielded **23,515 COVID-19 drug related inquiries** from the general public, including health care providers, consumers and manufacturers

For more information, please visit <https://www.fda.gov/drugs>

<https://www.fda.gov/drugs/coronavirus-covid-19-drugs/center-drug-evaluation-and-research-response-coronavirus-covid-19-infographic>

FDA VACCINE FACTS

www.fda.gov/COVID19vaccines
#FDAVaccineFacts

¹ Part of FDA's evaluation of an EUA request for a COVID-19 vaccine includes evaluation of the chemistry, manufacturing, and controls information for the vaccine. Sufficient data should be submitted to ensure the quality and consistency of the vaccine product. FDA will use all available tools and information, including records reviews, site visits, and previous compliance history, to assess compliance with current good manufacturing practices.

² FDA has made clear in its October 2020 guidance entitled Emergency Use Authorization for Vaccines to Prevent COVID-19, that, for a COVID-19 vaccine for which there is adequate manufacturing information to ensure its quality and consistency, issuance of an EUA would require a determination by FDA that the vaccine's benefits outweigh its risks based on data from at least one well-designed Phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner.

The Path for a COVID-19 Vaccine from Research to Emergency Use Authorization

A vaccine manufacturer conducts laboratory research to develop a vaccine candidate.

The manufacturer compiles the results of laboratory research and testing in animals and information about the manufacturing technology and the quality of the vaccine and must submit an Investigational New Drug (IND) application to FDA before beginning human clinical trials. Such a clinical trial in humans is not permitted to proceed without the prior written authorization from FDA.

Clinical trials are conducted to generate data on safety and effectiveness of the vaccine.

A Data Safety Monitoring Board evaluates data from the Phase 3 clinical trial and advises the vaccine manufacturer regarding whether criteria for the pre-specified clinical endpoint, as discussed and agreed to in advance with FDA, has been met for their COVID-19 vaccine.

Company reviews data to determine whether the company's scientists and technical experts believe that the vaccine meets FDA's outlined expectations for safety and effectiveness.

Taking into consideration input from FDA, a company decides whether and when to submit a request for Emergency Use Authorization (EUA) to FDA.

Once submitted, career scientists and physicians in the FDA's Center for Biologics Evaluation and Research (CBER) will evaluate an EUA request taking into account the totality of scientific evidence about the vaccine that is available to FDA.¹

FDA convenes a public meeting of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) to discuss the data from the clinical trials.

Following the advisory committee meeting, CBER's career professional staff will consider the input of the advisory committee members and continue their evaluation to determine whether the available safety, effectiveness, and manufacturing data support authorization for use of the particular COVID-19 vaccine in the U.S.

If FDA determines that the criteria for an EUA are met, including that the known and potential benefits outweigh the known and potential risks of the vaccine and that the manufacturing information is adequate to ensure its quality and consistency, FDA may authorize the vaccine for emergency use.²

FDA informs the company that its EUA has been authorized.

<https://www.fda.gov/media/143890/download>

FDA Covid-19 Response Toolkit

Operation Warp Speed	Coronavirus Treatment Acceleration Program (CTAP)	Emergency Use Authorization	The PREP Act
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Emergency Use Authorizations

- Public health emergencies
- FDA criteria
 - Reasonable belief product “may be effective”
 - Benefits outweigh the risks
 - No alternatives available
- Subject to revocation
 - Operation Quack Hack

How is an EUA different?

- Both rely on data regarding safety and effectiveness and require a conclusion that potential benefits outweigh any potential risks
- Main difference is the ***quantity*** of data and the review ***timeline***

POLLING QUESTION

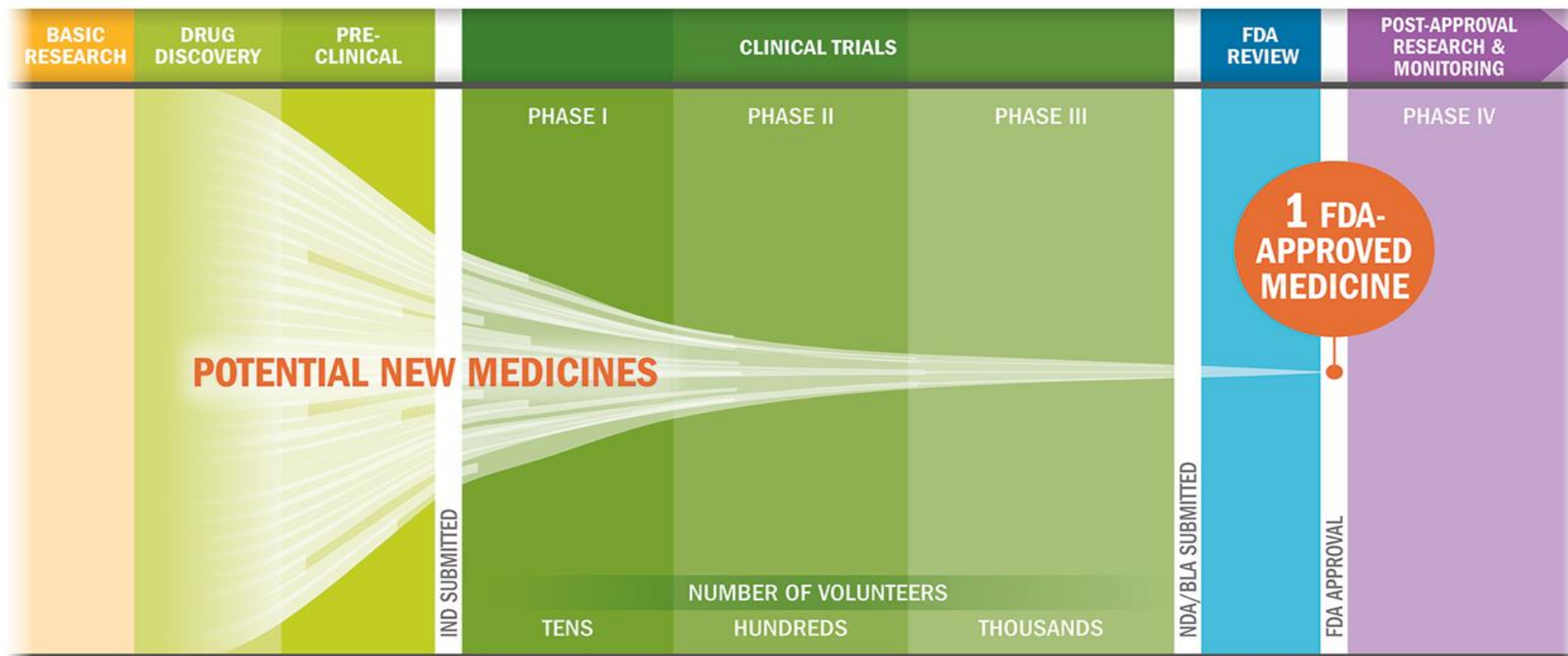
**What other health crises
might have triggered an EAU?**

What other health crises might have triggered an EAU?

- Spanish flu (1918)
- Swine flu (1976)
- AIDS epidemic (1980s)
- Avian flu (2005)
- Anthrax (2001)
- H1N1 swine flu (2009)
- MERS (2012)
- Ebola (2013)
- Zika (2015)

THE BIOPHARMACEUTICAL RESEARCH AND DEVELOPMENT PROCESS

From drug discovery through FDA approval, developing a new medicine takes at least 10 years on average and costs an average of \$2.6 billion.* Less than 12% of the candidate medicines that make it into Phase I clinical trials will be approved by the FDA.



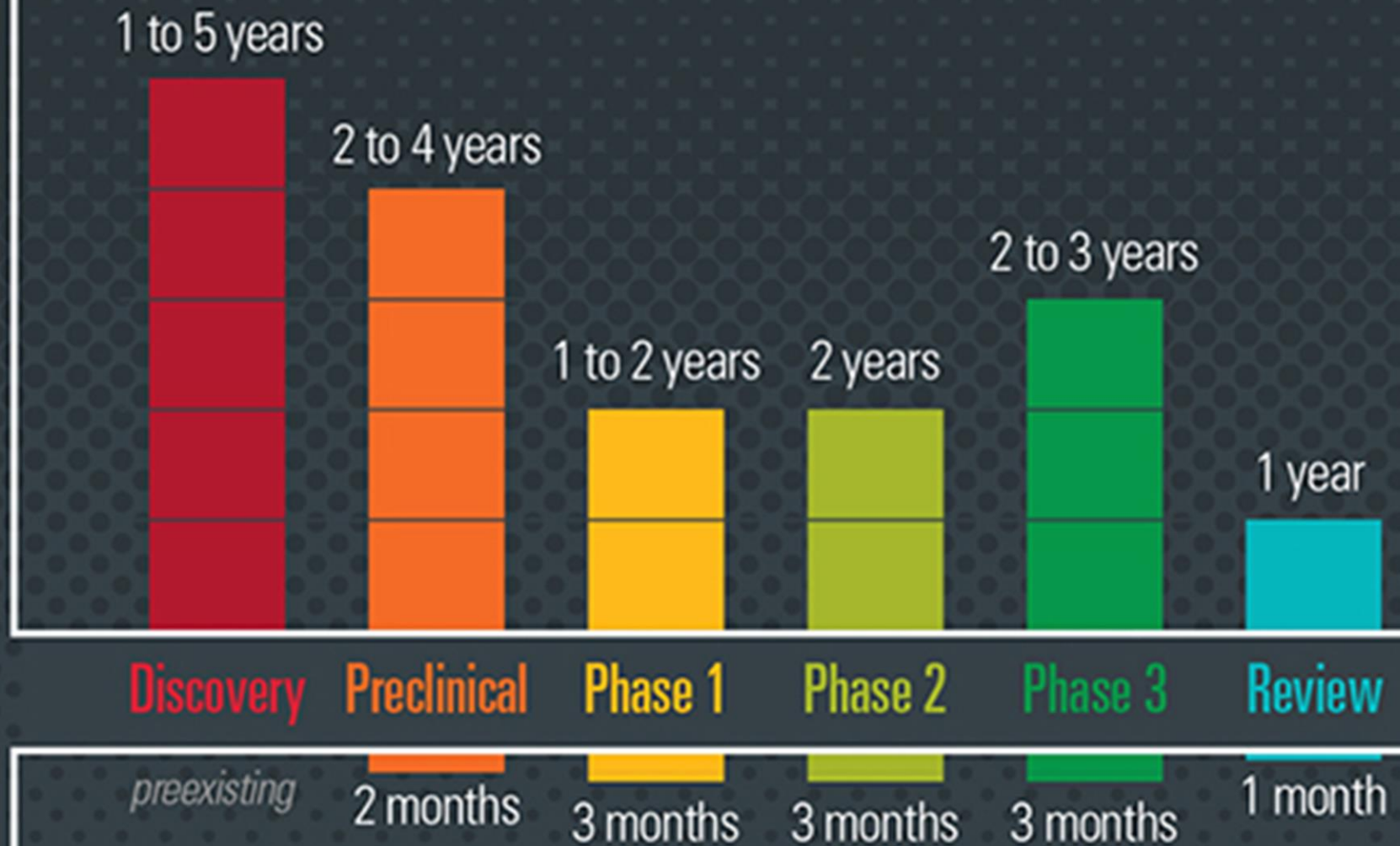
Key: IND: Investigational New Drug Application, NDA: New Drug Application, BLA: Biologics License Application

* The average R&D cost required to bring a new, FDA-approved medicine to patients is estimated to be \$2.6 billion over the past decade (in 2013 dollars), including the cost of the many potential medicines that do not make it through to FDA approval.

Source: PhRMA adaptation based on Tufts Center for the Study of Drug Development (CSDD) Briefing: "Cost of Developing a New Drug," Nov. 2014. Tufts CSDD & School of Medicine., and US FDA Infographic, "Drug Approval Process," <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/UCM284393.pdf> (accessed Jan. 20, 2015).

Source: Pharmaceutical Research and Manufacturers of America

TRADITIONAL VACCINE DEVELOPMENT



ACCELERATED VACCINE DEVELOPMENT

<https://www.nebraskamed.com/COVID/were-the-covid-19-vaccines-rushed>



CLINICAL TRIALS

STAGES OF CLINICAL TRIALS



LABORATORY STUDIES

A new treatment is tested in animal or cell studies to determine if it would be safe and effective for people.



PHASE 1

Tests the safety of medication and treatment on a small group of people



PHASE 2

Continues safety and effectiveness testing with a slightly larger group



PHASE 3

Studies safety, effectiveness and dosing of treatment on hundreds to thousands of people



PHASE 4

Studies long-term effectiveness, comparing new treatment to standard treatment

FACTS.
OVER FEAR
COVID-19



LOGISTICS

- Manufacturing
- Facility inspections
- Supply chain requirements



SAFETY MONITORING


- Risk Evaluation and Mitigation Strategy (REMS)
- Vaccine Adverse Event Reporting System (VAERS)



FDA ENFORCEMENT ACTIONS

- Over **1486** reports of fraudulent products related to Covid-19
- **180** warning letters
- **312** reports sent to online marketplace
- **299** abuse complaints sent to domain registrars

Source: FDA Covid-19 Response At-A-Glance,
<https://www.fda.gov/media/137005/download>



THE PREP ACT

- Protects **entities and individuals** who manufacture, distribute, or administer covered **medical countermeasures**.

DISCUSSION

Issues Related to Diversity

Additional Resources

- <https://www.shb.com/covid-19-resources>

