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CREATING INTERNATIONAL FACILITIES FOR TECHNOLOGICAL DEVELOPMENT AND PRODUCTION OF "ORPHAN VACCINES" IN DEVELOPING COUNTRIES

Report to UNDIO Under Special Service Agreement CLT 89/550

by

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Performance of Work Assignment

On December 5 and 6, 1989, the consultant visited Stockholm, Sweden. His visit there was organised by Professor Kari Goran Heden, the President of the World Academy of Arts and Science and a well-known Swedish microbiologist.

Professor Heden arranged for the consultant to visit the National Veterinary Institute in Uppsala. There he met with the Director of the Institute, Dr. Goran Hugoson; the Director of the Division of Vaccine Research, Professor K-A Karlsson; and Dr. Bo Sundquist, Associate Professor in the Division of Vaccine Research. He also met Dr. K-O Gronvik, head of the Section of Immunology and Cell Culture, where the Uppsala Cell Center is located.

The Cell Center is a joint project between the National Veterinary Institute, the Swedish National Board for Technical Development (STU) and industrial partners (Electrolux, Alfa Laval, Belach Biotechnics AB).

The work of the Cell Center aims at gaining general knowledge of large-scale culture of animal cells, including metabolism, adaption of suitable expression vectors and integration of equipment. The long-range aim is to create optimal conditions for producing biologically active substances with animal cells.

The Center is currently producing HIV antigens with gene manipulated epithelial cells and monoclonal antibodies from B lymphocyte hybridomas for obtaining diagnostic and vaccine antigens. The Center also undertakes culturing of cells and production of monoclonal antibodies on a contract

basis.

The Center is an integral part of the NVI Section of Immunology and Cell Culture where basic research in cellular immunology is undertaken. The main focus of the projects undertaken in this Section is on activation and regulation of the immune response and the influence of environmental toxins on thymic development and the immune status.

In addition, the consultant visited the Department of Bacteriology at the Karolinski Institute in Stockholm. A planned visit to the National Microbiological Laboratory was not undertaken because of the absence of key personnel.

In addition, the consultant had extended discussion with Professor Heden regarding next steps in carrying forward the initiative to strengthen capacity for vaccine development and production in developing countries. In particular, attention focused in these discussions on the role that might be played by the Biological Resources Development Corporation, an international undertaking now in the process of being established by Professor Heden and a distinguished group of international scientists and institutional leaders.

Soon after he returned to his home base in New York, the consultant proceeded to establish contact with Professor Jonas Salk of the Salk Institute in San Diego, California. Earlier contact was not possible because of Dr. Salk's absence from the Institute on extended travel over the preceding six weeks. Dr. Salk recommended that, after discussion with him on the overall nature of the consultant's assignment, the consultant visit the laboratory and production facilities of the Salk Institute's

Government Services Division in Swiftwater, Pennsylvania. Because of the end-of-year holidays, that visit could not be arranged until January 11. On that date, the consultant visited the Swiftwater facilities of the Institute's Government Services Division, where he held discussions with Dr. Alexis Shelokov, Director of Vaccine Research for the Institute, as well as with several of Dr. Shelokov's colleagues, including Dr. William J. Thomas, Director of Production; Dr. Harold W. Lupton, Quality Control Manager; Dr. Joyce M. Lockard, Supervisor, Vaccine Production; and Dr. Chung Keel Lee, Director of Quality Control/Assurance.

In the course of fulfilling this and earlier work assignments, the consultant has maintained contact with other experts in the field of vaccine development and research, including Dr. Rodolfo Guintero of UNAM (National Autonomous University of Mexico), Dr. Anthony Robbins of the Boston University School of Public Health, and Dr. Tom Ortiz, Coordinator of the Task Force for Child Survival at the Carter Center in Atlanta, Georgia (a cooperative undertaking of the World Bank, UNICEF, UNDP, World Health Organization, Rockefeller Foundation, and other leading national and international institutions.

Models for Development and Production of Vaccines in Developing Countries

In his discussion with the UNIDO consultant, Dr. Salk, a world-renowned scientist in the field, suggested that there were two basic models which he thought needed to guide any further efforts at strengthening the capacity of developing countries for meeting their own vital health care needs through development and production of "orphan vaccines" (i.e., vaccines for diseases that are widespread in developing countries but little known in the industrialised world).

The first is a small, relatively specialised facility that can play an important role in scaling up vaccines that have already been developed at the lab stage and given clinical tests. This is the model of the Swiftwater, Pennsylvania, facility of the Salk Institute's Government Services Division. This facility has the capacity to produce vaccines in the dosage range of 50,000 to 100,000 units. It also has all of the facilities of a world-class industrial facility in vaccine production with respect to quality control and quality assurance. Those facilities are absolutely vital to the production of high-quality vaccines.

The consultant explored with the Salk Institute experts with whom he met the possibility of either expanding the capacity of the Swiftwater facility or drawing upon the accumulated experience and expertise of that facility in helping developing countries create comparable facilities. Both seem to be possible, given a demonstration of vital need and the availability of adequate financial resources.

The principal bottleneck in expanding production capacity at Swiftwater is in the freeze drying facilities. These could easily be doubled with a capital expenditure on the order of $2 million to $5 million. And of course, with added expenditure, other aspects of the Swiftwater laboratories could be expanded to permit still larger production runs.

Swiftwater has already had some experience in providing training to individuals from other countries involved in or anxious to acquire skills in different aspects of vaccine production. The Salk Institute Government Services Division would, in principle, be willing to provide such training opportunties in the future if the cost of providing those facilities could be covered.

The other model suggested by Dr. Salk involves a replication of the facilities that now exist in industrialised countries for the large-scale production of high-quality vaccines. There are some such facilities in existence or being created already in the Third World. Mentioned by Dr. Salk are the collaborations in which the Indian Department of Biotechnology is now engaged with French and Soviet partners in the production of polio vaccine. (The UNIDO consultant discussed these facilities with the Secretary of the Indian Department of Biotechnology while he was in India in November.)

The feasibility of such facilities depends upon the country concerned having the necessary supporting scientific and industrial infrastructure. However, the production facilities themselves can be created on a "turn-key" basis.

The critical process of laboratory research and clinical testing is undertaken in different ways by different kinds of institutions in industrialised countries so there is no one single model. In general, however, this phase in the larger process of developing and producing vaccines is undertaken by institutions other than those which produce the vaccines. It is especially important in the clinical testing to have that testing in independent hands so as to assure that the tests are conducted in the most rigorous scientific manner possible.

Next Steps in Development and Production of Orphan Vaccines in Developing Countries

Several of the experts with whom the consultant discussed the process of creating facilities for the development and production of orphan vaccines in developing countries urged that a small meeting of experts be convened soon to address some of the issues raised in this report, as well as the consultant's earlier report, Vaccine Production in the Third World: The Search for Alternatives (report by UNIDO consultant, November 12, 1989).

One possibility would be to convene such a meeting in Vienna in May, perhaps around the time of the key organising meeting of the Biological Resources Development Corporation. Another possibility would be to convene such a meeting in North America under the auspices of either the Salk Institute or the Carter Center, which played a key role in organising and helps to staff the Task Force for Child Survival.

Although this report completes the formal work assignment under the Special Services Agreement CLT 89-550, the consultant expects to continue exploration of these possibilities in the weeks ahead. In that connection, he is planning to visit Atlanta and the Carter Center in early March as well as to have further discussion with Anthony Robbins, and his colleague, Phyllis Freeman, from Boston University in February.