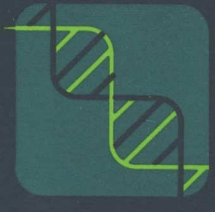
CANADIAN MEDICAL DEVICES SECTOR INITIATIVE

February 1991

Medical Devices Sector Initiative Business Climate Analysis



Industry, Science and Technology Canada
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Medical Devices Sector Initiative Business Climate Analysis

Health Care Products Division
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EXECUTIVE SUMMARY

Rather than trying to cover the entire gambit of issues normally contained in a business climate analysis, the Consultants have been asked to focus this report on four aspects only, namely: 1) Capital/Investment Accessibility/Availability; 2) Human Resources Accessibility/Availability; 3) Domestic Market Penetration; and 4) Regulatory. Other issues normally assessed in such a study are being covered by other researchers. Each component of this report is presented as a stand-alone study and may be read as such.

The observations contained in this report are primarily derived from a sample of representatives from industry sectors, associations and hospitals. Consequently, they do not necessarily reflect the attitudes and experiences of all the individuals involved in the industry. They are supported by information gathered in literature and by industry members with whom some of the findings were discussed.

Capital/Investment Availability/Accessibility

This section of the study is divided into four areas: analysis of the investment community participation; analysis of existing venture capital and investment programs; analysis of the potential for a medical device fund; and analysis of existing potential tax credit incentives.

Companies, and their financing requirements, fall into three main stages of growth and development. These stages are: the research stage; the start-up, or early development stage; and the substantial sales, or self-financing stage. Adequate funding seems to be available for the research stage and the self-financing stage. However, there is a definite void in funding sources for the early development stage. This report deals with all stages of financing, but the emphasis is placed on the need for start-up companies.

Major sources of funding are found in Canadian pension funds. Steps are presented to direct a small percentage of these funds into early stage development companies in target industries.

This report reviews the following funding programs: Quebec Stock Savings Plan; limited partnerships; private offering memoranda; stock exchanges; the Federal Business Development Bank; joint ventures; the Saskatchewan Community Bonds; the Western Diversification Program; provincial and federal tax-credit programs; investment networking; and general investor satisfaction. The report also reviews the following: MDS Health Ventures; the Immigrant Investor Program; and the Idea Corporation. Programs reviewed in the U.S. and Europe were mainly related to job creation and land and building incentives.

The study reveals that there is lack of true venture capital in Canada and that there is a real need to create capital pools that invest in opportunities with higher

risk. Companies in general, and especially in the medical devices industry, should also look to the U.S. and Europe for sources of capital.

There is a real need for a capital fund, or a number of funds, that could make available an amount of $250 million to stimulate growth in the medical devices industry in Canada. This study looks at potential criteria for investment as well as ways and means to create this pool of capital.

Comments from medical devices industry players indicate that tax incentives are strongly requested. This is especially true in the case of companies which have not yet developed sales and would like to pass off their losses to investors. The main structure discussed in the study is the flow-through mechanism.

Options brought out in this study are varied and numerous. They include the following: seminars and workshops; emerging technology trade fairs; international exchange programs; plant, sites and industrial parks program; the establishment of foreign representatives and a foreign representative assistance program; business development programs; and a networking newsletter and database.

In terms of venture capital, options presented include: special educational and promotional materials; venture capital case studies; venture capital seminars and workshops; funding preparation programs; and investigation of the venture capital communities in Canada, U.S. and Europe.

Additional concepts regarding the medical devices industry have been developed during the course of this study. They include: seed capital for the establishment of risk capital funds; a science and technology advisory board; financial and management advisory board; an investment and joint venture network; insured bond programs; and government-provided land and buildings.

Even though tax incentives may not be favourably looked upon by the Ministry of Finance at this time, options have been included in this study, including: the effects of tax credits on the funding of medical device companies; establishment of a tax-free or lower tax enterprise zones; key personnel tax reduction program; flow-through share mechanism; provincial tax credit programs; and job creation incentive programs.

Human Resources Availability and Accessibility

The objective of this section of the study was to determine what can be done to improve the availability and accessibility of personnel educated and trained in skilled positions for the Canadian medical devices industry.

Generally speaking, large companies are able to take care of their human resource requirements internally or have little trouble fulfilling these needs from the local or domestic work force. In several instances, companies interviewed

for this study were either down-sizing or not expanding their work force due to cost constraint characteristics present in the industry today.

Small- to medium-sized companies, on the other hand, are experiencing difficulties locating and attracting skilled/experienced personnel in the following areas: 1) senior manufacturing, process development and operations personnel; 2) personnel to conduct or supervise clinical research; 3) development personnel, i.e. applied R&D - those who understand the relationship between research, prototype development and marketing and to set up the entire infrastructure for the business; 4) general management, sales and international marketing expertise, especially U.S.; and 5) some requirements for scientists and engineers.

It is commonly agreed within the industry that management training is badly needed in the vast majority of companies, which tend to be small and entrepreneurial in nature. People starting up a business for the first time in this industry usually come from a technical background and have little or no business experience or know-how.

It was commonly felt that many of the generic management training courses are sufficient in content and scope to meet most needs of the medical device industry. However, the biggest problem is the cost.

When speaking with investors, the three most important requirements a company seeking financing must fulfill are: 1) management; 2) management; and 3) management. In most cases, when an investor is approached by an entrepreneur, the proposed venture is focussed on a product-driven rather than market-driven concept. However, without a market, there is no business. This is true for virtually all industries, and the medical devices industry is a prime example.

As the Canadian medical devices industry is so small, there is a very small base of skilled personnel from which to choose. It lacks the critical mass to attract the necessary human resources to facilitate its growth into a large thriving industry.

Local institutions of higher education often provide training in the generic skills required for management personnel in the medical devices industry. Once the individual commences employment with a company, he is trained in-house for any additional specific skills he requires.

Any Canadian medical device company of any size considering taking its products to the U.S., requires experienced people with a strong selling background in the U.S. environment.

The major barrier to importing human resources to Canada is the cost. In order the meet the American remuneration industry standards, the Canadian company would have to pay an American from one and one half to twice the salary of his Canadian counterpart, depending on the position being filled. If an employer

decides to import requisite personnel he must prove to his local Employment and Immigration Canada office that there are no Canadians here to fill the job. The employer must show that he has made considerable efforts to recruit a Canadian. Depending on the position which the employer is trying to fill, this may not be difficult, yet expensive.

The co-op student program is an individual relationship between a company and the college or university which the student is attending. The co-op student alternates between four months of study and four months of internship working in a company. Even though there was a positive response to the possible use of co-op students in the industry, consolidation and down-sizing trends within the larger medical device companies may make it difficult for co-op students to be gainfully employed within the industry at this time.

The co-op program works out well for short term or special assignments. There are about 85 educational institutions across Canada participating in co-op programs within the industry.

Interchange Canada is a federal government exchange program overseen by the Public Service Commission of Canada, established to exchange federal public servants with: provincial governments; universities; the private sector; and non-profit organizations, including associations. Interchange placements only take place with senior management.

Some suggested alternatives for management training programs are home study and video conferences on specific topics. These conferences could last two hours, two times per week.

The first, and perhaps the most important option put forth in this report, is to establish a Medical Devices Industry Human Resource Centre. All further options could operate under this Centre, be carried out independent of the Centre, or be conducted by outside consultants.

The mandate of the Centre would be to develop and maintain human resource self-sufficiency in the Canadian medical devices industry. The initial responsibility of the Centre would be to identify the explicate immediate,short-, medium- and long-term human resource requirements of the Canadian medical devices industry. Having accomplished this, the Centre would act as a liaison between the industry and a variety of training institutions and programs to ensure that training requirements are met, e.g. seminars/workshops, co-op student programs, exchange programs, MEDEC Round Table groups.

Domestic Market Penetration

The medical devices industry is in its infancy in Canada today. While it has grown considerably over the last decade and this pattern is likely to continue through to the next century, an opportunity exists for accelerated growth. The industry can also play a key role for Canada in terms of employment

opportunities, improved health care, investment opportunities and a substantial contribution to the Canadian economy. For these goals to be realized, however, steps must be take today to implement programs which can alter the course of events which have historically taken place. A dramatic improvement in the number and the success of device manufacturers in penetrating the domestic market can only happen if new ways of doing business are undertaken.

This study reviews some of the experiences of device manufacturers and their hospital customers alike, to identify some opportunities and threats, thereby enabling the industry to attain greater levels of achievement. Several viable options for ISTC and other organizations to consider are discussed in this report. These include the development of a "Selection Guideline Booklet" which lists criteria and a process for eventuating products.

An education program for manufacturers, encompassing a wide range of topics, will better prepare companies to successfully launch new products and capture a significant market share. A sourcing book that specifically identifies Canadian products can eventually lead to a customer's guide that provides hospitals with detailed information about products and companies, thereby reducing the effort and time currently invested by hospitals in selecting a product. Other options explored are centralized product reviews, partnerships between hospitals and manufacturers, and a "First Placement Program," where sample products are provided to users at no cost, thereby enabling initial market research and trials.

Regulatory

For Canada to develop a larger medical devices industry, it must promote the expansion of existing companies, and the establishment of new companies which can take advantage of niches in the marketplace.

Medical devices are subject to stringent safety and efficacy regulations worldwide. While there is a trend towards harmonization of requirements internationally, differences have not, and will not completely disappear between countries and trading blocks. Furthermore, even with some degree of harmonization, total regulatory demands are increasing in Canada, U.S., the EC and Japan. Growing environmental concerns such as disposability of used devices will only increase regulatory requirements.

Small companies are especially burdened in meeting these regulatory requirements. Therefore, to find approaches that can improve the access of Canadian manufacturers to information and assistance in navigating the regulatory process, regulatory climates, problems and programs of assistance have been analyzed in this report for Canada, the U.S., the EC and Japan.

Findings indicate a favorable regulatory climate in Canada, with relatively minor programs for further assistance needed.

The U.S., in spite of a more adversarial environment between government and industry, has a good program of assistance to companies. Suggestions have been made to help Canadian companies take greater advantage of this assistance.

The EC is in a state of regulatory change. While the outcome, sometime after 1993, should lead to easier access to the large European market, the current confusing situation is likely to continue for some time.

Finally, while regulations in Japan are fairly straightforward, non-regulatory barriers are a fact of life, not likely to change any time soon. Suggestions for meeting this reality are presented in this report.

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1.0 Capital/Investment Accessibility/Availability

ABBREVIATIONS

B.C.	British Columbia
CAFCE	Canadian Association for Cooperative Education
CDRH	Center for Devices and Radiologic Health
CEIP	Canadian Exploration Incentive Program
CEO	Chief Executive Officer
CIDA	Canadian International Development Agency
DSMA	Division of Small Manufacturers Assistance
EIC	Employment and Immigration Canada
EDC	Economic Development Corporation
EX	Executive
FBDX	Federal Business Development Bank
FDA	Food and Drug Administration
GMP	Good Manufacturing Practice Regulations
HPB	Health Protection Branch
IIP	Immigrant Investor Program
ITC	Investment Tax Credit
ISTC	Industry Science and Technology Canada
LCDS	Laboratory Centre for Disease Control
MBA	Masters in Business Administration
MEDEC	Medical Devices, Canada
NSERC	Natural Science and Engineering Research Council
OSDP	Ontario Skills Development Program
OSMA	Office of Small Manufacturers Assistance
PMA	Pre-market Application
PSC	Public Service Commission of Canada
R&D	Research and Development
SM	Senior Management
TIMEC	Technology Institute for Medical Devices for Canada

1.0 CAPITAL/INVESTMENT AVAILABILITY/ACCESSIBILITY

1.1 INTRODUCTION

The medical devices industry in Canada is an industry that is dominated by large multinational corporations. While this is not a concern in itself, Canada must develop a network of entrepreneurially-based companies if the country hopes to reverse the negative trade balance in the medical devices industry.

In the area of capital availability and accessibility, it is the smaller entrepreneurial companies that are at a stage of development where there is a void in funding sources. There is support for the research phase of development and for companies that have developed significant sales but little for developing companies and technologies.

All companies in the medical devices industry at all stages of development should be supported as much as possible for the industry to grow. But the medical devices industry needs to have a sustainable approach to growth and for the sake of balance in developing the industry, the emphasis in accessing funding should be placed on companies at an earlier stage of development.

1.2 OBJECTIVE

The objective of this study is to identify the degree of availability and accessibility of capital and investment for the medical devices industry in Canada. Sufficient funding is one of the essential components required to change the negative trade balance that reflects the performance history of this industry in Canada. The emphasis, based on the greatest need, will be placed on the development and improvement of the accessibility of risk capital.

1.3 SCOPE/DESCRIPTION

This study focusses on the funding of the companies that form the medical devices industry in Canada, but extends its investigation to the area of stimulating the development of risk or venture capital in Canada, U.S. and Europe.

The options presented are generally in seed form and in most cases will require further study and analysis for their proper implementation.

1.4 METHODOLOGY

The methodology employed for this study on the availability and accessibility of capital and investment for medical device companies in Canada included interviews with 52 individuals that represent a cross-section of the medical, business and financial communities. An interview questionnaire was developed to identify specific information sought under each section of the study. The interview questionnaire is attached in Appendix A. These findings, opinions and options are also based on the review of literature reviews, articles and reports.

The fundamental criteria used for selecting the medical companies, investment groups and generally related support groups was to create a balanced approach to the development through proper financing of the medical devices industry. The report endeavoured to review the opinions on a wide cross-section of these areas that affect the accessibility and availability of capital and investment for medical device companies in Canada.

1.5 ANALYSIS AND FINDINGS

1.5.1 ANALYSIS OF INVESTMENT COMMUNITY PARTICIPATION

1.5.1.1 GENERAL DISCUSSION

There is a general feeling and experience in the medical devices industry that there is insufficient funding allocated to the area of start-up or early stage companies. There is support for research through government grants and University programs. Although more could be done in the area of research funding, the greatest problems in funding for medical device companies seems to arise in the start-up, early stage phase. Companies with manufacturing and substantial sales are usually fundable through the existing investment channels. Start-up companies should be financially supported as long as there is significant growth and progress even if projections or milestones are not completely achieved. This does not mean that larger companies and multinationals should not be encouraged to expand and to initiate research, development and manufacturing in Canada.

Long-term financing is crucial for the development of successful companies and a successful industry. Investors, unfortunately, look for short-term returns on investment and to a large extent this industry should be regarded over the long-term. Americans are more likely to take risks in investments and look for the long-term whereas Canadians

are less likely to venture into risk areas or longer term investments. This indicates that medical device companies and the industry as a whole should not limit the search for funding to Canada alone.

Manufacturing costs are higher in Canada than in the U.S., which makes it difficult for companies to rationalize setting up manufacturing plants in Canada. This also makes it difficult to attract companies from other countries without incentives.

Canada needs to build up the smaller companies and to support cooperative marketing of their products through distribution companies. It is also difficult for the small companies to afford the seminars or workshops that are provided by the government or industry.

It is at these workshops and seminars where the industry could establish the networks that develop joint ventures or cooperative distribution. ISTC could play a roll in assisting small companies in attending such seminars.

The tax rate in Canada is definitely a hindrance to attracting foreign corporate growth. To attract international companies we may need to develop a lower international tax zone if we want to stimulate one industry where we have a negative trade balance.

Real estate in Canada is perceived to be very expensive and a deterrent to foreign and domestic companies. It was perceived by many companies that the U.S. offers much better incentives for land and building requirements of companies.

It was suggested that incentives not be given to companies that cannot pass all the due diligence and market evaluations.

1.5.1.2 PRIVATE INVESTORS

Industry representatives reported that in the early funding of companies, a small or single investor was the primary source of funding.

1.5.1.3 PENSION FUNDS

These pension funds are the largest source of capital in the country. Interviewees suggested that pension fund managers take a chance on high technology or start-up companies. But more should be done to encourage pension fund investment in the medical devices industry. Medical device companies do have the added feature of altruism in the potential health benefits along with the potential financial returns.

In the U.S., pension fund administrators invest 3-5% in higher risk, earlier stage companies while only 0.5 to 1% of Canadian portfolios are similarly invested. Quebec has used its provincial pension fund to a certain degree to fund areas that suit social purposes and overall goals of the province.

It was suggested that for pension funds to be registered as such and receive all the benefits associated with that registration, they should be required to allocate investment funds into areas which the country needs to stimulate. It was the opinion of a number of interviewees that pension funds should contribute more to the overall growth and the rapidly changing needs of the country.

It has been predicted that a large percentage of today's jobs will not exist in the coming decades. It is the responsibility of pension fund managers to assist in creating new jobs and industries for their contributors. The security of the pension alone is not sufficient in this rapidly changing, technologically advanced world.

Larger companies are more likely to have problems with innovation and changing direction whereas small companies are the greatest source of innovation and change. It is therefore crucial that they are supported.

It is expected that pension fund managers would have the following objections to early stage company venture funds:

- Early stage companies present a higher risk. Response: Higher risk can yield much higher returns. If the fund is properly managed and if the investments are distributed over a number of companies, the risk can be minimized;
- Insufficient good business deals or technologies exist in Canada. Response: Successful business opportunities and technologies would arise if funding were available. Foreign companies and technologies could be attracted to Canada because of available funding;
- Lack of top level entrepreneurs or managers in Canada. Response: Locate experts in foreign countries in the short-term period. Train Canadians for the long-term; and
- Properly structured business enterprises will always get funded. Response: This is not the experience of thousands of entrepreneurs in Canada and elsewhere. There is a recognized shortage of funding available for early stage companies.

Stages in the growth of a company:
1) Research
2) Development
3) Seed Capital - technology or product that is almost finished
4) First Stage - early manufacturing or production
5) Second Stage - the first expansion with some sales
6) Third Stage - significant sales are being developed
7) Mezzanine - final stage before the company goes public. Reports indicate that for stages two through four there is a void in the funding structure.

The federal government does have an incentive program for pension funds to be invested in venture capital. Until April of 1986, only 10% of a pension fund portfolio was allowed to be invested in a foreign firm. The federal government then created a program whereby $3 for every $1 of pension funds placed in a domestic firm with assets of less than $35 million could be invested outside Canada. Pension fund managers' interest in this proposal was short lived. [1]

The general opinion is that a more aggressive approach is needed to free some of the pension money for target industry investment. The point was also made that the limit of a company with $35 million in assets did not do anything for the void in funding for early stage companies.

1.5.1.4 LIMITED PARTNERSHIPS

Limited partnerships were a valuable source of funding until obligating the investor to be in the same business as his investment, were implemented. It is now much more difficult to match investors with companies.

1.5.1.5 PRIVATE OFFERRING MEMORANDUMS

These are still one of the best methods of gaining private funding without going public. Many of the companies interviewed arranged their initial funding through private investors and a private offerring memorandum.

1.5.1.6 STOCK EXCHANGES

There was a general consensus among industry players that a company must not go public too soon. They should be able to support the value of the stock in performance and "story" if not in direct sales.

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[1] Languedoc, C: More Venture Capital Stays In Canada, The Financial Post, June 1,1990

Vancouver is still the only place for venture capital or risk ventures in the form of a public market. It was felt that if a company goes on the Vancouver exchange that it should try to go onto another exchange and delist from Vancouver as soon as possible because of the negative reputation of the Vancouver stock exchange.

The Montreal and Toronto stock exchanges are not the the market for early stage companies because of their extensive registration requirements.

1.5.1.7 QUEBEC STOCK SAVINGS PLAN

This program provides provincial tax credits as an incentive for investment in companies going public on an exchange. Reaction to the program has been mixed. There was a significant amount of investment activity generated in small start-up operations and larger companies.

On the down side companies did not perform well in their development nor did the stocks hold their value. The companies' share values were especially hurt by the stock crash in 1987.

The general feeling concerning this program is that the incentives are not entirely to blame for the overall lack of success of this program. The problems were perceived to be the following:

- The incentive program may have encouraged companies to go public before they were ready to do so;
- The stock values were destined to fall because the secondary market did not have the benefit of the tax incentives as with the first round of investment;
- Smaller companies are vulnerable to change and did not weather the 1987 crash in a very healthy manner. Small companies share value decreased on the exchange whereas they might have gone unnoticed and held more of their value in a private investment situation; and
- Companies need proper promotion to be able to maintain their stock's value even in the best of times.

It was felt that this program is going to have difficulty attracting investors in the future because of the lack of success of the companies already funded.

1.5.1.8 FEDERAL BUSINESS DEVELOPMENT BANK

The Federal Business Development Bank (FBDB) fills a roll in the funding of companies that have not been able to find financing through the normal channels. They have both banking and venture capital

divisions. The problem is that the FBDB funds are often restricted by the limitations of co-investors.

1.5.1.9 JOINT VENTURES, STRATEGIC ALLIANCES AND MARKETING PARTNERS

Many companies which have been highly successful, gained that status because of a joint venture or strategic alliance with a partner that could provide funding and a marketing network. It is very difficult and expensive for a smaller company to develop its own marketing network. A larger partner can provide the marketing network that would take years for a small company to develop.

1.5.1.10 COMMUNITY BONDS

Saskatchewan has developed a Community Bond Corporation in conjunction with the municipalities in the province. The Province will insure the principal of all of the investment in this program but not the interest.[2] This program seems to be a copy of the Industrial Revenue Bond Program used in the U.S.

1.5.1.11 WESTERN DIVERSIFICATION PROGRAM

This program has received good reviews but it is thought to be cumbersome. This program can provide 25-35% of capital costs and up to 50% of funding with the stacking of other programs. There is also assistance for R&D of 50% of funding which can go up to 75% with stacking of other programs. [3]

1.5.1.12 PROVINCIAL TAX CREDIT AND INVESTMENT INCENTIVE PROGRAMS

Most provinces have a program similar to the Small Business Development Corporation in Ontario. Depending on the area, this program gives a cash grant or tax credit to investors to stimulate investment in certain industries. The problem is that the disclosures are very rigid and the amount of paperwork and legal documentation is excessive for the size of the funds. Interviewees have stated that they felt that the program is often more trouble that it is worth. There is also a number of restrictions that decrease the attractiveness for investors. It was the opinion of many that these programs should be simplified so as to be more effective.

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2 Government of Saskatchewan: Community Bonds Brochure, 1990

3 Western Economic Diversification Canada: Western Diversification Program, Helping Western Canadian Business Develop

1.5.1.13 INVESTOR SATISFACTION

The main criteria for maintaining investor satisfaction is growth in the value of the share or stock. The following points outline some of the steps that successful companies have taken to maintain share value:

1. It is important that the value of the stock goes up with each issue sold. This is a very important point for negotiation as the company wants each funding stage to appraise the share at a higher value.
2. If sales are not developed as yet, it is important that the company continues to develop its "story" so that the potential of the company is seen and the stock valued on future potential.
3. Proper sources of information for investors should be provided by the company. Some of the means available to support the share value are: detailed annual reports; newsletters; conferences, both scientific and financial; investor relations liaison within the company; and if possible a public relations consultant.
4. An investor should understand from the start that pioneering new technologies takes time but that is can be very profitable.
5. Canada needs a few success stories in the industry to encourage and reassure investors.

1.5.1.14 UNITED STATES PROGRAMS

Industrial Revenue Bonds: This program was often a combination of the Federal, State and Municipal levels of government. Governments insured loans for principal and interest usually at a rate 2 - 3% below the prime lending rate. The program was effective in stimulating growth but there were widespread abuses in the program.

North Carolina: The incentives vary from county to county. Most of the incentives are related to job creation with up to $1200 per year available for four years for each job created above the first nine jobs to a maximum of $250,000. [4] There are also low interest (4%) loans available for building renovations. North Carolina uses the Industrial Revenue Bonds at 3% below prime to a maximum of $10 million. More funds are available for production equipment and the building of roads to facilities. Cities or counties often provide buildings or put up money for buildings. The counties and cities in North Carolina are very aggressive in their marketing programs.

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[4] North Carolina Department of Economic and Community Development: North Carolina's Financial Advantages for Business

Report Card on Many of the States:

The fourth annual Development Report Card for the States, financed by corporations, labor unions and private foundations, stated there were new strategies being implemented as follows:

- 44 states are stimulating applied research through research centres and grants;
- 45 states help businesses develop new technologies or apply state-of-the-art technologies;
- 35 states offer non-traditional development finance instruments like product development, seed capital and venture capital;
- 40 states employ new mechanisms that leverage private resources to help meet business capital needs;
- 47 states have launched education reform measures; and
- 47 states devote state resources to improving the quality and productivity of their existing work force.[5]

1.5.1.15 UNITED KINGDOM

Most incentive or assistance programs are job-creation related and depend on the area where the company is locating:

- Developing areas - up to $20,000 per job;
- Intermediate level of development areas - $5000 to $6000 per job;
- Developed areas - no incentives; and
- Northern Ireland - up to 50% of capital expenditure is provided as an incentive.

Some local areas provide further assistance, especially with land and buildings.

1.5.1.16 FRANCE

The French Industrial Agency provides incentives. Their incentives are based on the amount of investment generated by a company.

- Less than $4 million - no incentives
- Over $4 million - incentives based on number of jobs created as a percentage of investment.

There are three investment areas:

- High industrial area - no incentives
- Middle industrial area - 12% to 17%
- Least industrial area - 15% to 25%
- Free land and buildings are available in some regions.

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[5] Associated Press: U.S. States Try New Strategies To Help Industries Develop, Toronto Star, April 6, 1990.

The French government has established three enterprise zones of approximately 750 acres each. These zones benefit from a preferential tax status. A corporation setting up operations in any one of these zones will be exempt from corporate income tax for the first 10 years under the following conditions:

1. It must be incorporated and have operating premises in the zone.
2. It must employ at least 10 persons after two years of operation. Companies receiving the tax advantage attendant to locating in the enterprise zones are not eligible for other government grant programs.

The French government has a tax credit program for R&D similar to the ITC program in Canada.

The French Industrial Development Agency provides assistance to foreign investors and companies by providing the following:

- relevant information on the French business climate
- access to the full range of incentives that are available from national and local sources
- site selection studies
- searches for potential joint-venture partners in France.[6]

1.5.1.17 INVESTMENT NETWORKING

A network of investors and companies has been established through Chambers of Commerce and Boards of Trade across Canada. The program is called Canada Opportunities Investment Network (COIN).[7] COIN's investors have between $25,000 and $1,000,000 to invest and the experience has been that there are more investors available than entrepreneurs. The program was launched in 1986 by the Ontario Chamber of Commerce, Price Waterhouse and Xerox Canada Ltd.

1.5.2 ANALYSIS OF EXISTING VENTURE CAPITAL AND INVESTMENT PROGRAMS

1.5.2.1 GENERAL DISCUSSIONS

It was the opinion of those interviewed for this study, that we do not have a true venture capital community in Canada. It is felt that most venture capital companies in Canada act more as merchant bankers than risk

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[6] French Industrial Development Agency: France, Industrial Investment File
[7] Francis, D: Financial Post, August 1, 1990

takers. This was not so much a statement of criticism as a statement of fact.

Venture capital companies often want control of the company, even at an early stage of financing. This can remove some of the incentive for the entrepreneur. The venture capitalists often remove the person with the vision who established the company and bring in outside management.

1.5.2.2 MDS HEALTH VENTURES

This is the only major venture capital firm that specializes in the medical devices industry. It is generally felt that MDS does a good job of funding companies but that alone they cannot possibly fulfill all the requests for capital.

It was expressed that being turned down by this group can have a negative effect on the fund-seeking company far beyond the immediate rejection. The rejection may not be the result of any problem with the company or MDS, just that MDS cannot fund all deals because of conflicts of interest, mandate, timing, insufficient funding, etc. But, because MDS is perceived as the expert in this area, other investors may overlook the company's potential if they have been turned down or overlooked by MDS. This strongly supports the proposition that more venture capital companies and funds are required to fulfill the financial needs of the medical devices industry.

MDS has about 66% of its investments in the commercial stage and 33% in the start-up development stage.

Investments are turned down primarily because of lack of proper management and insufficient world marketing vision, i.e. if the company does not look at the larger picture beyond Canada. For a venture capital company to be successful it must invest in companies that have a large market potential. Both technology and management are required for investments to be successful. Management would have the edge over technology in grading importance.

1.5.2.3 IDEA CORPORATION

Idea Corporation in Ontario was an example of a fund that failed to live up to expectations.

The reasons for failure have been stated as follows:
- Mismanagement and lack of a clear mandate;
- Political appointments misdirected;

- Most of the due diligence was on legal issues and not on business issues (eg. one $600,000 investment created $80,000 in legal fees); and
- The fund was not sufficiently motivated by market forces and performance.

1.5.2.4 VENTURE CAPITAL IN THE UNITED STATES

Most companies interviewed had only approached venture capital companies in Canada. The general opinion is that venture capitalists in the United States are more aggressive and open to medical companies and start-ups. There is also a source of a much greater pool of capital in the U.S.

1.5.2.5 VENTURE CAPITAL IN EUROPE

The general consensus is that the venture capital community and the general investment community in Europe seems to be much more aggressive and willing to take risks. Some have reported that for Canadian investment opportunities, they found venture capital more readily available in Europe than from domestic sources.

1.5.2.6. IMMIGRANT INVESTOR PROGRAM

Immigrant investors tend to have a greater long-term perspective concerning their investments and are willing to accept a lower rate of return.[8] These investors are also willing to be silent partners in projects but they do want to contribute their know-how. The program's emphasis, as developed for Employment and Immigration, is on job creation and capital expansion. This emphasis should help in redirecting some of these funds from real estate to investments in sectors such as the medical devices industry.

1.5.3 ANALYSIS OF MEDICAL DEVICES FUND

1.5.3.1 GENERAL DISCUSSIONS

There is a definite need for a special fund for the medical devices industry in Canada. Many of the problems facing the industry in Canada could be solved if adequate funding were available. The projected size of fund desired by most was an amount of $250,000,000. This would allow for the following: funding of potential world class companies; funding of a relatively large number of companies which would spread the risk and increase the possibility of a higher return for the investors; and funding that would have a significant impact on the industry in Canada. It was suggested that to allow for proper control, management, and allocation of

8 Horvitch, S: Commercial Real Estate, June 4, 1990

1.5.3.3 BUILDINGS AND FACILITIES OF MEDICAL DEVICE COMPANIES

There is a shortage of proper facilities for product development, research and manufacturing. This need could be fulfilled as part of the funding process. Networking could also help companies locate excess lab space available from other companies.

1.5.4 ANALYSIS OF EXISTING AND POTENTIAL TAX INCENTIVES

1.5.4.1 GENERAL DISCUSSION

Almost everyone interviewed felt the need for some type of incentive to attract investment to the medical devices industry. Although there were numerous suggestions and variations on the theme, the flowing through of expenses from the company to the investors was felt to be the most effective means of attracting investment.

It was also the consensus that tax incentives should be available for the following: research and development; development of new products; and assistance in developing early stage manufacturing. It was emphasized that tax incentives should not just be for R&D but should also encourage manufacturing and production.

Interviews disclosed that the United States provides more incentives for both research and development and for product and manufacturing development. This differs greatly from state to state and from area to area.

One company that deals only in funding start-up operations reported that tax incentives were involved in all of their investment arrangements and that those companies would not have been funded without the tax incentives.

1.5.4.2 INVESTMENT TAX CREDITS

The Investment Tax Credit program was criticized for a number of different reasons. Firstly, it was felt that the process of receiving the funds was very slow, time consuming and involved expensive accounting fees. Secondly, it was felt that Revenue Canada has the mandate to collect taxes and not to stimulate growth in industry.

1.5.4.3 TIMING OF CREDITS

A number of those interviewed suggested that tax credits that were received after the activity was performed were more market driven and therefore led to greater results.

1.5.4.4 FLOW-THROUGH SHARES

A number of oil, gas and mining companies were surveyed concerning the effectiveness of the flow-through share structure in attracting funds to these industries. In all cases, it was felt that the flow-through was a key component in attracting funds for exploration. The flow-through mechanism known as the Canadian Exploration Incentive Program (CEIP) was instituted in 1983, allowing for 133% of the expenses of exploration to be passed on to the investor. This particular program was cut in the Budget of Spring 1989. The program in Quebec offers flow-through of expenditures up to 166%, for provincial tax only.

In a memorandum to the Parliamentary Secretary for Energy, Mines and Resources Canada titled Current State of Affairs in the Canadian Mineral Exploration Industry there were a number of keys issues that are of interest concerning the implementation of a flow-through mechanism for the medical devices industry. The report comments that at least six countries in South America and Central America are looking at flow-through shares and other incentives to increase investment in mining and exploration. The report goes on to state,

> "Exploration spending levels in the United States, Australia and Canada were very comparable until flow-through shares propelled exploration to very high levels in Canada. Canada has been the most active mining exploration country in the world since 1983. In 1982, Canada ranked third behind the United States and Australia in terms of exploration expenditures, but by 1989, Canada was, by a wide margin, the world leader in exploration spending, in spite of the sharp decline in Canadian spending from the record levels of 1987 and 1988." [9]

> "Only Canada had the flow-through share mechanism that allows individual investors to use corporate tax deductions created by mineral exploration spending, thus encouraging investors to provide funds for exploration programs."

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[9] Memorandum To The Parliamentary Secretary: Current State of Affairs in the Canadian Mineral Exploration Industry, November 2, 1990

It should also be noted that it was the smaller or junior companies that benefitted most from the flow-through mechanism.

> "In 1983, exploration by junior companies accounted for only 15% of total exploration expenditures, or about $71 million. By 1987, the share of junior companies had increased to about two-thirds of the total, or about $700 million.
>
> "The almost ten-fold increase in the exploration expenditures of junior companies over the period 1983 to 1987 paralleled the increasing role played by flow-through shares in the financing of exploration. In 1983, seven percent of total exploration expenditures, or $34 million, was financed by flow-through shares; this increased to some 90 percent, or $1,183 million, by 1987. It is also estimated that juniors accounted for about 80 percent of the total funds raised by flow-through shares in 1988."

This indicates that it should be the start-up or smaller companies in the medical devices industry that would benefit the most from a flow-through program. This area has been identified in this report as that most lacking in funding.

The report predicts the following: "With the termination of CEIP, there is a possibility that exploration financing by juniors will decline by $100 - 150 million in 1991."

It is apparent that the smaller companies in all industries are the ones to most benefit from government incentive programs and the ones most affected by their demise.

It should be noted that in Quebec where the flow-through incentives were as high as 166 % that investment in exploration has declined recently. The report attributes this decline to the following:

> "1) the decline in gold price from $500 U.S./oz in late 1987 to the range of $360 U.S./oz in much of 1989 and 1990, 2) a relative lack of discoveries, 3) the stock market crash in 1987, and 4) investor losses on flow-through share investments made in earlier years."

This indicates that a flow-through mechanisms is not the only answer to funding problems but that special care must also be taken to evaluate investments properly independent of the potential tax benefits.

Interviews also revealed that the flow-through shares were most beneficial in attracting the small or individual investor versus the larger corporate or venture capital investor. The flow-through of expenses was of no value to the pension funds.

Dr Vijay M. Jog summarizes in his report to ISTC, "Not withstanding the success of the flow-through share programme for the mining sector, we have argued that the current conditions make it very difficult to introduce a similar programme for scientific research and experimental development". 10

According to accountants, a write-off mechanism still exists for mining and oil and gas but it is down to 100% write-off versus 133%. It was also suggested that the regulation bodies did not police the guidelines sufficiently and that caps should have been put on funding. Any such program needs very tight criteria to be successfully implemented.

1.6 OPTIONS

1.6.1 INVESTMENT COMMUNITY PARTICIPATION IN MEDICAL DEVICES FUNDING

1.6.1.1 SEMINARS AND WORKSHOPS

SCOPE/DESCRIPTION:
There is a need to connect investors with companies. ISTC can work with MEDEC and TIMEC along with the general investment community, including but not limited to venture capital companies, to fund seminars and workshops that can provide information from guest speakers as well as the opportunity for companies to make a 10 to 15 minute presentation. The emphasis, as with other activities, should be placed on international content and a world vision for the companies. This will open up Canadian companies to the international marketplace as well as introduce the international medical devices community to Canada.

It is the smaller companies that would benefit most from these workshops. Support structures and grants should be created by ISTC to

10 Jog,V: Flow -Through Share Mechanism and Research and Development, June, 1990

assist the attendance of smaller companies. ISTC could co-sponsor the seminar with potential investors, accounting firms, larger medical device companies and other professions benefitting from such conferences.

RESOURCES:

Annual conference contribution	$50,000
Conference management	50,000
Company expense support	40,000
	$140,000

These conferences should recover some of the cost through conference fees.

BENEFITS:

This type of program allows companies to connect with investors and with other companies and consultants. In addition, the conference would feature speakers that could provide valuable information to emerging technology companies as well as established companies. This setting also provides the opportunity for joint ventures to be discussed.

IMPLEMENTATION PLAN:

1. Select a conference project manager.
2. Arrange a cooperative agreement with potential investors and larger companies in the industry to share initial costs.
3. Define the target countries and then invite the international investment community to the conference.
4. Alternate the conference between eastern and western Canada.
5. Use high profile locations to attract the international companies and investors.

1.6.1.2 EMERGING TECHNOLOGY TRADE FAIRS

SCOPE/DESCRIPTION:

There should be a yearly international trade fair sponsored by ISTC to attract top scientists, international investors and world class medical device companies to Canada. This trade fair should include programs to introduce international companies to the opportunities and incentives available in Canada. It is important that some assistance be made available to small Canadian medical device companies so that they can attend such conferences. MEDEC and TIMEC should participate in this type of project.

RESOURCES:

Conference management	$50,000
Management assistant	30,000
Conference overhead	100,000
Conference promotional materials	30,000
Travel expenses	20,000
	$230,000

The above costs would fund the start-up of the project with a portion of the costs being covered by fees.

BENEFITS:

It has been emphasized that companies must have a world vision and one of the best ways to develop this is to bring the world to Canada. The attendance of international companies will promote joint ventures and strategic alliances with Canadian companies. This will also introduce international investors to Canada and Canadian companies.

IMPLEMENTATION PLAN:

1. Hire management.
2. Select international caliber site.
3. Organize Canadian companies.
4 Contact the equivalent of ISTC in targeted countries to get them involved in the project.
5. Prepare world-class brochures and invitations.
6. The conference project manager should travel to the major countries promoting the conference.

1.6.1.3 INTERNATIONAL EXCHANGE PROGRAMS

SCOPE/DESCRIPTION:

Contact should be made with a number of key countries to arrange an exchange program where select groups of foreign companies visit Canada for a conference, followed by a number of select Canadian firms visiting a conference in that foreign nation.

RESOURCES:

Overhead	$40,000
Travel	10,000
Assistance to Canadian companies	50,000
	$100,000

BENEFITS:
This provides an opportunity to introduce the international community to Canada and Canadian medical device companies. It should be particularly useful in developing joint ventures.

IMPLEMENTATION PLAN:
1. Contact the foreign country to be targeted to establish interest and cooperation.
2. Contact Canadian medical device companies to establish interest, cooperation and direction as to which countries and companies should be targeted.
3. Travel to country to investigate companies and technologies and invite them to Canada.
4. Arrange for conferences in Canada.
5. Arrange for conferences in foreign country.

1.6.1.4 SPECIAL INVESTMENT SEMINARS

SCOPE/DESCRIPTION:
Establish investment seminars for target groups in the investment community such as physicians, to investment opportunities in the medical devices industry. The emphasis could be placed on limited partnerships or other programs that would be most suitable for the target investment group. The seminar would also feature guest speakers that would be of interest to the target investors as well as the companies.

RESOURCES:

Conference overhead	$50,000
Conference management	50,000
Company expense support	40,000
	$140,000

BENEFITS:
This type of seminar should introduce a segment of the investment community to the potential of the medical devices industry. It also has the added feature of promoting technologies to potential clients.

IMPLEMENTATION PLAN:
1. Select a project manager who could act as a liaison between the medical devices industry and the physicians/investors.
2. Contact the Canadian Medical Association for assistance in defining the number of physicians and the categories of physicians.
3. Select a target market for a trial promotional project.

4. Select companies who would have products that would be of interest to physicians in a certain area. Special attention should be paid to the possible use of limited partnerships.
5. Arrange for a seminar to connect technologies and entrepreneurs with investors.

1.6.1.5 PLANTS, SITES AND INDUSTRIAL PARKS

SCOPE/DESCRIPTION:
Establish programs either through MEDEC, TIMEC or ISTC whereby foreign or domestic companies can be assisted in site selection, location of available buildings, evaluation of joint venture partners, and access and information regarding incentive programs. There is a magazine based in Florida called Plants, Sites and Parks that would be a useful source for advertising.

RESOURCES:

Program coordinator	$50,000
Overhead	20,000
Promotional material	15,000
Travel	15,000
	$100,000

BENEFITS:
This program should encourage foreign companies to locate their expansion plants in Canada. This program should also be useful in the expansion of Canadian companies. This is the type of program that could generate cooperation between federal, provincial and municipal levels of government and assist in spreading the network of program and contacts that should be developed.

IMPLEMENTATION PLAN:
1. Contact local areas concerning the availability, cost and other pertinent information on plant sites and industrial parks.
2. Encourage local area to provide material on their area.
3. Research the incentives that are available in different areas.
4. Compile an information package on the material provided.

1.6.1.6 FOREIGN REPRESENTATIVES

SCOPE/DESCRIPTION:
Establish information representatives in foreign countries and specified areas in the U.S. Many cities in Europe use a consultant in North America to represent and promote their area. This can be done at a fraction of the cost of setting up one's own office and staff. The key component for success is to provide the proper promotional materials for the localities and the medical devices industry and to have a sufficient promotional budget. Local communities should be encouraged to promote their area through such a net work in conjunction with the national program. North Carolina, for example, is very aggressive in the promotion of its business advantages on the level of the state, counties and cities. Bristol, England, uses a consulting firm in the United States to promote their city.

RESOURCES:
Consulting fees to consultants of $25,000 to $50,000 depending on the area. Promotional materials of $25,000 to $50,000 per consultant depending on the area. A commission could be paid based on performance.

BENEFITS:
Both the medical devices industry and the advantages and incentives of Canadian localities could be promoted at a fraction of the cost of establishing an independent office.

IMPLEMENTATION PLAN:
1. Contact cities or areas that have used this structure and evaluate its effectiveness of this concept.
2. Identify consultants that could act as representatives.
3. Create promotional materials for the representatives.
4. Incorporate the consultants or representatives into the overall promotion of the medical devices industry in Canada.

1.6.1.7 BUSINESS DEVELOPMENT PROGRAMS

SCOPE/DESCRIPTION:
Provide assistance to entrepreneurs in business development and market research. Business development support would be in the area of: marketing research; business plan development; operating systems; financial systems; and support in the development of a manufacturing plan. An example of division of costs would be one third federal, one third provincial, and one third company. This type of program could supplement any existing support programs. The market research support would be to identify the size of domestic and foreign markets, competition and receptivity of potential clients. The analysis carried out under this option would also prepare investors for investment community scrutiny.

RESOURCES:
The total allocation would be determined by the number of companies that apply for the program. It is suggested that the support be up to $35,000 per company for market research and up to $15,000 per company for business development support. It is hoped that the provincial governments would contribute to such a program.

BENEFITS:
The effect of this program would be to provide small companies with financial and technical support for much needed business development plans and marketing research. The crucial areas of business plan development and market research are often neglected because of insufficient funds. This program could lessen many of the smaller companies' problems with proper planning.

IMPLEMENTATION PLAN:
1. Establish a grant program that would process applications from small companies for assistance.
2. Provide a network of consultants who could provide specific needs, information and direction to companies.
3. Establish an advisory board that could evaluate business, manufacturing or marketing plans.

1.6.1.8 NETWORKING NEWSLETTER AND DATABASE

SCOPE/DESCRIPTION:
This newsletter and data base would provide listings of companies along with a description of their activities and immediate requirements. These requirements could be as follows: joint venture partners; strategic alliances; capital for various stages of development; management or scientific personnel. This newsletter could also connect with universities to provide information on technologies that may be ready for manufacturing and marketing. If at all possible this network should expand to include the U.S. and Europe even if it is just a section in the publication. This program should develop a substantial databank of information and requirements in the medical devices industry.

RESOURCES:
Part of the cost would be covered by subscriptions but it would be useful if ISTC could provide seed capital to MEDEC, TIMEC or private individuals to initiate such a publication. A grant of $75,000 to assist start-up could be provided.

BENEFITS:
This publication could provide valuable information to a medical devices company at relatively little cost. It would help connect the industry internally as well as connect the industry with the essential support groups and investors.

IMPLEMENTATION PLAN:
1. Inform through available channels that funding is available for the start-up of a networking newsletter.
2. Evaluate the proposals for the publication.
3. Inform investors and companies of the usefulness of the networking newsletter and database.
4. Collect the networking information into a data bank for access by companies, consultants and investors.

1.6.1.9 FOREIGN INVESTORS/COMPANIES' ASSISTANCE PROGRAM

SCOPE/DESCRIPTION:
ISTC should provide assistance to foreign investors and companies by providing: relevant information on the Canadian business climate; access to the full range of incentives that are available from national, provincial and local sources; sites selection studies and assistance; and searches for potential joint-venture or strategic alliance partners in Canada.

RESOURCES:

Research and writing of materials	$50,000
Printing of materials	25,000
Distribution of materials	10,000
	$85,000

BENEFITS:
This program would focus attention on the international medical devices market place and hopefully attract business to Canada.

IMPLEMENTATION PLAN:
1. Research and collect the pertinent information that would form the basis of the promotional materials.
2. Research target markets.
3. Distribute promotional materials.

1.6.1.10 PENSION FUND MEDICAL DEVICES INVESTMENT FUNDS

SCOPE/DESCRIPTION:
This option calls for the establishment of new federal policies regarding pension fund allocation of investments to early stage companies and medical device companies. For pension funds to maintain their registration as a pension fund, they would be required to allocate an additional 0.5% per year over a 10 year period to bring their investment in start-up, early stage companies or target industries up to 5% of the total investment portfolio.

It has been estimated that the amount of capital in pension funds in Canada is approximately $180 billion. An incremental introduction of 0.5% increase per year would add $900 million per year for investment in high technology companies. Pension funds could set up their own venture capital funds or use existing funds with a stipulation as to fund

allocation. Once pension funds were allocating 5% per year into early stage companies they would continue to allocate 5% of the new funds generated or received each year.

The roll of ISTC would be to lobby for this fundamental redirection of funds in Canada. A detailed study should be conducted to analyse the effect of these large pools of capital on pension funds and the medical devices industry. It would more be appropriate if the funds were directed to all high technology industries.

RESOURCES:

Project manager	$50,000
Assistants	60,000
Overhead	20,000
Travel	15,000
	$145,000

BENEFITS:
This redirection of very large pools of capital could fundamentally change the nature of the medical devices industry as well as other high technology companies in Canada. There would be significant enlivenment of the entrepreneurial sector in Canada.

IMPLEMENTATION PLAN:
1. Establish management for the development of the report.
2. Research pension funds and pension fund structure with the intention to lobby pension funds and the Department of Finance for the redirection of these funds.
3. Lobby pension funds and the Department of Finance for the creation of these pools of capital.
4. This lobbying effort should be in conjunction with an analysis of the venture capital companies and investors that fund early stage companies.

1.6.1.11 LIMITED PARTNERSHIP PROMOTION

SCOPE/DESCRIPTION:
Limited partnerships are a means to give tax incentives to investors that are in the same business as the funded technologies. For example, neurologists would have to invest in technologies related to neurology. Limited partnerships could be used to connect new technologies with potential investors. Promotional material would form the basis of an effort to fund new technologies in Canadian universities that are ready to

be marketed. The concept would be to connect entrepreneurs, technologies, investors and potential customers of the technologies under the mechanism of a tax incentive. This program should be integrated with the networking newsletter (see 1.6.1.8).

RESOURCES:

Research and development materials	$50,000
Printing of materials	15,000
Distribution of materials	5,000
	$70,000

BENEFITS:

This program would be a means to fund new technologies using a tax incentive. This program is applicable to the medical devices industry because the medical profession will have a number of wealthy investors who could also be clients or users of the technologies.

IMPLEMENTATION PLAN:

1. Research and collection of the pertinent information that would form the basis of the promotional materials.
2. Research target markets, i.e. potential investors.
3. Distribute the promotional materials.

1.6.2 EXISTING VENTURE CAPITAL AND INVESTMENT FUNDS/PROGRAMS

1.6.2.1 EDUCATIONAL AND PROMOTIONAL MATERIALS

SCOPE/DESCRIPTION:

There is a great need to inform and educate the venture capital community of the potential of the medical devices industry. There should be a number of cooperative ventures to introduce the companies and the industry in general to the venture capital community. If venture capital companies in Canada prove to be too conservative, the emphasis should be placed on U.S. and foreign funds. The Canadian companies need to be connected to the international funding sources.

RESOURCES:

Project manager	$50,000
Research and development materials	20,000
Printing of brochures	15,000
Distribution of brochures	5,000
	$90,000

BENEFITS:

This program will hopefully enliven interest in the venture capital community for potential investment in the medical devices industry. This type of information can project the strengths and performance of medical devices investments and get investors talking about the industry. Most importantly, this program should help attract funding into the targeted area.

IMPLEMENTATION PLAN:

1. Research and collect pertinent information that would form the basis of the promotional materials.
2. Research target markets.
3. Distribute promotional materials.

1.6.2.2 VENTURE CAPITAL CASE STUDIES

SCOPE/DESCRIPTION:

There is a lack of true venture capital or risk takers in Canada. Case studies would select a number of successful venture capital companies that have invested a significant percentage of their capital in start-up or early stage companies, and in particular, medical device companies.

RESOURCES

Case study management	$50,000
Assistant	30,000
Overhead	25,000
Travel	15,000
	$120,000

BENEFITS:

The understanding of how risk takers initiate and implement systems of investment will help form criteria for others to follow. The country and the medical devices industry needs to have risk capital available to develop and fund companies at an early stage of development.

IMPLEMENTATION PLAN:

1. Identify venture capital companies that invest in start-ups or early stage of development companies. Identify why they have chosen their investment pattern.
2. Identify the common patterns of action that are consistent with a number of true venture capital companies.
3. Analyze the success of their investments to establish funding criteria.
4. Compile the information gathered into a report format and distribute.

1.6.2.3 INVESTIGATION AND ANALYSIS OF THE VENTURE CAPITAL COMMUNITY IN CANADA, UNITED STATES AND EUROPE.

SCOPE/DESCRIPTION:

This analysis would determine the patterns of behavior and criteria of investment for venture capital companies that are true risk investors. The process should locate companies that are already investing in the medical devices industry or which are interested in investing in this industry. This information would be distributed to medical device companies in Canada.

RESOURCES:

MEDEC or consultants could be given a contract of $100,000 to investigate this area. This study should be done in conjunction with the investigation and analysis proposals of the United States and European venture capital community.

BENEFITS:

This process should create a better understanding of what funds exist and what needs to be done to access these funds. This program is important because it could introduce Canadian medical device companies to international investors. This program would further encourage Canadian companies to have a world vision for their technologies. It should also provide information that could lead to funding of Canadian medical device companies.

IMPLEMENTATION PLAN:

1. Identify companies that finance or would be interested in financing medical device companies.
2. Analyze the selected venture capital companies.
3. Provide the investment information to medical device companies seeking capital.

4. Inform venture capital companies of the potential investments available in the Canadian medical devices industry.

1.6.2.4 VENTURE CAPITAL FUNDS ESTABLISHED WITH AN INCENTIVE PROGRAM

SCOPE/DESCRIPTION:
ISTC should lobby for the creation of a tax incentive program that would help direct funds into the medical devices industry through the venture capital structure. The medical devices industry and especially the companies in the early stages of development are lacking in funding. Incentives are needed if we want to stimulate industries with large negative trade balances.

RESOURCES:
Assistance required for MEDEC to lobby the Department of Finance is $25,000. No funds should be expended until a favourable reaction is received from the Department of Finance.

BENEFITS:
Such venture capital funds would potentially create incentives for investment and eventually attract more investment in medical device companies. This program could attract substantial funds to medical device companies.

IMPLEMENTATION PLAN:
1. Lobby the Department of Finance to see if there is any possibility to introduce this type of program.
2. Collect data to support the case for incentive to direct funding into target areas.

1.6.3 MEDICAL DEVICES FUND

1.6.3.1 SEED CAPITAL FOR THE CREATION OF RISK CAPITAL FUNDS

SCOPE/DESCRIPTION:
Seed capital should be made available to entrepreneurs or investors who are interested in establishing risk capital funds to invest in early stage medical device companies. The seed capital would be on a matching basis with at least 50% of the funds contributed by the fund creators. The grant

funds would assist in market research and the development of a prospectus or offerring memoranda.

RESOURCES:
A grant of up to $50,000 could be make available.

BENEFITS:
This has the potential to create pools of capital that would fund start-up or early stage companies.

IMPLEMENTATION PLAN:
1. Establish the criteria for the development of an offerring memorandum.
2. Create a grant program to assistance in the creation of risk capital fund.

1.6.3.2 SCIENTIFIC AND TECHNICAL ADVISORY BOARD

SCOPE/DESCRIPTION:
This Board would evaluate the scientific and technical merit of medical devices technologies. This evaluation would assist companies in properly developing their technologies. This process would also be a concept testing and analysis program to see if the technology should be developed.

RESOURCES:

Committee or Board selection	$45,000
General Secretary salary	50,000
Assistant	30,000
Overhead	25,000
Travel	20,000
	$170,000

BENEFITS:
The evaluation could also act as a potential source of approval that could assist companies in passing the due diligence process and thereby improve the companies chances of receiving funding.

IMPLEMENTATION PLAN:
1. Establish a General Secretary for the board.
2. Finalize a mandate for the board.
3. Develop evaluation procedures and submission criteria so that companies or individuals can be properly prepared.

4. Assess the industry and scientific community for potential board members.
5. Inform the network of companies and technology sources that this evaluation program is available.

1.6.3.3 FINANCIAL AND MANAGEMENT ADVISORY BOARD

SCOPE/DESCRIPTION:
This board would evaluate the business, financial and marketing merit of business, manufacturing or marketing plans that are to be used for accessing funding. This evaluation would assist companies in successfully developing their business strategies.

RESOURCES:

Committee or Board selection	$45,000
General Secretary salary	50,000
Assistant	30,000
Overhead	25,000
Travel	20,000
	$170,000

BENEFITS:
Evaluations conducted by this advisory board would act as a potential approval mechanism that could assist companies in passing the due diligence process and improve the possibilities of receiving funding.

IMPLEMENTATION PLAN:
1. Establish a General Secretary for the Board.
2. Formalize a mandate for the Board.
3. Develop evaluation procedures and submission criteria so that companies or individuals can be properly prepared.
4. Assess the medical devices industry and financial community for potential board members.
5. Inform the network of companies and technology sources that this evaluation program is available.

1.6.3.4 MEDICAL DEVICES INVESTMENT OR JOINT VENTURE OPPORTUNITY NETWORK

SCOPE/DESCRIPTION:
This program would develop a database of the requirements of medical device companies in Canada. The program would register both companies seeking funding or joint venture partners ($150 fee to register a business

plan) and investors or large companies seeking potential technologies or investments ($250 registration fee). This program could operate through MEDEC or affiliated organizations throughout the country. This program should be connected with the networking newsletter.

RESOURCES:
Seed capital of $75,000 could be made available.

BENEFITS:
This is a proven method of connecting companies with investors.

IMPLEMENTATION PLAN:
1. Establish registration criteria.
2. Create promotional material.
3. Inform the medical devices industry and investment community of the program.

1.6.3.5 INSURED BOND PROGRAM

SCOPE/DESCRIPTION:
The Federal government, in conjunction with provincial governments and municipal governments, could provide insured loans to medical device companies. This would not require any funds up-front from the government. As long as the company is successful no funds would have to be paid out. This program might be reserved for companies that have a more established track record and have significant sales. This could be used for plant or production expansion. A royalty payment on the loan could be initiated so that the successful loan returns would balance the losses from unsuccessful companies. The Saskatchewan government has recently instituted a community bond program.

RESOURCES:
The initial investment would be for funds to lobby for the program through MEDEC or TIMEC.

A grant or $25,000 could be made available.

BENEFITS:
This is a program that could fund many companies that otherwise would have to pay very high interest rates or they would not get funded at all. The government would not have to put up any initial capital. The United

States has used this program with a high degree of success in stimulating development.

IMPLEMENTATION PLAN:
1. Arrange for a grant to MEDEC to lobby the Department of Finance.

1.6.3.6 MEDICAL DEVICES AND REAL ESTATE FUND

SCOPE/DESCRIPTION:
There is a need for special facilities for the medical devices industry. The idea of combining real estate investment and leasehold improvements with a medical devices company investment has been well received. This would decrease the risk for a potential investor as well as providing needed facilities and decreased land costs. ISTC could provide seed capital to initiate such a program.

RESOURCES:
Grant of up to $50,000 for each fund could be established.

BENEFITS
This has the potential to create pools of capital that would fund start-up or early stage companies. One of the key components in funding medical device companies is the creation of a risk capital industry in Canada.

IMPLEMENTATION PLAN:
1. Create a grant program to assistance in the creation of risk capital fund.

1.6.3.7 GOVERNMENT FUNDED/PROVIDED LAND AND BUILDINGS

SCOPE/DESCRIPTION:
Land and building costs in Canada are perceived to be very expensive. There is also a shortage of the proper lab space required by medical device companies. This program would provide federal land and buildings that are not used to their full capacity at little or no cost to the medical devices industry. The land value could be recovered through a royalty structure. This type of arrangement could be of particular use in attracting large foreign companies that require large manufacturing space.

RESOURCES:
This is a program that would require lobbying the different government departments that hold land and buildings suitable for medical device companies. No significant funds should be directed to such a program until a favourable response is generated from the Department of Finance.

BENEFITS:
This is a program that could attract major foreign companies to expand to Canada. There would not be any cash expenditures by the government. The program could also be structured on the basis of a long-term lease so that no land or building was lost.

IMPLEMENTATION PLAN:
1. Lobby the Department of Finance to judge the possibilities of introducing such a initiative.
2. Lobby the government departments that may have land and buildings that would be suitable to the medical devices industry.

1.6.4 EXISTING AND POTENTIAL TAX INCENTIVES

1.6.4.1 ANALYSIS OF THE EFFECT OF A TAX INCENTIVE MECHANISM ON THE FUNDING OF MEDICAL DEVICE COMPANIES

SCOPE/DESCRIPTION:
There is a general consensus that there is a need for some form of tax incentives to stimulate investment in the medical devices industry. This area of tax incentives, although perceived as important within the medical devices industry, is not likely to be accepted by the Department of Finance.

RESOURCES:
Very little should be directed towards this area unless there is a more positive response developed in the Department of Finance.

BENEFITS:
Tax incentives could stimulate investment in the medical devices community.

IMPLEMENTATION PLAN
1. Further investigation and lobbying should take place with the Department of Finance.

1.6.4.2 ESTABLISH TAX-FREE OR LOWER TAX ENTERPRISE ZONES

SCOPE/DESCRIPTION:
Establish enterprise zones such as those developed in France to allow for a lower or no tax rate, thereby attracting foreign companies to Canada. The higher tax rate in Canada versus the U.S. in particular, is a major obstacle to attracting foreign companies and investment. The effectiveness of this initiative in France should be investigated in more detail.

RESOURCES:
A $75,000 contract should be created to investigate the effectiveness of this type of arrangement in France, Ireland and other countries that use this program. Again no funds should be allocated unless there is a favourable response from the Department of Finance.

BENEFITS:
This could be a great stimulus to attract foreign companies to Canada. The Canadian tax rate is an obstacle to attracting large manufacturing companies. This type of program could open Canada to the international medical devices industry.

IMPLEMENTATION PLAN:
1. Investigate the effectiveness of this program in France, Ireland and other nations.
2. A tax comparison between the U.S., European countries, Pacific rim and Canada should be developed.

1.6.4.3 KEY PERSONNEL TAX REDUCTION PROGRAM

SCOPE/DESCRIPTION:
Establish a program whereby key management and/or scientists can be hired from the U.S. or other nations and receive a special tax holiday or lower tax rate as an incentive to attract them to Canada. It is very important that medical device companies can access the best possible management and scientists. The federal program could copy the program that has be instituted by the Quebec government.

RESOURCES:
No significant amount should be spent unless a favourable response is received from the Department of Finance. A $20,000 grant to MEDEC could be provided to investigate Quebec program.

BENEFITS:
This program would greatly assist companies in attracting the best possible personnel.

IMPLEMENTATION PLAN:
1. Investigate the response of the Department of Finance to this type of program.
2. Investigation the effectiveness of the Quebec program.

1.6.4.4 FLOW-THROUGH SHARE MECHANISM

SCOPE/DESCRIPTION:
This mechanism should be created for the medical devices industries. This program would be patterned after the 133% flow-through mechanism that was the basis of the Canadian Exploration Incentive Program. This is the one program that seemed to be universally requested. It could provide the basis for the creation of a special fund as well as funding for companies on an individual basis.

RESOURCES:
No major funds should be spent until it could be established that the Department of Finance would be flexible in developing a new program to suit the needs of the medical devices industry.

BENEFITS:
This type of tax incentive had a major impact on the exploration industries. A similar but restructured program could have a very significant impact on funding for the medical devices community.

IMPLEMENTATION PLAN:
1. Test the response at the Department of Finance before any major effort is put into this project.

1.6.4.5 PROVINCIAL TAX CREDIT PROGRAMS

SCOPE/DESCRIPTION:
Many of the provinces have an incentive program that gives an investor a cash grant or tax credit up to 30% of the amount of the investment for

targeted industries. The federal government could set up a program that could complement these provincial programs. The federal program could use much of the regulation that has been structured on the provincial level.

RESOURCES:
Again, no significant funding should be spent until the Department of Finance responds favourably.

BENEFITS:
This could stimulate funding in the medical devices industry. The advantage of this program is that much of the structure is already created by the provincial programs.

IMPLEMENTATION PLAN:
1. Approach the Department of Finance with the concept.

1.6.4.6 JOB CREATION INCENTIVES PROGRAMS

SCOPE/DESCRIPTION:
Under this type of program, companies would be given various financial incentives for creating jobs and hiring people. This type of program may be more acceptable to the Department of Finance because it is related to job creation. This type of incentive has been used extensively in the U.S. and Europe. The program is worth further study as the basis of a lobbying effort.

RESOURCES:

Project officer	$50,000
Overhead	25,000
Travel	20,000
	$95,000

BENEFITS:
This job creation incentive program has the potential to fit the mandate of both the industry and government. This mechanism would be most suited to larger companies that have a large number of employees and are in the process of expanding their operation.

IMPLEMENTATION PLAN:

1. Check with the Department of Finance to see if they are open to this type of program.
2. Study the programs that have been established in England, France and the United States.
3. Evaluate the medical devices industry to see how many jobs would be created.
4. Survey the medical devices industry to evaluate if this program would complement the companies funding plans.

1.7 CASE STUDIES OF SUCCESS STORIES

Information and opinions expressed in this section were provided by the management of the profiled companies interviewed for this project, unless otherwise noted.

1.7.1 ADI DIAGNOSTICS INC. [11]

VITAL STATISTICS

Founded:	1988
Location:	Rexdale, Ontario
Products:	*In-vitro* medical diagnostic kits
Employees:	85
Facilities:	2, totaling 55,000 sq. feet
Export Markets:	U.S., Austria, Spain, Italy, U.K., Australia, Singapore
Total Revenues 1989:	$2.2 million
Total Revenues 1990:	$4 million (projected)
Total Revenues 1991:	$9 million (projected)

FUNDING HISTORY / SOURCES

Start-up / R&D Stage

1987/88	$2 million	parent company, government grants

Prototype Stage

1988/89	$6 million	private placements

Marketing / Regulatory Studies Stage

1989	$2 million	private placements

(ADI acquired Connaught Diagnostics in a stock trade during this period).

Early Manufacturing / Marketing Stage

1990	$6 million	private placements, venture capital

11 Steven Hayter, President, ADI: Phone interview December 6, 1990.

Full-Scale Manufacturing / Marketing Stage
1991 $3 million private placements (projected)

All funding sources to date have been Canadian. Private placement funds came from corporations, insurance companies, banks, and management and employees. These last have participated in all stages of funding by purchasing stock through various incentive programs.

Management spends 65% of its time looking for money. This is a major, major problem that slows growth and development tremendously. As a result, many ppportunities must be ignored.

"Undercapitalization is the biggest problem facing the industry by far."

MAJOR FACTORS ATTRACTING INVESTORS

Quality of management was the primary factor attracting investment. Mediocre products can succeed with good management. But if management is not adequate, even good products may fail.

USE / USEFULNESS OF TAX CREDITS IN FUNDING

Tax credits were not sufficiently available to make a significant difference when ADI was founded. Had more been available they would have been of great help.

If the company had been founded in Quebec, more assistance would have been available in the form of tax credits. In addition, other assistance is available there. Quebec is reported to have the best investment climate in Canada, and one of the best in North America.

ADI is currently taking advantage of R&D tax credit programs, but it takes about a year to receive the money (they had still not received their 1989 money as of early December 1990). Revenue Canada audits before payment, and, in ADI's experience, makes it as difficult as possible to collect credits, questioning everything. This damages R&D. In contrast, Quebec is reported to pay tax credits up front and audit later.

EXPECTED RATE OF RETURN TO INVESTORS

No specific rate of return was discussed with investors. The company was selective, looking only for investors with a long-term perspective.

Sales were projected to reach $100 million by 1996 or 1997, with 20% going to the bottom line. To reach this goal all monies were to be reinvested until that time. At that point the company was expected to go public. Therefore, initial investors could not have expected a payback for 10 years. Later investors, depending on time of investment, could foresee somewhat more rapid returns.

This basic scenario remains in place. The company feels it needs 2 years of profitable operation to go public, and the new equities market is, in any case, not currently attractive.

Some investors are satisfied with the development of the company, and some are not.

PHILOSOPHY OF STOCK OWNERSHIP

The original philosophy was to maintain 100% Canadian ownership until the company went public. Due to the current investment climate this is no longer realistic, and the company needs to attract international monies. Paradoxically, it would be easier to find Canadian money if there were already foreign investment, due to the credibility this would provide. ADI believes there is a broad misperception in Canada that a $5 million investment is sufficient for a company in this industry. To become a significant player, $15-20 million is more realistic. In the U.S. investors are more experienced and better understand these requirements.

The company is committed to employee ownership. Management did not have any ownership at the beginning. Like all other employees, management was offerred stock at the same price as the initial investors, with the added kicker that shares could be doubled for an additional $.01 per share when the company reached break-even. Eighty percent of the original employees took advantage of this offer, and other purchase plans have been available since.

MANAGEMENT

ADI hired experienced managers for key positions from the very beginning, from competing companies such as Baxter, Abbott and Ortho.

ADI advises other new companies to look to their competitors to find management, especially people with international experience. "The commitment and knowledge of management are the most significant factors in a company's success."

MARKETING / DISTRIBUTION

Canadian marketing focusses on sales to blood banks (via the Canadian Red Cross). Compatible products of other companies are distributed through the Canadian sales force.

ADI has its own sales force of three to market in Canada. Significantly, its service staff is as large, with the greater emphasis placed on service.

Service staff have beepers and are available 24 hours a day. Response is immediate, and they are required to solve problems immediately. Service is the key to sales, and therefore to the growth of the business.

International sales are handled by distributors in target countries (i.e. Organon Technica in the U.S.). ADI looks for distribution partners who are similarly small and aggressive. This strategy got the company's products into the global market during the first year of operations..[12]

Companies are strong in some markets and not in others, so it is a mistake to give a single company, even a large and successful one, distribution rights for the whole world.

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12 More Solid Support for Canadian Companies Needed to Reduce Deficit in Medical Devices. MEDEC J 1 (3): 11-12, Summer 1990.

CURRENT STATUS

"On the verge of success." Growth is rapid and the products well received. The syphilis test kit introduced in September 1990 is now selling at the rate of two million units per year in the U.S. It is expected to account for 30% of that market and reach a running rate of 18 million units per year by December 1991.

NARRATIVE

ADI began as a division of Allelix Inc. Steven Hayter, experienced in the industry, was brought in as President in 1987 with a mandate to secure funding and take the division private. The company was spun off in 1988.

Of current products, only 2 were started at the parent company. The product line being developed at Allelix was aimed at the home test and physician's office markets. The products were expensive and unreliable.

The original product line was cancelled and the focus shifted to infectious-disease kits for diagnosis. The direction has remained unchanged since December of 1988.

RECOMMENDATIONS TO OTHER COMPANIES / THE INDUSTRY

You need an experienced, knowledgeable management team and a good financial person.

Treat everyone as a valued associate--customers, employees, suppliers.

Ask questions constantly.

Expect to need more money and time than anticipated. Be ultra conservative in projections.

Evaluate your market realistically. Does one really exist, what features must a product have to compete successfully, what and who are the competition?

Raise funds continually. Undercapitalization is a formula for disaster.

Make sure the manufacturing process is adequate to meet anticipated demand.

Hire or contract clinical research expertise.

Set up distribution with strong partners in each market.

Make sure you have adequate facilities for R&D and manufacturing.

Develop a presentable, easy to read business plan, without a lot of technical jargon, of no more than 10-15 pages. Have someone on your team who has excellent speaking skills present a summarized version (6-7 pages with graphics) to potential investors. Make sure that this presentation demonstrates your understanding of the market and competition, your marketing strategy, etc.

The industry needs a yearly fair. Companies could exhibit their new technologies to the investment community, and allow potential investors to follow their progress from year to year.

RECOMMENDATIONS TO GOVERNMENT

Implement the excellent incentive programs available in Quebec on a national level.

Give the public incentives to invest in medical device companies similar to the 133% flow-through allowance for oil, gas and mining. These could be used to establish a large investment fund managed by experienced people, to guarantee financing from start-up through full-scale marketing, based on performance targets. A fund of $250 million could finance 10-12 or more companies. Only two or three need to succeed to guarantee an excellent return to investors.

1.7.4 IAF BIOCHEM INTERNATIONAL INC. (IAF) [15]

VITAL STATISTICS

Founded:	1986
Location:	Montreal, Quebec
Products:	AIDS detection kits, vaccines, research chemicals
Employees:	200
Facilities:	N/A
Export Markets:	U.S., Europe, Asia, Latin America, Caribbean

Total Revenues 1989*: $3,157,732
Total Revenues 1990*: $6,206,044
Total Revenues 1991*: $15 million (projected by consultant)
(*Note: fiscal year ending January 31)

FUNDING HISTORY / SOURCES

Start-up / R&D - Full-Scale Manufacturing / Marketing Stage

Round 1 $13 million public offerring

Round 2 $4.5 million private placements

Round 3 $13 million private placements

Round 4 $25 million Glaxo Holdings

Round one funding was obtained primarily from the Quebec Stock Plan, a tax sheltered public offerring. Subsequent financing was by private placements, to mostly foreign investors.

Employees receive average wages but are compensated by generous stock options.

MAJOR FACTORS ATTRACTING INVESTORS

Initial investors were attracted by tax incentives. Subsequent financing resulted from the company's performance.

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15 Dr. Francesco Bellini, President, IAF BIOCHEM: Interview December 18, 1990.

"Raising money is not a problem once you have a track record."

USE / USEFULNESS OF TAX CREDITS IN FUNDING

Tax shelters were the basis for the establishment of the company. These are necessary to attract seed money for new companies, as there is virtually no real venture capital in Canada. "Canada is not a country that takes risks."

EXPECTED RATE OF RETURN TO INVESTORS

There was no target rate of return during the initial funding. Investors expected the company would lose money for four-five years.

Investors are generally happy with the company's performance. "You must deliver what you promise."

PHILOSOPHY OF STOCK OWNERSHIP

The company began with a public offerring. This is now seen by IAF as a mistake. Success via this route has been by chance, and is not recommended for other companies.

It costs IAF approximately $500,000 per year just to meet the legal, accounting, public relations and other expenses related to being public.

Several other start-ups also went public under the Quebec Stock Plan. When the market crashed in 1987, most of them crashed with it. In any case the public is now very skeptical of start-ups and it is virtually impossible to raise funds in this way anymore.

It is better to start private, and go public later. Founders must be willing to sell equity to attract investment.

With private funding there are only a few people running a company and decisions can be made more quickly and efficiently.

MANAGEMENT

Management is most important to the success of a technology company. IAF found people through placement agencies, industry contacts and friends. They looked for people willing to learn and work hard.

Bringing someone in from the U.S. is very expensive.

MARKETING / DISTRIBUTION

The company's diagnostic division sells directly in Canada, but has not had much success there. They sell in B.C., Alberta and Ontario but have not broken into the Quebec market. The provincial and federal governments do not buy significant quantities of IAF products even though they are doing well in other countries. Canadians seem reluctant to buy Canadian products.

Foreign sales are handled by multinational companies. In some markets this is through licensing agreements where the multinational manufactures and distributes. For other markets IAF manufactures in Canada and the multinational distributes locally in the foreign country.

BioChem's vaccine subsidiary, IAF BioVac, sells almost exclusively in Canada. A large portion of BioVac's sales are in Quebec with the remainder being throughout the rest of Canada.

CURRENT STATUS

IAF is well financed, with an additional $40-50 million in outstanding warrants and options.

Sales are growing. The company is developing new products and manufactures some for other companies.

Sixty percent of revenues are from sales. Forty percent are from royalties, interest, and milestone payments on product development agreements.

NARRATIVE

The company was set up in 1986 as a tax shelter. Subsequent financing was by private placements.

The company's product direction has not changed since its founding.

RECOMMENDATIONS TO OTHER COMPANIES / THE INDUSTRY

Find a niche market.

Find honest, good management.

Make revenues a top priority.

Control expenses.

Remain private until you complete R&D. Then go public or form strategic alliances with companies that can support you financially. For venture capital, look outside Canada.

Most expense is in development, not research.

Once you have completed research and are in the development stage, use the media to get your company known. This will help in raising funds.

Deliver what you promise.

You need lots of luck -- the right idea, time and place.

RECOMMENDATIONS TO GOVERNMENT

Risk/return ratios don't warrant investments in small start-up companies under current conditions. There should be tax advantages and a more favourable treatment of capital gains for investments in small companies.

A buy-Canadian policy is absolutely necessary, so long as the Canadian products are competitive.

Direct government money only helps the weak companies. Government support should go to help strong companies to help them become internationally competitive.

The government needs to support manufacturing and value-added industries in addition to its support of natural resource industries.

More funding is needed for development, not research. There is a lack of development people in Canada.

Government grant programs should focus on the quality of management, and applications for them should be simplified.

1.7.5 SUMMARY

Certain similarities appear in these successful companies--good management, willingness by the founders to give up equity, planning from the beginning to go public, strategic marketing alliances with strong partners, adequate capitalization and a great deal of luck.

While IAF BioChem has had a consistent direction from its founding, ADI, QLT and QSI were all able to successfully shift focus by virtue of strong management.

We queried each company as to the most realistic currently available sources of capital at each stage of development. Their assessments can be summarized as follows:

Start-Up / R&D Stage

Consensus: extremely difficult to nonexistent. There is some money for research, but virtually none for development.

Possibilities are: government grants; "love money" (investments by founders, relatives, friends); institutional investors (if you have excellent management, attractive technology, and a good "story").

Prototype Stage

The consensus is that this stage is extremely difficult.

Possibilities are: "love money;" institutional investors (if you have excellent management, attractive technology, and a good "story"); and public offerring on the Vancouver Stock Exchange.

Marketing / Regulatory Studies Stage

The consensus is that this stage is extremely difficult.

Possibilities as above. Canada is lacking "success stories" that would attract investment.

Early Manufacturing / Marketing Stage

The consensus is that this stage is easier.

Possibilities are: venture capital; strategic/marketing partners; and private placements.

Full-Scale Manufacturing / Marketing Stage

The consensus is that funds are available from many sources.

Possibilities are: venture capital; strategic/marketing partners; private placements; public offerings; and R&D collaborations.

Finally, a scenario of steps necessary to go from idea to success, based on the experiences and inputs of these four companies could be described as follows:

1. Idea;
2. Determine if a market for the idea really exists;
3. Develop a strong management team and Board of Directors;
    A. general management
    B. strong financial person
    C. technological expertise
    D. marketing expertise
    E. process development expertise (to be able to manufacture enough to meet demand)
    F. manufacturing expertise
    G. clinical research expertise

4. Find funding;
5. Set up strategic alliances with strong players in target markets;
6. Establish credibility with investors, media, and government every step of the way, by all means possible; and
7. Expect to spend more time and money than your greatest estimates.

APPENDIX 1A
INDIVIDUALS CONTACTED FOR CAPITAL/INVESTMENT AVAILABILITY/ACCESSIBILITY SECTION

1. Rashed Aziz
   Quadra Logics Technologies
   Vancouver, B.C.

2. Mitch Baran
   Trudell Medical Group
   London, Ontario

3. Richard Bonnycastle
   Cavendish Investing
   Toronto, Ontario

4. Al Brooks
   Halberg/Brook Tonometer/Keratonometer Inc
   Los Angles, California

5. Sandra Boucher
   M.D. Management Company
   Ottawa, Ontario

6. Caroline Brown
   Research Triangle
   North Carolina

7. Doug Byrd
   Triangle East of North Carolina, Inc
   Zebulon, North Carolina

8. Michael Cannata
   Quantified Signal Imaging
   Toronto, Ontario

9. Bill Chatham
   Chatham and Associates
   Hamilton, Ontario

10. Gordon Cornelius
    Ingram and Bell
    Toronto, Ontario

11. Scott Delgaty
Midland Doherty
Montreal, Quebec

12. Tom Dougherty
Ernst and Young
Minneapolis, Minnesota

13. Jeff Dreben
First Venture Founders Corporation
Toronto, Ontario

14. Kathleen Engle
Department of Trade and Economic Development
Seattle, Washington

15. David Evans,
Nordion
Ottawa, Ontario

16. Morley English
Department of Finance
Ottawa, Canada

17. Dale Foster
Fleet Aerospace
Culver City, California

18. Anne Gray,
Prince William County Economic Development
Prince William,Virginia

19. Chris Hanna
ADI Technologies
Vancouver, B.C.

20. Allen Hans
Allen Hans and Associates
Tarzana, California

21. Steve Hayter
ADI Diagnostics
Toronto, Ontario

22. Charlie Hodgins
First Merchants Equity
Saskatoon, Saskatchewan

23. Jim Hoggan
James Hoggan & Associates
Vancouver, B.C.

24. Harvey Jefferbaum
Plants, Sites and Parks
Coral Springs, Florida

25. Ron Jevning
Micro Medical Systems
Los Angles, California

26. David Johnson
BCIT
Vancouver, B.C.

27. John Kane
Kane and Associates
New York, N.Y.

28. Nancy Kay
Plant, Sites and Parks
Coral Springs,Florida

29. David Kolzow
Greater Tucson Economic Council
Tucson, Arizona

30. Ignace Krizancic
Vanguard Management
Toronto, Ontario

31. Mitch Kostuch
SB Capital
Toronto, Ontario

32. Giles Lessard
CRIQ
Montreal, Quebec

33. John Lindsay
TRIDEC
Washington, U.S.A.

34. Richard Lockie,
MDS Health Ventures
Toronto, Ontario

35. Frederick Mas,
French Industrial Development Agency
Chicago, Illinois

36. Tom Meskan
Medical Alley
Minneapolis, Minnesota

37. Bill Motley
Abbott Labs
Toronto, Ontario

38. Carol Muirhead
Department of Finance
Ottawa, Canada

39. Ken Murray
Deloite Touche
Ottawa, Ontario

40. Jerry Noren
Noren and Partners
Moose Jaw, Saskatchewan

41. Dave Patterson
Johnson & Johnson
Toronto, Ontario

42. Dr. Dave Patriquin
Dalhousie University
Halifax, Nova Scotia

43. Bob Pepper
Pepper/Weberg
Toronto, Ontario

44. Richard Picard
Quebec Ministry of Trade
Hull, Quebec

45. John Power
Power and Associates
New York, N.Y.

46. James Reis
World Trade Centre
Denver, Colorado

47. Kevin Reilly
Everest Medical Corp.
Minneapolis, Minnesota

48. John Rhodes
British Information Service
Chicago, Illinois

49. Richard Robertson
North Carolina Department of Economic Development
Winston Salem, North Carolina

50. Ross Stansfield
Zeus Mineral Corporation
Calgary, Alberta

51. Jerry Tapp
Industry Science and Technology Canada
Ottawa, Canada

52. Bill Toms
Department of Finance
Ottawa, Canada

53. April Valentine
Economic Development Office
Bristol, England

54. Frank Warland
Theratronics
Toronto, Ontario

55. Carl Zanon
North Star Consulting
Saskatoon, Saskatchewan

APPENDIX B
CAPITAL/INVESTMENT AVAILABILITY/ACCESSIBILITY SECTION - QUESTIONNAIRE

I-INVESTMENT COMMUNITY PARTICIPATION IN MEDICAL DEVICES FUNDING QUESTIONNAIRE:

Dates: INTRVW_____ PERM SENT_____ PERM REC._____
NAME:_____TITLE:_____
COMPANY_____
ADDRESS:_____
TEL:_____ FAX_____

1. How can the government improve the availability and accessibility of investment capital for various stages of company development for the medical devices industry?

2. How can the private and corporate investors improve the availability and accessibility of investment capital for various stages of company development for the medical devices industry?

3. Is it possible to get world class players involved in the medical devices industry in Canada?

4. What other options do companies have other than turning over large portions of their equity to investors?

5. How is it possible to increase the level of interest and investment of the private investment community in the medical devices field?

6 What is required of a company or investment to allow for a patience return of capital over a longer period?

7. How can the linkages between the investment community and the medical devices industry be strengthened in early and later stage financing?

8 Which sources might be most amenable to increasing investment in the medical devices sector and for which stage?

9 What methods should be used to attract funds to the medical devices industry? (seminars, medical publications etc.)

10. How can Canada improve the resident expertise or access expertise on medical devices in the financial community?

11. How can Canada improve the resident expertise or access expertise on medical devices in the technology community?

12. Who should be on an expert panel for these technical reviews and what would be the cost?

13 Are there consultants available to do the technical evaluations?

14. How do the consultants become known to the investment community?

15 What has Canada got to offer investors in other nations to attract theirfunds?

16 What options are available to have joint ventures with companies in other nations?

17. What role could the different stock exchanges play in funding medical devices technologies?

18 Would a multiple company investment fund be possible to finance on an exchange and if so which ones?

19. What are the major concerns to be dealt with in structuring a private offering?

20. What level of return do investors look for in different types of investments?

21 How much security is required to attract private funding?

22 Do private investors require to have majority ownership of companies?

23 Are medical devices companies able to self-finance?

24 How many rounds of financing do medical devices companies normally require before they are self-sufficient?

II-ANALYSIS OF EXISTING VENTURE CAPITAL AND INVESTMENT FUNDS/PROGRAMS QUESTIONNAIRE

Dates: INTRVW_____ PERM SENT_____ PERM REC._____
NAME:_____TITLE:_____
COMPANY_____
ADDRESS:_____
TEL:_____ FAX_____

1. How does the investment community view the medical devices industry in Canada? In the U.S.?

2 How is it possible to create a favourable view of the medical devices industry so as to attract investors over the 5% that is presently being invested in Canada?

3. What are the best sources to evaluate the venture capital community? How much money do they invest, where do they invest and at what stages do they invest?

4. What are the best procedures for the medical devices companies to connect with the venture capital and vice versa?

5 How many Canadian venture capital companies invest in medical technologies and what is their success rate?

6 How many venture capital companies would invest in this industry if more information and support was provided?

7. How many venture capital companies in the U.S. invest in medical devices companies and what is their success rate?

8. What rate of return do venture capital companies expect?

9. From the point of view of Venture Capital, what role does MEDEC and TIMEC have to play?

10 At what stage would venture capital consider investing in medical devices companies?

11 Would a pooled group of medical devices companies be of more interest to venture capital companies?

III-MEDICAL DEVICES INVESTMENT FUND QUESTIONNAIRE

Dates: INTRVW_____ PERM SENT_____ PERM REC._____
NAME:_____TITLE:_____
COMPANY_____
ADDRESS:_____
TEL:_____ FAX_____

1 Is there a need for an investment fund for medical devices for the early stage of development?

2 In what areas should an investment fund be directed--start-ups, first stage, or mezzanine export initiatives?

3. By whom and how should such a fund be managed?

4. Is there a need for ISTC to contribute seed capital to such a fund with the majority of the capital coming from the private sector?

5. What should ISTC accountability strategy be if it invests seed capital?

6 What would be the necessary investment strategy to attract strong new companies to Canada?

7. Who would evaluate the investment proposals, industry, government or a combined board?

8. What should be the size of the fund?

9. What should be the maximum investment in any one company? Should the fund require private sector partnership?

10 What should be the selection criteria for an investment?

11 Should the fund just have private financing, just government financing or both?

12 What form should the pay-back take (equity, interest, royalty) and what rate of return should be expected?

13. Should the companies funded be located across the country or in one area, and if so, where?

14. Should Universities be involved in the fund, and if so, in what manner?

15 What is the best way to connect the new fund with the existing financial community?

16 Should there be any limitations on foreign ownership as long as the research, development and manufacturing is done in Canada?

IV-ANALYSIS OF EXISTING AND POTENTIAL TAX INCENTIVES QUESTIONNAIRE

Dates: INTRVW_____ PERM SENT_____ PERM REC._____
NAME:_____TITLE:_____
COMPANY_____
ADDRESS:_____
TEL:_____ FAX_____
Section IV - Tax Incentives

1. What particular tax measures used for other industry sectors might have a favourable impact for the medical devices industry--flow-through shares; Quebec Stock Saving Program; Investment Tax Credits; or RRSP eligibility for certain investments?

2. What is the best approach in trying to gain government acceptance for Tax incentives for technology investments?

3. Is there evidence that special tax incentives have stimulated other sectors (e.g. flow-through shares)?

4. What improvement could be made on the weaknesses of past programs?

5. Are there innovative, more effective, ways of using the existing R&D tax credit programs in combination with other government programs?

6. What federal tax incentives already exist for medical devices companies?

7. What provincial tax incentives already exist for medical devices companies?

8. What would investors want in a tax incentive that would attract them to a high risk investment?

9. What should the federal or provincial government receive in return for the tax incentive?

10. Should there be a federal program to match programs such as SBDC in Ontario or other provincial programs?

TYPE B - SPECIFIC QUESTIONS:

Dates: INTRVW_____ PERM SENT_____ PERM REC._____
NAME:_____TITLE:_____
COMPANY_____
ADDRESS:_____
TEL:_____ FAX_____

1. What is the size of the Medical devices industry in Canada, in the U.S.?

2. Where do you find world class players in the medical devices area?

3. What is the prominent area for medical devices in Canada, United States and the EC?

4. How can industry and government improve the flow of information about the successes and opportunities in the medical devices industry?

5. What are the critical information needs and key factors for the acceptance of a company or product in the investment community?

6. What role can MEDEC and TIMEC play in bringing together the necessary expertise for specific technical reviews?

7. How does the government and the medical devices industry get the investment community to accept the idea that there is a need for a group of resident experts?

8. Are there examples of investment enhancement programs in other countries (United States, ECC or Japan)?

9. What role could Universities play in attracting the investment community o the medical devices industry?

10. At what stage of a company's development should a company try to go public on an exchange? (for Vancouver, Toronto, Alberta, Montreal).

11. How does the success rate in high technology industry compare with the Oil and Mining industries?

12. What rate of return do the oil and mining industries provide to attract funds to their investments?

13. What is the rate of success of oil and mining investments?

14. Do banks have any role to play in the funding of high technology companies, and if so, at what stage?

15. Is there a way to structure investment tax credits so that banks would except them as collateral for loans?

16. How does the medical devices industry overcome the perception that it is small and diverse?

17. How could the FBDB (Federal Business Development Bank) be made more available/accessible to the medical devices sector?

18. How can existing programs be combined creatively to be more attractive to investors and companies?

19. How can existing programs and new combinations be promoted?

20 What is the provincial approach to the medical devices industry and are any provinces putting special emphasis on this industry?

21 What role can the special funding programs such as the Small Business Development Corporation in Ontario, Small Business Equity Corporation in Alberta, and similar programs in other provinces play in the funding of medical devices companies?

22. How would a new investment fund affect or fit with FBDB and MDS?

23. What would be the role, if any, of MEDEC, TIMEC, ISTC, NRC, and FBDB in connection with a new fund?

24. What would be the nature and structure of any financial contribution from ISTC?

25. Should ISTC have a buy-back option such as that provided by the Vencap fund?

26. How could a new fund avoid the problems that were created by the IDEA Corporation in Ontario?

27. How can the required support technicians and consultants be attracted to the areas where the companies will be located and is it necessary for the consultant to be located in the same area as the companies?

28. Are there studies which show that the level of investment in a sector increase significantly as result of a specific tax incentive and was this increase maintained?

29. How could the Immigrant Investor Program administered by Employment and Immigration Canada (EIC) be made more available/accessible to the medical devices sector?

30. What is the feasibility and appropriateness of working with EIC to find a way of having immigrant investment directed to include a focus toward emerging/developing businesses?

APPENDIX 1C
PERSONS CONTACTED FOR CASE STUDIES

Steven Hayter
President
ADI Diagnostics Inc.
Rexdale, Ontario

Rashid Aziz
Vice President and Chief Financial Officer
Quadra Logic Technologies Inc.
Vancouver, B.C.

Dr. Francesco Bellini
President
IAF BioChem International Inc.
Montreal, Quebec

APPENDIX 1D
CASE STUDY QUESTIONNAIRE

1. YEAR FOUNDED?

2. PRODUCTS?

3. EXPORT MARKETS?

4. NO. EMPLOYEES?

5. SIZE OF PLANT?

6. TOTAL REVENUES 1989?

7. TOTAL REVENUES 1990 (PROJECTED)?

8. TOTAL REVENUES 1991 (PROJECTED)?

9. HOW DID YOUR COMPANY GET STARTED?

10. HOW DID YOU FIND YOUR TECHNOLOGY?

11. WHAT WAS YOUR PHILOSOPHY AT THE BEGINNING CONCERNING OWNERSHIP (RETAIN 100%, WILLING TO GIVE UP STOCK FOR $, WILLING TO FORM STRATEGIC ALLIANCES, ETC.)? HAS IT CHANGED OVER TIME?

12. HOW MUCH FINANCING WAS RAISED AT EACH OF THE FOLLOWING STAGES OF DEVELOPMENT, AND FROM WHERE (INCLUDE GRANTS, VENTURE CAPITAL, PRIVATE PLACEMENTS, PUBLIC OFFERINGS ETC.):
    A. START UP / R&D
    B. PROTOTYPE
    C. MARKETING / REGULATORY STUDIES
    D. EARLY MANUFACTURING / MARKETING
    E. FULL SCALE MANUFACTURING / MARKETING

13. WOULD A SPECIAL GOVERNMENT FUND FOR MEDICAL DEVICE COMPANIES HAVE BEEN OF USE TO YOU FOR FUNDING AT ANY OF YOUR COMPANY'S STAGES IF DEVELOPMENT? DO YOU THINK THIS IS A GOOD IDEA IN GENERAL?

14. WHAT WAS THE EXPECTED RATE OF RETURN ON INVESTMENTS IN YOUR COMPANY - OVER WHAT TIME PERIOD?

15. DID YOU TRY TO RAISE CAPITAL OUTSIDE OF CANADA AND HOW SUCCESSFUL WERE YOU?

16. WERE TAX INCENTIVES INVOLVED IN THE FINANCING - WOULD THEY HAVE BEEN OF ASSISTANCE IN RAISING FUNDS?

17. WHAT ATTRACTED INVESTORS TO YOUR COMPANY AND CONVINCED THEM TO INVEST - MANAGEMENT, PRODUCTS, BOTH?

18. HOW DIFFERENT ARE YOUR PRODUCTS NOW FROM THE INITIAL PRODUCT CONCEPTS UPON WHICH THE COMPANY WAS STARTED?

19. HOW DID YOUR COMPANY KEEP ITS INVESTORS SATISFIED UNTIL THERE WAS A RETURN ON INVESTMENT, OR WERE THERE EARLY RETURNS TO INVESTORS?

20. WHAT ARE THE BEST AVAILABLE SOURCES OF FUNDING FOR COMPANIES AT THE FOLLOWING STAGES OF DEVELOPMENT:
    A. START UP / R&D
    B. PROTOTYPE
    C. MARKETING / REGULATORY STUDIES
    D. EARLY MANUFACTURING / MARKETING
    E. FULL SCALE MANUFACTURING / MARKETING

21. ANY OTHER ADVICE OR INSIGHTS TO HELP OTHER START UP COMPANIES OBTAIN FINANCING?

22. DID YOU HIRE EXPERIENCED MANAGERS? IF SO, WHEN, AND WHERE DID YOU FIND THEM

23. HOW ARE YOUR PRODUCTS DISTRIBUTED (LINKS WITH LARGER COMPANIES, OWN SALES FORCE, ETC.)?

24. HOW DID YOU PENETRATE THE CANADIAN MARKET?

25. WHAT WAS YOUR MARKETING STRATEGY?

26. IF YOU COULD BOIL IT DOWN TO A SINGLE QUESTION, HOW WOULD YOU SAY YOUR COMPANY BECAME SUCCESSFUL?

27. IF YOU WERE TO LIST THE STEPS OF ACTION FOR A COMPANY TO GO FROM IDEA TO SUCCESS, WHAT WOULD THEY BE?

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2.0 Human Resources Accessibility/Availability

2.0 HUMAN RESOURCES AVAILABILITY AND ACCESSIBILITY

2.1 INTRODUCTION

Immediate, short- and medium-term requirements in the Canadian medical devices industry have been identified below. Long-term human resource requirements for the industry are unclear at this time. It depends on the success of the industry in the next three to four years. The industry is at a critical point in its development. There is a window of opportunity but it is rapidly closing.

2.2 OBJECTIVE

The objective of this study is to determine what can be done to improve the availability and accessibility of personnel educated and trained in skilled positions, (e.g. marketing, management, process control/design), for the Canadian medical devices industry.

2.3 SCOPE

This study focusses on the Canadian medical devices industry, but extends its investigation of potential human resource sources to the U.S., the EC and Japan. No attempt has been made to break human resource needs down by sector or subsector as an analysis of that depth would be beyond the scope of this study.

The observations contained in this section of the report are primarily derived from a small sample of representatives from the industry sectors. Consequently, they do not necessarily reflect the attitudes and experiences of all the individuals involved in the industry. They are supported by information gathered in literature[1] and by industry members with whom some of the findings were discussed.

No attempt was made to conduct any quantitative analysis to derive conclusions that are statistically significant. Instead, general directions and trends are revealed in the presented findings and the options that are proposed.

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[1] Volume I. Meeting the Challenge: An Overview of the Medical Devices Sector Initiative. Volume II. (Pilot Scale) Strategic Analysis of Six Medical Devices Industry Subsectors. Health Care Products Division, Biotechnology and Health Care Products Directorate, Resource Processing Industries Branch, Industry, Science and Technology Canada. August 1989

In addition, the status of planned and existing programs by organizations such as MEDEC and TIMEC have not been investigated in depth. These programs are undergoing significant change and it is not clear as to the roles which each organization will play in program development and management in the future.

2.3 METHODOLOGY

The methodology employed for this study on the human resources includes interviews with 16 senior executives of Canadian medical device companies,[2] [3] eight senior government officials, three associations and a review of literature and government publications regarding existing programs.

An interview questionnaire was developed to identify specific information sought under each section of the study. The interview questionnaire is attached in Appendix A.

The criteria used for selecting the companies to be interviewed endeavoured to capture a wide cross-section of companies and products in the Canadian marketplace. The criteria included the following:

a) Young Canadian companies (less than 8 years old) with new products brought to the market within the last three years.

b) Companies located in western and central Canada and in the Maritimes that represent the following products: medical-surgical supplies, assistive devices, implants, diagnostic and general hospital equipment.

d) Canadian subsidiaries or distributors of an American product(s).

The purpose of the above criteria was to ensure that an industry cross-section of the Canadian market was tapped and to compare diverse viewpoints on human resource requirements in this industry.

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2 Canadian Medical Device Directory. Biotechnology and Health Care Products Directorate, Department of Regional Industrial Expansion, 1988

3 Business Opportunities Sourcing System (B.O.S.S.). July 1990

2.5 ANALYSIS AND FINDINGS

2.5.1 GENERAL ISSUES

HUMAN RESOURCE REQUIREMENTS

Generally speaking, large companies are able to take care of their human resource requirements internally or have little trouble fulfilling these needs from the local or domestic work force. In several instances the companies interviewed for this study were either down-sizing or not expanding their work force. Even so, there may still be critical positions to be filled, e.g. computer programmers with a physics background, specialty machinists, etc. Local institutions of higher education often provide training in the generic skills required for management personnel in the medical devices industry. Once the individual commences employment with a company, he is trained in-house for any additional specific skills he requires.

Small- to medium-sized companies, on the other hand, are experiencing difficulties locating and attracting skilled/experienced personnel in the following areas:

- senior manufacturing, process development and operations personnel;
- personnel to conduct or supervise clinical trials;
- development personnel, i.e. applied R&D - those who understand the relationship between research, prototype development and marketing and to set up the entire infrastructure for the business and the industry as a whole. These needs are particularly evident when focussing on niche markets where the company may be somewhat insulated and can build the expertise along the way;
- general management,[4] sales and international marketing expertise, especially U.S.; and
- some requirements for scientists and engineers (e.g. process engineer in some diagnostic firms). However, the needs in this area are much less than pressing than those above.

[4]Hayter S: More Solid Support for Canadian Companies Needed to Reduce Deficit in Medical Devices MEDEC J 1 (3), Summer 1990.

When speaking with investors,[5] the three most important requirements a company seeking financing must fulfill are:

1. management;

2. management; and

3. management.

In most cases, when an investor is approached by an entrepreneur, the proposed venture is focussed on a product-driven rather than market-driven concept However, without a market, there is no business. This is true for virtually all industries, and the medical devices industry is a perfect example.

New companies require the kind of leadership and objectivity that can guide them from concept to commercialization. To begin with, the odds are that most will fail. Business acumen and integrity are of the utmost importance. As any salesperson will espouse -- the customer is buying into the person first, then the product.

In some medical device companies, shop-level personnel who have been perceived to possess leadership capabilities are being promoted into middle-management positions. This breed of middle manger is perceived to be doing a great job. The management function of senior management is being moved down to middle management, leaving the roles of planning and directing at the top. And yet many smaller companies function on a flat structure. The owners may do everything from representing the company at senior meetings, to taking out the trash at night. These owners don't want to move technical people out of their areas of expertise. They feel the technical personnel will be happiest in their current positions, immersed in technical work.

As the Canadian medical devices industry is so small there is a very small base of skilled personnel from which to choose. The industry requires people who are willing to learn and work hard. Recruiting is generally accomplished through agencies, friends and networks within the industry. The latter must be done very diplomatically as there are unspoken rules that one company does not try and approach the employees of another company in this industry. In the past, companies clearly did not attempt to recruit personnel, especially senior personnel, from other Canadian device companies. However, this is not as true today as it may have been even five years ago. An employer must also

5 Roy A. Anderson & Associates. Preliminary Analysis of Venture Capital Investment in the Canadian Medical Devices Industry, March 1990

be careful not to recruit employees of customers. This could certainly prove to be very bad for business.

Canadian medical device companies of any size who wish to penetrate the U.S. market, require experienced people with a strong selling background in the U.S. environment. The Canadian market is negligible compared to the world market or even the U.S. market for many subsectors in this industry. It takes a great deal of capital to attract these people to Canada to sell where they know best -- the U.S. A strategy used by many Canadian device companies is to establish representation in the U.S. where a much larger bank of qualified personnel already exists. Among several options, the most common are forming strategic alliances, joint ventures or U.S. subsidiaries. Such options enable the parent company to easily attract the personnel they require. The employee stays in his own country while working for a Canadian subsidiary or partner.

To avoid the high cost of hiring, training and maintaining their own sales force, small companies will often choose to hire a major distributor to deal with the domestic market. The trade-off is that profit margins are greatly reduced and also, not all distributors represent all products with the same amount of attention. A distributor must be assessed very carefully.

Most medical device companies in Canada are subsidiaries of U.S. or multinational firms and do not manufacture in Canada. They may have done so in the past but have moved their production facilities to the U.S. where manufacturing is less expensive. Companies that do manufacture in Canada are often niche or custom businesses covering areas which the multinationals do not. Because of shrinking markets, due in part to cost containment taking place in the health care industry, many of the larger companies in Canada are reducing their human resource requirements. Because of this down-sizing trend there is already an excess of management personnel in some subsectors and existing companies have the luxury of being more selective than other subsectors in hiring personnel. In many cases, development plans for the larger companies, usually U.S. or multinational subsidiaries, are done at corporate headquarters outside Canada and sent around the world to be adapted to regional needs. Product management, (e.g. R&D, product goals, entire packaging design, brochures, marketing plans, etc.) is done outside Canada. In yet other cases, brochures and marketing plans are done in Canada. In any event, Canada is lacking in personnel with development and product management skills.

It some cases it can be difficult training technical personnel for sales. They tend to be too technically detailed for the average customer and are therefore not as effective as they could be. However, technical knowledge will almost always be required for the sale of medical devices.

Applied research vs. theoretical research is significantly different. A PhD in the latter group with two years experience may earn $55,000 per year. He would encounter difficulty demanding this scale of income in industry.

In order to progress more rapidly from research to delivering market-ready products, the Canadian industry must stimulate the academics in the labs to respond to the urgency of the situation.

The major problem within the Canadian medical device industry is that it is very small. It lacks the critical mass to attract the necessary elements to facilitate its growth into a large thriving industry, e.g. human resources, and strong focussed leadership.

BARRIERS TO IMPORTING MEDICAL DEVICE PERSONNEL

The major barrier to importing human resources to Canada is the cost. In order the meet the American remuneration industry standards, the Canadian company would have to pay an American 1 1/2 to twice the salary of his Canadian counterpart, depending on the position being filled. This takes into consideration the differences in cost of living, personal tax rates and the exchange rate. In addition, from an industry planning perspective, parachuting in personnel from abroad represents a rather short-term approach. It may be fine for an individual company to hire foreign nationals, but a national strategy should aim at self-sufficiency by developing the training programs to train Canadians within Canada.

It is difficult to inspire an American to come to Canada. The climate may not be as pleasing as, say, California. A prospective foreign employee will also want some assurance that the company he is to work for is stable. Also, the change may cause significant corporate culture shock for the imported employee, especially if he leaves a very large firm and has to adapt to the more entrepreneurial style typical of smaller companies. Occasionally one may find a Canadian working in the U.S. medical device industry who is interested in moving back to Canada, but this is very rare.

EMPLOYMENT AND IMMIGRATION CANADA REQUIREMENTS FOR IMPORTING PERSONNEL[6 7 8 9 10]

If an employer decides to import requisite personnel he must prove to his local Employment and Immigration Canada (EIC) office that there are no Canadian residents to fill the job. The employer must show that he has made considerable effort to recruit a Canadian. Depending on the position which the employer is trying to fill, this may not be difficult. It may be hard to convince EIC that no Canadian is available for positions requiring the more generic skills such as marketing. To demonstrate the lack of Canadians trained for specialized work such as process development, would, however, be very easy. Nonetheless, this procedure is in itself expensive. One company interviewed spent $20,000 four years ago to go through this procedure. Proving unavailability of qualified Canadian personnel generally involves advertising nationally in major newspapers and having EIC search their databanks. Once these steps have been taken it is generally not difficult to bring an employee into Canada.

It is easier for an American than persons from other countries to obtain a work permit for Canada because of provisions under the Free Trade Agreement[11] with the U.S.

Once a foreign national has been approved to work in Canada he will receive a working visa for one to two years. This can be renewed as needed without a great deal of difficulty. After a number of years, however, EIC may ask the individual to become a landed immigrant, provided no Canadian has been found to fill the job.

EIC's national office in Ottawa reported that they are not aware of any specific needs of the medical devices industry, although regional offices may have greater knowledge in this regard. The industry is extremely

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6 Employment and Immigration Canada: Business Immigration Program. Government programs, services and contacts.

7 Employment and Immigration Canada: Business Immigration Program. Canada's dynamic Economy.

8 Employment and Immigration Canada: Business Immigration Program. Immigration regulations, guidelines and procedures.

9 Employment and Immigration Canada: Business Immigration Program. Doing business in Canada.

10 Employment and Immigration Canada: Business Immigration Program. The facts.

11 The Free Trade Agreement - Temporary Entry for Business Persons. Employment and Immigration Canada. August, 1989

small and varied. In terms of industrial classifications, EIC is not equipped to keep track of the industry's human resource requirements.

Another option for bringing in a foreign national to work in a Canadian firm is through the Immigrant Investor Program, which is a joint federal and provincial program. The provincial government reviews offering memoranda under this program with respect to economic benefit, while EIC reviews a request for compliance with immigration regulations and guidelines. This process is often slow and therefore perceived to be not very effective. The minimum investment the immigrant is required to make under this plan is $250,000, except in B.C., Ontario and Quebec, where it is $350,000. Prior to December 7, 1990, these minimums were $150,000 and $250,000 respectively.

In Japan personnel start their employment with a company about one year before they graduate from university. They proceed to work for that company until they retire. Switching companies several times during one's working career is not highly looked upon. Not withstanding the extremely high costs involved, this cultural characteristic would make it very difficult for a Canadian firm to recruit Japanese medical device personnel directly from Japan.

COMPETITIVENESS OF CANADIAN SALARIES

As already mentioned above, salaries in the U.S. are significantly higher for skilled personnel than in Canada. Salaries in Europe seem to be higher as well. From an employer's viewpoint, employee benefits are also much higher in Europe, for example, many employees have company cars. The higher the employee in the organization, the more expensive the car must be. Salaries in Japan may also be very high, however, Canada may be able to offer a comparatively higher standard of living.

It may be most economical to import personnel from India or the U.K. India has gained the reputation for having achieved a great deal of expertise in software development.

2.5.2 CO-OP PROGRAM

NEEDS WITHIN THE MEDICAL DEVICES INDUSTRY FOR A CO-OP PROGRAM

The co-op student program is an individual relationship between a company and the college or university which the student is attending. Industry has indicated that organizations such as MEDEC, TIMEC or

ISTC could assist primarily in helping to identify specific training needs within the industry and to provide a liaison between the industry and the co-op educational institutions.

The co-op program could create real benefits for the medical devices industry.

FEASIBILITY OF A MEDICAL DEVICES INDUSTRY CO-OP PROGRAM

Even though there was a positive response to the possible use of co-op students in the industry, consolidation and down-sizing trends within the larger medical device companies may make it difficult for co-op students to be gainfully employed within the industry at this time. In general, however, these companies would much rather have someone who is already trained in management. If these same companies were in an expansion mode, they may very well consider a co-op student, but not now.

Those companies who do hire business co-op students are rarely able to find someone with a background in medical devices. Perhaps nursing or engineering co-op students are more likely to be available.

EXISTING CO-OP PROGRAMS TO MODEL FROM

The co-op program works out well for short term or special assignments. There are about 85 educational institutions across Canada participating in co-op programs within the industry. About 25% of these students are in business faculties. The average age for co-op students is 25.

The Canadian Association for Cooperative Education, (CAFCE), governs all co-op programs. Universities are accredited through CAFCE. A university is required to have one set of graduates in order to apply for accreditation.

Admission for co-op students is usually quite selective. The students have, in a sense, been pre-screened. They are generally people who can work independently, are eager to work and have good leadership qualities. Companies can recruit valuable employees before they graduate. The students, in turn, circulate information about particular employment conditions in various companies.

Co-op students are available year-round. A new student can be employed every four months. The student then goes back to school for

the next four months and keeps alternating in this fashion until graduation. The student's co-op study program allows for one work semester to extend up to a total of eight months.

Wages for co-op students range from $450-660/week with an average of approximately $515. Generally no additional benefits are paid to the student. In most cases this program allows co-op students to complete their eduction without having to take out student loans.

MBA students from the University of Windsor co-op program are currently working in three or four larger medical firms. The university has about 15 science and nursing students who would be eager to work in the medical devices industry. Many science students come back for MBAs.

Universities have different specialities. For example, the University of Waterloo offers co-op in everything but business, whereas the University of Windsor offers a co-op MBA program.

It would be very valuable for co-op students to get some international experience during their work semester. It may be possible for students to gain international experience by aligning Canadian co-op institutions with the European community and Japan through their embassies and universities in those countries. Of particular interest would be any international business schools, e.g. York University's Faculty of Administrative Studies. Here, students completing the core MBA and special international management course, spend up to six months abroad on a working internship and a student exchange at another international business school. Foreign language capabilities would be a definite asset as it is always easier to do business in the language of the country. However, this is not a requirement.

In summary, attractive features of the co-op program are:
- the co-op students often offer a fresh approach for special projects;
- the program can be molded to suit the needs of the employer;
- co-op students tend to outperform non-co-op counterparts. They are looking for career possibilities. In many cases the co-op students go back to apply for full-time work in the company they co-oped in. In school they share the information with other students.

Another model of industry/educational program is the Natural Science and Engineering Research Council (NSERC). NSERC conducts research and provides grants for individuals to continue with graduate or postgraduate studies, postdoctoral fellowships and industrial fellowships. Scholarships are available for Canadians who want to

continue their training. It was reported that NSERC needs to be informed of the state of medical device development in Canada. This would eventually reduce the need to recruit personnel from foreign countries.

WHO SHOULD PARTICIPATE?

Universities, colleges, and specialized training institutions would participate as suppliers of training programs which require co-op students to intern in industry. Within the current business climate of the medical devices industry, the most likely size of company to participate within the industry would be smaller to medium-sized companies.

The primary benefit of co-op students to the medical devices industry is the channelling and focussing of specific training programs to meet the industry's needs.

CO-FUNDING REQUIREMENTS

A major obstacle to participation in the co-op program by smaller companies has been the cost. It was found that financial assistance in the form of co-funding would be very helpful.

In the past, the B.C. government supported co-op employers by paying up to 25% of the co-op student's salary. This was found to be very useful as it makes it much easier for employers to participate, for the only weakness in the whole co-op program is the salary cost to the small business employer.

Unionized environments can create a problem in some co-op situations but this usually doesn't come into play in management positions.

2.5.3 EMPLOYEE EXCHANGE PROGRAM

WHO SHOULD PARTICIPATE?

Employee exchanges would be of greatest value wherever greater communication is required. In general, industry would like to provide anyone in government with the direct industry point of view.

A consensus was observed within the industry that they should be looking at exchange programs in the future, although some employers report that they simply don't see any advantage to exchange programs for their businesses.

The most valuable exchange program for this industry would involve the participation of personnel with knowledge of the U.S. FDA. This would be of more value than an exchange with personnel from HPB in view of the volume of Canadian products going to the U.S. The problem with an exchange of this nature for most smaller Canadian device companies is that they may only have two or three people in their organization working in the regulatory area. The risk of an employee seeking employment in the U.S. after his tenure with the FDA may be too high for a Canadian employer.

Another exchange possibility raised during interview sessions is through the Economic Development Corporation (EDC). Such an exchange might eventually help a company's sales in some countries.

An exchange with someone from the Canadian consulate in Japan would be a valuable opportunity for many device companies. It could give them important insight into that market place and the whole export environment. The Japanese mind-set and culture is very different to Canada's. An exchange duration as short as two weeks could be of great value. In the same vein, exchange input from CIDA personnel may provide similar benefits to the Canadian industry.

In some instances companies are already doing exchanges with scientists from universities (e.g. University of Manitoba) and the Laboratory Centre for Disease Control (LCDS). Research agency personnel in exchange with industry players are valuable in that they allow researchers to get a better feel for the market place.

An important consideration for employee exchange will always be the size of the company. Removal of one person from a small company may create serious problems. A learning curve will always be expected when introducing new personnel. A small company may not have the time and energy to go through this learning curve as they are usually

trying to run with a minimum number of people who are often overextending themselves.

Smaller companies, in which it may be very difficult to exchange personnel, would be open to hosting appropriate government personnel. Short periods of even a couple of weeks may prove valuable.

EXISTING MODELS

International Executive Exchanges

It is easier for multinational companies to exchange executives than to recruit untried personnel, however, the exchange of executives would cost significantly more than a newly hired Canadian counterpart.

Interchange Canada

Interchange Canada[12] is a federal government program overseen by the Public Service Commission of Canada (PSC), established to exchange federal public servants with: provincial governments, universities, the private sector and non-profit organizations including associations.

Under this program, the federal public servant remains on the government payroll. The recipient organization is required to reimburse the federal government for the salary and benefits the individual receives during their exchange employment.

Full reimbursement of salaries and benefits is required for placements within the private sector. However if the federal public servant is placed with a provincial government, university or non-profit organization, assistance may be provided by the federal government. This assistance would be in the form of reduced reimbursement of salary or benefits. Approval for this would come from the Deputy Ministry of the ministry the public servant comes from.

For every interchange, a four-page agreement is signed by a senior executive of the participating organization, (usually the CEO), the Deputy Ministry of the ministry the public servant comes from, the participant, and an executive director at the PSC. Included within this agreement is a clause which states that the participant will not be offered any continuing work with the host organization after the term of exchange. In some cases it is possible for the participant to stay on providing all parties agree, that is, the participant, the host organization and the home organization.

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12 Public Service Commission of Canada: Interchange Canada Fact Sheets

Each year during the exchange placement, the host organization is requested to submit a performance appraisal to Interchange Canada and this in turn is sent to the personnel office in the ministry or department they came from.

The participant's relocation is a 50/50 shared responsibility. The recipient organization pays the relocation expenses. The home organization pays the expenses to move the employee back. Relocation expenses are per the rates set by the Treasury Board of Canada.

The duration of assignments are a minimum of six months, maximum of three years. Extensions can be made for a maximum total placement of five years, but this would have to be approved by the Treasury Board. The PSC can only approve maximum stays of three years.

An interchange representative, working in the provincial government's personnel office (human resources branches), feeds placement opportunities to the PSC Interchange office in Ottawa. Ottawa then provides the marketing function of placing these individuals within host organizations. Practically speaking, however, if a civil servant knows a company he wants to exchange with, it can make the whole process much easier.

Interchange placements only take place with senior management having the following salary ranges:

SM-2,	$60,000 maximum,	works for project leaders, analytical work, collection of data, etc;
SM-1,	$67,000 maximum,	commercial officers, project leaders;
SM,	$69,200 maximum;	
EX 1,	$78,300 maximum,	Directors, and;
EX 2	$86,900 maximum	Director Generals.

Interchange Canada works with University and provincial government interchange participants with salaries in the range of $45,000 a year.

The Interchange Canada program can also bring private sector participants into the government. The industry participant identifies an exchange opportunity. That department communicates their request to PSC and PSC prepares all the necessary documents and agreements.

2.5.4 MANAGEMENT TRAINING AND DEVELOPMENT PROGRAM

INDUSTRY NEEDS

It is commonly agreed within the industry that management training is badly needed in the vast majority of companies, which tend to be small and entrepreneurial in nature. People starting up a business for the first time in this industry usually come from a technical background and have little or no business experience or know-how. It is essential that they gain business knowledge. Probably the biggest problem in these start-ups is that these entrepreneurs often have the "know-it-all" or "can-do-it-all-myself" attitude. They need basic management skills, e.g. ability to raise capital and to convince an investor they are competent managers. They need to have a good feeling for marketing, administration, and research and development.

A broad variety of generic management training courses are available and widely marketed. Many medical device executives polled in this survey feel that these generic management training courses are sufficient.

In addition to the knowledge gained from these training courses, another major benefit involves meeting and networking with others in the industry.

In some cities, industry leaders are already meeting with educators to identify future human resource needs and specific courses for management and other levels, to be integrated into college curricula.

Even with the current recession, companies realize that they can't afford not to upgrade, especially the high tech companies. With the scarce human and financial resources available, companies try to cross-train as much as possible.

In some provinces, especially Ontario, assistance is already available for training and upgrading personnel. Under the Ontario Skills Development Program (OSDP) consulting services are offered to help employers meet their business objectives through a planned approach to training. In addition, under OSDP, training subsidies of up to 80% of the cost of training can be provided.

The company pays for the initial training. The company is reimbursed once OSDP receives documentation to verify that the company has paid the said fees. The mandate this year is that rebates for companies with less than 50 employees are 80%; for companies with 51 to 100

employees, 70%; and for companies with over over 150 employees, rebates are 60%. A maximum of $40,000 is available to any one company each year. The OSDP Ottawa regional centre budget is $2.2 million for fiscal year ending March 31, 1991. The total Ontario budget is approximately $60 million for the same period. It is expected to increase next year.

Interested companies contact the Ontario Skills Development Office in their area, fill out a questionnaire and submit a proposal outlining their training development needs and implementation plans. The applicant is then asked to meet with a training consultant in OSDP to review the application. There are no set criteria for approval for this program applications.

OSDP acts strictly as a consultant but does maintain a database of trainers, including colleges and private consultants, and covers a large range of skills. OSDP works in partnership with community colleges. OSDP will not advise as to the selection of trainers, leaving that decision strictly up to the company.

OSDP consultants assist companies in human resource planning. The fee for this service is $250. Most companies are taken on for about one year during which time a consultant follows their training plans and advises them as to appropriate steps to take.

For the most part, OSDP will work with employers who have been in business for more than five years and who have more than five employees. The reason is that companies not possessing these characteristics will not yet have developed a strong commitment to employee training. The only group they may take on with less than five employees is a small training company, which requires constant upgrading to stay competitive. Those needing help with business plans are referred to the Federal Business Development Bank.

Most companies who apply to OSDP have an idea of the kind of training they want to do. They may simply need to know how much it will cost and how to organize the process, e.g. who takes the courses. OSDP consultants advise companies on how to follow up on the training, and conduct cost-benefit analyses to determine payback on the total amount they put out, etc.

Each year the provincial government gives OSDP priorities regarding potential program participants. The mandate of the provincial government is to upgrade the skills of Ontario people. The program currently favours manufacturing companies and business services.

OSDP representatives indicated the only similar programs they were aware of existing in Canada were those in the B.C. and Alberta ministries of tourism.

Most training funded under this program takes place in Ontario. However, if appropriate training is not available locally, the program will fund training outside of the province or even abroad. If training is done outside Canada, the company will usually be asked to send trainers who can return to their home office and train others.

It is estimated that 50% of OSDP funding is for training in computers, with the remaining 50% in management training.

SCOPE OF MANAGEMENT TRAINING PROGRAM REQUIREMENTS

Any management training program which would be set up for this industry should cover basic management skills, such as:

- how to write business plans;
- recruiting staff;
- organizational infrastructure;
- quality control;
- setting product goals;
- how to get clinicals done and how much to pay for clinicals;
- financial administration;
- performance measures;
- stress management;
- presentation skills; and
- interpersonal skills;

Interest has been expressed from industry in the value of a health care MBA.

NECESSITY OF FINANCIAL SUPPORT

It was commonly felt that many of the generic management training courses are sufficient in content and scope to meet most needs of the medical device industry. However, the biggest problem is the cost. If at least part of the burden of this cost could be lifted from the employer, many smaller firms could take advantage of such programs. Programs such as the Ontario Skills Development Program could be a great boon to companies in this industry. However, similar assistance may not be available in all provinces.

MANAGEMENT TRAINING PROGRAM COORDINATION

One suggestion was to have an education coordinator at MEDEC to set up programs for personnel within the Canadian Medical devices industry through universities such as York or University of Manitoba, etc.

2.5.5 OTHER TRAINING CONCEPTS

MEDEC's HUMBER COLLEGE PROGRAM

MEDEC's distribution division has a training program currently being conducted at Humber College in Ontario which is going on all winter. It focusses on sales and distribution.

CEO ROUND TABLE

MEDEC has offered a CEO Round Table program in the past and it was reported to be very successful. The desire has been expressed by many industry players to re-establish this well regarded MEDEC program. Similar programs have been offered by the Junior Chamber of Commerce.

Putting together a CEO program is a costly activity. A university can't be used for this type of program. The cost to participate in the program was $2,400 per participant per year. Smaller companies are reluctant to expend scarce resources for programs of this nature until they gain full appreciation of the benefits such a program has to offer.

Sixteen to seventeen CEOs, and only CEOs, were invited to participate in any one Round Table group. No substitutes were accepted. Care was taken to select group participants who were not in competitive businesses. Each business was complementary to the other. Each group was comprised of people with strengths in a variety of backgrounds, e.g. finance, marketing manufacturing, distribution, engineering, etc. Participants were made up of CEO's from small and medium companies and division managers of large companies. This brought experienced managers from larger companies into the group along with entrepreneurs from smaller companies. By this selective approach, the group became its own best teacher.

The program was established to have a minimum of 12 CEO's at each meeting, held one day per month. To emphasize the importance of continuity, members who missed three meetings were invited to withdraw. The group was given its first 12-month program by MEDEC, however thereafter the group chose their own subjects for discussion. Topics covered were varied, e.g. process subjects, dealing

with the government, how to run quality control programs, dealing with the regulatory environment, developing team activity, compensation, team management, etc.

A leading North American expert on the topic for the day was brought in for each session. The meetings would begin with the guest speaker presenting the theoretical side of the day's discussion. The next two hours would be spent in group discussion with the lecturer. The group would have lunch with their guest after which the speaker would leave and the group would proceed to spend the afternoon working together discussing situations and problems any members of the group wished to discuss. In this way, each CEO was able to extract that knowledge applicable to his own business.

As successful as the program was, MEDEC did not have the resources to continue, and the program was discontinued. MEDEC feels that if co-funding of the program were to be made available, it could be set up across the country with groups in Vancouver, Edmonton, Winnipeg, Hamilton, Toronto, and Montreal with regional adaptation where applicable. Smaller centres such as Calgary and Ottawa that wish to offer the CEO Round Table Program could perhaps establish an alliance with other associations having related technologies, e.g. software development, plastics, and chemical the industries, etc.

The CEO Round Table was useful for CEOs but wasn't made available to middle management. Alternatives should be examined to make similar programs available for middle management, run on the basis of group needs. In this situation, however, senior management will have already had to recognize the need for building strong middle management teams.

QUALITY CONTROL PROGRAMS

Quality control is a major area of interest to all device companies, big or small. Quality is the concern of all employees, from the shop floor up, and training in this area is often an ongoing activity for a company, especially the larger ones. Everyone realizes that the bottom line can be enhanced by doing the job right the first time. Some of the larger companies even have their own quality control universities. In other instances, experts are brought into the company to provide training in this area.

Various quality control training programs are available to choose from. An example of one such system is the Cosby Quality Control System where each employee treats each other as customers and suppliers. They think in terms of resolving problems within a defined structure.

Requirements are agreed to up front. The supplier supplies the product in accordance with predetermined requirements. Zero defect is the standard. One U.S. subsidiary in Canada with about 300 employees has been involved with this program and works with about 20 employees at a time -- two hours per session, two times per week. They began the program in the U.S. about seven years ago and it has proved to be very successful, however it does take a great deal of attention and constant revitalization to become effective. In this particular company, it took about five years before the program became an integral part of the corporate culture.

The concepts are taught in such a manner as to become part of the employee's family life right up to the work place. It's a major cultural undertaking, but is necessary. These quality concepts have a major role in Japanese success and have become very popular in the U.S. Cadillac, for example, implemented major quality control programs and has recently received a quality award, which represents a major step forward for this corporation.

SUGGESTED ALTERNATIVES

Some suggested alternatives for management training programs are home study and video conferences on specific topics. These conferences could last two hours, two times per week.

2.6 OPTIONS

Several interviews and working group meetings brought up the concept of developing a focussed strategy for the Canadian medical devices industry. This involves identifying the areas of greatest opportunity and building on Canada's strengths to optimize these opportunities. This means that some sectors, subsectors, and companies may receive more attention than others. With the limited resources and energy available, Canada cannot afford to treat all as equals. This process takes place quite automatically in nature -- survival of the fittest. It also takes place in a freely functioning capitalistic system.

This may be a difficult concept for some to accept, but it is a necessity. To spread the limited resources thinly over some 500 companies would be ineffective. A selection process must take place. Decisions of who to support and who not to support are major. The Strategic Analysis of the Canadian Medical Devices Industry, conducted by other consultants, should point the direction of greatest opportunity for the Canadian industry for at least the next few years to come, if not more.

When interventions such as co-funding are put in place by 'outside' elements, caution must be taken to avoid creating an excessively artificial situation which, over time, creates imbalances that may be harder to rectify than problems which could arise if the system were left on its own. Such outside interventions may even prove to be a complete waste of time and energy.

Any intervention options, including but not limited to those listed below, should be applied to those sectors, subsectors and companies which have the greatest potential for achieving the goals of this sector campaign. To accomplish this, a screening process must be established. It should be simple, fast and efficient, and applicable to all companies applying for any assistance under this sector campaign.

How this screening process would be implemented is the subject of further discussion within the various working groups and the Kananaskis Workshop in early February. One process for consideration would be some form of peer review. Peer review committees could be established regionally. Under this scenario, any company requesting assistance from the programs set under this sector initiative would be evaluated for their 'readiness' prior to receiving assistance.

NOTE: For any or all of the options presented in this business climate analysis, co-funding assistance need not come only from ISTC. Provincial assistance may be possible in several cases, and should be strongly encouraged.

2.6.1 MEDICAL DEVICES INDUSTRY HUMAN RESOURCE CENTRE

SCOPE / DESCRIPTION:

The first, and perhaps the most important option put forth in this report, is to establish a Medical Devices Industry Human Resource Centre (the Centre). All further options could operate under this Centre, be carried out independently of the Centre, or be conducted by outside consultants.

The mandate of the Centre would be to develop and maintain human resource self-sufficiency in the Canadian medical devices industry. The initial responsibility of the Centre would be to identify the immediate, short-, medium- and long-term human resource requirements of the Canadian medical devices industry. Having accomplished this, the Centre would act as a liaison between the industry and a variety of

training institutions and programs to ensure that training requirements are met.

The Centre would keep abreast of the various federal and provincial training assistance programs and direct industry members to available assistance, e.g. the Ontario Skills Development Program described earlier in this report (see 2.5.4).

The Centre would make recommendations to government regarding modifications to training programs, or even design training programs which are needed to fulfill industry human resources requirements.

In addition, the Centre could provide a placement service for personnel within the industry. A database could be developed to assist both companies and individuals seeking employment.

RESOURCES:
Initially, the Centre could be established with a manager and one administrative assistant. It could be set up in MEDEC, TIMEC or ISTC, etc. The suggestion is for the Centre to be established in MEDEC as this is seen to be a trade association function. Other human resource options, along with the suggested resources (financial and human) listed below could be added to the responsibilities of the Centre.

Initially this Centre could be set up through funding assistance from ISTC. Member and nonmember fee structures could be established for all services to fund this Centre so that, over time, the Centre would become self-sufficient.

Annual Budget	
Director	$65,000
Administrative Assistant	30,000
Overhead	95,000
Travel	25,000
	$215,000

BENEFITS:

Many training requirements have been outlined by the industry. Establishment of a coordination Centre would provide the Canadian medical devices industry with a structured channel of communication, rapidly assisting with the development of its human resource requirements, and leading to self-sufficiency in the Canadian industry.

IMPLEMENTATION PLAN:

1. Recruit project officer and requisite support staff.
2. Identify the immediate, short-, medium- and long-term human resource requirements of the Canadian medical devices industry. This would be accomplished through initial meetings with major sector players in the industry. Subsequent meetings would take place with industry representatives within the various subsectors in order to fine-tune the understanding of human resource requirements in the industry.
3. Identify all provincial and federal training assistance programs which might assist the medical devices industry, e.g. the Ontario Skills Development Program.
4. Identify gaps in existing training programs and develop strategies to fill in any gaps which may exist. This could be accomplished through a wide variety of methods:
   - develop and/or make suggestions for modification of existing university and college programs;
   - develop and/or make suggestions for modification of existing programs such as the options listed below, e.g. seminars/workshops, co-op student programs, exchange programs, etc. This would be accomplished with the assistance of personnel listed in the following options; and
   - develop and/or make suggestions for modification of existing training programs available through private training organizations, etc.
5. Establish a personnel placement service to assist matching the human resource requirements of medical device companies and personnel experienced in the industry. A database could be set up to assist in this process.
6. Inform industry representatives of the establishment of the program through mailings and publications in the MEDEC Journal.

2.6.2 SEMINARS AND WORKSHOPS

SCOPE / DESCRIPTION:
Through the auspices of a Medical Devices Industry Human Resource Centre, establish sector specific workshops and training seminars.

Seminars could be provided in a number of scenarios, such as:

- CEO Round Table (see 2.5.5);
- given in conjunction with universities and colleges;
- private training consultants;
- video conferences; and
- videotaped training packages, etc.

Invitations for seminars and workshops would extend to all industry members, although the seminars would be designed to address specific needs in given sectors or address the needs of a large number of segments within the sectors. These seminars could consist of industry training tied in with that of colleges and universities. This process would allow Canada to teach and train its own people, drawing on international experts only when needed.

RESOURCES:
Adequate financial assistance for training seems to be readily available in Ontario. Assuming this assistance is also available in other provinces, additional subsidy may not be required over and above the salaries of administrative personnel at the Medical Devices Industry Human Resource Centre. If this assumption is incorrect, then in addition to the budget outlined below, an additional $100,000 - $200,000 could be provided per year through this sector campaign to co-fund training seminars and workshops. This co-funding could be in the range of a 1/3, 1/3, 1/3 split among ISTC, provincial governments and the training participants.

Annual Budget:

Program Officer	$55,000
Administrative Assistant	30,000
Overhead	85,000
Travel	25,000
	$195,000

plus
Possible co-funding $100,000 - $200,000

BENEFITS:

The primary benefit to the medical devices industry of such seminars and workshops is the channelling and focussing of specific training programs to meet the industry's needs. From a government perspective, the establishment of this office would meet the mandate to develop an employed, skilled work force which will contribute to the Canadian economy through consumption of goods and services and tax revenues.

IMPLEMENTATION PLAN:

1. Recruit project officer and requisite support staff.
2. Working closely with the Centre Director (see 2.6.1) establish human resource training requirements within the industry.
3. Coordinate the development and implementation of seminars/workshops. The actual delivery of these seminars/workshops would most likely be carried out by personnel outside the Centre on an as-needed basis. However, over time, full-time people may be taken on to deliver these training activities.
4. Establish criteria for co-funding assistance.
5. Administer applications for co-funding assistance.
6. Inform industry representatives of the establishment of the program through mailings and publications in the MEDEC Journal.

2.6.3 CO-OP STUDENT ASSISTANCE PROGRAM

SCOPE / DEFINITION:

Established under the Medical Devices Industry Human Resource Centre, this option would involve the establishment of a coordinating office and provide co-funding for co-op students. A program officer would be hired to contact all the various educational institutions offering co-op programs and identify those applicable to the medical devices industry, e.g. computer science, medical schools, etc. These education centres may wish to promote their co-op programs through the MEDEC Journal.

As a result of, or in conjunction with, the above industry assessment for future training needs (see 2.6.1), the Centre would develop a program whereby the needs of the industry may be addressed, at least to some extent, with the assistance of co-op students. This program could be targeted to small- to medium-sized firms where co-funding would be provided to offset the students' salaries.

The current average co-op student salary is $515 per week. Therefore a four-month working semester (17 weeks) = $9,350. If ISTC were to

co-fund 1/3 of this cost, their contribution would be in the range of $3,100 per student per work semester. A fund of $100,000 would assist the placement of 32 co-op students for one four-month working semester per year.

In addition, the program would assist co-op institutions by promoting their programs within the medical devices industry.

Companies requesting funding assistance would apply through the new office. Specific eligibility criteria would be established for funding assistance as well as duration of funding, i.e. number of semesters funding assistance would be provided. In keeping with the theme to focus resources on strengths, one criteria may be to select those applicant companies that show a good probability of success.

Potential criteria for eligibility for a student may include agreement to a pre-established work semester program. This program could include work semesters in a variety of medical devices industry components, such as a hospital, a medical device company, a government-related office, (e.g. Health and Welfare and/or Consumer and Corporate Affairs Canada patent office), etc.

A very important concept to keep in mind for this and any program is to keep the 'frustration level' to an absolute minimum. That is, keep the application procedure simple. This is very important, as many government assistance program applications are so frustratingly long and detailed that they are not taken advantage of.

Annual Budget:	
Co-funding of student salaries	$100,000
Program Officer	55,000
Administrative Assistant	30,000
Overhead	55,000
Promotional material	5,000
Travel and accommodation and misc.	15,000
	$260,000

After the first year the coordinator may not need to travel as much. This would allow for the increase of the co-funding to students if the budget were to be maintained at $260,000.

BENEFITS:

The co-op system lends itself best to projects rather than to ongoing activities for the host company. Projects such as business plans,

marketing strategies, etc. would provide employers with fresh insights and assistance at reasonable rates.

The trend seems to be that co-op students are generally placed in larger companies, as smaller companies find it harder to provide the budgets and supervisory resources necessary to make co-op employment feasible. A co-funded program would lessen the cost burden and make it easier for the small companies to become involved.

IMPLEMENTATION PLAN:

1. Recruit project officer and requisite support staff.
2. Contact all the various educational institutions offering co-op programs and identify those applicable to the medical devices industry, e.g. computer science, medical schools, engineering schools, etc., and match this with the industry needs derived in option 2.6.1.
3. Announce to the industry the establishment of this office through mailings and ads and articles in the MEDEC Journal. Inform the industry that if they are interested in gaining more information regarding the possibility of having co-op students work in their company, to contact this office for information assistance and to apply for co-funding.
3. Assist the above mentioned co-op educational institutions in marketing their programs within the industry. This could be accomplished through a variety of methods such as:
   - ads in the MEDEC Journal; and
   - coordination of distribution of co-op schools promotional materials to the industry.
4. Establish co-funding criteria for companies and students interested in hiring co-op students.
5. Administer co-funding applications.

2.6.4 CEO ROUND TABLE PROGRAM

SCOPE / DESCRIPTION:
This option calls for the re-establishment of the MEDEC, CEO Round Table program described earlier (see 2.5.5). This option calls for co-funding assistance by ISTC. As previously mentioned, the program was considered to have been very successful and that if it were to be co-funded, it could be extended across the country.

RESOURCES:
In addition to staffing an office, re-establishment of MEDEC calls for co-funding for the industry participants. The past CEO Round Table

Program cost $2,400 per year per participant. The 1991 cost may be roughly $2,800. If the program were to be established across Canada in six major centres with two groups each and in four minor centres with one group each, the total approximate cost would be as outlined below:

Annual Budget:		
Co-funding		
two groups, six major centres, 12 participants, $2,800 per participant, 50% funded	$201,600	
1 group, four minor centres, 12 participants, $2,800 per participant, 50% funded	67,200	$268,800
Program Officer		55,000
Administrative Assistant		30,000
Overhead		85,000
Travel		25,000
		$463,800

BENEFITS:

As CEOs of small companies often lack the business knowledge and experience of their counterparts in large multinationals, this program has proven to be very valuable in providing insight into what it takes to succeed in this, or in any industry.

IMPLEMENTATION PLAN:

1. Recruit project officer and requisite support staff.
2. Meet with previous coordinators of the CEO Round Table Program to develop strategies for reimplementing the program.
3. Inform industry representatives of the establishment of the program through mailings and publications in the MEDEC Journal.

APPENDIX 2A
INDIVIDUALS CONTACTED FOR HUMAN RESOURCES SECTION

1. Rashid Aziz
   VP Fin. & Admin.
   Quadra Logic Technologies Inc.

2. Fraqncesco Billeni
   President
   IAF Biochem

3. Ces Blaesi
   La Pala Investments

4. John Clapp
   CEO
   Canadian Bioclinical Ltd.

5. Carol Clemenhagen
   President
   Canadian Hospital Association

6. Gordon Cornelius
   President
   Ingram & Bell

7. Ian Drake
   President
   Manlab Instrumentation Ltd.

8. Chris Hanna
   President
   ALI Technologies Ltd.

9. Steve Hayter
   President
   ADI Diagnostics Inc.

10. Alan Jones
    Senior Industrial Consultant, Labour Market Services
    Employment and Immigration Canada

11. Andre Juneau
    Director General, Immigration Policy Branch
    Employment and Immigration Canada

12. Gordon Khan
President
Kendall Canada Inc.

13. Bruce Lawrence
President
Becton Dickinson

14. Allison Little
Program Specialist
Inland Operations Directorate
Immigration Ontario Region

15. Grace Murphy
Senior Program Officer
Interchange Canada
Public Service Commission of Canada

16. Phil Nance
President
MEDEC

17. Gordon Politeski
President
Biomira Inc.

18. David Roy
Sales and Marketing Manager
Bubble Technology Industries

19. Ed Rygiel
Senior VP Corporate Development
MDS Health Group Limited

20. Terry Scheehan
Executive Director, Immigration Operations
Employment and Immigration Canada

21. Mike Stoker
President
Central Canada Contact Lenses

22. Rosi Riopelle
Training Consultant
Ontario Skills Development Program

23. Donna Tonus
MBA Program
University of Windsor

24. Roy Trayhern
President
Smith & Nephew Inc.

25. Real Trudel
Program Officer, Immigrant Investor Program
Employment and Immigration Canada

26. Silvia Wannam
Office Coordinator
Canadian Association for Cooperative Education (CAFCE)

27. Bob Wolf
VP Human Resources and Administration
Theratronics

APPENDIX B
HUMAN RESOURCES SECTION - QUESTIONNAIRE

GENERAL ISSUES

1. What human resource requirements do you have in the near and long term?

2. What barriers do you perceive exist regarding HR importation to fulfill the industry's near and long-term human resource requirements, (e.g. political, legal, implementation practices, experienced personnel availability form outside Canada, etc.) ?

3. What are the requirements of Employment and Immigration Canada and how do they impact hiring needs and practices?

4. Are Canadian salaries competitive compared to U.S, Germany, France and Japan?

CO-OP PROGRAM

1. Is there a need for a Co-op Program in this industry?

2. Is such a program feasible, practical and useful?

3. Are there existing programs which could be adopted or used as a model (e.g. NSERC) to fill the needs for a Co-op Program for this industry? Are they successful?

4. What would a new program look like? Are there models to use as guides in designing a Canadian medical devices industry co-op program?

5. Who would co-ordinate such a program? e.g. MEDEC, TIMEC, etc.

6. Which Universities, Colleges, hospitals, training organizations and/or government departments could/would/should participate?

7. Which faculties within the above organizations should be targeted? How should they be approached?

8. What would be the nature, if any, of ISTC, MEDEC, etc. dollar contributions?

EMPLOYEE EXCHANGE PROGRAM

1. Who should participate? What position levels?

2. Are there Canadian or international models to refer to?

3. How do existing programs work, (e.g. the government Executive Interchange Program) ? Are they considered successful? Have they benefitted the company involved? Do these programs fulfil the needs of the industry? If no, what more could be done?

MANAGEMENT TRAINING AND DEVELOPMENT PROGRAM

1. Is there need for such a program? Does industry support such a program?

2. What should be the scope, coverage, content, budget, etc. of such a program?

3. Who would provide financial support for such training?

4. Who would co-ordinate such a program?

OTHER TRAINING CONCEPTS

1. What other training concepts may be useful to the Canadian medical devices industry?

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3.0 Domestic Market Access

Table of Contents

3.1 Introduction

The Canadian consumption of medical device products is expected to grow from an estimated $2.4 billion in 1990 to over $6 billion by the year 2000. While this 250% growth is significant over 10 years, the world market is expected to see a four-fold growth in size during the same time period.[1] This large and growing market provides an opportunity for Canadian manufacturers to prosper in the years to come as well as to put Canada on the map as a world-renowned leader in the industry.

Currently, Canadian manufacturers supply approximately $.5 billion or 20% of the Canadian market while the rest is provided by foreign companies. In addition, these same Canadian companies manufacture about $.2 billion for exports, totalling an estimated annual production in Canada during 1990 of $.7 billion. This output is expected to exceed $2.4 billion by the year 2000.[2] While most of our production is used for Canada, there is still a shortage of suitable Canadian-made products to supply our hospitals. The hospitals, which represent 90% of the market, must seek foreign companies to provide the level of health care that Canada is famous for, thus resulting in a significant trade deficit for this industry.

Both the need to supply adequate products domestically, and the opportunity to not only maintain but to increase our small penetration (<2%) of a quickly growing world market, are recognized today. Yet the medical devices industry in Canada is not keeping pace with the demands and the market growth. Bankruptcies abound, good products never make it to market, customers are unaware of available products and manufacturers do not recognize technology opportunities and market requirements. Unless a concerted effort is made and steps taken to build the industry now, the problems will be compounded in the future and the situation will only worsen.

3.2 Objective

The medical devices industry in Canada has a responsibility to address the issues that are at hand today and the ones it will face tomorrow in order to survive and prosper. These issues are not simply limited to raising of capital, R&D, regulatory constraints or pricing policies. They encompass every single aspect of

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1 Hayter S: More Solid Support for Canadian Companies Needed to Reduce Deficit in Medical Devices. MEDEC J 1 (3): p10, Summer 1990.

2 Meeting the Challenge: An overview of the Medical Devices Sector Initiative. Volume 1. Draft paper prepared for ISTC, August 1989.

the business from the sprout of an idea which results in technological innovation to the use of good management practices in developing long-term strategic plans.

This onerous responsibility, however, does not belong to the manufacturers alone. Government, both federal and provincial, hospitals, industry associations, provincial hospital associations and others all play a role in supporting this industry as they are principle beneficiaries in the industry's success.

The business climate analysis takes into consideration the current environment in which the industry operates and the forces that affect its growth. This section on the domestic market identifies some of the strengths and weaknesses within this market. Obstacles to effective market penetration have been brought out in this report and recommendations made to overcome some of these obstacles. The Options Section presents alternatives which can be reviewed with the aim of selecting the best ones to implement.

A primary objective of this study is to find ways to promote the industry. The focus is on smaller companies due to a greater need existing for these companies. For the industry to grow, new companies must be formed with new products developed. The large companies have adequate financial resources, technical and management experience as well as established marketing channels. It is the small companies that require more support and additional programs to catapult them to become larger and more successful companies.

3.3 Scope

This study focusses on the domestic market of the medical devices industry in Canada. While there may be reference to the international market from the perspective of companies that export product or institutions that import product, this discussion simply rounds out the subject of the domestic market by filling in the gaps that would not otherwise be evident.

The six subsectors that comprise the industry have been dealt with collectively rather than individually. The consideration here is that although each subsector has unique characteristics and can be addressed independently, the purpose of this study is to identify on a broad scale the obstacles encountered in penetration of the domestic market as well as the opportunities which exist that can improve the domestic market penetration.
The observations contained in this section of the report are primarily derived from a small sample of representatives from the hospital and industry sectors. Consequently, they do not necessarily reflect the attitudes and experiences of all the individuals involved in the industry. They are however, supported by information gathered in literature and by industry members with whom some of the findings were discussed.

No attempt was made to conduct any quantitative analysis to derive conclusions that are statistically significant. Instead, general directions and trends are revealed in the presented findings and the options that are proposed.

In addition, the status of planned and existing programs by organizations such as TIMEC have not been investigated in depth. These programs are undergoing significant change and it is not clear as to the roles which each organization will play in program development and management in the future.

3.4 Methodology

The methodology employed for this study on the Domestic Market includes a review of the literature, an analysis of key hospital journals and interviews with a broad cross-selection of companies, hospitals and hospital associations.

The literature review and a preliminary conceptual model formed the basis of an interview questionnaire which was tailored to suit the needs of both the medical devices industry and the hospital sector. The model appears in Appendix A. The interview questionnaire is attached in Appendix B. The review and analysis of key hospital journals assisted in the following:

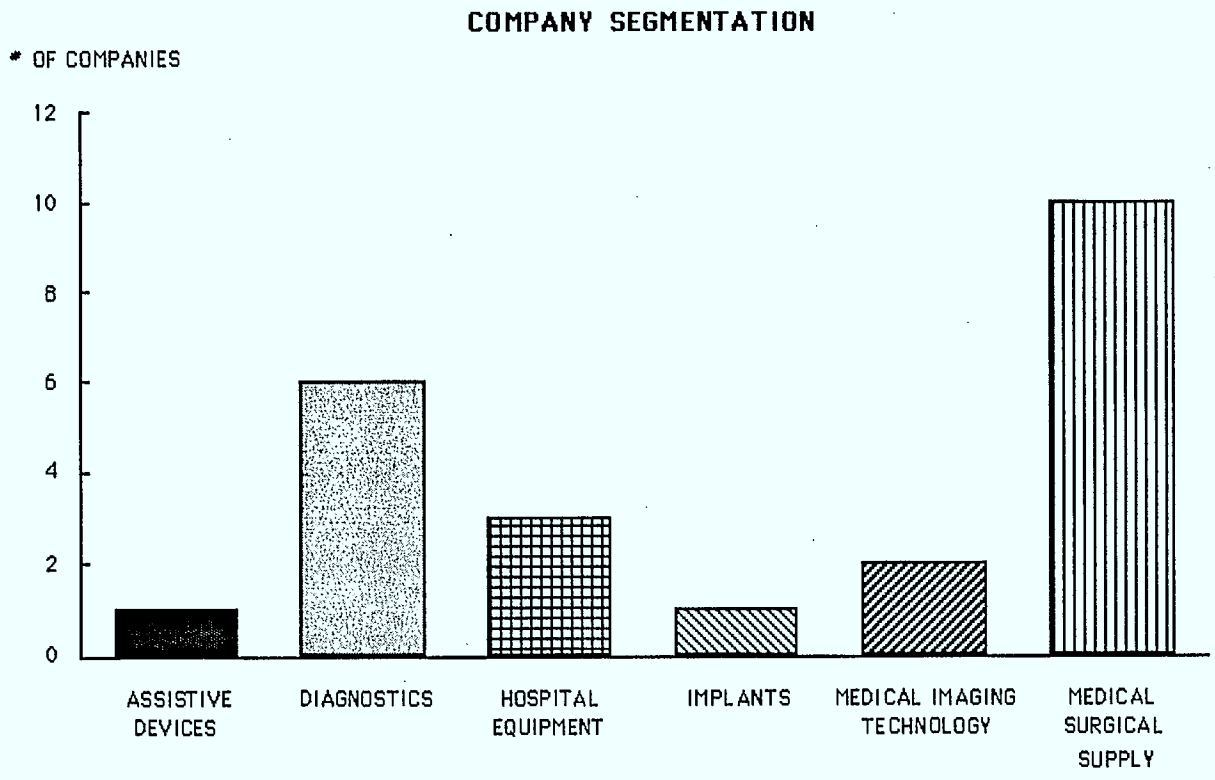
a) identifying the extent of product advertising by Canadian and American companies, and
b) reviewing articles written on new products and new companies and selecting several of these new companies for follow-up interviews.

The criteria used for selecting the companies to be interviewed endeavoured to capture a wide cross-section of companies and products in the Canadian marketplace. The criteria included the following:

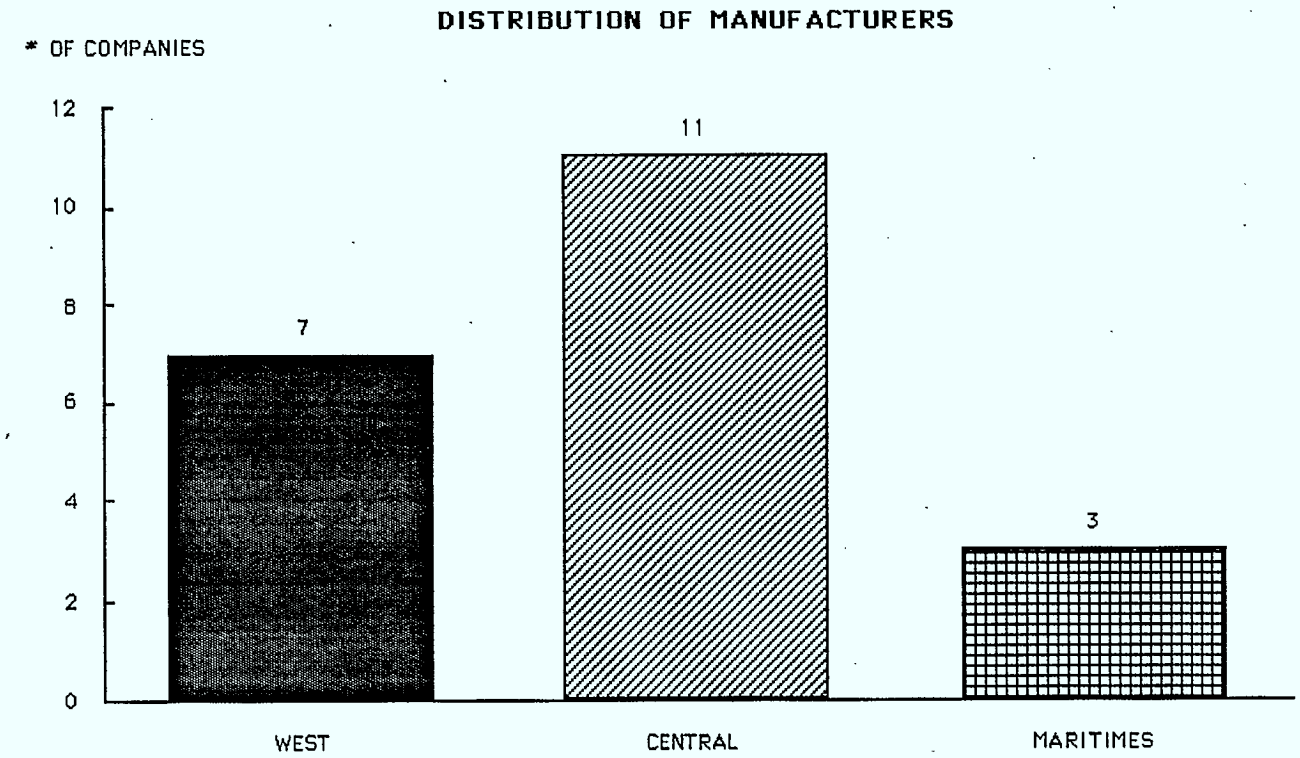
a) Young Canadian companies (less than 8 years old) with new products brought to the market within the last three years.
b) Companies located in western and central Canada and in the Maritimes that represent the following products: medical-surgical supplies, assistive devices, implants, medical imaging technology, diagnostic and general hospital equipment.
c) Established medium to large Canadian companies which have been successful in penetrating the Canadian and/or foreign markets.
d) Canadian subsidiaries or distributors of an American product(s).
e) Canadian companies specializing in distinctive health care products or services that have found a niche in Canada.

The purpose of the above criteria was to ensure that an industry cross-section of the Canadian market was tapped and to compare diverse viewpoints, objectives, attitudes and strategies in penetrating the Canadian Health Care market.

The companies selected and contacted for interviews are listed in Appendix C as are the names and titles of those interviewed. The companies are categorized in the table below by type of product manufactured and/or distributed:

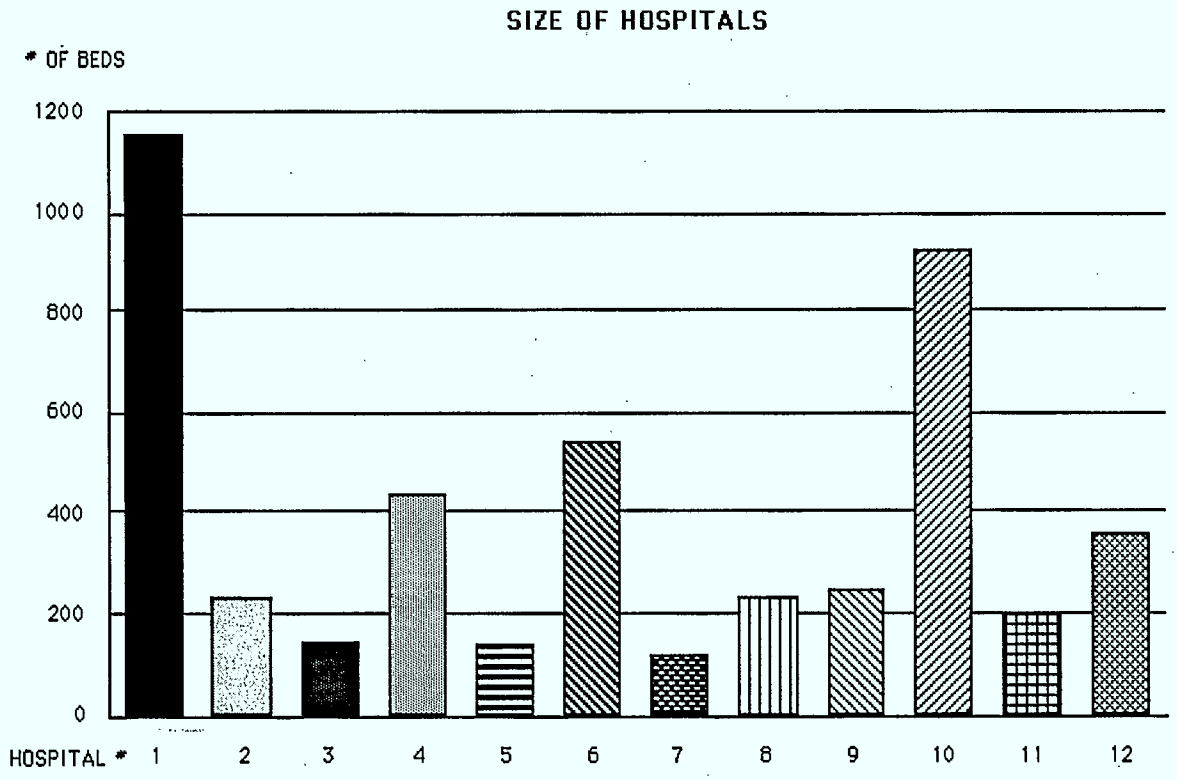


The next chart illustrates the geographical distribution of the same companies within Canada. The West includes all the provinces from Manitoba to British Columbia inclusive. The designation of Central refers to Ontario and Quebec only. Finally, the Maritimes include all of the Atlantic provinces.



Three of the new Canadian companies selected had recently become bankrupt. Two of those companies had advertised their new product(s) in Health Care within the last few years.

The selection criteria for hospitals included representative large, preferably teaching hospitals (greater than 500 beds) and representative small- to medium-sized community hospitals within each of the three regions (western, central, maritimes) in Canada. A total of twelve hospitals were reached and three of those had greater than 500 beds. The majority of hospitals interviewed were small to medium in size. This sample is representative of the majority of Canadian hospitals.



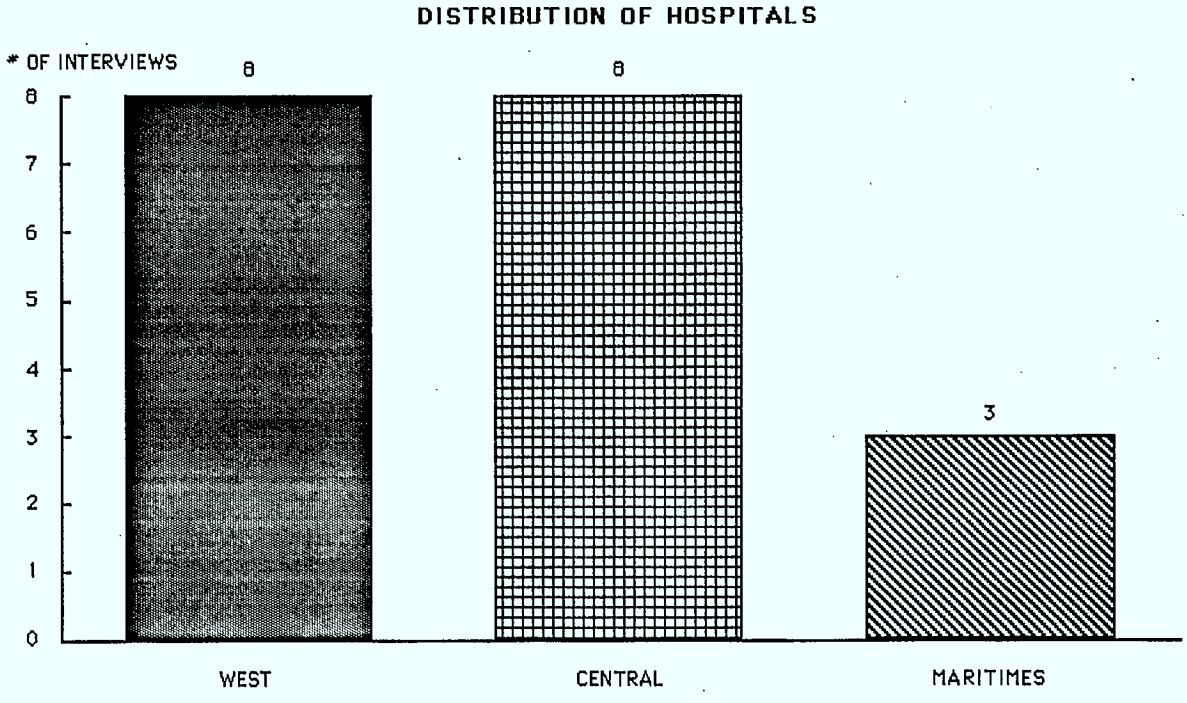
The professionals chosen for the interviews represented different facets of the hospital environment. As decision-makers responsible for ensuring that the hospital was fiscally and clinically responsible, they voiced their different perspectives of the medical devices industry and of their procurement process. The list included Chief Executive Officers, V.P.'s of Operations, Directors of Nursing, Professional Services, and Materials Management.

One-third of the provincial hospital associations were also interviewed. The provincial associations have the largest bulk purchasing programs for their member hospitals. Their clout allows them to make purchasing decisions for certain items such as common medical-surgical products and other consumables.

The list of people interviewed representing hospitals and associations and their titles appears in Appendix D. The locations for these institutions and the number of beds for the hospitals are shown in the next table.

Hospital/Association	Location	# beds
Vancouver General	B.C.	1160
St. Vincents	B.C.	232
Fort McMurray Regional	Alberta	142
St. Paul's	Saskatchewan	436
Concordia	Manitoba	136
Moncton	New Brunswick	539
Darthmouth General	Nova Scotia	114
C.H.E.O.	Ontario	230
N.D.M.C.	Ontario	244
Ottawa Civic	Ontario	922
Perley	Ontario	202
Greater Niagara	Ontario	356
Canadian Hospital Association	Ontario	-
Saskatechewan Hospital Association	Saskatchewan	-
Conseil de la Sante et les Services Sociaux	Quebec	-

The distribution within Canada of the hospital interviews can be seen in the chart which follows:



3.5 Findings/Analysis

The findings are assembled into 7 major categories based upon the information brought out during the course of 45 interviews in response to the questions posed. These categories are derived to simplify for the reader the wealth of information communicated. The list of people interviewed and the organizations which they represent can be found in Appendices C and D.

There was an effort made in obtaining an accurate view of the medical devices industry. For this reason, manufacturers and hospitals as well as provincial associations with mandates to evaluate products and negotiate contracts on behalf of the hospitals were included in the organizations interviewed. While most of the discussion that follows refers to manufacturers and hospitals, the associations are implied when hospitals are mentioned except when stated otherwise.

3.5.1 Product Evaluation Committees

The buying process is a complex one that encompasses many factors. Both tangible factors such as product knowledge and pricing as well as intangible ones like users' attitudes, perceptions and previous relationships with suppliers will have an impact on the final decision of purchasing a product and selecting the

company with which to do business. This section will deal with the process in broad terms by which this decision is made. The specific criteria which are used for the selection will be covered in the next section. It is important to differentiate between the environment in which the selection is done and the criteria that are used. This is because the recommendations for improvement will vary.

The purchase of a medical device product involves at least one authorized person within the hospital setting. In most cases, hospitals have created committees which meet regularly to review products that users wish to be purchased. These multidisciplinary committees comprise individuals representing various departments including Nursing, Materials Management, Physical Plant, Biomedical Engineering, Pharmacy, Lab Services and several end users. The provincial associations (Hospital Purchasing Programs section) are also comprised of product review committees, though the backgrounds of their members differ from one association to another. For instance, one association has representatives with biomedical engineering experience while another has members with a background primarily in materials management.

The composition of the hospital committee will often depend upon the product being reviewed. There may be 6-8 members and sometimes the committees are formed on an *ad hoc* basis. In some cases, a product is highly specialized and does not depend upon the committee for its purchase. For instance, biochemical reagents may be selected by a haematologist or biochemist. In general, high technology products involve the participation of a multidisciplinary team whereas some low tech, consumable products may be selected by individual end users.

The customers of medical device products, whether the hospital purchasing programs (HPP's) of the provincial associations or the persons responsible for the selection of products in the hospitals wield significant power. Collectively, they determine the fate of many companies within the industry. As a result, they can exert some pressure over the suppliers and possess strength in the negotiation process.

3.5.2 Selection Criteria

Selection criteria are critical factors for both the manufacturers of products as well as for the consumers of products, which in this case are hospitals. The manufacturer's existence usually depends upon hospitals, (or clinics, physicians, private labs), being prepared to purchase the product. A product is researched, designed, prototyped, developed and produced once a need has been identified. It is often the hospital's requirement (or the manufacturer's perception of it) that contributes to this creative process of research and development. Consequently, the reasons for the development of a product can define the criteria used in its

selection. Unless this is understood by a manufacturer, he will not be successful in marketing that product.

A hospital requires selection criteria for several reasons. The hospital administrator, who is ultimately responsible to the Board of Directors as well as to the Ministry of Health, must be fiscally responsible for the purchases made. It would not be good enough for him to suggest that *many* purchases can be justified while others can not. Value must be obtained in **all** cases. The issue here is how is the term "Value" defined? Value is the sum total of a combination of relevant factors, weighted according to their importance. These factors are referred to as selection criteria.

Within a hospital, in selecting a product for use, there could be many differing opinions about which product is better than the other. It could be a very difficult task to reach a consensus on a particular product between the decision makers without first agreeing on some basic features that the product should have. Criteria represent the most basic elements of the evaluation process, without which a product cannot be objectively evaluated.

Selection criteria can be considered to be both motivating and de-motivating factors in a complex decision-making process. For example, a diagnostic test that guarantees results to be 100% accurate can be a motivating factor for the selection of that product while a long lead time for spare parts can act as a de-motivating factor.

Often there are thresholds which are determined for a specific criterion. If these thresholds are not met, then the product will not be accepted. This is especially important in the health care environment where product specifications are created to ensure that life is preserved. While one product feature may be determined as essential for a product to be considered for acceptance, another feature can be viewed as an enhancement to the basic product.

This study focusses on two categories of criteria, one used in selecting a product and the other used in selecting a company. The reason for this distinction was to determine if there are any factors which can contribute to the success of a Canadian company, independent of the product which it represents. In fact, it was found that the final selection of a product involves the consideration of specific criteria with regard to company characteristics. These criteria will be discussed below.

In the selection of a product, a consensus of opinion suggests that the criteria used is highly specific to each particular product. While some sophisticated products are evaluated on the basis of many criteria, others like uniforms are reviewed

with only a few criteria in mind. Some of the criteria listed by manufacturers, hospitals and associations are listed in no particular order in the following table.

Selection Criteria for Products

1)	Functionality	2)	Quality
3)	Price (i.e. life-cycle cost)	4)	Comfort
5)	Warranties	6)	Installations
7)	Maintenance	8)	Service
9)	Ease of use,	10)	Delivery
11)	Availability of parts	12)	Financing
13)	Longevity	14)	Performance
15)	Reliability	16)	Safety
17)	Compatibility	18)	Upgradeability
19)	The degree to which the product meets specific standards (i.e. CSA, Hydro, FDA, etc.)		

While these criteria provide parameters by which a product is measured, the permutations and combinations that are available for these factors suggest an impossible task in defining a standard by which all products are measured. More importantly, the weighting of these criteria will also vary, not only by product but also by the individual hospitals. This poses an even greater difficulty in either implementing selection guidelines or implementing a centralized review process. Since criteria is subject to customer and institutional differences, standardization without an allowance for some flexibility would be impossible to sell. This will be discussed in more detail later.

The criteria used to evaluate and select companies are listed in the following table, again in no particular order.

Selection Criteria for Companies

1)	Size	2)	Stability
3)	After-sales service	4)	Support
5)	Willingness to partner	6)	Reputation
7)	Quality of Sales Representative	8)	References
9)	In-house testing facilities	10)	Image
11)	Number of current customers	12)	Track Record
13)	Previous relationship with supplier	14)	Profitability
15)	Degree of cooperation	16)	Investment in R&D
17)	Proximity to Hospital	18)	Responsiveness

Once again, the evaluation of companies runs the gamut from several criteria being used to hospitals which do not evaluate companies at all. As an example,

with medical and surgical supplies, there are many companies to choose from and the products are, in most cases, consumables. Therefore, there is less risk for a hospital to choose one supplier and switch suppliers if the need arises. If a hospital chooses a supplier of gauze, rather than evaluating strengths of the company, the hospital is likely to choose a supplier of convenience, one that it is currently used for the purchase of other products.

3.5.3 Partnerships

The criteria "willingness to partner" is worthy of elaboration as it is a growing trend in the medical devices industry. Hospitals are facing greater budgetary constraints than ever before while at the same time being expected to maintain, if not improve, the quality of care which they provide. These conflicting demands place enormous pressures on the hospital administrators and this filters down to affect everyone in the hospital, including the patients. Similarly, manufacturers are facing long sales cycles, increased competition and growing bureaucracy which all contribute to reduced profit margins while being expected to provide good returns on shareholders' equity.

These situations have created an urgent need for hospitals and manufacturers to work more closely together. It must be remembered, as discussed earlier, that these organizations start off with a lot in common. The products that are developed by manufacturers are designed to satisfy a need identified by hospitals. The synergistic relationship implies that one organization cannot exist without the other. The fact that one organization has become dependent on the other is now being recognized more fully. Unless a "partnership" relationship is developed, one organization will be working at odds with the other.

The partnership implies not only an understanding and respect of the problems faced by an organization's partner, but also the sharing of those problems. This translates directly into shared responsibility, risk and cost savings. For example, if a manufacturer, working in conjunction with a hospital, found a way to reduce the materials on a wound tray, the savings that were realized would be split between the manufacturer and the hospital. In this case, neither party exhibits greed and both benefit -- the manufacturer with increased profits, and the hospital with lower costs.

There are many forums for the exchange of information between manufacturers and hospitals.

3.5.4 Standardized Evaluation Guidelines

There are mixed views on whether standard guidelines would be useful. While some interviewees believed that standard criteria would have no impact

whatsoever, in general there is a positive reaction to the concept. One of the major problems which was identified was the establishment of a program that would work.

One of the reasons why this issue was raised is the fact that currently, evaluation criteria tend to be product specific. Users of medical device products often have unique requirements or different uses for the same products. For example, the selection criteria for beds often depend upon the type of patient and their particular needs (e.g. geriatric patients as opposed to post-operative or emergency patients). Depending upon the specific application, criteria like ease of mobility and patient comfort will vary. This leads to further difficulties in standardizing hospital review criteria for medical devices.

While guidelines are designed to create standards by which hospitals choose products and suppliers, it must be remembered that the evaluation process is not always completely objective. There exists some subjectivity that enters into the evaluation and buyers prefer to maintain some control over this aspect. There are several reasons that explain this attitude.

Firstly, buyers may have a long-term relationship with a supplier. Independent of why this has occurred, the trust that has taken years to develop cannot be eliminated with the introduction of guidelines. "Preferred supplier" status exists within many hospitals reflecting the service that the supplier has provided over the years and the confidence which the hospital places in the company.

Secondly, there is a natural resistance to any central authority that suggests guidelines by which a hospital must abide. Each hospital considers its needs as separate and distinct from those of other hospitals. The size and type of hospital, location (as in rural vs. urban), provincial regulations, the power of interest groups within the hospital, standardization or other hospital policies as well as other factors account for this view.

To be useful to the hospital community, the guidelines must be completely objective and free from personal bias. The guidelines, once written and distributed, can can also be subject to varying interpretations. The term "quality" has many distinct interpretations. In spite of these obstacles, the program is recognized as having many benefits. Many manufacturers have had serious difficulty in obtaining acceptance of their product within the hospital environment. Still others consider that their products surpass in many ways the quality and/or value of their competitors products that are in current use. In both of these cases, the manufacturers agree that establishing standard evaluation guidelines would provide industry with objective guidelines to assist them in becoming more competitive.

Hospitals are generally receptive to the idea of standardized criteria. They believed that it would provide useful guidelines for end users and product evaluation teams in the assessment of products and technologies. The guidelines would, however, supplement rather than eliminate or replace the independent criteria that hospitals choose to use in evaluations.

It is clear that the centralized guidelines are just guidelines which would complement the hospital's internal process. They can, however, go a long way to provide some standardization in the health care industry.

3.5.5 Centralized Product Reviews

It has been found that many products never make it into a hospital or are delayed for years before they are accepted into the hospital setting. Alternatively, there are some products that come into the hospital before they are fully evaluated. This is due to the significant degree of testing and evaluation that is often demanded by committees and individuals for a product to be finally accepted. The resources that are utilized are enormous. These resources include human, financial and facility-based. Product reviews often span months and sometimes even years of time. In spite of the significant effort involved in reviewing a product, a similar review is duplicated again and again hundreds of times because each hospital conducts them separately. There is a strong need for some form of centralized product testing and evaluation.

The concept of centralized reviews can take many forms. A "Hospital Centres of Excellence Program" (HCE program), which can be defined in numerous ways, is one example. This program has been understood by people in the industry differently than how it is defined by ISTC. Another program to support centralized reviews is an organization like the Canadian Hospital Association (CHA) or the Canadian Standards Association (CSA) to be given the mandate and resources to undertake all product reviews for the medical devices industry. A recommendation will be made in Section 3.6 for a modified version of the HCE program.

Some concerns about centralized reviews were, however, raised by the interview participants. From the manufacturer's perspective, there is a need to access this centralized body or committee which conducts the product reviews. This accessibility is not from the side of influencing the people involved but from the perspective that a product would no longer be able to be sold into the marketplace until it received a "stamp of approval" from the committee. A significant backlog could only contribute to the frustrations of the manufacturers. On the other side of the coin, if products were scheduled for reviews, a manufacturer could better plan the launch and financing of his marketing efforts.

As a by-product of centralized reviews, certain monopolies can be created whereby only one company's product is reviewed positively. While this potential problem was raised by manufacturers, it should be put into proper perspective. Firstly, the same possibility exists today even without centralized reviews. This can happen with testing of a product by independent labs or by a hospital's internal committee.

If one product is clearly superior to another, then it is unlikely that the inferior product will be widely accepted in the marketplace. The company which manufactures the superior product is likely to win out against the competition each and every time the same category of products is evaluated. However, the inferior product will have more opportunities to be evaluated rather than be categorically "blacklisted" if it fails to obtain a satisfactory review by a centralized body.

Rather than eliminating the free market, as has been suggested, the centralized review process, if operated equitably, will give each manufacturer and every product the same opportunity to be thoroughly reviewed. This review will be based upon a host of criteria deemed to be important to the particular product by a large number of people. A discussion of how this program can be planned and operated will follow later.

It has been suggested that the market is large enough for most products to have more than one company supplying the product. This is true not only internationally but also domestically. Therefore, it is feasible that, within a product category, a few companies' products will be reviewed favourably.

Moreover, a product will not simply be accepted or rejected by a centralized committee. Each product will be evaluated and rated on several criteria. This provides an opportunity for products to be differentiated from each other. In this way, hospitals may choose products based upon their relative importance of each criteria.

From the hospitals' perspective, the interview participants unanimously agreed that a centralized product review process would significantly help their internal evaluation process but not eliminate it completely. Consistent with the difficulty of implementing standardized guidelines, as discussed above, the hospitals have unique criteria and requirements when a product is reviewed.

Another issue which was raised continuously was the difficulty in selling the concept of centralized product reviews to the end users of products within the hospital. It would be very easy to create the "ivory tower syndrome" where the central body "knows it all" while the users, who operate in the environment where the products are used, "know nothing". If a spirit of cooperation between

users and centralized review committees is not achieved, then the objective of eliminating independent reviews will not be met. Users want to feel that they are a part of the process or that they are at least well represented.

Further problems arise with the "process" of developing standardized criteria for the centralized product review. It could be a difficult task since the effort in coordinating input from manufacturers, hospital personnel (representing the views of the various professional groups such as Nursing, Materials Management, Biomedical Engineers and Physicians), Hospital Associations and other stakeholders (i.e. Ministry of Health) across the country would be enormous.

It is clear that the centralized review process must be executed with fairness and without interference from any interested party, be it government, hospital or industry. This may be unrealistic to expect since even within a small hospital, there are different factions operating and some politics at work. However, a centralized review organization should reduce the occurrence of these problems because the problem is only compounded with the increase of product reviews at each individual hospital. If the hospitals accept this concept of centralized reviews, then the hospitals will experience a great advantage in the reduction of internal conflict.

3.5.6 Barriers/Obstacles to Market Penetration

There are many barriers which were identified by manufacturers and hospitals alike. Though each group shared some of the same ones, for the most part, their perspectives were different. It is felt that, since the purpose of reviewing the barriers will be to find strategies to reduce them wherever possible, it is unnecessary in this study to distinguish the ones from each group in the study.

One of the major barriers is the degree of conservatism in the health care industry. Tradition is a term that captures it all. There is a high tendency towards risk-avoidance when it comes to trying new products or new companies. A hospital will continue to use the same product even once improvements have been made or new technology introduced. If a hospital is satisfied with the product that they are using, there may not be any reason to look at the new product for many months or years. The switching of suppliers is also avoided unless there are substantial reasons to do so.

This traditional position also ties back into the long time-frames to conduct product evaluations. A new product or even a different version of the same product must first be evaluated before receiving approval to purchase it. This can take a very long time, especially for a manufacturer who is anxiously trying to enter the market.

Acceptance of Canadian products is initially low compared to U.S. or European products. If the product is first accepted into the U.S. market, then the Canadian hospital perspective will accept that the product must be good. This attitude which Canadian hospitals have of Canadian products can also be turned around over time, if it is made clear that the proximity and service of Canadian companies is generally better than foreign ones.

Operating in Canada is also more expensive. Manufacturing costs including labour, materials and shipping are higher in Canada. Trade barriers exist on some foreign materials such as cotton that do not exist in other countries. The corporate tax rate is higher in Canada than for other countries. All of these incremental costs make it more difficult for Canadian companies to compete successfully.

Price competition is a problem, especially for smaller Canadian companies, which are unable to withstand a reduction in margins for any length of time. The large multinationals also have an advantage of greater economies of scale and more corporate recognition. "Tied-selling" refers to some equipment that a supplier provides as long as the customer uses the same supplier's products. For example, a blood analyzer can be provided without charge to a customer but taken away if a competitor's reagents are found to be used. This marketing tactic is illegal in the U.S. but is allowed in Canada. Consequently, a smaller company is at a disadvantage.

The cost of market entry in Canada, relative to its size, is high compared to entry into other foreign markets. It has been suggested that manufacturers have to look beyond Canada to become successful.

The recent Free Trade Agreement (FTA) is perceived to be operating in only one direction for certain medical device products. This comment is not from the side of duties but from a standards perspective. Whereas Canada does not set specific standards for certain products, the U.S. generally has a tougher standard that must be met before a product will be allowed into the country. The FDA is considered to have more stringent regulations than Health and Welfare. Also the authorities in the U.S. apply tougher standards for foreign products than for their own. This results in a double standard in the U.S. but not in Canada.

The free trade deal contemplated with Mexico further exacerbates the problem. Labour costs, which for a lower technology product represents 25%-30% of its total costs, represent 20% of the Canadian wages in Mexico. Once again, fabric that is imported to Mexico will be tariff free there. If a free trade agreement is established between Mexico and the U.S., independent of what Canada does, the price disadvantage for Canadian manufacturers flows from Mexico through the U.S. and into Canada.

The lack of adequate information for hospitals and manufacturers contributes to market penetration not being higher than it is. The hospitals do not always understand products and their differences. One manufacturer suggested that what the customer asks for and what he wants may be two different things. For example, when a hospital must replace beds, instead of re-evaluating products, the hospital assumes that replacing the bed with an identical one is all that should be done. This is in spite of the fact that the worn bed may conform to standards which are 20 years old and have not been updated recently.

Manufacturers lack information on the changing needs that hospitals have. This information can not only help identify new product development opportunities but also assist with the marketing and modification of existing products. It may appear surprising at first but manufacturers are not familiar with the different decision makers within the hospitals and their respective areas of responsibility. This can be explained by the fact that the people and policies inside the hospital are not stagnant. People switch jobs between hospitals, restructuring of departments occur and new committees are formed. With all of this shifting and the focus of manufacturers on the products rather than the market, it is no wonder that this issue was raised.

Cost containment programs within hospitals are resulting in a downturn in the industry. Beds are being reduced because of cutbacks and hospital stays are shorter, which reduces the need for products. The margins for the industry are already thin and being squeezed further. The reduction in hospitals' budgets have brought about an increase in bureaucracy for the decision-making process (which paradoxically adds to the costs), a longer lead time for purchasing product and a more adversarial relationship between hospital and supplier. These all contribute to greater difficulty for manufacturers to conduct business.

Inadequate funding is prevalent in the industry, especially for smaller companies. It is very easy for a company to be under-capitalized since there is great uncertainty as to how long it will take for a product to get to the market. In most cases, the time involved for a company to make that first sale is substantially longer than was originally anticipated. There is also a lack of good experience in product development and/or marketing. The development component of the R&D process is a long-term effort with major costs. A company may have exceptional research capabilities. However, the necessary testing, prototyping, hospital evaluation, product modification and finally marketing is often underestimated.

It is also difficult to find investors (especially Canadian) who will look at investment for the long term. Many investors are interested in getting their money out in a few years and expect profits earlier than is realistic. This places pressure on the companies to provide optimistic forecasts that never materialize. The result is bankruptcies as well as a poor investment climate. Although

potential funding in the form of loans and grants are available, companies feel that the process is so involved and that there are so many applications waiting for many months, it often doesn't pay to apply.

There is a lack of independent testing facilities to carry out specific product tests. In-house testing facilities are expensive to establish. Moreover, when the results of a company's internal tests are provided to hospitals, they are often considered biased and non-objective. Without testing, a product will not be approved for use in the hospital. With in-house testing, the hospital is forced to conduct their own product tests and review.

The marketing programs used by manufacturers are not as effective as they can be. Hospitals cited the following problems which they feel contribute to the company's and/or product's lack of acceptance:

a) large turnover of sales representatives;
b) lack of product info;
c) lack of product testing,
d) inability of rep to answer questions;
e) no business cards;
f) lack of professionalism of reps; and
g) reps calling in person (from thousands of miles away) without even an appointment.

These are only a sample of some of the perceptions which plague the industry from the customers who are expected to buy the products. Manufacturers readily admit that their marketing efforts need improvement. In one instance, a company had hired a consultant to create a new image for that company and thereby compete effectively with their more dominant competitors and increase their market share. Another example is a company creating a catalogue of their product line only after a hospital refused to do business with them until the hospital knew what products were carried. Although the lack of marketing experience and ineffective techniques have created barriers to domestic market penetration, this area will be covered in more depth in the "Strategies for Success" section of the findings.

3.5.7 Strategies for Success

There is a consensus that to be successful, the company must start off with a good product. Without that as a minimum, the company might as well not even attempt to get into business. There is also agreement that either the product and/or the company must be differentiated from the competition. The differentiation can be in any of the criteria previously cited such as product reliability or corporate stability and will provide the company with a competitive advantage that will allow the company to prosper.

Finally, all participants in the study agreed that the strategies must be customized to the product and the market sought. The manner in which a product is marketed will vary depending on a wide variety of factors such as innovation in the product, demand in the marketplace and competition. Some of the strategies that were most frequently discussed follow.

A direct sales force is generally accepted as very effective. Although it represents the biggest expense in salaries and travel, it provides the best payback. These representatives educate, demonstrate and sell the product. They can also build a brand or corporate franchise, creating strong customer loyalty. This is important for a company to have this type of relationship with the customer to ensure that the company will survive for the long term. However, the sales rep can often represent a double-edged sword. While he can build a business for the company with customer loyalty, he can often take it away should he leave the company and work for a competitor. This risk is a real one and can be minimized if the company takes good care of the reps. This involves paying them well, providing proper training and providing a good environment in which to work where they feel challenged and their efforts recognized. The stability of the sales representatives within an organization is critical.

The use of manufacturers' agents or distributors (sales and marketing agreements) is another means to put the product in front of the customer. This is not as effective but is less expensive than a direct sales force. An agent or distributor will carry many product lines and usually does not represent one company exclusively. Therefore, their attention is divided between many interests. The manufacturer cannot exert as much control over a distributor since the distributor is running his own business. The direct sales rep usually has more training than a distributor and presents the product in a manner which the manufacturer prefers.

Proper support of a distributor is crucial if a manufacturer is expecting to obtain the most results. This can take the form of sharing exhibition costs, providing product advertising and developing product literature. There is also a need to select the right distributor since the distributor can make the difference between success or failure. Some distributors are more capable and experienced with handling certain product lines while others can do an equally good job but with other products.

Niche marketing is a very effective approach. This begins with developing a product that serves a highly specialized market which is not currently served. While competition does not pose as great a threat as when competing directly, finding and keeping that niche is a real challenge. A cancer detection kit, which is sold to specialized labs, is an example of a product that was developed for a niche

market. It is especially important for smaller companies not to compete with the large companies if at all possible since they will seldom win.

A strategy for smaller companies is to manufacture product that a large company will distribute. The large companies have effective distribution channels. If a product can be branded with the large company's name on it, then both companies (large and small) will benefit from this arrangement.

Finding a champion to do some internal selling in a hospital can often lead to a product being accepted. This champion can play a key role in influencing opinion among the decision makers as well as moving the process through the proper channels, thereby speeding up approval.

Bring customers to sites for visiting other users who have good experience with the product. It is advantageous to link up with key opinion leaders or gurus. Have a relationship with them such as offering royalties. They will influence the decisions of others within the hospital and the industry. They may also publish articles which influence sales. Speaking at conferences will also help. Diplomacy in selling is essential, especially with physicians. Complete support of users (i.e. physicians) in early stages of the sales cycle is critical.

Leasing options, service contracts, flexible features are ways to cater to the customer and differentiate your product. An automatic replacement warranty is also respected in the industry.

The product has to be good to begin with. Ensure the quality of documentation on how to use the product. Promotional gimmicks have helped with free VCR and/or TV along with the product. Free samples also allow the customer to try the product (some companies can't afford doing this). Service is an important strategy. An educational videotape on how to use the product may be useful. Being honest with the customer is a sounder approach, than just saying what he wants to hear, which is what the older, large, international companies are still doing. This will not work in the future.

Getting your product speced before a tender is released is a good strategy. Then competitors have to live up to your standard and have a difficult time with how you have differentiated your product.

Some trade shows are effective while others do not have the right people (decision makers) attending. Some companies feel that a North American trade show is better since Canadians often by-pass a Canadian trade show to attend the larger, more popular U.S. trade show. Trade shows can sow the seed for future sales. They also lend credibility to the company.

Working with associations and purchasing groups can build ties and understanding of your product. This can help with the writing of a tender and winning it.

Journals are usually North American based, not domestic. Getting into the U.S. market (whether it is just a test or stamp of approval), will make it for you in Canada.

Advertising is expensive and is not generally cost effective unless the company already has an established reputation. But it can be more immediate than trade shows. It is also difficult to measure. Alternatively, advertising can be used to lend credibility to your product. This is often done by manufacturers to help their distributors. Reference selling, especially if you publish which hospitals use the product, is very effective.

Another strategy is to form a strategic alliance with a large distributor (potential competitor or multinational) and private label for them. This wholesale type of arrangement makes available a good channel of distribution with smaller margins and more volume. The smaller margin is similar to HPP and tendering bids. The opportunity is always there to go independent again.

Better marketing techniques including creating image among customers, producing catalogues and glossy literature, advertising, etc. Direct mail of promotional pieces or fax is another strategy to offer specials to hospitals across the province.

Publication in journals is a good way to get your product known better. It is then used as promotional material.

Education of the customers is important so that they don't dictate to supplier what they think they need and settle for an inferior product. Customers must be knowledgeable.

A roll-out strategy is better than attacking the national market from the start. Ontario and Quebec are good places to start.

Generally, manufacturers don't track the effectiveness of any particular approach. They only have a gut feel as to what is more effective from experience.

3.5.8 Buy-Canadian Policy

Canadian manufacturers of medical device products employ people that contribute to the Canadian economy. These same people serve as patients at hospitals and are the reason for hospitals to operate. They pay personal income taxes, their companies pay corporate income taxes, all of which help to support

the hospitals. All of this would suggest that a "Buy Canadian" policy should be encouraged and supported.

However, there is a strongly mixed feeling within the industry on whether a "Buy Canadian" policy really exists in Canada. Some manufacturers feel that it would be more difficult to sell if their product was not Canadian. Others, however, feel that acceptance of Canadian products is initially low compared to that of U.S. or European products. Some customers treat Canadian manufacturers as second-class citizens. They will give Americans all sorts of leeway such as longer delivery times but are more strict with Canadian suppliers.

In any case, the existence of a policy doesn't matter a lot since it isn't used if one does exist. "Buy Canadian" is a motherhood statement that people only pay lip service to. It is price which dictates what a hospital will buy. This is especially true for low-tech products.

Canadian companies can't undercut competition but can win on innovation side but there are not enough manufacturers in Canada doing this.

There appears to be more regional loyalty than Canadian loyalty, an unwritten policy to buy local. Regional trade barriers exist and differ in each province (i.e. Nova Scotia minister tells hospitals to buy locally wherever possible, PEI will buy locally even if they pay more). There is a perception that "Made in Ontario" is superior. Interprovincial rivalry loses sight of the big picture. If Canadian industry is to be promoted, then provincial trade barriers have to be eliminated.

Hospitals may pay a small premium for a better quality product. Canadian manufacturers are thought to be innovative and good with R&D. However, in the world market Canada cannot use the Canadian experience to launch a successful international campaign.

Advertising on "Buy Canadian" would be good but may be difficult politically when the government is supposed to maintain support for the Free Trade Agreement. The government would lose credibility in trade deals if they supported a "Buy Canadian" policy. The policy can be promoted with stickers when product is shipped. Psychologically, it is bound to be cheaper if it's Canadian.

3.6 Options

3.6.1 Education

Educate manufacturers in marketing techniques and strategies by offering marketing seminars/workshops and a forum for exchanging business ideas and strategies as well as a networking opportunity.

3.6.1.1 Scope/Description

Educational seminars for manufacturers are positive, high-profile strategies that ISTC can offer the medical devices industry in a relatively short period of time. Manufacturers, especially new medical device companies, need to be aware of the complexity and political nature of hospitals. This is particularly true in an era of fiscal and regulatory pressures. Since these pressures are forcing hospitals to be more efficient, effective and safe in their adoption of new products and technology, a more thorough understanding of the internal processes behind the adoption of new medical devices and hospitals' needs/criteria will assist manufacturers in penetrating the domestic market more readily.

In addition to understanding the customer, manufacturers must be educated in effective marketing. It is no longer possible for a company to simply send out a brochure or make a sales call and expect significant results. A marketing management program should involve decisions on the selection of suitable products for specific markets, the pricing of products, the communications program and the channel of distribution to be used. The strategy must integrate these four elements and consider different levels of risk and scope (based upon the available resources). No matter how good a product is, it will not be purchased or used extensively unless it is marketed well.

Industry experts can be used to attract participation and provide their experience in the industry. Courses and workshops on the following topics can be provided:
a) The buying process in hospitals;
b) Competing effectively;
c) Channels of distribution;
d) Targeting your campaign;
e) Strategic alliances;
f) Servicing your customer;
g) Sales forecasting; and
h) Managing the business.

The educational program should be made available either free or at minimal cost to manufacturers attending. New companies and small companies cannot

generally afford educational seminars despite their importance. Government may wish to subsidize this worthwhile effort.

3.6.1.2 Benefits

The benefits gained by the medical devices industry should begin to materialize within the short term (i.e. 6 months to a year). Assuming that the seminars provide an excellent insight into the hospital's buying behaviour and expectations of the manufacturer, and that they offer various strategies to overcome some of the barriers to selling the product, this option should be a direct catalyst in helping manufacturers promote their products more successfully in the domestic market.

This option meets an expressed need/observation from both hospitals and manufacturers.

3.6.1.3 Implementation Plan

1. A task force under the direction of ISTC should be responsible for organizing the educational program.

2. Seminars/workshops should be organized in the major centres across the country at least once per year.

3. Experts in the field (e.g. successful Canadian and American manufacturers of medical devices, key individuals from investment companies, distribution companies, companies which service medical devices, universities, hospitals and hospital associations) should be invited to speak at these seminars and network with manufacturers.

4. Videotapes of prominent leaders in the field with expertise in management and marketing and/or in knowledge of both the health care and medical device industries should be presented to provide useful information, and inspiration.

3.6.1.4 Resources

The costs would reflect the extent of the program undertaken. It would require the services of two full-time organizers, travel expenses, renting of facilities and other seminar expenses (e.g. honorarium). The cost of facilities may be reduced by renting university space .

A two-day educational conference should be held twice a year in five of the major centres across Canada. The centres should be urban centres where high concentrations of device manufacturers are located and may include Montreal,

Hamilton, London, Winnipeg, or Vancouver. Alternatively, ten centres can each sponsor one conference annually.

The budget per seminar would be approximately $3,500. A total of ten conferences/seminars including salaries would amount to $145,000.

3.6.2 Standardized Evaluation Guidelines

ISTC should pursue the development and distribution of standardized evaluation guidelines to the hospital sector and to industry.

3.6.2.1 Scope/Description

The guidelines could be packaged as a booklet that contains a listing of criteria to use in product evaluation with definitions of each criterion and a process to follow for evaluation.

3.6.2.2 Benefits

The representatives from hospitals think that this concept is not only feasible but beneficial to hospitals. It will not eliminate the possibility of different criteria or a different process being used but will serve as guidelines for hospital committees to evaluate products more thoroughly and objectively. Not all hospitals even have a systematic process which is followed. Over time, the criteria may be fine-tuned as result of feedback from the hospital community.

The proposal could help hospitals reduce costs and potential liabilities in making bad decisions. When products are selected incorrectly through subjective impression only or without any formal process, the decision is often irreversible. Long-term contracts have an impact for years on the how the hospital uses the products. The areas affected may be financial, operational, or the risks that hospitals, and even more specifically, that physicians assume in providing health care.

A more systematic approach to product selection with supporting documentation will better rationalize the decisions made by hospitals. In addition, it will help the manufacturers who are not selected to identify deficiencies in their product and/or service. This will allow the manufacturers to make improvements, thereby improving the medical devices industry in Canada and the delivery of health care.

The medical devices industry will accrue benefits as a result of their awareness of the type of criteria used by hospitals to evaluate their products. Currently, the process and criteria used varies from one hospital to another and it is therefore difficult to properly "market" the product.

The documented evaluation process using standardized criteria by one hospital could be used by other hospitals in doing similar evaluations. This could be coordinated by a central body (refer to Centres of Excellence Committee) or it may evolve as a result of the hospital "grapevine".

3.6.2.3 Implementation Plan

The implementation would necessitate the hiring of a small consulting group to assimilate the information for the booklet, identify a target market for testing, and evaluate and update the results. It will require follow-up and may require some marketing of the idea as well. The following steps are seen as the process:

1. Assimilate information on criteria and how they are interpreted. Document the variety of evaluation criteria, their components and definitions for each. Outline ways in which an evaluation process can be conducted. For instance, a rating system for weighted criteria is one example.

2. Once material is prepared, it should be tested in a number of hospital environments (including provincial hospital associations) for comments and fine-tuning.

3. The delphi method can be introduced to obtain more input and consensus. This involves soliciting expert opinion on the initial results and incorporating all inputs into a new version. Each iteration generates more agreement and produces an improvement from the one before. Support for the booklet would be gained from the participants which would ensure that it is suitable for all environments. This process would increase the likelihood of hospital acceptance of the finished product.

3.6.2.4 Resources

The estimated cost for consulting fees is $50,000. The material could be prepared in approximately 3 months. There may be some travel and living costs if the program is to be "sold" to hospitals. This would ensure that the information is implemented more fully within the target market. In addition, there would be the publishing costs (~$2,000) and the cost of mailing (~$2,000) the booklets to Canadian Hospitals and Industry.

3.6.3 Centralized Reviews/Centres of Excellence

Centralize product reviews for Canadian-made products and disseminate the information to hospitals and the medical devices industry.

3.6.3.1 Scope/Description

Two alternate sites have been identified for the implementation of centralized product reviews:
1. Canadian Standards Association
2. Teaching Hospital(s)

The hospitals will have to be sold on the objectivity of the program and therefore the importance of the site cannot be underestimated. Smaller hospitals do not regard larger teaching facilities as free from bias. On the other hand, evaluations which take place in industry are not considered to be objective either.

Since the CSA evaluates products and creates safety standards for other industries, it is a potential site for centralized product reviews. Their lack of familiarity with the devices industry and the requisite testing involved is offset by their objectivity and perceived neutrality by product users and suppliers alike. However, they would generally lack the adequate facilities to undertake medical device evaluations.

A teaching hospital would be more visible in the health care community as a testing site for conducting clinical trials and thorough product evaluations than would the C.S.A. Physicians and other hospital professionals would be more readily involved, thereby making the buy-in process easier. Professional representatives from smaller hospital centres could be included. As long as the criteria and evaluation process is sound and documented objectively with input from regional hospitals, the hospital site is the preferred route.

The following critical success factors need to be addressed to ensure successful program implementation:

a) objectivity of the reviews;
b) how representative the committee is of the hospital community's interests;
c) the choice of facility;
d) the hospital community's perception of the political environment in the testing facility and the subsequent impact on product evaluations;
e) the type of products evaluated;
f) the criteria selected;
g) the amount and type of supporting documentation for the recommended product(s);
h) the rating system; and
i) the ability to "sell" the program to the hospital community.

The product evaluations should be in report format with justification for ratings on each criteria in order to create a high degree of objectivity and improve the credibility of program.
Not all products need be assessed by the testing facilities. For hospitals to buy into the process, emphasis should be placed on the product groupings which meet certain criteria:

a) High cost item;
b) Medium to high risk/liability;
c) Life threatening;
d) Many users;
e) Demands many resources;
f) Continuous or frequent use of device; and
g) Device can cure disease/save life/reduce pain significantly/improve quality of life.

3.6.3.2 Benefits

The benefits gained by hospitals, hospital associations and industry as result of a successful implementation of a centralized review process would be significant. If done properly, centralized reviews would be able to reduce and in some cases, eliminate individual product reviews. Hospitals need to feel confident in the products they choose yet they often do not have the manpower to conduct thorough evaluations. The costs of evaluating products as well as the costs of making a bad decision in selecting the wrong product could be largely reduced through centralized reviews. The information from centralized reviews would also lead to more timely decisions. This, in turn, may reduce the long sales cycle manufacturers currently experience especially for new products.

The extent to which the individual hospital evaluation process and the associated costs would be reduced cannot be readily determined. It depends on a variety of critical success factors. A cost-benefit analysis will have to be conducted after the first year.

3.6.3.3 Implementation Plan

1. Identify actual costs of individual hospitals in doing product evaluations and identify potential savings.

2. Formulate a steering committee comprised of a multi-disciplinary team from several hospitals (large and small), including disciplines such as biomedical engineering, materials management, physicians and administration, as well as representatives from MEDEC and or manufacturers.

There are two options available :

The centralized product review program could be **initially piloted using one province.** The "test" province could be selected by ISTC with input from CHA and/or provincial hospital associations. In this way, costs of the project may be partitioned among participants. The steering committee would be primarily selected from the pilot province. This option would acknowledge concerns by hospitals about "starting out on a small scale first" and "having more in common with regional hospitals" etc. The pilot project option is designed to "iron out the wrinkles" and obtain "buy-in" from the hospitals in the one province before spreading nation wide. The Provincial Ministry of Health may cover many of the costs of the program if a proposal for funding is submitted and approved. Interested hospitals could bid and the committee representing the health care community's best interests could select the test site(s).

The second option would be to skip the pilot stage and test the project feasibility on a national level. The steering committee would be representative of a much wider group. Interested hospitals could bid and the committee would select the test hospital(s) from anywhere across Canada. Although this is a fast tracking option which supersedes provincial barriers, it is fraught with difficulties. Financing, coordination and communication problems, and achieving consensus on critical success factors such as criteria would be more difficult. Collaboration among provincial hospital associations, key teaching hospitals and other stakeholders may pose problems. Overall, it is a more burdensome and riskier option than a pilot project.

Regardless of which option is selected by ISTC, a cost-benefit analysis is recommended at the end of year one to ascertain the net effect /impact of the project. The results should be compared to step 1.

In both of the above options, the steering committee will have the following roles:
a) Coordinate evaluation requests;
b) Priorize medical devices to be evaluated;
c) Select evaluation criteria to be used;
d) Identify test site hospital(s) to conduct reviews.

3. The steering committee would then:

a. oversee all centralized product evaluations within the province, and
b. coordinate both hospital requests for product reviews and existing product reviews conducted by individual hospitals in order to make this information available for other hospitals.

4. The Steering Committee should work under the auspices of ISTC initially.

5. A rating system for each product with supporting documentation should be available on an on-line data base through an 800 number for quick reference by hospitals.

6. The effectiveness of this program should be assessed after the first year to determine if hospitals are using the results of the centralized product reviews and how much has been saved as result of this program.

7. After the trial period, the program should be moved to a location where the affiliation with hospitals is strong. (i.e. the provincial hospital association).

8. If the benefits derived in the first year of the pilot program are positive, the program could be piloted in each province across the country and coordinated nationally.

3.6.3.4 Resources

Costs in the first year are roughly estimated at $500,000. ISTC will have to determine the best way to implement the program.

The first implementation option described above suggests implementation on a pilot basis in one of the provinces (with the greatest potential support for the program). The Provincial Ministry of Health may cover some of the start-up costs of the program provided a proposal for funding is submitted and approved. The provincial hospital association in the test province may also absorb some of the costs. If the program is successful after the first year of operation, the program could be financed from estimated savings. The provincial hospital association, with its strong regional ties to the hospital sector, could then oversee the program and charge hospitals for this service through the normal fee structure process.

The costs will be significantly higher if option 2 is carried out, that is, on a national level.

3.6.4 Partnerships

Create opportunities for partnerships between hospitals, hospital associations and the Canadian medical devices industry.

3.6.4.1 Scope/Description

The characteristics of the hospital industry can be described as traditional (i.e. maintaining relationships with established suppliers), risk-adverse regarding new

manufacturers, and cautious in adopting new products. These contrast with those characteristics of the devices industry which are often presented as progressive, speculative (i.e. risk-takers) and spontaneous. As important, there is an adversarial relationship between hospitals and their suppliers. This is based on the principle that suppliers are always looking for more sales and profits while hospitals are trying to save costs. These objectives appear to conflict with each other.

However, once a relationship is established between a hospital and a supplier, and often before, a true appreciation of the other's objectives begins to develop. This changes the nature of the relationship and can build a trust that is very productive.

Partnering means working together to identify requirements for product modification as well as product development opportunities. It necessitates an open channel of communication and continuous dialogue.

The opportunity to partner involves the right attitude, a recognition of the benefits of this relationship and an environment conducive to networking.

A forum for hospital and industry representatives to meet and discuss product needs, potential niche markets, etc. can be organized by ISTC. A "reverse trade show", as a part of this conference/workshop, can give hospitals the opportunity for outlining health-care trends and product requirements. This will show the industry the spectrum of unmet needs which exist. It will also provide a good forum for networking.

For this trade show/conference to be successful and to be able to hold an annual event, attendance must be high from both the hospital and the manufacturer sectors. The event should be well advertised and highly targeted. The most suitable people to attend from the hospital side are the people who develop and modify product (e.g. biomedical engineers) and the end users (e.g. physicians). From the manufacturer side, the best possible participants are R&D people and executives.

3.6.4.2 Benefits

The benefits for the Canadian industry in creating partnerships start with an improvement in the business climate. The atmosphere surrounding business transactions will support more agreements being made and problem-free negotiations leading to a greater number of Canadian contracts.

Once partnership relationships become more prevalent, there will be less costs involved in doing business from both sides of the fence. Manufacturers will be

able to rely less on expensive marketing programs since there are customer relationships already established. Therefore, market research and trials will have been completed with the hospitals that are acting as partners.

New opportunities for manufacturing can be identified by hospitals. This can include existing products that are produced outside Canada and imported from foreign companies as well as products that have not yet been developed. These opportunities can spawn the creation of new manufacturing companies and simultaneously build the current product line of existing Canadian companies. The result is a bigger industry in Canada with an improved trade balance situation.

Hospitals will spend less time and money in sourcing products and researching companies if a partnership exists with a supplier. Hospitals can also reduce the degree of involvement that biomedical engineering has in the design and prototyping of a needed product. This would be taken over, to some extent, by the supplier that is selected as a partner.

The government, and consequently Canadian taxpayers, can benefit if the cost of doing business is reduced. The time-frames involved in bringing a product to market would also be reduced, thereby stimulating the industry by generating sales earlier.

3.6.4.3 Implementation Plan

1. Information on the partnership concept could be disseminated to the health care community and to industry (e.g. articles through C.H.A.'s newsletters).

2. A "reverse trade show" to identify unmet needs and a conference/workshop can be held to give hospitals and manufacturers the opportunity of working together and to identify areas of common interest.

3. This annual event may be coordinated with TIMEC sponsored activities such as the Technology Transfer conferences. ISTC and MEDEC can also play a role by coordinating different aspects of the program.

4. Medical device companies should be encouraged to partner with a reputable hospital (preferably teaching hospital) in testing a specialized piece of equipment or upgrading a medical device. A leading physician could enhance the marketing of the product through research of the product leading to publication in journals.

5. Successes and benefits derived from partnership activities should be communicated to the industry and hospitals.

6. The hospital associations should be approached by industry and government (ISTC and provincial health ministries) and encouraged to provide support to Canadian medical device companies.

3.6.4.4 Resources

One person can manage the implementation of this program. The responsibility primarily revolves around promotional activities as suggested in the implementation plan below and the coordination of a "reverse trade show". Though the trade show/conference should be self-supporting after a couple of years through attendance receipts, there is a need for some support in the early years.

Costs would include bringing guest speakers from leading hospitals to address the conference, subsidizing the costs of attendance to ensure high attendance, renting facilities like a conference hall and meeting rooms and advertising/promotion. It is estimated that the costs for this option are in the range of $250,000 per year initially including salary and overhead.

3.6.5 Sourcing Book and Consumers Guide

Create, distribute and maintain a current Canadian Sourcing Book and Consumers' Guide for Medical Devices.

3.6.5.1 Scope/Description

The health care industry uses a variety of sourcing documents from Canada and the United States. Many of the sourcing documents from the U.S. are preferred over Canadian versions. Many of those interviewed could not identify how much of their products are Canadian. A "Buy Canadian" policy could not be effective without first providing relevant information on which products are Canadian to the hospital community.

At the present time, there is no equivalent to a consumers' guide to medical devices in Canada. In the U.S., the Health Devices Source is similar to a consumers' guide. A consumers' guide provides detailed information on how a product performs.

The option would first involve evaluating sourcing material currently available to identify the most comprehensive document and the format which would be most useful. The type of information included and format used is important in determining the extent to which the book will be used. For instance, while the Canadian Medical Device Directory (CMDD) is intended to be used for a similar purpose, it is not used widely by hospitals today. There is also a new Canadian

directory planned by TIMEC. The efforts in planning and preparing directories would have to be coordinated to avoid duplication and to serve a specific purpose.

Once sourcing material was reviewed, information about Canadian manufacturers and their products can then be compiled. All of the information can be organized into one book for distribution. It would be desirable to highlight the Canadian manufacturers of medical devices through a symbol or bolding to distinguish them from distributors of U.S. products.

The material must be comprehensive and current, at least for Canadian companies. This would entail companies providing updates as information changes materially. For instance, major R&D initiatives, new product announcements, change of ownership, etc. would be submitted as it develops. To ensure compliance, polling of the companies can be undertaken quarterly to ensure currency of information.

A database should be established with all of the Canadian company profiles and product information. This can be coordinated with MEDEC and the B.O.S.S. system to reduce redundancy of effort. An 800 line can be established for purchasers of medical devices to inquire about updates of specific companies or products since the last edition of the book.

A second phase of this option is to develop the sourcing book into a complete Consumers' Guide that contains evaluations of each product. This product evaluation information must first be obtained either through centralized reviews (see Section 3.6.2) or through the soliciting of evaluations from hospitals which use the product (Canadian or foreign).

3.6.5.2 Benefits

The single source could help the Canadian manufacturer be identified when hospitals are researching suppliers of product. Since all Canadian companies are listed, more opportunities exist for the use of Canadian companies. This would also result in better communication of product and company information. The hospitals can benefit by referring to only one source for all of their hospital needs. This option will be well supported by the hospitals since much time and legwork will be saved.

An authoritative and reliable consumers' guide will substantially reduce the effort used by hospitals to evaluate product prior to purchasing it. Duplication between hospitals and the exhaustive process in reviewing products can be minimized. See the benefits of centralized reviews under Section 3.6.2.

3.6.5.3 Implementation Plan

A team would be established to:

a) Research the available sourcing documents used by hospitals (e.g. U.S. based, etc.);
b) Obtain profiles of Canadian companies and their products;
c) Distinguish between companies that manufacture products in Canada from others that supply products produced elsewhere;
d) Work with other agencies such as the steering committee proposed in Section 3.6.2 to obtain product review information for inclusion in this sourcing book (for phase 2 only);
e) Coordinate all inputs for bringing the product to press;
f) Create a database to keep the information current;
g) Obtain updates on a quarterly basis;
h) Publish and distribute the book annually; and
i) Handle all inquiries for information.

3.6.5.4 Resources

The costs are dependent upon the extent to which the program is implemented and the current availability of information. Initially, two dedicated individuals can be assigned to undertake the activities. Some support would be required for the maintenance of a database. The estimated costs including salaries and publishing of a book are $150,000 annually.

3.6.6 Market Research

Provide support to Canadian manufacturers on market research and trials within Canadian teaching hospitals which should include the development of a First Placement Program.

3.6.6.1 Scope/Description

Canadian manufacturers of medical devices often start their businesses with excellent ideas for products that serve a specialized function. Years can be spent in research before a prototype is finally developed. It is at this stage that many companies encounter difficulty in testing and marketing the product.

These same companies also face strong competition from foreign manufacturers who are entrenched with their products inside the hospitals. It then becomes a formidable task for the Canadian company to replace the hospital's established supplier.

From the hospital's perspective, there is a need to test a product in the hospital environment before its purchase can be contemplated. This is particularly true

for consumable products such as test kits and reagents for diagnostics. Some hospitals have been known to ask manufacturers to donate tens of thousands of test kits at no cost. It is clear that many companies, especially new start-ups, cannot afford to provide this kind of contribution. However, the manufacturer can build a good reputation within the hospital and within the industry by offering some quantity of product to trial.

ISTC can fund the donation of certain types of product to teaching hospitals and university labs. The product would be used to conduct market trials and testing of the product. This First Placement Program can apply to both consumable products such as reagents as well as specific test equipment that may use these reagents (See tied-selling, Section 3.5.6).

There are 84 active teaching hospitals out of a total of over 1,200 hospitals in Canada. This number can be further reduced if another criteria such as size (as measured by number of hospital beds) is used. ISTC must first evaluate the trade-off between the number of products and/or manufacturers sponsored versus the number of teaching hospitals that are included in this program.

The more hospitals that are included for a particular product, the stronger will be the boost in sales for that product over time. On the other hand, as more products are included in this program, there will be a similar effect of sales increases spread over more companies and products. ISTC must be careful not to spread the program too far such that the effect is only marginal for each product and does not accomplish the intended purpose.

3.6.6.2 Benefits

The teaching hospitals are the centres where the next generation of medical professionals are trained. Not only physicians that work as interns and residents are being considered here but also the administrators, directors of nursing and materials management personnel of tomorrow often start from humble beginnings at the teaching hospitals today.

When these people are exposed to Canadian made products in their early years, there is a predisposition to using them again and again. When confronted with the selection process, these professionals tend to choose product that is familiar to them. In fact, the Canadian products become the defacto standard for use in hospitals.

Hospital personnel in general and physicians without exception gain experience in teaching hospitals before they relocate to other non-teaching facilities. Therefore, the effect of placing product in teaching hospitals will spread widely into the

hospital community at large. All hospitals will come to know and use Canadian made product.

By placing product samples in teaching hospitals, there is a an opportunity for these institutions to continue using the product long after the samples run out. This will directly benefit the manufacturers of these products. The sales effort within these hospitals would be reduced once the hospital has tried the product and is accustomed to using it.

The manufacturers can also use the teaching hospitals as reference sites for marketing the product elsewhere. Teaching hospitals carry a lot of weight and influence opinion in the hospital community. Word of mouth alone may contribute significantly to increased sales for a manufacturer.

3.6.6.3 Implementation Plan

1. The process is developed by which applications are reviewed, funds are distributed and the program is managed.
2. Criteria are defined by which products or type of products qualify for this program.
3. Application forms are designed and distributed to the industry.
4. Completed applications are reviewed and funding approved.
5. Feedback from teaching hospitals is obtained on the program and minor adjustments are made.
6. After one year, a study is completed on the efficacy of the program.

3.6.6.4 Resources

One dedicated person is required to manage the program. This person is supported by a committee to review recommendations made on the selection of products and companies chosen to receive funding. This program can also be supported by provincial health ministries. They could approve partial funding to hospitals of all ISTC-approved product participating in this program. The cost for salaries, overhead and materials is $100,000. In addition, a fund of $350,000 is suggested to be administered annually.

3.6.7 Licensing

Identify foreign companies which are interested in licensing their technologies to Canadian firms for local manufacturing and distribution.

3.6.7.1 Scope/Description

About 80% of the medical devices used in Canada are purchased from foreign manufacturers. In some cases, there is not a large enough domestic market to achieve the economies of scale required for a Canadian manufacturer to offer the product profitably in Canada. In others, Canada has simply not developed the technology originally. This provides an opportunity for Canadian companies to license the technology from abroad.

3.6.7.2 Benefits

Independent of the export market for Canadian medical devices, a major improvement in the trade imbalance in this industry can be obtained. The domestic demand can be better satisfied by Canadian companies with the increase of foreign technologies licensed to companies in Canada.

There will be a greater synergy between products and companies as more technology is brought to Canada. This can lead to an increase in strategic alliances or partnering (see Section 3.6.4) and new technologies being developed domestically through greater creativity. It should be expected that as more licensing agreements are signed, there will be a ripple effect in the industry causing an even greater number of agreements and technology developments.

3.6.7.3 Implementation Plan

1. Identify the Canadian resources and expertise used in the manufacturing and distribution of medical device products. Segment or categorize these resources based upon industry subsector, type of equipment and/or type of expertise.

2. Identify foreign technologies which are used in Canadian hospitals that are capable of being manufactured domestically.

3. Develop a program to promote Canadian capabilities in the manufacturing and distribution of medical device products to foreign companies.

4. Produce a marketing style brochure and catalogue to appeal to foreign companies. The intent would be to have them start a dialogue with Canadian companies in order to license their technology. This can be coordinated with External Affairs which can act as an intermediary.

5. Although the objective is to bring technology to Canada to be manufactured domestically, another purpose can be served if Canadian distribution agreements could be signed without local manufacturing.

3.6.7.4 Resources

ISTC can assign two people to this project at a cost of approximately $120,000/year. Alternatively, a outside consultant can be contracted to provide the deliverables outlined in the implementation plan.

3.6.8 Other Options

There are many options to consider for a manufacturer. Some of these are contained in Section 3.5.7, which describes successful strategies used by profitable companies that have had significant experience.

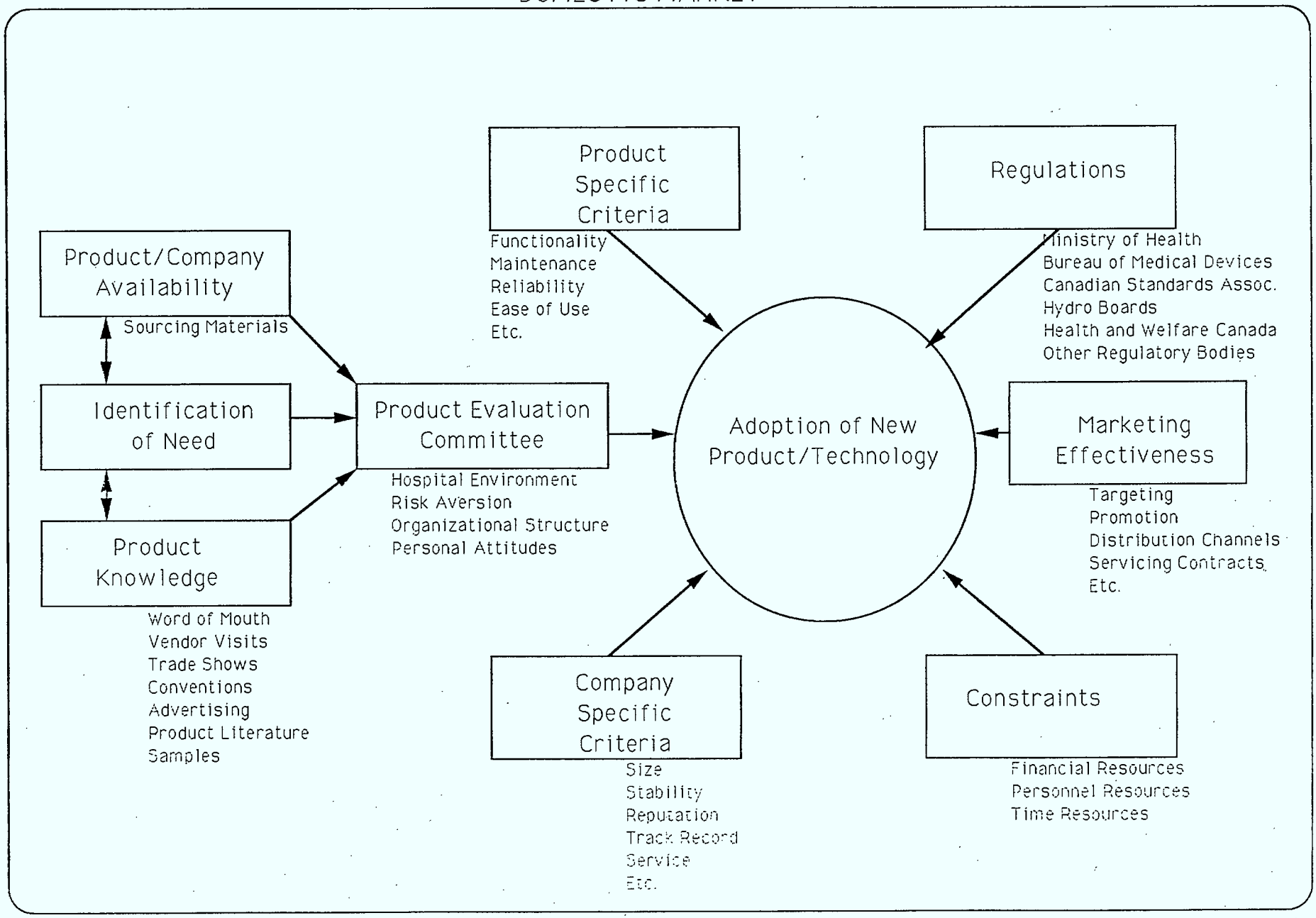
ISTC can sponsor and support the creation of independent testing facilities that can be used by manufacturers. These will provide more objectivity for product evaluations which can then be used by the manufacturers. They will also reduce the costs which some manufacturers have to assume to test their products.

Any cost savings which can be realized by a hospital in implementing a more efficient product (i.e. medical device) should be allocated by the Ministry of Health towards the hospital's budget in the following year. This would provide an incentive for the hospital to save on costs. The individual departments responsible for the cost reductions can be encouraged to continue this process through an incentive of funds availability. If only a portion of the savings is shared, then still the hospital and the Ministry come out ahead. This option would have to be sold to the proper authorities.

Use U.S.-based product testing and evaluation facilities to undertake work for Canadian organizations. This program can be co-funded by manufacturers, hospitals and government. The value of exploring this option is that duplication of facilities and programs between Canada and the U.S. can be avoided. Alternatively, improvements on existing programs can be developed.

APPENDIX A

PRODUCT ADOPTION FOR DOMESTIC MARKET



APPENDIX 3B

INTERVIEW QUESTIONNAIRE

1) Does your hospital/association have a technology assessment or product evaluation committee?

   What are their Terms of Reference (i.e. who is on it, what is their mandate, what criteria for selection is used, do they make recommendations or decisions, etc.)?

   If a committee does not exist, who is responsible for selecting the products and the companies? Do these individuals follow a process and use certain criteria for selection? Please provide details.

2) Do you see a need for the development of guidelines or standard selection criteria by the C.H.A. (or other organization) to assist hospitals in decision-making with respect to new technologies? What are the advantages and/or disadvantages of such a system?

3) If there was some centralized organization or regulatory body that evaluated products on a variety of factors and conducted acceptance tests, would the hospital require independent evaluation studies?
   If independent evaluation is deemed to be useful, what are the reasons for this?

4) According to ISTC, A Hospital Centres of Excellence Programme would include ten or more hospitals identified as excelling in certain specialties. These hospitals would be designated to conduct product reviews whereby the information would be disseminated to the medical community, thereby eliminating resources from individual hospitals being used to review all products.

   How do you view the strengths and weaknesses of this programme?

What is the best way of implementing this programme?

In developing the criteria for this programme, who should participate in its definition?

What are likely to be the costs and who should absorb these costs?

What kind of role do you see for TIMEC? MEDEC? CHA?

How do you see the information from this programme being disseminated?

5) Approximately what percentage of all of your hospital's purchases are made through companies associated with the provincial hospital purchasing program?

What factors contribute to this percentage not being higher?

Is your hospital involved in group purchasing with other hospitals?

Which product groupings are purchased in this fashion ?

6) What percentage of purchases are represented by U.S. (or foreign) manufacturers?

What advantages do these companies have over the average Canadian manufacturer?

What strategies do you believe are the most effective for a company to penetrate the Canadian health care market (eg. advertising, trade shows, seminars, referral selling?)

7) What are the greatest barriers facing new companies, and new products in penetrating the domestic market ?

8) How do you become aware of products and companies, particularly new ones? (e.g. trade shows, journals, promotional material, manufacturers reps, conferences)

What sourcing documents do you use to identify products and companies?

9) Is there a preference in your purchasing area to "Buy Canadian"? Do you think that this policy should be pursued by policy makers?

What would entice you to switch suppliers and try a new Canadian company which manufactures the same or similar product that is currently being used by the hospital?

10) What criteria are important to you in evaluating products?(e.g. functionality, flexibility, price, service)

11) What criteria are important to you in evaluating companies?(e.g. size, profitability, previous relationship, vendor proximity, reputation, good references)

12) What can a manufacturer do to minimize the risk that a hospital may experience in choosing to do business with the company?

13) Has anyone in your hospital invented a new or modified an old medical device to meet an internal need?

Was there any effort made in identifying whether this product was available or could be easily produced externally?

Has there been an attempt to promote this newly designed product to other hospitals? If so, what process was followed and what obstacles were encountered?

APPENDIX 3C
INDUSTRY INTERVIEWEES

Mr. Elwin Henwood
Sales/Manufacturing Coordinator
Atlantic Sleep Products Ltd.
Moncton, N.B.

Mr. Bruce Lawrence
Becton Dickinson Canada Inc.
Mississauga, Ont.

Mr. Gordon Politeski
President
Biomira Inc.
Edmonton, Alta.

Mr. Max Bonneau
VP Operations
Biotronics Development Corp.
Burnaby, B.C.

Ms. Cheryl Whytewood
Office Manager
C.M. Carpenter Ltd.
Stellarton, N.S.

Mr. David Roy
Sales & Marketing Manager
Bubble Technology Industries
Chalk River, Ont.

Dr. J. Clapp
Chief Executive Officer
Canadian Bioclinical Ltd.
?, Ont.

Mr. Clark Davis
Chief Executive Officer
Clark Davis Medical Systems Inc.
London, Ont.

Mr. Ron Tanaka
General Manager
Critical Assist Inc.
Toronto, Ont.

Mr. John Ployart
Division Manager
Davis and Geck,(Cyanamid Canada)
Willowdale, Ont.

Mr. Reg Allen
V.P. Marketing
Ebco Industries Ltd.
Richmond, B.C.

Mr. Gordon Cornelius
Ingram and Bell Inc.
Don Mills, Ont.

Mr. Robin Fair
Chief Executive Officer
Innovex Instrumentation Specialties Ltd.
Calgary, Alta.

Mr. Gordon Khan
Kendall Canada Inc.
Peterborough, Ont.

Mr. Ces Blaesi
La Pala Investments
Toronto, Ont.

Mr. Ian Drake
President
Manlab Instrumentation Ltd.
Winnipeg, Man.

Mr. John
President
Picker International Canada Inc.
Bramalea, Ont.

Mr. Gregory Ramsay
Chief Executive Officer
Ramsay Machine Works Ltd.
Victoria, B.C.

Mr. David Tam
General Manager
Scientek Medical Equip., div. of Cassidy's
Richmond, B.C.

Mr. Roy Trayhern
Smith and Nephew Inc.
Lachine, Que.

Mr. Brian O'Dwyer
President
Unitex N.B. Company Ltd.
Moncton, N.B.

APPENDIX 3D
HOSPITAL AND ASSOCIATION INTERVIEWEES

Institution	Contact	Title
Vancouver General Hospital	Burt Boyd Barry Pearce	V.P. Operations Director of Operations
Concordia Hospital	Mr. S. Enns Maria Cendou	Chief Executive Officer Director of Materials Mgmt.
St. Vincents Hospital	David North	Manager of Materials Mgmt.
Greater Niagra Hospital	Paul Darby Bob Mansfield	V.P. Professional Services Director of Materials Mgmt.
Fort McMurray Regional Hospital	Don Ford Bryan Younie	President Director of Materials Mgmt.
Childrens Hospital of Eastern Ontario	Betty Kannon	V.P. Nursing
St. Paul's Hospital	James Murtagh	V.P. of Operations
Moncton Hospital	Donna McIntyre	Director of Special Projects
Dartmouth General Hospital	Mike Collins Brenda Miller	Purchasing Manager Purchasing Agent
Ottawa Civic Hospital	Pat Bigras D.A. Morin	Ass't Director of Purchasing Director of Purchasing
National Defence Medical Center	Mike Gagne	Chief Executive Officer
Perley Hospital	Greg Fougere Andy Graham	Director of Hospital Services Purchasing Agent
Canadian Hospital Association	Carol Clemenhagen	Chief Executive Officer
Ontario Hospital Association Program	Brenda Gibbons Maria Batts	Acting Dir. of Purchasing Director of Trade Shows
Saskatchewan Hospital Ass'n	Matt Kaip	Dir. of Purchasing Program
Conseil de a Sante et le Services Sociaux	Pierre Brouillard	Dir. of Purchasing Program

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4.0 Regulatory

4.0 REGULATORY

4.1 INTRODUCTION

Medical devices are subject to stringent safety and efficacy regulations worldwide. While there is a trend towards harmonization of requirements internationally, differences have not and will not completely disappear between countries and trading blocks. Furthermore, even with some degree of harmonization [1] [2] total regulatory demands are increasing in Canada, U.S., EC, and Japan.[3] [4] [5] [6] Growing environmental concerns such as disposability of used devices will only increase regulatory requirements.[7]

While this situation affects all medical device manufacturers, the burden falls most heavily on small companies. Larger, more well-capitalized firms have the financial resources to pay for regulatory staffs to direct knowledgeably and thereby shorten the approval process. Increasing regulatory demand heightens existing barriers to entry while simultaneously enhancing the positions of companies with products already in the marketplace.[8]

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1 Nance P: The Rewards Outweigh the Difficulties. MEDEC J 1 (2): 6-7, Spring 1990.

2 McDowell J: Legislation to Enforce Good Manufacturing Practices. MEDEC J 1 (2): 14-15, Spring 1990.

3 Appler W: FDA Notes. Medical Device & Diagnostic Industry 12 (7): 32-35, July 1990.

4 Face to Face with FDA. Medical Device & Diagnostic Industry 12 (7): 16-21, July 1990.

5 Doriot C: No Rest for the Regulated. Medical Device & Diagnostic Industry 12 (7): 8, July 1990.

6 Gantz W: Welcoming Remarks. Presented to: First Global Medical Device Conference, Health Industry Manufacturers Association, October 22-23, 1990.

7 Dunn A: Competitiveness of the Medical Equipment Industry. Presented to: First Global Medical Device Conference, Health Industry Manufacturers Association, October 22-23, 1990.

8 Balkowski J: Wall Street's view of the Health Industry Manufacturing Companies. Presented to: First Global Medical Device Conference, Health Industry Manufacturers Association, October 22-23, 1990.

4.2 OBJECTIVE

For Canada to develop a larger medical device industry, it must promote the expansion of existing companies and the establishment of new companies which can take advantage of niches in the marketplace. This means an industry that has a continuing preponderance of small companies as well as an industry that must export to the far larger international markets to remain viable. Exporting, however, increases regulatory requirements exponentially.

Small companies are especially burdened in meeting regulatory requirements for reasons already mentioned. Therefore, this study was performed with the objective of finding approaches that can improve the access of Canadian manufacturers to information and assistance in navigating the regulatory process in Canada, the U.S. and overseas, particularly the EC.

4.3 SCOPE

This section analyses the regulatory climate, common problems, and available help in Canada, the U.S., the EC, and to a lesser extent, Japan.

Options are presented to help increase the competitiveness of Canadian firms domestically and internationally and to deal with identified problems.

4.4 METHODOLOGY

An extensive literature review was performed. A survey questionnaire was designed to elicit information concerning respondents' experiences with, and evaluations of, the domestic and international regulatory climates. Questions were included concerning options for assistance programs.

This document was used to conduct numerous phone interviews with personnel at HPB; FDA; FDA's Division of Small Manufacturers Assistance; relevant trade groups; and Canadian and American device manufacturing companies. Industry experts and device industry magazine editors were also queried.

The options presented in this section were suggested by industry personnel or felt to be useful by them.

4.5 ANALYSIS AND FINDINGS

Regulatory Climate in Canada

Regulators, regulated, and experts alike are almost unanimous in the opinion that compared to the U.S., Canada has a more favorable regulatory climate.

Because HPB does not take an adversarial approach, there is a great deal of cooperation between HPB and device companies.

Canadian device regulations are similar to and as rigorous as those in the U.S., but relations between HPB and manufacturers are based much more on cooperation.[9] Although the medical communities in the U.S. and Canada are similar, and therefore the number of devices introduced into both countries is also similar, HPB handles this similar load with fewer than 10% of the comparable staff at the U.S. FDA. This requires a system that relies much more on voluntary compliance. Most devices require only notification to HPB to be introduced into Canada, with efficacy and safety data available, but not submitted. Companies are rarely inspected by HPB unless a complaint is registered or the product has been recalled in another country.

HPB is felt by many to be an example of "small is beautiful." Because of its size it manages to avoid the communications problems typical of the FDA. HPB is widely held to be straightforward, less complicated, and technologically sound in its dealings with manufacturers.

Canadian regulations are the easiest to understand of those in the developed countries. Those in the U.S. are the next easiest. The current situation in the EC varies. However, following unification in 1992, the situation in Europe should begin to improve.

For devices requiring premarket review, the review process takes an average of 9 months.[10] This is significantly shorter than comparable review in the U.S.

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9 McDowell J: Legislation to Enforce Good Manufacturing Practices. MEDEC J 1 (2): 14-15, Spring 1990.

10 Dickson E: Gateways to Market and International Trade Issues. Presented to: First Global Medical Device Conference, Health Industry Manufacturers Association, October 22-23, 1990.

In general, clinical data adequate to obtain regulatory approval from HPB will be adequate for FDA. The reverse is also true. However, each agency generally wants to see a portion of the clinical studies conducted in their country. It is useful for manufacturers wanting to submit in the U.S. and Canada to do clinical research in both countries.

Although there are no formal good manufacturing practices regulations (GMPs) in Canada as yet, it is expected that these will be proposed in the near future. The Canadian GMPs will be modelled on the ISO 9000 series that have been or are being adopted in the EC and Japan.[11] These differ from GMPs in the U.S. in that certain quality requirements must be included in the design criteria. Although the U.S. is considering changes that would bring it more in line with the EC, these are only beginning to be adopted. Canada is not likely to implement EC-like GMPs until similar developments occur in the U.S. Although HPB currently has the regulatory authority to hold manufacturers to standards comparable to U.S. GMPs, it does not have the manpower for enforcement.[12]

Talks are ongoing between the U.S. and Canada about mutual acceptance of GMP inspections.

Prototype devices (and drugs) can be exported under Canadian law before regulatory approval, so long as they are in compliance with the requirements of the importing country.[13] This provides a significant advantage for companies that locate research and development facilities in Canada as compared to the U.S., where there are impediments to export of unapproved devices.

Canada's desire to harmonize regulations as much as possible with the U.S. and the EC, its advantage as a location for research and development, and the reduction of tariffs as a result of the U.S.-Canada free trade agreement, make it a good bridge between the U.S. and the EC.

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11 Girschweiler A: Access to EC Notified Bodies and the EC Market for Medical Products. Presented to: First Global Medical Device Conference, Health Industry Manufacturers Association, October 22-23, 1990.

12 McDowell J: Legislation to Enforce Good Manufacturing Practices. MEDEC J 1 (2): 14-15, Spring 1990.

13 Dickson E: Gateways to Market and International Trade Issues. Presented to: First Global Medical Device Conference, Health Industry Manufacturers Association, October 22-23, 1990.

Common Regulatory Problems in Canada

While the Canadian regulatory environment is seen as generally positive, problems do exist.

The proposal for bilingual labels could cause an increase in costs and complexity for Canadian manufacturers and especially for importers.

While Canadian regulations are modelled after those in the U.S., HPB's concerns can be different than those of FDA. This can increase the regulatory burden of companies selling in both countries, i.e. implantables for domestic manufacturers.

Companies that are not experienced with regulatory requirements and have limited resources will often attempt to find the shortest or cheapest solution, rather than the best solution. This does not work well in a regulated environment and causes serious problems down the road.

Small companies in particular are often unaware of sources of regulatory information. The regulations are often confusing to those not already familiar with them. Companies may not have resources to get proper medical input on design or to understand that they are selling a regulated device.

A phone call to HPB or MEDEC will direct a company towards information that will allow it to meet regulatory requirements for the majority of products needing only market notification ten days after first sale. Small companies in particular are frequently uninformed and unaware of where to find information and guidance regarding continuing regulatory requirements once a product is marketed, i.e. recording and reporting of complaints; adequate record keeping of design development and changes; manufacturing records; lot numbers; information adequate to do recalls if necessary, such as customer lists and sales records; etc.

While approximately 95% of products require only notification to be marketed, there must exist data to demonstrate their efficacy and safety prior to sale. Developing this data requires expertise and resources small companies often lack.

Companies frequently fail to designate a specific person or department to be responsible for regulatory compliance.

HPB does not currently make available Guidelines/Guidance documents for categories of products or general regulatory requirements, as is done by FDA.[14] [15] [16] Guidelines explain regulations and help manufacturers understand how best to meet them.

HPB conducts relatively few workshops and symposia for industry, nor does it carry out nonregulatory inspections to help manufacturers understand what they need for compliance.

For products requiring premarketing approvals, companies without regulatory staffs or experience in these submissions are routinely in need of assistance in: interpreting which regulations apply and how they must be met; designing and implementing adequate clinical research; and learning the mechanics of the submission process.

The review process for AIDS diagnostics, which require premarket approval, is reported to be very slow, with products often technologically obsolete by the time the approval process is completed.

Companies would like to be informed of impending regulatory changes in advance. Diagnostic products do not require premarket approval except those for AIDS, and this change was reported to have been instituted without sufficient notice.

Concerning AIDS diagnostics, under U.S. law they cannot be exported prior to FDA approval except with a "no objection to sale" letter from the regulatory agency in the importing country. This has been reported to create difficulty for importers in Canada, because this letter has been difficult to obtain. Perhaps HPB could help in some way.

Waste management is a growing problem for companies, both in Canada and abroad.

When clinical research is conducted domestically or internationally for regulatory or marketing purposes, certain problems are common:

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14 US Department of Health and Human Services: Everything You Always Wanted to Know About the Medical Device Amendments and Weren't Afraid to Ask. HHS Publication FDA 84-4173, August 1988.

15 US Department of Health and Human Services: Import and Export. HHS Publication FDA 88-4160, August 1988.

16 US Department of Health and Human Services: Regulatory Requirements for Medical Devices. HHS Publication FDA 89-4165, May 1989.

poor research design; inadequate data to establish efficacy and safety; failure to follow protocols; inadequate monitoring of studies because of cost; and how to do studies in foreign countries and use the data meaningfully.

Help Available from HPB

Assistance available from HPB depends upon attitude. If you are willing to work with HPB, HPB will be helpful. It is important to develop a good rapport and communicate with HPB.

Most industry people feel that meetings with HPB inspection staff are helpful to companies in understanding and complying with regulations. These meetings are readily available when significant issues have arisen and companies do not fear reprisals as a result of what is said. HPB is flexible in its approach but tends to be "reactive" in style. This means that companies must be aggressive in presenting exactly what they want to do, and in proposing options to HPB. They need to carefully spell out the reasons behind their proposals and have contingencies available.

HPB staff likewise report that meetings are beneficial and are readily available. They emphasize their willingness to help in all ways consistent with regulations.

When there are significant changes in regulations, HPB attempts to inform manufacturers via workshops.

Regulatory Climate in the U.S.

U.S. regulations are similar to those in Canada, but there is a much more adversarial relationship between companies and FDA. However, the Medical Devices Group at FDA has the reputation of being cooperative.

FDA is a large and bureaucratic organization. Product approval is very time consuming. Some premarket approvals (PMAs) take many years.

FDA regularly conducts GMP inspections of device manufacturers.

Current law requires device exporters to obtain regulatory approval by FDA prior to exporting their products. The exception is if the importing county accepts the product without FDA approval. In the case of Canada, this is often easy to accomplish.

FDA is a politically sensitive organization. If it approves a device that has subsequent problems, it is subject to criticism by the Congress and special interest groups, but if it does something right it gets no acknowledgement. Therefore there is no incentive to approve devices, and it is often safer to delay.

There is a high turnover of personnel at FDA which leads to a lack of expertise, especially in areas of new technology.

In light of movements toward harmonization of device regulations in other countries, FDA is attempting to do the same. On November 28, 1990, President Bush signed the Safe Medical Devices Act of 1990 which directs FDA to set up an Office of International Relations in order to negotiate agreements that harmonize U.S. device regulations with those of other countries. These moves in Congress would significantly increase device regulation.[17] [18] [19]

Even before this act, FDA negotiated an agreement with the U.K. for each country to accept the other's device inspections in all areas except sterilization. Talks are ongoing with Canada about mutual acceptance of GMP inspections and there are tripartite harmonization talks being held between the U.S., the U.K. and Canada.

Common Regulatory Problems in the U.S.

In the U.S. the relationship between companies and FDA is frequently adversarial. Industry sees the agency at an impediment to their functioning.

Large device companies have regulatory staffs and experienced consultants to help them meet requirements effectively. Problems that commonly affect small companies which lack these resources, include:

- not understanding what properly defines a device;

- not understanding or correctly interpreting the regulations;

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17 Appler W: FDA Notes. Medical Device & Diagnostic Industry 12 (7): 32-35, July 1990.

18 Face to Face with FDA. Medical Device & Diagnostic Industry 12 (7): 16-21, July 1990.

19 Doriot C: No Rest for the Regulated. Medical Device & Diagnostic Industry 12 (7): 8, July 1990.

- not knowing who to deal with at FDA (i.e. diagnostics can fall under the jurisdiction of either the Device or Biologics groups at FDA, depending on technology and application);

- not knowing when Premarket Approval or Investigational Device Exemption is necessary;

- not understanding or complying with filing requirements;

- not understanding that a small design change can have a large regulatory impact;

- not submitting required reports;

- formalization of procedures;

- inadequate documentation;

- not knowing what FDA inspectors will look for (primarily compliance to GMPs) during inspections;

- failure to do internal audits to prepare for inspections;

- not knowing what constitutes a recall when a recall is required, and how to carry it out;

- not understanding the distinction between complaint and field service records (if a device fails, FDA considers this a complaint and there are reporting requirements); and

- inadequate clinical research.

The number of device recalls (currently under 1000 per year) have been increasing.

Problems that commonly arise when conducting clinical research include: poor research design; inadequate data to establish efficacy and safety; failure to follow protocols; inadequate monitoring of studies because of cost; and how to do studies in foreign countries and use the data meaningfully.

Help Available from FDA

The primary vehicle by which FDA provides assistance to device manufacturers is the Division of Small Manufacturers Assistance

(DSMA), formerly known as the Office of Small Manufacturers Assistance (OSMA), of the Office of Training and Assistance, Center for Devices and Radiological Health (CDRH).

DSMA was created in 1977. Congress recognized that small manufacturers of medical devices would need assistance in complying with the 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act. It therefore called for the creation of DSMA with this provision: "an identifiable office to provide technical and other nonfinancial assistance to small manufacturers of medical devices to assist them in complying with the requirements of the Federal Food, Drug and Cosmetic Act."[20]

DSMA provides the following information and services to any company or individual who contacts them:

- free telephone access via 800 number;

- answers written, phone, or in-person requests for information on any aspect of device regulations;

- assists firms in obtaining and filling out necessary forms and documents;

- assists in directing inquiries and/or submissions to the proper offices at FDA if they can not be handled by DSMA;

- assists in arranging meetings with appropriate FDA personnel;

- conducts nonregulatory inspections of facilities (in the U.S. only) to help manufacturers come into compliance;

- annually conducts approximately forty 3-4 day free workshops (which are always filled to capacity) around the U.S. on Medical Device Laws and GMP subjects, open to any interested participant, and geared towards the needs of the companies in the area in which the workshop is being held. Specific day long workshops have been developed on "Regulatory Requirements for

20 Section 10, Medical Device Amendments, Federal Food, Drug and Cosmetic Act, 1976.

Marketing a Device," "The GMP Regulations," "Sterile Devices," and "Import-Export Requirements;"[21]

- distributes FDA and CDRH publications;

- provides complete information packets that contain forms and information on the basic FDA requirements for those new to the device field;

- prepares guidelines and educational materials;

- publishes the monthly Medical Device Bulletin to provide updates on workshop schedules, conferences, and publications available from DSMA; and

- serves as spokesperson for small manufacturers.

DSMA provides free information on:

- establishment registration;

- device listing;

- device classification;

- Premarket Notification (510[k]);

- Premarket Approval (PMA);

- Investigational Device Exemption (IDE);

- Good Manufacturing Practices (GMPs);

- performance standards, policies, and procedures;

- regulations, interpretations, petitions; and

- radiation-emitting devices.

DSMA, which began with 5 people in 1977, currently has a staff of 24 and an annual budget of US $200,000. This does not include salaries

21 US Department of Health and Human Services: Everything You Always Wanted to Know About the Medical Device Amendments and Weren't Afraid to Ask. HHS Publication FDA 84-4173, August 1988.

and other personnel costs that are figured at approximately US $60,000 per person. This yields a total annual cost of approximately US $1,640,000 to run the division. It is estimated that approximately 5000-6000 companies use its services per year. Other than a newsletter mailing to all U.S. device firms, little has been done in recent years to publicize DSMA.

Because its philosophy is to help everyone who asks, and because it is not perceived as having any regulatory "axe to grind," DSMA is considered to be among the best divisions at FDA.

DSMA would like to hold more workshops and hopes to eventually add more scientific and technical people to its staff to become even more effective.

In line with the Regulatory Flexibility Act and Executive Order 12291, DSMA officially suggests changes or alternatives to FDA policies or requirements, and also suggests different approaches for meeting safety and efficacy goals that are less restrictive or costly.

DSMA receives frequent calls for assistance from Canadian companies and is nondiscriminatory in providing its services.

Feedback from DSMA personnel, FDA field inspectors, device companies, and regulatory consultants is uniformly positive concerning the division.

While large companies with regulatory staffs or consultants do not often need DSMA services, small firms find it a blessing, especially new companies not familiar with FDA.

Assistance in filling out forms, explanations of regulations, workshops, educational materials, and nonregulatory audits to help compliance with GMPs are all reported to be of great use to smaller firms.

DSMA is responsive. Its personnel are helpful, well trained and knowledgeable in device laws, regulations, and procedures. Its educational materials are well done and the workshop series is excellent and well attended (workshops are always full). Nonregulatory inspections, while the most costly service to provide, are especially popular. They give a company a clear picture of what is expected from a real inspection and how to prepare for it, without fear of penalty as a result of a DSMA visit.

FDA field inspectors who are familiar with DSMA feel that it helps them get their job done. By educating companies about regulatory requirements, DSMA allows inspectors to spend more of their time inspecting. They have less of a burden trying to educate companies about what regulatory requirements are and how to meet them.

A new approach to assistance by FDA is the Small Business Representatives program. Similar in its services to those of DSMA, it is broader in its application, being available to companies producing all products regulated by FDA (devices, food, drugs, cosmetics).

One Small Business Representative is authorized for each of FDA's 6 regions. Although there are only 6 Small Business Representatives for the entire country, they each handle thousands of information requests annually.

Working out of local offices, these experienced former inspectors answer questions, provide FDA's educational and regulatory materials, do nonregulatory plant visits and conduct workshops, sometimes in conjunction with DSMA, for companies requesting their assistance.

Unlike DSMA, Small Business Representatives are available for in-house workshops and training programs. They keep in close contact with FDA headquarters to give companies the most current information and feedback possible. Like DSMA, the Small Business Representative program is well received by both manufacturers and FDA field inspectors who are familiar with it, and for the same reasons.

Finally, a specific program available to manufacturers located outside the U.S. is offered by the International Inspections Branch of FDA. On request, this group will inspect foreign plants to certify that they meet U.S. GMPs so their products can be imported into the U.S., assuming that other relevant requirements are also met.

While DSMA and Small Business Representative services are excellent and well received, it is important to point out that they are not a substitute for a company having access to its own regulatory expertise.

These services help companies, but in a general way. For instance, DSMA's plant visits do not go into the depth that an actual FDA inspection would. In highly technical areas, expertise is usually not available through these assistance programs.

Explaining regulations is not the same as a detailed regulatory review that a paid consultant or in-house expert would carry out. Companies must have ongoing programs to maintain GMPs and other regulations. This requires internal mechanisms to achieve compliance.

Regulatory Climate in the EC

A confrontational regulatory climate such as seen in the U.S. does not exist in the EC. There is greater willingness on the part of industry to bring its problems to government. The regulatory changes taking place as a result of EC economic union are strongly supported by the industry there.

These changes are dramatic, if not necessarily predictable. The EC community has mandated by law that there will be a single standard for all countries to allow completely free trade. The target date is January 1, 1993. It is clear already that this target will not be met and what form the final outcome takes is far from certain.[22]

The Benelux countries already have a single agency that handles devices and the Scandinavian countries have instituted uniform requirements between them.

While it seems likely that there will emerge a single standard for medical devices for all of Europe, estimates of when this will occur vary through the year 2000 and beyond.

Part of the problem is that medical and regulatory systems vary dramatically in the EC. Countries like England and Germany have strict requirements, demanding clinical research that meets internationally recognized standards. France and Italy, on the other hand, have approval systems more geared towards endorsement by prominent professors. Furthermore, Italy is not highly regarded for the quality of its clinical research, and France, much like the Japanese, is reported to use nonregulatory barriers to keep competing products out. Large numbers of laws and regulations must be changed in member countries to allow harmonization, and this process has a long way to go.[23]

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22 Duncan M: Interpretation and Implementation of Directives. Presented to: First Global Medical Device Conference, Health Industry Manufacturers Association, October 22-23, 1990.

23 Schorn G: EC 1992: System of Approval for Medical Devices Interpreting and Implementing the EC Directives. Presented to: First Global Medical Device Conference, Health Industry, Manufacturers Association, October 22-23, 1990.

The EC Council of Ministers' resolution of May 7, 1985, lays down a number of fundamental principles on which harmonization of standards is to be based. Member states, when implementing EC directives, are not allowed to introduce national legislation that goes beyond these directives.

European standards are to be promulgated by the European Standards bodies CEN and CENELEC. These are the European counterparts to the United Nations' International Standards Organization (ISO) and International Electrotechnical Commission (IEC) respectively. The nations of the European Free Trade Association (EFTA) are also committed to adopting these standards, making a total of 18 countries in Europe moving in this direction.

The path is designed to be one of mutual recognition. EC member states are required under article 30 of the Treaty to accept on their territory products legally produced or marketed in other member states, even if these originated outside of the Community.[24]

The idea is for a company to be able to submit in one member state, according to unified EC standards. Via approval in that one country an EC mark would be granted to the product, and sale would be permitted in the entire EC community, unless there is a good and sufficient reason for another member to prohibit it. Since the standards met would be the same as those for the EFTA nations, approval in these countries would also be expedited.

This system will not be in operation in 1993 and is not likely to function as described for years to come. Some experts doubt that countries will ever give up enough sovereignty to make this work, but they are in a minority. Whether there is ever complete harmonization however does remain in doubt. There is also speculation that a single FDA-like body will emerge in the Community empowered to grant an EC mark recognized in all member countries. Only time will tell.

The situation is a mess at present. Large companies have the resources to keep up with rapidly changing regulations and to set up subsidiaries in target export markets to help them through the regulatory process. But the demands on small companies wanting to export now to Europe can be daunting.

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24 Girschweiler A: Access to EC Notified Bodies and the EC Market for Medical Products. Presented to: First Global Medical Device Conference, Health Industry Manufacturers Association, October 22-23, 1990.

Help Available in the EC

At present, where available, assistance is provided to manufacturers at the national level by member states. There is no existing system of assistance at the EC level. There is, however, a great deal of interaction between regulatory authorities in each member state and the centralized EC authorities in Brussels. It is too early to predict whether there will develop an EC-wide system of assistance for device manufacturers. Currently, because 12 separate governmental bureaucracies are involved, the types of assistance vary. Their analysis is, unfortunately, beyond the scope of this study.

Regulatory Climate in Japan

Regulatory approval is not unusually difficult so long as research is carried out in Japan. However, Japan imposes nonregulatory barriers whenever possible, such as withholding approval for reimbursement of non-Japanese products.

Japan is the most difficult regulatory environment of the developed countries for in-vitro diagnostic products.

In order to effectively sell in Japan, it is usually necessary either to manufacture there or find a Japanese company highly experienced in their system to act as distributor or marketing partner.

Other Findings

The Canadian device industry has few large companies and must export to compete. Companies, especially small companies, need better availability of information concerning international regulations and clinical research.

Due to the complexity of regulations and variation between countries presently existing in the EC, regulatory approval can justifiably be described as a nightmare for non European companies.

Find a knowledgeable expert who follows the changes and who can advise on regulatory requirements in the country to which you wish to export.

In order to gain a realistic chance of approval, have international submissions handled by someone located in the country in question, (experienced law firm, consultant, affiliate, subsidiary, etc), who can deal with the regulatory body as needed.

As harmonization of requirements in Europe is likely to take until well after 1992, the best approach will be to submit in one country, (England is probably the most logical choice due to similarity of medical practice, legal system, and language), and attempt to secure an EC mark on that basis with the clear understanding that additional submissions and requirements may well be required in other EC countries for some time.

However, it is likely that it will eventually be possible to have one submission suffice in the majority of cases. Companies that consistently submit in one country will develop essential expertise and contacts.

For devices requiring extensive clinical data prior to marketing, most regulatory agencies like to see at least some clinical research done in their country.

Clinical research data obtained for regulatory purposes is also the initial data a company will use to market its product. Therefore careful planning is required to make certain that the clinical research base is adequate to tell a convincing story in the marketplace at the time of product introduction, and that studies have been done in each country for which this is a regulatory or marketing consideration.

For submissions that may not require clinical studies, i.e. 510(k) in the U.S., research is still necessary for effective marketing. A strategy must be implemented that takes this into account.

The expertise to carry out clinical research and to find competent research scientists is lacking at many small companies. For the many companies whose customer base cannot provide adequate sites for clinical research, assistance is needed.

4.6 OPTIONS

Based upon extensive interviews with companies, regulatory agencies, and knowledgeable experts in the medical device industry; review of the literature; and compilation of the above findings; we have developed a series of options that we believe can be of use in assisting the Canadian medical device industry to better deal with the increasing regulatory demands that affect it at home and abroad, and which should prove cost-effective in the long term.

4.6.1 ESTABLISHMENT OF A DSMA-LIKE GROUP

SCOPE:
As the climate in Canada is simpler and more user friendly than in the U.S., a DSMA-like group focussed solely on HPB regulatory issues is probably not necessary at this time. However, it would be very beneficial to the industry if this group were familiar with U.S. and international regulations; acted as a referral to and liaison with FDA's DSMA group which routinely assists Canadian firms; kept abreast of issues and contact information for the EC; and had programs similar to DSMA's for all relevant Canadian device regulations (HPB, environmental, radiologic, etc.).

Given its broad mission, this new organization might, but would not necessarily have to, be a part of HPB. It could also be associated with ISTC, MEDEC, or TIMEC. This decision could be made based upon the interests of these various organizations and the needs of the industry.

RESOURCES REQUIRED ANNUALLY:

Staff salaries (2)	$80,000
Clerical staff	$25,000
Overhead	$80,000
Materials, programs, etc.	$50,000
	$235,000

This group would require a staff of 2 to start, and with adequate clerical assistance, could immediately institute an 800-number service and begin guiding new and small companies through the regulatory process. Workshop series and other educational materials, based upon the models provided by FDA, could be developed over time.

The program could grow to include Small Business Representative-like functions, with staff located at the regional offices, as demand justified.

BENEFITS:
The benefits of a DSMA-like group to device companies would be large, especially to the new and small companies that are so important to the growth of products and technologies. They would have a single contact for information on regulations and referrals.

IMPLEMENTATION:
1. Determine which organization this group would be a part of (HPB, MEDEC, TIMEC, ISTC, etc).
2. Hire project manager.
3. Project manager determines services to be offered, locates office space and equipment, hires additional staff.
4. Establish liaison relationships.
5. Inform relevant groups and individuals of services available.
6. Begin operations.

4.6.2 ESTABLISHMENT OF A CENTRAL RESOURCE FOR CURRENT REGULATIONS OF EXPORT MARKET COUNTRIES AND IMPORTANT DEVICE PUBLICATIONS

SCOPE:
Many companies report difficulty in locating foreign device regulations anywhere in Canada. The alternative is to deal directly with the foreign regulatory agency which can be extremely difficult, time consuming and expensive for them.

A central resource for this information, available in translated form, as needed, would be invaluable to companies involved in or attempting to export. Translated summaries are often available and can provide a great deal of needed information.

The office for this service could be established separately or as an extension of services of the DSMA-like group described above.

The staff would assist companies by obtaining and translating regulations of export market countries as requested by manufacturers. These translated regulations would then be used to develop a library, which over time would become extensive.

In addition, subscriptions could be maintained to those major device and regulatory publications not otherwise readily available to most companies.

Eventually, if adequate resources became available, updated international regulatory information could be placed on an electronic database for easier access. Publications summarizing the changing international regulatory picture could be developed.

Initial steps in this direction are already being undertaken by MEDEC. TIMEC attempts to provide subscribers with a regulatory intelligence service.[25]

RESOURCES REQUIRED ANNUALLY:

Staff salaries (2)	$80,000
Overhead	$80,000
Subscriptions, translations, etc.	$100,000
	$260,000

BENEFITS:

Many small companies would be able to enter the export market much more easily, because regulatory requirements would be clearer.

IMPLEMENTATION PLAN:

1. Determine location for this group.
2. Hire project manager.
3. Project manager locates office space and equipment, hires second staff person.
4. Coordinate services with those already available at TIMEC and MEDEC.
5. Take subscriptions to relevant publications.
6. Establish liaison with international regulatory agencies.
7. Make arrangements for translations.
8. Inform relevant groups and individuals of services available.
9. Begin operations.

25 Nance P: MEDEC, Aided by Federal Government Grant, Starts Drive for More Canadian Devices. MEDEC J 1 (1): 6-7, Winter 1989.

4.6.3 INSTITUTION OF REGULAR WORKSHOPS, CONFERENCES AND COURSES ON EXPORT MARKET REGULATORY ISSUES

SCOPE:

A quarterly series of workshops, conferences, and courses could be structured to make available regulatory experts and officials from export market countries. Topics and speakers could be planned in advance based upon input from the industry.

Travel, accommodations, and conference fees would be paid by attendees, with "scholarships" as funding permitting smaller companies with limited resources to attend.

Conferences are already being organized to some extent by MEDEC and government. A DSMA-like group as described above would increase this type of activity and/or could be the responsible organization. ISTC would also be a suitable institution to run the program.

RESOURCES REQUIRED ANNUALLY:

Staff salaries (1)	$40,000
Clerical salary	$25,000
Overhead	$40,000
Advertising and promotion	$60,000
Scholarships	$100,000
	$265,000

Actual expenses for each conference (facility rental, speakers fees, etc.) would be paid for out of conference fees.

BENEFITS:

A serious commitment by government to sponsor a long-term educational effort of this sort, with regular, yearly meeting series would be extremely useful.

This would be a help to companies wanting to export. It would allow them to question officials and experts who know the requirements in great detail, and provide an initial contact in a foreign agency that could direct them further as needs progress and change.

IMPLEMENTATION PLAN:

1. Determine location for this group.
2. Hire project manager.

3. Project manager locates office space and equipment.
4. Contact relevant groups and individuals to determine topics and speakers most useful to the industry.
5. Plan conference dates and topics in coordination with similar industry and government efforts already underway.
6. Inform relevant groups and individuals of conference schedules.
7. Begin conferences.

4.6.4 USE OF EMBASSY, CONSULATE, AND OTHER GOVERNMENTAL PERSONNEL LOCATED IN EXPORT MARKETS TO DEVELOP RESOURCE CONTACTS

SCOPE:
Government already has personnel located in the export markets of interest to the industry. These highly skilled and experienced people could be used to locate local regulatory consultants, attorneys, contract agents, importers, and others involved in the device industry in a formal way.

RESOURCES REQUIRED ANNUALLY:

Staff salaries (1/2)	$20,000
Clerical salary (1/2)	$12,500
Overhead	$20,000
	$52,500

BENEFITS:
This program would assist Canadian firms in making the contacts so important to making inroads in foreign countries. As these people are already in place and this approach is being used to some extent already on a casual basis, this proposal should be easy to implement. The costs involved would be primarily those for keeping a central repository of findings, and should be relatively minor.

IMPLEMENTATION PLAN:
1. Determine location for this group.
2. Hire project manager.
3. Project manager locates office space and equipment.
4. Identify relevant embassy and consulate personnel.
5. Supply program information to identified embassy and consulate personnel.
6. Inform relevant industry groups and individuals of availability of the service.

7. Begin operations.

4.6.5 FUNDING TO ASSIST MEDEC TO ESTABLISH FORMAL LIAISON RELATIONSHIPS WITH MAJOR INTERNATIONAL DEVICE ORGANIZATIONS

SCOPE:
Groups such as the Regulatory Affairs Professionals' Society (RAPS), the Health Industry Manufacturers' Association (HIMA) etc. are on the cutting edge of regulatory thinking. They are also among the best sources of intelligence about upcoming changes in the industry internationally.

Canadian manufacturers need access to these resources through their industry organizations such as MEDEC.

RESOURCES REQUIRED ANNUALLY:

Staff salaries (1/2)	$20,000
Clerical salary (1/2)	$12,500
Overhead	$20,000
Travel	$12,000
	$64,500

BENEFITS:
To be competitive, exporters require up to date information not only on current regulatory requirements, but on how these are likely to change.

This information is often available through trade groups. This program would allow a very cost-effective way of obtaining it.

IMPLEMENTATION PLAN:
1. Determine location for this function.
2. Hire project manager.
3. Project manager locates office space and equipment.
4. Identify relevant international industry groups and establish liaison relationships.
5. Disseminate findings to the industry on a regular basis.

APPENDIX A
INDIVIDUALS CONTACTED FOR REGULATORY SECTION

Linda Cheng
Markus Research Inc.
West Nyack, N.Y.

Tom Brown
Vice President
EUMS Pharma
Metuchen, N.J.

Guilietta Campece
Manager of Regulatory and Clinical Affairs
EUMS Pharma
Metuchen, N.J.

Dr. William Troetel
Director of Regulatory and Research Coordination
Yamanouchi Pharmaceutical Company
New York, N.Y.

Stephanie Beling, M.D.
Consultant.
Richmond, M.A.

Maurice E. Silverstein
Senior Associate
CMR Associates
Wilton, CT

Joyce Rollins
Consumer Safety Officer
FDA
Division of Small Manufacturers Assistance
Rockville, MD.

Aileen Ryan
Director of Regulatory Affairs
Oxford Research International Corp.
Clifton, N.J.

Christine Richardson
Area Manager - BCG
Biotechnology Research Institute

Rockville, M.D.

Carl Johnson, M.D.
Consultant
Big Sky, MT.

Ami Daniel Ph.D
Director - In Vitro Diagnostics, Manufacturing
and Biotechnology Programs
Health Industry Manufacturers Association
Washington, D.C.

Larry Muenz Ph.D
Statistician
Gaithersburg, MD.

Lawayne Stromberg, M.D.
Consultant
Mundelein, IL.

Alan Goldhammer PhD
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Industrial Biotechnology Association
Washington, D.C.

Ernest Carabilla
Consultant
Concord, MA.

Bob Scales
Medical Device Specialist
HPB Regional Office
Winnipeg, Manitoba

Harold Jones
Small Business Representative
FDA Regional Office
Dallas, TX.

Dr. Neal Dunning
Director
Division of Small Manufacturers Assistance
FDA
Rockville, MD.

George Kerner

Editor
International Drug and Device Regulatory Monitor
Potomac, MD.

Steve Ferguson
Director of Regulatory Affairs
Cook Inc.
Bloomington, IN.

Fred Norman
Supervisory Investigator
FDA
San Jose, CA.

Frank Eng
Device Specialist
FDA
San Jose, CA.

W.J. Welsh
Chief, Pre-Market Division
Bureau of Radiation and Medical Devices
Ottawa, Ontario

John Riou
Director - Bureau of Field Operations
HPB
Ottawa, Ontario

Mark Roh
Small Business Representative
FDA
San Francisco, CA.

Gary Zaharek
Device Specialist
FDA
San Jose, CA.

Graham Tolfree
Manager of Operations and Business Development
Abbott Diagnostics
Mississauga, Ontario

Walter Downs
Product Manager - Treatment Systems

Theratronics International Ltd.
Kanata, Ontario

James McDowell
Vice President
MEDEC
Etobicoke, Ontario

Donna Mae Bergener
Chief Inspection Officer
HPB Regional Office
Winnipeg, Manitoba

Steven Hayter
President
ADI Diagnostics Inc.
Rexdale,Ontario

Tom Colclough
President
BDH, Inc.
Toronto, Ontario

Glen Smeltzer
V.P. Marketing
Clark Davis Medical Systems In.
London, Ontario

Regis Duffy
President
Diagnostic Chemicals
Charlottetown, Prince Edward Island

Mike Cannata
President
Quantified Signal Imaging, Inc.
Toronto, Ontario

Robert Westman
President
J.W. Westman Inc.
Mississauga, Ontario

William Galloway
President
Apotex, Inc.

Weston, Ontario

Richard Rivera
Consumer Safety Officer
FDA
Division of Small Manufacturers Assistance
Rockville, MD.

Lynn Rice
Consumer Safety Officer
FDA
Division of Small Manufacturers Assistance
Rockville, MD.

APPENDIX B
REGULATORY SECTION QUESTIONNAIRE

1. WHAT ARE THE PROBLEMS COMPANIES ROUTINELY FACE IN DECIPHERING AND MEETING THE MEDICAL DEVICE REGULATORY REQUIREMENTS (ENVIRONMENTAL, HEALTH AND SAFETY, LABELLING, CLINICAL RESEARCH ETC)?
   A. FOR CANADA
   B. FOR U.S.A
   C. FOR EC
   D. FOR OTHER FOREIGN MARKETS

2. WHAT SPECIFIC ASSISTANCE DOES YOUR COMPANY, OR THE INDUSTRY IN GENERAL, NEED IN DECIPHERING AND MEETING THESE REQUIREMENTS?
   A. FOR CANADA
   B. FOR U.S.A.
   C. FOR EC
   D. FOR OTHER FOREIGN MARKETS

3. WHAT WOULD YOU ESTIMATE ARE THE AVERAGE COSTS IN MEETING THE REGULATORY REQUIREMENTS TO BRING A NEW DEVICE TO THE MARKET OF EACH OF THE FOLLOWING, AND ARE THESE COSTS AFFORDABLE?
   A. FOR CANADA
   B. FOR USA
   C. FOR EC
   D. FOR OTHER FOREIGN MARKETS

4. HOW EFFECTIVE ARE MEETINGS WITH HPB INSPECTION STAFF IN ASSISTING COMPANIES MEET CANADIAN REGULATORY REQUIREMENTS, AND HOW AVAILABLE ARE THESE MEETINGS?

5. HOW COULD MEETINGS WITH HPB INSPECTION STAFF BE MADE MORE USEFUL?

6. WHAT OTHER ASSISTANCE COULD HPB OFFER TO DEVICE COMPANIES?

7. CONCERNING SERVICES OFFERED BY FDA'S DIVISION OF SMALL MANUFACTURERS ASSISTANCE (DSMA), WHICH SERVICE(S) DO YOU CONSIDER WORTHWHILE, AND WHICH NOT?

8. HOW COULD DSMA SERVICES BE IMPROVED?

9. WHAT OTHER ASSISTANCE COULD DSMA OFFER TO DEVICE COMPANIES?

10. WHICH DSMA SERVICE(S) DO YOU THINK ARE COST EFFECTIVE, AND WHICH ARE NOT?

11. DO YOU KNOW OF MECHANISMS IN EC OR OTHER COUNTRIES THAT HAVE BEEN SET UP TO ASSIST DEVICE COMPANIES DEAL WITH REGULATORY REQUIREMENTS?

12. HOW DO YOU LOCATE REGULATORY CONSULTANTS/SERVICES WHEN YOU NEED THEM?

13. DO YOU NEED ASSISTANCE IN LOCATING REGULATORY CONSULTANTS?

14. HOW DO YOU LOCATE COMPANIES OR INDIVIDUALS WHO DO CLINICAL TRIALS WHEN YOU NEED THEM?

15. DO YOU NEED ASSISTANCE IN LOCATING COMPANIES OR INDIVIDUALS WHO DO CLINICAL TRIALS?

16. ARE THERE OTHER APPROACHES YOU CAN SUGGEST THAT MIGHT HELP COMPANIES TO COMPLY WITH REGULATORY REQUIREMENTS?

17. WHAT EFFECTS DO YOU FORESEE FROM U.S.A.-CANADA FREE TRADE AGREEMENTS ON REGULATORY REQUIREMENTS IN THESE COUNTRIES?

18. WHAT EFFECTS DO YOU FORESEE FROM THE 1992 EC UNION ON REGULATORY REQUIREMENTS IN EUROPE?

19. ANY OTHER FACTORS THAT MIGHT BE IMPORTANT IN HELPING COMPANIES MEET REGULATORY REQUIREMENTS IN CANADA,U.S.A. OR EC?

20. ARE THERE OTHER INDIVIDUALS, ORGANIZATIONS OR PUBLICATIONS THAT YOU WOULD RECOMMEND I GET IN TOUCH WITH FOR THEIR VIEWS ON ANY OF THESE QUESTIONS?

21. ANY OTHER COMMENTS OR SUGGESTIONS?

PLEASE COMMENT ON THE FOLLOWING PROPOSALS. SHOULD THEY BE IMPLEMENTED, WOULD THEY BE USEFUL TO YOU, WOULD THEY LIKELY BE COST EFFECTIVE?

22. ESTABLISHMENT OF A "DSMA" - LIKE DIVISION AT HPB TO ASSIST MANUFACTURERS IN UNDERSTANDING DEVICE REGULATIONS AND REQUIREMENTS.

23. ESTABLISHMENT OF A FREQUENTLY UPDATED DATA BASE, EASILY ACCESSIBLE TO MANUFACTURERS, DETAILING REGULATORY REQUIREMENTS, BY COUNTRY, FOR EACH DEVICE SUBSECTOR AND SEGMENT.

24. PUBLICATION OF A NEWSLETTER BASED ON THE ABOVE MENTIONED DATABASE, TO INFORM INTERESTED COMPANIES OF IMPORTANT DEVELOPMENTS.

25. GOVERNMENT COST-SHARING PROGRAM FOR SMALL COMPANIES INVOLVED IN THE REGULATORY PROCESS DOMESTICALLY OR FOR EXPORT.

26. REGULAR CONFERENCE SERIES FOR DEVICE COMPANIES WITH INTERNATIONAL GOVERNMENTAL DEVICE REGULATORY PERSONNEL.

27. REGULAR WORKSHOP SERIES FOR DEVICE COMPANIES PRESENTED BY HPB DEVICE PERSONNEL.

28. COURSES ON DOMESTIC AND INTERNATIONAL REGULATORY PROCEDURES, ISSUES AND UPDATES.

29. APPRENTICE PROGRAMS IN WHICH DOMESTIC AND INTERNATIONAL COMPANIES ARE PROVIDED WITH FINANCIAL INCENTIVES TO HIRE CANADIAN CITIZENS FOR POSITIONS THAT WILL PROVIDE THEM WITH EXPERTISE AND EXPERIENCE IN THE REGULATORY PROCESS.

30. ANY OTHER PROGRAMS YOU WOULD SUGGEST?

Documents Available form Dsma at FDA - PARTIAL LIST

Division of Small Manufacturers Assistance

Publication Order Form

Supplies are limited. Please order only one copy. Requests for 10 or more documents will considerable slow down response time. CIRCLE Code for items you wish to receive.

Federal Register Documents

Code

05-001 Anesthesiology Devices
05-002 Cardiovascular Devices
05-003 Clinical Chemistry and Clinical Toxicology Devices
05-006 Ear, Nose, Throat Devices
05-008 Gastroenterology-Urology Devices
05-009 General Hospital and Personal Use Devices
05-010 General and Plastic Surgery Devices (Proposed)
05-011 Hematology and Pathology Devices
05-012 Immunology and Microbiology Devices
05-013 Neurological Devices
05-014 Obstetrical and Gynecological Devices
05-015 Ophthalmic Devices
05-017 Orthopedic Devices
05-019 Physical Medicine Devices
05-020 Radiology Devices
06-002 [Labeling] Reorganization Republication, and Recodification
06-012 Good Manufacturing Practices
06-025 Protection of Human Subjects; Informed Consent.
06-022 Procedures for Investigational Device Exemptions
06-015 Obligations of Clinical Investigators of Regulated Articles
06-004 Intrauterine Contraceptive Devices; Professional and Patient Labeling
06-042 Laser Products; Amendments of Performance Standard (Proposed)
06-009 Enforcement Policy: Recalls (Including Product Corrections) Guidelines on Policy and Procedures,
06-005 Establishment Registration and Premarket Notification
06-010 Enforcement Policy for Certain Compliance Correspondence: Notice of Adverse Findings Regulatory Letters
06-016 Non-Clinical Laboratory Studies (GLP's)
06-062 Good Laboratory Practices (GLP) Regulations; Final Rule
06-014 Classification Procedures
06-027 Menstrual Tampons; User Labeling
06-011 Ethylene Oxide, Ethylene Chlorohydrin, and Ethylene Glycol; Proposed Max. Residue Levels
06-003 Hearing Aid Devices; Professional and Patient Labeling and Conditions for Sale
06-039 Technical Data Amendments for Hearing Aids
06-006 Intraocular Lenses; IDE Requirements
06-034 Medical Device Reporting

Guidelines/Guidance

08-069 Preproduction Planning Quality Assurance Guidelines
09-007 Guideline on the General Principles of Process Validation

Documents Available form Dsma at FDA - PARTIAL LIST

Booklets & Manuals

02-010 Classification Names for Medical Devices
02-011 Classification Names for In-Vitro Diagnostic Products
02-009 Everything You Always Wanted to Know About the Medical Device Amendments and Weren't Afraid to Ask
02-014 Medical Device Federal Register Documents
02-001 Radiation Control for Health and Safety Act of 1968
02-008 Laws Enforced By FDA (Includes Food, Drug and Cosmetic Act)
02-023 Impact-Resistant Lenses (FDA 87-4002)
02-021 Establishment Registration -- Information and Instructions
02-024 Medical Device Reporting Q and A
02-018 An Introduction to Medical Device Regulations
02-022 Regulatory Requirements for Devices for the Handicapped
02-012 Medical Device Listing Information and Instructions
08-047 Device Recalls: A Study of Quality Problems
02-007 Requirements of Laws and Regulations Enforced by the FDA
12-003 Import/Export
12-005 Premarket Notification: 510(k)
12-006 Labeling
12-007 In-Vitro Diagnostic Devices; Guidance for a 510(k)
12-008 Investigational Device Exemptions
12-009 Premarket Approval

Leaflets

10-005 Have a New Medical Device? Please Notify Us!
02-017 Classifying Your Medical Device

Compliance Programs

02-020 Medical Device GMP Guidance for the FDA Investigator Call If you have a specific compliance program need. A complete Compliance Program Manual is available from National Technical Information Service call 703-487-4650

Uncategorized

23-001 Medical Device Regulatory Index
08-073 Non-DSMA Publication form. Available from outside DSMA.
19-006 Exemption List: Lists all final and proposed exemptions from Premarket Notification and GMP requirements.
07-004 DSMA order form (copies of this form)

Send Order Form to:

Division of Small Manufacturers Assistance HFZ-220
Office of Training and Assistance
Center for Devices and Radiological Health
5600 Fishers Lane
Rockville, Maryland 20857
Phone 800-638-2041; In Maryland and D.C., 301-443-6597

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