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## Partnership for Accelerating Results in Trade, National Expenditure and Revenue Activity (PARTNER)

# United States Personal Protective Equipment Market

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Gail Guseman  
Consulting Specialist Leader  
Deloitte Consulting LLP  
[gguseman@deloitte.com](mailto:gguseman@deloitte.com)

Joseph Alex  
Medical Supply Chain Expert  
Independent Consultant  
[Joseph.alex@comcast.net](mailto:Joseph.alex@comcast.net)

Kevin Youel Page  
Consulting Specialist Executive  
Deloitte Consulting LLP  
[kyouelpage@deloitte.com](mailto:kyouelpage@deloitte.com)

# Agenda



1

Background

2

US PPE Market

3

The Medical PPE Value Chain and Ecosystem

4

Selling to the United States Federal Government

5

Summary Observations



1

# Background

2

US PPE Market

3

The Medical PPE Value Chain and Ecosystem

4

Selling to the United States Federal Government

5

Summary Observations

## Meet your presenters



**Gail Guseman** is a Specialist Leader at Deloitte Consulting LLP with more than 30 years of experience in strategic planning, program management, and acquisition strategy and systems management for the Federal Health, Federal Defense and Security, and Federal Civilian sectors.



**Joseph Alex** is a supply chain management expert with more than 40 years of experience in commercial healthcare services and supply chain/logistics. He is currently the Industry subject matter expert at Deloitte Consulting LLP for the VHA Procurement & Logistics Office (P&LO).



**Kevin Youel Page** has 30 years of experience driving innovative business strategies in public sector operations. He was the Chief Operating Officer for the US Federal Acquisition Service, supplying over \$50B per year in goods and services to Federal agencies. He is a Specialist Executive with Deloitte Consulting's Enterprise Performance focused on Shared Services and Acquisition.

# Objective

Educate the Sri Lankan Joint Apparel Association Forum (JAAF) on the status and entry points to the United States (US) Personal Protective Equipment (PPE) market.



**“Manufacturers scramble to find raw materials for PPE”**

-The Canadian Press

**“Shortage of personal protective equipment endangering health workers worldwide”**

-WHO

**“Medical PPE is still so scarce after months of COVID-19, volunteers keep hunting for lifesaving supplies”**

-The Philadelphia Inquirer

The COVID-19 global pandemic has resulted in a **spike in demand for Personal Protective Equipment (PPE)** while decreasing demand for other goods and services, including apparel.

**“Remember the N95 mask shortage? It’s still a problem.”**

-Vox

**“Critical Supply Shortages — The Need for Ventilators and Personal Protective Equipment during the Covid-19 Pandemic”**

-The New England Journal of Medicine



1

Background

2

**US PPE Market**

3

The Medical PPE Value Chain and Ecosystem

4

Selling to the United States Federal Government

5

Summary Observations

# Global market demand for PPE is large, spiking, and unpredictable

This rapidly evolving crisis is having new ripple effects every day — service disruptions, volume shifts and evolving pandemic impacts

## Key insights snapshot



**89 Million**

Masks are required each month



**40%**

Estimated amount the industry must increase manufacturing in short term to quickly boost supply in the PPE market



**76 Million**

Medical gloves are required each month



**USD**

**81 Billion**

Expected global PPE Market by 2026

Source: World Health Organization

## Trends

- New demand from individuals is creating new market opportunities, including in non-FDA approved protective gear
- Increasing concerns of employers over the safety of its employees
- The fluctuating prices of raw materials might hamper the market growth
- Several major distributors manage the US Medical PPE market
- Past outbreaks (e.g., SARS) have been characterized by “boom/bust cycles” in PPE demand



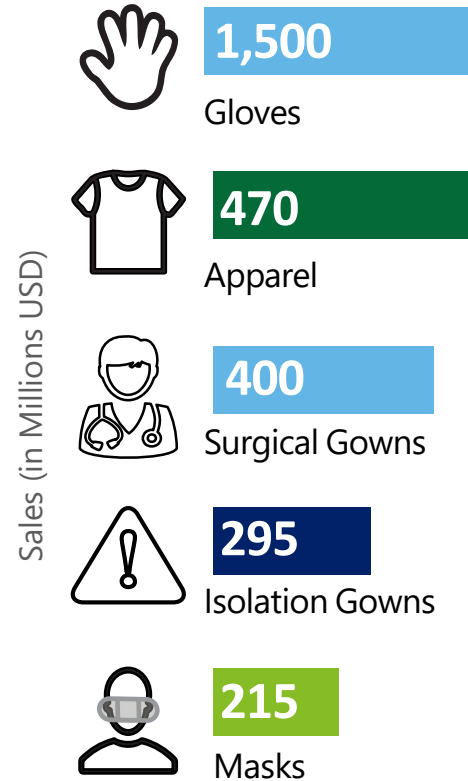


# US PPE Market:

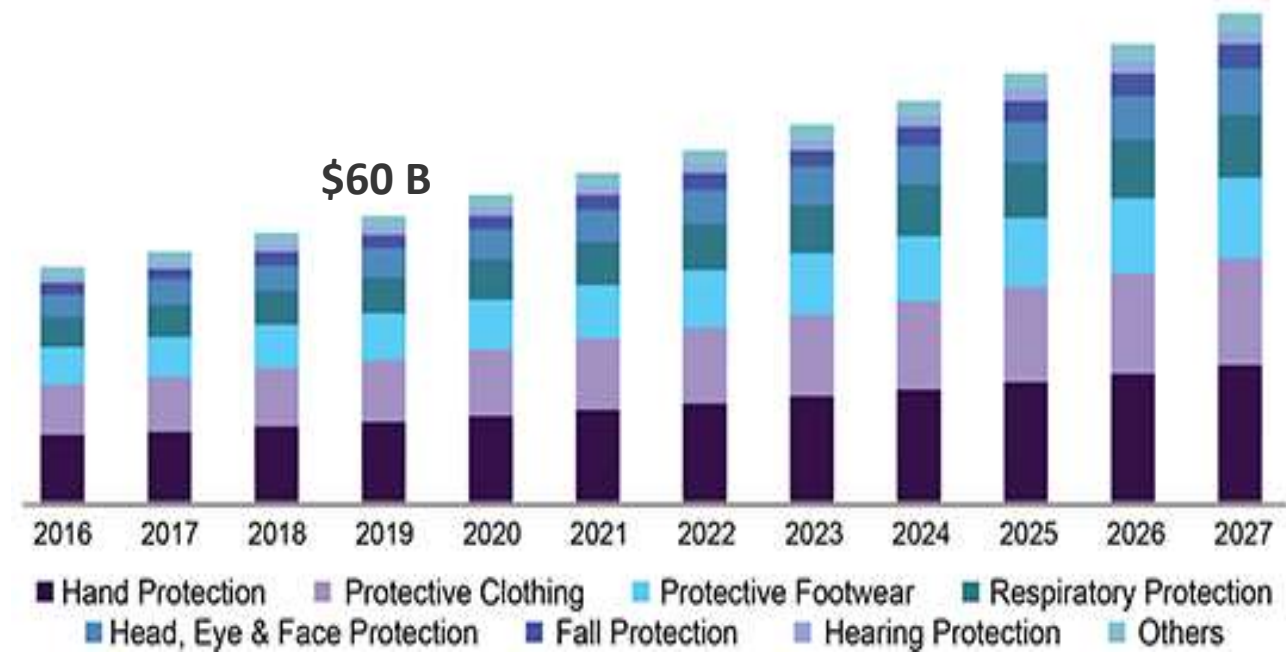
## Product Demand

Data to the right represents the **pre-COVID** growth estimates for the PPE market.

### Medical PPE Demand January 2019 to January 2020 (Source: US Medical Products Distributor)



### Projected US PPE Market (Source: Grandview Research)

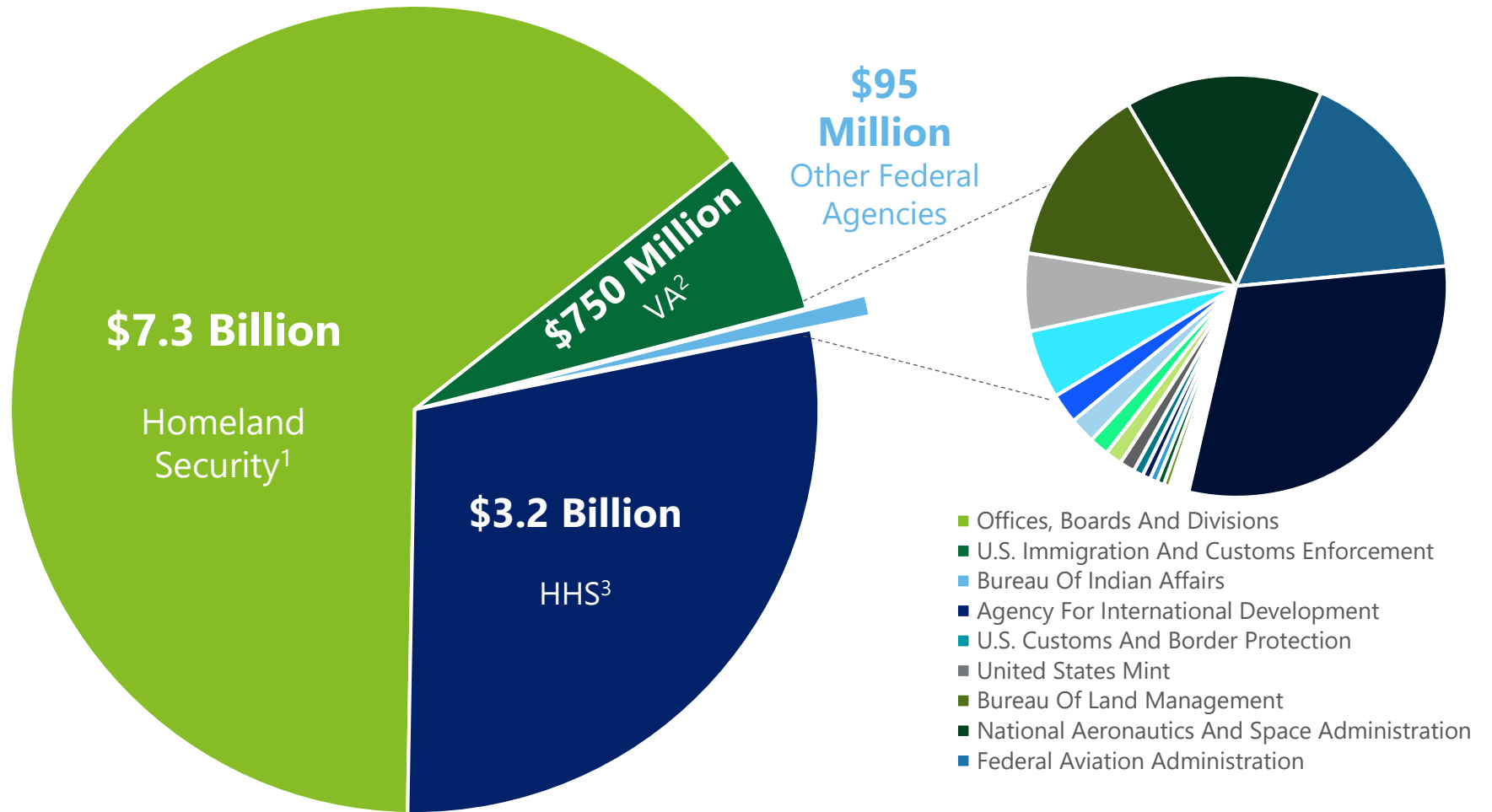


In the SARS experience, demand increase was immediate, followed by a rapid return to normal. COVID-19 PPE demand impact and duration is difficult to predict.

# US PPE Market:

## Federal Demand Side

Data to the right represents Federal Spend in direct response to COVID-19, totaling over **\$11 Billion**<sup>4</sup>



1. Federal Emergency Management Agency buying in response to national emergency (temporary)
2. Veterans Administration purchases for Federal hospitals for veterans
3. HHS oversees the National Stockpile
4. Department of Defense reporting delayed by 90 days for National Security reasons

Source: Federal Procurement Data System (FPDS) COVID report

**Entry to Federal and commercial markets is different and some commercial suppliers support both.**

# Current supply of coronavirus PPE in health care facilities across the U.S., by type of PPE



\*A total of 978 facilities responded to the survey. The "n" for each category refers to the number of facilities that addressed that particular question in their survey response.

Source: TIME Magazine

US PPE Market:

## US Medical PPE Inventories – April 2020

Data to the right represents surveyed institutions across the US who were asked "How long will your current PPE supply of each item last?"

This snapshot from April 20, 2020 illustrates the demand shock and demand remains high.

# Strategic National Stockpile (SNS)



## What is the Strategic National Stockpile?

The United States' national repository of antibiotics, vaccines, chemical antidotes, antitoxins, and other critical medical supplies.



## What is the purpose of the Strategic National Stockpile?

The Strategic National Stockpile is maintained to be prepared to respond to chemical, biological, radiological and nuclear (CBRM) events.



## Who oversees the stockpile?

Health and Human Services (HHS) is responsible under the organization structure of the Assistant Secretary for Preparedness and Response and the contents is determined by the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE).



## How often is inventory monitored?

The stockpiles are monitored daily so PHEMCE knows what is aging needs to be procured to restock and rotate out expired items.



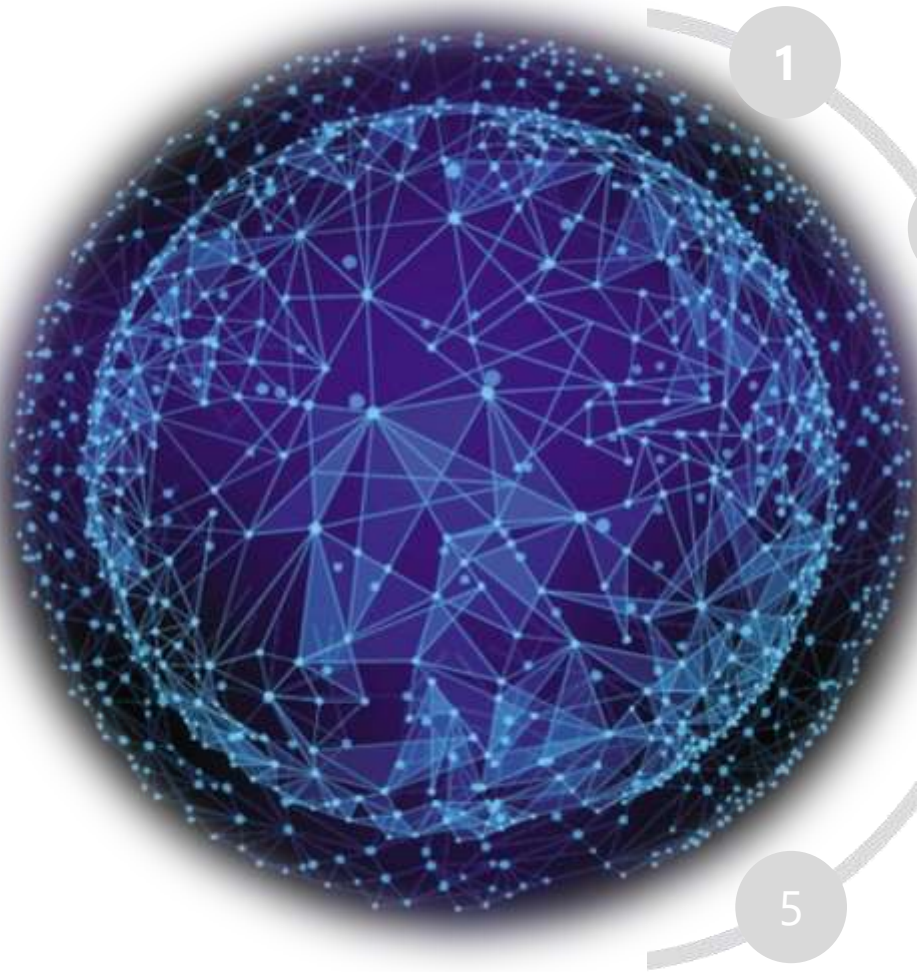
## What is in the stockpile?

About \$8 billion inventory of antibiotics, antitoxins, antidotes, vaccines, medical surgical material, federal medical stations, ventilators and other products. Precise content information is not released.



## Who are the beneficiaries of the Strategic National Stockpile?

Prior to April 3, 2020, the stockpile supported US state, local, tribal, and territorial entities with potentially life-saving pharmaceuticals and medical supplies for use in a public health emergency severe enough to cause local supplies to run out. Its current role is to act as a national supplement of medicine and medical equipment to a state's supplies, as a stopgap when the immediate supply of adequate amounts of these materials are not immediately available.



1

Background

2

US PPE Market

3

**The Medical PPE Value Chain and Ecosystem**

4

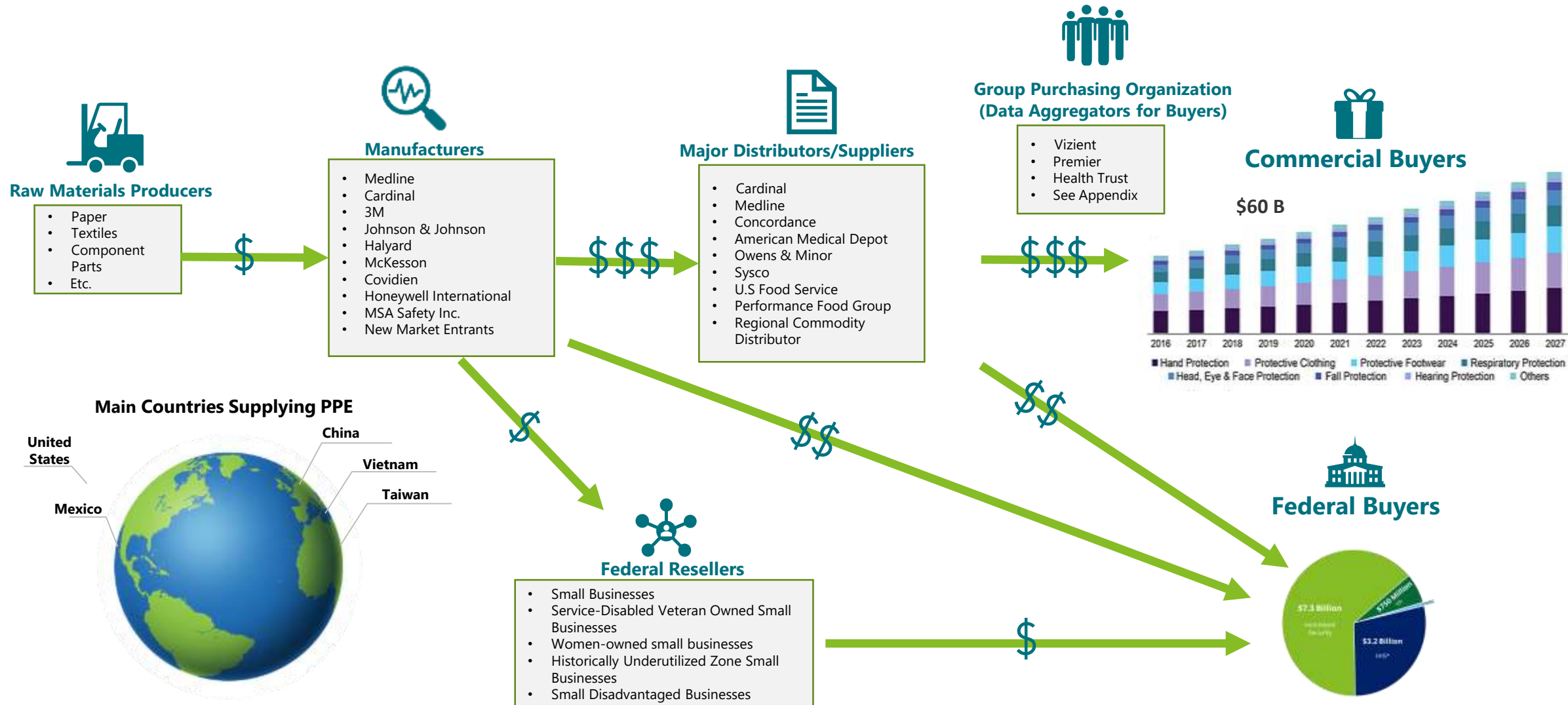
Selling to the United States Federal Government

5

Summary Observations

# US Medical PPE Market Value Chain

PPE is sold through distribution channels managed by a few firms



# PPE Items Needing Additional Supply Sources

PPE Supply Market, even pre-COVID-19, could benefit from greater supplier diversity, an opportunity for the JAAF



## Major Supply Outlook

### PPE in Demand

- N-95 Masks
- Gloves
- Shields
- Isolation Gowns
- Surgical Gowns

### Overall Shortage

- Isolation Gowns
- Surgical Gowns



## Market Considerations

- **Organizational Goals** – revenue, margin – \$ volume
- **What will be manufactured/distributed?** - products going to market
- **Market Complexity** - market populated by strong players with powerful industry relationships
- **Price Point** – in relationship to current market price points
- **Market Positioning** – prescriptive product targeting and quality of offering



## Pipeline to Opportunity

- Hire a representative that is tasked to contact GPO's, present the product and pricing, establish contracts, and have the GPO's negotiate directly with the hospitals
- Consult with medical product distributors (e.g., Cardinal Health, Owens & Minor, Medline, and Concordance) for guidance to the hospital marketplace
- Offer possibility of manufactured products as a private label for medical product distributor

# Sample Commercial Agreement Approval Requirements

As a supplier you would be expected by industry to meet certain criteria that could add to cost of goods sold beyond market willingness to pay

## Supplier Payment

- Source to Pay transactions (i.e., purchase orders, advanced ship notices, purchase order acknowledgements, invoices, payments, etc.) must be processed electronically (Ariba, Electronic Data Interchange [EDI], Supply Network Collaboration [SNC], etc.) or per the signed contract between supplier and business
- Each invoice must match the corresponding business Purchase Order, including businesses specified payment terms.
- Changes to Purchase Orders must be reported using electronic Purchase Order Acknowledgements
- Invoices not matching business Purchase Orders will be returned unpaid

## Supplier Selection

- Selected based on their ability to meet requirements including technical capability, product and service quality, innovative product and service improvements, responsiveness, timely and accurate delivery, total cost, financial strength and best overall value
- Requirements are consistent with the businesses' own expectations for service to their customers
- Reflects the spirit of partnership they expect with their suppliers
- Committed to identifying minority, women, small woman-owned, and small disadvantaged sources for goods and services

## Supplier Management

- Sourcing Operations is responsible for managing the entire purchasing process working with both internal clients and suppliers, and must approve all contracts for the purchase of goods or services
- As a supplier, you are expected to participate in your partner's Supplier Management Process
- Process has been developed to help assure continuous supplier improvement
- Process also involves regular meetings between business and key suppliers
- Allows better communications between business and its supply chain

**Companies use an "Introduce Your Company" form for inquiries about becoming a supplier. Buying teams evaluate supplier inquiries. Selected suppliers are expected to abide by Supplier Responsibility Code.**



# Sample Manufacturer/Supplier Responsibility Code

The Supplier Responsibility Code is the “next generation” of business expectations for supplier responsible practices, established to highlight suppliers’ environmental, health, safety, labor and transportation performance expectations





1

Background

2

**US PPE Market**

3

The Medical PPE Value Chain and Ecosystem

4

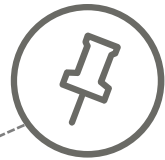
**Selling to the United States Federal Government**

5

Summary Observations

# How to Sell to the US Federal Government

The General Services Administration (GSA) oversees the registration and maintenance of vendors eligible to do business with the US Federal Government.



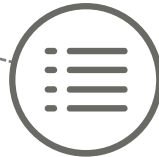
## Step One:

Get a DUNS number and NATO Commercial and Government Entity (NCAGE) Code assigned



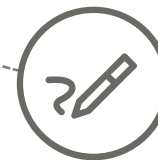
## Step Two:

Go to [www.sam.gov](http://www.sam.gov), create an account, then select "Register New Entity" from the navigation menu



## Step Three:

Follow the prompts to provide more information about your entity. When describing *why* you want to register in SAM, be sure to include your interest in bidding on procurement opportunities



## Step Four:

Complete the registration and note that questions marked with a red asterisk(\*) are required



## Step Five:

Submit the application after a final review. A confirmation message will verify your submission

## Quick Tips

### Start Early

Start this process well before your contract or grant application deadline. **Allow up to 12-15 business days** after submitting for your registration to be active in SAM, then an additional 24 hours for other systems to recognize your info.

### Write down your MPIN

On the Business Information page, you will create a Marketing Partner Identification Number (MPIN). **It is used as a password in other government systems** like Grants.gov.

### Verify need for TIN

If you do not pay U.S. taxes, **do not enter a TIN** or select a TIN type. Leave those fields blank.

### Match codes

Remember your legal business name and physical address for your **DUNS Number and NCAGE Code must match.**

### Identify yourself correctly

On the General Information page, only select Foreign Owned if your entity is owned or controlled by a foreign entity. **If you are also a Manufacturer of Goods, select that first,** then select Foreign Owned.

### Inform your POCs

In the Points of Contact section, list the names of people in your organization who know about this registration in SAM and why you want to do business with the U.S. government. **The Government Business POC is the primary contact for your organization.**

### Leave off Foreign Banking Info

On the Financial Information page, you do not need to provide Electronic Funds Transfer (EFT) banking information. If you do provide this info, it must be for a U.S. bank: SAM cannot accept foreign banking info. The **remittance name and address are the only mandatory sections on this page.**

For free help with your SAM entity registration, contact the Federal Service Desk (FSD) at <http://fsd.gov>

# Other Considerations for Selling to the US Federal Government

The US Federal Government is a niche market, even for firms already doing business in the USA

- Special buying rules for Federal buyers (Federal Acquisition Regulation [www.acquisition.gov](http://www.acquisition.gov)) make the US Federal market challenging for sellers, even for firms doing business commercially in the US.
- Each Federal agency buys under its own authority, so marketing and sales is best targeted to a small number of large Federal consumers; relationships, reputation and past performance matter.
- Not all opportunities to sell PPE are advertised because much PPE is acquired through standing distributor contracts or under programs or agreements designed to meet recurring needs, e.g.,:
  - The Veterans Administration runs a program enabling companies to obtain framework agreements, see <https://www.fss.va.gov/>
  - The Defense Logistics Agency signs Distribution and Pricing Agreements (DAPAs) (not contracts) with manufacturers to support their Medical Surgical Prime Vendor program, see <https://www.medical.dla.mil/Portal/DapaMS/DapaMS.aspx>
- The Federal market typically has very long sales cycles; less true for commercial items.
- For the Federal PPE market, the government uses commercial distributors as well as niche reseller companies focused on the Federal market and buyers; resellers are often small businesses that support US Federal Government socio-economic spending goals.

# US Federal Government Acquisition Regulation limits foreign acquisition

But does not control commercial market transactions

<https://www.acquisition.gov/content/part-25-foreign-acquisition>



Federal Buyers are required to follow the Federal Acquisition Regulation (FAR), including Part 25, which covers, inter alia, The Buy America Act (BAA) and Trade Agreements Act (TAA) – (FAR Parts 25.1 and 25.4)



The Buy American statute restricts the purchase of supplies that are not “domestic end products” defined in two parts as: (1) manufactured in the United States; and (2) the cost of domestic components must exceed 50 percent of the cost of all the components.

This is true except when: a) the Head of an Agency determines it to be in the **public interest** to waive; b) item is “**nonavailable**,” i.e., when not manufactured in the United States in sufficient and reasonably available commercial quantities and of a satisfactory quality; c) if a United States Contracting Officer determines that the **cost** of a domestic end product would be **unreasonable**; d) if purchased specifically for commissary resale; or e) if end product is information technology.



Most PPE is imported today, but there is a risk that if sufficient numbers of US manufactures get into the PPE marketplace, imported products could lose their “nonavailable” exception for sales to the Federal Government. *This has no bearing on sales to commercial end users.*



1

Background

2

**US PPE Market**

3

The Medical PPE Value Chain and Ecosystem

4

Selling to the United States Federal Government

5

**Summary Observations**

# 4 Questions to Ask before Re-Purposing

Carefully thinking through the following questions can help you decide whether PPE manufacturing would be a feasible and strategic, long-term decision

## Do you have the core competencies & existing capabilities to match current needs?

- Do you have access to labor and capacity?
- Can your network support the shift?

**Justify your Preparedness.**

## What inventory can you use — and can you get more?

- Can you repurpose existing raw materials?
- Do you have the support to replace those raw materials?

**Breakdown what can be manufactured.**

## How do you participate in the broader ecosystem?

- Can you share resources with other manufacturers?
- Can you partner to combine existing product components?
- How can you enable an ecosystem?
- How quickly can you identify key market players?

**Assess your collaboration.**

## Are you able to balance speed with compliance?

- Have you thought through the product approval timeline?
- Are your production plans realistic given the aforementioned questions?

**Anticipate & set realistic production goals.**

# Key Takeaways



## **This is New Territory**

The United States, and in fact the global Personal Protective Equipment (PPE) market is experiencing unique surge demand – but for how long?



## **Focus on PPE Items Routinely in Demand**

While most PPE is stripping current supply, some items are likely headed for surplus. Some items are more routinely in short supply. All are subject to changes in planned inventory levels, habits, and status of COVID.



## **Complex Value Chain Ecosystem**

The PPE market has unique rules and norms, and has key players you should engage to assess the opportunity as well as specific value you might provide to the supply ecosystem.



## **Commercial versus US Federal Government Market Focus**

A strong entry into the US marketplace would focus on the commercial market, which is larger and less restricted than US Federal Government, which also relies on commercial value chains.



## **Medical PPE versus non-medical PPE market**

The non-medical PPE market is much larger than the medical market, and is likely served by different value chain partners that could be more adjacent to the apparel industry.



# Questions?



**Thank you.**

# APPENDIX



# Group Purchasing Organization (GPO)

## What is a GPO?

- An entity that helps healthcare providers — such as hospitals, nursing homes and home health agencies — realize savings and efficiencies by aggregating purchasing volume and using that leverage to negotiate discounts with manufacturers, distributors and other vendors
- GPOs make and manage contracts for indirect services or products valuable to both GPO suppliers and members

## What are the benefits of a GPO?

- **Save Money:** On average, businesses save 5-15% on products and services through group purchasing
- **Save Time:** The solicitation process can take months and may not be the best method for every purchase
- **Save Effort:** Gathering data, interviewing vendors, and choosing suppliers requires many resources

## Who are the major GPOs?

- Vizient (Irving, TX) — \$150 billion annual spend
- Premier (Charlotte, NC) — More than \$50 billion annual spend
- HealthTrust (Nashville, TN) — \$30 billion annual spend
- Intalere (St. Louis, MO) — \$9 billion annual spend

## Why is a GPO important?

- Helps businesses control their purchasing
- Helps you get the consideration of important suppliers
- Can enable you to set aside some cash and time
- You will know upfront what your savings will be
- Wholesale rates, without having to buy more