

The Cuban Biotechnology Industry

A Report by Brookings Trustee Bill Haseltine

I visited Cuba for five days in mid-April 2012 under a people-to-people license issued to the Brookings Institution. While there, I visited the Center for Biotechnology and Genetic Engineering, located on the outskirts of Havana. Dr. Manuel Raices, a scientist and business development officer, briefed us.

The Cuban biotechnology industry is a remarkable success. It has produced a remarkable array of products, advanced vaccines, pharmaceuticals, and diagnostic products. The current set of drugs in development is robust. The industry also produces animal, fish and plant protection products. The Cuban biotechnology industry has played a central role in improving the health of the population. Despite being a very poor country where an average worker's salary is \$20-30 a month, Cuba has one of the lowest maternal/child death rates in the world and one of the longest average lifespans. These results are achieved in a country that is very poor.

In my opinion, the Cuban biotechnology industry is roughly comparable to one of the largest and most productive U.S. biotechnology firms or mid-sized international pharmaceutical company, as judged by size, output and products in development. The industry employs about 10,000 people, of whom more than 3,000 have university degrees, more than 500 have masters degrees, and more than 250 have received PhDs in science. Their work is done in about fifteen separate facilities that operate in concert, but apparently semi-autonomously. More than 40 products and technologies created by the industry are currently in use. The industry now produces 33 different vaccines, 33 anti-cancer drugs, 18 products to treat cardiovascular disease, and 7 drugs to treat additional diseases. The facilities seem excellent, although I did not see them first-hand. Officials claim the production facilities meet the most stringent regulatory requirements of both the U.S. and European authorities.

However, the sales and value of the industry, according to my estimate, is between one-fiftieth and one-hundredth of a counterpart company in other countries, as the market for its products is almost entirely domestic since intentional restrictions apply to the sale of its products abroad.

How can such a poor, communist system produce such a success? The answer is that from the earliest days the government placed health and health technology, along with education, at the center of its efforts.

The Cuban government's strategy for biotechnology can be outlined as follows:

1. Substantial sustained investment
2. Focus on creating products to meet the needs of the Cuban population

3. Integrating the industry into the National System of Preventive Health
4. Integrating the diverse centers into a single functioning whole
5. A closed cycle approach to product development

Strategies 1-4 are made possible by a central command and control. The closed cycle approach is unique and inventive and not necessarily dependent on a command structure. The closed cycle approach means in part that the same team stays with the project from inception and invention to marketing. This approach seems to me to be a recipe for success, as it assures that the deep insight and knowledge acquired at all stages of development are preserved and reflected in the outcome. In most pharmaceutical companies, products are handed off to teams with highly specialized expertise until they finally reach the marketing group, which may have very little or erroneous notions of how the product actually works.

The record of the Center for Biotechnology and Genetic Engineering that we visited is remarkable. They have produced a cutting-edge vaccine that protects children from five diseases in one series of injections, an effective hepatitis B vaccine that in practice is on the verge of eradicating this disease from the entire population (a goal achieved nowhere else), interferon alpha for the treatment of cancer and other diseases, and many more. This is a record of success that any company would be proud of.

The economics of the industry are opaque. I could not get an answer to my question regarding expenses and income. It may be that, like most industries in Cuba, the income generated from domestic and international sales is collected by the central government and redistributed. But the actual numbers remain obscure.

The industry's initial products were targeted to fight diseases of children and mothers. The results have been spectacular. Cuba has one of the lowest rates of infant and maternal mortality. Polio, neonatal tetanus, diphtheria, measles, rabies, mumps, whooping cough, and congenital rubella have been eradicated. Hepatitis B in the adult population is on the verge of eradication. Additionally, the rates of bacterial meningitis are amongst the lowest in the world.

Cuba has recently embarked on a program to diagnose rare, inherited neurologic diseases. They have implemented a universal screening program for infants for congenital hypothyroidism, phenylketonurea, congenital adrenal hyperplasia, biotindase deficiency and galactosemia, the only such comprehensive program of which I am aware. Cuba has also begun providing cochlear implants to all infants born deaf and blind and is planning to expand this coverage to all Cuban children in need.

The list of drugs under development is impressive. One such drug, for the treatment of diabetic foot ulcers, is of special interest to me as we at Human Genome Sciences tried without success to develop a similar drug. Diabetic ulcers are a large and growing problem globally; they often result in a successive series of amputations. By developing a new method of administration (direct injection of the epidermal growth factor into the wound), the Cubans seem to be succeeding in finding a treatment. The results of a global human trial are impressive, and such results would add substantial value to any other company.

Another drug of interest is a vaccine for the cure of hepatitis B. This new drug is a novel formulation of the Hepatitis B vaccines they had previously developed—it is prepared as micro particles and administered as a nasal spray. They report that in this form, the vaccine is sufficiently potent to

eliminate chronic Hepatitis B infection. Gilead, a U.S. based anti-viral company, recently purchased a U.S. biotech company for about \$10 billion in order to acquire a drug at the same stage of testing with similar potential.

Other innovative approaches to cancer therapy, and heart disease, would, I believe, be proud additions to the development pipeline at any pharmaceutical company.

The industry has also produced agricultural sector products, including a vaccine that reduces bovine tick-borne diseases (the vaccine produces antibodies that, when ingested by the tick, weaken it and reduce its ability to reproduce), a fish food supplement suitable for enhancing the growth of both fish and shrimp, and what I believe is an organic anti-nematode product suitable for use in intensive truck farming.

Cuba is a poor country undergoing the demographic crises of wealthy nations. The birthrate is well below the country's replacement rate. The demographic problem is exacerbated by massive immigration of young men and women who see no viable future for themselves in Cuba. Economic reforms are underway, but they are small and their implementation is very slow. The intention of the reforms seems to be to preserve, not change the political system.

The type of success enjoyed by the Cuban biotechnology industry does make the point that some state-run enterprises can be successful and meet demanding goals. The defense industry of the former Soviet Union and, to a large extent, the defense research establishment in the U.S. are other examples of successful state-run businesses.