Comments on

Subject: Comments on French International Therapeutic Solidarity Fund.

Upon reviewing this version, there does not seem to be much change from the last version that we have seen except for the additional detail in Section III **Funding Requirements**.

I think we all agree that the inequity of health care access between the developed and developing world is indeed tragic. However, HIV/AIDS is not unique. This extends to cancer therapies, trauma response, diabetes, etc. etc. We also agree with the French that there is a continuum between the prevention of HIV infection to the provision of selected components of AIDS care and that an integrated approach is essential. Providing selected and carefully considered care interventions can protect fragile infrastructures, maintain productivity, limit secondary epidemics like tuberculosis, and most importantly, enhance the prevention agenda.

First of all, there is essentially no mention of primary prevention programs and need to be assured that resources for therapeutic interventions are not taken from primary prevention. This is still where we get the biggest bang for our bucks! Then we must recognize that, most persons in the developing world who are infected with HIV do not have access to even the most basic biomedical and psychosocial support interventions.

[FAX page: 1]

INT - Countries - France

Most don't even know they are infected. In our programs we are building care and support systems from the ground up, with the most basic health and psychosocial needs to be addressed first. These key services include basic HIV testing (only 10% of the infected in the developing world even has access to testing and counseling!!) As part of these services, we establish referral linkages for psychosocial support through local NGOs, many of which are religious institutions. Then we need to address the most common opportunistic infections, especially TB, (which accounts for 35% of AIDS mortality) which can effectively be treated, at relatively low cost. ARV's (even when used for MTCT) should be built on these existing systems.

The description of the resources necessary to effectively reduce mother to infant transmission is woefully deficient. The drug costs are actually not the major expense:

1. HIV Testing and Counselling = $25.00/client,
2. Costs for training and infrastructure to support drug provision = $10.00
3. Costs for the short course AZT = $20.00
4. Costs for six months of dehydrated infant formula = $150.00

The proposal is also totally inadequate as far as its description of the cost and resources necessary to establish the health and support infrastructure that would allow ongoing delivery of combination therapies for the HIV positive mothers. For example, Project A described in Section III, seems to only present the specially lower costs for the drugs-nothing else! At a minimum one needs the laboratory capacity to perform Hct, liver function tests, viral load and T-4 counts. The training, logistics and control of the drug supply also incurr costs.

We clearly do not need one additional organization created (UNAIDS Secretariat and IAVI being the two most recent) Coordination and Collaboration is problematic already! The description of the oversight and management of this Fund is essentially absent! The potential for misappropriation, abuse, and inequitable resource allocation is immense!

But the most basic question is what ultimately are we trying to achieve? The scale of the program for adult care is so minuscule as to have essentially no impact on the annual AIDS mortality which we now calculate at about 2.7 million deaths this year. Antiretroviral care interventions would not decrease transmission of new infections of HIV, thus, we would not achieve any impact on the rapidly expanding global pandemic. While this may sound callous, Infected infants who die before the age of 5 do not pass the virus on.

Specific Comments:

On Page 2, we strongly agree with the EU, that therapeutic interventions must be integrated into existing programs, not be set up as a stand alone institution.

On page 2, it mentions that this proposal was drafted in close collaboration with UNAIDS. Is this true? I haven't heard this.

On page 3, effective prevention of MTCT must address testing, counseling and **safe** sustainable alternatives to breastmilk. The drug regimen is actually a rather minor component.

On page 9, it states that "UNAIDS has already made significant efforts to have the United Nations agencies pay for the medical expenses of people living with AIDS." This just isn't true.

Page 10, offering artificial alternative to breastmilk necessitates improving child survival services for the inevitable 5 time increase in infectious diseases that will occur for children off of breastmilk.

On page 14, the potential contributors should include the pharmaceutical industry. It seems that the only contribution that they are making is the "discounted" drugs for sale.

FINAL THOUGHTS:
Attending the recommended meeting wouldn't kill us. Hopefully, there would be enough sane voices to revise this noble concept into something a little more practical and useful.

Draft

Bernard

~~CONFIDENTIAL~~

EMERGING INFECTIOUS DISEASES

ISSUE

At Birmingham, the Eight reaffirmed a commitment to combat emerging infectious diseases (EIDs), including HIV/AIDS, and announced a new effort to reduce the death toll from malaria and other parasitic diseases. To further these goals, the U.S. proposes that the G-8 express its support at Cologne for WHO's global "Stop TB Project." Also at issue is a French proposal for a "Therapeutic Solidarity Initiative" which ~~would establish~~ is establishing a fund to mobilize resources to make expensive anti-HIV/AIDS treatments available to persons in developing counties.

KEY POINTS

Emerging Infectious Diseases

- At the upcoming Summit in Cologne, the U.S. proposes that the G-8 support WHO's effort to address the increasingly urgent issue of TB and its multi-drug resistant forms. TB is currently the leading infectious killer of youths and adults.

- Specifically, the G-8 should endorse WHO's Stop TB Project, which WHO Director General Gro Brundtland proposed last month. This initiative can serve as focal point for the G-8's efforts to strengthen public health infrastructure, enhance research, and address the critical emerging problem of drug resistant diseases - in both developed and developing countries.

- The U.S. has already taken the first steps. Last month, the First Lady hosted a meeting that included Secretary of Health and Human Services Donna Shalala, USAID Administrator Brian Atwood, Dr. Brundtland, World Bank President James Wolfensohn, and financier George Soros to discuss the global TB crisis. The result was a consensus to mobilize support for "Stop TB."

AIDS Therapeutic Fund
(If the French raise the issue):

- **Under no circumstances should we take a leadership role in this initiative. It is fraught with scientific, political and financial difficulties.** But we should not undermine France's efforts, just emphasize the need for refining goals and costs.

- We would participate in the French proposed experts meeting to evaluate the proposal, and help work out the many potential

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difficulties inherent in making expensive drugs available in poor countries, especially in Africa where even basic health care needs are not being met. This involves a clash between equity and cost-effectiveness.

- With ~~90~~95 percent of the ~~30~~33 million HIV-infected persons living in developing countries and over 16,000 new cases each day, we all can agree that we must find a way to deal with the growing need for health care for HIV-infected populations.

Other HIV/AIDS Initiatives

- It is also critical for the G-8 to reaffirm the commitments made at Denver and Birmingham to provide the necessary support to accelerate AIDS vaccine research and fulfill obligations to support the UNAIDS program. With G-8 backing, UNAIDS can play a critical role in mobilizing leadership in other countries, especially in Africa, to provide the political will and access to resources necessary to fight this disease.

- The research, development, and testing of a safe and effective vaccine to prevent HIV/AIDS infection continue to be a top priority for the U.S. The President has proposed nearly $180 million for AIDS vaccine research in FY 99, representing a 60% increase since FY 96.

Background

Tuberculosis

At their May 1998 meeting, the G-8 infectious disease experts agreed to continue to strengthen capacity at all levels - local, state, regional, and international - to improve surveillance and response to emerging infectious diseases, including malaria and TB. They also called for continued support for WHO's efforts in this area - particularly WHO's Roll Back Malaria initiative.

Currently, TB is the single leading infectious killer of youths and adults worldwide, causing between two and three million deaths each year. Despite the existence of a cost-effective intervention, the epidemic continues to escalate due to inappropriate or inadequate TB treatment and prevention strategies. Increasingly, multi-drug resistant (MDR) forms of the disease are emerging throughout the world as a result of poor TB treatment practices, while the HIV/AIDS pandemic is accelerating the TB epidemic where dual TB/HIV infection exists, especially in Africa and Asia.

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AIDS Therapeutic Fund

At the urging of France, the Birmingham Communique called for G-8 experts to look into the feasibility of a "Therapeutic Solidarity Initiative." Since Birmingham, Jean-David Levitte sent a letter and a non-paper to John Holmes asking that he organize the experts meeting, and offered to host it in Paris. Several follow-up meetings have been held in Paris chaired by the British and consisting entirely of French experts. Bernard Kouchner has written asking the USG to participate in future meetings of the International Steering Committee. ~~Since the September 1998 Sherpa meeting, we have received no further communication from France regarding the proposed experts meeting~~.

The proposed "International Therapeutic Solidarity Fund," intends to raise more than $400,000,000 over 5 years for the purchase of anti-retroviral drugs and treatment of HIV infected persons in developing countries. While a noble goal, the proposal far underestimates the costs and dramatically overestimates the ability of most developing country health care systems to care for the persons being treated. (It should be noted that the drugs do not cure AIDS, only improve quality and length of life.)

The treatment of those infected with HIV is dramatically different in rich vs. poor countries, partly because of cost. The cost of treating one adult in the U.S. with the state-of-the-art triple drug therapy is $10,000/year. Even the lowest (and wildly unrealistic) estimates of the French, put the cost at $3,600/year/person - 10 times the GDP per capita in many affected countries. Although the latest version of the proposal emphasizes reducing maternal transmission to the fetus - the least expensive of the proposed interventions - it still underestimates the cost and other problems.

The genesis of this idea came in a speech by Chirac in Abidjan in 1997. Minister of State, Bernard Kouchner has championed the idea thereafter. France has ~~offered to~~ contributed FFR 5 million to the fund in 1998 and intends to add FFR 20 million in 1999. Additional funding may be made available through commitments of the European Parliament. However, Many countries take the French offer of long term support with a grain of salt, as the promised FFR 100 million following France's highly publicized International AIDS Summit in 1994 never materialized.

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AIDS :

INTERNATIONAL THERAPEUTIC SOLIDARITY FUND

QUESTIONS - ANSWERS

Question 1 Who is at the origin of the International Therapeutic Solidarity Fund ?

Answer : The President of the French Republic as well as the Secretary of State for Health launched an appeal during the 10th international conference on AIDS in Africa at Abidjan to promote solidarity in medical care for patients suffering from HIV/AIDS in developing countries, especially African countries.

The French initiative was then taken up within the framework of the European Union, during the European Summit at Luxembourg in December 1997 where the Commission was requested "to study the terms and conditions for establishing a Therapeutic Solidarity Fund under the aegis of UNAIDS".

The Solidarity Fund plan was also examined by the Heads of State and the Governments of the G8 who met in Birmingham in May 1998 and who welcomed the initiative.

Thus, the Solidarity Fund is a project initiated by France, which has quickly taken an international dimension.

Question N° 2 Who are the partners in the Therapeutic Solidarity Fund ?

Answer : We want the Therapeutic Solidarity Fund not to be an initiative promoted by one individual or by one country, but a real international mobilization focussing on the main objective of access to treatment for people living with VIH/AIDS in developing countries.

The following are involved within this framework :

- the countries in the South with whom we are working, and who, in Africa, have launched a solemn appeal for access to medicines.

- The Organisation in the fight against AIDS who are participating in the working groups sept up by the Health Ministry.

- UNAIDS and its joint-sponsors

- The partners in the European Union
- The G7/G8 countries.- Multilateral, intergovernmental and bilateral institutions and agencies.
- Private foundations
- The pharmaceutical industry

Question N° 3. What is UNAIDS current role in the project ?

Answers :

1) France set up a Steering Committee in January 1998 whose is to define the international therapeutic solidarity initiative in terms of tasks, status, conditions of operating, management and financing.

UNAIDS, which is as a member of the Steering Committee is closely connected with this work. UNAIDS is also taking part in one of the two sub-groups which have been set up called "utilisation of the Fund".

2) In addition, the demonstration programs which France is going to set up together with Belgium and the European Commission have been designed in close cooperation with UNAIDS.

These programs will fit into UNAIDS action in countries where it has developed pilot sites for access to treatment, and where the demonstration programs will be set up, by supplying treatment and biological support for the mother/baby, whether during pregnancy or afterwards.

Lastly, partnerships with joint co-sponsors and thematic groups will be systematically sought.

Question 4. Will UNAIDS only be involved as a recommendation-making body ?

Answer.

- UNAIDS is regularly consulted on the setting up of demonstration programs because of its local knowledge, and the issues involved in treating AIDS. However, its role is much more than just making recommendations.

- It will be participating in the demonstration programs' follow up and assessment actions through its joint sponsors, and its thematic groups. The assessment will enable a strategy to gradually extend the projects to be developed.

Question 5. Is UNAIDS initiative to set up 4 pilot sites for access to medicine moving in the same direction as the Therapeutic Solidarity Fund ? Who are the countries benefiting from the projects set up by the Solidarity Fund ? What are the selection criteria ? Isn't there a risk of overlap ?

Answer :

1) UNAIDS has announced that 4 pilot sites for access to treatment will be set up in South Africa, Uganda, the Ivory Coast, and Vietnam, in cooperation with the governments concerned. This initiative is totally consistent with the idea of a Therapeutic Solidarity Fund to promote access to medical care for people living with HIV/AIDS in developing countries.

2) France has made its intention known to quickly set up several demonstration programs in certain countries in Africa and Asia, whilst waiting for the ITSF to be set up on a solid legal base, with a financial package enabling it to sustain its action.

The countries currently being envisaged are : South Africa, Côte d'Ivoire, Uganda, Congo-Brazzaville, Vietnam, Cambodia and Morocco with a special plan of action.

We can note that some of these programs are combined with UNAIDS pilot sites.

Secondly, the Solidarity Fund should enable the mother-baby aspect to be considered more specifically within the framework of UNAIDS pilot projects, notably by making medicines available, which will complement UNAIDS work. UNAIDS actually is not planning to supply these medicines, but rather to create the conditions for making them available.

There is no competition or overlap between the two initiatives in this context, but rather mutual support and complementarity in the field.

The selection criteria are, broadly speaking, the same for UNAIDS and the Solidarity Fund, namely :

- the government's commitment to a medical care perspective for people living with HIV/AIDS.
- the existence of an health infrastructure which will enable the patient to be treated and followed up satisfactorily with antiretrovirals.
- the pharmaceutical industry's commitment as a long-term partner for supplying medicines at appropriate prices.

Question 6. When will these pilot demonstration programs be set up, and in what form ?

Answer. The first ones will be set up in the second semester of 1998.
Almost all of them will involve programs to prevent transmission between mother and baby during pregnancy, followed by treatment for the mother after the birth, and for the baby if he/she is infected.
One project (Morocco) will involve tritherapy.

Question 7. Is there already detailed data on the financing of the Therapeutic Solidarity Fund ?

Answer.

New public or private sources of funds should be raised so that this initiative does not affect the legitimacy of existing strategies.

The Therapeutic solidarity fund could be supplied or supported by five sources of financing :

- States wishing to be involved in this initiative
- The European Union through its different financing mechanisms
- International multilateral, intergovernmental and bilateral institutions and agencies
- Voluntary contributions from physical or legal persons, including the countries involved.
- Creating a mechanism for solidarity between peoples through their health services. For example, by a contribution for each treatment administered in the industrialized countries.

Practically, contacts have been made with :

- The European Union,
- Certain potential donor countries. Thus, Belgium has stated its intention to contribute to the solidarity fund for some demonstration programs,
- Private foundations,
- The pharmaceutical industry.Certain companies have confirmed their commitment to supplying antiretroviral medicines at suitable prices,
- The French Caisse Nationale d' Assurance Maladie which has also stated its intention to be involved with the solidarity fund.

These discussions will continue for a broad and sustained mobilization of the main partners.

Within this framework, the European Parliament will shortly rule on a specific budgetary line. This point will also be discussed by a Council of Ministers of the European Union presided by Austria.

In the same time , without waiting for the results of this massive mobilisation, demonstration programs are going to be set up in a certain number of countries with the financial support of the European Commission and Belgium.

Question 8 How will the first demonstration projects be financed in practice ?

Answer Initially, these programs will be jointly financed by France, Belgium, and the European Union

Question 9. What is the timetable for setting up the Therapeutic Solidarity Fund?

Answer.

1) A Steering Committee was set up in January 1998 with the participation of practitioners, researchers, lawyers, representatives from the pharmaceutical industries, together with the NGOs and the Associations of people living with HIV/AIDS and UNAIDS.

2) In parallel, contacts are being made with the international and intergovernmental institutions and organizations as well as with potential donor countries.

- The Therapeutic Solidarity initiative will be examined, within the framework of the European Union, by the Council of Ministers under the presidency of Austria. In addition, the European Parliament will shortly rule on a specific budgetary line.

3) Contacts with the pharmaceutical industry have enabled the commitment of some companies to be confirmed. They will supply medicines at prices adapted to the countries in question, and reduced by up to 75%.

4) Whilst waiting for the outcome of these contacts, a number of demonstration projects will be set up in close cooperation with the European Commission, UNAIDS, and the Belgian Cooperation Ministry,

Question 10. What will be the legal form of the Therapeutic Solidarity Fund ?

Answer :

Experts have examined the various legal structures which could apply to the Therapeutic Solidarity initiative with their advantages and drawbacks. Several options can be envisaged :

- a foundation under national private law, with an international purpose,
- an agency set up under a regulation of the European Union, using the Agency for Safety at the Workplace as a model,
- an ad hoc international organization
- a fund, a body, or a program connected to an existing international organization.

None option has been decided for the moment. This matter will be debated at the Council of Ministers of the European Union under Austrian presidency.
The first option, of a foundation under private national law, with an international purpose, vhich has the advantage of a flexible functioning, and which can be set up quickly seems preferable to the others.

Question 11. Is there a risk that by stressing treatment, the attention of the populations affected will be diverted from away from prevention which remains fundamental ?

Answer : Prevention remains the priority in the absence of a vaccine. However, prevention and medical care can no longer be dissociated, even in terms of cost effectiveness ratio. They are the two complementary aspects of the fight against HIV, and they mutually support one another. It is illusory to think that a policy of prevention can be effective in the long-term and totally efficient unless it is connected to a real therapeutic offer.

In addition, the possibility of preventing the transmission of HIV from mother to child at the present time, by an antiretroviral treatment during pregnancy makes this separation even more questionable.

Question 12. Is there a risk that the Therapeutic Solidarity Fund will divert the money available for other diseases ?

Answer : In order to avoid this undesirable result new public or private funds should be raised, so that this therapeutic solidarity fund does not adversely affect existing strategies which will keep their legitimacy. The terms and conditions for financing the therapeutic solidarity initiative have been set out under question 7.

We believe in the positive effect of involving a therapeutic provision for AIDS in medical care system in general for 3 reasons :

- the first is that the health care infrastructures will be reinforced within this framework,

- the provision of medical care will give a renewed credibility to the biomedical system, which has lost much of its impact on the population due to its powerlessness facing the AIDS epidemic.

- lastly, the example of the industrialized countries has shown to what extent the provision of medical care for AIDS can have positive effects, beyond the disease itself.

Bernard

FONDS DE SOLIDARITE THERAPEUTIQUE INTERNATIONALE
(FSTI)
INTERNATIONAL THERAPEUTIC SOLIDARITY FUND

A CAPSULE SUMMARY OF EVENTS

What are the goals?

"Bridging the gap": **reducing inequalities**

The International Therapeutic Solidarity Fund or FSTI (we will use the French acronym for purposes of simplification) brings an answer to this strongly stated WHO objective. This concept has also been a central theme of the last World AIDS Conference, which was held in Geneva in June-July 1998. The purpose is to reduce inequalities, not only between North and South countries, but also between the scientific community and the communities which are the recipients of technological advances.

The main objective of the FSTI is to allow an increase in the access to treatment, including anti-retroviral treatment of persons living with HIV and AIDS in developing countries, keeping in mind that prevention efforts would not be compromised. Priority would first be given to mother to child prevention as well as to follow up care to mothers and newborns.

The initiative is founded on:

- **an ethical imperative** which prohibits indifference towards the suffering and death of millions of persons and which should be interpreted as a refusal of a two tear epidemic, sacrificing persons living with HIV and AIDS in southern countries.
- **public health considerations** based on the understanding that there cannot be a sustainable long term control of the epidemic without true complementarity between prevention policies and the provision of care.

Implementation:

As an interim measure, in the expectation of the creation of an established international framework , a structure has been set up under the umbrella of the "Fondation de l'Avenir", with an International Steering Committee as well as Technical Advisory Board in order to allow the start up of initial pilot projects.

The first meeting of the Technical Advisory Board took place on September 16 1998. Members of the board established the main guiding principles for future projects:

- combine partnerships and co-financing;
- have a core consideration for family units;
- have an existing viable scheme for distribution of drugs;
- ensure a high level of community participation.

All pilot projects (except for the Morocco project) will focus on the reduction of vertical transmission and ensure integration of care for mothers and infants within existing health initiatives.

The first meeting of the International Steering Committee, chaired by a British scientist (Pr Pechkam), was held on September 30, 1998 in Paris. At this meeting the committee reviewed and rated project proposals with the following recommendations:

- development of guidelines for the implementation of projects;
- active pursuit of financial partnerships;
- prepare detailed project budgets;
- ensure project monitoring and evaluation under the authority of UNAIDS.

The committee further reviewed specific projects: South Africa, Ivory Coast, Vietnam and Morocco. The committee entrusted the Technical Advisory Board with the authority to make final decisions regarding priority projects.

The second meeting of the Technical Advisory Board was held on October 16. It endorsed guidelines for the treatment of mothers and infants as well as psycho-social support to be provided, consistent with WHO recommendations *(Weekly Epidemiological Record, 1998, 73, 313-320, n34)* and UNAIDS recommendations (*Guidance Modules on Antiretroviral Treatments*). The Board further endorsed three priority projects: South Africa, Ivory Coast and Morocco). Three teams will be sent to the field in November in order to finalize modalities for the establishment and monitoring of the projects.

These decisions will be submitted to International Steering Committee for final approval.

Total financial commitments are nearing the US$ 10 million mark, combining the initial French of 1 million for 1998 and 3.5 million for 1999 as well as funds from the European Parliament and other interested parties (Belgium, Greece and Austria).

WHO, which is currently holding the chair of UNAIDS will have a key role to play in ensuring field coordination.