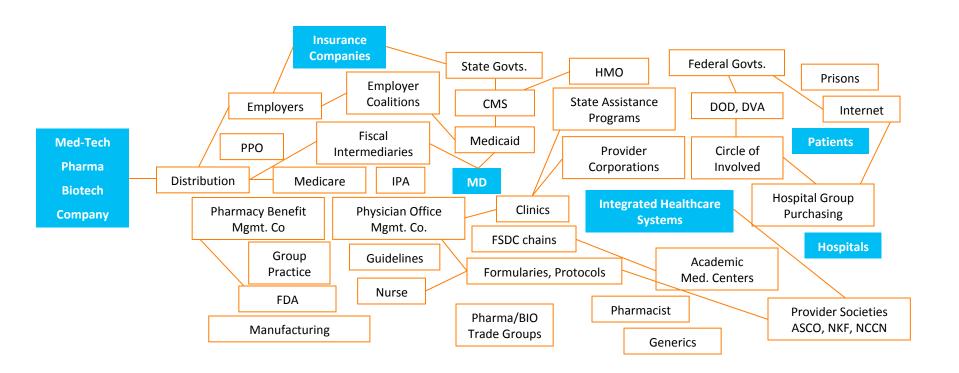
THE GATEWAY FOR LIFE SCIENCES INTO THE UNITED STATES

So YOU want To Do Business In the USA?



The Complexity Of The U.S. Healthcare Market





Snapshot Of The U.S. Medical Technology Market

\$340BN

41%

2MM

Total Sales

Total Volume of Global Sales

Jobs Generated
In The USA

< 50

19%

39%

Number Of Employees

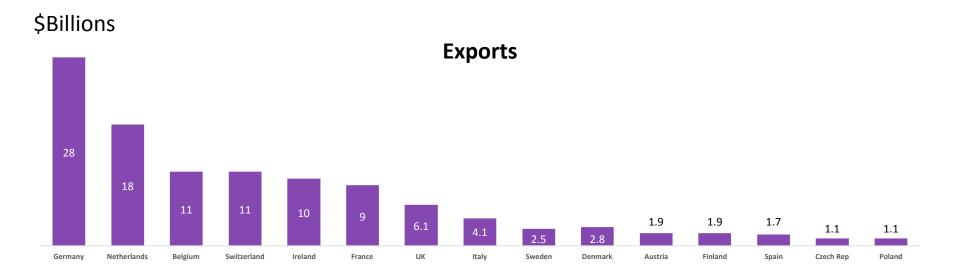
German Exports
To The U.S.

European Exports
To The U.S.





Export Of Medical Technology By Country





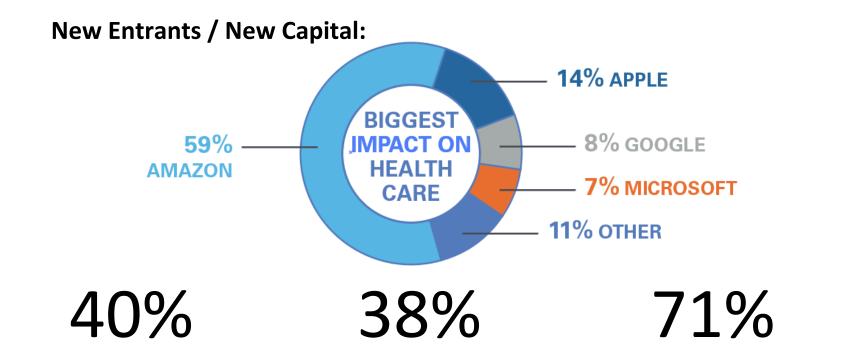
BioPortUSA and Successful US Market Entry

Questions you need to ask before entering the US Healthcare Market:

- Have I developed a solution for which there is no problem?
- What is the compelling need/pain your product will solve?
- How will your technology improve healthcare providers decision making process, patient outcomes and lower costs?
- How is your product better/different then the competition?
- What is your reimbursement strategy?
- What is your Go-To-Market plan?
- Do you have the necessary resources (people and money)?



Consumerism



Medicaid Financing Value/delivery system and Redesign reform

The American Landscape

- You are no longer working in a single payer environment.
- No one buys products or services, they buy benefits.
- How does your product add value?
- Have you developed a healthcare economic strategy!
- Hospitals want as few suppliers as possible how do you fit in?



The USA spends more on health care per capita (\$10,500) and as a percentage of its GDP (17.2%).



The **goals** in today's U.S. marketplace are to reduce costs, demonstrate value & improve conditions.



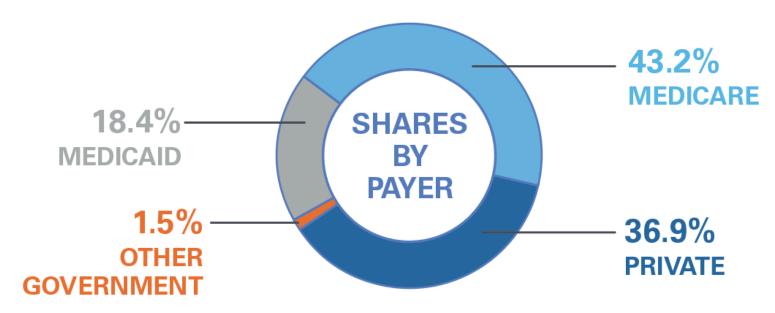
INPATIENT/OUTPATIENT REVENUES FOR COMMUNITY HOSPITALS

	Outpatient	Inpatient
1995	30%	70%
2015	47%	53 %
2016	48%	52 %
2017	49%	51 %

"TrendWatch Chartbook 2018: Supplementary Data Tables, Chapter 4, Trends in Hospital Financing," Annual Survey, American Hospital Association, May 2018; AHA Annual Survey data, 2017, for community hospitals



HOSPITAL AND HEALTH SYSTEM GROSS REVENUE IN 2017



American Hospital Association Annual Survey data, 2017, for community hospitals





Automation and Al could replace 45% of the activities that people are now paid to perform.



While no one can dispute the complexity associated with gaining FDA approval, too many companies underestimate the barriers associated with securing payer coverage.



What is your current process for assessing your readiness to enter the US Healthcare market with regard to gauging Product Desirability, Feasibility, and Sustainability?



10 Steps For Successful US Market Entry

U.S. Market Entry Checklist

- Market Launchpad Readiness Assessment
- Market and Competitive Landscape "Chance favored those that are prepared."
 Louise Pasteur
- IP Landscape FTO
- Pre-Market Assessment FDA Pathway
- Legal & Insurance
- Commercialization Plan
- Regulatory Filing with FDA
- Market Access Reimbursement
- Sales & Distribution CUSTOMER SERVICE!
- Branding & Marketing



Q+A

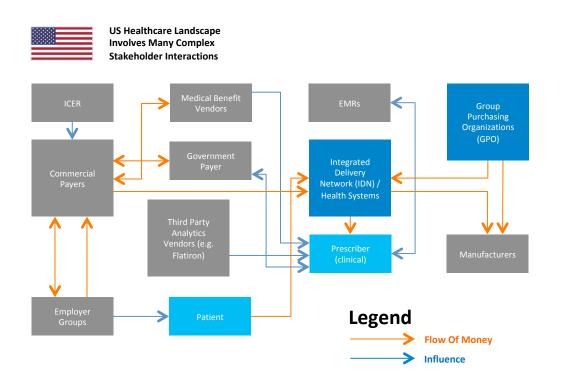
Of the Ten Steps outlined which is of the highest importance for you?

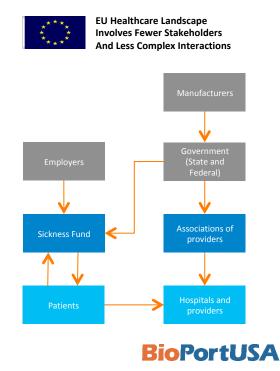


Larry Blandford



The **Complexity** Of The U.S. Reimbursement Process





In the **United States**, people are able to purchase health care services through enrollment in public and private health plans.

Market Access and Reimbursement Planning

Don't:

- Assume all stakeholders will value your product the same or that value "speaks for itself"
- Rely upon providers to know what to do for reimbursement
- Ignore health plans that make coverage decisions

Do:

- Assess the possible reimbursement pathways early to guide trials
- Understand appropriate coding and impact to reimbursement
- Monitor deadlines for coding submissions
- Create an evidence plan focused on value
- Understand your payer mix

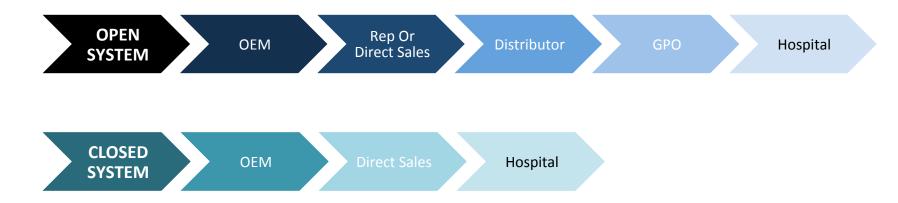


Trends Impacting U.S. Sales

- Emerging countries create low cost products creating competition
- Premium medical products need to prove that the device will lower total cost of patient care
- Tougher regulatory hurdles are increasing costs
- MedTech companies are shifting from selling product to selling solutions (i.e. Hill Rom acquisition of Welch Allyn)



How Do Hospitals Buy?





Partnering with a Distributor can help since they tend to have the relationship already. Expect to share 10-50% of the revenue with them.



Your Brand vs Partnership

Your Brand:

- More control
- Local office
- VP of Sales
- Requires more money
- Needs support from marketing
- Increased brand awareness
- Greater ROI

Sales Partner:

- Licensed reseller
- Private label
- Manages and controls all of the relationships
- Lower margin for you
- May provide own marketing support
- Provides sales support & customer service.



The U.S. Small Business Administration recommends spending 7% to 8% of your gross revenue for marketing & advertising if you're doing less than \$5 million a year in sales and your net profit margin after all expenses is in the 10% to 12% range.

Branding & Marketing

Don't:

Create sales support materials that provide a series of dense and obsure results from clinical trials.

Do:

Describe how your product is unique and differentiate your company from the competition.



Decisions by procurement officers when purchasing medical devices are NOT rational choices, they are **emotional** ones.



Digital Marketing Has Increased Momentum

- Use an online presence to execute inbound marketing
 - Use Blogs, Tweets (Philips Medical)
 - Offer live chat
 - Provide email support
 - Provide customer service online chat
- Establish an FAQ Section
- Don't just list a series of press releases
- Engage the visitors to your site be prepared to tell a compelling story



Corporate Branding Should Be A Priority

- It's not about the products, it's about the brand
- If you focus on the brand, people will know what your company stands for and will know what to expect from the product
- A strong brand will get you better access to key opinion leaders, wholesalers and distributors
- Understand your company's purpose and how well is it perceived in the marketplace
- How good is your service?



Marketing and Sales have to work together, they are not separate.

Marketing should lay the foundation for sales to build on.



Your Brand vs Private Label

Your Brand:

- Higher risk
- More liability
- Requires more money
- Requires FDA approval
- More control of the brand
- Increased brand equity
- Greater ROI

Private Label:

- Less risk
- Less liability
- Requires less money
- Requires FDA approval
- Less control of the brand
- No brand equity
- Lower ROI



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BioPortUSA Successful US Market Entry

BioPortUSA facilitates market entry for foreign-based Life Sciences companies wishing to enter the US Market. Quickly, Easily, Cost Effectively.



BioPortUSA Team Experience

















SIEMENS



Welch Allyn





BioPortUSA and Successful US Market Entry

Foreign-based companies can now partner with BioPortUSA and take advantage of our vast industry knowledge and market experience, enabling access to a menu of coordinated services designed to correctly determine early investment and accelerate the commercialization of their product lines.



BioPortUSA and Successful US Market Entry



Clinical



Marketing, Sales



Accounting



Regulatory



Reimbursement



Business Establishment



Manufacturing



Managed Care



Insurance



Communication



Human Resources

