



MEDICAL ALLEY
ASSOCIATION

U.S. Market Entry Considerations

THE GLOBAL EPICENTER OF HEALTH INNOVATION AND CARE



First, a bit about my home

Three Things Minnesota is Known for



Getty

World Famous Artist Prince was Born and lived most of his life in Minneapolis



The Honeycrisp Apple, the best on earth, was developed at the University of Minnesota



More visitors than Disney World

HOME OF THE
WORLD'S #1 HOSPITAL



U.S. News and World Report 2018-2019

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**MAYO
CLINIC**


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#1 IN THE UNITED STATES IN HEALTH CARE PERFORMANCE

#1	MINNESOTA
#4	MASSACHUSETTS
#23	CALIFORNIA
#40	TEXAS

Scorecard on State Health System Performance, 2014



How to visit my home and the
whole U.S., for fun and profit

Please note: I don't do and can't do
what you do.

These are my observations from
working with many companies.

Common Mistakes

- Failing to do validate the market
- Discounting the cost of change
- Assuming “saving health system money” matters
- Assuming the US system is like Australia’s
- Insufficient market focus
- Insufficient capital
- Discounting reimbursement and overemphasizing FDA
- Discounting Distribution and overemphasizing Product



Failing to Validate the Market

Just because there is a problem and you have a solution does not mean there is a market.

What is your evidence to demonstrate real market interest?

How big is the market and how much will it cost to address?

Validate before Launch



What to do?

Get professional help – find a consultant/advisor

Test your assumptions with the target customer

Test in many settings – Mayo Clinic is not comparable to a community hospital

Be willing to change/pivot



Discounting the Cost of Change

Change is hard.

If your product requires someone to change workflow, behavior, practice, it will be hard.

The benefit must be substantial enough to justify change.

And you have to plan for launch to take longer and cost more.



What to do?

Work on big problems with big impact

Or

Find niche markets you can dominate



Assuming “saving the health system money” matters

Savings are usually someone else’s revenue

Saving money does matter but so does context

Also, make sure you can PROVE you save money

Evidence matters



How to Avoid Mistake

- Understand your value
 - If you save money, where is the money saved from?
 - Will you create new revenue opportunities?
- Who are the stakeholders?
 - Doctors? Prestige, clinical outcomes, efficiency, ease of use.
 - Payors? Cost savings, outcomes
 - Patients? Lower out of pocket costs. Better recovery.



Assuming the US system is like Australia's

It is not.

- Public system in US is for elderly and poor
- Insurance is provided mainly by employers
- Payments are a mix of individual, employer, and government
- 30-40% of people do not have insurance or sufficient insurance
- Out of pocket costs are significant
- Hospitals are larger
 - 160 beds average in US
 - 70 beds average in Australia



How to Avoid Mistake

Understand the type of care provider that uses your product and learn as much as possible about their market.

Example:

- A surgical device that speeds up a procedure could be relevant to a specialist center that does high volumes of few procedures.
- A breakthrough implantable device with a complex surgery could be relevant to an academic medical center or other center of excellence.



Insufficient market focus

AKA “We are a platform technology”

- U.S. medical system is organized around specific diseases and specific actions.
- Procedure codes for reimbursement
- Indication for product approval

Doctors don't buy a platform; they buy a solution to a problem.



How to Avoid Mistake

- Pick a target market or target markets
- Research each target and prioritize
 - What are their sizes?
 - What are their growth rates?
 - How profitable are they today?
 - Are there policy trends that could alter the composition of the market?
 - Does one segment have greater need than another?



Insufficient capital

U.S. market is expensive

- Large – Sydney to Perth is about the same distance as New York to Los Angeles. With 320 million more people.
- Complex
- Hundreds of stakeholders



Example Expenses

	Three Months Ended	
	December 31,	
(In thousands, except share and per share data)	2017	2016
Revenues, net	\$ 34,886	\$ 28,478
Cost of goods sold	8,829	7,523
Gross profit	26,057	20,955
Operating expenses		
Sales and marketing	12,670	9,936
Research and development	1,361	1,162
Reimbursement, general and administrative	7,099	6,565
Total operating expenses	21,130	17,663



How to Avoid Mistake

- Raise money
- Narrow your target
- Don't launch in the US, launch in a part of the U.S.



Discounting reimbursement and overemphasizing FDA

- Historically FDA approval was the most important of milestones
- Today reimbursement is generally considered the most important milestone
- FDA has become a more rationale and predictable process; reimbursement has become less predictable.



How to Avoid Mistake

- Understand reimbursement pathways before you enter the U.S. market
- If you do not know the reimbursement path for your product then DO NOT proceed
- Reimbursement matters even if you sell a capital product



Discounting Distribution and Overemphasizing Product

If no one knows about your product or can get your product it doesn't matter how good your product is.

- Sales is expensive. Reps make good money.
- Sales is expensive. Doctors are hard to reach.
- Sales is expensive. Hospitals have seen your idea before. Probably 100 times. Why should they care.

SALES IS EXPENSIVE



How to Avoid the Problem

- Do market assessment BEFORE you get FDA, reimbursement code, open an office.
- Target a narrow market to start.
- Be capital efficient. San Francisco will cost you twice as much as Minneapolis/Rochester and has fewer resources.
- Houston is a wonderful city with no supply chain or specialist services – you'll end up hiring people in other cities.
 - Where you set up a corporate office is not necessarily where your customers are located.



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