

Leading FDA's Emergency Response to the COVID-19 Pandemic

**FDA Small Business Regulatory Education for Industry (REdI)
Annual Conference Plenary**

July 19, 2021

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Presentation Sequence

Order	Topic	Presenter
1	CDRH's Role in COVID-19 Response	Jeff Shuren, MD, JD
2	CDER's Role in COVID-19 Response	Patrizia Cavazzoni, MD
3	CBER's Role in COVID-19 Response	Peter Marks, MD, PhD

- Follow general chronology of FDA implementation of various emergency use authorizations (EUAs)

Perspective from CDRH

Jeff Shuren, MD, JD

Director

Center for Devices and Radiological Health (CDRH)

U.S. Food and Drug Administration

Emergency Use Authorization (EUA) Authority



Under FD&C Act § 564, FDA is authorized to issue EUAs when the HHS Secretary **determines** and **declares** that there exists a public health emergency (PHE) or significant potential of a PHE.

On January 31, 2020, the HHS Secretary declared
COVID-19 a public health emergency

Emergency Use Authorization (EUA) Authority



Criteria for issuance of EUA include:

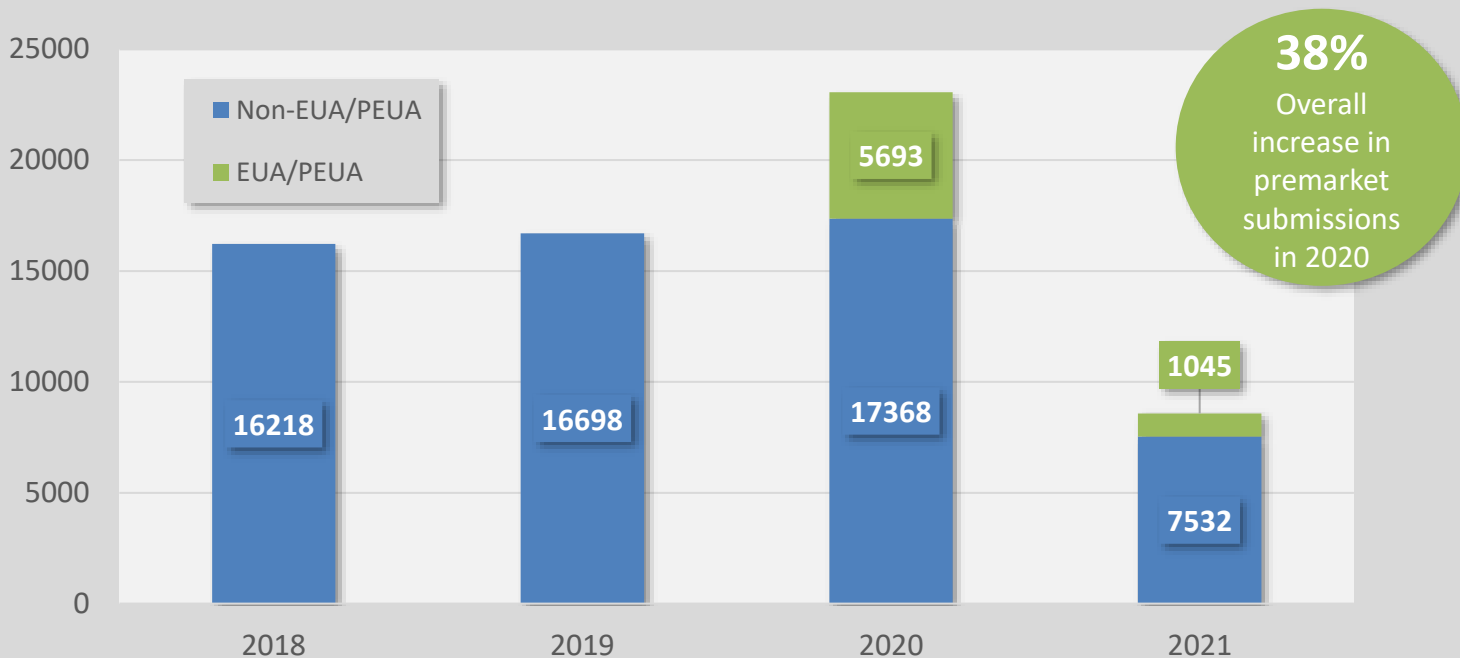
- Serious or life-threatening disease or condition caused by agent
- Product “**may be effective**” to diagnose, prevent or treat the condition (lower level of evidence than “effectiveness” standard)
- Known and potential benefits outweigh known and potential risks
- No adequate, approved, and available alternative; FDA has issued EUAs when there are insufficient supplies of the approved alternative

CDRH's Role in COVID-19



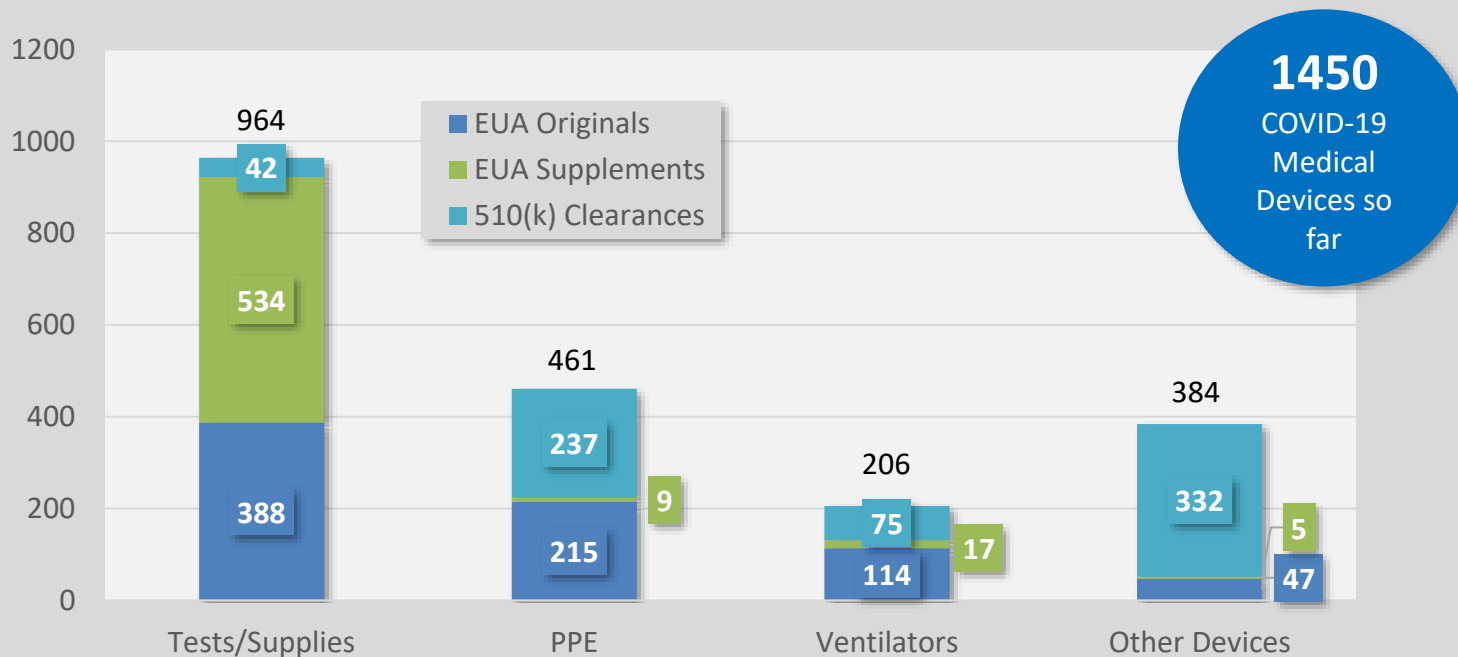
1. Facilitate availability of and access to medical devices
 - *Use of EUA authority*
 - *Engagement*
2. Mitigate supply chain shortages

Impact of COVID-19 on Submission Volume



Data as of June 7, 2021

COVID-19 Medical Devices



Data as of June 4, 2021

COVID-19 Tests Authorized

275

Molecular diagnostic tests

- 25 Pooling
- 39 Asymptomatic single use screening
- 3 Serial screening
- 15 Multi-analyte (i.e., SARS-CoV-2 + Influenza)
- 13 Point-of-care
- 63 Home collection
 - 12 Standalone home collection kits
 - 16 Direct-to-consumer
 - 1 Multi-analyte
 - 11 Saliva home collection
- 5 Standalone saliva collection devices
- 1 Prescription at-home test
- 2 Over-the-counter at-home test

28

Antigen diagnostic tests

- 23 Point-of-care
- 3 Prescription at-home tests
- 5 Over-the-counter (OTC) at-home tests
- 11 Serial Screening

81

Serology and other immune response tests

- 9 Point-of-care
- 1 Neutralizing antibody test
- 14 Semi-quantitative

Data as of June 11, 2021

Other Authorized Devices

Personal Protective Equipment

- Umbrella EUA for face shields
- Umbrella EUA for NIOSH approved respirators
- 38 non-NIOSH approved respirators
- 167 non-NIOSH approved respirators manufactured in China
- 36 surgical masks

Umbrella EUA for Ventilators

- 86 ventilators
- 4 tubing connectors
- 20 accessories

Other Medical Devices

- 4 extracorporeal blood purification devices
- 2 diaphragmatic pacing therapy systems
- 3 respiratory assist devices
- 1 infusion pump
- 3 continuous replacement therapy and hemodialysis devices
- 5 remote or wearable patient monitoring devices

COVID-19 Flexible Policies

21

Device-Specific Guidances

- PPE (4)
- Tests (4)
- Ventilators
- Clinical electrical thermometers
- Sterilizers, disinfectant devices, and air purifiers
- ECMO and cardiopulmonary bypass
- Non-invasive remote monitoring
- Coagulation systems
- Remote digital pathology
- Imaging systems
- Non-invasive fetal and maternal monitoring
- Telethermographic systems
- Digital health devices for psychiatric disorders
- Remote ophthalmic assessment and monitoring
- Infusion pumps

6

Guidances on General Processes

- Adverse event reporting
 - Clinical trials (2)
 - PMA and HDE supplements
 - Formal meetings and user fee applications
- Mammography Quality Standards Act

1

Guidance on Shortages

**= 28 Guidance Documents
+ 17 Revisions**

Data as of June 4, 2021

COVID-19 Engagement

325

Frequently Asked Questions

- 3D Printing
- Diagnostic Testing
- Face Masks (Non-Surgical)
- Shortages of Medical Gloves
- Home-use Blood Glucose Meters Utilized Within Hospitals
- Shortages of Surgical Masks and Gowns
- EUAs for Devices
- Personal Protective Equipment (PPE)
- Non-NIOSH Approved Respirators
- Ventilators

25

Letters to Healthcare Providers & Safety Communications

- 7 Diagnostic Tests
- 5 Antibody Tests
- 9 PPE
- 2 ventilators
- 2 other

394,164

Inquiries addressed through

- 17 mailboxes
- 2 phone lines

78

Webinars & Virtual Town Halls

- 61 Diagnostic Tests
- 15 PPE
- 2 other

13

Templates

- 6 Diagnostic Tests
- 3 Antibody Tests
- 2 PPE
- 2 other

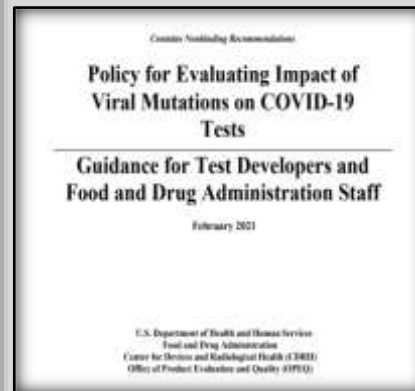
RADx

Participation in NIH's RADx

Data as of June 4, 2021

Viral Mutations

- FDA monitors global databases for emerging variants
- FDA conducts in silico analyses of the target sequences for all authorized molecular tests
- FDA recommends that test developers conduct their own surveillance and analyses, as well
- FDA provides information on specific tests for which the FDA has identified potential impacts on performance due to SARS-CoV-2 genetic mutations
- FDA provides recommendations to clinical laboratory staff and health care providers using tests for which FDA has identified potential impacts on performance due to SARS-CoV-2 genetic mutations



COVID-19 Shortages

Testing Supplies and Equipment



Swabs & Transport Media



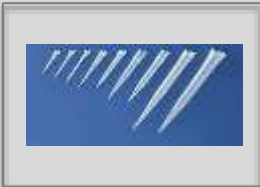
Test Kits



Laboratory Testing
Supplies



Laboratory Reagents



Pipette Tips

Ventilation



Ventilators

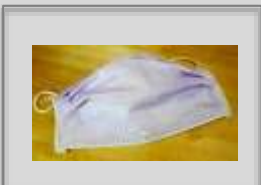
Personal Protective Devices



Respirators



Gloves



Surgical Masks



Examination
Gown



Surgical Gowns

COVID-19 Challenges Across the Respirator Supply Chain

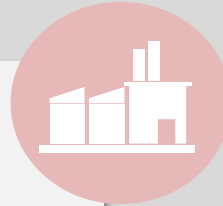


Raw Materials

- Shortage of melt-blown fiber
- Export restrictions on raw materials

Manufacturing

- Limited on-shore manufacturing
- Over-dependence on foreign manufacturing
- Export restrictions on finished product



End Users

- Demand Increase
- Product use in non-traditional facilities
- Just-in-time stockpiles



Distribution

- On-ocean lead time
- Port congestion and container shortage
- Labor shortage
- Counterfeit product introduction



Shortage Mitigation



Outreach to >1,000 manufacturing sites across 12 countries to assess supply chain vulnerabilities



Repurposed ~130 employees to work full or part time on shortages



Expanded device availability and sought out acceptable alternatives to certain testing supplies



Served as a clearinghouse for testing supply alternatives since March 2020



Collaborated with DOD and HHS on expanding industrial base



Facilitated airlift of swabs and pipette tips

Respirator Use Case Approach

Demand > Supply (2020)

- Determine conservation strategies (in conjunction with CDC)
- Identify alternatives
- Emergency use authorizations for respirators
- Emergency use authorizations for decontamination systems



Supply Increases

On June 30, 2021, FDA revoked non-NIOSH approved respirators and decontamination and bioburden reduction systems



Postmarket Actions Taken to Protect Patients

Collaboration

- Developed a reference panel for molecular diagnostic tests
- Worked with NIH to establish a capability at NCI to evaluate serology test performance

Actions Taken

- Issued **25 safety communications** and letters to healthcare providers
- Issued **49 warning letters**
- Revoked **70 EUAs**
- **225 devices have changed claims or stopped marketing** due to FDA follow-up on allegations regarding claims and/or device problems
- Placed **189 tests** from 157 firms on **Import Alert**
- **Refused admission to 90 shipments of tests** at the border, representing more than 238,000 tests

Lessons Learned from COVID-19

Value of Regulatory Flexibility

Throughout the pandemic, we've acted quickly and tailored our oversight to facilitate the availability of critical devices

Power of Engagement

We've provided multiple ways for technology developers to work with our scientific, engineering, and clinical experts in real or near-real time

Together, regulatory flexibility and engagement transformed the medical device landscape and resulted in...

>1400 new devices for COVID-19

Perspective from CDER

Patrizia Cavazzoni, MD

Director

Center for Drug Evaluation and Research (CDER)

U.S. Food and Drug Administration

Coronavirus Treatment Acceleration Program (CTAP)



- FDA created CTAP in response to COVID-19, as a special emergency program for possible coronavirus therapies
- To meet urgent need for therapies, CTAP has enabled CDER to leverage cross-agency scientific resources and experts to bear on COVID-19 therapeutic development and review
- Uses every available tool to facilitate access to new treatments for patients, as quickly as possible
 - Including earlier communication and guidance to researchers and developers
 - While determining whether treatments are safe and effective

CTAP Statistics

- 10 COVID-19 treatments currently *authorized for emergency use*
- 1 COVID-19 treatment currently *approved*
- Over 620 drug development programs in planning stages
- Over 460 trials of potential therapies reviewed by FDA for COVID

Figures as of May 31, 2021 – Available at: www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap

CTAP Principles

- While we have shortened timelines
- Regulatory review and decision-making processes have not changed
- We give all researchers and developers our best advice, apply our legal and regulatory standards, and make decisions on basis of science and data

First FDA-approved COVID Therapeutic

Veklury (Remdesivir)

- SARS-CoV-2 nucleotide analog RNA polymerase inhibitor
- May 2020: Initially authorized under EUA
- August 2020: NDA submitted to FDA
- October 2020: Approved

Veklury (Remdesivir)

- **Indication:**
 - Treatment of COVID-19 in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) requiring hospitalization
- **Current Status:**
 - Remains under EUA for certain pediatric patients not covered in FDA's approval
 - Clinical trials remain ongoing

Currently Authorized Monoclonal Antibody (mAb) Therapies

Authorized Use:

“...for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death”

Currently Authorized Monoclonal Antibody Therapies

Limitation of Authorized Use

Not for use in patients:

- hospitalized due to COVID-19, OR
- require oxygen therapy due to COVID-19, OR
- require increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity

Currently Authorized Monoclonal Antibody Therapies

- REGEN-COV
- Bamlanivimab and Etesevimab
- Sotrovimab

REGEN-COV

- EUA initially authorized in November 2020
- Combination of 2 IgG1 mAbs to spike protein of SARS-CoV-2:
 - casirivimab
 - imdevimab

REGEN-COV

Authorized Dose:

- 600 mg of casirivimab and 600 mg of imdevimab
- Administered together as:
 - single IV infusion OR
 - subcutaneous injection when intravenous infusion is not feasible and would lead to treatment delay

REGEN-COV

- Must be administered as soon as possible after positive viral test for SARS-CoV-2 AND
- Within 10 days of symptom onset

Bamlanivimab and Etesevimab

- EUA initially authorized in February 2021
- Combination of 2 IgG1 mAbs to spike protein of SARS-CoV-2

Bamlanivimab and Etesevimab

Authorized Dose:

- Single IV infusion
- 700 mg of bamlanivimab and 1400 mg of etesevimab
- Administered together as soon as possible after positive viral test for SARS-CoV-2 and within 10 days of symptom onset

Sotrovimab

- EUA initially authorized in May 2021
- IgG1 mAb to conserved epitope on spike receptor binding domain of SARS-CoV-2
- Does not compete with human ACE2 receptor binding
- Authorized Dose:
 - Single IV infusion of 500 mg
 - Administered as soon as possible after positive viral test and within 10 days of symptom onset

SARS-CoV-2 Variants

- Authorized Fact Sheets advise Healthcare Providers that circulating SARS-CoV-2 viral variants may be associated with resistance to monoclonal antibodies

Recommendations for Healthcare Providers

- Review Antiviral Resistance information in Section 15 of authorized Fact Sheet for details about specific variants and resistance
- Refer to CDC and information from state and local health authorities on reports of viral variants of importance in a particular region to guide treatment decisions

CDC site: About Variants of the Virus that Causes COVID-19
www.cdc.gov/coronavirus/2019-ncov/variants/variant.html

Bamlanivimab and Etesevimab

Table 3: Pseudotyped Virus-Like Particle Neutralization Data for SARS-CoV-2 Variant Substitutions with Bamlanivimab and Etesevimab Together (1:2 Molar Ratio)

Lineage with Spike Protein Substitution	Key Substitutions Tested ^a	Fold Reduction in Susceptibility
B.1.1.7 (UK origin)	N501Y	no change ^b
B.1.351 (South Africa origin)	K417N + E484K + N501Y	215 ^c
P.1 (Brazil origin)	K417T + E484K + N501Y	>46 ^c
B.1.427/B.1.429 (California origin)	L452R	9 ^d
B.1.526 (New York origin) ^e	E484K	31

^a For variants with more than one substitution of concern, only the substitution(s) with the greatest impact on activity is(are) listed. For B.1.351, P.1 and B.1.427/B.1.429, spike variants reflective of the consensus sequence for the lineage were tested.

^b No change: <5-fold reduction in susceptibility.

^c Bamlanivimab and etesevimab together are unlikely to be active against variants from this lineage. No activity observed at the highest concentration tested for the P.1 variant.

^d Etesevimab retains activity against this variant.

^e Isolates of the B.1.526 lineage harbor several spike protein amino acid substitutions, and not all isolates contain the E484K substitution (as of February 2021). This assay was conducted using pseudotyped VLPs with the E484K substitution only.

Table 6: Pseudotyped Virus-Like Particle Neutralization Data for SARS-CoV-2 Variant Substitutions with Casirivimab and Imdevimab Together

Lineage with Spike Protein Substitution	Key Substitutions Tested	Fold Reduction in Susceptibility
B.1.1.7 (UK origin)	N501Y ^a	no change ^d
B.1.351 (South Africa origin)	K417N, E484K, N501Y ^b	no change ^d
P.1 (Brazil origin)	K417T + E484K ^c	no change ^d
B.1.427/B.1.429 (California origin)	L452R	no change ^d
B.1.526 (New York origin) ^e	E484K	no change ^d
B.1.617.1/B.1.617.3 (India origin)	L452R+E484Q	no change ^d
B.1.617.2 (India origin)	L452R+K478T	no change ^d

^a Pseudotyped VLP expressing the entire variant spike protein was tested. The following changes from wild-type spike protein are found in the variant: del69-70, del145, N501Y, A570D, D614G, P681H, T716I, S982A, D1118H.

^b Pseudotyped VLP expressing the entire variant spike protein was tested. The following changes from wild-type spike protein are found in the variant: D80Y, D215Y, del241-243, K417N, E484K, N501Y, D614G, A701V.

^c Pseudotyped VLP expressing the entire variant spike protein was tested. The following changes from wild-type spike protein are found in the variant: L18F, T20N, P26S, D138Y, R190S, K417T, E484K, N501Y, D614G, H655Y, T1027I, V1176F

^d No change: ≤ 2 -fold reduction in susceptibility.

^e Not all isolates of the New York lineage harbor the E484K substitution (as of February 2021).

Sotrovimab



Table 1: Authentic SARS-CoV-2 and Pseudotyped Virus-Like Particle Neutralization Data for SARS-CoV-2 Variant Substitutions with Sotrovimab

Lineage with Spike Protein Substitution	Key Substitutions Tested ^a	Fold Reduction in Susceptibility (Pseudotyped VLP)	Fold Reduction in Susceptibility (Authentic Virus)
B.1.1.7 (UK origin)	N501Y	No change ^b	No change ^b
B.1.351 (South Africa origin)	K417N + E484K + N501Y	No change ^b	No change ^b
P.1 (Brazil origin)	K417T + E484K + N501Y	No change ^b	No change ^b
B.1.427/B.1.429 (California origin)	L452R	No change ^b	nd ^d
B.1.526 (New York origin) ^c	E484K	No change ^b	nd ^d
B.1.617 (India origin)	L452R + E484Q	No change ^b	nd ^d

^a For variants with more than one substitution of concern, only the one(s) with the greatest impact on activity is (are) listed.

^b No change; <5-fold reduction in susceptibility

^c Not all isolates of the New York lineage harbor the E484K substitution (as of February 2021).

^d Not determined.

Conditions of Authorization - mAbs

- Sponsor is required to establish process for monitoring genomic database(s) for emergence of global variant(s) of SARS-CoV-2
- Sponsor will provide monthly reports to FDA summarizing any findings from monitoring activities and assessments conducted
- FDA may require Sponsor to assess activity of authorized mAb therapeutic against any global SARS-CoV-2 variants of interest

Conditions of Authorization - mAbs

- When requested, Sponsor shall provide samples of authorized mAb therapeutics to U.S. Government for evaluation of activity against global viral variants of SARS-CoV-2
- Where appropriate, the Letter of Authorization will include conditions requiring Sponsor to submit remaining genomic sequencing information and virological data from clinical investigation(s) by a specific date

CDER Lessons Learned

- Sponsor should engage early and often with CDER scientific staff to develop investigational program for prevention or treatment of COVID-19
- Sponsors should utilize manufacturing sites with demonstrated high Quality Standards and engage early in discussions about Chemistry, Manufacturing, and Controls
- Sponsors should seek early FDA feedback on potential product labeling, including proposed carton-container labeling and associated fact sheets
- Participating in master protocols provides numerous efficiencies for both Agency and Sponsor, and may provide data for same endpoints collected in same way for multiple products

Perspective from CBER

Peter Marks, MD, PhD

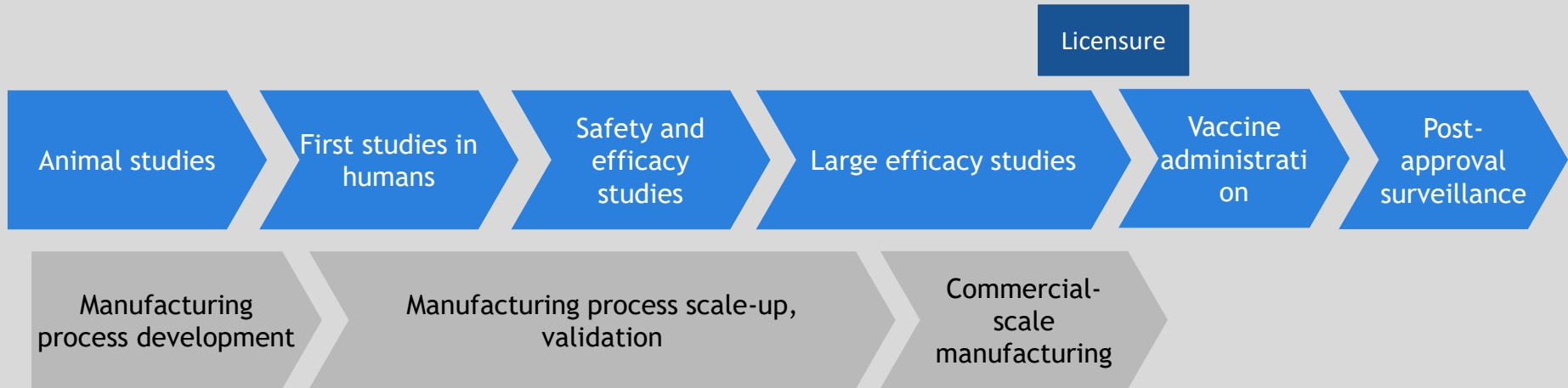
Director

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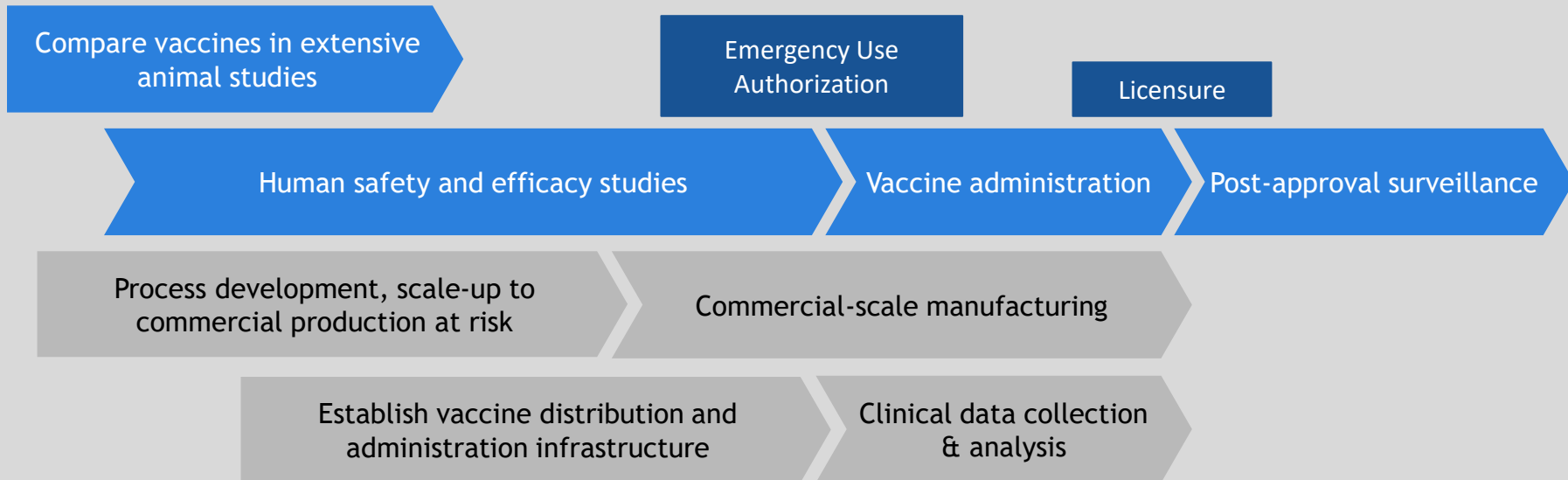
U.S. Food and Drug Administration

Emergency Use Authorized COVID-19 Vaccines

Traditional Vaccine Development



Accelerated Vaccine Development





Biologics License Application (BLA)

- Biologics are licensed under section 351 of the Public Health Service Act
- Product must be safe, pure, potent
- FDA considers evidence from adequate and well-controlled clinical trials

Emergency Use Authorization (EUA)

- Put in place after 9/11 to ensure that potentially lifesaving medical products could be available to people in medical need when there is not an approved and available alternative
- The standard used is that the product “may be effective” and its “known and potential benefits outweigh the known and potential risks”

EUA for a COVID-19 Vaccine

- FDA based authorization on clear and compelling efficacy in large well-designed phase 3 clinical trials
- Careful evaluation of quality, safety, efficacy
- Public advisory committee meeting
- Enhanced post-deployment surveillance

Advanced Candidates – June 2021

- **mRNA**
 - BNT162b2 (Pfizer-BioNTech) – EUA granted Dec 11, 2020
 - mRNA-1273 (Moderna) – EUA granted Dec 18, 2020
- **Non-Replicating Viral Vector**
 - Ad26.COV2.S (Janssen) – EUA granted Feb 27, 2021
 - ChAdOx1 (Astra Zeneca-Oxford)
- **Protein Subunit**
 - NVX-CoV2373 (Novavax)
 - MRT5500 (Sanofi-Translate Bio)

Vaccine Trial Demographics

Vaccine	Pfizer-BioNTech (2 doses 21 d apart)	Moderna (2 doses 28 d apart)	Janssen (1 dose)
Total patients	43,552	30,350	39,321
Receiving vaccine	21,768	15,180	19,630
Receiving placebo	21,784	15,170	19,691
Black/African Amer.	9.8%	9.7%	17.2%
Hispanic/Latino	26.2%	20.0%	45.1%
Am Indian/Alaska Native	0.6%	0.8%	8.3%
At least age 65	21.4%	25.3%	20.4%

Vaccine Efficacy in Phase 3

Primary efficacy was determined against moderate and severe/critical COVID-19

Vaccine	Pfizer-BioNTech	Moderna	Janssen
Primary efficacy (vaccinated/placebo)	95% (8/162)	94.1% (11/185)	d14 66.9% (116/348) d28 66.1% (66/193)
Young population	<u>age 16-54</u> 95.6% (5/114)	<u>age 18-64</u> 95.6% (7/156)	<u>age 18-64</u> d14 63.7% (95/260) d28 66.1% (52/152)
Older population	<u>age 55+</u> 93.7% (3/48)	<u>age 65+</u> 86.4% (5/114)	<u>age 65+</u> d14 76.3% (21/88) d28 66.2% (14/41)
Severe COVID-19	1/9	0*/30	d14 14/60; d28 5/34

*One severe case reported 2 months after vaccination

Vaccine Safety in Phase 3

Second dose

Reaction (2 nd injection)	Placebo*	Pfizer-BioNTech		Moderna		Janssen	
		<55	55+	<65	65+	<60	60+
Injection site pain	14%	78%	66%	90%	83%	57%	33%
Fatigue	22%	59%	50%	68%	58%	44%	30%
Headache	21%	52%	39%	63%	46%	44%	30%
Muscle pain	10%	38%	29%	61%	47%	39%	24%
Chills	4%	35%	23%	48%	31%	N/A	N/A
Joint pain	8%	21%	19%	45%	35%	N/A	N/A
Fever	0.4%	16%	11%	17%	10%	13%	3%

*Average value across all studies, all doses, all ages

Pfizer Pediatric Demographics

Characteristic	Age 12-15 Vaccine (N=1131)	Age 16-25 Vaccine (N=537)	Age 12-15 Placebo (N=1129)	Age 16-25 Placebo (N=561)
Female	49.9%	52.5%	48.2%	52.0%
Mean Age (years)	13.6	19.4	13.6	19.6
Median Age	14.0	18.0	14.0	19.0
Black	4.6%	8.8%	5.0%	8.9%
Hispanic/Latino	11.7%	20.9%	11.5%	18.7%
Comorbidity (yes)	21.9%	23.5%	21.3%	25.7%

Pfizer Pediatric Immune Response

Study Group	12-15 Years N=190 GMT (95% CI)	16-25 Years N=170 GMT (95% CI)	GMT Ratio [12-15 Years/ 16-25 Years] (95% CI)	Met Predefined Success Criterion
Vaccine	1239.5 (1095.5, 1402.5)	705.1 (621.4, 800.2)	1.76 (1.47, 2.10)	Yes

Noninferiority is declared if the lower bound of the 2-sided 95% CI for the Geometric Mean Titer (GMT) Ratio is greater than 0.67

Pfizer Pediatric Efficacy

Endpoint	Vaccine 12-15 Years N=1005 Cases	Placebo 12-15 Years N=978 Cases	Vaccine Efficacy % (95% CI)
First COVID-19 occurrence from 7 days after Dose 2 in subjects without prior SARS-CoV-2 infection	0	16	100.0 (75.3, 100.0)

Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period

Pfizer Pediatric Safety

Characteristic	Age 12-15 Placebo Dose 2 (N=1078)	Age 12-15 Vaccine Dose 2 (N=1097)	Age 16-25 Vaccine Dose 2 (N=488)
Injection site pain	17.9%	78.9%	77.5%
Fatigue	24.5%	66.2%	65.6%
Headache	24.4%	64.5%	60.9%
Muscle pain	8.3%	32.4%	40.8%
Chills	6.8%	41.5%	40.0%
Joint pain	4.7%	15.8%	21.9%
Fever	0.6%	19.6%	17.2%

Safety Monitoring by CDC and FDA



- Passive monitoring through the Vaccine Adverse Event Reporting System (VAERS) and the v-safe text monitoring system for COVID-19 vaccine safety
- Active monitoring through Vaccine Safety Datalink, the Clinical Immunization Safety Assessment, and large databases such as the CMS Medicare Database and Sentinel/BEST covering ≥ 100 million lives
 - Combination of claims data and EHR data
 - Monitoring about 15 safety outcomes of interest

Safety Signals

- **Severe allergic reactions** (Pfizer-BioNTech, Moderna)
 - Rare anaphylactic reactions within about 30 minutes of vaccination
 - Mitigation strategy implemented (30-minute observation for those with history of allergic reactions)
- **Thrombosis-thrombocytopenia syndrome** (Janssen)
 - Rare cases of rare blood clots (mostly cerebral venous sinus thrombosis) and low blood platelets (thrombocytopenia) primarily in younger women
 - Information added to product label
- **Myocarditis/pericarditis** (Pfizer-BioNTech, Moderna)
 - Chest pain following vaccination associated with laboratory or imaging abnormalities primarily in younger individuals
 - Association still under investigation

COVID-19 Vaccine Development

- Vaccine development timelines shortened while still ensuring high vaccine safety and efficacy standards
- Vaccine authorization or approval has followed a process that has been as open to the public as possible
- A transparent process is important for facilitating vaccine confidence

Summary

- FDA's emergency response to COVID-19 was multi-faceted across device, drug, and biologics review Centers
- Emergency Use Authorization allowed FDA to provide a timely response in protecting the public health

