Health-Care Entrepreneurship in Poland

It is very enjoyable for me to be able to talk to a group as significant as this one, in a country which has done such a fine job of making the transition to a modern society and economy in the last 25 years. I have been coming here on a regular basis since 1994 as a limited partner in the Polish venture capital company, Renaissance Partners, and have observed much of that transition. I want to cover three major topics this morning: The future of the practice of medicine and health care, the opportunities that the changing health-care environment may provide to Polish entrepreneurs and what role the government, EU, national and local, can and do play in furthering entrepreneurship in Poland.

The Future of Medicine

The greatest overall change in the practice of medicine will be an emphasis on keeping people well rather than curing diseases and ailments. The use of the knowledge of individual human genomes will play an important role in this new emphasis. The individual genome can be very determinative if it is a single gene mutation, called Mendelian mutation, but the genome itself and its mutations can normally only determine likelihood of disease or physical malfunction under certain conditions. The understanding of what external environmental or behavioral conditions can adversely affect an individual with a certain genetic makeup is a matter of some understanding now, and is the subject of intense research. For the time being, however, scientists and physicians have little ability of alter the genetic structure of an individual.

The monitoring of body functions on a frequent or continuous basis, and the transmission of those data to the individual and to related health-care professionals, can be of great assistance in preventative and individualized medicine. These data also can be part of a massive data base, which can be used to further relate genetic patterns and environmental conditions to human ailments and abnormalities. Such frequent measurements will be made for physical measurements such as respiration rate, pulse and blood pressure,
chemistry of blood, urine, breath, fecal matter and saliva. The chemistry of blood is particularly important for monitoring minute changes in DNA, and is already in use in detecting the DNA of fetuses in the mother’s blood to avoid the need for amniocentesis. The widespread availability of sensors and transmitters, the essentially universal use of hand-held devices and the increase sophistication of the Internet and analytical services available online make this capability of immediate importance in developed countries and will become important in less developed countries over time. The recently announced Apple watch is a major entry into this space.

Leroy Hood, PhD, president of the Institute for Systems Biology in Seattle, Washington, has described a new approach to medicine as “P4 Medicine,” and almost certainly correctly predicts its being larger than conventional curative medicine. His 4P’s are: Predictive, Preventive, Personalized and Participatory. “Predictive and Preventive” is using the genetic makeup and the environmental and behavioral conditions to anticipate what modifications of those conditions are necessary for a person to keep normally healthy and to prevent disease and physical abnormalities. “Personalized” refers to actions appropriate to an individual both in forestalling and treating abnormal conditions. Present treatments are often based on trials with large groups of people without considering the individual. “Participatory” is the involvement of the individual in the collection of data, and his or her ability to interpret the data, often with readily available advice, and the decision of what course of action to follow. “Normal” in this case has to be defined, but I presume Dr. Hood understands it to mean physical and mental health which can enable a person to carry on activities meaningful to him or her, and to maintain some level of those activities during a long life. That implies that what we think of as normal ageing can be substantially delayed.

Despite all the efforts in anticipatory and preventive medicine there will always be diseases, and physical and mental conditions, which require treatment. People are different in their genetic makeup. The way their genes function, however, is affected by their pre-birth and childhood conditions. The study of the effects of these conditions is the subject of intense study. Some areas of major changes in the practice of curative medicine will be in cancer treatment, prevention of inflammation, immune system malfunction, infectious diseases and vaccination, re-growth of damaged cells, nerve and brain conditions and the use of
personalized medicine in conducting clinical trials and getting approvals to use the drugs and other treatments.

Cancer treatment is already moving from identification of the source of cancer in the body, such as the breast, to classification of the cancers by their genetic structures. A cancer has its own genetic structure, which can be sequenced, and a treatment can be devised based on that structure and its genetic similarity to cancers in other people that have been treated effectively. Attacking the means of the cancer’s continuing growth of cells, such as with anti-CD-4 antibody, and making them more susceptible to the body’s immune cells, are pathways of current development. Surgery will often be necessary, but early detection of small amounts of cancer DNA in the blood stream before there is any normally visible or palpable evidence will alert the doctors to a developing condition that may be treated.

Very strong progress is being made in the study of immunology, with emphasis on inflammation caused by the immune system and its role in heart disease, arthritis and infectious diseases. Auto-immune disease occurs when the body’s immune system sees healthy cells as foreign cells and attacks them. Some well-known auto-immune diseases are type-1 diabetes, rheumatoid arthritis and Crohn’s disease. The greater understanding of the immune systems in many diseases, including those which are auto-immune, and the development of vaccines and treatments for them, is a major academic effort and, in particular, at the La Jolla Institute of Allergy and Immunology in California led by Mitchell Kronenberg, Ph.D. Dr. Kronenberg is quite optimistic that the understanding of the underlying genetic basis of the elements of the immune system will lead to vaccines for many diseases in near future, even infectious diseases, since the bacteria and viruses causing them can be made vulnerable to the immune system. Repair of areas of the brain and damaged areas of the heart, and replacement of damaged pancreatic cells, is being done now or is in advanced research. Stem cells appropriate to the ailment can be grown from very early stage of development and guided down a pathway to form the needed cells. In the brain, after a stroke, they can be placed near the damaged area and they will migrate to the site of the damage and form new cells, according to some work at Stanford University. Damaged heart muscle is being repaired using stem cells in a number of clinical labs, and a company in La Jolla, California, is in clinical testing of insulin-producing cells derived from stem cells, and implanting them in an immune
system-resistant enclosure. Damaged bones and joints may also be repaired by stem cell therapy. All these treatments fit in the category called cell therapy.

The study of the brain and nervous system diseases has made slow progress, but it is a subject of great intensity. These diseases include Alzheimer’s, Parkinson’s, Huntington’s, ALS, MS (multiple sclerosis), epilepsy and autism. With Huntington’s Disease and ALS, progress is underway at Stanford with activating a protein that with block the effect of the genetic mutation which causes those conditions. Myelin, which coats the nerves and makes up part of the brain, is believed to be attacked by the immune system and its degeneration causes MS, which may be eventually relieved with treatment of the myelin. Some of the other diseases may be aided by treatment of the myelin. A foundation in California, the Myelin Repair Foundation, is dedicated to sponsoring such research. Much ALS research is directed to the use of stem cells for treatment. One exciting experiment in this general field is that sensors are being placed on the brain and impulses are being transmitted directly to muscles so they can be utilized without a direct connection to the brain. Also, robotic limbs, replacing natural ones, can be moved without natural connection to the brain. Research is also going on to make robotic fingers have the capability to feel. Much of the robotic work is supported by the US government to aid servicemen and women who have lost limbs in combat.

One vital change that has been a long time coming is the idea of personalized medicine. Treatments and medicines that do not apply to everyone and can be developed with a specific genetic group in mind, even a small group. They are to be tested only on an appropriate group and approved by the Food and Drug Administration (in the USA) for use on that group. One complication in the US is that while a company cannot promote the use of a drug for an application that is not approved, and individual doctor is free to do so as “the practice of medicine.” The FDA has approved several products in the last two years for specified groups and progress is being made on this important concept.

Entrepreneurial and Innovational Opportunities in Poland in Health Care

Poland has had significant entrepreneurial activity in biotechnology and healthcare in recent years, with about 70 companies active in the field and over €100 million in sales, and some 8000 students studying the biological sciences in 36 schools. Because of the shift in emphasis to preventive medicine, and the
importance of the use of genetic information and other new approaches in treatment of diseases and other ailments, new entrepreneurial opportunities in both products and services will occur in Poland because of these changes ongoing in the health-care system. Some of these opportunities will be in data-related services, in bringing existing health technologies to market in new ways, forming companies around new science and technology being developed in Polish universities and laboratories and taking that technology to world markets, bringing science and technology developed elsewhere to Polish and EU markets, and in forming service companies that can help young companies in finding markets and serving them.

The gathering of data continually generated and transmitted by sensors from people, its transmission to the individuals and health care professionals, and relating of those data to genetic information about the person is an area of almost immediate interest to entrepreneurs. Virtually everyone in Poland and Europe has a portable device capable of keeping that person informed about his or his key measurements. With professionals or family members able get these data, conclusions for action can be given to the individual subjects. One interesting part of this opportunity is that the entrepreneurs will need to have data-related skills in order to gather and transmit the necessary information. This gives a whole new set of Polish citizens a chance to participate in the entrepreneurial opportunities in the changing health-care market. The interpretation of the data and the communication of advice to the person does, of course, require health-care skills. An entrepreneurial team in this field will require people covering both these skill areas, and the assembling of such teams will be a new challenge for Polish innovation. The markets for such a company are at least EU-wide, and probably world-wide.

Another major opportunity lies in applying presently known techniques much earlier in the progress of disease. We have an increasing ability to detect evidence of conditions through frequent sampling of body functions. Examples of this are changes in A1C hemoglobin as an indicator of type 2 diabetes, the presence of small amount of protein or DNA related to a nascent cancer and the presence of small amounts of fetal DNA in the blood of the mother, which may signify a condition of the fetus requiring attention immediately or soon after birth. The near-term innovative opportunities here lie in application of the detection techniques so that known treatment can be applied.
The emphasis in recent years on biological research in Polish Universities will result in products that can serve health-care market in new ways, especially in the field of genomics. Polish would-be entrepreneurs need to stay in close touch with, or even be in, such labs or the nearby incubators. The science which is developed has to be evaluated at to what market it might serve, engineered into a product to serve that market and then sold to the users. This is the essential job of the entrepreneurial team which takes the science to market. The team also has to make an economic case that a the size of the business serving that market will be large enough to have a value in the future that can give an attractive return to energy and capital invested today. The skill of analyzing the elements of building that business, having a plan to accomplish those elements, building a company with a strong value and realistically convincing investors that their share of that potential value will provide a strong return is a vital entrepreneurial skill. It is skill which can be learned by most people by study or previous experience.

Science and technology is undergoing rapid change in all the developed world. Polish entrepreneurs need to be alert to these changes, and they need examine and understand Polish markets well so these ideas developed elsewhere can be applied to building businesses in Poland. Polish markets are the same in some ways as in any developed country, but they have differences due to history, custom and possible genetic differences between the Slavic Poles and other historical ethnic groupings. Frequent reading of journals, study, and visits and conferences abroad will give Polish entrepreneurs ideas to use at home. First, however, they have to understand Polish markets for health-care products and services. The same applies to science developed in Poland. Because of economic advantages, companies may be started here to serve markets in Europe and the world using science developed elsewhere as well as in Poland. This is evidenced at present by the 20-25% of Polish biotech companies doing product development for others, including those in other countries. Polish (or any) entrepreneurs have to continually think of markets as they learn about or develop science and technology.

The availability of capital is a problem in Poland. Some of the sources not always considered lie beyond venture capital firms and government programs. They are corporate venture capital and individuals with the means to invest. Big American companies such as Intel, and Google ventures have been active in Europe, and Johnson and Johnson has emphasized investments in health-care
related deals. Entrepreneurs should not only contact venture capital companies or government agencies as investors, but should consider from the beginning contacting corporate venture capital arms and individuals or families with assets who are interested in start-ups. The latter will surely increase in number as Polish prosperity continues to grow.

**Government’s Role in Health-Care Entrepreneurship**

The government of Poland, within the EU, has a number of initiatives in place to further entrepreneurial activity in all fields, including health care. The direct aid to entrepreneurs comes from the National Council for Research and Development and the Innovative Economy Operational Programme, which originated with the EU. These programs have been effective in getting capital to companies for a few years, but the some recipients report substantial time spent dealing with the people administering the programs, which are oriented to companies doing research. Another government agency providing loans and guarantees for small and medium-sized operating companies is the Polish Agency for Enterprise Development. Health-care and biotech companies are included in the programs of all these agencies.

The government also has several programs to support and encourage venture capital firms. Those venture firms, using their judgment, back companies they judge to be likely successes, or provide growth capital firms already operating. The primary vehicle for this activity is the National Capital Fund, which can provide up to 50% of the capital, under a complex formula, to venture funds that finance innovative projects. The private investors in the funds make the investment decisions, within the limits, so that the evaluation of markets, technology, operations and eventual success are made by them. There are other institutions, such as the bank known as BCK, and Academic Business Incubators that operate on the federal and local level. A recent second effort at a broad policy level is the Presidential Program Experts. While the people appointed to that program will consider a whole group of national policies, the study of growth and competitiveness of the Polish economy will almost certainly have to take into account the role of biotechnology and health-care development in the future of Poland.

In my view, the ideal in the long run in Poland would be for privately funded venture capital funds, numerous and with adequate capital, to finance new and
growing companies. It would be in a competitive environment for both the investors and the companies created by entrepreneurs. The role of local and state governments would be to make it easy to start a company and to build the physical plant needed with a minimum number of permits. It would also provide the local education to enable its people to work in the sophisticated jobs the new companies would create and prepare suitable students for university training. The national government would use its resources to finance top-level research in the universities and other labs and to provide support for universities to have sophisticated science and technology students, as well as the all the well-trained students any democratic society needs. The present reality, however, is that Poland has to work hard to catch up or stay even with, or surpass other leading countries. As a consequence, the elected government needs to work toward the competitive ideal by continuing to help venture capital growth, assist companies in borrowing money, and keeping taxes low to encourage capital formation. It can and should begin to back off of direct investment in companies as the venture capital supply grows and let the market for financing new and growing companies work.

Because of the history of hard work and success through many difficult periods, Poland has emerged with a democracy that works and an economy that provides the opportunity for good lives for its people. Poland has taken its place as a successful country in a troubled world.

Pitch Johnson

Asset Management Company
Palo Alto, California, USA

Lecturer in Management
Graduate School of Business
Stanford University
References:

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Piotr Bardidin, Managing Partner, Renaissance Partners, Warsaw
Stanley Cohen, MD, Professor, Department of Genetics, School of Medicine, Stanford University, California
Mitchell Kronenberg, PhD, President, La Jolla Institute of Allergy and Immunology, San Diego, California
Louis Lange, MD, General Partner, Asset Management Partners, Palo Alto, California
Carla Shatz, PhD, David Starr Jordan Director of BioX, Stanford University, California

Speech and Paper:
Leroy Hood, MD, PhD, President, Institute for Systems Biology, Seattle, Washington
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