



**FDA**

## SECURING THE FUTURE FOR PUERTO RICO: RESTORING THE ISLAND'S ROBUST MEDICAL PRODUCT MANUFACTURING SECTOR

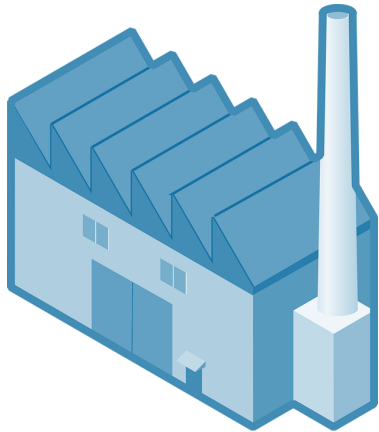
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## Disclaimer:

The results presented in this report represent our best estimate based on the available data, but are subject to change as we receive new information. This analysis reflects the state of Puerto Rico manufacturing and employment immediately prior to the devastation brought by Hurricanes Irma and Maria. It is our aim to see the manufacturing and jobs restored to the prior, robust condition before the tragedy struck.

# EXECUTIVE SUMMARY



Puerto Rico's pharmaceutical and medical device manufacturing industries are integral to the Island's economy

In 2016, approximately **30%** of Puerto Rico's GDP was composed of pharmaceuticals and medical devices manufactured on the Island and these products were two of Puerto Rico's largest exports.<sup>1</sup>

Medical product manufacturing help support a highly skilled workforce in Puerto Rico

Residents employed in the drug and medical device industries collectively earn approximately **\$800M** in wages in one year<sup>3</sup>



America relies on Puerto Rico for many key medical products **8%** of pharmaceutical expenditures by Americans are for products manufactured in Puerto Rico<sup>†</sup>; with many important drug categories including oncology drugs, HIV drugs, and blood fraction products<sup>2,5</sup>

†: Consumption based on dollar value of pharmaceuticals

# AMERICA RELIES ON PUERTO RICO FOR ITS PHARMACEUTICAL MANUFACTURING



Puerto Rico produces more pharmaceutical products for the U.S. (\$40B) than any foreign country. The next largest producer is Ireland with nearly \$20B in imports.<sup>6</sup>



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Puerto Rico also produces more pharmaceuticals than any state (by dollar value)

The next largest producers are Indiana and California

Puerto Rico produces more pharmaceuticals than both of these states combined<sup>7</sup>

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8% of pharmaceutical expenditures<sup>†</sup> by Americans are manufactured in Puerto Rico<sup>2,5</sup>

According to the National Drug Code directory, there are more than 1,000 individual drug products that are registered to be manufactured in Puerto Rico; of which several hundred of these drugs are considered by FDA to be medically important

Puerto Rico manufactures 30 drug products and approximately 10 biological devices/biologics that are of critical importance because Puerto Rico is a primary or sole manufacturing site and these drugs do not have clear therapeutic alternatives.

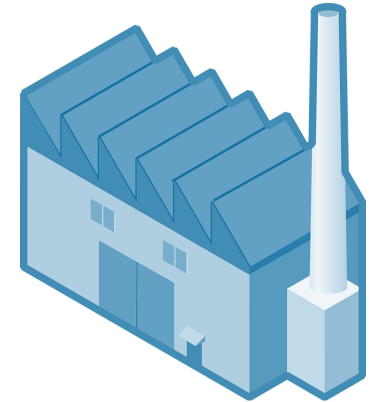
All 40 of these products are being carefully monitored by the FDA Drug Shortage Teams; 14 of these drugs are sourced only in Puerto Rico

<sup>†</sup>Note: Total customs import value from PR as a percentage of total US personal pharmaceutical consumption expenditures

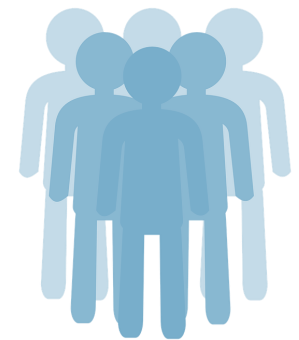
# Employment in the Medical Product Industry

The medical product industry employs 90,000 people<sup>8</sup>

Approximately 30% of Puerto Rico's total manufacturing employees are employed by companies that manufacture medical products<sup>3,4</sup>



Annual cumulative wages by those employed in this sector totals nearly \$800M<sup>3,8</sup>; medical product manufacturing represents a large source of high paying jobs



Pharmaceutical workers earn 60% more than the average manufacturing employee in Puerto Rico<sup>†</sup>

<sup>†</sup>Note: Average hourly wage of a pharma employee is \$21.5/hr at 41.2 hrs/wk. Average med device employee is \$12.99/hr. Average mfr employee is \$13.7/hr at 40.4 hrs/wk.



# PUERTO RICO MANUFACTURES MANY CRITICALLY IMPORTANT MEDICAL PRODUCTS FOR THE UNITED STATES



Many critically important medical products—**which includes sophisticated drugs, biologics, and medical devices**—are manufactured in Puerto Rico. The drugs and devices include:

- Oncology products: including anti-neoplastics, immunosuppressives
- HIV medications
- IV fluids: for example, saline solution
- IV nutritional products
- Blood fraction products
- Cardiovascular drugs and anti-depressants
- Glucose monitors and cardiac pacemakers
- Blood collection systems

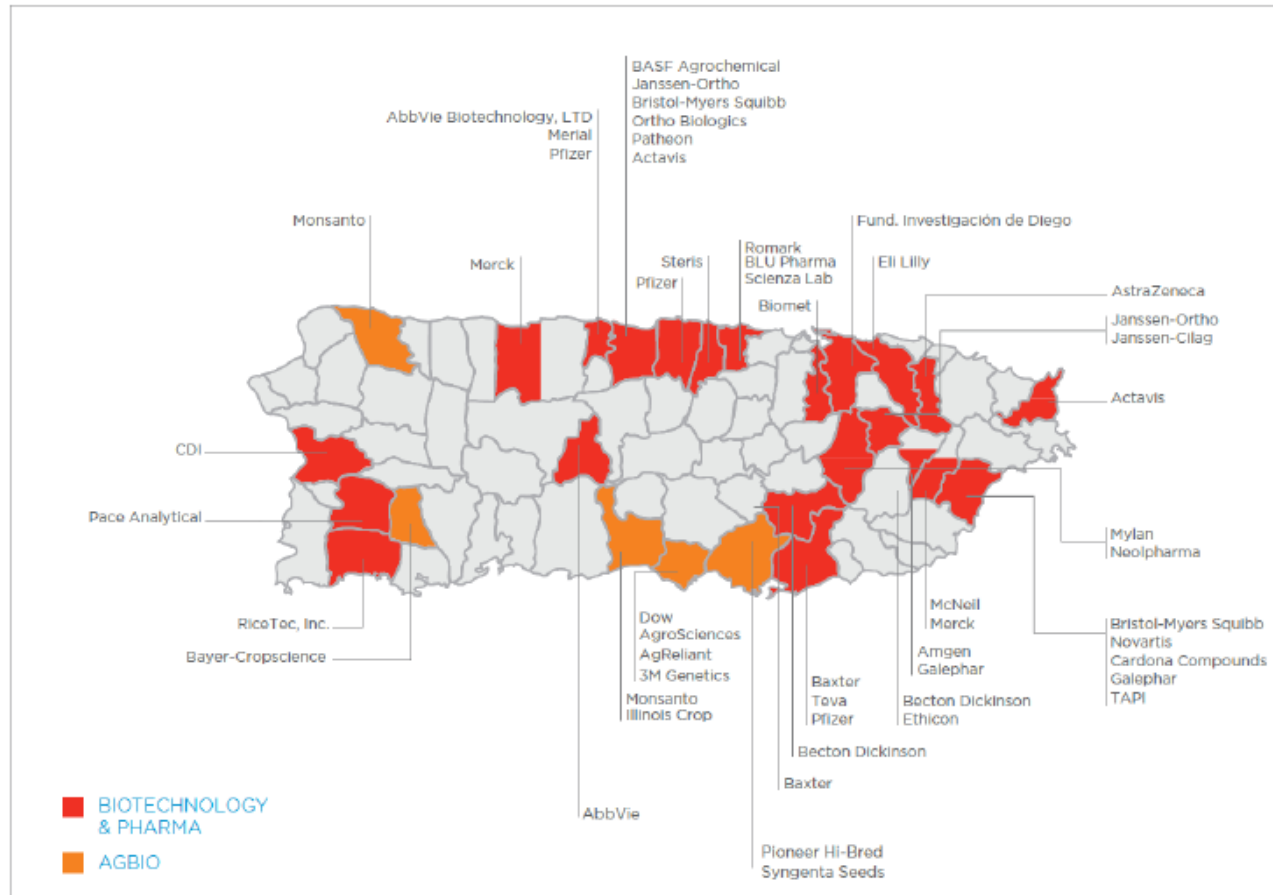
FDA is currently monitoring approximately **90** medical products to mitigate potential shortage situations

- Approximately **50** medical devices that are critically important to patient care — because they may be life-sustaining or life-supporting and/or because there may be only a single manufacturer of that device type
- Approximately **30** drug products and about **10** biological devices/biologics that have the potential to slip into shortage

# PHARMACEUTICAL MANUFACTURING IN PUERTO RICO

PRESENCE OF 11 OF THE TOP 20 GLOBAL PHARMACEUTICAL COMPANIES<sup>8</sup>

## LIFE SCIENCES IN PUERTO RICO

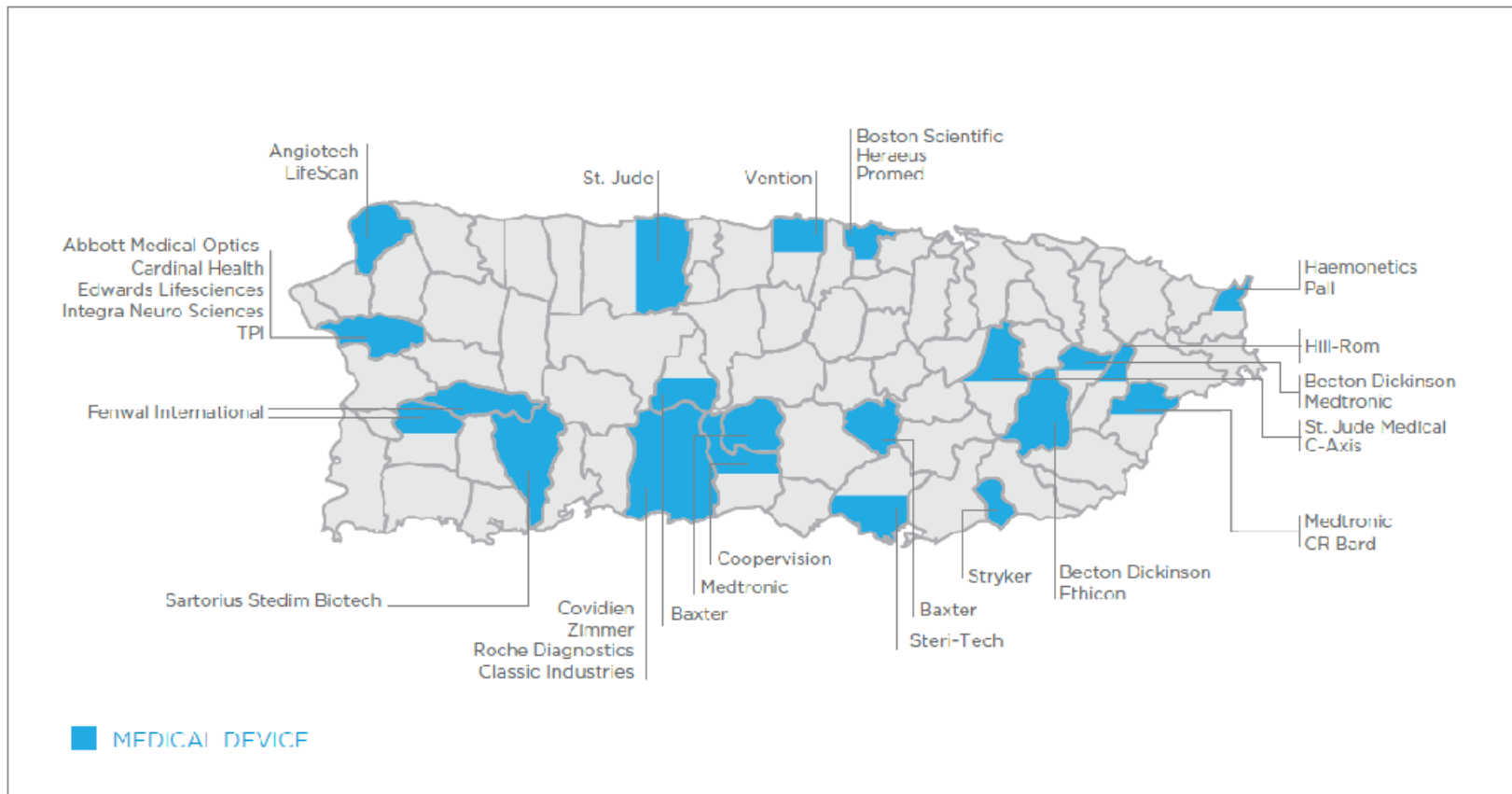


THE WORLD'S LEADING BIOTECHNOLOGY AND PHARMA COMPANIES ARE PRESENT IN PUERTO RICO



# MEDICAL DEVICE MANUFACTURING IN PUERTO RICO<sup>8</sup>

## MEDICAL DEVICES IN PUERTO RICO



THE WORLD'S LEADING MEDICAL DEVICE COMPANIES ARE PRESENT IN PUERTO RICO

# Appendix: References

## Citations

1. Puerto Rico Planning Board. Economic Report to the Governor - Statistical Appendix - 2016. <http://www.aafaf.pr.gov/spanish/assets/apendiceestadistico2016.pdf>.
2. U.S. Census Bureau. U.S. Trade with Puerto Rico and U.S. Possessions, 2016.; 2017. <https://www.census.gov/library/publications/2017/econ/ft895-16.html>.
3. Puerto Rico Bureau of Labor Statistics. Census of Manufacturing Industries in Puerto Rico - March 2015.; 2015. <http://www.estadisticas.gobierno.pr/iepr/LinkClick.aspx?fileticket=Zd3Kj7nFuFI%3d&tabid=186>.
4. FDA. Electronic Drug Registration and Listing System and Dun & Bradstreet data .; 2017.
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6. U.S. Census Bureau. United States Pharmaceutical Imports - Custom Report.; 2016. <https://usatrade.census.gov/>.
7. U.S. Bureau of Labor Statistics. Puerto Rico: Price Movements of Top Exports and Other Highlights .; 2017. <https://www.bls.gov/mxp/puertorico.pdf>.
8. Government of Puerto Rico Department of Economic Development and Commerce. Puerto Rico BioPharma and Med Devices Profiles.; 2016.

# Appendix: FDA Commissioner Statements

## **Commissioner Scott Gottlieb, M.D. Statements Regarding FDA Response to 2017 hurricanes**

- October 20, 2017 - [Statement by FDA Commissioner Scott Gottlieb, M.D. on medical device manufacturing recovery in Puerto Rico](#)
- October 13, 2017 - [Statement by FDA Commissioner Scott Gottlieb, M.D. on Baxter manufacturing recovery in Puerto Rico](#)
- October 06, 2017 - [Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA's continued assistance following the natural disaster in Puerto Rico](#)
- September 25, 2017 - [Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA actions to bring relief to citizens of Puerto Rico; to help the island recover its considerable and economically vital medical product manufacturing base; and to prevent critical shortages of life-saving drugs made in Puerto Rico](#)
- September 22, 2017 - [Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA's immediate steps to respond to Hurricane Maria and ongoing recovery efforts related to Hurricanes Harvey and Irma](#)