

AN OVERVIEW OF THE US HEALTHCARE DEVICES MARKET

Jun Peng

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Introduction

Introduction

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- Healthcare Industry Overview
- Medical Device Sector
- Regulations

Introduction

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- P&L Scientific Inc.
- Founded in Miami, USA in 2009
- There are offices in Florida and Beijing
- To provide regulatory and market services for the medical equipment enterprises with development of international business.



Introduction

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- Our Services
 - U.S. FDA regulatory services
 - Brazil ANVISA regulatory services
 - China CFDA regulatory services
 - International Medical Tradeshow



Healthcare Industry Overview

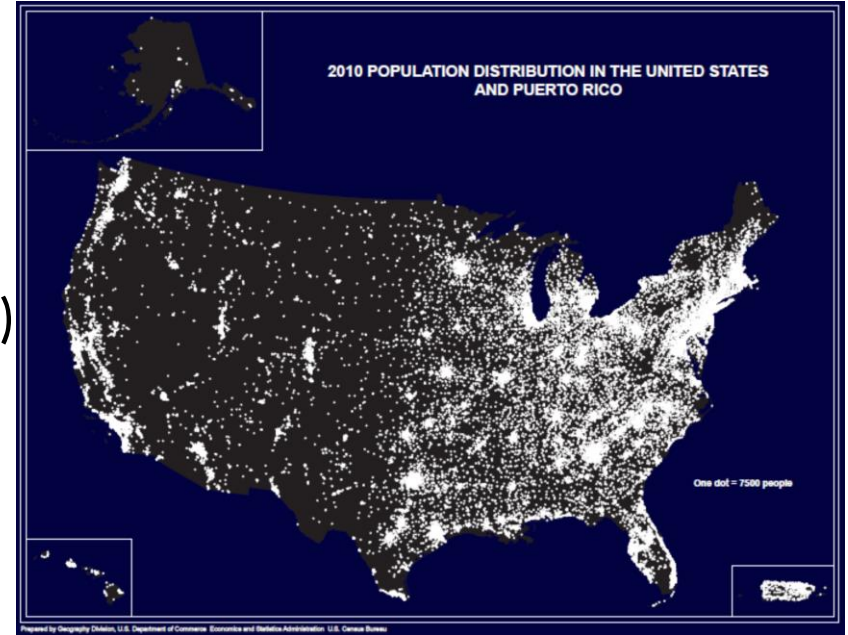
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- Total 2011 U.S. Healthcare expenditures = \$2.7T
 - Largest sector of U.S. economy
 - Highest global per-capita expenditure
 - 1% of U.S. population accounts for ~21% of healthcare spending
- In other words:
 - Per-person: \$8,650
 - %GDP: 17.7%
 - Year-Over-Year spending growth: +4.9%
 - Nearly doubled in 10 years: 2001 expenditure was \$1.49T

Population and Demographic Information

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- Population: 323 million (2016)
- GDP: \$18.6 trillion (2016)
- GNI(Per capita): \$56,180 (2016)
- Population in urban areas: 81% (2013)
- Urban community hospitals: 3,033
- Rural community hospitals: 1,829
- Annual Deaths: 2,688,900 (2013)
- Population over 60 y/o: 20% (2013)



United States Census Bureau, QuickFacts
The World Bank, Data

P&L Scientific Inc. 9/16/2018
World Health Organization, Global Health Observatory

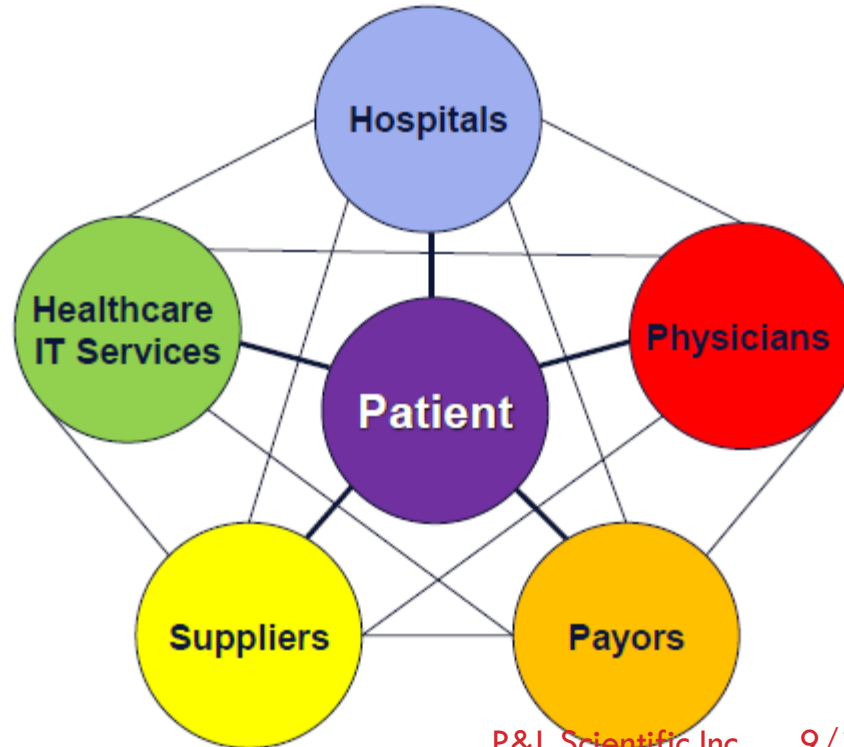
Population and Healthcare Information

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- Health care employees: 12.4 million (2015)
- Number of Registered Hospitals: 5,564 (2015)
- Total annual hospital visits: 35 million (2015)
- Life expectancy: 79 y/o (2012)
- Percentage of population insured: 89% (2015)
- Hospital expenses: \$937 billion (2015)

Interplay of Healthcare Sectors

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Healthcare Industry Sectors

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- Suppliers
 - Bio/Pharma
 - Devices
 - Diagnostics
 - Durable Medical Equipment
 - Consumer Health and Wellness Products and Services
- Payers
 - Insurance
 - Employers
 - Government
 - Consumers
- Providers
 - Hospitals
 - Physicians
 - Dialysis Services
 - Retail and Workplace Clinics
- Healthcare Information Technology (IT) and Services
 - IT Solutions for consumers, hospitals, payers, and providers
 - Technology Vendors
 - Personal genetic information services

Medical Device Sector

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- Equipment

- X-Ray, Ultrasound, CT, MRI

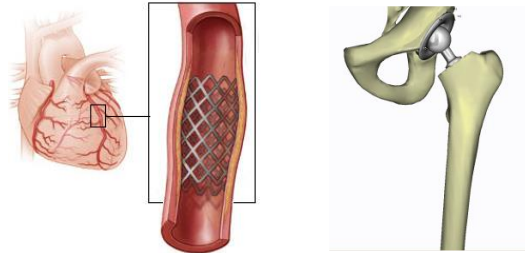


- Consumables

- Surgical gowns, forceps

- Implants

- Stents, Orthopedic implants



- IVDs

- Clinical Chemistry, Hematology, Toxicology

Regulations: Regulatory Body

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- Regulatory Body
- Department of Health and Human Services (DHHS)
- Food and Drug Administration (FDA)
- CDRH
- CBER

Regulations: Definition of Medical Devices

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- Medical device:
- An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device not achieved by pharmacological, immunological or metabolic means.
- From WHO definition of medical device.

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US Devices Market Overview

US Healthcare Devices Market Overview

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- Overall Large Market and Leading Brands
- Innovation is the lifeline
- Various Categories of Medical Devices

Overall Large Market and Leading Brands

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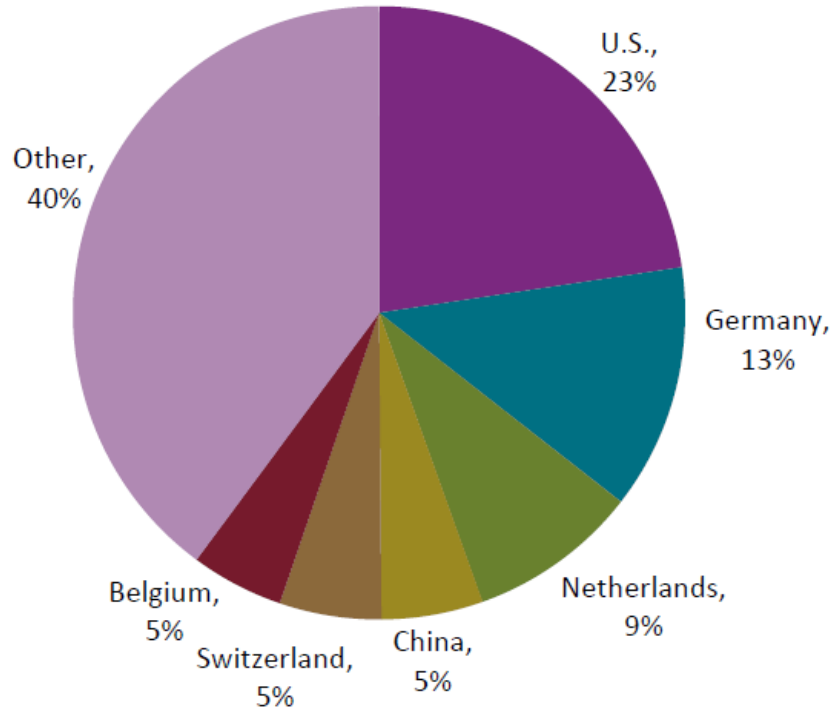
- The United States remains the largest medical device market in the world with a market size of around \$140 billion, and the U.S. market represented about 40 percent of the global medical device market in 2015.
- U.S. exports of medical devices in key product categories identified by the Department of Commerce exceeded \$44 billion in 2015.

USA was the World's Leading Single-country Exporter of Medical Devices, in 2012, 40.87\$B

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Total:
\$177.7billion

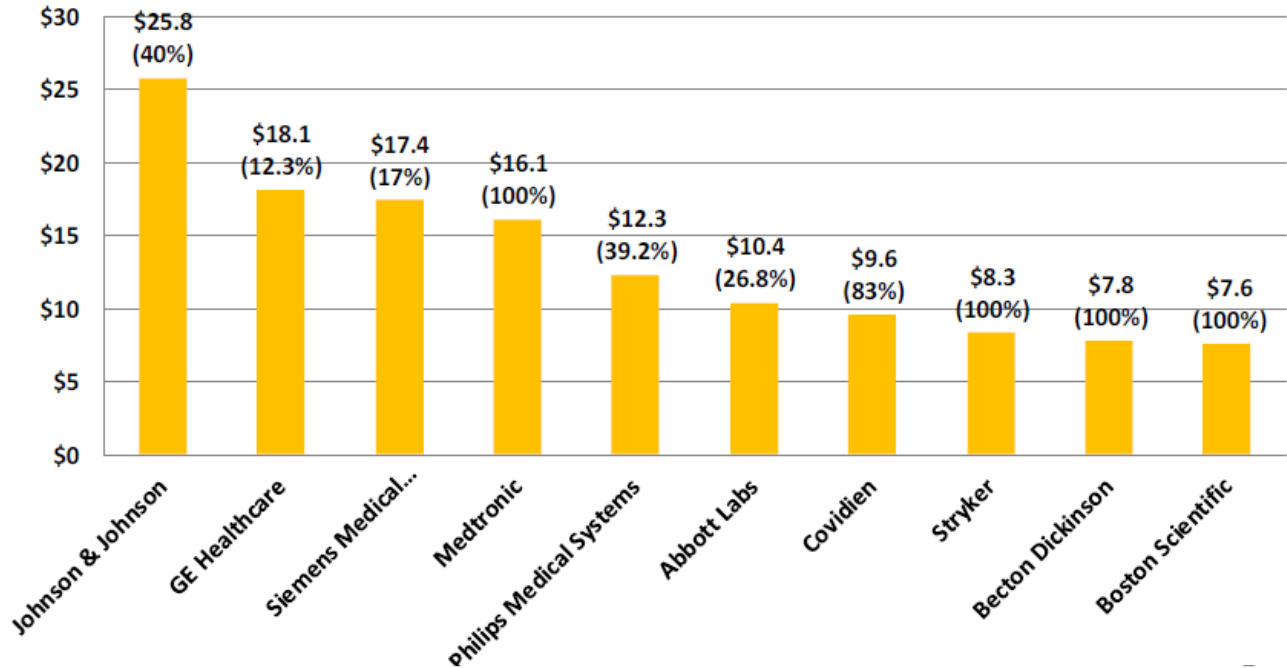
Source: Mihir P.
Torsekar, U.S.
Medical
Devices and
China's Market:
Opportunities
and Obstacles,
June 2014



Medical Device Companies

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Largest
Global
Medical
Device
Companies by
Medical
Device Sales
(and as % of
total sales),
2011 (\$B)



7 out of the world's top 10 leading medical device companies are in USA

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by revenue, in 2012,

Source: MPO, "The Top 30," July/August 2013

Rank	Company	Country Headquarters	Revenue billion \$	Specialty
1	Johnson & Johnson	U.S.	27.4	Diagnostics, surgical care, cardiovascular orthopedic
2	GE Healthcare	U.S.	18.3	Imaging
3	Siemens Healthcare	Germany	17.5	Diagnostics, imaging
4	Medtronic	U.S.	16.2	Cardiovascular, orthopedics
5	Baxter International	U.S.	14.2	Fluid and drug delivery
6	Philips Healthcare	Netherlands	13.2	Imaging
7	Covidien	Ireland	9.9	Surgical care
8	Abbot Laboratories	U.S.	9.8	Diagnostics, cardiovascular
9	Cardinal Health	U.S.	9.6	Surgical care
10	Stryker	U.S.	8.7	Orthopedics

Innovation is the lifeline

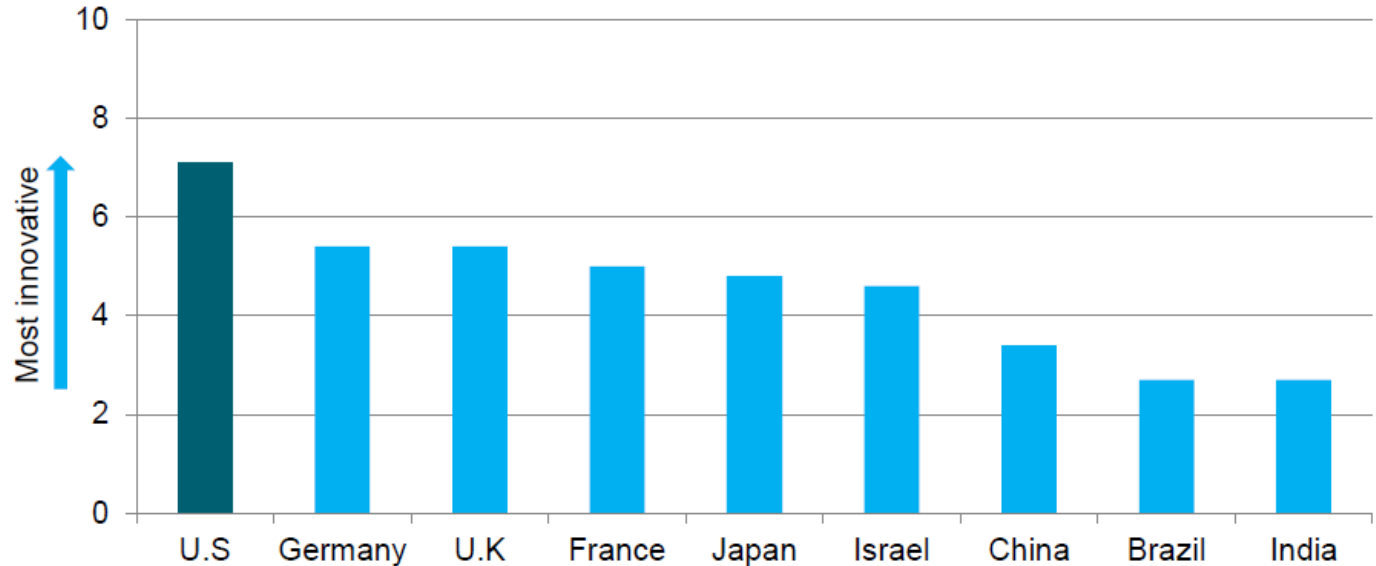
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- U.S. medical device companies are highly regarded globally for their innovations and high technology products. R&D spending continues to represent a high percentage of medical device industry expenditures, averaging 6.7 percent of revenue from 2011 to 2016.
- Compared to several other industries including automotive, defense, and telecom, the medical device industry invests a higher percentage of yearly revenues into product innovation. This reflects the competitive nature of the industry, and constant innovation and improvement of existing technologies.

Innovation is the lifeline

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The United States is considered the world leader in medical device innovation



Source: PwC, Innovation Scorecard, January 2010.

Various Categories of Medical Devices

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- Dental equipment and supplies:
 - Includes equipment, instruments, and supplies used by dentists, dental hygienists, and laboratories. Specific products include dental hand instruments, plaster, drills, amalgams, cements, sterilizers, and dental chairs.

- Electro-medical equipment:
 - Includes a variety of powered devices, such as pacemakers, patient-monitoring systems, MRI machines, diagnostic imaging equipment (including informatics equipment), and ultrasonic scanning devices.

- In-Vitro diagnostics:
 - Includes chemical, biological or radioactive substances used for diagnostic tests performed in test tubes, Petri dishes, machines, and other diagnostic test-type devices.

Various Categories of Medical Devices

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- Irradiation apparatuses:
 - Includes X-ray devices and other diagnostic imaging, as well as computed tomography equipment.
- Surgical and medical instruments:
 - Includes anesthesia apparatuses, orthopedic instruments, optical diagnostic apparatuses, blood transfusion devices, syringes, hypodermic needles, and catheters.
- Surgical appliances and supplies:
 - Includes artificial joints and limbs, stents, orthopedic appliances, surgical dressings, disposable surgical drapes, hydrotherapy appliances, surgical kits, rubber medical and surgical gloves, and wheelchairs.

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Trends and Opportunities

Trends and Opportunities

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- Trends in US Healthcare Device Market
- Trends in Global Market
- Opportunities

Trends: US Healthcare Market

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- Rate of Growth of U.S. Healthcare Spending Expected to Flatten
- ACA and Cost Containment
- Patients are Reducing Healthcare Spending
- Reduced Capital Expenditures for Hospitals

Trends: Global Healthcare Market

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- Harmonized Global Regulation
- Trade barriers
- Globalized Supply Chain

Opportunities

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- Global Growth
 - ▣ Globalized Supply Chain
- Trade barriers
 - ▣ Oversea Manufacturing Operation
- Harmonized global regulation
 - ▣ MDSAP

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Summary

Summary

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- Expanding Market
- Trade barriers
- Regulation Compliance

Contributions

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- Adam Eismont
- Ziqian Ma
- Jianjie Wei

Sources

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- Mihir P. Torsekar, U.S. Medical Devices and China's Market: Opportunities and Obstacles, June 2014
- 2016 Top Markets Report Medical Devices, International Trade Administration, Department of Commerce, USA
- United States Census Bureau, QuickFacts
- The World Bank, Data
- World Health Organization, Global Health Observatory

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Questions

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- Have a great FIME Show!

- Thanks!