#1450 GLAXO WELLCOME USA TODAY

Public Citizen

Buyers Up • Congress Watch • Critical Mass • Global Trade Watch • Health Research Group • Litigation Group
Joan Claybrook, President

July 29, 1998

Thomas Curley
President and Publisher
USA Today
1000 Wilson Boulevard
Arlington, VA 22229

Dear Mr. Curley:

We are writing to demand immediate action against all *USA Today* employees responsible for the decision to allow Glaxo Wellcome to have a "special edition" of *USA Today* distributed to 7,000 people at the recent International AIDS Conference in Geneva, Switzerland on June 30, 1998. When conference attendees picked up their *USA Today* they saw what looked to them like the normal front page of *USA Today*. This pseudoedition used the overall design and logo of a regular issue of *USA Today* to hawk Glaxo products. There is little reason to expect better from a for-profit pharmaceutical manufacturer, but for a major international newspaper to sell its name and reputation in the service of increased profit is a craven violation of journalistic ethics.

The Society of Professional Journalists is unwavering in its opposition to these sorts of arrangements. Its ethical code declares unequivocally: "Journalists should distinguish news from advertising and shun hybrids that blur the lines between the two."[1]

The "special edition" (see Attachment 1) was a single sheet document (front and back) on paper the same size and quality as a regular issue of *USA Today* and was delivered free of charge to AIDS conference hotel rooms in Geneva wrapped around the regular European issue, thus apparently using *USA Today's* usual distribution system. As indicated by a comparison with the regular U.S. issue of *USA Today* issued on the same day (see Attachment 2), the characteristic *USA Today* logo with the same coloring was used, flanked by two boxes. The left hand side of the front pages in both versions contains the usual *USA Today* "Newsline" feature and the bottom left has the customary *USA Today* graphic "USA Snapshots," now given over to promoting the benefits of Glaxo's Combivir, a drug that treats HIV infection. Fonts, print sizes and other design features are essentially identical to those in a regular edition of the paper.

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[1]Society of Professional Journalists. Code of Ethics, September 1996. Available at http://www.spj.org/ethics/index.htm

It is clear that your paper's logic has always been to provide people on the go a quick look at the most important news, starting with a glance at the front page. Whereas other newspapers have long had advertising inserts within the paper, you have taken a quantum leap by wrapping the "real" paper with a clever cover that is, in fact, advertising, not news, deliberately leading the reader to believe they are looking at news, not advertising.

The subject matter of the "special edition" is almost completely confined to matters related to Glaxo. Of 15 "news" items, only three do not mention Glaxo drugs directly and none mentions the products of any other company. The three remaining items are a description of a community program in which Glaxo is involved, discussion of a statistical issue apparently designed to justify the way data on Glaxo drugs are presented in other articles, and basic statistics on the AIDS epidemic. Glaxo's drugs and community activities are invariably portrayed in a favorable light in the articles, which have no bylines. A list of key conference presentations on the back of the "special edition" lists only 13 of the 5,003 presentations at the conference, all involving Glaxo products or programs.

Given the obvious and intended similarity of this "special edition" to a regular edition of *USA Today*, many readers could have confused this promotional material for an actual edition of *USA Today*. Although Glaxo's sponsorship of the "special edition" is disclosed in several locations (a bar with small print across the logo states: "This special promotional edition has been prepared by the *USA Today* Promotion Department on behalf of Glaxo Wellcome" and bars at the bottom of the first page and top of the second describe the issue as a "Special edition for Glaxo Wellcome" and "News from Glaxo Wellcome," respectively), the reader is in effect invited to consider this a regular issue of *USA Today*. After all, why else would Glaxo sponsor a "special edition" of the newspaper? It is only by deceiving the public into believing that this is a regular issue of *USA Today* that the promotion gains any force.

There is every indication that *USA Today* plans more of the same. In a box on the second page, the newspaper is put up for bid again. In a come-on for potential future advertisers, it is explained that "This special promotional edition ... is one example of the varied type of added-value programs that help extend the impact and increase the value of an advertising investment in *USA Today*."

This disgraceful episode leaves numerous questions unanswered:

* Who at *USA Today* gave approval for this flagrant violation of journalistic ethics?

* Who actually wrote the copy for the "special edition"? Given the technical nature of some of the contents, did Glaxo write or edit the material?

* What were the financial arrangements under which the "special edition" was produced?

* To whom has *USA Today* previously sold its name in a similar fashion?

We look forward to answers to these questions.

Newspapers survive by earning a good name for providing accurate, independent, unbiased information to the public, not by auctioning off that name to whomever is willing to pay the price. How dispiriting it must be for those excellent *USA Today* journalists who cover real news with integrity on a daily basis, only to see their work diminished when the paper turns around and rents out its identity, thereby blurring what should be a bright line between advertising and editorial content.

In the absence of immediate corrective action, any subsequent reporting by *USA Today* on matters regarding the pharmaceutical industry will be tainted. We trust you will take the strongest possible action to restore the tattered reputation of *USA Today* by holding the offending employees accountable and by refusing to allow the front page of your newspaper to be hijacked again.

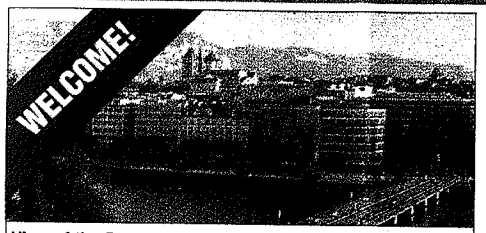
Sincerely,

Peter Lurie, MD, MPH
Research Associate

Sidney M. Wolfe, MD
Director, Health Research Group

Ben Bagdikian
Former Assisting Managing Editor for National News, the *Washington Post*
Former Dean, School of Journalism
University of California, Berkeley
Author of *The Media Monopoly*, a critique of growing corporate control of the media

THE NATION'S NEWSPAPER



View of the Pont des Bergues, the Rhone River and the Old Town with the St. Pierre Cathedral.

WELCOME TO THE 12th WORLD AIDS CONFERENCE

Conference organizers estimate 12,000 attendees at the Palexpo Exhibition Hall in Geneva.

For the first time, both scientific and HIV community representatives have been given equal say in the form and content of the conference.

USA TODAY

NO. 1 IN THE USA . . . FIRST IN DAILY READERS

ADHERENCE ISSUES A MAJOR PROBLEM

Forty-three percent of patients admit that they haven't adhered to their HIV drug regimens, according to a recent study published in the *Journal of the International Association of Physicians in AIDS Care.*

Many people with AIDS struggle with "pill burden." Overcoming the dosing complexities of new combinations of drugs to suppress HIV is the biggest challenge today in the clinical management of the disease.

TUESDAY, JUNE 30, 1998

NEWSLINE

A QUICK READ ON THE NEWS

INTERACTIVE CARE MANAGEMENT PROGRAM ASSISTS PEOPLE LIVING WITH HIV: T.H.E. (Tools for Health and Empowerment) Course is a ground-breaking HIV learning program designed to advance the skills required to help patients make more informed decisions about their own care. Trainers from local HIV/AIDS health and service organizations utilize "participant-centered" group learning techniques to lead the two hour workshops for patients and their care partners ("buddy," family members, friend). Preliminary results of a clinical trial indicate improvements in empowerment, knowledge, coping and adherence. Detailed results of T.H.E. Course study that assesses humanistic and adherence outcomes will be presented on July 2 in Session Hall 1 in the 3-5 p.m. session.

T.H.E. COURSE

POSITIVE ACTION PROVIDES WORLDWIDE UMBRELLA FOR AIDS EFFORTS: An international program created by Glaxo Wellcome in 1992, Positive Action works in partnership with community groups, healthcare providers, governments and international agencies to pursue the common goals of more effective HIV prevention, education, care and support for people living with or affected by HIV/AIDS. Since its formation, Positive Action has supported and implemented a wide variety of projects at both a national and international level. For more information, check out the Positive Action website at www.PositiveAction.com.

GRANTS SUPPORT NON-PROFIT: In order to channel contribution dollars to initiatives that address critical issues in HIV management, Glaxo Wellcome has implemented a Request for Proposal (RFP) process as part of its ongoing support for HIV community service organizations. Seventeen awards have recently been announced in response to the first RFP which focused on initiatives that extend the distribution of information to African-American or Hispanic audiences and simplify the data presented at the 12th World AIDS Conference. Later

Potency of Amprenavir+Abacavir explored

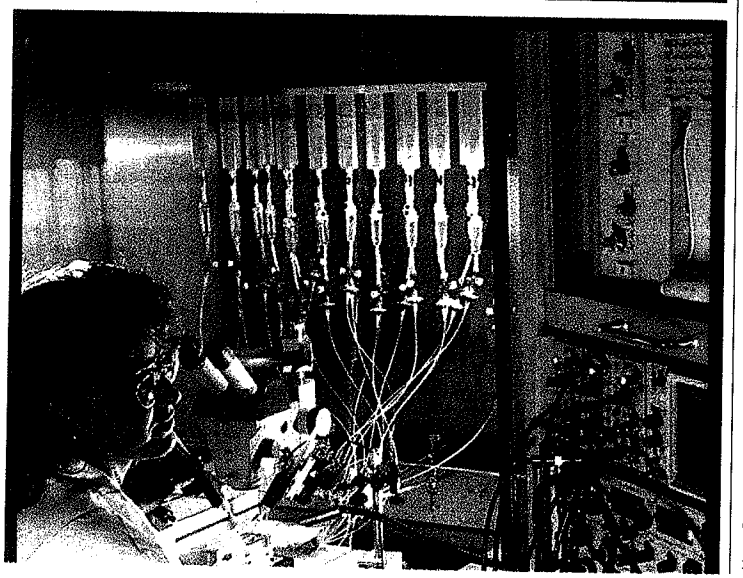
Protease enzyme—a target of anti-HIV therapy.

Preliminary results from a small phase II study suggest that the combination of amprenavir (formerly known as 141W94) and abacavir (formerly known as 1592) may effectively suppress HIV replication while being generally well tolerated. The study, an open-label design involving 40 treatment naive patients, was presented yesterday at the 12th World AIDS Conference in Geneva.

Early results from the study indicate that 89 percent of patients (25 of 28) who at the time of the analysis had completed 24 weeks of treatment, have undetectable levels of virus (less than 500 copies/ml). Moreover, 78 percent of patients (32 of 41) who had completed 4 weeks of treatment had undetectable virus, as did 97 percent (37 of 38) of patients who had completed 8 weeks of treatment. The study calls for patients to receive treatment for 72 weeks.

"While these are very preliminary results in a very small number of patients, we are encouraged by the antiviral potency observed thus far," said Lynn Smiley, M.D., vice president of Clinical Development, HIV and Opportunistic Infections at Glaxo Wellcome. "We are also encouraged by the initial indications of tolerability of this regimen."

Adverse events reported in this study included nausea, diarrhea, epigastric pain, headache and rash. At the time of the analysis, two patients had discontinued study drug due to rash. Three percent of patients in clinical trials with abacavir have experienced a hypersensitivity reaction. This reaction is described in the article "Abacavir Data Presented at 12th World AIDS Conference" also found on this page of USA TODAY.



Abacavir data presented at 12th World AIDS Conference

Phase III clinical trial results which further characterize the investigational anti-HIV compound abacavir (formerly known as 1592; nucleoside analogue reverse transcriptase inhibitor) were presented by researchers Monday afternoon at the 12th World AIDS Conference in Geneva.

In preliminary 16-week data from a randomized study of 173 patients enrolled in this study was also evaluated at week 16 by an ultrasensitive assay that can measure viral levels as low as 50 copies per ml of plasma. Using this assay, it was demonstrated that 54 percent of patients in the abacavir/Epivir/Retrovir group and 15 percent of patients in the Epivir/Retrovir group had a plasma viral load of less than

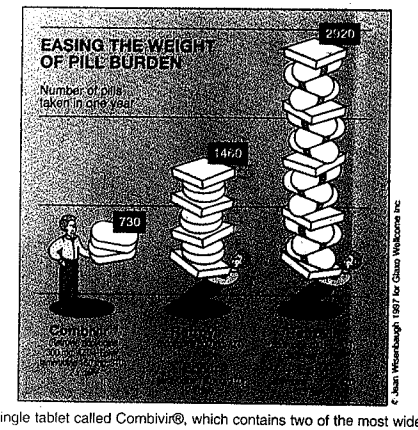
this year, two RFPs addressing programs in which incarcerated persons with HIV are linked to treatment programs while in prison and upon discharge, and programs to link disenfranchised HIV-positive individuals with needed medical services will be issued.

PATIENT DATABASE TO TRACK OUTCOMES: In an effort to provide a centralized, credible source for the most comprehensive HIV data available, Glaxo Wellcome developed a unique, multi-site computerized database system that will simultaneously produce observational information on clinical, economic and humanistic outcomes in patients with HIV/AIDS. The CHORUS (Collaboration in HIV Outcomes Research) database will enroll approximately 6,000 patients with HIV/AIDS in the U.S. and includes data on such parameters as clinical outcomes of patients, economic/healthcare utilization, quality of life, epidemiology and patient satisfaction with healthcare.

LOWERED DRUG PRICES MAKE TREATMENT IN AFRICA COST-EFFECTIVE: Glaxo Wellcome will lower the price of AZT up to 75 percent in some cases for vertical HIV transmission prevention in low-income countries. This announcement coincides with a study concluding that reducing the high rate of vertical HIV transmission in Sub-Saharan Africa with antiviral drugs can be cost-effective if drug prices are lowered. "These events open the way for large-scale drug interventions because we know that these therapies can make both medical and economic sense," said Elliot Marseille, DrPH, MPP, University of California San Francisco senior research associate and lead investigator of the study.

USA SNAPSHOTS®

A look at statistics that shape the nation



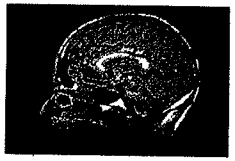
A single tablet called Combivir®, which contains two of the most widely used HIV medications. Epivir (lamivudine 150 mg; 3TC) and Retrovir (zidovudine 300 mg; AZT), was cleared for use by the Food and Drug Administration last fall. Combivir is taken twice a day, eliminating as many as two or six pills a day for appropriate patients.

By Glaxo Wellcome for USA TODAY

Data on promising new drugs were presented today at the 12th World AIDS Conference in Geneva.

A penetrating problem: drugs and the CNS

When it comes to HIV and the nervous system, science still has much to learn. We know the virus can penetrate the brain and cerebrospinal fluid (CSF), and that some antiretroviral drugs can follow right behind. What remains uncertain, however, is the actual meaning of all this.



Scientists and clinicians are exploring the clinical significance of drugs that penetrate the brain and cerebrospinal fluid.

Sections of the nervous system affected by HIV include the brain, the spinal cord and the CSF in which the brain and cord are suspended. Infection of the brain can lead to AIDS-related dementia complex. The impact on the spinal cord is less well understood.

HIV in the central nervous system (CNS) is usually measured by taking CSF samples. Obviously, spinal taps are less invasive than brain biopsies. While viral load measurements of CSF may give an indication of HIV levels in the brain, this likely is not the case in many instances.

So what's the clinical significance of drug penetration? "It's largely theoretical at this point. We

Please see PROBLEM next page ▶

COVER STORY

Combivir encourages adherence

Adhering to typically complex combination drug regimens that can include a large quantity of pills, food or water restrictions, or time requirements presents a significant challenge to many people with HIV/AIDS. Unfortunately, strict adherence to multi-drug regimens is essential to obtaining the full benefits of therapy, maintaining suppression of viral replication and preventing the development of drug resistance. Many patients struggle with adhering to the demands of their "pill burden" and may miss doses or take "drug holidays." The likelihood of adherence to a prescribed therapy is less when a regimen requires taking a high number of pills or increased frequency of dosing. In reducing the pill burden and dosing requirements, patient adherence to multiple drug combinations may be enhanced.

> "Strict adherence to multi-drug regimens is essential to obtaining the full benefits of therapy"

Combivir® (lamivudine/zidovudine), which contains half the daily doses of Epivir® (lamivudine; 3TC) and Retrovir® (zidovudine; AZT) and can be dosed with one pill in the morning and one at night, represents the first major step toward simplifying highly effective HIV combination drug regimens. For many patients whose medication regimens include Epivir and Retrovir, the use of Combivir may reduce by as many as six the number of pills that need to be taken each day.

"I was taking 20 pills a day," said one patient. "Now that I'm on Combivir, I'm only taking 14 pills a day and it's much more convenient."

Combivir was approved for use by the US Food and Drug Administration last fall and was developed as an alternative dosing option to encourage adherence to multiple drug regimens containing Epivir and Retrovir.

"Overcoming the dosing complexities of new combinations of drugs that we know to have a potent effect in suppressing HIV is one of the biggest challenges today in the real-world clinical management of patients with HIV," said Joseph P. Eron, M.D., associate professor of medicine at the University of North Carolina, Chapel Hill, School of Medicine.

"Hopefully, the development of Combivir is just the first step in efforts by the pharmaceutical industry to improve what are extremely demanding treatment regimens for patients to follow," said Amy Keller, international project leader, Epivir & Retrovir at Glaxo Wellcome Inc.

Adherence to HIV antiretroviral medications and combination therapies is becoming increasingly visible as an important aspect of successful HIV therapy. While pill burden associated with HIV treatments may only represent a part of the overall adherence challenge, the effective management of medication is a key issue in the ongoing pursuit of maximally suppressive treatment regimens.

antiretroviral treatment naive adult patients, treatment with the combination of abacavir+Retrovir® (zidovudine; AZT)+Epivir® (lamivudine; 3TC) resulted in undetectable levels of virus (less than 400 copies per ml) in 75 percent of patients (65 of 87). These data were based on an intent-to-treat analysis. When analyzed using an as-treated, or on-treatment, analysis, 86 percent of patients (62 of 72) had undetectable levels of virus at week 16. By comparison, the control arm of Epivir+Retrovir showed 35 percent of patients (30 of 86) at undetectable levels using intent-to-treat, and 43 percent (29 of 68) undetectable using an as-treated analysis.

Patients in the study who achieved undetectable levels of virus at week 16 in the abacavir/Epivir/Retrovir group will continue treatment for a minimum of 48 weeks. Patients who did not achieve undetectable levels by week 16 or whose viral levels became detectable after 16 weeks in this group, in addition to all patients in the Epivir/Retrovir group, were allowed to change treatments which could include all study medications plus available marketed products.

The level of plasma virus in 50 copies per ml.

Of patients entering this study with viral loads greater than 100,000 copies/ml and who were randomized to the abacavir-containing arm, 67 percent (12 of 18) had viral load that was undetectable (less than 400 copies per ml) using the intent-to-treat model, with 86 percent (12 of 14) having viral load that was undetectable in an as-treated analysis.

"These preliminary data suggest antiviral potency with abacavir in this patient population," said Dr. Margaret Fischl, principal investigator for the study. "This appears to be a potent regimen that can also be dosed very simply."

Patients in the abacavir arm of the study received one tablet of abacavir (300 mg) twice daily, one tablet of Epivir (150 mg) twice daily, and one tablet of Retrovir (300 mg) twice daily. At 16 weeks in the study, there was no significant difference in adverse events between the two treatment groups indicating that abacavir is generally well-tolerated. The most commonly reported adverse events were nausea, malaise and headache in both treatment groups. In addition, two patients experienced a hypersensitivity

Please see ABACAVIR next page ▶

Drug trial analysis: balancing hype and hope

Researchers from around the world have converged upon Geneva, site of the 12th World Conference on AIDS, to share thousands of results of clinical trials related to the treatment of HIV disease. But before the dizzying array of numbers, percentages and graphs make each poster or oral presentation sound the same, ask yourself an important question: Is it clear which data analysis is being presented, intent-to-treat or as-treated analysis?

While it would be most helpful for data to be presented showing results from both intent-to-treat and as-treated analyses, it is far more common for presentations to reflect only one analysis which is sometimes less than clearly identified. Trying to answer a research question by presenting either of these analyses in isolation is risky.

The FDA relies on intent-to-treat analyses when approving New Drug Applications (NDA). Proponents say it's the only way to get an unbiased profile of a drug's performance in the community at-large, warts and all. They say as-treated analyses create "hothouse" environments where those most susceptible to toxicities or failure are weeded out, leaving a biased sample in favor of the drug.

"Intent-to-treat is a worst-case scenario and as-treated is best-case," said one activist. "You really should look at both. You don't want to miss a good drug, or build hype around a bad one. The truth is probably somewhere in the middle."

STATLINE

International AIDS statistics at-a-glance

People newly infected with HIV in 1997	5.8 million
Adults	5.2 million
Children <15 years	590,000
Women	2.1 million
People living with HIV/AIDS	30.6 million
Adults	29.5 million
Children <15 years	1.1 million
Women	12.1 million
In Sub-Sahara Africa	20.8 million
In South and South-East Asia	6.0 million
In Latin America	1.3 million
In North America	860,000
In Western Europe	530,000
In East Asia, Pacific	440,000
In Caribbean	310,000
In North Africa, Middle East	210,000
In Eastern Europe and Central Asia	150,000
AIDS deaths in 1997	2.3 million
Adults	1.8 million
Children <15 years	460,000
Women	820,000
AIDS deaths since the beginning of the epidemic	11.7 million
Adults	9.0 million
Children <15 years	2.7 million
Women	4.0 million
AIDS orphans since the beginning of the epidemic	8.2 million
In Sub-Sahara Africa	7.8 million
Estimated number of new infections a day	16,000
Adults	14,000
Children <15 years	1,600
Percentage of HIV+ people living in the developing world	90%

Source: UNAIDS/WHO "Report on the Global HIV/AIDS Epidemic," December 1997.

Abacavir data presented

Continued from page 1

reaction to abacavir. This reaction has occurred in 3 percent of subjects in all studies and is characterized by fever plus one or more of the following: malaise, nausea (with or without vomiting) and possibly an accompanying rash. These systemic symptoms begin from several days to six weeks after initiating therapy and resolve within days following discontinuation of abacavir. Patients experiencing this reaction must not take abacavir-containing arm than in the control arm (38 percent versus 18 percent). There were three cases (3 percent) of hypersensitivity in the abacavir group.

"The early results from this trial suggest that abacavir will benefit HIV-infected children who have received prior antiretroviral therapy," said Russell Van Dyke, MD, principal investigator for the study. "Perhaps as importantly, it sets a precedent by including children in

Maternal-fetal HIV transmission prevention programs

Progress continues in developing countries

Under the direction of UNAIDS (the Joint United Nations Program on HIV/AIDS), efforts to initiate concerted international action to prevent mother-to-child transmission of HIV continue. In 1997, some 550,000 infants acquired HIV infection from their mothers, a figure that is expected to continue to rise.

Experts from national health authorities, development agencies and research institutes met in Geneva on March 24 and recommended that UNAIDS coordinate the implementation of programs to reduce mother-to-child transmission in the developing world. Speaking at the meeting, Executive Director of UNAIDS, Dr. Peter Piot, urged the international community to take immediate action, saying, "the question is no longer when or if we should act, but simply how."

The meeting in Geneva followed the announcement of landmark clinical trial results from Thailand in February. These data showed that treating HIV-infected pregnant women with a short course of Retrovir® (zidovudine; AZT) prior to delivery reduced their risk of transmitting the virus to their babies by more than 50 percent.

> "the question is no longer when or if we should act, but simply how."

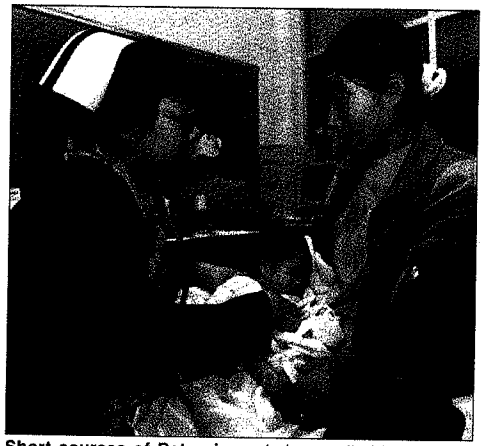
Treatment of HIV-infected pregnant women with AZT had already been demonstrated in the United States and France to be an effective means for reducing the risk of mother-to-baby transmission of HIV. However, the complex treatment regimen employed to reduce this risk in the U.S. is not applicable in most developing countries. The Thai short course study was conducted by the U.S. Centers for Disease Control and Prevention (CDC) as part of an international collaborative research effort coordinated by UNAIDS to help identify practical solutions for the developing world. Results from other studies are expected later this year.

Following the announcement of the Thai results, Glaxo Wellcome plc announced plans to implement large scale price reductions on Retrovir for use in the prevention of maternal-fetal transmission in developing nations.

"Our commitment is not only to support an effective public health initiative, but to offer pricing that satisfies World Health Organization and World Bank standards for cost-effective medical care," said Peter Young, vice president of Therapy Area Development, HIV and Opportunistic Infections for Glaxo Wellcome. "This will mean significantly lower pricing for Retrovir than in the West. This action reflects Glaxo Wellcome's commitment to continue working with the international donor community and national governments to find ways of reducing the number of new infections and improving the care of people with HIV/AIDS in developing countries."

International agencies and national governments will take the lead in devising programs with the necessary public health framework to support the role of anti-HIV medications in reducing the risk of maternal-fetal transmission of HIV. Not only will Glaxo Wellcome make Retrovir more economical to use in these settings, but the company intends to collaborate fully in program support including distribution, packaging, patient education and ongoing research.

Besides this announced pricing commitment, Glaxo Wellcome's commitment to fighting HIV in developing countries includes participation in the UNAIDS Access to Treatment pilot project in four countries (Cote D'Ivoire, Uganda, Chile and Vietnam) which is aimed at assessing how limited health infrastructures can be adapted to ensure effective distribution and use of HIV/AIDS related drugs.



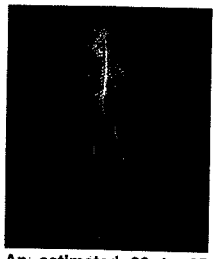
Short courses of Retrovir are being studied in pregnant women to determine the potential utility in developing countries.

Peripheral neuropathy

Pain and tingling resulting from HIV or AIDS associated peripheral neuropathy was significantly reduced in patients treated with Lamictal® (lamotrigine), according to preliminary results in a small study presented recently at the Eighth Annual Neuroscience of HIV Infection meeting in Chicago.

The study showed that patients receiving Lamictal reported less pain than patients in the placebo group. The reduction in pain from baseline to week 14 of this study was significantly greater in the nine patients receiving Lamictal (0.545) compared to the 19 patients taking placebo (0.168, p=0.036). Some patients noted pain relief as early as two weeks of treatment with Lamictal.

Peripheral neuropathy is a common complication of HIV and AIDS which, in many with epilepsy. Safety and efficacy in pediatric patients below the age of 16 have not been established. The idea for the study reported in Chicago resulted from anecdotal reports of the efficacy of Lamictal in the treatment of painful neuropathies.



An estimated 20 to 35 percent of patients with HIV or AIDS suffer from some degree of neuropathy.

In this double-blind, placebo-controlled study, patients randomized to receive Lamictal began the study taking 25 mg per day and had their doses gradually increased over six weeks to 300 mg per day. The primary endpoint of the study was the change in pain on the modified Gracely scale. The Gracely scale is a well-validated and reliable assessment of pain intensity.

Before initiating the study, there were no differences in pain scores between the two groups, with both groups reporting painful neuropathies. After 14 weeks of treatment, patients receiv-

abacavir again. Restarting abacavir after a hypersensitivity reaction has resulted in cases of a life-threatening, and in one instance fatal, reaction.

In another presentation, preliminary 16-week data from a study of abacavir in children with HIV suggest a significant benefit in viral load reductions for the arm containing abacavir. The study randomized 205 children who had been previously treated with anti-retroviral agents (primarily nucleoside reverse transcriptase inhibitors) to receive either abacavir+Epivir+Retrovir or Epivir+Retrovir. The study endpoints were the proportion of patients below 10,000 copies/ml and below 400 copies/ml at week 16.

Utilizing an intent-to-treat analysis, 49 percent (50 of 102) of patients in the abacavir+Epivir+Retrovir arm had less than 10,000 copies/ml at 16 weeks versus 35 percent (36 of 103) in the Epivir+Retrovir arm. Also, 13 percent of patients (13 of 102) in the abacavir arm had undetectable viral loads (less than 400 copies/ml) compared to 2 percent (2 of 103) in the Epivir+Retrovir arm.

With the exception of nausea, the incidence of common adverse events was similar in the two treatment groups. Nausea was reported significantly more frequently in the abacavir arm. The initial clinical development of a new antiretroviral agent. Pediatricians have long been frustrated by the delay in making new agents available for children."

An analysis of viral resistance among the pediatric patients in this study produced data which showed that abacavir is effective in some patients despite the presence of virus mutations associated with abacavir resistance. At week 16, 32 percent of those patients who achieved viral loads less than 10,000 copies while on treatment with abacavir had baseline reverse transcriptase mutations at codons 74 and/or 184 (mutations demonstrated in laboratory studies to occur in virus exposed to abacavir in culture), indicating that mutations at these positions do not preclude an antiviral response with this treatment regimen used in this way.

The children participating in this study received a banana-strawberry flavored formulation of abacavir which was administered twice a day. The liquid formulation will be introduced to the US market simultaneously with tablet formulation of the product. Abacavir was generally well tolerated by the children in the study with types and frequency of adverse events, including the incidence of hypersensitivity reaction, mirroring those seen in the adult naive trial.

cases, occurs for unknown reasons. However, treatment of HIV patients with dideoxynucleoside (antiretroviral) therapy is recognized as a cause of painful neuropathy, which often persists long after the discontinuation of the therapy.

It is estimated that 20-35 percent of patients with HIV or AIDS suffer from some degree of peripheral neuropathy. This number could range from 120,000 to 180,000 persons with HIV or AIDS. Symptoms of this condition usually include pain in the soles and dorsum of the feet, diminished feeling in the feet, decreased ankle reflexes and minimal foot weakness.

Lamictal is an anticonvulsant which is currently indicated as adjunctive therapy in the treatment of partial seizures in adults ing Lamictal reported less pain than patients in the placebo group.

Of 43 patients originally enrolled in the study, 15 did not complete the 14 week study period. Six of the 15 patients who failed to complete the study discontinued due to rash. In controlled trials for the approved indication of Lamictal, the most commonly reported adverse experiences were dizziness, headache, diplopia, ataxia, nausea, blurred vision, somnolence, rash and vomiting. Serious rashes requiring hospitalization and discontinuation of treatment have been reported in association with Lamictal. The incidence of these rashes, which have included Stevens Johnson Syndrome is approximately one in every 100 pediatric patients (age < 16 years) and three in every 1,000 adults.

Penetrating problem: drugs and CNS

Continued from page 1

don't have all the facts," said Dr. Richard Price, an AIDS researcher at the University of California at San Francisco. "But there are two reasons it might be important." One is treating dementia and the second is attempting "to eliminate a potential reservoir of infection." A small study indicated that higher than usually recommended doses of Retrovir® (zidovudine; AZT) appear to have a favorable impact on treating AIDS dementia complex.

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STATLINE

International AIDS statistics at-a-glance

People newly infected with HIV in 1997	5.8 million
Adults	5.2 million
Children <15 years	590,000
Women	2.1 million
People living with HIV/AIDS	30.6 million
Adults	28.5 million
Children <15 years	1.1 million
Women	12.1 million
In Sub-Sahara Africa	20.8 million
In South and South-East Asia	6.0 million
In Latin America	1.3 million
In North America	860,000
In Western Europe	530,000
In East Asia, Pacific	440,000
In Caribbean	310,000
In North Africa, Middle East	210,000
In Eastern Europe and Central Asia	150,000
AIDS deaths in 1997	2.3 million
Adults	1.8 million
Children <15 years	460,000
Women	820,000
AIDS deaths since the beginning of the epidemic	11.7 million
Adults	9.0 million
Children <15 years	2.7 million
Women	4.0 million
AIDS orphans since the beginning of the epidemic	8.2 million
In Sub-Sahara Africa	7.8 million
Estimated number of new infections a day	16,000
Adults	14,000
Children <15 years	1,600
Percentage of HIV+ people living in the developing world	90%

Source: UNAIDS/WHO "Report on the Global HIV/AIDS Epidemic," December 1997.

Abacavir data presented

Continued from page 1

reaction to abacavir. This reaction has occurred in 3 percent of subjects in all studies and is characterized by fever plus one or more of the following: malaise, nausea (with or without vomiting) and possibly an accompanying rash. These systemic symptoms begin from several days to six weeks after initiating therapy and resolve within days following discontinuation of abacavir. Patients experiencing this reaction must not take abacavir again. Restarting abacavir after a hypersensitivity reaction has resulted in cases of a life-threatening, and in one instance fatal, reaction.

In another presentation, preliminary 16-week data from a study of abacavir in children with HIV suggest a significant benefit in viral load reductions for the arm containing abacavir. The study randomized 205 children who had been previously treated with anti-retroviral agents (primarily nucleoside reverse transcriptase inhibitors) to receive either abacavir+Epivir+Retrovir or Epivir+Retrovir. The study endpoints were the proportion of patients below 10,000 copies/ml and below 400 copies/ml at week 16.

Utilizing an intent-to-treat analysis, 49 percent (50 of 102) of patients in the abacavir+ Epivir+Retrovir arm had less than 10,000 copies/ml at 16 weeks versus 35 percent (36 of 103) in the Epivir+Retrovir arm. Also, 13 percent of patients (13 of 102) in the abacavir arm had undetectable viral loads (less than 400 copies/ml) compared to 2 percent (2 of 103) in the Epivir+Retrovir arm.

With the exception of nausea, the incidence of common adverse events was similar in the two treatment groups. Nausea was reported significantly more frequently in the abacavir-containing arm than in the control arm (38 percent versus 18 percent). There were three cases (3 percent) of hypersensitivity in the abacavir group.

"The early results from this trial suggest that abacavir will benefit HIV-infected children who have received prior antiretroviral therapy," said Russell Van Dyke, MD, principal investigator for the study. "Perhaps as importantly, it sets a precedent by including children in the initial clinical development of a new antiretroviral agent. Pediatricians have long been frustrated by the delay in making new agents available for children."

An analysis of viral resistance among the pediatric patients in this study produced data which showed that abacavir is effective in some patients despite the presence of virus mutations associated with abacavir resistance. At week 16, 32 percent of those patients who achieved viral loads less than 10,000 copies while on treatment with abacavir had baseline reverse transcriptase mutations at codons 74 and/or 184 (mutations demonstrated in laboratory studies to occur in virus exposed to abacavir in culture), indicating that mutations at these positions do not preclude an antiviral response with this treatment regimen used in this way.

The children participating in this study received a banana-strawberry flavored formulation of abacavir which was administered twice a day. The liquid formulation will be introduced to the US market simultaneously with tablet formulation of the product. Abacavir was generally well tolerated by the children in the study with types and frequency of adverse events, including the incidence of hypersensitivity reaction, mirroring those seen in the adult naive trial.

Maternal-fetal HIV transmission prevention programs

Progress continues in developing countries

Under the direction of UNAIDS (the Joint United Nations Program on HIV/AIDS), efforts to initiate concerted international action to prevent mother-to-child transmission of HIV continue. In 1997, some 550,000 infants acquired HIV infection from their mothers, a figure that is expected to continue to rise.

Experts from national health authorities, development agencies and research institutes met in Geneva on March 24 and recommended that UNAIDS coordinate the implementation of programs to reduce mother-to-child transmission in the developing world. Speaking at the meeting, Executive Director of UNAIDS, Dr. Peter Piot, urged the international community to take immediate action, saying, "the question is no longer when or if we should act, but simply how."

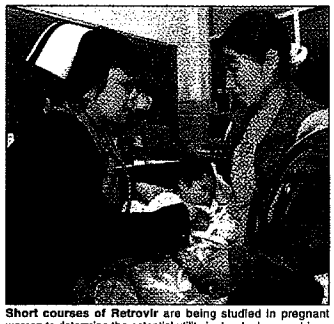
The meeting in Geneva followed the announcement of landmark clinical trial results from Thailand in February. These data showed that treating HIV-infected pregnant women with a short course of Retrovir® (zidovudine; AZT) prior to delivery reduced their risk of transmitting the virus to their babies by more than 50 percent.

> "the question is no longer when or if we should act, but simply how."

Treatment of HIV-infected pregnant women with AZT had already been demonstrated in the United States and France to be an effective means for reducing the risk of mother-to-baby transmission of HIV. However, the complex treatment regimen employed to reduce this risk in the U.S. is not applicable in most developing countries. The Thai short course study was conducted by the U.S. Centers for Disease Control and Prevention (CDC) as part of an international collaborative research effort coordinated by UNAIDS to help identify practical solutions for the developing world. Results from other studies are expected later this year.

Following the announcement of the Thai results, Glaxo Wellcome plc announced plans to implement large scale price reductions on Retrovir for use in the prevention of maternal-fetal transmission in developing nations.

"Our commitment is not only to support an effective public health initiative, but to offer pricing that satisfies World Health Organization and World Bank standards for cost-effective medical care," said Peter Young, vice president of Therapy Area Development, HIV and Opportunistic Infections for Glaxo Wellcome. "This will mean significantly lower pricing for Retrovir than in the West. This action reflects Glaxo Wellcome's commitment to continue working with the international donor community and national governments to find ways of reducing the number of new infections and improving the care of people with HIV/AIDS in developing countries."



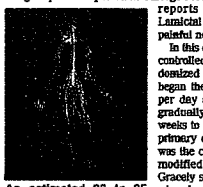
Short courses of Retrovir are being studied in pregnant women to determine the potential utility in developing countries. ©1998 Cary Herz

International agencies and national governments will take the lead in devising programs with the necessary public health framework to support the role of anti-HIV medications in reducing the risk of maternal-fetal transmission of HIV. Not only will Glaxo Wellcome make Retrovir more economical to use in these settings, but the company intends to collaborate fully in program support including distribution, packaging, patient education and ongoing research.

Besides this announced pricing commitment, Glaxo Wellcome's commitment to fighting HIV in developing countries includes participation in the UNAIDS Access to Treatment pilot project in four countries (Cote D'Ivoire, Uganda, Chile and Vietnam) which is aimed at assessing how limited health infrastructures can be adapted to ensure effective distribution and use of HIV/AIDS related drugs.

Peripheral neuropathy

Pain and tingling resulting from HIV or AIDS associated peripheral neuropathy was significantly reduced in patients treated with Lamictal® (lamotrigine), according to preliminary results in a small study presented recently at the Eighth Annual Neuroscience of HIV Infection meeting in Chicago.



An estimated 20 to 35 percent of patients with HIV or AIDS suffer from some degree of neuropathy.

The study showed that patients receiving Lamictal reported less pain than patients in the placebo group. The reduction in pain from baseline to week 14 of this study was significantly greater in the nine patients receiving Lamictal (0.545) compared to the 19 patients taking placebo (0.168, p=0.036). Some patients noted pain relief as early as two weeks of treatment with Lamictal.

Peripheral neuropathy is a common complication of HIV and AIDS which, in many cases, occurs for unknown reasons. However, treatment of HIV patients with dideoxynucleoside (anuretroviral) therapy is recognized as a cause of painful neuropathy, which often persists long after the discontinuation of the therapy.

It is estimated that 20-35 percent of patients with HIV or AIDS suffer from some degree of peripheral neuropathy. This number could range from 120,000 to 180,000 persons with HIV or AIDS. Symptoms of this condition usually include pain in the soles and dorsum of the feet, diminished feeling in the feet, decreased ankle reflexes and minimal foot weakness.

Lamictal is an anticonvulsant which is currently indicated as adjunctive therapy in the treatment of partial seizures in adults with epilepsy. Safety and efficacy in pediatric patients below the age of 16 have not been established. The idea for the study reported in Chicago resulted from anecdotal reports of the efficacy of Lamictal in the treatment of painful neuropathies.

In this double-blind, placebo-controlled study, patients randomized to receive Lamictal began the study taking 25 mg per day and had their doses gradually increased over six weeks to 300 mg per day. The primary endpoint of the study was the change in pain on the modified Gracely scale. The Gracely scale is a well-validated and reliable assessment of pain intensity.

Before initiating the study, there were no differences in pain scores between the two groups, with both groups reporting painful neuropathies. After 14 weeks of treatment, patients receiving Lamictal reported less pain than patients in the placebo group.

Of 43 patients originally enrolled in the study, 15 did not complete the 14 week study period. Six of the 15 patients who failed to complete the study discontinued due to rash. In controlled trials for the approved indication of Lamictal, the most commonly reported adverse experiences were dizziness, headache, diplopia, ataxia, nausea, blurred vision, somnolence, rash and vomiting. Serious rashes requiring hospitalization and discontinuation of treatment have been reported in association with Lamictal. The incidence of these rashes, which have included Stevens Johnson Syndrome is approximately one in every 100 pediatric patients (age < 16 years) and three in every 1,000 adults.

Penetrating problem: drugs and CNS

Continued from page 1

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NEW ERA, NEW LOOK FOR NCAA

▶ 'TRANSITION' TACKLES FINANCES, THE RULES, FOOTBALL PLAYOFF, 1C
▶ Q&A WITH CHIEF, 2C

McGWIRE SLAMS WAY ONTO NL ALL-STAR TEAM, VOTE TOTALS, 4C

AP
Mark McGwire: Top NL vote-getter, 4C

USA TODAY

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ALZHEIMER'S CATALYST IDENTIFIED, STYMIED 1D

▶ KILLER PROTEIN, 7D
▶ DRUGS FOR MIND, 7D

'ARMAGEDDON' PREMIERE ABUZZ 2D

▶ SCIENTISTS BLOW HOLES IN THE PLOT 7D

TUESDAY

Touchstone Pictures
Bruce Willis: Breakup the talk of premiere, 2D

TUESDAY, JUNE 30, 1998

NEWSLINE

A QUICK READ ON THE NEWS

WALL STREET: Dow Jones industrial average jumps 52.82 points to 8997.36; Nasdaq index climbs 21.55 to 1891.08; 30-year Treasury bond yield rises to 5.84%. 13B.

▶ Japan's Nikkei rose 332.42, 2.16%, to 15,698.15 at 1 a.m. ET today; the yen strengthened to 140.39. Hong Kong's Hang Seng index rose 120.47, 1.42%, to 8581.18.

ALL-USA BASEBALL

USA TODAY's high school state-by-state honorable mentions and state players of the year, 8C

TRANSPLANT TEEN CRITICAL: Maryland boy is in critical condition after receiving his third liver, pancreas, small intestine and stomach transplant. 9A.

UFO STUDY: Groups plan to step up efforts pushing for congressional hearings into Unidentified Flying Objects, in wake of international panel's report. 3A.

DI'S HOME OPENING: Althorp, ancestral home and burial place of Princess Diana, left, opens to the public Wednesday. Life in tiny nearby village of Great Brington could suddenly be changed. 1D.

AP
Diana: Controversy follows her to grave.

CHINA TRIP: Trade with China is back in the spotlight with President Clinton's visit to Shanghai, China's financial and economic capital. He'll spend two days there, meeting with community leaders as well as U.S. business leaders while touring country's most modern city. 6A.

▶ Where does Taiwan fit in? 1B.

TODAY'S DEBATE: Bilingual education. In USA TODAY's opinion, "Denver schools accused of discrimination, face loss of $30 million." 10A.

▶ "Denver has a new plan filled with a variety of loopholes, tricky screening questions and no bottom-line achievement standards," Ricardo Martinez says. 10A.

▶ A public high school English teacher looks back at the year. And likes what he sees. The Forum. 11A.

MONEY: Investors may get shot at Fox. 1B.

▶ America Online's supremacy threatened. 1B.

▶ Ohio workers may add to GM strike woes. 1B.

SPORTS: Sampras, Seles advance. Wimbledon. 1C.

▶ D.C. United coach to lead World Cup soccer team? 1,16C.

LIFE: FDA approves device that helps radiologists better detect breast tumors on mammograms. 1D.

▶ The Artist's *Soul Sizzles*; Jimi Hendrix's *BBC Sessions*, Janis Joplin's *Live at Winterland '68* are bigger than nostalgia boom. Music reviews. 1,10D.

▶ Out of touch with the cell phone phenomenon? 8D.

COMING WEDNESDAY

By Scott Troyanos
Missy Parr-Kaye

Sister support

Breast cancer struck golf's Parr sisters. Missy, left, wants to make sure her late sister Heather isn't forgotten.

Mid-year stocks

Checking in on the markets, off to another stellar year.

Written by John O. Buckley

Inside USA TODAY 4 SECTIONS

Crossword	9D
Editorial/Opinion	10-11A
Lotteries	9D
Marketplace Today	8-9D
State-by-state	8A
Stocks	4-10B

USA SNAPSHOTS®

A look at statistics that shape the nation

How bad is the fire season?

Since Memorial Day, fires in Florida have charred 232,985 acres. 38 of 67 counties still have fires. But the 700,000 acres burned nationwide are far fewer than the 2.4 million acres burned by this time in 1996. Wildland fires, 1995–1998:

	Fires	Acres burned
1998 (through 6/28)	29,885	696,367
1997	66,196	2,869,959
1996	96,363	6,065,998
1995	82,234	1,840,548

Source: National Interagency Fire Center, Boise, Idaho; Idaho Unified Area Command

By Anne R. Carey and Elys A. McLean, USA TODAY

NBA owners, citing impasse, impose lockout

By Roscoe Nance
USA TODAY

NBA owners Monday voted to impose a player lockout and shut down the league, putting the start of next season in jeopardy.

"The current system does not work," NBA commissioner David Stern said. "We can't afford to play next season under the current system. That's the reality. That's why owners elected to lockout."

The lockout was ordered because the league and the players union couldn't reach a new collective bargaining agreement. It goes into effect at midnight ET today.

AP

▶ Central issue: Revenue split, 1C
▶ Free agency on hold, In Focus, 3C

Pippen: Big impact, 3C

Under the lockout, there will be no trades, no free agent signings, no practices, no summer leagues and no signing of rookies. Players will be barred from NBA facilities.

This is the third player lockout in four years for the NBA, which is the only major sports league in the USA that has not lost any regular season games to a work stoppage.

That record could be in jeopardy. Both sides are talking tough and holding their ground, and Stern acknowledged that the lockout could last into November, December or even into 1999.

"There are a number of clubs that would do better not operating than operating," he said. "That's something the players don't seem to understand."

Owners say player salaries are growing faster than league revenues, and they want to institute measures to control them.

That would mean a hard salary cap, without the "Larry Bird exception," which allows teams to re-sign their free agents without regard to the cap.

The league has also proposed a five-year rookie pay scale instead of the current three-year one. Also up for discussion is the league's drug policy, which only covers cocaine and heroin. Owners want it to include marijuana and alcohol abuse.

New home sales set record

Reuters
Linda Tripp: Scheduled to testify before grand jury today

Lawyer says impeachment hearings are a possibility

By Kevin Johnson and Judy Keen
USA TODAY

WASHINGTON — A White House lawyer told a federal appeals court Monday that the possibility of impeachment hearings was a reason President Clinton's discussions with government lawyers should be kept private from independent counsel Kenneth Starr.

Starr and White House lawyer Neil Eggleston clashed in front of a three-judge panel considering whether deputy White House counsel Bruce Lindsey should be forced to testify before a grand jury.

The court hearing preceded today's scheduled grand jury appearance of Linda Tripp, whose tape-recorded conversations with former White House intern Monica Lewinsky triggered Starr's inquiry into sex and cover-up allegations involving the president.

Eggleston argued that Lindsey's communications with the president were protected by an "absolute privilege" afforded private attorneys and their clients. He characterized Starr's demands for grand jury information as beyond the "boundaries of imagination."

Defense against possible impeachment proceedings was a proper role for Lindsey and the White House counsel's office, Eggleston said in a rare public acknowledgement that Starr's probe could lead to such action on Capitol Hill.

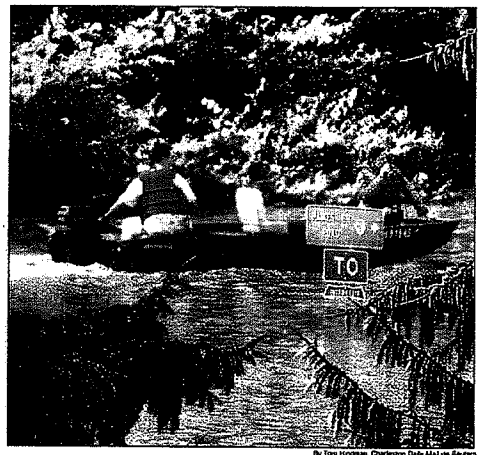
Starr countered that the privilege simply does not apply to taxpayer-paid lawyers.

"The position being advanced by the White House is quite contrary to what it means to be a government lawyer," Starr told the court.

The Justice Department, breaking with the White House, asserted that Lindsey could be compelled to testify if he held information "essential" to Starr's investigation and it could not be obtained from any other source.

The court did not immediately rule on the matter, but Monday's hearing represented yet another battle in the long legal war between the White House and Starr. The Supreme Court may ultimately decide whether Lindsey can claim lawyer-client privilege.

W. Virginia's deadly deluge



By Tom Hindman, Charleston Daily Mail via Reuters

Search is on: Rescue workers in Sissonville, W.Va., look for stranded residents Monday. Storms are blamed for three deaths in West Virginia and as many as 18 in the Midwest and Northeast. Parts of New England, Ohio and West Virginia face more rain today. (Not out of the woods, 3A)

1998 pace could reach 35-year high

By Christine Dugas
USA TODAY

NEW YORK — Sales of new, single-family homes reached a record level in May, providing more evidence of a strong economy and a hot housing market that continue to defy expectations.

Sales of new, single-family homes in May rose to an annualized rate of 880,000 units, according to the Commerce Department. That is a 0.3% increase over the previous record rate of 887,000 set in April.

If the pace persists, 1998 home sales would hit a 35-year high.

The increase was unexpected because home sales were unusually strong in January and February.

"So we thought we'd see a backing off in sales in the spring," says Stanley Duobinis of the National Association of Home Builders. "But consumer optimism and low interest rates have kept the market strong. It's nice to be wrong."

The news could have revived inflation fears in advance of the meeting today and Wednesday of Federal Reserve policymakers to discuss interest rates. But bond prices fell only slightly Monday, boosting the yield on 30-year Treasury bonds to 5.64% from 5.63% Friday.

The record sales in May were led by strong demand in the West, where the annualized rate of new home sales jumped 15.7%. In the Northeast, the sales rate rose a healthy 3.3%.

But May sales dropped 6.7% in the South, and they were off 4.1% in the Midwest.

Low mortgage rates are a key factor propelling the market, experts say. Last week, rates on 30-year fixed rate mortgages averaged 6.96%, according to Freddie Mac.

The average for 15-year, fixed rate mortgages was 6.64%, and 5.58% for one-year adjustable rate mortgages.

"When rates fall below below 7% that always brings out buyers," says Paul Taylor, senior economist at America's Community Bankers.

Economists expect home sales to remain strong through September. One reason: Applications to buy homes are almost at record levels.

Unknown no longer: Tomb remains identified as Blassie

By Andrea Stone
USA TODAY

ARLINGTON, Va. — The Vietnam remains exhumed from the Tomb of the Unknowns last month are Air Force 1st Lt. Michael Blassie, the Pentagon is expected to announce today.

The mother of another missing flier, who had been told her son's remains might be in the tomb, said a Pentagon official called her with the news Monday.

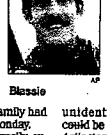
"She said the DNA (report is) out and it was Blassie's son. That's OK with me," said Althea Strobridge. Her son, Army Capt. Rodney Strobridge, died May 11, 1972, in the battle of An Loc, as Blassie did.

"I'm so mixed emotionally. I don't know whether to cry or be happy or what," she said.

Although it was lobbying by the Blassies that persuaded Defense Secretary William Cohen to order the remains exhumed for DNA testing, the family had not heard officially Monday.

"If it is true, we're really excited," said Judy Cozad, Blassie's sister. "It's going to bring closure to everything."

The remains, once officially declared to be Blassie, 24, will be returned for burial at Jefferson Barracks National Cemetery near St. Louis, his hometown.



AP
Blassie

"It's fantastic news," says Phil Budahn of the American Legion. "One down, 2,200 to go," he said, referring to others still listed as missing in action from Vietnam.

The Pentagon says there are other unidentified remains that could be placed in the Tomb at Arlington National Cemetery.

"Everyone has to stop and think this through," says Budahn. Because any remains might yet be identified, "Among the options is not putting anyone in there."

▶ Test only a decade old, 5A

Grand jurors clearly have own minds

By Kevin Johnson and Tom Squitieri
USA TODAY

COVER STORY

WASHINGTON — Occasionally, some of them show up late. More than a few times, some have dropped off to sleep in their chairs even as prosecutors and witnesses clashed before them.

Then there are days when, armed with probing questions and notebooks, very little seems to escape their attention.

In many ways, these 23 people are no different from any other group randomly assembled for courthouse duty.

But there is nothing common about the mission of the federal grand jury seated in the District of Columbia by Whitewater independent counsel Kenneth Starr.

This group of citizens — overwhelmingly black, predominantly female and mostly middle-age — may well determine the outcome of Starr's almost four-year probe of President Clinton.

The grand jury is "one of the most important and unappreciated tools of our truth-seeking system," Starr said last month in a commencement address at Texas Tech University.

As an investigative tool of the special prosecutor, the grand jury is being used to elicit testimony that could produce fodder for possible impeachment proceedings on Capitol Hill. And the jurors could be asked to return indictments against targets of Starr's inquiry, although some of the work may be given to a separate grand jury in Alexandria, Va.

The Washington panel has been in session since May, 1997, but since January its investigation has focused exclusively on

Please see COVER STORY next page ▶

THE NATION'S NEWSPAPER

View of the Pont des Bergues, the Rhone River and the Old Town with the St. Pierre Cathedral.

WELCOME TO THE 12th WORLD AIDS CONFERENCE

Conference organizers estimate 12,000 attendees at the Palexpo Exhibition Hall in Geneva.

For the first time, both scientific and HIV community representatives have been given equal say in the form and content of the conference.

THIS SPECIAL PROMOTIONAL EDITION WAS SOLELY PREPARED BY THE USA TODAY EDITORIAL STAFF AND PAID FOR ON BEHALF OF GLAXO WELLCOME

USA TODAY

NO. 1 IN THE USA . . . FIRST IN DAILY READERS

ADHERENCE ISSUES A MAJOR PROBLEM

Forty-three percent of patients admit that they haven't adhered to their HIV drug regimens, according to a recent study published in the *Journal of the International Association of Physicians in AIDS Care.*

Many people with AIDS struggle with "pill burden." Overcoming the dosing complexities of new combinations of drugs to suppress HIV is the biggest challenge today in the clinical management of the disease.

TUESDAY, JUNE 30, 1998

NEWSLINE

A QUICK READ ON THE NEWS

INTERACTIVE CARE MANAGEMENT PROGRAM ASSISTS PEOPLE LIVING WITH HIV: T.H.E. (Tools for Health and Empowerment) Course is a ground-breaking HIV learning program designed to advance the skills required to help patients make more informed decisions about their own care. Trainers from local HIV/AIDS health and service organizations utilize "participant-centered" group learning techniques to lead the two hour workshops for patients and their care partners ("buddy," family members, friend). Preliminary results of a clinical trial indicate improvements in empowerment, knowledge, coping and adherence. Detailed results of T.H.E. Course study that assesses humanistic and adherence outcomes will be presented on July 2 in Session Hall 1 in the 3-5 p.m. session.

T.H.E. COURSE

POSITIVE ACTION PROVIDES WORLDWIDE UMBRELLA FOR AIDS EFFORTS: An international program created by Glaxo Wellcome in 1992, Positive Action works in partnership with community groups, healthcare providers, governments and international agencies to pursue the common goals of more effective HIV prevention, education, care and support for people living with or affected by HIV/AIDS. Since its formation, Positive Action has supported and implemented a wide variety of projects at both a national and international level. For more information, check out the Positive Action website at www.PositiveAction.com.

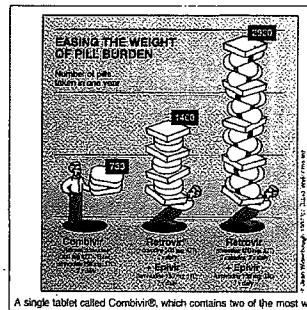
GRANTS SUPPORT NON-PROFIT: In order to channel contribution dollars to initiatives that address critical issues in HIV management, Glaxo Wellcome has implemented a Request for Proposal (RFP) process as part of its ongoing support for HIV community service organizations. Seventeen awards have recently been announced in response to the first RFP which focused on initiatives that extend the distribution of information to African-American or Hispanic audiences and simplify the data presented at the 12th World AIDS Conference. Later this year, two RFPs addressing programs in which incarcerated persons with HIV are linked to treatment programs while in prison and upon discharge, and programs to link disenfranchised HIV-positive individuals with needed medical services will be issued.

PATIENT DATABASE TO TRACK OUTCOMES: In an effort to provide a centralized, credible source for the most comprehensive HIV data available, Glaxo Wellcome developed a unique, multi-site computerized database system that will simultaneously produce observational information on clinical, economic and humanistic outcomes in patients with HIV/AIDS. The CHORUS (Collaboration in HIV Outcomes Research) database will enroll approximately 6,000 patients with HIV/AIDS in the U.S. and includes data on such parameters as clinical outcomes of patients, economic/healthcare utilization, quality of life, epidemiology and patient satisfaction with healthcare.

LOWERED DRUG PRICES MAKE TREATMENT IN AFRICA COST-EFFECTIVE: Glaxo Wellcome will lower the price of AZT up to 75 percent in some cases for vertical HIV transmission prevention in low-income countries. This announcement coincides with a study concluding that reducing the high rate of vertical HIV transmission in Sub-Saharan Africa with antiviral drugs can be cost-effective if drug prices are lowered. "These events open the way for large-scale drug interventions because we know that these therapies can make both medical and economic sense," said Elliot Marseille, DrPH., MPP, University of California San Francisco senior research associate and lead investigator of the study.

USA SNAPSHOTS®

A look at statistics that shape the nation



A single tablet called Combivir®, which contains two of the most widely used HIV medications, Epivir (lamivudine 150 mg; 3TC) and Retrovir (zidovudine 300 mg; AZT), was cleared for use by the Food and Drug Administration last fall. Combivir is taken twice a day, eliminating as many as two or six pills a day for appropriate patients.

By Glaxo Wellcome for USA TODAY

Potency of Amprenavir+Abacavir explored

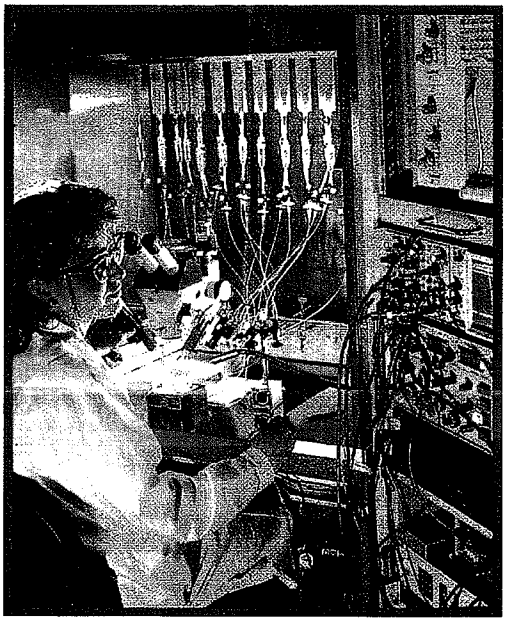
Protease enzyme—a target of anti-HIV therapy.

Preliminary results from a small phase II study suggest that the combination of amprenavir (formerly known as 141W94) and abacavir (formerly known as 1592) may effectively suppress HIV replication while being generally well tolerated. The study, an open-label design involving 40 treatment naive patients, was presented yesterday at the 12th World AIDS Conference in Geneva.

Early results from the study indicate that 89 percent of patients (25 of 28) who at the time of the analysis had completed 24 weeks of treatment, have undetectable levels of virus (less than 500 copies/ml). Moreover, 78 percent of patients (32 of 41) who had completed 4 weeks of treatment had undetectable virus, as did 97 percent (37 of 38) of patients who had completed 8 weeks of treatment. The study calls for patients to receive treatment for 72 weeks.

"While these are very preliminary results in a very small number of patients, we are encouraged by the antiviral potency observed thus far," said Lynn Smiley, M.D., vice president of Clinical Development, HIV and Opportunistic Infections at Glaxo Wellcome. "We are also encouraged by the initial indications of tolerability of this regimen."

Adverse events reported in this study included nausea, diarrhea, epigastric pain, headache and rash. At the time of the analysis, two patients had discontinued study drug due to rash. Three percent of patients in clinical trials with abacavir have experienced a hypersensitivity reaction. This reaction is described in the article "Abacavir Data Presented at 12th World AIDS Conference" also found on this page of USA TODAY.



Data on promising new drugs were presented today at the 12th World AIDS Conference in Geneva.

Abacavir data presented at 12th World AIDS Conference

Phase III clinical trial results which further characterize the investigational anti-HIV compound abacavir (formerly known as 1592; nucleoside analogue reverse transcriptase inhibitor) were presented by researchers Monday afternoon at the 12th World AIDS Conference in Geneva.

In preliminary 16-week data from a randomized study of 173 antiretroviral treatment naive adult patients, treatment with the combination of abacavir+Retrovir® (zidovudine; AZT)+Epivir® (lamivudine; 3TC) resulted in undetectable levels of virus (less than 400 copies per ml) in 75 percent of patients (65 of 87). These data were based on an intent-to-treat analysis. When analyzed using an as-treated, or on-treatment, analysis, 86 percent of patients (62 of 72) had undetectable levels of virus at week 16. By comparison, the control arm of Epivir+Retrovir showed 35 percent of patients (30 of 86) at undetectable levels using intent-to-treat, and 43 percent (29 of 68) undetectable using an as-treated analysis.

Patients in the study who achieved undetectable levels of virus at week 16 in the abacavir/Epivir/Retrovir group will continue treatment for a minimum of 48 weeks. Patients who did not achieve undetectable levels by week 16 or whose viral levels became detectable after 16 weeks in this group, in addition to all patients in the Epivir/Retrovir group, were allowed to change treatments which could include all study medications plus available marketed products.

The level of plasma virus in patients enrolled in this study was also evaluated at week 16 by an ultrasensitive assay that can measure viral levels as low as 50 copies per ml of plasma. Using this assay, it was demonstrated that 54 percent of patients in the abacavir/Epivir/Retrovir group and 15 percent of patients in the Epivir/Retrovir group had a plasma viral load of less than 50 copies per ml.

Of patients entering this study with viral loads greater than 100,000 copies/ml and who were randomized to the abacavir-containing arms, 67 percent (12 of 18) had viral load that was undetectable (less than 400 copies per ml) using the intent-to-treat model, with 86 percent (12 of 14) having viral load that was undetectable in an as-treated analysis.

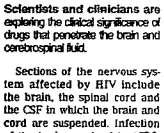
"These preliminary data suggest antiviral potency with abacavir in this patient population," said Dr. Margaret Fischl, principal investigator for the study. "This appears to be a potent regimen that can also be dosed very simply."

Patients in the abacavir arm of the study received one tablet of abacavir (300 mg) twice daily, one tablet of Epivir (150 mg) twice daily, and one tablet of Retrovir (300 mg) twice daily. At 16 weeks in the study, there was no significant difference in adverse events between the two treatment groups indicating that abacavir is generally well-tolerated. The most commonly reported adverse events were nausea, malaise and headache in both treatment groups. In addition, two patients experienced a hypersensitivity

Please see ABACAVIR next page ▸

A penetrating problem: drugs and the CNS

When it comes to HIV and the nervous system, science still has much to learn. We know the virus can penetrate the brain and cerebrospinal fluid (CSF), and that some antiretroviral drugs can follow right behind. What remains uncertain, however, is the actual meaning of all this.



Scientists and clinicians are exploring the clinical significance of drugs that penetrate the brain and cerebrospinal fluid.

Sections of the nervous system affected by HIV include the brain, the spinal cord and the CSF in which the brain and cord are suspended. Infection of the brain can lead to AIDS-related dementia complex. The impact on the spinal cord is less well understood.

HIV in the central nervous system (CNS) is usually measured by taking CSF samples. Obviously, spinal taps are less invasive than brain biopsies. While viral load measurements of CSF may give an indication of HIV levels in the brain, this likely is not the case in many instances.

So what's the clinical significance of drug penetration? "It's largely theoretical at this point. We

Please see PROBLEM next page ▸

COVER STORY

Combivir encourages adherence

Adhering to typically complex combination drug regimens that can include a large quantity of pills, food or water restrictions, or time requirements presents a significant challenge to many people with HIV/AIDS. Unfortunately, strict adherence to multi-drug regimens is essential to obtaining the full benefits of therapy, maintaining suppression of viral replication and preventing the development of drug resistance. Many patients struggle with adhering to the demands of their "pill burden" and may miss doses or take "drug holidays." The likelihood of adherence to a prescribed therapy is less when a regimen requires taking a high number of pills or increased frequency of dosing. In reducing the pill burden and dosing requirements, patient adherence to multiple drug combinations may be enhanced.

"Strict adherence to multi-drug regimens is essential to obtaining the full benefits of therapy"

Combivir® (lamivudine/zidovudine), which contains half the daily doses of Epivir® (lamivudine; 3TC) and Retrovir® (zidovudine; AZT) and can be dosed with one pill in the morning and one at night, represents the first major step toward simplifying highly effective HIV combination drug regimens. For many patients whose medication regimens include Epivir and Retrovir, the use of Combivir may reduce by as many as six the number of pills that need to be taken each day.

"I was taking 20 pills a day," said one patient. "Now that I'm on Combivir, I'm only taking 14 pills a day and it's much more convenient."

Combivir was approved for use by the US Food and Drug Administration last fall and was developed as an alternative dosing option to encourage adherence to multiple drug regimens containing Epivir and Retrovir.

"Overcoming the dosing complexities of new combinations of drugs that we know to have a potent effect in suppressing HIV is one of the biggest challenges today in the real-world clinical management of patients with HIV," said Joseph P. Eron, M.D., associate professor of medicine at the University of North Carolina, Chapel Hill, School of Medicine.

"Hopefully, the development of Combivir is just the first step in efforts by the pharmaceutical industry to improve what are extremely demanding treatment regimens for patients to follow," said Amy Keller, international project leader, Epivir & Retrovir at Glaxo Wellcome Inc.

Adherence to HIV antiretroviral medications and combination therapies is becoming increasingly visible as an important aspect of successful HIV therapy. While pill burden associated with HIV treatments may only represent a part of the overall adherence challenge, the effective management of medication is a key issue in the ongoing pursuit of maximally suppressive treatment regimens.

Drug trial analysis: balancing hype and hope

Researchers from around the world have converged upon Geneva, site of the 12th World Conference on AIDS, to share thousands of results of clinical trials related to the treatment of HIV disease. But before the dizzying array of numbers, percentages and graphs make each poster or oral presentation sound the same, ask yourself an important question: Is it clear which data analysis is being presented, intent-to-treat or as-treated analysis?

While it would be most helpful for data to be presented showing results from both intent-to-treat and as-treated analyses, it is far more common for presentations to reflect only one analysis which is sometimes less than clearly identified. Trying to answer a research question by presenting either of these analyses in isolation is risky.

The FDA relies on intent-to-treat analyses when approving New Drug Applications (NDA). Proponents say it's the only way to get an unbiased profile of a drug's performance in the community at-large, warts and all. They say as-treated analyses create "hothouse" environments where those most susceptible to toxicities or failure are weeded out, leaving a biased sample in favor of the drug.

"Intent-to-treat is a worst-case scenario and as-treated is best-case," said one activist. "You really should look at both. You don't want to miss a good drug, or build hype around a bad one. The truth is probably somewhere in the middle."

STATLINE

International AIDS statistics at-a-glance

People newly infected with HIV in 1997	5.8 million
Adults	5.2 million
Children <15 years	590,000
Women	2.1 million
People living with HIV/AIDS	30.6 million
Adults	29.5 million
Children <15 years	1.1 million
Women	12.1 million
In Sub-Sahara Africa	20.8 million
In South and South-East Asia	6.0 million
In Latin America	1.3 million
In North America	860,000
In Western Europe	530,000
In East Asia, Pacific	440,000
In Caribbean	310,000
In North Africa, Middle East	210,000
In Eastern Europe and Central Asia	150,000
AIDS deaths in 1997	2.3 million
Adults	1.8 million
Children <15 years	460,000
Women	820,000
AIDS deaths since the beginning of the epidemic	11.7 million
Adults	9.0 million
Children <15 years	2.7 million
Women	4.0 million
AIDS orphans since the beginning of the epidemic	8.2 million
In Sub-Sahara Africa	7.8 million
Estimated number of new infections a day	16,000
Adults	14,000
Children <15 years	1,600
Percentage of HIV+ people living in the developing world	90%

Source: UNAIDS/WHO "Report on the Global HIV/AIDS Epidemic," December 1997.

Abacavir data presented

Continued from page 1

reaction to abacavir. This reaction has occurred in 3 percent of subjects in all studies and is characterized by fever plus one or more of the following: malaise, nausea (with or without vomiting) and possibly an accompanying rash. These systemic symptoms begin from several days to six weeks after initiating therapy and resolve within days following discontinuation of abacavir. Patients experiencing this reaction must not take abacavir again. Restarting abacavir after a hypersensitivity reaction has resulted in cases of a life-threatening, and in one instance fatal, reaction.

In another presentation, preliminary 16-week data from a study of abacavir in children with HIV suggest a significant benefit in viral load reductions for the arm containing abacavir. The study randomized 205 children who had been previously treated with anti-retroviral agents (primarily nucleoside reverse transcriptase inhibitors) to receive either abacavir+Epivir+Retrovir or Epivir+Retrovir. The study endpoints were the proportion of patients below 10,000 copies/ml and below 400 copies/ml at week 16.

Utilizing an intent-to-treat analysis, 49 percent (50 of 102) of patients in the abacavir+Epivir+Retrovir arm had less than 10,000 copies/ml at 16 weeks versus 35 percent (36 of 103) in the Epivir+Retrovir arm. Also, 13 percent of patients (13 of 102) in the abacavir arm had undetectable viral loads (less than 400 copies/ml) compared to 2 percent (2 of 103) in the Epivir+Retrovir arm.

With the exception of nausea, the incidence of common adverse events was similar in the two treatment groups. Nausea was reported significantly more frequently in the abacavir-containing arm than in the control arm (38 percent versus 18 percent). There were three cases (3 percent) of hypersensitivity in the abacavir group.

"The early results from this trial suggest that abacavir will benefit HIV-infected children who have received prior antiretroviral therapy," said Russell Van Dyke, MD, principal investigator for the study. "Perhaps as importantly, it sets a precedent by including children in the initial clinical development of a new antiretroviral agent. Pediatricians have long been frustrated by the delay in making new agents available for children."

An analysis of viral resistance among the pediatric patients in this study produced data which showed that abacavir is effective in some patients despite the presence of virus mutations associated with abacavir resistance. At week 16, 32 percent of those patients who achieved viral loads less than 10,000 copies while on treatment with abacavir had baseline reverse transcriptase mutations at codons 74 and/or 184 (mutations demonstrated in laboratory studies to occur in virus exposed to abacavir in culture), indicating that mutations at these positions do not preclude an antiviral response with this treatment regimen used in this way.

The children participating in this study received a banana-strawberry flavored formulation of abacavir which was administered twice a day. The liquid formulation will be introduced to the US market simultaneously with tablet formulation of the product. Abacavir was generally well tolerated by the children in the study with types and frequency of adverse events, including the incidence of hypersensitivity reaction, mirroring those seen in the adult naive trial.

Maternal-fetal HIV transmission prevention programs

Progress continues in developing countries

Under the direction of UNAIDS (the Joint United Nations Program on HIV/AIDS), efforts to initiate concerted international action to prevent mother-to-child transmission of HIV continue. In 1997, some 550,000 infants acquired HIV infection from their mothers, a figure that is expected to continue to rise.

Experts from national health authorities, development agencies and research institutes met in Geneva on March 24 and recommended that UNAIDS coordinate the implementation of programs to reduce mother-to-child transmission in the developing world. Speaking at the meeting, Executive Director of UNAIDS, Dr. Peter Piot, urged the international community to take immediate action, saying, "the question is no longer when or if we should act, but simply how."

The meeting in Geneva followed the announcement of landmark clinical trial results from Thailand in February. These data showed that treating HIV-infected pregnant women with a short course of Retrovir® (zidovudine; AZT) prior to delivery reduced their risk of transmitting the virus to their babies by more than 50 percent.

> "the question is no longer when or if we should act, but simply how."

Treatment of HIV-infected pregnant women with AZT had already been demonstrated in the United States and France to be an effective means for reducing the risk of mother-to-baby transmission of HIV. However, the complex treatment regimen employed to reduce this risk in the U.S. is not applicable in most developing countries. The Thai short course study was conducted by the U.S. Centers for Disease Control and Prevention (CDC) as part of an international collaborative research effort coordinated by UNAIDS to help identify practical solutions for the developing world. Results from other studies are expected later this year.

Following the announcement of the Thai results, Glaxo Wellcome plc announced plans to implement large scale price reductions on Retrovir for use in the prevention of maternal-fetal transmission in developing nations.

"Our commitment is not only to support an effective public health initiative, but to offer pricing that satisfies World Health Organization and World Bank standards for cost-effective medical care," said Peter Young, vice president of Therapy Area Development, HIV and Opportunistic Infections for Glaxo Wellcome. "This will mean significantly lower pricing for Retrovir than in the West. This action reflects Glaxo Wellcome's commitment to continue working with the international donor community and national governments to find ways of reducing the number of new infections and improving the care of people with HIV/AIDS in developing countries."

Short courses of Retrovir are being studied in pregnant women to determine the potential utility in developing countries.
©1998 Cary Herz

International agencies and national governments will take the lead in devising programs with the necessary public health framework to support the role of anti-HIV medications in reducing the risk of maternal-fetal transmission of HIV. Not only will Glaxo Wellcome make Retrovir more economical to use in these settings, but the company intends to collaborate fully in program support including distribution, packaging, patient education and ongoing research.

Besides this announced pricing commitment, Glaxo Wellcome's commitment to fighting HIV in developing countries includes participation in the UNAIDS Access to Treatment pilot project in four countries (Cote D'Ivoire, Uganda, Chile and Vietnam) which is aimed at assessing how limited health infrastructures can be adapted to ensure effective distribution and use of HIV/AIDS related drugs.

Peripheral neuropathy

Pain and tingling resulting from HIV or AIDS associated peripheral neuropathy was significantly reduced in patients treated with Lamictal® (lamotrigine), according to preliminary results in a small study presented recently at the Eighth Annual Neuroscience of HIV Infection meeting in Chicago.

An estimated 20 to 35 percent of patients with HIV or AIDS suffer from some degree of neuropathy.

The study showed that patients receiving Lamictal reported less pain than patients in the placebo group. The reduction in pain from baseline to week 14 of this study was significantly greater in the nine patients receiving Lamictal (0.545) compared to the 19 patients taking placebo (0.168, p=0.036). Some patients noted pain relief as early as two weeks of treatment with Lamictal.

Peripheral neuropathy is a common complication of HIV and AIDS which, in many cases, occurs for unknown reasons. However, treatment of HIV patients with dideoxynucleoside (antiretroviral) therapy is recognized as a cause of painful neuropathy, which often persists long after the discontinuation of the therapy.

It is estimated that 20-35 percent of patients with HIV or AIDS suffer from some degree of peripheral neuropathy. This number could range from 120,000 to 180,000 persons with HIV or AIDS. Symptoms of this condition usually include pain in the soles and dorsum of the feet, diminished feeling in the feet, decreased ankle reflexes and minimal foot weakness.

Lamictal is an anticonvulsant which is currently indicated as adjunctive therapy in the treatment of partial seizures in adults with epilepsy. Safety and efficacy in pediatric patients below the age of 16 have not been established. The idea for the study reported in Chicago resulted from anecdotal reports of the efficacy of Lamictal in the treatment of painful neuropathies.

In this double-blind, placebo-controlled study, patients randomized to receive Lamictal began the study taking 25 mg per day and had their doses gradually increased over six weeks to 300 mg per day. The primary endpoint of the study was the change in pain on the modified Gracely scale. The Gracely scale is a well-validated and reliable assessment of pain intensity.

Before initiating the study, there were no differences in pain scores between the two groups, with both groups reporting painful neuropathies. After 14 weeks of treatment, patients receiving Lamictal reported less pain than patients in the placebo group.

Of 43 patients originally enrolled in the study, 15 did not complete the 14 week study period. Six of the 15 patients who failed to complete the study discontinued due to rash. In controlled trials for the approved indication of Lamictal, the most commonly reported adverse experiences were dizziness, headache, diplopia, ataxia, nausea, blurred vision, somnolence, rash and vomiting. Serious rashes requiring hospitalization and discontinuation of treatment have been reported in association with Lamictal. The incidence of these rashes, which have included Stevens Johnson Syndrome is approximately one in every 100 pediatric patients (age < 16 years) and three in every 1,000 adults.

Penetrating problem: drugs and CNS

Continued from page 1

don't have all the facts," said Dr. Richard Price, an AIDS researcher at the University of California at San Francisco. "But there are two reasons it might be important." One is treating dementia and the second is attempting "to eliminate a potential reservoir of infection." A small study indicated that higher than usually recommended doses of Retrovir® (zidovudine; AZT) appear to have a favorable impact on treating AIDS dementia complex.

The brain, in particular, is thought to be a sanctuary site for HIV. Recent studies show HIV may replicate in a different manner in the brain than in the rest of the body. "If current drugs don't reach the brain, it could serve as a site for the future escape of HIV," said Dr. Howard Grossman, a New York physician. "The virus will still be sensitive to therapy, but the implication is that you can never stop therapy."

Drug penetration of the CNS is usually measured by comparing levels of certain drugs in the CSF (measured in parts-per-milliliter) with levels of the same drugs in the blood. Plotted over time, this is referred to as the "area under the concentration curve." Ratios between these curves for CSF and blood can be compared, and can be used to compare the penetration of different drugs.

But it's still difficult for most people to evaluate claims that antiretroviral agents penetrate the CNS. "The information is usually expressed in very scientific terms," said Dr. Price, adding that more human studies are needed. He said people should consult their physicians when trying to determine drug penetrability. For now, he said, "the most important thing is clinical effectiveness. That's the ultimate measure."

Key presentations involving Glaxo Wellcome products at the 12th World AIDS Conference

PRESENTATION TITLE	PRESENTATION/ POSTER #	PRESENTER	DATE/TIME	SESSION	LOCATION
CNAA/B3003: Safety and activity of abacavir (1592, ABC) with 3TC/ZDV in antiretroviral naive subjects	127/12230	Margaret Fischl, Miami, Florida	Monday, June 29th, 3:00 PM	B17	Arena
CNAA3006: Antiretroviral activity and safety of abacavir (1592, ABC) with 3TC/ZDV in therapy-experienced children	128/12255	Russell Van Dyke, New Orleans, Louisiana	Monday, June 29th, 3:00 PM	B17	Arena
CNAA3006: Correlation of phenotypic resistance and clinical efficacy of abacavir in a phase III pediatric study	232/32283	Susan Danehower, GW Clinical Virology, Research Triangle Park, North Carolina	Tuesday, June 30th, 1:00 PM	B24	Arena
CNAB3001: Safety and efficacy of abacavir (1592, ABC) in AIDS dementia complex	561/32192	Bruce Brew, Sydney, Australia	Thursday, July 2nd, 1:00 PM	B44	Hall IV
CNAB2006: Combination abacavir (1592, ABC)/amprenavir (141W94) therapy in HIV-1 infected antiretroviral naive subjects with CD4+ counts >400 cells/µl and viral load >5000 copies/ml	286/12204	Pierre-Alexandre Bart, Lausanne, Switzerland	Tuesday, June 30th, 3:00 PM	B26	Arena
Research: Phenotypic HIV resistance in vitro correlates with viral load response to abacavir (1592, ABC) in vivo	231/32289	Randall Lanier, GW Clinical Virology, Research Triangle Park, North Carolina	Tuesday, June 30th, 1:00 PM	B24	Arena
Research: Abacavir (1592, ABC) prevents spread of HIV-1 un brain tissue of SCID mice with HIV-1 encephalitis	556/11233	J. Limoges, Omaha, Nebraska	Thursday, July 2nd, 1:00 PM	A43	Hall VII
T.H.E. (Tools for Health & Empowerment) Course: A unique disease management program	639/34236	W. David Hardy, Pacific Oaks Medical Group, Beverly Hills, California	Thursday, July 2nd, 3:00 PM	D45	Hall I
Combivir®(Lamivudine (3TC) 150 mg/Zidovudine (ZDV) 300 mg) given BID plus a protease inhibitor (PI) compared to 3TC 150 mg BID and ZDV 200 mg TID plus a PI	12220	Mark Shaefer, Glaxo Wellcome Inc., Research Triangle Park, North Carolina	Monday, June 29th	Track B	
Adherence to quadruple therapy with abacavir (1592), amprenavir, and Combivir® in subjects with acute and chronic HIV-1 infection	32326	Priti Jhingran, Glaxo Wellcome Inc., Research Triangle Park, North Carolina	Wednesday, July 1st	Track B	
Genotypic and phenotypic analysis of HIV from patients on ZDV/3TC/amprenavir combination therapy	32312	Margaret Tisdale, GW Research and Development, Stevenage Herts, UK	Wednesday, July 1st	Track B	
Pharmacokinetic drug interactions with amprenavir	12389	Brian Sadler, Glaxo Wellcome Inc., Research Triangle Park, North Carolina	Monday, June 29th	Track B	
Phase II study of amprenavir, a novel protease inhibitor, in combination with Zidovudine/3TC	12321	Richard Haubrich, USCD Treatment Center, San Diego, California	Monday, June 29th	Track B	