



COVID-19 Vaccines:

Effective Strategies to Communicate and Vaccinate. Where are we now? Tuesday, February 9, 2021

Presented by

Nelson Mullins attorneys **Kristin Ahr and Angela Hart-Edwards** as well as Principal and VP of Health Sciences at Colden Corporation, **Dr. Shannon Magari**

Moderated by Nelson Mullins Business Law Litigation Partner Michael Blumenfeld



Introduction



Kristin Ahr
Nelson Mullins
Partner
kristin.ahr@nelsonmullins.com
West Palm Beach, FL
(561) 366-8765



Dr. Shannon Magari
Colden Corporation
Principal and Vice President of
Health Sciences
www.colden.com
magari@colden.com
(315) 445-0847



Angela Hart-Edwards
Nelson Mullins
Partner
angela.hartedwards@nelsonmullins.com
Washington, DC
(301) 788-7488



Michael Blumenfeld
Nelson Mullins
Partner
michael.blumenfeld@nelsonmullins.com
Baltimore, MD
(443) 392-9402



Operation Warp Speed, FDA Emergency Use Authorization of COVID-19 Vaccines and Biden Administration Policies

Presented by

Kristin Ahr and Dr. Shannon Magari



Operation Warp Speed

- Intended to fast-track of multiple variations of a COVID-19 Vaccine – safety and efficacy
- Multiple Federal Organizations, public health officials and private partners INVOLVED
- Free or low-cost to recipients
- **States** also required to plans and implement own ROLLOUT "Playbooks" for distribution and allocation/prioritization





FDA Clinical Trials, Emergency Use Authorizations



- ✓ Current Status of Trials : U.S. and Global
- ✓ Two currently approved for emergency use authorization: Pfizer and Moderna (2 doses, cold chain distribution)
- ✓ More in the pipeline: J&J application for EUA
- ✓ Safety, efficacy, side effects, etc...

Fast-Tracking COVID-19 Vaccines Safely

- Maybe not so fast? mRNA Vaccine research started after 9/11
- mRNA vaccines are faster to produce than traditional vaccines.
- High prevalence of disease allowed outcomes to be studied rapidly.
- Thoughtful combination of Phase 2 and Phase 3 trials
- Researchers used existing networks to conduct COVID-19 vaccine trials.
- Financial Risk Manufacturing began while clinical trials were still underway. Normally, manufacturing doesn't begin until after completion of the trials.





Leading Vaccines

• Mechanism: mRNA

•Number of Doses: 2

•Storage: -70°C (-94°F)

• Efficacy: 95% Effective at Symptomatic COVID-19 Infection; (Measured 7 Days After 2nd Dose)

Pfizer



•Mechanism: mRNA

•Number of Doses: 2

•Storage: -24°C (-11°F)

•Efficacy: 94.1% Effective at Symptomatic COVID-19 Infection; (Measured 14 Days After 2nd Dose)

Moderna



 Mechanism: Adenovirus 26 Based Viral Vector

Number of Doses: 1

•Storage: Up to 3 Months Refrigerated at 2-8°C (36-46°F)

• Efficacy: 72% (US) effective at moderate and severe disease, 100% at hospitalization and death

Johnson & Johnson



•Mechanism: Non-Replicating Viral Vector

•Number of Doses: 2

•Storage: 8°C (46°F)

•Efficacy: TBD; estimated 70.4%

Astra Zeneca



 Mechanism: Recombinant protein using Matrix-M adjuvant
 Number of Doses: 2

•Storage: Up to 6 months Refrigerated at 2-8°C (36-46°F)

• Efficacy: 89.3% Effective at Symptomatic COVID-19 (Measured 7 days after second dose)

Novavax











COVID New Administration Plan

Priority on Day One

COVID Policy And Priorities

Under The

Biden Administration

Biden Administration Goals

- 1. Restore trust with the American people.
- 2. Mount a safe, effective, equitable vaccination campaign.
- 3. Mitigate spread through expanding masking, testing, treatment, data, workforce, and clear public health standards.
- 4. Immediately expand emergency relief and exercise the Defense Production Act.
- 5. Safely Reopen Schools, Businesses, And Travel While Protecting Workers.
- 6. Protect those most at risk and advance equity, including across racial, ethnic, and rural/urban lines.



BIDEN ADMIN GOALS, continued

7. Restore U.S. leadership globally and build better preparedness for future threats.



BIDEN ALSO SIGNED A NUMBER OF EXECUTIVE ORDERS on DAY ONE of Administration and

Memorandum to Extend Federal Support to Governors' Use of the National Guard to Respond to COVID-19 and to Increase Reimbursement and Other Assistance Provided to States.



Developing Successful Workplace Vaccination Policies

Presented by

Kristin Ahr and Dr. Shannon Magari

Employer Role

- Actively Encourage or Require
 - Decide company response and strategy.
 - Facilitate access if possible.
 - Consider fees for COVID-19 vaccines. Included in medical and pharmacy benefit?
 - Consider PTO for vaccine (1st and 2nd) and side effects.
- Incentivize
 - Consider timing including later in 2021 when shortages are relieved.
 - Begin programs when certain vaccine delivery is within weeks.
 - Each organization will have unique incentives.
- Accommodate
 - o Decide potential accommodations for employees declaring disability or religious exemption.
 - Devise accommodation procedure and documentation.





Vaccine Strategy Traditional Risk Communication

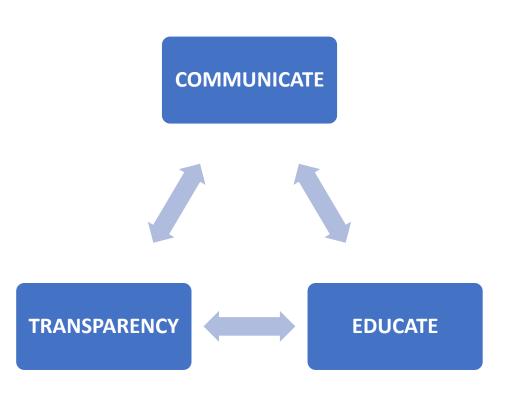
"There's no one-size-fits-all approach when it comes to vaccine communication."

Dr. Georges C. Benjamin, Executive Director, American Public Health Association

"Your ability to establish constructive communication will be determined, in large part, by whether your audiences perceive you to be trustworthy and believable."

Vincent Covello 1992, 1993, ATSDR, A Primer on Health Risk Communication and Principles and Practices

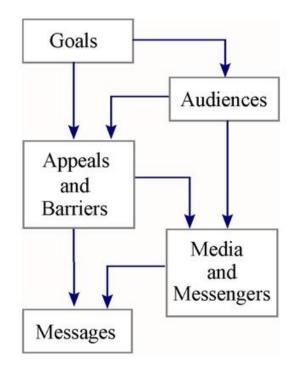






Risk Communication 101 Back to Basics: GAAMM

- Risk communication for the apathetic and the outraged
- Peter Sandman's GAAMM Strategy
 - Goals
 - Audiences
 - Appeals (and barriers)
 - Media/Messengers
 - Messages



"Strategic Safety Communication: The GAAMM Model to Inform People about Serious Risks," last modified 2015, http://www.psandman.com/col/GAAMM.htm.



Before You Communicate Your Policy to Employees

- What are your vaccination goals?
- Identify and characterize your audience.
 - Data driven vs. emotionally driven
- What can you appeal to in your employee population?
 - Preexisting needs (i.e., family, community, economy)
 - Attitudes
 - Emotions
- What are the barriers in your employee population?
 - Lack of information or trust
 - Religious or other beliefs
 - Differences by existing hesitation know these



Before You Communicate Your Policy

- What media will work for your audience to convey the written vaccination policy?
 - Emails, newsletters
 - Small group meetings
 - FAQs
- Who has real influence? Who do people trust?
 - Identify "Critical Communicators"
- Who should make the "ask" to get vaccinated?
- Who should educate?





Write the Policy Communication Style: Do's

Tailor your Message

• Perceptions about vaccines and their safety differ by political party, race, age, and geography.

Explain the Benefits

• Explain the benefits of getting vaccinated, not only the consequences of not doing it.

Focus on the People

• Talk about the people behind the vaccine. Refer to scientists, medical experts and researchers and not science, health, and pharmaceutical companies

Avoid Judgmental Language

• Acknowledge their concern of skepticism and offer to answer their questions.

Use Qualifiers

Use (and repeat) the word "every" to explain the development process.



NELSON MULLINS



Incorporate COVID-19 Vaccine Plan Document

- Review and update Covid-19 reopening plan document.
 - Use vaccine plan to review Covid-19 workplace protocols.
- Specify vaccine requirement if applicable.
 - Note exceptions for accommodation.
 - Dedicate individual/group to administer.
- Consider relevant state requirements.



Legal Implications: PPE, Tests, Vaccines, Incentives

Presented by

Angela Hart-Edwards





"One of the best ways to get to people is through employers."



Employer Role – Understand Legal Implications

Activity

- Vaccination
- Incentivization
- Accommodation
- PPE and Testing

Checklist

- CDC, HHS, and state health organizations
- Federal laws
- State laws
- Local Laws





42 States Legally Require Masks

Federal property				
Alabama	Florida	Massachusetts	New Jersey	Wisconsin
Arizona	Georgia	Michigan	North Carolina	Wyoming
Arkansas	Hawaii	Minnesota	Ohio	Alabama
California	Illinois	Mississippi	Oregon	Idaho
Colorado	Indiana	Montana	Pennsylvania	Missouri
Connecticut	Iowa	Nebraska	Puerto Rico	North Dakota
Delaware	D.C. *	Nevada	Rhode Island	South Dakota
Kansas	Kentucky	New Hampshire	West Virginia	South Carolina
Louisiana	Maine	Maryland	Washington	Tennessee
Texas	Utah	Vermont	Virginia	Oklahoma

EEOC Guidelines – VACCINES

- On Dec. 16, 2020, EEOC's advice Employers may require vaccines to eliminate the risk of harm to safety in the workplace caused by COVID.
- On March 21, 2020, EEOC stated that employers should not mandate a vaccine and suggests ADA-covered employers should consider simply encouraging employees to get vaccinated ... rather than requiring them to take it.





Litigation Trends in Workplace COVID-19 Matters Numerous Legal Implications



- Remote Work/Employee Leave Issues (375 Cases)
- EEO / Discrimination (320 Cases)
- OSHA Retaliation/Whistleblower (305 Cases)
- Wage and Hour Matters / FLSA (94 Cases)
- Unsafe Workplace Allegations (69 Cases)

- Negligence/ Wrongful Death (45 Cases)
- CARES Act (27 Cases)
- Traditional Labor (39 Cases)
- WARN Act (24 Cases)
- Do not lose PREP Act immunity
- *As of 1/15/2021



EEO Laws Implicated in Any Vaccine Program in the Workplace

- Americans with Disabilities Act (ADA)
 - Disability-Related Inquiries
 - Medical Exams
 - Confidentiality of Medical Information (no exceptions)
 - Reasonable Accommodation, including pregnancy-related condition
- Title VII of the Civil Rights Act of 1964
 - Religious Accommodation for sincerely held religious beliefs
 - National origin harassment or hostile work environment
 - Retaliation
- Genetic Information Nondiscrimination Act (prescreening vaccine questions that calls for genetic information may violate GINA)

ADA - Disability-Related Inquiries and Medical Exams



- No requirement to satisfy the "job-related and consistent with business necessity" requirement.
 - Optional / voluntary vaccine program
 - Required written certification of vaccine as part of a required vaccine program
 - Voluntary employee health or wellness

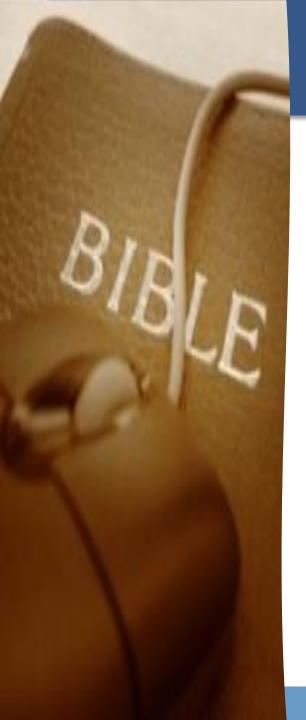


Testing

- An employer may choose to administer COVID-19 testing to employees before initially permitting employees to enter the workplace and/or periodically to determine if their presence in the workplace poses a direct threat to others.
- EEOC requires testing to be "accurate and reliable."
- Reliability is key PCR test is preferable.
- Rapid tests may be insufficiently reliable to withstand scrutiny under this standard.
- Antibody tests should not be used, as per the CDC and GINA.







Title VII – Religious Accommodations

 Is there a company policy and procedure for religious accommodation requests?

"Sincerely held religious beliefs, practices, and observances"

- What does this mean?
- Accommodation obligations engage in an "interactive dialogue" with the employee regarding potential accommodations in the COVID-19 environment.
- KEY QUESTION How can the employee perform the essential functions of his or her position without a vaccination and preserve the health and safety of the workplace?



- Begin or continue remote telework
- Implementing enhanced social distancing, personal protective equipment (PPE) (i.e., masks, face shields, gloves, etc.), additional sanitation requirements for employee/workplace.
- Changing job duties to allow for telework and/or work location in the workplace, etc.



EEOC on Incentives: Jan. 7 Proposed Rules



- Employers with wellness programs that are not offered as a part of a medical plan that require medical inquiries and/or examinations cannot offer more than "de minimis incentives" to employees to encourage participation.
- Employers with "health-contingent" wellness programs that are tied to, or qualify as, a group health plan can offer employees incentives of up to 30% of the total cost of coverage for the plan in which they are enrolled for either meeting or failing to meet a standard or health-related factor.
- Employers cannot require employees to participate in wellness programs that seek to obtain medical information or that take adverse employment actions against employees who choose not to participate in the wellness program or who fail to achieve certain health outcomes.



Rolling Out Your Vaccine Plans

- Manage with a Multi-Discipline Approach:
 - Communication strategies
 - Plan and policy development
 - Implementation protocols
 - Employment compliance and legal risk management
 - Litigation defense under new statutory schemes





Questions?





Contact Information



Kristin Ahr
Nelson Mullins
Partner
kristin.ahr@nelsonmullins.com
West Palm Beach, FL
(561) 366-8765



Dr. Shannon Magari
Colden Corporation
Principal and Vice President of
Health Sciences
www.colden.com
magari@colden.com
(315) 445-0847



Angela Hart-Edwards
Nelson Mullins
Partner
angela.hartedwards@nelsonmullins.com
Washington, DC
(301) 788-7488



Michael Blumenfeld

Nelson Mullins

Partner

michael.blumenfeld@nelsonmullins.com

Baltimore, MD

(443) 392-9402