

# THREATS TO PHARMACEUTICAL SUPPLY CHAINS

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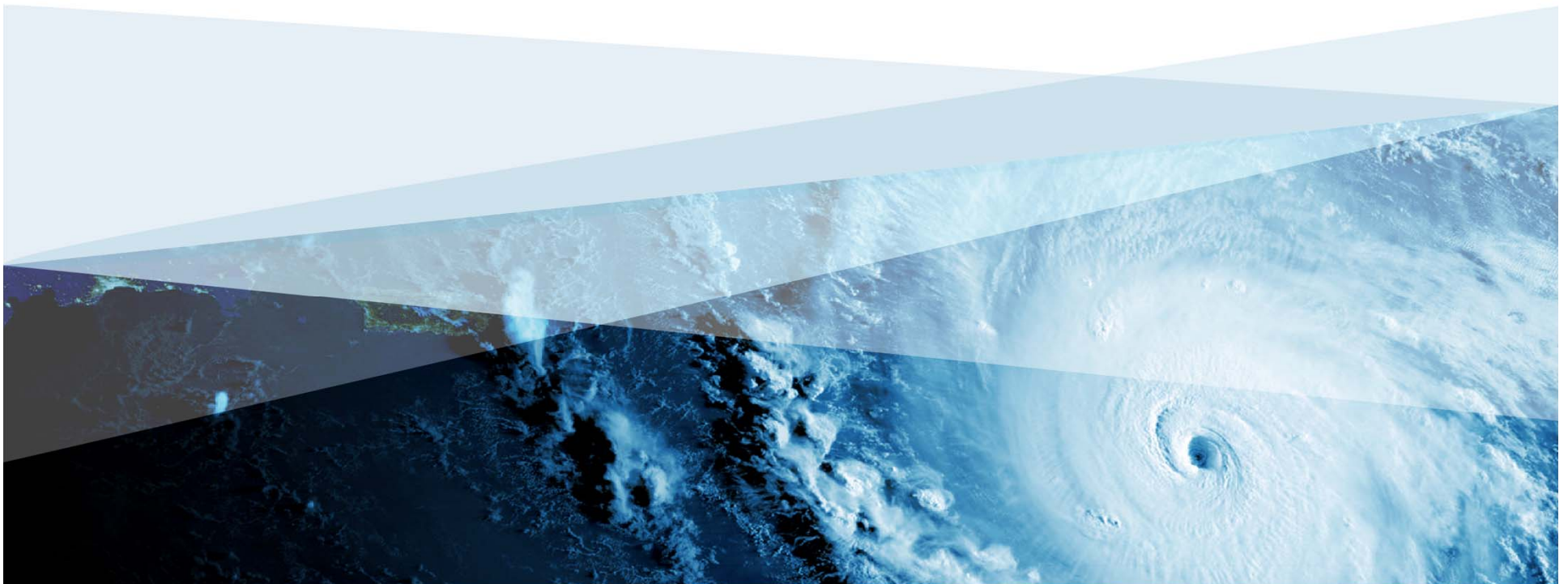
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## TOPIC SUMMARY

### Topic Description

- The Pharmaceutical Threats team explored vulnerabilities and threats to the pharmaceutical supply chain, as well as risks to U.S. companies, public health, and national security, by analyzing the effects of Hurricanes Irma and Maria as case studies.

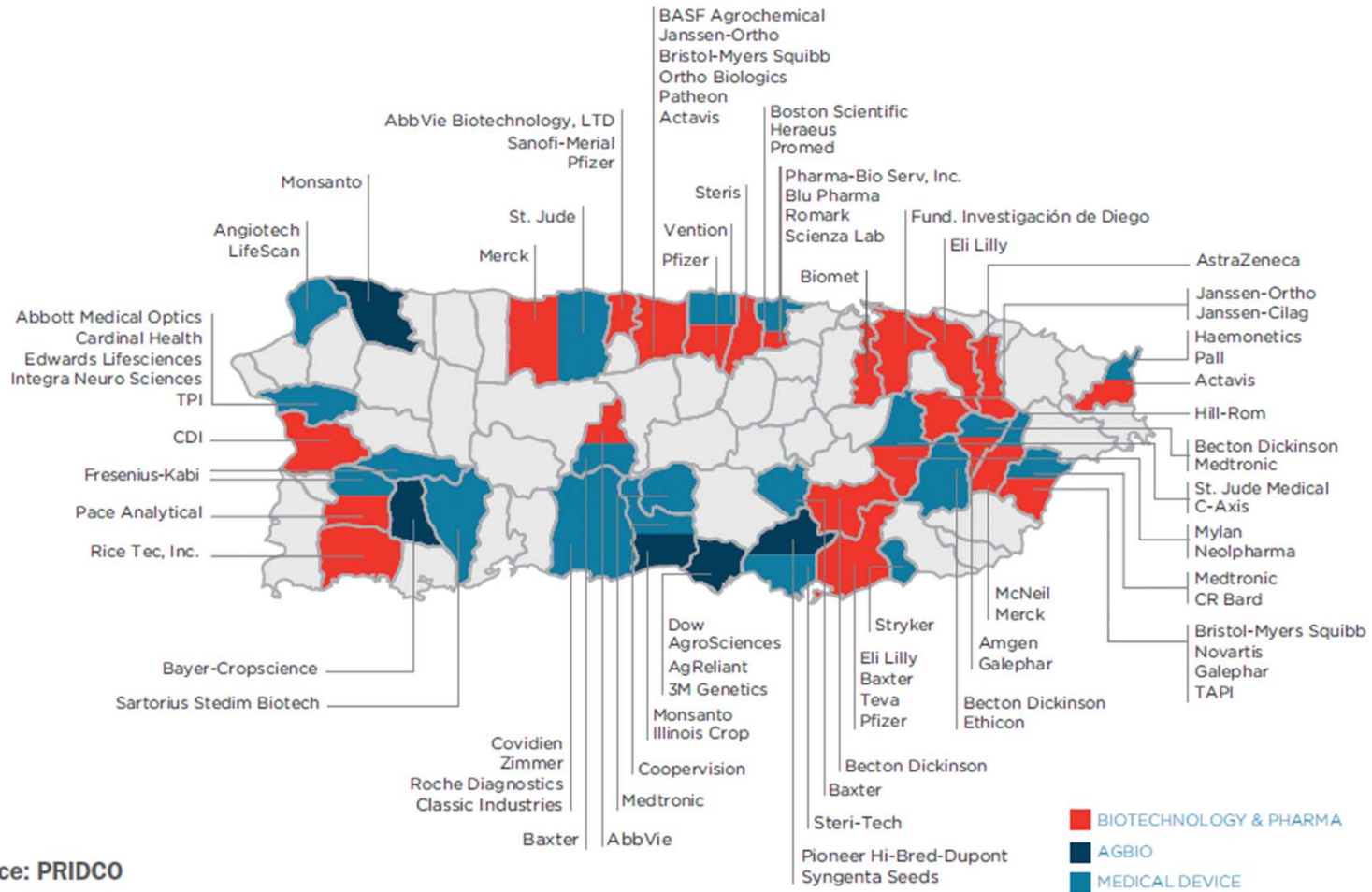
### Research Questions

- What effects did Hurricanes Irma and Maria have on Puerto Rico's concentration of biopharma manufacturing and facilities?
  - What vulnerabilities does the current pharmaceutical supply chain face?
  - What incentives are there that can encourage greater cooperation between the public and private sector to safeguard this critical piece of national infrastructure?
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## HOW HURRICANE MARIA AFFECTED PHARMACEUTICAL MANUFACTURING IN PUERTO RICO

- As of 2016, there were at least 49 U.S. Food and Drug Administration (FDA)-approved pharmaceutical plants in Puerto Rico and over 70 medical device manufacturing facilities on the island.
- Ten percent of all drugs consumed by Americans are manufactured in Puerto Rico.
- Prior to Hurricane Maria, Puerto Rico manufactured 43 percent of the saline used in the U.S.
- At least 101 brand-name drugs were produced in Puerto Rico between 2011 to October 2017, and 21 of these drugs were listed by the World Health Organization as “Essential Medicines” in August 2017.
- As of June 2018, 182 drugs are in shortage in the USA as FDA defines a drug shortage as a period of time “when the demand or projected demand for a medically necessary drug in the United States exceeds its supply.”

# MAP OF PUERTO RICO'S LIFE SCIENCE MANUFACTURING FACILITIES



Source: PRIDCO

## HOW BIOPHARMA BECAME SO CONCENTRATED IN PUERTO RICO

- Section 936 of the tax code provided significant benefits for pharmaceutical companies that established operations in Puerto Rico. Because of this provision, many drug firms made substantial capital investments in Puerto Rico.
  - To take advantage of this provision, a pharmaceutical company would develop a drug in its U.S. research facilities and transfer the drug patent to its wholly owned subsidiary operating in Puerto Rico. The subsidiary would produce the patented drug and claim the income obtained from the drug sales as tax-free income
  - A 1992 GAO report (GGD-92-72BR) noted that many of the most prescribed drugs were approved for production in Puerto Rico.
  - While these benefits expired at the end of 2005, many companies with investments in Puerto Rico continued to maintain operations there.
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## **BAD TO WORSE: HURRICANE MARIA AND THE 2017 - 2018 US SEASONAL FLU EPIDEMIC**

- Hurricane Maria, the tenth-strongest hurricane on record in the Atlantic Ocean, made landfall on Puerto Rico's southwestern coast on September 20<sup>th</sup>, 2017.
- Hurricane Maria created the largest storm-related electrical blackout in US history and second largest worldwide.
- Disruptions in the pharmaceutical supply chain meant that an already-low supply\* of IV bags became even scarcer throughout late 2017.
- The Centers for Disease Control and Prevention (CDC) declared the influenza outbreak in late 2017 and early 2018 to be of “high severity”.
- The list includes IV bags, injectable morphine, anesthetics, antibiotics, electrolytes, and cancer drugs. The AMA blames the current crisis in part on the damage caused to production facilities in Puerto Rico by hurricanes Irma and Maria in 2017



## EXPLAINING WHY HURRICANE MARIA HAD SUCH AN IMPACT

- **Overburdened Disaster Relief and Recovery Resources** — In the weeks prior to Hurricane Maria, Florida and the U.S. Gulf Coast were hard-hit by Hurricanes Harvey and Irma.
- **Poor Existing Infrastructure** — Damage to roads, airports, seaports, electrical grid, and the lowered fuel supply made it difficult for employees to travel to work and to transport goods off and on the island.
- **Debt and Recession** — Many companies closed their Puerto Rico branches after 2005 causing a spike in unemployment and decrease in overall wages.
- **Business Continuity** — Our research team interviewed several representatives of pharmaceutical manufacturers who maintained operations in Puerto Rico. Despite the decade-long economic recession, and the likelihood that another hurricane might hit the island again, none of these manufacturers indicated a desire to relocate.



## **BEYOND OUR CASE STUDY: EXAMINING RISKS AND HYPOTHETICAL SCENARIOS**

The case study on Puerto Rico and Hurricane Maria focuses on geographic concentration in a natural disaster area as a risk factor for supply chain disruption, but this isn't the only risk to U.S. pharmaceutical industry:

- **Third party risks**
  - **Counterfeit Risks**
  - **Environmental Risks**
  - **Cyber Risks**
  - **Geo-political Risks**
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## **OBSERVATIONS AND RECOMMENDATIONS**

- Expedite and Reinforce Manufacture Disclosure of Drug shortages
- Prioritize Disruptions to the Supply Chain or Manufacturing of Critical Drugs
- Improve Incentives for Manufactures to maintain pharmaceutical supply
- Prioritizing the Pharmaceutical Industry and Supply Chain Components as National Security Assets.
- Establish a national plan to include agreements with alternative manufacturing companies to produce critical drugs –in case of shortages.

## **DELIVERABLE DISSEMINATION PLAN**

- DOD– Chemical and Bio Defense
  - DHS – Countering Weapons of Mass Destruction (CWMD)
  - DHS - Federal Emergency Management Agency (FEMA)
  - DHS – Office of Intelligence and Analysis
  - DHS – National Protection and Programs Directorate (NPPD)
  - NSC – USG Biodefense Policy
  - US Health & Human Services (HHS)
    - Office of the Assistant Secretary for Preparedness and Response (ASPR)
  - Washington State Department of Health
  - Washington State Emergency Management
  - Washington State Fusion Center
  - Washington State Pharmacy Association
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# QUESTIONS?

