The International Cooperative Biodiversity Group Drug Development and Biodiversity Conservation in Africa: Case Study of A Benefit-Sharing Plan

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1. Overview

At the third meeting of the Conference of the Parties (COP) to the Convention on Biodiversity, a number of Decisions related to "benefit-sharing": Decisions III/11 (Conservation and sustainable use of agricultural biodiversity); III/14 (Implementation of Article 8j); III/15 (Access to genetic resources); and III/18 (Incentive measures). Benefit-sharing will be an important item on the agenda of the upcoming fourth meeting of the Conference of the Parties in May 1998, and to contribute to the deliberations at the COP, and wider efforts aimed at the practical implementation of benefit-sharing regimes, the following case study is circulated at this time. Produced in 1995, this benefit sharing plan has acted as the basis from which the benefit-sharing strategy of the African ICBG has developed, and provides a useful case study for policy makers and practitioners alike.

The International Cooperative Biodiversity Groups (ICBG) are part of a program jointly sponsored by the U.S. National Institutes of Health (NIH), the National Science Foundation (NSF) and the U.S. Agency for International Development (USAID) to address the related issues of biodiversity conservation and the promotion of sustained economic development through drug discovery from natural products. As described in the ICBG Request for Applications, these goals will be achieved through a combination of the following approaches: (1) assisting with the development of drugs while addressing the priority health needs of the United States and the participating country; (2) developing inventories of native species and indigenous knowledge; (3) training, targeted towards achieving the research goals of the program and meeting the needs of the participating country; and (4) improving the scientific infrastructure within the host country.

The African ICBG is a collaboration of The Bioresources Development and Conservation Programme (BDCP), Walter Reed Army Institute of Research, Washington, D.C., the Smithsonian Tropical Research Institute, the University of Dschang (Cameroon), The International Centre for Ethnomedicine and Drug Development (Nigeria) and thirteen other institutions in Africa and the United States. The main focus of the African ICBG project is the establishment of an integrated program for the discovery of biologically active plants for drug development and biodiversity conservation, and at the same time ensuring that local communities and source countries derive maximum benefits for their biological resources and their intellectual contribution. An integrated program such as this is usually under pressure to stress one aspect to the detriment of others. In the African-ICBG, however, integration was emphasized from the conception of the program and has remained a fundamental point in the execution of various projects under this program. As a result, the African ICBG program differs in many ways from similar projects elsewhere.

- It is a much larger project than the other ICBG programs. There are more than sixteen different institutions, contributing 45 active investigators to various aspects of the project.
- Unlike other ICBG projects which involve the collection of plant materials from the project group to then be tested in institutions outside the group, in this ICBG most of the processing and biological

testing will be performed within the ICBG group. In this way, we are working to establish a consortium of collaborating scientists who will actually do both the discovery of lead plants and the development of active molecules into drugs.

- Selected plant products will be developed all the way to pre-clinical stages, prior to negotiation with the commercial partners.
- Our compensation and benefit-sharing plan is based on deriving maximum benefits from the <u>process</u> of drug discovery, rather than relying mainly on the promise of huge future royalties that may never materialize. In this way, we feel that benefits will be felt both immediately and over time.
- The main target therapeutic categories for this project are tropical diseases such as malaria, leishmaniasis and trypanosomial. In this way, the scientific expertise held in the involved laboratories and pharmaceutical companies can be applied to the under-researched diseases afflicting the poor in developing countries.
- The ICBG program is not the beginning of an international scientific research project, but represents the expansion and elaboration of an existing collaboration between U.S. and African scientists.

2. Description of the context

Nigeria occupies a land area of approximately 923,773 km2, and a coastline that is about 830 km long. It boasts a population of over 100 million, which makes it the most populous in Africa. The country has one of the most varied ecosystems on earth. The savannah vegetation in the northernmost part of the country turns into guinea savannah, then to dry tropical forest and moist forest towards the coast. There are montane forests in the southeastern section, the middle belt and in the northeastern region. The delta regions have both fresh water and salt water mangrove forests. The major agricultural products from Nigeria include kola nut, coffee, oil palm, coconut, citrus, plantain and papaya. With over 250 distinct tribes and languages in Nigeria, the country is one of the most culturally diverse in the world.

The project area is within the rainforest belt of west and central Africa which contains the second largest contiguous expanse of moist tropical forest in the world. This immense biome represents about 15 percent of the world's remaining tropical forests, covering an area estimated to be between 2.8 to 3.2 million square kilometers of closed and open broadleaved forests. The rate of deforestation of the forest range is increasing rapidly due to anthropogenic pressures and demand from economic development projects. The West and Central African forests are very much at risk since the area has one of the highest human population densities in the continent.

Although there are many reports on the chemistry of tropical African plants, there has been no integrated program to date that is focused on a systematic evaluation of the flora and fauna of the region for biologically active compounds. Several medicinal agents have originated from plants

growing in the region, with examples ranging from the well known physostigmine (from *Physostigma venenosum*) used for the treatment of glaucoma, to the recently identified antiviral (anti-HIV-1 and -HIV-2) agent, michellamine B, a novel dimeric alkaloid (from *Ancistrocladus korupensis*).

3. The African "Drug Development and Biodiversity Conservation" ICBG

3.1 Scope, Objectives, Organizational Structure

The African ICBG has as its primary aim the development and implementation of an effective and constructive resource management and conservation plan based on an intimate understanding of the key factors driving medicinal plant use and the loss of biodiversity. The overriding concept is to increase the net worth of tropical forest as living resource base and to demonstrate the feasibility of an ecological management strategy which uses drug development as a catalyst for the conservation of biological diversity. The ICBG is a highly integrated team which will involve scientists from the participating developing countries in all aspects of the program so that lessons learned from this project can be internalized in Africa and continued after the end of this project.

For the drug development component of the program, the emphasis is on the identification of new therapeutic leads over as wide variety of plant sources as can be possible with the available resources. Compounds (not crude extracts) with remarkable biological activity would be co-developed with assistance from related drug development programs at the NIH or through the collaborative arrangement with the two participating pharmaceutical companies. Through this approach, value is added to the plant material before being offered to the commercial partners.

The specific objectives of this ICBG include the following:

- A) To provide an ethnobotanical inventory of the plants in the selected study area. Samples will be collected from the biodiversity plots and from wild flora for screening for possible biological activity. The database on African medicinal plants **AfricMed**, will be expanded to include plants collected during the proposed project.
- B) To establish permanent biodiversity plots for monitoring and documenting changes in plant diversity and ecology of the area. The plots will provide long-term data on the growth, mortality, regeneration, and dynamics of forest trees.
- C) To conduct an economic value assessment of the biological resources in the study area. This component of the study has four objectives: 1) to quantify the economic value of bioresources for comparison with other land use options; 2) to prioritize the production and marketing of bioresources in local markets which could provide a source of income for local residents; 3) to provide baseline data for the formulation of a sustainable management plan for the forest resources; 4) to train local natural resource managers and users at both national and community level to conduct economic and market research which takes into account the connection between conservation and development.

- D) To assist in capacity building in the source countries, through training of African scientists in the areas of ethnobiology, inventory, phytochemical analysis and research management.
- E) The ICBG aims at strengthening the capacity of Bioresources Development and Conservation Programme (BDCP) and other local institutions to enable them to be more effective in resource management and conservation programs and to continue the activities initiated even after the end of this project. Training will be organized in parataxonomy and economic value assessment for local communities.
- F) The ICBG will identify medicinal plants from West and Central African rainforest that contains new biologically active compounds. An inventory of plant extracts will be maintained so that re-testing in future as more sensitive test systems becomes available will not necessitate re-collection and processing. To develop up to pre-clinical stage active isolates for the treatment of tropical diseases. Other major therapeutic classes to be investigated include antiviral (such as anti-HIV), anticancer, antifungal, and CNS activity. Compounds will also be assayed for cardiovascular, antiinflammatory and immune-modulatory activities.

This ICBG aims at using proven methods to investigate medicinal plants from west and central Africa for plants containing biologically active compounds that can be developed as therapeutic agents. The basic approach is to use the activities outlined in this project to initiate long lasting environmental programs and at the same time yield economic benefit for the participating communities in Africa. All aspects of the projects include scientists from the United States and Africa, and this will enable an internalization of the whole concept. The plan seeks to strengthen the technical capacity of the collaborating institutes in Nigeria and Cameroon.

BOX 1: Activities of the ICBG

- 1. Plant Collection
- 2. Phytochemistry
 - -Plant Extraction for Bioassays
 - -Extract Fractionation/Isolation/Structure Elucidation.
- 3 Antiparasitic Activity
 - -In Vitro and In Vivo Antileishmanial
 - -In Vitro and In Vivo Antimalarial
 - -In Vitro and In Vivo Antitrypanosomial
- 4. Antifungal/Antiviral/Opportunistic AIDS Infections

Screening

- 5. Cytotoxicity Screening
- 6. Receptor Binding/Enzyme-Based Assays
 - -CNS Activity: Alzheimer's disease, sleep, stroke, depression etc.
 - -Cardiovascular activity: Regulation of blood pressure, artherosclerosis, thrombosis, etc.
 - -Dermatology and Immunology: Antiinflammatory agents, adhesion molecule inhibitors.
 - -Antimicrobial: Antibiotic resistant broad spectrum activity, mycobacteria
- 7. Ethnobiological Survey and Economic Value Assessment
 - -Evaluation
- 8. Conservation
 - -Inventory of Species
 - -Support for Extractive Reserves
- 9. Inventory
 - -Plant Uses and Distribution
 - -Extracts and Isolates, distribution, location and quantity
 - -Developmental Drug Status
- 10. Training Programs
 - -Parasitological laboratory techniques
 - -Ethnobotany
 - -Ecological evaluation techniques
 - -Parataxonomy
 - -Phytochemistry
 - -Biological Assays

3.2 ICBG Structure

Five Associate Programs (AP's) has been established by the ICBG to deal with the following subject areas:

1. Biodiversity Conservation (in situ programs and training):

Smithsonian Tropical Research Institute; Biodiversity Support Program (BSP, c/o World Wildlife Fund); Smithsonian Conservation Training Council; Biodiversity Programs of the National Museum of Natural History(Smithsonian); Conservation & Research Center of the National Zoological Park (Washington, DC); BDCP, MESRS, Yaounde.

2. Phytochemistry and Preliminary Bio-Assays:

Department of Organic Chemistry, University of Dschang, Cameroon; School of Pharmacy, University of Pittsburgh; InterCEDD; Shaman Pharmaceuticals Inc., California;

3. Drug Development - A (Antiparasitic):

Division of Experimental Therapeutics, Walter Reed Army Institute of Research, Washington, DC; Haskins Laboratories of Pace University, New York; College of Veterinary Medicine, University of Georgia, Athens; Division of Public Health, University of Massachusetts Amherst.

4. Drug Development - B (Antiviral/Cytotoxicity/CNS Activity etc.):

Center for Drug Discovery, University of Utah, Salt Lake City; Southern Research Institute, Alabama; Shaman Pharmaceuticals Inc., San Francisco, California; Pharmaceutical Research Institute, Bristol-Myers Squibb.

5. Ethnobiology, Economic Botany and Plant Inventory (including plant collection):
Bioresources Development and Conservation Programme (BDCP) [Nigeria and Cameroon]; Shaman Pharmaceuticals Inc..

The activities of the five associate program are directed towards the three themes of the ICBG, namely 1) conservation of biodiversity, 2) drug development, and 3) instrument for economic growth. All aspects of the design and implementation of this proposal will be focussed on these three core areas. Carefully selected activities have been proposed to achieve the desired objectives in the three areas.

4. The African ICBG Benefit-Sharing Arrangements

The ICBG has been designed to deliver a range of benefits to a variety of partners over a number of years. The benefit sharing plan attempts to answer the following questions:

- who should benefit?
- how should they benefit?
- when should they benefit?

While a process of discussion and negotiation is inevitably required to determine the detailed accounting of the nature and distribution of benefits, broad parameters can be sketched out from the start, and this is what we have tried to do in the following discussion. It is important to note, however, that many of the most significant benefits provided by this type of multi-disciplinary and multi-institutional program are the least obvious, the most mundane-seeming, and certainly those that have attracted the least attention. We cite, for example, the difficulty to quantify role of human and institutional relationships in developing capacity and expertise through informal exchanges. This might be manifested through access to funders, publications and literature, potential corporate collaborators, and the ideas of an expanded network of colleagues.

Following is a brief discussion of benefits accruing to some of the ICBG partners within Nigeria and Cameroon. This discussion is by no means complete, and "benefit-sharing" will be a constantly evolving area. Benefits are broken down into two categories: "process" benefits, which are those resulting from the research and development phase of the project and "long-term" benefits, which result from the commercial product phase of the project.

4.1 "Process" Benefits: the short- and intermediate-term

4.1.1 Universities

Universities in Africa play a unique role in both the conservation of biodiversity and in adapting modern technology to the processing of plant materials into drugs. Because universities function as part of the educational, cultural, economic and social systems, they are well placed to conduct the kind of multi-disciplinary research necessary for the sustainable utilization of biological resources. In recent years African universities have been under tremendous pressure due to inadequate funding from their governments and lack of access to international grants and resources. Chronic under-funding has compromised their ability to fulfill their role in society and, as a result, many African universities have been forced to enter into collaborations with foreign researchers as providers of unskilled labor. In return, they receive much-needed equipment and facilities. The ICBG project in Africa has taken a different approach by treating the African participants as equal partners who will conduct most of the investigation.

It may be necessary to state here that scientific expertise exists in both Nigeria and Cameroon to undertake the activities outlined in the ICBG program. Nigeria has over 36 universities, about 21 research institutes, and at least 3,000 active biological and medical scientists. Although the Republic of Cameroon does not have a similarly well-developed scientific base, it boasts many internationally renowned scientists. As in many African countries there are more qualified and experienced scientists in the universities than in the governmental departments and ministries; any genuine development project cannot afford to ignore or side track the universities. A problem, however, lies in the fact that universities are often elitist and do not readily link their laboratory research to the field situation and community needs. Another major problem is the chronic lack of incentive and absence of a conducive environment for innovative research, due in part to chronic poverty and to endemic political instability.

As has been noted previously by Okigbo (1994)¹, low salaries and poor conditions of service have resulted in low motivation, high levels of attrition, and brain drain. By creating a platform for the scientists and field staff to work as a team under the ICBG program, some of these problems have been ameliorated. One of the objectives of the ICBG is the strengthening of the capacity of BDCP, a local network created by University researchers to address the problems outlined above. For the first time in the history of the region, academics, policy makers and field staff share a common forum to design and implement projects that seek solutions to the problem of sustainability.

Perhaps, however, the greatest benefit for participating African countries will not be in the form of tangible and measurable things such as equipment and supplies, but in the catalyzing role of the ICBG in providing an enabling environment for scientists to develop a suitable model for the integration of the material needs of their communities with the equally urgent demand for conservation. As has been noted by several authors, sustainable development and conservation do not simply require applications of science and technology to the management and utilization of resources as developed countries have done in the past. This new goal calls for fundamental changes in development objectives, values, planning, strategies, institutions, technology characteristics, and production systems. There is no institution in Africa better equipped to initiate and manage these changes than the universities.

International Centre of Ethnomedicine and Drug Development (InterCEDD), Nigeria

InterCEDD participates in the ICBG on a number of levels. These include *in vitro* anti-microbial and anti-viral studies, and conducting the extraction for all plants collected in Nigeria. Extracts are then sent to the University of Ibadan, Walter Reed, and associated academic programs and contracted laboratories in the United States for testing. Examples of "benefits" accruing to InterCEDD include:

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¹ Okigbo, Bede N. (1991), the Nigerian born Director of the United Nations University Programme on Natural Resources in Africa stressed this point in his contribution to the *Symposium on Science* in Africa organized as part of the AAAS Annual Meeting in Washington, D.C.

Technology transfer: The ICBG collaboration will result in the supply of a bioassay for microbiological screening and advanced proprietary phytochemical methodology for spectroscopic structural elucidation work.

Infrastructure and equipment: Extraction equipment, basic running supplies, and access to a four-wheel drive vehicle through BDCP-Nigeria.

Expertise and know-how building and training: The ICBG will support two post-docs for one year each in the United States (at the University of Pennsylvania and for anti-viral drug-development at the Southern Research Institute in Alabama), will train researchers in the use of transferred technologies, and will impart know how for the drug development process. This will include seeing a drug through to the finished product, through exposure to commercial-oriented research, and involvement in the decision-making and selection process for the avenues to be followed by the research team. Academics are not normally exposed to such an environment, and it is thought that this will further their ability to collaborate with the commercial sector in the future.

Training has also resulted for natural scientists through a ten week ethnobiology and field taxonomy course held in 1994. The eight eastern state governments nominated botanists and foresters for this course. These professionals return to their positions with the State, but remain collaborators in the ethnobiological inventories underway by BDCP. In this way, a range of local experts are provided employment, and the data they collect from field plots is shared on an on-going basis with both local communities and states.

Training courses in biodiversity monitoring, forest inventory, the commercialization of biological resources (including biodiversity prospecting and intellectual property rights), and economic value assessments for forest products are also offered through ICBG funding.

University of Ibadan

The Malaria Research Center at the Postgraduate Institute of Medical Research of the University of Ibadan is responsible for *in vitro* and *in vivo* laboratory testing of malaria leads from extracts sent to them from InterCEDD. Examples of benefits include:

Technology transfer: Previously, through the type of established relationships upon which the ICBG grew, Walter Reed transferred sophisticated molecular biology technology to this laboratory. As part of the ICBG, funding has now been provided for post-doctoral fellows expert in this technology.

Infrastructure and equipment: The World Health Organization supplies the bulk of laboratory equipment, with the ICBG supplying supplemental computers and funding for basic supplies.

Expertise and know-how building and training: This area is more or less the same as that for InterCEDD.²

University of Dschang, Cameroon

The University of Dschang is conducting yield studies for *Ancistrocladus korupensis*, as well as phytochemical studies. Examples of benefits include:

Technology transfer: Much as the InterCEDD, the University of Dschang will receive bioassay technology for microbiological screening and advanced proprietary phytochemical methodology for spectroscopic structural elucidation work.

Infrastructure and equipment: Extraction equipment, basic running supplies, materials to conduct bioassay, and funding for two full-time staff members to conduct research.

Expertise and know-how building and training: In addition to the training of affiliated post-docs in the United States (three of five positions coming from Cameroon), staff at the University of Dschang will received training in bioassay techniques. Within Cameroon, and in conjunction with BDCP-Cameroon, an ethnobiology training course of the type given in 1994 in Nigeria, was offered in 1995. Other training courses in conservation and natural science-related fields, as detailed for InterCEDD above, will be offered within Cameroon, as well, in the coming years.

4.1.2 Local Non-Governmental Organizations

NGO's get mixed reviews in conservation and development circles due to 1) the obvious strengths and head-start provided by relatively small and un-bureaucratic, locally-based organizations with a focused mission, and 2) the unfortunate tendency for numerous NGO's to spring up in response to available funding, and not in heartfelt response to the problems they are supposedly created to address, with obvious results. Overall, however, NGO's are an invaluable component of the conservation and development community, and usefully form a bridge between the activities of government, business, and local communities, providing a flexibility and problem-oriented approach which is often missing outside of this sector.

Unlike in many other African countries (e.g. Nigeria, Ghana), local NGO's have generally played a small role in conservation and development activities within Cameroon. This is now changing, perhaps in part due to the emphasis placed on the positive contributions that can be made from such organizations and alliances during the UNCED meetings in 1992, and resulting financial support for smaller, "grassroots" initiatives, as well as the influence of preparations of a National Environmental Management Plan begun in 1992. According to a report commissioned by GEF, there are around 12

² Through an earlier CRADA funded largely by W.H.O. and the National Research Council, three Nigerian scientists are working at WRAIR and are acquiring useful expertise in various drug development techniques for parasitic diseases.

international NGO's and approximately 100 Cameroonian NGO's (with near 100% Cameroonian membership), in addition to numerous rural associations and village organizations.³

In Nigeria, NGOs have always been actively involved in conservation. There are over 200 active conservation NGOs in the country, many of them regional in both membership and operation. The oldest NGO, the Nigerian Field Society was founded in 1930 and has since remained active in various aspects of conservation. Even early editions of the society's journal, *The Nigerian Field*, contained articles on environmental debates, like that on the pros and cons of proposed large national parks, the need to adopt some traditional conservation methods, and reports on changes in the fauna and flora of Nigeria. More recently established NGOs include the Forestry Association of Nigeria (1970), Ecological Society of Nigeria (1973), Nature Club of Nigeria (1980), Nigerian Conservation Foundation (1982), Nigerian Environmental Study/ Action Team (NEST) (1987), Nigerian Environmental Society (1987), and the Nigerian Society for Environmental Management and Planning (1987). Several town and village development associations have included tree planting, wetland preservation and biodiversity conservation in their activities.

In general, Nigerian NGOs work closely with government in both the planning and the execution of environmental projects. Members of the Nigerian Field Society, for example, were active in the enactment of the Nigerian Forestry Act of 1938, the first law in Nigeria to specifically address forest resources. During the 1980s, many NGOs participated actively in the workshops that preceded the establishment of the National Policy on the Environment in 1989⁴. The Young Foresters Club, which is the youth section of the Forestry Association of Nigeria, was largely responsible for the reversal of the federal and state government policy of de-gazetting forest reserves. Most of the activities of WWF and IUCN in Nigeria are coordinated through a local NGO, the Nigerian Conservation Foundation.

Bioresources Development and Conservation Program

BDCP, which has now established autonomous branches in both Nigeria and Cameroon (as well as Guinea, which is not, however, involved in the ICBG), is also an international umbrella organization which, as discussed in other aspects of this paper, is primary administrator, monitor, and arbiter of the various interests involved in this ICBG. Benefits for BDCP will include:

Technology and expertise transfer: This category is, perhaps, not applicable to BDCP's role in this grant, unless one includes the technology and expertise of assembling and administering an unwieldy, multi-institutional grant, coordinating a variety of competing and not always cooperative interest groups, and honing the message of the vastly disparate members of the ICBG "team" into a cohesive and recognizable plan to achieve the extremely broad objectives of drug development,

⁴ A review of the Nigerian NGO activities in environmental conservation is available in "The Nigerian Environment: Non-Governmental Action", Proceedings of the Nigerian Environmental Study/ Action Team (NEST) Workshop, held at the University of Lagos, October, 1989.

improved health care, conservation and economic development for West-Central Africa. But perhaps "transfer" is a kind way of describing what was in reality a lesson "by fire".

Infrastructure and equipment: The ICBG will provide some basic infrastructure support for existing BDCP programs, such as: cultivation trials for the valuable medicinal species (once used as an ordeal poison) *Physostigma venenosum* in the Calabar region; assistance provided to local forest communities in acquiring legal rights to communal lands; and farm inventories conducted in both Northeastern and Southeastern Nigeria. The ICBG will also provide BDCP with basic funds to purchase herbarium equipment, which will be used jointly by InterCEDD, a four-wheel drive vehicle (one each for Nigeria and Cameroon), computers, and basic office costs for the Owerri, Nigeria and Yaounde, Cameroon offices.

4.1.3 Traditional Healer's Associations

One of the greatest disservices done to traditional African medicine by analysts is to group it with less rigorous forms of so-called "alternative" medicine or consider the practitioners as lay people with "folk" knowledge of healing herbs. Worse still is the belief that traditional medical practitioners are illiterate, ignorant and naive individuals who are likely to part with valuable secret remedies in exchange for mirrors or a watch-glass. In most parts of Africa, traditional medicine is a well-developed, professional, parallel system of medicine available to both the educated and the illiterate, rich and poor. However, because traditional medicine is more readily available and is cheaper than orthodox western medicine, it is most commonly patronized by the poor in rural areas. Traditional medical practitioners in Africa range from individuals with Ph.Ds in biomedical sciences to rural villagers without any formal education. Individual healers usually belong to one or more healers' guilds or associations, with clearly defined areas of medical practice.

In Nigeria, there are more than 100 traditional healers associations, with twenty of these having active memberships of one thousand or more. BDCP is collaborating with the main herbalist association in the country known as the Nigerian Union of Medical Herbal Practitioners, whose motto is "united to cure and to protect". The Association, which was founded more than twenty years ago, has branches in the 30 states of the country and at the Federal capital Abuja. According to the National President of the

⁵ Additionally, as Chief Cosmos Ozonnamalu, Secretary General of the Nigerian Union of Medical Herbal Practitioners, Enugu State Branch, said at a workshop held in conjunction with BDCP: "Traditional medicine covers metaphysical, physiological, spiritual diagnosis and treatments."

⁶ In Nigeria, a former Vice-Chancellor of Obafemi-Awolowo University Ife in the western state of Nigeria was a celebrated traditional healer. Dr. J. Ume, a professor of architecture and the former Deputy Vice-Chancellor of the University of Nigeria is a traditional healer. Rev. Fr. Arazu and Rev. Sr. Virginia of Enugu Diocese of the Catholic Church are practicing herbalists.

⁷ See, Iwu, M.M. (1993), Handbook of African Medicinal Plants, CRC Press, Boca Raton Fl.

Union, the membership list has about 60,000 names. BDCP is also collaborating with the Enugu State Branch of the Association, and hopes to extend the collaboration to other branches in the project area.

Traditional healers' associations in Cameroon are probably not as well-developed as those in Nigeria, but relative to many other tropical countries are highly organized. Healers associations are usually organized on a national basis, with provincial and local branches. These include the Association des Chercheurs Herboristes du Cameroon, the Association des Tradi-Practitioners du Cameroon, and the Association du Group d'Etude de la Medicine Traditionnelle du Cameroon.⁸

Examples of "process" benefits for healer organizations resulting from the ICBG include to date:

Nigerian Union of Medical Herbal Practitioners (N.U.M.H.P) Enugu State Branch; Headquarters, 9th Mile Corner, Enugu State

The Enugu Branch of NUMHP was established in 1970 as an umbrella organization for traditional herbalists living in the former East Central State of Nigeria (now made up of four states). It is a professional cooperative association with two main objectives: the legal protection of their members from the constant harassment by practitioners of western orthodox medicine and to campaign for Government recognition of indigenous medical knowledge. In 1985, the Union established a Traditional Herbal Medical Complex at the 9th Mile corner along the Enugu-Nsukka Express Road. This pioneer herbal medical complex was built with voluntary contributions from the healers themselves. It provides health care services to the rural population of the State and serves as a school for the formal training of herbalists. In 1988 the cooperative decided to begin planting a garden on the hospital grounds, made up of some of the medicinal plants commonly used in their practice. ICBG/BDCP staff have assisted in attaching botanical labels to the plants for educational purposes.

ICBG/BDCP staff have also facilitated the granting of \$2,500 to the association for basic running costs from a U.S. NGO, the Rainforest Alliance. Funds were used towards the purchase of a car for travel to remote villages for "house calls", and to transport people in to visit the doctors in town. ICBG funds were also applied to costs of building the herbal medicine hospital, including lights, electricity, painting, and louvers.

ICBG staff have also assisted the NUMHP in hosting a workshop on *National Congress on Traditional Medicine and National Development*. This was the first time that this organization had hosted a workshop and invited as participants international researchers. Research results demonstrating efficacy, toxicity, and recommended dosage from tests conducted as part of the ICBG are provided to all member healers. Members of the Union have also participated in workshops sponsored by BDCP to teach basic instrumentation techniques for the diagnosis of certain insidious diseases, like diabetes and hypertension, with late onset of symptoms. The Herbalist's Association and the State Branch of the

⁸ Dr. Daniel Lantum, of the University Center for Health Sciences (CUSS), coordinates a number of research programs on traditional medicine and the African pharmacopoeia, including a WHO/CUSS/IMPM research project.

Pharmaceutical Society of Nigeria commended BDCP for these workshops since they better equipped the healers to contribute to primary health care delivery.

The ICBG has also provided immediate financial reciprocity in the form of advance payments and access fees which the Union used to expand their herbal garden and pharmacy. The funds will also be applied to the following on-going projects: a) plant nursery facilities for the *ex-situ* collection and conservation of plants used by the healers in their practice; b) cultivation of selected medicinal plants as hedges for the demarcation of the herbal garden; and c) preparation and storage of samples in the community-based herbal pharmacies.

Individual members of the association will be compensated in two ways: direct cash payment for plant materials and services surrounding their collection; and, as contributors to the drug development process, they will be included in both the patents and the resultant royalty payment for the "inventors".

4.1.4 Local Communities

Local communities are important collaborators for the ICBG, particularly in the Nigerian research component, but increasingly in Cameroon, as well. To begin with, it would be useful to define what "local community" means in the context of this discussion, since the dilemma often arises that, while wonderful plans and policies can be made on behalf of "local communities", no one knows what is really meant by the term. Rather than become embroiled in debates about relative "indigenousness", the ICBG approaches the issue on a practical footing, working with existing local authorities (for example, chiefs, traditional healers, village councils, development associations, etc.), in communities in which ownership and authority are generally clearly defined. These communities usually share cultural and tribal ties, have well-structured systems of leadership, relative areas of specialty (e.g. healers, judiciary, etc.), and are self-defining entities. It is not our place to go in search of a "community" beyond what local people have defined for themselves, nor is it necessary to appraise the situation in order to decide on their behalf the "truly representative" bodies.

Forest communities in many parts of the world have a more collective approach to property and knowledge than their 'western" neighbours, and systems of ownership employed in Europe and America, for example, will hardly fit in the forest of southern Cameroon in which the Pygmies live. But this cannot be taken to be the case for all such forested areas. In most of Nigeria and Cameroon, communities have been anything but remote from the intense trading, and shifting between populations, that has occurred for hundreds of years, including the most recent colonial influences from Europe. Therefore, while communities may lack access to important technical and legal advice with regards to entering into agreements, the concepts of trade and property raised by the ICBG are not foreign.

⁹ See Richards, 1993. **Indigenous Peoples**. Thematic Issue of the Proceedings of the Royal Society of Edinburgh on the Lowland Rain Forest of the Guinea-Congo Domain, U.K. for an interesting discussion of this subject with regards to West Africa.

Perhaps most importantly, the tribal and family ties of African communities means that members of a community can live far away in urban centers, even overseas, but will always return to their "village" which they, and their children, and their children's children, will consider home. Therefore, in West-Central Africa, the cultural and socioeconomic split between urban and rural communities is not as severe as in other parts of the world, and the exchange of experiences and knowledge more fluid. Additionally, there is often a well-educated "elite" - scientists, lawyers, etc. - who have close ties with what would appear to outsiders as "simple" rural communities. While these "elites" have often been accused of taking the lion's share of local wealth and power, they can also serve an invaluable role in bridging the cultural and economic distance between rural communities and outside commercial and scientific interests.

The African members of the ICBG do not perceive themselves as detached intermediaries between foreign donors and the rural communities. Almost every member of the ICBG team has a village home in the project area of eastern Nigeria and western Cameroon. The working arrangements adopted for the ICBG are the outcome of several months of village meetings, discussions with influential members of the community, and negotiation with the appropriate government agencies.

Collection fees to individuals and communities.

Collections fees will be paid to individuals and communities for plant material and the services surrounding its collection. Plants will be collected directly from local communities and payment and compensation will be effected in three modes. First a "small" cash payment will be made to the informant/collector. Secondly, the community will be assisted with development projects they have selected as priorities, including health care, roads, schools, etc. Thirdly, the medical member(s) of the ethnobotanical team will consult with local healers and will assist them as requested in treating some acute, life threatening conditions.

It is estimated that up to \$50,000.00 will be spent in the first two years of the ICBG project for the payment of plant samples. This amount will be augmented (to approximately \$100,000 in five years) by funds received as sample fees charged to pharmaceutical companies with which the group is currently negotiating for joint biodiversity prospecting projects.

Each community will be asked to establish a consultative committee drawn from the executive of the village unions or town associations, village heads and professional guilds of healers. It is this village committee which will make decisions and select priorities regarding the nature and distribution of compensation.

Within a community, collaborating herbalists are given some form of immediate compensation in recognition of the time spent in the interview and to pay for the actual plant material collected. Although payments are not made at each visit, the overall amount must be considered significant and above the normal rate paid by pharmaceutical and research institutions for samples. This payment is considered as separate from the access fees paid to the Union or village council.

Umukabia Development Union

Umukabia is a village in Ehime-Mbano local government area of Imo State, Nigeria. There are 14 kindred units or families in Umukabia. The town has about 800 inhabitants, with a high concentration of healers. During the colonial days, people from the town were feared by their neighbours because of their famed healing powers and fetish festivals. Although most people in the town are now Christians, there is still a high level of herbal medical practice in the town. The healing festivals are still observed, the taboos are still in place, the elders dictate the issues of the day, and there are still vast tracks of undisturbed rainforest in proximity to the town.

BDCP has been collaborating with the Eze (the chief) of the town, and the council of elders and titled men, to set aside two of the community forested lands as extractive reserves. The program provided funds which were used for demarcation of the lands and for application for a legal instrument of ownership. The community would like to establish these communal forest areas as a medicinal plant sanctuary, but in order to do so must keep hunters and loggers out.

ICBG staff will collaborate with individual herbalists in the town in order to identify useful plants for investigation. Because the Umukabia people refused to embrace western culture as quickly and completely as their neighbours, they are still relatively traditional, but very much aware of the real value of their knowledge. ICBG/BDCP staff have facilitated the establishment of a Umukabia Community Development Fund, which was fed initially by payments made as a form of "access fee" in exchange for the inventory of local ethnobiological knowledge. Local community members were also paid for both information supplied and assistance in the field as guides, plant collectors, and porters.

Owai Community - Cross River State, Nigeria

BDCP is also working with *Owai* Town in the Cross-River State of Nigeria. The village has a population of about 300 people belonging to the Efik tribe. It is located in the rainforest zone near the Cameroon border. BDCP has provided the community with "access fee" funds as a form of immediate reciprocity, which they elected to use in the establishment of a small vocational education center. The small reciprocity fund was only enough to buy two typewriters and to complete a building to house the vocational center.

The ICBG also involves the active participation of six other communities in Northeast and Southeastern Nigeria. The nature of these collaborations, including forms of compensation, are much as described above for Umukabia.

4.1.5 State Governments

At the State Government level, ICBG/BDCP funds provided support to the Enugu State Forestry Department for the rehabilitation of Enugu Regional Herbarium. The herbarium, which served as a reference herbarium for the flora of Southeastern Nigeria and western Cameroon, was a victim of

drastic funding cuts by the Government following implementation of "structural adjustment". ¹⁰ In the Republic of Cameroon, BDCP provided legal assistance to the Ministry of Environment and Forests for an American attorney to review the terms of a proposed agreement between the U.S. National Cancer Institute and the Cameroonian Government regarding past collections made in Cameroon, particularly with regards to the potential anti-HIV vine *Ancistrocladus korupensis*.

4.2 Long-term benefits

Long-term benefits are generally financial in nature. While process benefits are a guaranteed, and in many ways more fruitful, product of this type of collaboration, financial benefits are most often used as a measure of fairness and equity. As a result, there is often a popular focus on documents, with less attention paid to the relationships upon which they are based. ¹¹ This is not to denigrate the importance of written agreements - they are an important tool for the representation of the ICBG's intent, both in the present and in the future, when the individuals involved have long ago moved on to other things. But, as we have said earlier, it must not be emphasized to the exclusion of the "process" benefits that can accumulate along the way, nor must the importance of the many relationships which make up the ICBG be eclipsed.

Following is a brief discussion of the elements contained within the Cooperative Research and Development Agreement, or CRADA, with particular attention paid to benefit-sharing, and the ICBG *Research Collaboration Plan and Declaration of Principles*, which is to be signed by each person that handles ICBG materials. A CRADA is a more elaborate document than a Letter of Intent, and is only considered in cases where projects are in a state of advanced research and development.¹² The CRADA deals directly with issues regarding research scope and administration, intellectual property rights (including licensing, royalty sharing, trademark, copyright, and trade secrets), and sourcing. Following is a brief summary of those aspects of the CRADA with direct relevance to benefit-sharing:

¹⁰ In his acknowledgment letter, the State Director of Forestry reported that funds provided by BDCP were immediately put to use, and that "the herbarium shall once more re-open for use by researchers."

¹¹ See Laird, S.A. 1993. <u>in</u>: Reid, W.V., Laird. S.A., Meyer, C.A., Gamez, R., Sittenfeld, A., Janzen, D.H., Gollin, M.A., and Juma, C. 1993. **Biodiversity Prospecting: Using Genetic Resources for Sustainable Development**. World Resources Institute, Washington, D.C. and Iwu, M. M. "Implementing the Biodiversity Treaty: how to make international cooperative work", Paper Prepared for **Trends in Biotechnology**, 1995 <u>in press</u>).

¹² In Article 1 the "CRADA for Drug Discovery and Biodiversity Conservation in Africa" states: "The members of the ICBG entitled "Drug Development and Conservation of Biodiversity in West and Central Africa" desire to enter into an agreement in which the IPR of the ICBG is properly protected, utilized, and compensated. The members of the ICBG seek to further the objectives of discovery of bioactive agents from natural products ensuring that an equitable economic benefit accrues to developing country organizations and individuals involved in the collection and identification of material from which these agents are derived and conserving biodiversity <u>in situ...</u>"

the distribution of royalties, trade secrets with regards to traditional knowledge, and sourcing issues. In summary:

Royalties

Intellectual property will be "managed" by Walter Reed, which must abide by the terms of the CRADA which include:

- Distributing 20% of all royalties and other considerations generated from licenses of IPR equitably among those parties contributing intellectually to the creation of the IPR, taking into account their relative contribution and ensuring that inventors in each case receive not less than 15%.
- Donating 50% of all royalty income and other considerations to BDCP to be used solely for programs and
 projects designed to promote sustainable economic development relating to biodiversity conservation in
 Nigeria and Cameroon. In order to distribute these benefits, "an independent Trust Fund shall be established
 as outlined in the "Compensation and Benefit Sharing Plan" (see *General Principles* below, which will guide
 the activities of this Trust Fund).
- 30% of all royalty income and other considerations will be donated to a Tropical Disease Drug Development Program based at Walter Reed in order to further research efforts on, often under-studied, diseases of the developing countries.

Protection and Perfection of the Intellectual Property Rights

Members of the ICBG decided to entrust Walter Reed Army Institute of Research with the task and responsibility of protecting and perfecting the IPR under the CRADA because WRAIR is the only non-commercial member of the ICBG with both the financial ability¹³ and the administrative structure to negotiate the best licensing agreement with potential licensees. The patents generated from the ICBG will be in the name of all the individual investigators who participated in the discovery of a particular drug, including of course the African scientists and traditional healers who contributed to the process leading to the new product.

Further, it was the opinion of BDCP legal advisers that since the legal instrument used for the execution of the CRADA is the U.S. Federal Technology Transfer Act of 1986, the entire agreement is subject to the Bayh-Dole Act, which gives preference for the IPR to non-governmental organizations, such as BDCP and the universities. The implication is that WRAIR is holding the IPR on trust for the ICBG¹⁴. The alternative arrangements will be to have the patents assigned to either of the commercial

¹³ It costs about \$5000 in legal fees and other administrative costs to file a single patent application. For the African ICBG this will total about \$200,000 for the 40 patents that may be filed during the 5 years of the project.

¹⁴ Beyond the provisions of the CRADA, the Attorney-Advisor of the Command Judge Advocate Office furnished a written guarantee and commitment to both Fogarty International Center and BDCP that the Army has the legal capacity to fulfill the intellectual property/ royalty sharing provisions of the CRADA. WRAIR has experience in establishing lawful arrangements for IPR licensing or assignment, which may not involve direct receipt of royalties by the U.S. Army.

partners for a fee. It is the position of the African members of the ICBG that no commercial establishment could equal the safe-guards and guarantees afforded by working directly with a U.S. government agency.

Although it may appear more elegant and would serve public relations to have the IPR vested and retained within the other non-profit, non-governmental ICBG partners, it is unlikely that multinational pharmaceutical companies would respect the IPR, knowing that poor developing country institutions lack the financial resources to prosecute a violation.¹⁵

Trade Secrets

Confidential information provided by a person in a source country, particularly a traditional healer, must be preceded by an agreement or the signing of an Informed Consent Form, unless the source is a member of the ICBG.

Sourcing

All licenses shall require ("to the extent it is commercially feasible") that the licensee seek to obtain future supplies of raw materials for R&D, as well as manufacturing, from the Source Country of original sample collection. "Payment for the samples will be determined on a case by case basis. In situations where large samples of plant material will be required for follow-up studies, the licensee will provide a written statement that the material will be collected in a sustainable manner and when appropriate an environmental impact assessment and/or a census of the species will be commissioned or has been conducted to ensure that the plant is not threatened by over-harvesting." 16

In summary, therefore, the CRADA outlines the following forms of benefit-sharing:

- Provision of funds for research on tropical country diseases;
- Reward of actively-involved scientists' intellectual contribution;
- Requirement of prior informed consent of individuals providing ethnomedical or ethnobotanical knowledge to direct the research, which will likely result in the return of benefits (not detailed in the CRADA).

The army will only be entitled to the percentage of the royalty which is assigned to it under the CRADA, which it will distribute according to Title 15 USC 371oc.

¹⁵ BDCP scientists have personal examples of outright violations of their patents in the past and the present arrangement was designed to prevent such abuses.

¹⁶ See discussion in S.A. Laird. 1995. Sustainable Sourcing of Raw Materials for Natural Products: Weighing the Benefits. WWF International, regarding the relative merits of this approach to benefit-sharing. Also, for discussions by Shaman Pharmaceuticals and NCI proponents of this method, see King, 1994. and Cragg, 1994. in: Greaves, T. 1994. Intellectual Property Rights for Indigenous Peoples: A Sourcebook, Society for Applied Anthropology, Oklahoma City, Oklahoma.

- Provision that companies seek as the first source of raw materials the country of origin (much as in the NCI Letter of Collection).
- Provision of 50% of royalties for BDCP work on development and conservation programs.

Emphasis on diseases endemic to source countries

Probably one of the most important benefits provided by this ICBG is its unique (to other ICBG's and to most pharmaceutical company natural products screening programs to date) emphasis on tropical diseases. Parasitic diseases of all kinds plague the tropics. Unfortunately, since most of the people living in these countries are poor and unable to afford to pay for costly prescription drugs, the diseases that affect them are of little interest to most pharmaceutical companies. Therefore, while malaria remains the number one killer disease in the world, there is no financial incentive to develop new drugs to combat it. By focusing on malaria, trypanosomiasis, and leishmaniasis, this ICBG hopes to return a significant benefit to tropical countries.

The ICBG research also has the added benefit for local communities of studying and standardizing, as a spin-off to work conducted for the ICBG, local traditional medicines, which can then provide a more affordable, and in some cases more effective, form of health care. The importance of data generated through the pharmaceutical R&D process for the study of traditional medicines for standardization, toxicity and active constituents is often under-estimated. A major part of the arrangement under this ICBG is to pass on information concerning acute toxicity of traditional remedies back to the healers so that they can use such remedies with caution. In many cases, plants can be formulated directly as phytomedicines based on chemical and biological information obtained from the ICBG results.¹⁷ In this way, both the healers and the health care providers will have at their disposal, in a relatively short time, readily affordable medicines derived from local herbs.¹⁸ Negotiations are on-going with two local pharmaceutical companies about manufacture, distribution and compensation for such remedies¹⁹.

4.2.1 Trust Funds²⁰: Distributing Financial Benefits Over Time

¹⁷ The W.H.O. has provided guidelines for the assessment of herbal medicines before they can be used for health care. In China, India and Japan, phytomedicines form the bulk of their medicinal plant use. In Europe, the highest selling medicine for the past 3 years, fetching over 500 million U.S. dollars, is the standardized extract of *Ginkgo biloba* sold as a phytomedicine.

¹⁸ See Iwu, M. M. (1994) African Medicinal plants in the search for new drugs based on ethnobotanical leads, in: G.T. Prance, Derek J. Chadwick and Joan Marsh eds. **Ethnobiology and the Search for New Drugs**. Ciba Foundation Symposium 185, John Wiley & Sons, Chichester. pp. 116-129.

¹⁹ BDCP convened a multi-institutional meeting in Lagos, Nigeria in 1995 for local pharmaceutical companies, regulatory agencies, traditional healers and research establishments, to explore the practical modalities of commercializing standardized extracts and whole plant materials as phytomedicines. A continent-wide Steering Committee has been established to meet during the *2nd International Congress on Utilization of Tropical Plants* in order to set-up an African Scientific Cooperative on Phytomedicine and Aromatic Plants (ASCOPAP).

²⁰ Barry Spergel of the World Wildlife Fund, Washington, D.C., describes a trust fund in the January 1993 paper *Trust Funds for Conservation*, as follows: "Trust fund" is a fairly loose and general term to indicate a sum of money that is

An independent Trust Fund is the distribution mechanism for the 50% royalty destined for BDCP "solely for programs and projects designed to promote sustainable economic development relating to biodiversity conservation in Nigeria and Cameroon," as described in the CRADA. It is intended that, in order to achieve its objectives, this Trust Fund will be fed by other sources, as well. The Healing Forest Conservancy, for example, recently donated \$40,000 to the Nigerian Trust Fund. The proposed breakdown of funds accruing to the independent BDCP Trust Fund through the 50% ICBG royalty payment is as follows:

- **10% BDCP-International** to spend according to the *Trust Fund General Principles* on conservation and development activities throughout Africa;
- 10% InterCEDD; 10% University of Dschang, Cameroon Explicitly for the purposes of training graduate students (with 20% of each allocation assigned to general supplies and equipment necessary to support graduate student research);
- **10% National Botanical Gardens and Herbaria** (split between Nigeria and Cameroon) not to replace existing government contributions;
- 50% Traditional healers' organizations, community development funds, etc. Based on relative contributions to the research process, funds will be distributed to all ICBG collaborators. Specific sums will have previously been decided upon with each group. However, additional income will be more widely distributed within collaborating countries in order to achieve broad-based conservation and development goals. Therefore, communities and conservation programs not directly involved in the ICBG might receive funding through this mechanism. Local community associations will have complete freedom over how and what they spend the money on, but within a pre-agreed guideline and scope.

While the International Trust Fund will fall under BDCP International and, as such, will have its administrative base in the United States, two independent Trust Funds will also be set up in Nigeria and Cameroon in order to disburse financial revenues allocated to local communities, traditional healer's organizations, and conservation and development projects. Financial benefits will travel through these National Trust Funds due to legal and administrative problems associated with establishing many, small trust funds capable of receiving revenues from overseas.

The Nigerian Trust Fund for Rural Development and Traditional Medicine (FIRD-TM) was inaugurated recently in Nigeria as "an independent, private, non-governmental and non-profit body." Its primary objective is to facilitate and ensure the equitable distribution of benefits derived from the utilization and economic exploitation of the biological diversity of rural communities and in the process promote and enhance the conservation of those resources (Kent Nnadozie, BDCP-Nigeria, 1997). The principal objectives of the Fund are:

legally restricted to being used for a specified purpose, separate from other funds, such as a government's general budget, and is managed by a trustee or board of trustees, which holds legal title to the funds. The specific legal form that a trust fund takes may either be that of a foundation, a non-profit corporation, a common law trust, or a trust established by an act of a national legislature.

- 1. serving as the channel through which the benefit and economic rewards are distributed to the areas from which source plants for drug and other product development are found and also compensate individuals, rural communities and relevant local institutions;
- 2. applying part of the funds available to projects or ventures that will promote conservation of biodiversity, drug development and traditional medical practices;
- 3. seeking to improve the standard of living of families in target areas through community development initiatives, information, education and communication, and to mobilise volunteer efforts of the rural people towards improving themselves, their environment and ensuring sustainable utilisation of the biological resources within their locality and sphere of control;
- 4. obtaining and channelling support and assistance to rural families, particularly women and children.

It is expected that in carrying out it objectives, the Board of Management will consult and collaborate with village heads and professional guilds of healers in determining the nature of compensation to apply or projects to embark upon in any given locality. In executing its mandate, priority is to be given to such projects and activities that promote or encourage biodiversity conservation. They cannot, however, participate directly in the execution of selected projects, but shall provide the appropriate funding and supervisory presence to ensure its proper execution. The Board will act independently of any control by either BDCP or any donors to the Fund, but may work in close co-operation with them.

The Fund is constituted of three principal organs

- 1. The Board of Trustee
- 2. The Board of Management
- 3. The Advisory Board.

The Board of Management is the executive/administrative organ of the Fund and will act on behalf of the Fund in respect of all matters within the capacity of the Fund. The Board of Trustees is established in accordance with the requirements of the law and all the property of the Fund is legally vested in them, which they shall hold on trust. The Advisory Board is, as the name connotes, advisory and is to be constituted by the Board of Management. It will consist of distinguished experts in areas that are related to the objects of the Fund as well as eminent leaders and individuals who identify with and can contribute positively to the fulfilment of those objects.

Members of the Board of management are 10 in number and comprise:

• 1 traditional ruler (who is also a retired State chief-pharmacist who, throughout his tenure sought to incorporate traditional medical practice in the formal medicare system).

- 4 traditional medical practitioners (who are executives in the associations of traditional medical practitioners from different sections of the country, one of whom is a consultant herbalist to a University);
- one representative from Department of Planning, Research & Statistics of the Federal Ministry of Health;
- the co-ordinating Director for Science of the National Agency for Science and Engineering Infrastructure:
- 2 Pharmaceutical scientists who have done extensive work with traditional medical practitioners (one in academia and the other in health administration as the Executive Secretary of the West African Pharmaceutical Federation); and
- one ecologist.

The professional and sectoral, as well as the ethnic diversity of the membership is part of the deliberate policy to ensure that as many relevant constituents as possible are represented. It is also so constituted to encourage meaningful cross-fertilisation of ideas, and at the same time capture and derive the best benefit from the rich and diverse experiences of the individual members. The stature and integrity of the members and their dedication to similar ideals as those for which the Fund was set up will further ensure that those ideals are properly implemented (K. Nnadozie, BDCP-Nigeria, 1997).

Trust Funds serve an important role as a mechanism for the distribution of benefits resulting from the ICBG. But Trust Funds are also a valuable way to guarantee long-term financial support for conservation and development programs, which often fall victim to the fluctuating and often short-term (2-5 years) support of government and donor agencies (Spergel, 1993). Spergel (1993) goes on to list a number of benefits provided by trust fund arrangements:

- the broad private and public sector participation involved;
- meeting recurrent costs which might otherwise be very difficult to fund, although this requires a system of careful monitoring and evaluation;
- improving absorptive capacity, i.e. the ability to use large grants over an extended period of time;
- providing a small grant-making capacity by "retailing" large international grants to a wide range of smaller projects;

sustained funding, mitigating risks of unexpected stoppage of funds due to political changes, budget cuts, economic austerity programs, etc. 21

²¹ Spergel (1993) notes, however, that it is important that trust funds not replace government funding, and that they be over and above existing levels of government funding, i.e. the concept of "additionality". In some cases, such as Bhutan, the legal documents establishing a trust fund will contain specific agreements from the government to maintain existing levels of funding for various conservation activities. Spergel also warns against allowing a trust fund to be viewed as belonging to a particular government department.

BOX 2: ICBG Compensation and Benefit Sharing Plan

Trust Fund General Principles (DRAFT)

The provision of compensation to institutions in source countries and distribution of royalties have been formulated to ensure that the following principles are adhered to:

- 1. The distribution of the benefits will ensure that economic benefits are channeled back to the area in which the source plant was found with provision made to compensate individuals, rural communities and local institutions. Modalities will be selected to address each individual circumstance, taking into consideration the fact that cash may not be the most appropriate benefit.
- 2. Revenues generated from this project will be used solely for projects that will promote conservation of biological diversity and drug development, as well as the economic well being of rural communities.
- 3. Local communities, through town associations, village authorities and professional guilds of healers should be empowered to make decisions regarding compensation and projects in their localities.
- 4. The African members of this ICBG will be involved at all stages and in all aspects of the drug development process and this experience will enhance their capacity to undertake similar ventures in the future on their own. It is our hope that our work will generate not only pure chemical isolates as pharmaceutical leads but will help the source countries in standardizing their phytomedicines and return such information as benefits to traditional healers. In all cases compensation will be on a case by case basis.

- 5. While the development of drugs may be the most visible activity under this ICBG, equal importance will be accorded to the conservation and economic development aspects of this project. The ICBG will establish a viable scientific partnership between the United States scientists and their colleagues in Nigeria and Cameroon, which will aim at <u>assisting</u> the source country scientists in strengthening their capacity to conduct research and to protect the biodiversity in their area now and in the future.
- 6. All the scientists and individuals who contributed intellectually in the identification and processing of the medicinal plants, and their subsequent isolation and development as medicinal agents, will be compensated as appropriate. This will include traditional healers who assisted in identifying the plant materials and/or contributed in the plant selection process.
- 7. Appropriate recognition must be given to the contribution of all parties to the development of a therapeutic agent. Individuals who provided information leading to the discovery of an active molecule from a plant must be acknowledged in all publications and patents arising from the work. The community from where the plant was sourced will also be cited in publications and patent applications. The methodology adopted for this project will rely more on information from specialist medicinemen and acquisition from lay people will be minimal.
- 8. The customary methods of protecting intellectual property rights (patents, copyrights, trademarks, trade secrets, etc.) may not be adequate for the purposes of this ICBG. The Group recognizes the need for alternative methods for effective protection of traditional knowledge, the need to receive prior informed consent, and the fact that access to legal assistance for the protection of land, resources, and intellectual/cultural rights is necessary in order for communities to monitor and receive equitable distribution of benefits from this project.
- 9. While the right of individuals to their land and resources derived from it will be respected in the allocation of benefits, the group is cognizant of the fact that information concerning the specific use of a plant drug is often not the exclusive property of an individual informant or healer but belongs in the realm of Cultural Resources (CRs), which belongs to the entire community or village. This raises ethical questions as to the competence of any one person to reveal information which has been entrusted to him as a custodian. This concern has to be balanced with the fundamental human rights of the professional herbalist to be treated as individuals with rights to their private property and knowledge.²²

5. Policy, legislative and administrative context

Prior to the Convention on Biological Diversity, the Nigerian Government had enacted in 1987 the National Crop Varieties and Livestock Breeds Act, and in 1992 the National Agricultural Seeds Decree, both of which touch upon issues relating to access to genetic resources, but are inadequate to address ABS under the Convention on Biological Diversity. More recently, the National Parks Act (No. 36 of 1991) was reviewed and revised to incorporate significant elements of Article 15, and may act as the model for a subsequent national access and benefit sharing

²² Chief Cosmas Ozonnamalu, the Secretary General of the Enugu (Nigeria) branch of the Herbalist Union wondered why Western analysts do not subject orthodox medical doctors to the same standard since in effect they were also trained at public institutions and educated with references from materials taken from published literature in the public domain.

system.²³ It includes provisions requiring the PIC of the Minister of Agriculture, and benefit-sharing in the form of: research collaboration with Nigerian scientists; results from research, and reports on use of materials; and, broadly, the sharing of benefits with the people of Nigeria.

Federal institutions with authority over issues relating to access and benefit sharing and biotechnology, including trade and intellectual property, include (Ajai, 1997):

- The Federal Environmental Protection Agency
- The Ministry of Science and Technology
- National Agency for Science and Engineering Infrastructure
- Federal Ministry of Agriculture and Natural Resources
- Federal Ministry of Industries
- National Agency for Food and Drug Administration and Control
- Registrar of Patents and Designs
- Ministry of Trade and Tourism
- National Office for Technology Acquisition and Promotion

Ajai (1997) makes the point that there is a pressing need for an inter-ministerial or inter-agency committee, or focal point, in order to streamline the process by which ABS issues are addressed.

Nigeria is a signatory to several international treaties aimed at the conservation of natural resources, including:

- African Conservation Convention for the Conservation of Nature and Natural Resources (Algeria, 1968; Depository: OAU Secretariat, Addis Ababa)
- Convention for the Protection of World Cultural and Natural Heritage (Paris, 1972; Depository: UNESCO Headquarters, Paris)
- Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), (Washington, D.C., 1973; Depository: Swiss Ministry of Foreign Affairs, Berne)
- Convention on Migratory Species of Wild Animals (Bonn, 1979; Depository: Federal Republic of Germany, Bonn)
- Convention on Biodiversity, Rio de Janeiro (Brazil, 1992; Depository: UNEP)

6. Policy conclusions

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²³Ajai, Olawale. 1997. Access to Genetic Resources and Biotechnology Regulation in Nigeria. **RECIEL**. Vol. 6, Issue 1, 1997.

- 1. In determining compensation packages for access to genetic resources, emphasis should be placed on R&D *process benefits* and capacity building rather than short term cash payments. Source countries should endeavor to add value to their resources before trading the samples. The objective is to build a lasting relationship between the parties, rather than negotiating only for immediate compensation. If properly planned, biological resources could be a viable vehicle for sustainable development. Research collaborations should be carefully structured so that there will be tangible benefits for all members of the partnership at all stages of the collaboration.
- 2. A national ABS focal point would help to improve coordination of the ABS policy process within Nigeria. It is important for the country to move forward in providing a national policy framework for commercial partnerships and benefit sharing plans such as this one.
- 3. Involving a range of stakeholders in ABS consultations will help to ensure the development of a workable ABS measure. Biodiversity prospecting is a multi-disciplinary and complex field, and the cooperation of a range of sectors in society is required in order to develop effective regulations.
- 4. Nigeria is uniquely qualified to undertake biodiversity prospecting partnerships given its high level of scientific and technological capacity. The country should develop a strategy for collaboration with the private sector based on an assessment of internal capacities, and identified needs.
- 5. Traditional knowledge is an important guide to drug-development, and as such should be valued and respected. Access and benefit sharing must always include local communities, indigenous peoples, and traditional healers.
- 6. Benefit sharing should increase domestic capacity for research into tropical diseases. Companies cannot be required to conduct this research, but partnerships should be structured in a way that builds domestic capacity and collaborations to study these badly under-researched diseases, afflicting large numbers of poor in Nigeria and other high biodiversity countries.
- 7. The conservation of biodiversity is best achieved in heavily populated countries, with great economic need, when biodiversity conservation is integrated with sustainable development. Biodiversity in these cases must compete with alternative land uses in a very real way, and non-consumptive uses such as biodiversity prospecting must be promoted. Benefit-sharing plans must integrate the conservation of biodiversity and sustainable development.