



## CCICADA Organizes a Workshop on Medicines, Vaccines, and PPEs During COVID-19

The rapid spike in COVID-19 cases in March and April, 2020 highlighted nationwide shortages of ventilators, test kits, masks, and other PPE, provoking competition between state and federal agencies and forcing us to rely on foreign sources for critical supplies. Vulnerabilities in critical supply chains became apparent.

A pandemic raises major questions for the nation’s stockpile of critical medicines. How big should such stockpiles be? How do you keep items fresh? What are the priorities for distribution – who gets items first and how is the decision made?

Now there is a rush to produce vaccines. But polls show that many people are reluctant to take a vaccine? Why?

Vaccines present a special supply chain problem. They have different efficacies, different requirements (e.g., refrigeration). Who should get them first? How will they be distributed?

Disasters inevitably bring out new kinds of crimes. What are the challenges we face with illegal or low quality PPEs, counterfeit medicines or vaccines, and other related crimes?

These issues prompted the [CCICADA Center of Excellence \(COE\)](#) led by Rutgers University to organize a virtual workshop on Medicines, Vaccines, and PPEs During COVID-19. Held on August 27, 2020, the workshop was organized around two panels: “Vaccines” and “Medicines and PPEs.”

The workshop was part of the [DHS University Centers of Excellence COVID-19 Supply Chain Initiative](#).

### THERE ARE SO MANY QUESTIONS ABOUT THE POTENTIAL COVID-19 VACCINES

As Juergen Richt, Director of the [CEEZAD](#) COE led by Kansas State University, pointed out, there are some 135 vaccines in the pipeline, and so there are 135 supply chains being established, with 21 in phase 1, 13 in phase 2, 8 in phase 3, and two approved for use (Russia, China for military use). Karin Shanahan, SVP of Global Biologics & Sterile Operations, Merck & Co., said

that the typical life cycle for developing a vaccine is four to ten years to test, develop a pipeline, and administer it to a lot fewer people than we will need to vaccinate for COVID-19. There are so many questions about the vaccines. Richt, Shanahan, and William McLaury, Rutgers University and retired as Executive Director of Pharma Supply Chain, Novartis Pharmaceuticals, raised many questions:

- The landscape of COVID-19 changes rapidly. How will future changes affect the efficacy of vaccines?
- How will we be able to produce orders of magnitude more vaccine doses than the industry has ever produced for the flu vaccine, and in a shorter amount of time?
- Will there be a single dose or two? Some vaccine manufacturers have already indicated that two shots will be required for vaccine efficacy.
- The global industry-manufacturing capacity currently is 5 billion doses per year, and ~5.6 billion vaccinated individuals will be needed to achieve “herd immunity.” If two doses are needed, we will need ~11 billion doses. Because 11 billion doses or even 5.6 billion doses won’t all be available right away, how will countries decide who gets it first?
- How do we overcome the manufacturing conflict with flu vaccines and other vaccine products using the same materials and manufacturing capacity? Can we have a flu + COVID combination vaccine?
- Will the vaccine be mandatory (at least in some countries)?
- Will people retain their immunity over the long term, or do we need shots each year?
- What is the immune response in older, pregnant, or immuno-suppressed people?
- Do we need a fully protective vaccine or is partial protection sufficient?
- Most vaccines typically require refrigeration during transportation and storage (cold chain). The industry doesn’t have enough cold chain capacity to transport many millions of doses in such a short time frame. Can UPS and other companies build up their cold chain capacity fast enough?
- How will it be distributed globally, especially in areas where there are extreme temperatures?
- How can manufacturing capability and key supplies be arranged well in advance?
- Will we be able to find enough skilled personnel capable of working in the sterile environment with temperature controls needed to manufacture the vaccines?
- No one entity owns the entire vaccine supply chain. How do we achieve the required collaboration and coordination to accomplish manufacturing of enough vaccine?
- The vaccine may be delivered through multiple distribution channels (e.g., hospitals, clinics, doctor’s offices, pharmacies, government agencies such as the CDC, nursing homes,



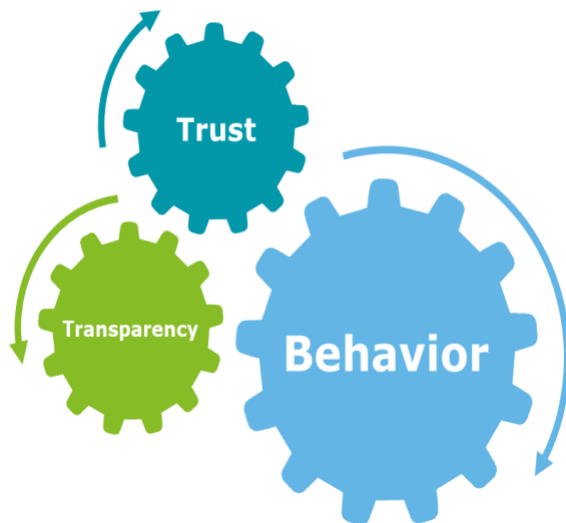
*With some 135 vaccines under development for COVID-19, questions abound. Among them several loom large: Can we make enough in a reasonable time? Will people agree to take it?*  
Image credit: Wikimedia Commons, National Cancer Institute, John Keith photographer

workplaces, prisons, military bases, schools, etc.). How will we work out the complex logistics of delivery?

- We need pre-clinical animal testing of vaccines and therapeutics and very few facilities can perform these tests. Will we be able to develop a national effort to support the existing facilities and develop more of them, at least for future epidemics?
- How will people respond to the anti-vaxxers messages?
- We already see fraud in counterfeit drugs, low-quality PPEs and vials; will we see counterfeit vaccines, a black market for vaccines? And how can we protect against these things?

## TRUST AND TRANSPARENCY ARE KEY DRIVERS OF SUPPLY CHAIN BEHAVIOR

In the early days of COVID, we saw shortages, hoarding, panic buying, and other reactionary behaviors. According to Joe Lewis, Managing Director, Deloitte Consulting, and leader of Deloitte’s US Life Sciences Supply Chain COVID-19 response programs, this was driven in a major way by a lack of transparency and trust. When there is a lack of trust in equitable distribution, it creates an “everyone for themselves” mentality.



Lewis said that there were largely sufficient supplies, but needs differed because the virus hit different places at different times. In such a situation, one can handle increased demand by collaborating and moving required material to areas of increased demand. This depends on the use of tools like real-time demand sensing to shape transparency and trust. Rory Yanchek, VP Government Markets for 3M, also commented that getting real-time data about COVID and requirements for PPE was a challenge during the early peak of the crisis. A uniform data collection strategy and ownership needs to be in place. Trust in the data is key for future success in handling a pandemic.

***Joe Lewis: Interrelated factors of customer behavior, transparency, and trust in the system drove how well supply chains responded in the first phase of the pandemic. This offers lessons for future vaccine distribution.***

Image credit: Deloitte Consulting analysis, courtesy of Joe Lewis

Lewis said that the use of blockchain increases transparency and expedites market accessibility for critical products through sharing trusted data sources among manufacturers, vendors, and regulators. The use of a control tower tool can provide visibility to inventory across the end-to-

end supply chain, enable alerts, generate prescriptive insights, and trigger self-driving execution, with the capability of acquiring data from multiple stakeholders and gaining insights from advanced analytics.

Applying these ideas to a new COVID-19 vaccine, Lewis observed that at the beginning, there will be insufficient supply to meet the demand, and transparency around how allocation decisions are made and trust that the distribution will be equitable are going to be key. During a

second phase when there is adequate supply to meet demand, collaboration and coordination will be critical factors in optimizing distribution—with transparency and trust in how allocations are made. It is only in a third phase that more traditional competitive markets such as with flu vaccine become the norm.

## LITTLE-KNOWN SUPPLY CHAIN ISSUES COULD HOLD UP AVAILABILITY OF A VACCINE

William McLaury pointed out that there are many related supply chain issues that could hold up availability of a vaccines:

- Potential shortages of medical glass vials and stoppers. These are sourced primarily from suppliers in China. Shortages date back to before the pandemic. There could be 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 related issue is that a few manufacturers dominate the stopper business, and some of them also make the vials.
- Potential short-term shortage of syringes. Becton Dickinson 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, PPEs, and other healthcare items.

## WE CANNOT HAVE ONE SUPPLY CHAIN FOR NORMAL TIMES AND ANOTHER FOR TIMES OF CRISIS

Daniel Gerstein is a senior policy researcher at the RAND Corporation, Homeland Security Operational Analysis Center and former DHS Under Secretary (Acting) and Deputy Under Secretary in the Science & Technology Directorate. He noted that people are calling for changes to restore manufacturing of critical items, decouple supply chains, and become more self-sufficient, and he asked whether that is possible and, if so, who would pay the increased cost.

Our “just in time” delivery systems have been designed to optimize costs through prediction and minimizing inventories, but they lack resiliency in times of crisis. The result during COVID-19, according to Dr. Gerstein, is that 95% of companies will be impacted by COVID-19 and only 56% had a plan to address supply disruption from China, a source of many of the key active pharmaceutical ingredients. Trade wars and excessive competition do not work in a global economy or in times of crisis, Gerstein said. We cannot have one system for daily use and another for times of crisis.

Gerstein added that we need to treat public health preparedness, including supply chains, as a national security issue and need to develop a strategic national supply chain approach. The Strategic National Stockpile (SNS) needs to be viewed as part of a broader national supply chain

that combines stockpiling, direct contracting with manufacturers, warm production lines for some key commodities, procuring of large quantities at the national level to take advantage of economies of scale, and shortening supply chains.

Gerstein called for the development of a methodology to:

- Improve current supply chain visibility
- Determine appropriate balance between efficiency and resilience
- Develop principles, strategies, policies, and regulations for supply chains
- Establish and validate the algorithms that will guide the supply chains
- Model new risks and costs (network flow models or time series forecasting)
- Improve situational awareness through use of advanced capabilities
  - Technology: Internet of Things, artificial intelligence, robotics, and 5G
  - Handling unforeseen challenges: COVID-19, trade war, act of war or terrorism, regulatory change, labor dispute, sudden spikes in supply or demand, natural disaster, or supplier bankruptcy

#### MANUFACTURING OF PRODUCTS FOR EMERGENCY RESPONSES CAN BE COMPLEX BECAUSE THE PRODUCTS ARE OFTEN FOR PROBLEMS THAT HAVE NOT YET OCCURRED

At a National Academies workshop on Global Health Risk Framework: Research and Development of Medical Products, Tadataka Yamada said that: “Manufacturing of products for emergency responses can be complex because the products are often for problems that have not yet occurred.” Viswanath Narayan from the Rutgers Business School, retired as Director of Supply Chain Analytics Business Technology at Pfizer, used this quote to explore issues involved in preparing products for the “next” pandemic. He pointed out that we have reduced capacity to meet cost goals and have not accounted for emergency growth in volume. Identifying and classifying product class early to define a service level is key to meet future surge in demand during a pandemic. Classifying products, for example, as medically necessary or medically essential will set the supply chain strategy to identify similar platforms to absorb shortages during a pandemic. This is akin to disaster recovery services in IT with a cold backup site for essential computer operation to run the business. Another problem is a proliferation of different SKUs for the same product aimed at different prospective purchasers. However, there are no capacity allocation distinctions for different SKUs. Planning for the next major event will require a more specific strategy, and we need to plan this before the next pandemic.

Narayan also posed some research challenges:

- Can a switch from batch to continuous manufacturing approaches benefit both routine and emergency production?
- Is stockpiling bulk or intermediate manufacturing components for finishing when needed (e.g., bulk vaccine stocks), potentially saving space and extending expiration, a viable strategy?
- Can a data-driven allocation model be developed to allocate and provide equitable distribution of drugs and PPEs?

- Can demand forecasting during a pandemic be developed with a certain confidence interval to meet supply and demand challenges?
- Can robust replenishment policies with stockpiling to keep the products fresh, using a continuous consumption mode for different classes of products, be developed and agreed upon?

## COMPANIES ARE COLLABORATING TO FIND INNOVATIVE WAYS TO BRING MORE PRODUCT TO MARKET AS SOON AS POSSIBLE

Rory Yancheck described ways in which companies can collaborate with each other without government involvement to develop a range of innovative solutions to protect healthcare workers and first responders and to ramp up the production of important products that are needed. 3M created an office to accelerate such collaboration. He gave the example of collaboration between 3M and Ford on a powered-air purifying respirator, where 3M had the capacity and approvals and Ford had the fans.

Yancheck said that their External Collaboration Response Team has reviewed over 500 external collaboration requests from all types of markets and businesses, getting on average 30 to 40 new requests per day. Major areas of focus/collaboration are: PPE capacity increase, disinfection of PPE automation, and non-3M product support. Yancheck said that the impact of these actions will continue beyond current efforts and involve connecting in new and impactful ways with other company partners.

## CRIME DURING COVID-19 AFFECTS MEDICINES, VACCINES, PPEs, AND MORE

In the early stages of the coronavirus pandemic, the FBI and U.S. Secret Service put out a [press release](#) about the potential for dramatic increases of new types of crimes that could arise:

“Swindles, scams, and outright thefts have long been a feature of major disasters. The more catastrophic the event, the more active the fraudsters. However, the COVID-19 pandemic provides criminal opportunities on a scale likely to dwarf anything seen before. The speed at which criminals are devising and executing their schemes is truly breathtaking.”

[Another workshop in this series](#) went into detail on such crimes.

Brian Weinhaus of the ICE-HSI led National Intellectual Property Rights Coordination Center described some of the health-related frauds they are finding in [Operation Stolen Promise](#).

- Unapproved and/or counterfeit pharmaceutical or supplement products
  - Medications
  - Fake “immunity” pills
  - Drugs marketed as cures for COVID-19
  - Fake vaccines
  - Virus shutout packs/lanyards
- Counterfeit or unapproved PPEs and life safety products:

- N95 respirator masks
- Protective gowns
- Protective gloves
- Protective eyewear
- Full face shields
- Sanitizing products
- Hygiene products
- Medical and laboratory equipment
- Hoarding and price gouging
- Scams of all kinds such as donations to nonexistent charities
- Increased cyber attacks
  - Increased financial fraud



***PPE manufacturers and pharmaceutical companies are fighting against counterfeit products and price gouging by setting up hotlines, taking legal action, and using technology.***

Image credit: Wikimedia commons, Timely Medical Innovations, LLC

Operation Stolen Promise was created to counter such crime. It partners with the private sector and with domestic and foreign partner agencies.

Karin Shanahan noted that every company has a robust fraud detection program, using advance surveillance techniques to identify fraud early. Rory Yanchek pointed out the importance of collaboration between government and the private sector in protecting against fraud and price gouging. He said that 3M, for example, has created a hotline for fraud, price gouging, and counterfeits, and is collaborating with national and local legal authorities to bring lawsuits in multiple states and Canada.

#### MEDILEDGER: USING BLOCKCHAIN TO PREVENT PHARMACEUTICAL FRAUD

MediLedger, an effort designed to defend against counterfeit drugs, originated as a joint effort of leaders from 25 companies in the pharmaceutical industry—manufacturers such as Pfizer and Novartis, wholesalers such as McKesson and Cardinal Health, and dispensers such as Walmart and Walgreens. Eric Garvin is Head of Pharma Solution at Chronicled, and lead of the MediLedger Project. Garvin told us that the project aims at tracing transactions, e.g., from manufacturer to wholesaler to dispenser and backwards with returns. By being able to track all of the transactions, one can hopefully defend against pharmaceutical fraud. MediLedger defines a real-time industry-wide network to automate the way trading partners do business together.

MediLedger is an attempt to use serialized data exchanges for prescription drugs using a blockchain/ledger-based system. Blockchain allows each player to maintain privacy over their private data while sharing information in a secure way. Proof of every update/transaction is published to blockchain. The pilot of MediLedger showed that business rules for each transaction can be enforced by blockchain smart contracts in real time while keeping each company's data 100% private. However, Garvin said, long-term success will require strong participation and

adoption from all segments of the supply chain (manufacturers, wholesalers, dispensers, and service providers).

**For further information:**

Contact Dr. Fred Roberts, Director of the CCICADA Center at Rutgers University:  
[froberts@dimacs.rutgers.edu](mailto:froberts@dimacs.rutgers.edu)

For more information on all of the COEs: <https://www.dhs.gov/science-and-technology/centers-excellence>. The COEs are funded by the [Office of University Programs](#) in DHS' Science and Technology Directorate.