

# Cutting Through the Noise

Market Evolution and Pathways to Access for  
COVID-19 Vaccines and Therapeutics

Live at 12:30 PM ET / 9:30 AM PT

Avalere Health | [avalere.com](https://www.avalere.com) | An Inovalon Company

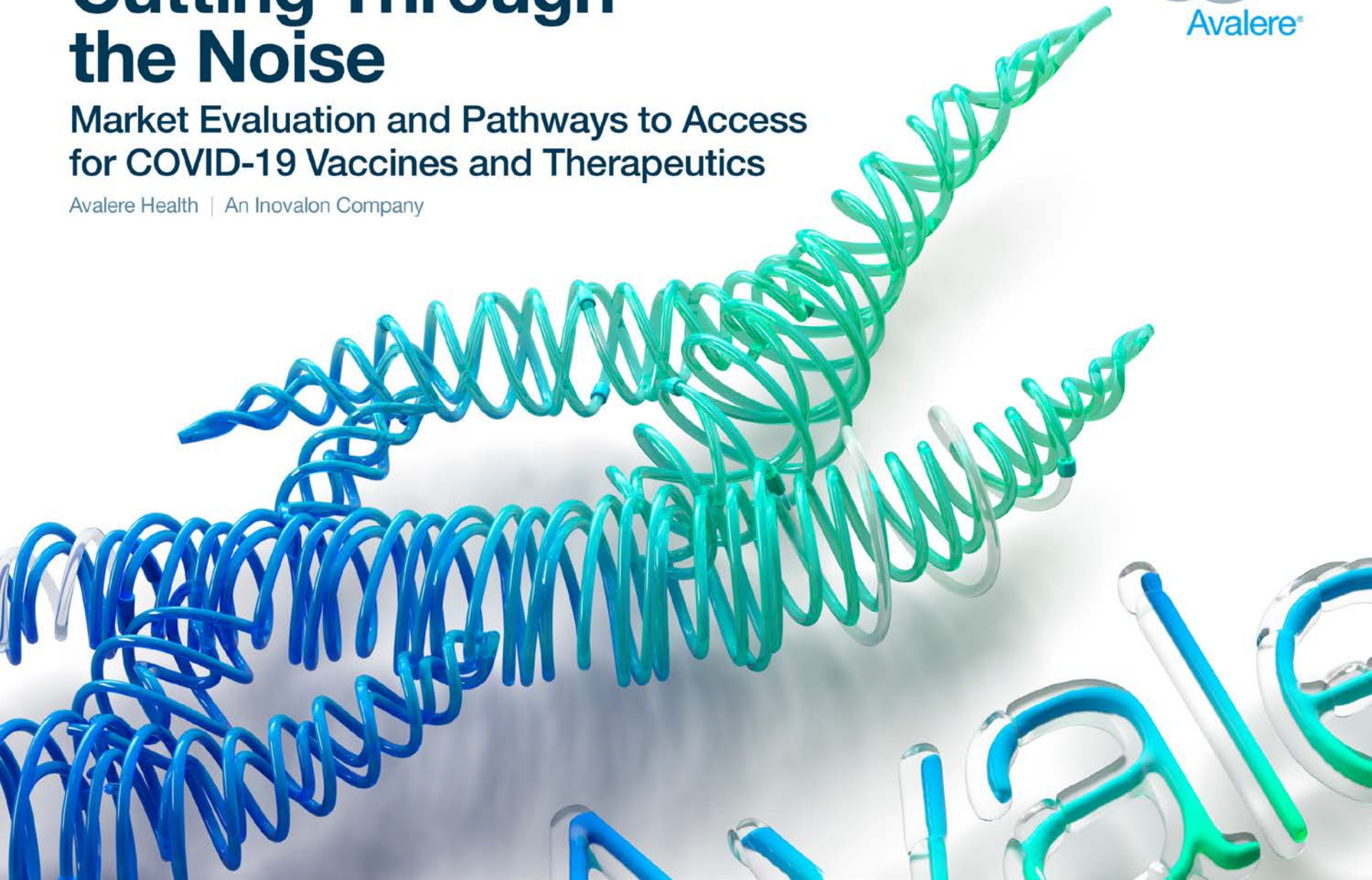


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# A Few Housekeeping Items



The audio and the visual presentation are both accessible through the WebEx link in your calendar invite.



Submit questions via the on-screen question and answer feature. Type your question in the Q&A box on the right side of your screen.



Having trouble with audio? Call in on your phone.

Dial In: 1-415-655-0003

Access Code: 161 901 9305

Attendee ID: Press #

Type your question in this box



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# Today's Speakers

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Moderator



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Speaker



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Speaker



**John C. Neal, MBA**  
Managing Director

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# COVID Tx and Vx Product Development Pipeline

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**510+**

Active Pre-IND  
Treatments

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**230+**

Safe to Proceed  
IND Treatments

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**2**

EUA  
Treatments

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**145+**

Active Pre-IND  
Vaccines

**18+**

Phase I and II  
Vaccines

**5**

Vaccines Initiating  
Phase III

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CTAP Dashboard. FDA. <https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap> Published July 14, 2020.

# Clinical Development and Regulatory Clarity to Support Timely Market Entry

## Policy & Oversight Evolutions /

- Clearly articulated guidance
- Expedited programs; CTAP

## Clinical Landscape Maturity /

- Unified trial protocols
- Endpoints reflecting various efficacy levels

## Market-Approval Pathway /

- Does the risk outweigh the benefit?
- Product specific



Tx: Therapeutic; Vx: Vaccine; EUA: Emergency Use Authorization

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# Evolving COVID Market as More Vx and Tx Are Approved and Become Available

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## Pre-FDA Approval: EUA /

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- Limited positive data available; Continuation of data collection
- EUA and CTAP expedited product review
- USG contracting, distribution, and priority treatment
- Highly managed and tightly controlled distribution

## FDA Approval: Limited Options /

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- Product administration to high-risk target populations
- USG purchase and potential distribution of novel products
- Increases in COVID testing

## Post PHE: Routine Commercial /

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- Routine diagnosis, product distribution, and payer management
- Use restrictions lifted

Vx: Vaccines; Tx: Therapeutics; EUA: Emergency Use Authorization; FDA: Food and Drug Administration; PHE: Public Health Emergency; USG; United States Government

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# Initiatives Designed to Accelerate Developing COVID Tx and Vx

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Operation  
Warp Speed

## Federal Interagency Partnership

Aims to speed development, manufacturing, and distribution of COVID Tx, Vx, and Dx

ACTIV

## Accelerating Coronavirus Therapeutic Interventions and Vaccines

Goal to prioritize vaccine and therapeutic development and connect clinical-trial networks

CTAP

## Coronavirus Therapeutic Acceleration Program

Combines aspects of multiple standard-expedited FDA programs into 1 initiative and focuses attention on the products that demonstrate the most promising results

CDRC

## CURE ID Drug Repurposing Collaboratory

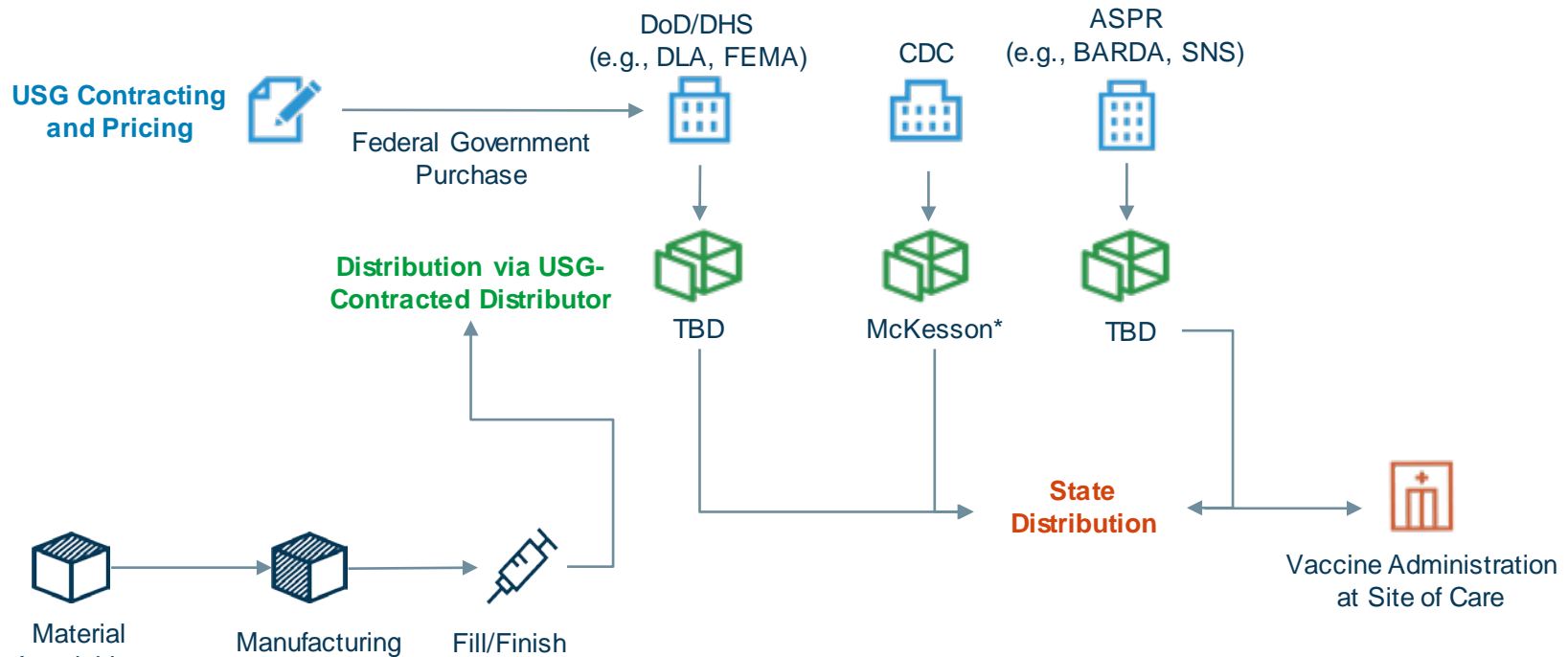
Identifies new uses of existing drugs by capturing real-world, clinical-outcome data

\*Not an exhaustive list, many other initiatives in tandem  
Tx: Therapeutic; Vx: Vaccine; Dx: Diagnostic



# COVID-19 Vaccines: Varied Purchasing and Distribution Pathways to Market

## Vaccine Pricing, Contracting, and Procurement Processes



## Vaccine Production and Supply Processes

\*McKesson has an Exclusive Distributor arrangement with CDC for the VFC program and has a Prime Vendor contract with the VA  
 USG: United States Government; DoD: Department of Defense; CDC: Centers for Disease Control; SNS: Strategic National Stockpile;  
 ASPR: Assistance Secretary for Preparedness and Response; BARDA: Biomedical Advanced Research and Development Authority  
 Source: GAO. Influenza Pandemic: Lesson from the H1N1 Pandemic Should Be Incorporated in Future Planning. 2011. Available [here](#).

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# In June, ACIP's COVID-19 Work Group Proposed Priority Groups for a Tiered-Distribution Approach

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Proposed Distribution for At-Risk Populations  
Followed by the General Population /

## Highest Priority Groups

Highest-risk medical, national security, and other essential workers

## Other High-Priority Groups

Healthcare personnel, essential workers, persons with high-risk medical conditions

## Additional Proposed Groups

Adults 65+, LTC-facility residents, children, pregnant women, high-risk racial and ethnic groups

ACIP: Advisory Committee on Immunization Practices; LTC: Long-Term Care  
Source: June 2020 ACIP Meeting.

# ICER Published on COVID Therapeutic and Vaccine Pricing Options

Greater Manufacturer Control

Status Quo or Unrestricted Pricing

Value-Based Pricing

Advanced Market Commitments and Subscription Models

Greater Government Control

Cost-Recovery Pricing

Monetary Prize

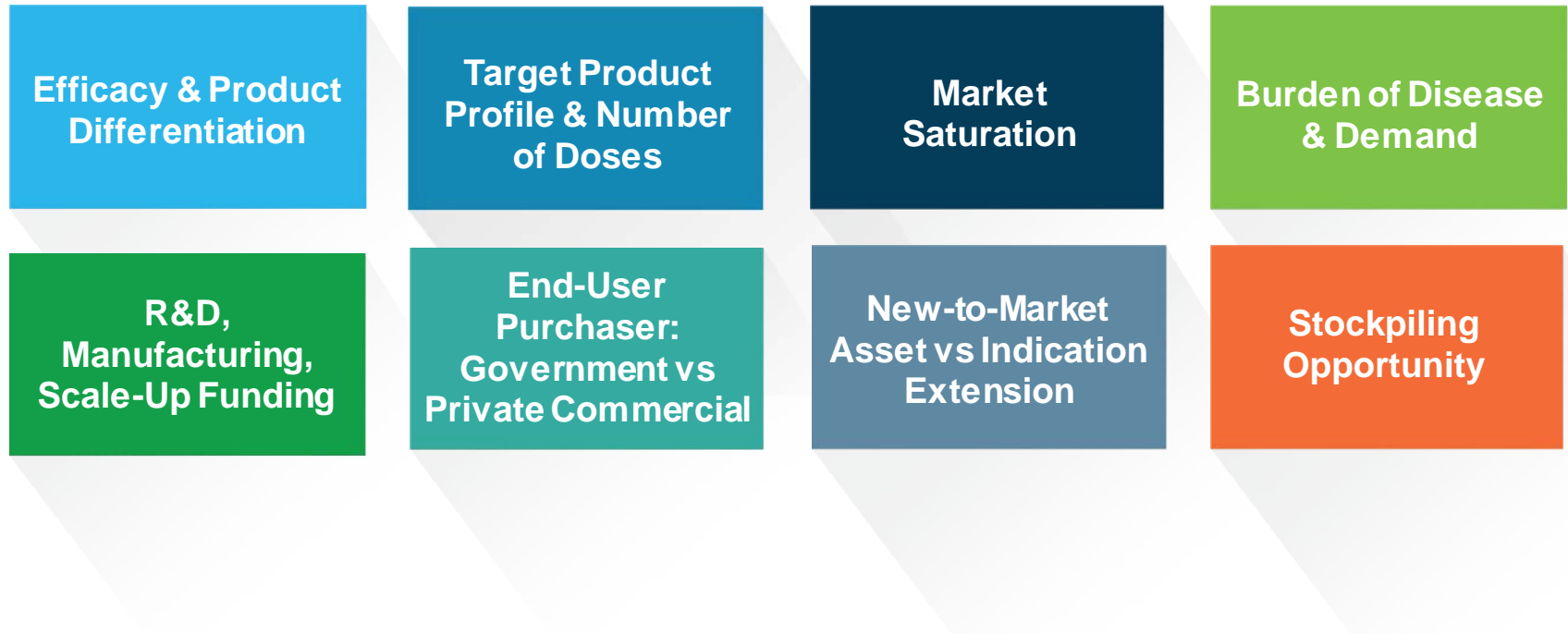
Compulsory Licensing

On July 2, 2020 **ICER published a white paper** on alternative policies for drug and vaccine pricing during a pandemic and will host a 3-part, cross-stakeholder series later this month and in early August.

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# Vx and Tx Price Negotiations and Supply Capacity Factors

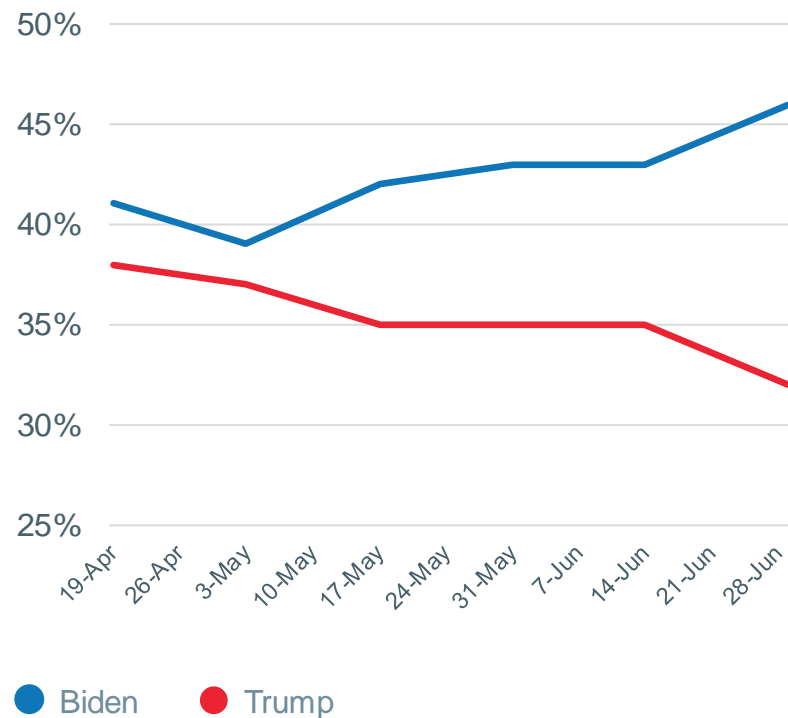
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R&D: Research and Development

# COVID-19 Continues to Drive Election Environment and Post-Election Outlook

## Voter Opinion on Trust of Candidates in Handling COVID-19 /



	Vice President Biden COVID-19 Plan	Trump Administration and Congress COVID-19 Action
No-cost COVID-19 testing and treatment	✓	
Enhance FMAP	✓	✓
COVID-19 vaccine price negotiation	✓	
Enhance telehealth flexibilities	✓	✓
Prepare for surge capacity with temporary hospitals	✓	
Accelerate vaccine and therapeutic development	✓	✓

Source: Morning Consult. How the Coronavirus Outbreak Is Impacting Public Opinion. Available [here](#).



Q&A

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