

A Report to Governor Gary Locke
and the Citizens of Washington State
from the Bio 21 Steering Committee

Prepared by the Technology Alliance

October 2004



BIO 21:

Implementing Washington State's Initiative in 21st Century Health

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I. EXECUTIVE SUMMARY

Bio 21 is a \$1.35 billion program that will make catalyzing investments over the next ten years to support research and commercialization activities at the convergence of life sciences and information technology in Washington State. Bio 21's strategic investments will result in a tripling of our life sciences research base and create more than 20,000 new jobs.

Bio 21 establishes a Strategic Trust Fund to make competitive grants to projects that bolster Washington's research capacity, accelerate commercialization of research discoveries, and improve both the efficiency of Washington's health care delivery system and the speed at which health-related discoveries are translated into clinical practice. These highly-leveraged grants will focus on reinforcing strengths, filling strategic gaps and stimulating collaboration across disciplines, institutions and corporations.

Bio 21, a true public/private partnership, will position Washington as a global center for the advancement of the emerging field of preventive and predictive medicine and will fund research and commercialization activities aimed at the prediction, prevention, early detection and cost-effective treatment of disease.

Overview

Washington's economy is changing in fundamental ways. All sectors of our state are becoming increasingly reliant on research and technology to succeed in a rapidly transforming global marketplace; innovation is the key to future economic success. If we are to remain competitive in the global innovation-based economy, Washington must be strategic in growing the sectors that will play an ever-increasing role in our future. Other states and nations have recognized this, and are jockeying for position as high-tech centers of excellence. Our state has the foundation to be a leader in tomorrow's economy if we act today to invest in our knowledge-based industries and build upon our existing assets.

We also have the potential to lead the nation – indeed, the world – in a revolution in human health.

In 2003, at the request of Governor Gary Locke, leaders from Washington's research institutions, industry, government and the community came together to develop the framework of a strategic initiative – “Bio 21” – that would capitalize on our existing assets at the convergence of the life sciences and information technology. The goal is to position our state to be a leader in the important emerging field of predictive and preventive medicine, generating health and economic benefits for the people of our state, by making targeted investments in research and commercialization and encouraging collaboration among institutions and industry. Washington is uniquely positioned to achieve this leadership position due to our combination of existing assets and a new stream of funding accruing to our state due to our leadership in the tobacco litigation.

In 2004, after the initial framework of Bio 21 was released, a Phase II steering committee was convened to take the next step: development of a plan for implementation by Washington State. Bio 21 calls for the state to direct a combination of public and private funds to our research sector through fiscal year 2017/18 to support research and commercialization at the convergence of the life sciences and information technology. The program is designed to catalyze funding from other sources to achieve an overall impact much greater than the initial public investment. Through Bio 21, we can elevate Washington to top-tier status as a center for life sciences R&D, revolutionize medicine through the application of information technology, and strengthen our economy for the future.

Washington's Research Assets, Our Foundation for Excellence

Our state will embark on this program with a distinct advantage: a healthy R&D sector comprised of world-class universities and non-profit institutions, innovative companies and world-renowned scientific talent. Our institutions draw new talent, spur new companies and attract over \$1 billion annually in federal research support. Many states and nations have made a concerted effort to invest in their own life sciences sectors, posing an increasing challenge to Washington's future competitiveness. In order to remain competitive and distinguish ourselves from other regions, Washington must pursue a highly coordinated, statewide effort to direct resources to our research institutions and consortia of institutions and industry. By implementing this strategic, long-range vision, our state has the opportunity to exert leadership in the sectors that will shape the future economy.

A Public-Private Trust to Catalyze Additional Investment and Build upon Our Strengths

Bio 21 will establish a Strategic Trust Fund comprised of public and private dollars for competitive grants to research institutions and their partners. The fund will be overseen by a governing board of seven distinguished individuals appointed by the Governor with the consent of the state Senate.

The source of the public portion of the funds will be \$350 million in Strategic Contribution Fund payments due Washington beginning in 2008. This money was awarded to Washington for its leadership in the tobacco litigation and master settlement negotiations between the states and the tobacco industry. The award is on top of the state's share of the tobacco settlement, and represents just 8% of the total tobacco-related funds accruing to Washington through 2025 under the terms of the Master Settlement Agreement. This relatively modest stream of funding, when combined with \$100 million in private funds being sought for this purpose, would support a \$450 million program for Washington administered over 13 years. The impact of Bio 21 is anticipated to be much greater than the sum of these program funds, however. Bio 21 grants are expected to leverage additional investment from federal and other sources, garnering an estimated minimum match of 2:1 overall for every dollar of Bio 21 funds invested or at least \$900 million over the life of the program. **In total, Bio 21 is expected to generate \$1.35 billion in investments** in research and commercialization in our state over the anticipated life of the program.

Bio 21 funds will be directed to areas in which Washington can enhance, develop or maintain a distinctive competence, and which present great opportunity for future economic growth and human health benefits. As part of Phase I of the Bio 21 effort, a study was commissioned to identify focus areas in which the potential markets are substantial; where Washington already has considerable expertise and advantage; and, where applied research could rapidly yield commercial applications. Those identified areas in which Bio 21 proposes to focus, at least for the first five years of operation, are ***diagnosing and treating disease; medical devices and imaging; and, software used in clinical settings.***

Bio 21 Strategies: Research, Health Care Innovation, and Commercialization

The Bio 21 program is designed with three key strategies for its grant-making activities: ***expand the state's research enterprise; speed research discoveries into clinical practice;*** and, ***increase the rate at which discoveries are turned into commercial successes.*** By adhering to these strategies, Bio 21 will build Washington's R&D sector, improve the health of our citizens, and create new companies and permanent, high-wage jobs.

Bio 21 will target grants to position our state's research institutions to compete for federal and industrial funding; invest in key facilities and purchase critical equipment; encourage collaboration among research facilities; attract and retain recognized top-ranked scientific talent, including their teams and committed funding sources; and, shore up important areas of weakness. Funds will also be used to more effectively translate research into clinical applications and improve health outcomes by supporting stronger linkages between institutions and health care delivery systems; stimulating the development of collaborative

information technology solutions; and building the delivery system infrastructure to support collaboration throughout the health care sector. Finally, Bio 21 would support research with commercial promise, fostering the movement of discoveries into the marketplace by supporting proof-of-concept, pre-prototype development, collaborative early-stage clinical trials and intellectual property protection; enable creation of training programs in gap areas such as F.D.A. regulatory affairs; and, address gaps in product commercialization such as pilot drug manufacturing facilities.

Bio 21 will pursue the strategies outlined above by providing funding in four main categories: ***Life Science & Global Health Research Awards***; ***Strategic Opportunity Fund***; ***Health Care Innovation Awards***; and, ***Commercialization Projects***. The largest portion of funding in the first two years that the program is fully operational is recommended to flow through Life Science & Global Health Research Awards, at 50-60%. The Bio 21 plan suggests the remaining three categories be allocated annual program funds in the range of 10-20% during this period. Once the initial investments have been made, the governing board of the trust should review the distribution of funds and determine where Bio 21 could make the most significant impact going forward. Thus, Bio 21 would begin with an emphasis on research, but leave open the possibility of shifting a larger portion of resources to the later-stage categories to support research outputs (health care innovations and commercialization projects). This structure and flexibility will enable the Bio 21 governing board to direct trust funds in the most effective way possible and respond to changing conditions to achieve the program's goals.

Bio 21 Goals: Critical Mass, High-Wage Jobs and Health Care Innovations for Our Citizens

Our research assets and the quality of life in our state present attractive opportunities for additional investment, talent and industry to take root in Washington. Those states and nations that have made significant investments have seen the benefits of reaching a critical mass in their life sciences sector, as the geographical concentration of resources, institutions, entrepreneurial and scientific talent and workforce have created an industry that, on its own, attracts more talent and investment,, generates products, companies, jobs, partnerships and capital, and improves the quality of life in the region. Therefore, the benefits that Washington can expect to accrue as a result of Bio 21 investments are new, expanding and relocating companies and research facilities; new, permanent, family-wage jobs; innovative products and methods of health care delivery; and, ultimately, improved health for the citizens of Washington.

A significant investment in our R&D sector will open doors to new discoveries, innovative technologies and collaborations that could have an enormous impact on the health and well-being of our state's citizens. Metrics regarding the health care-related impacts and improvements to quality of life as a result of Bio 21 are extremely difficult to accurately predict and so, while important, have not been included in this strategic plan. Based upon the experience of other states, the quality of our existing institutions and companies and the focus of the program itself, Washington can reap tremendous benefits from a program of strategic investment. We recommend health impact metrics be added as the funded program areas are identified.

There are, however, established methods of calculating related economic impact of a program like Bio 21 which will enable our state to partly quantify its success. As part of the Phase II effort, the Bio 21 Steering Committee requested a potential economic impact statement from Battelle, a nationally recognized expert in state life sciences strategies. According to the analysis, life sciences R&D is projected to nearly triple from its recorded 2002 level of just over \$500 million to nearly \$1.5 billion through FY 2017/18 as a result of Bio 21 investments. In the same period, the Bio 21 program will create at least 20,000 new, permanent jobs in the life sciences and other sectors, lead to the creation of over 100 new companies, and attract 50 additional, new-to-Washington companies. These and other specific metrics relating to increased research and commercialization activity are laid out in the Bio 21 plan to guide the governing board in assessing the program's positive impact for our state.

Bio 21 Next Steps: A Call to Action for Our State

Bio 21 will require leadership and a coordinated approach among Washington's public and private sector leaders. In order to successfully implement the program and ensure the necessary funding and processes are put into place to take advantage of the unique opportunity presented to our state, it is recommended that Washington's public and private sector leadership take the following actions:

- The newly-elected Governor propose legislation for the 2005 session to implement the Bio 21 program;
- The newly-elected state Attorney General work with the new Governor on the legal construct of the program, including the commitment of the non-securitized strategic tobacco funds to this purpose;
- State government, research and industry leaders engage in discussions with the philanthropic community from now through the legislative session to secure the necessary funding support for Bio 21 pending the disbursement of tobacco-related funds;
- The state legislature approve the legislation enacting the Bio 21 program by the spring of 2005; and,
- Public and private research and industry leaders serve as resources throughout the process and help build support for Bio 21 among legislators and the public.

By taking these steps, Washington will create a public-private partnership that will earn our state top-tier status as a center for research and commercialization at the convergence of life sciences and information technology, yielding far-reaching, positive impacts on our economy and the health of our citizens and making a positive contribution to the world, as our State has done in so many other key areas. With bold leadership, commitment and cooperation, Washington will realize this goal.

II. INTRODUCTION

Washington's Opportunity

In the next six months, Washington State faces an enormous opportunity. If we make the right choices, our state can expand our research and development sector three-fold, become a leader in 21st century health, and generate more than 20,000 new, permanent, well-paying jobs over the next 10-15 years and better health care prevention and treatment for our citizens. We have the world-class research institutions, innovative corporations, and strong talent base necessary to compete for that position. And, owing to bonus payments accruing to the state due to our leadership in the tobacco litigation, we have a unique opportunity to make investments that will leverage these enviable assets and make a significant difference to our future.

“Washington State has one of the most dynamic and collaborative biomedical research environments in the country. Having both characteristics in one locale is nearly unique and provides a very powerful engine for advancing the application of research to patients.”

– Dr. Lee Hartwell, President & Director,
Fred Hutchinson Cancer Research Center

But, this is truly a choice. Achieving this leadership position is no certainty. We have amassed considerable strength in both the research and industry segments of the life sciences and information technology without an organized effort or directed state investment. However, the competitive landscape has changed. Other states, regions and countries are recognizing the importance of the life sciences to their economies and the health of their citizens. They are investing heavily in this sector, challenging Washington's position. A recent report found that 40 states are targeting the life sciences as an economic development strategy, and all 50 states currently have one or more programs to support this sector.¹ Additionally, federal agencies are increasingly looking for their funds to be matched by state and other sources before making commitments. At the same time, the growth rate of federal grants is expected to diminish, making access to matching funds even more important.

“An environment that promotes a vigorous research and development community is a key to retaining and attracting biotechnology in Washington. Bio 21 represents another important step towards the development of a comprehensive approach to help ensure that innovative ideas turn into therapies to help patients.”

– Randy Hassler, Vice President,
Quality & Operations, Amgen

If we are to retain our competitive position and not squander the opportunity we have for the people of Washington, our state must actively engage in growing the industries that will fuel tomorrow's economy. Bio 21 aims to galvanize the forces that have earned Washington a reputation for excellence in research and commercial innovation and elevate our state to leadership status. With an infusion of approximately \$350 million of strategic tobacco payments combined with an additional \$100 million from private sources, Bio 21 is expected to leverage, at a minimum, an additional \$900 million from other sources for a combined impact of \$1.35 billion directed to research and commercialization activities in the life sciences and information technology sectors in our state.

While the program seeks an overall match of 2:1, the investments in our research capacity proposed under the Bio 21 program are expected to have the effect of much greater leverage, achieving a match of 10:1 or greater for some projects and increasing the overall impact beyond initial, conservative estimates. Life sciences research and development alone is projected to nearly triple by

¹ *Laboratories of Innovation: State Bioscience Initiatives 2004*, Battelle Technology Partnership Practice & SSTI, June 2004.

fiscal year 2017/18 as a result of Bio 21 investments. The results for our state, in terms of additional, leveraged investments, research expansion, and job and company creation and attraction, would be significant and widespread²:

- Bio 21 will create over 20,000 new, permanent jobs by 2017, including almost 6,400 in the life sciences and information technology sectors and an additional 13,700 in Washington's economy;
- Bio 21 will generate approximately 110 successful new startups by 2017, employing more than 3,300 people, and attract approximately 50 companies from other locations, employing another 3,060;
- These startups and other new-to-Washington firms would generate over \$1.7 billion annually in sales by 2017; and,
- Overall, life sciences R&D in our state will expand from approximately \$500 million recorded in 2002 to an estimated \$1.5 billion by the end of FY 2017-18.

What is Bio 21?

Bio 21 is a bold public-private program that will make catalyzing investments over the next ten years to support research and commercialization activities at the convergence of life sciences and information technology. Specifically, Bio 21 will position Washington as a global center for the advancement of the emerging field of preventive and predictive medicine. It will fund research and commercialization activities aimed at the prediction, prevention, early detection and cost-effective treatment of disease.

“Washington State has a distinguished history leading global technical revolutions. Aerospace was the first, software the second. The biotechnology stakes are the highest yet as it has the potential to deliver health benefits for every living being and create products and services that will touch one-third of the global economy. Bio 21 will anchor our competitiveness in global research and provide a critical platform for us to build commercial success.”

– Rob Arnold, President & COO,
Geospiza, Inc.

Bio 21 establishes a Strategic Trust Fund to invest in projects that bolster Washington's research capacity, accelerate commercialization of research discoveries, and improve both the efficiency of Washington's health care delivery system and the speed at which health-related discoveries are translated into clinical practice. These grants will focus on reinforcing strengths, filling strategic gaps and stimulating collaboration across disciplines, institutions and corporations.

This plan is the culmination of more than 2 ½ years of work, involving the contributions of dozens of Washington's most respected leaders in research, public policy, health care, higher education, and industry. This effort includes in-depth examinations of similar state programs around the country, consulting and reports from nationally recognized experts, and thousands of volunteer and staff hours. The Bio 21 plan builds on the research and conclusions published in January 2004 in *Bio 21: Washington State's Initiative in 21st Century Health*³.

² Battelle Technology Partnership Practice; for the complete set of projected impacts, see Appendix A.

³ A copy of the report, which includes a full recounting of the steps that led up to its completion, is available from the Technology Alliance's web site at www.technology-alliance.com.

Why Now? The Tobacco Settlement Funding Presents an Important Opportunity for Washington's Future

By 2025 Washington is expected to receive more than \$4 billion from the tobacco settlement. Our state has already received nearly \$1 billion from the settlement⁴. The initial payments were used to launch anti-smoking campaigns, address other immediate health-related matters, and balance the state budget. However, Washington is in a coveted position with regard to this settlement due to our leadership in the tobacco litigation.

Beginning in 2008, our state will receive additional payments totaling roughly \$500 million, over and above the standard state settlement. We can choose to pool this money with the \$4 billion the state is already receiving and spend it on addressing immediate needs, or we can use it to make a long-term investment that will change our future.

The state has already committed an estimated \$150 million of this bonus payment to balance the state's budget. The remaining \$350 million is a precious resource. Although it amounts to less than 8% of the total dollars the state will receive from the tobacco settlement by 2025, this \$350 million could have a far-reaching, long-term effect on the state. By leveraging this money with other sources and directing it to high-impact investments, Washington can use it to make a significant difference in the future health of our economy and our citizens.

Bio 21 in the Context of a Broader Statewide Approach

Growing and sustaining our future economy requires a comprehensive statewide approach. Bio 21 will bridge the gap between basic research funded by federal government agencies, and the stage at which research activities lead to practical applications, commercialized technologies, company and job creation, and ultimately improved health outcomes for the people of our state. However, Bio 21 is just the first step of a more comprehensive statewide approach. In addition to moving ahead with the Bio 21 plan, Washington's public and private leaders must also join forces to cultivate the regulatory and entrepreneurial climate that will allow our knowledge-based sectors to grow and thrive. In addition to the research and commercialization support proposed in this document, a comprehensive approach for our state needs to address elements such as capital availability⁵; regulatory climate; tax policy; workforce preparedness; infrastructure requirements and numerous other components.

Due to our unique positioning and existing strengths in the life sciences and information technology, we are already a recognized center for leading edge research, with many major multi-national companies, institutions and initiatives based here. Bio 21 and other complementary programs are essential to not only sustain our position but to elevate our state to top-tier status.

⁴ Kaiser Family Foundation, www.statehealthfacts.org.

⁵ See Appendix D for the report and recommendations of the Bio 21 Seed Funding Strategy Subcommittee.

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III. BACKGROUND

The Genesis of Bio 21

In 2002, Governor Gary Locke posited the question, “Does Washington have unique assets at the intersection of biotechnology and information technology that may be exploited for the benefit of our economy and the health of our citizens?” Our conclusion is that Washington has enormous assets and opportunities; but that we are losing ground to other states and nations that are heavily investing in these opportunities. Bio 21 is an important first step toward developing an overall coordinated plan backed by state resources.

From the program’s inception, those involved in shaping the initiative have noted that Washington is already well-positioned to focus on the convergence of the life sciences and information technology, an area which promises to yield important advances that will shape the future of health care. Similarly, the Governor and others noted that, due to the impending strategic tobacco payments, Washington has a unique opportunity to direct substantial resources to such an effort.

In 2003, dozens of research, industry and government leaders from across the state engaged in a rapid, focused process to develop a framework for Bio 21. The Technology Alliance was contracted to lead the project. A Steering Committee was formed co-chaired by Shan Mullin, partner with Perkins Coie and former chair of the board of the Fred Hutchinson Cancer Research Center (FHCR), and Lura Powell, former director of Pacific Northwest National Laboratory (PNNL) and the Advanced Technology Program at the National Institute of Standards and Technology and current President and CEO of Advanced Imaging Technologies. Additional input was sought from a group of scientific and industry experts organized by Dr. Lee Hartwell, President & Director of the FHCR, and the Washington Advisory Group was engaged to assess Washington’s strengths, weaknesses, and opportunity.

In January 2004, the Bio 21 Steering Committee delivered the Phase I report to Governor Locke, advocating for a bold program of strategic investments designed to expand Washington’s research capacity that would lead to breakthrough discoveries with clinical applications and exceptional commercial potential.

Development of the Bio 21 Action Plan

Research, industry, government and community leaders have coalesced around the Bio 21 plan to enact a statewide program of investment in research and commercialization at the convergence of our life sciences and information technology sectors. In the Spring of 2004, a Phase II steering committee of government, industry and research leaders was convened, under the continuing leadership of Shan Mullin and Lura Powell, to formulate a plan to implement the Bio 21 program for transmission to state government leaders, the gubernatorial candidates and candidates for Attorney General. Working subcommittees were formed to deliberate on specific issues – seed funding, patient outcomes, governance and organization, diagnostics and therapeutics, medical devices and imaging, and

“The state of Washington is uniquely positioned to lead a diagnostic revolution in predictive and preventive medicine, based on its unique range of information technology resources and life science, medical research and global health assets. Bio 21 will provide important leveraged funding and strategy to help catalyze the convergence of these two fields and further collaboration across the state, all of which are so important for the growing field of bioinformatics.”

– Chuck Hirsch, Managing Director,
Madrona Venture Group

communications and outreach – and to make recommendations to the Steering Committee for inclusion in the final proposal.

- Seed Funding Strategy – This subcommittee, co-chaired by Lura Powell and Steve Yentzer, partner at Perkins Coie, was charged with examining existing and planned public and private seed funding programs both inside Washington and across the country, assessing the needs in Washington, and considering if and how seed funding might be included as part of Bio 21.
- Patient Outcomes – Because the Bio 21 program will target investment at projects that are expected to yield important contributions to improving health care treatment, prevention and service delivery to Washington's citizens, this subcommittee, chaired by Group Health Cooperative President & CEO Cheryl Scott, was charged with defining the types of projects that Bio 21 could fund that would improve clinical relevancies of health-related research, particularly in the application of information technology to health care delivery.
- Governance and Organization – The Bio 21 program is envisioned as a public-private partnership, with funds held in trust and grants administered in accordance with appropriate criteria. This subcommittee, chaired by Jay Reich, partner at Preston Gates & Ellis LLP, was charged with developing the details surrounding the structure and oversight of the Bio 21 trust and drafting legislation.
- Diagnostics and Therapeutics, and Medical Devices and Imaging – Two small working groups were convened to discuss these two focus areas of Bio 21, chaired by Peggy Means, Senior Vice President for Strategic Development & Planning at the Fred Hutchinson Cancer Research Center and Denice Denton, Dean of the College of Engineering at the University of Washington. These groups determined Washington's strengths within each focus area and identified where Bio 21 can make the most significant impact.
- Communications and Outreach – Recognizing that Bio 21 will be most successful if there is broad public understanding of the positive economic and health care impacts that accompany a significant investment in the research enterprise, this subcommittee, chaired by Bill Grinstein, Associate Director of Public Affairs at Battelle/Pacific Northwest National Laboratory, was charged with engaging a broad circle of statewide stakeholders in discussions that build support for Bio 21 and developing a communications effort that fosters understanding and ongoing support for Bio 21 throughout the state.

The Steering Committee and subcommittees also engaged consultants with technical expertise to help formulate the final plan, foremost among them Dr. Walt Plosila, Vice President, Technology Partnership Practice at Battelle, who has extensive knowledge of state biosciences strategies across the country. In addition, Perkins Coie and Preston Gates & Ellis LLP provided pro bono legal counsel to aid the committees in their work. The State Attorney General's office was also consulted on an ongoing basis.

The Phase I report released in January 2004 has served as the foundation for developing this plan. This Phase II document addresses issues raised by the Phase I report in more detail and lays out specific plans for the establishment and operation of the Bio 21 trust, the source and distribution of funds, examples of high-impact projects and recommendations regarding additional, complementary strategies for Washington.

IV. CASE STATEMENT

The Drivers of Washington's Economic Future

There is widespread recognition among Washington's citizenry that our economy is changing in fundamental ways and that we are now part of a rapidly transforming global economy. All sectors of our state economy are becoming increasingly reliant on research and technology to succeed in the competitive, global marketplace. Innovation is key to future economic success. If we are to sustain the vibrancy of this state, we must support the sectors that will play an ever-increasing role in its future: knowledge-based industries that create family-wage jobs and have broad and positive impacts on the entire state's economy, urban and rural.

Thanks primarily to federal investments in our research institutions and a combination of luck and enterprise, Washington already has thriving life sciences and information technology industries that, combined, employ over 150,000 people statewide. These industries create jobs accompanied by salaries that are nearly double the statewide average. They also contribute significantly to other sectors of the economy; for example, each job within the biotechnology/medical device industry is estimated to generate another 2.23 jobs in Washington⁶. Additionally, the market for technologies and products coming out of the convergence of these sectors is expected to continue to grow substantially. By 2010, the global market for bio/IT-based diagnostics, therapeutics, devices, research tools and health care-related information technology systems is expected to reach \$243 billion⁷. In order to capitalize on the opportunities presented by the growth of these two sectors in which Washington already boasts considerable expertise, we must devote resources to further advancing this base and ensuring that the research and development conducted in our state translates into tangible benefits for our citizens.

“Research is an economic powerhouse. Not only does it provide our region with high-paying jobs, but sustained growth and consumer demands fuel the local economy as well. We have a unique opportunity to create new approaches to improve health care, while at the same time contributing to the development of a robust economy.”

– Dr. Paul Ramsey, Vice President for Medical Affairs and Dean, University of Washington School of Medicine

State Involvement is Crucial to Secure Our Future

Other states are facing the same difficulties as Washington – structural economic shifts and increasing global competition – and are moving aggressively to position their economies for the future. The competition, in fact, is not only with other states but other nations. (Michigan, North Carolina, New York, Florida, Arizona, Singapore, Australia, Malaysia and Sweden, to name a few, have all launched major government-funded research initiatives.) Even states like Massachusetts and California, already considered to be at the forefront of tomorrow's technology economy in the U.S., are investing heavily to bolster their strengths. The fact that they presently occupy a dominant position has not precluded these other states from attempting to elevate their position even further.

Washington has amassed considerable strength in the life sciences, information technology, and other sectors, boasting world-class research institutions, both public and private, and world-renowned scientists

⁶ Huckell/Weinman Associates, Inc., *The Biotechnology and Medical Device Industry in Washington State: An Economic Analysis*, prepared for Washington Biotechnology & Biomedical Association, 2002.

⁷ Alta Biomedical Group, LLC, *Bioinformation Market Study for Washington Technology Center*, 2003.

and companies. Washington's current enviable position has been achieved without significant state involvement; our state ranks 46th out of 50 states in state government spending on R&D on a per capita basis. With others devoting considerable resources to try to achieve success in the life sciences and other high-tech sectors, however, Washington can no longer afford to ignore this competitive environment.

The Importance of Leverage and Achieving a Critical Mass

Washington should not ignore the tremendous opportunity presented by our existing world-class institutions, talent and industry to attract even more federal funds, private investment, and talent and companies to our state. We need to significantly leverage the many assets we have.

In other states, most with less biomedical research capability than Washington, substantial state investments in research – in the range of \$50 million to \$300 million – have been matched dollar for dollar by federal or private funds. The near term results are increases in key elements of the “ecology” of economic innovation, growth, and job creation—immediate increases in employment of a highly-skilled workforce, a steady improvement in technology transfer for rapidly growing science and technology-based startups, and a significant increase in the State’s attractiveness as a location for new or relocating corporate and federal R&D facilities. Washington has not begun to tap these leveraging opportunities...

Bruce Guile
Washington Advisory Group

Washington institutions have a history of successfully leveraging what state funds they have received in the past. Collectively, our public research universities and private research institutions bring in over \$1 billion in federal funding annually. A relatively modest initial state investment has the potential to attract multi-year funding from other sources multiplied several times over the starting amount. Furthermore, biopharmaceutical and medical device companies tend to cluster their product development, marketing and manufacturing functions in geographic proximity to the research centers that make the discoveries on which their businesses are based. Washington can achieve a critical mass of talent, institutional activity and industry at the convergence of the life sciences and information technology if it makes a targeted, strategic commitment to fuel research and commercialization in these sectors.

The Potential to Be a Global Center for Predictive & Preventive Medicine with a Focus on Early Detection and Treatment of Disease

“Bio 21 is a scientific and societal accelerator. It will speed basic discoveries of our health science laboratories into the clinic and the marketplace. Consequently, it will help us better predict, prevent, and treat disease. And, it will enhance the quality of life and economic well-being of the citizens of Washington.”

– Dr. Paul Robertson, President, CEO & Scientific Director, Pacific Northwest Research Institute

Today's medicine is reactive: we wait until someone is sick before treating him or her. The medicine of the future will be predictive and preventive, looking into the biology of an individual to gauge the probability of disease and suggest appropriate treatments. It will also be much more personalized, because we will have the ability to tailor treatments to individual biological profiles.

New diagnostics will allow us to detect and treat a disease such as cancer when a tumor consists of only a few cells. This ability for early detection and early treatment means that millions of lives can be saved and treatment costs can be dramatically reduced. Because of the pioneering work being done at the Fred Hutchinson Cancer Research Center, the Institute for Systems Biology, the University of Washington School of Medicine, Pacific Northwest National Laboratory, Washington State University, and their partners,

we have the ability to be the global center for this emerging field of predictive and preventive medicine. World-renowned scientists such as Nobel prize winner Lee Hartwell and Kyoto prize winner Lee Hood have made this the focus of their life's work. Washington needs to make the most of this opportunity and magnify the health and commercial potential of this new paradigm⁸.

The Potential to Improve Health Care Delivery for Our State's Citizens through Innovation

With strategic state involvement, Washington will be able to leverage federal and private investment and make a significant, long-term difference not only to the economy, but also to the health of our citizens.

There is tremendous promise that the convergence of information technology with new biomedical research applied in health care can and will lead to predictive and preventive health care, fewer errors and significant cost savings. Even small percentage reductions in the cost of health care and small qualitative improvements in health care in the State can have an enormous impact on the economy and on the quality of life in the State.

Bruce Guile
Washington Advisory Group

Washington can ensure that discoveries in the research laboratory translate into products and protocols that directly impact health care delivery in our state. Across the country, health care delivery is fragmented and inefficient. This fragmentation generates duplicate and unnecessary services and expenses, and creates gaps and delays in care. At a time when medical knowledge and technology are advancing at an unprecedented rate, providers are often not connected in a way that fosters coordinated care, or find it difficult to incorporate the latest advances in research into their clinical practices. Several organizations in Washington are already developing innovative practices that, if expanded, could address these issues and have positive, far-reaching effects on the quality and efficiency of patient care. Given the leading edge research conducted in our various institutions, our established reputation as a center for global health, and our unique foundation in information technology that provides the electronic connective tissue to link and share information, Washington has a very real opportunity to instigate major improvements in the way health care is delivered across the state and serve as a model for others to follow.

Learning from Other States

While Washington may be late entering the race, the growth of our existing assets largely without state involvement has a silver lining. In crafting its strategy, Washington can learn from other states' successes and failures. Others have employed a variety of strategies in their quest to become the next high-tech center, including a combination of tax policies and targeted investments. Every state in the nation is looking at bolstering its biosciences sector, and 21 states are directing a portion of their tobacco settlement dollars to health-related research.

“The Bio 21 initiative represents a strategic investment in the state’s future. Research at Washington State University will produce new health care products, such as anticancer drugs or pain relievers, from plants. Our research will also protect food supplies, enhance global nutrition, protect against bioterrorism agents, and engineer new processes and medical devices, while at the same time enhancing educational opportunities in the state. As these technologies are transferred to private industry, this initiative will enable the creation of new family-wage jobs and will help ensure the state’s future economic vitality.”

– Dr. V. Lane Rawlins, President,
Washington State University

⁸ For a detailed analysis of the opportunities for Washington in this field, see Appendix B for the report of the Diagnostics and Therapeutics Subcommittee.

“Washington State is a leader in medical research and development through our world class institutions, scientists and entrepreneurs. A modest investment of 8% of tobacco settlement funds, about 10% of the investment the state made to land the 7E7, is a great way to continue to attract the brightest and best people and programs, leading not only to job creation but also to improved world health. Other states are making these types of strategic investments and the benefits should also be clear to our leadership.”

– Joseph Sasenick, Former Chairman & CEO, Alcide Corporation

Until now, we have done relatively well creating a robust research enterprise with an enviable concentration of talent. The changing competitive landscape dictates that we can not simply continue as we are: the stakes are too high, and we have too much to lose. Consider the most recent data on total R&D expenditures at academic institutions: although Washington's major research universities increased spending on academic research between 1999 and 2003, our position relative to other states slipped from 20th to 24th on a per capita basis. The data indicates that states are directing more and more funding to R&D, but Washington is not keeping pace with the competition.

To fulfill the vision of a thriving economy and healthy citizenry, Washington requires a comprehensive state strategy. A basic prerequisite and logical first step is to make a significant investment in our research enterprise. The strategic investments that will be made under the Bio 21 program will help Washington achieve a critical mass in the life sciences and information technology and become a magnet for new talent, additional investment, and new and relocating companies, generating the family-wage jobs, new products and collaborations that will improve the quality of life in our state.

We as a state have a watershed choice to make. If we fail to make a long-term commitment and pursue a sustained effort to invest in our research enterprise, we allow other states and regions to further erode our competitive edge. At this moment, the state is in a position to capitalize on our existing world-class assets and on a new stream of funding – the strategic tobacco payments – to initiate a visionary strategy to propel our economy forward. Washington must seize this opportunity.

V. BIO 21: THE PLAN

BIO 21'S VISION FOR WASHINGTON STATE

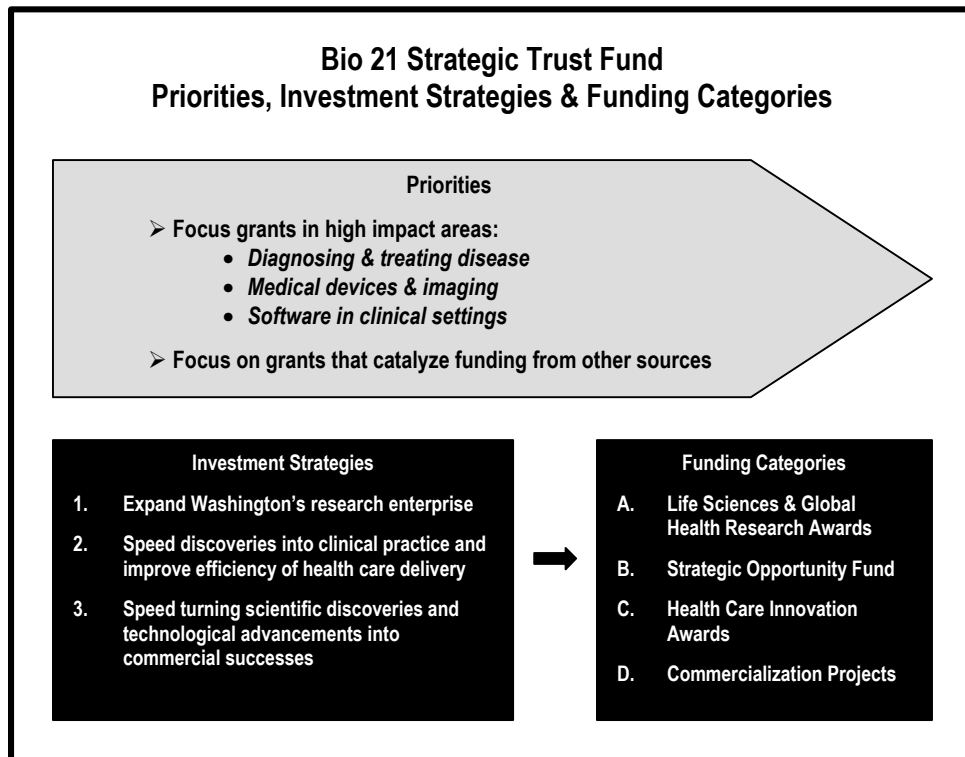
By 2017, Washington will be a top-tier center for 21st century medicine and global health, generating revolutionary health care advancements and thousands of high-paying jobs for a thriving economy and a healthy citizenry.

BIO 21'S MISSION

Bio 21 will advance Washington's position as a world leader in 21st century medicine and global health through a bold program of strategic and catalytic investments that expand research capacity and commercialize technology aimed at strengthening our economy and improving citizen health.

STRATEGIES AND PROGRAM ELEMENTS

The Bio 21 mission will be implemented through a Strategic Trust Fund administered by a board of distinguished individuals. The trust will combine state dollars from the strategic tobacco payments with philanthropic monies to invest in the state's research institutions and in partnerships with health care providers and other enterprises. Bio 21 funds will significantly leverage other private, federal and philanthropic funds by requiring recipients to match these grants, with a minimum of a 2:1 match overall. While the funding proposed is substantial, it can only have impact if it is focused and builds on existing strengths of Washington's institutions. Thus, the Bio 21 Strategic Trust Fund will center on investments in three areas: diagnosing and treating disease, developing medical devices and imaging, and advancing software used in clinical settings.



A. Establishment, Organization and Operation of the Bio 21 Strategic Trust Fund

The Bio 21 program will be implemented through a non-profit trust created by legislation and governed by an independent board of trustees who will administer a substantial fund that will include a grants program to the state's research institutions and their private-sector collaborators. This governing board will be comprised of seven distinguished leaders from around the state appointed by the Governor with the consent of the state Senate. Trustees will be appointed for 4-year terms. The Bio 21 trust will operate under the highest standard of public scrutiny with regard to bias and conflict of interest policies affecting the allocation of the funds. The trust will be authorized to enter into contracts with the state and other public and private entities to receive, hold and prudently manage funds, including the tobacco strategic contribution payments, to be disbursed under the trust's guidelines. (A full description of the source of funds is included in Section E.)

The Bio 21 trust will solicit proposals for project funding and administer grants through a competitive process in four program categories in accordance with appropriate selection criteria (See Section D). It will create committees of highly qualified individuals to perform peer review of proposals submitted for Bio 21 funding. The board will also establish procedures and hire staff as necessary to fulfill the Bio 21 mission. Expenses related to administration of the Bio 21 program will be conservative, informed by the precedents set by other states' programs.

To ensure that the Bio 21 program remains responsive to the rapidly evolving scientific and commercial environment and that it attains its stated goals, the trust will:

- Define and periodically redefine as appropriate the broad programmatic areas in which grants will be made;
- Design and approve each year's requests for proposals, including details of qualifying requirements and of evaluation criteria;
- Oversee the peer review process to guarantee that competing proposals are rated and ranked using the best available experience and judgment and consistent with the stated qualifying and evaluation criteria;
- Make the annual grant decisions and oversee any negotiations with grant recipients over budget, milestones or other grant conditions;
- Prepare a review and evaluation of the program's accomplishments annually; and,
- Undertake a comprehensive evaluation of the program's focus and dollar allocation targets every 3-5 years that results in guidelines for future allocations.

B. Priorities of the Bio 21 Strategic Trust Fund

The trust's grant-making activities will be guided by the following two priorities:

1. Focus the Bio 21 grants in areas with the potential for highest impact

For Bio 21 to have a material statewide impact, Washington should **direct resources to those areas where the state can enhance, develop, and maintain a distinctive competence**. Much of the research to build this plan looked at the experience of other states, market forces and our own strengths and gaps to illuminate the investments with the greatest potential for significant, long-term economic and health impacts. A third-party study identified the following three areas of research and development where the potential markets are substantial; where Washington has considerable expertise and comparative advantage; and where applied research can quickly lead to commercial applications. We recommend that the Bio 21 trust focus on these three high impact areas for at least its first five years.

- *Diagnosing and treating disease:* This area focuses on the application of the biological sciences to the creation of new drugs and diagnostics, including plant and animal research with human health implications.
- *Medical devices and imaging:* This area includes bioengineering, nanotechnology, and the application of computer and information technology to biological research.
- *Software used in clinical settings:* This area focuses on advanced information systems which increase efficiencies, lower health care costs, and rapidly translate new discoveries into clinical practice.

2. Focus on catalyzing additional, leveraged investments

The second priority for the Bio 21 trust is to **focus on making strategic investments that trigger additional and significant funds from federal, private, and other sources**. Washington must move aggressively if we are to successfully compete for funds available from other sources and achieve the significant impact we envision.

The Bio 21 program aims to achieve, at a minimum, an overall match of 2:1. This is a conservative estimate of the program's potential impact in terms of attracting additional investment. It is anticipated that the actual impact in terms of additional funds leveraged by the program will be many times greater, based upon past experience of how previous state investments in our institutions have been used to secure significant funding from other sources. Bio 21 will be a major catalyst for additional investment in our R&D sector by directing resources to projects that have commitments from or are planning to seek support from federal and other sources. The impact of the Bio 21 program on research activity in our state will, therefore, extend far beyond the initial, direct investment and give our institutions a competitive edge in seeking funding from non-state sources.

This use of leverage is not new to the state, and in fact, Washington has a history of success in leveraging limited state dollars.

Examples of How Washington Has Leveraged Limited State R & D Dollars in the Past

In 1998, Washington State funded the Advanced Technology Initiative (ATI) for its two research universities. The University of Washington used \$1 million a year of these state funds to recruit key people in infectious disease to fill gaps in the UW faculty. A few years ago, the new faculty mounted an extensive expansion of UW's research in infectious diseases, with significant success. The most notable and recent example is a \$50 million federal grant (\$10 million per year for five years) in biodefense and infectious diseases. UW fully expects the grant to be renewed, meaning that \$10 million will leverage \$100 million over ten years.

Leverage: 10 to 1

WSU leveraged the \$250,000 per year it received through the ATI to obtain more than \$18 million in new multi-disciplinary grants and contracts, including \$1.5 million from the National Science Foundation, nearly \$2 million from the Defense Advanced Projects Agency, and \$3.5 million from the U.S. Army in connection with the development of a portable power generation system. The system has been patented and is in the process of licensure for commercialization. WSU anticipates significant future funding to advance the technology further, meaning that the 10:1 return on the state's investment is also expected to continue into the future.

Leverage: 10 to 1

In 2001, UW launched a major effort in photonics. In subsequent months, the program received remarkable federal and commercial interest. The UW faced the problem of coping with success – more grant money was available than the university could use, given the limitations of its facilities. Last session, the Legislature made matching money available, and UW used the first installment to refurbish space for the photonics effort. UW is spending \$2 million in state money on a one-time basis in support of a grant program that currently brings in \$10 million per year and is growing. Also worthy of note, the photonics program already has significant involvement with Washington businesses: Boeing has a major federal contract tied to the UW technology, and a startup company, Lumera, has spun out of the program.

Leverage: At least 10 to 1

In 2000, the state of Washington funded the Safe Food Initiative. Washington State University used a portion its \$750,000 grant to hire new faculty and enhance research programs. As a result, WSU received several new awards, including \$10 million from the National Institute of Allergy and Infectious Diseases (NIAID) and over \$1.1 million in federal funds for the Washington Animal Disease Diagnostic Laboratory in its role as one of only seven in the nation that comprise the USDA National BSE Lab Network for high-volume BSE (mad cow) testing.

Leverage: More than 10 to 1

C. Three Strategies for Bio 21 Investments

The Bio 21 Trust will accomplish its mission by making significant investments that build Washington's research capacity, improve citizen health, and create jobs. These three investment strategies are outlined below.

Strategy #1: Expand the state's research enterprise by building upon existing strengths, addressing gaps, and attracting and retaining talented scientists.

Strategy #1: Expand the state's research enterprise

Bio 21 will address strengths, gaps, and opportunities in Washington's research enterprise by:

1. Positioning qualifying institutions to be highly successful competitors for federal and industrial research funding by providing state matching dollars for highly competitive federal grants;
2. Investing in key facilities and purchasing critical equipment;
3. Encouraging collaboration and connections among research facilities;
4. Attracting and retaining "star" scientists, their research teams and pledged funding streams; and,
5. Shoring up competitively important areas of weakness.

It is important to note that Bio 21 will not serve as a "mini-National Institutes of Health" or "mini-National Science Foundation," funding the types of research projects that would otherwise be suitable for federal support.

The heart of Washington's research enterprise is its enviable list of world class research institutions:

- **University of Washington** has led the nation's public universities in competing for federal research and training grants for nearly three decades, and its School of Medicine and departments of bioengineering, genome sciences, and computer science are among the strongest in the nation.
- **Washington State University** boasts one of the nation's leading plant biochemistry and biotechnology programs.
- **Microsoft Research** is ranked among the top computer science research organizations in the world.
- **Fred Hutchinson Cancer Research Center**, the largest recipient of NIH funding among the nation's independent research institutes, is world-renowned for its pioneering research in the understanding, prevention and treatment of cancer and related diseases.
- **Pacific Northwest National Laboratory** houses the most advanced cellular and molecular imaging instruments and the fastest civilian supercomputer in the nation.
- **Institute for Systems Biology** has attracted over \$140 million in funding in less than four years and has earned international recognition for pioneering the field of systems biology.
- **Program for Appropriate Technology in Health (PATH)** is engaged in the development and application of technologies and systems to advance public health in more than 100 countries.
- **Seattle Biomedical Research Institute** is the largest independent, non-profit research institute in the United States focused exclusively on infectious disease research.
- **Pacific Northwest Research Institute**, one of the oldest private, non-profit research institutes in the Northwest, is devoted to the prevention and cure of cancer and diabetes.
- **Benaroya Research Institute at Virginia Mason Medical Center** is internationally recognized for its research in molecular biology and genetics.
- **Allen Institute for Brain Science** is working to achieve new understanding of brain function and disorders and to support research in the treatment and prevention of Alzheimer's, autism and other diseases.
- **Puget Sound Blood Center** conducts research in areas such as gene transfer therapy and platelet disorders, and is recognized worldwide for its contributions to transfusion and transplantation medicine.

The following table summarizes some of Washington’s key areas of strength in information technology, biomedical research and medicine. The table is not exhaustive. (For example, we are also nationally known for research in Alzheimer’s, autism, and hearing disorders; we are a top-ranked state in pediatrics and geriatrics care; and, we are a top-ten state in endocrinology, orthopedics and veterinary medicine.) The areas of strength identified below are examples of areas where the linkage between the life sciences and information technology are particularly strong, where we are considered world class, and/or where Bio 21 could focus to maintain and grow Washington’s existing clusters of excellence. The table also includes areas for improvement that can be seen as opportunities for investment: strengthening these key areas will make us more competitive and will help us commercialize technologies more quickly.

STRENGTHS	INSTITUTIONS	KEY
Bioengineering	UW	
Genome Sciences	UW, ISB, Amgen, Benaroya Research Institute, FHCRC	
Imaging	UW, PNNL	
Infectious Disease/Global Health (HIV/AIDS, malaria, tuberculosis, etc.)	UW, FHCRC, SBRI, PATH	
Cancer Research/Oncology	FHCRC, UW Also PNRI, WSU and others	
Nanoscience & Nanotechnology	UW, PNNL, ISB	
Computer Science/Information Technology (software development, human interface, data management, knowledge management, networking, robotics, computing & biology, etc.)	UW, Microsoft Research	
Bioinformatics	PNNL, Merck Rosetta, FHCRC	
Photonics	UW	
Systems Biology	ISB, UW, FHCRC	
Proteomics	UW, ISB, PNNL, FHCRC	
Pharmacology	UW	
Reproductive Biology	WSU, UW	
Plant Genomics & Proteomics	WSU, FHCRC, UW	
Environmental Science	WSU, PNNL, UW	
Diabetes & Autoimmune Disorders	PNRI, Benaroya Research Institute, UW	
Family Medicine & Rural Health	UW	
AREAS TO IMPROVE		
<ul style="list-style-type: none"> ➤ Medicinal chemistry ➤ Clinical informatics ➤ Translational research in medical device development ➤ Translational research in drug development ➤ Training in FDA regulatory affairs ➤ Pilot drug manufacturing facilities 		

Bio 21 investments in research capacity can make a considerable difference in projects that promise better quality of life for our citizens. Below is just one example, provided by WSU, of how state funds, strategically applied in areas of promise, can catalyze the creation of research teams, build up infrastructure, and set off a chain reaction of increased activity surrounding the research being conducted by our institutions that can have far-reaching impacts on our economy and the health of our citizens:

State funding would enable the establishment of interdisciplinary research teams to work on fundamental and applied problems in four areas of strategic importance to Washington that would enhance human health: biomedical genomic sciences; health-related bioproducts; infectious diseases and pests; and, healthy, sustainable food systems.

Funds would be used for salaries, laboratory equipment, and critical infrastructure. This funding support would attract world class researchers of National Academy stature, who would in turn be able to leverage the state dollars to attract significant federal research programs and to enable the development of spin-off companies. Moreover, it is anticipated that the quality of the researchers would also attract existing technology-based companies specializing in the program areas, enabling effective interaction between university researchers and industry. The state investment would be leveraged to attract matching federal capital and operating dollars that could provide additional resources for associated undergraduate and graduate students, high technology equipment, and technical support.

With investment in these targeted university research areas, Washington's citizens will benefit from new drugs and other high value products, such as insulin or serum albumin; better control of infectious diseases, including diseases that are transferred between species (e.g. BSE, Avian Influenza); a more complete understanding of the metabolism of individuals, which would enhance drug efficacy while reducing complex drug interactions and provide improved health and control of diseases such as obesity; and, more healthful foods produced in more sustainable systems that reduce or eliminate dependence on pesticides. Moreover, these same studies will enable improvements in the health of crops and livestock, enhancement in the nutritional value and other health benefits of plants and animals, and reduction of threats from new invasive diseases and pests such as sudden oak death.

Strategy #2: Speed research discoveries into clinical practice and improve the efficiency of Washington's health care delivery system

Washington's considerable strengths in software and information technology are well known. Bio 21 investments can be used to creatively apply this knowledge to pioneer new and better approaches to health care in our state that can serve as international models. For instance, the statewide Community Health Network of Washington – one of the most progressive and successfully managed care systems for the underserved in the United States – is supported by state of the art proprietary technology recently selected to be used in establishing the first health care network for the country of India. As another example, the Inland Northwest Health Systems (INHS), located in Spokane, has developed a four-state regional medical information system that is a model for the country.

Strategy #2: Speed research discoveries into clinical practice and improve efficiencies

Whether advancing new protocols into clinical practice or addressing systemic health care issues in Washington, Bio 21 could have a far-reaching impact. In this second strategy, Bio 21 will focus on:

1. Facilitating the rapid translation of new discoveries and knowledge into clinical practice through stronger linkages between research and delivery systems;
2. Stimulating the development of collaborative information technology strategies that improve health care outcomes and reduce waste in the health care system;
3. Strengthening research and investment in the prevention and early detection of disease;
4. Encouraging the development of collaboration throughout the health care sector and building the delivery system infrastructure that would improve patient outcomes and reduce health care costs; and,
5. Fostering delivery system innovations that address the needs and desires of our aging population.

There are many ways in which this strategy could improve health care for Washington’s citizens. Below are descriptions of the types of projects that Bio 21 could potentially support in this category. Additional examples are discussed in Appendix C.

- *Improving the dissemination of cancer care protocols:* Clinical researchers at the FHCRC and the UW have developed important new protocols for the treatment of breast cancer that provide more effective treatment of cancer and lead to better patient outcomes. Through a collaboration between the Seattle Cancer Care Alliance and Group Health Cooperative, these treatment protocols are now available to a growing number of patients around the state. However, there are many patients who do not yet have access to these improved methods of care. Bio 21 could help speed the dissemination of knowledge in cancer care by supporting greater collaboration between research institutions and clinical providers.
- *Applying information technology to improve rural health care delivery:* Properly managed, shared clinical information systems offer huge potential for improving health care delivery. These systems would be especially beneficial in rural communities, which face shortages of health care specialists and other resource constraints. Bio 21 could support a public-private partnership to develop a shared clinical information initiative, building on the existing resources and collaborative programs across the state. One such program has been developed by INHS, which has built an integrated information system that is being used by more than 1,000 physicians in hospitals in the Spokane area. Data from this system is provided to public health agencies for assessing the health of the population and monitoring diseases on a broad scale.
- *Creating collaboration that speeds dissemination of the latest information about best practices to care givers:* The vision of a health care system in which clinicians, researchers, and patients are linked in a partnership to improve health outcomes is an exciting one. However, in today’s health care marketplace, organizations are often reluctant to share information because they view their relationship as primarily competitive rather than cooperative. If health care providers are willing to share information, they may not have the time or the infrastructure to support such an exchange. Bio 21 could facilitate the creation of a public-private partnership that will gather and disseminate information about advances in clinical care, best practices, and standards of clinical excellence through grant funding coupled with high-level community and industry support.

Strategy #3: Increase the rate at which scientific discoveries and technological advancements are turned into commercial successes

<p>Strategy #3: Increase the rate at which scientific discoveries and technological advancements are turned into commercial successes</p> <p>Bio 21 will make a significant difference in speeding scientific discoveries and advancements into the commercial pipeline by focusing on:</p> <ol style="list-style-type: none"> 1. Strengthening the environment for pre-commercial research development by: <ol style="list-style-type: none"> a. Providing resources to ensure intellectual property protection (from disclosures and patent protection to licensing); b. Providing support for proof-of-concept, pre-prototype development, and translational research; and, c. Supporting key early stage clinical trials involving institutions, providers and industry. 2. Creating a more robust environment for technology commercialization by: <ol style="list-style-type: none"> a. Supporting the creation of training programs in key gap areas, e.g. FDA regulatory affairs; and, b. Providing support in gap areas in product commercialization, e.g. pilot drug manufacturing facilities.
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The first two areas of Bio 21 investment will build the competitiveness of the state’s research enterprise, and seek to move research from the bench to the bedside. This third area focuses on ensuring that the state’s research organizations partner with industry and health care providers so that the results of investments in the first two areas move to commercialization.

Washington’s life sciences and information technology sectors already have a significant economic impact in the state. By providing researchers with proof-of-concept (validation) funding and encouraging closer industry collaboration with research institutions, Bio 21 will create a rich pipeline of innovations commercialized

in our state and spur the creation and growth of emerging companies. By focusing on areas of strategic commercial opportunity, Bio 21 is also aimed at achieving a high rate of job creation.

Each university and research institution in Washington has a technology transfer component. For the most part, such institutions are not able to provide much technology commercialization support. The Washington Technology Center (WTC) and Spokane Intercollegiate Research & Technology Institute (SIRTI) are two existing, state-funded organizations dedicated to supporting commercialization and could provide key commercialization efforts coordinated with Bio 21. One vehicle for targeting Bio 21 funds to this purpose could be the Investing in Innovation Fund previously established by the state legislature. Bio 21 would coordinate efforts with these entities to ensure that technology commercialization services are available to entrepreneurs and enterprises in the state.

Below is just one example of how proof-of-concept funding and other support for commercialization can yield positive benefits for Washington's institutions and economy:

In 1996, Lee Hood, Lee Hartwell, and a faculty member at FHCRC, Steve Friend, had an innovative vision for a new way to screen for drugs. They formed a company, Rosetta Inpharmatics, and licensed technology from UW and FHCRC to get started. In 2001, Merck acquired Rosetta Inpharmatics for \$630 million. Merck decided to maintain the Rosetta facility, located on South Lake Union in Seattle, and employs over 200 people there.

When the company was in formation, FHCRC provided approximately \$100,000 in technology development funds to enable continuation of proof-of-concept experiments while venture funding was secured. FHCRC received over \$10 million in the sale of stock when the Merck acquisition was completed.

D. Bio 21 Funding Categories

The Bio 21 program will award funding for projects in four main categories. The following sections include a recommended annual allocation of Bio 21 funds to each category once the program is fully funded and operational in 2008, along with the corresponding value of expected leverage from other sources and the combined expected program-related impact. It is recommended that the trust follow this distribution of funds among categories for the first two years of full operation. After this time, the governing board should do a comprehensive review of the Bio 21 program, including distribution of funds, to determine where the significant opportunities are for Bio 21 to make the most impact going forward.

I. Life Science & Global Health Research Awards

\$20-24 million, or 50-60% of Bio 21 funds + \$40-48 million leveraged = \$60-72 million total per year

In this category of the Bio 21 program, grants will be awarded to public institutions and their private sector collaborators for projects in the areas of predictive and preventive medicine and early detection and treatment of disease. These include diagnostics and therapeutics, medical devices and imaging, and health-related software development. We recommend that proposals in this category be evaluated through an independent, peer review process taking into account the following criteria:

- Strategic importance of the project to the relevant institution(s) and the state;
- Potential for clinical and commercial application;
- Commitment of matching funds from federal, corporate and/or philanthropic sources;
- Involvement of industry, including small and emerging companies;
- Collaboration among institutions; and,
- Potential health care efficiencies associated with the outcome of the project.

Projects involving collaboration among two or more institutions and/or health care organizations will be strongly preferred, and those that include collaboration with industry will be given preferential consideration. Priority will be given to projects with the largest commercial potential. The extent to which outside funds are committed or the potential for leveraging state dollars to obtain additional funding from outside sources will also figure prominently in the evaluation of projects submitted under the Bio 21 program. Ideally, projects awarded Bio 21 funding in this category will achieve a minimum of a 2:1 match from other funding sources, and most will be much larger.

II. Strategic Opportunity Fund

\$6-8 million, or 15-20% of Bio 21 funds + \$12-16 million leveraged = \$18-24 million total per year

This category of funding will be used to target strategic opportunities that arise which would advance Bio 21's goals. Because this is designed to take advantage of opportunities as they come up, funding decisions would be left to the discretion of the governing board of the Bio 21 trust. Examples of potential projects include competing for siting of biosciences-related federal centers and laboratories, recruiting "star" scientists, forming industry/academic/medical center consortia, and similar opportunities. Projects in this category would be subject to review both by the Trust Board and by others as required by the type of opportunity being considered.

III. Health Care Innovation Awards

\$4-6 million, or 10-15% of Bio 21 funds + \$8-12 million leveraged = \$12-18 million total per year

These awards will fund projects aimed at improving health care delivery and building the state's health care infrastructure. Strategic, targeted investments in this area will make an enormous impact in terms of

quality and efficiency of health care in Washington. Examples of the types of projects that could be eligible for funding include information sharing initiatives to improve efficiencies in the delivery of health care; the building of information networks across institutions and providers to facilitate care; and, innovative approaches to ease the dissemination of treatment protocols among providers across the state. Projects in this category would also be subject to a peer review process.

IV. Commercialization Projects

\$4-6 million, or 10-15% of Bio 21 funds + \$8-12 million leveraged = \$12-18 million total per year

This portion of the Bio 21 program will be devoted specifically to commercialization activities within institutions and among institutional-organizational-industry partnerships. This category includes funding for projects that identify promising technologies and discoveries and improve the capacity to move them through various stages and regulatory requirements to full commercialization.

Bio 21 will focus on a variety of projects that close gaps in technology transfer and commercialization support. Funding will also focus on providing the necessary technology infrastructure to support new firms and expand the product and service lines of existing firms (such as shared manufacturing facilities). Projects in this category will be subject to review both by the Trust Board and specific external groups as relevant to the type of opportunity being considered.

E. Source of Funds and Timeline

Bio 21 is envisioned as a \$450 million program funded by a combination of public and philanthropic dollars. The plan calls for the commitment of \$350 million in non-securitized strategic tobacco funds, which will be triggered in 2008, secured by a significant philanthropic contribution estimated at \$100 million total for the anticipated life of the program. The \$450 million in combined public-philanthropic funds is expected to leverage funding from outside sources 2:1. With the additional \$900 million in federal, industry and other support the total value of the investment associated with Bio 21 will be \$1.35 billion through 2017.

The Strategic Tobacco Payments

Washington is scheduled to receive approximately \$500 million from the Strategic Contribution Fund established as part of the master settlement agreement between states and the tobacco industry. Washington's share of the Fund is a bonus, added onto our master settlement allocation of approximately \$4 billion over the next 25 years. Seventy percent of the Strategic Contribution Fund is devoted to rewarding states for their leadership in the tobacco litigation and settlement negotiations, with the remaining portion distributed according to a formula. Washington's leadership in the litigation and subsequent settlement between states and the tobacco industry earned our state the highest total Fund award in the nation.

Washington will receive its first payment from the Fund in April 2008, and subsequent payments annually thereafter for ten years. Our state has already securitized a portion of those funds, roughly \$100 million, to address budgetary needs. We propose that the state commit the remainder of the bonus payments – estimated to be \$350 million – to support the Bio 21 program through FY 2017/18.

Funding Schedule

A front-end commitment of philanthropic funds, beginning in spring 2005, would enable the program to “ramp up” to initiate grant-making in 2006 and achieve full operation by 2008, when the public funds would be triggered. After 2008, the state portion would continue to be \$35 million annually through 2017, for a total public investment of \$350 million over ten years. The philanthropic contribution is projected to be reduced to \$5 million annually through 2017.

	FY 2005/06	FY 2006/07	FY 2007/08	FY 2008/09 – FY 2017/18	TOTAL
PHILANTHROPIC	\$5 M	\$20 M	\$25 M	\$5 M x 10	\$100 M
STATE	\$0	\$0	\$0	\$35 M x 10	\$350 M
SUBTOTAL	\$5 M	\$20 M	\$25 M	\$40 M x 10	\$450 M
LEVERAGE	\$10 M	\$40 M	\$50 M	\$80 M x 10	\$900 M
TOTAL	\$15 M	\$60 M	\$75 M	\$120 M x 10	\$1.35 BILLION

Implementation

Washington must focus on enacting and organizing the Bio 21 trust so that it is fully operational in all funding categories at the commencement of the strategic tobacco payments in 2008. If the authorizing legislation is approved and philanthropic support is secured during the 2005 legislative session, Bio 21

can provide its first grants in 2006 and build up to full operation over the ensuing three and a half years. This strategy allows Washington to launch its efforts in a timely manner, and means our state will not lose momentum on implementing the Bio 21 mission.

FY 2005/06	FY 2006/07	FY 2007/08	FY 2008/09 – 2017/18
<i>Philanthropic support enables ramp up of program awaiting state funds</i>			➤ Strategic tobacco payments triggered
<ul style="list-style-type: none"> ➤ Appoint governing board ➤ Hire executive staff ➤ Establish grant criteria and peer review panels ➤ Invite and award first round of research capacity grants 	<ul style="list-style-type: none"> ➤ Hire additional staff ➤ Invite and award second round of research capacity grants ➤ Invite and award first round of commercialization projects grants ➤ Invite and award first round of health care innovation grants 	<ul style="list-style-type: none"> ➤ Invite and award third round of research capacity grants ➤ Invite and award second round of commercialization projects and health care innovation grants 	<ul style="list-style-type: none"> ➤ Program fully funded and operational

F. Measures of Success

Bio 21 is a bold, ambitious program that is expected to have far-reaching impacts on Washington's economy and the health of our citizens well into the future. The return-on-investment will be accompanied by more than just dollar signs; the results of a strategic program of this magnitude, building upon the institutional and commercial assets, talent and reputation that our state has already amassed, will be to some extent immeasurable by traditional indicators. New diagnostic tools, new therapies, and new means of preventing and predicting disease are some of the outcomes that Bio 21 can help accomplish. A significant investment in our research capacity, commercialization capability and long-term competitiveness will make us an attractive center of innovation that will be a magnet for new companies, new talent and engender new collaborations and exciting possibilities that will improve the quality of life in Washington State.

While the vision of Bio 21 extends beyond that which can be measured in terms of quality of life for our citizens and potentially around the globe, a program of state-supported investment on the scale of Bio 21 will have tangible impacts on Washington's research and commercialization activity and larger economy that can be anticipated and evaluated. To aid the state in assessing the impact of the Bio 21 program, grants should entail appropriate reporting requirements for recipient institutions such as the total amount of additional funds leveraged from other sources tied to Bio 21 grant awards; patents based on Bio 21-funded projects; and, the number and types of institutions or other entities that are collaborating on Bio 21-funded projects.

To ensure accountability for the program's operation and oversight, beginning in 2010 and at regular intervals thereafter, the state should evaluate the impact of the Bio 21 program using the following measures:

A Bio 21 Opportunity in Ultrasound Technologies:

A case example of how investments in research deliver new medical technologies to Washington and the world

Provided by the Medical Devices and Imaging Subcommittee

Thanks to the breakthrough work of University of Washington bio-engineers almost 30 years ago, today Washington leads the world in the development and medical use of ultrasound imaging. Philips Medical Systems and Siemens Medical Solutions have located their ultrasound research & operations here. These companies and other smaller firms employ more than 4,000 people in our state.

Ultrasound technology is widely used for investigating and diagnosing a broad range of health conditions. Now, ultrasound promises to become a significant treatment tool. For example, UW researchers have developed the ultrasound technology to stop internal bleeding in a matter of minutes, without rushing a victim to an emergency room. The potential to save lives is enormous as people can be treated immediately at accident and crime scenes. Another example is handheld ultrasound devices that may someday take the place of the ubiquitous stethoscope. These devices detect far more accurate and robust information than stethoscopes will ever be capable of delivering. A third use of ultrasound technology currently under development is to accurately transport drugs and therapies to the parts of the body where they are most needed.

Even more exciting are the possibilities of combining ultrasound technology with work being done by Washington researchers in nanotechnology and bioresearch. It is well known that the earlier cancer is detected and treated, the higher the likelihood of success. UW bioengineers are working today to develop "smart dyes," that, when ingested, automatically find abnormal cells that could develop into early cancers, and that are only detectable using ultrasound or other imaging techniques.

Bio 21 could speed the advancement of these technologies through grants that fund prototypes and testing, and encourage collaboration between researchers in the university, the cancer research centers, medical care providers and others in the health sector. The result will be more accurate, early diagnoses and more effective therapies for all of the people in our state, and emerging companies that develop and market these life-saving tools.

Research Capacity:

- Bio 21 will leverage \$2 of additional investment for every \$1 in grants it makes, calculated as a program-wide average, with an investment of \$450 million generating \$900 million in match with an overall direct impact of \$1.35 billion by 2017.
- Overall, life sciences R&D in our state will expand from approximately \$500 million recorded in 2002 to an estimated \$1.5 billion by the end of FY 2017/18.

Entrepreneurship and Technology Commercialization:

- Washington will see an increase in institution spinoffs and startup firms in the IT and life sciences attributable to Bio 21, generating at least 50 successful new startups by 2011 and a cumulative total of 110 successful startups by 2017. These startups and other new-to-Washington firms would generate over \$1.7 billion annually in sales by 2017.

Industry Concentration and Competitiveness:

- Washington will become one of the top five states in specialization concentration in research and testing, and among the top ten states in medical devices by 2017.

Employment Creation:

- Washington will see at least 20,000 new, permanent jobs generated in the life sciences, information technology and other sectors of the state economy attributable to Bio 21 by 2017.

A significant investment in our R&D sector will open doors to new discoveries, innovative technologies and collaborations that could have an enormous impact on the health and well-being of our state's citizens. Metrics regarding the health care-related impacts and improvements to quality of life as a result of Bio 21 are extremely difficult to accurately predict and so, while important, have not been included in this strategic plan. Based upon the experience of other states, the quality of our existing institutions and companies and the focus of the program itself, Washington can reap tremendous benefits from a program of strategic investment. We recommend health impact metrics be added as the funded program areas are identified.

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VI. CALL TO ACTION

Bio 21 will require leadership and a coordinated approach among Washington's public and private sector leaders. In order to successfully implement the program and ensure the necessary funding and processes are put into place to take advantage of the unique opportunity presented to our state, it is recommended that Washington's public and private sector leadership take the following actions:

- The newly-elected Governor propose legislation for the 2005 session to implement the Bio 21 program;
- The newly-elected state Attorney General work with the new Governor on the legal construct of the program, including the commitment of the non-securitized strategic tobacco funds to this purpose;
- State government, research and industry leaders engage in discussions with the philanthropic community from now through the legislative session to secure the necessary funding support for Bio 21 pending the disbursement of tobacco-related funds;
- The state legislature approve the legislation enacting the Bio 21 program by the spring of 2005; and,
- Public and private research and industry leaders serve as resources throughout the process and help build support for Bio 21 among legislators and the public.

“Bio 21 will strengthen the partnerships among the state’s research organizations, enabling us to harness the power of science and technology for the benefit of all Washington citizens. We look forward to playing an integral role in helping advance the state’s standing as a global leader in the life sciences and information technology.”

– Dr. Len Peters, Director,
Battelle/Pacific Northwest National
Laboratory

By taking these steps, Washington will create a public-private partnership that will earn our state top-tier status as a center for research and commercialization in the life sciences and information technology, yielding far-reaching, positive impacts on our economy and the health of our citizens. With bold leadership, commitment and cooperation, Washington will realize this goal.

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APPENDIX A

State of Washington – Bio 21 Potential Impacts Model

Walt Plosila, PhD, Vice President, Technology Partnership Practice, Battelle
Martin Grueber, Program Manager, Technology Partnership Practice, Battelle

Potential Research Investments and Expenditures

- Based on Bio 21 plans, model structured around a 13 “year” horizon investing \$450 million over these years.
- Baseline bioscience-related R&D growth (NSF 2002 data and 2000-2002 current compound annual growth rate) is expected to reach \$648 million by 2005 and reach \$1.333 billion by the thirteenth year (in non-inflation adjusted dollars).
- Planned investment rate of Bio 21 proposed \$450 million will leverage additional funds at a 2:1 rate – leading to cumulative investment of \$1.350 billion over the 13 years (in addition to baseline growth).
- Total bioscience-related annual R&D should increase from approximately \$660 million in Year 1 (FY 2005/06) to \$1.453 billion in Year 13 (FY 2017/18).

Potential New Establishment and Employment Impacts

- Built around a research start-up efficiency of \$121 million in R&D generating 1 new start-up (derived using recent AUTM data for Washington), a U.S. industry bioscience industry sales per employee average of \$275,000, and an estimate of increasing relocation attractiveness of each \$250 million of R&D attracting 1 new company to the state (however, company size is conservatively figured as small).
- At this efficiency base-level research and its growth should lead to 102 new companies over the 13 year period. The additional Bio 21 investments should lead to an additional 11 start-ups over the 13 years, leading to a combined total of 113 new bioscience start-ups over the course of the initiative.
- Employment for each of these start-ups ramps up over time, ultimately generating over 3,300 new jobs by Year 13.
- Attractions/relocations will range from 2-5 per year with cumulative employment within these new to Washington firms reaching over 3,050 jobs by Year 13.
- These start-ups and other new to Washington firms can potentially generate over \$1.7 billion annually in sales in Year 13.
- Cumulative direct bioscience employment will reach nearly 6,370 jobs by Year 13.

- Additionally, using a U.S. derived bioscience employment multiplier of 2.15 ***additional*** in-direct and induced jobs for every new bioscience job yields an additional nearly 13,700 jobs in the Washington regional economy.
- The combined employment impact of continued bioscience R&D growth, enhanced through the Bio 21 initiative can potentially generate over 20,000 new jobs (bioscience-related and others) over the 13 years of the initiative.

Washington Bioscience Development -- Potential Bio 21 Impacts Model

Annual Investments/Resource Amounts in \$Millions

Strategy	Notes	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Year 11	Year 12	Year 13	
		FY 2005/06	FY 2006/07	FY 2007/08	FY 2008/09	FY 2009/10	FY 2010/11	FY 2011/12	FY 2012/13	FY 2013/14	FY 2014/15	FY 2015/16	FY 2016/17	FY 2017/18	
Philanthropic Investment		5.000	20.000	25.000	5.000	5.000	5.000	5.000	5.000	5.000	5.000	5.000	5.000	5.000	
Strategic Tobacco Settlement Investments		0.000	0.000	0.000	35.000	35.000	35.000	35.000	35.000	35.000	35.000	35.000	35.000	35.000	
Total Bio 21 Investments		5.000	20.000	25.000	40.000	40.000	40.000	40.000	40.000	40.000	40.000	40.000	40.000	40.000	
Total Bio 21 Research Investments in Washington Bioscience Efforts (\$ millions, leveraged 2:1 with additional funds)															
Annual Investments in \$M		15.000	60.000	75.000	120.000	120.000	120.000	120.000	120.000	120.000	120.000	120.000	120.000	120.000	
Baseline Washington Bioscience Institutional Research Funding (\$ millions, projections from Battelle calculations based on 2000-2002 CAGR of State of Washington's Institutional Life Science R&D Expenditures - from NSF)															
Regional Research Institutions Cluster Relevant R&D		0.062	647.805	687.964	730.612	775.905	824.005	875.087	929.336	986.948	1,048.131	1,113.107	1,182.111	1,255.393	1,333.218
Total Regional Research Investments															
Washington Institutional and Related R&D, and Programmatic Investments		662.805	747.964	805.612	895.905	944.005	995.087	1,049.336	1,106.948	1,168.131	1,233.107	1,302.111	1,375.393	1,453.218	
Research-based start-up efficiency (\$M per Start-up)		121.33	121.33	121.33	121.33	121.33	121.33	121.33	121.33	121.33	121.33	121.33	121.33	121.33	
Employment - Results of Bio 21 Research Efforts															
Start-up Firms															
From base-level Washington research funds		5	6	6	6	7	7	8	8	9	9	10	10	11	
From additional leveraged research funds		0	0	1	1	1	1	1	1	1	1	1	1	1	
Annual Totals		5	6	7	7	8	8	9	9	10	10	11	11	12	
Cumulative Start-ups		5	11	18	25	33	41	50	59	69	79	90	101	113	
Sales Progression Forecast		0.200	0.400	0.800	1.400	2.000	5.000	8.000	12.000	16.000	20.000	21.000	22.000	23.000	
Projected Sales from Start-ups		1.000	3.200	7.800	16.000	28.400	57.200	105.200	180.000	283.000	417.800	567.600	733.000	909.000	
Projected Total Employment from Start-ups	sales of \$275K per person	4	12	28	58	103	208	383	655	1,029	1,519	2,064	2,665	3,305	
Relocations															
Annual Totals	\$250M research attracts one company	2	2	3	3	3	3	4	4	4	4	5	5	5	
Cumulative Relocations		2	4	7	10	13	16	20	24	28	32	37	42	47	
Sales Progression Forecast		0.800	1.400	2.000	5.000	8.000	12.000	16.000	20.000	35.000	50.000	51.000	52.000	53.000	
Projected Sales from Relocations		1.600	4.400	9.200	20.600	38.600	67.600	108.400	161.800	249.800	374.800	516.600	677.000	842.000	
Projected Total Employment from Relocations	sales of \$275K per person	6	16	33	75	140	246	394	588	908	1,363	1,879	2,462	3,062	
Cumulative In-direct and Induced "Multiplier-Effect" Impacts															
Multiplier of Increased Bioscience Employment (2.15 for Cumulative In-Direct/Induced)		2.150	22	60	131	286	522	976	1,671	2,672	4,165	6,196	8,477	11,023	13,689
Total Additional New Employment															
Total Bio 21-Related Private Sector Regional Employment		32	88	192	419	765	1,430	2,448	3,915	6,102	9,078	12,420	16,150	20,056	

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APPENDIX B

Opportunities for Washington State Leadership in Biotechnology: Preventive and Predictive Medicine

Report of the Bio 21 Diagnostics and Therapeutics Subcommittee

October 6, 2004

The diagnostics and therapeutics industries are at a crossroads concerning how best to address the revolutionary changes brought on by the unlocking of the human genome. The opportunities are enormous: if we can determine individuals at risk, identify disease early, and treat it in a manner that is unique to the specific characteristics of the individual, the health of all of our citizens will be enhanced dramatically. The medicine of the future will be predictive and preventive, looking into the biology of an individual to gauge the probability of disease and suggest appropriate treatments. It will also be much more personalized, because we will have the ability to tailor treatments to individual biological profiles.

The first phase of this new era of predictive and preventive medicine will begin with early detection. New diagnostics will allow us to detect and treat a disease such as cancer when a tumor consists of only a few cells. This ability for early detection and early treatment means that millions of lives can be saved and treatment costs can be dramatically reduced.

Because of the pioneering work being done at the Fred Hutchinson Cancer Research Center, the Institute for Systems Biology, the University of Washington School of Medicine, Pacific Northwest National Laboratory, Washington State University, and their partners, Washington state is well positioned to become the global center for this emerging field of predictive and preventive medicine. However, there are enormous challenges ahead and our success will depend on our ability to invest in the future.

For Bio 21 to have a material statewide impact, Washington must direct financial resources to those areas where the state can enhance, develop, and maintain a distinctive competence. Much of the research to build this plan looked at the experience of other states, market forces and our own strengths and gaps to illuminate the investments with the greatest potential for significant, long-term economic and health impacts. A third-party study identified the following three areas of research and development where the potential markets are substantial; where Washington has considerable expertise and comparative advantage; and where applied research can quickly lead to commercial applications. We recommend that the Bio 21 trust focus on these three high impact areas for at least its first five years.

- a. Diagnosing and treating disease: This area focuses on the application of the biological sciences to the creation of new drugs and diagnostics, including plant and animal research with human health implications.
- b. Medical devices and imaging: This area includes bioengineering, nanotechnology, and the application of computer and information technology to biological research.
- c. Software used in clinical settings: This area focuses on advanced information systems which increase efficiencies, lower health care costs, and rapidly translate new discoveries into clinical practice.

The challenge is all of these areas are daunting. Success in this new arena requires coordination of research in ways that are foreign to current academic collaborations and industry arrangements. What is needed is the coordination of research and industry in the areas of data standards, reagents, and tissues, informatics and technology platforms, and a community of collaboration that permits sharing of data and a systematic “divide and conquer” approach. The traditional approach of funding academic investigators for small research projects and then licensing their discoveries to industry for further development is ineffective in this new environment.

Leaders in academia and industry are addressing these issues by forming strategic partnerships. Because of the cost of these types of arrangements, biotech and pharmaceutical companies are making bets on a few institutions and building strong relationships rather than being ecumenical and working with a broad spectrum of organizations.

Only a few regions have the capacity to be leaders in the revolution. The Pacific Northwest has the opportunity to lead in the area of molecular diagnostics. This opportunity is based upon leadership of individuals and institutions in the region.

- Lee Hood has been a champion of preventive, predictive medicine for over a decade, and is an established national leader and spokesperson. Hood and his colleagues at the Institute for Systems Biology have led in technology development of a new field called proteomics, which searches for markers of disease in bodily fluids. They are known world wide for their work in this area. Additionally, the Institute has formed a Nanotechnology Alliance with a team of scientists at Caltech and UCLA to develop simple and inexpensive blood diagnostic tools that will enable early detection of treatment of a wide array of diseases.
- Lee Hartwell is a national leader and spokesperson advocating for early detection of cancer as the best hope for reducing the number of cancer deaths. At the request of the National Cancer Advisory Board (which reports to the President) he is working with Eric Lander from the Broad Institute at MIT on a strategic plan to ensure that our nation is a leader in this emerging field. Fred Hutchinson has made early detection and intervention a key scientific strategy. The Center recently recruited new program heads in molecular diagnostics and computational biology and is a recipient of a new biotechnology discovery initiative grant from the National Cancer Institute. Fred Hutchinson’s cancer prevention and early detection program is the largest in the world, with more than 50 investigators working in this area.
- University of Washington has been a world leader in genomics and proteomics basic sciences for a long time. In addition, they have enormous strength in bioengineering and computing, which are essential disciplines in the development of these new technologies. The University of Washington and Fred Hutchinson both include a focus in their clinical research in cancer on early intervention and vaccines. The University is also a leader in molecular, animal and human imaging. Diagnostic imaging is an essential tool in preventing disease and predicting the most effective therapies. UW has over 100 faculty working in their various departments on these problems.
- Pacific Northwest National Laboratory has developed essential technologies in separations, mass spectrometry, imaging and related computing resources that no other institution can match. Richard Smith has developed and implemented unique ultra-high sensitivity and high throughput proteomics and metabolomics capabilities that enable new applications in preventative medicine. PNNL is presently planning the development of a large new facility to provide regional access to high throughput technologies for biological research as part of its long-term commitment to increase systems biology research at PNNL.

All of these organizations and individuals have been working together for the past five years, building on the strengths of each organization and collaborating to secure grants and philanthropy to demonstrate to industry, the federal government, and foreign governments, that Seattle is the place to invest if you want to partner in the effort to prevent and predict disease more effectively.

Several industry groups have expressed interest in participation in these efforts. Fred Hutchinson is exploring the potential for an academic/industry consortium with several pharmaceutical and biotechnology companies. The Institute for Systems Biology has numerous partnerships with industry and academia and has established a biotechnology incubator in Seattle with three of the most prominent biotech venture capital companies in the US to commercialize early stage companies. The University of Washington has a long history of relationships with industry in part through its university-industry cooperative research programs, including the UW Engineered Biomaterials corporate affiliates program, the longstanding Center for Process Analytical Chemistry, and the Technology Access Program in computer science and engineering, which provides its industrial members with first access to new software developments. Pacific Northwest National Laboratory (operated by Battelle Memorial Institute) has a long and successful record of technology commercialization and partnering with private industry. There are several local firms that also will be important players in the new order, including Merck, Amgen, Microsoft, Corixa, Zymogenetics, and others.

Finally, the importance of this focus area on the region's international relations cannot be underestimated. Governments and corporations in China, South Korea, Singapore, Malaysia and Taiwan have all decided that molecular diagnostics is key to their futures and they are partnering with research institutions such as Fred Hutchinson and University of Washington in this area.

Progress in making our region a powerhouse in molecular diagnostics depends upon the investment of resources. Fred Hutchinson's recent experience in development of the Early Detection and Intervention Initiative is instructive and will be used here as an example of the importance of this investment. When the initiative was in its early stages, the Center sought philanthropic support to recruit faculty, invest in infrastructure, and develop pilot data. The Allen Foundation and Keck Foundation committed several million dollars to this effort. In addition, a private donor, Don Listwin, committed \$13M over five years from his family foundation to the effort. These funds are being used in the following manner:

- Development of technology platforms needed to apply for collaborative grants across various institutions
- Development of data base standards and architectures for data sharing across institutions world-wide
- Development of tissue specimen standards for collection and storage
- Recruitment of investigators in disciplines needed for the initiative
- Equipping labs with mass spectrometry and other instruments needed for federal grants that could not be funded through the grants;
- Altering space to accommodate successful grant applications
- Committing to institutional support for foundation grants that don't cover the full costs of the projects
- Developing pilot data that can be used to demonstrate proof of concept so outside funding can be obtained
- Symposium to discuss academic/industry partnerships and how intellectual property issues can be addressed.

Without the efforts of the Listwin Family Foundation, the Allen Foundation and the Keck Foundation, much of the rapid progress that Fred Hutchinson has made in early detection would not have been possible. In addition, over \$25M in new grants will be received over the next three years as a result of these investments. Most of this revenue will pay salaries for new jobs created as a result of these grants. These jobs will be located in Seattle and in Richland.

As indicated above, convincing companies to invest in this region will require availability of capital investment. Decision making for these types of investments has to be straightforward and within a reasonable time frame. None of the institutions mentioned has readily available capital at the levels that will be needed. Statewide commitment will be essential.

In 1996, Lee Hood, Lee Hartwell and a faculty member at Fred Hutchinson, Steve Friend, had an innovative vision for a new way to screen for drugs. They formed a company, Rosetta Inpharmatics, and licensed technology from UW and Fred Hutchinson to get started. In 2001, Merck acquired Rosetta Inpharmatics for \$630M. Merck decided to maintain the Rosetta facility on Lake Union and employs over 200 employees there.

When the company was in formation, Fred Hutchinson provided approximately \$100,000 in technology development funds to enable continuation of proof of concept experiments while venture funding was secured. Without this \$100,000, the company would most likely not have moved forward.

There are several other examples of how small investments have had major payoffs. Funds in Fred Hutchinson's New Technology Development Fund (partially supported by Washington Research Foundation) provided \$150,000 to an investigator to obtain marketing approval from FDA for a new lupus assay. This assay is being developed by a California company, IDDI and represents the first new lupus test in over a decade. The fund is also supporting work on a new anticancer agent at the level of \$275,000 with the goal of licensing the new technology to a pharma company. Center funds have also been expended in seed funding for a new technology that has the potential to extend the shelf life of platelets and other tissues. Unfortunately, research organizations can only fund a few of these types of projects per year, and most discoveries do not move forward because technology funds are not available.

At present, novel diagnostics, therapeutics and reagents are under development at all of Washington State's major research institutions. New panels of diagnostics are under development for ovarian cancer. New reagents that can help imagers identify tumors at very early stages have been identified. New software that serves as a tool to evaluate proteomics and genomics data has been developed. New techniques that enable physicians to identify very early cancer of the esophagus when it is curable, and early relapse of leukemia when it is treatable, are ready for nationwide clinical trials. However, many of these diseases are relatively rare and pharma and biotech companies will not invest in them unless they are a sure bet. Without investment, the discoveries are unlikely to lead to new companies that provide patient benefit and new jobs for Washington state citizens.

Washington State is blessed with incomparable beauty and forward thinking civic leaders. It has been able to attract the best and brightest minds in science. Whether we have the collective will to make investments to retain these scientists and to support their efforts to revolutionize medicine remains to be seen. All of us have a major stake in this decision.

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APPENDIX C

Final Report to the Bio 21 Steering Committee from the Patient Outcomes Subcommittee

August 20, 2004

Introduction

Bio 21 is a bold public-private program that will make catalyzing grants over a 10 to 15-year period that support research and commercialization activities at the intersection of the biological and computer sciences. The program focuses on areas that have significant market and health-related potential, in which Washington already has considerable expertise, and where investments can lead quickly to commercial application, including:

- Expanding research capacity, leading to breakthrough discoveries with clinical application and commercial potential,
- Creating, attracting, and retaining high-growth companies by supporting and encouraging innovations that can be commercialized in Washington, and
- Advancing innovations in clinical practice that improve the health of the residents of the State by:
 - Improving the efficiency of our health care delivery systems, and
 - Significantly advancing the quality of health care for the citizens of Washington.

Bio 21 is an exciting opportunity for economic development and health care improvement. However, to achieve the potential gains in health outcomes, Bio 21 will need to address fundamental health system issues that affect our many outstanding health care institutions in Washington. This is both a challenge and an enormous opportunity: a challenge because these issues are difficult and endemic, and an opportunity because the potential impact of Bio 21 to serve as a catalyst for change and improvement in the health care system could reach well beyond our state's borders.

Systemic Health Care Delivery Issues

In considering how Bio 21 could truly improve health care outcomes of the citizens of Washington State, it is important to understand the key systemic issues we face. First, health care delivery is fragmented and inefficient. This fragmentation of care generates duplicate and unnecessary services and expenses, and creates gaps and delays in care. One study by the Midwest Business Group on Health estimates that 1/3 of all health care expenses are the result of administrative inefficiencies, overuse, underuse, and misuse of medical services. Furthermore, much care is episodic and patients and providers are often not connected in a way that fosters coordinated care. The lack of shared clinical information makes it very difficult to ensure that high-quality, safe care is consistently delivered and inhibits valuable health services research.

Additionally, at a time when medical knowledge and technology are advancing at an unprecedented rate, it is often difficult for physicians to incorporate these advances into their clinical practices. Many physicians are so overwhelmed by the day-to-day demands of seeing patients and handling paperwork that they have difficulty remaining current with the latest knowledge in clinical practice. They also may not have time to critically evaluate new therapies that may have limited efficacy, or they may be inundated with too much contradictory information about diagnostic and therapeutic strategies to know what actions to take.

Improving Patient Outcomes

Given these realities, we believe that Bio 21 could have a far-reaching impact on health care in Washington by focusing on the following five areas:

1. Facilitating the rapid translation of new discoveries and knowledge into clinical practice through stronger linkages between research and delivery systems
2. Stimulating the development of collaborative information technology strategies that improve health care outcomes and reduce waste in the health care system
3. Strengthening research and investment in the prevention and early detection of disease.
4. Encouraging the development of a public-private partnership that would foster collaboration throughout the health care sector and build the delivery system infrastructure that would improve patient outcomes and reduce health care costs.
5. Fostering delivery system innovations that address the needs and desires of our aging population.

In the following sections, we discuss each of these priorities, providing examples of current research or projects that could serve as models for the types of investments Bio 21 could make.

1. Facilitating Stronger Linkages Between Research and Health Care Delivery

Researchers and clinicians often work in separate worlds with limited direct communications with one another. This isolation slows the transfer of knowledge that could improve clinical practice and inhibits feedback from the field that could be beneficial to researchers. Strengthening the connections between the biotech/research community and health care providers could have widespread positive effects throughout this state. It could strengthen the biotech industry by accelerating the adoption of new products and services and by reducing the cost of data acquisition. It could simultaneously improve the health delivery system by introducing more effective clinical modalities and techniques into medical practice.

A critical priority for system improvement is developing new mechanisms that facilitate the transfer of the latest information about the most efficacious treatment options, promising new protocols, and/or guidelines for effective clinical care from researchers to clinicians. An example of the type of program that has been successful in disseminating knowledge is the State Department of Health's Diabetes Collaborative. The Collaborative teaches providers throughout the community about the most effective treatment strategies for diabetes patients. It also enables providers to learn about patient education and patient management techniques from one another. Through the use of improved technologies to monitor and administer medications, diabetes patients are more involved in self-care than ever before, and are able to live more independent, productive lives. Bio 21 could stimulate the development of additional collaborative arrangements that increase information sharing among researchers and providers.

Another area where Bio 21 could make a difference is in speeding the dissemination of knowledge in cancer care by fostering greater collaboration between research institutions and clinical providers. Clinical researchers at the Fred Hutchinson Cancer Research Center and the University of Washington have developed important new protocols for the treatment of breast cancer. These protocols provide more effective treatment of cancer and lead to better patient outcomes. Through the collaboration between the Seattle Cancer Care Alliance and Group Health Cooperative these treatment protocols are now available to a growing number of patients around the State. However, there are many patients who do not yet have access to these improved methods of care.

A third area for fostering linkages between researchers and clinicians is in connecting patients to clinical trials. Clinical trials enable researchers to test the efficacy of new treatment protocols and/or medications. They are critically important in transferring knowledge from the laboratory to the patient-care setting. Patients who participate in clinical trials can benefit from new treatments that might be more efficacious, and clinicians can gain new knowledge, while helping their patients. However, clinical trials are costly to support, and physicians are often unable or unwilling to enroll their patients in clinical trials because they

are time-consuming. Physicians also may be less interested in the outcomes of the research if they feel that current treatment approaches are sufficiently effective. Bio 21 could stimulate new collaborations and linkages that enable researchers to conduct clinical trials and that facilitate patient and clinician participation in the trials.

2. Using Health Care Informatics to Improve Clinical Quality, Efficiency, Effectiveness, and Safety

The health care system in the United States is inefficient, and one of the greatest sources of this inefficiency is the fragmentation of clinical information. The lack of timely, accurate clinical information often leads to duplicate, unnecessary tests and services, and contributes to costly misdiagnoses. The lack of shared clinical information systems also makes it more difficult to evaluate quality of care and to identify opportunities to improve clinical practice.

Properly managed, shared clinical information systems offer huge potential for improving health care delivery in this state. These systems would be especially beneficial in rural communities, which face shortages of health care specialists and other resource constraints. Bio 21 could help develop new information-sharing strategies that allow patients to receive accurate, appropriate care regardless of location, thus reducing unnecessary tests and inaccurate diagnoses. These shared information strategies would also enhance the ability of physicians and patients to manage chronic care more efficiently and with better clinical outcomes. Additionally, shared information systems could increase the ability of researchers to conduct population-based, longitudinal research. Population-based studies could help determine why some conditions or diseases affect certain populations more than others, and could test the long-term benefits of different drugs, treatments and therapies.

Bio 21 could support a public-private partnership to develop a shared clinical information initiative, building on the existing resources and collaborative programs across the State. One such program has been developed by Inland Northwest Health Services (INHS), a non-profit shared service organization, which has built an integrated information system that is being used by more than 1,000 physicians in hospitals in the Spokane area. Data from this system is provided to public health agencies for assessing the health of the population and monitoring diseases on a broad scale.

The INHS information system also enhances the value of its telehealth network, a telephone-based service that improves the delivery of care and patient safety in rural hospitals. INHS currently links 32 hospitals in Washington, Idaho, Oregon, and Montana in its integrated information system and 44 hospitals and clinics through its telemedicine network. But, INHS's program is only the beginning. These types of integrated information and telemedicine systems could form the foundation of a network that links research institutions and providers throughout the Region.

Our current health care delivery system has many hurdles blocking the way for health providers and researchers to share information. Bio 21 could foster the creation of a shared policy framework that supports the safe, fluid exchange of information among health providers and researchers. OneHealthPort, a company that was formed by a coalition of health insurer and provider organizations, has created a trusted community for the secure exchange of health information. OneHealthPort provides 4,000 health care organizations and 7,000 individual users with common digital credentials, information sharing agreements and single sign-on throughout the community.

Bio 21 could support a similar model for exchanging information between the clinical and research communities. The framework could facilitate common registration processes for clinical trials, data exchange agreements, non-disclosure agreements, and consent forms that would have wide-ranging impact. By developing a shared policy framework and utilizing integrated information systems and the World Wide Web, researchers and clinicians could collaborate more freely and efficiently to improve health outcomes.

3. Investing in Early Detection and Prevention

Many Washington residents suffer from diseases such as cancer and diabetes that can be significantly affected by early detection and treatment. Bio 21 could stimulate advances in early detection and prevention that would have a dramatic positive impact on the health of the population. Washington State has a strong research core in genomics, proteomics, and advanced imaging technologies that can lead to advances in early disease detection and treatment. We know, for example, that early detection of cancer significantly increases survival rates for most types of cancer patients, especially those with breast or colorectal cancer. Researchers at the University of Washington and the Fred Hutchinson Cancer Research Center (FHCRC) are learning more about genetic markers that indicate a predisposition for certain cancers or other congenital conditions. This information can help clinicians detect and treat health problems in an early pre-symptomatic stage.

Additionally, successful interventions in reducing smoking and obesity could have enormous benefits for patients and could generate significant cost savings for the health care system that could be reinvested into our systems. Washington State already has a very strong research base in epidemiology and population studies. Enterprises such as the FHCRC Public Health Sciences Division, the UW School of Public Health, and Group Health Cooperative's Center for Health Studies are at the forefront of exploring the effectiveness of prevention strategies across diverse populations. The intersection of advances in information technology and strong population-based research gives Washington a unique opportunity through Bio 21 to be a world leader in population-based health improvement.

4. Creating a "Switzerland" for Collaboration

The vision of a health care system in which clinicians, researchers, and patients are linked in a partnership to improve health outcomes is an exciting one. However, there is currently no state-wide structure or organization to achieve that vision. In today's health care marketplace, organizations are often reluctant to share information because they view their relationship as primarily competitive rather than cooperative. Even if health care providers are willing to share information, they may not have the time or the infrastructure to support such an exchange. Consequently, there is a need for a public-private partnership that will gather and disseminate information about advances in clinical care, best practices, and standards of clinical excellence.

There is also a need to create a "safe harbor" for clinical information sharing. It is unlikely in the near term that all providers could be linked in a single state-wide clinical information system. However, as INHS has demonstrated, it is possible to link multiple providers into a shared information network. There are a number of infrastructure elements, such as secure mechanisms for information exchange and standardized terminology, which would need to be in place to build such a network. INHS, OneHealthPort, the Forum, and HiNet are among the organizations in the state that are positioned to serve as leaders in developing collaboration among providers throughout Washington.

Bio 21 could provide the necessary seed funding and high-level community and industry support to create the types of public-private partnerships that will be needed to improve clinical practice and to build networked clinical information systems. Facilitating this development of a public-private partnership that helps build the infrastructure to support clinical information sharing and knowledge transfer could be one of the most important investments Bio 21 could make.

5. Other Opportunities

Finally, there are other emerging opportunities that may translate advances in the life sciences into improvements in health care delivery and better health outcomes. For example, developments in medical devices and nanotechnology may facilitate the ability of patients to be cared for in home settings or through supervised self-care. The non-profit Northwest Kidney Centers have pioneered using new advances in kidney dialysis to develop one of the nation's first home dialysis programs. Home dialysis can provide patients with safe, cost-effective care that increases their role in their treatment and supports greater patient independence. The emergence of a new generation of health care consumers who want to

be more actively involved in their own care creates additional opportunities to develop technologies that engage patients in chronic care management. Bio 21 could help stimulate linkages between the research/biotech sector and the clinical care community to capitalize on these new opportunities to serve health care consumers.

Conclusion

Washington State has a great opportunity to become a hub for advances in life sciences. Bio 21 can serve as an important catalyst for stimulating development in the research and biotechnology sector. It can also leverage the State's unique assets in computer and biological sciences into significant improvements in health outcomes for the citizens of the State. Bio 21 should focus on key investments that foster collaboration and facilitate the transfer of new knowledge, ideas, and information across the research, biotech, and clinical communities. We believe Bio 21 could make a significant difference in the future health of the people of this state.

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APPENDIX D

The Need for Early Stage "Seed" Funding for Emerging Biotech and Related Technology Companies in Washington State and Recommendations for Action

*A Report to the Bio 21 Steering Committee from Seed Funding Subcommittee Chairs
Steve Yentzer and Lura Powell*

Washington's Challenge

Washington's economy is changing in fundamental ways and we are now part of a rapidly transforming global economy. All sectors of our state economy are becoming increasingly reliant on research and technology to succeed in the competitive, global marketplace, and innovation is key to future economic success. Other states are facing the same difficulties as Washington – structural economic shifts and increasing global competition – and are moving aggressively to position their economies for the future. The competition, in fact, is not only with other states but other nations. (Michigan, North Carolina, New York, Florida, Arizona, Singapore, Australia, Malaysia and Sweden, to name a few, have all launched major government-funded research initiatives.)

Washington has amassed considerable strength in the life sciences, information technology, and other sectors, boasting world-class research institutions, both public and private, and world-renowned scientists and companies. We cannot underestimate the importance of this strength to the future of our state. Washington's current enviable position has been achieved without significant state involvement; our state ranks 46th out of 50 states in state government spending on R&D on a per capita basis. With others devoting considerable resources to try to achieve success in the life sciences and other high-tech sectors, however, Washington can no longer afford to ignore this competitive environment.

Bio 21 is designed to address this shortcoming. Using \$350 million of strategic tobacco payments that accrue to the state due to our leadership in the tobacco litigation, combined with an additional \$100 million from private sources, Bio 21 is expected to leverage, at a minimum, an additional \$900 million from other sources for a combined impact of \$1.35 billion directed to research and commercialization activities in the life sciences and information technology sectors in our state. Life sciences research and development alone is projected to triple as a result of Bio 21 investments, from \$443 million at the end of fiscal year 2005-06 to \$1.5 billion by the end of FY 2017-18. The results for our state, in terms of additional, leveraged investments, research expansion, and job and company creation and attraction, will be significant and widespread. (See the full Bio 21 report for additional details about its impact.)

With more than \$1 billion in new discoveries and technologies in the marketplace, Washington needs a parallel strategy to grow the new companies that will be formed from this enormous gain in activity. Although the success of these new companies will depend on many factors, access to capital is one critical component.

The Bio 21 Seed Funding Subcommittee

During development of the Phase I Bio 21 report in January 2004, questions arose surrounding the availability of capital for investment in early-stage companies, and whether the state and/or Bio 21 should play a role in this area. It was determined early on that one important element of the seed funding challenge could be addressed by Bio 21, and in fact, state funds could be used for this purpose – proof-of-concept funding. "Proof-of-concept" is defined as relatively small amounts of investment that can be made to projects within approved research institutions that could catalyze technology transfer and in turn commercialization opportunities. The challenge, though, is that even if Bio 21 does undertake such proof

of concept funding, without further investment capacity in the state, many important and potentially financially and economically feasible projects would be still-born. This led to Bio 21 agreeing to undertake a deeper look into this next phase of the funding continuum.

The Bio 21 Steering Committee formed a subcommittee to look into this issue during the second phase of this undertaking. Recognizing that capital investment into early stage companies is an important engine for growth for the biotech sector, the Bio 21 Seed Funding Subcommittee set out to 1) determine whether there is a need for early stage "seed" funding for emerging biotech and related technology companies in Washington and, 2) if so, how the state should address that need. Subcommittee members included leading venture capitalists that focus investments in the biotech sector, key representatives from biotech companies, the Washington State Investment Board, and others.

This report presents the findings and recommendations of this subcommittee. It provides a snapshot of the broad range of views surrounding early stage seed funding for biotech companies, and concludes that the state would benefit from additional private/public sector collaboration, including development of a fund-of-funds devoted to investing in early stage biotech and related companies.

In order to get a clear picture of the situation, the subcommittee solicited written comments from a number of perspectives including the local venture capital community, local biotech companies, and organizations involved in supporting and promoting technology transfer and early commercialization efforts. Additionally, the subcommittee commissioned a study from Dr. Walt Plosila, Vice President, Technology Partnership Practice at Battelle, who has extensive knowledge of state bioscience strategies. His paper examined approaches that various states and regions have taken to address funding needs in the convergence space of life sciences and related technology. It also included a list of the elements that must be addressed in pre-seed and seed financing for biotech and related technology firms. Finally, the subcommittee considered the experience of several states and the applicability of their programs to Washington State.

Throughout our analysis, we kept in mind one very important lesson from other states: fundamental to a robust technology sector is the availability of investment funding for young companies at every stage of development, from pre-seed, to seed, and on to later-stage investment rounds. States are recognizing this and designing many different approaches to address these many stages.

Those that fail to act are at a significant disadvantage for attracting the best and most capable innovators in the country. The Seed Funding Subcommittee focused on the needs of early stage companies that require funding for initial development of higher risk technologies because this is the critical step to growing and developing a healthy biotech community. This is the time when limited federal research funding is available, but before traditional funding sources are in strong supply. This time is also known as the "Valley of Death" because just as cash needs increase, entrepreneurs have few sources to go to for funding.

The "Valley of Death" Problem

Early stage funding for emerging technology companies is nearly always in scarce supply, but most particularly for life science companies because their capital needs are usually larger than other technology businesses and it takes many years for them to bring a product to market. For example, in the case of a therapeutic drug, the average time to market is fifteen years. Estimates of the fully burdened cost to bring a new pharmaceutical to market are as high as \$1.6 billion. The costs associated with building and maintaining laboratories and workforce-related expenses are extremely high compared to other technologies, and the FDA approval process adds years and millions of dollars to product development costs. Most life science firms find that the early period, when their technologies are unproven and cash is critical, is the most difficult in which to raise funding because the company is at the highest risk stage for investors. The solution, as Walt Plosila explains, is complex:

Venture capital firms may be willing to take these risks with management teams they regard as proven and markets they see as sufficiently attractive. However, in most regions outside

California and Massachusetts, many deals that might actually turn out to be worthy investments never get visibility before sources of investment willing to take that early stage risk....{A} bioscience company can consume an enormous amount of capital, which cannot easily be assembled by "friends and family," or even angel investors. In fact, a combination of multiple techniques may be necessary to get promising venture through the valley [of Death]. The challenge is to assemble a diversity of sources willing to take these very early-stage risks but subject to sufficient market discipline that one can avoid needlessly wasting public, philanthropic, or investor resources.

Of course, it is important to note that in previous years local high quality teams did attract investor attention and life science companies like Immunex (purchased by Amgen in 2000 for \$16 billion) and Icos (with a current market cap of \$1.6 billion) are the result. Together, these two companies employ over 1,500 people in the state of Washington.

The state of our local venture capital community

In order to determine whether there is a need for early stage "seed" funding for emerging biotech companies in Washington, the subcommittee began by examining our own venture capital (VC) community. In the last decade, the local VC community grew considerably. Additionally, a number of national level venture capital firms opened regional offices in the state. With the burst of the dot com bubble in early 2000, however, this growth substantially reversed and many national firms closed their local offices.

That being said, many would argue that Washington has come out the other side of the bubble with a stronger VC community than before—measured not just by dollars but by willingness across the board to build the community, syndicate investments and share the burdens, risks, and rewards. We are fortunate to have three very experienced funds with headquarters or local offices here whose focus is all or in part in the life science space: Frazier Healthcare; Arch Venture Partners and Polaris Venture Partners. All three funds have substantial amounts of committed capital and none shy from early stage investments if a company's management team and other factors so warrant. Additionally, OVP Venture Partners, another local VC with substantial capital, and Vulcan Capital, the private investment arm of Paul Allen, have experience in these areas. On a smaller scale, early stage investment firms like WRF Capital, Integra Capital and Pacific Horizon Ventures actively continue to seed transactions in this area. In fact, WRF Capital has investments in 14 Washington-based biotech companies.

Angel investors tend to shy away from companies that need large amounts of capital and long lead times before releasing a product, so their appetite for investing in life science companies is very limited. The Alliance of Angels, the largest local group of angel investors, which has deep experience and history in the software and wireless technology community and some investors with experience in medical devices, has few members from the diagnostics and therapeutics sector of biotech. Generally, the local biotech angel community is much smaller and is not organized into investing groups.

Two biotech incubator groups have recently been formed--specifically Scout and Accelerator Corporation--to provide cost-effective space and support services along with equity financing to help nurture early stage companies. Scout was supported primarily through initial backing by MPM Ventures from Silicon Valley and Accelerator Corporation was formed in partnership between three major funds, MPM, Versant, and Arch Ventures. Both have had mixed success to date. Also, many individual investors who backed the substantial venture capital fund growth in the late 1990s have retreated from venture capital. As a result, venture capital funds have returned to traditional institutional funding sources for their base. It is important to note that many of these institutions, themselves faced with substantial venture losses in recent years, have limited the percentage of their investments in emerging managers.

As a result, a smaller number of investors are now focusing on the life sciences market, and larger funds like Frazier, Arch, and Polaris are left to address the needs of the early stage investment opportunities. To manage the risk inherent in earlier stage investments, the larger funds often syndicate these (even

smaller early stage investments) with larger funds in other markets. Thus, as a growing number of companies seek capital from fewer funds, they may find it more difficult to attract investor attention.

Washington companies are not alone in experiencing this growing competition for attention. According to a recent article from *BioCentury*, an industry newsletter, San Diego companies are experiencing the same condition.

San Diego has been heralded as one of the nation's magnet biotech centers. Some industry watchers have even ranked the cluster above Boston/Cambridge and San Francisco Bay Area in terms of its attractiveness as a place to do biotech. But, according to a 2003 survey commissioned by BIOCUM, San Diego's biotech industry organization, the majority of CEOs in the cluster say they are starving for capital because they must compete with companies in other clusters for funding from investors located far from the city .

Beyond increased competition for attention, is there truly a financing gap in our market for early stage or seed funding of biotech companies?

There is widespread agreement from both companies and VCs that this increased competition for attention is creating a financing gap that is certainly perceived by the companies seeking funding. The subcommittee wanted to understand how extensive the gap is.

The following table looks at both the number of biotechnology venture capital investments by stage of financing, and the percentage funded at each stage. The data is compared for two time periods: during the "boom period" for biotech growth (1996-2000), and for the three years since (2001-2003) after the tech bubble burst.

Number of Biotechnology Venture Capital Investments by Stage of Financing												
Tech Boom Years (1996-2000)							Tech Bust Years (2001-2003)					
	Startup/ Seed	Early Stage	Expansion	Later Stage	Other	Total	Startup/ Seed	Early Stage	Expansion	Later Stage	Other	Total
US	295	942	955	226	254	2,672	114	553	678	173	4	1,522
Wash.	30	17	21	11	1	80	2	13	31	3	-	49

*PwC Moneytree Data, Battelle Calculations

% of Total of Biotechnology Venture Capital Investments by Stage of Financing (by time period)												
Tech Boom Years (1996-2000)							Tech Bust Years (2001-2003)					
	Startup/ Seed	Early Stage	Expansion	Later Stage	Other	Total	Startup/ Seed	Early Stage	Expansion	Later Stage	Other	Total
US	11%	35%	36%	8%	10%	100%	7%	36%	45%	11%	0%	100%
Wash.	38%	21%	26%	14%	1%	100%	4%	27%	63%	6%	0%	100%

*PwC Moneytree Data, Battelle Calculations

As the table illustrates, there is a dramatic difference in the number of biotech companies receiving funding at the startup/seed stage during the late 1990s and during the past three years. The relative decline in total number of investments between Washington and the United States are comparable and reflect, we believe, the general overall trend in reduction in technology and venture investments

*** "Starving in San Diego," Kathryn Calkins & Susan Schaeffer. *BioCentury*, *The Bernstein Report on BioBusiness*. Volume 12, Number 36. August 16, 2004.

throughout the United States during these years. What is more interesting, however, is the relative greater reduction in startup/seed investing in the state of Washington. For example, while the number of seed investments throughout the country decreased by more than 61%, they declined in Washington by more than 93%. The number of seed investments, defined generally as the initial investment capital provided to new companies to fund certain organizational and early research and development expenses, often is viewed as an indicator of the health of a technology community. The lack of seed investments can be an indication that a marketplace is not supporting the growth of its biotech companies.

It is statistically difficult to determine whether this substantial decline in seed investments in Washington reflects a hostile investment environment in 2003 or an overly exuberant environment before 2000. For example, during the boom years, more than one-third of the venture capital that went into Washington's biotech companies was invested at the startup/seed stage. In fact, Washington companies received a much higher percentage of funding at that stage (38%) than companies around the country (11%). If the companies that were seeded during this earlier period had continued to be successful, one would think that the post boom period statistics would reflect this disparity in venture, expansion and later stage financings. But, venture investing has remained rather static (6% increase), perhaps reflecting a "weeding out" of some of the weaker investments funded in the pre-2000 exuberance. Meanwhile, the relative number of expansion or later stage investments has grown substantially, perhaps reflecting some successes in these earlier years.

Obviously, statistics can be misleading without an understanding of the background, financing terms, nature and relative conditions of the companies being funded. Regardless of one's view of this data, however, it is clear that the number of companies receiving seed funding in Washington State has substantially declined when compared to what is happening nationally. Our state will experience the true consequences of this lack of seed funding years from now when we are unable to enjoy the employment, financial and other benefits these companies could have provided.

Does the lack of seed funding reflect a funding gap in the amount of capital available or a drop in the number of innovators and entrepreneurs in the region qualified to receive such funding?

The substantial drop in the number of seed financings can be viewed either as an outcome of the very competitive and smaller angel and VC community or a reduction in the number of qualified investment opportunities in our region. To understand this issue, the subcommittee interviewed and received commentary from a number of local venture capitalists. The local VCs emphasized that investors always do their best to invest in the companies whose combination of quality management and strong technology can justify and mitigate the risks associated with such investment. In seed and early stage investments, however, the management may not be fully organized and the research and development of the intellectual property is at its earliest stage of growth. Accordingly, these seed and early stage investments are often made on other subjective and objective criteria, making these investments inherently riskier than later stage investments. Thus, for example, innovators with proven track records will always find it easier to attract investments than those with little or no prior record.

Risks associated with these seed and early stage investments are often mitigated through investment terms and valuations. For example, investors may require additional governance controls and equity participation that founders may not otherwise be willing to give up. Those unwilling or unable to obtain venture financing may seek grants, government sponsored loans, funds from family/friend investors, or boot strap their operations by taking on consulting or contract work.

With the downturn in the economy and pressure on venture capital funds and other institutional investors to focus investments only in companies that they think might produce "home runs," it is exceedingly difficult for companies without proven track records to obtain financing. This does not mean, however, that these companies are not qualified investments that may prove successful to their investors and the regions in which they are based. As other states have shown us, a healthy life sciences community requires thriving companies in all stages of development and of differing histories funded by regional and national sources. Furthermore, from the point of view of the investors, a healthy "ecology" that includes

diverse capital sources and managers is more likely to create more and better investment opportunities, which is consistent with their objective to fund quality businesses.

Bioscience opportunities are not limited to firms that can be identified as “home runs” at their earliest research stages. Even assuming one could always reliably make this identification, pursuing only such “home run” opportunities does not maximize the potential of a region to leverage its research base and create companies, jobs, and wealth. Firms with significant but not globally pervasive markets also represent good growth prospects for a state or region and need to be nurtured. Appropriate funding mechanisms and incentives must be designed to serve these as well.

Dr. Walt Plosila

Conclusions

The subcommittee’s conclusions from the foregoing are as follows:

First, there is a perceived if not a real financing gap in our region. Statistics support the fact that the number of seed investments has substantially declined over the last few years. Furthermore, and perhaps more importantly, this decline has been echoed by entrepreneurs and founders of start up companies seeking such financing. Whether these companies would receive early stage funding if sufficient capital were made available is difficult to determine and depends upon one’s perspective. Nonetheless, the fact that they do not get financed supports an impression that the local financial market is not responding to their needs. Finally, this impression may be creating a self fulfilling reality, namely that quality companies have begun to view Washington as lacking sufficient investment funds to spur innovation.

The subcommittee therefore also concludes that the regional biotech market is at a fragile point of its development and growth. The downturn in financing, the perception of a difficult and competitive financial community, and the lack of any state funded or state participating investment program create an environment that is not attractive to innovation and development. After looking at other regions, the subcommittee has concluded that states can play a critical role in changing these perceptions and turning the trend of development and growth. A state sponsored investment program is one such role that a state should take in this regard. The subcommittee concluded that the existence of a state-backed seed funding program in Washington would send a positive message to the national investment community that is presently absent, make us competitive with other states and markets, and attract new innovation.

Creating a Washington State Sponsored Program

Washington has two sources of funds state leaders can consider when developing a state-sponsored program. The first is state funds, which are highly restricted by our state constitution. The second is trust funds managed by the Washington State Investment Board.

A. State Funds

Unfortunately, Washington’s options for a state-sponsored program are limited, although, as previously noted, proof-of-concept funding within approved research institutions is eligible. But as it concerns equity investments into early stage companies, Article 8, Section 7; Article 8, Section 5; and Article 12, Section 9 of Washington’s constitution have been read together to prohibit two broad categories of state transactions: (1) Gifts or loans of money or credit, and (2) Direct or indirect acquisition of an interest in stocks or bonds of a private entity.

The Washington State Supreme Court has long held that no matter how public the purpose, it may not be accomplished by public gifts or loans to private persons or organizations (except certain aid to the poor or infirm). This limits the state from taking direct equity positions in private companies and restricts the kind

of grants that can be made. However, the state can purchase a service or product from a company, and does so routinely to conduct its business.

The subcommittee recognizes that to create a viable state-funded program, a constitutional amendment must be passed by two-thirds of both the House and the Senate and then taken to a vote of the people. Although the task is daunting, it has been accomplished in other states that also had similar constraints to Washington. For example, our neighbor, Oregon, passed a constitutional amendment two years ago that provides the state with new flexibility in this regard. The committee recommends that Washington take similar steps, however challenging to implement. We encourage the Governor's office and state legislators to work with a committee of public and private parties to explore how best to address this issue.

B. Trust Funds

The Washington State Investment Board (WSIB) is a state agency governed by a 15-member board (10 voting and five non-voting members) that invests \$55.8 billion of assets for 33 separate funds. These funds are categorized as Retirement (Defined Benefit and Defined Contribution), Industrial Insurance, Deferred Compensation, Permanent Funds and Other Trust Funds (which include the GET College Tuition Program and the State Emergency Reserve Fund). The Board conducts its investment activities in accordance with policies and procedures designed to maximize return at a prudent level of risk. Because WSIB is a state agency, Board members and staff are required to comply with all statutory requirements and rules established for all agencies, officials, and employees in the performance of their public duties.

While not required by statute, as a matter of practice the WSIB follows Employee Retirement Income Security Act (ERISA) guidelines which spell out that the primary responsibility of fiduciaries is to run the plan solely in the interest of participants and beneficiaries and for the exclusive purpose of providing benefits and paying plan expenses. Fiduciaries must act prudently and must diversify the plan's investments in order to minimize the risk of large losses. In addition, they must follow the terms of plan documents to the extent that the plan terms are consistent with ERISA.

Venture investing and ERISA, however are not mutually exclusive. Venture funds have historically relied on pension and other benefit plans as investors in their funds. Venture capitalists rely on prescribed exceptions to ERISA to avoid benefit fiduciary obligations themselves, and the benefit plans get comfort that reasoned and managed investment in venture capital is an appropriate part of any large investment allocation. Furthermore, other states faced with similar investment criteria have been able to successfully work through these issues. We encourage the WSIB to explore, in collaboration with local leaders in the finance, venture, technology and government arenas, the possibility of increasing seed fund investments in the state of Washington.

C. Program Components

The subcommittee believes that a state-sponsored and/or WSIB investment program can be created that both satisfies the legal and investment criteria and begins the process of aligning state and local business interests to create a vital and growing biotech community. This program would include several components:

- First, the subcommittee recommends that the current dollar amounts necessary to start this program should be relatively small when compared to other state programs that we have reviewed. Because of the relatively small size, the subcommittee recommends that this program be combined with other investment initiatives in non-life sciences fields.
- Second, the state and WSIB should not be put into the position of doing this alone. The subcommittee encourages and recommends other private and public institutions like the Fred Hutchinson Cancer Research Center, the University of Washington's investment funds,

counties and cities within the state be invited to participate in an equity-based strategy in our state.

- Third, the subcommittee recommends that any application of WSIB trust funds be placed with quality and experienced investment professionals. The subcommittee wants to be very clear that this program is not to be viewed as a hand-out to troubled companies and funds. Traditional market and investment criteria must be applied in these investments.
- Finally, the subcommittee encourages the state and the WSIB to begin active discussions with other states to learn from their successes and failures, and possibly (in the case of Oregon) how to develop a leveraged, complementary program. The subcommittee has begun this review and provides additional insights below on how to create such a state-sponsored program.

Focus on the earliest funding stage; consider matching programs

As stated above, because of constitutional constraints, the state currently cannot take direct equity positions in companies and the WSIB cannot make investments unless they follow ERISA-type guidelines. In other states we reviewed, most state programs focus on funding research and development at the seed and early stages where conventional venture investors are most reluctant to participate. Grants to consortia or individual universities, non-profit research institutions, health-care organizations and/or companies enable those institutions to develop research results with clinical or commercial promise to the point of technology transfer and suitability for seed, angel or early stage venture investment. By moving laboratory insights into startup companies and increasing the number of new companies entering the development pipeline, these funds will help build the sector's viability. Bio 21 will be funding these types of projects.

In addition, if state funding rules were relaxed, the state could create a matching program for federal programs supporting technology companies doing R&D. Small Business Innovation Research (SBIR), Small Business Technology Transfer (STTR), Advanced Technology Program (ATP) and other federal programs fund more than a billion dollars each year nationally in early-stage research and development projects at small technology companies. Companies retain the intellectual property rights to technologies they develop under these programs. Funding is awarded competitively and sometimes requires matching funds, but the process is streamlined and user-friendly. It is possible that a state program could simply match SBIR, STTR, and ATP grants that focus on our core areas and efficiently increase capital to promising life science and technology companies.

Create a fund of funds

The subcommittee reviewed the experience and various equity funding models used in other states. Based upon our state's needs, we focused primarily on exploring the multi-investor fund-of-funds option. This fund-of-funds approach has several advantages. First, the amount of capital is sufficient to interest professional managers who work for an SEC-registered investment advisor (RIA). Second, more risk-averse investors such as pension funds find it much easier to participate in a fund that is being managed by an RIA, which provides transparency and accountability. Third, in order to achieve necessary scale and expected ROI (return on investment), funds-of-funds extend beyond the life sciences industry.

Indiana and Oregon are both beginning to develop these funds. In both cases, the Customized Funds Investment Group at CSFB (Credit Suisse First Boston) is managing the funds.

- **The Indiana Future Fund** will be capitalized with \$72 million through limited partnership investments by several state pension funds, pharmaceutical giant Eli Lilly Co., device manufacturer Guidant, Anthem (the privatized Blue Cross operator), American United Insurance,

and the endowment foundations of IU, Purdue, Ball State and Indiana State. The investment policy of this fund of funds is as follows:

- 60 percent will be placed through Indiana-focused or -based venture partnerships
- 70 percent in funds that intend to invest in early- or seed-stage companies
- 60 percent of ultimate investments in Indiana-based companies
- 60 percent of ultimate investments in the biosciences, consistent with regional strategy
- In **Oregon**, there is a new \$105 million fund capitalized jointly by the Treasurer's Oregon Growth Account (which is capitalized by 1.5 percent of lottery proceeds) and CSFB. This effort focuses on the new legal requirement that the state pension funds look first to Oregon and regional firms for diversification opportunities where prudent. The Oregon Growth Account already invests with seven external venture managers selected both directly and through external professional advice. Through the new fund-of-funds vehicle, \$85 million will be invested in eligible funds, while \$20 million will be reserved for direct investments. an additional four or five will be identified with exposure to early-stage in-state deals. CSFB has invested \$5 million in this effort.

There is much Washington needs to do to create a successful strategy that addresses the funding issues of early stage biotech companies. Members of the subcommittee reviewed the potential effectiveness and possibility of creating a fund-of-funds with several local private and public asset managers. Based on our review and discussions, the Bio 21 Seed Funding Subcommittee recommends that the state work closely with private sources, other public institutional investors and WSIB to explore the formation of a fund-of-funds to be used for investment in bioscience and related technology industries.

- The subcommittee acknowledges that investments must be disciplined and focused. Accordingly, the initial amount of funds will be limited until the program unfolds and the market needs can be more fully addressed.
- Amounts should be made available for investment in existing biotech-focused funds or with other emerging IT based funds with a requirement that they increase their focus on Washington State companies.
- Targeted fund managers should be encouraged to syndicate their investments with larger investment firms to align the interests of early and later round financing parties.
- The state should select an appropriate gatekeeper (such as Customized Funds Investment Group at CSFB or Frank Russell) to determine which funds should have access to such investment capital.
- Finally, the state's investment in any fund should not exceed a specified percentage of the fund's total available capital.

Next Steps

Additional work is needed to thoroughly understand the needs of early stage companies, the experience of other states, and the most effective steps that the public and private sector entities can undertake. Creation of a funding strategy, whether a fund-of-funds approach or another, exceeds the scope of Bio 21 and the charge of this subcommittee. However, if Washington is going to realize the potential we have in the life sciences sector, and effectively commercialize the new technologies coming out of our research institutions, we must address this issue.

As a subcommittee, we recognize that if this is to happen, those organizations that represent the high-tech community, such as the Technology Alliance, which incorporates the full range of advanced technology companies, and major individual sector-focused organizations like the Washington Biotechnology & Biomedical Association (WBBA) and WSA, need to collectively support and advance this program together with state agencies such as the Washington State Investment Board which obviously has great expertise in such matters. We believe that such an effort will significantly benefit the people of Washington State for many years to come.

* * *

The co-chairs of the Bio 21 Seed Funding Subcommittee, Steve Yentzer, partner with of Perkins Coie, and Lura Powell, CEO of Advanced Imaging Technologies, gratefully acknowledge the active participation, time and hard work that the subcommittee members and other contributors devoted to this effort. Their input and assistance in drafting this document are greatly appreciated.

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