Executive Summary

from

Strategy Report

for

Saginaw Future Inc.

Medical Device and Technology Initiative

prepared by:

The Washington Advisory Group an LECG company

January 24, 2006

Executive Summary

The Washington Advisory Group project team for the Saginaw Future Inc. Medical Device and Technology Initiative makes the following core recommendations:

Recommendation #1: For broad economic development outcomes, the Medical Device and Technology Initiative needs to be regional, not local, in scope.

Finding: Saginaw, Midland and Bay counties do not possess the necessary critical mass as individual entities to develop a Biomedical Device Industry Corridor (BDIC). Each county has complementary strengths: Saginaw is a clinical hub and center of precision manufacturing, and Midland is home to Dow Chemical and Dow Corning, two world leaders in advanced materials. But the entire region lacks entrepreneurs who are experienced and familiar with medical device formulas and models of success. To attract these individuals and expand beyond a small base of companies, the region needs to aggregate and combine resources that are relevant to the formation of a Biomedical Devices Industry Cluster (BDIC). This effort should also involve key institutions in neighboring counties and leading organizations throughout the State.

Resources Needed: Saginaw Future Inc. (SFI), which commissioned The Washington Advisory Group to research and produce this strategy report, should convene a Mid-Michigan Biomedical Device Coalition and Steering Committee with Midland Tomorrow and other economic development organizations in the region. The Steering Committee should be a joint and regional body and have overall responsibility for implementing the core recommendations.

Recommendation #2: To develop a Biomedical Device Industry Cluster (BDIC), the region should pursue three parallel "thrust" areas: Contract Manufacturing, Corporate Spin-Outs, and "Greenfield" Companies.

Thrust Area #1: Contract Manufacturing

Contract manufacturing is the business of manufacturing products that another company owns and brings to market. To attract new business in the contract manufacturing of medical devices, the Saginaw region should:

- leverage the region's skilled labor force and precision engineering and manufacturing capabilities
- tap the expertise of Dow Corning "alumni" with medical device experience
- maximize the use of existing Dow Chemical, Dow Corning and Delphi-Saginaw Steering facilities
- take advantage of the low total cost of doing business in mid-Michigan in the rapidly-growing sector of reprocessed single-use devices
- cultivate long-term relationships with industry leaders in sectors related to the region's manufacturing know-how in metals and silicones, and to clinical areas where local specialists have personal contacts (e.g., neurosurgery and cardiovascular medicine).

Thrust Area #2: Corporate Spin-Outs

The research and technologies of Dow Chemical, Dow Corning, and Delphi-Saginaw Steering are potentially as valuable to the region as one or more Tier I research universities. To mine this resource for economic development, the region should engage corporate leadership at the highest level and:

- develop solutions with state support to manage risk and shield the major corporations from liability
- create institutional structures for corporate spin-outs, e.g. technology profiling, like a technology transfer office at a university
- emphasize "pull" by entrepreneurs and venture capitalists rather than "push" by the corporations
- enable the corporations to participate in the high value that small medical device companies create

Thrust Area #3: "Greenfield" Companies

New companies and products that address unmet clinical needs generate the highest value in the medical device industry. To diversify the regional economy, the region should establish a program to support new company creation and foster interaction between local clinicians, investors, entrepreneurs, and technology/manufacturing companies. This "greenfield" program would include:

- a Mid-Michigan Medical Device Incubator (includes a rapid prototyping and design capability); this will require a \$10 million investment in staff and programs to support all three thrust areas
- \$20 million in matching funds for venture investments in new companies that originate in or move to the Tri-Cities
- curriculum and technology collaborations with Michigan's leading research universities
- marketing, FDA compliance, and reimbursement support

Resources Needed: The three recommended thrust areas are "stretch" recommendations designed to help the Tri-Cities area develop a fully-fledged BDIC. Each thrust area strengthens the other; to be successful, the thrusts need to be implemented in parallel. Significant funding will be required to implement these recommendations. To obtain the needed funding, the regional Steering Committee should commission and submit a proposal to the State of Michigan 21st Century Jobs Fund for medical device economic development on behalf of the Tri-Cities region. Based on our fact-finding, The Washington Advisory Group believes that the state would realize a significant return-on-investment by implementing these recommendations to create a Biomedical Device Industry Cluster in Mid-Michigan.

Recommendation #3: Support existing companies with marketing, technical and business development services for medical device contract manufacturing.

Finding: Saginaw County and the Tri-Cities region are home to a discernible base of companies that manufacture medical devices. It is estimated that these companies currently employ nearly 500 people and generate approximately \$75 million in annual revenues. **Providing marketing, technical and business support to these companies and to other companies that seek to enter the medical device field is the most cost-effective near-term strategy for regional job creation.**

Resources Needed: The Washington Advisory Group project team recommends that Saginaw Future Inc. (SFI) and its partners recruit three to four full-time experts or consultant equivalents to help local companies attract customers and/or re-engineer their manufacturing capabilities to compete effectively in the medical device field. The experts would have skills and provide extension services in the following key areas:

- marketing and business development (industry understanding and awareness of the opportunity, including potential customers)
- medical device technologies and manufacturing processes (strong product background and practical manufacturing experience)
- regulatory compliance (understanding of FDA requirements)
- cost analysis (ability to develop financial models for sales pitches)

The Washington Advisory Group project team believes that a \$1.5 million investment in these resources is the minimum that is needed to support existing companies. To catalyze this effort, the project team recommends that the region look closely at the Delphi-Saginaw Steering tools for computer-aided design and manufacturing linked to master product files. Adapted for FDA compliance, this technology could become a market differentiator for medical device companies in the region. The recommended investment could also provide cost-sharing leverage in a 21st Century Jobs Fund proposal. If the 21st Century Job Fund proposal is not submitted or is unsuccessful, it can provide a more limited but valuable strategy for regional job creation based on the contract manufacturing "thrust."