White Paper

The President's 21st Century Interdisciplinary Conference on Medical Devices

Leading the Change for Breakthroughs in Health Through Medical Device Advancements

University of Minnesota
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Introduction

The President's 21st Century Interdisciplinary Conference on Medical Devices was held on April 15, 2005 at the Radisson Hotel Metrodome in Minneapolis, Minnesota. As part of the Design of Medical Devices Conference sponsored by the Biomedical Engineering Institute at the University of Minnesota, the day-long President's conference highlighted policy issues integral to bringing academia, industry, and government together to create partnerships to promote breakthroughs in medical devices and advance Minnesota as a leader in biotechnology initiatives.

This white paper provides a summary of the key opportunities and challenges presented by a panel of speakers representing the interests of government, industry, and academia in the state of Minnesota. The paper is divided into three main sections. The first two sections highlight key issues facing Minnesota in creating partnerships among industry, academia, and government to become a national and global leader in medical device technology. The third section describes an initiative currently underway in Minnesota to encourage and support innovative biobusiness in Minnesota -- an initiative that both highlights ways for collaborative partnerships and that illustrates the strong commitment already in place in Minnesota for these partnerships to take shape and thrive.

Section I. Leading Change Through Creative Partnerships With the State of Minnesota on Behalf of Medical Device Breakthroughs

To distinguish Minnesota as a leader in medical devices, a panel of government and health care administrative representatives highlighted Minnesota's strength as home to nationally recognized health care institutions and medical industrial giants that provides fertile ground for cross pollination between private and public partnerships in the biosciences. Panel members included:

- **Robert Bruininks**, President, University of Minnesota
- **Frank B. Cerra**, Chair, Senior Vice President, Academic Health Center, University of Minnesota
- **Norm Colman**, U.S. Senator, State of Minnesota
- **Tim Mahoney**, Minnesota House of Representatives
- **Timothy Mulcahy**, Vice President for Research, University of Minnesota
- **Kenneth H. Keller**, Professor, Hubert H. Humphrey Institute, University of Minnesota

Opening remarks by Robert Bruininks, President of the University of Minnesota, focused on the commitment by the University of Minnesota to foster strong partnerships with industry and to the medical device industry in particular. Commenting on last year's inaugural conference he said that it had generated a great deal of dialogue that was carried over to the Governor's taskforce on the biosciences, which in turn has had a profound impact on the University's thinking and planning for the future. One of the ideas coming out of this is to build a medical device center, which is a top priority for the Institute of Technology and will be a top priority for the entire university.

"Leading the change for breakthroughs in health through medical device advancements, the theme of this conference, I think is a very exciting commitment to the future. And a very exciting challenge for all of us to think about. It's a call to action."

Additional opening comments by Frank Cerra, Chair, Senior Vice President, Academic Health Center, University of Minnesota also emphasized the creative partnerships needed to promote breakthroughs in medical devices.

"What is described as the continuum of getting an idea to market, in my view, is really a series of partnerships where skills and roles come together to move something toward the market."

The partnerships also define the people, materials, and processes that are necessary for success. Conceptually, an idea begins to get traction in the university. Professional faculty then develop the idea funded by grants or contracts, and intellectual property is protected. Business minds become connected, provide needed financing, and finally there is sufficient value for a company to form or become interested. The next critical success factor is the creation of an inviting business environment and hopefully a new Fortune 500 company is born from the state of Minnesota.

"This pathway illustrates the need for workforce, an environment of innovation, multiple partnerships between people, public and private entities, and the need for policies that promote the movement of technology to the market. This theme of partnerships across and within public and private sectors is really the theme of what this panel is about this morning."

View from Government

Leading off the panel discussion, Norm Coleman, U.S. Senator, State of Minnesota, lauded the University of Minnesota for its vision in promoting strategies that will help position Minnesota economically in the future.

"This institution has a vision, and it is a vision that understands the importance of strategic positioning. It's a vision that understands the importance of leadership. It's a vision that understands the importance of partnership. It's a vision that understands the importance of excellence. And I think it's a great vision, and we do ourselves a disservice as a state if we don't fully support that vision because our future is tied. And it's not low-wage jobs that's going to fuel this economy. It's going to be innovation, it's going to be entrepreneurship, and we are at the

cutting-edge of that."

Along with the leadership by the University of Minnesota, Coleman emphasized the strong medical industrial base that puts Minnesota in a unique position to lead in the biosciences.

"When you add up 3M and Boston Scientific and Guidant and Medtronic and 800 other medical companies, you have a concentration of economic power in the state of $5 million. It's really pretty awesome. What we can't do is we can't rest on our laurels."

Colman emphasized the need for a shared vision to succeed, and the need for business, academia, and government to work together despite their differences.
"We need government officials to understand the needs of research and the demands of business. We need academic professionals to understand the government's need for accountability and business' need for measurable results. And we need business people to have the vision to invest in the research and the patience to relate to the government bureaucracy."

Representative Tim Mahoney from St. Paul acknowledged that the state of Minnesota has tried to create a partnership with the University of Minnesota and the business community to advance bioscience industry, but stressed that the state could do more.

"We have made attempts at trying to get start-up capital access to small companies, and we end up with a tax break for small companies. Small biotech startups generally don't make money for the first number of years. So you don't need a tax break. You need access to capital investment."

He emphasized the need for more qualified and experienced managers and researchers, middle-level managers that can take the scientist's idea and turn it into a profit, and help from the state to move things forward.

"If we are to grow our state, if we are to make this state as great as it possibly can be, it's much better to have a $60,000 job than a $30,000 job. The bioindustry is the industry that is bringing lots of high-paid jobs to whomever is willing to take the risk to invest, to learn, and to move forward."

View from Academia

Using the highly organized structure and efficiency of the nervous system as a metaphor for how networks operate, Tim Mulcahy, Vice President for Research at the University of Minnesota, emphasized the academic and research strength of the University of Minnesota that make it a strong partner with industry in advancing medical device technology.

"One of the things about the University of Minnesota is over its history, it has accumulated an incredibly strong collection of neurons with strong action potential. . .I like to think of the University as a set of neurons in the network which impact upon the very active, high-potential neurons, our faculty, staff, and students."

To tap on this potential of the University to become a creative partner with industry, however,

several factors that dampen innovation need to be recognized and addressed. First is the lack of awareness on the part of faculty, staff, and students on the importance of transferring intellectual property. Second is a tendency to think that it is not appropriate for a public research university to think of commercialization. Mulcahy stressed the need to better educate both faculty and the entire academic community that it is part of the mission of a land-grant institution to translate knowledge to application where appropriate.

"I think as an institution, an enlightened institution, we need to recognize that it is in fact our role and our imperative, where it's appropriate, to transfer what we generate in the line of new knowledge to application to benefit the quality of life."

A third factor inhibiting innovation is the lack of a reward system for applied research. Currently, academic rewards and value systems do not adequately recognize those contributions. Another factor is that scientists are not business oriented and have not been trained to develop a business plan and market their ideas. The newly developed Office of Business Development at the University of Minnesota is designed to help scientists develop a business plan, market their idea, and connect with investors.

Overall, Mulcahy highlighted the University's need to improve communication with corporate partners, the business community, and with state and local governments.

Ken Keller, Professor at the Hubert H. Humphrey Institute, University of Minnesota, highlighted factors that are creating the opportunity to grow and advance in the biosciences. Citing the greatest change in knowledge as currently coming from the biological sciences (molecular biology, cellular biology, and materials science), he stressed that medical technology is being pushed by a confluence of nanotechnology (an element of materials science) and information technology. In addition, the needs of society and industry are pulling for devices that are both reliable as well as affordable and accessible.

"We need devices and technologies that empower patients. We're already moving in directions of that sort. All of those represent the factors that make it important for us to be working together and added to that are the new dynamics of research and development. "

"The dynamics of how we develop those research and development systems and interact between the university and the society are the challenges that we face in developing these partnerships in the right way."

In describing how partnerships should work, Keller focused on some of the problems encountered by the regulatory demands of the federal government that make in difficult to move technologies into use. One problem is the lack of good feedback systems in post-market surveillance that are required to provide needed information to move a product through the regulatory system. Because of this, Keller emphasized the need to figure out ways to make the system more flexible to get devices out into use and, at the federal level, through the regulatory system. Another problem at the federal level is difficulty in obtaining federal funding from places such as the National Institutes of Health and the National Science Foundation, which traditionally base their funding support on

projects related to disease processes, not on exploratory research necessary for advancement of medical devices.

One solution to these restrictions is to try to gain more state funding, which allows for more flexibility than at the national level. "What can we do as a state that's cleverer in building these connections between industry and the University and making sure that the University has the flexibility to do work in one place or another so that it achieves the balance that isn't always possible to achieve at the national level."

"In other words, the state partnerships ought to look at the inertia that we're trying to change at the national level, but see whether or not in the moments of that inertia we can do something in the state which is cleverer and faster to substitute and isn't necessarily just spending that much more money."

Keller also emphasized the need to strengthen the University as a whole while striving to create its leadership capacity in the medical device arena. "Every university that's really been doing good work in this and other areas starts from fundamental strength. It builds on the fundamental strength, and it focuses from the fundamental strength."

"For example, the whole revolution in biotechnology makes sense in the state of Minnesota if we focus its application on what it can do for the medical device industry or what it can do for agriculture, the two things in which we have a very significant advantage. We are not competing with Silicon Valley. We're not competing with people who do just general genomics. We're dealing with ways in which we can adapt our research in the biotechnology area to things that we're particularly strong on. And here, combination devices, tissue engineering, hybrid organs, the things that you've been talking about are the things that make sense here. But that gets built on a base of strength in engineering, in materials, in basic biological sciences. And that's the challenge that we face in the state, is having people understand that balance that has to take place."

Other challenges include the need for physical locations that can bring people physically together in collaborative work. "I look to the Basic Sciences and Biomedical Engineering building with fond hopes for the future that we really can put things together there or elsewhere. We understand its importance in translational research, and I'm very enthusiastic about the great advances that are being made there. But it's equally important to physically put people together in a facility where there is this cross-fertilization. Where engineers understand what the problems are in medicine by being part of it. Where physicians understand the sophistication that's necessary to do good work in engineering."

Section II. Leading Change With Industry to Enhance Research and Development and Engage the Next Generation of Health Professionals in the Development and Use of New Medical Devices

Developing creative partnerships between academia and industry is vital in positioning Minnesota as a leader in the development of and use of new medical devices. In this section, leaders from industry and academia discussed some of the opportunities and challenges in working together to

accomplish this goal. The panelists included:

•**Richard W. Bianco**, Chair, Assistant Vice President for Regulatory Affairs, Office of the Vice President for Research, University of Minnesota
•**Jeffrey McCullough,** Director of Biomedical Engineering Institute, University of Minnesota
•**Jagjit Gill**, Vice President of Marketing and Business Development, Advanced Bionics/Boston Scientific
•**Scott Augustine**, CEO, Augustine Biomedical Design

Richard Bianco, Chair, Assistant Vice President for Regulatory Affairs, Office of the Vice President for Research, University of Minnesota introduced the session by discussing some of the barriers that need to be addressed for industry and academia to work successfully together.

"There remain barriers to change, and these have to be addressed before real progress can be made. And I've listed them in order. Intellectual property, intellectual property, intellectual property, publication, confidentiality, academic progress. Now academic progress and dealings with industry can be mutually exclusive, and it's a real problem."

In terms of intellectual property, research contributions by University faculty must result in some income to the University of Minnesota. For publication, it is a part of the mission of a land-grant institution to publish its research. In terms of confidentiality, there are many ways to protect proprietary information -- to protect the information prior to patent application. For academic progress, there must be an internal system within universities and recognition in the academic world that promotes academic progress through such things as invention disclosures, patent applications, and industry and grants and contracts. Currently, no academic credit is available for this, and faculty are not allowed to devote any time to these activities while working toward tenure. These issues need to be discussed more openly and more frankly than they have been.

Academic perspective

Jeffrey McCullough, Director of the Biomedical Engineering Institute at the University of Minnesota provided a perspective from academia on how to foster and strengthen the interaction and collaboration with industry. He emphasized the importance of first recognizing the fundamentally different major objectives and products between these two organizations. In academia, the products are the development of new knowledge and the production of educated graduates. The products of industry, on the other hand, are things like devices, software, or test results.

"As these two kinds of organizations look at how they can productively work together and find synergies, you have to start with this understanding that these are very different kinds of organizations with very different major objectives. And they have very different products."

Another important thing to recognize is the difference in how each of these organizations define success. In academia, publishing is critical to success as a way to share new knowledge with the broad scientific and medical community, of obtaining grant funding and support for research, and

particularly, for obtaining federal funding from the National Institutes of Health (NIH) and National Science Foundation (NSF). It also is the way that faculty acquire national or international status, and allows people to become a leader in their field, to be on the cutting-edge of generating new ideas, of bringing in new research grants, and in participating in the establishment of federal and public policy related to their field.

Publishing, therefore, is the primary way to achieve success in academia. However, in the last few years, one of the things that has slowly made its way onto most of the annual faculty evaluations forms is whether or not the faculty member has obtained any patents in the previous year. But this is considered only a small and secondary activity for faculty in terms of academic success. Receiving grants for industry-sponsored work is considered very low on the list of achievements in academia, whereas federal grants for research tops the list. For example, when universities or particularly medical schools are ranked around the United States, one of the major, if not the major factor that goes into that ranking, is the amount of federal funding that one obtains. If a university wants to move from number 27 to number 19, you have to find a way to generate another 20, 30, or 50 million dollars a year in federal funding.

For industry, success is defined presumably be obtaining patents, generating new intellectual property, and developing innovations in existing or new products. All of these activities are geared toward the ultimate goal of increasing revenue to support the financial strength of the company and to satisfy stockholders.

Such fundamentally different kinds of activities between academia and industry highlight why it is sometimes difficult for these two organization to work together in a collaborative manner. There are ways, however, to accomplish this.

"There are many wonderful opportunities to collaborate and we can do great things together. [But] It’s not always easy."

Traditionally, academia and industry have worked together by each being responsible for certain activities. For example, take the development of hard devices. Most of the up front work begins in academia. The work begins in a basic research lab, which for the most part is likely to occur within academia rather than within industry. Following that, some work would be done to establish a proof of principle, which again is probably more likely to occur in academia. This in turn would lead to small animal studies, which can be done in industry, but is more commonly done at universities. At that point, there might be a need for modifying the methods that were developed in the basic research laboratory to try to determine how to carry this process forward. The methods modification and methods development might occur in collaboration with industry or it might occur in an academic center. Then one may need to develop a prototype device, which can be done in collaboration between the two organizations. A subsequent step might involve larger animal studies. Some companies in industry may have the wherewithal to carry out studies in pigs or dogs or primates, but for the most part probably not. So either industry is going to contract with a primate center or this kind of work is going to be done at the university.

When the maturation of a product gets to this point, it is time to scale up. At this point, what is

needed is fundamentally different than the way the original basic scientist may have worked with the product. A fundamentally different kind of device is needed to scale up and begin to validate and initiate manufacturing. Phase 1, 2, and 3 trials then are needed, which are primarily suited for academia because of the access to patients. Of course, industry is involved in structuring studies and helping to design the protocols, but a different kind of organization is needed to carry out clinical trials. Industry plays a primary role when it comes to regulatory submission and applying for licensure.

What is needed are ways to make this collaborative partnership between academia and industry easier and more effective. From the academic point of view, there are several reasons to improve collaboration with industry. First, any sort of external funding carries indirect costs with it, and these funds are an attractive part for central administration. Second, depending on what the particular project involves, industry collaboration may support the purchase of new instruments or the establishment of new methods. It may provide a critical mass for implementing new methods and procedures. Third, for existing projects, collaboration with industry can help universities leverage their costs for active research activities by helping faculty members to be more efficient by making their research activities less expensive to carry out.

Finally, critical to encouraging more creative partnership with industry, academia must find ways to publish the results of this work that will lead to success and increased stature within the academic setting. However, a number of disadvantages may impede this type of research and collaboration. Collaboration with industry usually involves a very targeted, very specific kind of project. Many faculty members are not responsive to this because these types of projects do not enhance their ability to get tenure and to succeed within the medical school. These kinds of projects may also divert the faculty member from their basic research interests, from higher-priority projects, and from their ability to apply and obtain NSF or NIH funding. Also, these types of projects do not contribute to the university rankings, so, for example, something like a one million dollar research contract from industry does not move the medical school from a ranking of #27 to a ranking of #18.

Another issue is the role of students in industry-sponsored research. Once financial constraints come into play and possible limitations on how things can be published, this begins to put in place potential constraints on how students can function. Students need to be able to pursue knowledge where the research takes them, and they need to disseminate the knowledge and the results of their work.

Industry Perspective

Jagjit Gill, Vice President of Marketing and Business Development, Advanced Bionics/Boston Scientific, spoke about the technologies that have achieved financial and clinical success at Boston Scientific and the integral role played by collaboration with academia in achieving these successes.

Historically, Boston Scientific has been involved with interventional medicine, catheter-based technologies for endoscopy, oncology, and neurology. Up to 90% of the business revenue is cardiovascular-based, with most of the intellectual property, research and development, marketing,

and manufacturing occurring at the Minnesota-based cardiovascular headquarters. Over the last year and a half, Boston Scientific has expanded its investments in interventional medicine and acute care of chronic disease. With this expansion, a number of challenges have arisen.

To meet the challenges of developing and investing in a new technology, Boston Scientific first asks four basic questions: 1) Is there an unmet clinical need and can we prove it?, 2) will the technology address it?, 3) can we develop clinical data vis-à-vis a controlled, randomized study so that the customers will believe the data? Is it compelling enough to them?, and 4) what is the size of the market and what is our ability to recognize it?

The need to collaborate with academia is underscored by the importance Boston Scientific places on understanding the science behind the technologies they develop and invest in.

"One way we address the challenges is to understand the basic tenant of why we want to get involved in this space. And one of the basic tenants is the science. The playbook for us has always been to focus on intervention, focus on therapies and clinical indication. And I cannot stress this enough. We are not clinically agnostic. We need to understand more and more the science, the mechanism of action, because I cannot say this more clearly. All the therapies, all the devices that we have developed and sent out to the market, those that have enjoyed the greatest clinical and commercial success have a very clean, clear, well-articulated scientific-mechanism action. And that was, for the most part, developed in a university setting."

Providing another view from industry of the importance of working closely with academia, Scott Augustine, CEO, Augustine Biomedical Design discussed the need for working with the strengths of industry and academia to achieve the ultimate goal of improving the health care of patients.

"We have to build defined solutions to the problems, first of all, and then obviously we need to be able to get that solution out to the patients. Academic scientists or practicing doctors or other healthcare people frequently have ideas and may even have solutions to problems, but they can’t get the solution to the patient. Industry is really good at development and dissemination of ideas, but it’s really poor at coming up with the actual solution."

To truly develop creative partnerships between industry and academia to advance medical devices, a number of realities need to be addressed. First, although medicine promotes the image that it is using only cutting edge 21st century technologies, in reality most of the technologies were developed and remain largely unchanged from 50 years ago. This creates a huge potential for innovation and development. Second, the reason that more fundamental innovations are not coming out may have to do with doctor's remarkable acceptance of tradition, which is rooted in medical education that relies largely on memorizing and suppresses creativity. In addition, medical education fosters a sort of secret society that encourages physicians to share only amongst themselves and not be open to change. Getting rid of this traditional view of the world would allow for more acceptance of new devices and technologies. Third, innovation in medical devices rely on an understanding of the disease process and an understanding of anatomy and physiology. Therefore, unlike pharmaceutical products that can be developed in industry, the ideas for devices need to start in academia - with doctors, scientists, and other clinicians. But because physicians

tend to operate within a secret society, they are not inclined to work with other disciplines, like engineers, to create new devices. They also are not inclined to create devices on their own in part because they are too close to the problem, which tends to make it more difficult to come up with solutions.

"If we're going to come up with fundamentally new things, it has to be starting with the clinicians and then go to the companies as a second thing."

Industry therefore needs the academic side to move forward in developing new medical devices. Academia, on the other hand, needs industry to take an idea and run with it.

" John Arnold of MIT some years ago said,' Few ideas are in and of themselves practical. It's for want of imagination in applying them rather than acquiring them that they fail. The creative process does not end with the idea, it only starts with the idea.' "

The point of developing and commercializing ideas needs to be given more credit on the academic side, and the industrial side needs to give more credit to the academic side for what it has contributed.

A number of things are important to developing a creative partnership between academia and industry. First, it has to be truly a partnering relationship. Both sides need to win or neither side will win.

"At least in the 20 years or so that I've been in business, almost every deal that has actually worked out are the ones that work out where both sides win. And when these deals win, they win so big that there's plenty for everybody."

It's important to remember that everything in this world happens because of motivated individuals. Institutions do not get things done, companies do not get things done, but a few key individuals get things done. From the academic side, developers, scientists, and clinicians should not be prevented from pushing his or her product forward. From the industrial side, it is important to get industry on board to help push a product forward. "When the pushers stop pushing, everything just stops moving. It is almost always a few key people that change the world."

"As an inventor, or a scientist, you need to appreciate the value added by the company and the financial risk that they're taking."

Academics need to recognize as well that innovation, and specifically patents, do have academic merit. As previously discussed, faculty performance at most academic institutions is assessed by publishing, research, and clinical work, but not by patents obtained. The universities need to reassess their position on academic worthiness of patents. Also, academia needs to celebrate the faculty members who have good ideas and celebrate when they decide to leave to pursue them, rather than characterizing them as traitors or pariahs. Faculty members ought to be encouraged to come back and keep working part-time at the institution, even if it is as a volunteer. Universities

should try to get some stock in their company.

"Back to our original goal. We're trying to cure diseases and help patients. And if that's what it's about, we have to have the solutions and we have to be able to get those solutions to the patient. The solutions come from institutions like this and the people in them, and the getting them there comes from the various companies that are out there. It's only useful to the patient, though, if it gets to the patient. So anybody that has a great idea and they don't move with it should get zero credit for that idea. You either take it and you do something with it or it's not worthy of getting credit, in my opinion. Therefore, I urge all of you that have ideas to move on them and to do something there. "

Section III. Leading Change with the BioBusiness Alliance of Minnesota to Ensure the State Remains Leader in the Medical Device Industry

Panelists included:
•**Dale Wahlstrom**, Chair, Vice President, Medtronic
•**Tim Laske**, Senior Director of Platform Technologies, CRM, Medtronic
•**Timothy Mulcahy**, Vice President for Research, University of Minnesota
•**Jeremy Lenz**, Project Executive, BioBusiness Alliance of Minnesota

The commitment to advancing Minnesota as a leader in medical device technology can be illustrated by the creation of the BioBusiness Alliance of Minnesota. Dale Wahlstrom, Chair, Vice President, Medtronic provided an overview of the alliance.

"The Biobusiness Alliance of Minnesota is an industry-led organization of concerned citizens representing Minnesota companies, universities, and government devoted to positioning Minnesota as a global leader in biobusiness."

Created in 2004, the organization's focus on biobusiness refers to all economic activity devoted to the development and commercialization of bioscience (knowledge based on the life sciences, especially emerging molecular and cellular biology) or bioscience-related technologies, products, or services. Biobusiness covers the spectrum of enterprises from start-ups to established firms, together with associated infrastructure and support services.

Formed by private citizens who believe in the power of Minnesota, the organization is committed to action - to act as a catalyst to bring the great resources of Minnesota together to achieve a better outcome for the citizens of Minnesota, to lead efforts to establish focus and a vision of the future, and to help businesses fulfill this shared vision. The Alliance is not meant as a replacement for industrial organizations currently representing Minnesota companies, for the Department of Employment and Economic Development (DEED), or for any other economic development entity or governance body.

"We're private citizens who believe in the power of the state and are committed to action."

The overall vision of the Alliance is to build and solidify Minnesota into one of the strongest

bioscience centers of the world, the outcome of which will be the creation of a welcoming and rich environment for incumbent and emerging investors in bioscience businesses that will result in economic growth and retention and creation of high value jobs for Minnesotans.

The charter of the Alliance is comprised of three components:

1. Identify and benchmark the strengths and weaknesses of Minnesota's private, public, and academic assets needed to attain the vision
2. Build an action-based alliance that creates a vision and a strategy for implementation that brings together all sectors in a coordinated effort to ensure the long-term health and success of Minnesota's bioscience industry
3. Establish an organization that will function as an advocate for emerging and established biosciences business.

Organizational Structure: One Stop Shop

The BioBusiness Alliance of Minnesota is considered a "One Stop Shop" organization meant to provide a centralized place for people interested in biobusiness initiatives to get contact information on key players in academia, industry, and local government. It covers three main domains of technology -- human health (the focus in this paper), food/agriculture, and energy/industrial -- and is composed of eight strategic component committees.

Academics
Provides assistance on research resources, expertise, work force, professional development, and education.
Finance and tax
Provides help in understanding how Minnesota is positioned competitively with the rest of the world, and determining long-term financing.
Infrastructure
Provides assessment and understanding of infrastructure issues in Minnesota, such as roads, electricity, or networks for distribution of information.
Informational technology
(Focus under development)
Legal
Provides assistance in examining legal-related issues.
Regulatory
Provides help on issues in the state law and regulatory policies that create a negative competitive environment.
DEED
Provide a partnership with the Department of Employment and Economic Development (DEED) to help focus their activities with the activities of the Alliance.
Legislative/Education of the Public
Provides an annual update that will be distributed to the legislature detailing and prioritizing the needs of all the different constituents, as well as educate the public on the needs for long-term

investment in biobusiness.

The "One Stop Shop" is a real organization currently housed under Medical Alley. By the end of 2005, it is expected to staff five to six employees that will include technical leaders, program managers, and medical directors. The staff will work closely with companies and academic centers, have access to industry and strategic team experts, and will focus on making investment in Minnesota easier and faster.

Overview of the Academic Strategic Sub-Team

Timothy Mulcahy, Vice President for Research, University of Minnesota provided an overview of the current structure and status of the academic strategic sub-team charter. The scope of this subcharter includes several goals: 1) ensure that the State's academic research is capable of supporting the economic growth objectives of the Minnesota, 2) advance state-wide efforts to align public and private university/post-secondary systems to ensure academic curriculum is adequate to meet work force needs, 3) advance efforts to integrate biosciences into K-12 educational systems, 4) support continuing education and professional development for incumbent workers making transitions into the biosciences, and 5) provide consulting support for the Bio-Biz One Stop Shop.

"The Biobusiness Alliance is trying to create a very effective network that will actually connect with a whole series of other networks out there. We want to make it easy for someone who's approaching the state of Minnesota with interests in locating here or interests in expanding their business here or developing new business here. We want to make the connections easy for them."

During the first year of a three-year plan, the sub-team is focused on establishing functional domains or work groups that includes research resources (e.g., facilities, clinical trials), expertise (e.g., consultants, faculty and business experts), work force (e.g., students, internships), professional development (e.g., staff opportunities, training programs), and education (e.g., bioscience curriculum, teacher workshops).

The goal is to work with a range of educational sectors from private technical schools to private colleges and universities, to the University of Minnesota and Mayo Clinic, to K-12 education in establishing these functional domains. Ultimately, emphasized Mulcahy, the subcharter's aim is to develop "a concrete set of recommendations that can be shared with the educational institutions, the state, our corporate partners, and the universities to try to convince them to move in the direction that will facilitate development."

Human Health Domain: Medical Devices

Tim Laske, Senior Director of Platform Technologies, CRM, Medtronic spoke on the current status of the work done by the subcommittee on the human health domain of the Alliance, which is focused on the first aim of the charter -- to identify and benchmark Minnesota's strengths in human health.

Minnesota's Strengths in Human Health

Minnesota has a long history of leadership in human health. Along with the internationally recognized clinical care, education, and research coming out of the Mayo Clinic and the University of Minnesota, over 500 biomedical engineering companies, including 3M, Boston Scientific, Guidant, St. Jude Medical, and Medtronic, reside in this state. This combination of talents makes Minnesota particularly strong in medical devices, along with other areas such as bioinformatics, medical imaging, and biologic agents.

"Where is Minnesota strong? Ideally, we'll leverage our strengths and not try to become something we're not. It would be very difficult to compete with the East Coast and basic biologic components and manufacture of proteins."

With the new biologics changing the practice of medicine in Minnesota as well as globally, Minnesota needs a plan on how to tap into these strengths to remain and grow as a leader in these areas. In the area of medical devices, this means a decreased focus on the current emphasis on therapy-related devices to an increased focus on diagnostics related to bioinformatics, proteomics, genomics, and monitoring.

"In devices, there's diagnostics, therapeutics, and monitoring, and healthcare delivery would include providers, imaging, and patient management systems. To be successful here, we need a broad cross-section of minds thinking about this problem."

Currently, Minnesota does not have a clear future plan on how to do this. The Human Health Committee within the Alliance proposes a number of goals to help Minnesota retain and grow in its strengths:

•Improve state and global healthcare
•Retain and enhance existing firms
•Attract new firms to Minnesota
•Focus in-State education that is globally competitive (K-12, university, continuing education)
•Succeed through local and global partnering

"We like to think of this as the Biobusiness Alliance of Minnesota and for Minnesota, but it's a partnership for around the world. So you can think of it hopefully in the future as the Biobusiness Alliance of Planet Earth."

Statewide BioBusiness Assessment

With 40 states and 61 countries worldwide making biosciences a top economic development priority, Minnesota will need to focus on its current strengths and identify new ones to compete. Jeremy Lenz, Project Executive, BioBusiness Alliance of Minnesota discussed the state-wide assessment currently underway to provide a baseline assessment of biobusiness in Minnesota against which the state may be benchmarked.

"We have an opportunity to reinforce our strengths, but then also to define new ones. And that's exactly what we want to do with this assessment."

A further goal is to provide thoughtful well-researched recommendations to help make the state highly competitive in targeted areas of biobusiness. Identifying which technologies, products, and markets are strong in Minnesota will help market the state to potential companies.

"As we go through this process and identify these companies, we think that Minnesota's opportunities are going to lie in the overlapping areas in particular. Think of biofuels, medical devices, and drug coatings. From today's standpoint, this is where Minnesota is excelling."

Summary

As home to nationally recognized health care institutions and medical industrial giants, Minnesota provides fertile ground for cross pollination between private and public partnerships in the biosciences. Along with firmly established institutions and organizations in Minnesota, the time is ripe for initiatives in medical device technology because of the great changes occurring in the biological sciences. To be competitive, Minnesota needs to develop creative partnerships between industry, academia, and the government and address a number of barriers to change interfering with the development of these partnerships. The BioBusiness Alliance of Minnesota, an organization developed in 2004 to encourage and foster investment in biobusiness in Minnesota, illustrates the strong commitment already in place for Minnesota to grow as a leader in the biosciences and in the medical device industry in particular.