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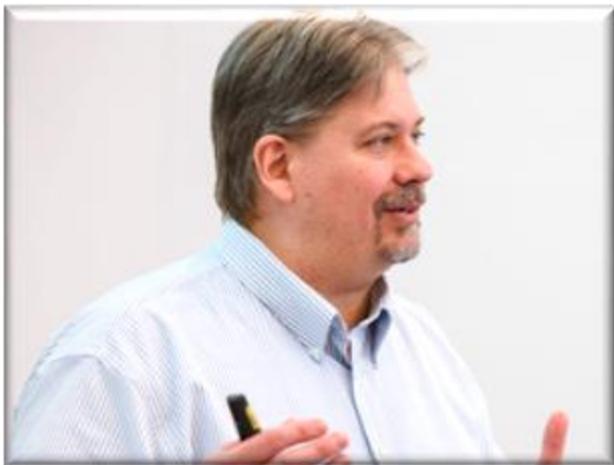


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## Panel I: Vaccines Opening Remarks



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# Vaccine Supply Chain Issues - Manufacturing Capability

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- Vaccine manufacturing capability is highly dependent on the **vaccine technology** being used (*e.g., protein-based, non-replicating viral vectors, DNA vaccines, etc.*).
  - Manufacturers have been **investing heavily** in equipment and infrastructure and **rushing to scale up capacity**, but we are not there yet.
- The **filling materials** vary as well (*e.g., multi-dose vials, single dose syringes, etc.*)
- Manufacturing must be done in a highly **sterile environment** with **temperature controls** and using **skilled personnel**. Steadily available workforce may be an issue.
- Need to produce **orders of magnitude more coronavirus vaccine** than the industry has ever done with flu vaccine, and under tremendous **time pressure**.
- At least 5.6 billion people need to be inoculated to achieve herd immunity globally, and they may require **more than one dose**.
  - Global vaccine manufacturing capacity is approximately **5 billion doses annually** for all vaccines (*including 1.5 billion seasonal flu vaccine doses*).
- Manufacturing **conflict** with the production of seasonal flu vaccine and other products using the **same materials and manufacturing capacity**.

# Vaccine Supply Chain Issues - Critical Shortages

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- Potential shortages of medical **glass vials** and **stoppers**. These are sourced primarily from suppliers in China. Shortages dates back before the pandemic.
  - Shortage of the sand used to make glass vials.
  - Stoppers are a potential issue as well. They are heavily regulated as the rubber or latex components can't interact with the product inside the vial.
    - ✓ A few manufacturers dominate the stopper business, and some of them also make the vials.
- Potential short-term shortage of **syringes**. BD reported that there is not enough capacity in the industry to produce billions of syringes and needles in a significantly compressed time frame.
- Foreign sources of **raw materials** and **chemical ingredients** needed to produce the vaccine. Some **adjuvants** and **plasmids** are in short supply
- There will likely be **global competition for some materials**, and the country where that material is produced will have the ability to control capacity and distribution.
  - We saw this happen with some drugs, PPE's, and other healthcare items.

# Vaccine Supply Chain Issues - Distribution

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- Most vaccines require **refrigeration** during transportation and storage.
  - The industry doesn't have **enough cold chain capacity** to transport many millions of doses, in such a short time frame, through global distribution channels that will be subject to **tight security**, and **temperature controls**.
    - ✓ UPS and other Third-Party Logistics companies have begun to step-up their cold chain capabilities in preparation.
  - A significant amount of pharmaceutical products (including vaccines) are transported by **air freight**, and much of that goes in the **cargo hold of passenger planes**.
    - ✓ With the **elimination of passenger flights** during the pandemic, the supply chain will need to work with the airlines to **increase passenger plane capacity**, or that will negatively impact the flow of the coronavirus vaccine.
- Vaccine distribution will likely be complex.
  - May be delivered through **multiple distribution channels** (e.g., Hospitals, Clinics, Doctor's Offices, Pharmacies, Government Agencies such as the CDC, Nursing Homes, Workplaces, Prisons, Military Bases, Schools, etc.)
  - Distribution priority is yet to be determined but the initial doses would likely go to **front-line health workers** and **vulnerable populations**.

# Applying Lessons Learned

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## ■ Planning

- We cannot do enough planning. Planning for what we want to do, and for what might go wrong.
- We need to develop contingencies for the short-term and develop surge capacity for the long-term. We are likely to experience waves.

## ■ Collaboration

- No one company owns the end-to-end vaccine supply chain, so collaboration between the trading partners in the supply chain will be critical.
  - ✓ Companies will need to cooperate on infrastructure.
- Frequent and sustained information sharing between companies in the private sector and with government.
- Partnerships between government, academia, and private industry can help advance vaccine production. It has benefitted other industries in the past.
  - ✓ Government funding (*e.g., Operation Warp Speed*)