

**A STRATEGIC ANALYSIS OF INVESTMENT
OPPORTUNITIES WITHIN BRITISH COLUMBIA'S
PRIVATE HEALTHCARE SECTOR FOR A NON-PROFIT
GENOMICS RESEARCH ORGANIZATION**

by

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ABSTRACT

Advances in the genome sciences are leading to the development of new healthcare innovations relevant to the principles of personalized medicine. Genome BC, a non-profit research organization, invests in projects that will help facilitate the integration of these innovations into the delivery of healthcare. This analysis assesses the strategic positioning of private healthcare firms in BC to be early users of such innovations. The analysis assesses the suitability of investment from Genome BC into private healthcare firms as a supplement to the public healthcare system in BC. The analysis develops a three-component strategy for facilitating investment opportunities into private healthcare firms by Genome BC.

Keywords: Genomics; Private Healthcare; British Columbia; Personalized Medicine

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EXECUTIVE SUMMARY

Personalized medicine is the concept of the systematic use of information about an individual patient to select or optimize that patient's preventative and therapeutic care. The promise of personalized medicine relates to understanding how an individual's genome influences disposition to disease and response to therapy. Since the completion of the Human Genome Project the cost and speed of whole-genome sequencing has reduced at a dramatic rate. This is starting to lead to the development of new healthcare innovations that could have profound impact on the delivery of healthcare. For example, it may soon be economically feasible for individuals to have their own genome sequenced.

Genome British Columbia (Genome BC) is a non-profit research organization that invests in and manages large-scale genomics and proteomics research projects and science and technology platforms. The investments focus on areas of strategic importance, such as human health. Genome BC invests in human health projects focused on the delivery of innovations to the healthcare system in BC through formal funding programs. These programs primarily focus on delivering the innovations to BC's public healthcare system. The rigidity of the public healthcare system in BC may cause the integration of new healthcare innovations to be difficult. However, there are private for-profit firms outside of the public system that also deliver healthcare services to patients. It may be strategic for Genome BC to involve private healthcare firms in its funding programs and initiatives, as a supplement to the public system. The goal of this analysis

is to assess the suitability of investment opportunities into private healthcare firms in BC by Genome BC.

An analysis of the private healthcare market in BC will help demonstrate that the strategic positioning of private healthcare firms in BC to be early users of new healthcare innovations is strong. Specifically, these firms can be early users of genomics-based innovations that are relevant to the principles of personalized medicine. Researchers at private healthcare firms are technically able to participate in projects funded through Genome BC funding programs. However, the goals of these programs may not match the strategic objectives of the private healthcare firms. Therefore, there is a need for alternative funding mechanisms.

The analysis presents a strategy to facilitate investment opportunities into private healthcare firms. The strategy includes three primary components:

- Invite key representatives of private healthcare firms in BC to attend workshops organized by Genome BC focused on discussions of genomics and human health.
- Update the *Towards a Genomics & Health Strategy* document and include a representative from a private healthcare firm in BC on the task force that develops the document.
- Develop a funding program that private sector organizations could utilize to source investment to facilitate the adoptions of genomics-based healthcare innovations.

DEDICATION

I dedicate this project to my family and friends that have been so incredibly patient with me over the past two years, especially Sarah. I also dedicate this project to my classmates in the 2008 MOT cohort for making the time as enjoyable as possible.

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GLOSSARY

FDA	U.S. Food and Drug Administration
Genome	The entire genetic information content of an organism.
Genomics	The science that aims to decipher and understand the entire genetic information of an organism.
HEP	Human Epigenome Project
HGP	Human Genome Project
HMP	Human Microbiome Project
MRI	Magnetic Resonance Imaging
MSP	Medical Services Plan
NIH	National Institutes of Health
Proteomics	The science that studies which proteins of the genome are expressed and when.
SME	Small and Medium Enterprises
SNP	Single Nucleotide Polymorphism

1: INTRODUCTION

June 26th, 2010 marked the ten-year anniversary of the Human Genome Project (HGP). This large-scale research initiative determined the sequence of the human genome for the first time. The HGP aimed to catalyze a movement towards the era of personalized medicine. However, the era of personalized medicine has not yet arrived. Some question the value of the HGP due to the lack of medically relevant outcomes. Thus, some question the value of the HGP. However, new genomics-based healthcare innovations are moving closer to clinical application. Many of these innovations are relevant to the principles of personalized medicine. Soon, the delivery of healthcare will include Genomics-based innovations.

This analysis examines the strategic positioning of private healthcare firms in British Columbia to be early users of new healthcare innovations. The analysis focuses on innovations relevant to the principles of personalized medicine. The goal of this analysis is to assess the suitability of investment opportunities into private healthcare firms in BC by Genome British Columbia (Genome BC). The investments would occur through its funding programs and initiatives. Genome BC is a research organization that invests in and manages large-scale genomics and proteomics research projects and science and technology platforms. The investments focus on areas of strategic importance such as human health, forestry, fisheries, agriculture, bioenergy, mining and the environment. The analysis will provide Genome BC with strategic alternatives.

Including this introduction, the analysis is broken down into eight sections. It begins with an overview of the state of genomics-driven personalized medicine. The overview provides information regarding how the technology has progressed since the completion of the HGP. An overview of Genome BC is next. The overview includes a description of its funding initiatives that are relevant to personalized medicine. Next, is an analysis of the private healthcare market in BC. The analysis provides a description of the relevancy of private healthcare firms to Genome BC. Following this, there is an analysis of the strategic positioning of private healthcare firms to be early users of genomics-based innovations relevant to personalized medicine. The analysis then explores the ways in which Genome BC can invest these firms. Finally, there the analysis develops a strategy for facilitating investment opportunities into private healthcare firms by Genome BC.

Personal genetic testing is a commercialized innovation that is relevant to the principles of personalized medicine. Therefore, this analysis uses personal genetic testing as a specific example throughout.

2: PERSONALIZED MEDICINE & GENOMICS

2.1 Introduction

Personalized medicine is the concept of the systematic use of information about an individual patient to select or optimize that patient's preventative and therapeutic care (PricewaterhouseCoopers' Health Research Institute, 2009). A common phrase used to describe personalized medicine is "the right treatment for the right person at the right time" (Genome British Columbia, 2009). In terms of a functional description, personalized medicine is the integration of two different technological silos: diagnostics and therapeutic intervention (Lester, 2009). Personalized medicine is not necessarily a new concept. However, it is now most commonly associated with genomics. Genomics is a field of biology that studies how an organism's genome affects various functions and processes within it (Genome British Columbia, 2010). An organism's genome refers to all of its genetic information (Genome British Columbia, 2010). Thus, genomics is a tool that can help researchers understand how genetic information influences human health. There is hope that genomics will help researchers develop new healthcare innovations that will be specific to the unique needs of individual patients. The new healthcare innovations could be in the form of personalized medications, diagnostics, prognostics and procedures.

Large-scale research initiatives have developed insight into how an individual's genetic information influences disposition to disease and response to therapy. Such initiatives include the Human Genome Project (HGP) and the International HapMap

Project. The cost of genome sequencing is decreasing at such a dramatic rate that it may soon become affordable for everyone to have his or her own genome sequenced.

However, an individual's genetic sequence does not provide all of the information necessary to understand all of the factors that influence disease disposition and response to therapy. It is necessary to understand the other factors that influence the expression of genes relevant to health. Specifically, it is necessary to understand the environment in which genes operate.

Genomics-based research activities have led to the development of new healthcare innovations relevant to the principles of personalized medicine. There are now diagnostic tests that are available that can help clinicians determine whether a patient will respond to a specific drug. Companion diagnostics is the term for these types of tests. There are also diagnostics in development that will help clinicians determine the best treatment strategy for a patient. Furthermore, companies have emerged that analyze the genomes of individuals for disease risk and drug response. These companies are controversial because the test results are of questionable validity and they operate outside of the healthcare system. However, a revolution of personalized medicine has yet to arrive despite the progress to date. This is because the rate of development has been slower than originally anticipated after completion of the HGP.

Integrating the use of genomic information into the standard delivery of healthcare will be difficult. Effective integration of genomic information will need to address many different issues. Providers, payers and regulatory bodies will all need to adapt to the integration of genomic information into the delivery of healthcare. In other

words, the use of genomic information in the standard delivery of healthcare could prove to be disruptive to current healthcare systems.

2.2 Genome Sequencing & Scanning

The DNA sequences of any two individuals are approximately 99% the same (National Human Genome Research Institute, 2010). However, that 1% difference between individuals is relevant to the differences in disease risk and response to therapy (National Human Genome Research Institute, 2010). Therefore, there has been much research into identifying the key differences between individual's DNA sequences. By identifying and understanding the differences, it may be possible to personalize preventative and therapeutic care based on an individual's DNA sequence.

2.2.1 The Human Genome Project

The completion of the Human Genome Project (HGP) was a major milestone in the pursuit of developing a personalized approach to healthcare. Starting in 1990, the HGP was a 13-year effort coordinated by the U.S. Department of Energy (DOE), the National Institutes of Health (NIH) and the Wellcome Trust, and included contributions from other international participants (U.S. Department of Energy Office of Science, 2009). The overall goals of the project were the following:

- Identify all the approximately 20,000-25,000 genes in human DNA,
- Determine the sequences of all the 3 billion chemical base pairs that make up human DNA,
- Store this information in a database,

- Improve the tools for data analysis,
- Transfer the related technologies to the private sector, and
- Address the ethical, legal and social issues that may arise from the HGP.

(U.S. Department of Energy Office of Science, 2009)

In June of 2000, the International Human Genome Sequencing Consortium announced the completion of a rough draft of the human genome sequence. In April of 2003, the Consortium announced that the sequence was essentially finished¹. The total cost of the HGP was approximately \$2.7 billion (National Human Genome Research Institute, 2009). The perceived promise of the HGP was that by knowing the sequence of the human genome it would be possible to determine and develop medical treatment based on an individual's specific sequence. The sequencing of the first human genome was not sufficient to accomplish this goal. However, the HGP provided a platform for other research initiatives to understand the role of genetics in human health.

2.2.2 International HapMap Project

The International HapMap Project was a research initiative that followed the HGP. The purpose of the project was to develop a tool to allow researchers to find genes and genetic variations that are implicit in disease risk (National Human Genome Research Institute, 2010). In other words, the project discovered common patterns in

¹ The difference between the draft and finished versions is the amount of coverage, the number of gaps and the error rate. The draft sequence covered 90% of the genome at an error rate of one in 1,000 base pairs, but there were more than 150,000 gaps and only 28% of the genome had reached the finished standard. In the April 2003 version, there are less than 400 gaps and 99% of the genome is finished with an accuracy rate of less than one error every 10,000 base pairs. The differences between the two versions are significant for scientists using the sequence to conduct research. (National Human Genome Research Institute, 2009)

genetic variations among humans. In addition, the HapMap is a resource of studying genetic factors contributing to variation in response to environmental factors, in susceptibility to infection and in the effectiveness of, and adverse reactions to, therapeutics such as drugs and vaccines (National Human Genome Research Institute, 2010).

2.2.3 Genome-Wide Association Studies

Researchers can now perform genome-wide association studies. This tool is a result of the HGP and the International HapMap Project. These studies involve rapidly scanning complete genomes in order to identify genetic variants known as single nucleotide polymorphisms² (SNPs) (Singer, 2010). This process is a way to identify genetic variations associated with a particular disease or health condition (National Human Genome Research Institute, 2010). Simply, there is association between a genetic variation and a disease if it the variation is found in the samples of individuals with that particular disease and not found in the samples of individuals who do not have the disease. Therefore, a researcher can scan a genome for these genetic variations without the individual's entire genome being sequenced (National Human Genome Research Institute, 2010).

A genetic variation associated with a disease may not actually be the direct cause of the disease. In other words, the variation is present when the disease is present but it is not the cause of the disease. In such cases, it may be necessary to take further steps to

² A SNP is a variation in a single base (A, T, C or G) within a sequence of DNA. For any single base variation to be called a SNP it must be found in more than 1% of the population. So far, more than 6 million SNPs have been discovered in the human genome. SNPs do not generally cause disease directly but some SNPs may indicate an individual's susceptibility to disease or the response to drugs and treatments (Genome British Columbia, 2010; Genome British Columbia, 2010).

determine if a specific genetic variation is the direct cause of the disease (National Human Genome Research Institute, 2010). For example, sequencing a particular region of the genome may help determine the specific changes directly related to causing the disease.

2.2.4 Declining Genome Sequencing Costs

The cost of sequencing the first human genome was nearly \$3 billion USD (Humphries, 2010). The cost of sequencing a human genome has decreased at an exponential rate since the HGP sequenced the first human genome. This rate of decrease will continue until the cost of sequencing a human genome will be similar to other routine medical diagnostic procedures, such as an MRI (Humphries, 2010). In fact, \$1,000 USD per genome is a figure that media outlets often use in reference to declining sequencing costs (Humphries, 2010). However, even \$100 USD per genome may be possible in the next five years (Humphries, 2010). The low cost to sequence a genome may be due to the use of other advance technological tools in sequencing instruments, such as nanofluidic devices (Humphries, 2010). The use of microfluidics and nanofluidics reduce the volume of chemical reagents required for analysis. Chemical reagents are responsible for a large fraction of sequencing cost (Humphries, 2010). The exponential rate of decrease in sequencing cost has given rise to the idea that there is a Moore's Law³ for genetics. Genome sequencing produces large amounts of data.

Analysis of the data will become the primary constraint as sequencing costs continue to

³ The prediction made by Gordon Moore, co-founder of Intel, which states that the number of transistors on a chip will double about every two years (Intel, 2010).

decrease. Therefore, translating genomic data into medically useful information requires a breakthrough in the analysis of genomic data (Singer, 2010).

2.2.5 Clinical Application of Whole-Genome Sequencing

The ability to sequence an individual's genome and use it for clinical application is moving closer to reality. A recent study suggested that whole-genome sequencing could yield useful and clinically relevant information for individual patients (Ashley, et al., 2010). In the study, a patient had his genome analyzed for rare or novel variants that would predispose the patient to disease. The whole-genome sequencing identified previously described rare variants in genes associated with common disease, previously described rare variants in genes associated with rare disease, previously described variants of unknown importance in disease-associated genes, and novel variants potentially associated with rare disease (Ashley, et al., 2010). Identified gene variants helped determine disease risk. First, the investigators determined pre-test disease risk probabilities from established evidence-based medicine protocols, such as an assessment of family history. The pre-test risk value was the starting point. The investigators then adjusted this risk value based on the presence of identified SNPs that are associated with each disease (Ashley, et al., 2010). For each disease analyzed, the result was a post-test risk value that integrated both established risk factors and the results of the sequencing analysis. The authors of the study considered environment and behavioural factors as well. The authors developed a diagram to show how environmental and behavioural factors influence the diseases with high post-test risk probabilities (Ashley, et al., 2010). Sequencing of the patient's whole genome also identified genes relevant to drug response, such as to warfarin and atorvastatin (Ashley, et al., 2010). Standard clinical

protocols have not integrated this approach of using whole-genome sequencing to assess disease risk and response to therapy. However, the study demonstrates that the information resulting from whole-genome sequencing may be able to provide clinically meaningful data.

2.3 Environmental Impact on Genetics

An individual's complete genome sequence does not provide all of the information required to predict disease risk or response to therapy with complete accuracy. For example, the authors of the study described in Section 2.2.5 recognized that identification of SNPs associated with disease are in a context of environmental and behavioural influences. Gene variants identified through genomic sequencing or scanning only account for a small percentage of an individual's overall disease risk (Singer, 2010). In other words, an individual's specific DNA sequence is not the only thing relevant to disease risk and drug response. It is also necessary to understand the environmental factors that affect gene expression to be able predict disease risk and drug response. Pursuant to this need, there are several fields of research that aim to determine the factors within a gene's environment that influence gene expression. These fields of research may lead to the development of more innovations with potential clinical application. The following examples are for illustrative purposes only. These examples are not exhaustive of all research areas dedicated to understanding the role of the environment on gene function and expression.

2.3.1 Epigenetics

Epigenetics is a field within the genome sciences that studies inherited changes to the expression, or phenotype, of genes controlled by mechanisms other than changes to the actual sequence of DNA nucleotides. In other words, epigenetics studies the mechanisms controlling heritable differences in gene expression not caused by variation in the DNA sequence (Talens, et al., 2010). Generally, there are three epigenetic processes: DNA methylation, histone modification and chromatin remodelling (Gal-Yam, Saito, Egger, & Jones, 2008). Epigenetics may be the missing link connecting genetics, disease and the environment (Human Epigenome Consortium, 2010).

Epigenetic risk factors contribute to the development of common cardiovascular and metabolic diseases, as well as cancer (Gal-Yam, Saito, Egger, & Jones, 2008). Epigenetic targets are attractive for the development of cancer therapies due to their dynamic nature and potential reversibility (Gal-Yam, Saito, Egger, & Jones, 2008). In fact, FDA has approved drug products for epigenetic targets. Examples include drugs for the treatment of certain types of cancers, such as the DNA methylation inhibitor azacitidine. Furthermore, there are classes of drugs, such as histone deacetylase inhibitors (HDACs), that are under development by a variety of drug development companies, such as MethylGene in Montreal, Quebec (Gal-Yam, Saito, Egger, & Jones, 2008).

A consortium of public and private organizations, collectively referred to as the Human Epigenome Consortium, is collaborating on the Human Epigenome Project (HEP). The HEP will identify, catalogue and interpret genome-wide DNA methylation patterns of all human genes in all major tissues (Human Epigenome Consortium, 2010).

Simply, the HEP aims to help further understand the role the epigenome plays in human health.

2.3.2 Human Microbiome

Microbial cells may outnumber human cells by a factor of ten to one in healthy human adults. However, the influence that these microbial communities have on human development, physiology, immunity and nutrition is not well understood (The NIH Common Fund, 2010). Microbial communities may play a larger role in controlling human health than previously thought. The NIH in the United States has initiated the Human Microbiome Project (HMP) in order to understand how microbial interactions affect human health. The goal of the project is to generate resources that will enable comprehensive characterization and understanding of the microbial communities present within individuals. The HMP will also analyze the role of these communities with respect to human health and disease (The NIH Common Fund, 2010).

2.3.3 Nutrigenetics & Nutrigenomics

It is common knowledge that a healthy diet is important in maintaining proper health. However, an optimal healthy diet may vary among individuals. Nutrigenetics and nutrigenomics are emerging fields of study that examine how an individual's diet and genes interact. Nutrigenomics examines how diet affects expression of a genome (Kusmann & Fay, 2008). Nutrigenetics examines how an individual's genetic make-up influences how individuals respond to dietary intervention (Kusmann & Fay, 2008). Nutrigenetics and nutrigenomics lead to personalized nutrition, an analog to personalized

medicine. These fields of study may lead to the discovery of biomarkers⁴ that may help identify optimal nutrition for individuals (Kussmann & Fay, 2008).

2.4 Personalized Medicine Innovations – Diagnostics & Therapeutics

A revolution in personalized medicine has not yet arrived. This is especially true in the case of personalized drug products. However, companion diagnostics now accompany an increasing number of drugs. A companion diagnostic is a test that looks for genetic, proteomic or gene expression biomarkers to predict whether a drug will work in someone or what kind of dose that person should take (Swanson, 2009). Specifically, companion diagnostics show whether the therapy with which the test is associated is likely to have positive results for the patient (Miller & Batchelder, 2009). One of the best-known examples of a companion diagnostic is for Genentech/Roche's breast cancer drug Herceptin. This test identifies if a patient is suitable for treatment by Herceptin. The test determines if there is over expression of the HER2 gene in a particular patient. Patients who test positive for over expression of HER2 typically respond better to Herceptin treatment than patients who do not test positive for HER2 over expression (Genentech, 2010). The FDA actually requires this test prior to Herceptin treatment (Allison, 2008). There are only a few examples of drugs that require the use of a companion diagnostic by the FDA (Allison, 2008). The FDA also recommends, but does not require, companion diagnostic tests for some drugs, such as the test for UTG1A1 variants for Pfizer's Camptosar (Allison, 2008).

Diagnostic tests that help direct patient therapy are also in development. "Multi-therapy diagnostics" is a term for this kind of test (Miller & Batchelder, 2009). These

⁴ In general, a biomarker is a substance that is an indicator of some sort of biological state.

independent diagnostics are not necessarily specific to a particular type of therapy. In other words, the diagnostic test could demonstrate what follow-up procedures are necessary or what procedures are not necessary. There is a strong value incentive for multi-therapy diagnostics for payers of healthcare services. Multi-therapy diagnostics could reduce the costs incurred to payers by decreasing the number of unnecessary medical procedures. For example, a test for a particular biomarker could signal whether or not a patient requires surgery for a particular type of cancer. Therefore, multi-therapy diagnostic derive their value from actual clinical utility (Miller & Batchelder, 2009). Genomic Health's Oncotype DX test is an example of a commercially available multi-therapy diagnostic test (Miller & Batchelder, 2009). The test predicts the likelihood of chemotherapy benefit and recurrence for patients with node-negative breast cancer that is estrogen-receptor positive and/or progesterone-receptor positive (Genomic Health, 2010).

The identification and validation of biomarkers, genetic or otherwise, is central to the promise of personalized medicine. There are also examples of groups in BC conducting research into biomarkers for various disease conditions. For example, the PROOF Centre of Excellence at St. Paul's Hospital is leading the "Biomarkers in Transplantation" initiative. This project is testing gene and protein biomarker panels for their ability to predict or diagnose whether a heart or kidney transplant is rejecting in an individual patient (PROOF Centre of Excellence, 2009).

2.5 Personal Genetic Testing

A new industry has emerged due to the recent advances in genomic analysis. However, this industry does not necessarily represent the promise of delivering "the right treatment for the right person at the right time". There are now companies that provide

information regarding disease risk and drug response directly to consumers. Consumers send a sample of their saliva to the company in a collection kit. Then after approximately 6-8 weeks, the results of the analysis are available to the customer (Ng, Murray, Levy, & Venter, 2009). “Direct-to-Consumer Genetic Testing” and “Consumer Genomics” are common terms for this industry. This is because the service is available to consumers outside of any formal healthcare system. In other words, individuals are able to learn about their potential disease risk and drug response without the consultation of a healthcare professional, such as a physician. The most prominent companies in this industry are 23andMe, Navigenics and DeCode Genetics. There are as many as 39 such companies currently in operation in the United States (The Genetics and Public Policy Center, 2010).

These companies determine disease risk by identifying known risk markers in the customer’s DNA sample associated with diseases. The identification of these known risk markers results in a relative risk factor. The relative risk factor multiplied by the average disease risk among the population results in the absolute disease risk. The risk value that the customer receives is the absolute disease risk (Ng, Murray, Levy, & Venter, 2009).

Most personal genetic testing companies use the microarray technology platform to identify single SNPs that are associated with diseases (Technology Review, 2010). A microarray is a slide or membrane with small bits of DNA of known sequence fixed to it. Microarrays allow the detection of genetic sequences by complementary binding of unknown DNA samples (Genome British Columbia, 2010). The price for this service ranges anywhere from \$200 to \$1000 USD depending on the company and detail of analysis (Technology Review, 2010). Some companies, such as Knome, now offer

whole-genome sequencing (Technology Review, 2010). The price of Knome's full genome sequencing service is \$68,500 USD (Technology Review, 2010). Knome's whole-genome sequencing service also includes an in-person consultation by its team of scientists. The cost of using microarray technology to scan for genetic variations is currently much less than sequencing a full genome. The difference in service pricing between companies that offer microarray scans versus those who offer whole-genome sequencing demonstrates the difference in cost. However, more companies may soon offer whole genome sequencing due to the rapid decrease in genome sequencing costs (Davies, 2010).

To date, the uptake of personal genetic testing services has been relatively slow among consumers. For example, 23andMe has only approximately 35,000 customers after two and a half years of service (Pollack, 2010). Furthermore, about one quarter of these customers only paid \$25 for the service, as opposed to the advertised \$499 (Pollack, 2010). The lack of market penetration has also forced some companies to downsize their staff. For example, 23andMe downsized its staff from over 70 to fewer than 40 in 2009 (Pollack, 2010). However, 23andMe has still been successful in raising money from private investors, despite the lack of market penetration. The company was able to raise \$27.8 million from private investors in 2009 (Pollack, 2010).

2.5.1 The Regulatory Environment of Personal Genetic Testing

The U.S. Food & Drug Administration (FDA) currently does not regulate personal genetic testing services offered by direct-to-consumer genetics companies. The FDA has not approved their services to provide any medical advice, diagnosis or treatment. The services are supposed to be for information purposes only. Thus, these

companies market their services as being laboratory-developed tests (LDTs) (Ray, 2010). LDTs are under the authority of the Centers for Medicare and Medicaid Services (CMS) in the United States (Ray, 2010). The CMS regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA) (Centers for Medicare & Medicaid Services, 2010).

However, the FDA has recently asserted that these services do not qualify as LDTs (Ray, 2010). The FDA's believes that these firms are actually marketing unapproved diagnostic devices (GenomeWeb, 2010). The FDA asserts that the tests are for use in the diagnosis of disease or other conditions (GenomeWeb, 2010). Therefore, the tests should fall under the same regulation as medical devices (GenomeWeb, 2010). The FDA sent warning letters to 23andMe, Knome, Navigenics, Illumina and Decode Genetics on June 10, 2010 (U.S. Food and Drug Administration, 2010) regarding this matter. The letters instructed these companies to contact the FDA in order to initiate discussions to determine whether the tests do in fact qualify as medical devices. The FDA must review and approve the tests if they are medical devices (GenomeWeb, 2010).

Furthermore, the U.S. Congress also opened an investigation into providers of personal genetic testing services. The House Committee on Energy and Commerce sent letters to Pathway Genomics, 23andMe and Navigenics requesting information on aspects of the tests that they sell directly to the consumer. The letters asked for a list of the diseases and drugs for which the services provide genomic risk data, policy documents and materials on genetic counselling or physician consultation (GenomeWeb, 2010). Furthermore, the letters asked for data showing the accuracy of the risk predictions delivered by these services, details on policies regarding handling of DNA samples, and

documents relating to the services' compliance with FDA regulation (GenomeWeb, 2010).

2.5.2 Variability of Disease Risk Predictions between Companies

It has also been reported that the results of personal genetic testing services do not always agree between different companies (Ng, Murray, Levy, & Venter, 2009). A study compared the results between 23andMe and Navigenics for 13 diseases from five individuals. The two companies reported different disease risk predictions approximately one third of the time (Ng, Murray, Levy, & Venter, 2009). For example, 23andMe reported a decreased risk of Crohn's disease for a subject while Navigenics reported an increased risk for the same subject. However, the raw data actually agreed over 99% of the time (Ng, Murray, Levy, & Venter, 2009). Therefore, the two companies appear to use different methods of calculating the absolute disease risk (Ng, Murray, Levy, & Venter, 2009). As mentioned, the absolute disease risk is the value reported to the individual. The differences in risk calculation between 23andMe and Navigenics can result in a very different message to the individual when the risk values do not agree.

2.5.3 Questionable Value of Personal Genetic Testing

Many experts regard personal genetic testing services to be of questionable prognostic or diagnostic value (Pray, 2008). The services may be of questionable prognostic value regardless of regulation or accuracy (Pray, 2008). This is because many of the genetic tests are for conditions that do not have any known effective risk-reduction strategies, such as Alzheimer's disease and many types of cancers (Pray, 2008). If the results of the genetic test do not have an effective risk-reduction strategy then it is

possible that the results of the test will just create distress for the individual. The tests only indicate increased or decreased relative risk for diseases in which there are effective risk-reduction strategies, such as cardiovascular disease. The tests do not predict whether the individual will actually develop such diseases. Furthermore, complex interactions of multiple genes and environmental factors can cause disease. Thus, a simple genetic test may not be sufficient to be of any prognostic value (Pray, 2008).

2.5.4 The Ethical Implications of Personal Genetic Testing

The marketing of personal genetic testing services by direct-to-consumer genetics companies creates a variety of ethical implications. There is a substantial amount of written literature exploring these ethical issues. These ethical considerations have applicability to both the individual and the community level (Samuel, Jordens, & Kerridge, 2010). Perception of genetic test results by the individual is a key ethical issue. Furthermore, the ethical considerations must also account for the results of the individual's perception. For example, false positive test results may lead the individual to develop unnecessary anxiety and depression regarding the possibility of developing the disease. The test results may also cause the individual to take unnecessary preventative measures at his or her own cost (Samuel, Jordens, & Kerridge, 2010). Conversely, false negative tests may give the individual false reassurance. This may cause the individual not to take preventative health measures, such as adhering to a healthy diet (Samuel, Jordens, & Kerridge, 2010).

Furthermore, ethicists have described the potential for harm at the community level resulting from these tests. For example, false positives among a population could potentially lead to large amounts of follow-up procedures and investigations within a

medical system. This could end up being costly to providers and payers of healthcare services (Samuel, Jordens, & Kerridge, 2010). In a public healthcare system, such as in Canada, unnecessary follow-up investigations will ultimately be at the expense of the taxpayer.

2.6 Barriers to Adoption of Personalized Medicine & Genomics

There is a variety of barriers to the adoption of new healthcare innovations relevant to the principles of personalized medicine by the healthcare system. These barriers are technological, economic and operational. In the past, technological limitations have presented the largest barriers for personalized medicine to overcome. Technological progress and limitations may soon no longer be the primary barrier to the adoption of personalized medicine innovations by the healthcare system. The primary barriers to the adoption of personalized medicine will relate to the alignment of the economic and operational incentives for the multiple stakeholders of the current system (Lester, 2009). The relevant stakeholders include patients, physicians, payers and regulatory bodies, as well as the companies that commercialize healthcare products and services, such as pharmaceutical and diagnostics companies (Lester, 2009).

To date, payers have been slow to invest in personalized medicine even though it may be able to reduce healthcare costs (Davis, et al., 2009). Payers include those who actually pay for healthcare procedures, such as healthcare insurance companies or the government in public healthcare systems. The reasons for the lack of investment include an inability to determine which tests truly reduce costs and the lack of longitudinal accounting that would allow payers to make long term cost savings from near term testing (Davis, et al., 2009). Furthermore, there could be difficulty enforcing the standard

protocols that ensure that physicians follow through with the appropriate patient care based on test results (Davis, et al., 2009). In addition, there is the threat of misuse of test information that could harm the patient (Davis, et al., 2009).

The promise of personalized medicine may not be in alignment with the economic incentives for physicians. Physician reimbursement models are generally activity based (Davis, et al., 2009). “Pay-per-procedure” is an appropriate term for the activity-based reimbursement model. Therefore, there is poor economic incentive for physicians to conduct tests that may prevent downstream activity (Davis, et al., 2009). In other words, the physician reimbursement models will need to change if personalized medicine is actually able to decrease the amount of unnecessary medical activities (Davis, et al., 2009). The change to reimbursement schemes may help facilitate adoption by physicians. Perhaps, physician economic incentives will align to personalized medicine through an outcome-based reimbursement model (Davis, et al., 2009).

Furthermore, many physicians are not yet fully educated with respect to genomics (Guttmacher, Porteous, & McInerney, 2007). Physicians will need to be educated on genomics in order for them to be able to understand how to use the genome sciences within the context of their practices. Physicians, and other relevant healthcare professionals, may need to gain more knowledge on modes of inheritance and the role of family history, what genetic results are indicated and what do the results mean, how to calculate risk and the indications for referral to a genetic specialist (Guttmacher, Porteous, & McInerney, 2007). Furthermore, physicians will need to develop the appropriate skills relevant to genomics, such as communicating genetic information and

facilitating informed decision making by patients (Guttmacher, Porteous, & McInerney, 2007).

There is also a misalignment of economic incentives for the companies that sell healthcare products and services, such as pharmaceutical and biotechnology companies. Traditionally, pharmaceutical companies have employed a “one size fits all” method of drug development. In other words, a specific drug is essentially for everyone with the targeted indication. This allows a pharmaceutical company to be able to capture the greatest market share possible. However, some pharmaceutical companies are now using biomarkers and companion diagnostics to aid in the drug development process. The co-development of a drug with a companion diagnostic has the potential to increase the efficiency of the drug development process by decreasing the size of clinical trials, reducing the incidences of serious adverse events and supporting higher prices (Davis, et al., 2009). Nevertheless, adoption of the use of biomarkers and the development of companion diagnostics has been slow, despite the potential benefits. Estimates state that only 30% to 50% of drugs in development have an associated biomarker program (Davis, et al., 2009). Furthermore, only 10% of new drugs will include a companion diagnostic in the next ten years (Davis, et al., 2009).

There could be a variety of reasons for the relatively slow rate of adoption of the use of biomarkers and companion diagnostics by pharmaceutical companies. The primary reason for the slow rate of adoption could be that the pharmaceutical companies place higher priority on increasing market share and price rather than increasing drug development efficiency and productivity (Davis, et al., 2009). Furthermore, some evidence suggests that, in practice, the use of biomarkers may not actually increase

development efficiency and productivity (Davis, et al., 2009). The lack of benefit, in terms of development and productivity, may be due to the lack of clarity concerning which biomarkers will actually be predictive, or the requirement by regulatory bodies to include “marker-negative” subjects in clinical trials (Davis, et al., 2009). “Marker-negative” subjects are individuals who do not possess the biomarker for which a therapy is determined.

2.7 The Need to Facilitate the Integration of Personalized Medicine

In brief, personalized medicine and genomics have advanced to the point in which medical application is no longer limited primarily by technological limitations. Perhaps within the next five years it will no longer be cost prohibitive to have an individual’s whole-genome sequenced. However, as technological barriers decrease there will still be economic and operational barriers that may prevent the uptake of personalized medicine by the healthcare system. Therefore, there will need to be as much effort on determining how to integrate personalized medicine and genomics into the healthcare system as there is on developing the actual healthcare innovations. The life sciences community has not overlooked this fact. Various public and private organizations have developed initiatives to help facilitate the integration of personalized medicine into the delivery of healthcare.

3: GENOME BRITISH COLUMBIA

3.1 Introduction

Many for-profit and not-for-profit organizations have been involved in the funding of research and development of new healthcare innovations relevant to the concept of personalized medicine. These funding initiatives and programs will not be of any benefit to patients and physicians without proper integration into the actual delivery of healthcare. Therefore, funding is required for initiatives that help facilitate the integration of new healthcare innovations into clinical use. Fortunately, members of the life sciences community have recognized this need. This section will provide an overview of Genome British Columbia (Genome BC). There will be particular focus on the human health funding programs at Genome BC. The focus will highlight how these funding programs will help deliver the promise of personalized medicine to the Province of British Columbia.

3.2 Organizational Overview

Genome BC is a non-profit research organization that invests primarily in large-scale genome sciences research projects and technology platforms focused on areas of strategic importance to BC, such as human health, forestry, fisheries, agriculture, bioenergy, mining, and the environment. Genome BC is the catalyst for a vibrant life sciences cluster with far reaching social and economic benefits for BC and Canada. Genome BC works collaboratively with government, universities, and industry to help accomplish this goal. To date, the Genome BC has managed research programs with a

total value of over \$425 million. This funding has supported more than 75 research projects and Innovation Centres⁵. Genome BC's primary investors include Genome Canada⁶, the Province of British Columbia and Western Economic Diversification Canada⁷.

Genome BC's business model is a blend of a traditional granting council and a venture capital firm. This is because Genome BC does not award traditional research grants. The project leader and the affiliated research institution enter into a research contract with Genome BC in order to receive funding. The terms of the contract include reporting on the scientific and financial progress of the project at predetermined reporting periods. Therefore, the funding awarded is as an investment rather than a traditional research grant. Genome BC also expects a return on its investment. The return on the investment may include access to rights and residuals arising from the commercialization of the research. Genome BC negotiates the rights with the lead organization.

3.3 Genome BC's Funding Programs

Genome BC invests in research projects and technology platforms relevant to the genome sciences through formal funding programs and competitions. Genome BC or Genome Canada administers these funding programs. The roles that Genome BC in these

⁵ Innovation Centres are the science and technology platforms funded by Genome BC and include the Genomics Platform at the Michael Smith Genome Sciences Centre, BC Cancer Agency, the Microarray Centre at the VGH-Prostate Centre, the Proteomics Centre at the University of Victoria and the Technology Development Platform.

⁶ Genome Canada is a not-for-profit organization established in February 2000 by the Government of Canada with a mandate to develop and implement a national strategy for supporting large-scale genomics and proteomics research projects, for the benefit of all Canadians. Genome Canada is one of Genome BC's primary investors.

⁷ Western Economic Diversification Canada (WD) is a department of the Government of Canada with a mandate to promote the development and diversification of the economy of Western Canada and advance the interests of the West in national economic policy.

two types of program scenarios are quite different. The differences are in respect to the interactions with the applicants, and portion of the total project value that Genome BC will fund.

Genome Canada runs national funding competitions that are open to all eligible researchers across Canada. Genome Canada's Board of Directors, as recommended by a peer review panel, determines the proposals selected for funding. Applicants send their proposals to a regional genome centre⁸, such as Genome BC, for Genome Canada competitions. The regional genome centres send the proposals from their jurisdictions to Genome Canada. It is the goal of Genome BC to help BC-based research teams to acquire as much of the federal funding as possible for Genome Canada competitions. Genome BC offers assistance in the development of the researcher's applications to help accomplish this goal. Genome BC also provides guidance and assistance in preparing the research teams for the face-to-face meeting with Genome Canada's assigned peer review panel. Genome BC generally funds up to 25% of the total project budget for projects lead by researchers in BC for Genome Canada programs. Genome Canada will fund up to 50% the total project budget. The final 25% of co-funding may be obtained from a variety of Canadian or foreign sources, such as institutional funds, trust funds or foundations; departments and agencies of the federal government, with exceptions⁹; departments and agencies of provincial and municipal governments; firms and

⁸ There are six regional Genome Centres across Canada: Genome British Columbia, Genome Alberta, Genome Prairie, the Ontario Genomics Institute, Genome Quebec and Genome Atlantic.

⁹ Funding from the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC), the Social Sciences and Humanities Research Council (SSHRC), and tri-agency programs (e.g. the Networks of Centres of Excellence, Centres of Excellence for Commercialization and Research and the Canada Research Chairs) are not eligible sources of co-funding for Genome Canada funding programs (Genome Canada, 2010).

corporations; voluntary organizations; individual; and venture capital or other investment funds (Genome Canada, 2010).

Genome BC also runs programs and competitions that are independent of involvement from Genome Canada. These programs are only open to researchers based in BC. Genome BC's Board of Directors, as recommended by a peer review panel, determines the proposals selected for funding. Genome BC will fund anywhere from 20% to 50% of the total project budget, depending on the program. The project team is responsible for providing the remainder of the co-funding. Genome BC's co-funding eligibility is similar to that of Genome Canada. However, funding from CIHR, NSERC, SSHRC or the tri-agency programs are eligible as co-funding for Genome BC programs. Genome BC does not offer the same assistance in proposal development and preparation as with the Genome Canada programs.

3.4 Genome BC's Human Health Programs

As of July 2010, Genome BC has funded 30 human health research projects and initiatives of strategic importance to the Province through a variety of funding programs and mechanisms. These programs intend to expand existing capabilities in the human health sciences through the translation of discovery science into everyday life. In 2003, Genome Canada & Genome BC launched the Applied Human Health (AHH) program. AHH funded proposals focused on the development and application of genomics and proteomics tools to improve the prediction, prevention and treatment of human disease for individuals and populations. In September 2007, Genome BC launched the Translational Program for Applied Health (TPAH). This program was only open to the six funded projects from the AHH competition. The purpose of TPAH was to provide

follow-up funding so that the translational components of these projects to be realized. TPAH is a \$17 million program and Genome BC contributed \$5.6 million. The three translational research projects funded in this program include research examining adverse drug reactions, biomarkers in organ transplantation and new drugs for iron overload disorders (Genome British Columbia, 2009).

Furthermore, in June 2010 Genome BC launched the Genomics and Health: Personalized Medicine Program. The primary goal of the program is to demonstrate that genomics-based research can integrate into the healthcare system in a cost effective manner (Genome British Columbia, 2010). The effort is a \$9M program with \$3M provided by Genome BC. Projects approved under this initiative will launch approximately by April of 2011.

3.5 Genomics & Health Strategy

Genome BC believes that British Columbia is well positioned to become a world leader in adopting new innovations in healthcare. This positioning will allow BC to become the “Personalized Medicine Province”. Characteristics of the population of BC support this view. For example, the population of BC is thought to be relatively well educated and health conscious (Genome British Columbia, 2009). Furthermore, BC has an excellent record of accomplishment in biomedical research. It is the belief of Genome BC that this biomedical research is now maturing to a point where translation to clinical practice is feasible in the next few years (Genome British Columbia, 2009).

Resulting from this view, Genome BC released the document *Towards a Genomics & Health Strategy* in 2009. The document assembled input from a task force

of individuals representing a variety of stakeholders, including representatives from academia, research institutes, the public healthcare system and the private sector. The document outlined the development of strategies focused on the application of genomics in order to facilitate the integration of innovation into healthcare delivery. These strategies will maximize the potential of provincial, federal and private sector investment towards a sustainable modern healthcare system. Genome BC will build partnerships with health authorities and their research institutes, funding agencies and the private sector to accomplish this goal. It will also initiate processes that develop the creation of multidisciplinary teams needed to translate knowledge to users. Furthermore, Genome BC will continue to launch competitive funding programs that will provide funding for focused translational research relevant to personalized medicine (Genome British Columbia, 2009)

3.6 Investment into Healthcare Beyond the Public System

As mentioned above, Genome BC seeks to build partnerships with the health authorities in BC. This will help facilitate the adoption and integration of innovations into the healthcare system. The health authorities are representative of the public health system in BC. However, there are other organizations that deliver healthcare to individuals in BC. These organizations provide healthcare outside of, or parallel to, BC's public healthcare system. These are private and for-profit firms that provide healthcare services. These firms represent another group that may be suitable to receive investment from Genome BC. An examination of the private healthcare industry in BC will assess the possibility of investment opportunities.

4: BRITISH COLUMBIA'S PRIVATE HEALTHCARE SECTOR

4.1 Introduction

A public system primarily delivers healthcare to patients in Canada. However, the delivery of core healthcare services is becoming increasingly available through private sector alternatives. This increase in the delivery of private healthcare is a result of efforts to deregulate the delivery of healthcare in Canada. Efforts to deregulate the delivery of healthcare have arisen out of inefficiencies within the public system, such as the lengthy waiting lists for medical procedures. There is much controversy surrounding the increased delivery of healthcare through private firms. This controversy is in spite of the belief, held by some, that private healthcare firms are meeting a need that is now unmet by the public healthcare system.

This section will examine private healthcare firms in BC. Physician-based private healthcare firms in BC fall into two primary groups. The two groups are private surgical and imaging centres and integrated preventative healthcare clinics. Furthermore, a model that segments the market into four different categories describes the market for private healthcare in BC. The type of service offered and whether or not there is a public alternative determines the category. Each market category also has its own set of motivations as to why an individual may source a healthcare service through a private healthcare firm, as opposed to the public healthcare system.

The examination in this section also describes the research activities and investment model for private healthcare firms in BC.

4.2 Healthcare in Canada

The Canada Health Act guides the public healthcare system in Canada. The delivery of healthcare in Canada is primarily associated with the public system. However, the private sector accounts for approximately 30% of the total healthcare costs in Canada (Canadian Institute for Health Information, 2005). This 30% was valued at approximately \$39 billion in 2005 (Canadian Institute for Health Information, 2005). Private healthcare spending mostly went towards services not covered, or only partially covered, by the public system. These services include drugs, dental services and optometry, as well as niche-services such as work-related injuries and cosmetic surgery (Canadian Institute for Health Information, 2005).

The provinces of Canada are responsible for the management and delivery of healthcare (Steinbrook, 2006). The Federal Government of Canada has the primary responsibility for taxation (Steinbrook, 2006). The Canadian constitution states this. In British Columbia, the Medical Services Plan (MSP) of BC insures medically required services provided by physicians and supplementary healthcare practitioners, laboratory services and diagnostic procedures (Ministry of Health Services, 2010). PharmaCare covers prescription drug costs (Ministry of Health Services, 2010). BC's Ministry of Health covers the costs of hospital services through "block funding" to the hospitals (Ministry of Health Services, 2010).

The Canadian healthcare system is relatively unique when compared to the rest of the world. There is a ban on the coverage of core healthcare services by private insurance (Steinbrook, 2006). However, private insurance can provide supplemental insurance for perquisite services (Steinbrook, 2006). The ban on private insurance coverage for core services impedes the development of the infrastructure required for a parallel private medical or hospital industry in Canada (Steinbrook, 2006).

4.2.1 Problems with Canada's Public Healthcare System

There are problems associated with the delivery of healthcare through Canada's public system. Healthcare spending totals approximately 27 to 45% of provincial budgets in Canada (Steinbrook, 2006). Currently the Province of British Columbia spends approximately \$13 billion annually on the delivery of healthcare. This figure represents approximately 40% of the provincial budget (Genome British Columbia, 2009). There has been a 5-7% increase in annual healthcare spending in BC (Genome British Columbia, 2009). This annual increase may be unsustainable.

The increasing costs of providing healthcare are not unique to Canada. Developed countries around the world are also facing this issue. Reasons for the rising costs of healthcare in developed countries include the increase in costs of newly developed life-saving treatments and diagnostic and prognostic tests for chronic diseases, the rise in the incidence of certain chronic diseases that impact dramatically on healthcare budgets, and the lack of integrated informatics solutions in healthcare delivery comprehensive electronic patient health records and systems to deal with data from forthcoming genomics-based tests in all aspects of healthcare (Genome British Columbia, 2009).

In recent years, the Canadian healthcare system has received criticism for being inefficient and lacking sufficient funding (Steinbrook, 2006). Some criticize the Canadian public healthcare system for not meeting patient needs in a timely manner (Steinbrook, 2006). Specifically, the time from referral by general practitioners to treatment is often longer than clinically reasonable. The median wait times for medical procedures illustrates the inability to meet patient needs within a clinically reasonable timeframe. The total median wait time is longest for Saskatchewan (Steinbrook, 2006). BC's total wait time of 18.4 weeks is about one week below the national average of 19.5 weeks (Steinbrook, 2006). In terms of medical speciality, the total median wait time is longest for orthopaedic surgery (Steinbrook, 2006). The total median wait time for orthopaedic surgery is almost four weeks longer than the next longest, plastic surgery (Steinbrook, 2006).

Tables 1 and 2 summarize the median waiting times, categorized by province and by speciality.

Table 1- Median wait times from General Practitioner to specialist and specialist to treatment in weeks, categorized by province.

	Wait from general practitioner to specialist (weeks)	Wait from specialist to treatment (weeks)
British Columbia	7.2	11.2
Alberta	8.2	8.6
Saskatchewan	7.2	18.3
Manitoba	7.0	9.6
Ontario	7.6	8.7
Quebec	9.1	8.4
New Brunswick	12.9	11.6
Nova Scotia	10.4	11.1
Prince Edward Island	6.2	10.7
Newfoundland	13.0	9.4
Canada	8.3	9.4

Source: Adapted from (Steinbrook, 2006).

Table 2 - Median wait times from General Practitioner to specialist and specialist to treatment in weeks, categorized by province.

	Wait from general practitioner to specialist (weeks)	Wait from specialist to treatment (weeks)
Plastic Surgery	15.4	20.9
Gynaecology	7.7	7.1
Ophthalmology	14.3	13.1
Otolaryngology	5.3	9.0
General Surgery	4.2	6.2
Neurosurgery	11.0	7.8
Orthopaedic Surgery	14.7	25.3
Cardiovascular Surgery (elective)	3.1	5.2
Urology	7.5	5.3
Internal Medicine	4.5	6.3
Radiation Oncology	1.6	4.1
Medical Oncology	3.0	2.6
<i>Weighted Median</i>	8.3	9.4

Source: Adapted from (Steinbrook, 2006).

The increasing costs and perceived inefficiencies of the public healthcare system in Canada have many trying to find solutions. Some attempt to fix the problems within the context of the current system of healthcare delivery, such as increased funding to the areas identified to have the greatest need (Steinbrook, 2006). However, others assert that the public healthcare system itself is the problem. This statement implies that the system itself must be drastically changed (Copeman, 2010).

4.2.2 Deregulation of Healthcare in Canada

One proposed solution to the problems with the delivery of healthcare in Canada is to provide more medically necessary services through private healthcare firms (Steinbrook, 2006). In other words, the delivery of medically necessary services offered through the public system, through a private sector alternative. Media outlets often refer to this process as the privatization of healthcare in Canada. However, privatization may not actually be the appropriate word. Privatization is the as the process of transferring ownership of a business, enterprise, agency or public services from the public sector to the private sector (Chowdhury, 2006). This is not what is occurring in Canada with respect to healthcare. Deregulation of healthcare may be the more appropriate term for this process. Deregulation is the removal or simplification of government rules and regulations that constrain the operation of market forces (O'Sullivan & Sheffrin, 2002). The deregulation of healthcare includes the private delivery of publically financed core healthcare that are covered in the public system, such as family physician services, elective operations and imaging studies; private financing of care through health insurance; or direct payments by patients (Steinbrook, 2006).

The real and perceived inefficiencies of Canada's public healthcare system have generated demand for services outside of the system. There are individuals that are willing to pay their own after-tax income for expedited healthcare services outside of the public healthcare system (Copeman, 2010). This willingness to pay for expedited services has resulted in an emergence of for-profit private healthcare firms that provide medically necessary services typically provided through the public system. This emergence has become a contentious issue among Canadians. A 2005 opinion poll reported that 54% of Canadian felt that a parallel private system of financing healthcare risks weakening the public system (Steinbrook, 2006). Conversely, proponents of the deregulation of healthcare believe that a private system may actually benefit the public system. A parallel private system for core health services may help reduce patient waiting times and control public spending (Steinbrook, 2006).

The Canada Health Act of 1984 does not directly prohibit the private delivery and private insurance for health services that are available through the public system (Steinbrook, 2006). However, individual provinces are able to legislate laws that prohibit or curtail private healthcare (Steinbrook, 2006). This is due to the arrangement between the provincial governments and the Federal Government regarding the delivery of healthcare described in Section 4.2. In 1997, there was a challenge to a provincial law prohibiting private delivery of core healthcare services. A patient and his physician sued the Province of Quebec after a one-year long wait for hip surgery. Dr. Jacques Chaouli, the physician, asserted that when the public healthcare system does not provide reasonable access to medically necessary services, the prohibition of private healthcare violates both the Quebec Charter and the *Canadian Charter of Rights and Freedoms*

(Canadian Institute for Health Information, 2005). As a result, the Supreme Court of Canada ruled 4-3 in favour of invalidating Quebec's long-standing ban on private insurance for services that are available under Quebec's public healthcare system. The implication of this ruling was that provincial governments cannot ban the delivery of private healthcare and private insurance if the public system cannot meet the patient's medical needs without excessive waits (Steinbrook, 2006).

Resulting from this case, a group of private healthcare advocates in BC have filed a lawsuit claiming that aspects of British Columbia's Medicare Protection Act are unconstitutional. The lawsuit is similar to *Chaoulli v. Quebec (Attorney General)*. It argues that citizens should be able to access the private delivery of core healthcare services if the public system is unable to meet the patient's medical needs within a clinically reasonable amount of time (Canadian Medicine, 2009). The plaintiffs in the case include Brian Day of the Cambie Surgery Centre, Anna Stylianides of the False Creek Surgical Centre and Zoltan Nagy of the Canadian Independent Medical Clinics Association (Canadian Medicine, 2009).

4.2.3 Impacts of Private Healthcare on the Public System

Those who are opposed to the delivery of healthcare care through a parallel private system in Canada assert that it will negatively affect the public system. The belief is that private alternatives to the public system will lead to a two-tier healthcare system. The implication of a two-tier system is that those who can afford private healthcare will be able to access better healthcare, in terms of scope and quality of services, than those who cannot (Globerman & Vining, 1998). Conversely, proponents of a parallel private system assert that will benefit the public system through the alleviation of resource

demands. This position states that a parallel private healthcare system may reduce waiting times for patients using the public system and control public spending (Steinbrook, 2006).

The evidence supporting either position is mixed. The results of some studies provide evidence that private financing and delivery of healthcare does not contribute to reduced access to publically delivered healthcare (Globerman & Vining, 1998). Furthermore, there is evidence that restrictions on the availability of private healthcare delivery and financing will erode the support for a public healthcare system that does not have the resources to meet demand in an adequate amount of time (Globerman & Vining, 1998). There is also evidence that suggests that healthcare systems that allow for parallel publically and privately financed sectors do not actually reduce pressure on resources within the public system (Tuohy, Flood, & Stabile, 2004). Some studies suggest that a resort to the private delivery and financing of healthcare is more likely to harm than help the public healthcare system (Tuohy, Flood, & Stabile, 2004). However, this is not an argument against the private delivery of healthcare *per se*. These studies may provide evidence against resorting to the use of private healthcare systems as a tool of improving the public healthcare system (Tuohy, Flood, & Stabile, 2004).

4.3 Physician-Based BC Private Healthcare Firms

Examination of the private healthcare firms in BC is limited to firms that offer core healthcare services that are also available in the public system, for the sake of discussion. In other words, the examination will include those firms that have emerged through the deregulation of healthcare. Private healthcare firms that have always had delivered their services outside the public system, such as optometry, are not examined.

Private healthcare firms in BC fall into two general categories when using these constraints. The two categories are not necessarily mutually exclusive. The two general categories are private surgical and imaging centres and integrated preventative healthcare clinics.

4.3.1 Private Surgical & Imaging Centres

Private surgical and imaging centres offer a private alternative to surgical procedures and diagnostic imaging procedures in the public system. The business model of private surgical and imaging centres is to generate revenue through payments directly from the patient and from employer extended health plans (False Creek Healthcare Centre, 2010). Private surgical and imaging centres offer procedures that have a public system alternative and procedures that do not have a public system alternative. These firms offer value to those individuals who are willing to pay more to have a procedure completed in less time than in the public system. For example, the median wait list time for orthopaedic surgery is 25 weeks in the public system (Steinbrook, 2006). Conversely, a private surgical and imaging centre, such as the False Creek Healthcare Centre, quotes a wait time of one to six weeks from consultation to surgery (False Creek Healthcare Centre, 2010). Therefore, private surgical and imaging centers cater to those patients with the financial resources required to have a procedure done in less time than in the public system.

4.3.2 Integrated Preventative Healthcare Clinics

Integrated preventative healthcare clinics offer a private alternative to the general practitioner care of the public system. These clinics focus on preventative healthcare

strategies and the management of chronic disease conditions. Non-insured physician and health professional services combine with publically insured physician services to offer this alternative. The non-insured health professional services are healthcare-related services not provided by a physician. These services may include the access to health professionals such as physiotherapists and dieticians.

These firms generate revenue based through the billing of services directly to the client, a client's employer extended health plan and MSP. These firms bill the services covered by insurance to the client's extended health plan or MSP as appropriate. However, the client directly pays for services not covered by an insurance plan. These firms may also offer membership plans to their clients. The membership plan is an alternative to the client paying per procedure or service. Thus, membership plans are another way to cover the costs of services not covered by MSP or an employer extended health plan. The patient may receive unlimited care and support from a team of health professionals under such a membership program. A physician leads the team of health professionals. The team may also include dieticians, physiotherapists, psychologists and personal trainers (Copeman Healthcare Centre, 2010).

These firms, such as the Copeman Healthcare Clinic, typically offer health assessment services. "Comprehensive Health Assessments" or "Executive Health Services" are common terms for this type of service. The assessments may include more than 50 tests and physical examinations as a means of assessing the patient's health status and health risks (Copeman Healthcare Centre, 2010). The results of these tests intend to drive the development of an individual health plan for the client. The health assessment may include laboratory testing such as a complete blood count, biochemistry profile,

urinalysis, thyroid function test, prostate-specific antigen test. The assessments may also include cardiovascular, vision, hearing, fitness, and diet and nutrition evaluations (Medisys, 2010)

The results from a health assessment guide the development of a personal health plan. The physician uses the personal health plan to recommend follow-up services and procedures. The services are of additional cost to the client unless the client has a membership plan that covers such follow-up services and procedures. Therefore, this creates an incentive for the individual to purchase a membership package to the private healthcare firm. As mentioned, MSP covers physician services at integrated preventative healthcare clinics. However, access to such services requires a membership.

4.4 Private Healthcare Market in British Columbia

Health-related services, ranging from prevention to medical treatment, drive the demand for healthcare services from private firms in BC. These services may or may not have a public healthcare system alternative. Therefore, a model that captures this information illustrates the private healthcare market in BC. The model describes preventative and treatment services offered by private healthcare firms based on the availability of a public alternative. The preventative and medical treatment healthcare services offered by the private healthcare sector are not static with respect to having an alternative in the public healthcare system. This is because the list of procedures that are covered by the public healthcare system changes. For example, MSP may add an existing medical treatment procedure for coverage if deemed medically necessary. Conversely, MSP can also remove a procedure from coverage. A similar model can also

describe the motivations for those who utilize private healthcare services. Figures that illustrate this model are below.

Figure 1 - Model describing the services offered by private healthcare firms in BC.

Public Alternative	-Routine physical “check-ups” by a general practitioner	-MRI
No Public Alternative	-Comprehensive/Executive Health Assessments -Integrated physician services with non-physician healthcare professionals (e.g. dieticians, physiotherapists, personal trainers)	-Oral Care -Eye Care -Cosmetic Surgery
	Prevention	Medical Treatment

Figure 2 - Model describing the motivation for the types of services offered by private healthcare firms in BC.

Public Alternative	<i>-(no clear motivation)</i>	-avoid the longer waiting times of the public healthcare system
No Public Alternative	-access to services that are not covered by, or available through, the public healthcare system specific to disease prevention	-access to services that are not covered by, or available through, the public healthcare system specific to treatment of a diagnosed medical condition
	Prevention	Medical Treatment

4.4.1 Medical Treatment Services with a Public Alternative

The first market category is medical treatment services with a public alternative.

This category most commonly represents the delivery of healthcare through private firms.

Similarly, Medical treatment services with a public alternative commonly represent the recent activities regarding the deregulation of healthcare in Canada. Firms that serve this market provide medical treatment for a particular disease or condition that is also available to patients within the public healthcare system. The value to those in the market for this type of service is primarily the decreased amount of time spent waiting for the procedure to be performed after consultation. Private surgical centres in BC are able to perform surgeries much quicker than their counterparts in the public system. Some firms can quote a time estimate of one to three weeks from consultation to surgery (Cambie Surgery Centre, 2010). The patient pays for the procedures directly. Those in this market must be willing to pay a premium to have a procedure performed in less time after referral or consultation. Therefore, those in this market must have the financial resources required to pay for the services directly. An existing medical treatment service may also become unavailable in the public system. For example, MSP may remove a medical treatment service from coverage. In such a case, it will become a medical treatment service without a public alternative.

4.4.2 Medical Treatment Services without a Public Alternative

There is a market for healthcare services that not covered by the public system. For example, the public healthcare system generally does not cover eye care and dental services. Services not covered by the public healthcare system include those that have become de-insured and those deemed not to be medically necessary (Canadian Institute for Health Information, 2005). Therefore, these services are essentially unavailable in the public system except when in scenarios in which the procedure is medically necessary. For example, public healthcare plans generally do not cover cosmetic and plastic surgery.

However, the public healthcare system covers cosmetic and plastic surgery in medically necessary scenarios, such as procedures involving burns and reconstructive surgery performed in a hospital (Canadian Institute for Health Information, 2005). This private healthcare market category also includes new medical treatment innovations not yet covered by the public system. In other words, an innovation may not currently be available in the public healthcare system but it will be available at some point in the future. A medical treatment service without a public alternative can also become a medical treatment service with a public alternative. For example, a hospital may approve the use of an innovation through its approval process. This allows the coverage of the procedure through the hospital's "block funding" provided by the Ministry of Health.

4.4.3 Preventative Services with a Public Alternative

Preventative healthcare services that have a public alternative are inclusive of routine physical examinations by a general practitioner. The motivation for this market is somewhat unclear. In 1992 there was a "natural experiment" in which 81 general practitioners in BC "opted-out" out of the public system and began to bill their patients directly (Epp, Vining, Collins-Dodd, & Love, 2000). At this time, the opted-out physicians could also charge the patients extra for their services. "Extra-billing" is the common term for this practice. Direct and extra-billing resulted in average payment increase of 10% to general practitioners (Epp, Vining, Collins-Dodd, & Love, 2000). Female visits to opted-out physicians dropped by 9% during this period and male visits did not drop (Epp, Vining, Collins-Dodd, & Love, 2000). This suggests that there is some sort of market for general practitioner services outside of the public system. However, it is unclear whether the patients specifically sought out opted-out physicians

or if they chose to stay with their general practitioner after he or she opted-out. In addition, it is unclear if the patients specifically sought out the opted-out physicians for preventative services, such as routine physical examinations, or for treatment services.

The general practitioner services in private healthcare firm, such as the Copeman Healthcare Centre, do not offer clarity with respect to this market's motivation. This is because integrated preventative healthcare clinics offer MSP covered general practitioner services in conjunction with preventative healthcare services that do not have a public alternative. Furthermore, the firms also offer other medical treatment services. Therefore, there may not actually be an identifiable market for private preventative healthcare services. This could be the case even though preventative healthcare services with a public option technically do exist. These services may only be available due to the presence of the other three market categories of private healthcare in BC as described in this model.

4.4.4 Preventative Services without a Public Alternative

Some believe that the primary objective of the public healthcare system in BC is medical treatment and intervention, as opposed to prevention. Healthcare professionals in the public system do encourage preventative health measures. However, the majority of services covered by the public system are specific to treatment of a particular medical condition. Thus, some believe the public healthcare system does not well serve those more concerned with disease prevention. There are individuals who wish to make a more proactive role in managing their health. As such, these individuals want to take the necessary steps to prevent diseases and other health-related conditions from actually occurring. Individuals who wish to take a proactive role in disease prevention often turn

to services that exist outside of the healthcare system in order to meet this need. For example, individuals may utilize the services of the fitness industry, such as personal training, in order to maintain a healthy cardiovascular fitness level. Furthermore, others will turn to quasi-healthcare services such as naturopathic physicians. Naturopathy is an alternative medical system that focuses on natural remedies and the body's ability to heal and maintain itself (University of Maryland Medical Center, 2010). Many jurisdictions have licensed naturopathic physicians as primary care physicians (University of Maryland Medical Center, 2010). Furthermore, some extended employer health coverage programs cover services from naturopathic physicians. Therefore, integrated preventative healthcare firms, such as the Copeman Healthcare Centre, appear to be addressing a real market need. Specifically, integration of preventative healthcare services with medical treatment services meets a market need.

4.5 Private Healthcare Firm Alignment to the Market Categories

The firms that offer private healthcare service do not necessarily fit exclusively within one quadrant in **Error! Reference source not found.** Private surgical and imaging centres, such as the Cambie Surgery Centre and the False Creek Surgical Centre, offer both medical treatment services with a public alternative and medical treatment services without a public alternative. Integrated preventative healthcare clinics, such as the Copeman Healthcare Centre and Continuum Medical Care, offer healthcare services that can be included in all four quadrants of Figure 1. However, these firms have a stronger emphasis on preventative healthcare services. Figures 3 and 4 illustrate the alignment of examples of private healthcare firms in BC to the private healthcare market in this model.

Figure 3 - Alignment of services offered by private surgical and imaging centres to the private healthcare market.

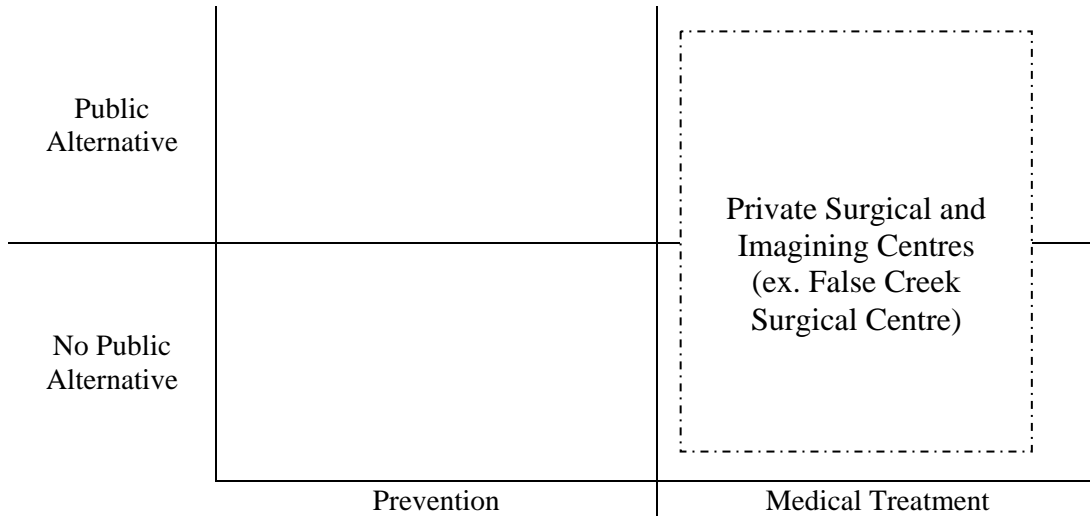
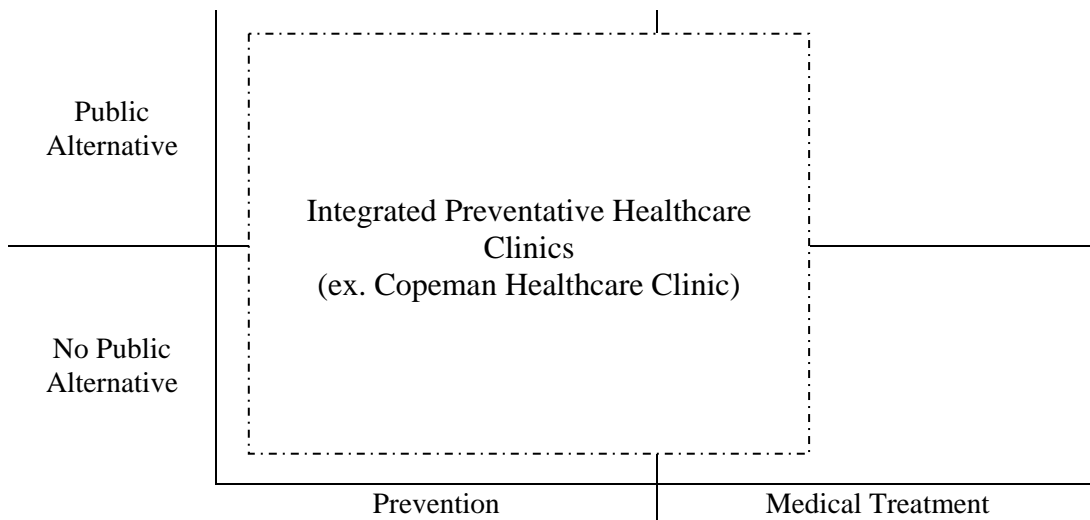


Figure 4 - Alignment of services offered by integrated preventative healthcare clinics to the private healthcare market.



4.6 Research Activities

Private healthcare firms in BC also participate in research activities. For example, the Copeman Healthcare Centre conducts research activities relevant to disease prevention and chronic disease management (Copeman, 2010). The research conducted by the Copeman Healthcare Centre allows the company to qualify for Scientific Research

& Experimental Development¹⁰ tax credits from the Federal Government of Canada. Hospitals in the United States frequently contact the Copeman Healthcare Centre in order to conduct research focused on prevention and chronic disease management (Copeman, 2010). The Copeman Healthcare Centre is an ideal site for certain research initiatives because it can follow study protocols that are difficult to implement in a hospital setting. Hospitals can be difficult settings to conduct certain study protocols due to resource constraints. Simply, the staff at the Copeman Healthcare Centre is able to spend more time with research study participants. Thus, they are able to follow protocols that require more time with the participants than public hospitals can afford (Copeman, 2010). This ability is a primary driver for research groups to select the Copeman Healthcare Centre as a study site.

4.7 Investment Model for Private Healthcare Firms

The investment model for private healthcare firms in BC is similar to that of other industries (Copeman, 2010). Specifically, ‘founder, family and friends’, angel and venture capital are all potential sources of investment funding. However, physician-owned private healthcare firms are able to utilize debt financing to a larger degree than others do. This is because banks are more willing to offer loans and lines of credit to physicians due to their high earning potential.

¹⁰ The SR&ED program is a federal tax incentive program, administered by the Canada Revenue Agency (CRA) that encourages Canadian businesses of all sizes, and in all sectors to conduct research and development (R&D) in Canada. It is the largest single source of federal government support for industrial R&D. The SR&ED program gives claimants cash refunds and/or tax credits for their expenditures on eligible R&D work done in Canada (Canada Revenue Agency, 2008).

4.8 An Opportunity for Personalized Medicine

This section served to provide an examination of private healthcare firms in BC. A description of the public healthcare system in Canada places the delivery of core health services through private firms into context. The analysis model presented in this section describes the key characteristics of these firms. Proponents of the deregulation of healthcare in Canada contend that private healthcare firms are simply trying to meet patient needs resulting from inefficiencies in the public healthcare system. The attributes of private healthcare firms in BC may position private healthcare firms to be early users of innovations relevant to personalized medicine. Therefore, private healthcare firms may be relevant to the investment activities of Genome BC.

5: PRIVATE HEALTHCARE RELEVANCE TO GENOME BC

As described in Section 3, Genome BC expects a return on its investments. The return on the investment may include access to rights and residuals arising from the commercialization of the research. However, earning a financially measurable return on investment is not the only goal. The investments by Genome BC into the research projects and programs intend to deliver socio-economic benefits to the province. This is part of the mandate of the funding received from the Province of British Columbia. Genome BC will not have totally achieved the mandate of the provincial funding if the innovations resulting from the investments are not available for use in BC. For example, the public healthcare system must actually adopt a new healthcare innovation in order for physicians and patients in BC to benefit. The innovation will produce no benefit to BC without integration into the delivery of healthcare. This situation presents a scenario in which residents of BC may be unable to access new healthcare innovations through the public system.

Genome BC is looking to develop strategies to facilitate the integration of innovation in the genome sciences into healthcare delivery in British Columbia. Genome BC's *Towards a Genomics & Health Strategy* describes these strategies. Genome BC has traditionally built partnerships with providers of healthcare from the public system, such as the health authorities and their research institutes, in order to accomplish this goal. However, focusing entirely on the delivery of healthcare in the public system may delay

the integration of innovations resulting from advances in personalized medicine and the genome sciences.

The cause of this delay, at least in part, is the rigidity of the public healthcare system itself. The rigidity can even discourage the integration of innovations into the delivery of healthcare (Genome British Columbia, 2009). Part of the rigidity of the public healthcare system is the review process required for a healthcare service to be included on the list of MSP coverage or for approval for use within a hospital. Patient access to a healthcare service within the public system is contingent upon such approval. A formal review process determines MSP coverage for a new procedure. Similarly, a formal review process determines use of a new procedure in a hospital. The hospital's budget will account for the cost of approved procedures.

The MSP approval process is exceptionally long and difficult to navigate as compared to other provincial healthcare coverage plans in Canada and private insurance plans in the United States, according to anecdotal information. In addition, the approval of new healthcare innovations relevant to personalized medicine may be difficult in BC's hospitals due to the barriers described in Section 2.6. This problem is especially relevant to innovations developed by BC-based researchers with investment from Genome BC. Therefore, patients and physicians in BC may not benefit from new healthcare innovations without supplemental strategies.

One strategy could be for Genome BC to develop partnerships with private healthcare firms in BC as a supplement to the partnerships with the representatives of the public healthcare system. Partnerships in this context broadly refer to collaboration on specific initiatives. For example, investment by Genome BC into a private healthcare

firm is a partnership in this context. Private healthcare firms in BC represent some of the potential users of innovative technologies and services resulting from advances in the field of genomics and personalized medicine. Therefore, private healthcare firms should be engaged in the activities of Genome BC. Engagement of these private healthcare firms may also determine the possibility of future investment opportunities for Genome BC.

Genome BC has developed partnerships with private sector companies. However, these private sector firms have been drug development and diagnostic companies. To date, Genome BC has yet to develop partnerships with private healthcare firms. Therefore, Genome BC does not have any experience working with these firms. Furthermore, it is unclear whether the private firms are aware of Genome BC, let alone any of its funding programs and strategic initiatives. The strategic positioning of private healthcare firms in BC to adopt new healthcare innovations relevant to personalized medicine requires assessment. This assessment could determine ways in Genome BC can invest in private healthcare firms in BC.

6: THE PRIVATE HEALTHCARE SECTOR & PERSONALIZED MEDICINE – STRATEGIC FIT

6.1 Introduction

This section will detail the strategic positioning of private healthcare firms in BC to be early users of new healthcare innovations relevant to personalized medicine. Private healthcare firms can offer services to their clients that do not have coverage in the public healthcare system. Furthermore, private healthcare firms are able to make firm-level assessments of a new healthcare innovation. A firm can perform the assessment in terms of medical utility and financial viability. Therefore, private healthcare firms are in a strategic position to be innovative in ways that the public healthcare system cannot. For example, the strategic positioning of private healthcare firms to offer personal genetic testing is strong. The MedCan Clinic illustrates the strong strategic positioning of private healthcare firms to offer personal genetic testing. However, private healthcare firms in BC may not have all of the resources required to replicate MedCan's success. In addition, there is concern among private healthcare firms with respect to offering such a service.

6.2 Early Users of New Healthcare Innovations

The strategic positioning of private healthcare firms in BC to be early users of genomics-based healthcare innovations relevant to personalized medicine is strong. Private healthcare firms in BC can offer services to its clients that do not have an alternative in the public healthcare system. The lack of availability in the public system may be due to a lack of MSP coverage or approval for hospital use. As mentioned, it can

be difficult to obtain the appropriate approvals for the public healthcare system.

Therefore, private healthcare firms in BC can utilize their strategic positioning to be early users of new healthcare innovations prior to the public healthcare system. However, physicians at private healthcare firms still practice medicine under the authority of the College of Physicians and Surgeons of British Columbia (CPSBC). The CPSBC is the licensing and regulatory body for all physicians and surgeons in BC (College of Physicians and Surgeons of British Columbia, 2010). Therefore, the use of new healthcare innovations by private healthcare firms must meet the standards of CPSBC.

The public healthcare system may not immediately adopt new commercialized healthcare innovations resulting from advances in personalized medicine and the genome sciences. This could be due to the barriers to integration described in Section 2.6. This will create a period in time in which the service is technically commercially available but it is not available to patients who utilize the public healthcare system in BC. For example, MSP insures medically required services provided by physicians and supplementary healthcare practitioners, laboratory services and diagnostic procedures (Ministry of Health Services, 2010). Therefore, it could be the stance of those in BC's Ministry of Health that a new healthcare innovation is not actually medically required. This could especially be the case for new healthcare innovations resulting from the genome sciences. The genome sciences are an integral part of biomedical research. However, for many clinicians and healthcare professionals the genome sciences have not become completely relevant to their delivery of healthcare (Guttmacher, Porteous, & McInerney, 2007). As a result, new healthcare innovations could face longer periods to receive coverage by BC's public healthcare system.

The potential for slow integration for new healthcare innovations into BC's public healthcare system creates an opportunity for private healthcare firms in BC. The delivery of healthcare in the public system is under the control of the BC Ministry of Health and BC's six Health Authorities¹¹. Private healthcare firms in BC are not under the governance and management of the Ministry of Health and the health authorities. Therefore, private healthcare firms are able to make firm-level decisions regarding the healthcare services that they provide. In other words, these firms can conduct their own individual assessment of the medical value of a particular healthcare innovation. Then the firm can determine whether offering a particular new healthcare innovation to its clients is appropriate from a medical and a financial perspective. This also allows private healthcare firms to be innovative in the services that they offer to their clients. This could be an advantage over the public healthcare system (Copeman, 2010).

The strategic positioning and opportunity for private healthcare firms also relates to their clients. Individuals that utilize the services of private healthcare firms in BC are generally relatively affluent. The ability to pay for healthcare services with after-tax income is evidence of their relative affluence. In other words, they have already contributed to the public healthcare system through tax payments and have still chosen to pay additional money for healthcare services through private providers. Therefore, those who pay for additional healthcare services may also consider paying directly for a new healthcare innovation offered by a private healthcare firm. However, payment for new

¹¹ The health authorities in British Columbia are Northern Health, Interior Health, Vancouver Island Health Authority, Vancouver Coastal Health, Fraser Health and the Provincial Health Services Authority. The five health authorities govern, plan and coordinate services regionally within 16 health service delivery areas and participate with the Provincial Health Services Authority (PHSA). The PHSA coordinates and/or provides provincial programs and specialized services, such as cardiac care and transplants (Ministry of Health Services, 2010).

services could also be included in annual membership fees by those firms that offer that type of payment plan, such as the Copeman Healthcare Centre.

6.3 Providers of Personal Genetic Testing Services

BC's public healthcare system is unlikely to offer personal genetic testing system in the near term. As described in section 2.5, the scientific and medical evidence for the accuracy and reliability of personal genetic testing is not yet established. Therefore, there is not enough evidence to support personal genetic testing services as being medically necessary. Therefore, personal genetic testing appears may be suitable for integrated preventative healthcare clinics that offer comprehensive health assessment services. Specifically, personal genetic testing services appear to be a strategic supplement to the comprehensive health assessment services that integrated preventative health clinics already offer. This is because comprehensive health assessments and personal genetic testing services both intend to provide individuals with information regarding their risk to certain diseases, as well as risk mitigation strategies.

Furthermore, physicians in the public system will not use the results of personal genetic testing to drive any follow-up procedures. Thus, it is unlikely that an individual would undergo personal genetic testing and then have a physician in the public healthcare system suggest a follow-up procedure based on the results. This is because personal genetic testing services are still relatively nascent and the integration of test results into the delivery of healthcare is unclear. Furthermore, it may be ethically questionable for a physician in BC to bill MSP, and ultimately the taxpayer, for a procedure based on a service unsupported by sufficient medical evidence. In brief, the public healthcare system is unlikely to cover personal genetic testing for determining disease risk. In addition,

physicians in the public healthcare system are unlikely to use the results of personal genetic testing to suggest follow-up procedures. This creates an opportunity for integrated preventative healthcare clinics to offer this service.

The potential value to the clients of integrated preventative healthcare firms that utilize personal genetic testing services is primarily in the form of motivation. Information regarding an individual's genetic risk to certain disease conditions may motivate individuals into making lifestyle changes that promote healthy living. Furthermore, information regarding disease risk may help drive follow-up procedures within the private clinic to screen for the disease. This may lead to early diagnosis and treatment. This information could supplement traditional risk factors for determining disease risk, such as family history. For example, if the results of a personal genetic test indicated that an individual was at significantly greater risk for developing prostate cancer, the physician could use this information to recommend traditional screening procedures. These clinics typically include a clientele that is relatively affluent, informed and proactive in regards to their health and well-being (Davies, 2010). Therefore, this clientele may be more willing to undergo screening procedures as a means of ensuring early detection. Thus, this clientele may also be comfortable with personal genetic testing as a preventative measure. Furthermore, physicians in the private clinics could be more amenable to recommending follow-up procedures as a preventative or early-detection measure if paid for by directly by the patient.

6.3.1 Case Example – The MedCan Clinic

Similar organizations that already offer personal genetic testing services illustrate the opportunity for private healthcare firms in BC to utilize innovations relevant to

personalized medicine and the genome sciences. There are private healthcare firms in Canada that have already integrated the use of personal genetic information into their service offerings. Most notably among these firms is the MedCan Clinic located in Toronto, Ontario. The MedCan Clinic offers a personal genome testing service. The service is available on its own or as part of MedCan's Comprehensive Health Assessment service. The service allows clients to gain access to the personal genetic testing service offered by Navigenics. As mentioned, Navigenics is one of the most well known direct-to-consumer genomics companies. The Navigenics service provides individuals with information regarding their genetic predisposition to a variety of health conditions such as breast cancer, hemochromatosis and osteoarthritis (MedCan Clinic, 2010). The service also includes an in-person consultation with a genetic counsellor¹² before and after the testing. These consultation sessions describe the potential practical implications of test results (Davies, 2010). The resulting information from the test can be used in order to recommend lifestyle changes in terms of diet and exercise (MedCan Clinic, 2010) and guidance for further follow-up tests and procedures under physician care (Davies, 2010). The physicians consult with the genetic counsellor in order to determine the need and utility of any follow-up procedures based on the results of the Navigenics personal genome test (Davies, 2010).

The MedCan Clinic has been offering genetic counselling services since 2005. However, the genetic counselling primarily focused on genetic risk with respect to family history. The MedCan Clinic added the personal genetic testing service in 2009. The

¹²Genetic counsellors are health professionals that provide information and support to families at risk for or affected by a genetic condition. Genetic counsellors translate complex genetic information into everyday language to help people make informed decisions about the issue at hand. They strive to discuss information and present options in a non-biased way to encourage patients to make decisions fitting with their own personal values and beliefs. (Genome British Columbia, 2010)

addition was due to client interest in knowing what their genetic information could mean with respect to their health (Davies, 2010). The service has been extremely popular among MedCan's clients. The service has been so popular that there has been approximately twice as much interest in the service than originally anticipated by MedCan (Davies, 2010). The service has been profitable enough for the firm to consider adding expanding the service by adding more genetic counsellors (Davies, 2010). Navigenics offers their personal genetic testing service directly to consumers at a cost of \$999 USD. MedCan offers patients access to the same service for \$1,495 CDN. The price increase by MedCan is to cover the costs of providing genetic counselling to those who use the service, and for profit (Davies, 2010).

The effects of Navigenics' personal genetic testing service on the behaviour of the MedCan's Clinics clients are unclear. The MedCan Clinic has not offered the service for long enough to be able to make any sort of conclusions as to how the service has influenced client behaviour with respect to their health. However, MedCan has attempted to acquire some preliminary feedback from those who have used the service. The MedCan acquired the feedback through client surveys. Those clients that chose to respond to the survey report that the results of the genetic testing service did motivate them into making positive lifestyle changes (Davies, 2010).

The popularity of this service at the MedCan Clinic is counter to what is has been reported in other media outlets with respect to consumer uptake of genetic testing. Personal genetic testing companies such as 23andMe and Navigenics have not attracted many customers, according to an article in the New York Times in March of 2010 (Pollack, 2010). The article suggested that consumers have not yet embraced the

‘genomics age’ (Pollack, 2010). The success the MedCan Clinic has experienced offering the Navigenics service is perhaps suggestive that ‘direct-to-consumer’ may not be the most appropriate channel in which to market the service. The success of the MedCan Clinic may suggest that consumers are more willing to pay for such services when delivered in a more formal healthcare setting. In other words, consumers are more likely to adopt the service when the results of are presented in consultation with some sort of knowledgeable professional, such as a genetic counsellor (Davies, 2010).

6.3.2 Resources Required for Personal Genetic Testing by Private Healthcare Firms in BC

Private healthcare firms in BC face resource related issues that could be barriers to being able to offer personal genetic testing services. The first is issue is to determine how to offer the service. One option would be to invest in the infrastructure required in order to carry out the genetic testing, such as the appropriate instrumentation. Another option would be to send off the samples to a commercial provider of personal genetic testing services, such as the MedCan Clinic does with Navigenics. For example, the cost of Illumina’s HiSeq 2000 DNA sequencing platform is \$690,000 per instrument (Tirrell & Lauerman, 2010). This is likely still cost prohibitive for a firm to purchase a sequencing instrument that does not specialize in the capability, such as Canada’s Michael Smith Genome Sciences Centre¹³. Therefore, an arrangement similar to the MedCan Clinic and Navigenics is more likely. As mentioned, the price of whole-genome sequencing is decreasing dramatically. Thus, the cost of sequencing instruments may no longer be cost prohibitive for private healthcare firms in BC within the relatively near

¹³ The Genome Sciences Centre is one of fifteen research programs that operate as part of the BC Cancer Research Centre. It has a primary mandate to develop and deploy genomics technologies in support of the life sciences research, and in particular cancer research. (BC Cancer Agency, 2010)

future. This ignores the technical ability required to operate such an instrument. It may be necessary for these firms to employ individuals adequately trained in operating sequencing instruments, such as a technician.

Secondly, private healthcare firms in BC are also currently unable to offer personal genetic testing services in the same manner as the MedCan Clinic. This is because these firms do not currently employ an individual adequately trained to communicate the results. At the MedCan Clinic, a trained genetic counsellor performs this function. However, the MedCan Clinic enjoys the benefit of employing the only trained genetic counsellor outside of the public healthcare system in Canada (Davies, 2010). Furthermore, the genetic counsellors in the public system in Canada primarily focus on genetic risk with respect to family history. They are not typically knowledgeable in interpreting data resulting from genomic scanning and sequencing (Davies, 2010). Therefore, it may difficult to acquire the appropriate personnel qualified to communicate the results of genomic analysis techniques. This will be the case until genetic counselling training programs begin to include formal instruction on interpreting and communicating this type of information.

A private healthcare firm could also outsource the genetic counselling function to a third party. One such third party is the Foundation for Informed Medical Decision Making (FIMDM). The FIMDM is a non-profit organization that works to ensure that healthcare decisions include the active participation of patients (Foundation for Informed Medical Decision Making, 2009). The FIMDM includes a network of genetic counsellors (Foundation for Informed Medical Decision Making, 2009). The FIMDM has experience working in the personal genetic testing field, such as the recent partnership agreement

with 23andMe and AccessDNA (GenomeWeb, 2010). Thus, a private healthcare firm, such as the Copeman Healthcare Centre, could also enter into a partnership with an organization like the FIMDM. The partnership would serve to provide the Copeman Healthcare Centre's clients with providing genetic counselling. Furthermore, some providers of personal genetic testing services also employ their own genetic counsellors, such as Navigenics (Navigenics, 2010). Thus, Navigenics could also provide the necessary genetic counselling. However, outsourcing the genetic counselling service to a third party may not fit well within the brand of an integrated preventative healthcare firm. For example, the value of a firm like the Copeman Healthcare Centre is integrated and multidisciplinary healthcare management all in one setting. Therefore, having a trained genetic counsellor within the firm, such as the MedCan Clinic does, would be more suitable to its brand and image.

6.3.3 Perception of Personal Genetic Testing by BC Private Healthcare Firms

As mentioned, offering personal genetic testing services has been financially successful for the MedCan Clinic. Personal genetic testing services do seem to be a good strategic fit for integrated preventative healthcare clinics. This is because personal genetic testing aims to provide individuals with information regarding their risks to certain diseases and conditions. The comprehensive health assessments offered by these firms also assess disease risk. However, some representatives of BC's private healthcare system are not convinced that personal genetic testing can predict disease risk as well as the current methods that they employ (Copeman, 2010). Therefore, they do not feel that personal genetic testing offers any additional benefit to their clients. Private healthcare

firms may be amenable to the service once there is sufficient evidence that personal genetic testing services can accurately predict disease risk (Copeman, 2010).

The scepticism towards personal genetic testing also relates to brand and image concerns (Copeman, 2010). In other words, offering personal genetic testing services at this stage may have a negative impact upon the brand of the firm. The negative impact would be due to the lack of scientific evidence supporting the validity of personal genetic testing. The concern of the potential negative impact may also relate to the criticisms of the delivery of private healthcare in Canada by public healthcare advocacy groups, such as the Canadian Health Coalition¹⁴. These advocacy groups criticize private healthcare for seeking profit at the expense of patient care. Therefore, offering a service that is of questionable medical utility may exacerbate the negative perception that private healthcare firms already experience.

The desire by private healthcare firms to only offer services supported by sufficient medical evidence generally only concerns physician services. These firms are comfortable offering services with anecdotal evidence of benefit for non-physician health services, such as massage therapy (Copeman, 2010). However, this position may be contrary to actual practice. According to many physicians, some of the tests included in comprehensive health assessments are also of dubious medical utility. For example, the use of full-body cardiovascular and tumour MRI to screen for disease in patients who do not display any suspicious symptoms is of questionable utility. Full-body MRIs can often

¹⁴ The Canadian Health Coalition is a not-for-profit, non-partisan organization dedicated to protecting and expanding Canada's public health system for the benefit of all Canadians. The CHC was founded in 1979 at the Canadian Labour Congress-sponsored S.O.S. Medicare conference attended by Tommy Douglas, Justice Emmett Hall and Monique Begin. The coalition includes organizations representing seniors, women, churches, nurses, health care workers and anti-poverty activists from across Canada (Canadian Health Coalition, 2010).

detect abnormalities in patients that are of no consequence to any individual's health (Health Canada, 2006). There exists the possibility that the detection of abnormalities could lead to unnecessary follow-up procedures. Full-body MRIs to screen for disease is very similar to personal genetic testing to determine disease risk, in this regard.

6.4 Possible Investment Opportunities for Genome BC

In brief, there appears to be a genuine desire among private healthcare firms in BC to be innovative. Private healthcare firms do not operate under the same constraints as healthcare professionals within the public healthcare system. This enables private healthcare firms to be more innovative in the services that they deliver. This could be a key advantage over the public healthcare system. However, there is concern in regards to offering services not well supported by medical and scientific evidence, such as personal genetic testing. These concerns relate to the impact that offering such services could have on the brand of the private healthcare firm. The controversy surrounding the delivery of core healthcare services by private healthcare firms exacerbates these concerns. The analysis within this section, and information from previous sections, can develop ways in which Genome BC can invest in private healthcare firms in BC. The following section will analyze these potential opportunities and methods of investment.

7: POTENTIAL INVESTMENT MECHANISMS FOR GENOME BC INTO PRIVATE HEALTHCARE FIRMS

7.1 Introduction

This section will examine the possible ways in which Genome BC can invest in private healthcare firms in BC through its funding programs and initiatives. Private healthcare firms could be the early users of new healthcare innovations developed through Genome BC funding programs. This involvement would include a strategy of knowledge transfer to the private healthcare firm by the research team that is developing the innovation. The use of an innovation within a private healthcare firm may also help facilitate adoption of the innovation within the public system by providing the clinical evidence necessary for approval.

Private healthcare firm could actively be involved in a project funded by Genome BC. The eligibility criteria do vary by program. However, in most cases a researcher at a private healthcare firm would need to collaborate with researchers affiliated with a BC based academic research institution. Genome BC recently announced a program in which a research a private healthcare firm would be able to apply without this form of collaboration. The intent of the program is to accelerate the commercialization of an innovation based in genomics. This intent may not be within the strategic scope of any private healthcare firms performing research that are operating in BC. There could also be a number of challenges associated with involving private healthcare firms in Genome BC funded research programs. Many of the perceived challenges involved could be

political in nature, due to the controversy surround the deregulation of healthcare in Canada.

Thus, possible future alternative funding mechanisms, perhaps in the form of post-commercialization investments, could provide a suitable investment opportunity between a private healthcare firm and Genome BC. Although Genome BC awards research investments, as opposed to traditional research grants, post-commercialization investing would be a new endeavour for Genome BC. The lack of experience in this regard could limit success in this area. Furthermore, private healthcare firms are able to source investment from traditional sources. Therefore, the need for private healthcare firms to source investment from Genome BC is unclear.

7.2 Users of New Healthcare Innovations Developed Through Genome BC Funding Programs

As described, private healthcare firms can provide healthcare services that have a public alternative and services that do not have a public alternative. This allows private healthcare firms to be more innovative in the services that they offer their clients. The ability to be innovative could be a clear benefit over the public system. As described in Section 6, the positioning of private healthcare firms to be early users of new healthcare innovations resulting from advances in personalized medicine and the genome sciences is strong. Therefore, private healthcare firms could be suitable as early users for healthcare innovations developed through Genome BC funding programs.

As described in Section 3.4, Genome BC manages funding programs focused on the translation of innovations into the delivery of healthcare. Proposals to these funding programs require strategies for knowledge transfer to the ultimate user of the innovation.

Support from the user of the innovation strengthens the proposal. For example, a research team could submit a proposal for an innovation relevant to disease prevention or chronic disease management to a Genome BC funding program. The Copeman Healthcare Centre may be a suitable user for such a proposal. Similarly, a private surgical and imaging centre, such as the Cambie Surgery Centre, may be an appropriate early user if the healthcare innovation was relevant to one of their procedures.

7.2.1 Considerations

Innovations developed through projects funded through Genome BC funding programs are not only for use in BC. Genome BC will potentially earn a greater return on its investment if as many national and international users adopt the innovation as possible. However, the funding provided to Genome BC by the provincial government intends to deliver socio-economic benefits to the province. The human health projects funded by Genome BC intend to deliver the benefit of improved healthcare within the province. Essentially all of the citizens of BC utilize the public healthcare system. Conversely, only a minority of citizens utilize the services of private healthcare firms in BC. Therefore, more will realize the benefit of new healthcare innovations funded by Genome BC if the innovation is available in the public healthcare system.

In 2006, private healthcare only accounted for about 1% of core healthcare services (Steinbrook, 2006). The clientele of private healthcare firms in BC are generally relatively affluent. They are able to pay for additional healthcare services outside of the public healthcare system. Fewer people will benefit from a new healthcare innovation if it is only available through a private healthcare firm. Therefore, the proposed research project to a Genome BC funding program would have to clearly articulate why a private

healthcare firm is a more suitable early user for the proposed healthcare innovation than the public healthcare system. For example, the proposal could assert that BC's public healthcare system is unlikely to adopt the proposed healthcare innovation in the short term. Furthermore, the use and success of a new healthcare innovation by a private healthcare firm may provide the sufficient clinical evidence needed in order to justify adoption by the public healthcare system. Therefore, initially targeting a private healthcare firm as the early user of a new healthcare innovation could be a strategy for catalyzing the adoption of the same innovation by the public healthcare system. In other words, innovation in the delivery of healthcare by private firms may stimulate innovation in the public healthcare system (Globerman & Vining, 1998).

7.3 Member of the Research Team of a Genome BC Funded Project

As briefly mentioned in Section 4.6, there are private healthcare firms in BC that are involved with research activities, such as research studies involving disease prevention and chronic disease management at the Copeman Healthcare Centre (Copeman, 2010). These research activities appear to be occurring outside of the life sciences community in BC. This is because the private healthcare firms in BC are not active within the network of organizations of BC's life sciences community. In other words, private healthcare firms are not actively engaged in BC's life sciences community of which Genome BC is an active participant. Therefore, it seems unlikely that these private healthcare firms have ever considered that Genome BC could be a source of funding for their research activities. Similarly, there might be the possibility that there are private healthcare firms that are engaging in research activities that would be of interest to Genome BC and would consider funding under the appropriate circumstances.

However, currently Genome BC only funds research projects within the context of specific funding programs. The type of funding program at Genome BC determines the eligibility of interested applicants. Most of Genome BC funding programs target researchers at one of BC's universities or affiliated hospitals, colleges, the BC Institute of Technology, or other BC-based research institutions, including government laboratories. However, a researcher at a private healthcare firm may be able to apply as long as there is collaboration with a researcher affiliated with a BC based academic research institution. Therefore, a researcher at a private healthcare firm may be suitable as a co-applicant or a collaborator on a Genome BC funded project. In Genome BC's terminology, a co-applicant is a researcher who makes a substantial intellectual contribution to the proposed research. A collaborator is an individual whose role in the proposed research is to provide a specific service but who is not involved in the overall intellectual direction of the research project. The special service could include access to equipment, provision of specific reagents, training in a specialized technique, statistical analysis and access to populations or samples. For example, a private healthcare firm could function as a type of service provider for a project. The arrangement would be similar to how the Copeman Healthcare Centre conducts research activities for for-profit hospitals in the United States (Copeman, 2010).

Genome BC recently announced a funding opportunity that specifically targets industry, as opposed to academia and other BC-based research institutions. Therefore, a private healthcare firm may be eligible to apply directly to the program, the Strategic Opportunities Fund for Industry (SOFi). The SOFi program is open to SMEs operating in

BC¹⁵ (Genome British Columbia, 2010). This program may be a suitable source of funding for a private healthcare firm. However, this is providing that the firm has proposed a research project relevant to the programmatic goals of SOFi. The program will help accelerate the commercialization process of new genomics-based scientific and technological innovations (Genome British Columbia, 2010). Presently, it does not seem likely that there are any private healthcare firms in BC that are currently in the process of commercializing any new genomics-based healthcare innovations. In other words, the commercialization of a genomics-based innovation may not be of any strategic interest to any private healthcare firms in BC now. However, a private healthcare firm may develop a more defined research and development function in the future. Such a research and development function may start to produce innovations with the goal of commercialization. Then a Genome BC program such as SOFi would be a suitable source for funding if such a scenario was to occur. This scenario may not be totally outside the realm of possibility. As described, the Copeman Healthcare Centre does perform some research activities, although the activities are not directly relevant to genomics. Furthermore, the firm is expanding its current operations in Vancouver, Calgary and Edmonton to nine more cities across Canada (Copeman Healthcare Centre, 2010). Therefore, the expansion in operations may lead to more research activities. In the meanwhile, for Genome BC to invest in private healthcare firms there may be a need to explore alternative funding mechanisms and programs.

¹⁵ Industry Canada refers to SMEs as businesses with less than 500 employees (Genome British Columbia, 2010).

7.3.1 Considerations

There are challenges for Genome BC to invest in private healthcare firms as early users for new healthcare innovations developed through Genome BC funded projects. There are also challenges to investment into a research project in which a researcher at a private healthcare firm is involved. These challenges primarily relate to the sources of Genome BC's funding, such as the Province of British Columbia. The funding of an organization that invests or collaborates with private healthcare firms in BC could be controversial among voters. This primarily relates to the controversy surrounding the deregulation of the delivery of healthcare in Canada, as described in Section 4.2.2. The public announcement of this information may lead to negative response among voters. A negative response could lead to a change in government at the following provincial election. Furthermore, a new government after the next provincial election may have a strong position against the deregulation of healthcare in the province. Therefore, a future ruling party of BC may be less amenable to providing funding to Genome BC than in the past. However, there are ways to mitigate the risk of decreased provincial funding support. Genome BC could ensure that any investments into private healthcare firm are from funding sources other than the provincial funding. For example, Genome BC could use funds from the interest gained on short-term investments or the return on investment from innovations that have commercialized through Genome BC funded projects.

7.4 Post-Commercialization Investment from Genome BC

In Section 3.2, Genome BC's business model is a blend of a venture capital firm and a granting council. The process of determination of what projects receive funding from Genome BC is more similar to a granting council. Genome BC is exploring

investment models that are less similar to a granting council and perhaps more similar to venture capital, such as the SOFi program. Investment into post-commercialization opportunities may be a means of diversifying Genome BC's investment portfolio. The return generated on such investments could also be used to help decrease Genome BC's reliance on its current funders, such as the Province of British Columbia and Genome Canada. Genome Canada's failure to receive an expected \$120 million in the 2009 federal budget highlighted the need for Genome BC to develop additional sources of funding (Jay & Zafar, 2009). Genome BC's 2010 to 2015 strategic plan briefly mentions to the possibility of post-commercialization investment activities. However, if Genome BC were to invest in post-commercialization initiatives it would be through a for-profit arm within the organization.

There are numerous examples of non-profit organizations that have added a for-profit function. A for-profit arm helps an organization generate revenue beyond its funding sources. There are examples of this even within BC's life sciences community. For example, the Centre of Drug Research and Development (CDRD), a non-profit organization that provides drug development expertise and facilities to enable researchers throughout BC to develop promising drug candidates (Centre for Drug Research and Development, 2009), added a commercial arm to the organization. Drug Development Inc (DDI) is the name of the commercial arm of the organization. The role of DDI is to act as an interface between the CDRD and industry and to in-license intellectual property generated by selected CDRD projects directly from affiliated institutions' technology transfer offices or inventors (Centre for Drug Research and Development, 2009).

7.4.1 Considerations

Post-commercialization investment would be a new investment model for Genome BC. Therefore, Genome BC, as an organization, does not possess the same level of expertise in this investment model as compared to its experience in funding large-scale genomics-based research projects. There would be numerous challenges for Genome BC in establishing a fund for post-commercialization investing. For example, the scope of investment opportunities that would be eligible for funding would have to be established. Furthermore, Genome BC would also have to determine the potential terms of the investment that would allow for an appropriate return. For example, Genome BC could request shares in the private healthcare firm or conditional repayment of three times the investment value, as per the SOFi program.

The scope of the post-commercialization investment fund would need to be determined. Presumably, the investments would have to relate somehow to the genome sciences. Therefore, a private healthcare firm would need to be providing some sort of service that is relevant to genomics in order to receive funding from Genome BC. Otherwise, the private healthcare firm would need to acquire funding from traditional funding sources, such as through venture capital firms or commercial banks. In other words, the investment in a private healthcare firm would have to be of strategic interest to Genome BC. For example, a private healthcare firm could source investment from Genome BC in order to expand its capabilities in new healthcare innovations that are relevant to personalized medicine and genomics.

The terms of the fund would also need to be suitable for the private healthcare firm. In other words, the terms of the fund would need to be competitive against the other

investment options available to the firm. As previously described in Section 4.7, private healthcare firms generally acquire investment from standard sources, such as ‘founder, family and friends’, angel investors and venture capital firms. However, physician-owned private healthcare firms are able to acquire commercial bank loans and lines of credit more readily than other professionals are. This is because commercial banks are comfortable extending loans and lines of credit to physicians due to their high earning potential. Therefore, the terms of an investment from Genome BC will need to be competitive against the traditional investment sources. For example, Genome BC will need to be willing to invest a larger amount of money than could be sourced from a bank. Alternatively, the investment from Genome BC could be of better value to the private healthcare firm than other investment sources.

Genome BC will need to go through the valuation process of these firms. This is especially true if an investment model similar to venture capital is used. Traditionally, private healthcare firms are valued based on income, market and asset approaches (Carden, Chamberlain, & Hill, 2010). The income approach, such as discounted cash flow (DCF), and market approaches, such as comparing to relative-value to similar firms, are most common for smaller healthcare firms (Carden, Chamberlain, & Hill, 2010). Government regulation can greatly influence the value of a private healthcare firm (Carden, Chamberlain, & Hill, 2010). This is especially important in Canada where the public system delivers the majority of healthcare and individual provinces have laws that curtail or prohibit the role of private healthcare firms (Steinbrook, 2006). Furthermore, the successful integration of new healthcare innovations into clinical practice could be disruptive to the current healthcare systems (Carlson, 2009). The disruption to healthcare

delivery systems could greatly affect how healthcare firms are valued (Carden, Chamberlain, & Hill, 2010). In addition, the focus on the types of healthcare services provided by different private firms may require different valuation methods. For example, the valuation methods for an integrated preventative healthcare clinic may need to be different from a private surgical and imaging centre.

7.5 Facilitation of Investment Opportunities

Genome BC does not prescribe the research activities to the applicant groups that apply to its funding programs. Therefore, Genome BC will not force applicant groups to utilize the services of a private healthcare firm that may be of strategic value to the applicant group, the private healthcare firm and Genome BC. Likewise, Genome BC is not in a position to direct or influence the research activities at a private healthcare firm. In other words, Genome BC cannot deliberately target a particular private healthcare firm in BC to act as a tool to facilitate its own strategic goals and objectives. This would present a conflict of interest when reviewing a proposal to one of Genome BC's funding programs. However, the analysis of the potential opportunities between Genome BC and private healthcare firms in BC can still inform the development of strategic alternatives. These strategic alternatives can help facilitate and develop potential opportunities that could be of value to both a private healthcare firm and Genome BC.

8: STRATEGY TO FACILITATE INVESTMENT OPPORTUNITIES FOR GENOME BC

The goal of this analysis is to assess the suitability of investment opportunities into private healthcare firms in BC by Genome BC. This section will present an overall strategy to help facilitate the development of these investment opportunities. The strategic positioning of private healthcare firms to adopt new healthcare innovations relevant to personalized medicine and ways in which Genome BC could invest in these firms informs the development of this strategy. There are three primary components to the strategy. The three components are as follows:

- *Component 1:* Invite key representatives of private healthcare firms in BC to attend workshops organized by Genome BC focused on discussions of genomics and human health.
- *Component 2:* Update the *Towards a Genomics & Health Strategy* document and include a representative from a private healthcare firm in BC on the task force that develops the document.
- *Component 3:* Develop a funding program that private sector organizations could utilize to source investment to facilitate the adoptions of genomics-based healthcare innovations.

8.1 Strategy Components

Component 1: Invite key representatives of private healthcare firms in BC to attend workshops organized by Genome BC focused on discussions of genomics and human health (Workshop). The first strategy component for Genome BC to consider is to invite representatives from private healthcare firms in BC to workshops organized by Genome BC. These workshops help develop future initiatives. Specifically, representatives from private healthcare firms could to participate in workshops relevant to human health and genomics. This would help familiarize these firms with the initiatives of Genome BC, such as the healthcare innovations developed through Genome BC funding programs. Workshop participation by private healthcare representatives would also have the added benefit of networking opportunities between the private healthcare firms and the human health researchers at the major research institutions. The private healthcare firms and human health researchers may be able to identify synergies in their activities that could lead to mutually beneficial outcomes.

This invitation for private healthcare firms to participate in discussions relevant to human health and genomics should occur at a time when the innovations are sufficiently close to clinical application. Ideally, there should be tangible examples of new healthcare innovations that may be relevant to the strategic objectives of specific private healthcare firms. Private healthcare firms may become disinterested in Genome BC's initiatives if they are engaged too early in the development of genomics-based healthcare innovations. There is risk that representatives of private healthcare firms will see the genomics-based innovations as not advanced enough to be of utility to their firms.

As a sub-strategy component, one of these workshops could include discussion on personal genetic testing. Personal genetic testing does not appear to be of strategic interest to private healthcare firms in BC now. However, Genome BC should consider the MedCan Clinic's experience of offering the service and the recent FDA letters to companies that offer personal genetic testing services. It would be prudent to involve representatives of private healthcare firms in these discussions.

Component 2: Update the *Towards a Genomics & Health Strategy* document and include a representative from a private healthcare firm in BC on the task force that develops the document (Task Force). A task force consisting of a variety of members of the life sciences community in BC, including representation from Genome BC, developed the document *Towards a Genomics & Health Strategy*. The document included the integration of feedback from participants at a workshop on May 21st, 2008 (Genome British Columbia, 2009). One of the outcomes of the document is Genome BC's Personalized Medicine Program. Therefore, after the launch of the projects awarded funding through the Personalized Medicine Program Genome BC should consider updating the strategy document. The expected launch date for these projects is July 1, 2011 (Genome British Columbia, 2010). The updated document can take into account the further advances in genomics-based healthcare innovations and persistent challenges to the delivery of healthcare since the development of the original *Towards a Genomics & Health Strategy* document. The task force mandated with the development of the updated strategy document can include representation from a private healthcare firm in BC. This would provide an alternative perspective on the healthcare issues detailed within the document.

There could be reservations among the current members of the original task force with respect to having representation of private healthcare firms in BC. The original task force consisted of a variety of representatives of organizations affiliated with the public healthcare system, such as the BC Cancer Agency, Child & Family Research Institute and the Vancouver Coastal Health Research Institute (Genome British Columbia, 2009). The task force did include representation from the private sector, but not from any private healthcare firms. Therefore, some members of the task force may not feel comfortable with representatives of private healthcare firms on the task force. This position may be due to the many contentious issues surrounding the deregulation of core healthcare services in BC. In other words, the political issues surrounding private healthcare in BC will be a barrier to the inclusion of private healthcare firms in the development of a revised strategy document. Genome BC should be careful communicating the inclusion of a representative of a private healthcare firm in BC among the other members of the task force.

Component 3: Develop a funding program that private sector organizations could utilize to source investment to facilitate the adoptions of genomics-based healthcare innovations (Investment Fund). The third strategy component relates to a post-commercialization investment fund operated out of a for-profit arm of Genome BC. The strategic goal of the program would be to facilitate the adoption of new genomics-based healthcare innovations that are relevant to the concept of personalized medicine. For example, the investment dollars from Genome BC could purchase new genomics-based healthcare tools that for use within a private healthcare firm. A private healthcare firm would not be the only type of firm eligible for investment through this fund. The

fund would be open any SME in need of investment funding for post-commercialization activities relevant to the adoption of genomic-based tools. The fund could be of benefit to private healthcare firms as new healthcare innovations based in genomics continue to move towards clinical application. Genome BC should also hold information sessions with potentially interested and eligible firms before and after the launch of the program.

As described in Section 7.4.1, the primary challenge to this strategy component is developing a type of funding program in which Genome BC has less experience managing. There will need to be much discussion among Genome BC's management and Board of Directors concerning the scope and terms of investments through such a fund. Furthermore, Genome BC will need to determine the appropriate methods of valuation of a healthcare firm if using a model similar to venture capital. The valuation could be complicated given the potential changes to government regulation and disruption to systems of healthcare delivery resulting from the integration of new healthcare innovations.

8.2 Strategy Barriers

Variations of the three strategy components are all likely to occur in the future, regardless of this analysis. For example, Genome BC will still likely organize workshops relevant to topics in genomics and human health regardless of inclusion of representatives of private healthcare firms. In other words, the initiatives described in this strategy to facilitate investment opportunities into private healthcare firms are not actually specific to private healthcare firms. The strategy suggests engaging and including private healthcare firms in these initiatives. Therefore, implementation of the three strategy components does not present additional financial costs to Genome BC as compared to

implementing the strategy components without the inclusion of private healthcare firms. The barriers to implementation of this strategy are primarily political because of the controversial nature of private healthcare in Canada. However, opposition to engaging or investing in private healthcare firms will likely affect all components of this strategy.

Another primary barrier to strategy implementation is complete disinterest by private healthcare firms. As described in Section 8.1, ensuring that there are tangible examples of clinically relevant genomics-based healthcare innovations will help prevent disinterest among the firms.

8.3 Strategy Implementation

The order of the implementation of the components of the strategy to facilitate investment opportunities into private healthcare firms is important. There is a logical order to the implementation of the three components of the strategy. However, Genome BC may choose not to implement all three components of the strategy. Therefore, it is important to consider the preferred combination of two strategy components and implementation order of those components. Furthermore, Genome BC may only choose one component of the strategy to implement.

8.3.1 Full Strategy

The Workshop strategy component should be the first component implemented. The Task Force and Investment Fund strategy components should be the second and third components implemented, respectively. This is because the Task Force strategy component is somewhat contingent upon the Workshop. In other words, the need for the Task Force is a potential outcome of the Workshop. Therefore, membership on a task

force mandated to develop a future strategy document related to genomics and health in BC should be contingent upon active participation in the preceding workshop. This is because the workshop provides the basis for the content of the document. Participation in the workshop will also inform Genome BC of the potential benefit of having a representative of a private healthcare firm on the task force. In other words, the outcome of the Workshop strategy component may indicate that it would not be beneficial to Genome BC to pursue the Task Force strategic alternative.

The Investment Fund strategy component is somewhat ancillary to the Workshop and Task Force components. The development of a post-commercialization fund to facilitate the adoption of new genomics-based healthcare innovations relevant to personalized medicine does not require participation from private healthcare firms in workshops or in the development of strategy documents. However, such participation from private healthcare firms in BC may help inform Genome BC of the investment needs of private healthcare firms. A better understanding of the needs of private healthcare firms in BC could help form the development of a post-commercialization funding program. Therefore, the Workshop and Task Force strategy components could potentially help strengthen the Investment Fund component.

Figure 5 illustrates the preferred order of implementation of the three strategy components.

8.3.2 Two-Component Strategy

Genome BC should implement the Workshop and the Investment Fund strategy components, if only two are possible. Exclusion of the Investment Fund component only

allows Genome BC to invest in private healthcare firms through its current types of programs. As described, the goals of these programs may not fit the goals of the private healthcare firms. The Workshop component is more desirable than the Task Force alternative when it is necessary to choose between the two. This is because membership on a task force may require involvement in the preceding workshop. In other words, the Task Force component may only be useful when following the Workshop strategy component. Genome BC can still learn about the perspectives of private healthcare firms through their participation in any human health workshops. In terms of the Investment Fund component, individual meetings and information sessions with the private healthcare firms will be able to inform Genome BC of their investment needs.

The second best combination of two strategy components is the Workshop and the Task Force. This is because the outcomes of the Workshop and the Task Force components may provide information that indicates the Investment Fund component may not be suitable for the needs of private healthcare firms. By default, the Task Force and Investment Fund combination ranks third. As mentioned, it may not make sense to have the Task Force component without the Workshop component first.

Figure 5 illustrates the preferred ranking and order of implementation of combinations of two strategic components.

8.3.3 One-Component Strategy

The Investment Fund component ranks first if Genome BC can only select one strategy component to implement. Genome BC can still learn about the investment needs of private healthcare firms through information sessions and individual meetings prior to

implementing the Investment Fund component. The Workshop as a single strategy component ranks second. The participation in human health workshops lead by Genome BC can still engage private healthcare firms into Genome BC’s initiatives. Furthermore, this still presents the opportunity for researchers from private healthcare firms to network with researchers from other institutions in order to identify possible research synergies. Again, the Task Force strategy component does not make sense on its own due to the need for prior workshop participation.

Figure 5 illustrates the preferred ranking of single strategy components.

Figure 5 – The implementation order for the Full Strategy, Two-Component Strategy and One-Component Strategy.

Strategy to Facilitate Development Investment Opportunities				
Number of Strategy Components Implemented	Strategic Components Implemented	Recommended Component Implementation Order		
		1st	2nd	3rd
One-Component Strategy	(1) Investment Fund	Investment Fund	n/a	n/a
	(2) Workshop	Workshop	n/a	n/a
	(3) Task Force	Task Force	n/a	n/a
Two-Component Strategy	(1) Workshop & Investment Fund	Workshop	Investment Fund	n/a
	(2) Workshop & Task Force	Workshop	Taskforce	n/a
	(3) Task Force & Investment Fund	Task Force	Investment Fund	n/a
Full Strategy	Workshop, Task Force, & Investment Fund	Workshop	Task Force	Investment Fund

Note: The numbers in parentheses indicate the ranking of Two-Component and One-Component Strategies.

9: CONCLUSION

The goal of this analysis has been to assess the suitability of investment opportunities into private healthcare firms in BC by Genome BC. Genomics-based healthcare innovations are moving closer towards actual medical applications. The investments of Genome BC into human health innovations intend to deliver benefit to British Columbia's healthcare system. The integration of these innovations into the public healthcare system in BC may be difficult. This difficulty may affect the integration of innovations developed with investments from Genome BC. However, the strategic positioning of private healthcare firms in BC to be early users of these innovations is strong. Therefore, investment into private healthcare firms may be an appropriate supplement to Genome BC's initiatives with the public healthcare system. There are political challenges to Genome BC investing in private healthcare firms, such as the controversy surrounding the deregulation of healthcare in Canada and the public sources of Genome BC's funding. The result of this analysis is a strategy to facilitate investment opportunities into private healthcare firms by Genome BC.

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