The Minnesota Medical Devices Cluster

Microeconomics of Competitiveness

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1. Executive Summary

The United States, which has been one of world's most productive and innovative countries, is facing challenges in maintaining its competitiveness. This is primarily driven by macroeconomic challenges, a retrenchment in protectionism, overly stringent regulations and insufficient education and R&D spending. Minnesota faces a similar competitiveness challenge. It has been a state with high levels of prosperity and productivity. It is home to many globally renowned companies, talented people and innovative activity. Nevertheless, lack of a coherent cluster strategy, low levels of entrepreneurship, declining innovation and issues in attracting talent threaten long-term competitiveness.

The globally competitive medical devices cluster has been a cornerstone of Minnesota's economy, with leading firms, important academic institutions, specialized suppliers and good institutions for collaboration (IFCs). Based on a literature review, data analysis, and 20 interviews with cluster participants and policymakers, it is clear that the cluster's loss of position stems from issues at the federal, state and cluster level. These issues include the lack of a holistic cluster strategy, difficulty in attracting talent due to the unfavorable location, cluster's limited expertise in complementary fields such as biotechnology and electronics, limited engagement from large companies, low innovation and commercialization of research and unnecessarily burdensome and costly federal regulations.

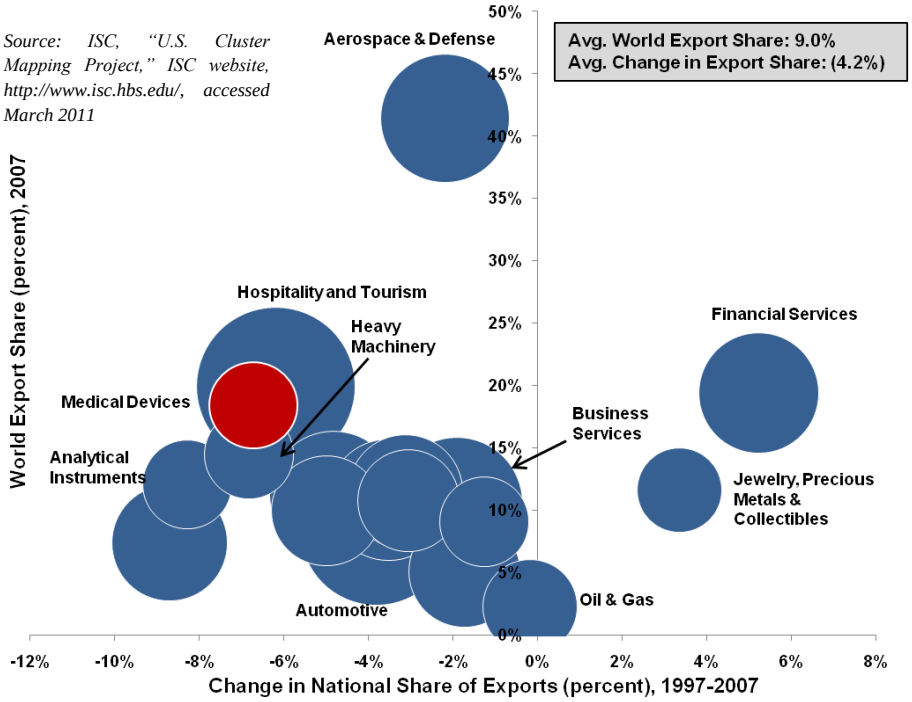
Revitalizing Minnesota and the cluster will require collaborative action from firms, the government, and IFCs. This report proposes the following key recommendations:

Minnesota	• Support cluster development both within state and within region with strong leadership from governor and engagement with the private sector
	• Encourage commercialization and entrepreneurship by reducing bureaucracy and enabling technology sharing and co-investments
Cluster	• Attract and develop talent by (a) developing funded research positions (b) increasing internship/placement programs (c) improving specialized and cross-disciplinary curricula
	• Address and lead industry trends by (a) developing devices to integrate health delivery and improving frugal innovation skills (b) increasing cross-disciplinary innovation with pharmaceutical and biotechology companies

2. The United States and its competitive position

The U.S. is the world's largest economy with a nominal GDP of $14.6 trillion in 2010[1] and Total Factor Productivity growth which has exceeded Germany and Japan over the past three years.[2] However, the U.S. is gradually losing competitiveness. It is ranked No. 4 in the Global Competitiveness Index in 2010, after Switzerland, Sweden and Singapore, signaling a downward trend from its previous ranking (GCR, 2010). It has been hit significantly by the 2008 financial crisis, with real GDP shrinking by c. 3% in 2009, and only a moderate rebound to a positive growth rate in 2010.[3] The unemployment rate peaked at 10% in early 2010 and has yet to fall back to its 10-year average of 6%.[4] Moreover, the country's budget deficit, which reached 9% of GDP in 2010,[5] implies the need for government spending cuts.

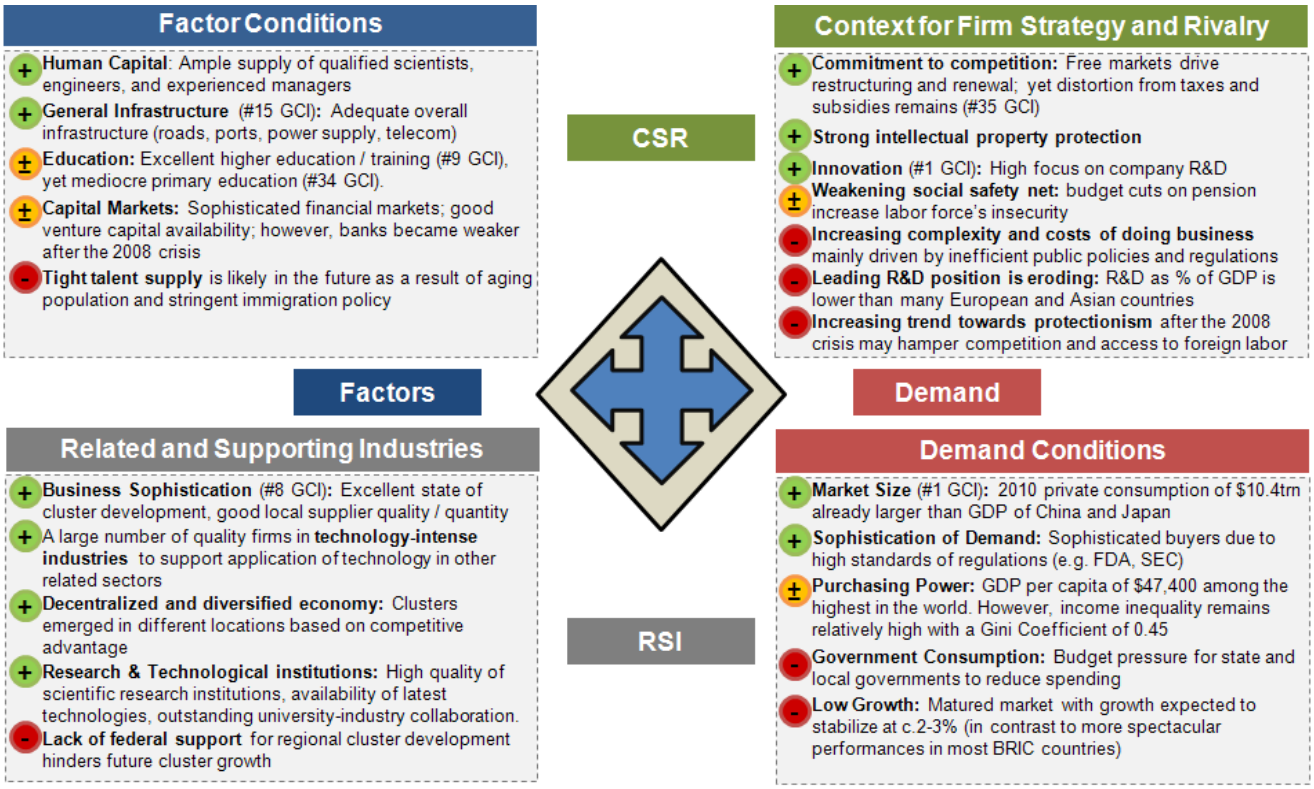
***Figure 1**: US Export Portfolio by Cluster (with 2007 export value > $30bn)*



The U.S. public debt has reached 62% of GDP in 2010, its highest level over the past three decades.[6] Furthermore, at the cluster level, most major export clusters in the U.S. are losing share in the global market (**Figure 1**). There are several factors that are causing the decline of the competitive position of U.S., which are shown in **Figure 2** below.

[1] Bearfacts, Bureau of Economic Analysis, accessed March 2011.
[2] Economist Intelligence Unit, Total Factor Productivity Growth, www.eiu.com, accessed March 2011.
[3] Economist Intelligence Unit, GDP Growth, www.eiu.com, accessed March 2011.
[4] Bureau of Labor Statistics, "National Unemployment Rate,", BLS website, http://data.bls.gov/timeseries/LNS14000000, accessed March 2011.
[5] Economist Intelligence Unit, Budget deficit as % of GDP, www. eiu.com, accessed March 2011.
[6] Economist Intelligence Unit, Public debt as % of GDP, www. eiu.com, accessed March 2011.

Figure 2: *Diamond Analysis of the United States*



Source: GCR 2010, Porter 2008, CIA Factbook.

In terms of strengths, the U.S. is a premier innovation engine (GCR, 2010), fueled by company R&D spending and research institutions. The U.S. also has arguably the world's best talent in science, engineering and management. In addition, the nation ranks high in terms of general infrastructure and has the world's largest market, with sophisticated buyers as a result of stringent regulations.

However, the analysis in **Figure 2** surfaced several weaknesses that have eroded the nation's competitiveness. Despite the strong higher education system, the quality of primary education is only ranked 34th globally (GCR, 2010). The sophisticated capital markets are now at a crossroads with many banking assets wiped out in the financial crisis. Although R&D spending has been high, R&D as a share of national income is stagnating, whereas in Western Europe and China it is increasing[7] (Porter, 2008).

Furthermore, protectionism has regained popularity after the 2008 crisis (Porter, 2008), with the U.S. ranking only 67th on the prevalence of trade barriers (GCR, 2010). In addition, the U.S. is only

[7] Economist Intelligence Unit, R&D as a share of GNP, www.eiu.com, accessed March 2011.

ranked 71st on the extent and effectiveness of taxation (GCR, 2010), which may limit incentives to work or invest. Public policies and regulations have often needlessly driven up the complexity and costs of doing business, especially for smaller companies (Porter, 2008). Finally, the federal government is lacking a national strategy and a coherent set of policies to combat the aforementioned problems and it is also failing to support the regional cluster development that drives the economy (Porter, 2008).

3. Minnesota and its competitive position

3.1 State Overview

Minnesota is a comparatively affluent state, located in the Midwestern United States, with a GDP of $258bn in 2009, ranking 16th amongst the states.[8] It has an inland location with the headquarters of 25 of the "Fortune 500".[9] GDP per capita has been consistently higher than the national average over the past 10 years.[10] By population (5.3m people), it ranks 21st in the U.S.[11] Minnesota's inland location creates disadvantages due to a concentration of activity in the U.S. along the coasts. Minnesota's climate is characterized by cold and long winters, which is repeatedly quoted as creating problems in attracting talent. 60% of the population is concentrated in Minneapolis and St. Paul, the so-called "Twin Cities", and 89% of the population is white, which is higher than the national average of 80%.[12] The large gap in the high school graduation rate between the white and the black populations contributes to the disparity among races in economic achievement.[13]

3.2 Performance snapshot – Position and Trends

Minnesota's performance mirrors closely that of the overall U.S. economy. While it enjoys a good position *currently* with high productivity and innovation, its competitiveness is eroding. In terms of position, Minnesota currently ranks in the top quintile among US states in innovation and labor

[8] Bearfacts, Bureau of Economic Analysis, accessed March 2011
[9] CNN Money, http://money.cnn.com/magazines/fortune/fortune500/, accessed March 2011
[10] Bearfacts, Bureau of Economic Analysis, accessed March 2011
[11] Ibid
[12] Population, U.S. Census Bureau, http://censtats.census.gov/cgi-bin/cbpnaic/cbpsel.pl, accessed March 2011
[13] Education, U.S. Census Bureau, http://censtats.census.gov/cgi-bin/cbpnaic/cbpsel.pl, accessed March 2011

mobilization and in the second quintile in prosperity and productivity. However, Minnesota is among the states with the lowest cluster strength (5th quintile) in terms of the leading clusters' contribution to the local employment (Porter, 2011). In terms of future looking trends in innovation, labor mobilization, prosperity and productivity, data are not encouraging. Minnesota ranks in the 2nd quintile in 10-year productivity and innovation trends and in the 3rd quintile in 10-year prosperity and labor mobilization trends. Despite the poor position in cluster strength, the trend, as measured by the state's increasing national share across strong clusters, is positive and in the top quintile. (Porter, 2011)

3.3 Endowment

Natural resources, which comprise of over 11,842 lakes and 6,564 natural rivers[14] as well as forest that covers almost 1/3 of the state's land area,[15] led to early businesses such as fishing, farming, logging and flour mills. As of 2007 there were nearly two dozen rail corridors in Minnesota[16] and plenty of water transportation along the Mississippi River system and from the ports of Lake Superior.[17]

3.4 Macroeconomic competitiveness

Despite the high GDP per capita ranking noted above, Minnesota was one of the states most affected during the 2008 financial crisis, with many of the problems seen at the federal level also surfacing at the state level, in some cases to an even greater extent. Its real GDP dropped more than the national average in 2009.[18] While currently its labor market appears on a path to recovery, it has regained only one third of the jobs lost since the 2008 financial crisis.[19] Similar to the national level, business confidence continues to be weak with concerns over increasing public debt service costs. In response, the state government plans to rationalize K-12 funding, cut health and human services and

[14] Minnesota Department of Natural Resources, "Lakes, rivers, and wetland facts", Minnesota Department of Natural Resources website, http://www.dnr.state.mn.us/faq/mnfacts/water.html, accessed March 2011
[15] Bewer, Tim (2004), "*Moon Handbooks Minnesota* (First ed.)," Avalon Travel Publishing
[16] Minnesota Department of Transportation, http://www.dot.state.mn.us/ofrw/maps/RailLines20070806_1.pdf, accessed March 2011
[17] Minnesota Department of Transportation, http://www.dot.state.mn.us/ofrw/waterways.html, accessed March 2011
[18] Bearfacts, Bureau of Economic Analysis, accessed March 2011
[19] Minnesota Management & Budget, "Forecast Document," Minnesota Management & Budget website, http://www.mmb.state.mn.us/doc/fu/11/complete-feb11.pdf, accessed March 2011

increase the tax rate for the top 5% income class[20] (**Figure 3 & 4**). These cuts, and their potential impact, are discussed further in the Diamond Analysis of Minnesota on page 8.

***Figure 3**: YoY Change in Budget (Pre-Cuts)*

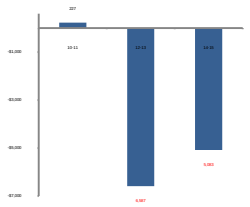
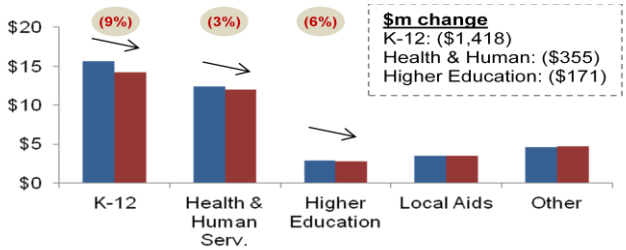


***Figure 4:** Budget cut areas*



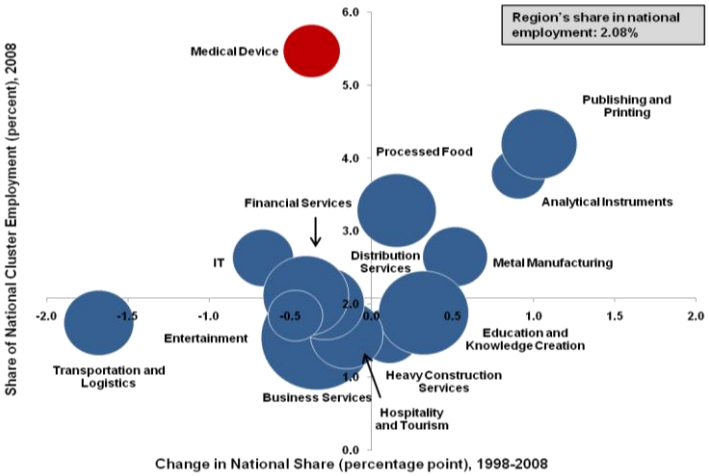
Source: Minnesota Management & Budget, "Forecast Document," Minnesota Management & Budget website, http://www.mmb.state.mn.us/doc/fu/11/complete-feb11.pdf, accessed March 2011.

3.5 Clusters

3.5.1 Cluster evolution

In Minnesota, the top five clusters in terms of employment ranking[21] are processed food, publishing and printing, information technology, medical devices and analytical instruments. These clusters have developed over a number of years, with their origin stemming primarily from the state's endowments highlighted above. For example, a number of cities such as Minneapolis and Saint Anthony Falls became milling centers in 19th century (Danbom, 2003). This is the root of the processed food cluster, now led by a number of multinationals such as General Mills and Cargill. The state's education institutions, especially University of Minnesota, historically also developed a number of scientists and engineers who later became entrepreneurs.

***Figure 5**: Specialization by Traded Cluster (clusters with 2008 Employment > 20,000)*



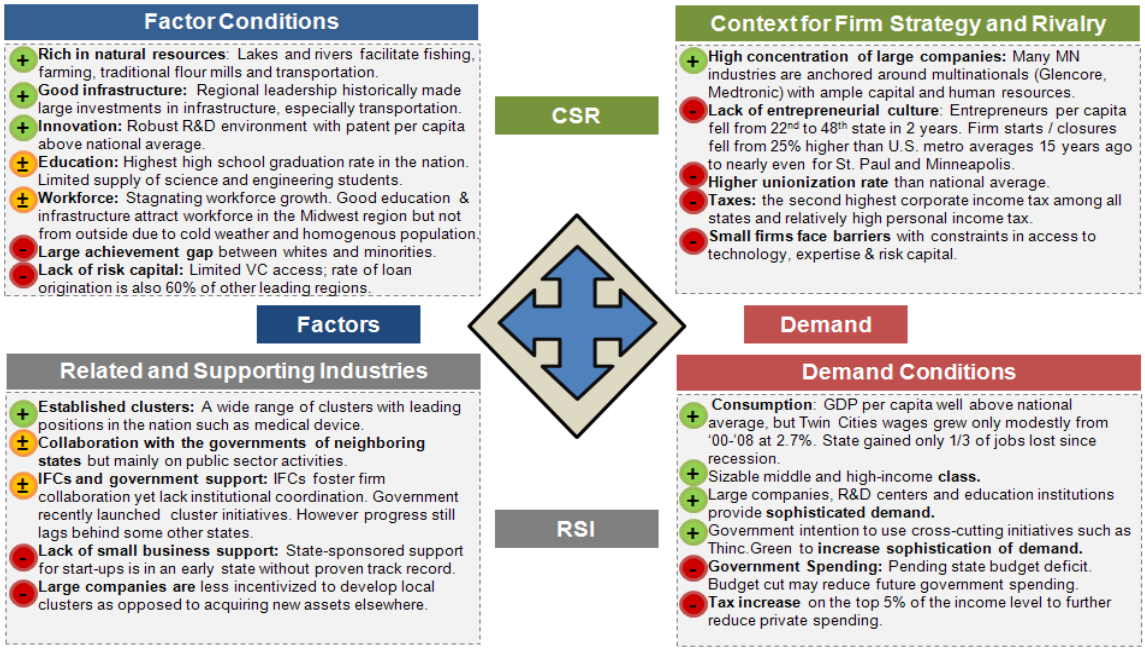
ISC, "U.S. Cluster Mapping Project," ISC website, http://www.isc.hbs.edu/, accessed March 2011

[20] Minnesota Management & Budget, "Forecast Document," Minnesota Management & Budget website, http://www.mmb.state.mn.us/doc/fu/11/complete-feb11.pdf, accessed March 2011.
[21] Michael E. Porter, "Michael Porter at the National Governors Association Winter Meeting 2011," ISC website, http://www.isc.hbs.edu/stateprofiles.htm, accessed March 2011.

3.5.2 Diamond analysis

While Minnesota continues to show growth in a few clusters, many others are losing share, including the medical devices cluster (**Figure 5**). The diamond model for Minnesota analyzes sources of the state's prosperity and potential challenges that could undermine competitiveness (**Figure 6**).

***Figure 6**: The Diamond Analysis of Minnesota*



Sources: Interviews, St Paul government website, Minnesota Financial Report, Institute for Strategy and Competitiveness, US Census Bureau, Minnesota Department of Education

Demand Conditions: State demand is relatively robust with GDP per capita well above the national average[22] and there is a large middle and high income class. Even more importantly, the sophistication of demand is strong and likely to remain so. The presence of large companies, R&D centers, hospitals and education institutions provides sophisticated demand for goods and services. Where government spending is sophisticated, especially in areas such as ICT and energy efficiency, plans to cut government spending over the coming years may be concerning.[23] The recently proposed

[22] Bearfacts, Bureau of Economic Analysis, accessed March 2011.
[23] Minnesota Management & Budget, "Forecast Document," Minnesota Management & Budget website, http://www.mmb.state.mn.us/doc/fu/11/complete-feb11.pdf, accessed March 2011.

tax increase on individuals in the top 5% income bracket[24] as well as the slow job recovery since the 2008 recession could also negatively impact the sophisticated private consumption highlighted above.

Factor Conditions: Over the years, Minnesota has invested in good innovation infrastructure and education. As a result, the state is known today for its robust R&D environment (patent per capita of 9.9 per 10,000 employees vs. 6.2 for national average[25]), excellent education system (highest percentage of people 25 years and over with high school degree in the nation[26]), and an innovative workforce. However, the growth rate of Minnesota's workforce is stagnating, which poses a challenge.[27] Finally, compared to other leading commercial centers in the U.S. such as Massachusetts, California and New York, Minnesota's venture capital industry is not as mature.[28]

Related and Supporting Industries: With a well-established network of multinational companies, Minnesota ranks favorably in the quality of its related and supporting industries. Many of the state's clusters command leading positions in the nation such as medical devices and processed food.[29] Furthermore, existing academic institutions such as The Mayo Clinic and The University of Minnesota are reasonably strong in collaborating with related industries. However, there are only a small number of such institutions and, for example, The Mayo Clinic is only specifically advantageous to the medical devices cluster. At the government level, state involvement in cluster strategy and institutional collaboration is at an early stage of implementation. For example, Minnesota's fledgling *Entrepreneurial Accelerator* program, designed to provide risk capital and technical expertise to firms, still lacks a proven track record and adequate scale. In addition, there is inadequate engagement by large multinationals in developing the local clusters, potentially due to their limited understanding of the role

[24] Ibid
[25] ISC, "U.S. Cluster Mapping Project," ISC website, http://www.isc.hbs.edu/, accessed March 2011
[26] U.S. Census Bureau, "Population who are High School Graduates or Higher, map by state", U.S. Census Bureau website, http://factfinder.census.gov/servlet/ACSSAFFPeople?_submenuId=people_5&_sse=on, accessed March 2011
[27] Bureau of Labor Statistics, "Employment status of the civilian noninstitutional population, 1976 to 2010 annual averages," BLS website, http://www.bls.gov/lau/staadata.txt, accessed March 2011
[28] Principal, Minnesota-based private equity firm, telephone interview, March 2011
[29] ISC, "U.S. Cluster Mapping Project," ISC website, http://www.isc.hbs.edu/, accessed March 2011

of the cluster in supporting their own success. Limited activity by these players in organizing cluster players for collective action, supporting projects that improve the local talent and supply base, or producing spin-out companies leads to missed opportunities in deepening cluster expertise.

Although Minnesota has many established IFCs for various clusters, such as BioBusiness Alliance and Defense Alliance of Minnesota, many rarely coordinate with cross-cluster institutions such as the Urban Land Institute[30]. These cross-cluster institutions need to find a way to better connect to IFCs in order to better foster collaboration and innovation within and across clusters.

Context for Firm Strategy and Rivalry: The competitive landscape in Minnesota benefits from the presence of multinationals with ample capital and human resources. However, entrepreneurship has been deteriorating, indicated by the national ranking of entrepreneur per capita declining from the 22nd to 48th state in 2 years.[31] While firms started net of closures in St. Paul and Minneapolis used to be 25% higher than national average 15 years ago, today this figure is nearly equal.[32] Unionization rates also remain higher than the national average[33] and the current corporate tax rates are the second highest among all U.S. states.[34]

In response to the state's current challenges, St. Paul and Minneapolis developed a business plan draft in November 2010 containing five economic development priorities[35]: 1) the *Regional Economic Development Partnership*, a leadership alliance with leaders from both private and public/nonprofit sectors, 2) the *Regional Cluster Initiative* that primarily supports the medical devices cluster, 3) *Thinc.Green*, a green manufacturing alliance, 4) the *Corridors of Opportunity* that aims to improve the lives of low-income people and their urban area, and 5) the *Entrepreneurial Accelerator* to provide risk

[30] Urban Land Institute is a non-profit research institution that engages public and private sector leaders to foster collaboration and meaningful action to create thriving, sustainable communities
[31] The Urban Land Institute. "St. Paul The Minneapolis-St. Paul Regional Business Plan," accessed March 2011
[32] Ibid.
[33] Fiscal Policy Institute, "Unionization rates by state and race/ethnicity," accessed in March 2011
[34] Federation of Tax Administrators, http://www.taxadmin.org/fta/rate/tax_stru.html, accessed March 2011
[35] St. Paul Government, "Regional Economic Development," St. Paul Government website, http://www.stpaul.gov/index.aspx?NID=4244, accessed March 2011

capital and help entrepreneurs get ideas to market. This plan is supported by the top level government officials including the Mayor of St Paul, Chris Coleman, and the Mayor of Minneapolis, R.T. Rybak, which is critical.[36] The plan involves collaboration between a number of institutions such as the Minnesota Department of Employment and Economic Development (DEED) and IFCs such as BioBusiness Alliance of Minnesota. This plan appropriately addresses many important issues such as cluster development and entrepreneurship development. However, it seems to lack private sector engagement.[37] Moreover, it has not addressed other important issues such as the achievement gap among races and the shortage of engineering and science talent. The state is still at an early stage of implementing it and progress remains to be seen.

3.5.3 Recommendations for the U.S.

First, the Unites States must adopt an integrated economic strategy focused on fostering technological innovation and rejuvenation of clusters. In terms of education, although the U.S. has the best science, engineering and managerial talent, the government needs to reform the public education system to solve inefficiency and inequality of education across communities. This includes consolidating some of the current 14,000 school districts (Porter 2008), strengthening the science and math curricula, and redesigning incentive systems to improve education quality.

In order to support clusters in gaining a larger world export share, the federal government should simplify administrative processes to lower complexity and cost of doing business in order for entrepreneurship to thrive. The federal government must be more involved in coordinating a development strategy with regional clusters at the state level, so as to ensure sufficient allocation of resources for local IFCs, information and technology sharing among various regions, and better coordination among clusters.

[36] St Paul Minnesota, "Regional Economic Development," St Paul Minnesota website, http://www.stpaul.gov/index.aspx?NID=4244, accessed May 2011
[37] No companies was mentioned in the acknowledgements section of the business plan, except for Target Corporation. Urban Land Institute, "The Minneapolis – St. Paul Regional Business Plan," Urban Land Institute website, http://minnesota.uli.org/~/media/DC/Minnesota/Minnesota%20Docs/BrookingsRegionalBusinessPlanAPRIL.ashx, accessed March 2011

3.5.4 Recommendations for Minnesota

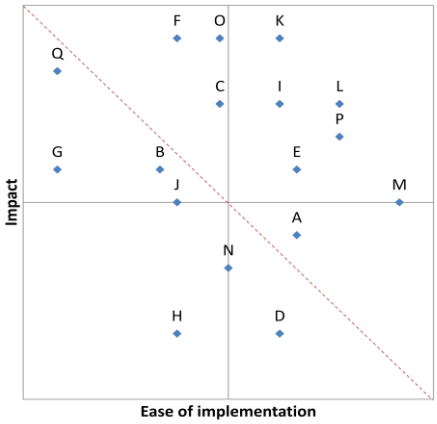
To address the challenges highlighted above, Minnesota should build a cluster-based economy driven by innovation and entrepreneurship. The specific recommendations are summarized below:

Figure 7: *Recommendations for Minnesota*

		Recommendation	Challenge being addressed	Institution	Level	Priority
Macro / SIPI	A	Increase education spending on minority students	Achievement gap	Minnesota Department of Education	State	1
	B	Improve the efficiency of primary education to maintain the quality despite of spending cuts	Co-existence of government spending cuts and inefficiency in education expenditure		State	2
DC	C	Collaborate with other states to improve public purchasing standards	Need to stimulate demand despite limited public funding	State government; DEED	State/ Region	1
	D	Offer tax incentives on new investment and R&D projects			State	2
FC	E	Provide scholarships to international science and engineering students	Limited supply of science students	State government, universities	State	1
	F	Engage clusters to tailor university curricula for cluster needs		DEED, IFCs, and universities	Cluster	1
	G	Educate MN corporations on benefits and procedures of recruiting more immigrant workers	Stagnating labor force growth and homogenous work force	Department of Labor and Industry	State	2
	H	Offer subsidized real estate and tax incentives to venture capitalists	Lower access to risk capital than other leading U.S. states	State government	State	2
	I	Leverage private capital to scale up the *Entrepreneurial Accelerator*		Minneapolis-St. Paul governments	City	1
RSI	J	Facilitate knowledge sharing between the government and IFCs	Adequate presence of IFCs but lack of coordinated efforts	DEED	State	2
	K	Local IFCs to collaborate with IFCs in other states		IFCs	Cluster	1
	L	Leading government officials to facilitate public/private dialogue more actively and engage executives in large corporations	Lack of engagement from large corporations in supporting local clusters in MN	State government officials (e.g., Governor)	State	1
	M	Roll out the Regional Cluster Initiative in other clusters	Current initiative's focus on the medical devices cluster only	DEED	State	1
CSR	N	Shorten the time needed to start a business	Lack of small business support	State government	State	1
	O	Set up small business incubators		DEED	State	2
	P	Use Thinc.Green to cultivate new entrepreneurs in green technologies across industries	Lack of entrepreneurial culture and declining firm starts	Minneapolis-St. Paul governments	State	1

	Q	Enhance collaboration between multinationals and start-ups in MN for technology sharing and co-investments	Competitive disadvantage of small companies due to barriers to expertise and technology. Domination of MN clusters by large companies	State government, companies	State	2

***Figure 8**: Prioritization*



Source: Team Analysis

The recommendations are ranked in the right hand column of **Figure 7** based on an assessment of the impact and the ease of their implementation, with the ranking assessed for each part of the diamond individually.[38] The matrix representation of these initiatives and the diagonal used to separate them into two groups for prioritization is presented in **Figure 8**.[39]

A detailed description of the recommendations is given below:

Macroeconomic and Social & Political Infrastructure *(A&B)*: Despite pressure for budget cuts, Minnesota must continue to improve the efficiency and effectiveness of education spending,[40] so as to maintain the quality of the state's primary education system. The proposed postponement of K-12 education funding would worsen the existing achievement gap, which in the long run could affect Minnesota's competitiveness in today's knowledge-based economy. Instead, the state should redirect funding towards primary education especially in communities with a high concentration of underachieving minorities. With the implementation of this education initiative in parallel with the recently proposed *Corridor of Opportunity* designed to provide better living conditions in urban areas, Minnesota can ensure a more structurally sustainable environment for its residents from all social groups.

[38] In assessing ease of implementation, three criteria were considered: degree of behavior change required, multiplicity of actors involved and whether it is an extension of the existing systems and policies. Similarly, the three criteria for impact assessment were: whether the result can build sustainable competitiveness, whether the initiative is scalable without substantial increase in public spending, and positive spill-over effects on other initiatives. Each criterion was valued as a step function from 0 to 1. A weighted average of the criteria was used to compute the final level of ease and impact. This methodology provides an illustrative grouping of these initiatives.

[39] Team analysis

[40] Itasca Project, "Minnesota's Future: Wold Class Schools, World Class Jobs," Itasca Project website, http://www.theitascaproject.com/Minnesota%27s%20Future%20-%20World%20Class%20Schools%20World%20Class%20Jobs.pdf, accessed March 2011.

Demand Conditions: (C&D) In order to maintain sophisticated demand in the context of budget cuts, Minnesota should partner with other states to enhance public purchasing standards. For example, Minnesota can leverage its current collaboration with Wisconsin to roll out the Thinc.Green initiative beyond the "Twin Cities". In addition, to further stimulate private demand, Minnesota should provide tax incentives on new investment and R&D projects.

Factor Conditions: (E,F,G) Minnesota's utmost priority should be improving its talent and innovation pool, nurturing entrepreneurship, and providing a more favorable environment for firms to compete and share resources. Achieving these objectives requires action from many different parties, including the state government, IFCs, universities and companies. In order to increase the pool of science and engineering experts, the government should coordinate with state universities to offer scholarships to students beyond the Midwest and coordinate with existing clusters to introduce curricula catering to local cluster needs. In order to sustain its knowledge based competitive advantage, Minnesota must work to attract talent, and retain it within the state. For international talent, the Department of Labor and Industry should actively reach out to local firms and provide consultation services on the legal complications of the work visa application process to attract more immigrant knowledge workers.

(H&I) To address lack of access to capital for small businesses, incentives, such as subsidized real estate and tax incentives, should be provided to attract more venture capital firms to Minnesota. With the current government sponsored *Entrepreneurial Accelerator* providing only $60m[41] of capital, private sector involvement would increase access for small businesses to capital and to specific technical expertise beyond what the state can provide.

Related and Supporting Industries: (J,K,L) State level involvement with clusters will ensure effective coordination of various IFCs and local firms for technology sharing, co-investments, and business opportunities. IFCs in Minnesota should also reach out to IFCs in neighboring states to share

[41] The Urban Land Institute. "St. Paul The Minneapolis-St. Paul Regional Business Plan," accessed March 2011.

information and foster regional cluster growth. Furthermore, with the current lack of interest from many large corporations in developing local clusters,[42] the state leadership should step in to engage executives from these corporations in cluster development and create a more favorable environment for small firms to thrive competitively.

(M) While Minnesota should continue with the current Regional Cluster Initiative, which is currently primarily focused on medical devices, the state should not favor specific clusters and dictate the success of industries based policymakers' preference. After successful implementation in the medical devices cluster, the state must replicate this initiative for other industries, starting with major traded clusters such as printing and publishing, processed food, and analytical instruments.

Context of Firm Strategy and Rivalry: ***(N&O)*** In order to encourage start-ups, the state government should further shorten the time needed to start a new business. In addition, DEED should work with organizations such as the Small Business Administration to set up more small business incubators[43] where entrepreneurs can build networks and commercialize products. **(P&Q)** *Thinc.Green* is a good lever to cultivate new businesses since green initiatives cut across many manufacturing industries. In addition, to harmonize the relationship between large and small companies, DEED should demonstrate to multinationals the benefits of a cluster which is composed of both large companies and start-ups. In order to do this, DEED should create a forum for senior executives and entrepreneurs to meet and facilitate technology sharing and licensing agreements.

4. The Global Medical Devices Industry

4.1 Overview[44]

Medical devices are a broad product category, including all instruments and apparatus used in diagnosis, prevention, monitoring and treatment of disease. The industry is characterized by innovation

[42] Former mayor, a Minnesota city, telephone interview, March 2011.
[43] There is currently only one business incubator in Minnesota, the University Enterprise Labs in St Paul
[44] All numbers in the overview are from Frost & Sullivan (2008). "U.S. Medical Devices Industry Overview," accessed March 30, 2011

and frequent introduction of new technologies. In the past 50 years breakthroughs in devices have revolutionized healthcare such as pacemakers, x-ray, mechanical heart valves, Computed Tomography (CT), Magnetic Resonance Imaging (MRI), and drug-eluding stents. Major product categories include:

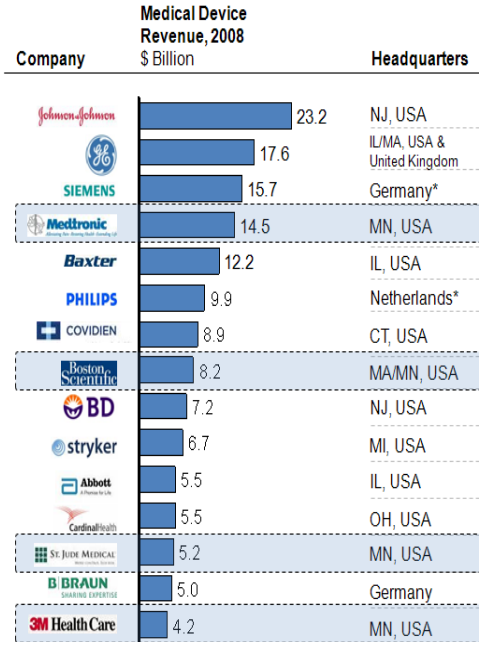
1. Large capital equipment ($500K+), such as MRIs and CTs, requiring a long sales cycle, with multiple decision-makers, often involving senior executives
2. Small/medium capital equipment (<$500K), such as IV pumps, requiring a long sales cycle followed by continuous account management for replacements
3. Therapeutic devices, such as pacemakers, drug-eluting stents and orthopedic implants, driven by high-tech innovation and therapy development catering to specialists
4. High volume commodities which are driven by cost containment, such as bandages

In 2008, total demand for medical devices worldwide was $273bn. US, Europe and Rest of the World accounted for 45% ($123bn), 30% ($82bn) and 25% ($68bn) of worldwide demand respectively. Going forward, emerging markets (especially Asia) are surfacing as the destination for expansion with 5-year expected CAGR of c.12% compared to 7% in the US (Frost & Sullivan, 2008).

4.2 Global Competitive Landscape

The global medical devices industry is relatively concentrated, with the top 15 players accounting for c. 60% of worldwide sales,[45] with US players (e.g. J&J, GE, Medtronic, Baxter, Covidien) dominating the market (**Figure 9**). Even the largest European players such as Siemens, Philips and B Braun have very sizable US operations in California, Massachusetts

***Figure 9**: Industry players worldwide*



*Siemens, Philips and B. Braun have major presence in the US in PA, MA and PA respectively.
Source: Medical Products Outsourcing Magazine, company annual reports, company websites

[45] Calculated by dividing the total medical device revenue from top-15 players by the global industry revenue

and Pennsylvania respectively. There is some degree of specialization along the 4 major product categories. For example, GE and Siemens are particularly strong in medical imaging, whereas Medtronic is strong in therapeutic devices, particularly in cardiovascular applications. However, as companies are developing capabilities in different therapeutic applications, this is leading to increasing convergence among products offerings.

4.3 US Competitive Landscape

In the US, where the top suppliers are located, activity is concentrated in 5 geographies: California, Pennsylvania, Minnesota, Massachusetts and Florida (**Figure 10**). [46] California commands the largest share of employment at 17.6%. Minnesota and Wisconsin[47] combined ranks second, at 9.8%. Minnesota also has the highest location quotient, indicating the importance of the cluster to the state. Employment growth has been positive, but low. Pennsylvania is one of the highest-growth states. However, wages are lower than national average due to lower value-add activities. Massachusetts is increasingly playing in the high-end segments, with highest average wages in 2008 and highest wage growth between 1998 and 2008.

***Figure 10**: Medical Devices Activity in the US*

Present in the MN cluster*

Rank	State	2008 Employment Thousands	2008 share of national employment	CAGR of Employment 1998-2008	2008 Average Wages	CAGR of Wages 1998-2008	Location Quotient
1	California	72.7	17.6%	1.09	$76,124	4.38	1.57
2	Pennsylvania	26.4	6.4%	4.81	$53,944	3.52	1.49
3	Minnesota	22.3	5.4%	0.51	$69,960	4.90	2.63
4	Massachusetts	21.5	5.2%	-0.06	$86,839	5.45	2.07
5	Florida	21.2	5.1%	0.93	$50,659	4.08	0.85
6	New York	20.2	4.9%	-0.15	$52,390	3.36	0.79
7	Indiana	20.1	4.9%	4.02	$55,095	2.57	2.27
8	Wisconsin	18.3	4.4%	6.34	$79,745	5.90	2.17
9	Texas	15.0	3.6%	-1.35	$54,023	5.02	0.48
10	New Jersey	14.8	3.6%	0.73	$75,176	3.55	1.2
	United States	**417,165**	**n/a**		**$61,796**	**3.93**	

Source: Professor Michael E. Porter, Cluster Mapping Project, Institute for Strategy and Competitiveness, Harvard Business School

[46] All data in this paragraph are from Figure 10

[47] Western part of WI, where the majority of medical device activity is happening, is considered as part of Minneapolis-St. Paul-St. Cloud economic area, and therefore included in the Minnesota Medical Devices Cluster.

4.4 Value Chain: medical devices industry value chain consists of 5 stages. (**Figure 11**)

R&D activity is primarily done in-house. Talented engineers and close linkages with universities and the broader life sciences industry are key for in-house product development. However, many players are increasingly pursuing inorganic growth options, which has led to the diffusion of R&D across multiple locations specialized by therapeutic area. Despite the high-tech nature of the industry, R&D accounts for only c.15% of the cost base (Frost & Sullivan, 2010), partially due to a trend of increasing M&A for technology acquisition.

***Figure 11**: Medical Devices Value Chain* *Source: Team analysis*

	R&D	Regulatory & Reimbursement Approval	Materials Supply	Manufacturing	Marketing & Sales
Key success factors	▪ Improved **efficacy** ▪ Improved **durability** ▪ **M&A** capabilities ▪ Linkages with **universities, broader life sciences cluster** and specialized **technology transfer** organizations	▪ Experience with the **regulatory process** ▪ Engagement of **payors** in the R&D process ▪ Proof of **cost effectiveness** against alternatives	▪ **Stable** supply of materials at low cost	▪ **Joint product design/ development** with contract manufacturers ▪ **Quality** control ▪ **Lean** operations ▪ **Precision machining** and increasingly the application of coatings	▪ **Relationships** with **specialists** (for therapeutics) and key **decision makers at hospitals** (for capex investments) ▪ **Geographic coverage** ▪ **Brand and credibility**
Share of cost base	15%		35%		50%

Companies must seek *regulatory and reimbursement approval* for their products, which means early engagement with relevant government and private parties is critical. Clinical trials usually take place in-house, and largely in the US. However, many firms are anticipating placing a significantly higher proportion of clinical trials outside the U.S. in the future to tap into emerging market demand and reduce cost.[48] In the US, regulatory approval takes place by the FDA at the national level. Depending on product complexity, time for product approval varies between 90 days and 6 years, with costs varying

[48] Interview with Director of Corporate Regulatory Affairs, Leading Minnesota Medical Device Company, March 2011

between $500K-$100M. [49] Typically, large-scale clinical trials are required (randomized controlled, multiple-arm clinical trials involving hundreds of patients).[50]

In contrast, in the EU, conformance is not regulated by a central body; the manufacturer is responsible for obtaining certificates from 'Notified Bodies', which are independent commercial organizations designated by Member States. Clinical trials are only sometimes required and are typically less resource-intensive (nonrandomized, single arm studies involving 50-100 patients).[51] Nonclinical data (i.e., animal testing) and 'proof of equivalence' to an already approved device is allowed. The devices get approved in 1/3 of the time and at 1/3-1/4 of the cost of US.[52] The number and therapeutic mix of recalls is similar in US and the EU (Boston Consulting Group, 2011), which suggests that the more stringent process in the US does not necessarily come with additional benefits for patient safety.

Flexibility, cost-efficiency and speed of the EU regulatory process have recently led many players to initially launch in the EU. As a result, competence in product development and launch may migrate out of the US, hurting competitiveness. In addition, due to lower resource-intensity of a product launch, start-up activity is growing faster in the EU compared to the US,[53] which might hurt the US innovation pipeline and competitiveness in the future.

Materials supply and manufacturing are becoming increasingly commoditized and taking place outside of a specific cluster. In the last 5 years, 56% of new or expanded manufacturing facilities for the major medical devices companies were outside of the US (AdvaMed, 2011).

Marketing and sales require very good relationships with specialists (for therapeutics) and key decision makers at hospitals (for capital expenditure), good geographic coverage and high brand

[49] Interview with the Senior Executive Vice President, AdvaMed, March 2011
[50] Jeremy Tinkler, "Regional Differences in Medical Device Development," Applied Clinical Trials Online, Feb 3, 2009, http://appliedclinicaltrialsonline.findpharma.com/appliedclinicaltrials/Online+Extras/Regional-Differences-in-Medical-Device-Development/ArticleStandard/Article/detail/579063?contextCategoryId=44908, accessed on March 6th, 2011
[51] Ibid
[52] Interview with the Senior Executive Vice President, AdvaMed, March 2011
[53] Interview with President & CEO, Medical Device Manufacturers Association, March 2011

recognition. These activities require large financial investments; 56% of the cost base for a product is spent on marketing & sales (Frost & Sullivan, 2010).

4.5 Trends

Going forward, the industry is facing cost, quality and service delivery pressures from multiple stakeholders. The ability of companies and clusters to respond to these trends will help to determine if they will be able to sustain their current competitive position.

First, there is increased physician and regulatory emphasis on cost-effectiveness. This implies that in physician relationships there will be lower emphasis on premium branding and more emphasis on economic evidence. On the regulatory side, capabilities in delivering strong health economics that result in launching new, high-value products will be critical. Second, there is an increasing importance of the patient as a customer. This implies that the medical devices industry needs to increase transparency of quality, outcomes, and cost. Finally, the source of competitive advantage is shifting away from a pure device play. Going forward, non-product offerings (e.g., services) will be important in differentiation. In addition, drug-device combinations are gaining importance due to their increased efficacy (e.g. drug-eluding stents), requiring pharmaceutical expertise.

5. Minnesota's Medical Devices Cluster

5.1 Cluster History and Evolution

Pioneering clinical practitioners. Back in the 1930's, Dr Owen Wangensteen, a leading surgeon at the University of Minnesota, instituted the practice of surgeons performing research.[54] This fostered a climate of innovation and a group of clinicians started developing and using sophisticated medical devices (e.g. Wangensteen Suction in 1931[55]), creating the demand for the repair of such devices.

Medtronic evolves. In response to this demand, Earl Bakken founded a repair shop for devices in

[54] University of Minnesota, "Wangensteen Historical Library," University of Minnesota website, http://hsl.lib.umn.edu/wangensteen/benefactor, accessed April 2011
[55] Ibid

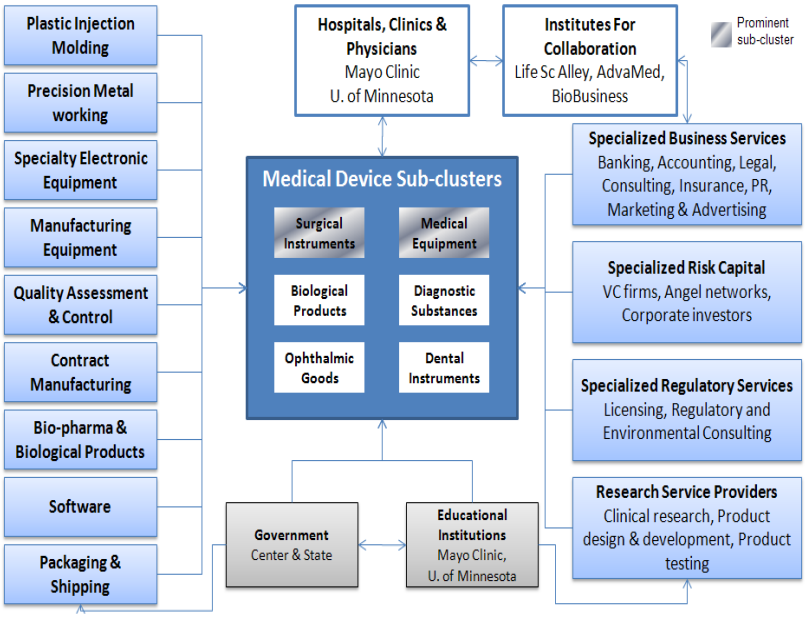
1949 and earned a reputation for quality service.[56] The University of Minnesota was becoming a leading cardiac care center with the world's first successful open heart surgery undertaken there in 1952.[57] In 1957, Dr Lillehei, who participated in this surgery, sought the invention of a pacemaker independent of the electricity mains. [58] Earl Bakken was given the task and developed a wearable battery powered cardiac pacemaker, which became the flagship product of his company, Medtronic.

The Medical Device Industry evolves. Over the next few decades, Medtronic grew significantly and a number of other companies spun off, including St Jude Medical in 1976.[59] In 1984, Medical Alley, a trade association, was founded to support the industry and in 1991 the biotechnology trade association, MNBIO, was founded.[60] In 2005, these trade associations merged to become LifeScience Alley.[61] In the last decade there have been a number of mergers, such as between Boston Scientific and Guidant.[62] A number of a Minnesota based medical device companies, including St Jude Medical, 3M and Medtronic, have gone on to become leading global players.

5.2 The Cluster Map:

The medical devices cluster has a high level of sophistication, as illustrated in the cluster map **(Figure 12)**. A wide range of industries supplying specialized products and services and

***Figure 12**: Minnesota Medical Devices Cluster Map*



Sources: Michael E. Porter, "MassMEDIC The Massachusetts Medical Device Industry Council" HBS No. 9-706-498 (Boston: Harvard Business School Publishing, 2006,) p. 12 and interviews with LifeScience Alley and Medtronic

[56] Medtronic, "Our story," Medtronic website, http://www.medtronic.com/about-medtronic/our-story/, accessed April 2011
[57] University of Minnesota, "Lillehei Institute," University of Minnesota website, http://www.med.umn.edu/lhi/about_lhi/cwl/home.html, accessed April 2011
[58] 1957 Time Capsule, "http://1957timecapsule.wordpress.com/2010/10/," accessed May 2011
[59] St Jude Medical, "History of St Jude Medical," St Jude Medical website, http://www.sjm.com/corporate/about-us/history.aspx, accessed April 2011
[60] Life Science Alley, "About Us," https://www.lifesciencealley.org/about/history.aspx, accessed April 2011
[61] Ibid
[62] Boston Scientific, "Guidant press release 2006," http://bostonscientific.mediaroom.com/index.php?s=64&item=113, accessed April 2011

the Federal and State governments play an important role. The Mayo Clinic and The University of Minnesota Hospital serve both as sophisticated customers, as well suppliers of expertise and talent. IFCs have been active in facilitating information sharing and networking. However, they have had insufficient focus on developing a coherent cluster strategy and leading its implementation. The cluster constitutes six sub-clusters. Minnesota is predominant in two of these, medical equipment and surgical instruments.

5.3 Specific Activities in the Minnesota Medical Devices Cluster

Medtronic, St Jude and 3M are all headquartered in Minnesota. While all of these companies have operations globally, in Minnesota, St Jude and Medtronic specialize in a number of cardiac related devices, such as pacemakers, defibrillators and heart stents.[63] Boston Scientific, while headquartered in Massachusetts, produces heart stents in Minnesota.[64]

5.4 Cluster Performance

Wage performance in Minnesota has historically been strong, with wages growing 61% between 1998 and 2008, compared with the national average of 50% (**Figure 13**).[65] However, in terms of employment, the cluster has grown only 5% between 1998 and 2008, compared with the national average of 11% (**Figure 14**).[66]

***Figure 13**: Medical Device Cluster wage by State*

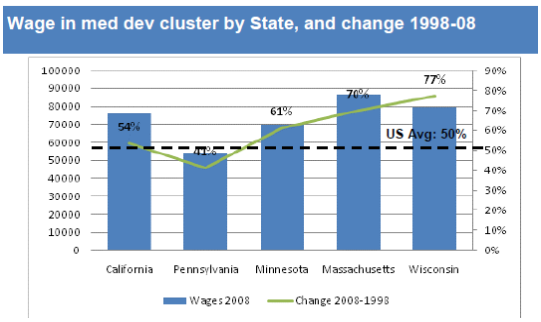
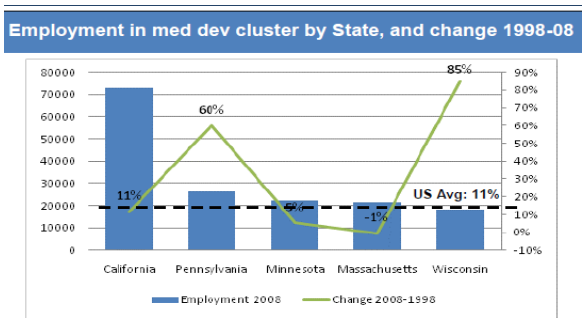


***Figure 14**: Medical Device Cluster employment by State*



Source: Institute for Strategy and Competitiveness, http://www.isc.hbs.edu/, accessed March 2011

[63] Minnesota Partnership for Biotechnology and medical Genomics, http://www.minnesotapartnership.info/upload/biotechfact.pdf, accessed April 2011
[64] Boston Scientific, "Our History", Boston Scientific website, http://www.bostonscientific.com/templatedata/imports/HTML/history/2000.html, accessed May 2011
[65] Institute for Strategy and Competitiveness, "http://www.isc.hbs.edu/," accessed March 2011
[66] Ibid

In terms of share of national employment by sub-cluster, in medical equipment Minnesota ranks 4th with 9.1%, and in surgical instruments Minnesota ranks 5th with 9.8%.[67] In addition to the concerning employment growth statistics in the overall cluster noted above, in the predominant sub-clusters, performance has also been concerning. While Minnesota's absolute level of employment in medical equipment is 7,560, which is 9.3% of the 82,692 national employment, between 1998 and 2008 it decreased 2.3%.[68] In surgical instruments it increased only 0.13%.[69] This compares particularly unfavorably with neighboring Wisconsin (**Figure 15**). Western Wisconsin, where the majority of the medical device activity is happening, is considered part of the Minneapolis-St Paul-St Cloud economic area and therefore could enhance Minnesota's competitiveness. However, it could also create challenges if Wisconsin leverages Minnesota's local strengths at Minnesota's expense.

***Figure 15**: Sub-cluster metrics*

Medical Equipment		Location Quotient	Change in national employment, 1998-2008
1	CA	1.63	2.31
2	WI	7.02	6.65
3	MN	4.39	-2.30
4	MA	3.58	-0.59

Surgical Instruments		Location Quotient	Change in national employment, 1998-2008
1	CA	1.58	0.49
2	IN	3.05	1.22
3	FL	N/A	0.75
4	PA	1.43	0.75
5	MN	2.78	0.13

Source: Institute for Strategy and Competitiveness, http://www.isc.hbs.edu/, accessed March 2011

As discussed below, cluster's loss in position stems from the lack of a holistic cluster strategy, issues in attracting talent due to the unfavorable location, cluster's limited expertise in complementary fields such as biotechnology and electronics, limited engagement from large companies, low innovation and commercialization of research, as well as some national level issues such as burdensome regulation.

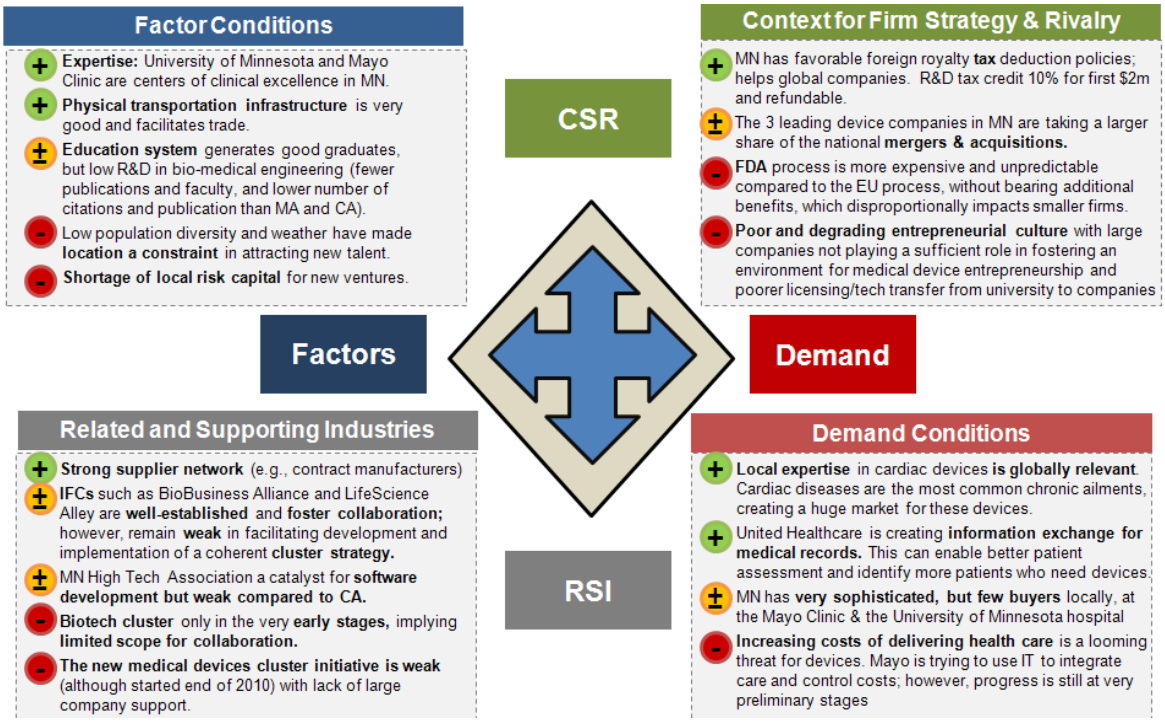
5.5 The Cluster Diamond

The Minnesota medical devices cluster has several strengths across the four facets of the Diamond (**Figure 16)**. These range from expertise available at the local academic institutions and companies (FC), favorable tax conditions for global companies (CSR), presence of institutes for collaboration and a strong supplier network (RSI) and, finally, strong local expertise that is relevant

[67] Ibid
[68] Ibid
[69] Ibid

globally and sophisticated (albeit few) consumers (DC). However, the diamond also highlights important weaknesses. Minnesota needs to develop new skills and capabilities, both around innovation of products, as well as commercialization of these innovations and an entrepreneurial environment.

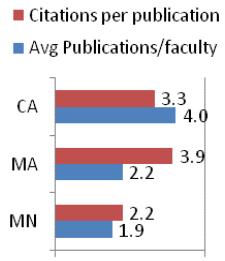
***Figure 16**: The Cluster Diamond*



Sources: Various Interviews, National Research Council (2006), MHTA "Tax and Regulatory Position Statement"

***Factor Conditions**:* The cluster draws its strength in factor conditions from the strength of the state's factor conditions. A strong physical transport infrastructure that allowed for development of clusters in the state also facilitated the movement of people and goods in the medical devices cluster. The experts in medicine and engineering at The University of Minnesota and The Mayo Clinic contributed strongly to the development of new devices. Experts in related areas (e.g., health economists) also played an important role in this development. While the state has strong schools, research in bio-medicine and bio-engineering is not as strong at the national level,[70] which has contributed to cluster's loss of position. Minnesota generates fewer publications in biomedical engineering per faculty member

***Figure 17**: Publications statistics*



Source: National Academies Press

[70] National Academies Press, "A Data-Based Assessment of Research-Doctorate Programs in the United States", National Academies Press Website, http://www.nap.edu/rdp/, accessed April 2011

and those publications get fewer citations, when compared to research undertaken in California and Massachusetts (**Figure 17**). The cluster also faces problems in attracting talent, another key reason underlying cluster's loss of position. While some challenges are common across other US clusters (e.g., immigration policies), this cluster's particular location has been commonly cited as an additional constraint. For example, harsh weather conditions and low population diversity are important factors in people's decisions to not relocate to Minnesota. Finally, lack of risk capital for new ventures has often been quoted as an impediment in Minnesota. However, it is intertwined with other factors, such as a weaker entrepreneurial culture and poorer performance of past venture investments in Minnesota.

Related and Supported Industries: There are a number of large related suppliers that provide support for this cluster. For example, local supplier Lake Region Medical is the world's largest OEM and contract manufacturer of wire formed medical devices.[71] In terms of IFCs, LifeScience Alley has supported the cluster by providing a number of services such as forums to build industry relationships, a jobs board, educational programs, discount purchasing programs and a monthly e-newsletter.[72] Recently, LifeScience Alley formed a strategic affiliation with BioBusiness Alliance, a trade association for the bioscience industry, in order to further strengthen support of both industries.

However, until recently, there has not been a sufficiently coherent approach towards cluster development, using cluster theory. A medical devices cluster board was only recently established, with the planning beginning in late 2010.[73] It is led by BioBusiness Alliance, with collaborative effort from educational and state bodies. The board is aiming to foster more formal linkages between the industry and government and academic institutions to examine how to create a better environment for new product development and to impress on the State the need for pre-emptive action to sustain this cluster.

[71] Lake Region Medical, http://www.lakergn.com/, Lake Region Medical website, accessed April 2011
[72] LifeScience Alley, "Membership benefits," https://www.lifesciencealley.org/members/member_benefits.aspx, accessed April 2011
[73] Interview with Chief Operating Officer, BioBusiness Alliance, April 2011

The cluster initiative is very much at the formative stage, with approximately 12 attendees at the meeting in February 2011.[74] So far, the plan is to meet every six weeks with the agenda being set by BioBusiness Alliance and the Council of Mayors. However, the big three companies are not involved in this initiative and leadership is coming primarily from IFC's rather than directly from the private sector.

Finally, related industries such as biotechnology and technology also pose a weakness. Minnesota's relative lack of deep expertise in related industries will be detailed in the section comparing four US clusters on page 28. This lack of depth allows for fewer opportunities to undertake collaborative work with these clusters and has contributed significantly to cluster's loss of position.

Context for Firm Strategy & Rivalry: Rivalry is characterized by a small number of very large companies and a large number of small companies. There appears to have been a trend toward consolidation, with larger companies acquiring smaller companies at a discount. Other exits for smaller companies have proved challenging. As of mid 2010, the last major IPOs were Virtual Radiologic and EnteroMedics back in 2007.[75] The three leading medical device companies in Minnesota are, in fact, also taking an increasingly larger share of national M&A.[76] While this provides an exit for smaller companies, particularly given the difficulties in other exits noted above, it also weakens rivalry, particularly in Minnesota where these companies are headquartered and have dominance.

In terms of strengths, at the state level, despite the high level of general corporation tax rates, Minnesota has a number of tax policies which are particularly favorable for global companies, including medical devices players, for example an R&D Tax Credit and a Foreign Royalty Deduction.[77] There are also a number of tax policies which aim to address the shortage of risk capital noted in the analysis of

[74] Interview with Chief Operating Officer, BioBusiness Alliance, April 2011
[75] Thomas Lee, "Minnesota's medical device cluster consolidates," Mass Device, May 2010, http://www.massdevice.com/news/minnesotas-medical-device-cluster-consolidates, accessed March 2011
[76] Mergers and Acquisitions data, Capital IQ, Inc., a division of Standard and Poor's.
[77] MHTA, "Tax and Regulatory Position Statement," Minnesota High Tech Association website, http://www.mhta.org/uploads/Taxation%20Position%20Statement.pdf?PHPSESSID=783791dfa28d048e639691c5b664d2f9, accessed March 2011

factor conditions, such as the Angel Tax Credit introduced in 2010.[78] However, at the national level, a significant area of disadvantage is the expensive and unpredictable FDA process without necessarily an increase in efficacy, as detailed in Section 4 above. This is a major risk for the industry in Minnesota and in the US as a whole. At the state level, an area of concern is the conservative approach of University of Minnesota in sharing rights during the commercialization of research, which could lead to reduced incentives for researchers and hinder private sector engagement.[79]

Demand Conditions: Demand conditions for medical devices in Minnesota are strong. The University of Minnesota Hospital and The Mayo Clinic are highly sophisticated local customers. However, this sophisticated demand is concentrated only in these two hospitals. Nevertheless, the cluster's expertise in cardiac devices is globally relevant. Cardiovascular disease will continue to be the leading chronic diseases in developed and developing countries across the world (Yach et al., 2004). As income levels in developing countries rise, new markets for cardiac devices are opening up globally.

Increasing costs of delivering health care is a looming threat for devices. There is strong pressure on policy makers to lower reimbursements and on regulators to be critical of non-frugal innovations. Minnesota is starting to develop expertise to address this challenge. For example, UnitedHealth Group is developing capabilities in sharing medical data across providers, which could lead to reduced healthcare delivery costs. This, in turn, will ease the cost-driven pressure on medical devices manufacturers. However, such initiatives are new and are only in the formative stage.

5.6 Comparative Analysis of the Medical Devices Clusters in the US

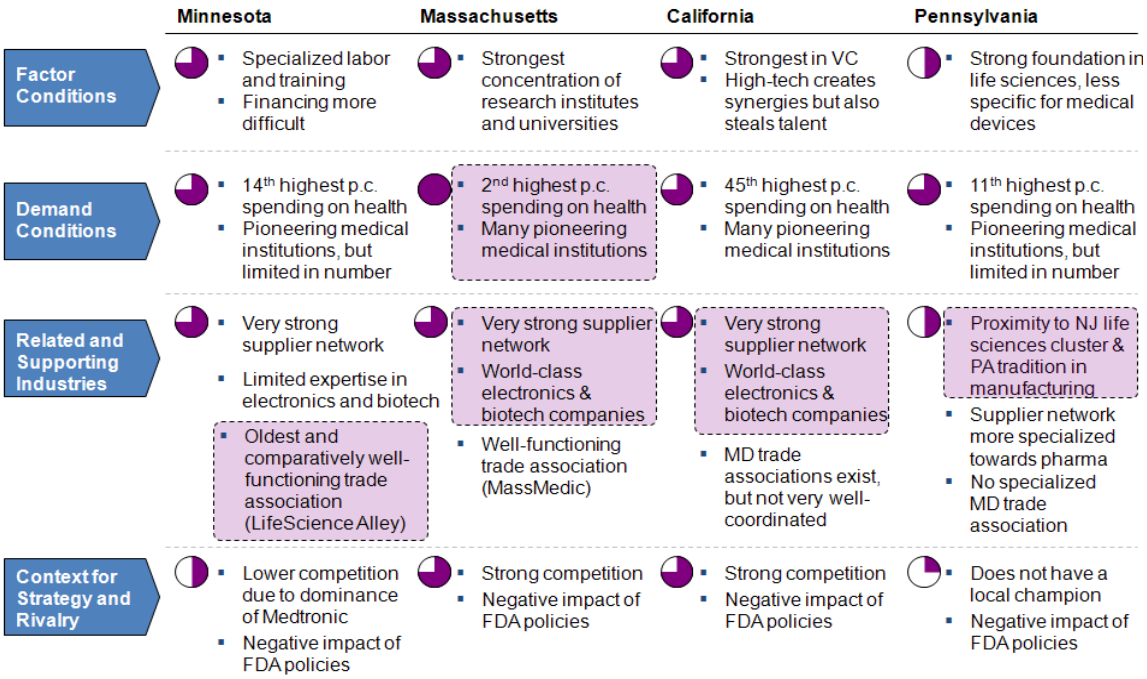
Four clusters have dominated the medical devices industry in the US. **Figure 18** on page 28 shows an in depth analysis of the strengths and weaknesses from the perspective of the diamond framework. Massachusetts and California have a clear advantage in RSI, with a combination of strong

[78] Ibid
[79] Interview with Medical Devices Professor, University of Minnesota, April 2011

supplier networks and presence of world class electronics and biotechnology companies. While Minnesota has a strong legacy, it has been unable to build comparable strengths in electronics and biotechnology.

Massachusetts also has a distinct advantage in demand conditions, with the 2nd highest per capita spending on healthcare in the country and a multitude of pioneering medical institutions.[80]

***Figure 18**: Comparison of major US medical device clusters*



Source: Team Analysis and health spending numbers from Centers for Medicare and Medicaid Services, http://www.cms.hhs.gov/NationalHealthExpendData/downloads/res-us.pdf, accessed on March 10, 2011

5.7 Recommendations for the Minnesota Medical Devices Cluster

The analysis above highlights the strengths and weaknesses of the Minnesota medical device cluster through the diamond framework and explains the reasons behind the cluster's historical success and subsequent loss of position. In order to meet the challenges posed by the weaknesses, and build on the strengths, we propose several recommendations, a summary of which is set out in **Figure 18** below.

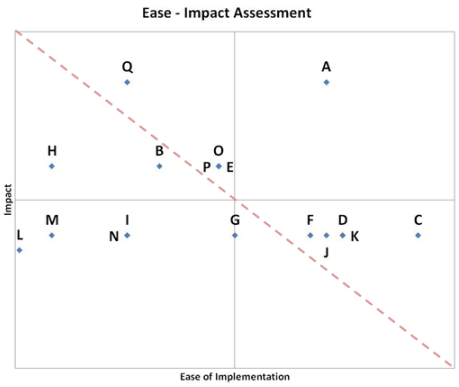
[80] Centers for Medicare and Medicaid Services, http://www.cms.hhs.gov/NationalHealthExpendData/downloads/res-us.pdf, accessed March 2011

***Figure 18**: Cluster Recommendations*

		Recommendation	Challenge being addressed	Institutions Responsible	Level	Rank
DC	A	Devices to integrate health delivery	Increasing cost of healthcare delivery in the US	LifeScience Alley, Mayo Clinic, UoM hospital, UoM	Cluster	1
	B	Collaborative research for frugal innovation			Cluster	2
FC	C	Funded positions for research	Inability to attract talent	LifeScience Alley, UoM, large med device cos.	Cluster	1
	D	Increase internships / placement programs		UoM, LifeScience Alley, med devices cos.	Cluster	1
	E	Research parks for co-location		State government	State	1
	F	Tax breaks for risk captial	Insufficient sources of local risk capital	State government	State	1
	G	Study start-up process challenges		LifeScience Alley, DEED[81]	Cluster	2
RSI	H	Attract bio-tech subsidiaries	Related clusters in technology and bio-technology are weaker than MA/CA	State Government, LifeScience Alley, DEED	State	2
	I	Collaboration across IFCs		LifeScience Alley, Biobusiness Alliance, Minnesota Hi-Tech Association, State government	State	2
	J	Cross-disciplinary PhD programs		LifeScience Alley, Mayo Clinic, UoM hospital, UoM	Cluster	1
CSR	K	Support small firms on regulations	FDA process is expensive and time consuming	LifeScience Alley, State Government	Cluster	1
	L	Champion FDA reform		LifeScience Alley, Biobusiness Alliance, AdvaMed, State government	National	2
	M	Encourage large companies to support start-ups	Poor entrepreneurial culture	State Government, LifeScience Alley, DEED	State	2
	N	Share more IP rights with innovators		State Government, LifeScience Alley, UoM, DEED	State	2
Cluster Initiative	O	Include customers and suppliers	Recently launched initiative is in early formative stage	State Government, Biobusiness Alliance, Large Medical Device Cos.	State	1
	P	Private sector leadership			State	1
	Q	Focused management of new initiative			State	1

[81] Department of Employment and Economic Development

***Figure 19**: Prioritization*



Source: Team analysis

The recommendations are ranked in the right hand column based on an assessment of their impact and the ease of their implementation.[82] The matrix representation of these initiatives and the diagonal used to separate them into two groups for prioritization is presented in **Figure 19.**[83] A detailed description of the recommendations is set out below:

Demand Conditions (A&B): By working with, and leveraging, the Mayo Clinic and the University of Minnesota Hospital, medical devices companies have the opportunity to develop networked devices to integrate health delivery across continuum of care as a way of reducing costs dramatically. This could provide a new growth engine for the cluster and turn the threat of rising healthcare costs into an advantage. The rising cost of healthcare also creates an imperative to conduct collaborative research with partners outside the US to develop frugal innovation skills. This can be achieved by providing fellowships to foreign researchers and creating exchange programs for Minnesota based staff to work outside the US.

Factor Conditions (C,D,E): The problem of attracting talent can be addressed by encouraging large companies to create funded positions at The Mayo Clinic and The University of Minnesota for bio-medical engineering experts, which they will benefit from in the long term. By bringing in some 'star academics', it may be possible to create a virtuous cycle of attracting even more talent. In addition, internship and placement programs between private companies and The University of Minnesota, will contribute to solving the problem. The state government should also develop research parks that provide infrastructure to facilitate co-location of medical devices, pharmaceutical and bio-tech experts, thus enabling cross-fertilization and attracting talent. **(F&G)** To tackle the problem of insufficient risk

[82] In assessing ease, four criteria were considered: the level at which implementation happens (i.e. cluster, state, or national), degree of behavior change required, multiplicity of actors involved and whether it is an extension of the existing system. Similarly, the four criteria for impact assessment were: whether the impact is on the industry or just the cluster, whether the result is an innovation (product) or factors that are expected to yield products, potential for the initiative to be replicated elsewhere and the positive spill-over effects on other initiatives. Each criterion was valued as a step function from 0 to 1. A weighted average of the criteria was used to compute the final level of ease and impact. This methodology provides an illustrative grouping of these initiatives.

[83] Team analysis

capital, the state government should introduce tax breaks for risk capital invested by local VC firms and commission a study to identify process challenges in investing in medical devices start-ups.

Related and Supporting Industries (H-J): There are opportunities to improve the possibilities for collaboration between the medical devices cluster and related clusters, for example in the development of drug delivery devices, by strengthening the related clusters. The IFC's and state government should engage existing biotech companies to set up subsidiaries in Minnesota and there should be co-ordination across all relevant IFCs to support such collaboration. Academic institutions should develop cross disciplinary PhD programs to ensure an adequate supply of talent going forward.

Context of Firm Strategy and Rivalry (**K&L**): The problems with the FDA process need to be addressed at the national level and the national IFCs, such as AdvaMed, should coordinate clusters to champion the reform of the FDA process to be more streamlined. However, local IFCs should provide technical support for smaller firms trying to navigate the regulatory process. (**M&N**) To help improve the poor entrepreneurial culture, the IFCs should find thought leaders in larger companies to support small company development and demonstrate benefits of this approach on reducing development risk and increasing the acquisition pipeline. To incentivize entrepreneurship, The University of Minnesota should also take a more liberal attitude towards innovation by sharing more of IP rights and structuring creative deals with the industry via licensing and selling during commercialization.

New cluster initiative: (O-Q) In order to significantly improve the chances of success, the new cluster initiative should actively include customers and suppliers to prevent reinforcement of status quo and the tendency to wish to seek subsidies and limit competition. BioBusiness Alliance should ensure that the initiative is properly led by the private sector in order to reduce political content. Smaller companies are already involved. However, large companies need to be engaged and their opinion leaders should be approached to join the leadership of the initiative.

Bibliography

AdvaMed (2010), "The AdvaMed Industrial Competitiveness Survey," Internal research access through Senior Executive Vice President of Advamed
Bearfacts, Bureau of Economic Analysis, accessed March 2011

Bewer, Tim (2004), "Moon Handbooks Minnesota (First ed.)," Avalon Travel Publishing

Bureau of Labor Statistics, "Employment status of the civilian noninstitutional population, 1976 to 2010 annual averages," BLS website, http://www.bls.gov/lau/staadata.txt, accessed March 2011

Bureau of Labor Statistics, "National unemployment Rate,", BLS website, http://data.bls.gov/timeseries/LNS14000000, accessed March 2011

Capital Markets Director, Leading Minnesota based insurance provider, interview by Team, Boston, MA, March 2011

Chief Operating Officer, BioBusiness Alliance, telephone interview by Team, April 2011

CIA Factbook, "United States," https://www.cia.gov/library/publications/the-world-factbook/geos/us.html, accessed March 2011

Davis, S., Gilbertson, E. and Goodall, S. (2010), Boston Consulting Group, "EU Medical Device Approval Safety Assessment: A comparative analysis of medical device recalls 2005-2009"
Director Corporate Investing, Leading Minnesota Medical Device Company, telephone interview by Team, March 2011

Director of Business Development, Minnesota State Department, telephone interview by Team, April 2011

Director of Corporate Regulatory Affairs, Leading Minnesota Medical Device Company, telephone interview by Team, March 2011

Director Strategy and Corporate Development, Leading Minnesota Medical Devices Company, telephone interview by Team, March 2011

Director, LifeScience Alley, telephone interview by Team, February 2011

Director, Minnesota governmental organization, telephone interview by Team, March 2011

Division Chairman, Mayo Foundation, telephone interview by Team, April 2011

Economist Intelligence Unit, Budget deficit as % of GDP, www. eiu.com, accessed March 2011

Economist Intelligence Unit, GDP Growth, www.eiu.com, accessed March 2011

Economist Intelligence Unit, Public debt as % of GDP, www. eiu.com, accessed March 2011

Economist Intelligence Unit, R&D as a share of GNP, www.eiu.com, accessed March 2011

Economist Intelligence Unit, Total Factor Productivity Growth, www.eiu.com, accessed March 2011

Education, U.S. Census Bureau, http://censtats.census.gov/cgi-bin/cbpnaic/cbpsel.pl, accessed March 2011

Executive Director, The Bakken Museum, telephone interview by Team, February 2011

Former Business Development and R&D engineer, Leading Minnesota Medical Device Company, interview by Team, Boston, MA, March 2011

Former Mayor, District of Minnesota, telephone interview by Team, March 2011

Frost & Sullivan (2008). "U.S. Medical Devices Industry Overview," accessed March 30, 2011

Frost & Sullivan (2010). "An Overview of Medical Device Supply Chain and Trends in Europe," accessed March 31, 2011

Interview with Health Policy and Payment Director, Leading Minnesota Medical Device Company, March 2011

Investor Relations, Leading Minnesota Medical Device Company, telephone interview by Team, March 2011

ISC, "U.S. Cluster Mapping Project," ISC website, http://www.isc.hbs.edu/, accessed March 2011

Itasca Project, "Minnesota's Future: Wold Class Schools, World Class Jobs," Itasca Project website, http://www.theitascaproject.com/Minnesota%27s%20Future%20-%20World%20Class%20Schools%20World%20Class%20Jobs.pdf, accessed March 2011.

Medical Devices Professor, University of Minnesota, telephone interview by Team, April 2011

Merchandise Manager, Leading Minnesota based Retail Company, interview by Team, Boston, MA, March 2011

Microeconomics of Competitiveness Professor, University of Minnesota, telephone interview by Team, March 2011

Minnesota Management & Budget, "Forecast Document," Minnesota Management & Budget website, http://www.mmb.state.mn.us/doc/fu/11/complete-feb11.pdf, accesssed March 2011

Population, U.S. Census Bureau, http://censtats.census.gov/cgi-bin/cbpnaic/cbpsel.pl, accessed March 2011

Porter, M. E. (2011), "Michael Porter at the National Governors Association Winter Meeting 2011," ISC website, http://www.isc.hbs.edu/stateprofiles.htm, accessed March 2011

Porter, M.E. (2008), “On Competition”, Harvard Business School Publishing Corporation, Boston, MA

President & CEO, Medical Device Manufacturers Association, telephone interview by Team, March 2011

Principal, Minnesota based private equity firm, telephone interview by Team, March 2011

Private wage, U.S. Census Bureau, http://censtats.census.gov/cgi-bin/cbpnaic/cbpsel.pl, accessed March 2011

Senior Executive Vice President, AdvaMed, telephone interview by Team, March 2011

St. Paul Government, “Regional Economic Development,” St. Paul Government website, http://www.stpaul.gov/index.aspx?NID=4244, acessed March 2011

U.S. Census Bureau, “Population who are High School Graduates or Higher, map by state”, U.S. Census Bureau website, http://factfinder.census.gov/servlet/ACSSAFFPeople?_submenuId=people_5&_sse=on, accessed March 2011

Urban Land Insitute. “The Minneapolis – St. Paul Regional Business Plan,” Urban Land Institute website, http://minnesota.uli.org/~/media/DC/Minnesota/Minnesota%20Docs/BrookingsRegionalBusinessPlanAPRIL.ashx, accessed March 2011

Yach, D., Hawkes, C., Gould, L., & Hofman, K. (2004), “The Global Burden of Chronic Diseases,” Journal of the American Medical Association (JAMA), 291(21):2616-2622