
Morgan Lewis
NAVIGATING
THE NEXT.
Supply Chain, Manufacturing,
and Licensing
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Presenters

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Where Are We?

- Total doses administered in the US — 260M adults
- People fully vaccinated — 114M
- Percentage of adult US population — 34.8% (as of May 9, 2021)
- 3 Approved vaccines — Pfizer, Moderna, J&J
- 1 Vaccine may be approved in 3rd Q, 2021 — Novavax
- Other manufacturers still working on alternative vaccines
- Few effective therapeutic options

New Challenges That Will Affect the Supply Chain

- Virus Variants—**B.1.1.7 (UK), B.1.351 (RSA), P.1 (BRAZIL), B.1.617 (India), and need for boosters**
- Vaccine hesitancy and lack of herd immunity
- Pediatric and student vaccination
- Vaccine rules around reopening
- Vaccine validation and data aggregation
- Product displaced by COVID development and manufacturing

How the Supply Chain Has Been Affected by Government Involvement

- Vaccine research and development/COVID Testing/PPE/Ventilators
  - Financial support
  - Use of government experts and resources, e.g., NIH, DOD, HHS/FDA/BARDA
  - Clinical trial support
  - Regulatory filing support
  - Manufacturing support
    - Raw materials
    - Supplies/equipment
    - Facility approval/staffing/quality control, e.g., Emergent
    - Capacity, e.g., Merck-J&J agreement on manufacturing

What Changes/Opportunities May Be on the Horizon?

- Less direct financial and support involvement in:
  - Developing boosters, additional vaccines, vaccine strategies (mix and match vaccines)
  - Developing new DTC or other COVID tests
  - Developing additional therapeutics
  - Directing suppliers/supplies, domestically and globally
- Greater use of additional third-party suppliers for multi-tiered testing, vaccine distribution, and education, e.g.,
  - Schools/day care
  - Employers
  - Tourism
- Greater use of third-party suppliers for vaccine validation/monitoring activities

Supply Chain Issues Affecting Vaccine Production and Distribution

- Congress has provided the president and his designee a range of emergency authorities that grant broad flexibility to manage, reallocate, and change manufacturing and delivery timelines
- These authorities have been exercised through issuance of Executive Orders and regulations
- Agencies with primary jurisdiction in this context include the Department of Health and Human Services and FEMA
- Key statutes that have been used in the vaccine context include:
  - The Defense Production Act
  - The International Emergency Economic Powers Act
  - The National Emergencies Act
  - Customs laws and regulations

Supply Chain Issues Affecting Vaccine Production and Distribution

- In addition to existing authorities, on February 24, 2021 President Biden issued EO 14017 (America's Supply Chain) authorizing federal government agencies to begin a 100-day review of America's supply chain
- The review was designed to:
  - Assess gaps in the supply chain
  - Reorient and identify policy objectives related to supply chain
  - Highlight the need for regulatory changes to enhance the supply chain
  - Study existing regulations to identify ones that should be revoked, revised, amended, or renewed
  - Address access to key products, technology, and related services that were essential to the public health and welfare, as well as broader multilateral issues

Supply Chain Issues Affecting Vaccine Production and Distribution

- COVID-19 and concomitant shortages of essential health and public welfare products resulted in the use of emergency authorities to ensure supplies within individual countries:
  - Early on in the pandemic, countries used export laws to prohibit the export of essential products through the use of export licenses that were approached with a presumption of denial (i.e., PPE restrictions by Germany)
  - The US used Customs laws to establish authorizations for exports and imports that allowed US companies to provide essential products to affiliates and related parties, but not to third parties without additional authorizations
  - The Department of Health and Human Services, the Department of Commerce, and FEMA issued "rated orders" that required companies that accepted the orders to shift their product and delivery to meet US government requirements first, regardless of commercial processes

Supply Chain Issues Affecting Vaccine Production and Distribution

- COVID-19 and concomitant shortages of essential health and public welfare products resulted in the use of emergency authorities to ensure supplies within individual countries:
  - Use of these authorities resulted in:
    - Supply chain production shifts
    - An inability to meet existing contractual obligations
    - Supply shortages
    - Use of force majeure clauses to terminate or suspend contracts
    - Determinations of the viability of force majeure provisions
    - Challenges with the use of mandatory flow down provisions from rated orders – i.e., can these rated order flow downs extend to non-US suppliers

Supply Chain Issues Affecting Vaccine Production and Distribution

- Changes in responsibility, liability, and risk
  - Confirm or identify the supply chain – e.g., many companies discovered that supply chain information was incomplete or inaccurate
  - Address the lack of visibility into the lower tiers of the supply chain – e.g., while most companies are aware of tier 1 and tier 2 suppliers, fewer are aware of tier 4, 5, and 6 or raw material suppliers unless health, safety, or other standards apply
  - Manage the global supply chain – e.g., where do redundancies exist; are most suppliers located in one jurisdiction; are suppliers fungible; sole or single source suppliers
  - Consider where and how management may bear additional responsibility for exercising business judgment when complying with rated orders or other requirements based on requests based on the government's use of emergency authorities
  - Reassess the effectiveness of contract clauses that cover at least - termination (unilateral, for cause, or without cause), dispute resolutions, conflicts of laws, damages, force majeure provisions, and export and import obligations

Where Are We Going?

- 33% of the country is vaccinated…but who? Big data! Validation? Digital logistics.
- First things first. Who even has our data? CDC? Insurance? State?
- Privacy issue that laws, even in the US's "relaxed" privacy regime, can prevent rapid deployment of solutions. Bulk data licensing is not a viable option.
- The "opt-in" nature of vaccination records will help ensure that the discussion is very political. Do we take it public?
- Unclear public opinion. What do we want? What are we willing to pay for in terms of options and safety? Hint: There is no "we."

Into the Unknown…

Public

- State laws prohibiting private companies from requiring vaccines?
- Government travel restrictions and the "Vaccination Passport." Airline's role.

Private

- Schools. Certain universities are requiring all students to be vaccinated to come to class in the fall.
- Mass gatherings. Will concert attendees pay more for or be more willing to attend a "Taylor Swift #VaxOnly" concert? Consumer support can go a long way to direct the future.

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Giovanna M. Cinelli is the leader of the international trade and national security practice. As a practitioner for more than 30 years, she counsels clients in the defense and high-technology sectors on a broad range of issues affecting national security and export controls, including complex export compliance matters, audits, cross-border due diligence, and export enforcement, both classified and unclassified.

Education

Harvard University John F Kennedy School of Government, 2013, EE certificate, National Security & International Security

Catholic University of America, Columbus School of Law, 1986, J.D.

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Kathleen Sanzo is the leader of the Morgan Lewis FDA practice and co-chair of the firm's life sciences industry group. Kathleen centers her practice on regulatory and compliance issues connected to FDA regulated products. She leads and counsels clients on all legal and regulatory issues concerning product development and testing, manufacturing and marketing of prescription, OTC drug, biologic and vaccine products, and orphan drugs; food, dietary supplements, and cosmetic product manufacture, approval, marketing, and distribution; food, drug, and device compliance and enforcement matters; and consumer product issues regulated by the US Consumer Product Safety Commission (CPSC) and state enforcement agencies.

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The George Washington University Law School, 1985, LL.M.
Emory University School of Law, 1982, J.D.
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Education

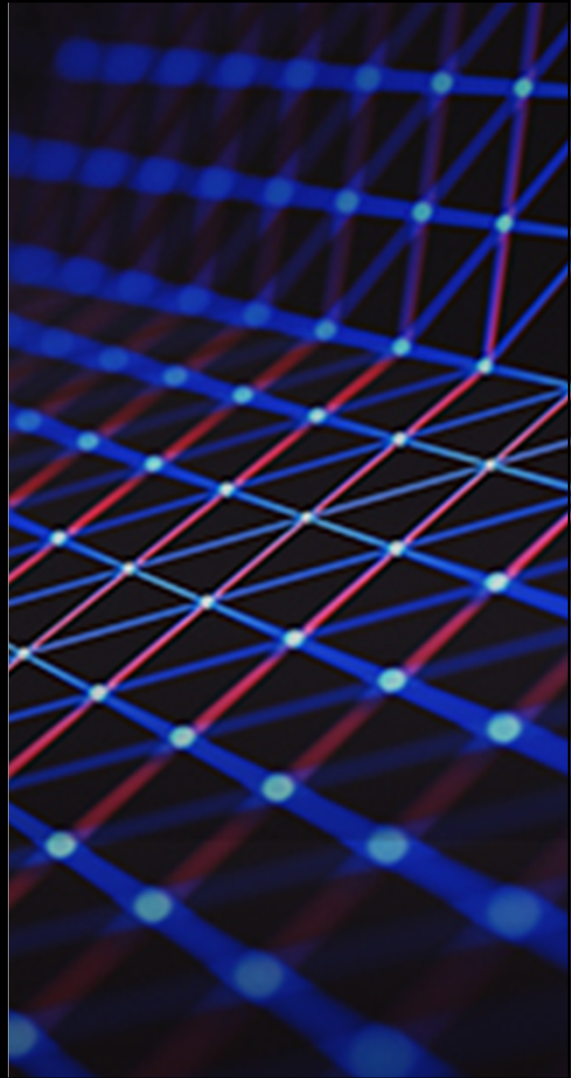
Duquesne University School of Law, 2002, J.D.
Duquesne University, 1999, B.A.

Coronavirus/ COVID-19 Resources

We have formed a multidisciplinary **Coronavirus/COVID-19 Task Force** to help guide clients through the broad scope of legal issues brought on by this public health challenge.

To help keep you on top of developments as they unfold, we also have launched a resource page on our website at **www.morganlewis.com/topics/coronavirus-covid-19**

If you would like to receive a daily digest of all new updates to the page, please visit the resource page to **subscribe** using the purple "Stay Up to Date" button.



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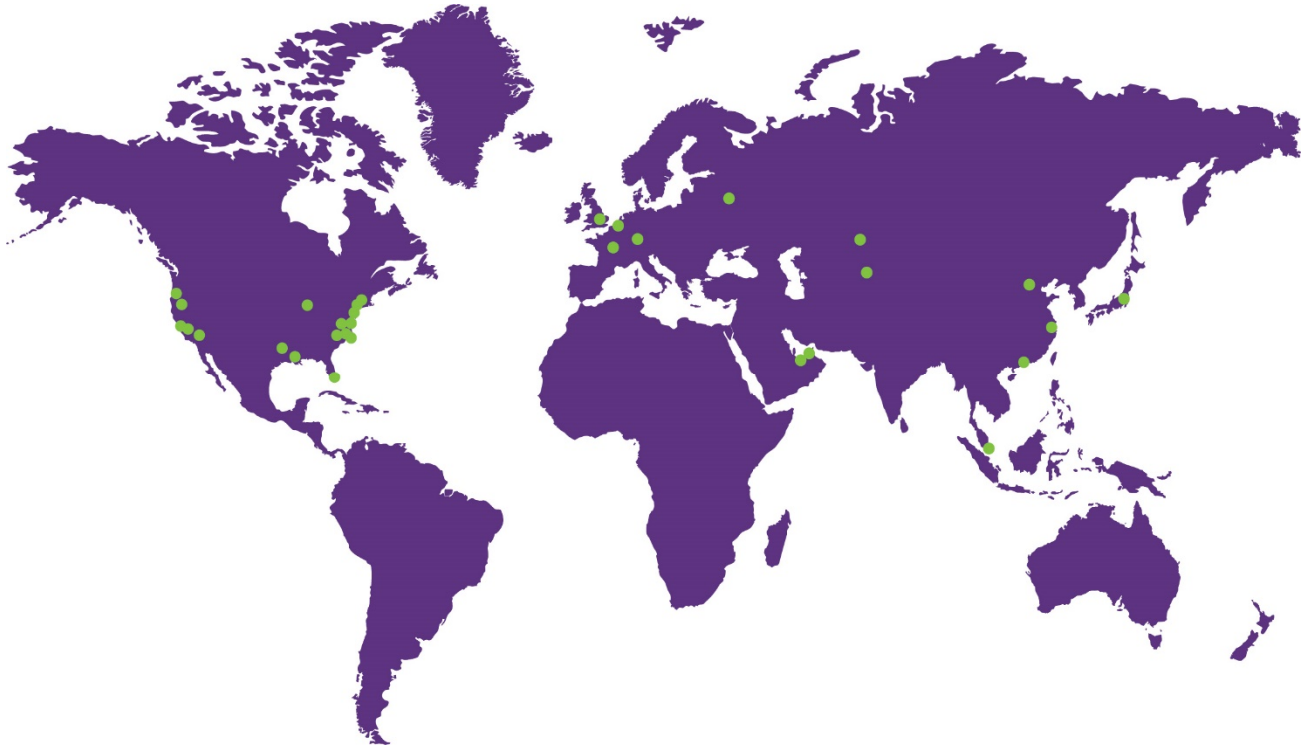

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THANK YOU