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Commercializing medical technology

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Abstract As medicine moves into the 21st century, life saving therapies will move from inception into medical products faster if there is a better synergy between science and business. Medicine appears to have 50-year innovative cycles of education and scientific discoveries. In the 1880's, the chemical industry in Germany was faced with the dilemma of modernization to exploit the new scientific discoveries. The solution was the spawning of novel technical colleges for training in these new chemical industries. The impact of those new employees and their groundbreaking compounds had a profound influence on medicine and medical education in Germany between 1880 and 1930. Germany dominated international science during this period and was a training center for scientists worldwide. This model of synergy between education and business was envied and admired in Europe, Asia and America. British science soon after evolved to dominate the field of science during the prewar and post World War (1930's–1970's) because the German scientists fled Hitler's government. These expatriated scientists had a profound influence on the teaching and training of British scientists, which lead to advances in medicine such as antibiotics. After the Second World War, the US government wisely funded the development of the medical infrastructure that we see today. British and German scientists in medicine moved to America because of this bountiful funding for their research. These expatriated scientists helped drive these medical advances into commercialized products by the 1980's. America has been the center of medical education and advances of biotechnology but will it continue? International scientists trained in America have started to return to Europe and Asia. These American-trained scientists and their governments are very aware of the commercial potential of biotechnology. Those governments are now more prepared to play an active role this new science. Germany, Ireland, Britain, Singapore, Taiwan and Israel are such examples of this government support for biotechnology in the 21st century. Will the US continue to maintain its domination of biotechnology in this century? Will the US education system adjust to the new dynamic of synergistic relationships between the education system, industry and government? This article will try to address these questions but also will help the

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reader understand who will emerge by 2015 as the leader in science and education.

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The challenges

The scientific and technological innovations created by universities and research institutes have driven local, regional and global economies for the past 50 years. The United States Government has funded medical research at a comparable level to that of the industry sector. However, this government-funded research has created very few successful consumer products relative to the funded science. Why have so many potential life science opportunities that could improve health care failed? The mixing of innovative science with good business strategies is a high-risk venture for most companies that make these marketable products. Validation of novel concepts into viable products is a time consuming and a costly experience.

There are two fundamental commercialization problems facing academics and the business communities are the following: (1) the ability of the academic community to change the culture of the scientists to commercialize their technology and (2) the ability of the business community to communicate successfully with the scientists. The innovative science usually comes out of the government funded academic research. The academic-entrepreneur must either license the technology or become more knowledgeable in commercializing their patented ideas. As medicine moves into the 21st century, life saving therapies will move from inception into medical products faster if there is a better synergy between science and business. We have seen the accomplishment of business to collaborate with science in the creation of genetic insulin. We need to improve our success rate for more biotechnology products.

This article will help to define the complex process of transforming novel concepts into medical products. This development process of creating medical products has many challenges and opportunities. Medical products are defined as any new molecular (biological or chemical) entities, diagnostic for in vivo or in vitro use and any medical device that fulfills an unmet medical need. Each type of medical product has a different process through the pipeline requiring an understanding of the managers needs of each segment and the company's culture. The evolution of a medical concept into a product requires an appreciation of challenges at each step in this pipeline. The three basic criteria for transforming a concept are the following:

- Is the concept novel and validated?
- Has the concept cleared the regulatory and FDA requirements?
- Is the product faster, better or cheaper then the competition?

If the technology comes out of an academic environment, the design of a medical product will be dependent on mentoring, funding, the involvement of a business incubator and the investment community. At the later stages of development, support for selling to the customer and expanding the market will require the help of the pharmaceutical industry.

The pharmaceutical industry

Medicine appears to have 50-year innovative cycles of education innovations, scientific discoveries, government support and business development. Historically, the pharmaceutical industry had its origins in the mid-19th century in Europe. This was due to two events: the development of the medical products from the petroleum-chemical industry and the rise of the science and technical colleges in Germany. In the 1880's, the petro-chemical industry in Germany was faced with the dilemma of modernization to exploit the new scientific discoveries. The solution was the spawning of novel technical colleges for training scientists for these new chemical industries. The impact of those new employees and their

groundbreaking compounds had a profound influence on medicine and medical education in Germany between 1880 and 1930. The pharmaceutical industry grew up around this government sponsored scientific passion. Germany dominated international science during this period and was a training center for many scientists from around the world. German became the first language of science. Their model of synergy between government, education and business was envied and admired in Europe, Asia and America.

British scientists soon after evolved to dominate the sciences during the prewar and post World War (1930's–1970's). Science in Britain was quickly influenced by German scientists fleeing Hitler's government. These expatriated scientists had a profound impact on the teaching and training of British scientists, which led to advances in medicine such as antibiotics. The clinical development of Penicillin was a marvel of British science but also showed the clash of two scientific cultures: German (commercialization of science) or British (science as purely academic). The successful manufacturing of Penicillin in the United States was due to several opportunistic reasons: the focus of the war economy on British industry; availability of safe manufacturing facilities in the US and numerous fermentation plants that could be converted over to the rapid production of kilogram quantities of Penicillin. The impact of antibiotics on infectious diseases was a miracle and Penicillin became a wonder drug. Modern medicine was born out of the clinical implications of new therapies to treat human.

After the Second World War, the US government comprehended the medical and commercial impact of these successful therapies in the management of human diseases. They wisely funded the development of our current medical infrastructure. This academic medical support was achieved through funding research on cancer in the 1970's, AIDS research in the 1980's and the Human Genome Project in the 1990's. The hope was to repeat the successful impact of drugs for human diseases with new therapies to treat other catastrophic human diseases. Young European and Asian scientists moved to America because of this bountiful funding for this medical research. America had become the center for medical education and scientific advances. English has become the language of international science. But the American educational institutions became a clash of two scientific cultures: commercialization of science or science for the purely academic endeavor. This conflict continues today on academic campuses even after the government has passed laws (1982) for government-funded research to be commercialized. Will medicine in America continue to dominate science or will new scientific innovations appear in Europe or Asia?

The biotechnology industry

The United States had a fairly successful 30 years of producing biotechnology products but have also seen a significant share of failures. Perhaps we should reflect on why spawned California spawn the biotechnology revolution in the 1970's?

Biotechnology started in California because science (molecular biology) met business (investment banking). The government had funded research most cities in the US. There were major investment banks in all the large cities across America as well as Europe and Asia. One scientist and one businessman in San Francisco were able to successfully communicate with each other and outline a common goal: the commercialization of a medical product—insulin. The cloning of the insulin gene for treating diabetes was the catalyst for the development of the biotech industry worldwide. The expatriated scientists from Europe and Asia helped drive the next wave of medical advances into commercialized products by the 1980's. Insulin was the first major commercialized medical product. Insulin set the bar on expectations for successful medical products. However not all scientists were interested in this type of drug development.

Why was Insulin and Genentech successful? They created a breakthrough technology that was better at producing insulin faster, better and cheaper than the old method. The method was to slaughter hogs remove their pancreas and the purify insulin. This manufacturing process for making insulin was not keeping pace with the demands for diabetic patients. Genentech had a

critical product for a high growth market and built alliances with the major pharmaceutical company in the diabetes field, Lilly. Genentech had a fast revenue growth and a high return on investment for their shareholders. The pharmaceutical industry had focused on the chemistry and synthesis of small molecules for treating diseases and their sales/marketing force was focused on distributing these low molecular weight drugs. The biotechnology sector became the center for discovery and manufacture of biological (protein) therapies. Today there are several successful synergies between pharmaceutical and biotechnology sector to lower the risk of products failing and playing to the strength of each sector. What is currently unknown is how will the human genome project impact drug development therapies in the future: genes, small molecular entities, proteins or cells. Today, the American trained international scientists are returning to their home countries in Europe and Asia. These scientists and their governments are very aware of the commercial potential of biotechnology. Those governments are now more prepared to play an active role in this new science. China, Singapore, Taiwan, Japan, Hong Kong, New Zealand, Ireland, Britain and Israel are such examples of these governments that support biotechnology in their country.

Entrepreneurs and startups

The culture in America and especially in California in the business community supports entrepreneurs that are not afraid of failure. This personality trait is both a strength as well as a weakness. However, many academic entrepreneurs lack an understanding of the process of commercializing their ideas, and the basic skill set required for success. The scientist is skilled in publishing their research and obtain government funding. The commercialization process of science requires a different set of disciplines. Concepts need to be validated and models tested. The more the concept has been validated in a prototype, conversely, the lower the investment risk. The process for obtaining funding from the investment community is in principle similar to obtaining research funding from government research agencies. Scientist/entrepreneurs need mentoring and funding if they are to become profitable. This requires supportive environment in a business incubator and collaborating investment community.

The investment community

When investors are evaluating a business idea, they are asking three important questions:

(1) Is the technology novel and unique and patented?
(2) Does the scientist listen and take advice well?
(3) Is there a customer and market that will give a good return on investment?

Success in science and success in business require two very different skill sets. The successful scientist has a very powerful, very narrow focus, nearly to the point of obsession, within their area of research. A businessperson needs to take a broader view and look at the science from a practical point of view, sometimes ruthlessly. He or she can not afford to fall in love with a line of scientific inquiry that is not directly relevant to the clinical development and approval process for a novel therapeutic.

The pre-venture capital community (angel investor) provides opportunities for entrepreneurs to be mentored and funded. These investors provide have played an important role in the deal flow of bringing technology concepts forward into products. The Angel investors can enhance the rate of success by supplying funding for testing these concepts, determining the feasibility of manufacturing the product and carefully defining the customer/market. Angel community has especially demonstrated their success by limiting the number of common business mistakes by the entrepreneurs. The venture capital community then has the ability to partner with these start-up companies to effectively launch the product into the market. The business process of creating a profitable enterprise will thus benefit all the participants involved. How can we make this process more efficient? The next generation of

entrepreneurs must be educated in the understanding of these new dynamics of commercialization. In fact, the major universities in Europe, Asia and the North America are playing vital roles in educating and supporting their entrepreneurs. The Tech Coast Angels of Southern California (www.techcoastangels.com) are one of the largest organizations in the US and most imitated models for supporting start-up companies. Their track record for profitably launching start-up companies and reducing the risk of transforming novel concepts into commercial products is copied globally. We live in a digital world of instant information exchange; there is no longer a time lag to acquire the latest scientific information or obtain access to a current web cast of scientific medical conference. Thus, a collaborative network between the university, government and the investment community is vital for supporting entrepreneurs and a strong economy. These novel medical products may have a similar impact on the global health system, as antibiotics did on infectious diseases in the 1950's. Where will the next advances in gene therapy treatments of cancer be made?

Incubators

In this article we discuss a metamorphosis that takes place when the academic community takes on significant scientific discovery for commercialization purposes. It also discusses the ability of the scientist to change their outlook toward commercialization of technology, rather than focus purely on the pursuit of science for academic purposes. The process of technology incubation must focus on the latter goal. The principal reason for this shift in attention and purpose is that by the time scientists resolve to commercialize their invention, they have already decided:

- Upon a product for their technology;
- Upon a market for their product;
- The value of their product for a customer.

As a result, the inventor must now immediately transition from a scientist at the bench to a businessperson on the Board of Directors. An incubator is the ideal location for an individual scientist to continue on the journey toward commercialization. Incubators provide a number of important support functions for the fledgling businessperson, and educated scientist to develop a commercialization project. This support is provided through both training in soft and hard business skills. It often also provides facility support that may include low-cost rent, management of facility operations such as phone and Internet services, copier, as well as secretarial or administrative support. This assistance allows the individual to focus on building a business, rather than on the distracting, mundane operations. More importantly the incubator provides the new business venture with community support.

Incubators provide two communities of support for the burgeoning entrepreneur. At this time the scientist has started to develop from scientist to entrepreneur. Incubators provide a culture of innovation designed for the development of technology entrepreneurs.

Incubator communities consist of other entrepreneurs, who are peers and former scientists as well, in commercializing their technologies. Many face similar problems as new entrepreneurs. This network of peers provides a comfort zone for entrepreneurs new to commercialization: CEO-to-CEO networking internally within this community of support. Another networking opportunity provided by incubators is support from the business community. Incubators have many contacts within the financial community as well as a support network of experienced practitioners who that provide guidance and support. This network may include attorneys, intellectual property experts and transactional experts CPA's, marketing and sales professionals, product and support specialists, design experts, and human resource professionals to help the entrepreneur grow the business.

Incubators create a positive economic environment for success. Incubators focus on the entrepreneur's growth and learning experience. They often have the resources to provide an entrepreneur with the necessary skills to become an effective leader of the organization with business and management capabilities. At the end of the

day, it is not simply a great idea that creates success, but rather the capacity to execute operationally on that idea.

Conclusions

If we are going to create an environment for commercializing concepts into medical products there are several steps that will be required:

(1) The government will need to encourage American students into stronger science programs. These science programs will need to be more competitive with the European and Asian education systems. Today in America we will not have a competent scientists if half of the population does not believe in the science of Darwin. Foreign students have made the US their destination for scientific education for the past 50 years. We have now seen a down turn in student visas during the past 5 years. Governments in Europe and Asia have realized the importance of biotechnology in the 21st century and are now calling back American trained scientists to well equipped research institutes. Digital information and the Internet allow for complex medical research to be carried out any where in the world. Creating opportunities for commercialization of the life sciences will grow the economy in a similar way engineering did to the US economy in the 1950's.We have two cultures of commercialization of science on the academic campuses.

(2) There must be a better effort to educate, mentor and fund the scientist/entrepreneur by the business community. We need to increase their numbers but also lower their risk of failure by encouraging the younger scientists to explore these career choices. The investment community will need to reach out further to the academic institutions. The governments of Europe and Asia have implemented many such out reach programs.

(3) The US education system must adjust to the new dynamic of synergistic relationships between the education system, industry and government. If the US is to maintain its premier position in the world of science there must be a shift in the dynamics of the science and the business communities. The government has created a successful medical research environment but it is no longer unique. The strengths of the US economy are the entrepreneurial nature and culture demonstrated in California and several other regions of the US.