

FOIA MARKER

This is not a textual record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

Collection/Record Group: Clinton Presidential Records

Subgroup/Office of Origin: National AIDS Policy Office

Series/Staff Member:

Subseries:

OA/ID Number: 21063

FolderID:

Folder Title:

Compulsory Licensing [2]

Stack:

S

Row:

67

Section:

1

Shelf:

1

Position:

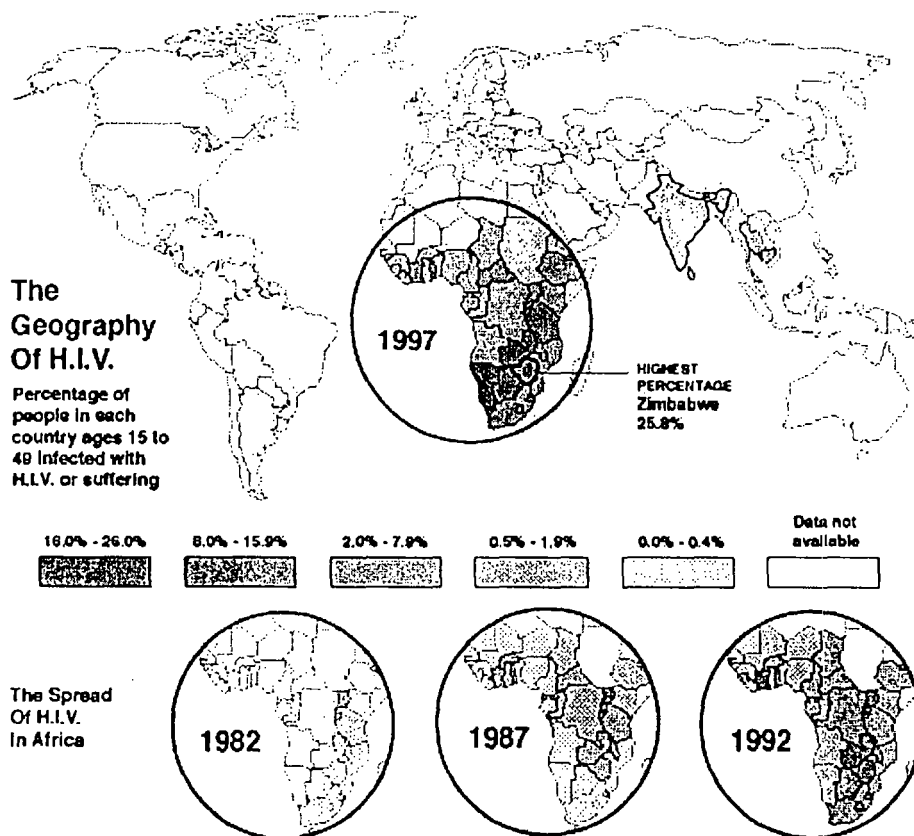
1

DRAFT

A WHITE PAPER

WORKING TOWARD A PILOT PROJECT TO DELIVER PATENTED HIV/AIDS THERAPIES AND OTHER TREATMENTS TO PATIENTS IN DEVELOPING AND LEAST DEVELOPED COUNTRIES

Graphic © NY Times



DRAFT VERSION 3.1.1

PRINTED: 06-09-99 02:48

LEE FELDMAN

SANTÉCH INSTITUTE, INC.

P:301-593-7864 • F:301-593-7865

LFeldman@Santech.org

BRUCE LEHMAN

INTERNATIONAL INTELLECTUAL PROPERTY INSTITUTE

P: 202-544-6610 • F: 202-478-1955

BLEhman@iipi.org

Precis

The need to better control the spread and treatment of HIV and other diseases such as tuberculosis in the developing countries is a widely known and serious issue that calls for diligent and aggressive attention. This proposal addresses three critical problems:

- the lack of infrastructure needed to effectively deliver treatment and support services to patients, and
- the high cost of many pharmaceutical treatments,
- inadequate incentives and assurances needed to stimulate additional subsidies and investments in the impacted countries

In the developing countries, inadequate infrastructure and the lack of funds makes it impossible to develop and maintain the kinds of market mechanisms that drive health care services in the rest of the world. Since the economies of these countries cannot generate the resources required to deal with the spreading crisis of HIV, it will be necessary to create a system of subsidization to artificially create a market environment in which health care services and treatments can be provided. Before such pseudo-markets can be created, it will be necessary to demonstrate that:

1. an effective health delivery infrastructure can be implemented that can efficiently provide complex therapies to individuals in a highly targeted manner;
2. a framework dealing with the rights of patent holders, beneficial pricing and subsidization coupled with innovative technology can achieve sustained and effective service delivery to patients thereby yielding improved outcomes, and
3. mechanisms and market protections can be established that will insulate existing national markets from price erosion and allow the major powers to establish a program of large-scale internationally supported subsidization in the developing world.

These measures would remove barriers and create incentives for pharmaceutical companies to actively participate in the delivery of essential therapeutics. Accordingly it should be possible to attain the level of multi-party cooperation and clinical effectiveness needed to build a program that brings meaningful treatments to the developing world.

This white paper discusses the creation of a pilot project to develop and then demonstrate that an operable market environment can be created in a large-scale (country wide) environment. The goal is to achieve a level of robustness that justifies a follow-on, multi-country program of subsidization and intervention as part of the international response to HIV/AIDS in the developing world.

The Role of Pharmaceuticals

Pharmacological interventions are a critical component in the management of HIV/AIDS, opportunistic infections and other high-impact diseases in the developing world. Affordability is a critical issue. Yet, efforts to simply restructure the price of pharmaceutical treatments to make them more affordable do not per se bring treatment to the patient in need. Affordability does not, by itself, translate into availability. Few developing nations have the service infrastructure needed to properly deliver the full spectrum of HIV and other treatments and critical patient support services that are required over a sustained period of time. Available pharmacological interventions and accessible clinical interventions are the necessary predicates for a successful disease containment program.

This paper discusses the implementation of policies and technologies that would help assure the affordable and effective delivery of pharmaceuticals, treatments and support services resulting in improved outcomes. In particular, the framework discusses:

- how a full spectrum of care can be effectively delivered to patients
- the creation of an environment where subsidization of pharmaceutical purchases needed by the impacted countries can be made by developed nations and international organizations with assurance that:
 - treatments are being delivered in a manner that is clinically effective,
 - a framework of program management provides the necessary monitoring.
- how to lay a foundation that encourages developing countries to accept the rights of patent holders in a way that encourages their active participation. Specifically addressing:
 - the concerns of patent holders and the creation of incentives to stimulate participation in both beneficial pricing models and programs that bring the benefits of the latest innovations to the developing world
 - reducing the potential formation of gray markets that might otherwise erode the fundamentals of their business.

The policies and technologies discussed are not revolutionary, but there is an obvious need for a demonstration project. While a pilot project would necessarily include private industry, a number of international entities, by virtue of their mandates, should coalesce to shepherd the effort: (a) UNAIDS with the support and cooperation of its sponsoring organizations, in particular, the World Bank and WHO, and (b) the World Intellectual Property Organization.

A successful pilot program will:

1. Demonstrate that the effective case management of patients coupled to a rational pharmaceutical distribution model has a measurable impact on HIV, opportunistic and other high-impact disease.
2. Demonstrate the creation of an isolated market environment (country-wide or region-wide) with its own pricing structure, product delivery systems and treatment coordination services.
3. Provide the necessary assurances required by international subsidization that efforts result in the delivery of clinically effective services to patients and not result in large-scale product diversion, fraud and misuse of subsidies.

INTRODUCTION

In recent years HIV/AIDS and tuberculosis have become the principal public health crisis for a number of countries in the developing world, particularly in sub Saharan Africa. While new advances in drug therapy such as AZT, protease inhibitors, non-nucleoside reverse transcriptase inhibitors and antiretrovirals have drastically lowered morbidity in the United States and developed countries, these therapies are virtually unknown in impacted areas of the developing world. First line therapies for TB are becoming less effective as multiple drug resistant strains evolve. Second line therapeutics and other more complex interventions are often considerably more expensive and difficult to administer.

The problem of making effective therapies available in developing and least developed countries stems from several causes. First, of course, is the high cost of treatment. In the United States the annual bill for prescriptions of protease inhibitors usually exceeds \$10,000 per patient. This is a price beyond the reach of individuals in countries where annual per capita incomes may be a fraction of this annual cost. Second, these pharmaceuticals require a sophisticated medical infrastructure and level of patient cooperation beyond the capacity of many developing and least developed nations. Third, political and economic factors create an environment where subsidies often do not result in services being delivered to the intended patients. Finally, the relative poverty of populations in these countries and their resulting inability to stimulate market demand deprives developers of the necessary incentive for investing in solutions. Absent potential consumer demand, the patent system is ill equipped to impel producers of these therapies to risk scarce venture capital.

This paper proposes an integrated policy and technological approach to resolving these difficult problems. The first section describes technological measures based on sophisticated information systems, established models of patient care and controlled pharmaceutical delivery. The second section outlines a policy based on principles of beneficial pricing and subsidized pharmaceutical purchases.

PART I IMPLEMENTING A REGIME TO MANAGE DISTRIBUTION AND TREATMENTS

The success of this program relies on the ability to successfully deliver drugs to patients in combination with an effective treatment regime. HIV risk management and HIV/AIDS treatments are complex and require sustained therapeutic management. Accordingly, pharmacological therapies alone are insufficient absent other clinical management and support services.

Three major challenges must be met in order to deliver meaningful treatments to patients:

1. An effective clinical case management program must exist to help coordinate the delivery of a full spectrum of care (including pharmaceutical therapeutics, HIV and other disease risk management, clinical services, social services, etc.) so as to achieve the maximum clinical benefit

2. A regulated pharmaceutical distribution network to help: (a) control delivery of these specific pharmaceutical products to patients, (b) achieve appropriate utilization, and (c) reduce product diversion and the development of a gray market
3. A multi-tiered, resource optimized, case management infrastructure to coordinate patient care, risk management and the delivery of pharmaceutical product.

In addition to these core components of a delivery infrastructure that is focused on patient care, it may be appropriate to provide additional support to regional sentinel laboratories. These labs monitor the onset and progression of serious infectious agents so as to be able to provide rapid response in the event of regional outbreaks that may occur in significantly immuno-depressed populations.

Resource Optimized Case Management Services

Section II of this paper describes a mechanism for creating a subsidization program to underwrite the cost of pharmaceuticals. But supplying pharmaceutical interventions alone will not provide the level of measurable clinical benefit and improved outcomes required to make this proposed program a success. The complexity of the disease necessitates execution of a case management capability to help provide patient support services and appropriate clinical management of each case.

In the developing nations, case management services can be provided by an array of providers arranged in tiers according to level of sophistication and training. Examples are the Northern Nurses and the First Nation's programs in Canada that employ local residents as "front line" care workers working under the remote supervision of specially trained nurses and clinicians along with telemedicine technologies developed at Dalhousie University in Nova Scotia. Other examples are midwife programs operated and supported by Pathfinder International that successfully operate in rural regions throughout Pakistan.

In these programs, local care workers provide the wide array of fairly comprehensive, hands-on support services required by patients during intervals between visits by more highly trained case managers. While not a requirement for this program, rudimentary telemedicine systems can also be implemented. Front line care workers can be remotely supervised and assisted to provide an even higher level of support service.

Key to the development of the proposed pilot are the programs already established by UNAIDS. While the knowledge gained from UNAIDS efforts is substantial, one of the issues is how to scale up their existing pilot project models to support large populations. Our plan is to work with UNAIDS to build upon their existing projects, supplemented by the training and development work being pioneered in Uganda by Pathfinder and supported by the addition of core technologies that will allow these programs to scale to large populations.

Case Management Tiers

Patients require continuous, but varying levels of support over the duration of their treatments. It is reasonable to provide services with the least expensive resource capable of accomplishing the task. Different "tiers" of case management resources and primary care services would be assembled. Each tier would be trained and outfitted to provide services based on the complexity of the support activity and the skill level of the caseworkers in that tier. Patients requiring services beyond the skill/capabilities of the tier are identified and moved to the next tier.

DRAFT

The critical ingredient to managing a tiered care delivery system is an underlying set of protocols and technologies that:

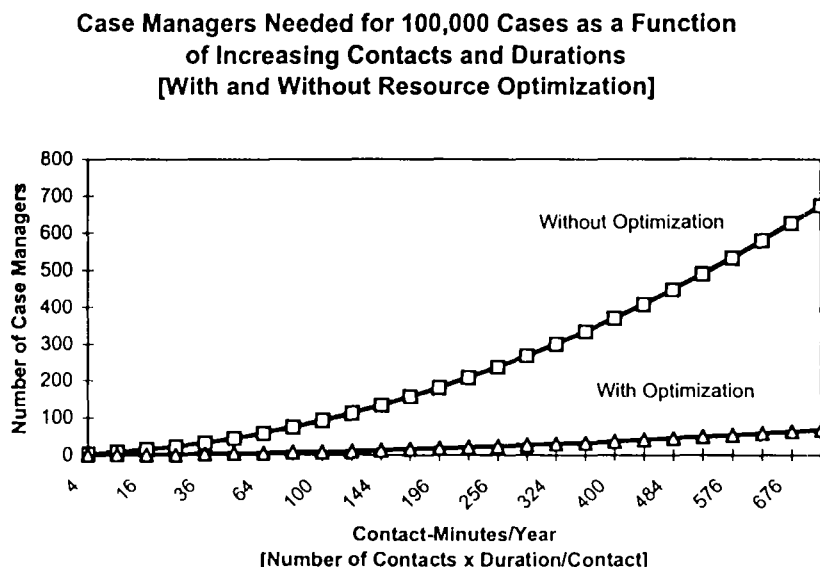
1. help senior case managers properly evaluate the level of support required by a patient at any particular point in time, and
2. help determine how and when services are provided to those patients.

It is envisioned that the most senior nurse case managers and a network of participating clinicians will have access to a sophisticated, but easy to use, modeling and optimization technology. This technology enables the nurse case managers to understand how to schedule interventions with patients and, utilizing geographic overlays, can help them coordinate their rotations (visits with patients). Optimization technology also helps case managers task care coordination by local care workers who perform basic support services. Local care workers can also utilize the system to access case managers when an episode occurs that requires a more complex type of intervention. The infrastructure to implement and operate such a technology in the developing world is currently available and the advanced algorithms and computational platforms employed can be operated remotely where required.

This technology can substantially leverage the population that can be served by one senior nurse case manager. Therefore, it is possible to cost-effectively create a system that uses lower-skilled and lower wage local workers to provide many of the hands-on interventions that would otherwise have to be provided by an expensive nurse case manager. In those locations where it is possible to organize local HIV support groups, the clinical case management program can support the program and services can be provided through the support group. With supervision and occasional visits from more highly trained nurse case managers, patients will be assured of receiving an appropriate level of care sufficient to achieve an improved outcome.

Without the technology, meaningful case management would likely be impossible as it would require hundreds of personnel to support the large number of patients and the level of coordination would overwhelm management's ability to rapidly respond to patient needs. Without a sustained program, the treatment regime collapses and the outcomes are poor.

The following table shows one analysis of the labor required to provide equivalent levels of case management interventions with and without the support of optimization technology.



Regulated Pharmaceutical Distribution Network

In the industrialized nations, pharmaceuticals are delivered through a homogeneous, well-developed product distribution system. A logistically sophisticated delivery pipeline includes wholesalers, distributors and retailers. In this distribution model, many different parties retain quantities of product as inventory before it is delivered to the consumer. This inventory is often maintained in regional and local warehousing facilities with automated picking systems designed to minimize labor costs. Just-in-time delivery capabilities, eliminate the need to maintain inventory at retail locations where space is very expensive.

This robust model of distribution can not work in countries where the distribution infrastructure does not exist and where there are tremendous opportunities to engage in arbitrage by diverting product from one market to another. It is especially difficult to manage dissemination of pharmaceuticals if:

- the product is sold domestically at a price substantially below the world price (thereby creating a demand for diversion)
- there are limited inventory management and control systems to track inventory
- there are large quantities of product available in the distribution system that are subject to “inventory leakage” and diversion
- there is no way to ascertain patient utilization to ensure that the product is reaching those patients in need
- the product is manufactured locally under license and excess production is not controlled.

In the developing world, it will be necessary to implement a “pull” distribution model. The underlying premise of a pull distribution system is that product does not enter the local-market distribution pipeline in large quantities, and it only enters the pipeline when there is a known consumer (patient) demand in a controllably small geography. Furthermore, product is paid for in a manner that inhibits the formation of local black markets. A “pull” distribution model operates much like a drop shipment system wherein product is not shipped from the manufacturer or controlled warehouse until the end consumer generates an “order” (much like how a catalog order is processed). Rather than distributing and warehousing the inventory in any quantity, the product is distributed to a geography only in anticipation of a particular order being generated (i.e., a refill is going to come due). Because there is no infrastructure to create the “order”, a modeling approach coupled to the case management system is used to determine when demand necessitates re-supply and this generates the insertion order. Orders can be aggregated, but no large stockpiles are allowed. Shipments can be tracked and monitored to the point where it is delivered or administered to the patient or to a local distributor (this does not have to employ a great deal of physical or labor infrastructure). Because of the wide disparity between the value of the product and the income of people who work in the distribution system, there is always the issue of local black market diversion. A number of techniques can be used to reduce the incidence of diversion including paying distributors a percentage of product value for successful delivery to the patient. Another technique is to make the product freely available at the local level, thus reducing its “street value.” Product is paid for at the national or regional level where it is easier to implement controls that prevent diversion. By eliminating the street price and paying a commission only for successful delivery to patients, there is less incentive to divert product from patients to be sold on a local black market.

Coordinating Case Management with Pharmaceutical Supply

Because the management of HIV and the treatment of AIDS and other high-impact disease requires a clinical and social case management adjunct to patient care, there is an opportunity to implement a drug delivery system that runs concurrently with the case management system. The case management system is approximately aware of the quantities of pharmaceutical and other supplies being used by patients under management. At the “right” time, the optimized case management system triggers the insertion of refill orders into the pipeline for ultimate delivery by a visiting case worker or fulfillment by a local pharmacy or clinic.

Factors such as the inherent latency of the pipeline and the projected demand for product in a given geography are computed by the optimizer as is the projected interval until each patient is expected to need supplies. The optimizer also computes when case management interventions will be required based on a number of factors including case plans and episodic incidents. The scheduling algorithm then uses the output from these models to calculate when the patient will next see a skilled care worker or case manager. These case managers can be entrusted to arrange the delivery of pharmaceuticals directly to patients in that geography. In those cases where direct observational therapy is required, the system can tightly couple the delivery of case management services and pharmaceutical distribution.

Such a system makes it possible to “feed” the distribution pipeline in a much more controlled way, reducing latent inventory and reducing the incidence of untraceable diversion. Other control measures can be implemented to reduce the likelihood of significant quantities of product being outside of control while in the distribution pipe. This approach makes it significantly more difficult for the gray market to assemble and divert meaningful quantities of product and dramatically increases the costs of doing so.

It must be pointed out that even in the developed nations there have been instances of gray market product diversion for “street” resale of products by patients (and others) that need money (e.g., for food or housing). Yet, when drug delivery strategies have been coupled to clinical case management services, appropriate utilization increases and the instances of “street resale” have been significantly reduced. This has been shown to result in better compliance and improved patient outcomes – especially as measured by the incidence of hospital admissions related to opportunistic disease.

Even in those areas where a reliable retail distribution system exists, the technology will help caseworkers oversee and coordinate appropriate drug utilization – a critical factor in managing this disease.

Product Tracking

To further enhance the effectiveness of the program it will be necessary to establish a simple to use, but effective product tracking system that can operate effectively in the developing world. One such system utilizes a compliance packaging model that packages product for each registered patient in segregated foil-wrap at the point of product origin. The compliance packs are aggregated for distribution to primary care delivery centers which can be pharmacies or local primary care clinics (for example, there are 2,000 clinics in Uganda).

Patented technology exists that can be used to create a sophisticated, but easy-to-use product tracking and courier payment function. For example, United Parcel Service has developed such a system. And one of the authors (Feldman) has previously developed a system where high-value

packages are labeled (or packaged with a smart-card) with a hash-encrypted number that can only be interpreted by a certificate that has been previously downloaded to a simple-to-use information system at each distribution point. The courier presents the package to the primary care clinic which then scans the package (or enters the hash-encrypted number by hand). The information system then generates and issues an encrypted scrip which can be turned in by the courier for payment. Of course this is a highly simplified description of how such a system would actually operate, but in principal it is possible to track many small packages utilizing this kind of system and therefore maintain assurance of delivery and the integrity of the delivery system..

PART II

BENEFICIAL PRICING AND SUBSIDIZED PURCHASING

At the present time developers of state-of-the-art therapies look to the exclusivity, which they enjoy in developed country markets, as the means to command a product price enabling them to amortize the cost of their investment and produce a profit. To the extent that individual patients lack the financial means to pay for these prescription therapies, governments pay the costs.

Until recently, few countries in the developing world offered patent protection to pharmaceutical products. Therefore, the basic market foundation underlying manufacture and distribution of newly developed drugs has not been a factor in making pharmaceuticals available in the developing world. As a result of the Agreement on Trade-Related Aspects of Intellectual Property rights ("TRIPS Agreement") adopted as part of the Uruguay Round of Negotiations, all WTO member countries must begin the process of integrating into the patent-based system of developing and distributing pharmaceuticals.

The TRIPS Agreement allows developing countries until January 1, 2005 to provide product patent protection for pharmaceuticals and least developed countries until January 1, 2006, with a possible extension. Due to fears that patent protection will adversely impact costs, a number of non-governmental organizations and policy makers in the developing world have begun to investigate mechanisms within TRIPS that would allow for compulsory licensing and parallel importing of protected pharmaceutical agents. While this would not address the cost of the fine chemicals used in the production of many of drugs at issue, it could potentially impact the worldwide pricing structure for these products.

Clearly, the lower cost of drugs hoped-for under a regime of compulsory licensing may help address some of the issues related to drug affordability. However, it is not likely that a major impact on availability will occur in the absence of a more holistic approach that also addresses issues of distribution and patient care. Furthermore, it is not clear that widespread use of compulsory licensing (if it should occur) would significantly impact affordability. Today, the absence of patent protection in many countries is not providing inexpensive or effective access to patients in need of many of these treatments. Nevertheless, even if it does not impact availability, a large-scale effort to use compulsory licensing to address issues of affordability could have serious impact on the integrity of the international system of patent protection and could undermine the incentives at the heart of a very successful system of innovation. Furthermore, the sophistication of manufacture and delivery of state-of-the-art HIV treatments is beyond the means of most developing countries. Therefore, compulsory licensing could only create reliable sources of supply of some of the more complex therapeutics if countries imported product from sophisticated generic-producing countries.

Again, large-scale importing of products produced under compulsory licenses could have the effect of undermining the cost structure of these same products in countries where parallel import is legal. In other countries, gray markets will likely develop if reliable sources of alternative “low-price” product become available. Accordingly, the challenge is to develop a plan that both harnesses the powers of innovation and investment of product developers and addresses the cost issues of populations in developing and least developed countries while facilitating effective treatment.

Such a plan has two components:

1. a system of determining price levels appropriate to the ability to pay in a segregated market segment constructed around the disease demographics and particular economic circumstances of the geography;
2. a system of sustainable subsidization to assist the purchase of a pharmaceutical when the ability to pay is out of reach even at a below market price point.

Setting Price Levels Appropriate to Developing and Least Developed Country Markets

The market price of sophisticated HIV/AIDS treatments is clearly beyond the reach of consumers in developing or least developed countries. Therefore, a key element in supplying drugs such as AZT and protease inhibitors to these markets must be a method of establishing appropriate price levels likely below the world market price. In conjunction with an internationally sponsored and funded program of subsidization, it will be possible to construct a segmentation of the markets in the developing nations based upon the local patterns of morbidity which implies a certain ultimate demand for products and the local economic circumstances of the region. Employing a model of advantageous pricing and subsidization support levels, each market segment can be construed in a form that is beneficial both to the country and to the product provider. There are implications regarding intellectual property rights of the producers and this is briefly addressed in Appendix II.

Beneficial pricing models already offered by manufacturers to their largest customers should be examined as a basis for establishing price levels appropriate to specific developing and least developed countries and the subsidization program. Although producers generally oppose any kind of non-market price setting, the advantage of such a system for them is that it would open up and create markets and revenue streams in the developing world that are currently unavailable to them (there currently is no market in these countries). Manufacturers would have to be assured that drugs sold at subsidized and/or non-market price points would not find their way into non-regulated markets. As in any large-scale purchase arrangement, with a set of agreements dealing with the property rights of the manufacturers and cooperation between patent owners, subsidizers and health authorities there should be a convergence between price points set by patent owners and health authorities.

International Subsidization of Pharmaceutical Purchases

Even assuming a significantly lower price level could be established for HIV/AIDS drugs sold in a given developing country market, few developing or least developed countries enjoy income levels enabling them to pay. This is particularly true in sub Saharan Africa. Therefore, any comprehensive effort to supply state-of-the-art pharmaceuticals to these countries will require a significant program of international subsidization. The moral imperative involved, the costs of political destabilization resulting from unchecked epidemics, and the significant risk of new disease strains which could defy treatment and find their way back into the developing world

justify a program of international subsidization. The World Bank has a history of organizing such programs. Along with UNAIDS and sponsoring organizations it could put together a coordinated plan, involving international aid programs of developed countries and private sector humanitarian organizations to supply the necessary funding. Over time it will be necessary to create a subsidization regime that is sustainable. Given an appropriately controlled product delivery infrastructure, such an effort can include long-term price support by manufacturers for imported product and local production facilities.

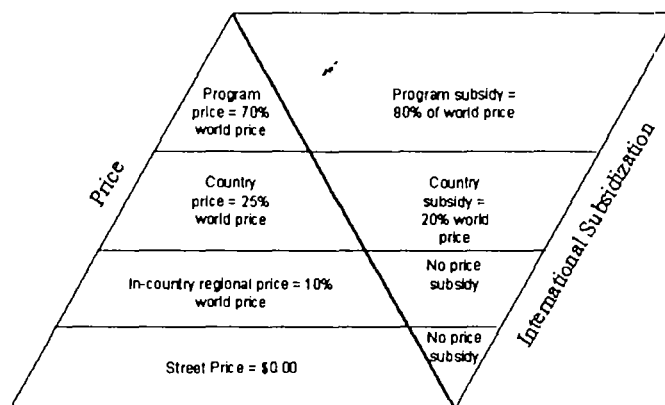
The Burden of Pricing Pharmaceutical Interventions

Our operating premise is that the full range of pharmaceutical interventions must be available to patients for free or at a minimal cost that is, for all practical purposes, free. There are two reasons for this:

1. The economic impact of HIV on patients in the developing world is dramatic. While the annual per capita GDP in many developing nations is below \$250 USD, the situation for HIV infected individuals is far worse. If there is a “street price” for therapeutic interventions, many HIV patients will sell their own drugs to provide essential services for their families. It should be added that the patient’s perceived therapeutic value of the drug is often associated with the price, so some level of patient payment may be necessary.
2. To thwart the development of a local black market for product it will be necessary to reduce the incentives for those individuals who wish to divert product. The wide-scale availability of drugs at no cost to patients with identified needs will help reduce the formation of local black markets. In some cases, this black market is stimulated by individuals who do not wish to acknowledge their HIV status (and therefore wish to purchase drugs outside of the normal therapeutic system of delivery). While it is probably impossible to eliminate this demand, it is critical to keep the street-price (black market price) of the drugs as low as possible to reduce the incentive for legitimate patients to sell their supply. Widely available, cheap (free) supply in the normal delivery system is the best way to reduce the black market price.

We propose the formation of a beneficial pricing strategy that has a structure that assumes a price to the patient of close to free with tiers of cost to governmental purchasers in the structured market that are some fraction of the world price for the product. Each tier would be funded through a subsidization program with each country providing for a portion of its own subsidy and an international program of subsidization providing for the bulk of the product cost. The following graphic shows an example of the kind of pricing and subsidization that might be created for a country. The exact price and degree of subsidization would be established on a case-by-case basis as warranted by the economic situation and burden of disease in each isolated market. The isolated market created for each country/region would have its own regulated system of distribution and treatment management so as to maintain the isolation of the pricing/subsidization program.

The international subsidization program would negotiate with patent-holders and other product suppliers to establish the best “world” price for the product in this program. Much like contracting for military equipment, the international purchaser would negotiate a price that allows for a fair profit for the product manufacturer. Likewise, the manufacturers may choose to establish special foundations that would allow them to maintain their world-price at the point of manufacture, and then, through a process of cross-subsidization through the foundation(s) would allow for a meaningful discount to the international subsidization program.

***Conclusion: The Need for a Pilot Project***

The costs and administrative complexity of a global effort to supply new drug therapies to developing and least developed countries are sufficiently high that it would be imprudent to attempt such an effort without testing its feasibility first. Therefore, this proposal is focused on identifying one developing country in a position to host a pilot project.

Drawing on the expertise and technology available from private industry, a number of international specialized agencies have the mandate, expertise, and ability to organize the pilot project outlined above. They are UNAIDS with the support and cooperation of its sponsoring organizations, in particular the World Bank and WHO; and, the World Intellectual Property Organization.

Expertise and norm setting authority over international patent law lies with the World Intellectual Property Organization in Geneva. Establishing an international consensus on how rules of territorial exhaustion should apply to developing country pharmaceutical markets clearly is within the jurisdiction of WIPO. UNAIDS with the support of WHO and other sponsors has the expertise to develop a program directed at the training and medical infrastructure issues critical to the effective administration of state-of-the-art anti-AIDS pharmaceuticals. Finally, the World Bank (also a UNAIDS sponsoring organization) is in a position to put together the international effort to raise the funds necessary to subsidize the purchase of patented pharmaceuticals.

THE PILOT PROJECT

We propose to assemble a team of experts in each of the relevant domains to construct a pilot implementation of these concepts. The pilot project would test whether a controlled pseudo-market can be created thereby creating the appropriate infrastructure and incentives needed to provide complex therapeutic interventions and the justification for a large-scale program of international subsidization. The Pilot Program would incorporate:

- ◆ A subsidization program and pharmaceutical pricing regime appropriate to the pilot market. For the pilot project, this may include donations of product.
- ◆ A controlled product (pharmaceuticals and testing tools) packaging, tracking, distribution and delivery system
- ◆ A resource optimized, managed case-worker-based intervention program to coordinate treatment, testing, follow-up and delivery of therapeutic agents
- ◆ A comprehensive field training program for case workers
- ◆ A comprehensive program of population education and prevention services to run concomitantly with the clinical intervention program
- ◆ An outcomes research component to measure the effectiveness of the delivery system, monitor product diversion and ascertain therapeutic effectiveness for a statistically valid subset of the population being served

The goal of the pilot is to learn how to best implement the core concepts in a real-world, large-scale environment with the objective of replicating the infrastructure in other countries if the program is shown to be effective.

The next steps to establishing the pilot program is to assemble the core team to develop a detailed program plan that elucidates all of the components of the program. The participants in this effort would be:

1. UNAIDS – to build upon their existing pilot work and relationships. The thought is to run this proposed pilot on top of the existing pilot project in Uganda.
2. Santech Institute – To provide the technological foundation for the resource-optimized case management and product tracking/distribution systems.
3. IIPi – to provide the economic framework needed to establish the economic and legal theory and practice of creating a pseudo-market environment.
4. Pathfinder Fund – To create and implement the in-country case-worker training programs.
5. Other as identified.

CONCLUSION

A powerful arsenal of new treatments now exists to help manage the course of HIV and other high-impact disease such as TB. Information management technologies have been developed that make it possible to cost-effectively deliver treatments and the adjunctive patient support needed to improve outcomes. HIV infection is being treated with some real success in the developed world and there is a reasonable expectation that it is now possible to manage the treatment of HIV

DRAFT

and other intractable diseases in the developing world. A mandate to create the policy and legal foundation to make these treatments available is forming. There are compelling reasons of global dimension to find a way to bring these capabilities together.

A coordinated pilot program consisting of:

- innovative policies,
- international cooperation and funding

can be combined with

- sophisticated information technology,
- established models of case-managed patient care, and
- controlled pharmaceutical delivery systems

to achieve an affordable and effective effort to stem the course of a pandemic.

DRAFT

APPENDIX I - EFFORT TO DEVELOP A PROPOSAL FOR THE PILOT PROJECT

Submitted by:

Santech, Institute, Inc.
11459 Encore Drive
Silver Spring, MD USA 20901
Contact: Lee Feldman
Phone: 301-593-7864
Fax: 301-593-7865
LFeldman@Santech.org

International Intellectual Property Institute
201 Massachusetts Avenue, NE
Suite 3C
Washington, DC USA 20002
Contact: Bruce Lehman
Phone: 202-544-6610
Fax: 202-478-1955
BLEhman@iipi.org

INTRODUCTION***Purpose of this Proposal***

HIV/AIDS, opportunistic disease and a number of severe communicable diseases (such as Tuberculosis) have reached a point of saturation where the risk to the developing world and the developed world requires a serious, full-scale international response. While meaningful and heroic efforts are being made by dedicated institutions and individuals, the resources from the developed world currently being employed to address the problem are inadequate in the face of the devastation that these countries are experiencing. The risk to all is real and immediate. Given the current rates of infection, spread of highly communicable opportunistic disease and the sheer number of individuals infected, we can expect that over the next several years the magnitude of the problem will make it impossible for the developed world to continue a mostly laissez-faire approach to this problem. Many of the public and private institutions who could be doing more have suggested that the magnitude of the problem makes it impossible to address the problem – “we simply do not have the resources or technologies needed to address the problem.” We believe that this statement is untrue and that new technologies – some based on systems originally developed for sophisticated military and defense intelligence applications – create the imperative to aggressively engage this problem. Furthermore, difficulties related to intellectual property rights, the lack of normal market mechanisms in the developing world and the unusually high cost of interventions can be overcome through creative approaches.

This proposal outlines the steps required to fully develop a novel approach to deal with a number of the critical issues surrounding the treatment of this disease in the developing world.

The Santéch / IIPi white paper suggests a collection of activities that can be employed to provide meaningful interventions for HIV/AIDS and other high-impact diseases in the developing world. A pilot project will be required to properly ascertain the viability of these concepts and to fine-tune the systems, infrastructure, methods, policies, and business arrangements that will be required to ultimately enlarge the scope of the program to provide meaningful relief to the impacted countries.

In order to elucidate and properly design the pilot project, a research period of approximate three to four months is required. The team will undertake further planning and research with UNAIDS personnel and others to develop a detailed plan and budget for the proposed pilot project. During this initial period, the team will identify the scope and specific characteristics of the proposed pilot project and from that, will develop a pilot project budget, detailed implementation plan and detailed proposal for the pilot. Potential funding sources and partners for the effort will also be identified.

The pilot project plan will identify:

1. the candidate site(s) for the pilot implementation,
2. the budget, time-line and project plan for the pilot
3. a strategy for funding both the pilot and roll-out if successful

DRAFT

4. the success criteria that will be used to assess the viability of the core concepts, technologies and methods with respect to implementation on a large-scale in the impacted countries.

The team has either assembled, developed or is aware of where to procure virtually all of the technologies, protocols, systems, etc. that are required to make the pilot project a success. However, given the unique nature and scale of the problem, the pilot project will be designed to study specific implementation issues in detail to validate the applicability to countries of the type selected for the pilot. The pilot project proposal that results from this funding will explore the methods, processes, systems and infrastructure that will be required for each component of the pilot. Specifically:

1. The case identification methods used to solicit and qualify patients into the program
2. The optimized case management techniques that work best for the candidate populations being served
3. The interface between the existing clinical infrastructure and the new systems implemented for this project. This will also include technology transfer issues, applicability to other countries, and impact of deficient technological infrastructure (i.e. work-arounds for unreliable system components – e.g., telephony)
4. The clinical infrastructure required to deliver the treatment services required (based on existing UNAIDS and Pathfinder research)
5. The methods and technologies to be used to merge the optimized case management system with a drug distribution capability.
6. The design of the inventory management and distribution system including the tagging and tracking components
7. The training protocols and procedures used for field case-workers
8. The structure of the beneficial pricing and subsidization arrangements that will work for both the manufacturers and governmental bodies that will subsidize the program
9. The distribution reimbursement model and controls that will be used to prevent product diversion to gray and black markets
10. The audit procedures used to identify “correctable” program deficiencies. These are problems that would be corrected during the pilot phase and then would be used during operations to manage the systems and personnel supplying services.
11. The audit procedures to be used to set success criteria and measure the overall results of the pilot project.
12. The management of critical communication issues such as community relations, political issues, regulatory issues, etc. all of which can have a serious impact on the success of these programs.

THIS PROPOSAL

This proposal solicits funding for three to four months of effort required to develop the Pilot Project Proposal. In addition, during this initial phase of the project, it will be necessary to maintain some oversight of the political and public relations issues that can impact the undertaking.

To develop the pilot project proposal and manage the ongoing issues related to this project, we have separated the effort into three stages as follows:

Stage 1: Develop Scope of Pilot Statement

Description of Task: Work with UNAIDS personnel to define and achieve consensus for the scope of the proposed pilot project and essential components of the effort including:

1. Technological components (non-country specific)
2. Policy components
3. Disease states to be managed
4. Treatment regimes to be employed
5. Participating pharmaceutical suppliers
6. Participating funding agencies
7. Other logistics support required

Identify potential partnerships and establish scope of their participation. Ascertain the technology required in general. Identify pilot program metrics to establish success criteria. Ascertain who will perform measurements.

Duration of Task Approximately 2 months

Stage 2: Identify Pilot Site(s) Candidate

Description of Task: Identify one or more potential pilot candidates (countries) and local participating agencies. Define the technological and other infrastructure required in-country to support the pilot. Have discussions with necessary in-country representatives and UN agencies that will need to participate in the pilot. Develop a "straw-man" implementation plan for the required systems and roll-out of the pilot project in the candidate country.

Duration of Task: 2 months to run concurrently with Stage 1 activities.

Stage 3: Develop Pilot Budget and Formal Proposal

Description of Task: Develop a cost-analysis for the pilot project including sources and uses of funds. Prepare detailed budget for review by funding sources. Prepare detailed proposal for pilot project including project plan, timeline and management approach. Submit budget and Pilot proposal to funding sources.

DRAFT

Duration of Task: 1 Month

Proposed Budget

We believe we have assembled a first-rate team that will successfully move this effort forward. The key teams that will develop the pilot project with UNAIDS and WIPO are:

- ✓ Santéch Institute – the developer/owner/licensee of the proprietary case management, optimization and distribution management technology to be used in the pilot project. The principals of Santéch that will be working on this effort are:
 - ◆ Lee Feldman, Keith Johnson – Co-Managing Directors and both experts with international reputations for developing and implementing complex technology-based projects in health and other domains. Feldman and Johnson have been the inventors and lead scientists on the defense applications of the technologies to be employed in this effort and have been developing healthcare systems that use components of these technologies for ten years.
 - ◆ David Dingwall – the former Canadian Federal Minister of Health and an advisor to numerous governments and international bodies. Mr. Dingwall has extensive experience in managing both the political aspects and the policy/regulatory issues encountered in large-scale health projects. He has been working with the rest of the Santéch / Santéch team to implement a system in Canada that utilizes many of the same technology components that will be employed in this effort.
 - ◆ and a team of approximately seven other content experts that will be assigned to work on this initial phase of the effort.

Santéch will also provide project management and administration support services for this effort.

- ✓ International Intellectual Property Institute – IPI is the institute founded by Bruce Lehman – the recently retired US Commissioner of Patents and Trademarks. Mr. Lehman is an expert on international intellectual property issues and the principal co-author with Lee Feldman of the white paper that is the foundation of this proposal.
- ✓ Pathfinder Fund – Pathfinder is a leading NGO that has been developing comprehensive in-country case worker training programs and managing delivery systems in the developing world. It is the largest recipient of US-AID funds for its work in Uganda and has extensive experience with HIV/AIDS work in sub-Saharan Africa.
- ✓ Witeck • Combs – A communications firm with particular and unique expertise in dealing with HIV/AIDS issues. Witeck • Combs has been retained by a number of well known international firms to help manage communications and government relations on issues related to HIV/AIDS. Their participation in this effort will be critical to successfully managing communications with all of the parties that have a major stake, and therefore a major interest, in issues involving HIV/AIDS in the developing world.

The following table lays out the budget for the effort to fully develop the pilot project plan and proposal. Not included are the costs to be incurred by UNAIDS, WIPO or other UN agencies that may participate in the effort.

DRAFT

Sources of funding for this effort may include UN agencies, philanthropic foundations, one or more pharmaceutical companies, trade associations, private companies and national governments.

The budget for development of the pilot project proposal is as follows:

Phase 1 Project Budget	Proposal Development Effort			
Month >>>>>	1	2	3	Total
Organizations:				
Santéch Institute	40,000	65,000	75,000	\$180,000
International Intellectual Property Institute	10,000	15,000	15,000	\$40,000
Pathfinder Fund	10,000	10,000	10,000	\$30,000
Witeck - Combs Communications	20,000	20,000	20,000	\$60,000
Sub-Total	\$80,000	\$110,000	\$120,000	\$310,000
Overhead Allocation @ 8%	6,400	8,800	9,600	\$24,800
TOTAL	\$86,400	\$118,800	\$129,600	\$334,800

Travel, per diem, lodging and other direct expense will be billed as incurred according to funding agency policy.

APPENDIX II
A DISCUSSION OF NATIONAL AND INTERNATIONAL EXHAUSTION OF RIGHTS

Segregation of Territorial Markets – The Issue of Exhaustion of Rights

A longstanding controversy in international intellectual property law has been whether a patent holder exhausts his or her rights to control the resale or use of a product in a territorial market different than the one into which the product was first sold. In general patent holders have argued that the principle of national exhaustion applies, meaning that their loss of control after the first sale of a given patented product applies only in the territory of the country in which it was first sold. Opponents support the principle of international exhaustion; meaning that rights to control resale and use of a legally manufactured product exhaust anywhere in the world after the first sale takes place. Consumer groups have generally supported the principal of international exhaustion.

With regard to pharmaceutical products, public health policy makers in the developing world have generally favored the principle of international exhaustion. This is consistent with the point of view that the less control pharmaceutical manufacturers have the fewer difficulties poorer countries will have obtaining and administering needed pharmaceuticals.

However, a practical side effect of international exhaustion is that it is much more difficult for drug manufacturers to consider ability to pay in establishing different price points for different markets. Were pharmaceutical companies to establish significantly lower prices for developing country markets, they would risk having products sold in those markets re-imported into their profit-generating home markets. These re-imports are generally known by the name “gray market” products. Consumer groups in developed countries such as the United States naturally favor the “gray market” and oppose marketing strategies that result in consumers in their societies subsidizing lower prices in other markets.

Even under a regime of international exhaustion, countries can adopt systems of price controls which reduce the cost of drugs within national markets. The difficulty with this strategy, standing alone, is that drug companies may refuse to manufacture in or export to those markets. And, with full implementation of the WTO/TRIPS agreement, developing countries that wish to be a part of the international trading system will be unable to copy without a license from the patent owner. While the WTO/TRIPS agreement does allow countries to grant compulsory licenses, they can only be granted once some comparatively strict preconditions are met. In any event, many therapeutic agents such as protease inhibitors are difficult, if not impossible, to replicate and administer without the cooperation of their developers. This calls for a cooperative relationship between patent holders and licensees rather than a relationship imposed upon them by the state. Therefore, in the post WTO/TRIPS world developing countries may have to reconsider where their self-interest lies in the debate over territorial versus international exhaustion. Effective implementation of the principle of national exhaustion requires its broad acceptance at the international level – in particular among higher-priced countries so that the differential pricing scheme described above may work. If not, it is inevitable that the products placed on the market at a lower, concessional price in one country will find their way into a higher-priced country.



ORGANIZAÇÃO MUNDIAL DA SAÚDE
SEDE REGIONAL EM ÁFRICA

TEMPORARY LOCATION IN HARARE - ZIMBABWE
TELEPHONE: (263) 4 70 69 51 - FACSIMILE: (263) 4 70 56 19 OR (263) 4 72 89 89

FACSIMILE

Message: 1.....of 1.....Page(s)

Date: 24 Avril 1998

FROM: Dr Ebrahim M. Samba
Regional Director

To: Dr Thelma Awori
Assistant Administrator UNDP
New York

Originator: DSD 

Fax: (212) 906 64 78

REF: B/27/2

Subject: TECHNICAL REVIEW MEETING FOR THE PROPOSED
PROJECT ON ENHANCING PHARMACIST &
PHARMACY PERSONNEL SKILLS & THE USE OF THE
THE PHARMACY IN THE PHARMACY IN THE
PREVENTION & CONTROL OF HIV/AIDS/STDs,
BANJUL, THE GAMBIA, 9-10 march 1998

Please kindly refer to our previous communications on the above mentioned subject and particularly to the letter from UNDP New York dated 30 September 1997 requesting me to make a technical assessment of the above project.

I am very glad to inform you that a technical review meeting for the proposed project was organised in Banjul, The Gambia, from 9th to 10th March 1998. The meeting reviewed the project document and found it technically sound. A certain number of amendments were proposed and adopted. Work is under way to revise the document in line with the views expressed during the meeting. As soon as this work is completed, I will transmit the revised version of the document to you.

Kindly find attached the final report of the technical review meeting with recommendations made by the participants.

Yours sincerely,

cc: All participants to the technical review meeting (with copy of report)
Director DAP/HQ (with copy of report)

Encl:: as mentioned

WORLD HEALTH ORGANIZATION		TRAVEL REPORT SUMMARY/REPORT COVER PAGE	
Submitted by: Dr Moses Chisale EDP/AFRO 23.04.98 (Name) (Div/Unit) (Date)		Through: DSD/AFRO	Programme Classification: EDP/AFRO .B3/27/2.GAM
Visit to Banjul, The Gambia.			
Inclusive travel dates 9 March 1998 10 March 1998 (From) (To)		Co-travellers: Dr Ball, STD/AFRO-DDC (Name(s))/Div/Unit(s)	
Purpose/Objective of travel: Technical Review meeting for the proposed project on enhancing pharmacist and pharmacy personnel skills and the use of the pharmacy in the prevention and control of HIV/AIDS/STDs.			
Brief summary The technical review meeting was organised by WHO at the request of UNDP. It was attended by 11 people from WAPF, HUSCE, The Gambia Ministry of Health, The Gambia Pharmaceutical Society and WHO (list of participants in Annexe 2). The objective of the meeting was to finalise all the technical, logistical and administrative arrangements for the implementation of the project. The proposed project is designed to: 1. Train pharmacists to increase their knowledge about HIV/AIDS/STDs. 2. Mobilise pharmacies and their staff members to provide HIV/AIDS/STD education. 3. Establish pharmacies as widely used centres for public education about HIV/AIDS/STD prevention and control. Participants to the meeting reviewed the project document section by section and found it to be technically sound. Some amendments on the formulation and technical content of some sections were proposed and adopted: modification of title, inclusion of syndromic approach in the education and training of pharmacists, social marketing of STD drugs, collaboration with national AIDS/STD programmes, use of UNDP and WHO evaluation indicators, extension of project time line by 6 months, budget revision. These and other amendments will be taken into account in the revision process of the project document. At the end of the meeting, participants proposed four follow up activities (see Annexe 1) which should lead to the submission of the revised project document to UNDP and other partners by Dr E.M. Samba, Regional Director for WHO African Region.			
Recommendation(s)/Action to be taken		Distribution	
1. WHO to continue providing technical guidance for the further development and implementation of the project.		RD DPM DSD DDC	
2. Dr E.M. Samba, Regional Director for WHO African Region to kindly forward the revised project document to UNDP and other partners for funding.		Dr Thelma AWORI, UNDP NY Dr A. Antezana, ADG Dr F. Varet, ADG Dr J. Quick, DAP/HQ Dr P. Piot, UNAIDS/HQ	
3. The next meeting concerning the project (project work plan review with sponsors and development of programme evaluation framework) to take place in the WHO Regional Office for Africa in Harare, Zimbabwe.		WR/Gambia MOH The Gambia WAPF HUSCE The Gambia Pharma. Soc.	

WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR AFRICA

ORGANIZATION MONDIALE DE LA SANTE
BUREAU REGIONAL DE L'AFRIQUE



ORGANIZAÇÃO MUNDIAL DA SAÚDE
SEDE REGIONAL EM ÁFRICA

**TECHNICAL REVIEW MEETING FOR THE PROPOSED
PROJECT ON ENHANCING PHARMACIST AND PHARMACY
PERSONNEL SKILLS AND THE USE OF THE PHARMACY IN
THE PREVENTION AND CONTROL OF HIV/AIDS/STDs**

Atlantic Hotel, Banjul, The Gambia, 9-10 March 1998

FINAL REPORT

TECHNICAL REVIEW MEETING FOR THE PROPOSED PROJECT ON ENHANCING PHARMACIST AND PHARMACY PERSONNEL SKILLS AND THE USE OF THE PHARMACY IN THE PREVENTION AND CONTROL OF HIV/AIDS AND STDs

Atlantic Hotel, Banjul, the Gambia, 9-10 March 1998

FINAL REPORT

1. INTRODUCTION

- 1.1 The meeting was chaired by Dr Moses Chisale, Regional Advisor for the AFRO Essential Drugs Programme (EDP/AFRO). He gave an overview of the project proposal and informed the meeting that the proposal was prepared by the West African Pharmaceutical Federation (WAPF) in collaboration with Howard University School of Continuing Education (HUSCE) and submitted to United Nations Development Programme (UNDP) in New York for funding. The UNDP in turn sent the proposal to Dr E. M. Samba, Regional Director for the WHO Regional Office for Africa (WHO/AFRO) requesting his comments and technical guidance for the implementation of the project. Specifically, UNDP requested AFRO to organise a technical review meeting before the project could be considered for funding.
- 1.2 The Regional Director responded positively to this request and was pleased to learn that UNDP could support the project through its regional facility and could also facilitate discussions with potential contributors. Dr Samba therefore authorised that the technical review meeting be organised with the aim of finalising all the technical, logistical and administrative arrangements for the further development and implementation of the proposed project.

2. OPENING CEREMONY

- 2.1 In his opening remarks, Dr Samba emphasized the importance of the meeting and the need for partnership since no organisation could do it all alone. He said the proposed project was important in view of the fact that pharmacists are usually the first point of call for patients in general and those with sexually transmitted diseases (STDs) in particular. He assured the meeting of his full support for the proposed project. He welcomed the extension of the project at a later stage to other countries beyond the WAPF members (Gambia, Ghana, Liberia, Nigeria, Sierra Leone).

3. MEETING PROCEEDINGS

- 3.1 During the meeting, EDP/AFRO presented the project background, aim, component and objectives, as well as strategies in order to attain the set objectives. He also thanked UNDP, WAPF and HUSCE for the confidence

reposed in WHO/AFRO to lead the technical review meeting and soliciting collaboration in the implementation of the project. Dr Ball, HIV/STD/AFRO, made a presentation on the "the Role of Pharmacists in the prevention and control of HIV/AIDS/STD". He emphasized the need to get pharmacists deeply involved in the following areas: prevention of new infections, treatment of those with symptoms, assisting in partner notification and the promotion of care-seeking behaviour. Dr Ball also highlighted strategies for STD and HIV prevention.

3.2 Mrs Clavenda Bright Parker, Foundation President of the WAPF gave some background information on WAPF and the collaboration between WAPF and HUSCE. She thanked the Regional Director for accepting to host the Technical review meeting. Dr Rosalyn King, HUSCE, provided more details on the expected results and the strategies to be used in project implementation.

3.2.1 Some Expected Results.

- Over 1000 pharmacists trained to act as information providers through their pharmacies;
- National and regional capacity building in continuing education strengthened through eight centres;
- model developed that can be duplicated in Africa and other regions of the world;
- An increase in accessibility of relevant information on HIV/AIDS and STDs to the public;
- Reduction in the spread of HIV/AIDS and STDs.

3.2.2 Strategies to achieve greater public awareness.

- Media outreach activities will be conducted to generate public awareness of the new program in 1000 pharmacies across the Region (Press conferences, distribution of press materials, encouragement of local media stories);
- Produce and distribute public service announcements (PSAs);
- Display of program material in pharmacies.

3.2.3 Strategies to achieve pharmacist and pharmacy personnel education and training.

- Conduct Training of Trainers Workshop;
- Conduct Seminars for Pharmacists Participating in the Project;
- Develop HIV/AIDS/STDs Resource Book to accompany CE seminars;
- WAPF & member organizations to publish CE articles and tests in their publications;
- Ensure that local trainers also receive instruction in distance learning

- methods, self-instructional techniques and use of the Internet;
- Assist in the establishment of CE centres in each country which would include an income generating electronic classroom to ensure sustainability.

3.2.4 Strategies to achieve research and monitoring objectives.

- Hold meetings with relevant professional groups to enlist their support and commitment to the project;
- Program evaluation by participants to assess effectiveness;
- Media monitoring will be conducted to determine the extent of media coverage;
- Review & adapt existing educational materials for inclusion in the program;
- Mobilize practicing pharmacies to form focus groups on KAB;
- Conduct research to determine the role of pharmacists in HIV/AIDS and STD education;
- Conduct a self-administered survey with practitioners to assess their knowledge & educational needs in HIV/AIDS and STDs

3.2.5 Strategies to achieve project management objectives.

- Develop a project work plan using a defined task list and time line, program goals and objectives and indicators of successful performance.

4. PROJECT DOCUMENT REVIEW

4.1 During the project review sessions, the meeting considered the project document page by page and proposed some amendments on the formulation, technical content of some sections. The inclusion of national aids control programmes in country coalition was proposed as well as the addition of various information in order to make the document more up to date. A list of acronyms and references is to be prepared. The following specific amendments were proposed:

4.2 Title

- The title was modified to read **Enhancing Pharmacist and Pharmacy Personnel Skills and the use of the Pharmacy in the Prevention and Control of HIV/AIDS/STDs.**

4.3 Background and Rational

- STD Syndromic approach should be included;
- Current statistical information on HIV/AIDS/STD cases in Sub-Saharan

Africa to be provided;

4.4 Project Management.

- Provide for a Regional Project Administrator;
- Available standard WHO and UNDP indicators to be used;
- Geographical location of project centres should be clearly stated and supported with appropriate maps;
- The distribution of participants at the various centres should be stated;
- The Regional Office will be located at the WAPF Secretariat;
- Change country representative to Country Coordinator and Local Coordinator to Project Officer;

4.5 Project Time line.

- The meeting reviewed the draft project time line and made amendments where necessary. The project duration was extended by 6 months (total 30 months) to give sufficient time for execution and evaluation of the project. The meeting decided that the final project document will be sent to Dr E.M. Samba, RD/AFRO, for onward transmission to UNDP and other donors and contributors.

4.6 Budget.

- To be revised since the figures are almost two years old;
- Budget should also provide for project evaluation and other costs to be incurred by WHO during the implementation such as for subsequent meetings;

4.7 Project Components.

- The meeting reviewed the project components and made amendments where necessary. These amendments will be reflected in the final project document as well as the final project budget.

4.8 Financial and Administrative Matters.

- It was envisaged that funds provided by donor agencies for project implementation will be disbursed through their country representatives. However the exact modalities for disbursement of funds will have to be worked out with the respective donors and contributors.

4.9 Follow Up Activities and Recommendations.

- At the end of the meeting the recommendations and follow up activities in annex 1 attached were presented to Dr Samba who accepted them.

4.10 Conclusion

- The meeting found the draft project document to be technically sound, well presented and of acceptable standard. Amendments were made where necessary. Participants to the meeting expressed their sincere appreciation to the Regional Director for his support for the proposed project and for his personal presence during the review meeting.

ANNEXE 1

OBSERVATIONS AND RECOMMENDATIONS OF THE PROJECT TECHNICAL REVIEW MEETING ON THE PHARMACIST AND HIV/AIDS/STD,

Atlantic Hotel, Banjul, The Gambia, 9-10 March 1998

The technical review meeting for the project proposal on Enhancing Pharmacist and Pharmacy Personnel skills and the use of the Pharmacy in the prevention and control of HIV/AIDS/STD was held at the Atlantic Hotel, Banjul, The Gambia, from the 9 to 10 March 1998. Participants were drawn from the West African Pharmaceutical Federation (WAPF), Howard University School of Continuing Education (HUSCE), World Health Organisation Regional Office for Africa (WHO/AFRO), the Ministry of Health of the Gambia, and the Pharmaceutical Society of the Gambia.

The meeting was opened by Dr E.M. Samba, Regional Director for the WHO Regional Office for Africa. In his opening remarks, the Regional Director emphasized the importance of the project and the need for effective partnership. He assured participants of WHO support for the further development and implementation of the project.

The meeting reviewed the project document and found it to be technically sound, well presented and of acceptable standard. Some relevant amendments were proposed for inclusion:

- STD Syndromic approach in the education and training of pharmacists.
- Social marketing of STD drugs and the introduction of STD pre-packaged kits.
- Collaboration with National AIDS / STD Control Programme as a component of country coalition.
- Use of available WHO and UNDP evaluation indicators.

RECOMMENDATIONS

At the end of the meeting the following recommendations were made:

1. The meeting appreciated the interest of WHO in the project and strongly recommended that it continues to provide technical guidance for the implementation of the project.

2. The meeting requested the Regional Director to kindly forward the amended project document to the African Regional Director of UNDP and if necessary to other agencies.
3. The meeting recommended that one of the subsequent technical meetings during the implementation of the project should be held in AFRO.
4. The meeting also proposed the following follow-up activities:

ID	Activity	RESPONSIBLE	TIME FRAME	COMMENTS
1	Letters to Ministries of Health	AFRO	End March 1998	For information in view of project implementation
2	Finalise meeting report	Rapporteur, AFRO	1st Week April 1998	To be sent to UNDP and all participants
3	Finalise project proposal	WAPF, HUSCE, AFRO	2nd week April 1998	AFRO to submit to UNDP and other partners.
4	Submission of revised proposal to UNDP and other partners	AFRO	4th week April 1998	To be followed by the preparation of work plan and its review with sponsors as per proposed project timeline

Finally participants recorded their sincere appreciation to the Regional Director for providing technical and material assistance towards the meeting as well as for his personal presence during the project review meeting.

In his closing remarks, the Regional Director thanked all participants for the work done and urged that work should proceed towards the implementation of the project. He welcomed the proposed follow up activities as well as the recommendations made by the meeting. He particularly welcomed the proposal that the next follow up meeting should take place in AFRO and requested that proposed dates be communicated to him as soon as they are decided upon.

ANNEXE 2

LIST OF PARTICIPANTS

1. **Dr Ball Mamadou**
WHO/AFRO
Lome. Togo. Tel 228 21 33 60 / 21 08 23
2. **Saihou Ceesay**
N.A.C.P, Department of State for Health, Social Welfare and Women's Affairs
The Quarangle
Banjul. The Gambia. Tel 220 22 37 53 / 22 87 62 Fax 220 20 13 01
3. **Dr Mariatou Tala Jallow**
Chief Pharmacist, Department of State for Health
The Quadrangle
Banjul. The Gambia. Tel. 220 22 5 374 Fax: 220 22 58 75
E-mail: Talacms @Commit.gm
4. **Thomas Manly Rollings**
Private Practice (Observer)
1 Hagan Street
P.O. Box 35
Banjul. The Gambia. Fax / Tel 220 22 62 96
5. **Uford S. Inyang**
WAPF - Past Executive Secretary
3 Wilmot Point Rd
P.O. Box 73221
Victoria Island, Lagos. Nigeria. Tel 01 61 03 18 Fax 09 52 33 903
6. **Mrs Clavenda Bright-Parker**
Foundation President - WAPF
1220 East - West Highway Apt. 612
Silver Spring, MD. 20910 Tel. 1. 301.585.0922
7. **Dr Rosalyn C. King,**
Howard University Continuing Education,
Office International Programs,
1100 Wayne Ave Suite 600
Silver Spring, MD 20910 Tel.: 1. 301.585.0922
E-mail Rking @ Con-ed.Howard.Edu

8. **Elijah Sokomba,**
Executive Secretary WAPF,
Taylon Drive, Medical Compound
Yaba, Lagos. Nigeria Tel.: 234 1.689.050

9. **Dr Moses Chisale**
Regional Advisor
WHO/AFRO Essential Drug Programme,
Parirenyatwa Hospital Medical School Ward C,
P.O. Box BE 773 Belvedere,
Harare. Zimbabwe Tel: 263 4 70 69 51 Fax: 263 4 79 12 14 or
1 407 733 9160 e-mail: chisalem@whoafr.org

10. **Dr Ebrahim M. Samba,**
Regional Director WHO/AFRO,
Parirenyatwa Hospital Medical School - Ward C
P.O. Box BE 773 Belvedere
Harare. Zimbabwe Tel 263 4 70 69 51 Fax 263 4 79 12 14
e-mail: sambae@whoafr.org

11. **Dr David . Tembo**
WHO Representative
Banjul. The Gambia
Tel: 251 22 72 29 / 22 98 89 Fax 251 22 98 89

PROJECT TECHNICAL REVIEW MEETING

**ENHANCING PHARMACIST AND PHARMACY PERSONNEL SKILLS
AND THE USE OF THE PHARMACY IN THE PREVENTION AND
PROGRESSION OF HIV/AIDS/STDs**

Banjul, The Gambia, 9-10 March 1998

PROPOSED AGENDA

Monday 9 March 1998

- | | |
|---------------|---|
| 08.45 - 09.00 | Arrival of Regional Director and invited guests |
| 09.00 - 09.10 | Greetings and Self Introduction |
| 09.10 - 09.25 | Introductory Remarks by Dr. Moses Chisale - EDP/AFRO |
| 09.25 - 09.40 | Presentation by Dr. Ball - The Role of Pharmacists in the Prevention and Control of HIV/AIDS/STD |
| 09.40 - 10.15 | Presentation of the Project by Dr. R. King and Mrs C. Bright-Parker |
| 10.15 - 10.30 | Opening Speech by the Regional Director |
| 10.30 - 11.00 | B * R * E * A * K ** and the Regional Director Departs |
| 11.00 - 11.15 | General Comments on the proposal from Participants |
| 11.15 - 12.30 | Specific discussions on the proposal <ul style="list-style-type: none">* Title* Justification (background and rational)* Goals, Objectives (component by component) |
| 12.30 - 14.00 | Lunch Break |
| 14.00 - 16.00 | Specific discussions on the proposal (cont'd) <ul style="list-style-type: none">* Strategies (component by component)* Project Management* Project Implementation |
| 16.00 - 16.15 | Break |

16.15 - 18.00 Specific discussions on the Proposal (cont'd)

- * Budget
- * Financial and administrative matters
- * UNDP intervention
- * Follow-up Steps

TUESDAY 10 MARCH

08.00 - 09.00 General Overview of the Previous Day's Work

09.00 - 10.30 Preparation of Meeting Recommendations and Follow-up Activities

10.30 - 11.00 C*O*F*F*E*E *** B*R*E*A*K

11.00 - 12.30 Preparation of Meeting Recommendations and Follow-up Activities (Cont'd)

12.30 - 14.00 Lunch Break

14.00 - 15.00 Preparation of Draft Meeting Report

15.00 Arrival Regional Director and Invited Guests

15.05 - 16.00 Closing Ceremony

- * Presentation of meeting outcome (Rapporteur/Chairperson)
- * Final Remarks DSOH/Gambia, UNDP, WAPF, Howard Univ.
- * Closing Speech by Regional Director

16.00 Refreshments and Departure of the Regional Director



UNITED STATES MISSION TO
INTERNATIONAL ORGANIZATIONS
11, ROUTE DE PREGNY
1292 GENEVA, SWITZERLAND

TEL: (41-22) 749-4865
FAX: (41-22) 749-4717

Page: 1 of Page(s) 3

Date: 1/24/00

FROM THE OFFICE OF:
Linda Vogel
Health Attaché

TO: Sandy Thurman

Fax: 202-456-2438

Urgent

Tom Novotny asked me to fax this
to you ASAP. I will telephone
with further information.

Linda Vogel

From: treatment-access-admin@hivnet.ch
Authorised by: treatment-access@hivnet.ch (TREATMENT-ACCESS - Jame...
To: treatment-access@hivnet.ch (Treatment-access)
Reply to: treatment-access@hivnet.ch (treatment-access)
Date Posted: Wednesday 26 January 2000 01:33:55
Subject: [715] US pressure to amend WHO Resolution

'Treatment Access' is an independent forum provided by
the Fondation du Present <http://www.fdp.org>

I just heard from people on the ground in Geneva, that the US
Government is lobbying to remove language in the World Health Assembly
Executive Board Resolution on HIV/AIDS (EB 105/12, on the web at:

<http://www.who.org/wha-1998/EB105/PDF/ee12.pdf>

The Clinton/Gore administration is apparently working with the
International Federation of Pharmaceutical Manufacturers, Merck and
other parties to remove this language from page 6 of the HIV/AIDS
resolution:

The Executive Board . . . REQUESTS the Director-General:

7) on their request, to advise governments
on their options under the Agreement on
Trade-Related Aspects of Intellectual Property
Rights (TRIPS) to increase their capacity to
negotiate for more affordable HIV/AIDS-related
drugs;

This is similar to the language that passed the World Health Assembly
in 1999, after a bitter two year fight between the developed and the
developing countries. The drug companies are very unhappy having the
WHO involved in these trade issues, but the USG supposedly just
endorsed this for our own trade policy.

This is a strange development, coming so soon after Vice President
Gore and President Clinton's recent speeches on HIV/AIDS and US trade
policy. According to one MSF official, "it is same old same old
policy" from the US, and the "US embassy is all over this."

Apparently the US government has also asked that other language in the
resolution be replaced with language that came from an IFPMA
roundtable session on HIV/AIDS.

I'll ask for some explanation from the White House, and I would encourage others to make some calls. This is happening right now. The WHA Executive Board will be meeting again tomorrow (Wednesday).

Jamie

James Love, Consumer Project on Technology
v. 1.202.387.8030, fax 1.202.234.5176
love@cptech.org, <http://www.cptech.org>
<http://jama.ama-assn.org/issues/v283n3/full/jmn0119-2.html>

-
- A posting from treatment-access@hivnet.ch
 - To submit a posting, send to this address
 - For anonymous postings, add the word "anon" to the subject line
 - To join or leave this forum, add the word join or leave to the subject line
 - Browse previous postings or post new messages at:
<http://www.hivnet.ch:8000/topics/treatment-access/>
 - Reproduction welcomed, provided source and forum email address is quoted
 - The forum is supported and managed by the Fondation du Present (FdP)

The views expressed in this forum do not necessarily reflect those of FdP, unless otherwise stated

HIV/AIDS: CONFRONTING THE EPIDEMIC

Agenda Item 3.3 // EB105/12

U.S. Delegation Suggested Changes to Proposed WHO Resolution 01/25/00:

(1) Preamble. To reaffirm the current WHO policy per the Revised Drug Strategy resolution, insert a new preambular paragraph between paragraphs 2 and 3, as follows:

"Reaffirming the consensus reached with resolution WHA52.19 as approved by the 52nd World Health Assembly, which outlines WHO's cooperative role with Member States and with international organizations in monitoring and analysing the pharmaceutical and public health implications of relevant international agreements, including trade agreements,"

(2) Operative Paragraph 2(5)

- (1) Delete the phrase "reducing the costs of" "and"
(2) Substitute the word "affordable" with "accessible through cost reduction, infrastructure development, and financing"

Amended to read as:

"to pursue dialogue with the pharmaceutical industry with a view to making HIV/AIDS-related drugs increasingly accessible to Member States and their populations through cost reduction, infrastructure development, and financing;"

2(5) accessible instead of affordable

(3) Operative Paragraph 2(7)

OPTION 1: Delete in its entirety.

OPTION 2: Suggested Amendment (EU Proposal below)

Amended as follows:

Deep in original from RDS
"on their request, to cooperate with governments and other international institutions regarding possible options under relevant international agreements, including trade agreements, to improve access to HIV/AIDS-related drugs."

DOF Communications 202 456 2685 P.01/01
EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE
WASHINGTON, D.C. 20508

JAN 27 2000

Mr. Paisan Tan-Ud
Chairman of PHA Network of Thailand

Dear Mr. Paisan Tan-Ud:

I am writing in response to your letter to President Clinton regarding efforts to improve access to treatment and care for HIV positive Thai citizens. We recognize and support the Government of Thailand's goal of extending effective health care to all its citizens - including people now living with AIDS. This is a goal we fully endorse and believe can be achieved while providing appropriate protections for intellectual property.

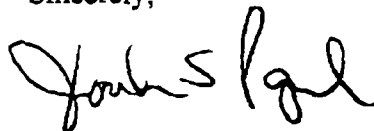
As the President announced last December in his speech to the WTO ministerial, and the Vice President reiterated in his January speech at the United Nations Security Council, the United States is committed to helping developing countries gain access to affordable medicines, including those for HIV/AIDS. As a result, the United States will ensure the application of U.S. trade law related to intellectual property remains sufficiently flexible to respond to public health crises.

We encourage Thai officials to explore all options for extending access to effective treatments, including ongoing direct dialogue with pharmaceutical manufacturers. But the final choice is one for Thailand to make.

If the Thai government determines that issuing a compulsory license is required to address its health care crisis, the United States will raise no objection, provided the compulsory license is issued in a manner fully consistent with the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

We share with the Government of Thailand a belief that access to modern pharmaceuticals can be enhanced in a manner that assures the safety and efficacy of the drugs, preserves intellectual property rights, and promotes the worldwide pursuit of newer, more effective medicines.

Sincerely,



Joseph S. Papovich
Assistant U.S. Trade Representative for
Services, Investment and Intellectual
Property

[Date Prev][Date Next][Thread Prev][Thread Next][Date Index][Thread Index]

June 7 PACHA meeting

- *To:* pharm-policy <pharm-policy@essential.org>
 - *Subject:* June 7 PACHA meeting
 - *From:* James Love <love@cptech.org>
 - *Date:* Tue, 08 Jun 1999 14:07:08 -0400
 - *Organization:* http://www.cptech.org
 - *Sender:* jamie@genoa.essential.org
-

Last night's meeting of the International Issues subcommittee of Presidential Advisory Council on HIV AIDS (PACHA) went well, as far as I could tell, given the fact that this was a new topic for the Council. There was a surprisingly large turn out, including members of the Council who were not on the subcommittee, and many NGOs. Apparently the US government (USG) was asked to explain its position, and refused (declined) to send anyone. It was Tom Bombelles from PhRMA, me, Jacob Gayle from the World Bank, Dr. David Wilpson (MSF-Thailand) and Eric Sawyer (Act Up!, Health Gap coalition, etc), plus a pretty extensive and free discussion. The meeting lasted from 4 pm to about 6:30 pm, and was covered by some press and what appeared to be a free lance video crew doing a documentary.

CPT asked PACHA to recommend that:

1. The US government should end trade related opposition to parallel importing of essential medicines,
2. The US government should end trade related opposition to compulsory licensing of essential medicines, so long as countries abide by WTO/TRIPS Article 31 safeguards.
3. The Department of Health and Human Services (DHHS) should enter into an agreement with the World Health Organization, permitting the WHO to use US government intellectual property rights in government funded medical inventions to broaden access to essential medical technologies in less developed countries.

Eric Sawyer made a similar request on behalf of the Health Gap coalition.

Bob Fogel, the subcommittee chair, did a very nice job of moving the meeting along and facilitating the discussions. AIDS experts like Paul Boneberg, David Hoos and Daniel Berman made good contributions to the discussions, and the council itself was very animated, interested and engaged.

PhRMA did not dispute that parallel imports or compulsory licensing were legal under trade agreements like the WTO/TRIPS, but claimed they were bad policy. PhRMA said that drug prices were not a barrier to access. (I believe HL Menken once said that when someone says it is not about

the money, its usually about the money). According to Bombelles, the real problem is the government's lack of willingness to pay, since drugs are such a good value for society. At one point Bombelles made the puzzling claim that India does not manufacture or export AZT or other HIV drugs. Bombelles held out Brazil as a good model to follow, apparently because the Brazil government is paying for HIV/AIDS drugs. The World Bank also mentioned Brazil as a good model.

Dr. Wilson's presentation about the Thai case was very moving, but there were unanswered questions about the ddi case in Thailand. MSF was not sure why the Thai national drug company had not manufactured ddi, and what had transpired between the Thai and BMS over ddi. I have heard rumors that BMS claims to have offered deep discounts for ddi in Thailand, perhaps to avoid generic production from the Thai government, but this was not discussed in the meeting, and elements of the Thai case remain a bit of a mystery. The case of Fluconazole was discussed, where the removal of exclusivity last september lead to a decrease in the price of the drug by 93 to 95 percent in nine months, following the introduction of 2 generic versions in the Thai market.

Interesting to me was the presentation by Jacob Gayle, who is a CDC employee, on loan to UNAIDS, where he is a liason to the World Bank. Gayle read what appeared to be a prepared statement, apparently on behalf of Debrework Zewdie <dzewdie@worldbank.org>, a World Bank employee. Jacob Gayle began by chastising those who claim that compulsory licensing is *the* solution to the AIDS crisis (who are these people? I later asked), and went on to state all the reasons why compulsory licensing is not important. In my opinion, most of Gayle's statement on compulsory licensing could have been written by PhRMA or the USTR, in terms of minimizing the importance of price or intellectual property rights as barriers to access, but he stopped short of saying countries should not do compulsory licensing, and he seemed to acknowledge that it might have some non-zero role. Then he said that UNAIDS, the World Bank, Unicef, WHO, UNESCO, UNFPA and UNDCP are coming out with a joint policy on compulsory licensing. I asked if the World Bank and these other international organizations would cut off aid to countries that did not conform to the World Bank et. al. "policy" on compulsory license. Gayle said that this would be out of character for the World Bank, a view that others did not share. In the break I asked Jacob for a copy of his prepared remarks and he said there were none, and that he was speaking from notes.

Gayle's statement raises some interesting issues. Can groups like UNICEF, UNAIDS or others that seek to raise money from the drug companies alienate their donors by issuing positions in favor of compulsory licensing? If this is a problem, what role should they play in trying to set international norms on these issues? Who will be consulted by the World Bank, UNICEF, UNAIDS and others on this policy statement? Will the USG simply use its clout in these agencies to undermine the World Health Assembly's revised drug strategy? One bit of evidence that some caution is warranted would be the decision by UNICEF and the WHO to release a publication on intellectual property the day of the WHA vote on the revised drug strategy, that was distributed by the IFPMA during the meeting, and referred to by the IFPMA as a document that reflected the IFPMA views.

In general, however, the real news from the meeting was the very favorable response of the subcommittee members to the concerns about current US trade policy and access to essential medicines. It appears as though PACHA will be meeting with US government trade officials to discuss these matters further. Apparently USG trade officials are asking that these discussions be more private, and shielded from the press and activists, but there does appear to be some support for having USG trade officials address these topics in a future public meeting. I would hope that PACHA could endorse the idea that the USG enter into an

agreement with the WHO on access to USG intellectual property on essential medicines, an action that would seem to be positive step that the Administration could take that does not involve appropriations and simply uses intellectual property rights the USG already owns but is not using.

Much credit goes to David Hoos for working with the Council to move this on the PACHA agenda, to Bob Fogel for his leadership within the Council, and to the many activists who have pushed this isssue forward. This should be the beginning of a new initiative with the PACHA, and it would seem to make sense to think about the next meeting in October.

Jamie

--

James Love, Director, Consumer Project on Technology
I can be reached at love@cptech.org, by telephone 202.387.8030,
by fax at 202.234.5176. CPT web page is <http://www.cptech.org>

-
- Prev by Date: **David Corn, Gore to South Africa: Drop Dead**
 - Next by Date: **The Children's Vaccine Initiative Document on Intellectual Property Protection**
 - Prev by thread: **David Corn, Gore to South Africa: Drop Dead**
 - Next by thread: **The Children's Vaccine Initiative Document on Intellectual Property Protection**
 - Index(es):
 - **Date**
 - **Thread**

DRAFT

**A WHITE PAPER
WORKING TOWARD A PILOT PROJECT TO DELIVER
PATENTED HIV/AIDS THERAPIES AND OTHER
TREATMENTS TO PATIENTS IN DEVELOPING AND LEAST
DEVELOPED COUNTRIES**

DRAFT VERSION 1.3.1

PRINTED: 06/08/99 12:03 PM

LEE FELDMAN
CO-MANAGING DIRECTOR
SANTÉCH HEALTH SCIENCES, INC.
888-358-9129 / 301-593-7864
LFeldman@HealthMinder.com

BRUCE LEHMAN
INTERNATIONAL INTELLECTUAL PROPERTY INSTITUTE
202-544-6610
BLEhman@iipi.org

DRAFT*Precis*

The need to better control the spread and treatment of HIV and other diseases such as tuberculosis in the developing countries is a widely known and serious issue that calls for diligent and aggressive attention. This proposal addresses three critical problems:

- the high cost of pharmaceutical treatments,
- the lack of infrastructure needed to effectively deliver treatment and support services to patients, and
- inadequate incentives and assurances needed to stimulate additional subsidies and investments in the impacted countries

This paper proposes a framework of national exhaustion, tiered pricing and subsidization coupled with innovative technology that can achieve sustained and effective service delivery to patients thereby yielding improved outcomes. These measures would remove barriers and create incentives for pharmaceutical companies to actively participate in the delivery of essential therapeutics. Accordingly it should be possible to attain the level of multi-party cooperation and clinical effectiveness needed to build a program that brings meaningful treatments to the developing world.

Pharmacological interventions are a critical component in the management of HIV/AIDS, opportunistic infections and other high-impact diseases in the developing world. Affordability is a critical issue. Yet, efforts to simply restructure the price of pharmaceutical treatments to make them more affordable do nothing to bring the treatment to the patient in need. Affordability does not, by itself, translate into availability. Few developing nations have the service infrastructure needed to properly deliver the full spectrum of HIV and other treatments and critical patient support services that are required over a sustained period of time. Available pharmacological interventions and accessible clinical interventions are the necessary predicates for a successful disease containment program.

This paper discusses the implementation of policies and technologies that would help assure the affordable and effective delivery of pharmaceuticals, treatments and support services resulting in improved outcomes. In particular, the framework:

- Lays a foundation that encourages developing countries to accept national exhaustion of patent rights and support for patent holder rights.
- Discusses how a full spectrum of care can be effectively delivered to patients
- Creates incentives for patent holders to participate in both special pricing models and programs that bring the benefits of the latest innovations to the developing world.
- Helps address the concerns of patent holders that special pricing would lead to the formation of gray markets that erode the fundamentals of their business.
- Helps create an environment where subsidization of pharmaceutical purchases required by the impacted countries can be made with greater assurance that treatments are being delivered in a manner that is clinically effective.

The policies and technologies discussed are not revolutionary, but there is an obvious need for a demonstration project. While a pilot project would necessarily include private industry, three international entities, by virtue of their mandates, should coalesce to shepherd the effort: (a) the World Bank, (b) the World Intellectual Property Organization and (c) UNAIDS.

A successful pilot program will demonstrate the effective case management of patients, a regulated and rational pharmaceutical distribution model and a measurable impact on HIV, opportunistic and other high-impact disease.

DRAFT**INTRODUCTION**

In recent years HIV/AIDS and tuberculosis have become the principal public health crisis for a number of countries in the developing world, particularly in sub Saharan Africa. While new advances in drug therapy such as AZT, protease inhibitors, non-nucleoside reverse transcriptase inhibitors and antiretrovirals have drastically lowered morbidity in the United States and developed countries, these therapies are virtually unknown in impacted areas of the developing world. First line therapies for TB are becoming less effective as multiple drug resistant strains evolve. Second line therapeutics and other more complex interventions are often considerably more expensive.

The problem of making effective therapies available in developing and least developed countries stems from several causes. First, of course, is the high cost of treatment. In the United States the annual bill for prescriptions of protease inhibitors usually exceeds \$10,000 per patient. This is a price beyond the reach of individuals in countries where annual per capita incomes may be a fraction of this annual cost. Second, these pharmaceuticals require a sophisticated medical infrastructure and level of patient cooperation beyond the capacity of many developing and least developed nations. Finally, the relative poverty of populations in these countries and their resulting inability to stimulate market demand deprives developers of the necessary incentive for investing in solutions. Absent potential consumer demand, the patent system is ill equipped to impel producers of these therapies to risk scarce venture capital.

This paper proposes an integrated policy and technological approach to resolving these difficult problems. The first section outlines a policy based on principles of national exhaustion, tiered pricing and subsidized pharmaceutical purchases. The second section describes technological measures based on sophisticated information systems, established models of patient care and controlled pharmaceutical delivery.

PART I
NATIONAL EXHAUSTION, TIERED PRICING AND SUBSIDIZED PURCHASING

At the present time developers of state-of-the-art therapies look to the exclusivity, which they enjoy in developed country markets, as the means to command a product price enabling them to amortize the cost of their investment and produce a profit. To the extent that individual patients lack the financial means to pay for these prescription therapies, governments pay the costs.

Until recently, few countries in the developing world offered patent protection to pharmaceutical products. Therefore, the basic market foundation underlying manufacture and distribution of newly developed drugs has not been a factor in making pharmaceuticals available in the developing world. As a result of the Agreement on Trade-Related Aspects of Intellectual Property rights ("TRIPS Agreement") adopted as part of the Uruguay Round of Negotiations, all WTO member countries must begin the process of integrating into the patent-based system of developing and distributing pharmaceuticals. Fear of this change has caused a backlash among public health professionals in the developing world, leading recently to a heated debate in the World Health Organization over a code of conduct, which would conflict directly with the TRIPS agreement.

The TRIPS Agreement allows developing countries until January 1, 2005 to provide product patent protection for pharmaceuticals and least developed countries until January 1, 2006, with a possible extension. Due to fears that patent protection will adversely impact costs, a number of non-

DRAFT

governmental organizations and policy makers in the developing world have begun to look for mechanisms within TRIPS that would allow for compulsory licensing and parallel importing of protected pharmaceutical agents. While this would not address the cost of the fine chemicals used in the production of many of drugs at issue, it could potentially impact the worldwide pricing structure for these products. It is not clear that widespread use of compulsory licensing will significantly impact affordability and certainly it does nothing to address availability. Today, the absence of patent protection in many countries is not providing inexpensive or effective access to patients in need of many of these treatments. Nevertheless, even if it does not impact availability, a large-scale effort to use compulsory licensing to address issues of affordability could have serious impact on the integrity of the international system of patent protection and could undermine the incentives at the heart of a very successful system of innovation. Furthermore, the sophistication of manufacture and delivery of state-of-the-art HIV treatments is beyond the means of most developing countries. Therefore, compulsory licensing could only create reliable sources of supply if countries imported product from generic-producing countries. Again, large-scale importing of products produced under compulsory licenses could have the effect of undermining the cost structure of these same products in countries where parallel import is legal. In other countries, gray markets will likely develop if reliable sources of alternative "low-price" product become available. Accordingly, the challenge is to develop a plan that both harnesses the powers of innovation and investment of product developers and addresses the cost issues of populations in developing and least developed countries.

Such a plan has three components:

1. segregation of territorial markets so that ability to pay can be figured into the pricing of a pharmaceutical product in a developing country;
2. a system of determining price levels appropriate to the ability to pay in such a market;
3. a system of sustainable subsidization to assist the purchase of a pharmaceutical when the ability to pay is out of reach even at a below market price point.

A discussion of each of these three components follows.

Segregation of Territorial Markets – The Issue of Exhaustion of Rights

A longstanding controversy in international intellectual property law has been whether a patent holder exhausts his or her rights to control the resale or use of a product in a territorial market different than the one into which the product was first sold. In general patent holders have argued that the principle of national exhaustion applies, meaning that their loss of control after the first sale of a given patented product applies only in the territory of the country in which it was first sold. Opponents support the principle of international exhaustion; meaning that rights to control resale and use of a legally manufactured product exhaust anywhere in the world after the first sale takes place. Consumer groups have generally supported the principal of international exhaustion.

With regard to pharmaceutical products, public health policy makers in the developing world have generally favored the principle of international exhaustion. This is consistent with the point of view that the less control pharmaceutical manufacturers have the fewer difficulties poorer countries will have obtaining and administering needed pharmaceuticals.

However, a practical side effect of international exhaustion is that it is much more difficult for drug manufacturers to consider ability to pay in establishing different price points for different markets. Were pharmaceutical companies to establish significantly lower prices for developing country markets, they would risk having products sold in those markets re-imported into their profit-

DRAFT

generating home markets. These re-imports are generally known by the name "gray market" products. Consumer groups in developed countries such as the United States naturally favor the "gray market" and oppose marketing strategies that result in consumers in their societies subsidizing lower prices in other markets.

Even under a regime of international exhaustion, countries can adopt systems of price controls (discussed in the next section) which reduce the cost of drugs within national markets. The difficulty with this strategy, standing alone, is that drug companies may refuse to manufacture in or export to those markets. And, with full implementation of the WTO/TRIPS agreement, developing countries that wish to be a part of the international trading system will be unable to copy without a license from the patent owner. While the WTO/TRIPS agreement does allow countries to grant compulsory licenses, they can only be granted once some comparatively strict preconditions are met. In any event, therapies such as AZT and protease inhibitors are difficult, if not impossible, to replicate and administer without the cooperation of their developers. This calls for a cooperative relationship between patent holders and licensees rather than a relationship imposed upon them by the state. Therefore, in the post WTO/TRIPS world developing countries may have to reconsider where their self-interest lies in the debate over territorial versus international exhaustion. Effective implementation of the principle of national exhaustion requires its broad acceptance at the international level – in particular among higher-priced countries so that the differential pricing scheme described above may work. If not, it is inevitable that the products placed on the market at a lower, concessional price in one country will find their way into a higher-priced country.

Setting Price Levels Appropriate to Developing and Least Developed Country Markets

The market price of sophisticated HIV/AIDS treatments is clearly beyond the reach of consumers in developing or least developed countries. Therefore, a key element in supplying drugs such as AZT and protease inhibitors to these markets must be a method of establishing appropriate price levels likely below the world market price. The use of price controls is not unknown in the pharmaceutical world. Government regulation of prices has been utilized in the past in highly developed countries such as Canada. As an alternative to direct price regulation, the single payer health systems of some European countries operate in such a way as to set prices at a level lower than would be the case where there are multiple consumers. These developed country models should be examined as a basis for establishing below world market price levels appropriate to specific developing and least developed countries. Although producers generally oppose any kind of price controls or non-market price setting, the advantage of such a system for them is that it would open up markets and revenue streams which are currently unavailable to them. Two factors would be of critical importance in gaining their cooperation in such a system. First, they would have to be assured that drugs sold at non-market price points would not find their way into non-regulated markets. This implies both a relationship between a system of national exhaustion and price controls and a need for cooperation between health authorities and patent holders. As discussed above, a broadly accepted system of national exhaustion allows patent owners to consider ability to pay in a given country in setting prices for pharmaceutical products. Price controls are imposed by health authorities also on the basis of ability to pay. Thus, with a system of national exhaustion and cooperation between patent owners and health authorities there should be a convergence between price points set by patent owners and health authorities.

The second factor in obtaining the cooperation of the pharmaceutical producers in a system of price controls would be that developed countries not use such a system as a precedent to establish additional price controls themselves.

DRAFT*International Subsidization of Pharmaceutical Purchases*

Even assuming a significantly lower price level could be established for HIV/AIDS drugs sold in a given developing country market, few developing or least developed countries enjoy income levels enabling them to pay. This is particularly true in sub Saharan Africa. Therefore, any comprehensive effort to supply state-of-the-art pharmaceuticals to these countries will require a significant program of international subsidization by wealthy states and manufacturers. Given the moral imperative involved, the costs of political destabilization resulting from unchecked epidemics, and the significant risk of new disease strains which could defy treatment and find their way back into the developing world, a program of international subsidization is reasonable. The World Bank has a history of organizing such programs. Along with UNAIDS it could put together a coordinated plan, involving international aid programs of developed countries and private sector humanitarian organizations to supply the necessary funding. Over time it will be necessary to create a subsidization regime that is sustainable. Given an appropriately controlled product delivery infrastructure, such an effort can include long-term price support by manufacturers for imported product and local production facilities.

Of course, in addition to assisting in the coordination of fund raising, UNAIDS has an extremely important role to play in organizing the means to deliver the therapies involved to patients, including the training programs, patient education programs, and the infrastructure for delivering sophisticated pharmaceutical products in general. The last section of this proposal suggests the implementation of a patient care delivery and pharmaceutical distribution system.

Conclusion: The Need for a Pilot Project Coordinated by Three Specialized Organizations

The costs and administrative complexity of a global effort to supply new drug therapies to developing and least developed countries are sufficiently high that it would be imprudent to attempt such an effort without testing its feasibility first. Therefore, this proposal is focused on identifying one developing country in a position to host a pilot project.

Together with private industry, three international specialized agencies have the mandate, expertise, and ability to organize the pilot project outlined above. They are the World Bank, the World Intellectual Property Organization and UNAIDS.

Expertise and norm setting authority over international patent law lies with the World Intellectual Property Organization in Geneva. Establishing an international consensus on how rules of territorial exhaustion should apply to developing country pharmaceutical markets clearly are within the jurisdiction of WIPO. UNAIDS, also located in Geneva, has the expertise to develop a program directed at the training and medical infrastructure issues critical to the effective administration of state-of-the-art anti-AIDS pharmaceuticals. Finally, the World Bank is in a position to put together the international effort to raise the funds necessary to subsidize the purchase of patented pharmaceuticals.

PART II

IMPLEMENTING A REGIME TO MANAGE DISTRIBUTION AND TREATMENTS

The success of this program relies on the ability to successfully deliver drugs to patients in combination with an effective treatment regime. HIV risk management and HIV/AIDS treatments are complex and require sustained therapeutic management. Accordingly, pharmacological therapies alone are insufficient absent other clinical management and support services.

DRAFT

Three major challenges must be met in order to deliver meaningful treatments to patients:

1. An effective clinical case management program must exist to coordinate the delivery of a full spectrum of care (including pharmaceutical therapeutics, HIV and other disease risk management, clinical services, social services, etc.) so as to achieve the maximum clinical benefit
2. A regulated pharmaceutical distribution network to help: (a) control delivery of these specific pharmaceutical products to patients, (b) achieve appropriate utilization, and (c) reduce product diversion and the development of a gray market
3. A multi-tiered, resource optimized, case management infrastructure to coordinate patient care, risk management and the delivery of pharmaceutical product.

Resource Optimized Case Management Services

Supplying pharmaceutical interventions alone will not provide the level of measurable clinical benefit and improved outcomes required to make this proposed program a success. The complexity of the disease necessitates execution of a case management capability to help provide patient support services and appropriate clinical management of each case.

In the developing nations, case management services can be provided by an array of providers arranged in tiers according to level of sophistication and training. Examples are First Nation's programs in Canada that employ local residents as "front line" care workers working under the remote supervision of specially trained nurses and clinicians. Other examples are midwife programs that successfully operate in rural regions throughout Pakistan.

In these programs, local care workers provide the wide array of fairly comprehensive, hands-on support services required by patients during intervals between visits by more highly trained case managers. While not a requirement for this program, rudimentary telemedicine systems can also be implemented. Front line care workers can be remotely supervised and assisted to provide an even higher level of support service.

Case Management Tiers

Patients require continuous, but varying levels of support over the duration of their treatments. It is reasonable to provide services with the least expensive resource capable of accomplishing the task. Different "tiers" of case management resources and primary care services would be assembled. Each tier would be trained and outfitted to provide services based on the complexity of the support activity and the skill level of the caseworkers in that tier. Patients requiring services beyond the skill/capabilities of the tier are identified and moved to the next tier.

The critical ingredient to managing a tiered care delivery system is an underlying set of protocols and technologies that:

1. help senior case managers properly evaluate the level of support required by a patient at any particular point in time, and
2. help determine how and when services are provided to those patients.

It is envisioned that the most senior nurse case managers and a network of participating clinicians will have access to a sophisticated, but easy to use, modeling and optimization technology. This technology enables the nurse case managers to understand how to schedule interventions with patients

DRAFT

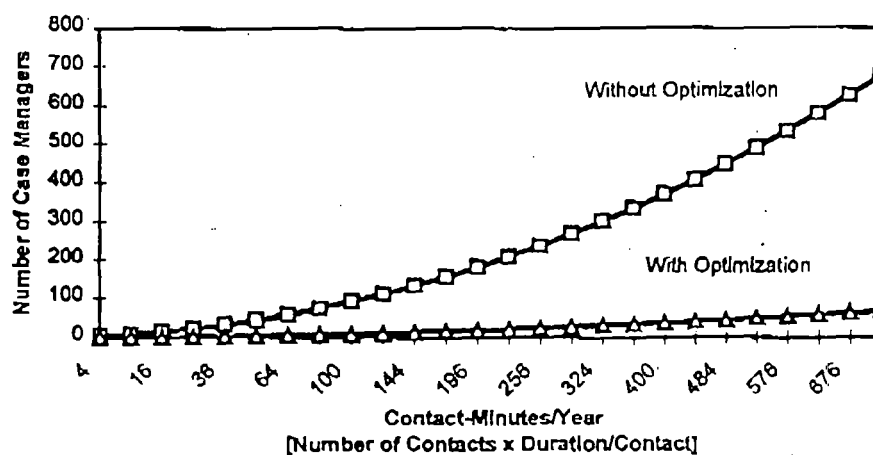
and, utilizing geographic overlays, can help them coordinate their rotations (visits with patients). Optimization technology also helps case managers task care coordination by local care workers who perform basic support services. Local care workers can also utilize the system to access case managers when an episode occurs that requires a more complex type of intervention. The infrastructure to implement and operate such a technology in the developing world is currently available and the advanced algorithms and computational platforms employed can be operated remotely where required.

This technology can substantially leverage the population that can be served by one senior nurse case manager. Therefore, it is possible to cost-effectively create a system that uses lower-skilled and lower wage local workers to provide many of the hands-on interventions that would otherwise have to be provided by an expensive nurse case manager. With supervision and occasional visits from more highly trained nurse case managers, patients will be assured of receiving an appropriate level of care sufficient to achieve an improved outcome.

Without the technology, meaningful case management would likely be impossible as it would require hundreds of personnel to support the large number of patients and the level of coordination would overwhelm management's ability to rapidly respond to patient needs. Without a sustained program, the treatment regime collapses and the outcomes are poor.

The following table shows one analysis of the labor required to provide equivalent levels of case management interventions with and without the support of optimization technology.

**Case Managers Needed for 100,000 Cases as a Function
of Increasing Contacts and Durations
[With and Without Resource Optimization]**



Regulated Pharmaceutical Distribution Network

In the industrialized nations, pharmaceuticals are delivered through a homogeneous, well-developed product distribution system. A logistically sophisticated delivery pipeline includes wholesalers, distributors and retailers. In this distribution model, many different parties retain quantities of product as inventory before it is delivered to the consumer. This inventory is often maintained in regional and local warehousing facilities with automated picking systems designed to minimize labor

DRAFT

costs. Just-in-time delivery capabilities, eliminate the need to maintain inventory at retail locations where space is very expensive.

This robust model of distribution can not work in countries where the distribution infrastructure does not exist and where there are tremendous opportunities to engage in arbitrage by diverting product from one market to another. It is especially difficult to manage dissemination of pharmaceuticals if:

- the product is sold domestically at a price substantially below the world price
- there are limited inventory management and control systems to track inventory
- there are large quantities of product available in the distribution system that are subject to "inventory leakage" and diversion
- there is no way to ascertain patient utilization to ensure that the product is reaching those patients in need
- the product is manufactured locally under license and excess production is not controlled.

In the developing world, it will be necessary to implement a "pull" distribution model. The underlying premise of a pull distribution system is that product does not enter the local-market distribution pipeline in large quantities, and it only enters the pipeline when there is a known consumer (patient) demand in a controllably small geography. Furthermore, product is paid for in a manner that inhibits the formation of local black markets. A "pull" distribution model operates much like a drop shipment system wherein product is not shipped from the manufacturer or controlled warehouse until the end consumer generates an "order" (much like how a catalog order is processed). Rather than distributing and warehousing the inventory in any quantity, the product is distributed to a geography only in anticipation of a particular order being generated (i.e., a refill is going to come due). Because there is no infrastructure to create the "order", a modeling approach coupled to the case management system is used to determine when demand necessitates re-supply and this generates the insertion order. Orders can be aggregated, but no large stockpiles are allowed. Shipments can be tracked and monitored to the point where it is delivered or administered to the patient or to a local distributor (this does not have to employ a great deal of physical or labor infrastructure). Because of the wide disparity between the value of the product and the income of people who work in the distribution system, there is always the issue of local black market diversion. A number of techniques can be used to reduce the incidence of diversion including paying distributors a percentage of product value for successful delivery to the patient. Another technique is to make the product freely available at the local level, thus reducing its "street value". Product is paid for at the national or regional level where it is easier to implement controls that prevent diversion. By eliminating the street price and paying a commission only for successful delivery to patients, there is less incentive to divert product from patients to be sold on a local black market.

Coordinating Case Management with Pharmaceutical Supply

Because the management of HIV and the treatment of AIDS and other high-impact disease requires a clinical and social case management adjunct to patient care, there is an opportunity to implement a drug delivery system that runs concurrently with the case management system. The case management system is approximately aware of the quantities of pharmaceutical and other supplies being used by patients under management and, at the right time, it triggers the insertion of refill orders into the pipeline for ultimate delivery by a visiting case worker or fulfillment by a local pharmacy.

Factors such as the inherent latency of the pipeline and the projected demand for product in a given geography are computed by the optimizer as is the projected interval until each patient is expected to need supplies. The optimizer also computes when case management interventions will be required

DRAFT

based on a number of factors including case plans and episodic incidents. The scheduling algorithm then uses the output from these models to calculate when the patient will next see a skilled care worker or case manager. These case managers can be entrusted to arrange the delivery of pharmaceuticals directly to patients in that geography.

Such a system makes it possible to "feed" the distribution pipeline in a much more controlled way and reduce the incidence of untraceable diversion. Other control measures can be implemented to reduce the likelihood of significant quantities of product being outside of control while in the distribution pipe. This approach makes it significantly more difficult for the gray market to assemble and divert meaningful quantities of product and dramatically increases the costs of doing so.

It must be pointed out that even in the developed nations there have been instances of gray market product diversion for "street" resale of products by patients (and others) that need money (e.g., for food or housing). Yet, when drug delivery strategies have been coupled to clinical case management services, appropriate utilization increases and the instances of "street resale" have been significantly reduced. This has been shown to result in better compliance and improved patient outcomes – especially as measured by the incidence of hospital admissions related to opportunistic disease.

Even in those areas where a reliable retail distribution system exists, the technology will help caseworkers oversee and coordinate appropriate drug utilization – a critical factor in managing this disease.

CONCLUSION

A powerful arsenal of new treatments now exists to help manage the course of HIV and other high-impact disease such as TB. Information management technologies have been developed that make it possible to cost-effectively deliver treatments and the adjunctive patient support needed to improve outcomes. HIV infection is being treated with some real success in the developed world and there is a reasonable expectation that it is now possible to manage the treatment of HIV and other intractable diseases in the developing world. A mandate to create the policy and legal foundation to make these treatments available is forming. There are compelling reasons of global dimension to find a way to bring these capabilities together.

A coordinated pilot program consisting of:

- innovative policies,
- international cooperation and funding

can be combined with

- sophisticated information technology,
- established models of case-managed patient care, and
- controlled pharmaceutical delivery systems

to achieve an affordable and effective effort to stem the course of a pandemic.



OFFICE OF NATIONAL AIDS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT
THE WHITE HOUSE

FACSIMILE TRANSMITTAL SHEET

TO: ~~Todd Dickinson~~ FROM: Todd Summers
COMPANY: Joe Papovich DATE:
FAX NUMBER: ~~(703) 305-0446~~ 5-3891 TOTAL NO. OF PAGES INCLUDING COVER:
PHONE NUMBER:
RE:

☒ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

Secretary Shalala is going to be meeting with the authors of the attached paper next week. We got this through back channels, but then were told that we should send this to the VP's folks and USTR. Not normal channels, so I am nervous. If you know anything about this please let us know!

Regards,
Todd

*Sandy -
Thought you
might want to
read this.
Jed*

SA/Dms

The media attention given to the disruption of Vice President Al Gore's June 16 announcement of his presidential candidacy by a handful of AIDS activists was possibly the most media attention that the Vice President has received in the past few months. A few AIDS activists disrupted the otherwise placid event shouting headline-grabbing hyperboles that millions of Africans would die as a consequence of Gore's alleged support of possible trade sanctions against South Africa to bolster the pharmaceutical industry's opposition to South Africa's 1997 Medicines Act.

Very few people take the time to read and reflect on the specific consequences of proposed and actualized legislation. I doubt that 99 percent of the activists speaking out or the media reporting on the Medicines Act issue have read the document. When journalists pontificate on the Vice President's position on the Medicines Act and then misstate the legislation's actual provisions, they contribute to the increasing lack of understanding of the issues and to the growing cynicism about much of what is reported in the media. Even many of the "reliable" media sources who followed up on this story by quoting the Vice President's official position statement on these complex issues failed to research the documentation that would support or conflict with Gore's statement.

Some activists have unfortunately become as intellectually lazy as the journalists that they tantalize with their placards and shouts. Some use their red ribbon righteousness to justify their often well-meaning but uninformed pronouncements. Having HIV or serving as an advocate for someone with HIV does not exempt one from professional responsibilities.

How many Africans' lives are and could be compromised by the World Trade Organization's heavy handed and morally questionable trade policies is speculative. Compulsory licensing and parallel importing of AIDS drugs could by many rational estimates save thousands of lives. But how many? And exactly how? The direct and indirect consequences of the World Trade Organization's policies on lives in South Africa and in other resource-limited countries is complex. Therefore, simplistic rhetoric devoid of fact-based substance and insight may do great harm to those whose cause activists champion. The Medicines Act, compulsory licensing, and parallel imports address only a fraction of the obstacles to a more humane response to the challenges of disease, poverty, and human rights in South Africa.

This millennium ends with unfathomable numbers of lives lost to and at risk of AIDS, tuberculosis, hepatitis, and other diseases that rival the seven plagues of Egypt, and with millions more lives compromised by poverty unimaginable by most of us in the industrialized North. We live in a world in which irrational debts cripple the poorest of nations, a world marked by the systematic erosion of human rights, genocide, ethnic cleansing, violence against women, forced prostitution, malnutrition, poor sanitation, and often non-existent or fragile healthcare infrastructures that often cannot support access to the pharmaceutical and diagnostic advances that too many of us take for granted. Each of these challenges may well compete with the World Trade Organization's trade policies as a cause of unnecessary suffering and untimely death.

Solutions to the problems of global healthcare access must address the economic and ethical roots of these diverse but interlaced challenges and be forged through that increasingly rare quality of leadership in which the mission and not the missionary is paramount. — *Gordon Nary*

Editorial Board

D. William Cameron, MD, FRCP
Ottawa, Ontario, Canada

Bonaventura Clotet, MD, PhD
Barcelona, Spain

Charles Farthing, MD
Los Angeles, California, USA

Christine Katlama, MD
Paris, France

Joep MA Lange, MD, PhD
Amsterdam, Netherlands

William Powderly, MD
St. Louis, Missouri, USA

Praphan Phanuphak, MD, PhD
Bangkok, Thailand

Celso Ferreira Ramos-Filho, MD, MSc
Rio de Janeiro, Brazil

Schlomo Staszewski, MD
Frankfurt, Germany

Stefano Vella, MD
Rome, Italy

Mike Youle, MB, ChB
London, United Kingdom

In memoriam

Jonathan M. Mann, MD, MPH

Editor

Gordon Nary

Assistant Editor

Lisa McKamy

Designer

Holly Emanuelson

Political Editor/Assistant Editor

José Zuniga

Contributing Writers

David MacDougall, Mark Mascolini, Carmen Retzlaff,
Bob Roehr, John Vanchiere, Becky Voelker

Non-corporate-member advertising

Integrity Magazine Publisher's Representative
Company: (323) 656-9582 or (323) 656-8375

All material published, including editorials and letters, represents the opinions of the authors and does not necessarily reflect the official policy of Medical Publications Corporation, the International Association of Physicians in AIDS Care, or the institutions with which the authors are affiliated.

Journal of the International Association of Physicians in AIDS Care (Journal) welcomes responses to the material presented. Letters should be sent to the editor at Medical Publications Corporation, 33 N. LaSalle Street, Suite 2600, Chicago, Illinois 60602-2601.

Journal of the International Association of Physicians in AIDS Care (ISSN 1081-454X), Volume 5, is published monthly by Medical Publications Corporation, 33 N. LaSalle Street, Suite 2600, Chicago, Illinois 60602-2601. Telephone: (312) 795-4930, FAX: (312) 795-4938 E-mail: journal@iapac.org Web site: <http://www.iapac.org>. Subscription rates: US and Canada, \$50 per year; elsewhere, \$100 per year. Single copy, \$5.95 at newsstands, \$10 from Medical Publications Corporation including shipping and handling. Application to mail at second-class postage rates is pending at Chicago, Illinois, and additional mailing offices. POSTMASTER: send address changes to Medical Publications Corporation, 33 N. LaSalle Street, Suite 2600, Chicago, Illinois 60602-2601.

Journal of the International Association of Physicians in AIDS Care © 1999, Medical Publications Corporation. Reproduction of any part without written permission is prohibited. This information shall not, in whole or in part, be redistributed, reproduced, or entered into a computer without prior permission.

The New York Times

Founded in 1851

ADOLPH S. OCHS, Publisher 1896-1935
 ARTHUR HAYS SULZBERGER, Publisher 1935-1961
 ORVILLE DRYFOOS, Publisher 1961-1963
 ARTHUR OCHS SULZBERGER, Publisher 1963-1993

WILLIAM B. BELLER, Managing Editor
 GERALD M. ROYD, Deputy Managing Editor
 JOHN M. GEDDES, Deputy Managing Editor

Assistant Managing Editors
 SOMA GOLDEN BEHR JACK ROSENTHAL
 CAROLYN LEE ALLAN M. SIEGAL

HUWELL RAINES, Editorial Page Editor
 PHILIP M. BOFFEY, Deputy Editorial Page Editor

JANET L. ROBINSON, President, General Manager
 SCOTT H. HREKIN-CANEDY, Senior VP, Circulation
 JYLL F. HOLZMAN, Senior VP, Advertising
 MARC Z. KRAMER, VP, Production and Labor Relations
 ALYSE MYERS, VP, Marketing Services
 DENNIS L. STERN, VP, Human Resources
 JAMES L. TRIGUILL, VP, Chief Financial Officer
 DENISE F. WARREN, VP, Planning
 MICHAEL G. WILLIAMS, VP, Chief Information Officer

THOMAS K. CARLEY, President, News Services

Drugs for AIDS in Africa

The average African nation spends less than \$10 per person each year on health care. The mix of drugs, including the new protease inhibitors, necessary to turn AIDS from a death sentence into a chronic disease costs at least \$12,000 per person each year. That disparity virtually guarantees that most of the 22 million Africans infected with the AIDS virus will not get the best available treatment. Few will even be able to afford less expensive life-prolonging drugs such as AZT or ddI or — far cheaper and just as crucial — medicines to fight the infections that accompany AIDS.

Washington is now arguing with South Africa about a new law in that country that could allow South Africa to make cheap versions of still-patented drugs or import them at less than the manufacturers want to charge. The debate is important, and it has revealed the need to broaden the Administration's policy, which has been dominated by trade issues and the desire to protect American pharmaceutical patents. Washington should stop pressuring South Africa to change the law, but even then far more will need to be done to get lifesaving medicines to poor Africans with AIDS.

Part of the challenge is to increase the availability of already affordable drugs. Last month, the Administration announced a \$100 million effort to fight AIDS in Africa. It will buy and help countries use some cheap treatments, like medicines for tuberculosis and other AIDS-related infections and drugs to prevent mother-child transmission.

While some pharmaceutical manufacturers, most recently Bristol-Myers Squibb, are making substantial donations to fight AIDS in poor countries, they want to see governments or health organizations bear the cost of AIDS drugs. But most of the newer ones are far too expensive. Many third-world countries have long responded to the high cost of patented drugs by copying them, sometimes for a tenth of the patented price. The pharmaceutical industry argues that this pirating discourages the search for new medicines, as patented drugs are priced high in part to allow manufacturers

to recover the research and development costs of all their projects, even the unsuccessful ones.

The drug companies, and the Clinton Administration's trade negotiators, have fought the efforts of third-world countries to manufacture or import cheap versions of still-patented drugs. American trade pressure on Thailand throughout the 1990's, for example, caused the country to put restrictions on its manufacture of cheap patented drugs and ban their import, which AIDS doctors say reduced the country's ability to fight the disease.

What really worry the drug industry today, however, are the new intellectual property rules of the World Trade Organization. Over Washington's objections, poor nations won the right to make patented drugs in certain situations, especially when there is a "national emergency." While Washington says it objects to technicalities in the new South African law, the larger reason trade officials have pressed so hard is that the industry fears South Africa could set precedents, within the world's trade rules, for the manufacture of cheap drugs. Drug makers have sued in South African courts to block the law.

While defending intellectual property is important, the narrowness of the Administration's views is dismaying. Pharmaceutical companies would lose little if they found legal and controllable ways to let poor countries — which offer scant market anyway — reproduce drugs or buy them cheaply.

In addition, some of the most important AIDS drugs were discovered in the National Institutes of Health, or with Government grants. Two examples are ddI and the protease inhibitor Norvir. That financing may well give Washington the right to allow the World Health Organization to license the drugs' manufacture, for sale only in poor nations in case of emergency. The Administration should explore this option for all such vital medicines developed at taxpayer expense. The desires of America's pharmaceutical companies have been the overwhelming force driving American policy on the issue of drugs in poor nations. Surely the needs of 35 million people infected with H.I.V. worldwide should count for more.

Executions Made Easier

Consumer Project on Technology

P.O. Box 19367, Washington, DC 200036

<http://www.cptech.org>

voice 202.387.8030 • fax 202.234.5176

SA Drugs

June 29, 1999

The Honorable James E. Clyburn
Chairman, Congressional Black Caucus
U.S. House of Representatives
Washington, DC 20036

via fax 202.225.2313

Dear Representative Clyburn,

The Vice President's June 25, 1999 letter to James E. Clyburn, as Chair of the Congressional Black Caucus, appears to signal a welcome and important change in US policy on the issue of US trade policy and access to essential medicines. Most notable was the Vice President's statement that he supports:

South Africa's efforts to enhance health care for its people — including efforts to engage in compulsory licensing and parallel importing of pharmaceuticals -- so long as they are done in a way consistent with international agreements.

On its face, this is a clear statement in support of compulsory licensing and parallel imports as mechanisms to broaden access to essential medicines in Africa, and one assumes, other developing countries. However, our enthusiasm is restrained by the way that this support is qualified. Specifically, the words "in a way consistent with international trade agreements" has been subject to highly controversial interpretations by the staff of the US Trade Representative (USTR), the US Patent and Trademark Office (USPTO) and the US Department of State, as expressed in numerous forums.

Consider the relatively straightforward case of parallel imports. Parallel imports involve cross border trade in goods, without the consent of the manufacturer. This may occur where a drug company charge different prices in different countries. For example, Claritin, a popular anti allergy drug, has a wholesale price of \$218 in the United States, and \$61 in Canada. And Cipro, a prescription drug to treat infections, is priced at \$399 in the US, and \$161 in Canada. If the US government permitted parallel imports of pharmaceuticals, US consumers could buy Claritin from Canadian suppliers, or from suppliers in Spain, France or other countries where the prices are lower. This is what the government of South Africa wants to permit. South Africa wants to buy drugs at the best world price. This is important for South Africa, where local markets are not particularly competitive. For example, according to a March 29, 1998

article in the *New York Times*, South Africa could save 84 percent on Chloroquine, an antimalarial drug, 92 percent on Amoxicillin, and 86 percent on Mebendazole (a drug to treat worm infections), through parallel imports.

US trade officials have claimed in numerous forums that Article 28 of the World Trade Organization's TRIPS accord on intellectual property makes this practice illegal for patented drugs, because it gives the patent owner the exclusive rights to import a product into a country. However, this isn't an accurate statement about what Article 28 does. Article 28 also says this right is "subject to the provisions of Article 6" of the TRIPS agreement. What does Article 6 say? It says that if countries determine, under their own laws, that patent rights are "exhausted" when goods are first sold (the so called "first sale doctrine"), the decision will not be subject to WTO sanctions under dispute resolution mechanisms. Trade experts know that Article 6 of the TRIPS is the relevant provision on parallel imports, and that it was put in the TRIPS to ensure that there was no ambiguity about the legality of parallel imports. Parallel imports are indeed legal under the WTO/TRIPS, they are legal under US patent law, and parallel imports of pharmaceuticals are common in many European countries. US trade officials have engaged in tortured attempts to portray parallel imports as somehow illegal but not prohibited by the TRIPS, in attempts to cloak US trade sanctions as something more noble than superpower bilateral bullying.

Likewise, US trade officials have offered highly stylized and inaccurate interpretations of Article 31 the WTO/TRIPS, which sets standards for compulsory licensing of patents. As you may know, under Article 31, countries can issue licenses to patents to third parties. In most cases, this will involve government set royalties to patent owners, a condition that South Africa and other African countries will gladly honor. Article 31 of the TRIPS also requires countries to provide a number of legal safeguards to protect patent owners. That said, the WTO rules permit countries very broad discretion. As noted by the World Health Organization:

Member states are not limited in regard to the grounds on which they may decide to grant a license without the authorization of the patent holder. They are in practice only limited in regard to the procedure to be followed.

At a meeting in Geneva on March 26, 1999, Lois Boland of the US Patent and Trademark Office said the US government's position was that as a matter of policy, compulsory licensing should be limited to only those cases where "the market fails, i.e., there is a violation of competition laws" or where "a declared national emergency" exists, so that its use is limited to "exceptional circumstances." Then, when turning to legal issues, Ms Boland asserted that:

a compulsory licensing provision in a given law that would affect certain categories of inventions, such as pharmaceuticals, would not be consistent with Article (a) of Article 31, which requires that "authorization ... shall be considered on its individual merits."

In other forums US government officials have claimed that compulsory licensing laws that specifically deal with medicines would run afoul of Article 27 of the TRIPS, which states that

"patents shall be available and patent rights enjoyable without discrimination as to . . . the field of technology." Neither of these interpretations are given weight by experts on the TRIPS, and officials from the World Trade Organization, the World Intellectual Property Organization and the World Health Organization have all rejected this view. Moreover, many European and US compulsory licensing statutes would run afoul of such a reading of the TRIPS, including the compulsory licensing provisions in the US Clean Air Act (42 USC Sec 7608) and for nuclear power (42 USC Sec 2183).

South Africa and other developing countries have very practical reasons to focus on pharmaceutical drugs for compulsory licensing. More than 20 percent of young adults in South Africa are infected with HIV/AIDS and will die without access to treatment, and there are widespread problems with malaria, tuberculosis and other illnesses. Compulsory licensing, when combined with good procurement policies, can be used to drive drug prices closer to manufacturing costs, with significant reductions in prices. Last year Thailand removed exclusivity protections for Fluconazole, a drug used to treat cryptococcal meningitis, a deadly disease associated with HIV/AIDS, and new competition led to a reduction in price of 95 percent, making the drug now affordable to poor patients in Thailand. In South Africa, however, Fluconazole is still protected by patent (South Africa has yet to issue any compulsory licenses on pharmaceuticals). Because of its high price, public health authorities in the South African Province of Kwazulu-Natal have recently stopped making Fluconazole available. And it goes without saying that more South African HIV/AIDS patients could afford HIV/AIDS drugs if the government would issue compulsory licensing to firms such as CILPA, the Indian firm that currently sell government funded HIV/AIDS inventions such as AZT, ddI and 3TC at a fraction of the prices charged by Glaxo and Bristol-Myers Squibb.

Therefore, to better evaluate the Vice-President's letter, it would be useful to have additional clarification regarding the legal issues. For example, does the Vice President believe the South Africa government would violate any international law by permitting parallel imports of pharmaceutical drugs? And, if not, why has the US government been waging a two year war against parallel imports in South Africa?

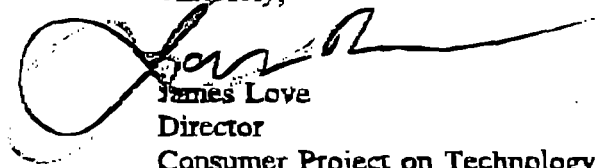
Also, does the Vice President believe the South African government is violating any international agreement by simply having broad legal authority to issue compulsory licenses, so long as its actual practice follows WTO rules regarding procedures? Does the Vice-President believe it is illegal under the WTO to have a compulsory licensing statute that singles out medicines? If not, why has the US government brought trade pressures against South Africa for considering compulsory licensing of essential medicines?

There are, of course, many other issues that might be raised with the Vice President. For example, to the degree that the Vice President's letter signals a departure from current US policy, what if anything will be done to communicate this new view to the people working at the USTR, USPTO and the Department of State who are presently pressuring South African and other countries over pharmaceutical policies. How will the US government resolve the current 301 "out of cycle" review of South Africa that is scheduled to be concluded in September. Will the US government change its positions in other bilateral negotiations, such as those involving Israel or Thailand?

Also, how will the US government respond to requests from public health groups to give the World Health Organization permission to use U.S. government rights in taxpayer funded pharmaceutical inventions? These intellectual property rights, which may be shared with the WHO for public health purposes, include such important HIV/AIDS drugs like d4T, 3TC, ddI, ddC and Ritonavir. Also, will the Vice President's support for compulsory licensing and parallel imports in South Africa apply to other African countries, or to other poor countries, such as Thailand, which has an estimated one million HIV/AIDS patients?

Thank you very much for considering these issues.

Sincerely,



James Love

Director

Consumer Project on Technology

love@cptech.org

202.387.8030

THE WHITE HOUSE

Office of the Press Secretary
(Seattle, Washington)

For Immediate Release

December 1, 1999

PRESS BRIEFING

BY

UNITED STATES TRADE REPRESENTATIVE CHARLENE BARSHEFSKY,
NATIONAL ECONOMIC ADVISOR GENE SPERLING,
AND WHITE HOUSE PRESS SECRETARY JOE LOCKHART

The "W" Hotel
Seattle, Washington

4:07 P.M.

MR. LOCKHART: Hello, everybody. Can you hear in the back? We're going to get started right away. Our United States Trade Representative, Charlene Barshefsky is here. The head of the National Economic Council, Gene Sperling, is here. They will walk you through the day, take your questions, and then I will be glad to take any questions on any other subject that's on your mind. Thanks.

AMBASSADOR BARSHEFSKY: We felt we would just give you a brief factual rundown of how the WTO talks are progressing, and also to highlight two initiatives that the President announced in the speech he gave before the trade ministers this afternoon.

With respect to the work that's proceeding, as you know from our discussion yesterday, there are four working groups that are actively drafting text, essentially simultaneously, in the areas of agriculture, market access, a variety of rules-related issues, and a variety of new issues such as competition, investment, so on and so forth.

I had an opportunity to meet with all of the trade ministers this morning, and following that meeting the working groups, which are at the ministerial level, resumed their work. Very late last night, we generated a new agricultural text. This was done by the chair of the agricultural working group, which is Singapore. That text was reviewed this morning. Further drafting is going on, but plainly a number of differences are being narrowed. I will not go into specifics on the narrowing, except to say that the draft text from late last night and the text revisions that are going on now will help to yet further narrow differences that are already beginning to diminish.

Equally, there is quite revised text on issues of market access in general, also, which have narrowed considerably a range of differences. Two of the other -- the other two working areas on a variety of rules-related issues and new issues began meeting about noon today -- 11:00 a.m. today, I'm sorry. They're still meeting now, and I don't have a readout of that at this juncture.

But I am quite comfortable with where we are right now. We will have another ministers' meeting tomorrow morning at 9:00 a.m. where we will review precisely area by area where we are, where the outstanding issues are, and we'll be discussing some ways of resolving those outstanding differences.

There are two initiatives that are somewhat separate from the WTO proceedings which the President announced today. One has to do with

increased market access for the least developed countries, that is, the poorest countries, the largest concentration of which, as you know, is in sub-Saharan Africa, although there are very poor countries also elsewhere. And on this, as agreed by the President and by President Prodi of the European Union when they met last month, the United States will commit to enhanced and preferential market access for imports from the least developed countries, and in addition will promote very substantial technical assistance and capacity building functions. And to that end -- and Gene will report on this more fully -- the President is meeting as we speak with the heads of the multilateral institutions like the World Bank, the IMF and others to discuss that series of initiatives.

The second initiative the President addressed has to do with HIV/AIDS and intellectual property rights. There has been a growing concern among poor countries which are facing a health crisis emergency, particularly in respect of HIV/AIDS, with respect to the availability and affordability of medicines, AZT being an example. We faced the question of the intersection between health policy and intellectual property rights protection with respect to South Africa and, in particular, with respect to the HIV/AIDS crisis in South Africa. And in that case, we found a means to ensure that the minimal requirements of WTO agreements in this area could be met while providing flexibility for South Africa to ensure the more ready availability of lower priced medicine.

The President today announced that per an agreement between the U.S. Trade Representative's Office -- me -- and Donna Shalala of HHS, that for the first time the two agencies will now work together at any point at which a country identifies a health care emergency, particularly in respect of HIV/AIDS, in order to ensure that together we can apply the appropriate flexibility, consistent with our international laws in this regard, to assist in the dissemination and availability of lower-cost medicines with respect to the health care emergency that is identified.

Apart from that, as you know, HHS itself works very closely, particularly with developing countries, on effective treatment regimens, because obviously simply importing medicines is not enough. One has to be sure of their safety and efficacy, and one also has to be assured that the treatments that are being provided are effective. And that is obviously within the province of HHS, and their programs with respect to developing countries will be enhanced in that regard.

So those are the two initiatives that the President announced today. I would also say that today is HIV/AIDS awareness day globally.

With that, let me turn this over to Gene Sperling.

MR. SPERLING: I have little to add. But just to say that the President is now going to be meeting with the heads of several international organizations, including Juan Samovia, at the ILO, Mike Moore of the WTO, James Wolfensohn of the World Bank, Stanley Fisher of the IMF, and as many as eight heads or representatives from eight or nine other organizations.

He will, after that, meet with environmental leaders from the National Wildlife Federation, the World Wildlife Federation -- Mark Van Putten from the National Wildlife Federation; Kathryn Fuller from the World Wildlife Fund; Durwood Zaelke from the Center for International Environmental Law; Carl Pope from the Sierra Club; and William Ruckelshaus from the World Resource Institute. Following that, the President will have a one-on-one meeting with John Sweeney of the AFL/CIO.

So Charlene and I are available to take your questions.

Q Charlene, could you talk a little bit more specifically about the sort of state of play at the particular negotiations? Are you predicting that there will be specifically an agricultural agreement? What do you mean by market access? Are those tariff cuts? And, one other thing, has anyone put on the table, is it still on the table, the issue of dumping?

AMBASSADOR BARSHEFSKY: The issue of dumping remains on the table. It is obviously not an issue that is resolved, except to say that the United States does not believe that new negotiations on dumping are appropriate. However, we do want to see enhancement of the discussions revolving around implementation of Uruguay Round rules on dumping. The Uruguay Round added a broad range of procedural rules with respect to application of the dumping law, largely to ensure due process, an appellate process, so on and so forth. Many countries have not implemented any of those procedural changes or only partially implemented the procedural changes, and we would like to see those changes implemented before any discussion of reopening a negotiation on dumping as a whole.

With respect to market access and what I mean, largely we are looking at the nonagricultural market access issues.

Services, the issue of industrial tariffs and non-tariff measures. I think progress in those areas is absolutely excellent. I think that as I said a day or two ago, there is something of an attitudinal sea change on the question of services trade, which in the Uruguay Round, was highly controversial and which led in the Uruguay Round to merely an agreement among countries that their current services regime would not get more restrictive. But the Uruguay Round did not effect any significant market access opening in the existing services regimes at that time.

There is an attitudinal change of quite substantial magnitude now among countries in large part because of things like the Global Telecommunications Agreement and the Global Financial Services Agreement which were negotiated after the Uruguay Round closed. Countries are beginning to see more and more that services-based trade is not only necessary to a modern economy, it's infrastructure-related. Telecom is infrastructure. Financial services, banking, insurance, securities is infrastructure. Construction is infrastructure. Professional services are also a form of infrastructure. They are looking at the services issues radically differently from the way they did in the Uruguay Round.

I think that the advent of the Internet and the advent of much more modern telecommunications has really affected this kind of attitudinal change. The result is that we've made very, very good progress on a very strong mandate, and broad mandate, on the services issue. There are no services that are excluded. You're looking at the full range -- telecom, financial services, construction, the professions, distribution -- anything and everything one could think of, because there will be no exclusions allowed in the text and countries, I believe, are fully comfortable with that formulation.

Tariffs, tariffs is an issue with which everybody is familiar. We want to maximize zero-for-zero tariffs. If countries will go to zero, we'll go to zero. And we're working with a number of countries. And remember this isn't the negotiation; this is setting the agenda. But we are working with a number of countries, even beginning now, so that in the coming months, as we put proposals on the table, we are going to do everything we can to maximize, including in the agricultural sector, zero-for-zero tariffs. And I think that exercise is also coming along very well.

Q Yes, Madam Barshefsky, you said the President took several opportunities today to say that these demonstrations in the street represented a shift away from a sort of closed-door policy of trade policy formulation to a more open sort of a forum. Was he in essence saying that we've reached a sort of high-water mark for global trade? I mean, now it's time to retrench, step back, take a deep breath? How would you distinguish that?

MR. SPERLING: What the President was talking about was really reiterating the call that he made, not just this summer in Geneva, but the previous year in the summer of '98 when he went to the WTO and spoke directly to the WTO and stated that there needed to be greater openness.

And he called for very specific measures, including having panel reports made immediately available, having a system for amicus briefs, having open proceedings and having submissions being made public. Those were the specific tangibles behind a broader point -- which is, as the President has repeatedly said, trade will never again be only an issue for the experts and industries. Its ramifications are too large. Its impact too significant to not seek processes that bring in the voices and the interest of concerns from child labor to the environment to human rights, as well as the interest of economic liberalization and tariff reduction.

And so what the President was saying is not at all that we've reached the high-water mark. The President believes that this is an opportunity to reach to another level of economic market opening, but that that market opening now must be accompanied by opening of the trade processes to new voices and new concerns. And that only by doing that will you be able to get the type of participation and support that will allow continued market opening to continue into the next century.

Q Ambassador Barshefsky, are you still pressing for the creation of a working group on biosafety? Is that something you're still pushing for? Europeans are very worried about this -- whether there had been some movement.

AMBASSADOR BARSHEFSKY: We've taken, actually, a cautious approach on the question of a working group in biotechnology. We had not originally been pushing for a working group on biotechnology because of our concern that the scope of that working group might be so ill-defined as to bring in any one of a number of issues, including, for example, the issue of biotechnology with respect to pharmaceutical trade. Insulin is bioengineered. Are we going to discuss insulin in the WTO?

So there was a real concern on our part. So we proceeded very cautiously. Canada originally put in a proposal for a working group on biotech. It was a proposal of such breadth and scope that even Canada withdrew it because it was far too broad, including in the areas of expertise needed for the WTO.

Now, what we have done is to put a paper in the WTO which basically says what we need to see in biotech is not a discussion of the science. The WTO is incapable of assessing the science, and the scientific evidence will lay where it lays.

But the WTO can play an important role with respect to the process by which countries approve bioengineered agricultural products. And so our position has been that if there is to be a working group, its essential mandate should be to look at the question of science-based timely and transparent regulatory processes for the approval of bioengineered product. We don't go into the question should they be approved or not, that's a matter for science. But we know in our experience with Europe there is absolutely a complete process breakdown.

The process is politicized, it's opaque. The EU doesn't even follow its own regulations on the most basic elements, for example, time frames. Data requirements are unknown and keep changing.

So we would like a process solution. And we've indicated that if a working group can address the process-related issues, that would be a valuable edition. And that's really where the issue rests right now.

Q The Wall Street Journal reported Monday that you were trying to get this round dubbed the Clinton Round. And I wondered if you were still trying to do that?

AMBASSADOR BARSHEFSKY: No, no, no. I'm not trying to get it dubbed any particular name. Our focus is very much on the substance of what we're doing. Gene and I, and the President, are quite unconcerned about the name, provided the United States feels the agenda that's developed will cover all of our principle aims. If the agenda doesn't cover that, then we have a real cause for concern.

Q What do you think it ought to be called?

Q The "Barshefsky Round."

AMBASSADOR BARSHEFSKY: There you go. You got a winner.

Q Gene, on the lists of the groups that he is meeting with today, it seemed like it was mostly environmental groups and Sweeney of the AFL/CIO. Is there a reason why those and not some of the other groups --

MR. SPERLING: Well, he met with agriculture. He spoke with some agriculture -- he did an agriculture event today and obviously had a chance to speak with some -- the interest. The international organization meeting that he is doing today is very much related to the initiative that we've done. And many of you will also remember that as part of the financial architecture process over the last year-and-a-half, the President and Treasury Department have reached out to the IFIs, to the International Financial Institutions, in trying to broaden their role to consider issues of poverty reduction and social safety nets.

I think this is another situation where the President is recognizing the breadth of the issues being dealt with and the degree that these institutions can help deal with the capacity building that allows the poorest countries to benefit from export opportunities and what kind of technical assistance that they can provide. So this first meeting is very much related to the initiative that was put out today.

And then really the President just wanted to have some opportunity to talk with representatives of some of the groups or interests that are of interest. Obviously, labor and environment are two of the issues that he has mentioned since the campaign of 1992 on trade. And any of you who followed the President's initial position on NAFTA in 1992 know that he stressed the importance of labor and environment, and that's been something he's been pushing for six or seven years. So it's not unexpected, with a limited schedule, that he would want to reach out to both environmental and labor groups.

As to the composition, I think that was something really that just John Podesta and Karen Tramontano tried to talk to the interested parties and reflected, I think, the desires of the representatives of those interests.

Q Are those are the ones he agreed with -- the protesters he agrees with are the ones he's meeting with. Is he not meeting with any of the

protesters he disagrees with?

MR. SPERLING: Well, first of all, if you've paid attention to statements on the China WTO agreement that Charlene and I were instrumental in, you would know that it's -- there's obviously significant disagreements with the AFL/CIO on issues. And so I don't think that that is -- so I don't agree at all. I think what he is doing is he is meeting with the labor and environmental interests that reflect two of the broad interests that he has stressed inclusion of in trading discussions since the summer of 1992.

Q Has there been any softening to your -- a composition to your proposal for a labor working group? And in which of the five groups is that being addressed?

AMBASSADOR BARSHEFSKY: It's being addressed mainly by all of them. No, there is no softening in our position. The EU, as you know, put forward a proposal as well on labor and trade, and we've been working with the EU and with other countries with respect to the overall issue. There's no question it is highly controversial. You have a number of developing countries in particular who are concerned that wealthier countries, as the President said in his lunch speech, will use the issue of labor or, indeed, the environment as a protectionist device designed to hamper the development of the developing world.

That's not remotely the case and certainly is not reflected in the proposal that we made for a working group, because the working group is explicitly a non-negotiating, analytic working group; it is not a negotiating group. And the EU proposal, likewise, is essentially an analytic proposal, a non-negotiating proposal.

The two proposals are similar in some ways. The EU wants a joint forum, WTO/ILO. The U.S. would like a working group but, on the working group would be the ILO, the Bank, the Fund, UNCTAD the OECD. And so I think we both have envisioned the working group is not isolated from any of the other key multilateral institutions. But the idea was to join forces, essentially with them, both in our proposal and in their proposal, to ensure that you had the analytic expertise and to ensure that you had the person power to do the kind of work that we thought needed to be done in the area.

So we are continuing to work on it and we hope to make some progress in that regard. I think also, just in response to one of the questions earlier, I think we will make progress on the transparency issues with respect to the WTO, particularly in connection with dispute settlement. And I think we will make some very good progress on the environmental side.

In all, I think we are reasonably, comfortably positioned at this point.

Q The WTO spokesman, Mr. Rockwell, seems to be a little bit more negative about how things are going. He said the talks have sort of been stymied and that's why the dinner and reception were canceled this evening. Can you respond to that?

AMBASSADOR BARSHEFSKY: Yes, the dinner and reception were canceled because Mike Moore and I felt that we were making progress late into the night on, for example, agriculture. And once you have progress going, you don't stop for a reception, much as people might like receptions. But once you have momentum going, you just don't stop. And he and I actually talked about this very late last night and we conferred again in the morning. And when we announced that our expectation was that the groups would meet today and tonight, people were extremely positive on that because I think people feel there is a momentum that's building,

delegations are clearly moving, in terms of position, in a number of areas. And once that starts, you don't stop it for a 7:00 p.m. reception.

MR. LOCKHART: Anything else on your mind?

Q The Secret Service has -- they locked down the Westin. What's the situation over there and why the --

MR. LOCKHART: I'm not aware of any change and certainly none has been reported to me. I know that there are some restrictions getting in and out, as there always are when we go to stay some place. But I haven't heard of anything new in the last couple hours.

Q And was there tear gas used outside the hotel?

MR. LOCKHART: I don't know, I've been with the President most of the day. So I don't know.

Q Joe, could you take that and get back to us on it?

MR. LOCKHART: Well, listen, I would put that question to the Secret Service. You know who to call in their Public Affairs, if they've got any restrictions that they want to talk about, they'll talk about it.

Q Joe, did the protestors get close to the President at all? Did he see them? Did he have a sense of their being out there?

MR. LOCKHART: You know, you could see them from the hotel room this morning, they were marching up a street away from the hotel. Along the motorcade route there were generally just the kind of crowds that we see when we travel around, people who are standing -- trying to get a look at the President, waving and such. So I'd say, no; I'd say the exposure that the President had was when we arrived last night. Before going to bed he watched some of the local news and saw some of the footage that was taken yesterday.

Q Can you talk about the ILO signing tomorrow, what the President hopes to accomplish with that?

MR. LOCKHART: Well, I think it's -- we've been working on this for some time. The President spoke to the organization some time ago. This is a landmark agreement in terms of protecting and promoting proper labor standards around the world. And I think the President will speak directly to that tomorrow at the signing.

Q Did the U.S. ever work out the problem with respect to children working on farms, family farms?

MR. LOCKHART: Let me check on that for you, Mark. I'm not familiar with that.

Q Anything on Vieques?

MR. LOCKHART: No. I think, as you know, we've been consulting closely with the Department of Defense and promoting a dialogue between Defense and interested parties in Puerto Rico. The President, I think, has taken time over the last few weeks to deal with all the interested parties, gain a further understanding into the issues and try to work through a solution to this problem. We still await the Secretary of Defense's recommendation. When we get that, I think the President will have something to say shortly thereafter.

Q So he hasn't worked out --

MR. LOCKHART: No.

Q Why are we -- why not more labor leaders?

MR. LOCKHART: I think we went to labor and told them that we had some time this afternoon, as we did with the environmental organizations and the multilateral organizations. And I think the labor people felt that the best use of their time was to have Mr. Sweeney come in and talk one on one. We certainly would be open to, you know, whatever configuration they wanted to do. But, obviously, we think they're in the best position to decide how they want to use the time.

Q Anything on Boris Yeltsin? Has the President had any communication with him?

MR. LOCKHART: No, I don't think we have any further substantive update since yesterday. As he indicated yesterday, we believe the reports are accurate, that it's a case of pneumonia. I think the President said yesterday that, you know, we've been told that he expects to get well and wished him a speedy recovery.

Q How long is the meeting with Sweeney and with the environmental leaders?

MR. LOCKHART: I think they're scheduled for about 45 minutes.

Q Forty-five minutes each?

MR. LOCKHART: Yes. So I think what we will do on that is John Podesta and Karen Tramontano and some others are in all three, so we'll find some way to get some brief readout later in the day. I will have somebody work on that for you all, because I am sure you will be here a little bit longer.

Q Joë, have you learned what other foreign trip the President was referring to yesterday, when he said he wouldn't go to Panama because he might have something else?

MR. LOCKHART: No.

Q Have you asked him?

MR. LOCKHART: Have I asked him? Yes, I asked him and he won't tell me. (Laughter.)

Okay, thank you.

END 4:40 P.M. PST

Final 11/29/99 1:00pm
Jeff Shesol

**PRESIDENT WILLIAM J. CLINTON
REMARKS ON TRADE
PORT OF SEATTLE
SEATTLE, WASHINGTON
December 1, 1999**

Acknowledgments: Secs. Glickman & Slater; SBA Admin. Alvarez; Sens. Gorton & Murray; Rep. McDermott & members of Congress TBD; farmer TBD & the other farmers here today; Patricia Davis, Pres., Port Commission; students from WTO Trade Winds Program

I'm grateful for the tour I've just received of the Port of Seattle. It's an impressive facility – and about to get a whole lot more so, now that you've broken ground for the huge new terminal on Harbor Island. I understand it's going to be the largest container terminal in the Pacific Northwest by the time it's completed, in 2001 – generating jobs and business revenue for the people of this region. That's exciting news.

The view from the control tower, the comings and goings of great ships, evokes the great sweep of history that passes through port cities. It's places like Seattle – or New York, or Boston, or Galveston – where so many of our ancestors stepped off the ship, literally, and began a new life in the new world. We think of a port as a point of arrival. A destination. But today we're reminded that it is also a point of departure – a gateway to the world for our people and all we produce. Last year, the Seattle area sold \$34 billion in exports to foreign markets – making it the largest exporter among American cities.

So the control tower I just climbed offers a great vantage point on the world. And Seattle, I believe, is a perfect place to talk about opening markets and expanding opportunities – from the world's newest business, e-commerce, to the world's oldest business, farming, which is our focus today.

We have come to Seattle to talk trade – but to do more than that. This constructive dialogue is part of our effort to forge a new consensus on trade. It is part of our effort to ensure that expanded trade not be an end in itself, but a means to expand peace and prosperity and opportunity. That means listening to the voices of people who haven't always been heard – like the non-governmental organizations that met with the WTO two days ago. It means building partnerships where they haven't always existed: With important economies and enormous markets like China. With developing nations. Between government and industry. . . labor and management. . . community leaders and ordinary citizens.

In the streets outside, and in the public squares of Seattle, voices are urging us to put a human face on the global economy. I welcome their views. When I spoke to the WTO last year, I said our first tasks for the 21st Century were to open the organization to public scrutiny and

participation; and, as we open markets around the world, to take greater account of labor and the environment.

Now, there are a good many concerns being voiced that I do not agree with. But I do believe that this great democratic discourse, this intense interest in our meeting, says something important. It says even as we open markets, we can and must open our process. It says even as we bring down walls of protection or oppression, we can and must lift the quality of life and work and the environment. These are our challenges – as those who benefit from trade, as those who believe in it – and I say we can meet them.

As I have said, I want this meeting of the World Trade Organization to launch a new round of global trade negotiations for a new century: a new type of round that's about jobs and development and broadly shared prosperity; about improving the quality of life and work in America and around the world. I want this round to ensure that the global trading system honors our values and meets our goals for the 21st Century.

The impact of our efforts will be profound. Since the very first trade round, 50 years ago, we have cut major industrial nations' tariffs on manufactured goods by 90%. It is no coincidence that this period has seen global trade grow fifteen-fold, as well as the most rapid, sustained economic growth ever recorded. A strong global trading system is good for all the nations of the world. It is certainly good for America, where exports create millions of jobs... where exports support one in five manufacturing jobs... and where these export-related jobs pay wages 15% higher, on average, than other jobs.

The apple farmers here today will tell you what trade means to them, and to America. Listen to this: the typical American eats almost 20 pounds of fresh apples each year, but the typical European consumes about 46 pounds. So it's no wonder that America exported \$353 million worth of apples last year. More than a quarter of that total – 46,000 metric tons' worth – were shipped straight out of Seattle. Red Delicious from the Lake Chelan region. Granny Smiths from the Columbia Basin. Winesaps, Fujis, Galas – grown in Washington State, boxed and bound for Mexico and Malaysia and more than 40 countries around the world.

In America, as in so many other nations, farmers are the lifeblood of our land. One of every three acres planted in America is growing exports, making us the world's largest exporter of agricultural products. Five years ago, America joined with our trading partners to put agriculture on the WTO's agenda. We made some progress then, but pledged to come back and do more.

Today, in Seattle, our agenda is this and nothing less: to win the fight for the family farm. To level the playing field for farmers and ranchers. And to ensure that agriculture is treated every bit as fairly as any other sector of the global economy. I think that's your due – one that's long overdue.

Whether you're an apple farmer in the Cascades or a banana farmer in Cameroon, you deserve the chance to compete on the quality and value of your goods – not against state-owned

enterprises, or restrictive regulations, or the size of other countries' government grants, which stack the deck against you. In the European Union, which accounts for 85% of the world's farm export subsidies, fully half of the overall budget is spent on agricultural supports.

Now, America has always believed in strong rural communities. We have always supported the family farm – through drought and floods and financial crises abroad. But we do not believe it is right to do so as a guise for protectionism, or to put the burden on some other farmer's back, in some other country. That's a practice we are here to eliminate.

At the same time, we have to lower tariff barriers. They are just too high – on average, official rates are five times higher abroad than they are in America. Taking apples as an example, the tariff in Korea is 45%. In China, it's 30% – which is why, as part of China's accession to the WTO, we negotiated a steep cut in this tariff, to 10% by the year 2004. We have targeted these barriers and others like them.

We will also work to reduce domestic supports that do not "support" trade so much as distort it – by paying farmers to overproduce, and driving prices down. We know that this should not – and need not – be the case. We know our farms can produce a vast and varied supply of food, at affordable prices, generating a boom for farmers, a boon for consumers, and a tremendous boost to the fight against hunger and malnutrition.

We should also see that the promise of biotechnology is realized by consumers as well as producers and the environment – ensuring that the safety of our food is guaranteed by science-based and transparent domestic regulations, and maintaining market access based on that sound science.

Later this afternoon, when I meet with trade ministers from more than a hundred nations, I will press this agenda; and I will talk in a little more detail about it. I will talk about the ways we can ensure that working people – from Seattle to Singapore and beyond – feel they have a stake in global trade, a chance at a better life, and an assurance that spirited economic competition will never become a race to the bottom for labor or the environment.

Some say that open trade is at odds with these goals. I disagree. The emergence of life-affirming, community-building, and economy-boosting technologies is changing the world for the better. Along with the promise of technology we are seeing a renewed respect for the sanctity of our lands and the dignity of every man, woman, and child. This gives us an unprecedented opportunity to bring more people and nations into the circle of growth and prosperity than ever before. I believe a strong system of trade, and a dialogue like the one we are having here, in Seattle, are our best means of reaching that goal.

An apple farmer's horizons are surely broader than they used to be – reaching as far as Indonesia, or Venezuela, or anyplace in the world where consumers seek out the fruit grown in your orchards, looking for that "Washington State" label as a sign of surpassing quality. With the 21st Century less than one month away, more and more of us see our horizons stretching

outward, and find our best new opportunities in the places that once seemed so far away. This is a moment of great promise for America, and for the world. Let us move forward together and seize those opportunities. Thank you.



UNITED STATES MISSION TO
INTERNATIONAL ORGANIZATIONS
11, ROUTE DE PREGNY
1292 GENEVA, SWITZERLAND

TEL: (41-22) 749-4865
FAX: (41-22) 749-4717

Page: 1 of Page(s) 3

Date: 1/26/00

FROM THE OFFICE OF:
Linda Vogel
Health Attaché

TO: Sandy Thurman

Fax: 202-456-2438

Urgent

Tom Novotny asked me to fax this
to you ASAP. I will telephone
with further information.

Linda Vogel

From: treatment-access-admin@hivnet.ch
Authorised by: treatment-access@hivnet.ch (TREATMENT-ACCESS - Jame...
To: treatment-access@hivnet.ch (Treatment-access)
Reply to: treatment-access@hivnet.ch (treatment-access)
Date Posted: Wednesday 26 January 2000 01:33:55
Subject: [715] US pressure to amend WHO Resolution

'Treatment Access' is an independent forum provided by
the Fondation du Present <http://www.fdp.org>

I just heard from people on the ground in Geneva, that the US
Government is lobbying to remove language in the World Health Assembly
Executive Board Resolution on HIV/AIDS (EB 105/12, on the web at:

<http://www.who.org/wha-1998/EB105/PDF/ee12.pdf>

The Clinton/Gore administration is apparently working with the
International Federation of Pharmaceutical Manufacturers, Merck and
other parties to remove this language from page 6 of the HIV/AIDS
resolution:

The Executive Board . . . REQUESTS the Director-General:

7) on their request, to advise governments
on their options under the Agreement on
Trade-Related Aspects of Intellectual Property
Rights (TRIPS) to increase their capacity to
negotiate for more affordable HIV/AIDS-related
drugs;

This is similar to the language that passed the World Health Assembly
in 1999, after a bitter two year fight between the developed and the
developing countries. The drug companies are very unhappy having the
WHO involved in these trade issues, but the USG supposedly just
endorsed this for our own trade policy.

This is a strange development, coming so soon after Vice President
Gore and President Clinton's recent speeches on HIV/AIDS and US trade
policy. According to one MSF official, "it is same old same old
policy" from the US, and the "US embassy is all over this."

Apparently the US government has also asked that other language in the
resolution be replaced with language that came from an IFPMA
roundtable session on HIV/AIDS.

I'll ask for some explanation from the White House, and I would encourage others to make some calls. This is happening right now. The WHA Executive Board will be meeting again tomorrow (Wednesday).

Jamie

James Love, Consumer Project on Technology
v. 1.202.387.8030, fax 1.202.234.5176
love@cptech.org, <http://www.cptech.org>
<http://jama.ama-assn.org/issues/v283n3/full/jmn0119-2.html>

-
- A posting from treatment-access@hivnet.ch
 - To submit a posting, send to this address
 - For anonymous postings, add the word "anon" to the subject line
 - To join or leave this forum, add the word join or leave to the subject line
 - Browse previous postings or post new messages at:
<http://www.hivnet.ch:8000/topics/treatment-access/>
 - Reproduction welcomed, provided source and forum email address is quoted
 - The forum is supported and managed by the Fondation du Present (FdP)

The views expressed in this forum do not necessarily reflect those of FdP, unless otherwise stated

HIV/AIDS: CONFRONTING THE EPIDEMIC

Agenda Item 3.3 // EB105/12

U.S. Delegation Suggested Changes to Proposed WHO Resolution 01/25/00:

(1) Preamble. To reaffirm the current WHO policy per the Revised Drug Strategy resolution, insert a new preambular paragraph between paragraphs 2 and 3, as follows:

"Reaffirming the consensus reached with resolution WHA52.19 as approved by the 52nd World Health Assembly, which outlines WHO's cooperative role with Member States and with international organizations in monitoring and analysing the pharmaceutical and public health implications of relevant international agreements, including trade agreements,"

(2) Operative Paragraph 2(5)

- (1) Delete the phrase "reducing the costs of" "and"
(2) Substitute the word "affordable" with "accessible through cost reduction, infrastructure development, and financing"

Amended to read as:

"to pursue dialogue with the pharmaceutical industry with a view to making HIV/AIDS-related drugs increasingly accessible to Member States and their populations through cost reduction, infrastructure development, and financing;"

2(5) accessible instead of affordable

(3) Operative Paragraph 2(7)

OPTION 1: Delete in its entirety.

OPTION 2: Suggested Amendment (EU Proposal below)

Amended as follows:

Keep in original from RDS
"on their request, to cooperate with governments and other international institutions regarding possible options under relevant international agreements, including trade agreements, to improve access to HIV/AIDS-related drugs."

Newsweek.com Index Search Services Archive	PRINT EDITION	TOP NEWS	ARTSCOPE	FOCUS	GALLERY	STOCKS
U.S. EDITION		INTERNATIONAL EDITIONS		SPECIAL ISSUES		

Nation
U.S. edition
PRINT EDITION

**65 of the top 100 FORTUNE 500® companies
run Oracle for e-business.**

• Learn how Oracle Software Powers the Internet.™

VOIC
br
Ne

Featured Advertiser:



Partners:

washingtonpost.com

National Affairs

• [Has the White House Really Changed Its Tune on AIDS Drugs?](#)

• [Good Time Politics](#)

• [A Boom Like No Other in History](#)

• [A Big Surplus of Ambitious Promises](#)

• [Who Gets the Credit](#)

• [How to Ride the Wave](#)

• [Economic Expansions Ain't Eternal](#)

• [The Boom Generation](#)

• [Let Them Be Lame Ducks](#)

• [Finding God](#)

• [The Battle in the Mosh Pit](#)

• [A Bloody 'Army' on Trial](#)

• [International](#)

• [Society](#)

• [Arts & Entertainment](#)

• [Departments](#)

- [Periscope](#)
- [Conventional Wisdom](#)
- [Cyberscope](#)

WEB EXCLUSIVE

Has the White House Really Changed Its Tune on AIDS Drugs?

Washington says it has shifted its policy on patents. But not everyone has gotten the message.

By Michael Hirsh

Newsweek, February 1, 2000

It was with great fanfare that Bill Clinton announced a dramatic shift in America's policy on AIDS drugs at the World Trade Organization meeting in Seattle. The president, in one of several moves intended to appease raucous protesters, declared on Dec. 1 that Washington would no longer stand in the way of cheaper medicines for AIDS victims. Until then, the Clinton administration had mostly taken the side of major pharmaceutical manufacturers, which in order to preserve profits and royalties have sought to ban cheap knockoff drugs. But in Seattle, Clinton said that drug-patent rights were secondary, and "people in the poorest countries won't have to go without medicine they so desperately need." On Jan. 10, more than a month after Clinton's announcement, Vice President Al Gore reaffirmed the policy shift during a historic appearance before the U.N. Security Council, which convened to address AIDS in Africa.



Politics or policy shift? At the United Nations, Vice President Al Gore announces a \$150 million initiative to fight AIDS (Doug Mills — AP)

All well and good. So why in late January was the administration still pursuing its hardline policy of protecting corporate patents in Thailand, one of the worst-hit AIDS countries? A few days after Gore's U.N. appearance, on Jan. 14, an official with the U.S. Trade Representative's office, Sean Murphy, reminded the Thais that they could face U.S. trade sanctions if they issued a "compulsory license" to manufacture a drug called ddI. Like AZT, ddI helps to fend off full-blown AIDS; new research also suggests such drugs may also help to stem infection. A compulsory license would compel the U.S. pharmaceutical company that makes the drug, Bristol-Myers Squibb, to allow Thai or other overseas manufacturers to produce it themselves more cheaply. A key reason for Clinton's Seattle announcement was to facilitate that process. Again on Jan. 19, the U.S. embassy in Bangkok presented the Thais with a position paper that still emphasized U.S. disapproval of compulsory licensing.

Such actions were typical before the administration's policy shift. AIDS activists complained that the administration applied the same unfeeling standard to defending U.S. intellectual property rights whether the issue

ALSO

[Web Camp News 2000's Festiv](#)

[From U.S. E](#)

[Cover Rocks Inside Natio The E Keep Intern Burm Twins Arts & Oscar the Ye Direct](#)

[From Intern](#)

[Davos Playin Curre Euros World Russia Sons Books Autho Asia Burm Pakist Honey Taiwa Freedo Busin Shinin World Rober Interv Laure](#)



- [Cyberscope](#)
- [My Turn](#)
- [Letters](#)
- [Perspectives](#)
- [Newsmakers](#)
- [Last Word](#)
by [George Will](#)

International Edition

Special Issues

standard to defending U.S. intellectual property rights whether the issue was cassette tapes or life-and-death drugs. Yet in Thailand the U.S. actions were "particularly irritating," says James Love, head of the Consumer Project on Technology, a Ralph Nader-affiliated legal advocacy group. It wasn't just the obvious hypocrisy of announcing a policy shift in public and then ignoring it in practice, he says. Worse, ddi had actually been invented on a grant from the U.S. government, which itself held the patent for it (Bristol-Myers Squibb only holds a patent for formulating the drugs into pill shape).

It was only after Leon Fuerth, Gore's national security advisor, intervened that the Thai issue was resolved late last week, Newsweek has learned. Following a complaint from Love, Fuerth asked the U.S. Trade Representative's office to clearly state the new policy to the Thai government, according to an administration official familiar with the matter. The USTR's assistant trade representative for the issue, Joseph Papovich, finally responded with a letter on Jan. 27, which the U.S. ambassador to Thailand hand-delivered to the Thai Health minister. "The United States will raise no objection," the letter said, if the Thai government decides that it needs to issue a compulsory license. Love says similar changes of approach have not yet been seen in other countries such as the Philippines and Dominican Republic.

Thai officials are now reassessing what to do. Previously the Thai government said it would refrain from issuing a license because of U.S. pressure. Bristol-Myers Squibb says it is currently negotiating with Bangkok on a compromise plan to produce the drug cheaply that would not require compulsory licensing. Most big drug corporations fear that a compulsory license for any AIDS drug would open a Pandora's box, setting a precedent for other drugs and robbing the companies of royalties. "You're looking at the possibility that a compulsory license could impede research," says company spokesman Patrick Donahue. U.S. trade official Murphy, meanwhile, says he intended no threat of sanctions to Thai officials. But he concedes that the government was concerned that in Thailand compulsory licensing "was the only option being looked at." Asked whether he also reminded the Thais that the president had announced a new policy on AIDS drugs, Murphy said only that he "may have alluded to it."

Why have U.S. officials persisted in implementing the administration's old trade agenda of protecting the drug companies— after the president himself switched position? Some activists suggest Clinton's announcement was largely a matter of presidential politics. ACT-UP, an AIDS activist group, has repeatedly interrupted the vice president's campaign stops with "zaps," or well-orchestrated disturbances, focused on the drug licensing issue. These included the unfurling of a protest banner at Gore's kick-off announcement in July in Carthage, Tenn. But some activists believe that Gore and Clinton have genuinely come around on the issue. Love says the slowness to respond probably has more to do with the bureaucratic difficulties of altering a long-entrenched policy. When it comes to defending the intellectual property of U.S. companies, U.S. trade officials "have been fired up and [focused] on these countries for 15-to-20 years, and they have got great relationships with these companies," he says. Indeed, to persuade the trade representative's office, Fuerth had to argue that Thailand is a key ally of America's in Asia and that, as Gore outlined in his U.N. speech, the administration now sees the AIDS epidemic abroad as a national security issue.

That's not just rhetoric. A new U.S. national intelligence estimate has found that that millions more people will die of AIDS-related deaths than official estimates have calculated, Newsweek has learned. The estimate, which is now classified but is scheduled to be released to the public within days, was prepared by the National Intelligence Council, a government body that draws officials from most of the federal intelligence agencies such as the CIA as well as from experts in the private sector.

A U.S. government official who is familiar with the estimate said it concludes that, globally, 33.4 million people are infected with AIDS or HIV, the virus that causes the disease, with more than two-thirds of these cases in Sub-Saharan Africa. Previous predictions said that 1.7 million were expected to die by 2005. "We exceeded that last year with 2.5 million," says the government official. He says that there could be as many as 13.9 million deaths by 2008. "It's not slowing in the developing world," he said. "There is no money and they may never get it." Most of these will occur in Africa, but the estimate also concludes that the highest growth rate of infection is not in Africa, but in Asia and in India, Ukraine and Russia. By 2010, says this official, HIV infection in Asia will likely equal that of sub-Saharan Africa.

Echoing Fuerth's view of AIDS as a national security issue in Africa as well as Asia, the official says, "the U.S. has equity in these countries. We look to South Africa and now Nigeria to bring stability to the region." He says the worst-case scenario in the new intelligence report is that "Aids is a catastrophe, unstoppable." But the final prediction is this: "We believe we're likely to see a worsening of the situation in the next ten years." After that, he says, education programs and other remedies, possibly including cheaper anti-AIDS drugs, will hopefully lead to a slowing of the disease.

With Gregory L. Vistica

© 2000 Newsweek, Inc.

[Back to the top](#)

Get a Quote

WHITE HOUSE STAFFING MEMORANDUM

Date: 5/9/00 ACTION / CONCURRENCE / COMMENT DUE BY: ASAP
 Subject: DRAFT EO ON ACCESS TO HIV/AIDS DRUGS

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	☒	☐	LOCKHART	☐	☒
PODESTA	☒	☐	LEWIS	☐	☐
ECHAVESTE	☒	☐	MARSHALL	☐	☐
RICCHETTI	☒	☐	MOORE	☐	☐
LEW	☐	☐	NASH	☐	☐
BAILY	☐	☐	NOLAN	☒	☐
BERGER	☒	☐	REED	☒	☐
BLUMENTHAL	☐	☐	SPERLING	☒	☐
BRAIN	☒	☐	STREETT	☐	☐
BURSON	☒	☐	TRAMONTANO	☒	☐
CAHILL	☒	☐	UCELLI	☒	☐
EDMONDS	☐	☐	VERVEER	☐	☐
FRAMPTON	☐	☐	<u>SANDY THURMAN</u>	☒	☐
IBARRA	☐	☐	_____	☐	☐
JOHNSON, B.	☐	☐	_____	☐	☐
JOHNSON, J.	☒	☐	_____	☐	☐
LANE	☐	☐	_____	☐	☐

REMARKS:

COMMENTS TO STAFF SECRETARY

RESPONSE:

DRAFT

Executive Order
(May 8, 6:50pm)

ACCESS TO HIV/AIDS PHARMACEUTICALS AND MEDICAL TECHNOLOGIES

By the authority vested in me as President by the Constitution and the laws of the United States of America, including sections 141 and chapter 1 of title III of the Trade Act of 1974, as amended (19 U.S.C. 2171, 2411-2420), section 307 of the Public Health Service Act, section 104 of the Foreign Assistance Act of 1961, as amended (22 USC 215(1)(b)), and section 301 of title 3 of the United States Code, and in accordance with the executive branch's policy on health-related intellectual property matters to promote access to essential medicines, it is hereby ordered as follows:

Sec. 1. Policy:

- a. In administering sections 301-310 of the Trade Act of 1974, the United States shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan African country, as defined in the Trade and Development Act of 2000, that regulates HIV/AIDS pharmaceuticals or medical technologies if the law or policy of the country:
 - i) promotes access to HIV/AIDS pharmaceuticals or medical technologies for affected populations in that country, and
 - ii) provides adequate and effective intellectual property protection consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) referred to in section 101(d)(15) of the Uruguay Round Agreements Act.
- b. The United States shall encourage all beneficiary sub-Saharan African countries to implement policies designed to address the underlying causes of the HIV/AIDS crisis, including through efforts to encourage practices that will prevent further transmission and infection and to stimulate development of the infrastructure necessary to deliver adequate health care services; and encourage policies that provide an incentive for public and private research on and development of vaccines and other medical innovations that would contribute to combating the HIV/AIDS crisis facing Africa.

Sec. 2. Rationale:

This order recognizes that:

- (1) since the onset of the worldwide HIV/AIDS epidemic, approximately 34,000,000 people living in sub-Saharan Africa have been infected with the disease;
- (2) of those infected, approximately 11,500,000 have died;
- (3) the deaths represent 83 percent of the total HIV/AIDS-related deaths worldwide; and
- (4) access to effective therapeutics for HIV/AIDS is determined by issues of price, health system infrastructure for delivery, and sustainable financing.

Therefore,

- (1) it is in the interest of the United States to take all reasonable steps to prevent further spread of infectious disease, particularly HIV/AIDS;
- (2) there is critical need for effective incentives to develop new pharmaceuticals, vaccines, and therapies to combat the HIV/AIDS crisis, including effective global intellectual property standards designed to foster pharmaceutical and medical innovation;
- (3) the overriding priority for responding to the crisis on HIV/AIDS in sub-Saharan Africa should be to improve public education and to encourage practices that will prevent further transmission and infection, and to stimulate development of the infrastructure necessary to deliver adequate health care services;
- (4) the United States should work with individual countries in sub-Saharan Africa to assist them in development of effective public education campaigns aimed at the prevention of HIV/AIDS transmission and infection, and to improve their health care infrastructure to promote improved access to quality health care for their citizens in general, and particularly with respect to the HIV/AIDS epidemic;
- (5) an effective U.S. response to the crisis in sub-Saharan Africa must focus in the short term on preventive programs designed to reduce the frequency of new infections and to remove the stigma of the disease, and should place a priority on delivery of basic health care products and services that can be used to treat the illness and complications associated with HIV/AIDS so as to prolong the duration and improve the quality of life of those afflicted with the disease;
- (6) an effective U.S. response to the crisis must also focus on the development of HIV/AIDS vaccines to prevent the spread of the disease;
- (7) American innovative capacity in the commercial and public pharmaceutical research sectors is unmatched in the world, and the participation of both these sectors will be a critical element in any successful program to respond to the HIV/AIDS crisis in sub-Saharan Africa;
- (8) the TRIPS Agreement recognizes the importance of promoting effective and adequate protection of intellectual property rights and the right of countries to adopt measures necessary to protect public health;
- (9) individual countries should have the ability to take measures to address the HIV/AIDS epidemic, provided that such measures are consistent with their international obligations; and
- (10) successful initiatives will require close partnerships and cooperation between governments, international organizations, non-governmental organizations and the private sector, and greater consideration should be given to financial, legal and other incentives that will promote cooperation toward the goal of improving prevention efforts, as well as treatment and health care support.

Sec. 3. Scope: This order prohibits the U.S. Government from taking action pursuant to section 301 of the Trade Act of 1974 with respect to any law or policy in beneficiary sub-Saharan African countries that promotes access to HIV/AIDS pharmaceuticals or medical technologies and that provides adequate and effective intellectual property protection consistent with the TRIPS Agreement. However, this order does not prohibit U.S. Government officials from evaluating, determining, and/or expressing concern about whether such a law or policy promotes

access to HIV/AIDS pharmaceuticals or medical technologies or provides adequate and effective intellectual property protection consistent with the TRIPS Agreement. In addition, this order does not prohibit U.S. Government officials from consulting with or otherwise discussing with sub-Saharan African Governments whether such law or policy meets the above conditions. Moreover, this order does not prohibit the U.S. Government from invoking the dispute settlement procedures of the World Trade Organization to examine whether any such law or policy is consistent with the TRIPS Agreement.

THE WHITE HOUSE
Office of the Press Secretary

For Immediate Release

May 10, 2000

EXECUTIVE ORDER

- - - - -

ACCESS TO HIV/AIDS PHARMACEUTICALS
AND MEDICAL TECHNOLOGIES

By the authority vested in me as President by the Constitution and the laws of the United States of America, including sections 141 and chapter 1 of title III of the Trade Act of 1974, as amended (19 U.S.C. 2171, 2411-2420), section 307 of the Public Health Service Act (42 U.S.C. 2421), and section 104 of the Foreign Assistance Act of 1961, as amended (22 U.S.C. 2151b), and in accordance with executive branch policy on health-related intellectual property matters to promote access to essential medicines, it is hereby ordered as follows:

Section 1. Policy. (a) In administering sections 301-310 of the Trade Act of 1974, the United States shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan African country, as determined by the President, that regulates HIV/AIDS pharmaceuticals or medical technologies if the law or policy of the country:

(1) promotes access to HIV/AIDS pharmaceuticals or medical technologies for affected populations in that country; and

(2) provides adequate and effective intellectual property protection consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) referred to in section 101(d)(15) of the Uruguay Round Agreements Act (19 U.S.C. 3511(d)(15)).

(b) The United States shall encourage all beneficiary sub-Saharan African countries to implement policies designed to address the underlying causes of the HIV/AIDS crisis by, among other things, making efforts to encourage practices that will prevent further transmission and infection and to stimulate development of the infrastructure necessary to deliver adequate health services, and by encouraging policies that provide an incentive for public and private research on, and development of, vaccines and other medical innovations that will combat the HIV/AIDS epidemic in Africa.

Sec. 2. Rationale: (a) This order finds that:

(1) since the onset of the worldwide HIV/AIDS epidemic,

approximately 34 million people living in sub-Saharan Africa have been infected with the disease;

(2) of those infected, approximately 11.5 million have died;

(3) the deaths represent 83 percent of the total HIV/AIDS-related deaths worldwide; and

(4) access to effective therapeutics for HIV/AIDS is determined by issues of price, health system infrastructure for delivery, and sustainable financing.

(b) In light of these findings, this order recognizes that:

(1) it is in the interest of the United States to take all reasonable steps to prevent further spread of infectious disease, particularly HIV/AIDS;

(2) there is critical need for effective incentives to develop new pharmaceuticals, vaccines, and therapies to combat the HIV/AIDS crisis, including effective global intellectual property standards designed to foster pharmaceutical and medical innovation;

(3) the overriding priority for responding to the crisis of HIV/AIDS in sub-Saharan Africa should be to improve public education and to encourage practices that will prevent further transmission and infection, and to stimulate development of the infrastructure necessary to deliver adequate health care services;

(4) the United States should work with individual countries in sub-Saharan Africa to assist them in development of effective public education campaigns aimed at the prevention of HIV/AIDS transmission and infection, and to improve their health care infrastructure to promote improved access to quality health care for their citizens in general, and particularly with respect to the HIV/AIDS epidemic;

(5) an effective United States response to the crisis in sub-Saharan Africa must focus in the short term on preventive programs designed to reduce the frequency of new infections and remove the stigma of the disease, and should place a priority on basic health services that can be used to treat opportunistic infections, sexually transmitted infections, and complications associated with HIV/AIDS so as to prolong the duration and improve the quality of life of those with the disease;

(6) an effective United States response to the crisis must also focus on the development of HIV/AIDS vaccines to prevent the spread of the disease;

(7) the innovative capacity of the United States in the commercial and public pharmaceutical research sectors is unmatched in the world, and the participation of both these

sectors will be a critical element in any successful program to respond to the HIV/AIDS crisis in sub-Saharan Africa;

(8) the TRIPS Agreement recognizes the importance of promoting effective and adequate protection of intellectual property rights and the right of countries to adopt measures necessary to protect public health;

(9) individual countries should have the ability to take measures to address the HIV/AIDS epidemic, provided that such measures are consistent with their international obligations; and

(10) successful initiatives will require effective partnerships and cooperation among governments, international organizations, nongovernmental organizations, and the private sector, and greater consideration should be given to financial, legal, and other incentives that will promote improved prevention and treatment actions.

Sec. 3. Scope. (a) This order prohibits the United States Government from taking action pursuant to section 301(b) of the Trade Act of 1974 with respect to any law or policy in beneficiary sub-Saharan African countries that promotes access to HIV/AIDS pharmaceuticals or medical technologies and that provides adequate and effective intellectual property protection consistent with the TRIPS Agreement. However, this order does not prohibit United States Government officials from evaluating, determining, or expressing concern about whether such a law or policy promotes access to HIV/AIDS pharmaceuticals or medical technologies or provides adequate and effective intellectual property protection consistent with the TRIPS Agreement. In addition, this order does not prohibit United States Government officials from consulting with or otherwise discussing with sub-Saharan African governments whether such law or policy meets the conditions set forth in section 1(a) of this order. Moreover, this order does not prohibit the United States Government from invoking the dispute settlement procedures of the World Trade Organization to examine whether any such law or policy is consistent with the Uruguay Round Agreements, referred to in section 101(d) of the Uruguay Round Agreements Act.

(b) This order is intended only to improve the internal management of the executive branch and is not intended to, and does not create, any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

WILLIAM J. CLINTON

THE WHITE HOUSE,
May 10, 2000.

#

THE WHITE HOUSE
Office of the Press Secretary

For Immediate Release

May 10, 2000

TEXT OF A LETTER FROM THE PRESIDENT
TO SENATOR DIANE FEINSTEIN

May 10, 2000

Dear Senator Feinstein:

I am pleased to inform you that today I will sign an Executive Order that is intended to help make HIV/AIDS-related drugs and medical technologies more accessible and affordable in beneficiary sub-Saharan African countries. The Executive Order, which is based in large part on your work in connection with the proposed Trade and Development Act of 2000, formalizes U.S. government policy in this area. It also directs other steps to be taken to address the spread of HIV and AIDS in Africa, one of the worst health crises the world faces.

As you know, the worldwide HIV/AIDS epidemic has taken a terrible toll in terms of human suffering. Nowhere has the suffering been as great as in Africa, where over 5,500 people per day are dying from AIDS. Approximately 34 million people in sub-Saharan Africa have been infected and, of those infected, approximately 11.5 million have died. These deaths represent more than 80 percent of the total HIV/AIDS-related deaths worldwide.

To help those countries most affected by HIV/AIDS fight this terrible disease, the Executive Order directs the U.S. Government to refrain from seeking, through negotiation or otherwise, the revocation or revision of any law or policy imposed by a beneficiary sub-Saharan government that promotes access to HIV/AIDS pharmaceuticals and medical technologies. This order will give sub-Saharan governments the flexibility to bring life saving drugs and medical technologies to affected populations. At the same time, the order ensures that fundamental intellectual property rights of U.S. businesses and inventors are protected by requiring sub-Saharan governments to provide adequate and effective intellectual property protection consistent with World Trade Organization rules. In this way, the order strikes a proper balance between the need to enable sub-Saharan governments to increase access to HIV/AIDS pharmaceuticals and medical technologies and the need to ensure that intellectual property is protected.

I know that you preferred that this policy be included in the Conference Report on the Trade and Development Act of 2000, as did I. However, through this Executive Order, the policy this Administration has pursued with your support will be implemented by the U.S. Government. The Executive Order will encourage beneficiary sub-Saharan African countries to build a better infrastructure to fight diseases like HIV/AIDS as they build better lives for their people. At the same time, the Trade and Development Act of 2000 will strengthen African economies, enhance African democracy, and expand U.S.-African trade. Together, these steps will enable the United States to forge closer ties with our African allies, broaden export opportunities for our workers and businesses, and promote our values around the world.

Thank you for your leadership on this critically important issue.

Sincerely,

WILLIAM J. CLINTON

#