

Chapter 9

Emerging Pharmaceutical Infrastructure in Sub-Saharan Africa

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AIDSfreeAFRICA is a non-profit organization dedicated to establishing sustainable drug production in Sub-Saharan Africa. This chapter discusses how the organization was founded and the initial steps made towards establishing pharmaceutical production in Cameroon. This chapter also indicates how lack of infrastructure and resources has limited the expansion of such facilities. The educational system in Cameroon is discussed along with barriers to the training of industrial chemists. The chapter concludes with the outlook for AIDSfreeAFRICA in Cameroon.

Introduction

From global warming to global terrorism, today we know that what happens in a remote corner of the world can affect us all. In Africa, where the vast majority of the population lives on less than a dollar per day, desperation may lead to desperate actions, with catastrophic results. What happens in Africa matters to the rest of the world. There is general agreement that improving overall health is a necessary prerequisite to lifting a country out of poverty. African governments already spend a considerable portion of their gross domestic product on health care for their citizens. However, according to World Health Organization estimates, 270 million people in Africa lack access to even the most essential medicines (1). This “lack of access to medicines...kills an estimated 6 million people every year, mostly in Sub-Saharan Africa.” (2) My experiences in Africa highlight the paramount role that pharmaceutical production in Africa will have to play to reaching the goal of achieving universal access to medicine and to facilitate economic development.

The Melinda and Bill Gates foundation supported the Grand Challenges in Global Health initiative with US\$450 million, believing that science can and will provide solutions for the world's most pressing health issues (3, 4). For global issues such as global warming, terrorism, health, tsunamis, and asteroids, to name a few, scientists will find solutions. Today we take breathing smoke-free air for granted, thanks to catalytic converters and lead-free gasoline. The world is now free of the scourge of Smallpox. Polio will soon be eradicated as well. We do not know in advance just what a solution will look like, but solutions are found every day.

To better understand the impact of globalization on industry, and the need for chemistry programs to educate scientists better suited to fill the resulting new positions, I will point out obstacles encountered during the past five years in my efforts to advance local drug production in the African country of Cameroon. This will be followed by some historical facts and a description of the educational system. Discussion of my multicultural work in economically impoverished regions will hopefully provide insights into what it means to teach and organize in an environment with spare resources. After describing day-to-day challenges in drug production, limits to education, and the unique opportunities and factors that are present that offer real hope, I hope to convey the importance and tenability that drug production is possible in Africa.

The Founding of AIDSfreeAFRICA

AIDSfreeAFRICA was conceived in 2003 as the first non-profit organization that would advocate for, and implement drug production in Sub-Saharan Africa. Efforts to develop the infrastructure for medical care, and importation of the drugs necessary to provide care, however, have been ongoing in this region. From the beginning of Christianization, the local Churches in Africa have been successful in establishing hospitals that provide quality care in addition to, or sometimes exceeding, the care provided by government-owned and managed district hospitals. However, African hospitals lack access to a sufficient quantity of quality drugs and medical supplies. Until an infrastructure is created that supports in-country drug production, this problem will persist.

My experiences with AIDSfreeAFRICA suggest that while the Clinton Foundation, Doctors Without Borders, the Bill and Melinda Gates Foundation, and numerous other philanthropic organizations have made persistent efforts to provide much needed medicines in a timely manner in continents such as Africa, the sheer volumes of medicine needed in a sustained way, along with the need to reach remote regions, has exceeded the capacity of these organizations to provide the quantity of drugs needed to make a significant difference in the lives of the people in need.

In Cameroon, where my efforts have been focused, pharmacists who struggle day in and day out to provide the hospitals with imported drugs have long been thinking about how to establish local drug production. Thus, in Africa, hospital care and drug production go hand in hand. In most western countries, doctors know drugs are available and they prescribe whatever they feel the patient needs without

even thinking of the possibility that the drug may not be in the pharmacy. In Cameroon, for example, hospitals are plagued by stock outs (empty warehouses), so drug availability is always on the doctor's mind. If a drug is produced far away, it cannot be made available on short notice. Life-saving drugs can also be withheld for political reasons. If the drugs are produced locally, the drugs can be made available on short notice and government bureaucracy may be circumvented by private industry initiatives. On a visit to Cameroon, the first thing doctors told me was: "Please, Doctor, bring us drugs but make sure they are continuously available." In the US we do not appreciate how much it means to have drugs available on demand.

In the process of founding AIDSfreeAFRICA, I studied successful organizations and how their structure and modus operandi allowed them to be successful. I was looking for role models and events in history to guide me. I chose "The Hunger Project," a twenty five year old established non-profit organization working around the world with the goal of eradicating hunger, as a good model. The organization's roots are firmly anchored in the teaching philosophy of Landmark Education Corporation, with which education I am familiar. I adopted the visionary style of Landmark, and combined it with the "hands-on, boots-on-the-ground" practical approach of The Hunger Project.

In 2003 I took the opportunity to represent Servas, an international peace organization at the United Nations Economic and Social Council (ECOSOC). I had been a member since 1989. In my capacity as representative of Servas I attended an international conference where President Lula da Silver gave the keynote address. He told us how drug production of antiretrovirals had turned the tide and stemmed the pandemic in Brazil by making the costs of drug production and distribution affordable to the government, allowing them to provide the drugs at no cost to many infected individuals. Sitting in the audience in 2003, I thought: "This is cool; we will do this in Africa!"

While the story of Africa has yet to be written, Brazil has demonstrated how readily available drugs can have a huge effect on citizens' health. In 1990, with over 10,000 Brazilians infected with HIV, the World Bank predicted that, by the year 2000, 1.2 million people in Brazil would be living with HIV (5). Owing to the development of improved drugs by 1996, now used as cocktails that could simultaneously attack different stages of the HIV lifecycle (designated highly active antiretroviral therapy; HAART) (6, 7) combined with the effectiveness of stepped-up prevention campaigns (comprised of drug production, distribution, and education) in conjunction with numerous non-government organizations (NGOs), the actual number of individuals living with HIV in 2000 was estimated to be 600,000, half of what had been predicted by the World Bank (3). In contrast, HIV infection was spreading exponentially in Africa and the Caribbean where no such campaigns were in place. This bold program in Brazil illustrates how readily and powerfully available drugs can impact health outcomes.

In monetary terms, the Ministry of Health estimated in 2002 that the availability of antiretrovirals had prevented approximately 358,000 HIV-related hospitalizations, saving more than US\$1.1 billion." (8) By the end of 2007, it was estimated that 80% of those requiring the drugs were receiving them (7). According to the World Health Organization (WHO), this level of treatment

coverage is more representative of that of a more developed nation, owing in great part to Brazil's ability to produce several AIDS drugs locally. By 2006, Brazil's large pharmaceutical industry was producing approximately 40% of its ARVs (9).

Since 1996, Brazil has complied with the international Agreement on Trade Related Aspects of Intellectual Property (TRIPS), which was established to protect the patent rights of pharmaceutical companies. A major tool in these negotiations was a clause in the TRIPS agreement that allows developing countries to issue 'compulsory licenses' for drugs. Compulsory licenses allow countries to override patent laws and produce their own generic (copied) versions of company-owned drugs, and can be issued when the government of a developing country deems it to be a public health emergency (10).

Brazil demonstrated that local drug production makes a dramatic difference. But Brazil is hardly thought of as developing country and it already had local drug production capacity. For Brazil, it became crucial to produce antiretrovirals whose patent protection had to be broken due to the nation's health crisis. This made it monetarily possible to provide these drugs to so many of those in need.

Given the realization that this kind of approach is likely to be needed in other nations, including those far less developed than Brazil, it is critical to ask if there are precedents for establishing drug production in developing nations. Indeed, only fifty years ago, Chemical, Industrial and Pharmaceutical Laboratories, Ltd. started operation of a plant in Vikhroli, Mumbai. Popularly known by the acronym CIPLA, today, the company exports drugs to 180 countries world-wide (11). In 2005, India joined the World Trade Organization and agreed to adhere to international patent and trade agreements (TRIPS). According to AIDSfreeAFRICA collaborators in Cameroon, an estimated 85% of the antiretrovirals drugs available in Sub-Saharan Africa are generics delivered by CIPLA. According to doctors and medical professionals in Cameroon, today, the majority of drugs they have problems importing are generics which are NOT in the category of antiretrovirals. India, a developing country with a population of over a billion, has developed two of the world's four largest generic drug manufacturing companies, namely CIPLA and Ranbaxy. Of the other two, GlaxoSmithKline also exports drugs to Africa, while Teva (Israel) as is the world largest generic drug manufacturer focuses more on Latin America and has only a small share of the African market.

It is a pity that despite all efforts by non-profit organizations and commercial enterprises the current total import of drugs into Africa falls an estimated 50% short of what is urgently needed (12). Certainly, there is a need and a market for quality drugs. More importantly, my experience with AIDSfreeAFRICA indicates that drugs do not have to be donated to fill this gap; they can and need to be sold. Principally, there are four ways drugs come into Cameroon and to the patient:

- First, foreign non-profit organizations raise money, buy drugs, import them into African countries and distribute them for free. This approach involves no licensing requirements, no taxes and no government interference. The disadvantage to this approach is that its lack of regulation invites abuse. Organizations often close their eyes to the fact

- that these donated drugs are frequently *sold* to patients, and not given to them as they were intended.
- Second, drugs are imported and bought through a distribution agency managed by the government and by private wholesalers. The government requires that all drugs have to be registered by a cumbersome system similar to that used by the United States Food and Drug Administration for new drug approvals. This does not work within the context of African governments and creates huge backlog and long waiting time. It inappropriately treats applications for generic essential drug licenses with the same rigor as new drug applications. In addition, imports of drugs are limited by the size of the government budget.
 - Third, drugs are obtained from a flourishing black market that operates unchecked. While black market drugs fill a desperate need, they are unregulated and lacking in any traceable history or guarantee (with many of these drugs coming from Nigeria). Thus, their chemical composition, dosage, impurities, and treatment in transport are all unobtainable. More recent developments are further complicating the situation by confusingly equating generic drugs with counterfeit drugs.
 - Fourth, drugs can be produced locally. The advantage to local production is that this can close the gaps in the availability of drugs, and in their continuity, as seen in the example of Brazil. The disadvantages right now are that Cameroon, and many other underdeveloped nations, lack not only the infrastructure for production, but also appropriate government regulation and means of drug distribution. Locally produced drugs, as we envision it, will be registered with the government, and sold to local wholesalers and hospitals. Production and facilities will be quality controlled through appropriate government agencies and eventually WHO approved.

As mentioned before, fifty years ago there was no pharmaceutical drug production in India, but today the Indian company CIPLA and others provide the bulk of the pharmaceuticals consumed in Sub-Saharan Africa. It is time for Africa to build its own pharmaceutical production capacity. For this purpose, I visited Kenya and Cameroon in 2005 to conduct needs assessments and feasibility studies for the founding of in-country drug production facilities. Since then, AIDSfreeAFRICA has focused on Cameroon.

Background and History of Cameroon

AIDSfreeAFRICA has been working in Cameroon for the past five years. When I present my work to an audience someone will inevitably ask, “Why Cameroon?” It happened by chance, and it turned out to be a good choice. I had been asking friends if they knew someone who worked in Africa who could make a recommendation. I was visiting friends in Kansas when Dr. Gunda Georg, who was at the University of Kansas, Department of Medicinal Chemistry, recommended her friend Dr. Carole McArthur, a Professor at the University of

Missouri, Kansas City, who, according to Dr. Georg “was working somewhere in Africa.” As it turned out, Dr. McArthur has an on going research collaboration with a Cameroonian, Dr. Paul Achu, at the Mezam Polyclinic in Bamenda, Cameroon. I presented my idea, and the rest is history.

I found Cameroon to be a microcosm of Sub-Saharan Africa. A midsize country, it is somewhat larger than California, with almost twenty million inhabitants <http://www.maplandia.com/cameroon/>. Culturally it belongs to West Africa, but economically it belongs to Central Africa. It occupies the right angle on Africa’s western coast, and stretches from the Saharan dessert in the north to the equator in the south where it has 400 km (216 miles) of coast line, rainforest, savanna, volcanic ranges flecked with crater lakes, and the highest mountain on the west side of the continent. Mt. Cameroon stands 4095 meters tall (13,435 feet), rising directly from the ocean shore. The country is 16% Muslim, 33% Christian, with the rest holding native tribal beliefs. Officially bilingual in French (government) and English (North West and South West Region), and most people speak Pidgin English and one of 270 distinct native tribal languages. President Paul Biya, in power for 29 years, and not willing to hand over the reins, has been only the second President since the country’s independence from the French on January 1, 1960. He succeeded Ahmadou Ahidjo, who had held power for 22 years, in 1982. Biya recently changed the country’s constitution, allowing him to run again for president in 2011. The result of his reelection is likely to be a foregone conclusion for the many disappointed citizens who yearn for a change in government.

Cameroon is a stable and peaceful country which has never had a civil war. The government spends 3% of the gross national income (GNI) on health, 12% on education and 10% on defense according to UNICEF data from 2007 (13). However, the population has much to complain about. The gross national income (GNI) per capita is listed as US\$1,150. One third of the population has a daily income of US\$1.25/day or less, well below the US\$29.67/day of the U.S. poverty line. For women the lifetime risk of maternal death due to complications from childbirth is a staggering 1-in-24. Valued strongly by Cameroonians, primary school attendance is 86% for boys and 81% for girls. High school attendance drops significantly for both genders to 28% for boys and 22% for girls. The gender gap becomes more obvious when looking at the 72% literacy of 15 to 24 year old boys, *versus* 59% for the same age female population. Teenage girls can be found everywhere as unpaid domestic workers, working for room and board only (13). Boys on the other hand are glad if they manage to find work driving a car or motorbike as a taxi.

The agricultural sector employs three-quarters of the work force, and contributes approximately half of the gross domestic product. Favorable agricultural conditions, such as rich volcanic soil and plenty of water in conjunction with landownership by local families, would suggest a level of survival incommensurate with the poverty levels observed. Cameroonians tell me that the country is so peaceful because there is always food available. Since people have plenty to eat they don’t fight the government. Although this may be true for most of the country, it changes dramatically traveling north is where one encounters desertification and hunger.

Cameroon exports energy generated from hydro-electric power and is currently erecting its first off-shore oil drilling platform. The country mines precious metals and exports timber and rubber. So far, Cameroon has not taken advantage of the potential to make money through tourism, but there is promise for the future.

The chemical industry is small. There is the French-owned company Air Liquide in Douala which sells compressed gas in cylinders. A few international chemical and pharmaceutical companies keep marketing and sales offices. Chemicals are generally imported through Nigeria. Chinese goods flood the local markets everywhere, endangering fragile local production and craftsmanship. European beer breweries are plentiful -- with highly secured, fenced-in production facilities that are well managed, and fleets of in-house trucks rivaling all others in the country. Cameroon is rumored to be close to Ireland and Germany in per capita beer consumption even though 660 ml (22.3 ounce) bottle of delicious beer costs 500 CFA (the equivalent US\$1.00), which represents the average daily income for roughly 1/3 of the country's inhabitants!

Despite this, I was delighted when I saw my first billboard depicting the vats of beer, copper piping, and gowned workers brewing beer. I reasoned that since Cameroonians can brew beer, they can be trained to produce pharmaceuticals. After all, beer production must be clean and controlled, needs purified water and handling of products for human consumption. The goods must be processed, packaged, labeled, shipped and monitored. The facilities must be maintained and repaired. Security must be in place, with the raw materials imported and stored safely and under controlled conditions. The billboard illustrated that there are people who have been trained to perform and manage all of these tasks. In fact, the first person we hired was an accountant who had formerly worked for one of the beer breweries.

To this day, I believe Cameroon was a good choice for the country in which to set out our mission. The most notable advantages are the stability of the country and the peace-loving nature of the people. There is little violent crime. The fact that there is plenty of food is always cited as the reason for the peaceful nature of the otherwise tribal and inhomogeneous population. Cameroon is not on the United Nations list of the fifty poorest countries. Thus, as weak as the infrastructure is, there are plenty enough resources to work with and there are educated people eager to learn and collaborate.

First Steps towards Pharmaceutical Drug Production

Since 2005, I have spent a total of thirteen months in Cameroon. During my first two-month trip to Cameroon, my chief focus was to establish needs assessments. I needed to learn as much as possible and to assess what there was in the country to build on, what was missing, what was needed, and where the bottlenecks were with respect to drug production and access to drugs. Perhaps the most surprising finding was that *access to antiretrovirals was not the biggest problem*. In fact, it was not even a problem, since these drugs were provided and paid for by the Global Fund. As a consequence, AIDSfreeAFRICA shifted

its focus from producing antiretrovirals to what was needed the most: *essential generic drugs* for the most common maladies.

But first, more about my host Dr. Paul Achu, member of a large and well respected family in Cameroon. His oldest brother Simon Achu had been the Prime Minister of Cameroon. Paul had standing in the Society which allowed him to introduce me in a most proper and useful manner. I am grateful for these advantageous introductions. I also had the opportunity to learn the basics. Amongst other things I learned how people live and do business in Cameroon. Dr. Achu is a British educated pathologist who is today the proprietor of the Mezam Polyclinic, an approved HIV/AIDS treatment facility in Bamenda, in the North West region of Cameroon. I have had the opportunity to meet with doctors, pharmacists, nurses, social workers, business men and women, politicians, professors, students, storeowners, women selling goods at the market, and various others -- too many to count.

Focused as I was on pharmaceutical production, I met and assessed possible local collaborators. It was never the intent of AIDSfreeAFRICA to build a factory ourselves. Instead, we have wanted to find Cameroonians interested in collaborating with us so that we could support *their* endeavors!

During the first three years of AIDSfreeAFRICA the work focused on one start-up company, namely Diamond Pharmaceuticals which was located in Douala, the largest city in Cameroon. I was repeatedly asked if the company would survive and what I would do were it to fold. Statistics from the Small Business Administration (SBA) show that "two-thirds of new employer establishments in the USA survive at least two years, and 44 percent survive at least four years." This confirms what my business coach from "SCORE" (Senior Core of Retired Executives) told me, *i.e.*, that in the USA, 60% of all business start-ups fail (14). Thus, my answer was and is, "If 60% of start-up businesses in the US don't make it past four years, why would I expect 100% success in Cameroon?" So far, neither Diamond Pharmaceuticals nor Meditech, both start-up companies for which we consulted, managed to survive. Determined to learn from these experiences I am convinced it has brought us step closer to finding solutions.

In my opinion, it will take a critical mass of several companies to achieve the overall goal of establishing a pharmaceutical industry in Sub-Saharan Africa. After that, it will be easier for others to follow in their footsteps. Attracting the interest of the Cameroonian Prime Minister Philemon Yang, and the US Embassy Business Development Services in Cameroon, has proved very helpful in making connections with business people and Cameroonian investors. We looked for more established groups and were introduced to the head of the Cameroonian Baptist Convention, Professor Pius Tih. In addition to operating 5 large hospitals and 23 Health Clinics, the Cameroonian Baptist Convention operates a production site in Mutengene south of Douala (15). This site produces sterile intravenous fluids, eye drops and ointments. However, their non-profit church status limits them to in-house production and in-house distribution of these products. In other words, the Baptist hierarchy, in order to avoid government requirements such as taxation, inspections and licensing, made the choice to limit production for distribution within their own hospitals.

Currently, Genemark an established company in Douala has become our main focus. The company is family owned, in operation for more than five years and expanding steadily. They are the only company in the country to produce children's medicines in the form of syrups, mainly quinine (for treating drug resistant malaria), paracetamol (Tylenol) and carbocysteine (a cough syrup). They have recently expanded into producing vitamins, especially the urgently needed iron/B12 vitamin combination to address the severe iron deficiency of Cameroonian women. The iron supplement is usually formulated with vitamin B12 since processes involving blood generation need both, iron and B12. When one realizes that women who test positive for the HIV virus cannot be placed on antiretroviral treatment if their blood iron level is below normal, one can appreciate the consequences of iron deficiency. In the absence of iron supplements, doctors resort to giving iron-deficient women blood transfusions. Given the lack of blood banks, the standard source of blood for transfusions is from an insufficiently tested relative, who the patient is required to bring to the hospital, increasing the threat of contracting HIV and highlighting the importance of making iron/vitamin supplements available.

It can be argued that producing syrups is pharmaceutical production and I would not object. However, AIDSfreeAFRICA's gold standard for pharmaceutical production has been to push for production of *blister-packed solid oral tablets*. Liquids such as intravenous or IV fluids or syrups have been produced in Cameroon for some time. However, their use is limited. Most medicine needed is dispensed in tablet form and blister packaging protects drugs from heat, humidity and breakage. Thus we are very proud that we are now in the process of financing the purchase of blister packaging/labeling equipment. When this is accomplished, Genemark will have become the first factory to produce solid oral tablets of the malaria drug quinine, to treat the number one killer in Africa: malaria.

Another possible source for drug production in Cameroon is the ISO9001-approved formulations and packaging outfit, Kakwa Biopharm, located south of Douala (16). To this day, Cameroonian shareholders who live and work in the US have invested USD\$ 3,000,000 and thus own the company. The goal has been to produce malaria drugs based on the WHO approved artesunate/amodiaquine combination drug. However, production has yet to begin. AIDSfreeAFRICA has been looking for US investments and is currently talking to a company in California. This company approached me asking for possible collaboration to bring their malaria drug on the market. Today the company is considering moving production to Cameroon. Hopefully, with these investment partners, the site can be validated and made ready to produce the generic drugs needed so desperately by Cameroonians. AIDSfreeAFRICA's role is to offer the US based investor's independent verification and long term oversight that is needed to bridge the gap in work culture and customs that may lead to a successful outcome.

On a recent trip to Cameroon, I had the opportunity to visit another possible center for drug production in Cameroon. Thanks to the US Embassy, the US Export Assistant Centers Gold Key Service, I had the opportunity to visit and tour of the production facilities of Cinpharm, in Douala. Cinpharm has ambitious plans for drug production, but as of today has not started production. Described as a state-of-the-art facility with stand alone source of purified water,

electricity and clean air production, they are living up to the international standards for modern-day drug production. Their quality control-laboratories feature analytical equipment commonplace in the US but never seen in Cameroon, such as instruments for high pressure liquid chromatography and mass spectrometry. My first impression was that my job was done, as they had the capacity to produce drugs that could supply more than the needs for Cameroon. However, AIDSfreeAFRICA advisor William F. Haddad, Chairman and CEO of Biogenics, Inc. (Brewster, NY) pointed out a few of the challenges Cinpharm was bound to face.

Cinpharm had done what I advise international investors to avoid, namely to build a company with features that do not fit Cameroonian reality. For example, although Cameroon is an exporter of energy, it is a very expensive commodity. Cinpharm was built for a country like India where energy costs much less. Furthermore, the equipment is high-tech, not easy to operate, and difficult to maintain and repair. Few people in Cameroon, if anyone, have the experience running and maintaining such complex production machines, particularly as such training is not provided in university settings. It will be a great challenge to maintain the current standards and to operate the facility in such an infrastructure poor country. Considering that it took three years for one hundred employees to be trained in these complex matters, and according to their chief pharmacist the company needs to hire and train three hundred more employees before running at full capacity, there is more work ahead. With the help from CIPLA and a six million euro loan from the German Investment and Development Association (DEG), they have managed to place a “Rolls Royce in the dessert”. We hope the sand will not bring the engine to a grinding halt. AIDSfreeAFRICA is ready to do what it takes to see Cinpharm succeed. They have made a huge investment, ripe for the arrival of some experienced scientists willing to make the trip to Cameroon and to apply their expertise, to be generously rewarded by an experience only a third world country can offer.

As our mission states, we are interested in providing what is necessary for Cameroonians to produce affordable medicine. I believe that the best way to accomplish this goal is to help Cameroonians start and/or continue the building and expansion of pharmaceutical companies that can affordably produce medicine in the country. Now that we are convinced that production is inevitable, our focus has expanded to determining where these drugs will need to go and how they will succeed in getting there. According to the Minister of Public Health, 45% of the drug market in Cameroon is limited to the two largest cities, Douala and Yaoundé. Distribution beyond these two cities is severely hampered by road conditions and the lack of capital for purchasing drugs.

Through my involvement with the United Nations, I became familiar with the concept of the revolving drug fund, a concept endorsed by the United Nations. The concept is simple; a non-profit organization provides the capital needed to buy enough drugs to stock a hospital's pharmacy. The drugs are then sold to the patients and a portion of this money is paid back to the non-profit, which spends that money to buy more. In the absence of this commitment, it is frequently too tempting to use any accumulated amount of cash for one or another emergency. My collaborators in Limbe, with whom we established our first revolving drug fund,

were not able to accumulate US\$200 without misappropriating some money. Now we require daily deposits of smaller payments. The income generated through the revolving drug fund is used in part by AIDSfreeAFRICA to buy more drugs and supplies, thus ensuring continuous access to drugs and the hospital's ability to treat patients. The additional income generated has been used to pay salaries owed to nurses and for paying back-rent. In the future, this additional income can be used to expand the hospital service. Concomitant with these changes, patient attendance has increased ten-fold. This constitutes a favorable situation.

Although I personally raised over US\$100,000 in cash donations and five-fold in in-kind services, it became obvious that our ability to finance our goals through donations only was not realistic since these donations were covering only small projects and the day-to-day running expenses of the organization. The next step for AIDSfreeAFRICA was to finance production equipment that runs into the hundred thousands. In 2009, as the economy continued to decline, we began looking for investors both in the US and in Cameroon. We also approached the pharmaceutical industry here in the US. Our first inquiries were met with the suggestion that we should start drug production, and that this would then generate interest in companies to invest. Well, this was putting the cart in front of the horse. We needed the money to start production, but were asked to start production in order to receive money. I did not give up.

In 2008, the Swiss-based pharmaceutical giant, Hoffman-La Roche, had offered us the possibility of a technology transfer to spin-coat an AIDS drug in Cameroon. Roche scientist Luc Schnitzler presented the program to our collaborators at the Cameroonian Baptist Convention production site in Mutengene. He then inspected the facility. Unfortunately, the Baptist facility was not in accordance with international production standards and lacked the space and necessary machines to spin coat an AIDS drug. The project has not progressed because Roche expects the technology transfer to proceed without them making any financial investments into upgrading a facility or to purchase machines and quality control equipment. Having visited Cinpharm in Douala, however, it is my intention to approach Roche again, particularly as Cinpharm has been approved by international standards and already has the spin-coating equipment. Unfortunately, Roche responded by informing me that this initiative has been completed.

While AIDSfreeAFRICA's main focus is on local drug production, we have also explored the benefits of importing and selling drugs that are produced elsewhere. I have forged a valuable interaction with the Belgian company Tibotec, a subsidiary of the US-based Johnson & Johnson, in bringing the much needed antifungal medication, Miconazole, to Cameroon. Tibotec offered us the drug and financing for registration and marketing. The project got us in communication with government agencies and gave us experience with drug licensing procedures, both of which will be valuable when drugs are produced locally. To date, we have succeeded in obtaining a license from the Ministry of Public Health, Department of Pharmacy, to import and sell the antifungal Miconazole nitrate 10 mg, muco-adhesive tablet. Miconazole is an imidazole antifungal agent, developed by Janssen Pharmaceutical. It is commonly applied topically, to the skin or mucous membranes, to cure fungal infections. It works

by inhibiting the synthesis of ergosterol, a critical component of fungal cell membranes. Miconazole is used externally for the treatment of athlete's foot, ringworm and jock itch, and internally for oral or vaginal thrush (yeast infection). Depending on the application, miconazole is prescribed as an oral gel, topical cream 2%, pessary (vaginal deposit), or vaginal cream. Most of the miconazole products are available in cost efficient generic versions (17). The miconazole we import has been specifically developed as an easy to use oral adhesive that withstands the harsh climate conditions encountered in Africa. To be consistent with AIDSfreeAFRICA's focus on HIV and AIDS it is fitting that the drug is effective against oral thrush, a painful opportunistic infection that affects 20% of AIDS patients. Though the drug is produced in Ireland, is patented by the Belgium-based pharmaceutical company Tibotec, which makes the drug available to AIDSfreeAFRICA on a non-profit base. They use a non-profit distribution model specific for developing countries AIDSfreeAFRICA conducted a two-year pilot program to train doctors in the use of the drug. During that time the drug was made available free of charge. This program concluded successfully by creating the framework for AIDSfreeAFRICA, now authorized and licensed to sell the drug. Interestingly, as in most developing countries, Cameroon's government does not have the policies and regulatory agencies in place to handle an emergent pharmaceutical infrastructure. It took us 18 months to get the license and another 6 months to receive a printed copy of it! Imagine any pharmaceutical company starting production and then having to wait two years to get the authority to sell. Impossible, but true!

Cameroon needs more than pharmaceuticals and systems to distribute them. Hospitals, HIV/AIDS treatment centers, and diagnostic centers are all understaffed. Cameroon, like other countries in Africa, needs doctors, nurses and laboratory technicians. All of these experts are in short supply. Creating infrastructure to educate young people in these professions is also paramount. While the main focus of AIDSfreeAFRICA is the establishment of an infrastructure for pharmaceutical production, I will discuss some ways we are working to enroll others to help solve some of the related problems as well.

Cameroon's Education System

In order for AIDSfreeAFRICA to fulfill its mission of establishing pharmaceutical production in Sub-Saharan Africa, it has been necessary to assess the state of education. The factories need highly trained and specialized workers. Globalized chemical education will ultimately require that developing countries consider the critical nature of providing adequate scientific education—and that more developed countries educate scientists and science students about the needs of developing countries. AIDSfreeAFRICA aims to provide insights and connections to help increase awareness of the needs of developing countries, which will hopefully help alleviate the situation in less developed countries.

Let's begin where we all start schooling, in kindergarten. The Cameroonian schools can be split into three types; government-run, faith-based, and private. Children start school as young as three years of age, and attend three years of

nursery school. Most children move on to primary school. Cameroon charges school fees which differ significantly according to the type of school. In general the school fees per year per student are US\$8 for government-run public schools, attended by 57% of students in urban areas and 86% in rural areas. In government schools, teachers are underpaid and often not paid on time. The education is widely substandard. Faith-based schools charge US\$30 and teach 12% of students (18) Private schools charge US\$40 and operate almost exclusively in urban areas where they take 29% of the share of students (18). Faith-based schools are subsidized by the government, and are not necessarily better than private schools, which receive no government subsidies at all, but are overseen by the government.

Only 27% of students attend secondary school (32% of boys and 22% of girls). Secondary school in Cameroon is comparable to middle school in the US. Of these, 22% fail to pass the final exam and another 24% drop out. Those passing "O" level ("O" for ordinary) or "A" level ("A" for advanced) secondary (middle school) and upper secondary (high school), respectively, can go for training and be awarded diplomas in teaching, agriculture, nursing and several technical subjects. The trade schools prepare students for the job market rather than the University. After a good "A" level, a student applies to a University for undergraduate studies. The system is not consistent throughout the country and varies particularly between the Anglophone and Francophone provinces (19).

Students struggle to get a place in one of the six public universities: University of Buéa; University of Douala; University of Dschang; University of Ngaoundéré; University of Yaoundé I; University of Yaoundé II at Soa, or a place in one of five private Universities. A bachelor's degree is awarded after three to four years' of study at the university.

The minister of higher education makes final policy decisions regarding universities, although each university has a governing council that is responsible for personnel recruitment. The creation of new departments, degrees, courses and changes in regulations must receive ministerial consent. Each university receives a budget from the state.

The University of Buéa is headed by a vice-chancellor, nominated by the government, who in turn chairs the administrative council. Other public universities are headed by a rector. A Catholic University Institute was established in 1990. Several higher education institutions do not fall directly under the Ministry of Higher Education, but the Minister must ascertain that they meet academic standards. Some are run by other ministries and offer specialized training in agriculture, health, post and telecommunications, forestry and public works. Schools and Institutes in Administration, Technology, Social Work, and Public Works award diplomas in economics, management or law after two years. These are generally recognized as equivalent to an associate's degree in the US. A license can be obtained after three years in the Humanities, in the Sciences, or in Engineering. At Buéa, a bachelor's degree is awarded after three to four years' study. Students pursuing graduate programs must to go abroad. Many go to Nigeria to obtain higher education.

I had several occasions to visit the University in Buéa, which achieved its status in 1992, and features a well developed website. I would caution the reader when reading the website to keep in mind that in reality Cameroon is a

resource-poor country, and perhaps this may need to be taken with a grain of salt (20). For my work in Cameroon I adopted former president Ronald Reagan quoting Vladimir Lenin: “trust, but verify.” (21) Home to 12,000 students, until now the university offers dormitories only for first-year female students. A highly qualified and diversified staff of lecturers (300 permanent and 200 part-time) teach and undertake research. The University also employs about 473 support staff. The Chemistry department kindly showed me the classrooms and laboratories. Laboratory equipment seemed to be limited to analytical chemistry. Instrumentation, such as electronic pH meter, ion-selective electrodes, titration burettes, and some glassware were visible. Collaborations with European and US researchers are desired, pursued, and taking place.

A two-week long seminar called “Hands-on Research on Complex Systems,” for example, is planned for this summer (August 2010). Among the half-dozen U.S. universities involved is my alma mater, The City University of New York, and also New York University. According to the organizers, the two weeks will provide an interactive hands-on research experience involving tabletop experiments with real-time computer data acquisition and associated computational modeling. The research promises to be interdisciplinary and can be conducted by individuals or small groups using rather modest instrumentation. International faculty will lecture and lead small groups through the experiments and computer modeling. The Hands-on Research School has already conducted these seminars in Brazil in 2008, and in India 2009 (22).

The University has two libraries. The books are still catalogued with hand written index cards, but the librarian promised me that they are working on digitizing the system. There were a few computers. As I was to find out later, the university library was equipped with six computers and all with internet capability. The gap among universities in Cameroon became apparent to me when I visited the University of Yaoundé, built in 1962 in the capital of Cameroon (23). The university has two campuses, Yaoundé I hosts the sciences and Yaoundé II hosts the humanities. Being located in the capital and a much larger than the University in Buéa I may have expected too much, but nothing could have prepared me for the shock I had when I entered the universities main library. It was dusty, dingy, and in disarray. The handwritten card catalog showed that the books listed were from the 1970s and older. Eventually we were sent to a smaller library attached to the Department of Science and Medicine. This highly specialized library had a copy of the Merck Index from 1999 in French. The head librarian was overwhelmed by the promise of two copies of a current Merck Index and went immediately to inform the Chancellor of the University. Still in the library, I discovered six computers, all covered in plastic. I was told they were specifically hooked up to access the internet but since the internet was not working they were all covered up. I got a similar answer when visiting two chemistry professors who had just finished teaching. The professors gave me their private e-mails telling me that the school does not provide internet access.

The chemistry laboratory functioned as both lab and classroom. The lab benches all featured Buchi rotary evaporator equipment, and some glassware necessary to run an organic reaction. It was confirmed that the students had performed an esterification. As far as I understood from our conversation which

was conducted in French and English at the same time, analysis is generally limited to thin layer chromatography. As far as I can tell, there is not a single nuclear magnetic resonance (NMR) machine in all of Cameroon. NMR machines are routinely used even by undergraduate students in the US for organic molecular structure elucidation and are invaluable for myriad research purposes.

I am very pleased that as a member of the International Activities Committee of the American Chemical Society, I have been asked to initiate collaborations between the US and African scientists. I am pleased to make my recommendations to the committee and facilitate to bring what is needed most, namely, equipment, chemicals and hands-on training courses on any donated equipment. A working session at the University of Yaoundé with the department chairs of chemistry, medicine and library, revealed what I had suspected, that sending US undergraduate students there in the hope that they could perform research in a laboratory and present their work in the form of a poster was not practical and not an appropriate first project, due to the lack of essential equipment, reagents and chemicals. A more suitable starting project might be for a professor to come with a few students and some basic laboratory equipment, such as an infrared and ultraviolet spectrophotometer, and spending time with students and professors alike, analyzing some of their natural extracts and other samples. Professors in Cameroon want support in educating the next generation of scientists in Africa. This new generation will be needed to fill the jobs opening up in the nascent pharmaceutical industry. This is indeed an exciting moment.

Overcoming Adversity - Training in Resource-Poor Areas

Despite these limited resources, it is possible to train chemists well. The story will give the reader a glimpse into what it took to train a technician to make a diagnostic solution. A diagnostic solution is a reagent, in this case a water-based solution, containing salts, buffers and stabilizers. The reagent I was making functions to transport blood to be analyzed through a fine glass capillary where a laser beam detects the number and size of the different particles in the blood sample. A diagnostic reagent is not a drug, but it is used in a medical laboratory to analyze samples of body fluids, in this case blood. The final solution that AIDSfreeAFRICA wanted to produce is comprised of two inorganic salts and three organic additives, with a total concentration of dissolved solids of less than 1.5%.

Since AIDSfreeAFRICA focuses on drug production, the question arises, why it was important to train chemists to produce this diagnostic reagent. These diagnostic reagents play a crucial role in patient care. I learned this when I visited Kenya and Cameroon for the first time in 2005. At that time, Triomune was the drug of choice for first line treatment for HIV/AIDS. It is a three-drugs-in-one treatment, called the cocktail. The triple combination is designed to prevent drug resistance as much as possible. When resistance occurs or when a patient shows symptoms of side-effects, such as hepatic failure, the drugs have to be switched to second line treatment. In Cameroon, Triomune is provided and paid for by the Global Fund, and was readily available and dispensed for free. However, children's AIDS drugs and second line treatments are expensive and difficult to

get. With first line treatment available and free to the patient, I did not understand why so many HIV positive patients were not placed on the drugs, although they met WHO guidelines for antiretroviral treatment. It turns out that patients are often simultaneously sick with either malaria, tuberculosis, fungal infections, and/or other infections for which drugs are often out of stock. I heard the term “out of stock” over and over in other hospitals. Even if the patient had the money to buy the prescribed medicine, it was not available because it was out of stock. AIDS patients could not take the available AIDS drugs because they were too sick with other illnesses for which the medicine was not available. Usually, the arrival of new supplies is unpredictable. “Just wait,” the patients are told. Considering the distance and expense of travel for patients, if they go, they often fail to return. If they could afford the transport they would come back hoping the drugs had arrived.

Another reason why AIDS drugs sit on the shelves is that laboratory diagnostics are usually too expensive for the patients to afford. AIDS activists successfully fought and succeeded in securing availability of AIDS drugs and lowering drug prices, but not much was done to make diagnostics affordable. While a one month supply of Triomune cost US\$6, full blood analysis costs US\$32. The diagnostics were so expensive because each model of blood analyzer requires specific reagents and a considerable amount of liquid for the analysis. That reagent is typically composed of 98% water, two salts, buffer, stabilizer, and an antifungal agent. This simple solution is sold at full competitive market prices. In addition, the blood analyzer model used in Cameroon is out of date in the US; thus, while the reagent (specific for each model) was at that time produced for consumption only in developing countries, it was still fully priced. This situation can be remedied by making these reagents locally.

What if we could make the diagnostic reagent ourselves? Thus the solution was analyzed to find out the exact quantity and nature of the chemicals it was made off. Standard laboratory quantitative and qualitative analysis plus nuclear magnetic resonance spectroscopy was sufficient to find out the reagents composition. The next step was to find out where to buy the chemicals. I was able to find three of them in Cameroon, imported from Nigeria. I bought the remaining three in the US and took them with me on the airplane (24). I had only six days in Cameroon to train the technician, produce a test batch, and hand over production to the Africans. On the first day, I asked to see the lab. I wanted to make sure that all the chemicals had arrived. I had brought an analytical balance and a pH meter with a sufficiently sensitive pH electrode with me from the US. Indeed, everything had arrived in good condition. We were ready to start, but at that very moment the electricity went off. I waited for the noise that tells you a back-up generator kicks in. I am used to spending time in hospitals where these generators are a standard feature. However, because the production area was not part of a hospital unit, there was no backup generator!

The next day, my Cameroonian technician studied the procedure written by Dr. Elliott Bay, process chemist and member on the board of Directors of AIDSfreeAFRICA. This was no simple affair, even with my help. It became apparent that he did not know how to calculate molar concentrations, something I had hoped he would have learned in a first-year chemistry course. I showed him

how to do it, and we began to make 25 liters of solution. There was no graduated cylinder, no balance with that capacity, and no container large enough to hold this amount of a liquid. We went to the market to buy a large container made of semi-translucent plastic. With a 1-liter measuring cup, we added five liters, one at a time, and marked the new container with masking tape. We did that five times for a total of 25 liters. I looked at the markings and found them somewhat uneven, although guessing was difficult since the container had a larger circumference at the top than at the bottom. I knew of a scale with 32-kg capacity, and I insisted we get special permission to carry the container into the sterile unit where it was located. We succeeded to put our solution on the balance to double check it, and thankfully realized that one of the five-liter units missed exactly one liter.

The plan was to produce the 20 liters of our diagnostic reagent by the third day. The technician analyzed the distilled water to make sure it was of the right quality; which meant he was titrating to check the hardness of the water. He then proceeded to prepare a stock solution of one of the two salts to make a series of solutions to establish a concentration curve. Sitting close to the tap water, I reminded him that he had to use distilled water to avoid contamination with other ions of unknown concentration. He looked up and innocently declared: “but Doctor, the distillation machine is broken and we have not ordered the new burn elements from the United States.” That brought everything to a grinding halt. The supervisor of the water production unit had not been informed of the breakdown either. The technicians said that distilled water production was not scheduled for another month, so they wanted to wait. Upon hearing that, I asked if there was distilled water stored somewhere. Yes, there was, but analysis showed it to be contaminated. Most likely, the distillation was still in progress when the burners died, contaminating the only storage container.

When I am in Cameroon, I have three contingency plans for every task I am planning. In this case, I had to go to backup plan number three. I called a student from my collaborator’s laboratory in Bamenda and asked him to go to the provincial hospital and buy 50 liters, or two containers, of distilled water. I knew the student was well trained and did not worry about his using a contaminated container or making a thoughtless mistake. Luckily he had the spare money to buy the water and the hospital distillation unit was working. I took an eight-hour night bus from Mutengene to Bamenda and got the water. Luckily, the next day I ran into another collaborator, Dr. Charles Boyo, a pharmacist and caught a ride back in a more comfortable vehicle. This left us two days for production and analysis. We were able to complete both without further incident.

In conclusion I must say that, however difficult it was, or however long it took to get the first 20 liters produced, in my experience, Africans work with precision, and are incredibly accurate. Batch after batch, the analysis came out with almost absolute precision. Producing this solution is one thing, however, but actually getting it into the hospital laboratories requires another long road filled with obstacles. Although we are producing a reagent twenty times cheaper than the import version, full-scale production has not been established. We are dealing with issues that range from finding a suitable factory to finding people who are willing to do something new to them. Furthermore, a diagnostic reagent must be registered in Cameroon as if it were a new drug application, requiring attention

comparable to that required for FDA drug approval. In addition, the Minister for Public Health and the commissions dealing with these drug approvals are slow and not very responsive to inquiries concerning the approval process. Finally, because Cameroonians are so used to importing everything, they mistrust products made by their own citizens. To add to the complexity of the matter, there are taxation issues. It seems every time we climb one mountain, there is another in sight to overcome.

Concluding Remarks and Future Outlook

AIDSfreeAFRICA has big goals and these goals must evolve as we proceed. Take a for-profit pharmaceutical drug production and reframe it within the context and limitations of non-profit rules. Take an industrial chemist and drop him or her into a university laboratory in Africa. Take a program born in the air-conditioned offices of a pharmaceutical company whose employees have never been in a developing country and introduce that program to African pharmacists. Take an industrial chemist and turn him or her into a public relations person or a spokesperson for industrial development in underdeveloped countries. Take a volunteer brimming with “white people’s” ideas and drop him or her into a village hospital without a centrifuge, microscope, diagnostic equipment, reagents, tests or blood storage facility. Take an African student who has never heard of chemical synthesis, and who thinks the only way to make drugs is by extracting plants and tree leaves. Then, somehow make these drugs available in a poor country where maybe half of the population can afford them.

From what I have seen in Cameroon over the last five years, it looks like it is time for a new paradigm of assistance. In general, most non-profit organizations are primarily concerned with education, which is an absolutely critical factor for success. But, too often, they focus on shipping donated goods that they think are needed, and hand them over with few or no requirements or feedback from the recipients. In fact, this type of charity, for all of its fine intentions, is only a momentary fix at best, but more damaging when planning for developing sustainable projects. The following story will hopefully demonstrate how the hope of free charitable money is foiling serious attempts to build long term sustainable development. When I first met Dr. Achu, I proposed finance micro-loan programs in the villages his organization was already working with. A possible requirement was that some the income generated be used to pay back the loan and then to pay for AIDS treatment related expenses of people who could not afford it. Dr. Achu turned to me and said, “If I have to pay the money back I don’t want it. I will wait for the next white guy who gives it to me for free.” It is regrettable, but this ended our beginning interest in working together.

Traditionally, philanthropic organizations have not established programs that are self-sustainable. Few such donations and efforts generated sustainable income. This is changing slowly however, as demonstrated by the popularity of the micro loan programs and organizations such as Kiva (24). According to Zambian native Dambisa Moyo, international economist and author of the *New York Times* best-selling book *Dead Aid: Why Aid is Not Working and How There is a Better Way*

for Africa, we have a long way to go (25). Kofi Annan commented on the cover of the book that Dr. Moyo is too harsh in her critique on the role of aid, but agrees that “the determination of Africans, and genuine partnership between Africa and the rest of the world, is the basis for growth and development.” We ought to consider moving on from simply donating goods and services to promoting full economic business development in partnership with the people we claim we wish to help. We ought to move more from giving fish to teaching how to fish, creating the infrastructure that allows the creation of jobs and the establishment of more than just a pharmaceutical company. This is why it is so important to connect to the universities in African countries and support efforts for student exchange and partnerships with universities across the Atlantic to provide books, laboratory equipment, teachers and professors. Educational opportunities supported by the basic resources needed to succeed can provide the basis for a continuum of job opportunities at home and a whole new prospect for sustainability.

AIDSfreeAFRICA wants to teach people how to fish, not just give them fish. Self-sustainability and sound business decisions must guide our work. When I visited Kenya I was introduced to a project that sends and replaces six medical doctors from Germany to the slums in Nairobi every eight weeks. The doctors come, deliver much needed medical care treating patients, and are saving countless lives. But they go back home with negligible training and development of the Kenyan medical staff. Sending doctors to the US for training is not practical either since the US, being short on doctors, is inviting foreign-born doctors to stay in the US. Much has been published concerning the “brain-drain” developing countries are suffering with their brightest people immigrating to developed countries (26). In fact, I have been approached by hospitals asking me to facilitate recruiting nurses from Cameroon, a country well known in the health industry for excellent nursing programs. Salaries, access to advanced technology, and comfortable lifestyles entice people to take up residence in the US, thus further depleting Cameroon of urgently needed medical experts. AIDSfreeAFRICA seeks to create sustainable programs that can flourish in Cameroon.

There are plenty of donated generators, motor bikes, and even autoclaves (sterilization equipment), but no financial source to keep them going, and no technical expertise to keep them maintained and fixed when broken. Chemical and technical education and an income-generating activity that serves as a dedicated funding source to keep these projects going is a must if we want to avoid littering the African landscape with broken down and abandoned equipment, some of them oozing fuel, lubricants and other chemical hazards.

The Prime Minister of Cameroon, Philemon Yang, received AIDSfreeAFRICA enthusiastically. I hope the government will support our efforts by providing licenses and inspections in a timely fashion. We also hope to be able to negotiate generous tax agreements on imports of raw materials and production equipment. The design of AIDSfreeAFRICA, and the plan describing how the organization aims to solve these problems was recognized in the Buckminster Fuller Architectural Design Contest in 2009, where it advanced to the semifinal stage. As founder of AIDSfreeAFRICA, I was awarded my first humanitarian award, a US\$30,000 prize from the US Astellas Foundation, and awarded in an American Chemical Society Presidential Event hosted in

conjunction with the American Chemical Society meeting in Washington, D.C. in August, 2009.

In Africa, there is no size that fits all. Solutions will vary significantly from one African region to another, more so than is currently practiced in pharmaceutical production in the US and other developed countries. Production in Africa will have to look and feel “African” if it is to succeed in a sustainable way.

As I do my last editing, I am back again in Cameroon. I welcome and appreciate the very latest development. To understand the significance, one must appreciate that in 2005 India joined the World Trade Organization. To be admitted to this distinguished club of countries, India had to promise to recognize international patent laws. As soon as that was announced, prices for drugs and drug production in India went up. Indian manufacturer CIPLA has been looking for less expensive places to move to and expand their drug production. It found one partner in Uganda, which, to the best of our understanding, and after three years, has not yet succeeded in starting production. CIPLA, however, backed up by the German Bank, made a similar arrangement to partner with Cinpharm, which is owned and operated in Cameroon. Yesterday, I had the privilege of inspecting the factory and meeting the people in charge.

I am pleased. The facility is applying for WHO standard approval and may only be a few months away from production. It will now be the task of AIDSfreeAFRICA to monitor, troubleshoot, expand and support this effort with expertise and encouragement. Africa's emerging pharmaceutical industry is seeing the light at the end of the tunnel. Congratulations to everyone who has persevered.

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