

# Making supply chain sense of the CARES Act & pending legislation

## CARES Act increases FDA activity and opportunity to strengthen position

The COVID-19 pandemic has impacted the global economy and day-to-day business activities of life sciences companies. With the CARES Act signed into law, federal agencies will use nearly \$100 billion to address the supply chain breakdowns in medical products needed to combat the COVID-19 pandemic. This will create new requirements and added challenge, but also opportunity for life sciences companies. During this disruptive period, it is critical to start addressing key supply chain provisions of the CARES Act. Doing so will allow you to strengthen your position while helping to save lives and return communities to health.

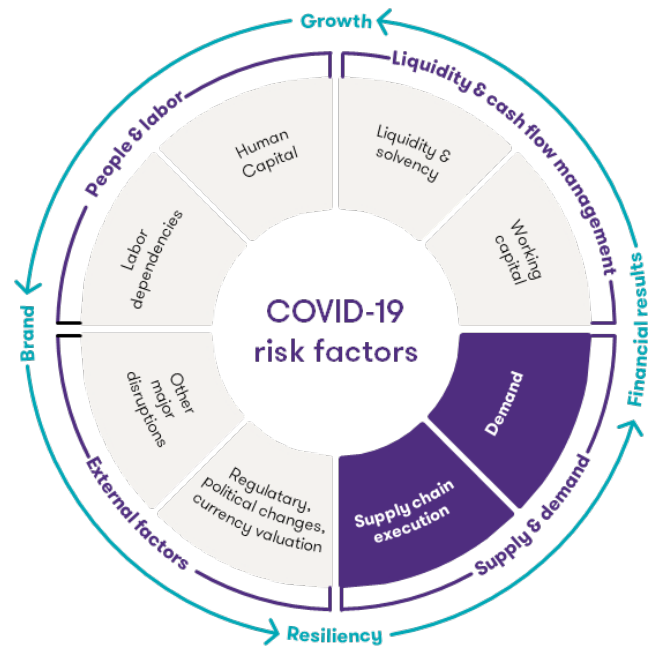
### PROVISIONS

- Notify FDA of drug or medical device shortages (e.g. API, drug volume, etc.) (Sec. 3112)
- Develop and maintain risk management plans (Sec. 3121)
- FDA to prioritize and expedite review of device applications that can help mitigate or prevent shortages (Sec. 3121)
- Manufacturers with critical products in public health emergencies to submit device information at request of FDA (Sec. 3121)
- National Academies and HHS required to analyze manufacturer's supply chains (Sec. 3101)



### IMPACTS

- Shifts toward domestic manufacturing resulting in an increase in production cost, direct materials and labor
- Opportunity to expand facilities and / or shift lines to manufacture critical products
- Change in quality and regulatory processes; increased scrutiny from FDA and other regulators
- Increased reporting complexity will require technology / process changes
- More precision needed in determining tax incentive mechanisms for pharma companies



### PENDING LEGISLATION HAS SUPPLY CHAIN IMPACT

Congress is currently addressing multiple pieces of legislation that will significantly impact supply chain readiness, and likely be a bellwether for legislative activity in the near future. Highlights of supply chain "touch" include:

**The China Act** – proposes to completely move pharmaceutical production from China.

- Mandate FDA to track APIs
- Prevent federal facilities from purchasing products with APIs produced in China
- U.S. government to provide incentives for domestic manufacturing

**The Securing America's Medicine Cabinet Act** – encourages drug makers to bring manufacturing back to the U.S. and provides these enhancements:

- Create an "advanced manufacturing technologies unit" within the FDA to prioritize issues
- Authorize \$100 million to develop Centers of Excellence in advanced pharmaceutical manufacturing



## Our Life Sciences Rapid Response Team is on standby to help you

Grant Thornton's Life Sciences Rapid Response Team stands ready to provide supply chain and risk management insights to help you navigate your business during this fundamentally disruptive period. This team draws upon more than 400 dedicated life sciences professionals, including supply chain life sciences specialists, and business interruption insurance recovery specialists. Specific skill sets and experience include:

### Supply chain resiliency analysis and risk assessment

- Our professionals bring comprehensive experience in quantitative risk analysis to identify the greatest areas of financial risk.

### Supply chain optimization

- Our professionals bring a strong vision, backed by decades of experience in dealing with the disruptive forces that impact our clients supply chains and operating models.

### Supply chain design and tax planning

- Mitigating financial risk often requires supply chain design decisions and changes to the physical operating model, which can also lead to a need for tax analysis and planning.
- Our professionals bring speed to organizing and standing up a risk-informed, tax-effective supply chain design.
- Experience includes in-depth tax planning and analysis required to determine effective tax rate based on tax changes, optimization of legal entities and changes to intellectual property taxation.

## Here's how we can help



### Robust risk management planning

Robust risk assessment planning to address drug shortages and improvement of quality management systems (QMS), with solutions including:

- Risk Management resiliency assessment
- Enhanced business continuity architecture
- Quality management system assessment



### Optimized supply chain

Optimization of the supply chain to identify cost savings in areas of production, planning, sourcing, etc., with solutions including:

- Supply chain resiliency analysis (e.g., capacity & planning management)
- Supply chain re-design
- Tax analysis of supply chain impacts



### Enhanced reporting capabilities

Assist in enabling enhanced reporting mechanisms to address regulatory elements having supply chain impact, with solutions including:

- FDA reporting requirements analysis
- End-to-end operating model design
- Technology assessment to identify fit-for-purpose reporting solutions

## Contacts



### Lisa Walkush

Life Sciences Sector Leader  
T +1 216 814 4000  
E [lisa.walkush@us.gt.com](mailto:lisa.walkush@us.gt.com)



### Jonathan Eaton

National Supply Chain Leader  
T +1 704 632 3523  
E [jonathan.eaton@us.gt.com](mailto:jonathan.eaton@us.gt.com)



### Michael Sinese

Life Sciences Tax Leader  
T +1 215 814 4031  
E [michael.sinese@us.gt.com](mailto:michael.sinese@us.gt.com)



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