SUBMISSION TO THE BRITISH COLUMBIA COMPETITION COUNCIL

BC BIOTECHNOLOGY INDUSTRY: COMPETITIVE ADVANTAGES, COMPETITIVE DISADVANTAGES

MARCH 9, 2006

BIOTECH Independent Advisory Committee

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"My hope is that over the next five to ten years, British Columbia becomes recognized as one of the world's biotechnology centers."
- Premier Gordon Campbell, 2004

INTRODUCTION

In 2006, Premier Gordon Campbell struck the BC Competition Council with a mandate to develop recommendations to make the BC's economy "more competitive, more productive and more attractive to job-creating investment."[1] In this submission, BIOTECH Independent Advisory Committee (BIAC) has attempted to objectively outline the competitive advantages and disadvantages of BC's health science industry in its efforts to contribute to a more diversified and competitive economy. There is recognition of the commitment government has made in support of innovation and health sciences. There is also objective description of the anti-innovative consequences of the BC's present healthcare system. This latter part is a critical issue for BC Biotech and a subject upon which we hope the Competition Council will see fit to champion in terms of opening a meaningful and transparent debate between the health science industry and the appropriate government officials.

Our colleagues at the Business Council of BC (BCBC) have recently presented in detail to the Competition Council, the issues around national/regional competitiveness[2]. BIAC concurs with their perspectives on competitiveness as they relate to BC's health science industry and in particular the correlations to the common determinants identified as central to developing a more productive economy. BCBC found these common determinants to be:

- human capital;
- strong export base and focus;
- specialization and the creation of competitive advantage;
- innovation;
- the nature of the regional business climate;
- the quality of the infrastructure supporting economic development and connectivity to external markets; and
- the presence within the region of high-value/high-productivity industries.

BC Biotech along with its linked economic partners – government, academic and dedicated life science research institutions and the capital markets – correlate with all of the identified determinants. This submission on our industry's competitive advantages and disadvantages will

[1] Government of British Columbia (Office of the Premier) New Release 20050TP0047-000372 March 30, 2005
[2] Business Council of British Columbia, Submission to the BC Competition Council, February 14, 2006, Vancouver BC

help the Competition Council understand the long term importance of the BC health science industry to BC's economic depth and growth.

Attached to this submission is the recently published BC Biotech position paper titled "Building World-class Biotech in British Columbia: The Industry Position." In addition to information supporting this submission, BC Biotech's position paper can also serve as an analysis of the position of our industry. It is important to note that BC Biotech's industry position paper is the result of an exhaustive consultative effort with industry (biotech, pharmaceutical and device), academia and BC's dedicated research centers.

It is also important to properly characterize the commercial participants in the BC biotech industry. Biotech as defined by the Canadian government is an umbrella term covering a broad spectrum of scientific applications used in many sectors.[3] It involves the use of living organisms, or parts of living organisms, to provide new methods of production, make new products and find new ways to improve our quality of life. BC Biotech defines biotech for practical terms as all health science related endeavours seeking to produce innovative medicines and medical devices. This includes not only medicines from biologics, but drugs and devices as well. BC's health science industry is focused on discovering, developing and commercializing innovative medicines and treatments that will improve health outcomes for the human race. The focus of BC's government in their partnerships with the health science industry should be to enable this industry not only to achieve its product goals, but to endeavour to make Canada and BC world leaders and capture within our borders a significant share of the enormous associated economic activities.

BACKGROUND

Presenting a factual and objective position of the BC health science industry is critical to the credibility of this report. Using available independent macro studies, it is as easy to portray a positive competitive position as it is to express a negative placement in the domestic or international industry. The purpose of this report is to acknowledge the positive data points while at the same time outlining, without regard for political sensitivities, the barriers to our industry achieving world-class competitiveness and sustainability.

It is also interesting to note the nature of public perception of the industry. First, the citizens of BC and indeed Canada universally believe that pursuing improvements for human health and solutions for unmet medical needs is a noble and just quest[4]. Public policy supporting health science research and development is apolitical save for issues on genetic engineering. One rarely sees any negative press or negative public response to these endeavours. In addition, media in general bestow a disproportionate amount of coverage to the advancements of health science in relation to the economics of the industry. This media position stems from the same reason that health science is an apolitical pursuit; the improvement of human health care is a priority to all.

To understand the competitive position of BC's health science industry in Canada, it is critical to understand our health care system itself. Due to the present methodology of health care delivery in Canada and BC, there is a myopic focus on individual line costs as opposed to a focus on

[3] Canadian Biotechnology Advisory Committee definition accessed May 14, 2006 at http://www.cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/ah00006e.html
[4] Pollara Strategic Public Opinion and Market Research, Public Opinion Concerning the Canadian Biotechnology Sector, September 2005 (86% of respondents agreed that biotechnology would bring benefits to health sciences)

inter-related costs in totality. This approach has the unintended consequence of stifling innovation in health care products which by their very definition are designed to improve health care outcomes, improve the economics of the work force and reduces the burden on health services. Thus you have the single largest area of government operating expenditures being managed without regard to the economics of innovation.

It should be noted that the life sciences industry is destined to remain as one of the largest industries in the world[5]. Demographics and the unrelenting drive of humans to extend and improve their health are behind this secular trend and so it should come as no surprise to public policy makers that there will be conflicts between the costs of medicines and the industry developing and marketing the medicines. However, from a public policy point of view it is critical to strive to achieve a balance if not in the short term, certainly in the long term. Today in Canada, virtually every medicine that we consume is foreign owned. Indeed, most of the economic value of our government funded health science R&D is not being captured within our borders and as a result, we as a nation are paying a premium for our inventions. If there is message for the policy makers that can come from this report, it is this - ***If you are going to fund innovation on one side of the provincial ledger, than you must develop the corresponding commercial industry to capture economic value add in BC. Otherwise, BC's innovation becomes nothing more than off-balance sheet R&D for the rest of the world.***

The following information will provide Competition Council members with some hard facts, anecdotal comments and objective commentary on our local industry and the health care system within which we must operate.

COMPETITIVE ADVANTAGES

CANADA'S BIOTECH INDUSTRY

In 2004, based on the number of companies, Ernst & Young ranked Canada as the number two biotech country in the world – behind only the US[6]. In that same year, KPMG ranked Canada number one in biomedical cost of business competitiveness among G7 nations[7]. And in 2003, Canada was ranked #1 by the Economist as the international country of choice for doing business[8]. In 2005, the UBC Sauder School of Business published a study that found Canada has higher exit values (of venture technologies) per dollar of GDP, R&D spending and venture capital investment than the US. And from the same study, it was found that while Canada has smaller average exit values than the US (US$59 million compared to US$192 million), the exit tends to occur faster.[9]

To date, Canada has developed six profitable biotech companies: Bio-Chem Parma (acquired by Shire, UK), Biovail, QLT, Angiotech, Axcan and Aspreva. (Generic manufacturers are not

[5] Ernst&Young, Millenium in Motion: Global Trends Shaping the Health Sciences Industry; accessed May 14th, 2005 at www.ey.com/global/download.nsf/UK/Millenium_in_Motion/$file/EY_Millenium_In_Motion.pdf
[6] Ernst & Young, Beyond Borders – Global Biotechnology Report 2005
[7] KPMG, Competitive Alternatives Report, 2004
[8] Economist Intelligence Unit, Press Release "Economist Intelligence Unit ranks Canada as best place to do business", July 17th 2003
[9] UBC Sauder School of Business and Leading Edge BC, Value Creation in Venture Capital: A Comparison of Exit Values across Canadian Provinces and US States, October 2005

included as they are neither innovative nor respective of intellectual property coming from the discovery process.) This is a significant achievement given that there are arguably no more than 30 - 40 profitable biotech companies in the world.

The three major clusters for Canadian biotech are Quebec, Ontario and BC. These provinces have 146, 130 and 93 biotech companies respectively[10]. Interestingly, the market capitalizations are approximately $1.68 billion, $6.08 billion and $6.16 billion, respectively[11]. BC's value is striking when you consider that there are significantly fewer companies in BC.

Statistics Canada reports there are approximately 500 biotech companies in Canada (over one-third are spinouts from Canadian universities)[12] which account for approximately $3.8 billion in revenues, $1.5 billion in research and development expenditures and directly employ approximately 12,000 skilled workers[13]. Biotech Human Resources Council estimates that biotech activities in Canada support 2,500 organizations and over 200,000 jobs[14].

There are other Canadian metrics to consider in the context of BC's health science industry. However, what really matters is where international competition stands. Governments from around the world have looked at not only the costs of imported health care discoveries, but at the growing world market for health care products. Governments have moved to develop incentives, decrease regulatory barriers, improve infrastructure and expand funding of higher education. Asian countries outside of Japan such as Singapore, India, and China are focused on not only meeting their own health product needs, but at capturing a share of the international market. Europe has focused on health science for a long time and the US is the acknowledged leader. However, despite existing international competition and new larger players looming on the horizon, given a reasonably level playing field, Canada and BC's health science industry is more than capable of competing.

So, what is it that has allowed Canada and BC to progress to the level that it has done to date? Frankly, the answer is rather simple. Canada as a country has always supported basic research at its learned institutions, regardless of the government of the day. That has attracted great minds from around the world because Canada is a free and respected nation. While the research support is not at the same nominal level of the US, or even some of the new up and coming competing nations, it is significant and continues to be reasonable. In BC, government support combined with our entrepreneurial spirit and a little luck has borne the results discussed above. ***The real issue is can we continue this success in the face of growing world-wide competition?***

BC'S BIOTECH INDUSTRY

BC is the home of 60% of the profitable Canadian biotech companies. Its industry is as valuable as Ontario's with 28% fewer companies. According to Ernst & Young, BC is the 8th largest biotech area in North America[15]. BC is also home to significant and well-funded academic

[10] Statistics Canada, Biotechnology Use and Development Survey 2003
[11] Market capitalization data supplied Raymond James, November 2005
[12] Statistics Canada, Craig A. Byrd, Profile of Spin-Off Firms in the Biotechnology Sector, 2002
[13] Statistics Canada, Biotechnology Use and Development Survey 2003
[14] Biotechnology Human Resources Council, Converging Science and Leadership, The Key to the Future – The 2004 Canadian Biotechnology Human Resources Study
[15] Ernst & Young, Beyond Borders – Global Biotechnology Report 2005

institutions and dedicated research institutions. We are an industry that despite very public setbacks of some of its leaders (Inex and QLT), has continued to grow. What are the reasons that have led to this and what are our competitive advantages?

The reasons are again, quite simple. BC and the federal government have been very supportive of basic research in the health sciences. Our academic and dedicated research institutions have attracted world class scientific talent and have been supporting the spinout of health science technologies for a long time. BC is also home to many technology entrepreneurs. Taken together, BC was in a position to respond to the favourable financial markets in the mid 90's to 2000 such that the BC life sciences industry saw the creation of 60 companies over 10 years. There are many other reasons related to BC's success in biotech, but aside from luck, the above mix is an appropriate general description.

So, what are our advantages? Industry observers would reiterate the contents of the paragraph above and provide mountains of statistics with respect to taxes, operating costs, etc. These statistics reflect structural operating issues which in the end contribute to but do not drive the growth of the industry and are therefore not relevant for the purpose of this submission. It is perhaps sufficient to say that our competitive advantages are slight. And it is perhaps better to say that industry observers are more concerned about how long we will be able to maintain our position in the face of growing competition from Singapore, China, India, Japan and Europe, let alone the international leadership of the US. Industry observers look at the well-funded programs of these other nations who have decided to play catch-up and predict that our present position and advantages are not secure. This last statement is true and drives our industry to run to maintain our place and to continue to lobby government for the support that is required to reach long-term industry sustainability.

Finally, there are a number of published metrics that lead a rational person to be quite proud and confident of BC's pharmaceutical and biotech industry. Indeed, the BC government has been incredibly supportive of the industry and should be appropriately proud of its public policy related to the industry. Its recent innovative legislation to include health science patents in the *International Financial Activity Act* is ground breaking in North America. Its funding of basic research at our institutions is the life blood of health science technology development. However, the positive metrics and public policy are only relevant in context of the increasing challenge that BC's health science industry faces. So, it is the competitive disadvantages to which this submission must focus.

COMPETITIVE DISADVANTAGES

Logically, if we are studying an industry that is essentially dependent on nothing more than easily transportable human and financial capital, then we can assume the factors of competition are rapidly changing amongst competing jurisdictions. From all studies, BC is neither the largest nor the smallest health science industry cluster. In fact, we can not even describe our industry as self-sustainable for without massive amounts of ongoing government funding for our public research institutions, the industry would soon be eclipsed and marginalized by competing jurisdictions. Our commercially profitable companies, Angiotech, Aspreva and QLT have yet to demonstrate that they can commercialize multiple products and establish sustainable organizations/industry. Therefore, while it is important to take pride in our industry's successes

to date, it is equally critical to understand that we are not yet entrenched nor secure in our future. That precarious position is a critical point of reference when developing public policy around our research institutions and the commercial health science industry.

The following discussion is on the major competitive disadvantages that our industry faces. There are some political issues that are broached which are simply statements of conflicts that exist between an innovative industry developing health care solutions for humans and our present health care delivery system in Canada and, in particular, BC. These conflicts are disadvantageous as they do not exist in jurisdictions where our competitors operate.

ACCESS TO RISK CAPITAL

The risk capital pool in Canada and British Columbia as it pertains to the life sciences is widely acknowledged as inadequate. This status is alarming given all of the life science innovation initiatives broadly promoted by our federal and provincial governments. The shallow pool of risk capital leads directly to poor results in the commercialization of public policy driven R&D efforts and inevitably to the export of Canadian developed technology for little economic value capture relative to the inputs. In fact the end result can properly be described as "off-balance sheet R&D" for the rest of the world. Clearly this kind of de-linked public policy is unsustainable in the long term.

There have been many different government initiatives to lever government funds (i.e., tax advantages, labour funds, capital pools, R&D tax credits, etc.) into the private sector venture capital industry. These programs are well meaning, but simply not large enough to meet the requirements of life science venture funding. (Note – The risk capital issues are the same for all of our BC technology industries.) What is needed by the life science industry is access to foreign risk capital pools.

Access to foreign risk capital and in particular US risk capital would create the required critical capital mass to accelerate the commercial development of Canada and BC's life science industry. Some might argue that the present trend of foreign risk capital to shop, buy and move our technology south of the border would be accelerated. However industry disagrees with that assessment as BC in fact represents an improving and attractive location to carry on commercial life science activities.

US venture capital has discovered life sciences in Canada and BC. All of the recent significant transactions are led by US VC's. We have made great strides in terms of our visibility and that process continues with the sustained efforts of BC Biotech, its members and the BC government. Visibility is an ongoing marketing challenge, but is no longer a gating factor.

The major issues for foreign risk capital in BC and Canada are related to critical mass and tax. Critical mass in this case relates to the availability of human resources. When attracting foreign professionals to this risky industry, a critical mass of companies and professionals is important as it mitigates the risk of having to move again to a new geographic location under the circumstance of company/technology failure. BC is starting to see critical mass, but it is fragile and not yet a sustainable state.

Tax issues are easily identified and the Biotech Industry Advisory Committee has already submitted a paper on tax issues. However, in terms of risk capital, the following are the major issues. Each issue is followed by a recommendation.

Limited Liability Corporations

Issue: Most US venture capital funds (the risk capital pools) are organized as Limited Liability Corporations ("LLC"). An LLC provides limited liability to its investors and is not subject to US federal income tax unless its partners elect to be treated as a corporation. Normally the LLC is treated as a partnership for US tax purposes and as such the investors get the benefits of limited liability and the flow-through tax treatment. (Profits and losses are in the hands of the limited partners). Under Canadian tax principles the LLC does not have access to treaty benefits.

Canada's treatment of an LLC as not a resident of the US under Canadian tax principles increases the complexity of any Canadian investment, punitively burdens potential returns and as a result, creates an unnecessary barrier to invest for the largest pool of risk capital in the world. Consequently, when US risk capital pools do have an interest in our largely government funded research; they simply buy the technology or start-up company and move it south. They do so due to the following issues:

1. Dividends distributed from a Canadian company to a US LLC are subject to Canadian withholding tax of 25%. Generally, when a dividend is paid to a US corporation, the amount of Canadian withholding tax is reduced to either 5% (if the distributee owns at least 10% of the value of the shares) or 15% under the present Canada-US Tax Treaty ("Treaty"). However, because the US LLC is a flow-through entity for US tax purposes and does not pay US corporate tax (the LLC investors pay tax on the distributions from the LLC), Canada does not recognize the LLC as a resident which is liable to tax under the Treaty and does not allow the LLC benefits under the Treaty even though the members of the LLC would be entitled to benefit from the reduced treaty rates if they invested individually.

2. If a US LLC sells shares of a Canadian private company, the LLC will be taxable in Canada from the sale of those shares. Generally when a US person sells shares of a Canadian corporation, any gain is exempt from Canadian tax under the Treaty, unless the values of the shares are derived principally from real property situated in Canada. However, because the US LLC is a flow-through entity for US tax purposes and therefore does not pay US tax (again the partners pay tax on the LLC distributions), Canada does not recognize the LLC as a resident of the US subject to tax under the Treaty and refuses to allow the LLC the benefits of the Treaty. This results in a Canadian tax charge where there should not be any.

   Investors in US VCs are sensitive to their personal tax information being made available to foreign tax authorities. When selling shares of a Canadian private company a US VC will be required to procure from the CRA a clearance certificate, or have the purchaser withhold 25% of the purchase price and remit it to the CRA on the US VC's behalf. To obtain the clearance certificate from the

CRA the US VC has to provide personal tax information including the identity of each member of the US VC and their respective tax status in their country of residence. [16]

In order to obtain the clearance certificate and avail itself of relief to the extent provided under the Treaty, the US Investor must provide sensitive financial information regarding its members, or partners to the CRA, a foreign tax authority.

Recommendations:

1. Support the amendment of the Treaty such that an LLC is entitled to the Treaty Benefits

Presently there are negotiations ongoing between Canada and the US to permit an LLC to enjoy the benefits under the Treaty. Other countries have already recognized the importance of US based LLC's as they are the largest pool of risk capital in the world and access to that pool is necessary to finance risk capital dependent technology industries. The UK has done so and they are now clear beneficiaries of US risk capital moving into that nation.

Should the Treaty not be amended, any of the following alternative steps could be taken by the Canadian Federal government to accomplish the same thing:

a. The CRA could develop an administrative position that would provide for LLCs to be covered by the Treaty.
b. A legislated definition of a Venture Capital Limited Partnership (or LLC) substantially engaged in this activity could be created for purposes of the Treaty.
c. An administrative position could be considered by the CRA or implemented with legislation, providing for "look through" rules to determine the application of the treaty to LLCs.
d. Remove from the definition of Taxable Canadian Property, certain corporations such as those targeted by VCs for investment.
e. Similar to the legislation for the Canadian Film or Video Production tax credit, developing pre-formatted criteria for qualifying investor and/or investee corporations, such that where a Ministry of Industry certificate is granted and attested to by a chartered firm, only one clearance certificate is required, however, the information required to process them is maintained in case of audit by the CRA at a later date.

The BC government should make the above issues a priority agenda item with their Federal counterparts.

2. Support the adoption a US Model for Sale of Shares by Foreigners

[16] Research provided by PricewaterhouseCoopers

The US allows foreigners to sell their shares in the US tax free. Removing withholding tax on foreign investors would remove a competitive disadvantage for Canadian companies seeking capital to develop their industry growth.

The BC government should make the above issue a priority agenda item with their Federal counterparts.

Foreign risk capital is highly mobile and highly competitive. Both the provincial and federal governments need to acknowledge that Canada simply does not have sufficient risk capital focused on the life sciences (or any of the other technology sectors) and that this is not likely to occur in the future without the leadership of accomplished foreign risk managers dedicated to the life science industry. Domestically, Canadians look to less risky and/or better developed risk capital markets that Canadians understand such as real estate and resources, and that is where our domestic risk capital largely resides. If the governments accept this obvious fact, then they need to take the necessary steps to at least remove the impediments to foreign capital and let Canadians compete on even footings. As it stands, in the competition for risk capital, we are handicapped not by our industry, but by our tax treaties.

FUNDING GAPS – SOME ISSUES AND SOME SOLUTIONS

The health science industry in BC as a whole is still a relatively young industry. Recent publications have touted BC's biotechnology industry as ranking 8th in North America and 1st in Canada. Although BC has the largest critical mass of companies (by value) in Canada, that is a relative metric. The majority of these are small, early stage companies with less than 50 employees[17]. For the maturing process to continue it is essential that the right pieces – specifically science, management, human and capital resources – be in place to allow the sector to reach critical mass in BC and to grow in the long run.

Today, without proper access to international risk capital as described earlier, we have two primary gaps in the funding cycle of health science companies – the early stage proof of concept and the larger rounds of Series C money to enter human clinical trials.

Proof of Concept – Translational Research

The first funding gap is the early stage proof of concept. Companies are often forced to leave the academic centers prior to formal proof of concept and about 12 - 24 months earlier than their US counter parts because they no longer qualify for funding at their institutions.

The quality of BC's life science basic research is unquestionable and our public funding of academic research has been improving. But, a funding gulf occurs in the translational research or proof of concept stage where there is a lack of infrastructure and funding. For clarity the companies spinning out of BC universities are using shallow pools of largely tax-driven Canadian pools of venture capital money to further basic research. This same basic research in the US would still be conducted within the academic research community and be supported largely by US government grants. Moreover, the Canadian

[17] BIOTECanada, Facts: Biotechnology in Canada, accessed at http://www.biotech.ca/EN/facts.html, May 14th, 2006

tax-driven pools of risk capital (VCC's, labour funds, etc.) do not have the depth to be funding from early stage through to public market liquidity events. More fundamental than the depth of Canadian risk capital is that our start-up companies spun out of our academic and research institutions are generally too early in their development to actually be a company.

Translational research is the bridge required to shift basic research to drug development. Most prominent American academic centers have sizable well-funded translational research facilities. BC has been focusing on these issues for the past several years. The University of British Columbia is one of Canada's early examples and has had early success in this area, and it has played a role in a number of BC's health science success stories such as Angiotech, QLT and Inex Pharmaceuticals. Other worthwhile centers of translational research include the BC Cancer Agency's Advanced Therapeutics program and the Prostate Research Center in Vancouver. However, the funding is not enough for these institutions as evidenced by the number of companies struggling for funding for their still very early stage technology.

It is also important to put into context the economics of existing government expenditures in health science research. Since 2001, the BC Government has committed over $650 million to basic research and research infrastructure for Life Sciences[18]. In addition, the government provided the bulk of funding for post-secondary education which saw BC universities grant 18,739 degrees in 2005, of which 3,100 were in biology and health sciences[19]. This is a significant investment in the Life Sciences. These direct government investments will not be leveraged into BC based economic activity if there is not a vigorous and growing life science industry in BC. The clear outcome of a sub-critical mass and weak BC life science industry is to see technologies developed under government funded research exported to non-BC based companies and later imported in the form of commercial products, the economic value add having been captured somewhere else. Likewise, graduating students will be required to migrate to those provinces and perhaps other countries in order to use their government subsidized education. Again, without a healthy and growing life science industry, our public/private life science product output can be aptly described as off-balance sheet research and development for the rest of the world.

BIAC believes the government can and should lead the nation to support the development of translational research infrastructure in our primary academic institutions. This should focus on two recommendations as follows.

Recommendations:

1. Provide financial support ($25M) to the Center for Drug Research and Development

Medical research conducted in universities and hospital associated research institutions contribute significantly to the development of new drugs and new

[18] BC Biotech calculation
[19] University Presidents' Council of BC, TUPC Facts and Figures Table 5.3 accessed at http://www.tupc.bc.ca/facts_figures/pdf/tupc5.3.pdf May 14th, 2006

approaches to therapeutics. Our medical research capabilities in BC have improved in recent years, largely due to a renewed government commitment that has increased funding for research infrastructure and personnel. However, efforts to convert the results of this internationally competitive research into new drugs and associated technologies that give rise to economic and health gains for Canadians have not met expectations. As discussed earlier, the premature licensing and spinout of technologies is cited as the main cause. Simply put, technologies need to be advanced further within academia before being spun out into the commercial world where venture and public capital have shorter time lines for return.

The Centre for Drug Research & Development (CDRD) is a University of British Columbia (endorsed and supported by every other BC university and all of BC's dedicated life science research facilities) initiative to provide the resources, infrastructure and expertise to address this "commercialization gap". The CDRD will address this "gap" by advancing promising drug compounds discovered in academia to a stage where sufficient preclinical data is available to make a compelling case for subsequent commercial and clinical development through licensing to existing companies or the establishment of "spin-off" companies. This maturation of technology also broadens the potential pool of risk capital investors (lowered relative risk attracts more bidders) and therefore increases the potential of successful financing. The CDRD will also address the critical need to train highly qualified personnel in the drug discovery and development processes as well as the need for existing companies to have access to a discovery pipeline generated by academia.

The CDRD will enhance the innovation process in drug development by focussing on five key objectives:

a. **Advance Promising Drug Compounds to the Preclinical Stage:** The CDRD will provide the facilities and expertise to advance promising drug compounds and related technologies from early stage discoveries to the preclinical stage thereby increasing the value of these drug candidates and the probability that any commercial potential will be realized.

b. **Facilitate Drug Licensing and Formation of "Spin-off" Companies:** The CDRD will prepare the comprehensive drug dossiers required to attract qualified investment or facilitate licensing agreements. In addition, the CDRD will act as agents to bring investment and management expertise together to facilitate the "spin-off" process for promising drugs or technologies.

c. **Train Highly Qualified Personnel in Drug Discovery and Development:** The CDRD will implement training programs to expand the number of highly skilled personnel in the areas of drug research and development.

d. **Build Drug Development Capacity:** The CDRD will provide focus and resources for groups conducting medical research in BC's universities and

hospitals. A unique feature of CDRD is that it will have access to provincial-wide research and will be seen as the "go to" location for commercialization. The different research groups across universities and teaching hospitals will be the sources of drug candidates and drug development expertise.

e. **Create Partnerships with Academia, Government and Industry:** The CDRD will form partnerships with academic institutions, provincial and federal government agencies and the biotechnology industry. Given CDRD's leading edge position, the Centre will be in the position to bring a cohesive nature to the BC's drug development infrastructure. CDRD will also provide specialized services in support of drug discovery and development activities for the biotechnology industry.

2. Create a Transitional Research Fund

We propose the establishment of a $20 million annual granting budget to fund approximately 15 - 20 proofs of concept programs at our institutions per year. The grant approval process should involve investor representatives to ensure that the programs are commercially viable and that, assuming their scientific success, they are likely to receive further investor financing. This effort would help the maturation of the long-term gap in BC's biotech industry development. In so doing we would then be providing a level playing field for our scientists to be as productive as their counterparts south of the border.

Venture Capital

The second gap in industry funding is at the later stage larger rounds (the series C rounds). The larger rounds are now typically led by US VC's and whose often first step is to begin the migration of the company and technology south of the border. The lead investor is usually taking control of the board of directors at this stage and migration is the usual result. Our Canadian VCs are simply not large enough to take the lead at this stage and as a result, participate at a token level or not at all. Changing this dynamic requires critical mass in our industry and the growth of the Canadian pool of risk capital.

The BC government has attempted to grow the VC pool through the VCC initiative and the Labour Sponsored funds, all tax related programs. While arguably successful, they are still not large enough to be funding in the later stages. The government should be patient with these initiatives while focusing on how to improve the overall pool of risk capital.

As discussed in the previous section, the federal and provincial governments must take all steps to remove the barriers to foreign risk capital. Foreign risk capital and in particular US VCs, will help our industry build critical mass. Our Canadian VCs can only benefit from participating along side the more experienced and larger US VCs. As barriers for foreign risk capital are lowered, more of the investee companies and technologies will be left here to grow. Indeed, BC Biotech would be very active in promoting the location of

US VC branch offices in BC if the barriers discussed above could be removed. This will provide the Canadian VC's with company and leadership at the investment table. This can only help the development of our domestic VCs.

In terms of BC's life science industry's record to date, and compared to many provinces in Canada, BC has been successful in raising larger sums and in later rounds of venture financing. Companies such as Aspreva, NeuroMed, Celator and Xenon have all raised venture capital rounds at the US$40M plus level. However these transactions were largely led by US VC's and in the case of NeuroMed and Celator, the ownership and future of the companies are in the US as opposed to being developed here in BC. This is confirmation of the lack of Canadian VC depth. However, that status can be changed if we are able to get unfettered access to US VCs who are not compelled to "buy and take" because of the tax act.

Recommendations:

1. See Access to Capital above.

ACCESS TO SKILLED PROFESSIONALS

Development of the BC health science industry is not just limited by the lack of sophisticated risk capital. It is also handicapped by our present immigration laws that make it very difficult to recruit the experienced professionals that are necessary to develop our industry. This barrier compounds the issue of critical mass. Critical mass is one part of any professional immigrant's decision process. They must consider the possibility that the job may not work out and if so, is there a critical mass of companies that may provide alternative employment? The obvious point is that industry cannot reach critical mass without immigrant professionals and the lack of critical mass makes immigrant recruiting that much harder. The equally obvious step to improve the situation is to remove the existing barriers to professional immigration so that industry can increase its potential target pool.

The following sets out the background and recommendations relating to decreasing the barriers to immigration for skilled workers and executives in the BC life science industry.

British Columbia's Provincial Nominee Program

British Columbia is one of several provinces that have negotiated an agreement with the Federal Government to set up a Provincial Nominee Program ("PNP") to ease applications for permanent residency under the *Immigration Act* of Canada.

British Columbia's PNP has been extremely successful at reducing both waiting time and bureaucratic impediments to the long term immigration of skilled applicants. The program has been successful on two fronts. The first is in the facilitation of permanent residency and work permit applications. The second is in sending delegations to areas such as California to advertise the

program and seek out highly qualified individuals who may consider relocating to British Columbia, particularly in the high tech and life science industries.

Further delegates are and will be visiting other areas, particularly in Asia. This reflects the dramatic change in source country immigration in the last twenty years. In the 1980s, immigrants from India, China and Hong Kong accounted for 35% of BC landings and the United States and United Kingdom accounted for 14.54%. In the 1990s over 43% of BC landings came from India, China and Hong Kong while only 5.45% came from the United States and the United Kingdom.[20]

Issue

The entrepreneurial nature of the PNP and its efforts to date to facilitate the immigration of highly skilled individuals have been quite successful for the applicants. However, when one speaks of an applicant immigrating to BC, in most cases one is also speaking of the applicant's family. A significant impediment to the attractiveness of BC as a destination for many of these applicants is the inability of the applicant spouse in many cases to continue their career or profession in the province.

Many of the highly skilled applicants brought in via the PNP are married to highly skilled spouses who may not fall within the current target groups of the PNP. These barriers not only reduce the attractiveness of BC as a destination but also result in a lost opportunity to the BC economy.

The spouses of these applicants would in many cases be unable to work in BC due to lack of recognition of their professional accreditations. The Conference Board of Canada estimates that $4.1 to $5.9 billion in annual income is lost due to non-recognized learning[21].

Systemic barriers to entry to regulated trades and professions are traced to:

1. poor information about the requirements for Licensure;
2. inadequate systems for prior learning assessment;
3. unfair or culturally biased testing procedures;
4. inadequate retraining opportunities to address language and skill gaps;
5. lack of opportunity to gain Canadian work experience; and
6. insufficient avenues for appealing decisions.

[20] Citizenship and Immigration Canada, Landed Immigrant Data System (LIDS)
[21] Michael Bloom and Michael Grant, Conference Board of Canada, Brain Gain – The Economic Benefits of Recognizing Learning and Learning Credentials in Canada 323-01 Detailed Findings, 2001

Physicians from outside Canada present a clear example of potential immigrants that face existing barriers. Non-Canadian physicians can only be hired if it is demonstrated that they are more qualified than all other applicants (Canadian or permanent resident). Further, in order to obtain a medical licence in BC, applicants must have graduated from an accredited Canadian or U.S. Medical School, have completed an approved residency, have passed the Royal College Exam for the speciality, and be a Licentiate of the Medical Council of Canada. Finally, even if an applicant has met all these requirements he or she will not be issued a licence by the College of Physicians and Surgeons of British Columbia unless the applicant is a Canadian citizen or permanent resident (temporary licences are available in some circumstances).

Efforts to Date

In December of 2001, the BC Government launched the "International Qualifications Program" which supports institutional, sectoral, and regional capacity building to better assess foreign credentials and to reduce systemic barriers to licensing and credentialing. This program has created a *Road Map to Recognition Fact Sheet Series*, *Occupation – Specific Fact Sheets*, a *Transition into Nursing On-Line Resource*, an *On-Line Employer's Resource*, an *Immigrant Loan Program*, and a *Language Benchmark in Training Kit*. The program has also been responsible for implementing a provisional licence for foreign trained engineers, some alternative prior learning assessments for nurse practitioners and dental technicians, a pre-residency orientation for international medical graduates, a Canadian Pharmacy Graduate Program to introduce foreign trained and out of practice Canadian pharmacists to current pharmacy practice in BC, and has conducted a review of regulatory legislation, policy and practices to improve access to Licensure for immigrants.

In February of 2005, the BC government also launched the "Skills Connect for Immigrants Program"[22]. This is a three year, $14.5 million pilot program that supports the delivery of career assessment and employment bridging services targeting newly arrived skilled immigrants with intermediate to advanced English language proficiency. Through this program, foreign-trained persons with partial qualifications and relative pre-landing experience are prioritized in a flexible assessment and re-training system to enable expedited employment-entry for recent immigrant arrivals to BC.

There are also further initiatives under development such as a two-year $2.6 million Canada - BC initiative to further increase awareness and capacity related to the full utilization of skilled immigrants to address labour shortages. And the province is placing an increased emphasis on "prior learning assessment" as an alternative assessment tool for employers, post-secondary institutions, and regulatory authorities.

[22] Government of British Columbia (Office of the Premier and Ministry of Community, Aboriginal and Women's Services, News Release 2005MCAWS0010-000141, February 12th, 2005

Recommendations

1. Creation of a government of BC mandated International Qualifications Authority ("IQA") to add independence and oversight related to foreign-credential recognition processes of independent bodies in British Columbia.

The IQA would be staffed with specialists in comparative education, document validation, curriculum development, preparation of learner portfolios, and database management. The IQA would:

a. deal with weaknesses in the assessment capabilities of regulatory authorities and employers;
b. act as a resource to individual applicants, regulatory authorities, and employers;
c. monitor testing procedures and address discrimination to ensure foreign qualifications are fairly considered; and
d. serve as an appeal Tribunal for unsuccessful applicants to independent licensing bodies having a sound basis for review.

2. Work with the Federal Government to create a national "precedence" database of credential assessments.

Provincially based credential assessment services currently assess international credentials for Canadian and provincial academic equivalency. Each of these agencies have developed and recorded precedence cases which they can use to expedite the assessment process by drawing on previous experiences. A harmonization of this database would be of significant value to provinces in reducing the waiting period for immigrants seeking Canadian credential equivalency.

3. Support and expand the role of PNP officials providing for a pro-active liasing role with independent licensing bodies in British Columbia.

The Provincial Nominee Program and its officials have demonstrated an entrepreneurial culture that varies quite significantly from the more process-oriented structure of Citizenship and Immigration Canada. The provincial government should continue to support and encourage the expansion of this program and potentially add further liasing responsibilities to the duties already being performed by officials within the program. PNP officials currently deal with both the requirements for permanent residency and the development of British Columbia as a destination for highly skilled applicants. Accordingly, these individuals have direct knowledge of not only the impediments but also the personal circumstances of a great number of these applicants. This knowledge and experience could be very useful in

playing a liasing role with independent regulatory authorities in the province.

PROVINCIAL STRUCTURAL BARRIERS TO HEALTH SCIENCE INNOVATION

Innovation in the health science industry by definition brings new products and procedures to meet old and new unmet medical needs. In Canada and BC, the health science industry is faced with a government funded and directed health care delivery system that is arguably in disarray, under funded and underperforming. Appropriately, government focus is on containment of costs, especially as they relate to drugs and devices while trying to improve delivery and outcomes. Industry participants understand this and applaud the efforts. However, we also believe that government must open up its efforts to an interactive dialogue between participating constituents if it is to achieve appropriate healthcare outcomes. Today, the health science industry would argue that appropriate cost effective systems are not functioning as well as they could be and as a result, while it is possible to point to line item cost containment, it is not possible to relate that to sustainable cost effective programs.

In February, 2006 the Conference Board of Canada released a report benchmarking provincial health care delivery[23]. This study is a benchmarking study and contains 119 indicators. The authors openly acknowledge that their benchmarking of our "health care system is still in its infancy and is not without challenges". Given that it is the first such benchmarking study, the relative weighting of the benchmarks is not yet statistically significant nor exact. Results are therefore subject to interpretation and can and already have been used for political gain and positioning by various self-interest groups. BIAC looks at the study as a start. For example, we are proud to see that BC is ranked #1 in terms of overall ranking of the indicators. However, of great concern and perhaps pointing to the relevance of benchmarking to other provinces versus other jurisdictions in the world, is that BC was ranked dead last in terms of patient satisfaction. In other words, the consumers of health care in BC are the most dissatisfied in all of Canada. In addition, BC Biotech takes the position that the comparators should not be the provinces, but rather they should be other countries. Our goals should be focused on nations that have demonstrated great health care delivery and outcomes for all of its population and in a financially sustainable manner. Much of Europe and England have struggled through the same issues and have produced these sustainable models that we should be benchmarking against and not the Canadian provinces which together with the federal government have produced an unsustainable and completely dissatisfactory health care system.

Also in February, 2006, the Cancer Advocacy Coalition of Canada issued its "Report Card 2005"[24]. This long standing study ranked BC as having the best funded and most timely access to cancer drugs. The BC government should be proud of this finding. However, it should be noted that cancer drugs (and AIDS drugs) in BC are not approved in the same manner as pharmaceuticals or biologics. Drugs and biologics are subject to a different review process (see Restrictive Access Policies – Therapeutics Initiative below) and in this category, BC falls far behind the rest of the country.

[23] Conn Hamilton, Conference Board of Canada, Healthy Provinces, Healthy Canadians: A Provincial Benchmarking Report, February 2006
[24] The Cancer Coalition of Canada, Report Card, Volume 8 Winter 2005-2006

The BC Government prides itself on its health science sector and aims to turn BC into one of the world's top technology centers by 2010. Achieving this bold vision requires the creation of an innovation culture that promotes the discovery, clinical testing and marketing of innovative medicines in a competitive manner. Yet BC's record in the approval of new medicines relative to its provincial counterparts and international jurisdictions is significantly askew from the norm. While industry is frustrated with the approval rate of its output, it also believes that BC is not appropriately exploring the potential gains in cost effective delivery of medicines that can be achieved. In essence, we argue that the unintended consequences of delaying and inhibiting access to new medicines not only impedes the potential for significant growth of our industry, but also subjects British Columbians to a slower rate of improvement to healthcare than otherwise possible. There is simply room for a debate regarding the present doctrine in BC, a debate that no constituency should be afraid to begin as it can only lead to better solutions than we have now.

Restrictive Access Policies - Therapeutics Initiative

Drug re-imbursements is an easily targeted cost for the Ministry of Health, as this Ministry attempts to reduce the cost of health care delivery in our province. Despite Pharmacare comprising only 8% of our 2004/2005 provincial healthcare budget[25] (and no higher than the national average), the cost of drug re-imbursement is continually cited as a major reason for our high health care expenditures in this province. This representation is in our industry's opinion, without documented and disclosed support. It appears that targeting drug costs as a line item is a cost containment tool to be used without any ability for developers and providers of innovation medicines to determine the process for decisions being made. Clearly it is just easier for the bureaucrats to keep drug re-imbursement costs low than it is to affect improved operational efficiencies in the entire system or hire more medical personnel to meet the needs of an ageing and growing population. It is not surprising therefore, that BC citizens are not being afforded the same level of medical innovation that other Canadians are able to benefit from.

While we realize the challenges in meeting the health care needs of an ageing and expanding population, the BC health science community also strongly supports an open and fair drug review process in our province. Recent statistics illustrate just how poorly BC is fairing compared to other Canadian provinces when it comes to listing new drugs in our provincial formulary. With only 4 full and restricted drug listings (excluding cancer drugs) between March 1, 2003 and February 28, 2005, BC faired dismally compared with Quebec which had (37), Saskatchewan (30), Manitoba (24), Nova Scotia (22), Ontario (18) and Alberta (16). The prior 2000 – 2002 record also showed up lower drug approvals in BC relative to other provinces such as Alberta, Saskatchewan, Manitoba and Quebec[26]. This record has placed many important new medicines completely out of reach of British Columbians while these medicines were already the gold standard of care elsewhere in Canada. It is only in the area of cancer drugs, which

[25] BC Ministry of Health, Annual Service Plan Report 2004/2005, accessed at http://www.bcbudget.gov.bc.ca/Annual_Reports/2004_2005/hs/Appendix_C_-_Core_Business_Areas.htm , May 14, 2006
[26] IMS Health, Provincial Reimbursement Advisor, November 2005

are not filtered through the Therapeutics Initiative, that BC actually has a good track record.

BC's track record with respect to new and innovative medicines, places yet another hurdle in the way of our local health science companies. In conducting clinical trials, when our BC companies are testing their drugs against current gold standard treatments, these gold standard medicines are in many instances simply not available. This necessitates our companies to conduct their clinical trials outside of this province with significant economic loss to BC.

The de facto gate keeper in BC for biologics and pharmaceuticals (with the exception of cancer and AIDS drugs as mentioned above) is the Therapeutics Initiative. The TI was established in 1994 by the previous government with a mandate to provide physicians and pharmacists with up to date and evidence-based practical information on rational drug therapy[27]. The TI has also played the key role in recommending new drug listings to the government's Ministry of Health for addition to the provincial drug formulary. It is believed that the Ministry of Health accepts most if not all recommendations made by the TI, but the limited public access to such information makes this assessment uncertain. In addition, while the TI describes itself as an independent organization, which is at arms length from government, pharmaceutical industry and other vested interest groups, there is no transparency to that claim. They are not themselves subject to any transparent reviews or audits. Indeed, funding from the Ministry of Health is approaching $1M per year. Our industry does not find the TI to be independent or at arms length and certainly does not find it accountable.

While the TI does perform a useful function in physician and pharmacist education, the extension of this body into the gate keeper for the provincial formulary is flawed for many reasons as follows:

1. The TI is not representative:

It is our understanding that the TI committees are selected and not elected. Because of this, the TI cannot be representative of the medical profession in our province. Leading physicians across multiple clinical disciplines have previously raised serious concerns about the TI and the provincial drug review process including many articles published in the British Columbian Medical Journal[28]. Anecdotal evidence further supports the views expressed in these articles.

2. The TI process is not peer reviewed

The review, recommendation and approval process by the TI and Ministry of Health is not peer reviewed. Limited input from key medical opinion leaders or from the very physicians who would be prescribing the drug under review is obtained. Most importantly however, is the fact that local experts perceive their

[27] Therapeutics Initiative website accessed at http://www.ti.ubc.ca/ , May 14, 2006
[28] i.e. BC Medical Journal Volume 43, Number 2, March 2001, 86-87; Authored by 11 physicians; The Drug Review Process in BC: A Critique

input, when it is sought, as a formality rather than a valuable contribution that is seriously considered. Key opinion leaders in our medical community and patient advocacy groups question the right of the TI in its current form to make recommendations that profoundly affect the treatment options of patients in this province.

3. The TI is anti-industry

It is believed many medical clinicians, academic clinicians and by local biotechnology executives that the TI views the health science industry negatively. Public comments made by TI members have demonstrated a clear negative bias towards industry and even patient groups. Clearly, any initiative established to review new drug approvals in BC should be impartial.

4. The TI is not accountable

Since it was established, and as far as BC Biotech can ascertain, the TI leadership has not been changed. In addition, no review of which we are aware has been performed on the TI or its drug review and recommendation process. Neither has an independent review been performed on the drug approval process within the Ministry of Health. This clearly ignores the government's strong position on transparency and accountability.

The BC health science community views the TI and the process of drug approvals in this province as a significant and misguided roadblock to the delivery of quality healthcare and to innovation. Moreover, the industry finds it unacceptable in this time of public focus on proper governance that any "independent" organization related to government expenditures is not open to scrutiny.

The time taken and, in many instances, the inability to get important innovative medicines approved, is also a major disadvantage to the growth and competitiveness of the biotechnology industry in BC. With our province having amongst the worst record of drug approvals in this country, it is no wonder why the pharmaceutical industry continues to drive a disproportionately smaller amount of its R&D dollars into BC compared with other larger Canadian provinces.[29]

As an example, despite the size of our health science sector (both in value and in number of companies) and our excellent academic institutions in the life sciences, BC receives approximately 50-60% of pharmaceutical funding compared with Alberta on a per capita basis.[30] The fact remains that BC has been, and continues to be, the most challenging provincial environment for the pharmaceutical industry in this country.

[29] P. Lavalle, T.vanBiesen, J. Kriss, Bain & Company Inc., The Impact of Pharmaceutical Regulations and Pricing Policies, 2004
[30] Patented Medicine Prices Review Board (PMPRB)

According to the Manitoba Bureau of Statistics, every $1 million invested in R&D, generates 33 new jobs and $1.3 million in indirect revenues[31]. Disincentives to pharmaceutical investment are placing important restrictions on the growth of the health science sector in BC. BC's health science companies need international pharmaceutical investments. The advancement of health science companies from small start-ups (of which this province has many) to more mature revenue generating companies (of which this province has very few relative to other international jurisdictions) is dependent on the generation of discoveries funded by government, the VC community and importantly, the international pharmaceutical industry. Limiting the interest to invest in this province has had, and will continue to have, a major impact on the ability of the BC health science industry to be globally competitive.

Recommendations

1. A formal and independent review of the drug review process in British Columbia is required. This review should be undertaken by a committee comprised of practicing non-academic clinicians, representatives from academia, industry (pharmaceutical and biotechnology), government, and persons from the general public.

2. The review should be submitted to the BC government and these recommendations should be made publicly available for review.

Reference Based Pricing

In 2002, the BC government announced the endorsement of therapeutic substitution (a form of reference based pricing) as an effective health care policy. This announcement was made even though the government's own reference-based pricing panel had not made any recommendations to support the endorsement of therapeutic substitution. There was no explanation for the seemingly premature endorsement nor was there any data disclosed to support the action.

Restrictive policies such as reference-based pricing (RBP) create an environment, which does not give patients access to the latest and most effective therapies. This impedes innovation by:

1. Decreasing the demand for newer and more innovative therapies (that may be higher priced than the referenced products). The motivation to develop improved medicines is removed as the central tenet of RBP therapeutic substitution, is that all drugs in a class are the same so there is no reason to research any new chemical entity.

2. Prioritizing cost-consciousness as opposed to health-consciousness of patients and prescribers.

[31] Manitoba Bureau of Statistics, Figure 3: Manitoba Economic Multipliers

3. RBP shifts the balance of pricing power from innovative products to older products. By limiting the profit potential of new products in this way, RBP stifles innovation in drug and biologic manufacturing markets.

Recommendations

1. An independent board should review the RBP policy of the government and report on the actual costs saved. The Board should further review the economics of the anti-innovative effect of RBP.

Patent Protection

The BC government has not supported strong patent protection and in fact information from the Ministry of Health indicates that the BC government is supportive of changing the linkage regulations to allow generics earlier entry into the market place. Linkage regulations are designed to prevent the illegal entry of a generic copy before the innovator's patent expires.[32] Changing linkage regulations dismisses the value of innovation and reduces the country's ability to attract more investment.

Patents protect inventions resulting from R&D and are a critical driver of innovation and technology transfer. In fact, without adequate patent protection for their inventions, individuals and businesses would not invest in nor undertake the often large-scale risks associated with the expensive R&D processes in Canada or other countries.

The regulatory regime has a unique impact on the health science industry because of the length of patent protection. Intellectual property protection (IPP) has one overriding purpose: to foster innovation. IPP rights that protect against copying of innovations for a set period of time, provide the incentive necessary to turn ideas into discoveries. In return, innovators make details about those discoveries available so that they can stimulate other research efforts. Patent protection, therefore, encourages innovators to invest in new inventions and enables society to reap the benefits of those inventions.

International differences in the level of IPP impact the willingness and ability of firms to attract manufacturing, research and other forms of investment. Compared to our major international trading competitors, Canada offers weaker standards of patent protection.[33] Recognizing and encouraging innovation requires strong national intellectual property protection laws. This is particularly relevant for the innovative health science industry, as R&D investment decisions are determined by the market climate of which IPP is a key component.

As noted, one specific example of discussions to weaken patent protection in Canada and supported by senior BC health bureaucrats revolves around modification of existing rules related to the linkage regulations to allow generics into the market place sooner. Significant business uncertainty has resulted from the constant wavering of federal

[32] Canada's Research-Based Pharmaceutical Companies, Linkage Regulations Factsheet accessed at http://www.canadapharma.org/Patient_Pathways/Patents_Pricing/Linkage_e.pdf , May 14, 2006
[33] Canada's Research-Based Pharmaceutical Companies, Intellectual Property Protection Factsheet accessed at http://www.canadapharma.org/Industry_Publications/Fact_Sheets/sheet3_e.pdf, May 14, 2006

authorities and the lack of support from provinces on peripheral issues and the on-going skirmishes between pharmaceutical and biologic companies and generic manufacturers. If Canada wants to develop a significant knowledge-based economy, it must have a clear and stable IP framework, dealing with the specifics of each industry.

Recommendations

1. The BC government must be seen to be supporting patent law, especially if they are to maintain their focus on creating a world class health science industry. The BC government must immediately reverse its support of modifying linkage rules that would allow generics into the market place sooner than allowed by patent law.

SUMMARY RECOMMENDATIONS

The following is a summary of the recommendations to the BC government that would help address the competitive disadvantages of the BC health science industry:

1. Risk Capital

   Risk Capital is the fuel that is driving health science innovation around the world. It is fluid and moves to the jurisdiction with the best possible risk-adjusted return. The BC government should take all steps as listed below to remove the barriers to international risk capital investment in BC.

   a. Cause the federal government to give tax treaty benefits (or equivalency) to the US Limited Liability Corporation structure.
   b. Support the adoption of a US model for the tax free sale of shares by foreigners.

2. Funding Gaps

   BC government should acknowledge funding gaps that exist for the development of BC heath science companies and take the following steps to provide longer term solutions.

   a. Deal with item #1 above with expediency.
   b. Take leadership in funding the Center for Drug Research & Development, an initiative program endorsed and supported by every BC university and all of BC's dedicated life science research facilities.
   c. Establish a Transitional Research Fund of $20 million annually to fund approximately 15 – 20 proofs of concept programs at our institutions.
   d. BC government should look to solving item #1 above in order to help expand and develop the shallow pool of venture capital in the province. Existing initiatives can only be bolstered by the entrance of foreign risk capital.

3. Access to Skilled Professionals

a. Create a BC government mandated International Qualifications Authority to add independence and oversight related to foreign-credential recognition processes of independent professional bodies in BC.
b. Work with the federal government to create a national "precedence" data base to access duplicated data and historical experience amongst the provinces.
c. Support and expand the role of the Provincial Nominee Program providing for a pro-active liasing role with independent licensing bodies in BC.

4. Provincial Structural Barriers to Health Science Innovation

a. Establish a formal and independent review of the drug review process by the Therapeutic Initiative in BC by a committee comprised of non-academic clinicians, representatives from academia, health science industry executives, government and general public representatives. Recommendations to be published for public scrutiny.
b. Establish an independent board to review the province's Reference Based Pricing Policy including the economics of innovation.
c. BC government should study the public policy consequences of its present support of modifying linkage rules usurping the rights of intellectual property. The BC government should immediately repudiate its present position supporting reduced linkage rules.

CONCLUSION

BC has a unique opportunity to establish a sustainable world-class health science industry. The industry meets or enhances all of the determinants described by the Business Council of British Columbia as critical to developing a more productive economy. It is well positioned with government, academia and the capital markets in its development and has met with some commercial success. The BC health science industry has even achieved international recognition. Industry observers might opine that the industry is in great shape. BIAC respectfully disagrees. We are in a fragile state and competition is coming.

The BC health science industry is not yet at a level of sustainability without a disproportionate amount of government funding. And critically, the industry and its partners in academia need more funding which the government can and should provide. However, many of the recommendations discussed above do not require direct government funding. Rather, many of the recommendations are to improve regulatory roadblocks to human and financial resources which in fact would aid in the development of all technology based industries in BC and reduce, over time, government funding requirements.

The goal of BC Biotech must be to establish a sustainable industry that is contributing greater amounts to the development of BC based technology from actual profits. It is important at this time for the government to continue to support tax driven development initiatives and to fund academic research, but it is equally important and critical in the long run for the industry to get to a sustainable profitability model. No industry, especially given international competition for technology driven endeavours, should expect the government to fund in perpetuity. This

submission is directed towards the competitive impediments to our industry in order to achieve that state of sustainability.

BC Biotech is grateful for the opportunity to provide commentary on the competitive status of our industry to the BC Competition Council. We hope that through the Council we are able to increase dialogue with the government and especially in ministries where our innovative solutions have not yet achieved mainstream recognition for their value to all British Columbians.

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