Alliant

Road to Recovery

Vaccine Authorization, Now What?

2021 Event Accreditation Status

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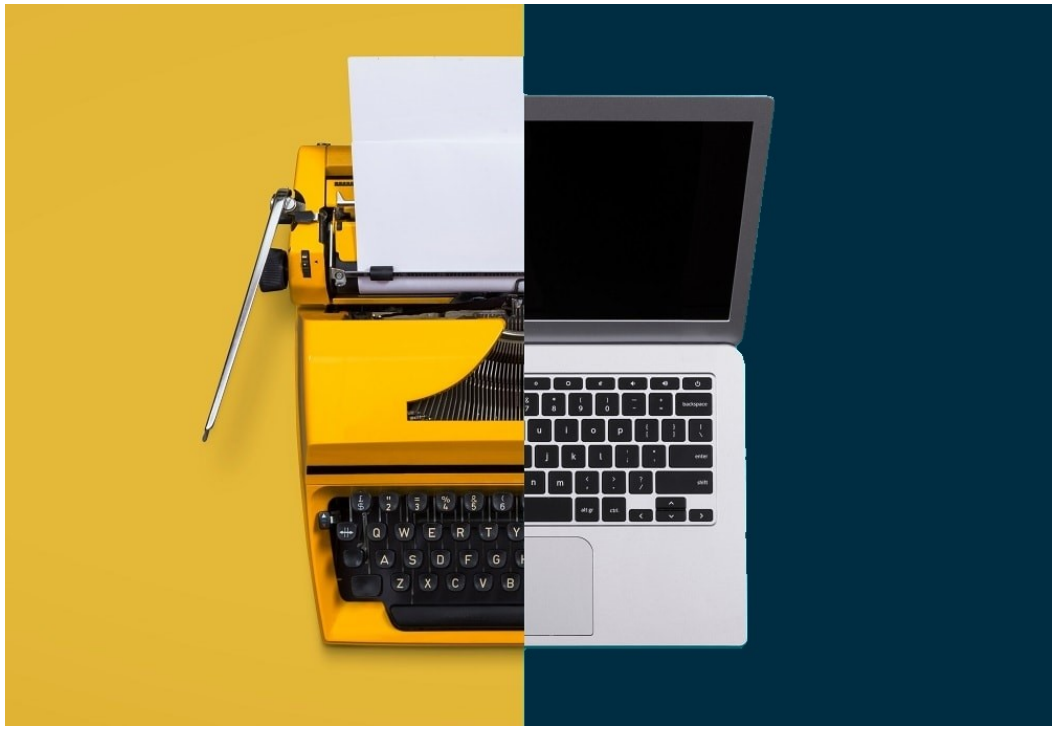

The information contained in this presentation is subject to change at any time and should be treated accordingly. This presentation is confidential and proprietary.

Information in this presentation is current as of January 13, 2021. Due to the rapidly evolving nature of the COVID-19 virus, its mutation(s) and existing treatments and vaccines are subject to quick and drastic change. Vaccine access and distribution considerations will also evolve quickly over the coming weeks and months. Employers should closely follow the changing recommendations and guidelines to ensure timely access to vaccines for employee populations.

Addressing Preliminary Questions

We received several questions leading up to this webinar and have developed content to address as many of these questions as possible. Please note certain questions were not addressed due uncertainties and unknown factors.

Today's Presenters

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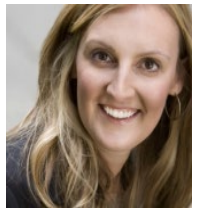

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Agenda

- **Vaccine Development & Efficacy**
- **Vaccine Distribution & Access**
- **Compliance Considerations**
- **Employee Well-Being Best Practices and Recommendations**

Vaccine Development & Efficacy

COVID-19 Vaccine Development

Pre-Clinical
Laboratory based experiments using blood samples and laboratory animals for testing. Investigatory and experimental work only. If results are promising, official phased work begins.

0 Months

Phase I
Uses small sample sizes of populations using blinded techniques with prototype vaccine and placebo. Using general guidelines for dosing, etc., individuals blindly receive an injection. Results are evaluated for efficacy and for safety. After meeting CLIA and FDA standards, larger scale trials begin. Estimated 70% move forward.

1 Year

Phase II
Uses larger sample sizes of populations, typically 100 + participants. Similar to Phase I, Phase II seeks to improve results from earlier phases and are double-blinded with a focus largely on safety and side effects. A longer clinical study period is required. After meeting CLIA and FDA standards, mass scale trials begin. Estimated 33% move forward.

2 Years

Phase III
Thousands of sample size populations are used to evaluate effectiveness, safety and outcomes from the vaccination attempt. Double-blinded and extended clinical trial period time is required. Side effects and infections in those with a vaccine over placebo are carefully examined and analyzed. After meeting CLIA and FDA standards, regulatory approval is sought. Estimated 25%-30% move forward.

3 Years

4 Years

5 Years

Regulatory Review
Quality control, safety, effectiveness, side effects, patient satisfaction, specificity against virus/bacteria, financing, and manufacturing are all assessed and analyzed. An emergency use authorization (EUA) may be issued based on preliminary findings and the need to inoculate against a pandemic or deadly epidemic.

This process can take several months to several years depending on the scope and magnitude of the vaccine's impact. Upon receiving clearance, the manufacturer receive vaccine approval and distribution authority.

Distribution
Vaccine is manufactured and distributed in accordance with international, federal, state and local laws and ordinances.

Total processing time from start to finish can take as long as 5 years to produce a vaccine for review and another 3-4 years before approval and distribution occurs.

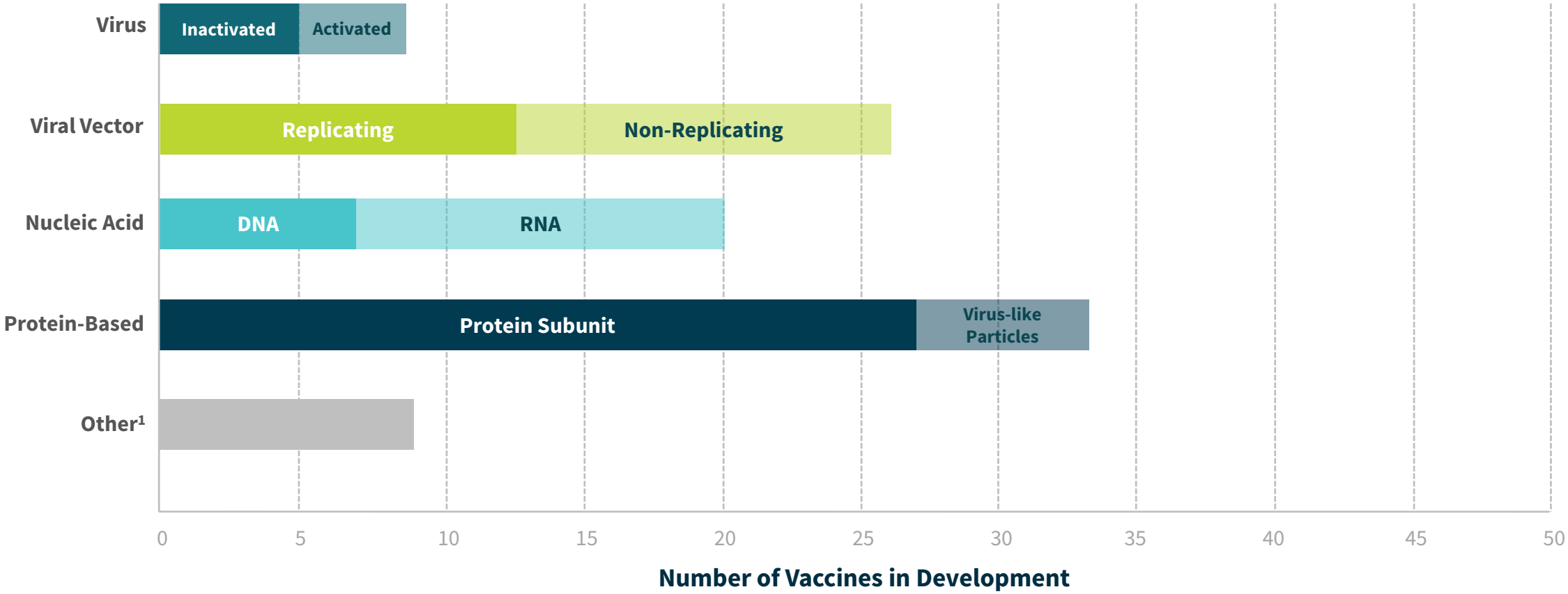
FDA's Fast Track Designation

The Fast Track Designation (FTD) program was created to circumvent red tape within the FDA to advance the development and clinical review of drugs that treat serious conditions where medical care is ineffective (as largely seen with COVID-19).

COVID-19 Vaccine Candidates:

- Receive more meetings with FDA regulators
- Obtain critical feedback to more forward
- More written communications with the FDA
  - i.e., increase sample size, augment dose, etc.
- Priority Review Queue (Accelerated Review)
- Rolling Review for Biologic License Application or New Drug Application
  - Before waiting for every section of the application to be completed

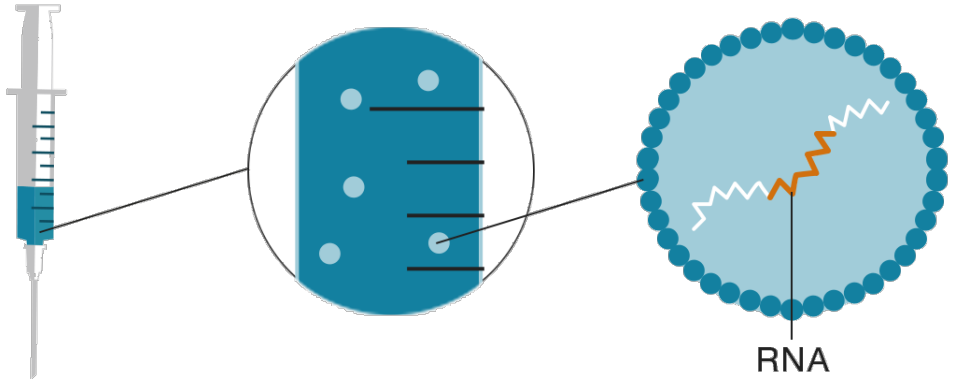
An Array of Vaccines in Production

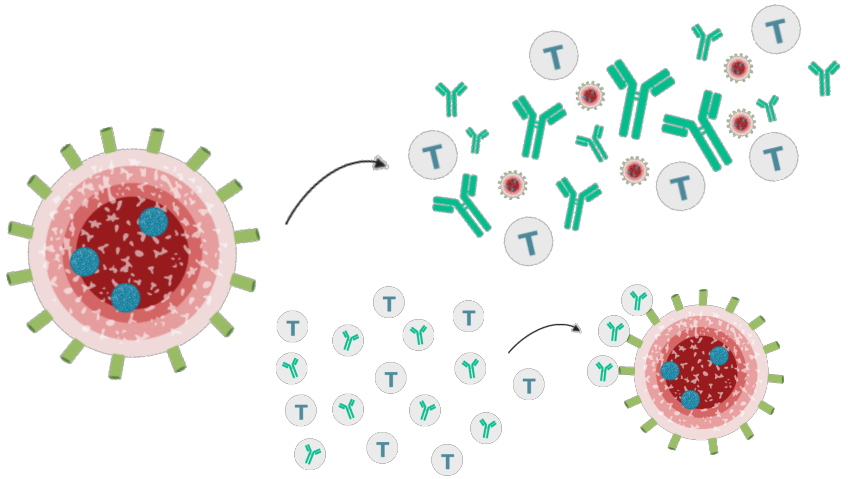


[1] Other testing includes technology used to develop polio or tuberculosis vaccines that are believed to be effective against SARS-CoV-2 by eliciting a general response rather than adaptive immunity. Includes testing that genetically modifies immune cells to target the virus.

Source: Nature analysis based on: WHO COVID-19 Vaccine Landscape/Milken Institute COVID-19 Treatment and Vaccine Tracker/T. Thanh Le et al. Nature Rev. Drug. Disc. https://doi.org/ggrnbr (2020)/F. Amanat & F. Krammer Immunity 52, 583–589 (2020)/W. Shang et al. npj Vaccines 5, 18 (2020).

COVID-19 mRNA Vaccine Mechanism of Action





Use of mRNA technology for COVID-19 vaccine

- Once injected, vaccine's lipid attaches to a human cell
  - This triggers a coronavirus spike protein
  - T-cells are alerted and isolate the spike protein
  - T-cells dismantle and destroy the spike protein
    - Creating antibodies against coronavirus
- Any future exposure to the actual virus will illicit an immune response, protecting cells from infection
    - Duration of immunity is **still unknown.**

- Viral genetic sequence code is extracted from the SARS-CoV-2 virus and rewraps it in a lipid protein
  - This "code" tells the virus how to infect and protect itself
  - Scientists reprogram the sequence to alert human T-cells (killer cells) that a virus exists
  - The reprogramming gives T-cells the "key" to kill the virus.

Moderna vs. Pfizer (Leading Vaccine Makers)

What are the main differences between these two vaccines?

Vaccine Attribute	Moderna	Pfizer / BioNTech
Vaccine Technology:	mRNA (mRNA-1273)	mRNA (BNT162b2)
Clinical Trial Participants:	30,000	44,000
Participant Infections:	95 (90/95 given a placebo)	94 (85/94 given a placebo)
Effectiveness Rate:	95%	95%
Doses Required:	2 Intramuscular injections	2 intramuscular injections
Refrigeration / Stability:	36 to 46 degrees Fahrenheit: Stable for up to 30 days 12 Hour stability at room temperature	-94 degrees Fahrenheit: Stable for up to 24 hours
Common Side Effects:	Injection site pain, fatigue, headache, and joint pain	Injection site pain, flu-like symptoms, muscle pain and fever
Time to Immunity:	In most cases, one to two weeks after initial dose; stronger presence of antibodies indicating more effective immunity seen after second dose and after 30 days. Initial dose is expected to deliver approximately 50% effectiveness against the virus and up to 95% after the second dose.	
Immunity Duration:	Unknown	Unknown

Ones to Watch: Vaccine Pipeline

Company	Country	Type	Trial Participants	Doses	Effectiveness[1]	Storage	US Authorized?
Oxford University AstraZeneca	United Kingdom	Viral Vector (genetically modified virus)	> 30,000	2	62% to 90%	Regular refrigeration temperature	No
Moderna	United States	RNA (part of the virus code)	> 30,000	2	95%	36 to 46 degrees Fahrenheit: Stable for up to 30 days 12 Hour stability at room temperature; -20 Celsius / - 4 Fahrenheit up to 6 months.	Yes
Pfizer/BioNTech	United States/ Germany	RNA (part of the virus code)	> 30,000	2	95%	-94 degrees Fahrenheit: Stable for up to 24 hours	Yes
Gamaleya (Sputnik V)	Russia	Viral vector)	> 30,000	2	92% (in Russian trials)	-18 degrees Celsius / 0 degrees Fahrenheit: Stable > 24 hours	No
Sinovac CoronaVac	China	Virus	> 30,000	2	70% (Chinese trials)	36 to 46 degrees Fahrenheit: Stable for up to 3 years	No

Sample Phase 3 Clinical Trial Candidates

Company	Country	Type	Trial Participants	Doses	Notes
Johnson & Johnson / Janssen	United States	Non-replicating viral vector	> 60,000	2 (Exploring 1)	The ENSEMBLE trial was on hold pending a review of an adverse event a participant developed in one of the study arms, but Janssen has been cleared to resume the trial in the U.S. and Brazil after the Independent Data Safety and Monitoring Board recommended the trial resume recruitment.
Novavax	United States	Nanoparticle vaccine	> 4,000	2	The Phase 3 PREVENT-19 trial has been launched in the United States and Mexico (NCT04611802).

[1] Not peer reviewed, subject to various interpretations of effectiveness and protection. Effectiveness may change over time.

Source: Infographic: How effective are the COVID-19 vaccine candidates? (2020, November 17). Statista COVID-19 Storage and Stability. https://www.statista.com/chart/23510/estimated-effectiveness-of-COVID-19-vaccine-candidates/

What We Know / What We Don't Know

- There are only two (2) vaccine manufacturers authorized in the United States
  - Moderna
  - Pfizer / BioNTech
- The flu shot does not protect against COVID-19; the COVID-19 vaccine does not protect against the flu
- Common side effects for most vaccines are:
  - Pain at injection site
  - Fatigue or tiredness
  - Headache and joint pain
- The mRNA vaccines have elicited an immune response
- You cannot get COVID-19 from taking one of the two authorized vaccines in the United States (mRNA)

- When other vaccines will be authorized for distribution and use in the United States
- Vaccine immunity duration is unknown
- Long-term side effects of both COVID-19 itself and the vaccines are unknown
- All U.S. authorized vaccines require 2 doses; vaccine effectiveness with one dose is unknown
- The frequency of having to get a vaccine against COVID-19 is still being researched
  - It is unknown if the vaccine is like the annual flu shot or other with longer immunity

Vaccine Distribution & Access

Vaccine Distribution & Access

Phase 1: Limited Access & Prioritized Distribution

Things to know: CDC controls access & distribution; ACIP published recommendations; only approved providers can access vaccines for distributions (lists maintained at the state level); Points-of Distribution applications accepted/approved by CDC.

Phase 1a
Healthcare workers and LTCF staff & residents

Phase 1b
Frontline Essential Workers and persons aged 75+

Phase 1c
Persons age 65+ and those with high-risk medical conditions

ACIP updated recommendations last on December 20th; HOWEVER, States and Jurisdictions have the authority to distribute to fit local needs.

Key question: *What is the definition of Frontline Essential Worker?*

Phase 2: Sufficient Supply to meet demand

Things to know: CDC will control access & distribution through phase 2; timeline for reaching phase 2 will vary by state and initial uptake in vaccinations for phase 1 priorities.

Access expands beyond initial populations

Use of broader provider network and settings including:
*Retail Pharmacies
*Healthcare settings

Important Updates: Due to delays in vaccination administration across the country, on January 6th, HHS Secretary (Azar) announced that States should bypass COVID vaccine priority plan if causing administration slow-downs. On January 12th, the current Administration released plans for all available vaccine inventory be used for 1st dose vaccinations, rather than holding back allotments to ensure 2nd doses are given within recommended timeframes; these changes also included focusing on individuals age 65+ and with underlying health conditions as the priority.

State & Local Distribution Doesn't Equate to a 'Simple' Employer Strategy

Variations in Priority Distribution by Jurisdiction: Phase 1a, b, c

ACIP Recommendations

Phase 1a
Healthcare workers and LTCF staff & residents

Phase 1b
Frontline Essential Workers and persons aged 75+

Phase 1c
Persons age 65+ and those with high-risk medical conditions

Georgia

Phase 1a
Healthcare workers and LTCF staff & residents
Adults 65+ AND their caregivers
Law enforcement, EMS, etc.

Phase 1b
Essential workers who perform job tasks across critical infrastructure sectors

Phase 1c
Persons aged 16-64 with medical conditions that increase risk

Texas

Phase 1a
Healthcare workers & direct care (EMS, First Responders) and LTCF staff & residents

Phase 1b
Persons aged 65+ or 16+ with at least one chronic medical condition, including pregnancy

Phase 1c
TBD

Ohio

Phase 1a
Healthcare workers & direct care (EMS, First Responders) and LTCF staff & residents

Phase 1b
Persons aged 65+, school teachers & staff

Phase 1c
TBD

What should employers be doing right now? *Think locally.* Because distribution/access is being driven by public health districts, and access will vary from state to state, it would be prudent for employers to reach out to local health department contacts. Local health departments (and or State Health Department websites) may be able to shed additional light on points of access within the community, as well as anticipated allocations based on Population Group assessments that were submitted in late 2020.

Resources:

*Providers are required to file inventory updates on a daily basis through **VaccineFinder** – but until vaccine access is more widespread – they do not have the consumer/public facing option turned on, specific to COVID vaccines. State and local health department websites will be the place to confirm approved providers until the national database is published.
[Note: Alliant will be publishing a list of all state and jurisdiction links that are publically available for client access following this webinar].

What We Know / What We Don't Know

- CDC will continue to manage distribution through phase 1 and phase 2.
- States have the authority to set guidelines for priority distribution – and they are exercising that right to meet local needs.
- Vaccine administration is not meeting levels of distribution thus, priorities in states and local jurisdictions are continually evolving.
- Employers are going to have to turn to local resources to identify options for vaccinating employees – at least for now.
- **Employers must cover the cost of ADMINISTRATION of the vaccine;** for now, the federal government is picking up the tab for the cost of the vaccine. Most plan administrators are following CMS reimbursement guidelines = $16.94 for the first dose, $28.29 for the second dose.
- Employers who are allowing local providers to come onsite to administer vaccines should have legal counsel weigh in on plans to ensure (1) equitable access (2) liability considerations are covered (3) all preventive measures for adverse event treatment are made available.

- How quickly states will move through phases.
- What shifts states will make to ensure they are administering vaccines as soon as they receive allocations (change or removal of priorities).
- How individuals will 'prove' essential worker status to access vaccines where this is part of a phase 1a/b/c strategy.
- When employers can expect to roll-out a more consistent strategy across their employee population (e.g., getting to Phase 2). At this point, large direct-to-employer vaccination partners (e.g., Quest, Occuvax, retail pharmacy chains) do not have widespread access to the vaccine to support vaccination clinics, but that is evolving quickly and we expect to see additional access points in the coming weeks.

What We Know / What We Don't Know

- Access to the vaccine is most critical
  - Employers should cover vaccines under both pharmacy and medical benefits
  - PBMs are prepared to adjudicate claims under either benefit
- Pharmacies will play a critical role in vaccine distribution
  - CVS and Walgreens have been vaccinating residents of long-term care facilities and have significant capacity
  - Broad geographic dispersion, accessibility and trust
  - HHS has approved qualified pharmacy technicians and state authorized pharmacy interns to administer the vaccine and tests
  - Most pharmacies can adhere to cold chain requirements
  - Likely by appointment only, with much of the process managed through an app, including notifications to book the 2nd vaccination of the series

- Timing for pharmacies to begin broader vaccinations under the new administration guidance
- Management of anaphylaxis (severe allergic reaction) in pharmacies
  - To date, this is very rare with only 29 cases reported, and does not impact CDC guidance for who should be vaccinated
  - CVS and Walgreens have confirmed observation and emergency protocols will be in place
- The role of independent pharmacies in reaching rural areas
- The role that pharmacy chains will play in assisting an employer with vaccine administration
  - Some chains are willing to partner, for a setup fee, to come onsite and do COVID vaccine clinics
  - Criteria for employer size and scope is TBD
- COVID vaccine reducing transmissibility

Compliance Considerations

Vaccine Program Approaches

An employer can require employees to be vaccinated . . . with significant caveats

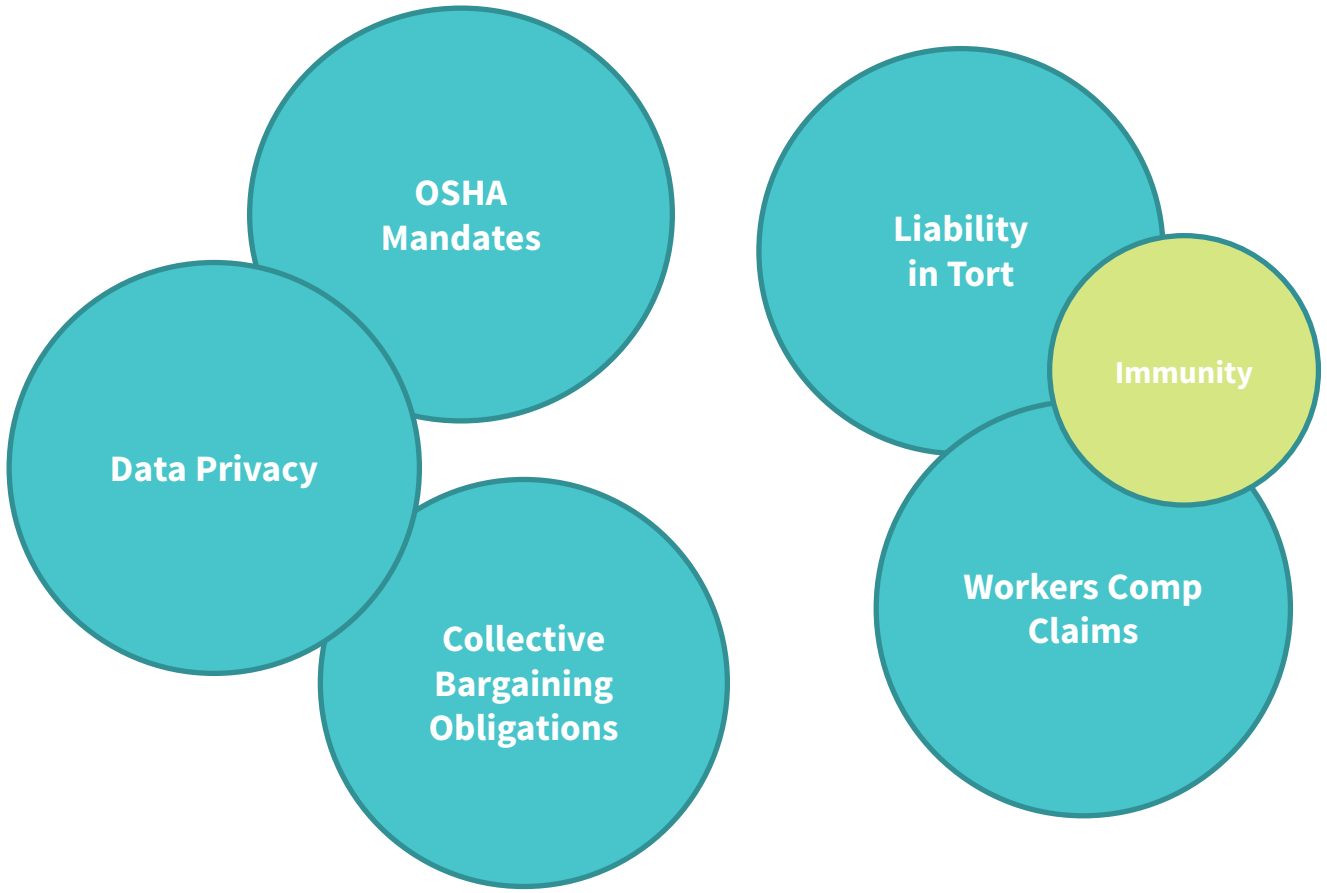
Caveat 1:

- Medical screening is required in advance of vaccine administration
- An employer administering the vaccine or contracting with an entity to administer the vaccine must show it is "job related and consistent with business necessity" for each position
- Employers that simply accept proof of vaccination from outside sources are not required to make the same showing
  - No medical information should be provided with proof

Caveat 2

- Accommodation required for religious and disability-related objections (Title VII and the ADA)
- Interactive process and reasonable accommodation
- If work must be onsite, employer must establish a "direct threat" of causing a "significant risk of substantial harm" to other employees

Vaccine Program Approaches



Key Considerations

- Adverse reactions to the vaccine
- Risk of not mandating the vaccine
- Limited immunity for small # of employers
- Mandatory program is subject of bargaining
- Employer cost v. plan cost

Vaccine Program Approaches

To require or not to require . . . factors to consider

- Risk factors (industry specific)
  - employees, vendor, and service recipients/client safety
  - potential adverse reactions
  - liability for not mandating vaccine
- Ongoing ability to perform essential operations remotely
- Capacity to administer accommodations and data privacy issues
- Cost and workers' compensation insurance implications
- State and local essential worker designations
- Collective bargaining obligations

In the face of uncertainty on all fronts a strongly encouraged but voluntary approach for employers outside of high risk fields is a reasoned approach

Employee Well-Being Best Practices & Recommendations

Perceptions Matter

Although all adults should be able to receive the vaccine when supply allows, not all will. Perceptions of the COVID-19 vaccine vary drastically. An average **43% of consumers would get a COVID-19 vaccine across 12 different polls.** Statistics across varying platforms have fluctuated, however according to a Gallup poll in early November, **58% of Americans would be willing to get the vaccine[1]**.

According to polls, the primary concern driving some Americans' hesitancy about the COVID-19 vaccine is the potential for negative side effects.

Sources:

1. Gallup; "More Americans Willing to Take COVID Vaccine" ; November 2020

Employer-Based Immunization Clinics

The opportunity to offer onsite clinics for COVID-19 vaccines will require patience and persistence.

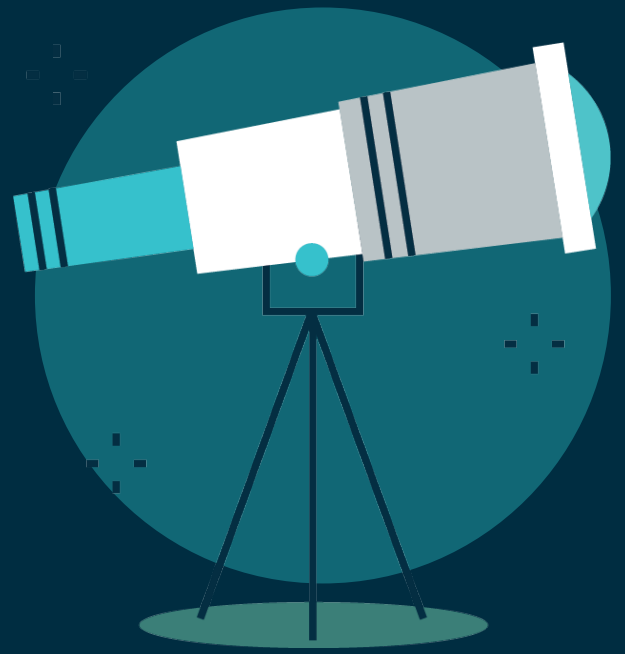
- Availability will be varied for the coming weeks and months, employers need to work with local state agencies and health departments to identify access opportunities.
- Vendors such as Quest Diagnostics, Occuvax, LabCorp and others are formulating plans to offer onsite employer-based clinics when sufficient quantities of vaccine become available.
- Individuals in high-risk categories should work with their primary care physician to gain access to a vaccine.
- Leverage free tools such as the CDC's Vax Text[SM] COVID-19 Vaccination Second-Dose Reminder.

Employers Are Being Thoughtful in Their Approach

- Most employers plan on using the carrot approach to encourage employees to get vaccinated.
- Most organizations are being sensitive to cultural and personal beliefs regarding vaccines.
- Legal ramifications are a concern and employers are taking the “wait and see” approach before making vaccines a mandatory requirement.
- Many organizations are starting to think about how they bring the entire workforce back to the office and are considering limiting employees without a vaccine from certain activities.
- There is optimism that once the availability of the vaccine increases, there will be a return to work in a greater capacity later this year.

Continue to Follow RTW Safety Protocols

1. Keep Wearing Masks/Face Coverings
2. Practice Physical Distancing
3. Use Daily Health Checks
4. Replenish Cleaning Supplies
5. Limit In-Person Meetings
6. Avoid Large Group Activities
7. Close Common Areas/Breakrooms
8. Communicate Clearly & Frequently
9. Conduct Periodic Surveys or Check-Ins
10. Take It Slow and Adjust as Needed



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