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The entire United Nations General Assembly will focus on the AIDS epidemic next week. About 5,000 people are expected to register for this meeting, most of which is closed to the public; however, many satellite events are open to public participation. The entire session will be broadcast worldwide via the Web, and archives and transcripts will also be available. This article provides some Web sites to start with, and outlines some of the major controversies around this session.

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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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United Nations: Special AIDS Session Next Week

by John S. James

On June 25-27 the entire United Nations General Assembly will focus on AIDS. The goal is worldwide commitment and consensus on dealing with the epidemic. The negotiations leading up to this Special Session have been contentious, even more so than most diplomatic meetings.

No matter what the outcome, this meeting will be historic and will be a major focus of world attention. Here is some background, and resources that you can use as a starting point for finding information.

Official Web Page

The Web page for the United Nations General Assembly Special Session on HIV/AIDS (often called UNGASS) is

<http://www.un.org/ga/aids/>

Here are some of the important documents available there before the meeting:

* Under the heading "A call to action" are several recent statements by United Nations Secretary General Kofi Annan, who has provided exceptional leadership on this issue in advance of the United Nations special session;

* The "Documents" section includes the "Revised Draft Declaration of Commitment on HIV/AIDS" -- a single-text statement that is being negotiated in order to reach as much agreement as possible. (At this time, June 16, the current draft is the 2nd published version, dated May 11.)

* The "Bulletin" is an electronic news bulletin to keep participants informed. At this date (June 21) only one issue has been published, with general background such as AIDS statistics, overview of the meeting, and

media accreditation. Two more issues are planned by June 25.

* A "calendar" of dozens of official UN and unofficial events around the time of the session.

* Other sections on background information, NGOs and civil society, and media.

From the official media advisory:

Governments Will Convene to Plan Intensified Action to Combat the Global Epidemic

The United Nations will hold a Special Session on HIV/AIDS to galvanize leadership at the highest levels, intensify international action and mobilize the resources needed to combat the epidemic. The Special Session, to take place from 25 to 27 June 2001 at UN Headquarters in New York, will be the first ever to address a public health issue.

UN Secretary-General Kofi Annan and high-level government delegations will address:

* The importance of political leadership in developing effective responses and decreasing the stigma associated with HIV/AIDS

* Encouraging all sectors of society to play a major role

* Increasing resources for treatment, prevention, and care

* Preventing new infections and alleviating the social and economic impact of the epidemic

* Access to care and the development of new technologies and treatments that are both effective and affordable

Governments are expected to adopt a Declaration of Commitment setting targets and timetables. In addition to statements in the Plenary, four interactive round tables will discuss human rights, international funding and cooperation, prevention and care, and the socio-economic impact of HIV/AIDS. These will involve participants from NGOs, the private sector and other civil society groups. A full programme of press conferences and special events will provide additional media opportunities.

Live Webcast, Plus Archive and Transcript

Kaisernetwork.org, a service of the Henry J. Kaiser Family Foundation, is webcasting the entire UN Special Session on HIV/AIDS, June 25-27. Anyone around the world can watch it for free.

An archive and transcript will also be available, a few days after the session.

For more information, or to watch the webcast, visit

<http://www.kaisernetwork.org/healthcast/un/aids/jun01>

Areas of Agreement

On June 16 the Background section of the official Web site includes a one-paragraph summary under "What Will the Outcome Be?" It summarizes some of the major areas of at least nominal agreement:

Given the urgency of the epidemic, at the special session governments are expected to agree on a Declaration of Commitment that will outline priority areas where stronger action must be taken. These are likely to include prevention, improved access to care and treatment, care of children orphaned by AIDS, expanded public/private sector partnerships, the need for an accelerated multisectoral response to the epidemic and for resources commensurate with the crisis.

Controversies

Some of the major areas of disagreement are:

* Whether to name vulnerable groups, such as men who have sex with men, in the Declaration of Commitment. The current draft includes the following section, which some countries object to:

By 2003, develop national strategies, policies and programmes, through a participatory approach, to promote and protect the health of those most vulnerable to, and at greatest risk of HIV infection, such as: children in espe-

cially difficult circumstances, men who have sex with men, sex workers and their clients, injecting drug users and their sexual partners, persons confined in institutions and prison populations, refugees and internally displaced persons and people separated from their families due to work or conflict;

According to a June 15 Associated Press story, an Egyptian diplomat commented, "Does it have to be so explicit? This is shocking for my society." He proposed "irresponsible sexual behavior" instead. And the Iranian Ambassador said negotiations should "not be considered as an opportunity by certain quarters in the Western world to push the envelope on areas where there is cultural sensitivity, ideological sensitivity, ethical sensitivity" (from same Associated Press story).

Apparently the U.S. wants to use general language such as "vulnerable individuals" instead of naming the groups.

Many AIDS professionals and activists consider the issue important because they want to use the document that emerges to pressure their governments to focus prevention resources where the epidemic is spreading fastest. Many countries, including the U.S., have targeted prevention resources irrationally because of a population's disadvantaged or unpopular political position, or minority status.

* Human rights. Here is the current text, which some countries want changed, although as of today (June 21) there seems to have been progress toward narrowing the areas of controversy:

HIV/AIDS AND HUMAN RIGHTS

Respect for human rights reduces vulnerability to HIV/AIDS

Respect for the rights of people living with HIV/AIDS drives an effective response

By 2003, complete policy reviews of existing non-discrimination legislation and protective

laws, drawing as appropriate on the United Nations Guidelines on HIV/AIDS and Human Rights, in order to adopt new or strengthen existing legislation to protect the human rights of people living with HIV/AIDS, eliminate discrimination and ensure their equal rights in education, employment and services;

By 2005, ensure that national legislation is in place to promote, protect and respect the rights of people living with HIV/AIDS to information, quality care, support, confidentiality and privacy;

By 2005, develop and implement national strategies that: assist women to exercise control over and make their own decisions relating to their sexuality in order to protect themselves from HIV infection; and promote shared responsibility of men and women to ensure safe sex and prevent HIV infection;

By 2005, implement measures to increase capacities of women and young girls to protect themselves from risk of infection, principally through gender-sensitive prevention education and the provision of reproductive health services;

By 2005, develop and begin to implement national strategies to promote women's full enjoyment of all human rights and reduce their vulnerability to HIV/AIDS through the elimination of all forms of violence against women and girls, including harmful traditional and customary practices, abuse and rape, battering, and trafficking in women and girls;

Apparently the U.S. does not want any movement toward health care as a human right. And some countries do not like the idea of human rights and are reluctant to see it extended.

* Treatment Access vs. Prevention and/or Intellectual Property

The current draft focuses on prevention and only two paragraphs on treatment and care. But pharmaceutical companies -- and therefore the U.S. and some other delegates -- have problems with the following paragraph, apparently because they do not want any language suggesting collective action toward

differential pricing or other ways of making medications affordable:

By 2003, ensure that national strategies are developed in close collaboration with the international community, civil society and the business sector to increase substantially the availability of antiretroviral drugs and of essential drugs, for the treatment of HIV infection and opportunistic infections, by addressing factors affecting the provision of these drugs, including technical and system capacity, pricing, including differential pricing and by examining alternatives for increasing access and affordability of HIV/AIDS related drugs.

There is also controversy over whether to provide antiretroviral treatment in Africa and other poor regions, vs. focusing on prevention and limiting treatment to low-cost, unpatented antibiotics, and only using antiretrovirals for prevention of mother-to-infant transmission.

Recently two U.S. officials created a firestorm of controversy by suggesting that Africans could not take their medicines on time -- first an unnamed senior Treasury Dept. official in late April, then over a month later, Andrew Natsios, the new director of the U.S. Agency for International Development -- leading to calls for the latter's resignation, including an op ed in *The Washington Post*, June 15, and a student campaign to send him watches. Some observers are less concerned about the unfortunate remarks themselves than by what they may reveal about moves toward a U.S. policy of writing off tens of millions of people already infected in poor countries -- whether to defend prevention program funding, to save money, or to avoid intellectual-property challenges resulting from raised expectations and efforts to obtain access to patented antiretrovirals.

One code word to watch is "care." Often it means hospice care or other inexpensive treatment -- not including antiretrovirals to address the central cause of the illness.

For More Information

To follow these and other issues during and after the United Nations General Assembly Special Session on HIV/AIDS, see:

* The official session Web site (described above), <http://www.un.org/ga/aids/>

* The official email discussion forum, Break the Silence. To join, send an e-mail message to: join-break-the-silence@hdnet.org To see the archive of messages already sent, go to <http://www.hdnet.org> (at this time there is a full archive for those who have joined the list, and a selected, categorized archive open to anyone).

* The news bulletin of the meeting. The easiest way to find is it to check the official Web site for copies as they are published.

* For information about the campaign for treatment access in developing countries, see: <http://www.accessmed-msf.org/> (You may need to click on the logo to enter the site), and <http://www.globaltreatmentaccess.org>

Drug Patents and Developing Countries: New Proposal

by John S. James

A creative new idea on using existing patent laws and procedures to deal with the conflict between intellectual property and access to medication in developing countries was posted on the World Bank's Annual Bank Conference on Development Economics ("A Patent Proposal for Global Diseases," by Jean O. Lanjouw, Yale University, the Brookings Institution and NBER, April 2001, http://econ.worldbank.org/files/1733_lanjouw.pdf).

We cannot judge the technical merits, but certainly new ideas on this issue need attention -- especially at this time when access to treatment will be considered at the United Nations General Assembly Special Session on HIV/AIDS, June 25-27, 2001.

The current problem is that the existing TRIPS (intellectual property) provisions of the World Trade Organization treaty require every country to have U.S./European style patent laws in force by 2006. This provision, adopted with no thought for its effect on access to health care, could be a disaster for poor countries, because pharmaceutical companies price their drugs for rich-country markets, and have incentives to write off the poor who do not count financially, instead of having greatly varying prices which might lead to public-relations problems in rich countries. But at the same time, some intellectual-property advocates hope that the new patentability of drugs for developing-country diseases might lead to medical research and drug development on diseases which are largely limited to poor countries, diseases largely neglected until now. [Medicines could be sold profitably in poor countries, but they would have to be developed and marketed differently than in

rich countries.]

The proposal is to use a procedural change in the patent offices of rich countries, to make pharmaceutical companies choose whether to protect their new drug patents in rich countries or in poor countries -- but not in both. Then for diseases like cancer, which affect both rich and poor countries, companies would choose to protect their patents in rich countries -- allowing low-cost generic copies to be sold in poor countries, which are a negligible market in comparison. But for diseases like malaria, which affect poor countries almost entirely, companies would choose patent protection in poor countries. In theory prices would not be prohibitive, as the medications would have to be priced for poor countries in order to sell at all.

This policy could be implemented entirely by one or a few developed countries, without requiring any change in international treaties.

Abstract of "A Patent Proposal for Global Diseases":

There are two identifiable types of diseases in developing countries. Some, such as malaria, are specific to poor countries, but many others, such as cancer, have a high incidence in all countries. These differences give rise to quite distinct drug markets. In particular, for global diseases, pharmaceutical industry profits derived from having a monopoly over sales in poor countries make only a marginal contribution to total world-wide profit and therefore the incentives to invest in research. At the same time, even a small price increase due to such a monopoly in a poor country can greatly reduce the number of people able to purchase patented drugs and the welfare of those who do. This paper describes a policy that could improve on the current patent regime by acknowledging these differences in markets and what they imply for optimal patent protection. It allows protection to strengthen for diseases specific to developing countries where a clear argument can be made that some form of new incentives are warranted. At the same time, it effectively keeps protection at its current level

in situations where increased profits are less likely to generate new innovation.

The paper is available at:

http://econ.worldbank.org/files/1733_lanjouw.pdf

Comment

Clearly the preferred solution would be to change the WTO TRIPS so that it does not block most of the world's population from access to new medicines. But we do not know if such a change is possible. In case it is not, devices like the one proposed by Lanjouw need to be considered.

Bone Disease: Report on the Web

A 54-page background report on bone disease in persons with HIV (including avascular necrosis, and also osteopenia) can be found in Bone Metabolism and HIV Disease Meeting Report, published by the Forum for Collaborative HIV Research.

Contents include:

- * Bone disease and HIV
- * Overview of the local regulation of bone
- * Crosstalk: Bone and the Immune System
- * Cytokine aspects of bone biology
- * Increased prevalence of avascular necrosis in HIV-infected adults, and
- * Bone metabolism in HIV Disease: New and old paradigms

This paper reports on a meeting that occurred August 29, 2000, so readers should also check more recent information.

The report is available at <http://www.hivforum.org>; currently it's under "Publications and Reports," then under "Metabolic Abnormalities." Note that Forum

reports are more focused on research policy than on practical treatment or management information.

Mitochondrial Toxicity: Report on the Web

A 67-page background report on mitochondrial toxicity -- widely suspected though not proven to be a basic cause of many serious side effects of certain antiretrovirals -- has been published on the Web by the Forum for Collaborative HIV Research. Since this paper reports on a meeting that took place June 5-6, 2000, readers should also check more current information.

Topics include background on mitochondrial dysfunction, clinical aspects in adults and children, and diagnosis and therapeutics.

The report is available at <http://www.hivforum.org>; currently it's under "Publications and Reports," then under "Metabolic Abnormalities."

ADAP (AIDS Drug Assistance Program) Funding: Action Needed

Almost half of all states have already indicated that they may have to restrict their AIDS Drug Assistance Program by the end of 2001. Restrictions can include waiting lists, caps on services, cutting drugs off the formulary, or even closing the program to new enrollment because money is low. Additional states may be affected as well.

Recently we learned that California is looking at its program to decide what drugs to remove from its program if necessary.

The basic problem is that federal and state funding has not kept up with the greater number of patients who need treatment, since people today are living longer. The new guidelines that call for starting treatment somewhat later will help to balance expenses, but is not enough to make up the difference.

On June 14 Project Inform's Treatment Action Network sent out an alert listing some of the states soon to be affected:

In the last appropriations bill, ADAP received \$60 million less than projected as needed to provide standard of care for its clients. In addition, the number of new clients and the costs of drugs continue to rise, putting an additional strain on many state ADAPs. Many programs are expected to face serious problems in the next few months without an emergency supplemental. According to a recent report by the National Alliance of State and Territorial AIDS Directors (NASTAD), nearly half of all states have indicated that they might have to place emergency restrictions on their programs this year, such as implementing or expanding waiting lists, capping services, and/or making cuts to the list of available drugs. Currently, there are ADAP waiting lists in Alabama, Arkansas, Georgia, Indiana, Kentucky, Maine, Montana, Oklahoma, South Carolina, and South Dakota. Even states with the most comprehensive ADAPs such as California, New

York, and Pennsylvania are expected to feel the effects of the budget shortfall.

That action alert asked recipients to call or email President Bush, and their two U.S. Senators (you can find contact information for Senators from their Web sites, which can be reached through <http://www.senate.gov>).

What You Can Do

The ADAP situation is changing daily. To be informed how you can help on this and other treatment and access issues, you can join Project Inform's Treatment Action Network. Send an email to tan@projectinform.org, and ask to receive their action alerts.