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Statement of Purpose:

AIDS Treatment News reports on experimental and standard treatments, especially those available now. We interview physicians, scientists, other health professionals, and persons with AIDS or HIV; we also collect information from meetings and conferences, medical journals, and computer databases. Long-term survivors have usually tried many different treatments, and found combinations which work for them. *AIDS Treatment News* does not recommend particular therapies, but seeks to increase the options available.

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September 11: What Happens Now?

by John S. James

Several major AIDS organizations in Manhattan were in the disaster area near the World Trade Center. It appears that everyone in those offices got out alive, although some lost friends or relatives. The long-term consequences for the global fight against AIDS, tuberculosis, malaria, and other major infectious diseases remain unknown but ominous.

Every day HIV infection alone kills more people than died at the World Trade Center and other terrorist attacks on September 11 (*AIDS Epidemic Update: December 2000* by UNAIDS estimated 3 million deaths in 2000 -- over 8200 per day -- and the numbers have risen since then). But even on September 10 the prospects for worldwide response did not look good. The epidemic did get media attention during the previous year. But it was becoming clear that the U.S. and other rich countries did not have the political will to pay more than a fraction of the cost of a serious program for controlling the disease. (The total cost would be about \$10 billion per year from the entire world -- about \$2 billion from the U.S. if the cost were shared in proportion to the size of each country's economy). The problem wasn't lack of money; in just one week after the September 11 attack, the U.S. had found and signed into law \$40 billion -- money no one had thought about, let alone proposed, just seven days before.

We still believe as we did on September 10 that ultimately there is enough interest and good will in the U.S. to support a proportional contribution to the money and leadership of an effective worldwide AIDS and infectious epidemic program. The central problem is that nobody has found an effective strategy for dealing with the three fundamental political divisions that have always blocked an effective response to the epidemic.

1. The international pharmaceutical industry is more interested in protecting its patent rights than in controlling the epidemic. Some companies cut prices to some poor countries by 80 to 90 percent when they had to, but then largely washed their hands of the global problem, leaving prices that will largely remain unused (except for prevention of mother-to-infant transmission) because they are still so far beyond reach. There is no plan that pharmaceutical companies, medical professionals, and activists can get behind enthusiastically and bring to Congress, international agencies, foundations, and other decision makers (as they can with the AIDS Drug Assistance Program for funding treatment for U.S. patients).

Industry so far has tried to lead an unworkable campaign to preserve drug patents everywhere, with piecemeal charity for some poor countries -- negotiated between each country and company, revocable any time, and with secret political quid pro quo. What could work instead is to preserve drug patents in rich countries while relaxing them in poor ones where there is no significant market anyway, then pushing for global funding for systematic bulk purchases, which can and should be profitable to the patent holders (we want them with us when going to funders). Countries neither rich nor poor will need a mixed system. This approach could greatly relieve the global access problem -- and end industry's horrible public relations from people dying because they cannot pay impossibly high prices for needed medications. Events are already moving in this direction, but with industry impeding this solution instead of helping to lead it (for example, see "U.S., Switzerland Oppose Developing-Country Proposal on Access to Medicines," in this issue).

2. Also critically important is the conflict around sexuality throughout the world, and the resulting stigma around AIDS. A great many individuals and institutions have so much invested in saying "No!" that they find it difficult to pivot emotionally and be helpful to someone infected through sex or drugs, or to support measures to make behavior they oppose less dangerous. As a result, it is hard to mobilize consistent support for rational, can-do responses to this worldwide health emergency.

3. In addition, the HIV epidemic increasingly affects mostly the poor, whose life and death interests are usually not taken seriously. This problem increases with the growing inequality in the modern world.

All this was in place on September 10, and still is. No one can predict what will happen now. Some concerns:

* A major war now will further divert money, attention, and other resources away from other issues, including health, education, and development. With no clear enemy, there could be a permanent war against terrorism, not seeking victory but rather building a constituency for continuing conflict, like the drug war. It could become a race to the bottom among governments and terrorists, each trying to outdo the others in death and destruction.

* The harm to the U.S. economy from the attacks will result in fewer resources for health programs of all sorts.

* Wars always result in curtailment of civil liberties. Over the years AIDS activists have relied heavily on direct action (demonstrations, often including civil disobedience) to get AIDS onto the table of decision makers, when otherwise it would not have been. Our impression since September 11 is that while most demonstrations have been called off, more people are coming to activist meetings than ever before because

they need to talk with others about what has happened and what it means. But there is much concern about what kinds of activism will or will not be allowed in the future -- especially in view of the major efforts to make big changes in laws in days, with little or no chance for public discussion or input (for fact sheets and other information, see <http://www.aclu.org>; for recent Web links, see <http://www.indymedia.org> -- especially the 'IMC News Blast' or other edited summaries on that site).

Yet there has also been more solidarity among Americans in the week and a half since the disaster -- from willingness to help those affected, to expressions of patriotism, to activism for peace, to people being less isolated from each other in everyday life.

No one can predict what will happen. There is no U.S. precedent for the attack of September 11 -- and few attacks in any country with so many killed and so little warning. We can only do our best work each day.

Tuberculosis: Guidelines Changed for Latent TB Treatment

The U.S. Centers for Disease Control and the American Thoracic Society have issued new guidelines calling for more caution in using the two-month regimen of rifampin and pyrazinamide. The change resulted from reports of 21 cases of severe liver injury with the two-drug regimen. Five of these patients died, and 16 recovered.

The new guidelines were published in the August 31, 2001 *MMWR (Morbidity and Mortality Weekly Report)*, volume 50, number 34, pages 733-735. We cannot summarize them because there are many special cases. For most patients, especially those who are HIV-negative, the older nine-month regimen of isoniazid (INH) should be used. The persons with HIV, the guidelines include the following:

"Available data do not suggest excessive risk for severe hepatitis associated with RIF-PZA treatment among HIV-infected persons. In a large multinational trial, HIV-infected patients treated with RIF-PZA had lower rates of serum aminotransferase (AT) elevations than those given INH alone. The RIF-PZA regimen also was well tolerated when given twice weekly to HIV-infected persons in Zambia and Haiti. However, experience from trials may not translate to all clinical practice settings, and it may be prudent to use 9 months of daily INH for treatment of HIV-infected persons with LBTI [latent TB infection] when completion of treatment can be assured."

The August 31 *MMWR* is available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5034a1.htm>

HIV/HCV Coinfection: One-Day Conference October 11 in Washington

The Forum for Collaborative HIV Research is sponsoring a one-day meeting on HIV and hepatitis C coinfection on October 11 in Washington D.C. "Speakers will focus on the pathogenesis, prevalence, and treatment of coinfection with the goal of highlighting what we do and do not know to identify the need for additional research efforts and facilitate progress in research on HCV/HIV coinfection."

For more information, see <http://www.hivforum.org>

AmfAR Announces Research Grants: Letters of Intent Due October 23

The American Foundation for AIDS Research has announced targeted research grants up to \$75,000, fellowships, and travel grants, for studies of new viral and cellular targets for anti-HIV agents, including use of combinatorial libraries. The letter of intent is due 5 p.m. October 23, 2001.

More information and application forms are available at <http://www.amfar.org>

ICAAC Postponed to December 16-19; "Salvage" Workshop Also Postponed

Due to the recent terrorist attack and concerns about air travel, the 41st Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), originally scheduled for September 22-25 in Chicago, has been postponed until December 16-19; it will be held at the McCormick Place in Chicago. This conference focuses primarily on new antibiotics, and also has a strong HIV/AIDS track. For more information, see the conference Web site at <http://www.icaac.org>

Also, the International HIV Workshop on Management of Treatment-Experienced Patients, which had been scheduled for September 19-21 in Chicago, has been postponed. For more information, see <http://conferences.intmedpress.com/mtep/>

ADAP Funding Crisis: Talking Points

The AIDS Drug Assistance Program (ADAP) is running out of money in increasing numbers of states; already hundreds of people who cannot pay for drugs through insurance or out of pocket are not getting the medicines they need. The ADAP Working Group is an industry-activist coalition to seek funding for this program, which is administered separately by each state. On September 20 the Glaxo Wellcome representative to the ADAP Working Group circulated the following talking points -- facts about ADAP as of September 2001 -- to use for supporting this program, in Congress or elsewhere:

- * The AIDS Drug Assistance Programs (ADAPs), funded primarily under Title II of the Ryan White Care Act, are in trouble across the nation.
- * ADAP programs around the country provide needed medications to treat HIV disease to low-income and underinsured individuals living with HIV/AIDS.
- * Last year, a \$130 million increase was requested to fund ADAP programs in fiscal year 2001. Congress appropriated only \$61 million for a total funding level of \$589 million in federal funding for fiscal year 2001, approximately \$87 million less than needed.
- * We are now seeing the impact of this shortage on states, particularly in the South. Nine state ADAPs have already closed [to new patients] including: Alabama, Arkansas, Georgia, Indiana, Kentucky, Maine, Montana, and South Dakota.
- * Prior to the end of this fiscal year, 7 more states may cap enrollment or institute other program restrictions including: Idaho, Florida, Missouri, Nevada, Oregon, Rhode Island, and West Virginia.
- * Currently, there are over 600 people on waiting lists. As the funding crisis grows, this number will increase.
- * The number of clients served nationwide by state ADAPs has more than doubled between 1996 and 2000, with ADAPs serving approximately 70,000 clients a month.
- * Recent reports of declining death rates and decreasing HIV-related morbidity point directly to the importance and cost savings of access to antiretroviral treatment and treatment advances using combination therapies.
- * In all parts of the United States, new HIV infections are disproportionately affecting communities of

color, rural populations, inner city communities and women of color.

* The ADAP program is effective and accessible, providing the gift of life to people across the country. The very success of HIV disease treatments continues to increase the need for ADAP.

* There have been several congressional delegation letters expressing the need for fiscal year 2002 increased appropriations of \$120 million for ADAP. We urge your careful consideration of those requests.

* We join with our colleagues in speaking for patients across the country that this increase would ensure that those enrolled in ADAP treatment programs will not be cut off from these essential treatments and necessary therapies will be available for those identified by nationwide HIV outreach programs this year.

For additional information, see the ADAP Working Group site, <http://www.aidsinfonyc.org/awg/>

U.S., Switzerland Oppose Developing-Country Proposal on Access to Medicines

by John S. James

At a September 19 meeting in Geneva, Switzerland on access to medicines, 52 developing countries asked the members of the WTO (World Trade Organization) to agree that rules on international patent protection (known as TRIPS) be interpreted in ways that allow governments to ensure access to affordable medicines; they were not asking for changes in the wording of TRIPS itself. The United States and Switzerland, supported by Japan, Australia, and Canada, opposed their proposal. The European Union did not support either side and sought a negotiated solution; Norway was the only rich country that sided with the developing countries. The U.S./Swiss position "echoed the well-rehearsed views of the international pharmaceutical companies," according to a press release issued jointly by Doctors Without Borders, Oxfam, and Third World Network.

The September 19 meeting was to prepare for the World Trade Organization's fourth Ministerial Conference, scheduled for Doha, Qatar, November 9-13, 2001.

For more information, see:

MSF (Doctors Without Borders -- Campaign for Access to Essential Medicines):
<http://www.accessmed-msf.org/index.asp>

IFPMA (International Federation of Pharmaceutical Manufacturers Associations) :
<http://www.ifpma.org/>

AIDS Treatment News Publication Schedule

AIDS Treatment News usually is published twice a month, on the first and third Friday. Because we have been behind schedule recently, we are publishing only one issue in August and one in September.

Subscriptions are paid by number of issues, not calendar year, and will be extended to replace the missing issues.

Malawi Plan to Control AIDS Epidemic: Interview with David Scondras, Search for a Cure

by John S. James

In May 2001, when David Scondras was in Malawi, the headlines on the May 19-20 *Weekend Nation* newspaper read, "Few on the AIDS drugs; Babies May Be Saved; No Hope for the Poor." Almost the whole front page was devoted to the epidemic.

Scondras was there working with health experts from Malawi and the U.S. trying to change that picture -- by developing a plan to control the epidemic in Malawi, a plan that could become a model for other countries if it succeeds. While the number one goal is to reduce HIV transmission, this plan will also include medical treatment for those who need it -- and extensive operations research to make sure that the program is working effectively. This September, officials from Malawi are coming to Boston for meetings to finalize the plan and begin steps toward implementation. [The meeting was postponed after the September 11 terrorist attacks, but is still scheduled for

September, with a smaller delegation from Malawi.]

AIDS Treatment News asked David Scondras to explain this project to our readers. The interview took place on August 27, 2001.

ATN: Tell us what is happening now.

SCONDRAS: This will be the second trip that people from Malawi are making to the United States to get help. Experts and officials, including those responsible for Malawi's five-year plan to control AIDS, are coming to Boston to, among other things, meet with Jeffrey Sachs and others at Harvard's Center for International Development. They will continue a process begun several months ago in a previous trip, of having their countrywide plan reviewed by a group of scientists that Search for a Cure pulled together, and brought to Malawi as well as to Boston. Then, with the blessing of the scientific community that is reviewing the plan, they will seek funding from at least three different sources to implement that countrywide plan as soon as humanly possible.

On this trip, Search for a Cure and Harvard are hosting them in Boston for about a week.

ATN: How did this project develop?

SCONDRAS: Two years ago when I first went to Malawi, the president of the country was on television and radio, explaining that there were some medicines that could help this disease, but unfortunately no one could afford them in Malawi, so they were going to have to do without them. This entire picture changed when we met with the Vice President and explained how these drugs work. When it became clear that lowering viral load with these drugs might help reduce transmission, it became obvious that these drugs were a necessary part of the prevention program, not just help for people who are sick. In that context people became much more determined to see that there was access to them.

Finally, when CIPLA (a drug manufacturer in India) and other generic producers offered generic drugs that were much, much less expensive, there was an increase in morale in Malawi. And when the Global AIDS Fund was announced, that morale reached the point that the vice president of Malawi accepted an invitation from Search for a Cure to come to the United States, and went to Harvard with me and met with Jeffrey Sachs and put this whole program in motion.

Malawi is determined to do a countrywide treatment program that will stop the epidemic -- that's the

objective. This will be one of the tools.

ATN: Tell us about the country.

SCONDRAS: Malawi is a small country in sub-Saharan Africa, one third of which is a giant lake. About 70% of the population of ten million is small farmers. It has two big cities, Lilongwe and Blantyre. It is one of the poorest countries in Africa, with a per capita income in U.S. dollars around \$250 per year. It has three main Bantu languages; a major one is called Chichewa. English is a second language for most people who are educated, because Malawi was an English colony.

It is a very new democracy; it emerged from a struggle to end a dictatorship only six years ago. The dictator had refused to allow the word "AIDS" to be used. The first thing the new government did was launch a prevention program across the country, with the President singing anti-AIDS and behavior change songs on television with schoolchildren -- to try to get people to understand that AIDS is a crisis and people had to change their behavior.

Development experts and economists came in to try to get the country going after the dictatorship ended. But they quickly realized that this country has about five years left to live. Malawi has ten million people, over one million HIV-infected. It has about 400,000 orphans who do not have HIV but whose parents are dead as a result of the epidemic. Up to a point, extended families and relatives can absorb orphans. But the ability to sustain life is being stretched to its limits, as members of the extended families are now dying, as workers are dying and productivity is collapsing. The vice president compares the situation to an earthquake or other natural catastrophe, and asks why is the world so willing to help a country when there is a sudden disaster like an earthquake, but so slow when there is a crisis of equal magnitude that takes time to develop.

There has been a change. Malawi went from hopeless resignation to a sense of aggressive optimism. They decided they are going to live, and going to fight to live. This year Vice President Justin Malewezi said:

"Malawi has not been spared this worldwide epidemic. Sixteen percent of the population aged between 15 and 49 are HIV positive. These people are commonly called People Living with HIV/AIDS. However, these are not the only people living with the disease. Every day we are burying our children, our sisters and brothers, our workmates, our neighbors, our leaders, our teachers, doctors and other professionals. In the suffering and

death of our brothers and sisters we face grief beyond words, sorrow beyond tears. We will not stand by and watch while our people are dying."

A study by Hamoidi and Sachs looked at how the epidemic affects individuals and families:

"To take an individual case, a husband and father of young children, who earns a market income and who becomes HIV infected. He is likely to face years of declining market income due to absenteeism from work and reduced productivity before suffering a premature death. Household income will be diverted to pay for medical care, he is likely to sell assets and borrow at very high interest rates to get minimal access to palliative care. Upon his death, funeral costs will absorb savings from the extended family while his children may be sent away to live with relatives and their future education will be severely compromised. Tragically this scenario is repeated in Malawi every day."

SCONDRAS: Malawi's plan [from which the above quotes are taken] is a direct call for help, in human terms that are unmistakable and explicit. If we don't respond to it, then there's something wrong with us. We cannot say we didn't know about it.

ATN: Once the plan is ready, where does it go for funding?

SCONDRAS: Malawi already had a large and well-funded tuberculosis program, using directly observed therapy (DOT), with community workers who give medicine to individuals. Tuberculosis had been almost wiped out -- but AIDS brought it back. So the DOT people are willing to finance part of the program, as it affects their ability to control tuberculosis. (A recent South African study of people with HIV who use antiretrovirals vs. those who do not shows a dramatic difference of five times more tuberculosis among those who do not use the HIV drugs. So one can argue correctly that the antiretroviral program is an effective tuberculosis program, as 70% of tuberculosis patients in Malawi are co-infected with HIV.) The tuberculosis program is funded by the English contribution to the European Community.

Malawi will have a DOT program for its HIV drugs, along the line of what Dr. Paul Farmer has done on a smaller scale in Haiti. But here it will be expanded to the whole country.

A second source of potential funding will be a request from the Global AIDS Fund. The World Bank will be asked to change the payments that Malawi is presently making on its debt, which are considerable, and returning them to Malawi as grants targeted specifically

for this AIDS program.

In addition, Malawi is asking for a start-up grant from the World Bank -- which has been directed to make 50% of its future investments in developing countries in the form of grants instead of loans. Incidentally the Bush Administration is supportive of this shift from loans to grants.

There is also an effort to organize an international concert to ask for support from the world community.

And in the U.S. Congress, Congresswoman Barbara Lee (D., California) is leading an effort to contribute an additional \$150 million immediately to treatment.

ATN: How would Malawi purchase the drugs?

Malawi could use the International Dispensary Association (the IDA) as a vehicle for drug purchases. The IDA (<http://www.ida.nl/>) is a nonprofit organization based in Holland that has had a terrific reputation over the years for being the purchaser of the most inexpensive essential drugs for poor countries. They have decided to add HIV drugs to their list. They don't just buy the drug on behalf of the country; they also test the drugs on an ongoing basis to maintain their quality. Clearly for small developing countries, it is essential to have a dependable buyer who will get you the best price and guarantee the quality of the product. Malawi may choose to use the IDA for their HIV drugs, especially since they already use it for their tuberculosis drugs.

Besides funding, other support is from volunteers who are helping this effort and not getting paid, among them being quite a few U.S. scientists, including Peter Salk, M.D., from the Jonas Salk Foundation, and Robert Redfield, M.D., from the Institute of Human Virology, and people from the U.S. Public Health Service.

Several of pharmaceutical companies are also going to try to help.

ATN: How is the AIDS program in Malawi organized?

SCONDRAS: Over a year and a half ago we helped put together a meeting in Malawi, under the leadership of UNAIDS, which helped create the Technical Working Group, a kind of committee with the sanction of the cabinet of Malawi. This committee was given the responsibility of developing a plan to use antiretrovirals in Malawi, and overseeing its implementation. It is the only committee I know of its kind that includes foreigners on it.

The Technical Working Group includes all the major stakeholders in Malawi working with HIV, including the

private hospitals and so forth. That organization is headed by the director of the AIDS program in Malawi. This is the organization that, if you are going to do anything with HIV in Malawi, you have to get approval from. Last week the Cabinet of Malawi gave the approval for moving forward.

ATN: Is there any opposition?

SCONDRAS: The government of Malawi is fighting hard for this plan, but not everyone is supportive. There is a lot of skepticism. Part of the donor community has been trying to get Malawi to not do this plan, still saying it's unrealistic, you should do prevention only. Malawi is going forward anyway, because it does not see any choice. Malawi knows that even a perfect vaccine tomorrow would be too late to save the country. And besides that it would be immoral not to try to save those already infected. This struggle has not been made public, but people have a right to know about it.

ATN: What about foundation funding?

SCONDRAS: We will be seeking a planning grant to help finish putting the program together.

Malawi wants to prove that you can stop an epidemic, and that antiretrovirals can be part of that program, that it can be done. But the first target for this program is reduction in transmission of HIV.

ATN: Tell our readers about the research plans.

SCONDRAS: The plan itself makes a compromise between the demands of science and the demands of the economy, ethics, and politics. The scientific community wants to make sure through research on the ground that the choice of medicines is correct, that the delivery system is actually working, and so forth -- and that the type of therapy used is the right one, and wants to see which types of therapy might be better. Should we use interrupted therapy? Does nutrition have a role? What about use of immune-based therapies? You can imagine how many questions scientists have. But it would take years to answer them all. Meanwhile the country would collapse.

So Malawi is starting the program by basically enrolling everyone into a best-guess approach -- using community-based directly observed therapy that can be taken once a day. But many people, in fact the majority, will be involved in a set of interlocking clinical trials, which the scientists refer to as operations research. These trials will test the different regimens and different styles of delivering them, to find out which work better. And as they learn what is best, they will phase out certain treatments and switch people to others.

Malawi will maintain the research component, so that Malawi will not only be a country that tries to stop the AIDS epidemic, but also will become the world's largest clinical-trial system, to find out the best way to reduce HIV transmission and improve on existing therapies across the world. For example, studies could test microbicides and see if they can reduce the rate of spread, or test vaccines. The research component, the ability to track data, analyze it, and feed it back to the working group and have the government make decisions about what to do, has to be much more advanced and larger than you would expect for a treatment program. The advantage is that this research will help everyone in the world, including people in the United States.

ATN: Could you summarize what's happening now?

SCONDRAS: In a few months Malawi will make history -- as its leaders present this ambitious, country-wide program for stopping AIDS in an African country to funders at the World Bank and the Global AIDS Fund.

Malawi will not survive unless this program succeeds. Today a million people are infected, there are 400,000 orphans, and the whole country has only ten million people. If this plan works in one of the poorest countries, then it can work elsewhere and will become a beacon of hope for Africa and the rest of the world.

This effort has been put together by a team of volunteers including some of the best medical minds in the world, students from Harvard Business School, politicians, ministers, people with HIV, people of good will from all walks of life, working together with leaders from Malawi. It is possible because activists from around the world have pushed for a worldwide AIDS fund, and for reduced prices of antiretrovirals. Malawi will come to the United States to work with some of this country's finest experts and activists, all committed to finishing the design of the program and finding the funds to put it into operation now.

Anyone interested in helping is welcome to call or write us and join this effort. Many of us feel that one measure of our civilization will be how the rich nations and people of the Earth behaved during the most devastating epidemic in the history of the world.

[For more information about the Malawi program, contact David Scondras or Dede Ketover at Search for a Cure, 617-536-2474, or email them at hope@sfac.org]