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Compulsory
Licensing

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April 8, 1999

Vice President Albert Gore
Washington, DC

Dear Vice President Gore,

We are writing to express our outrage that you have used your office to pressure the South African government to repeal its statutory authority for providing for compulsory licensing of patents for essential medicines. This comes in the beginning stages of the largest new public health crisis of our generation. The United States Surgeon General has likened the HIV/AIDS epidemic in Africa to the plague which decimated Europe in the 14th century. Public health officials estimate that one in five pregnant women in South Africa are HIV positive, and that more than 45 percent of the South African military personnel are infected.

As Chairman of the United States/South Africa Binational Commission (BNC), you have engaged in an astonishing array of bullying tactics to prevent South Africa from implementing policies, legal under the rules of the WTO, that are designed to expand access to HIV/AIDS drugs.

We are attaching several documents. Appendix A is a report prepared by the United States Department of State and provided to the House Committees on Ways and Means, Appropriations and International Relations, on February 5, 1999. Appendix B is a copy of Article 31 of the WTO/TRIPS agreement, which sets out the rules under which nations can use compulsory licensing of patents to achieve public interest objectives. Appendix C is a four page section from a 1999 World Health Organization (WHO) report that explains how compulsory licensing of essential medicines is done under the WTO/TRIPS agreement. Appendix D is a copy of the presentation to the Executive Board of the World Health Assembly by Peter Goosen, Charge d' Affairs at the South African Permanent Mission in Geneva. Appendix E is a background paper on compulsory licensing prepared by the Consumer Project on Technology (CPT) for a March 26, 1999 meeting in Geneva on compulsory licensing.

Appendix F is a US government position paper on compulsory licensing that was presented by Lois Boland from the US Patent and Trademark Office. Appendix G is a presentation by Adrian Otten, the Director of the Intellectual Property Division for the World Trade Organization (WTO), for a meeting of the World Health Assembly's ad hoc working group on the Revised Drug Strategy, held in Geneva on October 13, 1998.

Taken together, these documents provide a chilling account of the US government's abuse of its superpower status.

Let us start with the February 5, 1999 Department of State report to Congress on the Clinton/Gore Administration's efforts to undo the South African Medicines Act. It begins with this statement:

The intellectual property rights protection issue surrounding Article 15(c) of the December 1997 amendments to the South African Medicines and Related Substances Act of 1965 ("Medicines Act") is a top priority for the United States Government's (USG's) economic relations with the Republic of South Africa. Resolving this bilateral trade conflict has been and remains a vital component of our bilateral commercial relationship. All relevant agencies of the U.S. government - the Department of State together with the Department of Commerce, its U.S. Patent and Trademark Office (USPTO), the Office of the United States Trade Representative (USTR), the National Security Council (NSC) and the Office of the Vice President (OVP) - have been engaged in an assiduous, concerted campaign to persuade the Government of South Africa (SAG) to withdraw or modify the provisions of Article 15(c) that we believe are inconsistent with South Africa's obligations and commitments under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

This 10 page single spaced report provides chapter and verse of a two year campaign to use the weight of US power, short of military warfare, on South Africa to prevent that country from implementing policies to obtain cheaper sources of essential medicines. What is particularly brazen is the suggestion that the South African government is acting outside of its obligations under the WTO/TRIPS agreement. This is untrue and US trade negotiators know this is untrue.

The two disputed issues in 15(c) of the South African medicines act are parallel imports and compulsory licensing. These are unambiguously legal under the WTO/TRIPS. Indeed, with respect to parallel imports, the United Kingdom and several European Union countries have extensive trade in parallel imports of

pharmaceutical drugs, and there have been countless cases before the European Court of Justice that have upheld this practice. If the US government is so concerned about parallel imports, why doesn't it bring a trade action against EU countries? The reason is simple. Under Article 6 of the TRIPS, parallel imports are perfectly legal. The Department of State even acknowledges this briefly on page three of its own report to Congress when it notes "On the parallel imports issue, however, US government attorneys note that under the terms of the TRIPS agreement, disputes related to parallel importation are not subject to WTO dispute settlement procedures." The reasons that this is the case are that parallel imports are legal under the TRIPS agreement and are commonly used throughout the world. Recent Supreme Court and legislative actions in Japan, New Zealand, Australia and even the United States have all supported this, as your trade officials fully know, and which has been pointed out by CPT on several occasions. Yet your own staff continues to pillar Minister of Health Dr. Nkosazana Zuma and the South Africa government as if they were outlaws on international scene. This is a form of political slander that should deeply offend all who respect the rule of international law.

The other primary issue concerns compulsory licensing of patents. As is described in the attached background paper on compulsory licensing, the United States government uses compulsory licensing frequently for a wide variety of purposes. South Africa has never issued a compulsory license on a pharmaceutical product. The United States has done this several times in the past three years. And the United States employs compulsory licensing in countless other cases. For example, in November of 1998 the US Department of Justice obtained more than 150 compulsory licenses to a Monsanto biotech patent. Kenneth Starr was involved in a compulsory licensing dispute involving Hughes Aircraft company. The US maintains compulsory licensing statutes for government use, for clean air, for nuclear power and for other purposes. A federal district court recently ordered compulsory licenses that involve Intel, and the US Justice Department is considering compulsory licensing that involves Microsoft. It is gross hypocrisy to act as if South Africa is an outlaw in the world community because it is considering the use of compulsory licensing for essential medicines. But this is far worse than hypocrisy. Africa is confronted with a public health crisis of historical proportions. Of course South Africa should use compulsory licensing to expand access to essential medicines! This is an emergency, and millions of lives are at stake. Why should President Nelson Mandela, Deputy President Thabo Mbeki and Dr. Nkosazana Zuma permit their population to be defenseless simply because Glaxo Wellcome and Bristol-Myers Squibb want the power to set prices for US taxpayer funded and government developed HIV/AIDS drugs in Africa?

Compulsory licensing is not an attack on the patent system, it is

part of the patent system. Compulsory licensing of patents is not an attack on the TRIPS agreement, it is part of the TRIPS agreement. (Article 31)

The WTO itself is quite clear that countries can use compulsory licensing for whatever purposes they choose, so long as they abide by Article 31 conditions, including payment to patent owners. These are the comments of Adrian Otten, the Director of the Intellectual Property Division at the WTO, in an October 13, 1998 presentation to the ad hoc working group on the WHA's Revised Drug Strategy. Speaking of the TRIPS, Mr. Otten said:

[T]he Agreement also allows Members to authorize use by third parties (compulsory licenses) or for public non-commercial purposes (government use) without the authorization of the patent owner. Unlike what was sought by some countries in the negotiations, the grounds on which this was done are not limited by the Agreement, but the Agreement contains a number of conditions that have to be met in order to safeguard the legitimate interests of the patent owner. [emphasis added]

At the same meeting, Richard Wilder, an American working for World Intellectual Property Organization (WIPO) who previously worked for the pharmaceutical industry, said quite plainly, "the right to exclude others from using a patented invention may be subject to limitations in some countries, including by the right of the government to use the invention or by the grant of compulsory licensing." [emphasis added]

There are many examples where countries set out specific criteria for compulsory licensing. French law authorizes compulsory licensing when medicines are "only available to the public in insufficient quantity or quality or at abnormally high prices." Many countries have similar provisions, including the United States as part of the Bayh-Dole Act, which specifically singles out cases where compulsory licensing is needed to "alleviate health or safety needs which are not reasonably satisfied." In 42 USC Sec 2183, the United States permits the compulsory licensing of patents for nuclear energy that are "affected with the public interest."

As the United States Federal Trade Commission has recently pointed out, the new era of biotechnology will create a number of areas where compulsory licensing will be essential to permit innovation in new high technology fields of medicine. Consider, for example, this commentary by Michael Kern on a recent compulsory licensing decision in Germany:

[W]e now are confronted with the situation that plaintiffs and defendants may employ their respective

patents to block each other from exploiting interferon as a therapeutic agent against rheumatoid arthritis. If the market does not rectify this 'patent failure,' the public may have to wait twenty years before gaining access to this therapeutic agent. A compulsory license in situations involving dependent patents, as provided for in various countries, is a means to correct patent failure coupled with market failure. One should not forget that patents represent a interventionist instrument, ultimately for the sake of community welfare. [emphasis added]

The fact that compulsory licensing is legal under international trade law and under the TRIPS agreement is acknowledged by US officials in other settings, such as when they are in the presence of informed persons. For example, in a March 26, 1999 meeting in Geneva on compulsory licensing, US PTO official Lois Boland acknowledged that countries have the right to use compulsory licensing under international law and under the WTO/TRIPS agreement. But she added:

The fact that [the current US] view is not reflected in the TRIPS agreement, in the multilateral context, is fully acknowledged. In our bilateral discussions, we continue to regard the TRIPS agreement as an agreement that establishes minimum standards for protection and, in certain situations, we may, and often do, ask for commitments that go beyond those found in the TRIPS agreement.

This is the key point. The US is seeking something more than what is required by the TRIPS. The US government's bullying of South Africa has been justified to poorly informed reporters and Members of Congress as if it was simply a matter of getting South Africans to abide by international law. But once one understands that South Africa is seeking to live with the terms of the TRIPS agreement and that it is the US government that is unhappy with the TRIPS, one has to confront fundamental questions. Why is the US doing this? Does it make any sense given the AIDS epidemic in South Africa?

Like the Americans, the French, the Germans, the Japanese and virtually all OECD countries, the South African government has the authority and the responsibility to implement intellectual property laws that serve the interests of its own citizens. South Africa is acting according to international law. It is the United States government that refuses to follow WTO dispute resolution mechanisms, and seek a legal judgement on the South African compulsory licensing practices. It is the United States government that is taking matters into its own hands and deploying an astonishing assault on South African sovereignty and critical public health responsibility. It is the United States

government that is literally asking South Africa to abandon the lives of millions of infected citizens in order to receive reductions in US barriers to trade or economic aid. What kind of Vice President are you if you cannot take time out from frantic political fundraising and today recognize the immorality of US policy toward the South African people on this issue?

We have written your office and other officials in the Clinton/Gore Administration calling for consultations with public health groups on US government policies on intellectual property rights and the international AIDS crisis. This has not occurred.

Today we are asking that you reverse US policy toward South Africa. We ask that you instruct Secretary Madeleine Albright, Under Secretary Stuart Eizenstat at the Department of State, Secretary William Daley at the Department of Commerce, United States Trade Representative Charlene Barshefsky, Stuart Nightingale at the US Food and Drug Administration and others to stop their opposition to South African policies on compulsory licensing and parallel imports of pharmaceutical drugs. We and the HIV/AIDS and public health communities who are increasingly concerned about this issue await your response.

Sincerely,



Ralph Nader



James Love
Director
Consumer Project on Technology



United States Department of State

Washington, D. C. 20520

February 5, 1999

Dear Mr. Gejdenson:

On behalf of the Secretary, I am herewith submitting a revised report on steps taken by the United States Government to work with the Government of the Republic of South Africa to negotiate the repeal, suspension, or termination of section 15(C) of South Africa's Medicines and Related Substances Control Amendment Act No. 90 of 1997 required by the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (P.L. 105-277)

I hope you find this report useful to you. If I can be of further assistance, please do not hesitate to contact me.

Sincerely,

/s/

Barbara Larkin
Assistant Secretary
Legislative Affairs

Enclosure:

As Stated

The Honorable

Sam Gejdenson,

Committee on International Relations,
House of Representatives.

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**U.S. GOVERNMENT EFFORTS TO NEGOTIATE THE REPEAL,
TERMINATION OR WITHDRAWAL OF ARTICLE 15(C) OF THE SOUTH
AFRICAN MEDICINES AND RELATED SUBSTANCES ACT OF 1965**

The intellectual property rights protection issue surrounding Article 15(c) of the December 1997 amendments to the South African Medicines and Related Substances Act of 1965 ("Medicines Act") is a top priority for the United States Government's (USG's) economic relations with the Republic of South Africa. Resolving this bilateral trade conflict has been and remains a vital component of our bilateral commercial relationship. All relevant agencies of the U.S. Government -- the Department of State together with the Department of Commerce, its U.S. Patent and Trademark Office (USPTO), the Office of the United States Trade Representative (USTR), the National Security Council (NSC) and the Office of the Vice President (OVP) -- have been engaged in an assiduous, concerted campaign to persuade the Government of South Africa (SAG) to withdraw or modify the provisions of Article 15(c) that we believe are inconsistent with South Africa's obligations and commitments under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

The Administration understands the South African Government's wish to fulfill its commitment to make medicines more affordable for its people. Although Article 15(c), as it now stands, would authorize abrogation of pharmaceutical patents and would permit parallel imports, both WTO-inconsistent actions, the South African Government to date has not allowed parallel importation of a U.S.-patented pharmaceutical nor has it suspended any patents or other intellectual property rights held by U.S. pharmaceutical producers. The U.S. Government has nonetheless made clear that it will defend the legitimate interests and rights of U.S. pharmaceutical firms. In our multi-level, broad-based discussions with the SAG, USG officials have explained that abrogating intellectual property rights of pharmaceutical firms is not a viable means of accomplishing SAG objectives to make medicines more affordable for South Africans. We have often reiterated that such action on the SAG's part will have a long-term deleterious impact on the development of new, critically important drugs and on the availability of these drugs in South Africa. Until and unless the South African

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Government addresses our concerns, our efforts will continue on several fronts.

Preempting Adoption of the Amendments

Even before the South African parliament adopted the 1997 amendments, the State Department with the full support of USTR, Commerce/USPTO and pharmaceutical industry representatives, instructed the Embassy in Pretoria to deliver strong demarches opposing the undermining of patent protection and potential abrogation of South Africa's international commitments and obligations.

In June 1997, the Embassy in Pretoria, echoing testimony by U.S. pharmaceutical companies operating in South Africa, presented USG views at a parliamentary hearing on the proposed amendments to the Medicines Act. Embassy officials stressed the position that the USG would never abide abrogation of patent protection or acquiesce in parallel importation of patented medicines. U.S. Ambassador James Joseph has made frequent public statements and multiple private demarches to high-ranking South African officials against the legalization of parallel imports since mid-1997. Ambassador Joseph met with the members of the parliamentary Health Committee during their consideration of this draft of the amendments to the Medicines Act. The parliamentarians listened intently to his arguments for why the bill would be problematic. As a result, the legislators withdrew the proposed amendments from parliamentary consideration with the intent of modifying them.

During the July 1997 U.S.-South Africa Binational Commission meeting, Secretary of Commerce Daley again voiced opposition to the proposed amendments to South African Trade and Industry Minister Erwin. Minister Erwin assured Secretary Daley that U.S. concerns would be alleviated by a "revision" of the bill that would be presented to parliament later in 1997. They agreed to establish an ad hoc working group on intellectual property issues to resolve the controversy raised by the proposed amendments to the Medicines Act and obligations set forth TRIPS Article 39.

While the objectionable language contained in the original proposed amendments was removed as promised, the

South African Government's revised amendments, which parliament ultimately passed in October 1997 and President Mandela signed into law in December 1997, contained a new provision, Article 15(c), that is so ambiguous as to make the new bill worse than the earlier version. Article 15(c) seems to permit the South African Minister of Health to abrogate pharmaceutical patent rights and/or permit parallel importation of patented pharmaceutical products.

Introduction of "New" Amendment

When U.S. Government officials in Washington and Embassy staff repeatedly requested clarification on the impact of Article 15(c), during early 1998, South African Government officials gave their assurances that there was no intention to use the authority of 15(c) to abrogate patents. South African Health Minister Zuma and her senior staff have stated repeatedly that the SAG has no intention of using the powers conferred by the bill to abrogate patent rights. Nevertheless, U.S. Government experts determined that provisions of 15(c) authorize action clearly inconsistent with South Africa's obligations under TRIPS. At the State Department's instruction, the Embassy in Pretoria has, over the past year, disseminated widely within the South African Government the U.S. Government view that 15(c) authorizes conduct that would violate TRIPS. On the parallel import issue, however, U.S. Government attorneys note that under the terms of the TRIPS agreement, disputes related to parallel importation are not subject to WTO dispute settlement procedures.

Since the passage of the offending amendments in December 1997, U.S. Government agencies have been engaged in a full court press with South African officials from the Departments of Trade and Industry, Foreign Affairs, and Health, to convince the South African Government to withdraw or amend the offending provisions of the law, or at the very least, to ensure that the law is implemented in a manner fully consistent with South Africa's TRIPS obligations.

During early 1998, Embassy officials and the Assistant U.S. Trade Representative for African Affairs made repeated requests to review the implementing regulations for Article 15(c) in order to ensure that application of the amendment would be consistent with South Africa's TRIPS obligations

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and commitments. However, the regulations for 15(c) have never been shared with the U.S. Government, nor have they ever been formally published and implemented. South African officials said a pending legal challenge of the amendments by pharmaceutical manufacturers precludes them from providing the USG with documents which could prejudice the case.

An International Effort

In early 1998, the Embassy in Pretoria approached the Swiss and EU member embassies in South Africa to suggest a joint effort to protest the provisions of Article 15(c) since European pharmaceutical companies could be adversely affected by the amendments, and some are party to the pending litigation. Although European Governments preferred to let the U.S. Government take the lead in demarching the South African Government on pharmaceutical patent protection, French President Chirac raised France's concerns during his July 1998 state visit to South Africa and the Swiss and German presidents also raised the issue privately with Deputy President Mbeki.

The United States Government Makes its Case

Assistant U.S. Trade Representative for Africa Rosa Whitaker traveled to South Africa in the Spring of 1998 and raised U.S. Government concerns with both the Minister of Health and the Minister of Trade and Industry. She reiterated our request to review the draft implementing regulations. Her personal intervention reinforced the Embassy's clear message to the South African Government that the United States would not abide actions inconsistent with WTO obligations.

The ad hoc working group on intellectual property created at the July 1997 BNC held its first meeting in March 1998. The two hour conference call meeting did allow the U.S. delegation -- including representatives of the Departments of State, Commerce, the U.S. Patent and Trademark Office and the Office of the U.S. Trade Representative -- to eliminate several lingering misunderstandings and clarify once more U.S. Government views. However, since only officials of the South African Department of Trade and Industry attended the conference

call, the South African delegation was not in a position to answer questions on the Medicines Act authoritatively nor were they empowered to negotiate on matters related to the amendments to the Act, since the Medicines Act is the bailiwick of the South African Department of Health.

Special 301 Watch List

On April 30, 1998, with the full endorsement and support of the Department of State, the United States Trade Representative designated South Africa a Special 301 "Watch List" country during USTR's annual worldwide review of intellectual property rights protection. This designation was based largely on the potential impact of Article 15(c), not only in the South African market but also due to its global precedent and the undermining of WTO principles. The State Department joined with other USG agencies with trade responsibility to insist on this designation in the hope that this special attention would spur South Africa to change or withdraw Article 15(c)

Withholding GSP

The Department of State, USTR, and the Department of Commerce developed an Administration decision to withhold preferential tariff treatment from certain South African exports in the early summer of 1998. On June 30, the White House announced that four items, for which South Africa had requested preferential tariff treatment under the Generalized System of Preferences (GSP) program, would be held in abeyance pending adequate progress on intellectual property rights protection in South Africa. This action was widely reported in the South African press, but SAG reaction was muted.

Securing South African Assurances

In March 1998, Secretary of Commerce Daley met with South African Health Minister Zuma to underline USG resolve to ensure South Africa would not use the provisions in 15(c) to undermine pharmaceutical patent rights or allow parallel imports.

Dr. Ian Roberts, a senior official from the South African Department of Health, visited Washington in May 1998 and met with U.S. Government patent experts and congressional staff, and attended a USTR-chaired U.S. Government interagency meeting attended by State Department officials. At this meeting, U.S. Government officials reiterated the U.S. demand that South Africa comply with its international obligations to ensure adequate and effective protection to pharmaceutical patents. Dr. Roberts repeated South African Health Minister Zuma's pledge that it was not the SAG's intention to use Article 15(c) to abrogate patents or open the floodgates to parallel imports.

Repeated Efforts to Resolve the Issue

An Embassy official traveled to Midrand, South Africa to speak at the June 1998 "Pharmecon SA '98" pharmaceutical industry conference. The official's remarks reinforced in a public forum the strong negative U.S. views on Article 15(c) and made clear the possible ramifications of the Article's implementation, including trade sanctions.

In July 1998, Assistant U.S. Trade Representative for African Affairs Rosa Whitaker met with the South African Charge d'Affaires in Washington to stress once again the U.S. Government's concerns about pharmaceutical patent protection and parallel importation in South Africa. She also repeated the U.S. Government's position that South Africa's requests for preferential tariff treatment on four key exports would be held in abeyance pending adequate progress on intellectual property rights protection.

During his September 1998 trip to South Africa, Commerce Secretary Daley made pharmaceutical patent protection a key item in his discussions with South African Trade and Industry Minister Alec Erwin. Daley reemphasized the U.S. Government position on Article 15(c) and reminded Minister Erwin of South Africa's obligations under the TRIPS agreement.

The Vice President's Plan for a Negotiated Solution

During the August 1998 U.S.-South Africa Binational Commission meetings in Washington, Vice President Gore made the issue of intellectual property rights protection, and

pharmaceutical patents in particular, a central focus of his discussions with Deputy President Mbeki. They agreed on a basis for a mutually satisfactory, Government-to-Government negotiated solution to the impasse. Suspended GSP benefits would be restored as progress was made in these negotiations. This basis was developed and unanimously supported by all interested U.S. Government agencies. USTR was identified to lead the U.S. Government's negotiation efforts.

Initial discussion between the Assistant U.S. Trade Representative for Services, Investment and Intellectual Property and the Deputy President's legal advisor took place in September 1998 and follow-on talks were conducted in November. During these discussions, the South African officials attempted to persuade the U.S. Government to intervene with the U.S. pharmaceutical industry to suspend or terminate its pending legal challenge to the offending provisions of the South African Medicines Act. The State Department, together with the Commerce Department and USTR, decided that such an action might undermine the leverage that U.S. companies were exerting through their legal challenge. U.S. officials told the South Africans that since the U.S. Government is not a party to the litigation, the USG was unable to agree to this request. A subsequent round of face-to-face negotiations between USTR officials and Deputy President Mbeki's advisors is tentatively scheduled to be held in Cape Town just prior to the February 1999 Binational Commission meeting.

A "New" Medicines Law

Meanwhile, during the fall of 1998, the South African parliament drafted and considered a new medicines law that would replace the existing Medicines Act, including the offending amendments. The State Department's Economic Minister Counselor in Pretoria met with a key Mbeki advisor in September 1998 to advocate the removal of Article 15(c) provisions from the new proposed law. In October 1998, at the State Department's suggestion, the Embassy dispatched an economic officer to Cape Town to monitor the committee and full chamber debates. He forcefully advocated the U.S. position and advised parliamentarians that the new law should not include provisions that jeopardize patent rights. Despite these strenuous efforts, a new medicines

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bill was passed including provisions identical to Article 15(c), in November 1998.

Health Minister Opens Negotiations with Industry

Shortly after the new law was passed, South African Health Minister Zuma began discussions with pharmaceutical industry executives. Their dialogue has offered hope for an eventual settlement of the pending litigation and satisfactory resolution of the pharmaceutical patent protection issue. On December 4, 1998, the Assistant U.S. Trade Representative for Services, Investment, and Intellectual Property sent a letter to Deputy President Mbeki's legal advisor Mojanku Gumbi noting the USG's interest that the discussions lead to a mutually agreeable settlement. As a way of spurring the discussions, he informed Gumbi that the USG would be prepared to release a significant portion of the withheld GSP benefits should such a settlement be reached. Progress has been slow, but we understand talks are continuing.

In November 1998, the State Department's Economic Minister Counselor in Pretoria met with South African Department of Foreign Affairs officials to discuss resolution of the pharmaceutical patent controversy. The South Africans were eager to find a satisfactory solution to the ongoing dispute before the upcoming February 1999 Binational Commission meeting. Embassy officials reiterated the U.S. position and noted that USTR officials' talks with Mbeki advisors were the appropriate venue for seeking a negotiated settlement.

Secretary Daley paid a return visit to South Africa in December 1998. In his meetings with Deputy President Mbeki and Trade and Industry Minister Erwin during that visit, pharmaceutical patent protection was the most important bilateral issue under discussion. Deputy President Mbeki was hopeful that recent discussions between the pharmaceutical manufacturers and the South African Minister of Health would yield a solution. Secretary Daley noted the possibility of negative consequences should progress on resolving this most important issue stall.

The Embassy closely monitored the Zuma-pharmaceutical industry discussions, which continued through December 1998. Pharmaceutical industry officials have indicated

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that these talks have reached a sensitive stage and that further U.S. Government efforts at this time could be counterproductive. The Embassy and Washington agencies have therefore deferred to the U.S. pharmaceutical industry to take the lead. In mid-January, the Assistant U.S. Trade Representative for Services, Investment and Intellectual Property sent a letter to Legal Advisor Gumbi suggesting that specific discussion of pharmaceutical patents and Article 15(c) be put aside while Health Minister Zuma negotiates with the interested pharmaceutical manufacturers. The pharmaceutical companies' discussions with Minister Zuma continue and their constitutional court challenge in South Africa remains pending. USTR officials and Mbeki's advisors plan to meet in February 1999.

Latest Efforts

In January 1999, in the context of preparing for the February 1999 U.S.-South Africa Binational Commission, the State Department's Economic Minister Counselor in Pretoria raised the pharmaceutical patent protection issue with Deputy President Mbeki's economic advisor. Despite the Minister Counselor's reiteration of the U.S. position, as well as a description of the ramifications of the suspension of aid to South Africa in the USG's FY 1999 appropriations law, Mbeki's advisor said the SAG was not considering repeal of the offending language in the either the Medicines Act or the new bill.

As indicated in previous sections, several adversely affected U.S. pharmaceutical manufacturers have filed a constitutional court challenge to the amendments to the Medicines Act in South African courts. While the case remains pending, the South African Government is adamant that government-to-government discussions not prejudice the outcome. U.S. Government attorneys share this view. Thus, our efforts are, in part, circumscribed by the ongoing litigation as well as a desire to be responsive to U.S. industry's request to allow its current efforts time and opportunity to be effective. We hope the State Department's and other agencies' efforts to convince the South African Government to fulfill its international obligations and commitments on intellectual property rights together with a domestic legal challenge will provide sufficient incentive to achieve the suspension or removal of Article 15(c).

Next Steps

The State Department, its Embassy in Pretoria, the Commerce Department and USTR will monitor closely the ongoing discussions between the pharmaceutical industry and the South African Minister of Health. We will continue our unflagging efforts to convince the South African Government to either repeal Article 15(c) or make it consistent with the TRIPS agreement, and thus eliminate the possibility that any abrogation of U.S. pharmaceutical patent rights in South Africa. Should there be an actual violation of any U.S. pharmaceutical patent right (e.g., patent abrogation) this Administration will respond forcefully in accordance with appropriate trade remedy legislation.

106TH CONGRESS
1ST SESSION

H. R. 1885

To amend the Federal Food, Drug, and Cosmetic Act to provide for facilitating the importation into the United States of certain drugs that have been approved by the Food and Drug Administration.

IN THE HOUSE OF REPRESENTATIVES

MAY 20, 1999

Mr. BERRY (for himself, Mr. SANDERS, Mrs. EMERSON, Mr. ROHRBAUGH, Mr. ABERCROMBIE, and Mr. LEWIS of Georgia) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for facilitating the importation into the United States of certain drugs that have been approved by the Food and Drug Administration.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "International Prescription Drug Parity Act".

SEC. 2. FACILITATION OF IMPORTATION OF DRUGS APPROVED BY FOOD AND DRUG ADMINISTRATION.

(a) IN GENERAL.—Section 801(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(d)) is amended—

(1) by redesignating paragraphs (3) and (4) as paragraphs (4) and (5), respectively; and

(2) by striking "(d)(1)" and all that follows through the end of paragraph (2) and inserting the following:

"(d)(1) If a covered drug (as defined in paragraph (3)) is domestically approved and is manufactured in a State and then exported, or is domestically approved and is for commercial distribution manufactured in a foreign establishment registered under section 510, the manufacturer shall, as a condition of maintaining the domestic approval of the drug, comply with the following:

"(A) For each shipment of the drug that is manufactured in compliance with current good manufacturing practice and other standards under section 501, the manufacturer shall maintain a record that identifies the shipment and states the fact of such compliance, without regard to whether the shipment is intended for importation into the United States.

1 “(B) For each such shipment, the manufacturer
2 shall maintain a record that identifies the shipment
3 and provides the labeling required for the drug pur-
4 suant to section 501 and pursuant to the application
5 for domestic approval, without regard to whether the
6 shipment is intended for importation into the United
7 States.

8 “(C) Upon the request of a person who intends
9 to import into the United States drugs from such
10 shipment (and who meets applicable legal require-
11 ments to be an importer of covered drugs), the man-
12 ufacturer shall provide to the person a copy of each
13 of the records maintained under subparagraphs (A)
14 and (B) with respect to the shipment.

15 “(2) For the purpose of facilitating the importation
16 into the United States of covered drugs, the Secretary
17 shall by regulation establish the following criteria:

18 “(A) Criteria regarding the records required in
19 paragraph (1) and the use of the records to dem-
20 onstrate the domestic approval of the drugs and
21 compliance of the drugs with sections 501 and 502.

22 “(B) Such criteria regarding the labeling of the
23 drugs as the Secretary determines to be appropriate.

24 “(C) Criteria regarding the amount of charges
25 that may be imposed by manufacturers of the drugs

1 for maintaining and providing the records specified
2 in subparagraph (A).

3 “(3) For purposes of this subsection:

4 “(A) The term ‘covered drug’ means a drug
5 that is described in section 503(b) or is composed
6 wholly or partly of insulin.

7 “(B) The term ‘domestically approved’, with re-
8 spect to a drug, means a drug for which an applica-
9 tion is approved under section 505, or as applicable,
10 under section 351 of the Public Health Service Act.
11 The term ‘domestic approval’, with respect to a
12 drug, means approval of an application for a drug
13 under such a section.”.

14 (b) CONFORMING AMENDMENT.—Section 801(d) of
15 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 381(d)) is amended in paragraph (5) (as redesignated by
17 subsection (a)(1) of this section) by striking “paragraph
18 (3)” each place such term appears and inserting “para-
19 graph (4)”.

○

*Public Law 105-277
105th Congress

An Act

Making omnibus consolidated and emergency appropriations for the fiscal year ending September 30, 1999, and for other purposes.

Oct. 21, 1998
[H.R. 4328]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

DIVISION A—OMNIBUS CONSOLIDATED APPROPRIATIONS

That the following sums are appropriated, out of any money in the Treasury not otherwise appropriated, for the several departments, agencies, corporations and other organizational units of the Government for the fiscal year 1999, and for other purposes, namely:

SEC. 101. (a) For programs, projects or activities in the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 1999, provided as follows, to be effective as if it had been enacted into law as the regular appropriations Act:

Omnibus
Consolidated and
Emergency
Supplemental
Appropriations
Act, 1999.

Buried on page 155 of a 919 page document is the following on South Africa:

\$2,500,000 may be transferred to "International Organizations and Programs" for a contribution to the International Fund for Agricultural Development (IFAD): *Provided further*, That none of the funds appropriated under this heading may be made available for any activity which is in contravention to the Convention on International Trade in Endangered Species of Flora and Fauna (CITES):

Provided further, That none of the funds appropriated under this heading may be made available for assistance for the central Government of the Republic of South Africa, until the Secretary of State reports in writing to the appropriate committees of the Congress on the steps being taken by the United States Government to work with the Government of the Republic of South Africa to negotiate the repeal, suspension, or termination of section 15(c) of South Africa's Medicines and Related Substances Control Amendment Act No. 90 of 1997: *Provided further*, That of the funds

appropriated under this heading that are made available for assistance programs for displaced and orphaned children and victims of war, not to exceed \$25,000, in addition to funds otherwise available for such purposes, may be used to monitor and provide oversight of such programs: *Provided further*, That of the funds appropriated under this heading, not less than \$1,500,000 should be made available for agriculture programs in Laos: *Provided further*, That of the funds appropriated under this heading not less than \$500,000 should be made available for support of the United States Telecommunications Training Institute: *Provided further*, That, of the funds made available by this Act for the "Microenterprise Initiative" (including any local currencies made available for the purposes of the Initiative), not less than 50 percent of the funds used for microcredit should be made available for support of programs providing loans of less than \$300 to very poor people, particularly women, or for institutional support of organizations primarily engaged in making such loans.



JAMA

The Journal of the American Medical Association

Medical News & Perspectives - April 28, 1999
From the Surgeon General

The Global HIV/AIDS Epidemic

An enormous human tragedy is unfolding in many less-developed countries because of the spread of HIV/AIDS. Of the 33.4 million HIV-infected people around the world, there are an estimated 22.5 million in sub-Saharan Africa, 6.7 million in South and Southeast Asia, 1.4 million in Latin America, and 665,000 in the United States. Globally, more than 14 million people have died of the disease, including 2.5 million last year.

In many southern African countries, HIV/AIDS has become an unprecedented emergency, with 20% to 26% of people between the ages of 15 and 49 infected. In Botswana, Kenya, Malawi, Mozambique, Namibia, Rwanda, South Africa, Zambia, and Zimbabwe, HIV/AIDS will reduce life expectancy from 64 to 47 years by 2015. The progress of decades of work immunizing children, controlling diseases, and improving nutrition is being negated by HIV/AIDS.

Conditions in many parts of the world promote rapid spread of the HIV/AIDS epidemic. For example, India, with a population approaching 1 billion, has estimated that 3 million to 5 million of its people are infected, and the number of new infections will double every 14 months.

Social and political issues surrounding sex, injecting drug use, and blood transfusion in many countries have created special circumstances in which the disease has been able to spread unchecked. Some less-developed countries also bear a burden of political and economic instability that makes prevention even more difficult. It was only a few years ago that epidemiologists offered projections of disease prevalence for sub-Saharan Africa that were met with disbelief. If the present warnings go unheeded, South Asia, Southeast Asia, and, perhaps, China will follow the disastrous course of sub-Saharan Africa.

More than a decade of experience has taught us how to control HIV/AIDS—we know what works. Many

developed countries have successfully checked the spread of the epidemic. While development of therapy and a vaccine continue, prevention must be emphasized. The basic elements of prevention include education, behavior change, voluntary testing and counseling, prevention of perinatal transmission, and political commitment. Each country must find the mix of methods appropriate to its particular conditions.

Education about HIV/AIDS is necessary but alone does not change the behavior of populations. Promotion of voluntary testing and counseling must complement education. Testing and counseling break the deadly silence around HIV/AIDS and empower individuals to make informed decisions and change behaviors. Breaking the silence also will begin to diffuse the stigma surrounding the disease. We have seen success with behavioral change in Uganda and Thailand, the only two less-developed countries with extensive capacity for voluntary testing and counseling.

It is known that perinatal transmission of HIV can be reduced by more than 50% by using antiretroviral therapy; however, problems with access to these drugs limit their use in some countries. Transmission of HIV through breast-feeding and poor survival of orphans make the avoidance of disease via treatment for perinatal transmission more complex. We continue to work with international organizations, other governments, and pharmaceutical companies to lower costs and expand access to antiretroviral drugs. Current treatment for perinatal transmission (as well as use of antiretrovirals in general) in less-developed countries is also limited by the fact that very few people have been tested for HIV infection.

Treatment of other sexually transmitted diseases (STDs) is important to control the spread of HIV. One of the reasons HIV has spread so rapidly in Africa is that so many STDs go untreated. Untreated STDs break down natural barriers that prevent transmission. Access to even basic treatment for STDs remains a problem for many less-developed countries.

Perhaps most important in the global battle against HIV/AIDS is political commitment. Leaders at the national, provincial, and local levels of government must speak out about HIV/AIDS and encourage businesses and nongovernmental organizations to commit to work against the disease. I was encouraged by US Vice President Al Gore and Deputy President Thabo Mbeki of

South Africa, who put the HIV/AIDS threat at the top of the international agenda at the recent meeting of the United States-South Africa Joint Commission. They set an important example for leaders in developed and less-developed countries.

American medicine and public health have an important role to play in the global battle against HIV/AIDS by supporting international organizations such as the Joint United Nations Program on HIV/AIDS, the World Health Organization, and the World Bank.

HIV/AIDS can be likened to the plague that decimated the population of Europe in the 14th century. While the modern epidemic affects people of all age groups, those of working age are at highest risk, posing potentially dire economic, social, and political consequences for the global community. Unfortunately, the world continues to devote greater attention and resources to traditional national security issues such as wars, postponing notice of an epidemic that, if left to spread unchecked, will kill more people than any of the terrible conflagrations that have so marked this century.

**—David Satcher, MD
Surgeon General of the United States and Assistant
Secretary,
Department of Health and Human Services**

(JAMA. 1999;281:1479)

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Selected provisions in the TRIPS agreement

Article 6 Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

Article 7 Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8 Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

SECTION 5: PATENTS

Article 28 Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:
 - (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing (See footnote 6) for these purposes that product;
 - (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.
2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Footnote: 6 This right, like all other rights conferred under this Agreement in respect of the

use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.

Article 30 Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31 Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use (See footnote 7) of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Footnote 7: "Other use" refers to use other than that allowed under Article 30.

*Public Law 105-277
105th Congress

An Act

Making omnibus consolidated and emergency appropriations for the fiscal year ending September 30, 1999, and for other purposes.

Oct. 21, 1998
[H.R. 4328]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Omnibus
Consolidated and
Emergency
Supplemental
Appropriations
Act, 1999.

DIVISION A—OMNIBUS CONSOLIDATED APPROPRIATIONS

That the following sums are appropriated, out of any money in the Treasury not otherwise appropriated, for the several departments, agencies, corporations and other organizational units of the Government for the fiscal year 1999, and for other purposes, namely:

SEC. 101. (a) For programs, projects or activities in the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 1999, provided as follows, to be effective as if it had been enacted into law as the regular appropriations Act:

Buried on page 155 of a 919 page document is the following on South Africa:

\$2,500,000 may be transferred to "International Organizations and Programs" for a contribution to the International Fund for Agricultural Development (IFAD): *Provided further*, That none of the funds appropriated under this heading may be made available for any activity which is in contravention to the Convention on International Trade in Endangered Species of Flora and Fauna (CITES):

Provided further, That none of the funds appropriated under this heading may be made available for assistance for the central Government of the Republic of South Africa, until the Secretary of State reports in writing to the appropriate committees of the Congress on the steps being taken by the United States Government to work with the Government of the Republic of South Africa to negotiate the repeal, suspension, or termination of section 15(c) of South Africa's Medicines and Related Substances Control Amendment Act No. 90 of 1997: *Provided further*, That of the funds

appropriated under this heading that are made available for assistance programs for displaced and orphaned children and victims of war, not to exceed \$25,000, in addition to funds otherwise available for such purposes, may be used to monitor and provide oversight of such programs: *Provided further*, That of the funds appropriated under this heading, not less than \$1,500,000 should be made available for agriculture programs in Laos: *Provided further*, That of the funds appropriated under this heading not less than \$500,000 should be made available for support of the United States Telecommunications Training Institute: *Provided further*, That, of the funds made available by this Act for the "Microenterprise Initiative" (including any local currencies made available for the purposes of the Initiative), not less than 50 percent of the funds used for microcredit should be made available for support of programs providing loans of less than \$300 to very poor people, particularly women, or for institutional support of organizations primarily engaged in making such loans.

**OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE
EXECUTIVE OFFICE OF THE PRESIDENT
WASHINGTON, D.C.
20508**

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(202) 395-3230**

USTR ANNOUNCES RESULTS OF SPECIAL 301 ANNUAL REVIEW

United States Trade Representative Charlene Barshefsky today announced the results of the 1999 "Special 301" annual review which examines in detail the adequacy and effectiveness of intellectual property protection in over 70 countries. Ambassador Barshefsky also announced that she will, as a result of this year's Special 301 review, initiate WTO consultations with Argentina, Canada and the European Union. This brings to 13 the number of intellectual property-related WTO complaints filed by the United States since 1996. The Special 301 report also addresses developments, and concerns in such countries as Israel, Malaysia, South Africa, Ukraine, India, Hong Kong, Brazil, Mexico, Korea and Bulgaria.

page 22:

South Africa: South Africa's Medicines Act appears to grant the Health Minister ill defined authority to issue compulsory licenses, authorize parallel imports, and potentially otherwise abrogate patent rights. Implementation of the law has been suspended pending the resolution of a constitutional challenge in the South African courts. Undisclosed test data is also not adequately protected under South African law. During the past year, South African representatives have led a faction of nation's in the World Health Organization (WHO) in calling for a reduction in the level of protection provided for pharmaceuticals in TRIPS. Copyright piracy and trademark counterfeiting is widespread and the U.S. copyright industry estimates that trade losses due to piracy of copyrighted works increased more than 35 percent between 1997 and 1998. However, the South African Government recently took the welcome step of adopting a implementing strategy to its 1997 Counterfeit Goods Act which could strengthen enforcement. We call on the Government of South Africa to bring its IPR regime into full compliance with TRIPS before the January 1, 2000 deadline, ensure that all Government offices use only legitimate software, and clarify that the powers granted in the Medicines Act are consistent with its international obligations and will not be used to weaken or abrogate pharmaceutical patent protection. We will continue to address these issues with the South African Government and will conduct an out-of-cycle review of South Africa's progress towards addressing these concerns in September 1999.

COMPULSORY LICENSING IS NOT
AN ASSAULT ON INTELLECTUAL
PROPERTY RIGHTS

HON. MARION BERRY

OF ARKANSAS

IN THE HOUSE OF REPRESENTATIVES

Tuesday, April 27, 1999

Mr. BERRY. Mr. Speaker, I am thankful that today, by an overwhelming majority of 422 to 1, the House of Representatives passed H.R. 1554, the Satellite Home Viewer Act of 1999, which I supported. This legislation ensures that many of my constituents will continue to receive television network programming. The bill extends for five years compulsory licenses, which require superstations and distant broadcast stations to allow their signal to be retransmitted by satellite carriers. In order to promote competition, the bill sets specific prices at which the intellectual property owners, or broadcasters, will be paid for having their signal rebroadcasted.

It is ironic that even as we vote to allow compulsory licensing today, we are interfering in another country's attempt to address a public health crisis through giving consumers access to international markets and through the use of compulsory licensing. It is estimated 3.2 million South Africans are HIV positive, including 45 percent of its military. One in five South African pregnant women test positive for HIV. Access to affordable medicine is also a critical issue for the elderly and others suffering from chronic diseases and medical conditions. Prescription drugs are not currently an option for many patients in South Africa, where the drugs often cost more than they do in the United States. The 1997 per capita income in South Africa was estimated to be only \$6,200 annually.

To address the problem, President Mandela and the South African Government enacted a law in 1997 to reform the country's prescription drug marketplace. The law amends the South African Medicines Act to allow prescription drugs to be purchased in the international marketplace where prices are lower. It would also allow compulsory licensing in some cases. Regulations implementing the law have not been implemented while the law is being constitutionally challenged in South African courts by drug makers in their country.

However, the pharmaceutical industry has persuaded the United States government to work to have the South African law repealed. In February, the United States Department of State released a report titled, U.S. Government Efforts to Negotiate the Repeal, Termination or Withdrawal of Article 15(c) of the South African Medicines and Related Substances Act of 1965.

While special interest groups have tried to convince members of Congress and the administration that implementation of the South African Medicines Act would cause violations of international intellectual property rights agreements, I have seen no evidence that such violations are likely to occur. Compulsory licensing is not an assault on intellectual property rights. Instead, it is part of the copyright and patent systems which enable the interest of the public to be served. Compulsory licensing is permitted under Article 31 of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). In fact, French law authorizes compulsory licensing when medicines are "only available to the public in insufficient quantity or quality or at abnormally high prices."

Today, the House of Representatives wisely exercised its power to continue the use of compulsory licensing in the broadcast industry to allow consumers to have access to broadcast signals, that in many instances they would otherwise be unable to receive. Certainly, the United States government should recognize the need of a government to allow its citizens to have access to needed medicine in order to address a public health crisis and should not interfere with the situation in South Africa.

United States Patent
Kempf, et al.

5,541,206
July 30, 1996

Retroviral protease inhibiting compounds

Abstract

A retroviral protease inhibiting compound of the formula: ##STR1## is disclosed.

Inventors: **Kempf; Dale J.** (Libertyville, IL); **Norbeck; Daniel W.** (Crystal Lake, IL); **Sham; Hing Leung** (Gurnee, IL); **Zhao; Chen** (Gurnee, IL)

Assignee: **Abbott Laboratories** (Abbott Park, IL)

Appl. No.: **423387**

Filed: **April 25, 1995**

U.S. Class: **514/365; 548/204; 548/194; 548/187; 548/235; 548/227; 548/228; 548/229; 514/374; 514/369; 514/370; 514/376; 514/377**

Intern'l Class: **A61K 031/425; C07D 413/12; C07D ; 417/12**

Field of Search: **514/365,374,369,370,376,377
548/204,194,187,235,227,228,229**

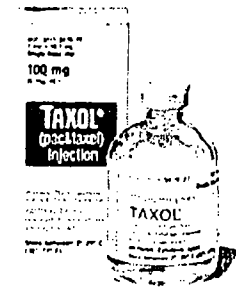
Primary Examiner: Fan; Jane

Attorney, Agent or Firm: Crowley; Steven R.

Government Interests

This invention was made with Government support under contract number AI27220 awarded by the National Institute of Allergy and Infectious Diseases. The Government has certain rights in this invention.

Semisynthetic **TAXOL®** (paclitaxel) Injection



TAXOL® injection is indicated as first line therapy, in combination with cisplatin, and subsequent therapy for the treatment of advanced ovarian cancer. **TAXOL** is indicated for breast cancer, after failure of first-line or subsequent chemotherapy. **TAXOL** is indicated first line, in combination with cisplatin, for the treatment of non-small cell lung cancer, in patients who are not candidates for surgery and/or radiation. **TAXOL** is indicated as second line treatment of

AIDS-related Kaposi's sarcoma.

The NCI sponsors Phase I clinical trials of paclitaxel against numerous cancers. However, allergic reactions, attributed to the solvent in the formula, cause some trials to be discontinued and others to be delayed.

1983

The NCI begins Phase II trials of paclitaxel.

1985

The NCI begins Phase III trials of paclitaxel.

1990

TAXOL is approved for use after failure of first-line or subsequent chemotherapy for the treatment of metastatic carcinoma of the ovary.

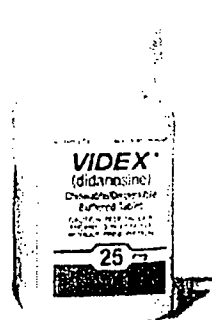
1992

NIH invented Taxol and sponsored all clinical trials for FDA approval. BMS became involved in 1991. Taxol was approved for marketing the next year.

1991

Bristol-Myers Squibb is selected by the NCI to be its commercial partner in developing **TAXOL®**(paclitaxel) and signs a CRADA with the NCI.

VIDEX (didanosine) also known as ddI



VIDEX (didanosine) also known as ddI is indicated for the treatment of HIV infection when anti-retroviral therapy is warranted.

United States Patent [19] **Patent Number:** 4,861,759
Mitsuya et al. [45] **Date of Patent:** Aug. 29, 1989

[54] ANTIVIRAL COMPOSITIONS AND METHODS	[56] References Cited U.S. PATENT DOCUMENTS
[75] Inventors: Hiroaki Mitsuya, Rockville; Samuel Broder, Bethesda, both of Md.	4,081,534 3/1978 Elion et al. 424/180 4,434,788 3/1984 Nakatsutawa 424/180 4,377,012 3/1986 Tsurushima et al. 536/24
[73] Assignee: The United States of America as represented by the Department of Health and Human Services, Washington, D.C.	FOREIGN PATENT DOCUMENTS 206497 12/1986 European Pat. Off.
[21] Appl. No.: 84,055	OTHER PUBLICATIONS Prisbe, E. J. et al, Chemical Abstracts, 1985, vol. 103, abstract 123846h. Waqar, M. A. et al, J. Cellular Physiology, 121: 402-408, (1984).
[22] Filed: Aug. 11, 1987	Primary Examiner—A. Lionel Clingman Attorney, Agent, or Firm—Browdy and Neimark
Related U.S. Application Data	[57] ABSTRACT
[63] Continuation-in-part of Ser. No. 937,925, Dec. 4, 1986, abandoned, which is a continuation-in-part of Ser. No. 769,016, Aug. 26, 1985, abandoned.	Compositions containing 2',3'-dideoxyadenosine, 2',3'-dideoxyinosine, and dideoxyguanosine and their triphosphates for use in treating retroviral infections including acquired immune deficiency syndrome (AIDS) are disclosed with preferred methods of treatment which provide protection against cytopathic effects of human immunodeficiency virus (HIV).
[51] Int. Cl. ⁴ A61K 31/70; C07D 473/16; C07H 17/00, C07H 19/06	22 Claims, 4 Drawing Sheets
[52] U.S. Cl. 514/46; 514/43; 514/47; 514/48; 536/24; 536/26; 536/27; 536/23	
[58] Field of Search 514/49, 45, 51, 934, 514/43, 46; 536/24, 26, 27	

Note:

Both of these drugs were licensed to BMS during the Bush Administration, and were subject to a fair pricing clause in the license agreement. The Clinton Administration has never enforced the fair pricing clauses for these drugs.

Zerit (stavudine) also known as d4t is indicated for the treatment of HIV-infected patients who have received prolonged prior zidovudine therapy.



United States Patent [19]

Lin et al.

[11] Patent Number: 4,978,655

[45] Date of Patent: Dec. 18, 1990

[54] USE OF 3'-DEOXYTHYMIDIN-2'-ENE (3'-DEOXY-2',3'-DIDEHYDROTHYMIDINE) IN TREATING PATIENTS INFECTED WITH RETROVIRUSES

[75] Inventors: Tai-Shun Lin, North Haven; William H. Prusoff, North Branford, both of Conn.

[73] Assignee: Yale University, New Haven, Conn.

[21] Appl. No.: 942,666

[22] Filed: Dec. 17, 1986

[51] Int. Cl.³ A61K 31/70

[52] U.S. Cl. 514/50; 514/934

[58] Field of Search 536/23; 514/49; 574/50

References Cited

U.S. PATENT DOCUMENTS

3,322,747 5/1967 Shen et al. 536/23
3,817,982 6/1974 Verheyden et al. 536/23
4,360,522 11/1982 Shaeffer et al. 514/263
4,710,492 12/1987 Lin et al. 536/23

FOREIGN PATENT DOCUMENTS

0027783 3/1977 Japan 514/50
2027782 3/1977 Japan 536/23
254552 10/1986 Japan
8700089 8/1988 Netherlands

OTHER PUBLICATIONS

Mitsuya et al., *Proc. Natl. Acad. Sci. USA*, 82 pp. 7096-7100 (1985).
Mitsuya et al., *Proc. Natl. Acad. Sci. USA*, 83 pp. 1911-1915 (1986).
Fischl et al., *The New England J. of Medicine*, 317 No. 4, pp. 185-191 (1987).
Herdewijn et al., *J. Med. Chem.*, 30 pp. 1270-1278 (1987).
Lin et al., *Biochemical Pharmacology*, vol. 36, No. 17, pp. 2713-2718 (1987).
Lin et al., *J. Med. Chem.*, 30 pp. 440-444 (1987).
Kim et al., *J. Med. Chem.*, 30 862-866 (1987).
Lin et al., *Biochemical Pharmacology*, 36, No. 3, 311-316 (1987).
De Clercq, *J. Antimicrobial Agents and Chemotherapy* 14, Suppl. A, 85-95 (1984).
De Clercq et al., *Biochemical Pharmacology*, 29, 1849-1851 (1980).
Machuga, *Antimicrobial Agents and Chemotherapy*, 29, No. 3, 524-526 (1986).
De Clercq et al., *J. Med. Chem.*, 29 213-217 (1986).
Robins, "Synthetic Antiviral Agents", (4 EN, Jan. 27, 1986).
D. Dormant, B. Spire, F. Barre-Sinoussi, L. Montagnier and J. C. Chermann, *Ann. Inst. Pasteur/Virol.*, 75, 136E, (1985).
W. Rosenbaum, D. Dormont, B. Spire, E. Vilmer, M. Gentilini, C. Griscelli, L. Montagnier, F. Barre-Sinoussi and J. C. Chermann, *Lancet*, i, 450, (1985).
D. D. Ho, K. L. Hartshorn, T. R. Rota, C. A. Andrews, J. C. Kaplan, R. T. Schoolkey and M. S. Hirsch, *Lancet*, i, 602 (1985).

J. B. McCormick, J. P. Getchell, S. W. Mitchell and D. R. Hicks, *Lancet*, ii, 1367, (1984).
E. G. Sandstrom, J. C. Kaplan, R. E. Byington and M. S. Hirsch, *Lancet*, i, 1480, (1984).
P. S. Sarin, Y. Taguchi, D. Sun, A. Thornton, R. C. Gallo and B. Oberg, *Biochem. Pharmacol.*, 34, 4075, (1985).
R. Anand, J. L. Moore, A. Srinivasan, V. Kalyanaraman, D. Francis, P. Feorino and J. Curran, *Abstracts of the International Conference on Acquired Immune Deficiency Syndrome (AIDS)*, Apr. 14-17, Atlanta, Ga. p. 72, (1985).
H. Mitsuya, M. Popovic, R. Yarchoan, S. Matsushita, R. C. Gallo and S. Broder, *Science*, 226, 172, (1984).
H. Mitsuya, S. Matsushita, M. E. Harper and S. Broder, *Cancer Res.*, 45, 4583, (1985).
E. DeClercq, *Cancer Lett.*, 8, 9 (1979).
A. Pompidou, D. Zagury, R. C. Gallo, D. Sun, A. Thornton and P. S. Sarin, *Lancet*, ii, 1423, (1985).
P. Chandra and P. S. Sarin, *Drug Res.*, 36 184, (1986).
R. Anand, J. Moore, P. Feorino, J. Curran and A. Srinivasan, *Lancet*, i, 97, (1986).
P. S. Sarin, R. C. Gallo, D. I. Scheer, F. Crews and A. S. Lippa, *New Engl. J. Med.*, 313, 1289, (1985).
W. Ostertag, T. Cole, T. Crozier, G. Gaedicke, J. Kind, N. Kluge, J. C. Krieg, G. Roselser, G. Sheinheider, B. J. Weimann and S. K. Dube, *Proceedings of the 4th International Symposium of the Princess Takamatsu Cancer Research Fund*, Tokyo, 1973, Differentiation and Control of Malignancy of Tumor Cells, Eds. W. Nakahara, T. Ono, T. Sugimura and H. Sugano, p. 485, University of Tokyo Press, Tokyo, (1974).
W. Ostertag, C. Roseler, C. J. Kreig, T. Cole, T. Crozier, G. Gaedicke, G. Steinheider, N. Kluge and S. K. Dube, *Proc. Natn. Acad. Sci. USA*, 71, 4980, (1974).
S. L. Dube, G. Gaedicke, N. Kluge, B. J. Weimann, H. Melderis, G. Steinheider, T. Crozier, H. Beckmann and W. Ostertag, *Proceedings of the 4th International Symposium of the Princess Takamatsu Cancer Research Fund*, Tokyo, 1973, Differentiation and Control of Malignancy of Tumor Cells, Eds. W. Nakahara, T. Ono, T. Sugimura and H. Sugano, p. 99, University of Tokyo Press, Tokyo, (1974).
S. K. Dube, I. B. Pragnell, N. Kluge, G. Gaedicke, G. Steinheider and W. Ostertag, *Proc. Natn. Acad. Sci. USA*, 72, 1863, (1975).
H. Mitsuya, K. J. Weinhold, P. A. Furman, M. H. St. Clair, S. Lehman Nussioff, R. C. Gallo, D. Bolognesi, (Last continued on next page.)

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[57] ABSTRACT

This invention relates to the use of 3'-deoxythymidin-2'-ene (3'-deoxy-2',3'-didehydrothymidine) in treating patients infected with a retrovirus.

8 Claims, No Drawings



USE OF 3'-DEOXYTHYMIDIN-2'-ENE (3'-DEOXY-2',3'-DIDEHYDROTHYMIDINE) IN TREATING PATIENTS INFECTED WITH RETROVIRUSES

GOVERNMENT RIGHTS

This invention was made with United States government support under Grant CA-28852 from the NIH. The United States Government has certain rights in this invention.

BACKGROUND OF THE INVENTION

1. Field of the Invention
The present invention concerns the use of 3'-deoxythymidin-2'-ene (3'-deoxy-2',3'-didehydrothymidine) in treating patients infected with retroviruses.

2. Background Information
Acquired immunodeficiency syndrome (AIDS) is generally accepted to be a consequence of infection with the retrovirus variously termed human T-lymphotropic virus type III (HTLV-III), lymphadenopathy-associated virus (LAV), AIDS associated retrovirus (ARV), or human immunodeficiency virus (HIV). A number of compounds have demonstrated antiviral activity against this virus which include HPA-23 (D. Dormont, B. Spire, F. Barre-Sinoussi, L. Montagnier and J. C. Chermann, *Ann. Inst. Pasteur/Virol.*, 75, 136E, (1985) and W. Rosenbaum, D. Dormont, B. Spire, E. Vilmer, M. Gentilini, C. Griscelli, L. Montagnier, F. Barre-Sinoussi and J. C. Chermann, *Lancet*, i, 450, (1985)), interferons (D. D. Ho, K. L. Hartshorn, T. R. Rota, C. A. Andrews, J. C. Kaplan, R. T. Schoolkey and M. S. Hirsch, *Lancet*, i, 602, (1985)), ribavirin (J. B. McCormick, J. P. Getchell, S. W. Mitchell and D. R. Hicks, *Lancet*, ii, 1367, (1984)), phosphonoformate (E. G. Sandstrom, J. C. Kaplan, R. E. Byington and M. S. Hirsch, *Lancet*, i, 1480 (1984) and P. S. Sarin, Y. Taguchi, D. Sun, A. Thornton, R. C. Gallo and B. Oberg, *Biochem. Pharmacol.*, 34, 4075, (1985)), ansamycin (R. Anand, J. L. Moore, A. Srinivasan, V. Kalyanaraman, D. Francis, P. Feorino and J. Curran, *Abstracts of the International Conference on Acquired Immune Deficiency Syndrome (AIDS)*, April 14-17, Atlanta, GA, page 72, (1985)), suramin (H. Mitsuya, M. Popovic, R. Yarchoan, S. Matsushita, R. C. Gallo and S. Broder, *Science*, 226, 172, (1984); H. Mitsuya, S. Matsushita, M. E. Harper and S. Broder, *Cancer Res.*, 45, 4583, (1985) and E. DeClercq, *Cancer Lett.*, 8, 9, (1979)), imithiol (A. Pompidou, D. Zagury, R. C. Gallo, D. Sun, A. Thornton and P. S. Sarin, *Lancet*, ii, 1423, (1985)), penicillamine (P. Chandra and P. S. Sarin, *Drug Res.*, 36, 184, (1986)), ribavirin (R. Anand, J. Moore, P. Feorino, J. Curran and A. Srinivasan, *Lancet*, i, 97, (1986)), AL-721 (P. S. Sarin, R. C. Gallo, D. I. Scheer, F. Crews and A. S. Lippa, *New Engl. J. Med.*, 313, 1289, (1985)), 3'-azido-3'-deoxythymidine (W. Ostertag, T. Cole, T. Crozier, G. Gaedicke, J. Kind, N. Kluge, J. C. Krieg, G. Roselser, G. Sheinheider, B. J. Weimann and S. K. Dube, *Proceedings of the 4th International Symposium of the Princess Takamatsu Cancer Research Fund*, Tokyo, 1973, Differentiation and Control of Malignancy of Tumor Cells, Eds. W. Nakahara, T. Ono, T. Sugimura and H. Sugano, page 485, University of Tokyo Press, Tokyo, (1974); W. Ostertag, G. Roseler, C. J. Kreig, T. Cole, T. Crozier, G. Gaedicke, G. Steinheider, N. Kluge and S. K. Dube, *Proc. Natn. Acad. Sci. USA*, 71, 4980, (1974); S. L. Dube, G. Gaedicke, N. Kluge, B. J.

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Weimann, H. Melderis, G. Steinheider, T. Crozier, H. Beckmann and W. Ostertag, *Proceedings of the 4th International Symposium of the Princess Takamatsu Cancer Research Fund*, Tokyo, 1973, Differentiation and Control of Malignancy of Tumor Cells, Eds. W. Nakahara, T. Ono, T. Sugimura and H. Sugano, page 99, University of Tokyo Press, Tokyo, (1974); S. K. Dube, I. B. Pragnell, N. Kluge, G. Gaedicke, G. Steinheider and W. Ostertag, *Proc. Natn. Acad. Sci. USA*, 72, 1863, (1975) and H. Mitsuya, K. J. Weinhold, P. A. Furman, M. H. St. Clair, S. Lehman Nussioff, R. C. Gallo, D. Bolognesi, D. W. Barry and S. Broder, *Proc. Natn. Acad. Sci. USA*, 82, 7096, (1985)), and more recently various 2',3'-dideoxynucleosides (H. Mitsuya and S. Broder, *Proc. Natn. Acad. Sci. USA*, 83, 1911, (1986)), of which 2',3'-dideoxycytidine (ddCyd) is the most potent. A review of these and other compounds evaluated for their activities against HIV, as well as a discussion of the AIDS problem in general, has been presented (E. DeClercq, *J. Med. Chem.*, 29, 1561, (1986)).

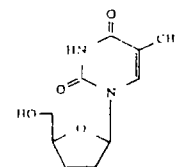
Applicants previously found 2',3'-dideoxycytidin-2'-ene (2',3'-dideoxy-2',3'-didehydrocytidine, d4C) a derivative of 2',3'-dideoxycytidine (ddCyd) to have antiviral activity against HIV (Lin et al., *Biochem. Pharmacol.*, in press). This provided the stimulus to synthesis 3'-deoxythymidin-2'-ene (3'-deoxy-2',3'-didehydrothymidine) even though Mitsuya and Broder, supra found 2',3'-dideoxythymidine (3'-deoxythymidine) to be a very poor inhibitor of HTLV-III/LAV. Applicants' finding of potent antiviral activity with 3'-deoxythymidin-2'-ene was, therefore, unexpected based on their report.

SUMMARY OF THE INVENTION

The present invention is directed to the treatment of warm blooded animals, including humans, infected with a retrovirus comprising administering to a warm blooded animal, e.g., a human patient, an anti-retroviral effective amount of 3'-deoxythymidin-2'-ene (3'-deoxy-2',3'-didehydrothymidine), either alone or in admixture with a diluent or in the form of a medicament.

DETAILED DESCRIPTION OF THE INVENTION

The structure of 3'-deoxythymidin-2'-ene (3'-deoxy-2',3'-didehydrothymidine; d4T) is as follows:



3'-Deoxythymidin-2'-ene (3'-deoxy-2',3'-didehydrothymidine) has antiviral activity against retroviruses, e.g., murine leukemia virus and human immunodeficiency virus, i.e., HIV; HTLV III/LAV virus (the AIDS virus).

Retroviruses are RNA viruses whose genome contains copies of high-molecular weight single-stranded RNA. The virion contains reverse transcriptase. Non-limiting examples of retroviruses include leukemia and

Intellectual Property provisions in HR 434, the "Growth and Opportunity Act"

In Section 4, the bill states:

(a) IN GENERAL- A sub-Saharan African country shall be eligible to participate in programs, projects, or activities, or receive assistance or other benefits under this Act if the President determines that the country does not engage in gross violations of internationally recognized human rights and has established, or is making continual progress toward establishing, a market-based economy, such as the establishment and enforcement of appropriate policies relating to--

(3) trade issues, such as protection of intellectual property rights, improvements in standards, testing, labeling and certification, and government procurement;

This is a general and quite **open ended** provision. PhRMA has already indicated it will use this provision as a lever to force African countries to to oppose policies like parallel imports, compulsory licensing, generic drug substitution and measures to speed the introduction of generic drugs following patent expiration. This is broader than the current GSP language, because it will extend this linkage far beyond GSP.

Intellectual Property Provisions of HR 772, the "Hope for Africa Act."

SEC. 601. REQUIREMENTS RELATING TO SUB-SAHARAN AFRICA INTELLECTUAL PROPERTY AND COMPETITION LAW.

Funds appropriated or otherwise made available to any department or agency of the United States may not be used to seek, through negotiation or otherwise, the revocation or revisions of any sub-Saharan African intellectual property or competition law or policy that is designed to promote access to pharmaceuticals or other medical technologies and such law or policy, as the case may be, complies with the Agreement on Trade-Related Aspects of Intellectual Property Rights referred to in section 101(d)(15) of the Uruguay Round Agreements Act.

The Hope for Africa bill has a specific criteria for intellectual property rules that pertain to access to pharmaceutical and other medical technologies. It says that if sub-Saharan African countries are in compliance with the WTO/TRIPS agreement, that is enough.

Selected Compulsory Licenses in the USA

The United States often uses compulsory licenses to address problems of excessive monopoly power, for non-commercial public use, or for other purposes. Here are just a few examples:

- November 30, 1998. The US Department of Justice announced it was requiring Monsanto to license Holden's corn germplasm to over 150 seed companies for use in creating corn hybrids with transgenic improvements.
- March 24, 1997. The FTC required Ciba-Geigy and Sandoz, two Swiss firms that merged into Novartis, to license a large portfolio of patents, data and know-how relating to HSV-tk products, hemophilia gene rights and other products to Rhone-Poulenc Rorer. Novartis was then required to grant non-exclusive licenses to all requesters for patent and other rights to Cytokine products, with royalties no greater than three percent (3%) of the net sales price, and to provide non-exclusive licenses to the Anderson gene patent, for one percent.
- July 6, 1994. The FTC required Dow to license to a potential entrant intangible dicyclomine assets, including "all formulations, patents, trade secrets, technology, know-how, specifications, designs, drawings, processes, quality control data, research materials, technical information, management information systems, software, the Drug Master File, and all information relating to the US FDA approvals." Moreover, during a transition period, while the new entrant sought FDA approvals of its own, the FTC required Dow to manufacture and deliver dicyclomine tablets and capsules to the new entrant at a government determined price.
- June 19, 1996. In a case involving Hughes Aircraft (then represented by Kenneth Starr), the US government granted itself the right to use the "Williams Patent" for use in Satellites positioned in orbit around the earth. The royalty granted to Hughes was one percent. On the appeal of the royalty rate, the court said "because recovery is based on eminent domain, the proper measure is 'what the owner has lost, not what the taker has gained.'"
- September 17, 1998. The Librarian of Congress announced the rates and terms for compulsory licenses involving noncommercial educational broadcasting use of the repertoires of the American Society of Composers, Authors and Publishers (ASCAP) and Broadcast Music, Inc. (BMI), for the Public Broadcasting Service (PBS), National Public Radio (NPR) and other public broadcasting entities.

Health Care and IP : Compulsory Licensing

Page on March 1999 meetings in Geneva on Compulsory Licensing of Essential Medical Technologies

The following are background items on compulsory licensing of patents and other intellectual property. It is designed to be relevant to the debate over compulsory licensing of essential medical technologies. There are discussions of compulsory licensing of intellectual property from other areas, to provide a broader understanding of the approaches that are possible.

- Frequently asked questions about compulsory licenses
- February 18, 1999, Ralph Nader and James Love letter to Secretary of State Madeleine Albright requesting NGO meeting on intellectual property aspects of International HIV/AIDS policy. Mentions compulsory licensing.
- Background on compulsory licensing, a paper distributed by public health groups at the May 1998 World Health Assembly meetings.
- International law on compulsory licensing
 - The Paris Convention for the Protection of Industrial Property of March 20, 1883, as revised (several times). Article 5 deals with compulsory licensing. Among the provisions are Article 5(A)(2), which says:

Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.

This treaty is administered by the World Intellectual Property Organization (WIPO). Here is the WIPO list of the 151 countries that are party to this treaty.

- WTO/GATT/TRIPS provisions on compulsory licensing of patents It is worth noting that Article 2.1 of the TRIPS requires compliance with Articles 1 through 12, and Article 19 of the Paris Convention (see above).
- NAFTA provisions compulsory licensing of patents
- MAI provisions
- On February 1, 1996, Michael Kantor, then the United States Trade Representative, wrote a letter to Alfred B. Engelberg defending the USTR policies with respect to the generic industry. Mr. Kantor noted that the "Bolar" provisions in US law regarding exceptions to patent rights for medical research were permitted by the TRIPS, that the Bolar exception was supported by US trade negotiators, and that the USTR did not "pursue unthinkingly all of the international IPR concerns of the so-called innovator pharmaceutical industry." On the issue of compulsory licensing and the TRIPS, Mr. Kantor said:

We have been balanced in our approach to the protection of pharmaceutical products. The relevant provisions of the TRIPS Agreement reflects this problem:

- *TRIPS specifically sets out a considerable number of conditions under which compulsory licensing may be utilized for use by those countries wishing to impose limits on intellectual property protection within its own borders.*
- *TRIPS contains no transition period phasing-out the use of these compulsory licensing provisions, they may be relied upon for the indefinite future*

- **Thailand /USA disputes regarding compulsory licensing and AIDS drugs.** Today the crisis in AIDS treatment is driving an International debate over compulsory licensing. Here are a few articles about a dispute in Thailand, where the United States has been pushing for repeal of compulsory licensing authority.
 - Notes from Thai public health groups
 - August 26, 1998, Thailand and TRIPS - info for campaign.

- Thai Movement on Drug Patent, September 9, 1998
- Articles from English Language Thai newspapers
 - September 4, 1998, The Nation, Group seeks legislation making drugs affordable to those in need.
 - September 4, 1998, Aphaluck Bhatiasavi, in the Bangkok Post, Activists step up pressure to defeat patent law amendment: Protest outside US embassy planned.
 - September 5, 1998, Anjira Assavanonda, in the Bangkok Post, NGOs rally against patent law changes: Call on US to stop pressuring Thailand.
 - January 23, 1999, Aphaluck Bhatiasavi, in the Bangkok Post, Access to anti-Aids drugs to remain hard: Essential Drug List won't help patients.
- **Compulsory licensing in the United States**
 - US Laws on compulsory licensing
 - 17 USC 111. Limitations on exclusive rights: Secondary transmissions. 17 USC 11 (d) is the provision that provides for "Compulsory License for Secondary Transmissions by Cable Systems."
 - 17 USC Sec 115, Scope of exclusive rights in nondramatic musical works: Compulsory license for making and distributing phonorecords.
 - March-in Rights Under the Bayh Dole Act : 35 USC 203. See also the Bayh-Dole Act statement on Policy and Objective.
 - 42 USC Sec 7608, to provide mandatory licensing of air pollution prevention inventions under Title 42, the Public Health and Welfare. This is from the Clean Air Act.
 - 28 USC Sec 1498, concerning uses of patents or copyrights, when the use is by or for the government. A Lexis search turns up 438 cases that cite this statute. A note by NASA describes this provision as follows:

... 28 U.S.C. 1498, which provides that a suit against the Government in the U.S. Court of Federal Claims is the exclusive remedy for patent holders who allege their patented invention has been infringed by the U.S. Government or by one acting for the Government. The primary purpose of this statute is to protect and relieve contractors from any liability for infringement by the owner when an invention is used by or manufactured for the United States. By virtue of this statute, the Government may be held liable to the patent owner for payment of the "reasonable and entire compensation" for its unauthorized use of the patent. Unlike a private party, however, the Government cannot commit the tort of "patent infringement." Governmental use of a patented invention is viewed as an eminent domain taking of a license under the patent and not as a tort.

The Government may delegate its eminent domain power over patents to contractors acting on its behalf. This is accomplished through inclusion of the "Authorization and Consent" clause in the contract [FAR clause 52.227-1]. This clause is usually included in research and development contracts and is a very significant power to grant to a contractor as it makes the Government responsible for the contractors' infringement of any patents during the course of performance of the contract; the patent owner must bring her/his action against the Government, not the contractor.

Sometimes the Government does not wish to fully delegate its eminent domain power to a contractor. This is accomplished by inclusion in the contract of the "Patent Indemnity" clause [FAR clause 52.227-3] which obligates the contractor who infringes a patent to indemnify the Government for any liability it incurs.

■ 42 USC Sec 2183, for atomic energy.

(a) Declaration of public interest

The Commission may, after giving the patent owner an opportunity for a hearing, declare any patent to be affected with the public interest if (1) the invention or discovery covered by the patent is of primary importance in the production or utilization of special nuclear material or atomic energy; and (2) the licensing of such invention or discovery under this section is of primary importance to effectuate the policies and purposes of this chapter.

(b) Action by Commission

Whenever any patent has been declared affected with the public interest, pursuant to subsection (a) of this section - (1) the Commission is licensed to use the invention or discovery covered by such patent in performing any of its powers under this chapter; and (2) any person may apply to the Commission for a nonexclusive patent license to use the invention or discovery covered by such patent, and the Commission shall grant such patent license to the extent that it finds that the use of the invention or discovery is of primary importance to the conduct of an activity by such person authorized under this chapter.

o Medicines and biotechnology

- 1999, John F. Merza, Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Medicine. *Clinical Chemistry*. 1999;45:324-330.
- November 30, 1998, US Department of Justice compulsory license with Monsanto. The compulsory license is a condition of a proposed combination of Monsanto and Dekalb. Monsanto agreed to license Holden's corn germplasm to over 150 seed companies for use in creating corn hybrids with transgenic improvements.
- June 4, 1998, . This is Appendix D to Report of the National Institutes of Health (NIH) Working Group on Research Tools. Appendix D describes the US government's compulsory licensing rights under the Bayh-Dole Act.
- Rebecca S. Eisenberg, Technology Transfer and the Genome Project: Problems with Patenting Research Tools* Discusses compulsory licensing of research tools. The paper is from Risk, 5.163 (1994).
- March 24, 1997, Decision and Order from the Federal Trade Commission regarding the merger between Ciba-Geigy Ltd. and Sandoz Ltd. into Novartis AG. Ciba-Geigy and Sandoz were required to license a large portfolio of patents, data and know-how relating to HSV-tk products, hemophilia gene rights and other products to Rhone-Poulenc Rorer. The new merged entity was also required to grant non-exclusive licenses to all requesters for patent and other rights to Cytokine products, with royalties that can be no greater than three percent (3%) of the net sales price and the Anderson gene patent for one percent. See also Separate Statement of FTC Chair Robert Pitofsky and Commissioners Steiger, Starek and Varney on this decision, who were responding to comments by Commissioner Azcuenaga. See also the FTC's April 8, 1997 advisory on this decision.
- 1997, CellPro request for compulsory licensing. As far as we know, this was the first request for a compulsory license under the Bayh-Dole Act. The request was denied by NIH Director Dr. Varmus, who had earlier terminated the NIH fair pricing clause in NIH license agreements and CRADAs. This is a very interesting story involving, among other things, a company that developed an innovative FDA approved device that saved its own CEO's life. But Johns Hopkins University asked a court to remove the device from the market, alleging it violated a patent from a government funded invention. Cellpro is now bankrupt.
- September 27, 1996, introduction of HR 4270. Section 6 of this bill proposed a government use compulsory licensing authority with respect to materials used in medical research.
- July 6, 1994, Dow Chemical compulsory license for dicvelomine. The FTC required

Dow to license to a potential entrant intangible dicyclomine assets, including "all formulations, patents, trade secrets, technology, know-how, specifications, designs, drawings, processes, quality control data, research materials, technical information, management information systems, software, the Drug Master File, and all information relating to the United States Food and Drug Administration Approvals" that are not part of the acquired company's physical facilities or other tangible assets. Moreover, during a transition period, while the new entrant sought FDA approvals of its own, the FTC required Dow to manufacture and deliver dicyclomine tablets and capsules to the new entrant at a price that did not exceed 48 percent of the average wholesale price of the acquired company's dicyclomine tablets as of July 2, 1993.

- March 3, 1994, Article on Congressman Jerry Nadler's proposal for compulsory licensing of RU-486. US Congressman Nadler (D-NY) was quoted as follows:

My essential pharmaceuticals bill would, rather than outright canceling a patent, provide for subjecting a patent for a pharmaceutical to a compulsory-licensing procedure, akin to that now in place with respect to music copyrights. Where [HHS] determines (1) that a patent holder 'has not taken all the reasonable steps toward the commercial marketing' of the patented drug and (2) that the 'availability of the product to the public is of vital importance to the public health or welfare,' any pharmaceutical company could manufacture and sell the drug. A company that did so would be required to pay royalties, in an amount to be determined by the Commissioner of Patents and Trademarks to represent fair compensation to the patent holder."

Here is the full text of Representative Nadler's HR 4151, the 'Essential Pharmaceuticals Act of 1994.

- United States v. S.C. Johnson & Son, Inc. & Bayer A.G. According to Anne Bingaman:

[This} is a case in which, we alleged that a patent license agreement between the defendants violated Section 1 of the Sherman Act. Johnson dominated the highly concentrated U.S. household insecticide market. Bayer developed and patented a new active ingredient for household insecticides and prepared to enter the U.S. market with its own product. It then abandoned its plans and granted a license for its active ingredient to Johnson. It did not license any other U.S. manufacturer. The case was settled by consent decree, which in part requires Bayer to license its ingredient to other interested parties for the United States.

- Selected cases under 28 USC 1498, the US statute which provides for eminent domain of patents and copyrights.

- June 19, 1996. Decision by the US Court of Appeals for the Federal Circuit, in *Hughes Aircraft Company v. The United States*, 94-5149,95-5001. (86 F.3d 1566). Kenneth Starr represented Hughes in an unsuccessful appeal, where Hughes was seeking a higher royalty rate on a compulsory license of US Patent No. 3,758,051 (the Williams Patent). The Williams patent "relates to an apparatus for controlling the orientation of the spin axis of spin-stabilized space vehicles such as satellites positioned in orbit around the earth." The US Court of Federal Claims set a royalty rate of 1 percent in a 1994 decision (31 Fed. Cl. 481). Worth noting was the appeals court observation that "Because recovery is based on eminent domain, the proper measure is 'what the owner has lost, not what the taker has gained,'" quoting *Leesona* (599 F.2d at 969).
- March 31, 1998. Decision by the US Court of Appeals for the Federal Circuit in *Brunswick Corporation v. the United States*, 97-5017, 97-5021. The case involves US patent 3,733,606 (the 606 patent), and the government's purchase of camouflage screens, some of which were held to infringe on the 606 patent. Brunswick appealed

an earlier US Federal Court of Claims case setting compensation for a compulsory license of the 606 patent. Brunswick sought "lost profits" for its license, while the court awarded a "reasonable royalty." In its decision, the court indicated that the US Congress directed the Army to "expand its industrial base for the production of camouflage screens in order to maintain a reliable industrial mobilization capacity," and noted that "This type of outside policy making and political influence is peculiar to the federal government and is properly taken into account when considering whether a reasonable royalty would adequately compensate an aggrieved patentee." The court further indicated that the number of units purchased by the government was greater than would have been the case in the absence of the compulsory license, and that this supported a lower amount of compensation than that sought by Brunswick.

- May 20, 1997, decision of the United States Court of Appeals for the Federal Circuit, in *Gargoyles, Inc. and Pro-Tec, Inc. v. the United States*, 96-5089, -5094 (113 F.3d 1572). This is another case where the private plaintiff sought "lost profits" rather than a "reasonable royalty" as compensation. The royalty set by the Court of Federal Claims was 10 percent. The government considered this excessive and sought a reduction (of half or more). The dispute involves US patent 4,741,611 (the 611 patent), for protective eyewear. Gargoyles, a company that sells commercial eyewear, was seeking compensation for a compulsory license of the patent, which had been used by American Optical to provide the US Army with several thousand pairs of ballistic/laser protective spectacles. The Appeals court upheld the lower court decision. Again, the court quoted Leeson (599 F.2d at 969), "Because recovery is based on eminent domain, the proper measure is 'what the owner has lost, not what the taker has gained.'"
- Satellite, cable and open video systems.
 - July 1, 1998, the Copyright Office, Library of Congress final rule regarding royalty fees for compulsory licenses of certain broadcasts on cable television, Published in the *Federal Register*, July 24, 1998 (Volume 63, Number 142) pages 39737-39739.
 - March 1998, Before the Copyright Office, Library of Congress Washington, D. C. In re Satellite Carrier Compulsory License, Docket No. RM 98-1 Reply Comments of the Staff of the Federal Trade Commission.
 - January 21, 1998, Notice of Rulemaking by the Office of Copyright and the Library of Congress regarding compulsory license of satellite carriers retransmitting over-the-air broadcast network stations to subscribers who reside within the local markets of those stations. *Federal Register*, (Volume 63, Number 16), pages 3685-3686. See also TV Access Now, by the National Rural Telecommunications Cooperative.
 - FTC's 1996 comments in support of compulsory licensing for open video systems.
- Computers and Software
 - In ongoing litigation, Intergraph is seeking compulsory licensing of technical information needed to create computer chips that are interoperable with Intel Pentium chips.
 - November 2, 1995, FTC press release regarding compulsory license for Dell Computer's VL-Bus patent. This is essentially a zero royalty public license, as a remedy to alleged anticompetitive practices. The American Intellectual Property Law Association (AIPLA) expressed concern about impact of this license on international patent policies.

The extraordinary remedy in Dell must clearly be perceived by the public as appropriate in order to avoid international treaty consequences and unintended chilling on needed participation by private industry in standard setting. . .

The appearance of a United States government agency imposing a compulsory patent license, especially a royalty-free compulsory license, must be avoided except in response to egregious conduct. Other countries could cite such an action as the basis for imposing broad and onerous

compulsory licensing requirements upon United States patentees abroad.

For these reasons, AIPLA urges the FTC to act with caution in this case. The FTC should explicitly state in the order that it is not intending that this remedy or this action be the standard response in a patent enforcement action involving industry standards.

In another pleading, the FTC explained the case as follows:

the FTC charged that Dell Computer Corporation restricted competition in the personal computer industry and undermined the standard-setting process by threatening to exercise previously undisclosed patent rights against computer companies adopting the VL-bus standard, a mechanism to transfer instructions between the computer's central processing unit and its peripherals, such as a hard disk drive or video display hardware.

After the VESA VL-bus design standard became successful and computer manufacturers had sold more than 1.4 million personal computers incorporating the VL-bus, Dell contacted certain VESA members and asserted that it had obtained a patent in 1991 that they were violating by using the VL-bus standard. To settle the FTC's charges, Dell agreed not to enforce its patent rights against computer manufacturers using the VL-bus.

- 1995, Silicon Graphics. This case involves a compulsory license of technical information, including software applications programming interface (API) information, as part of a settlement of FTC concerns regarding the anticompetitive impact of the acquisition of software companies Alias and Wavefront.
 - June 9, 1995, FTC Press Release on settlement.
 - November 16, 1995, FTC statement regarding final FTC approval of settlement.
 - FTC Analysis to Aid Public Comment.
- 1997 FTC case: Cadence Design Systems, Inc./ Cooper & Chyan Technology, Inc. Docket No. C-3761. Involves compulsory license of software APIs.
 - May 8, 1997 FTC press release.
 - September 2, 1997 FTC press release.
 - FTC Complaint.
 - Decision and Order.
 - Statement of Chairman Pitofsky and Commissioner Janet D. Steiger announcing the consent decree.
 - Dissenting Statement of Commissioner Roscoe B. Starek, III.
 - Statement of Commissioner Mary L. Azcuenaga, Concurring in Part and Dissenting in Part.
- Misc Copyright cases
 - September 17, 1998, Announcement by the Librarian of Congress regarding the rates and terms for a compulsory license involving noncommercial educational broadcasting use of the repertoires of the American Society of Composers, Authors and Publishers and Broadcast Music, Inc. The licenses benefit the **Public Broadcasting Service (PBS), National Public Radio (NPR)** and other public broadcasting entities for the period 1998-2002. *Federal Register (Volume 63, Number 181), Pages 49823-49837*.
 - October 1998, Bob Kohn, A Primer on the Law of Webcasting and Digital Music Delivery. Includes discussions of compulsory licensing as it relates to Internet "webcasting" of music.
 - October 30, 1997. Public hearings on the Copyright Licensing Regimes Covering Retransmission of Broadcast Signals. Includes several testimonies on compulsory

licensing.

- 1994, Jessica Litman, The Exclusive Right to Read, The Herbert Tenzer Memorial Conference: Copyright in the Twenty-First Century The Role of the Copyright Office, cite as 13 CARDOZO ARTS & ENT. L.J. 29 (1994). Includes a discussion of compulsory licensing in copyright cases. A few words from the article:

The model suggesting that production and dissemination of valuable, protectible works is directly related to the degree of available intellectual property protection is much too simplistic. In fact, history teaches us a more equivocal lesson. Whenever we have discovered or enacted a copyright exception, an industry has grown up within its shelter. Player piano rolls became ubiquitous after courts ruled that they did not infringe the copyright in the underlying musical composition; phonograph records superseded both piano rolls and sheet music with the aid of the compulsory license for mechanical reproductions; the jukebox industry arose to take advantage of the copyright exemption accorded to "the reproduction or rendition of a musical composition by or upon coin-operated machines." Composers continued to write music, and found ways to exploit these new media for their works. . . The videotape rental business swept the nation shielded from copyright liability by the first sale doctrine. . . Cable television began spreading across America with the aid of a copyright exemption;(80) it eclipsed broadcast television while sheltered by the cable compulsory license.

- West Publishing. This is a compulsory license for legal citations to published court opinions in the United States.
 - Dec. 23, 1996, US District Court Opinion in West/Thomson merger case. Section E concerns the compulsory license of the citations. (The "star pagination" issue).
 - July 5, 1996, Federal register notice of the Compulsory license and diversitures related to the Thomson/West merger.
 - June 26, 1996, HyperLaw Comments on Citation License Agreement in United States v. The Thomson Corporation and West Publishing Company.
- May 7, 1997, press release, RIAA Opposes Compulsory Licensing of Internet Retransmission of Broadcasts.

• Compulsory licensing outside of the United States

Nearly every country has some type of compulsory licensing authority, but the grounds under which compulsory licenses are granted vary significantly from country to country. Common grounds are non-working of patents, dependent patents, and various forms of patent misuse or for remedies of anticompetitive or monopoly practices. In some cases the compulsory license could be a consequence of litigation, as it sometimes is the United States. Or the country may have specific statutory provisions. The following examples are not exhaustive, and illustrative of the types of approaches taken in different countries.

- Europe
 - European Union
 - The Magill decision
 - April 6, 1995 EEC high Court decision. Competition - Abuse of a dominant position - Copyright
 - June 30, 1994, John Temple Lang, Defining Legitimate Competition: Companies's duties to supply competitors, and access to essential facilities. Here are some excerpts from this article, which contains a discussion of the McGill case. One section of the article is subtitled "Compulsory licensing of intellectual property rights."
 - 1995, Robbie Downing, Magill and the Software Directive: are they

interoperable?"

- 1984 Undertaking with IBM. Requires IBM to provide non-discriminatory access to technical information and intellectual property needed to create products that are interoperable with IBM mainframes.
- United Kingdom
 - Plant Variety Rights Office, [Guide to applying for a compulsory licence](#).
 - The Patent Office, [page on compulsory licenses of Registered Designs](#).
 - Robert Battcock, "[IPRs, software copyright and competition law: restricting the rights of intellectual property owners in the wider public interest](#)." Battcock says the current UK system for compulsory licensing of patents dates back to 1883. From the article:

In practice, compulsory licensing is not greatly used. Between 1991 and 1993 the Patent Office did not receive any applications for compulsory licences, although between 1988 and 1990 it received eight (9). As Jeremy Phillips has pointed out however, these figures do not necessarily tell the whole story. The licensing provisions also act as a form of deterrent against abuse - or, to look at it another way, of encouragement to grant licences voluntarily. Actual applications under s.48 may therefore be regarded as instances where the compulsory licence provisions have failed, while on many other occasions they may have been successful in encouraging voluntary agreements.

- Scotland
 - February 12, 1997, Liz McRobb, [Software Developers Search for Cover in Patents](#) The author expresses support for more liberal support of compulsory licenses of patents to protect the UK software industry from anticompetitive effects of US software patents.
- France
 - According to WHO's publication, "Globalization and Access to Drugs, Implications of the WTO/TRIPS agreement," November 1997:

French law, for example, provides that "if required in the interest of public health" (Article L.613-16 of the Code on Intellectual Property), patents issued for drugs may be subject to the regime of compulsory licenses. The law authorized this procedure when the patented drugs "are only made available to the public in insufficient quantity or at abnormally high prices."

- Norway
 - From [A Lawyer's Guide to Doing Business in Norway](#), "If the invention is not worked in Norway when three years from grant and four years from the filing date have passed, compulsory licenses may be granted. This is of rare occurrence."
- Germany
 - 1996, Michael Kern, [Recent Federal Supreme Court decisions on Experimental Use and Compulsory Licensing](#). From the article:

As a result, we now are confronted with the situation that plaintiffs and defendants may employ their respective patents to block each other from exploiting interferon [W]ic agent against rheumatoid arthritis. If the market does not rectify this 'patent failure', the public may have to wait twenty years before gaining access to this therapeutic agent. A compulsory license in situations involving dependent patents, as provided for in various countries, is a means to correct patent failure coupled with market failure. One should not forget that patents represent a interventionist instrument,

ultimately for the sake of community welfare. Thus intervention to restrict some of the effects of patents may be required, when the community welfare is [no] longer served, e.g. when product patent and dependent patent block each other.

- May 1996, Trevor Cook, Discussion of German Federal Supreme Court decision regarding compulsory license for experimental use, in gamma-interferon litigation. From *Biosciences Update*.
- June 7, 1991. According to Arnold (1993), Germany issued a compulsory license for a pharmaceutical product: "Judgement of 7 June 1991--3 Li 1/09 (EU) concerning a patent for a polypeptide with antiviral properties." Germany permits compulsory licensing when it is "indispensable to the public interest."
- Greece
 - According to Arnold (1993), "for imperative reasons of public health, if the invention has been insufficiently exploited to satisfy local needs a license may be granted."
- South America
 - Argentina
 - Provisions in 1996 patent law Law compulsory licensing, as reported by Moeller & Co, which notes the law was passed on August 15, 1996, as Federal Act No. 24.573.
 - Brazil
 - The Brazil patent law in english. The provisions on compulsory licensing are Chapter VIII- Licenses, Section III - Compulsory Licenses, Articles 68, 69, 70, 71, 72, 73 and 74.
 - Denis Borges Barbosa, The New Brazilian Patent Law.
 - Barbados
 - According to Arnold (1993), compulsory licenses are granted for "a substance being used as a ... medicine" or "any invention capable of being used as or as part of a surgical or curative device."
 - Columbia
 - According to Arnold (1993), compulsory licenses are granted for "a substance capable of being used as a ... medicine" or "any invention capable of being used as or as part of a surgical or curative device."
 - Costa Rica
 - According to Arnold (1993), compulsory licenses are granted for "a substance capable of being used as a ... medicine" or "any invention capable of being used as or as part of a surgical or curative device."
 - Chile
 - August 1996, Sergio Escudero, Achieving Effective Protection to IPR's, which says:

Compulsory licenses for patents have been incorporated to Chilean legislation, but only in case of monopoly abuse of the right holder, circumstances which is qualified by a special court which deals with economic cases. compulsory license may be grant only under non exclusive basis, must have an specific duration and the licensee must pay a royalty to the right holder.

- Asia Pacific
 - Japan
 - Japan provisions for compulsory licenses. See in particular:

93.--(1) Where the working of a patented invention is particularly necessary in the public interest, a person who intends to work the invention may request the patentee or the exclusive licensee to hold consultations on the grant of a non-exclusive license.

(2) If no agreement is reached or no consultation is possible under the preceding subsection, a person who intends to work the patented invention may request the Minister for International Trade and Industry for an arbitration decision.

- New Zealand
 - Section 46 of the Patent Act regarding Compulsory licenses.
- Philippines
 - Philippine Intellectual Property Code - Part Two. [Republic Act No. 8293] Chapter X concerns compulsory licensing.
 - February 24, 1997, the International Intellectual Property Alliance (IIPA) Special 301 Recommendations, to the USTR, which mention the Philippines compulsory reprint license for books.
- People's Republic of China
 - Compulsory licensing provisions in patent law.
- Taiwan, R.O.C.
 - Patent Laws.. See Section five, Article 78-83 for provisions on compulsory licensing. The compulsory license is available for "national emergency," "promoting the public welfare," or when a person cannot obtain a license for "reasonable commercial terms and conditions." The non-transferable compulsory licenses are "restricted to supply largely the need of the domestic market," and shall pay "adequate compensation of the patentee."
 - Amended Articles of the Patent Law in Taiwan, includes provisions regarding compulsory licensing of patents.
 - TIPLO's discription of changes in Taiwan patent law. Apparently one area of controversey concerns semi conductors.
- Thailand
 - The Thailand Board of Investment provides this description of Thai laws regarding patents and other intellectual property. The Thai Act provides as one ground for compulsory license:

[If] for no legitimate reason, there is no sale of the product produced under the patented process or there are sales of the same at unreasonably high prices or such sales do not meet the public demand."

The US government is seeking a repeal of Thai legal authority to use compulsory licenses for pharmaceuticals.

- Notes from Thai public health groups
 - August 26, 1998, Thailand and TRIPS - info for campaign.
 - Thai Movement on Drug Patent, September 9, 1998
- Articles from English Language Thai newspapers
 - September 4, 1998, The Nation, Group seeks legislation making drugs affordable to those in need.
 - September 4, 1998, Aphaluck Bhatiasavi, in the Bangkok Post, Activists step up pressure to defeat patent law amendment: Protest outside US embassy planned.
 - September 5, 1998, Anjira Assavanonda, in the Bangkok Post, NGOs rally against patent law changes: Call on US to stop pressuring Thailand.
 - January 23, 1999, Aphaluck Bhatiasavi, in teh Bangkok Post, Access to anti-Aids drugs to remain hard: Essential Drug List won't help patients.
- Vietnam
 - According to Arnold (1993), compulsory licesnes may be issued for the "prevention and treatment of human disease and other vital public interests."
- India
 - One person wrote to quote an unname document that said this about the Patent Law of 1970 (now being revised):

Compulsory licenses can be granted by the Controller General of Patents on application by a person interested in working the patent upon his satisfaction, after hearing both the parties (the applicant and the patent holder), that "the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not available to the public at a reasonable price". The term "reasonable requirements of the public" generally refers to the adequacy of the availability, on reasonable terms, of the product in the country through manufacture, import or other forms of commercial exploitation. The term is also applied when other commercial or industrial activities are impeded as a result of the patent not being worked or because of the conditions attached to the grant of licence. However, in practice, compulsory licensing is rarely invoked."

- Russia and Eastern Europe

- Russia

- Russian Patent Law provisions on compulsory licensing.

- Hungary

- Hungary's law on the Protection of Inventions by Patents. The compulsory licensing provisions are Chapter IV.

- Slovenia

- Slovenian compulsory licenses to patents may be granted if:

If an invention is in the public interest or if the patentee misuses the rights granted by a patent as described in Article 32 of this Law, a compulsory license for the use of the invention may be granted to another person.

*It shall be deemed that a misuse . . . takes place particularly when the patentee, either himself or through a third party, does not work or insufficiently works a patented invention and refuses to license other persons to work the protected invention or **imposes unjustified conditions on them.***

- Croatia

- According to Arnold (1993), "An official license may be granted if the patented invention is of general social interest. . . compulsory licenses may also be granted on patented inventions that are used to achieve unreasonably high prices on the Croatian market.

- Lithuania

- Provisions on compulsory licenses of patents. In addition to non-working, there is a provision for "state or public interests."

- Bulgaria

- Patent Laws. Article 32 is for compulsory licenses.

- Middle East

- Israel

- October 1997, Michael Cohen, Compulsory Licence for the Manufacture of a Hepatitis B Vaccine: Exploitation of the Invention for R&D Prior to Compulsory Licence Proceedings in Israel, from Patent World.

- December 30, 1997, Nechama Goldman Between a patent and a hard place. This article discusses the dispute over Teva's rights to use patents for research purposes prior to the expiration of the patent. Because Israel did not have a Bolar exemption at the time, Teva received compulsory licenses. Michael Cohen is quoted, and the report also says Dr. Cohen's firm represents Ciba Geigy, Merck, and Hoffman LaRoche in patent

disputes.

- Egypt
 - US government report which complains about Egyptian laws on compulsory licensing of patents.
 - Patent Law in Egypt. Section IV covers compulsory licenses.
- Jordan
 - Patent laws of Jordan. Article 22 covers compulsory licenses.
- Africa
 - Botswana
 - 1997, Ladas and Parry Newsletter, indicate that the New Industrial Property Act in Botswana provides compulsory licensing of patents, consistent with the Paris Convention. The article also notes that Botswana provides patent exceptions for: *discoveries, scientific theories, mathematical methods, aesthetic works, schemes, rules or methods for doing business, performing a mental act or playing a game, programs for computers, methods for treatment of the human body or animal body by surgery and diagnostic methods practiced on the human body.*
- Canada
 - March 1997, Drug Patent Protection, Compulsory Licensing, and International Trade Law. This is from the March 1997, Volume 1 Newsletter for "Senior's Voice," which is published by a group of non-profit seniors organizations, mostly in Saskatchewan.
 - November 1996, Joel Lexchin, M.D., BILL C-91 coming up for review: Drug firms wallowing in profits -- but they want more, from The CCPA Monitor. See also: Lexchin J. Pharmaceuticals, patents and politics: Canada and Bill C-22. *International Journal of Health Services* 1993;23:147-60, and Lexchin J. After compulsory licensing: coming issues in Canadian pharmaceutical policy and politics. *Health Policy* 1997;40:69-80.

Note: References to Arnold (1993) are Gianna Julian Arnold, "International Compulsory Licensing: The Rationales and the Reality," 33 IDEA: the Journal of Law and Technology, 349, 372 Appendix A, A Survey of Non Working and Compulsory Licensing Provisions Existing in Various Countries.

Suggestions or corrections to James Love, love@cptech.org

[CPT home page](#) **[CPT Intellectual Property page](#)** **[CPT on IP and Health Care](#)**

Subject: fwd: Africa: Debt/HIV-AIDS Proposal

Date: Fri, 28 May 1999 12:23:54 -0400

From: "David Cohn" <dcohn@usaid.gov>

To: <AROSS@AFR-SD.ORG>, <"internet[IHUSAIN@AFR-SD.ORG]"@usaid.gov>

FYI

Original Text

From: Meredith Scovill@AFR.SA@AIDW, on 05/28/1999 9:46 AM:

To: dcohn@AFR.SA@AIDW, William A. Jeffers@AFR.SA@AIDW

You need to scroll past all the internet addresses until it gets to AIDS in Zambia. Meredith

From: Dana Ott@AFR.SD@AIDW, on 05/28/1999 8:22 AM:

To: Meredith Scovill@AFR.SA@AIDW, Robert Groelsema@AFR.SD@AIDW,
smtp@barrb0204@servers[lpeterso@rrs.cdte.org], William Lysterly@AFR.SD@AIDW

fyi....

AFR/SD/DG

East Africa Backstop

(202) 712-5883

dott@usaid.gov

From: <apic@igc.org>, on 05/26/1999 11:23 PM:

To: internet[<apic@igc.org>]

Africa: Debt/HIV-AIDS Proposal

Date distributed (ymd): 990526

Document reposted by APIC

+++++Document Profile+++++

Region: Continent-Wide

Issue Areas: +economy/development+ +US policy focus+

Summary Contents:

This posting contains a summary of a new Zambian proposal for debt reduction, with funds going to support a new national HIV/AIDS initiative. The summary comes from the AF-AIDS on-line discussion list. The posting also contains brief excerpts and a link to a May 24, 1999 San Francisco Chronicle article reporting the conflict between U.S. trade policy and efforts to make HIV/AIDS drugs more affordable to African countries.

+++++end profile+++++

Africa Policy Web Site Announcement

Coming June 1-15:

Africa Policy West Coast On-line Poll on Economy and Development. Watch for it on <http://www.africapolicy.org> and in your mailbox. This poll will be open to anyone resident in one of the nine states of Alaska, Arizona, California, Hawaii, Idaho, Nevada, Oregon, Utah, and Washington, states included by the National Summit on Africa in planning for the West Coast Regional Summit in San Francisco on June 4-5, 1999

(www.africasummit.org/west/westhome.htm)

In the meantime check out the new theme pages on
<http://www.africapolicy.org>:

Economy and Development
(<http://www.africapolicy.org/docs99/econ.shtml>)

Democracy and Human Rights
(<http://www.africapolicy.org/docs99/pol.shtml>)

Peace and Security
(<http://www.africapolicy.org/docs99/peace.shtml>)

Plus

Starting Points for Education in and about Africa
(<http://www.africapolicy.org/featdocs/educ.htm>), with new
links to resources for K-12 as well as university-level
education

From: AF-AIDS <af-aids@hivnet.ch>
To: af-aids@hivnet.ch <af-aids@hivnet.ch>
Date: Thursday, May 20, 1999 7:12 AM Subject: [200] Zambia :
"Debt for development agreement" to combat HIV-AIDS

Moderator's note : The Zambian Government aims to exchange
international debt servicing costs (i.e., interest on
debts/loans) for funds to support the national HIV/AIDS
response. This is a novel strategy that may also have
implications for other countries of the region.

The following is a summary of the Zambian strategy. A full
description will be made available through the AF-AIDS forum
on 28 May, once it has been presented formally to
international creditors at the Paris Club meeting next week.

If other countries are also considering or discussing such
mechanisms, please let this forum know.

ACCELERATING ACTION to COMBAT the HIV-AIDS EPIDEMIC in ZAMBIA
using a MULTIDONOR 'DEBT for DEVELOPMENT' AGREEMENT
(Briefing Memo as of 16 May 1999)

GOAL

To support an expanded multisectoral response to the Zambia
HIV-AIDS pandemic to scale-up the delivery of effective
interventions by Government, NGOs, and the private sector.

CONTEXT

Devastation of HIV-AIDS in Zambia

Zambia has one of worst HIV-AIDS pandemics in the World, with
an estimated 20% of the adult population HIV-positive.
AIDS-related deaths are rapidly escalating, and expected to
peak in 2005. Life expectancy is plummeting, with the average
Zambian lifespan dropping from 54 years to 37 years. The

pandemic is also leading to an unprecedented AIDS orphan crisis, with an estimated 1, 000,000 orphans by the year 2000, representing approximately 10% of the total population of Zambia. A secondary tuberculosis pandemic is also debilitating the economically productive work force. Historic improvements in child survival are also being lost in the specter of HIV-AIDS. In summary, the Zambia HIV-AIDS pandemic seriously threatens the country's prospects for sustainable economic development as it depletes the country's most educated, energetic, and productive population.

Zambian Response

To combat this crisis, President FJT Chiluba announced in March 1999, a new commitment to rapidly expand the national response with a war against AIDS when he said, "We must all unite in the fight against AIDS." The Government of the Republic of Zambia (GRZ) is in the final stages of planning for the implementation of a new National HIV-AIDS Council and an HIV-AIDS Secretariat which has been designed to support an expanded multisectoral response.

Debt Burden Hinders Effective Response

A major factor hindering an effective HIV-AIDS response in Zambia response is the macroeconomic situation and the unsustainable debt burden. During 1998, the real gross domestic productivity (GDP) per capita is estimated to have declined by 5%. Inflation rose from 18.6 percent at the end of 1997 to 30.6 percent at the end of 1998. Interest rates rose sharply while the Kwacha depreciated rapidly. These factors led to tight fiscal constraint as revenues were below targets, while expenditure pressures increased. The 1998 GRZ debt servicing obligations of \$123 million paid to the Paris Club Members and the multilateral institutions was equivalent to 69% of the amount budgeted by the GRZ from its own resources for the social sectors. For example, District Health Boards only received 30% of their expected budget in 1998, therefore they were unable to effectively implement HIV-AIDS prevention and control activities, TB control, or control of sexually-transmitted infections. The GRZ currently has no formal mechanism for providing financial support to civil society NGOs that are at the front lines in the battle against HIV-AIDS. The debt burden severely compromises the ability of GRZ and the civil NGO sector to effectively respond to the HIV-AIDS crisis.

DECLARING WAR ON HIV-AIDS BY SCALING-UP RESPONSE

Accelerating Action Through a Multidonor 'Debt for Development' Agreement

The GRZ is in the final stages of developing a proposal for "Accelerating Action Against the Zambia HIV-AIDS Pandemic Using a Multidonor 'Debt for Development' Agreement." This proposal will be presented to bilateral and multilateral cooperating partners during the May 26-28, 1999 Consultative Group Meeting in Paris. To accelerate the Zambia development process, by accelerating the national response to the HIV-AIDS pandemic, a multidonor 'Debt for Development' Agreement is proposed. This agreement is based on the following

implementation steps:

Plans of Action:

Government of the Republic of Zambia (GRZ) and non-governmental organizations (NGOs) finalize HIV-AIDS Response Plans of Action (GRZ Ministries and NGO Response Plans). These plans will include a multiple year strategic plan, budget, and a monitoring and evaluation framework;

HIV-AIDS Response Fund:

GRZ establishes a "HIV-AIDS Response Fund" to receive agreed upon resources from creditors. The implementation of this fund shifts resources towards supplementary domestic investment in the national HIV-AIDS response. Actual GRZ and NGO expenditures will serve as the baseline for monitoring supplementary investments in the HIV-AIDS response;

Performance Milestones:

The "HIV-AIDS 'Debt for Development' Agreement" will be based on agreed upon performance milestones that support the implementation of the Zambia HIV-AIDS Plan of Actions. Performance milestones will be developed to establish targets for legal, policy, technical performance, and people-level impact, as well as, the establishment and implementation of systems of financial accountability;

The development phase of the Zambia HIV-AIDS 'Debt for Development' is driven by an unprecedented positive response from the people of Zambia. As the full impact of the AIDS pandemic is affecting all Zambians, the HIV-AIDS 'Debt for Development' Agreement is providing a "ray of hope" in an otherwise desperately fatalistic environment.

Options for Creditors

Bilateral and multilateral cooperating partners will have different options for channeling resources into the "HIV-AIDS Response Fund." These include, but are not limited to:

Debt Servicing Swap: so that principle and interest due to creditor countries would be paid into the HIV-AIDS Response Fund instead of to creditor countries;

Moratorium of Debt Servicing: creditor have the option of issuing a moratorium on debt servicing which would defer debt servicing obligations (principle and interest) into the HIV-AIDS Response Fund;

Debt for Development Mechanisms: creditor can transfer debt obligations into the HIV-AIDS Response Fund;

Direct Contributions: creditor countries and multilateral institutions could provide direct contributions to the HIV-AIDS Response Fund as part of their overall assistance to the GRZ.

ORGANIZING FOR ACTION

Task Force for the Multidonor 'Debt for Development' Agreement to Accelerate Action to Combat the Zambia HIV-AIDS Pandemic

The GRZ has formed an Interagency Task Force to support the development, implementation, and monitoring of the multidonor HIV-AIDS 'Debt for Development' Agreement.

GRZ Institutional Oversight

The GRZ is in the final phase of establishing a National HIV-AIDS Council and a National HIV-AIDS Secretariat which is charged with the responsibility of coordinating a multisectoral response to the HIV-AIDS pandemic. The National HIV-AIDS Council and Secretariat are the proposed GRZ institutions that will be responsible for the development, implementation, and monitoring of the proposed HIV-AIDS Multidonor 'Debt for Development' Agreement. The National HIV-AIDS Council and Secretariat would make recommendations on funding priorities to be supported by the HIV-AIDS Response Fund.

GRZ-Cooperating Partners HIV-AIDS Response Fund Steering Committee

A joint "GRZ-Cooperating Partners HIV-AIDS Response Fund Steering Committee" would be formed from various interest groups, such as Government, Cooperating Partners (including creditor countries and multilateral agencies, NGOs and other interest groups. The Steering Committee would make final decisions on resource allocation disbursements, monitor the performance of the implementation institutions against the agreed upon milestones. The National HIV-AIDS Secretariat would be responsible for managing the proposed "GRZ-Cooperating Partners HIV-AIDS Response Fund Steering Committee."

ACTION PLAN

1. GRZ will present initial HIV-AIDS 'Debt for Development' Proposal to Creditors Target date for Action: May 30, 1999
2. Finalization of "HIV-AIDS 'Debt for Development' Agreement with Creditors Target date for Action: August 30, 1999
3. GRZ and Participating Creditors Signing Ceremony at the XIth ICASA Target date for Action: September 12-16, 1999
4. GRZ finalizes negotiations with Participating Creditors Target date for Action: September -December 1999
5. HIV-AIDS Response Fund Established and Accelerated HIV-AIDS Response Launched Target date for Action: January 2000

Support for this Initiative is actively under discussion among UN Agencies, US government officials, and other creditors.

This document was made available to AF-AIDS by:

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- A posting from af-aids@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/af-aids/tdm>

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

Brief Excerpts from

"New Crusade To Lower AIDS Drug Costs;
Africa's needs at odds with firms' profit motive"
San Francisco Chronicle, May 24, 1999
by Sabin Russell, Chronicle Staff Writer

<http://www.sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/1999/05/24/MN104738.DTL> [type URL on one line]

The problem is this: At Western market prices of \$1,000 a month, the multidrug therapies are hopelessly out of reach in the very countries hit hardest by the epidemic -- in African and other developing nations where 90 percent of AIDS cases occur. ...

But the quest to flood Africa with cheap AIDS drugs has run headlong into conflict with American trade policy. High level Clinton administration officials are blocking attempts to tamper with AIDS drug patents, saying that they undermine the entire system of intellectual property protection that encourages businesses to find new drugs.

One of the best examples of this new front in the battle over AIDS drugs is South Africa, where a recently enacted law would override pharmaceutical company patents and allow "gray market" imports of cheap drugs from other countries.

Prescription drug prices vary dramatically from country to country, based on deals cut by the manufacturer. The antibiotic Amoxicillin, for example, costs 50 cents a pill in Johannesburg, 4 cents in Zimbabwe. The South African law would let the country pursue the lowest cost drugs on the world market.

But court challenges have delayed the law's being put into

effect. Also, U.S. officials are threatening trade sanctions. One State Department memo to Congress boasted of a "full court press" involving the Vice President Al Gore, Commerce Secretary William Daley and four U.S. agencies to change the "offending" law. ...

Veteran AIDS activists are angry. The Clinton administration, they charge, seems content to let multinational drug companies set American trade policy ...

Drug companies have all but ignored markets in Africa. Less than 1 percent of AIDS drugs are sold in African nations south of the Sahara Desert, where 70 percent of new HIV infections and 90 percent of all AIDS deaths occur. Some 11.5 million people in sub-Saharan Africa have died of AIDS since the epidemic began.

Dr. Ian Roberts, special adviser to the South African Health Ministry, said the United States is showing little understanding of his country's public health catastrophe.

"Medicines to treat HIV/AIDS are far too highly priced for the mass of our people," he said. "With up to 16 percent of our people already HIV positive, this can be seen as a national disaster."

Despite South Africa's gold and diamond mines, most of its people remain poor, with an average annual income of \$2,600. "Clearly, we cannot afford retrovirals at a cost of \$1,000 per month," said Roberts.

South Africa has emerged from the shadow of apartheid only to become a major center of the AIDS epidemic. An estimated 3.2 million South Africans are infected by the virus, including 45 percent of the nation's military personnel. Most of those infected are poor and black. ...

In a sharply worded letter to Gore, who chairs a commission on South African trade, [consumer advocate Ralph] Nader accused the United States of abusing its superpower status: "You have engaged in an astonishing array of bullying tactics to prevent South Africa from implementing policies . . . designed to expand access to HIV/AIDS drugs."

Nader's Consumer Project on Technology advocates two steps -- both of them legal under international law -- by which poor countries can slash the cost of AIDS drugs.

The first is for poor countries to issue "compulsory licenses," granting rights to make copies of patented drugs without the approval of the patent holder. Compulsory licenses are permitted in health emergencies under international trade agreements.

The second step is to allow countries to shop around on the international market for AIDS drugs and import the cheapest available. Forbidden in the United States, such "parallel market" or "gray market" purchases are routinely permitted in Europe. ...

But the pharmaceutical industry and the Clinton administration

take the view that compulsory licenses and gray markets pose a threat to the entire system of intellectual property protection. ...

Experts in the international AIDS crisis agree that merely lowering the price of AIDS drugs will not solve the problem, and potentially could make the epidemic worse.

"If you spread anti-HIV drugs in a population, but not in sufficient quantities, you ... could make people sicker, rather than better, and increase the possibility for development of drug-resistant HIV strains," said Tom Coates, executive director of the University of California at San Francisco AIDS Research Institute.

Coates said the limited money available to fight AIDS in Africa would save the most lives if it were directed at prevention first. Most African nations do not even have funds to pay for testing of the blood supply, and in 1997, only \$650 million was spent on all African AIDS programs. "If, as UNAIDS (the Joint United Nations Programme on HIV/AIDS) has suggested, we raised spending to \$2.5 billion, we could prevent half the HIV infections from occurring," Coates said.

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A human rights perspective on HIV/AIDS in sub-Saharan Africa

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Introduction

Awareness of the fundamental connection between HIV and human rights has led to increasing collaboration between public health officials and human rights workers. In sub-Saharan Africa, those concerned with HIV/AIDS prevention and control initially became interested in human rights because they recognized that discrimination against HIV-infected people and people with AIDS was counterproductive to the effectiveness of public health prevention efforts [1,2]. Interest expanded because of increasing recognition that lack of respect for human rights and dignity at the personal and society levels was closely linked to individual and collective vulnerability to HIV/AIDS [3]. Prevention of HIV transmission, as well as good care for people with HIV/AIDS, requires rectifying the adverse impact of discrimination toward groups considered vulnerable to HIV/AIDS, including women, racial, ethnic, linguistic and sexual minorities, people with disabilities and economically disadvantaged groups [4].

There has been an intense debate, that sometimes continues, about the measures most useful for responding to the AIDS pandemic. For example, tensions remain between those who emphasize protection of the public health in the traditional sense, and thus the restriction of rights of certain individuals considered 'dangerous', and those who advocate a minimum amount of interference with the lives of individuals. Policy makers often have to reconcile these conflicting concerns and, although the importance of full recognition of human rights as an integral part of HIV/AIDS policies and programs is increasingly acknowledged, numerous actions by governments reinforce existing patterns of discrimination and clearly violate human rights norms [5,6].

HIV/AIDS has an increasing impact on the lives of adults and children in sub-Saharan Africa [7]. As HIV/AIDS takes its toll on the physical, mental and social well-being

of individuals, one can see the force of the pandemic where everyone in the region is concerned in one or several ways by the HIV/AIDS epidemics. Women, men and children may be infected, affected or vulnerable to HIV/AIDS. People infected with HIV continue to face marginalization and discrimination, as well as violations of many of their rights relating to health, education and social services, including inadequate or inaccessible health services, treatment, education and social programs [8]. People are affected by HIV/AIDS in that their close or extended families, their communities and, more broadly, the structures and services which exist for their benefit are strained by the consequences of the HIV/AIDS pandemic. For example, systems that are already poor in resources are affected not only by the loss of health professionals but by the overwhelming magnitude of the burden of HIV/AIDS on health-care systems [9-11]. One of the most devastating impacts is, of course, on children when their immediate family environment and support system is challenged by the sickness, disability and premature death from AIDS of one or both of their parents [12-14]. Vulnerability to HIV/AIDS concerns the extent to which individuals are born, grow and become sexually active in a world which has added the risk of acquiring HIV infection to their lives. The specific vulnerability of young people is reflected by the fact that the majority of new infections occur in this age group. In addition, in many societies, the unequal role of women and their social status makes them unable to refuse unwanted or unprotected sexual intercourse, thereby increasing their vulnerability to HIV [15-17]. In sub-Saharan Africa in particular, low intensity and open conflicts, massive refugee flows, migration, population displacement, and austere circumstances also contribute to the vulnerability of individuals to the HIV/AIDS pandemic [18-20].

Here we attempt to set out some of the major concepts relevant to human rights thinking and practice in sub-Saharan Africa, to call attention to official documents

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relevant to these concepts and to provide a perspective for protecting human rights in the context of HIV/AIDS in the region. Human rights law offers an approach for negotiating differing perceptions of public and private 'good' in an effort to secure a safe and healthy environment for all individuals. Our initial discussion of human rights law will, by necessity, focus on the recognized international framework as it sets out standards equally applicable to countries in all regions and at all stages of development.

Human rights law is concerned with the obligations of governments to ensure the conditions that make life as humane as possible. The focus is generally on the relationship between the individual and the state, and includes civil, political, economic, social and cultural rights which human beings everywhere are entitled to enjoy. States are responsible for not violating our rights directly as well as for ensuring the conditions which enable us to realize our rights as fully as possible. This is understood as an obligation on the part of governments to respect, protect and fulfill rights. For example, a government violates its responsibility to respect the right to education when children are barred from attending school on the basis of their HIV status [21]. A government's responsibility to protect rights includes making it illegal to deny housing or employment to people on the basis of their HIV status, as well as offering some means of redress should such a situation arise [22,23]. The obligation to fulfill is violated when States do not take appropriate legislative, administrative, budgetary, judicial or other measures towards full realization of rights, for example, if a State fails to develop a national HIV/AIDS prevention and care strategy realistically targeted to the needs of the population, including marginalized populations.

A major human rights problem in the context of HIV/AIDS involves discrimination against those known or perceived to be infected and those affected by HIV/AIDS, as well as discrimination leading to denial of access to entitlements and services, resulting in increased vulnerability to HIV/AIDS [24,25]. Each of the major human rights treaties specifically sets out the principle of non-discrimination with respect to certain categories such as race, color, sex, language, political or other opinion, national or social origin, property, birth and, as it is called, 'other status'. Adverse discrimination ensues when a distinction is made against a person which results in their being treated unfairly and unjustly on the basis of their belonging, or being perceived to belong, to one of these categories. The principle of non-discrimination is central to human rights thinking and practice. The prohibition of discrimination does not mean that differences should not be acknowledged, only that different treatment must be based on reasonable and objective criteria [26].

Most human rights are not absolute. Governments can justify interference with most rights if necessary for an overriding public good. Public health is recognized as an

overriding public good and is therefore considered a legitimate ground for restricting human rights. Nonetheless, interferences with human rights are only considered acceptable under narrowly defined circumstances. Any interference with the enjoyment of rights must be: provided for and carried out in accordance with the law; in the interest of a legitimate objective of general interest; strictly necessary in a democratic society to achieve such a goal; imposed without a less intrusive means being available to reach the same goal; and not imposed arbitrarily, in other words in an unreasonable or otherwise discriminatory manner [27].

In the context of HIV/AIDS, legitimate interferences with human rights can only occur in very exceptional circumstances. Interferences with the rights of individuals, even if they are justified as necessary to protect the public health, must be recognized as human rights violations if they do not satisfy the criteria for valid restrictions on rights.

The United Nations (UN) Charter establishes general obligations that apply to all its member states, including respect for human rights and dignity [28]. Under the auspices of the UN, more than 20 multilateral human rights treaties exist which create legally binding obligations on the nations that have ratified them [29,30]. In addition, the Organization of African Unity has put into place its own regional human rights treaty which is open for signature and ratification to all countries in Africa [29,30]. A chart detailing the status of human rights commitments by the nations of sub-Saharan Africa is given in Table 1.

HIV/AIDS policies and human rights

The international response to HIV/AIDS has acknowledged the importance of protecting human rights from the very beginning. Starting in 1987, the World Health Organization (WHO) Global Programme on AIDS incorporated human rights concerns into its global AIDS strategy and its guidelines on a range of issues including testing, travel and immigration policies, blood safety, prison health, mother-to-child transmission and employment. A selected chronology of international and regional documents mentioned here and relevant to the human rights aspects of HIV/AIDS appears in Table 2.

By 1990, every country in the African region had a National AIDS Program (NAP) in place [31]. The focus of every NAP was on prevention, and human rights issues were given some attention in program design, notably with respect to issues concerning privacy and freedom of movement. As the impact of HIV on the lives of individuals put increasing demands on health systems in countries throughout the continent, the lack of attention to care and support for HIV-infected people became apparent [32]. The need to devise programs that include strategies for the care of HIV-infected people became

Table 1. Status of human rights commitments in sub-Saharan Africa by country.

Country	A	B	C	D	E	F	G	H
Angola	1990	1992	1992	–	1990	1986	–	1981
Benin	1986	1992	1992	1967 (s)	1990	1992	1992	1962 (d)
Botswana	1986	–	–	1974	1993	1996	–	1969
Burkina Faso	1984	–	–	1974	1990	1987	–	1980
Burundi	1989	1990	1990	1977	1990	1992	1993	1963
Cameroon	1989	1984	1984	1971	1993	1994	1986	1961 (d)
Cape Verde	1987	1993	1993	1979	1992	1980	1992	–
Central African Republic	1986	1981	1981	1971	1992	1991	–	1962 (d)
Chad	1986	1995	1995	1977	1990	1995	1995	1981
Comoros	1986	–	–	–	1993	1994	–	–
Congo	1982	1983	1983	1988	1993	1982	–	1962 (d)
Côte d'Ivoire	1992	1992	1992	1973	1991	1995	1995	1961 (d)
Djibouti	1991	–	–	–	1990	–	–	1977 (d)
Equatorial Guinea	1986	1987	1987	–	1992	1984	–	1986
Eritrea	–	–	–	–	1994	1995	–	–
Ethiopia	–	1993	1993	1976	1991	1981	1994	1969
Gabon	1986	1983	1983	1980	1994	1983	1986 (s)	1964
Gambia	1983	1978	1979	1978	1990	1993	1985 (s)	1966 (d)
Ghana	1989	–	–	1966	1990	1986	–	1993
Guinea	1982	1978	1978	1977	1990	1982	1989	1965 (d)
Guinea-Bissau	1985	1992	–	–	1990	1985	–	1976
Kenya	1992	1972	1972	–	1990	1984	1997	1966
Lesotho	1992	1992	1992	1971	1992	1995	–	1981
Liberia	1982	1967 (s)	1967 (s)	1976	1993	1984	–	1964
Madagascar	1992	1971	1971	1969	1991	1989	–	1967
Malawi	1989	1993	1993	1996	1991	1987	1996	1987
Mali	1981	1974	1974	1974	1990	1985	–	1973 (d)
Mauritania	1986	–	–	1988	1991	–	–	1987
Mauritius	1992	1973	1973	1972	1990	1984	1992	–
Mozambique	1989	–	1993	1983	1994	1997	–	1983
Namibia	1992	1994	1994	1982	1990	1992	1994	1995
Niger	1986	1986	1986	1967	–	–	–	1961 (d)
Nigeria	1983	1993	1993	1967	1991	1985	1988 (s)	1967
Rwanda	1983	1975	1975	1975	1991	1981	–	1980
Sao Tome & Principe	1986	1995(s)	1995(s)	–	1991	1995 (s)	–	1978
Senegal	1982	1978	1978	1972	1990	1985	1986	1963 (d)
Seychelles	1992	1992	1992	1978	1990	1992	1992	1980
Sierra Leone	1983	1996	1996	1967	1990	1988	1985 (s)	1981
Somalia	1985	1990	1990	1975	–	–	1990	1978
South Africa	1995 (s)	1994(s)	1994(s)	1994 (s)	1995	1995	1993 (s)	1996
Sudan	1986	1986	1986	1977	1995	–	1986 (s)	1974
Swaziland	–	–	–	1969	1995	–	–	–
Togo	1982	1984	1984	1972	1990	1983	1987	1962 (d)
United Rep. of Tanzania	1984	1976	1976	1972	1991	1985	–	1964
Uganda	1986	1987	1995	1980	1990	1985	1986	1976
Zaire	1987	1976	1976	1976	1990	1986	1996	1985
Zambia	1984	1984	1984	1972	1991	1985	–	1969 (d)
Zimbabwe	1986	1991	1991	1991	1990	1991	–	1981

A. The African Charter on Human and People's Rights; B. International Covenant on Economic, Social and Cultural Rights; C. International Covenant on Civil and Political Rights; D. International Convention on the Elimination of All Forms of Racial Discrimination; E. Convention on the Rights of the Child; F. Convention on the Elimination of All Forms of Discrimination Against Women; G. Convention Against Torture and other Cruel, Inhuman or Degrading Treatment or Punishment; H. Convention relating to the Status of Refugees. Year given is ratification date. –, Not listed as having signed or ratified; (s), signature date; (d), succession date.

Table 2. Chronology of selected international and regional documents relevant to the human rights aspects of HIV/AIDS in Africa

Year	Document
Regional	
1990	Ethical and Social Aspects of AIDS in Africa, a background paper for a meeting of Representatives of Member States, Lusaka, Zambia, 4-6 June 1990.
1990	Maputo Statement on HIV and AIDS in Southern Africa, Fourth International Conference on Health in Southern Africa, Maputo, Mozambique, April 1990
1992	Declaration on the AIDS Epidemic in Africa, Organization of African Unity, Dakar, Senegal, 1992.
1994	Tunis Declaration on AIDS and the Child in Africa, Organization of African Unity, Tunis, Tunisia, 13-15 June 1994, AHG/Dec. 1.
1994	Proceedings of the Intercountry Consultation, African Network on Ethics, Law and HIV, UNDP, Dakar, Senegal, 27 June-1 July 1994
1994	Dakar Declaration, African Network on Ethics, Law and HIV, Dakar, Senegal, 1 July 1994.
1995	Brazzaville Declaration, 'Rights, Responsibilities and Principles for Action in the Response to the HIV Pandemic', Brazzaville, 2 December 1995
1996	'Newsletter of the African Network on Ethics, Law and HIV', No. 1, June 1996, No. 2 December 1996, UNDP Regional Project on HIV and Development, Dakar, Senegal.
Global	
1987	WHO Consultation on International Travel and HIV Infection (Doc. WHO/SPA/CLO/87.1).
1987	Global Strategy of the Prevention and Control of AIDS (Res. WHA40.26).
1988	WHO Meeting on HIV Infection and Drug Injecting Intervention Strategies (Doc. WHO/GPA/SBR/89.1).
1988	Avoidance of Discrimination in Relation to HIV-infected People and People with AIDS (Res. WHA41.24).
1988	Discrimination Against Persons with the HIV Virus or Suffering from AIDS (Decision 1988/111 of the Sub-Commission for Prevention of Discrimination and Protection of Minorities)
1989	Heterosexual Transmission of HIV and Certain Common Social Situations (Doc. WHO/GPA/INF/89.5).
1989	Consensus Statement of WHO Consultation on Partner Notification for Preventing HIV Transmission (Doc. WHO/GPA/INF/89.3).
1989	Non-discrimination in the Field of Health (United Nations Commission on Human Rights, res. 1989/11).
1989	Final Document of the International Consultation on AIDS and Human Rights (UN Doc. HR/AIDS/1989/3)
1989	Discrimination Against HIV-infected People or People with AIDS (Sub-Commission on the Prevention of Discrimination and Protection of Minorities, res. 1989/13).
1989	Prevention and Control of Acquired Immunodeficiency Syndrome (AIDS) (UNGA res. 44/2.13)
1990	Avoidance of Discrimination Against Women in National Strategies for the Prevention and Control of AIDS (CEDAW, General Recommendation No. 15)
1990	Discrimination Against HIV-infected People or People with AIDS (United Nations Commission on Human Rights, decision 1990/65).
1990	<i>Note verbale</i> of the WHO Director General referring to Avoidance of Discrimination in National AIDS programs Worldwide (Doc. C.L.7.1990).
1990	Preliminary Report on Discrimination Against HIV-Infected People and People with AIDS, from the Special Rapporteur of the Sub-Commission on the Prevention of Discrimination and Protection of Minorities (E/CN.4/Sub.2/1990/9).
1991	Progress Report on Discrimination Against HIV-Infected People and People with AIDS, from the Special Rapporteur of the Sub-Commission on the Prevention of Discrimination and Protection of Minorities (E/CN.4/Sub.2/1991/9).
1992	Rights and Humanity Declaration and Charter on HIV and AIDS, submitted by the Gambian government to the Commission on Human Rights at its 48th session (E/CN.4/1992/82).
1992	Final Report on Discrimination Against HIV-Infected People and People with AIDS, from the Special Rapporteur of the Sub-Commission on the Prevention of Discrimination and Protection of Minorities (E/CN.4/Sub.2/1992/10).
1993	Conclusions and Recommendations from the Special Rapporteur on Discrimination Against HIV-Infected People or People with AIDS, Sub-Commission on the Prevention of Discrimination and Protection of Minorities (E/CN.4/Sub.2/1993/9).
1993	Decision on The Protection of Human Rights in the Context of HIV or AIDS, United Nations Commission on Human Rights (E/CN.4/1993/L.7.4)
1993	Discrimination in the Context of HIV or AIDS, United Nations Sub-Commission on the Prevention of Discrimination and Protection of Minorities (E/CN.4/Sub.2/1993/L.11/Add.2).
1994	The Protection of Human Rights in the Context of HIV and AIDS, United Nations Commission on Human Rights (E/CN.4/1994/L.60).
1994	Discrimination in the Context of HIV or AIDS, United Nations Sub-Commission on the Prevention of Discrimination and Protection of Minorities (E/CN.4/Sub.2/1994/L.29/Add.2).
1994	United Nations, Report of the International Conference on Population and Development and Various Recommendations of the World Health Organization, Cairo, 1994 (UN Doc. A/Conf.171/13)
1994	Declaration of the Paris AIDS Summit of Heads of Government or Representatives Paris, 1994.
1995	United Nations, Report of the World Summit for Social Development, Copenhagen, 1995 (UN Doc. A/Conf.166/9 (1995)).
1995	The Protection of Human Rights in the Context of HIV and AIDS, United Nations Commission on Human Rights (E/CN.4/1995/44).
1995	Discrimination in the Context of HIV or AIDS, United Nations Sub-Commission on the Prevention of Discrimination and Protection of Minorities (E/CN.4/Sub.2/1994/L.21/Add.2).
1995	Beijing Declaration and Platform for Action, Fourth World Conference on Women, Beijing, China, 15 October 1995 (UN Doc. A/CONF.177.20).
1996	Report of the Secretary General on Human Rights and HIV/AIDS (E/CN.4/1996/44, 10 January 1996).
1996	The Protection of Human Rights in the Context of HIV and AIDS, United Nations Commission on Human Rights (E/CN.4/1996/43, 19 April 1996).
1997	Report of the Secretary General on the Second International Consultation on HIV/AIDS and Human Rights (E/CN.4/1997/17).
1997	The Protection of Human Rights in the Context of HIV and AIDS, United Nations Commission on Human Rights (E/CN.4/1997/L.37, 4 April 1997).

UNDP, United Nations Development Program; WHO, World Health Organization.

progressively clearer, even though such strategies require a level of financial expenditure which might not seem immediately available or accessible [33–36]. Under the rubric of human rights law, governments have an obligation to take steps toward ensuring that those rights which require resources, such as access to health and social services, are progressively realized. This imposes an obligation on countries of the region to make efforts toward implementation of care and support strategies and, in the call for 'international assistance and co-operation' found in the relevant documents, for wealthier states to co-operate in this effort [37]. The human rights texts recognize that governments will be able to expand their actions and improve their human rights performance as resources become available, which is of extreme relevance to resource-constrained countries in Africa.

In response to the enhanced understanding of the relationship between HIV prevention, care and support at the national level, guidelines and policy statements issued by international health organizations and human rights bodies focused on the relationship between human rights protection and HIV prevention, with particular emphasis on the primacy of the non-discrimination principle. This approach has been carried forward in the work of the Joint United Nations Programme on HIV/AIDS (UNAIDS). For example, human rights are both explicitly included as an essential aspect of UNAIDS' commitment to a 'multi-faceted response to the epidemic' and set out as a 'core value and guiding principle' of the UNAIDS International Strategic Plan 1996–2000 [38]. These international standards and statements are meant to help guide work at the international, regional, national, local and community levels. They are therefore relevant to any review of human rights issues in the African region.

The gap between HIV/AIDS-related laws and practices and human rights

Governments of the region have ratified many of the human rights documents. A large number of standards concerning HIV/AIDS and human rights have been articulated at both the national and international level (Table 3). Government policies and actions relevant to HIV/AIDS, however, continue to fail to adequately protect human rights in many ways. A contradiction exists between international and national commitments and what takes place at the local level, both in terms of law and implementation. Those populations who should be able to hold their governments accountable for their commitments are often unaware of their rights, and do not demand them. Thus, few voices have been raised against restrictions imposed on those already infected with HIV or thought to be vulnerable to infection, such as migrants and sex workers.

In 1993–1994, the Global AIDS Policy Coalition conducted a survey of managers of governmental national AIDS programs (GNAP) on policies and programs forming the governmental national response to AIDS [39,40]. This is the last published survey of which we are aware which attempts to address both laws and practice relevant to human rights in the context of HIV/AIDS around the world. Questions to 187 GNAP managers focused on issues pertaining to testing policies and to restrictions based on HIV status. One hundred and sixteen responses were received in which 115 GNAP managers had completed, either partially or fully, the section pertaining to law and practice. Of these, responses were received from 31 countries in sub-Saharan Africa (Table 3).

The focus of this discussion is on the African region, although a review of reported national laws, policies and practices reveal a lack of consistent adherence to human rights standards everywhere in the world. For example, the survey found that in Africa, as in the rest of the world, involuntary testing remains part of many AIDS prevention and control programs. Governments continue to categorize individuals into 'high-risk' groups in order to impose testing as well as to restrict their activities. Categories subjected to testing include sex workers, pregnant women, prisoners, health-care workers, patients with tuberculosis, military recruits, gay/homosexual men, migrants, travelers, refugees, foreign laborers, students, nationals applying for certain forms of employment and blood donors. The choice of groups tested does not always follow the epidemiological pattern nor the dominant mode of transmission.

The responses also highlight the differences that exist between law and practice in some countries. For example, four out of the 31 sub-Saharan African countries surveyed reported that they test pregnant women, and at least another four reported that they test sex workers, although in both cases they reported no law in place which authorizes them to do so.

The compulsory testing of individuals continues to raise human rights concerns. When HIV testing is not voluntary, potential benefits associated with testing must be balanced against potential adverse consequences to the individual, and to their families, if test results become known. For example, throughout the region, in addition to violations of the right to privacy when test results are given to family members, employers and others, there continue to be reports that people known or suspected of being HIV infected are denied housing, health care, employment, scholarships and educational opportunities [39–45]. It should be noted here that much of the testing of students applying for international scholarships results from guidelines imposed by academic institutions within the receiving countries. The HIV test is often part of what is required for an international student to be accepted by

Table 3. Government national AIDS programs (GNAP), laws and practices regarding HIV/AIDS restriction and obligatory testing of specified groups (as reported by GNAP managers), 1993.

Country	Countries imposing restrictions based on HIV status						Countries practicing obligatory (compulsory and mandatory) testing of specified groups																					
	1a		1b		1c		2a		2b		2c		2d		2e		2f		2g		2h		2i		2j		2k	
	P	L	P	L	P	L	P	L	P	L	P	L	P	L	P	L	P	L	P	L	P	L	P	L	P	L	P	L
Angola	No	No	No	No	-	No	No	-	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	Yes	No	No	No
Benin	No	No	No	No	No	No	Yes	-	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	Yes	Yes	No	No
Botswana	No	No	-	Yes	No	No	No	-	No	No	No	No	No	No	No	No	No	No	No	No	No	No	-	No	Yes	No	No	No
Burkina Faso	No	No	No	No	No	No	-	-	No	No	-	No	No	No	No	No	No	No	-	-	No	No	Yes	No	Yes	No	-	No
Cameroon	No	No	No	No	No	No	No	-	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	Yes	Yes	No	No
Cape Verde	-	No	-	No	-	No	-	No	-	No	-	No	-	No	-	No	-	No	-	No	-	No	-	No	-	Yes	-	No
Chad	No	No	No	No	-	No	No	-	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
Comoros	No	No	No	No	No	No	Yes	-	No	No	Yes	No	No	No	No	No	Yes	No	Yes	No	No	No	Yes	No	Yes	No	No	No
Congo	No	No	No	No	No	No	No	-	No	No	Yes	No	No	No	No	No	No	No	Yes	No	No	No	No	No	Yes	Yes	No	No
Côte d'Ivoire	No	No	No	No	No	No	No	-	No	No	No	No	-	No	No	Yes	No	No	No	No	No	No	No	No	Yes	No	No	No
Djibouti	No	No	No	No	No	No	Yes	-	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	Yes	Yes	No	No
Ethiopia	No	No	No	No	No	No	No	-	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	Yes	No
Gabon	No	No	No	No	No	No	No	-	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	Yes	No	No	No
Ghana	No	-	-	-	No	No	-	-	-	-	-	-	-	-	-	-	-	-	No	No	No	No	No	No	No	No	No	No
Guinea	No	No	No	No	No	No	No	-	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	No	No
Guinea-Bissau	No	No	No	No	No	No	No	-	No	No	No	No	No	No	No	No	Yes	No	Yes	No	No	No	Yes	No	Yes	No	No	No
Lesotho	No	No	No	No	No	No	No	-	No	No	Yes	No	No	No	No	No	Yes	No	No	No	No	No	No	No	Yes	No	No	No
Madagascar	No	No	No	No	No	No	Yes	-	Yes	-	Yes	No	No	No	No	No	Yes	-	No	No	No	No	-	No	Yes	No	No	No
Mali	-	-	-	-	Yes	No	No	-	No	-	No	-	No	-	No	-	No	-	Yes	-	No	-	No	-	Yes	-	No	-
Mauritania	No	No	-	-	No	No	-	-	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No
Mauritius	No	-	No	-	No	No	No	-	No	-	No	-	No	-	No	-	Yes	-	No	-	No	-	No	-	Yes	-	No	-
Rwanda	No	No	No	No	No	No	No	-	No	No	No	No	No	No	No	No	No	-	-	No	No	No	No	Yes	Yes	Yes	No	No
Senegal	No	No	No	No	No	Yes	Yes	-	No	No	No	No	No	No	No	Yes	No	Yes	Yes	No	No	Yes	No	Yes	Yes	No	No	No
Seychelles	No	No	No	No	No	No	No	-	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No
South Africa	No	No	-	-	-	No	No	-	No	No	Yes	No	Yes	No	Yes	No	Yes	No	-	-	Yes	-	No	No	Yes	Yes	-	-
Tanzania	No	No	No	No	No	No	No	-	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
Togo	No	No	No	No	No	No	No	-	-	-	No	No	No	No	No	No	No	Yes	No	No	No	No	No	Yes	No	No	No	No
Uganda	-	-	No	No	No	No	No	-	-	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	No	No
Zaire	No	No	No	No	No	No	No	-	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	Yes	No	No	No	No
Zambia	No	No	No	No	No	No	No	-	No	No	No	No	No	No	No	No	No	No	-	No	-	No	-	Yes	-	No	-	-
Zimbabwe	No	No	No	No	No	No	No	-	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No
Sub-Saharan Africa totals:																												
Yes	0	0	0	1	1	1	5	0	1	0	5	0	1	0	1	0	9	0	9	1	1	0	6	0	27	12	2	0
No	28	27	25	25	26	30	12	1	26	26	23	28	28	27	28	28	20	27	18	24	29	27	22	28	3	16	27	28
No response (-)	3	4	6	5	4	0	4	30	4	5	3	3	2	4	2	3	2	4	4	6	1	4	3	3	1	3	2	3

P, are these activities enforced in the absence or presence of laws? L, in your country, is there a law, regulation, or decree mandating the following activities? 1a, restrictions on persons with HIV to marry; 1b, restrictions against sex workers/prostitutes; 1c, compulsory admissions of persons with HIV or AIDS into special centers. 2a, sex workers/prostitutes (because of a survey design error, the law section of this question was not answered by a majority of respondents); 2b, gay/homosexual men; 2c, pregnant women; 2d, prisoners; 2e, health care workers; 2f, patients with tuberculosis; 2g, military recruits; 2h, nationals applying for certain employments (i.e. in the tourist sector); 2i, citizen applying for student fellowship; 2j, blood donors (although the question was asked about the HIV testing of blood donors, some respondents may have answered about HIV testing of blood donations); 2k, prior to marriage.

these institutions. In European Union countries, this practice runs contrary to their own internal regulations.

Strategies for action

The record concerning protection of human rights in the context of HIV/AIDS remains mixed throughout Africa. There is potential for increased attention to human rights concerns as a result of expanded partnerships between governments, non-governmental organizations (NGO) and AIDS support groups within countries and at the regional level. These efforts provide a crucial link between public health and human rights promotion and protection at the individual and community level. For example, the African Network on Ethics, Law and HIV is a regional network which, including national networks in 15 countries, was created to respond to the legal, ethical and human rights challenges created and exacerbated by the HIV/AIDS pandemic [46–48]. [Other related regional efforts include the regional secretariat of the International Council of AIDS Service Organizations (AfriCASO) and Environment and Development Actions (ENDA) in the Third World and the Southern Africa AIDS Information Dissemination Service (SAfAIDS). National networks currently exist in Botswana, Burundi, Central African Republic, Congo, Côte d'Ivoire, Ghana, Kenya, Nigeria, Rwanda, Senegal, South Africa, Tanzania, Uganda, Zaïre and Zambia. The work of the network is primarily funded through the UNDP Regional Project on HIV and Development, UNAIDS and the German Technical Cooperation Agency (GTZ).]

An information and education campaign within the framework of human rights, championed by Africans, is the critical next step if human rights protection within the context of HIV/AIDS is to take place. These efforts must address health workers, the general population and those in positions to make and implement policy-level decisions. A step in this direction is the emergence of NGOs, both in response to the HIV/AIDS crisis and those connected to development and human rights. A critical element necessary to progress will be increased links in the work of these organizations in mutually strengthening ways [49–51]. The usefulness of governmental commitments, both political and legal, are ultimately dependent on the ability of individuals and communities to hold their governments accountable.

Health workers trained and informed about appropriate policies and procedures for the management of HIV/AIDS within the framework of human rights will be central to this effort. Their role will include awareness of human rights concerns relevant not only to their patients known to be HIV infected, but to all their patients. Interaction with people with HIV/AIDS, social workers, and relevant support organizations could be first steps in progressive realization toward this goal. Specific training illustrating the applicability of the human rights

framework to their work would also be of use [52,53]. Training manuals have been designed to bridge this gap [53] and, in addition, an increasing number of courses are being offered for professionals in a variety of settings. Relevant to this training are research, analysis and dissemination of comparative data showing the links between support of a human rights framework in HIV/AIDS management and the success of HIV/AIDS programs.

The extent to which people living with HIV/AIDS are aware of their rights and feel they have the support and tools at their disposal to fight for their rights both reflect and directly impact on a community's ability to bring the effects of HIV under control. In addition, without information and education, individuals and communities may be unable to exercise the leverage necessary to hold their governments accountable for their commitments or to work toward changing the policies and practices that make them vulnerable to HIV/AIDS. Therefore, education of the general population, with particular attention to segments of the population particularly vulnerable to HIV/AIDS, will be crucial. Realization of women's human rights will continue to be central to reducing the spread of HIV/AIDS in the African region [54–56]. If human rights are not respected, societies will continue to create and enhance individual and collective vulnerability to HIV, and more generally to ill health.

Those involved in policy and decision making, as well as implementation within each sector of the government, must be made aware of the commitments made by their representatives in both national and international forums, as these commitments are often neglected or overlooked. This applies equally to those specific to HIV/AIDS, and to broader health and human rights issues. The challenges illustrated through efforts at HIV prevention, treatment and care in the region have helped uncover fundamental dynamics in the broader relationship between health and human rights. Enhanced community participation in the implementation of strategies relevant to HIV/AIDS will help ensure attention to human rights concerns and improve their effectiveness. National level mechanisms concerned with HIV/AIDS and human rights must be strengthened, recognized and acknowledged as forming an integral part of the response to the pandemic.

Conclusion

The importance of bringing HIV/AIDS policies and programs in line with human rights law is generally acknowledged. The course of the AIDS epidemic has shown that public health efforts to prevent and control the spread of HIV/AIDS are more likely to succeed (e.g. lower HIV incidence, increase in the quality of life of those infected) if policies and programs promote and protect human rights. Information, education and advocacy in the context of a human rights framework

continues to provide an opportunity to ensure that public health efforts will positively impact the response to the HIV/AIDS epidemic in the next century.

The survey of GINAP managers, as well as the examples cited here, confirm two major conclusions. First, discrimination towards HIV-infected people, people with AIDS and people considered within each society at high risk for HIV infection remains an important and enduring problem. Second, bringing the general population, health workers, non-governmental and governmental sectors into conformity with the international consensus on non-discriminatory approaches to HIV/AIDS prevention, treatment and control will require vigilance and a sustained effort.

References

- Mann J, Tarantola D, O'Malley J, and the Global AIDS Policy Coalition: **Towards a new health strategy to control the HIV/AIDS pandemic.** *J Am Soc Law Med Ethics* 1994; 22:41-52.
- International Red Cross and Red Crescent Societies: **AIDS, Health and Human Rights.** Boston: François-Xavier Bagnoud Center for Health and Human Rights; 1995:9-12, 33-38.
- Mann J, Tarantola D, Netter T: **Assessing vulnerability to HIV infection and AIDS.** In *AIDS in the World*. Edited by Mann J, Tarantola D, Netter T. Cambridge, MA: Harvard University Press; 1992:577-602.
- Chikumbwa W, for the National Association of People with HIV/AIDS in Malawi (NAPHAM): **Women Living with HIV/AIDS.** In *AIDS in the World II*. Edited by Mann J, Tarantola D. New York: Oxford University Press; 1996:349-350.
- World Health Assembly: **Avoidance of discrimination in relation to HIV-infected people and people with AIDS.** World Health Assembly Resolution; May 12, 1988 [Res WHA41.24].
- Network of African People Living with HIV/AIDS (NAP+): **Background Paper Prepared for the Second International Consultation on HIV/AIDS and Human Rights.** Geneva, September 23-25 1996:2-11.
- Tarantola D, Schwartländer B: **HIV/AIDS in Africa: status, trends (stable, declining), projections, newly affected areas.** *AIDS* 1997, 11 (suppl B):S5-S21.
- The AIDS Support Organization (TASO), World Health Organization (WHO): **TASO Uganda — The Inside Story.** Geneva: World Health Organization; 1995 [WHO/GPA/TCO/HCS/95.1].
- Buyé A, Foister SD, Mbwili C, Mungo E, Tollenare N, Zeko M: **Mortality among female nurses in the face of the AIDS epidemic: a pilot study in Zambia [letter].** *AIDS* 1994; 8:196.
- Anonymous: **Impact of HIV on delivery of health care in sub-Saharan Africa: a tale of secrecy and inertia [editorial].** *Lancet* 1995; 345:1315-1317.
- Kalyabara IN: **Care and social services for HIV/AIDS. Stress, burnout and coping among health workers, caregivers and families.** *International Conference on AIDS, Yokohama, August 1994* [abstract P10758].
- UNICEF: **Report on a Meeting About AIDS and Orphans in Africa.** New York: United Nations; 1991.
- UNICEF: **AIDS and Orphans in Africa.** New York: United Nations; 1991.
- Hunter SS, Williamson E: **Developing Strategies and Policies for Support of HIV/AIDS Infected and Affected Children.** Washington DC: USAID; 1997.
- Musumba Ndala ML: **Strengthening women's rights to protect themselves against sexual transmission of HIV: an educational programme in Zaire.** *African Network on Ethics, Law and HIV newsletter*, December 1996:4-5.
- Oppong C: **A high price to pay: for education, subsistence or a place in the job market.** *Health Transition Review* 1995; 5 (suppl):35-56.
- Reid C: **Young Women: Silence, Susceptibility and the HIV Epidemic.** New York: United Nations Development Programme; 1992.
- Decosas J: **Migration et sida en Afrique de L'Ouest.** *Le Journal du Sida* 1996; 86-87:97-100.
- Simoya O, Phiri A, Sanjoko N, Sichilima W: **Sexual behaviour and issues of HIV/AIDS prevention in an African prison.** *AIDS* 1995; 9:1388-1399.
- UNHCR: **UNHCR policy and guidelines regarding refugee protection and assistance and the Acquired Immune Deficiency Syndrome (AIDS).** Geneva: UNHCR; 1988.
- Gasu I: **Legal and ethical aspects of sexual health and living with HIV/AIDS.** *African Network on Ethics, Law and HIV Newsletter*, December, 1996:8.
- Gasu I: **Responding to the legal, ethical and human rights challenges raised by the HIV epidemic: the experience of the Ghana Network.** *African Network on Ethics, Law and HIV Newsletter*, December, 1996:10.
- Appendix D: **Government National AIDS Programs Survey.** In *AIDS in the World II*. Edited by Mann J, Tarantola D. New York: Oxford University Press; 1996:497.
- United Nations Human Rights Commission: **Non-Discrimination in the Field of Health.** United Nations Resolution 1989/11; March 2, 1989.
- Mann J: **Human rights and AIDS: the future of the pandemic.** *The John Marshall Law Review* 1996; 30:195-206.
- Gruskin S, Hendriks A, Tomasevski K: **Human rights and responses to HIV/AIDS.** In *AIDS in the World II*. Edited by Mann J, Tarantola D. New York: Oxford University Press; 1996:326-340.
- Sughrat P: **AIDS & Human Rights — A UK Perspective.** London: British Medical Association Foundation for AIDS; 1989-12.
- United Nations: **Charter signed on 26 June 1945, entered into force on 24 October 1945.** [see, in particular, preamble and articles 1, 2, 7, 13, 55, 56, 62, 73, 74 and 75-85].
- United Nations High Commission for Human Rights website: <http://www.unhcr.ch/html/infinst.htm>.
- Center for the Study of Human Rights: **Twenty Five Human Rights Documents.** New York: Columbia University; 1994.
- Mann J, Tarantola D, Netter T: **National AIDS programs.** In *AIDS in the World*. Edited by Mann J, Tarantola D, Netter T. Cambridge MA: Harvard University Press; 1992:297.
- Tarantola D: **Grandes et petites histoires des programmes sida.** *Le Journal du SIDA* 1996; 86-87:109-116.
- World Bank: **Tanzania AIDS Assessment and Planning Study.** 9825-TA. Washington DC: Population and Human Resources Operations Division, Southern Africa Department, World Bank; 1992.
- Broomberg I, Steinberg M, Masobe P, Behr G: **Economic impact of the AIDS epidemic in South Africa.** In *AIDS in South Africa: The Demographic and Economic Implications*. Edited by Doyle PR. Johannesburg: Centre for Health Policy, University of Witwatersrand; 1991.
- Forsythe S: **Economic impact of HIV and AIDS in Malawi.** Durham, NC: AIDSTECH/Family Health International; 1992.
- Forsythe S, Sokal D, Lux L, King T: **Assessment of the Economic Impact of AIDS in Kenya.** Arlington, VA: AIDSCAP/Family Health International; 1992.
- United Nations GAOR: **International Covenant on Economic, Social and Cultural Rights, Article 2.** United Nations Resolution; 1966 [C.A. Res. 2200 (XXII), UN GAOR, (suppl 16):49, UN Doc A/6316].
- UNAIDS: **UNAIDS Strategic Plan 1996-2000.** Revised. Geneva: UNAIDS; 1995:5-6, 13.
- Gruskin S, Hendriks A, Tomasevski K: **Human rights and responses to HIV/AIDS.** In *AIDS in the World II*. Edited by Mann J and Tarantola D. New York: Oxford University Press; 1996:336-337.
- Appendix E: **Laws and practices in the context of HIV: a survey of Government National AIDS Program managers.** In *AIDS in the World II*. Edited by Mann J, and Tarantola D. New York: Oxford University Press; 1996:578-587.
- Amnesty International: **Human Rights Abuses in the Context of HIV/AIDS Relevant to the Mandate.** Amnesty International; 1994.
- Seidel G: **The competing discourses of HIV/AIDS in sub-Saharan Africa: discourses of rights and empowerment vs discourses of control and exclusion.** *Soc Sci Med* 1993; 36:173-194.
- Oosthuizen I: **The management of AIDS in South African schools.** *Annual Meeting of the National Organization on Legal Problems of Education*, Philadelphia, November 1993.
- Barnett T: **Des systèmes agraires inégaux devant l'épidémie.** *Le Journal du SIDA* 1996; 86-87:27-28.
- Seidel G: **Le deuxième sexe de la prévention.** *Le Journal du SIDA* 1996; 86-87:32-35.

46. UNDP HIV and Development Regional Project Team: *The African Network on Ethics, Law and HIV: looking toward the future* [editorial]. African Network on Ethics, Law and HIV Newsletter, December 1996.
47. Sy A, Etchepare C, Etchepare M, Bacha A, Djigaly L: **Prevention strategies at community level: the example of ENDA actions in west Africa.** *VIII International Conference on AIDS*, Amsterdam, July 1992 [abstract PoD.5316].
48. Kerkhoven RC, Jackson H, Loewenson R: **Rethinking HIV/AIDS in southern Africa: a problem of development.** *XI International Conference on AIDS*, Vancouver, July 1996 [abstract We.D.3681].
49. O'Malley J: **Nongovernmental organizations.** In *AIDS in the World II*, Edited by Mann J, Tarantola D. New York: Oxford University Press, 1996:341-361.
50. Cosmas C, Schmidt-Ehry B: **Human rights and health in developing countries: barriers to community participation in public health in Cameroon.** *Health and Human Rights* 1995, 1:244-254.
51. Ankrah EM, Hayman I, Aisedu K, et al.: **Gender and AIDS: training the top policy maker.** *XI International Conference on AIDS*, Vancouver, July 1996 [abstract Th.D.5005].
52. Bayer R: **AIDS and the ethics of public health: challenges posed by a maturing epidemic.** *AIDS* 1993, 7(suppl.1):S217-S221.
53. International Red Cross and Red Crescent Societies: *AIDS, Health and Human Rights*. Boston: François-Xavier Bagnoud Center for Health and Human Rights, 1995.
54. Mulanga-Kabeya C, Esu-Williams E, Luo N, Meilo H, Anyangwe S: **Challenges facing women's AIDS NGOs: the experience of SWAA.** *XI International Conference on AIDS*, Vancouver, July 1996 [abstract Tu.D.2736].
55. Wells V, La Rosa E: **Gender and HIV/AIDS in east and southern Africa (ESA): are women 'getting what they deserve?'** *XI International Conference on AIDS*, Vancouver, July 1996 [abstract Th.C.4333].
56. Nshoga YK, Bossa SB: **The cultural, legal and ethical issues in the wake of HIV/AIDS: which way for the African women.** *XI International Conference on AIDS*, Vancouver, July 1996 [abstract We.D.492].

HIV/AIDS epidemics in sub-Saharan Africa: dynamism, diversity and discrete declines?

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Introduction

It has been more than a decade since the wide spread of HIV in sub-Saharan Africa was recognized. A considerable body of knowledge has emerged through research, the evaluation of prevention and care programs and the experience gained in combating the epidemic in communities and within health-care settings. Much of the knowledge acquired in sub-Saharan Africa has impacted the ways the HIV/AIDS global pandemic is understood and responded to around the world. Drawing from an abundant literature on HIV/AIDS in sub-Saharan Africa, this paper reviews recently documented developments and has a deliberate single focus on HIV/AIDS. It highlights some of the current and most significant epidemiological features of the spread of HIV and attempts to describe the dynamism and diversity of ongoing epidemics. It does not, however, include such important features of the epidemiology of HIV/AIDS as other sexually transmitted diseases (STD), tuberculosis and other HIV-related diseases. In an attempt to provide a current perspective on the state and trends of HIV/AIDS in the region, an effort has been made to bring together only information drawn from publications and presentations dating after 1992.

There are clear signs today that the HIV epidemics in Africa are not insurmountable; they can be challenged and hopefully brought under control. There is some evidence that the HIV epidemics affecting certain communities are leveling off, or even declining, as is the case in parts of western and eastern Africa, where HIV had begun to spread rapidly in the early 1980s. These encouraging declines, however, are somewhat tampered by the more recent occurrence of abrupt and violent epidemics in southern Africa.

Overall status and trends of HIV/AIDS epidemics in Africa

With a population of 588 million (about 10% of the world total), distributed among 48 countries, sub-Saharan Africa accounted for an estimated 14 million adults and children living with HIV infection or AIDS (62% of the world total) as of December 1996 (Fig. 1). Of people living with HIV/AIDS around the world, six in every 10 adult men, eight in every 10 adult women and seven in every 10 children who are HIV-infected near or at birth are residing in Africa. Every day, over 4000 new HIV infections occur in this region where, since the mid-late 1970s, more than 20 million adults and children have acquired HIV/AIDS. By the end of 1996, close to 5 millions adults (divided almost equally among men and women) in sub-Saharan Africa and 1.5 million children born with HIV infection had developed AIDS. Of these, 3.8 million adults and more than 1 million children had died of AIDS. In sub-Saharan Africa, about 9 million children younger than 15 years of age have lost their mother to AIDS.

These figures, estimated by the Joint United Nations Programme on HIV/AIDS (UNAIDS), are extrapolated from seroprevalence estimates made on a country-by-country basis by the World Health Organization (WHO) Global Program on AIDS (GPA) in 1995 for a mid-year point in 1994 [1,2]. The model applied to estimate AIDS cases and deaths from HIV prevalence rates assumes that: (1) HIV incidence rates in African countries reached a plateau in the early 1990s; (2) the mean incubation period (interval between HIV infection and the onset of AIDS) is 10 years, an interval drawn from cohort studies in North America; and (3) a mean survival after the onset of AIDS in adults of 2 years. Studies have recently shown, however, that the latency period in sub-Saharan Africa may actually

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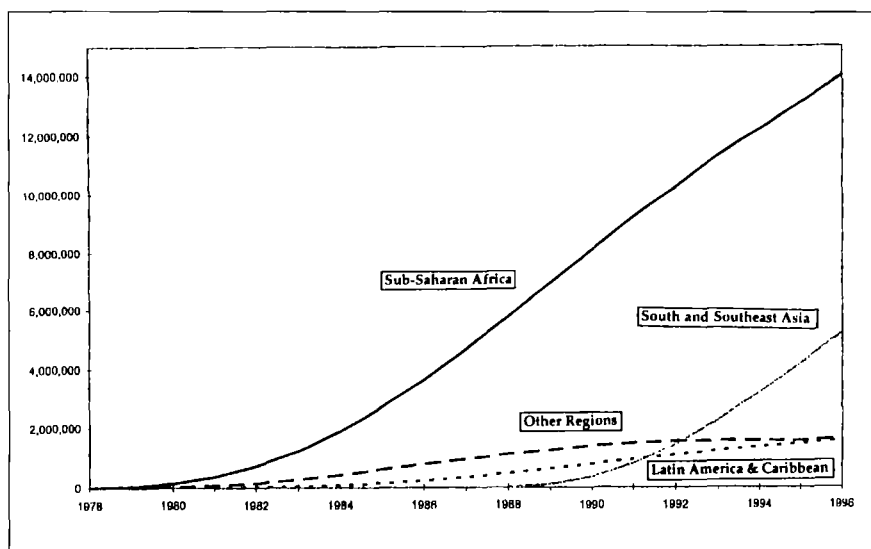


Fig. 1. Persons living with HIV/AIDS.

be in the order of 5–7.5 years and the survival interval only about 1 year [3,4]. These rates may vary considerably with age; in Uganda, the median survival time from HIV infection to death was estimated at 7 years for those aged 13–54 years, but only 2.5 years for those aged 55 years and older, with little difference between men and women [5]. The application of shorter intervals to the WHO model would result in higher back-estimates of AIDS cases and AIDS deaths than those that have been published [6]. Other effects of postulating shorter incubation and survival periods would include recognition of a greater impact of the epidemics on demography, orphan-hood and population structure [7].

The geography of HIV/AIDS in Africa: dynamism and diversity

The application of the term 'HIV/AIDS pandemic' to Africa tends to convey a misguided impression of homogeneity about the ways HIV spreads and affects communities across the continent. The HIV/AIDS 'pandemic' in Africa must be regarded as a mosaic of HIV epidemics of varied intensity and maturity, in many cases linked to one another and fueled through a complex array of intertwining bridges within and between countries. Each of the many concurrent HIV/AIDS epidemics that are currently under way could be individually characterized on the basis of traditional epidemiological principles: by the viral agents involved (e.g. HIV virus types and subtypes), the hosts (e.g. defined by their age, sex and sexual behaviors) and the environment (e.g. social and economic features, local sexual networks, patterns of residence and mobility, quality and coverage of health and social services) [8]. At a first level of analysis, Africa can be schematically divided into five areas, each composed of countries with similar epidemiological features (Fig. 2).

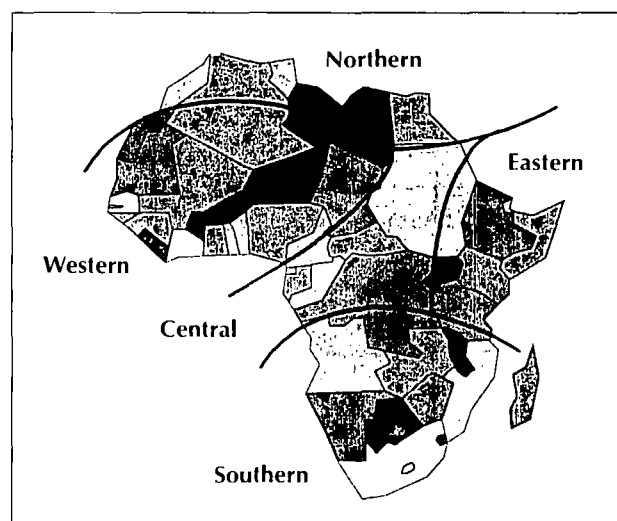


Fig. 2. HIV/AIDS areas of affinity in Africa.

Western Africa

The western African area includes Benin, Burkina Faso, Cape Verde, Côte d'Ivoire, Gambia, Ghana, Guinea, Guinea Bissau, Liberia, Mali, Mauritania, Niger, Nigeria, Senegal, Sierra Leone and Togo (Fig. 3). It is dominated by the epidemiological situation in Côte d'Ivoire, which has for several decades acted as an economic magnet in the region, drawing intense migration from neighboring and other countries [10,11]. In Abidjan, the capital city, prevalence rates in women attending urban antenatal clinics (ANC) have fluctuated between 10–15% for HIV-1 since 1990, while the prevalence rate for HIV-2 has remained stable at about 1% and the rate of dual serologic reactivity at about 4% [12]. A significant feature of the HIV epidemics in Côte d'Ivoire is the narrow difference in the HIV prevalence rates noted in Abidjan and in smaller towns and rural areas, attesting to the extent of sexual networks in this country. Uncertainties about

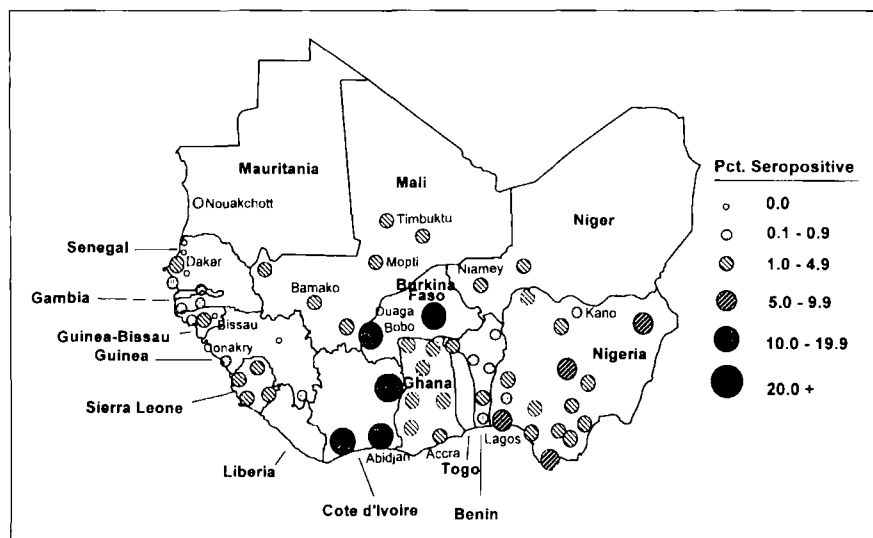


Fig. 3. Seroprevalence of HIV-1 for low-risk populations in west Africa, January 1997. Data from [9].

the degree of correlation between dual reactivity to HIV-1 and HIV-2 antibody detection tests and dual infection with HIV-1 and HIV-2 are discussed in this supplement [13]. Eight per cent of women attending antenatal clinics in rural areas in Côte d'Ivoire were HIV-infected in 1993, attesting to the wide geographic spread of the virus in the country [14].

In Ghana in 1994, a seroepidemiological survey conducted at nine sentinel surveillance sites found rates of 1.6, 2.1 and 2.8% in samples of pregnant women in the northern, upper east and upper west regions, respectively [15]. Since 1994, the seroprevalence of HIV-1 in sex workers has been approximately 30% or higher in Abidjan as well as in Bamako (Mali), Ouagadougou (Burkina Faso), Conakry (Guinea), Cotonou (Benin) and Lagos (Nigeria) [16,17].

A spread of HIV-2 also characterizes this area; HIV-2 is found in population samples in nearly all west African countries, with infection rates exceeding 7% in women attending urban ANC in Guinea Bissau. The wide spread of HIV-2 in this area in the 1970s and 1980s preceded that of the more transmissible and pathogenic HIV-1 [18,19]. In most of these countries, increasing HIV-1 infection rates now tend to exceed those of HIV-2, or rates of dual reactivity, both of which have remained stable over the past several years. In Abidjan, the dynamics of HIV spread, reconstructed from mortality data attributed to HIV/AIDS, suggest that two successive epidemic waves have occurred since the early 1980s (see The future course of the HIV epidemics on page S17). HIV infection rates among people prone to engage in high-risk behaviors remain at remarkably high levels; in Abidjan, in 1992–1994, 80% of a sample of female sex workers were found seropositive for HIV, including 47% seropositive for HIV-1, 3% for HIV-2 and 30% for both HIV-1 and HIV-2 [20].

Additional evidence of the gradual introduction of HIV-1 comes from Guinea Bissau, a country where prevalence

rates of HIV-2 in the general population are higher than in any other country [21]. In Bissau, the capital city, in 1994, seroprevalence rates of 1.4, 6.7 and 0.3% for HIV-1, HIV-2 and dual HIV-1 and HIV-2 serologic reactivity, respectively, were found in pregnant women attending ANC [22]. A cohort study of police officers of both sexes in 1990–1995 showed a prevalence of HIV-1 and HIV-2 at 1.0 and 10.9%, respectively. Significantly, a disproportionately high incidence of HIV-1 in relation to prevalence (0.9 and 0.7%, respectively) compared with a low incidence of HIV-2 in relation to prevalence (1 and 10.9%, respectively), suggested that the spread of HIV-1 was more recent and powerful than that of HIV-2 [23].

Empirical seroepidemiological data and the modeling of the apparent competition between HIV-1 and HIV-2 indicate that HIV-1 is likely to displace HIV-2 in populations when both viruses are being transmitted concomitantly [24,25].

Central Africa

The central African area consisting of Chad, Cameroon, the Central African Republic, Congo, Equatorial Guinea, Gabon, Sao Tome and Principe, Southern Sudan and Zaïre (now called the Democratic Republic of the Congo) has been somewhat less affected than west Africa, with rates of HIV infection typically at 5% or less in most samples of pregnant women (Fig. 4). Between 1989 and 1991, a relatively low (3.1%) and stable prevalence of HIV was found in pregnant women attending ANC in the Shaba province of Zaïre and 5% in the capital, Kinshasa [26,27]. A similar pattern was observed in Gabon where a 2.1–2.2% prevalence of HIV in the general population appeared to have remained stable over the period 1986–1994 [28]. Higher HIV prevalence rates have, however, been found more recently in pregnant women in the Congo (about 7% in Brazzaville and 10% in Pointe-Noire in 1994) and in Bangui, Central African Republic (16% in 1993) [9,29].

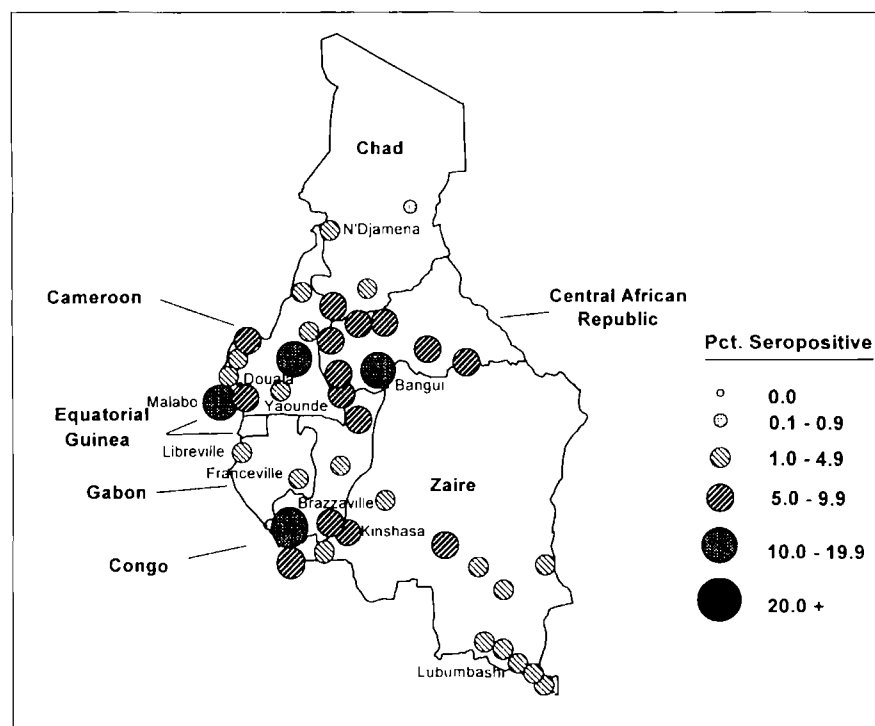


Fig. 4. Seroprevalence of HIV-1 for low-risk populations in central Africa, January 1997. Data from [9].

When compared with neighboring western, eastern and southern Africa, this area seems to have benefited from a few years delay in the spread of HIV. However, the apparent stabilization or relatively slow rise of HIV prevalence in the area should not be considered as a sign of epidemic recess. In Kinshasa, Zaire, HIV prevalence rates among sex workers attending one STD clinic, at 35% in 1989, had remained unchanged by 1994, but this apparently stable epidemic was in fact fueled by a constant 10% annual incidence of HIV during this period [30]. By the mid-1990s, HIV prevalence rates in samples of sex workers were 29% in Lagos, Nigeria, and 45% in Douala, Cameroon, underlining the potential for the HIV epidemics to gain momentum [31].

An example serves to illustrate the vulnerability of this area to the more intense spread of HIV. In the late 1980s, it was thought that Cameroon had been spared from major HIV spread but, by 1994, a population-based seroepidemiological survey in southwest Cameroon found a 9.9% HIV prevalence rate in the 15–44-year-old male and female population, with infection rates at 5.4, 13.6 and 8.7% in the 15–19, 20–34 and 35–44-year-old age groups, respectively [32].

Eastern Africa

The eastern African area, consisting of Burundi, Djibouti, Eritrea, Ethiopia, Kenya, Rwanda, Somalia, Tanzania and Uganda, contains 25% of the sub-Saharan population and 36% of all current HIV infections in the subcontinent. In these countries, HIV began to spread rapidly and widely in the late 1970s and early 1980s (Fig. 5). HIV prevalence

rates in samples of women attending ANC are generally between 15 and 25% in urban areas. An annual HIV incidence of 3–5% in women attending ANC in Kigali during 1989–1990 led, by 1995, to a prevalence of 25.4% which, surprisingly, involved not only HIV-1 but also HIV-2 and dual serologic reactivity (14.4, 1 and 10%, respectively) [33,34].

In many cities, HIV prevalence rates among sex workers exceed 20%, reaching a staggering 85.5% in a population of sex workers in Nairobi [35]. The epidemic is now driven by high mobility along the Trans-African Highway and other main transportation routes, as reflected in high HIV prevalence among truck drivers and the communities of sex workers with whom they have transactional sexual contact (see below). As discussed below, rates in rural areas tend to be lower than in urban and semi-urban areas, although the definition of 'rural' testing sites and the proximity to trading routes can considerably influence the measured levels of HIV infection.

Although the impact of recent regional conflicts in Burundi, Rwanda, Zaire and southern Sudan has not been assessed and is hard to predict, persisting insecurity, military movements and civilian population displacements are likely to have further aggravated the HIV situation in these and neighboring countries.

Southern Africa

The southern African area includes Angola, Botswana, Malawi, Mozambique, Namibia, Lesotho, South Africa, Swaziland, Zambia and Zimbabwe (Fig. 6). Although, at

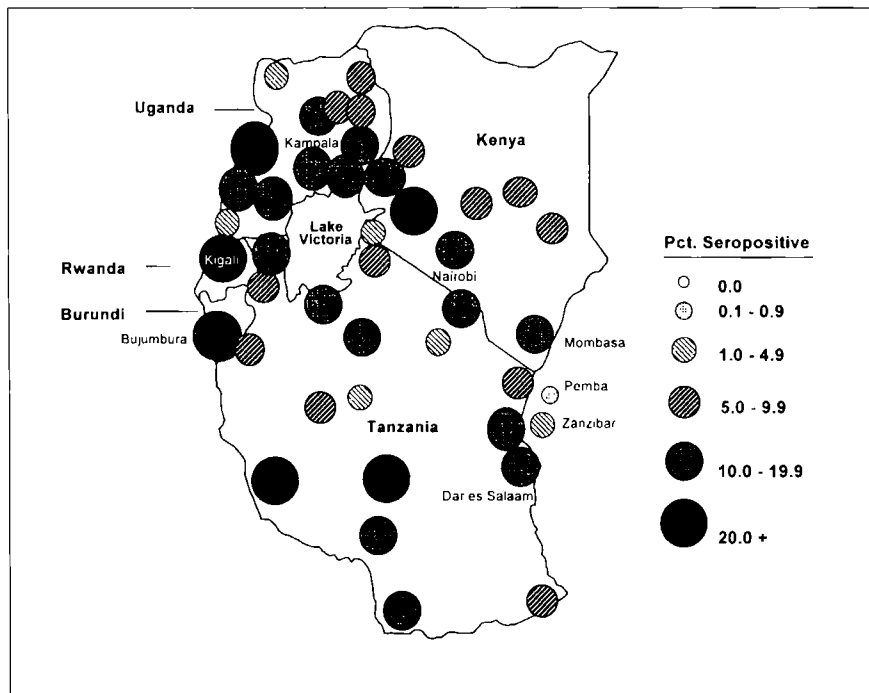


Fig. 5. Seroprevalence of HIV-1 for low-risk populations in east Africa, January 1997. Data from [9].

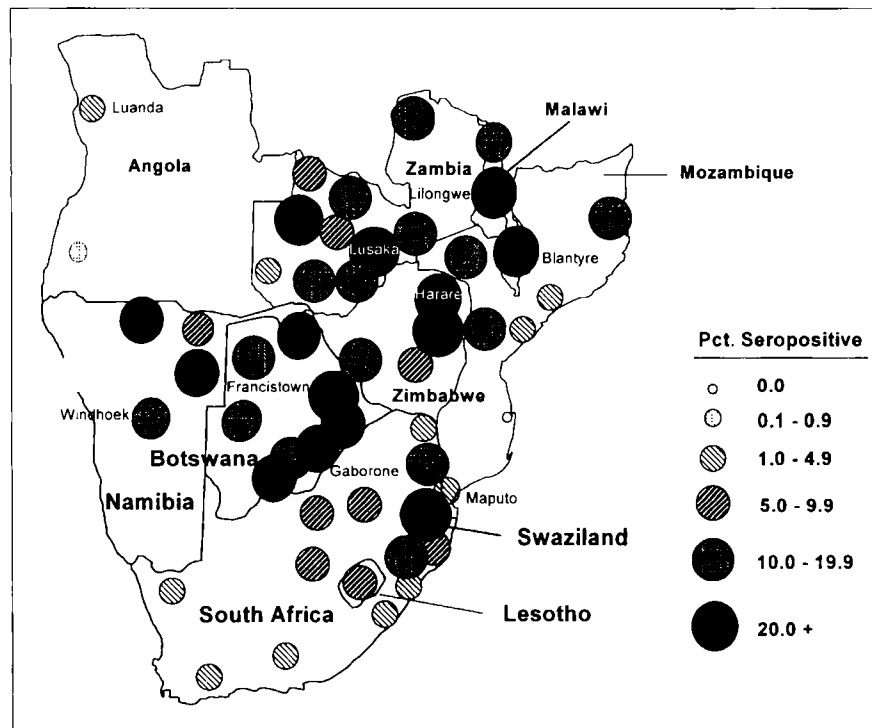


Fig. 6. Seroprevalence of HIV-1 for low-risk populations in southern Africa, January 1997. Data from [9].

first glance, few general epidemiological features differentiate the southern African area from the eastern African area, patterns of mobility within the area, and the major pole of economic migration created by South Africa, have been associated with sudden and severe epidemics. It can be postulated that social, cultural and family uprooting, combined with lower access to local health and social services as well as gender imbalance among domestic and international migrant populations,

have increased the frequency of risk-taking sexual behavior and, as a result, the vulnerability of these populations to HIV infection. This area is characterized by both the high rate of growth of the epidemics (the highest noted in Africa in recent years) and by the persistent severity of more mature epidemics, reflected by prevalence rates in Zimbabwe and Zambia, for example, which are similar to those observed in eastern Africa (Boxes I and II).

Box I. Continued rise in HIV trends in Zimbabwe

Tom Zhuwau

High levels of HIV prevalence and incidence have been recorded in Zimbabwe since the introduction of sentinel surveillance in 1990. Sentinel surveillance reporting from the nine administrative provinces of Zimbabwe indicates there was an explosive epidemic leading into this decade, relative stability between 1991 and 1993, then another upwards surge from 1994. Prevalence levels in excess of 40% are currently being recorded among women attending ANC in a number of urban centers. The HIV trend in Zimbabwe strongly mirrors that of the rest of sub-Saharan Africa in that it shows a peak in the 20–29-year-old age groups for females and 30–39-year-old age group for males (Fig. 1). It is estimated that young women between the ages of 15 and 19 years are more than five times as likely to be infected as males in the same age group (National AIDS Control Programme, unpublished data, 1997). More than 70% of AIDS cases are found among adults between the ages of 20 and 49 years, of which more male cases have been reported to date than female. This would seem to follow the usual pattern for a sub-Saharan HIV/AIDS epidemic in that more male cases occur during the initial states of the epidemic. As the epidemics continue and prevalence rates rise, as in the case of Zimbabwe, these differences disappear to the point that an equal number of males and females become newly infected.

The national prevalence is currently estimated to be between 18–21% and is expected to continue to rise into the next millennium before leveling off and declining. HIV is widespread throughout the whole country although, according to 1995 surveillance figures (National AIDS Control Programme, unpublished data, 1996), levels of prevalence are slightly higher in urban areas, ranging from 36% in Harare to 42% in Masvingo. Prevalence levels in rural areas show a much wider variation ranging from 11% in Lupane to 43% in Beitbridge. However, rural areas (where 70% of the country's population are based) are experiencing some of the highest rates of incidence at the current time. In the Mberengwa rural district of Midlands Province, HIV prevalence among pregnant women increased from under 8% in 1992 to 25% in 1994 [36]. In Chiredzi, Masvingo Province, HIV prevalence rose from 40% in 1992 to 70% in 1995 and dropped to 47% in 1996. In a cohort study of male factory workers conducted in Harare between 1993 and 1995, 19% of participants were found to be infected at enrollment and an incidence rate of 2.93% per annum was recorded [37].

The current pattern of HIV prevalence in Zimbabwe is somewhat different from most countries in the region in that there is a mosaic of high and low HIV prevalence rates in both rural and urban areas. In contrast, in Uganda, Kenya, Malawi and Zambia, populations with high HIV prevalence are mostly found in specific geographical areas, such as the Rakai district in Uganda, the Copperbelt in Zambia, and in the city of Lilongwe in Malawi. Several factors appear to contribute to the diversity, rapid spread and severity of the epidemics in Zimbabwe. One of these may be the high levels of circular mobility of large numbers of people sharing their time between residences in urban areas and rural areas, in a country where this mobility is facilitated by a vast road network. Changing sexual behaviors associated with high mobility, rising levels of poverty and dislocation caused by such factors as unemployment and occasional droughts fuel the spread of HIV infection and other STD in Zimbabwe.

The dynamism of HIV spread in Zimbabwe is highlighted by the worrisome results of sentinel surveillance in Masvingo Province where, through the age of 39 years, HIV prevalence rates were consistently higher in 1995 than in 1994 (Fig. 1).

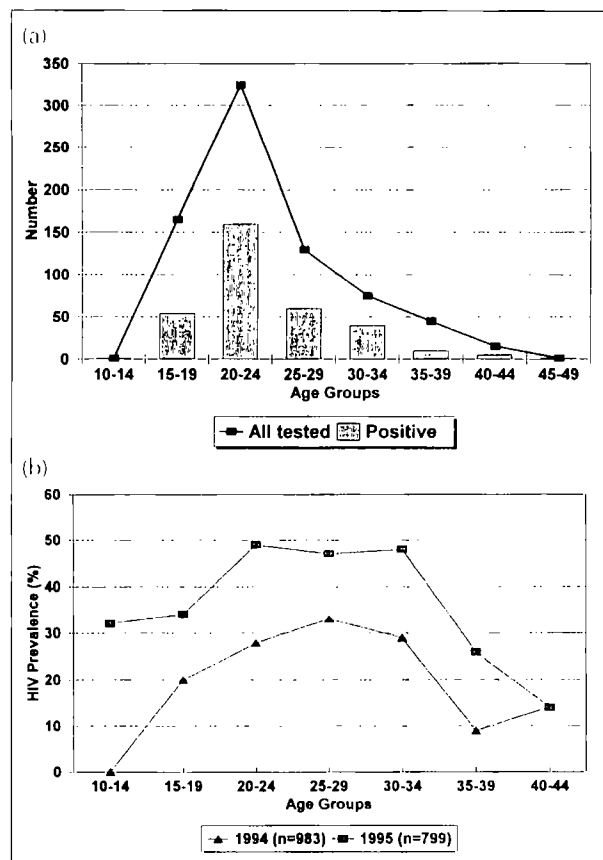


Fig. 1. (a) Age distribution in antenatal clinics in 1995 and (b) HIV seroprevalence 1994 and 1995, in the Masvingo Province.

In Francistown, Botswana, the prevalence rate of HIV in women seen at ANC increased from 6% in 1991 to over 30% 2 years later. The rate of HIV infection in similar sentinel surveillance populations in KwaZulu Natal, South Africa, rose almost 10-fold within a 5-year period, from 1.6% in 1990 to 4.8% in 1992 and to 14.4% in 1994 [41]. By 1997, the South African government estimated that 2.4 million people (or 6% of the population), including 1.4 million women, were living with HIV in the country, a rise of one-third over 1995 [42]. Signs of similarly pronounced epidemic growth are unfortunately common in the area: the mean HIV rate in women attending ANC in Swaziland increased sharply from 3.9% in 1992 to 26% in 1996 and in Namibia, following the country's independence and the return of exiled populations, the rate of HIV infection among women attending ANC rose from less than 1% in the early 1990s to 17.6% in cities and 10.3% in rural areas by 1996 [43,44].

The low-intensity wars and open warfare which plagued the area also led to considerable population displacement but data are insufficient to establish the impact of these events on the spread of HIV. For example, Mozambique, one of the countries which has experienced long-lasting civil conflicts since the 1970s, displays lower HIV rates than neighboring countries: 2.7% among ANC attendees in the capital city, Maputo, in 1994 and 1.5% among pregnant women in displaced populations in a rural area near the border to Zimbabwe [45]. No recent HIV information is available from Angola, which has been the locus of civil strife for over a decade. The presence of HIV-2 has been documented in Angola and Mozambique, which both have historical links to Portugal and Guinea Bissau.

In Malawi and Zimbabwe, rates of HIV infection at ANC are comparable to those found in eastern Africa: leveling off at approximately 30% in urban ANC since the early 1990s, with high and rising rates in rural areas [46].

African neighbors: north Africa and island countries

HIV epidemics in countries of the Maghreb, Egypt, and the Indian Ocean do not conform to the same patterns as those observed in sub-Saharan Africa. The rates of infection among women seen at ANC remains lower than 1%, with rates of a few per cent found in sex workers and STD patients [9,47]. In north African countries, the modes of transmission of HIV acquired abroad involve a mix of heterosexual and homosexual contacts and injecting drug use, resembling more the patterns of HIV spread observed in Europe than those in sub-Saharan Africa. Indigenous transmission of HIV seems to result mostly from heterosexual contacts [48]. The lack of data in this composite group of countries seriously hampers an analysis of the status and the projection of trends of HIV infection in the area.

Predominant modes of HIV transmission

It has been estimated that 93–95% of all HIV infections in the 15–49 year age group in sub-Saharan Africa were due to heterosexual transmission and that, by 1996, more than half of these infections were in women [1,49]. Retrospective behavioral inquiries among HIV-infected people would tend to support these estimations, but there are unanswered questions concerning the contribution of other modes of HIV transmission to the epidemics in sub-Saharan Africa. For example, how much infection is acquired through the use of skin-piercing instruments within or outside the health-care setting, as well as the transfusion of contaminated blood and blood products [50]. Because of the lack of information, these questions will only be briefly addressed.

The male-to-female ratio of HIV infection, approximately 1:1 in population-based seroepidemiological surveys in sub-Saharan Africa, supports the assertion that heterosexual transmission is by far the predominant mode of HIV spread in the region. Yet, the patterns and extent of men having sex with men (and therefore of related HIV transmission) remain largely unexplored in sub-Saharan Africa as a result of strong stigma attached to, and denial of, this expression of sexuality. Studies in Sudan, Nigeria, Kenya and South Africa are among the few that have documented sexual contacts between men [51]. Increased knowledge of epidemiological, behavioral and social aspects of HIV transmission among men having sex with men is a prerequisite for effective prevention in this ignored population.

Heterosexual transmission of HIV

Early in the epidemics, HIV spread (in many countries with high velocity) in the context of transactional sex. HIV prevalence rates rose among commercial and casual sex partners when HIV was either not found or present at low prevalence rates among women attending ANC. A correlation between HIV prevalence rates among sex workers and among pregnant women in urban populations helped predict the spread of HIV when seroepidemiological surveillance systems were limited to occasional surveys conducted among sex workers [52]. As HIV was spreading, the rise in HIV prevalence among women attending ANC and the occasional conduct of population-based surveys which included both women and men provided a growing body of knowledge about factors influencing the heterosexual spread of HIV and the great diversity in epidemic patterns within populations in the same country.

Women throughout the region tend to become HIV infected at younger ages than men, as illustrated by community-based seroprevalence surveys conducted in Masaka, Uganda (Fig. 7). Population-based studies have shown a 5–10 year interval between the peak of HIV prevalence in women (reached between the ages of 25

Box II. Comparing sentinel surveillance and population-based HIV prevalence rates in Zambia

Knut Fylkesnes^{*†}, Kevin Kasumba^{*†}, Zacchaeus Ndhlovu^{*†} and Rosemary M. Musonda[§]

Zambia's sentinel surveillance system has been gradually expanded and the data drawn from it are now relatively comprehensive. Surveillance data show an overall stability in HIV infection in both urban and rural sites in recent years, suggesting that the current difference in urban and rural rates (now about 27% in urban areas and around half that in rural areas) will persist in the near future.

In 1995–1996, the first of a series of planned cross sectional HIV surveys in random population samples ($n = 4196$) was conducted to: (1) establish a baseline for follow up; (2) assess the reliability of the sentinel surveillance system; and (3) examine patterns and determinants of HIV infections and sexual behavior [38]. As the first population based-survey of this type, the collection of saliva specimens for HIV testing was included in the survey [39]. The use of this non-invasive method of specimen collection resulted in a high compliance rate of 93.5% with no recognizable bias.

Figure IIa, in which HIV prevalence rates are shown by 5-year age group, by sex and by sampling method, reveals that: (1) in the younger age group (15–19 years of age), the rate of HIV prevalence in the sentinel surveillance sample is about twice the rate found among women in the population-based sample. This is possibly because the latter includes teenage women who are not (or less) sexually active and, perhaps as well, teenage women who may be more likely to use condoms; (2) in older age groups, the HIV prevalence rates among women in the population-based sample exceeds those found in antenatal clinic samples, perhaps because of an association between lowered fertility and HIV infection; and (3) in the population-based sample, the HIV prevalence rate is consistently and considerably higher among women in the general population than among men in the 15–29 year age group while in older age groups the rate is higher among men.

Figure IIb shows a further analysis of HIV prevalence rates in the younger age group (15–19 years of age), although the 15–16 year age group was combined for reasons of sampling [40]. Several additional features of the spread of HIV are unveiled: (1) within the 15–19 year age group, the age structure of the sentinel surveillance sample and of the population-based sample differ significantly, with an under-representation of 15–16-year-old women in the sentinel surveillance sample (17 versus 44% in the population-based sample) and an over-representation of the 18–19 year age group (accounting for 63.6% of the sentinel surveillance sample versus 34% in the population-based sample), thus tipping the mean HIV prevalence rate in the sentinel surveillance sample toward the higher HIV rates found in the 18–19 year age group. Adjusting the age structure of the sentinel surveillance sample on the basis of the age structure of the population-based sample gives a mean HIV prevalence rate of 19% in the sentinel surveillance sample instead of the mean rate of 22.6% in the unadjusted population sample; (2) across ages, the HIV prevalence rates were consistently higher in teenage women seen at ANC than among teenage women in the population-based sample which, in turn, were higher than the rates among men of the same age; (3) the prevalence rates increased among teenage women in both samples by a factor of two between the ages of 15–16 and 19 years; and (4) by the age of 15 or 16 years, more than 6% of female teenagers in the population-based sample and more than 12% of female teenagers seen at ANC were already infected with HIV.

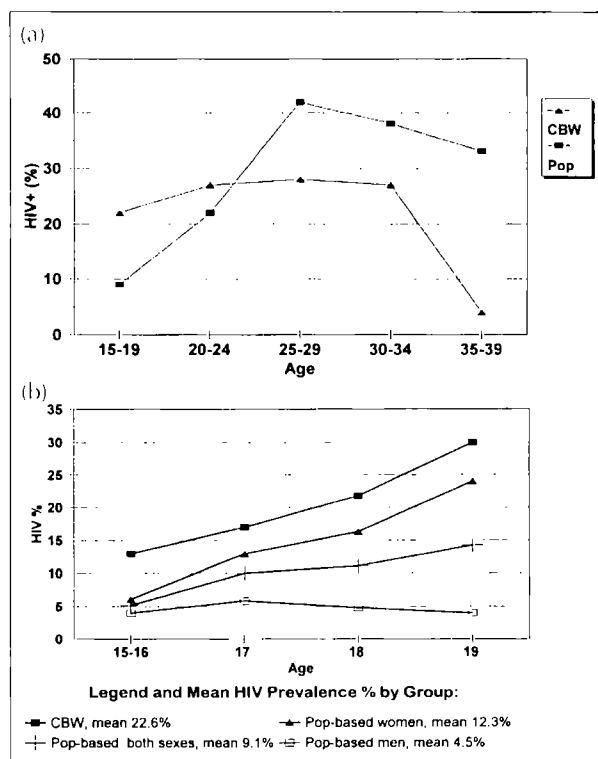


Fig. II. Age-specific HIV prevalence in child-bearing women (CBW) (a) attending an antenatal clinic in Chelston, Lusaka and (b) results of a population-based (pop-based) HIV prevalence study, by age and sex.

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Box II (continued)

The comparison of HIV prevalence rates between the population-based sample, analyzed by age group and sex, and the sentinel population drawn from antenatal clinics, analyzed by age group, leads to a much better understanding of the current dynamics of HIV spread in the population, particularly when HIV prevalence rates are analyzed by single year of age in younger age groups. This approach facilitates the 'calibration' of the HIV prevalence results obtained from sentinel surveillance, thereby increasing the accuracy of extrapolation of HIV prevalence rates in sentinel surveillance samples to populations located within the catchment area of sentinel surveillance sites. This study underlines the usefulness, limitations and options for improvements of ANC sentinel surveillance as a method to monitor HIV status and trends.

and 34 years) and the peak of HIV prevalence in men (observed in the 30–39 year age group). A similar interval in the peak of AIDS incidence in women and in men can be observed, with an upwards shift of 5–10 years towards the older age groups for both [19]. Among women attending periurban ANC and assumed not to be associated with high-risk sexual behavior, the risk of HIV infection is largely determined by their male partner's sexual behavior [54].

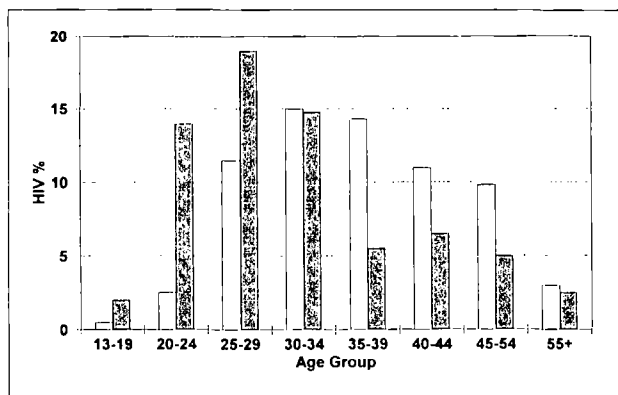


Fig. 7. HIV seroprevalence by age and sex in adults in 15 rural villages in the Masaka district of Uganda, 1995. □, Men; ■, women. Data from [53].

Residence and heterosexual transmission of HIV

Residence and mobility patterns have long been recognized as factors influencing vulnerability to HIV/AIDS. Bridges between higher and lower HIV prevalence populations are influenced by a number of social factors, including occupational mobility, economic migration or population displacements, particularly when these result in the building of communities with a severe gender imbalance, as is seen in Abidjan and around industrialized sites of southern Africa (Fig. 8).

Throughout Africa, differentials between the high HIV rates in urban populations and lower rates in rural populations persist but are constantly narrowing. Communities located along trade routes and highways are often at intermediate levels of vulnerability to HIV. Some illustrations of this pattern come from studies in several districts in Tanzania. In rural Mbeya in 1988–1995, for example, the prevalence rates of HIV in women

attending ANC along the roadside were consistently higher than the rates found in remote rural areas [55]. However, by 1995, the difference between rates in roadside and remote population samples (14 and 12.8%, respectively) had narrowed considerably. In the Mwanza district, the prevalence rate of HIV in adults was twice as high in the community living along the roadside (7.7%) than in villages distant from the main road (3.8%) [56]. In the Arusha district, a population-based survey found rates of 14.4, 6.9 and 2.3% in women in urban areas, semi-urban areas and rural areas, respectively. A history of urban residence or of having traveled within or outside the country were among factors associated with increased rate of HIV prevalence [57]. There are notable exceptions, however, to the general picture of important differences between urban and rural HIV prevalence rates. Such exceptions can be found in Côte d'Ivoire and some areas in Zimbabwe and Uganda where urban and rural HIV prevalence rates only differ by a few per cent.

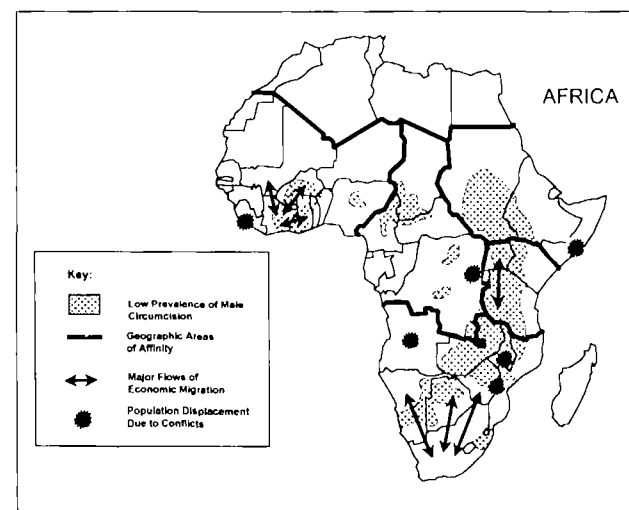


Fig. 8. HIV/AIDS prevalence among low-risk populations in Africa, prevalence of male circumcision and major patterns of population mobility in the mid-1990s.

Similarly, in the Rakai district, Uganda, populations living close to the highway had a 38.5% HIV seroprevalence, compared with 25.4% in trading centers and 8.6% in rural villages [58]. Men are the predominant source of new infections in rural villages, as shown in the southwestern

Ugandan population where the use of condoms was higher in couples in which the man was known to be the uninfected partner (17.1%) rather than the woman (9.5%) [59]. The seroincidence rate was about 10-times higher in men and women in discordant relationships (8.7 and 9.2 per 100 persons-years, respectively) than in concordant seronegative couples (0.82 and 0.87 per 100 persons-years, respectively).

Finally, in Kenya in 1995, HIV prevalence in adults between the ages of 15 and 44 years was estimated at 13–14% in urban populations and at 6–7% in rural populations, for an overall rate in the country of 7.5%, more than twice the 3.5% prevalence estimated in 1990, and rising [60].

Mobility and heterosexual transmission of HIV

Migration, combined with declining age at first sexual intercourse can, in the absence of targeted prevention programs, lead to increased risk-taking sexual behavior. For example, the combined findings from two surveys in Senegal indicated that seasonal migration correlated with at-risk sexual behavior and, as was shown in an earlier study, with higher HIV infection rate [61]. In this population, age at first marriage increased from 25 to 32 years for men and from 21 to 24 years for women between 1989 and 1994, while age at first sexual intercourse decreased by about 10 years on average during the 30 years preceding the survey [62].

Migration and mobility between rural areas and cities involves two-way traffic. Single men and women tend to move to cities for reasons of employment and return home to visit their family or to seek treatment when they fall ill [63,64]. This mobility pattern impacts both the spread of HIV and the fragile economy of rural households which have to rely on remittances from urban areas.

Higher rates of HIV infection have been found in people who travel frequently and over long distances, such as truck drivers and their assistants, traders and military personnel [65]. Behavioral studies have shown that occupational travel was often associated with high rates of changes in sexual partners, participation in transactional sex and unsafe sex practices, suggesting that these populations play a role in bridging epidemics in higher and lower HIV prevalence areas [66–69].

The tenuous nature of sexual mixing between urban and rural populations may be one of the factors delaying the leveling-off between urban and rural HIV prevalence rates [70]. In Uganda, apart from a small group of men with high rates of partner change, small urban/rural traders did not seem to represent a significant bridge population as movements between towns and rural areas involved little sexual mixing between rural-based and urban-based populations [71].

Biological factors

The history of STD in women and men and the lack of male circumcision have been identified as relevant to the spread of HIV infection in sub-Saharan Africa. The synergy between HIV infection and STD has been well established and is particularly powerful in women [72]. Male circumcision has been found to be associated with a lower rate of HIV infection in adult males in Africa [73–75]. Most, but not all, studies have demonstrated the relative protective role of male circumcision against the acquisition of HIV infection [76]. The Mwanza trial in Tanzania, in fact, found a significantly higher rate of HIV infection in circumcised males [56].

Mother-to-infant transmission of HIV

Over 70% of infants born with perinatally acquired HIV infection are residing in Africa. The rate of infection in infants born to HIV-infected mothers in sub-Saharan Africa ranges between 24–42%, threatening to offset the reduction in childhood mortality achieved through several decades of disease prevention and control programs [77,78]. Two studies, one in Abidjan, Côte d'Ivoire, and the other in Dakar, Senegal, showed that HIV-1 transmits from mother to infant at a higher rate (24.7 and 30.4%, respectively) than HIV-2 (1.2 and 3.8%, respectively) [79,80].

A share of this transmission is attributable to breast-feeding, raising the daunting challenge of developing prevention strategies that strike the optimal balance between reducing the rate of HIV infection transmitted through breast milk while enabling children to draw maximum benefits from breast-feeding [81–85]. In a Kinshasa study, the HIV transmission risk for intrauterine, intrapartum/early postpartum (0–2 days), and late postpartum (3–5 months) were estimated at 6, 18 and 4%, respectively, confirming that if most transmission occurred during labor and at or shortly after delivery the risk of HIV transmission through breast-feeding was substantial [86].

It has become increasingly clear that the likelihood of transmission from HIV-1-infected mothers to their infants is strongly influenced by the mode of delivery and breast-feeding practices. In Soweto, South Africa, cesarean sections performed before the onset of labor are associated with a high reduction of transmission (from an overall rate of 38.1 to 14.3%) while no significant reduction was noted when cesarean section was performed after the onset of labor (associated with a transmission rate of 35%) [87]. Importantly, transmission to breast-fed infants was 46%, against 18% to those who were not breast-fed. Yet another factor which seems to influence the vertical transmission of HIV is the pregnant woman's stage of evolution of HIV disease. In Uganda, for example, the median plasma RNA in women whose infant became infected (184 000 copies/ml) was, at study entry, over 10-times that of women whose infant did not become infected (16 000 copies/ml) [88].

HIV transmission in the health-care setting

The transmission of HIV through contaminated blood and blood products in Africa remains poorly documented. Estimates suggest that, in 1995 alone, 550 000 of the 2.3 million blood units donated in the region (23.8%) had not been screened for HIV antibodies [50]. Assuming that the rate of HIV infection among blood donors ranges between a most conservative 2% and a more likely 10%, between 1100 and 55 000 HIV infections might have been acquired in sub-Saharan Africa in 1995 as a consequence of the transfusion of unscreened blood.

Data are similarly lacking on HIV transmission which may be occurring in the health-care setting through the re-use of unsterile injection and other skin-piercing instruments. Surveys in several sub-Saharan countries have shown that half of the adult population may receive an average of approximately five injections per year, urban residents being more likely than rural populations to report having received injections for medical purposes, although the risk of HIV transmission through such practices has not been assessed [89]. One of the few illustrations of the risk of nosocomial HIV infection in children comes from Burkina Faso, where 60 children aged 4–48 months seen at a pediatric ward in Bob-Dioulasso for malnutrition were found to be HIV-infected. Mother-to-child transmission could be established in 77% of these but at least 23% had been infected through other means, presumably contaminated injection equipment or unscreened blood [90]. Among 10 HIV-infected 5–12-year-old children in Uganda, it was found that six had been perinatally infected, while blood transfusion and injections accounted for one case each. Of the remaining two, one was attributed to sexual exposure and the other unexplained [91]. It would be unreasonable to draw conclusions applicable to the whole sub-Saharan region from these results. They are, however, indicative of risks of HIV transmission through medical practices which have been insufficiently documented and addressed from the perspective of prevention.

Also poorly documented is the rate of HIV infection among health-care providers through occupational exposure. In a Zambian hospital in 1994, where the HIV seroprevalence in surgical patients was 22.3%, the relative cumulated seroconversion risk for surgeons was 15-times higher than in Western countries. It was estimated that each year, one out of 300 employees working in this type of setting may become infected with HIV as a result of occupational exposure [92].

The threatening increase in substance abuse in sub-Saharan Africa

A worrisome factor in projecting future trends is the increasing availability of illicit drugs in Africa, in particular substances that may be injected such as heroin. The risk associated with injecting drug use in Africa is real as drugs most often find their way into local populations around

transit points. The routes of international drug trafficking pass through coastal cities (Abidjan, Accra, Banjul, Dakar, Lagos, Monrovia), international airports (Kigali, Nairobi) and Indian Ocean island countries (Mauritius) [93]. There may have been as many as 50 000–100 000 injecting drug users in Nigeria in 1992 [94]. The use of smoked or injected heroin has also been documented in Côte d'Ivoire and in the Cameroon [95]. Reinforced surveillance and prevention programs are needed in sub-Saharan Africa to better understand the patterns and curb the growth of substance abuse, while investigating its impact on health, including HIV infection.

Information gaps concerning HIV transmission in sub-Saharan Africa

Overall, abundant data exist on HIV prevalence status and trends drawn from pregnant women seen at ANC selected for the purpose of epidemiological sentinel surveillance (ESS), and from several community-based cohort and cross-sectional studies. Although a compelling need remains to improve the understanding of the heterosexual spread and impact of HIV in adolescents and in adults of reproductive age as well as in infants, unexplored or insufficiently known aspects of the dynamics of HIV spread and impact should also receive more attention. These include: (1) estimation of the incidence of HIV throughout the life-cycle resulting from nosocomial infection, homosexual sex, as well as from drug-injecting practices and associated to other forms of substance abuse; (2) HIV prevalence and incidence in relation to specific modes of transmission in children below the age of 15 years, in particular sexual abuse, skin piercing practices (health-care related or not) and female genital mutilation; and (3) patterns of HIV prevalence, incidence and HIV disease in populations older than 54 years (Fig. 9).

Discrete declines in HIV trends?

In several countries, studies have documented that the average age at first sexual intercourse for women is slowly rising, the number of men and women reporting non-regular and/or multiple sexual partners is declining, the age differential between occasional sexual partners is narrowing (although still involving the pairing of younger women and older men) and the frequency of transactional sex is declining in several populations of young adult males. In contrast, few favorable trends have been noted concerning regular condom use.

In Tanzania, during a 2-year observation period in the mid-1990s, the proportion of men reporting more than one sexual partner within the last month declined from 22.3 to 12.2%. The proportion of men reporting casual sex over the last month was almost halved (from 9.8 to 5.2%), but condom use remained low [96]. In Uganda, major and widespread changes toward safer sexual

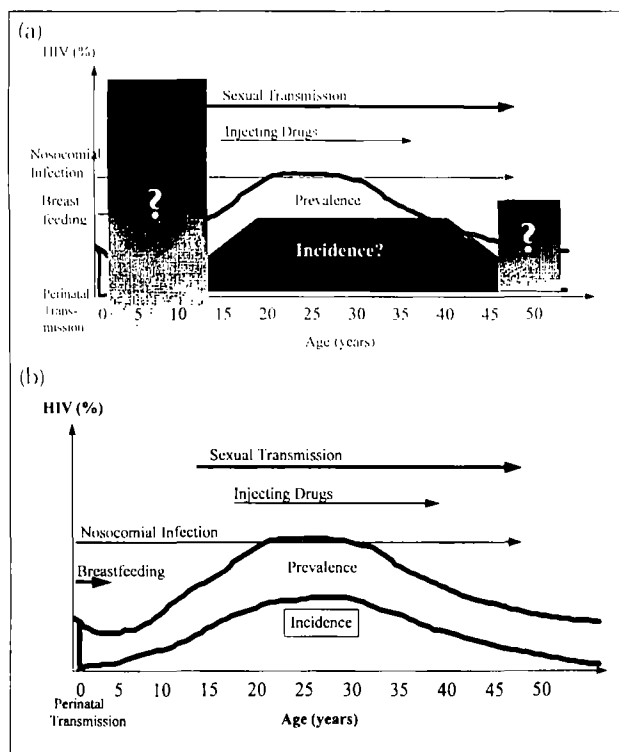


Fig. 9. HIV prevalence and incidence throughout the life-cycle: a hypothetical country scenario. (a) What we know and do not know and (b) what we would like to know.

behaviors have also been documented, including in this case an increased level of experience with condoms to an albeit modest 20–25% of the currently sexually active population [97].

While these behavioral changes were being noted, HIV prevalence declines were reported to have occurred in younger age groups in several HIV testing sites in Uganda (Fig. 10) [99,100]. In the Karakole district of western Uganda in 1994, the decrease of HIV prevalence in 11–20-year-old women attending ANC seemed to indicate a similar declining trend in incidence. This trend was more pronounced in urban than in semi-urban or rural areas [101].

Although the discrete declines in HIV prevalence observed in several populations are encouraging and are occurring concurrently with shifts toward safer sexual behaviors, other factors could also be associated with these trends. One of these factors might be the changing velocity of the spread of HIV as it shifts its main focus from individuals with high levels of exposure to HIV (for example, individuals with a high rate of unprotected sexual contacts with multiple partners) to others (for example, regular sexual partners of these individuals). These declines do shed some hope on the future of the epidemics, however, and should add vigor to ongoing prevention programs.

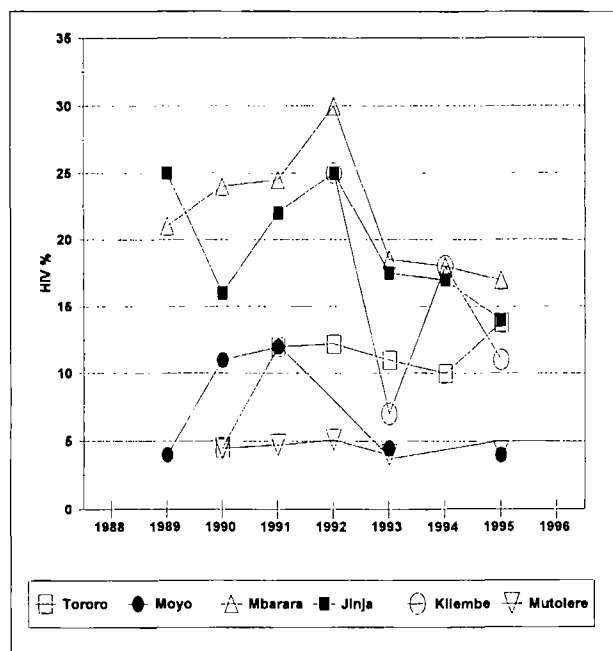


Fig. 10. HIV seroprevalence for pregnant women in selected cities in Uganda in 1989–1995. Data from [98].

In addition to observed changes in behavior, there are other indications that HIV epidemics can respond to effective prevention. The first randomized, controlled trial on the impact of STD treatment on the transmission of HIV was conducted in Mwanza, Tanzania, in 1995–1996 [102]. The aim of this study was to implement improved STD treatment services and fully integrate them into the primary health-care system, thus rendering them easily accessible to the population. For comparison, six communities with improved services and six with pre-existing STD services were included in the study. A random sample of 12 000 adults was followed over 2 years to record the prevalence of selected STD and the incidence of HIV. Baseline prevalence of HIV was about 4% and incidence of HIV infections during the follow-up period was 1.2% in the communities with the improved services and 1.9% in the comparison communities, showing a reduction of about 38%. Similarly, the prevalence of active syphilis was reduced by up to 40% and of active urethritis in men by 50%.

The results of this intervention study should stimulate increased interest in, and commitment to, the strengthening of STD prevention and care programs in Africa and elsewhere in the world.

The future course of the HIV epidemics

The course, both present and future, of each of the HIV epidemics affecting sub-Saharan Africa depends on a variety of factors, including the virulence of the HIV virus genotype involved, the prevalence of STD and of

male circumcision, sexual mixing patterns within and across communities, as well as social variables [103,104].

The assumption that HIV epidemics have peaked in several populations in sub-Saharan Africa is supported by studies of HIV prevalence and incidence in women from younger age groups attending ANC, by community-based cohort studies, by the analysis of AIDS incidence, and by retrospective analyses of adult mortality [105,106]. An initial decline in incidence should not, however, distract from the possibility of a subsequent increase in incidence as populations at lower risk, but in greater number, than those initially infected by the virus run the risk of exposure. The resulting epidemic curve would show a temporary decline in the incidence of HIV followed by a slow but long-lasting rise, as less immediately vulnerable populations with attenuated links to high-risk sexual networks become infected.

The evolution of the HIV epidemics in Abidjan, Côte d'Ivoire, reconstructed from mortality data, helps illustrate these dynamics of spread, although this example involves complex and incompletely documented factors such as the gradual displacement of HIV-2 by HIV-1 viruses and changing patterns of migration [107]. Back-calculation from mortality data suggests that the incidence of HIV in Abidjan rose in the early and mid-1980s, reaching a peak in 1985–1986. It then declined, but rose again to reach a second peak in 1992. The hypothesis put forward by the authors is that the first epidemic 'wave' was predominantly associated with transactional sex, while the second resulted from sexual contacts within stable relationships.

Projecting the course of the HIV epidemics in sub-Saharan Africa today must take into consideration the fragmentation and diversity of the epidemics. In 1995, an assessment of the HIV situation in the region was performed by the WHO GPA on a country-by-country basis for a mid-point in the year 1994 [2]. It was estimated that, in a population of 260 million adults aged 15–49 years, 11.3 million were living with HIV/AIDS, giving a prevalence rate of 4.35%. No breakdown of these data by sex was available. Several trends have marked the evolution of the HIV epidemics in the region in the last few years: (1) as discussed earlier, the incidence of HIV has shown some signs of decline in some populations, particularly in younger age groups in eastern Africa where the epidemics are more mature; (2) epidemics have suddenly increased in other areas, in particular in southern areas; and (3) the rates of HIV prevalence in many rural areas (where over 70% of the African population live) continue to rise. It would seem fair to assume that the number of people currently living with HIV in sub-Saharan Africa is at least at the 1994 level. UNAIDS is conducting a new country-based analysis of HIV situations and trends which should be completed by the end of 1997. It can be anticipated that the accuracy of these data will be hampered by the

difficulties in reaching meaningful estimates in a context of increased fragmentation and diversity of HIV epidemics.

Toward improved monitoring of HIV status and trends epidemics

In the mid-1980s, the acquisition of knowledge about the state and trends of HIV epidemics in sub-Saharan Africa relied on diverse methods which have evolved over time. The initial approach was to rely on occasional cross-sectional seroepidemiological surveys conducted in groups considered to be at high risk of acquiring HIV, for example sex workers or patients attending STD clinics. Similar, occasional surveys were carried out among women attending ANC. The results of these ad-hoc surveys received much attention as prevalence rates in populations considered to be at 'low risk', mostly women attending ANC, began to climb. In the late 1980s, the WHO GPA developed a method to systematize these cross-sectional surveys and allow for comparisons of their results both over time and between testing sites [108]. The method was based on anonymous and unlinked cross-sectional seroprevalence surveys performed at regular intervals in selected sites. The so-called 'sentinel sites' included ANC, blood transfusion centers and STD clinics. These ESS systems fitted the needs at the time they were created. Their purpose was to provide some broad indication of the presence or absence of HIV infection in selected groups, and of crude trends across age groups when these trends began to be measurable. Since that time, ESS has generated a wealth of information which, unfortunately, has not always been published, reported to international organizations or presented publicly. Currently, all but four sub-Saharan African countries are implementing ESS systems [109]. These remaining four have not set HIV surveillance on their list of priorities.

ESS needs further refinements today if it is to help discern HIV-incidence trends in younger age groups or to interpret these and other trends in the context of social and behavioral changes. There is a critical need to protect the anonymous nature of the ESS, first and foremost in order to preserve privacy and, second, because the potential for loss of privacy would introduce biases in women tested at ANC. Only limited amounts of social information and the lack of behavioral information are currently collected under ESS schemes. This is justified by the concern that collection of behavioral and social data in ANC could lead to a chain of events involving identification of respondents, fear or occurrence of breaches of confidentiality, possible stigma and negative impact on women, their families and their community, self-exclusion from antenatal services where essential care is provided, and the concomitant loss of sources of precious epidemiological information.

Another limitation of ESS is that data collected at sentinel sites are only applicable to the non-random sample of the population tested, and thus not applicable to the entire population from which they are drawn. Such issues as care-seeking patterns (who comes to ANC and who does not?), fertility patterns (what is the HIV prevalence in girls and women who are not currently sexually active or who are not pregnant?), adjustments of the results of the sampled population to match the age structure of the general female population (which age group is over- or under-represented in the sample?), patterns of sexual partnership and age-specific infection rates in boys and men have to be addressed in order to take fuller advantage of the information collected through ESS [110,111].

One of the issues limiting the interpretation of ESS information is the application of broad age groups to data collection and analysis. ESS relies on serological testing of populations of adolescents and adults seen at ANC. Results are analyzed and presented according to 5–10-year age groups starting at the age of 15 years, or as a mean prevalence rate for the entire 15–44-year-old population. The use of such broad age groups in collecting ESS data may currently mask trends in HIV incidence in younger age groups, such as teenagers and adults in their twenties, as shown in Zambia (Box II).

Collecting and analyzing HIV prevalence in single-year age groups among the youngest (15–24-year-olds) and adjusting the sample size accordingly would help to provide meaningful results and lead to a better understanding of the dynamics of the epidemics.

The extrapolation of data collected at ANC to the population at large requires the 'calibration' of sentinel surveillance data. This can be attempted through the comparison of sentinel surveillance data with seroepidemiological data collected through occasional, cross-sectional, population-based surveys. For example, in Mwanza, Tanzania, in 1990–1992, HIV prevalence rates in the general population were compared with rates derived from ANC-based sentinel surveillance. The rate for women in the general population was higher than that for the ANC population, suggesting lower fertility in women with HIV [112]. In the Karakole district of western Uganda, sentinel surveillance data tended to overestimate HIV prevalence rates in semi-urban and rural areas, while underestimating them in the urban area [113]. The approach applied in Zambia (Box II) provided, among other critically useful information, adjustment factors for the interpretation of sentinel surveillance data.

Community-based cohort studies have also been conducted to estimate the incidence of HIV infection, probe into the association between HIV trends and socioeconomic determinants, and explore the evolution of HIV disease and its impact on morbidity, fertility and mortality. These studies provide quality data but their

design, implementation and data analysis are complex and costly, thus limiting their replication [114].

Alternate approaches for exploring a possible association between social and behavioral variables and trends in HIV infection rates include collecting behavioral and social data in catchment areas surrounding sentinel surveillance sites or, when this is the only available option, in populations away from these sites but deemed to share the behavioral and social characteristics of the population covered by sentinel surveillance. Information collected through these approaches may provide crude indications of a possible association between trends in HIV infection, behavioral and social determinants, and the impact of prevention programs. This type of information is critical to the evaluation and refinement of prevention strategies. Surveillance methods should, however, be adapted to meet specific country needs and capacity; these methods are contingent on the intended use of surveillance data, the stage of maturity reached by the epidemics, the availability of resources and the strength of the local infrastructure [115].

Conclusion

The abundant information generated from HIV epidemiological surveillance and research in sub-Saharan Africa has contributed to a great extent to advancing the global knowledge of the dynamics of HIV epidemics in populations where the heterosexual transmission of HIV predominates. The development and progressive refinement of surveillance methods, now applied in many countries around the world, is in its own right a major contribution to the collective capacity to understand the epidemics and respond to them more effectively.

The HIV epidemics in sub-Saharan Africa remain as powerful and diverse as ever, but there are clear signs that, when appropriately addressed, they can be challenged and destabilized. There is unfortunately little doubt that the future holds rather predictable developments, such as the increased impact of HIV on people already infected, on those who provide them with needed care and support, and on nations who are reaching or have already surpassed the limits of their coping capabilities. The future also holds a number of uncertainties; for example, the nature and determinants of abrupt and devastating outbreaks of HIV, as being witnessed in southern Africa, are inadequately understood.

Expanding the capacity of epidemiological surveillance should provide the needed information on evolving patterns of HIV incidence, the occurrence of behavior change associated with these trends, and on the effectiveness of prevention efforts. It is hoped that this constant process of discovery will stimulate increased interest on the part of decision-makers to more systematic applications of the growing body of knowledge to policy

and program development in sub-Saharan Africa as well as in the rest of the world.

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References

- WHO/UNAIDS: *HIV/AIDS: The Global Epidemic*. Fact Sheet. Geneva: UNAIDS/AWHO; 1996:4.
- WHO: *World Health Organization's Weekly Epidemiological Record*. Geneva: WHO; 1995, **70**:351-360.
- Mulder DW, Nunn AJ, Wagner HU, Kamali A, Kengeya-Kayondo JE: **HIV-1 incidence and HIV-1-associated mortality in a rural Ugandan population cohort**. *AIDS* 1994, **8**:87-92.
- Anzala OA, Nagelkerke NJ, Bwayo JJ, et al.: **Rapid progression to disease in African sex workers with human immunodeficiency virus type 1 infection**. *J Infect Dis* 1995, **171**:686-689.
- Nunn AJ, Kamali A, Kengeya-Kayondo JE, Mulder DW: **Four year HIV-1 associated mortality and median survival times in a rural Ugandan population**. *IX International Conference on AIDS and STD in Africa*. Kampala, December 1995 [abstract MoB437].
- Tarantola D, Mann J: **Global overview: a powerful HIV/AIDS pandemic**. In *AIDS in the World II*. Edited by Mann J, Tarantola D. New York: Oxford University Press; 1996:5-40.
- Gregson S, Garnett GP, Shakespeare R, et al.: **Determinants of the demographic impact of HIV-1 in sub-Saharan Africa: the effect of a shorter mean adult incubation period on trends in orphanhood**. *Health Transition Rev* 1994, **4** (suppl):65-92.
- De Cock KM: **The emergence of HIV/AIDS in Africa**. *Revue d'Epidémiologie et de Santé Publique* 1994, **44**:511-518.
- U.S. Bureau of the Census: *Recent HIV Seroprevalence Levels by Country: January 1997*. Washington DC: Population Division, U.S. Bureau of the Census; 1997, **23**:36-44.
- Anarfi JK: **Female Migration and Prostitution in West Africa: The case of Ghanaian women in Côte d'Ivoire**. *Studies in Sexual Health No. 1*. Accra, Ghana: GTZ Regional AIDS Programme for West and Central Africa; 1995.
- EIMU: **Enquête Ivoirienne sur les Migrations et l'Urbanisation (EIMU)**. *Séminaire de dissémination des résultats*. Ministère De L'énergie après du premier Ministre chargé de Plan et du Développement Industriel, Ministère de l'Enseignement Supérieur de la Recherche et de l'Innovation Technologique, République de Côte d'Ivoire, Abidjan, October 1996.
- Sylla-Koko E, Ezoua-Ehuni C, Traoré-Anaky ME, et al.: **Séroprévalence de l'infection à VIH dans les consultations prénatales d'Abidjan, Côte d'Ivoire**. *IX International Conference on AIDS and STD in Africa*, Kampala, December 1995 [abstract TuC626].
- Kanki PJ, Peeters M, Guéye-Ndiaye A: **Virology of HIV-1 and HIV-2: implications for Africa**. *AIDS* 1997, **11** (suppl B):S33-S42.
- Ministère de la Santé Publique: *Plan National de Lutte Contre le SIDA 1996-1999*. Abidjan: Ministère de la Santé Publique, République de Côte d'Ivoire; 1996:11.
- Laarrie J: **HIV sero-surveillance in northern Ghana, 1994; GTZ AIDS Project**. *IX International Conference on AIDS and STD in Africa*. Kampala, December 1995 [abstract MoCQ15].
- Bamba B, Soumah M, Lutumba P: **Etude de prévalence du VIH et des autres MST chez les filles libres à Conakry**. *IX International Conference on AIDS and STD in Africa*. Kampala, December 1995 [abstract TuC619].
- Bagamizi E, Alary M, Guedeme A, Padonou E, Davon N, van Dyck E: **HIV infection in female prostitutes from Benin: association with symptomatic but not asymptomatic gonococcal or chlamydial infection**. *IX International Conference on AIDS and STD in Africa*. Kampala, December 1995 [abstract TuC616].
- Kanki PJ, De Cock KM: **Epidemiology and natural history of HIV-2**. *AIDS* 1994, **8** (suppl 1):S85-S93.
- Djomand G, Greenberg A, Sassin-Morokro M, et al.: **The epidemic of HIV/AIDS in Abidjan, Côte d'Ivoire: a review of data collected by project RETRO-CI from 1987 to 1993**. *J Acquir Immune Defic Syndr* 1995, **10**:358-365.
- Ghys PD, Diallo MO, Etiénné-Traoré V, et al.: **Dual seroreactivity to HIV-1 and HIV-2 in female sex workers in Abidjan, Côte d'Ivoire**. *AIDS* 1995, **9**:955-958.
- Wilkins A, Ricard D, Todd J, Whittle H, Dias F, Da Silva AP: **The epidemiology of HIV infection in a rural area of Guinea-Bissau**. *AIDS* 1993, **7**:1119-1122.
- Anderson S, Albert J, Nongren H, Dias F, Naucière A, Biberfeld G: **Trends of incidence and prevalence of HIV-1 in Guinea-Bissau, West Africa, and preliminary data on subtypes**. *IX International Conference on AIDS*. Vancouver, July 1996 [abstract MoC1480].
- Norgren H, Anderson S, Naucière A, Dias F, Johansson I, Biberfeld G: **HIV-1, HIV-2, HTLV-I/II, and *Treponema pallidum*: incidence, prevalence, and HIV-2-associated mortality in an occupational cohort in Guinea-Bissau**. *J Acquir Immune Defic Syndr* 1995, **9**:422-428.
- De Cock KM, Adjorlolo G, Ekpini E, et al.: **Epidemiology and transmission of HIV-2. Why there is no HIV-2 pandemic**. *JAMA* 1993, **270**:2083-2086.
- Anderson RM, May RM: **The population biology of the interaction between HIV-1 and HIV-2: coexistence or competitive exclusion?** *AIDS* 1996, **10**:1663-1673.
- Magazani K, Lalemant G, Perriens JH, et al.: **Low and stable HIV seroprevalence in pregnant women in Shaba Province, Zaïre**. *J Acquir Immune Defic Syndr* 1993, **6**:419-423.
- Bureau Central de Coordination du Programme National de Lutte contre le SIDA: *Rapport de surveillance séroépidémiologique*. Kinshasa, Zaïre: Ministère de la Santé; 1993.
- Delaporte E, Janssens W, Peeters M, et al.: **Epidemiological and molecular characteristics of HIV infection in Gabon, 1986-1994**. *AIDS* 1996, **10**:903-910.
- Bazabana M, Loukaka JC, M'Pele P: **Evolution de la séro-surveillance de l'infection à VIH chez les femmes enceintes au Congo de 1990 à 1993**. *IX International Conference on AIDS and STD in Africa*. Kampala, December 1995 [abstract MoC497].
- Nzilambi N, Malele B, Kivuvu M, Tuhiza M, Luila K: **Stabilization of HIV-1 seroprevalence in female prostitutes in Kinshasa, Zaïre, masks a dynamic infection**. *IX International Conference on AIDS and STD in Africa*. Kampala, December 1995 [abstract MoC205].
- Monny-Lobe M, Ella M, O'Dell V, Ngoumou P, Boupda A: **A comparative HIV seroprevalence study among sex workers in Yaounde and Douala, Cameroon**. *IX International Conference on AIDS*. Berlin, June 1993 [abstract PO-C31-3300].
- Sam-Abbenhvi A, Akumba JL, Zekeng L, Agoum G, Schmidt-Ehry B: **High seroprevalence rates of syphilis and HIV among sexually active subjects in Limbe District (South-West Cameroon)**. *IX International Conference on AIDS and STD in Africa*. Kampala, December 1995 [abstract MoCQ14].
- Bucyendore A, Van de Perre P, Karita E, Nziyumira A, Sow I, Fox E: **Estimating the sero-incidence of HIV-1 in the general adult population in Kigali, Rwanda**. *AIDS* 1994, **7**:275-277.
- Ntawiniga P, Leroy V, Gazille-Rugema C, et al.: **High seroprevalence of HIV infection and syphilis among pregnant women: Kigali, Rwanda, May 1995**. *IX International Conference on AIDS and STD in Africa*. Kampala, December 1995 [abstract TuB573].
- Munga IN, Ombette J, Kimani L, et al.: **Laboratory findings for the prevalence of HIV, *Neisseria gonorrhoeae* and *Chlamydia trachomatis* infections among prostitutes attending an STD clinic in Nairobi, Kenya**. *VII International Conference on AIDS in Africa*. Yaounde, November 1992 [abstract WP 139].
- van der Horstberg H: *HIV Sero-Status Survey in Midlands Province - Phase 1-3*. Midlands Province: Ministry of Health Epidemiology and Disease Control Unit; 1996.
- Mbuzo MT, Machekano R, McFarland W, et al.: **HIV sero-incidence and correlates of seroconversion in a cohort of male factory workers in Harare, Zimbabwe**. *AIDS* 1996, **10**:895-901.
- Fylkesnes K, Musonda RM, Kasumba K, et al.: **The HIV epidemic in Zambia: socio-demographic prevalence patterns and indications of trends among childbearing women**. *AIDS* 1997, **11**:139-145.
- Fylkesnes K, Sichone M, Kasumba K: **A population-based HIV study using saliva specimens: socio-demographic determinants**

- of infection in Zambia. 1997 (in press).
40. Fylkesnes K, Kasumba K, Ndhlovu Z, Musonda RM: **Studying dynamics of the HIV epidemic: how representative is surveillance of the population at large?** 1997 (in press).
 41. Ilam J, Stuart J, Steinberg M, Abdool Karim S, Swanenvelder R: **Surveillance of HIV/AIDS in KwaZulu-Natal, 1990-94.** IX International Conference on AIDS and STD in Africa, Kampala, December 1995 [abstract MoC495].
 42. Nkosazana: **Prevalence increases markedly in South Africa.** Press Announcement, Republic of South Africa: Minister of Health; April 27 1997.
 43. Nxumalo R: **HIV sentinel surveillance in Swaziland.** Evidence of Behavioural Change in the Context of HIV Decline in Uganda — A UNAIDS Best Practice Workshop, Nairobi, February 1997 [working paper].
 44. National AIDS Control programme: **Report on National HIV Sentinel Survey, 1996.** Namibia: Ministry of Health and Social Services; October 1996.
 45. Barreto A, De Hulsters B, Noya A, Bastor R, MacArthur Jr A: **Trends in HIV prevalence among different target groups: data from the national sentinel surveillance system of Mozambique.** IX International Conference on AIDS and STD in Africa, Kampala, December 1995 [abstract MoC502].
 46. Kalwa OL, Kornfield R: **Trends in HIV seroprevalence and behaviour related to risk of HIV infection in Malawi.** Evidence of Behavioural Change in the Context of HIV Decline in Uganda — A UNAIDS Best Practice Workshop, Nairobi, February 1997 [working paper].
 47. Rasamindrakotroka A, Andriamahanina R, Behets E, May J, Andrianandana J, Kavaorimalala C: **High syphilis and low but rising HIV seroprevalence rates in Madagascar.** XI International Conference on AIDS, Vancouver, July 1996 [poster Mo.C.1488].
 48. Sidhom M, Fekih Z: **HIV infection in Tunisia (1986-1995). Variations of principal epidemiologic indicators.** XI International Conference on AIDS, Vancouver, July 1996 [abstract Mo.C.1481].
 49. Mann J, Tarantola D, Netter T (eds): **Appendix.** In *AIDS in the World*. Cambridge, MA: Harvard University Press; 1992, 2:2384.
 50. Van de Perre P, Diakhate L, Watson-Williams J: **Prevention of blood-borne transmission of HIV.** AIDS 1997, 11 (suppl B):S89-S98.
 51. Cleland J: **Sexual behavior.** In *Preventing and Mitigating AIDS in Sub-Saharan Africa: Research and Data Priorities for the Social and Behavioral Sciences*. Edited by Cohen B, Trussell J. Washington, DC: National Research Council, National Academy Press; 1996, 4:134.
 52. Mann J, Tarantola D, Netter T: **The HIV Pandemic, Status and Trends.** In *AIDS in the World*. Edited by Mann J, Tarantola D, Netter T. Cambridge, MA: Harvard University Press; 1992:2-72.
 53. Nunn AJ, Kengeya-Kayondo JE, Malamba SS, et al.: **Risk factors for HIV-1 infection in adults in a rural Ugandan community: a population study.** AIDS 1994, 8:81-86.
 54. Hunter DJ, Maggwa BN, Mati JKC, Tukei PM, Mbuga S: **Sexual behavior, sexually transmitted diseases, male circumcision and risk of HIV infection among women in Nairobi, Kenya.** AIDS 1994, 8:93-99.
 55. Riedner G: **Eight Years Sentinel Surveillance of HIV and Syphilis in Mbeva Region, Tanzania: Trend Observations in Different Populations and their Relevance in the Context of AIDS/STD Control.** M.Sc. Thesis, London: University of London; 1996.
 56. Grosskurth H, Mosha F, Todd J, et al.: **A community trial of the impact of improved sexually transmitted disease treatment on the HIV epidemic in rural Tanzania: 2. Baseline survey results.** AIDS 1995, 9:927-934.
 57. Mnyika KS, Klepp KI, Kvåle G, Ole-King'ori N: **Risk factors for HIV-1 infection among women in the Arusha region of Tanzania.** J Acquir Immune Defic Syndr 1996, 11:484-491.
 58. Wawer MJ, Serwadda D, Musgrave SD, Konde-Lule JK, Musagara M, Sewankambo NK: **Dynamics of spread of HIV-1 infection in a rural district of Uganda.** BMJ 1991, 303:1303-1306.
 59. Serwadda D, Gray RH, Wawer MJ, et al.: **The social dynamics of HIV transmission as reflected through discordant couples in rural Uganda.** AIDS 1995, 9:745-750.
 60. Okeyo TM, Baltazar GM, Stover J, Johnston A: **AIDS in Kenya. Background Projections Impact Interventions.** Nairobi: National AIDS and STD Control Programme; 1996:6-8.
 61. Pison G, Le Guenno B, Lagarde E, Enel C, Seck C: **Seasonal migration: a risk factor for HIV infection in rural Senegal.** J Acquir Immune Defic Syndr 1993, 6:196-200.
 62. Lagarde E, Pison G, Enel C: **A study of sexual behavior change in rural Senegal.** J Acquir Immune Defic Syndr 1996, 11:282-287.
 63. Buvé A, Foster SD: **Will AIDS widen the gap between urban and rural development in Zambia?** IX International Conference on AIDS/IV STD World Congress, Berlin, June 1993 [abstract PO-128].
 64. Antoine P, Dubresson A: *Pour Comprendre la Question de l'Habitat Abidjan Côte d'Ivoire*. Paris: ORSTOM; 1987.
 65. Carswell JW, Namaara W, Lloyd G, Howells J: **HIV infection among lorry drivers and their assistants in eastern Africa.** VI International Conference on AIDS, Montreal, June 1989 [abstract A.617].
 66. Bwayo J, Plummer F, Omari M, et al.: **Human immunodeficiency virus infection in long-distance truck drivers in east Africa.** Arch Intern Med 1994, 154:1391-1396.
 67. Mbugua GG, Muthami LN, Mutura CW, et al.: **Epidemiology of HIV infection among long distance truck drivers in Kenya.** East Afr Med J 1995, 72:515-518.
 68. Baltazar GM: **The prevalence rate of HIV/AIDS increases with the proximity to the Kenya/Uganda border.** X International Conference on AIDS, Yokohama, August 1994 [abstract PC0042].
 69. Nzyuko S, Nyanwaya D, Lurie P, Mandel J, Hearst N: **Adolescent high risk sexual behavior along the Trans-Africa Highway in Kenya.** XI International Conference on AIDS, Vancouver, July 1996 [abstract Mo.C.1487].
 70. Nunn AJ, Wagner HU, Okongo M, Malamba SS, Kengeya-Kayondo JE, Mulder DW: **HIV-1 infection in a Uganda town along the Trans-African highway: prevalence and risk factors.** Int J STD AIDS 1996, 7:123-130.
 71. Pickering H, Okongo M, Bwanika K, Nnalusiba B, Whitworth J: **Sexual mixing patterns in Uganda: small-time urban/rural traders.** AIDS 1996, 10:533-536.
 72. Vuylsteke B, Sunkutu R, Laga M: **Epidemiology of HIV and sexually transmitted infections in women.** In *AIDS in the World II* Edited by Mann J, Tarantola D. New York: Oxford University Press; 1996:97-109.
 73. Moses S, Plummer FA, Bradley JE, Ndinya-Achola JO, Nagelkerke NJD, Ronald AR: **Male circumcision and the AIDS epidemic in Africa.** Health Trans Rev 1995, 5:100-103.
 74. de Vincenzi I, Mertens T: **Male circumcision: a role in HIV prevention?** AIDS 1994, 8:153-160.
 75. Caldwell J, Caldwell P: **The neglect of an epidemiological explanation for the distribution of HIV/AIDS in sub-Saharan Africa: exploring the male circumcision hypothesis.** Health Transition Rev 1994, 4 (suppl):23-46.
 76. Carael M, Buvé A, Awusabo-Asare K: **The making of HIV epidemics: what are the driving forces?** AIDS 1997, 11 (suppl B):S23-S31.
 77. Lallemand M, Lapointe N, M'Pelé P, Lallemand-Leclerc S: **Perinatal HIV transmission.** In *AIDS in the World*. Edited by Mann J, Tarantola D, Netter T. Cambridge, MA: Harvard University Press; 1992:629-645.
 78. Working Group on Mother-to-Child Transmission of HIV: **Rates of mother-to-child transmission of HIV-1 in Africa, America and Europe: results from 13 perinatal studies.** J Acquir Immune Defic Syndr 1995, 8:506-510.
 79. Adjorlolo-Johnson G, De Cock KM, Ekpin E, et al.: **Prospective comparison of mother-to-child transmission of HIV-1 and HIV-2 in Abidjan, Ivory Coast.** JAMA 1994, 272:462-466.
 80. Mbaye N, Sarr M, Fall M, et al.: **Etude prospective de la transmission périnatale du VIH-1 et VIH-2 à Dakar, Sénégal.** IX International Conference on AIDS and STD in Africa, Kampala, December 1995 [abstract ThC285].
 81. Heymann SJ: **Is breast feeding a risk? The challenge of AIDS.** In *AIDS in the World*. Edited by Mann J, Tarantola D, Netter T. Cambridge, MA: Harvard University Press; 1992:616-629.
 82. Ekpin ER, Wiktor SZ, Satten GA, et al.: **Late postnatal mother-to-child transmission of HIV-1 in Abidjan, Côte d'Ivoire.** Lancet 1997, 349:1054-1059.
 83. Le Coeur S, Lallemand M: **Breast feeding and HIV/AIDS.** In *AIDS in the World II*. Edited by Mann J, Tarantola D. New York: Oxford University Press; 1996: 273-277.
 84. van de Perre P, Cartoux M: **Retroviral transmission and breast feeding.** J Clin Microbiol Infect 1995, 11:6-12.
 85. van de Perre P: **Postnatal transmission of human immunodeficiency virus type 1: the breastfeeding dilemma.** Am J Obstet Gynecol 1995, 173:483-487.
 86. Bertoll J, St Louis ME, Simonds RJ, et al.: **Estimating the timing of**

- mother-to-child transmission of human immunodeficiency virus in a breast-feeding population in Kinshasa, Zaïre. *J Infect Dis* 1996; **174**:722-726.
87. McIntyre JA, Gray GE, Lyons SF. **Maternal and obstetrical factors in mother to child transmission of HIV in Soweto, South Africa.** *X International Conference of AIDS*. Vancouver, July 1996 [abstract TU.C.342].
88. Gray R, Nakabito C, Munro E, *et al.* **HIV-1 response to oral AZT in pregnant Ugandan women.** *IV Conference on Retroviruses and Opportunistic Infections*. Washington DC, October 1996.
89. Ferry B. **Risk factors related to HIV transmission: sexually transmitted diseases, alcohol consumption and medically-related injections.** In *Sexual behaviour and AIDS in the Developing World*. Edited by Cleland J, Ferry B. London: Taylor and Francis; 1995, 7:193-207.
90. Prazuck T, Tall E, Nacro B, *et al.* **HIV infection and severe malnutrition: a clinical and epidemiological study in Burkina Faso.** *AIDS* 1993; **7**:103-108.
91. Kengeya-Kayondo JE, Malamba SS, Nunn AJ, Seeley JA, Ssali A, Mulder DW. **Human immunodeficiency virus (HIV-1) seropositivity among children in a rural population of south-west Uganda: probable routes of exposure.** *Ann Trop Pediatr* 1995; **15**:115-120.
92. Consten ECJ, van Lanschot JJB, Heny PC, Tinnemans JGM, van der Meer IM. **A prospective study on the risk of exposure to HIV during surgery in Zambia.** *AIDS* 1995; **9**:585-588.
93. Anonymous. *Observatoire Géopolitique des Drogues: Etats des Drogues, Drogue des Etats*. Paris: Hachette; 1994:67-120.
94. Mann J, Tarantola D, Netter T (eds). *AIDS in the World*. Cambridge, MA: Harvard University Press; 1992:408.
95. Labrousse A. **Traffic de drogues et toxicomanies en Afrique subsaharienne.** *Le Journal du SIDA* 1996; **86-87**:56-58.
96. Ng'weshemi JZL, Burma JT, Pool R, *et al.* **Changes in male sexual behavior in response to the AIDS epidemic: evidence from a cohort study in urban Tanzania.** *AIDS* 1996; **10**:1415-1420.
97. Barton T. **Epidemics and behavior: a review of changes in Ugandan sexual behavior in the early 1990s: Summary paper for the Joint United Nations Programme on HIV/AIDS. Evidence of Behavioural Change in the Context of HIV Decline in Uganda — A UNAIDS Best Practice Workshop.** Nairobi, February 1997 [working paper].
98. U.S. Bureau of the Census. *Trends and Patterns of HIV/AIDS Infection in Selected Developing Countries*. Washington DC: U.S. Bureau of the Census; 1996.
99. Asimwe-Oknor G, Musinguzi J, Opio A, *et al.* **Declining HIV prevalence in women attending antenatal clinic sentinel surveillance sites in Uganda. Summary paper for the Joint United Nations Programme on HIV/AIDS. Evidence of Behavioural Change in the Context of HIV Decline in Uganda — A UNAIDS Best Practice Workshop.** Nairobi, February 1997 [working paper].
100. Musinguzi J, Asimwe-Oknor G, Opio AA, *et al.* **Sexual behaviour change due to HIV/AIDS: Results of populations based KABP surveys conducted in five districts in Uganda. Summary paper for the Joint United Nations Programme on HIV/AIDS. Evidence of Behavioural Change in the Context of HIV Decline in Uganda — A UNAIDS Best Practice Workshop.** Nairobi, February 1997 [working paper].
101. Kilian AHD, Sahlmüller G, Ndyababangi B, *et al.* **Trends in HIV sentinel surveillance in Western Uganda and comparisons with data from population based surveys.** *IX International Conference on AIDS and STD in Africa*. Kampala, December 1995 [abstract W6C203].
102. Grosskurth H, Mosha E, Todd J, *et al.* **Impact of improved treatment of sexually transmitted diseases on HIV infection in rural Tanzania: randomised controlled trial.** *Lancet* 1995; **346**:530-536.
103. Fontanel A, Piot P. **State of our knowledge: the epidemiology of HIV/AIDS.** *Health Transition Rev* 1994; **4** (suppl):11-23.
104. Anderson R. **The spread of HIV and sexual mixing patterns.** In *AIDS in the World II*. Edited by Mann J, Tarantola D. New York: Oxford University Press; 1996, 4:71-86.
105. Stoneburner K, Low-Beer D, Tembo C, Mertens TE, Asimwe-Oknor G. **Human immunodeficiency virus infection dynamics in East Africa deduced from surveillance data.** *Am J Epidemiol* 1996; **144**:682-695.
106. Garenne ML, Madison M, Tarantola D, Zanou B, Aka J, Dogore R. **Mortality impact of AIDS in Abidjan, 1986-1992.** *AIDS* 1996; **10**:1279-1286.
107. Garenne M, Friedberg F, Zanou B. **Reconstructing the dynamics of the HIV/AIDS epidemic in Abidjan, Côte d'Ivoire, 1986-1995.** *IUSSP: The Socio-Economic Impact of AIDS in Africa*. Durban, February 1997 [working paper].
108. WHO Programme on AIDS. *Unlinked Anonymous Screening for the Public Health Surveillance of HIV Infections. Proposed International Guidelines*. Geneva: World Health Organization; 1989 [WHO/GPA/SFI/89.3].
109. Sato P. **Sentinel HIV surveillance.** In *AIDS in the World II*. Edited by J Mann, D Tarantola. New York: Oxford University Press; 1996:7-8.
110. UNAIDS. *Report on the UNAIDS Regional Workshop on Evidence of Behavioural Change in the Context of HIV Decline in Uganda*. Geneva: UNAIDS, 1997 (in press).
111. Boisson E, Nicoll A, Zaba B, Rodrigues LC. **Interpreting HIV seroprevalence data from pregnant women.** *J Acquir Immune Defic Syndr* 1996; **13**:434-439.
112. Bongdoff M, Barongo L, van Jaarsveld E, *et al.* **Sentinel surveillance for HIV-1 infection: how representative are blood donors, outpatients with fever, anaemia, or sexually transmitted diseases, and antenatal clinic attenders in Mwanza Region, Tanzania?** *AIDS* 1993; **7**:567-572.
113. Kilian AHD, Sahlmüller G, Ndyababangi B, *et al.* **Trends in HIV sentinel surveillance in Western Uganda and comparisons with data from population based surveys.** *IX International Conference on AIDS and STD in Africa*. Kampala, December 1995 [abstract W6C203].
114. Nunn AJ, Mulder DW, Kamali A, Ruberantwari A, Kengeya-Kayondo JE, Whitworth J. **Five-year HIV-1 associated mortality in a rural Ugandan population.** *IUSSP seminar on The Socio-economic impact of AIDS in Africa*. Durban, February 1997.
115. AIDS CAP/Family Health International. **Minimal and advanced surveillance systems at different stages of HIV/AIDS epidemics. In The Status and Trends of the Global HIV/AIDS Pandemic, Final Symposium Report.** Vancouver: UNAIDS; 1996:51-55.