Addressing the COVID-19 Crisis: An Open Forum Webinar Series for Pharmacists

February 25, 2021

Michael D. Hogue, PharmD, FAPhA, FNAP
Dean and Professor
Loma Linda University School of Pharmacy
President, APhA

Host and Moderator

Today's Focus:

Discuss the available data on the Johnson & Johnson single-dose Janssen COVID-19 vaccine's effectiveness and safety.

Colonel (Ret.) John Grabenstein, RPh, PhD, FAPhA

Editor, Immunization Action Coalition

President, Vaccine Dynamics

Guest Speaker

Mitchel Rothholz, RPh, MBA
Chief of Governance & State Affiliates
American Pharmacists Association

Executive Director
American Pharmacists Association Foundation

Speaker

Daniel Zlott, PharmD, BCOP
Senior Vice President
Education and Business Development
American Pharmacists Association

Speaker

Michael Baxter
Senior Director, Regulatory Policy
American Pharmacists Association

Subject Matter Expert: Q&A

Format for Today's Webinar

1:00 pm: Introductions

1:05 pm: Interview with John Grabenstein, Mitch Rothholz, and Dan Zlott

1:25 pm: Open Forum: A Minute for Your Thoughts

1:50 pm: Wrap Up: Review of APhA's Ongoing Activities and What's Coming

Open Forum Ground Rules

- Use the **Questions** field on the GoToWebinar toolbar to submit comments and questions related to the topic discussion.
- We will try to get to as many comments and questions as possible!
- Refer to the Handout in the GoToWebinar toolbar to access today's slides.

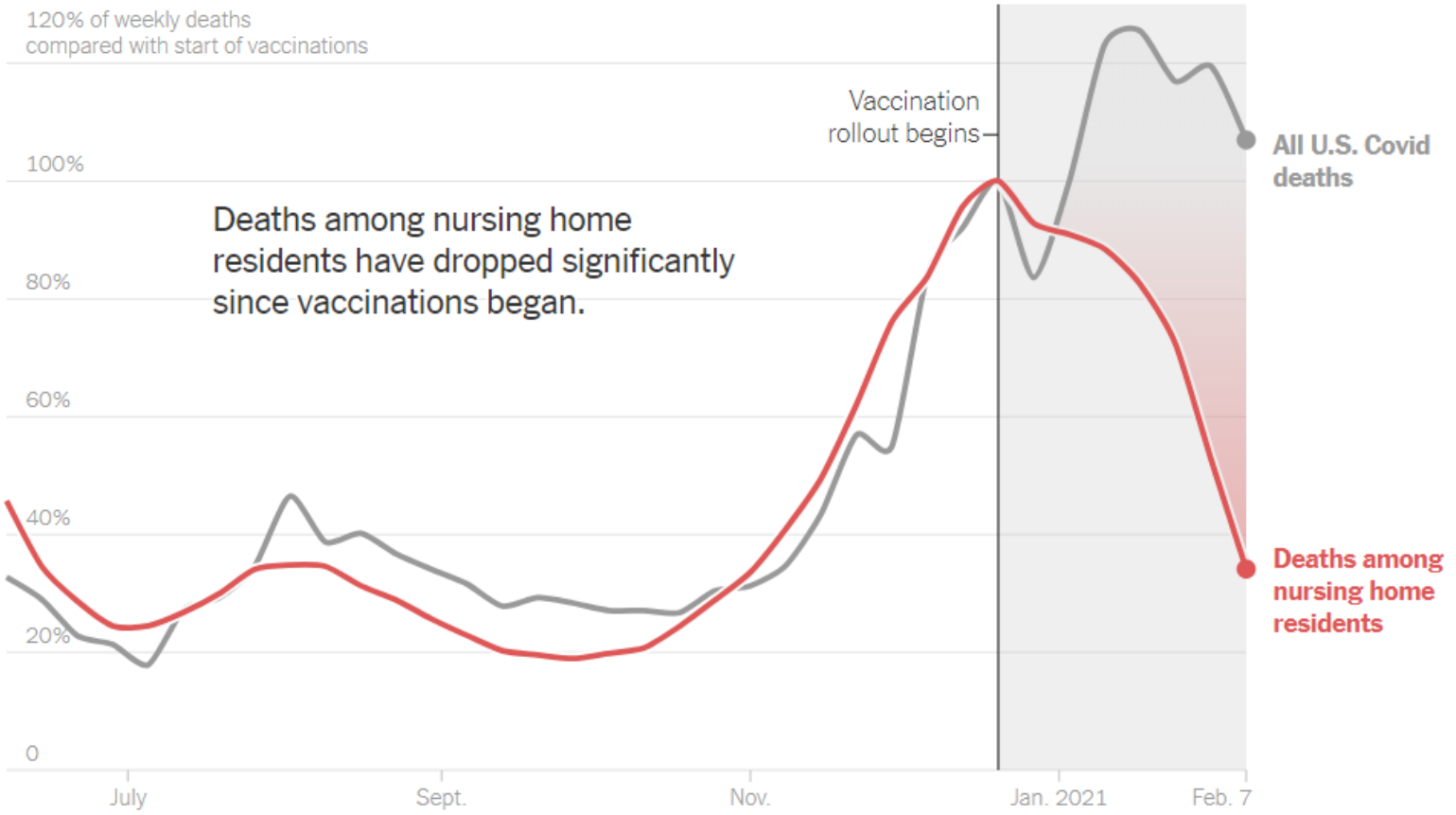
Discussion with John Grabenstein, Mitch Rothholz, and Dan Zlott

Discuss the available data on the Johnson & Johnson single-dose Janssen COVID-19 vaccine’s effectiveness and safety.

The New York Times

Nursing Homes, Once Hotspots, Far Outpace U.S. in Covid Declines

By Matthew Conlen, Sarah Mervosh and Danielle Ivory Feb. 25, 2021



Source: New York Times database; U.S. Department of Health and Human Services ▪ Data shown is normalized compared with the weekly deaths for the week ending Dec. 20, 2020 and is through Feb. 7.

Source: NY Times, 25 Feb 21, Page A1, www.nytimes.com/interactive/2021/02/25/us/nursing-home-covid-vaccine.html

COVID-19 Vaccines: Product Descriptions

Vaccine Sponsor	BioNTech with Pfizer	ModernaTX USA	Janssen Vaccines (division of J&J)
Designator	BNT162b2, tozinameran	mRNA-1273	Ad26.CoV2.S
Vaccine Type	mRNA	mRNA	Adenovirus 26 vector
Product Features	Lipid nanoparticle dispersion	Lipid nanoparticle dispersion	Replication-incompetent adenovirus type 26
Production Medium (origin)	Cell free (synthetic)	Cell free (synthetic)	PER.C6 (human)
Dose	30 mcg in 0.3 mL	100 mcg in 0.5 mL	$5x10^{10}$ viral particles in 0.5 mL
Route + Regimen	IM: Days 0 + 21	IM: Days 0 + 28	IM: single dose
Expected Packaging	Frozen liquid. 6-dose vial, no preservative	Frozen liquid. 10-dose vial, no preservative Applying for 15-dose fill.	Liquid suspension, 5-dose vial, no preservative
Expected Storage & Handling Conditions	Ship, store with dry ice. Under FDA review @ 2-8°C ≤ 5 d. Rm temp: Dilute, use in 6 h	Ship @ -20°C. @ 2-8°C ≤ 30 d. Unpunctured: RmTemp ≤12 h Punctured: ≤ 6 h	@ 2-8°C up to 3 months. Unpunctured: 9-25°C ≤ 12 h Punctured: 2-8°C ≤ 6 h or room temp (max 25°C) ≤ 2 h

25 Feb 21

Sources: FDA and company reports.
www.fda.gov/advisory-committees/advisory-committee-calendar at Dec 10, Dec 17, Feb 26

COVID-19 Vaccines: Evidence for Efficacy

Vaccine Sponsors	BioNTech with Pfizer	ModernaTX USA	Janssen Vaccines (division of J&J)
Designator	BNT162b2, tozinameran	mRNA-1273	Ad26.CoV2.S
Vaccine Type	mRNA	mRNA	Adenovirus 26 vector
Dosing Regimen	Days 0 + 21	Days 0 + 28	Single dose
# of Volunteers	12-55, 56-85 : 40,277	18-64, 65+ : 30,351	18-59, 60+ : 43,783
Efficacy, overall	95.0% (CI: 90, 98%), starting 7 d after Dose 2	94.1% (CI: 89, 97%), starting 14 d after Dose 2	66.9% (CI: 59, 73%) Starting 14 d after Dose 1
Efficacy, stratified by age	56+ y/o: 93.7% (81, 99%) 16 to 55: 95.6% (89, 99%)	65+ y/o: 86.4% (61, 96%) 18 to 64: 95.6% (91, 98%)	60+ y/o: 76.3% (62, 86%) 18 to 59: 63.7% (54, 72%)
Additional analyses	Severe disease: 89% (20%, 99%) Betw Doses 1-2: 52% (30%, 68%)	Severe disease: 100% (CI ?) Between Doses 1-2: 80% (55, 92%)	**Severe disease: 85% (54, 97%)** Overall: US 72%, LA 66%, SA 57%
Asymptomatic infection	Being evaluated	Between Doses 1-2: 14 vs 38 (0.1% vs 0.3%), nasal swabs	Beyond Day 29, suggestion of 60% reduction, PCR or serology

Sources: FDA and company reports.
www.fda.gov/advisory-committees/advisory-committee-calendar at Dec 10, Dec 17, Feb 26

25 Feb 21

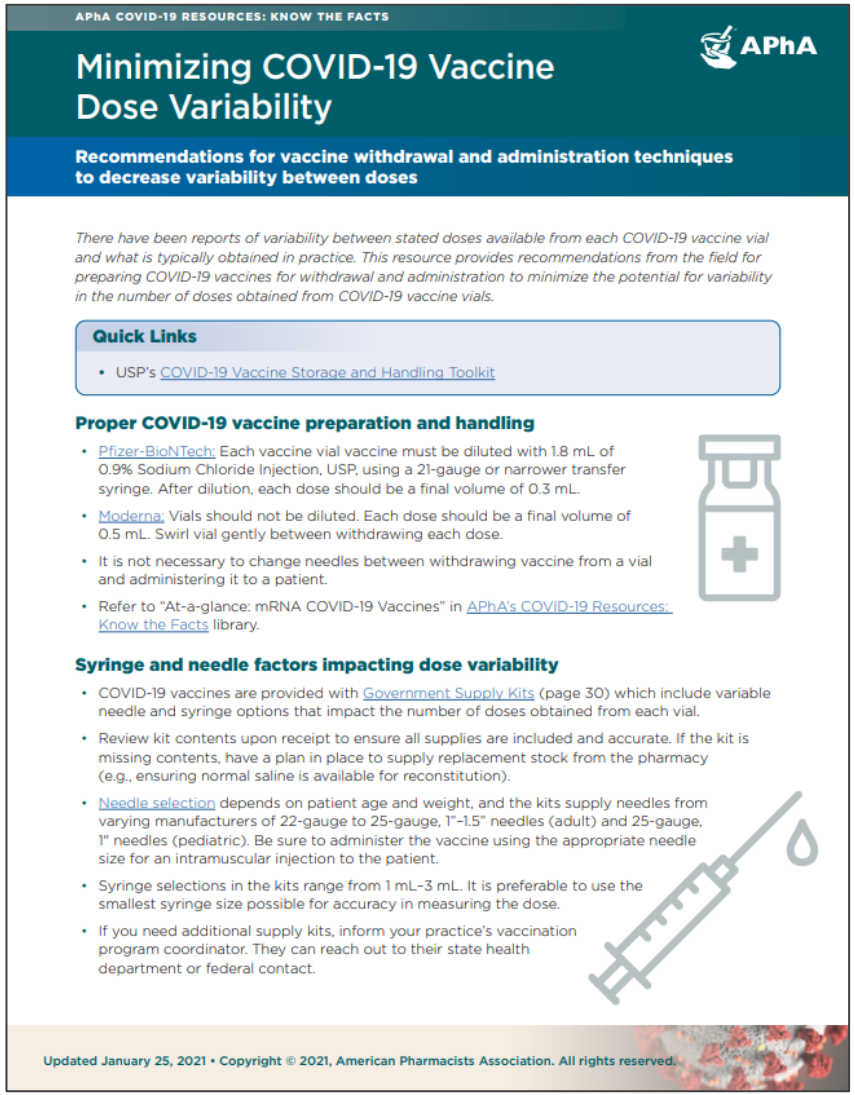
COVID-19 Vaccine Candidates: Evidence for Safety

Vaccine Sponsors	BioNTech with Pfizer	ModernaTX USA	Janssen Vaccines (division of J&J)
Designator	BNT162b2, tozinameran	mRNA-1273	Ad26.CoV2.S
Vaccine Type	mRNA	mRNA	Adenovirus 26 vector
Safety	Common: inj-site rxns (84%), fatigue (63%), headache (55%), muscle ache (38%), chills (32%), joint ache (24%), fever (14%)	Common: inj-site pain (92%), fatigue (69%), headache (63%), muscle ache (60%), joint ache (45%), chills (43%)	Common: inj-site pain (49%), headache (39%), fatigue (38%), muscle ache (33%)
Grade 3 Events	Fatigue 3.8%, headache 2.0%	Fatigue 10%, muscle ache 9%, joint pain 5%, ha 5%, pain 4%	Fatigue 1%, muscle ache 1%, any systemic 1.8%
Serious Adverse Events (AEs)	Serious AEs: 0.0% to 4.6%. More often after Dose 2 than 1. SAEs if 56+ (≤3%) vs ≤55 (≤5%). No meaningful imbalances	Severe AEs: 0.2% to 9.7%. More often after Dose 2 than 1. Fewer SAEs if 65+ y/o No meaningful imbalances	Serious AEs: 0.4% to 0.4% SAEs if 60+ (0.5%) vs ≤60 (0.3%). No meaningful imbalances
Deaths	2 vaccine vs 4 control arm	6 vaccine arm vs 7 control arm	3 vaccine vs 16 control arm
For discussion	Bell's palsy: 4 vs 0	Bell's palsy: 3 vs 1	Bell's palsy: 2 vs 2

Sources: FDA and company reports.
www.fda.gov/advisory-committees/advisory-committee-calendar at Dec 10, Dec 17, Feb 26

25 Feb 21

Maximize the Doses in Each Vial



APhA COVID-19 RESOURCES: KNOW THE FACTS

APhA

Minimizing COVID-19 Vaccine Dose Variability

Recommendations for vaccine withdrawal and administration techniques to decrease variability between doses

There have been reports of variability between stated doses available from each COVID-19 vaccine vial and what is typically obtained in practice. This resource provides recommendations from the field for preparing COVID-19 vaccines for withdrawal and administration to minimize the potential for variability in the number of doses obtained from COVID-19 vaccine vials.

Quick Links

- USP's COVID-19 Vaccine Storage and Handling Toolkit

Proper COVID-19 vaccine preparation and handling

- Pfizer-BioNTech: Each vaccine vial vaccine must be diluted with 1.8 mL of 0.9% Sodium Chloride Injection, USP, using a 21-gauge or narrower transfer syringe. After dilution, each dose should be a final volume of 0.3 mL.
- Moderna: Vials should not be diluted. Each dose should be a final volume of 0.5 mL. Swirl vial gently between withdrawing each dose.
- It is not necessary to change needles between withdrawing vaccine from a vial and administering it to a patient.
- Refer to "At-a-glance: mRNA COVID-19 Vaccines" in APhA's COVID-19 Resources: Know the Facts library.

Syringe and needle factors impacting dose variability

- COVID-19 vaccines are provided with Government Supply Kits (page 30) which include variable needle and syringe options that impact the number of doses obtained from each vial.
- Review kit contents upon receipt to ensure all supplies are included and accurate. If the kit is missing contents, have a plan in place to supply replacement stock from the pharmacy (e.g., ensuring normal saline is available for reconstitution).
- Needle selection depends on patient age and weight, and the kits supply needles from varying manufacturers of 22-gauge to 25-gauge, 1"–1.5" needles (adult) and 25-gauge, 1" needles (pediatric). Be sure to administer the vaccine using the appropriate needle size for an intramuscular injection to the patient.
- Syringe selections in the kits range from 1 mL–3 mL. It is preferable to use the smallest syringe size possible for accuracy in measuring the dose.
- If you need additional supply kits, inform your practice's vaccination program coordinator. They can reach out to their state health department or federal contact.

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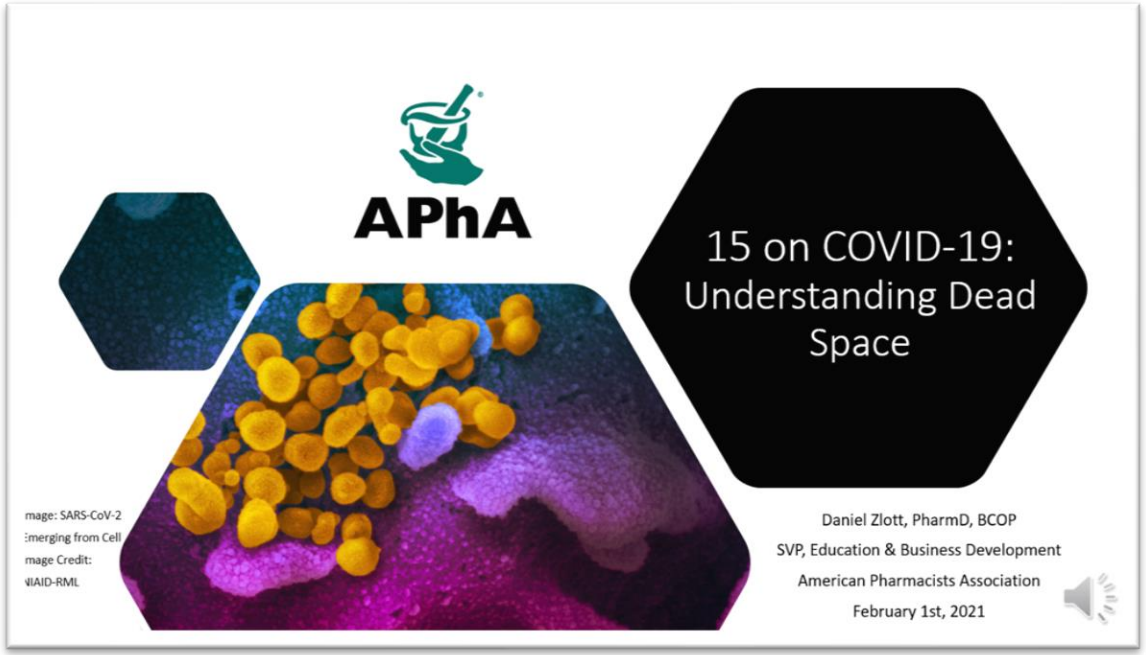
[Minimizing COVID-19 Vaccine Dose Variability]

[15 on 19: Understanding Dead Space]

0.25 hrs CPE

- A quick, but in depth, review of the concept of dead space & why it matters
- Tips on techniques to get as many doses out of each vial of COVID-19 vaccine as possible



Polling Question

Which of the following factors is MOST important to you for receiving a COVID-19 vaccine?

a. Prevention of any COVID-19 infection
b. Reduction in severe COVID-19 infection
c. Reduction in hospitalizations due to severe COVID-19 infection
d. Helping to achieve herd immunity

Open Forum Discussion:
A Minute for Your Thoughts
Comments, Questions, Feedback

Review of APhA's Ongoing Activities and What's Coming

Advocating for You

FDA

FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA Announces Advisory Committee Meeting to Discuss Janssen Biotech Inc.'s COVID-19 Vaccine Candidate

Share Tweet Email

Vaccines and Related Biological Products Advisory Committee Meeting
February 26, 2021

FDA Briefing Document

Janssen Ad26.COV2.S Vaccine for the Prevention of COVID-19

CDC Centers for Disease Control and Prevention

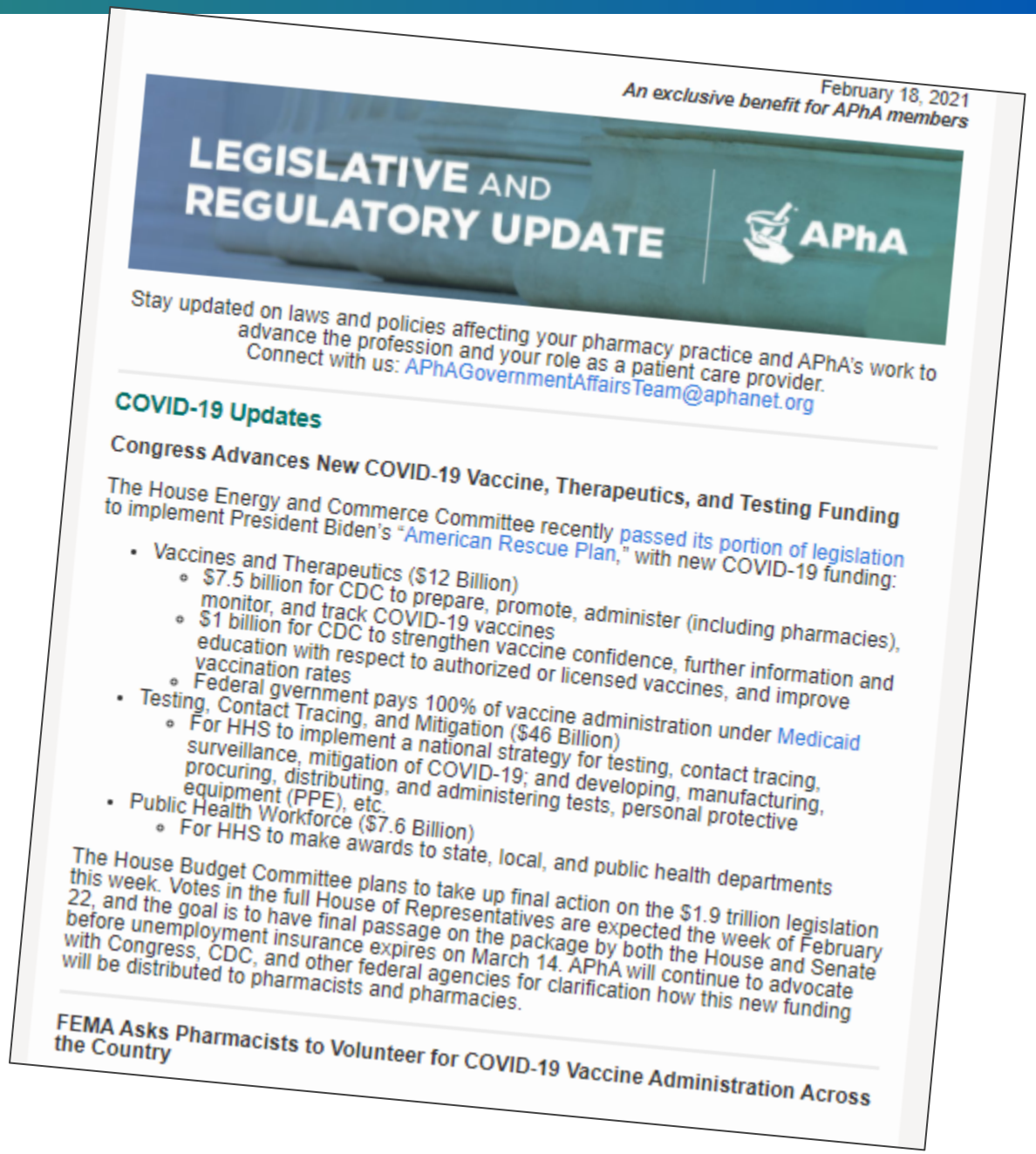
Advisory Committee on Immunization Practices (ACIP)

February 28 – March 1, 2021
Emergency ACIP Meeting. No registration is required.
Meeting times: Feb 28, 11:00am – 4:00pm EST; March 1, 11:00am – 3:00pm EST (times subject to change).

Check your inbox for yesterday's Legislative and Regulatory Update!

– *sent exclusively to APhA members*

Join APhA Today!



February 18, 2021
An exclusive benefit for APhA members

LEGISLATIVE AND REGULATORY UPDATE | APhA

Stay updated on laws and policies affecting your pharmacy practice and APhA's work to advance the profession and your role as a patient care provider.
Connect with us: APhAGovernmentAffairsTeam@aphanet.org

COVID-19 Updates

Congress Advances New COVID-19 Vaccine, Therapeutics, and Testing Funding

The House Energy and Commerce Committee recently passed its portion of legislation to implement President Biden's "American Rescue Plan," with new COVID-19 funding:

- Vaccines and Therapeutics ($12 Billion)
  - $7.5 billion for CDC to prepare, promote, administer (including pharmacies), monitor, and track COVID-19 vaccines
  - $1 billion for CDC to strengthen vaccine confidence, further information and education with respect to authorized or licensed vaccines, and improve vaccination rates
  - Federal gvernment pays 100% of vaccine administration under Medicaid
- Testing, Contact Tracing, and Mitigation ($46 Billion)
  - For HHS to implement a national strategy for testing, contact tracing, surveillance, mitigation of COVID-19; and developing, manufacturing, procuring, distributing, and administering tests, personal protective equipment (PPE), etc.
- Public Health Workforce ($7.6 Billion)
  - For HHS to make awards to state, local, and public health departments

The House Budget Committee plans to take up final action on the $1.9 trillion legislation this week. Votes in the full House of Representatives are expected the week of February 22, and the goal is to have final passage on the package by both the House and Senate before unemployment insurance expires on March 14. APhA will continue to advocate with Congress, CDC, and other federal agencies for clarification how this new funding will be distributed to pharmacists and pharmacies.

FEMA Asks Pharmacists to Volunteer for COVID-19 Vaccine Administration Across the Country

APhA COVID-19 Resources: Know the Facts

Practical Information for Pharmacists to Know Now

COVID-19 Resources:

- **New! Pharmacists' Referrals for Monoclonal Antibody Treatment – Assessing patients for potential COVID-19 treatment with monoclonal antibodies**
- **Reimbursement for Administration of COVID-19 Vaccine(s) – What We Know**

Check out the library of practice resources here

APhA COVID-19 RESOURCES: KNOW THE FACTS

Reimbursement for Administration of COVID-19 Vaccine(s)— What We Know

APhA COVID-19 RESOURCES: KNOW THE FACTS

Pharmacists' Referrals for Monoclonal Antibody Treatment

Assessing patients for potential COVID-19 treatment with monoclonal antibodies

The Food and Drug Administration (FDA) has issued emergency use authorizations (EUA) for monoclonal antibodies for the treatment of mild to moderate COVID-19 disease. **These treatments must be administered at an infusion center within 10 days of symptom onset; pharmacists can play an important role in bringing awareness to these important treatment options.** The purpose of this resource is to provide pharmacists with information about monoclonal antibody treatments and patient eligibility so that pharmacists are prepared to make these potentially life-saving referrals.

Which monoclonal antibody treatments are authorized by the FDA?

Three monoclonal antibodies (mAb)—bamlanivimab, bamlanivimab/etesevimab, and casirivimab/imdevimab—recently received EUAs. Monoclonal antibody treatments use exogenously generated antibodies to neutralize the SARS-CoV-2 virus's ability to infect cells, which can reduce the severity of COVID-19 symptoms in patients who have confirmed COVID-19 infections. Bamlanivimab has reportedly reduced hospitalizations by up to 70%; however, because these medications must be administered by infusion, they are often overlooked and underutilized.

- **Casirivimab/Imdevimab:** Access the FDA Fact Sheet for Health Care Providers and the Fact Sheet for Patients, Parents, and Caregivers.
- **Bamlanivimab:** Access the FDA Fact Sheet for Health Care Providers and the Fact Sheet for Patients, Parents, and Caregivers (Spanish Version).
- **Bamlanivimab/Etesevimab:** Access the FDA Fact Sheet for Health Care Providers and the Fact Sheet for Patients, Parents, and Caregivers.

What is the pharmacist's role in patient access to monoclonal antibody treatments?

Pharmacists in community-based settings can help increase patient awareness of these treatment options, assess for patient eligibility, and refer patients to their provider for treatment. Pharmacists are uniquely positioned to identify patients who may benefit from these underutilized and time-sensitive treatments through point-of-care COVID-19 testing, counseling, and/or clinical assessment. Pharmacists can help route patients to an appropriate provider and provide the location of an infusion clinic to initiate therapy.

How can patients access monoclonal antibodies?

Locate nearby infusion centers at: https://protect-public.hhs.gov/pages/therapeutics-distribution

- Positive coronavirus test
- Symptom onset within 10 days
- High risk

→ Referral to a medical provider → Find a nearby location for infusion services

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Helpful Toolkits

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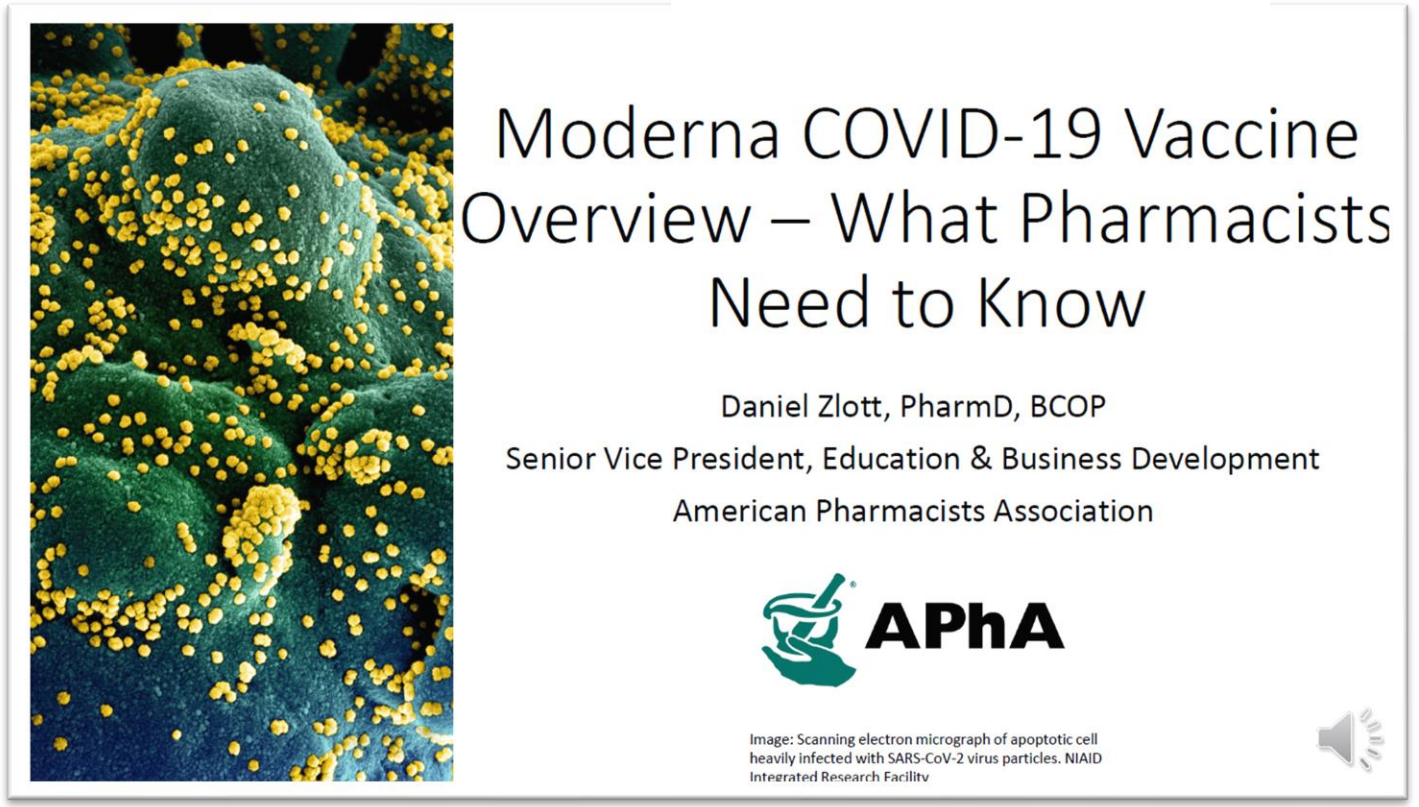
COVID-19 Education Opportunities – CE Available

Moderna Vaccine Overview

1 hr CPE

- Review everything that you need to know for the Moderna vaccine
- Mechanism of action
- Safety info
- Updated storage and handling recommendations
- Tips on overcoming vaccine hesitancy



APhA2021 Virtual

Mark Your Calendars!

March 12-15, 2021

Earn essential CPE credits during four days of inspiring live and recorded sessions exploring the latest updates in pharmacy practice and cutting-edge science.

10+ hours of BCACP Recertification credit available

Connect with peers and join thought leaders in determining pharmacy's future through the late stages of the pandemic and beyond.

Register by THIS SUNDAY, February 28 for early bird rates.

https://apha2021.pharmacist.com/

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Annual Meeting & Exposition
Virtual | March 12-15

Post on ENGAGE

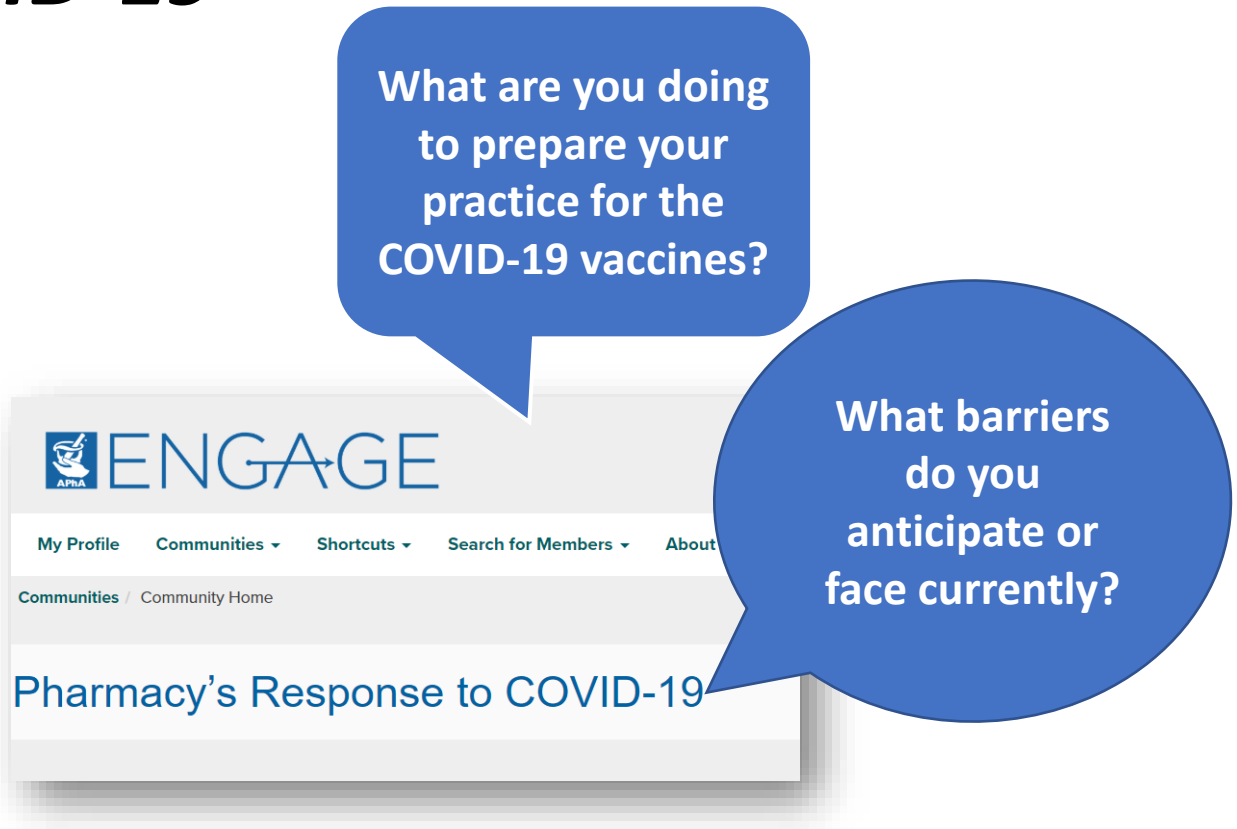
Pharmacy's Response to COVID-19

POST your questions

SHARE your lessons learned

SUPPORT your colleagues

ACCESS the latest information



Weekly Open Forum Webinars

Join Us!

CE Available - Thursday, March 4, 1-2pm ET

Public Health Partnerships in Practice: Collaborative COVID-19 Vaccination Efforts

Register Here

Today's webinar recording and slides will be available within 24hrs

https://www.pharmacist.com/coronavirus/weekly-webinars