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California Trip, February 1-5, 1994: Living with HIV and AIDS in L.A. [Los Angeles]

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COLLECTION:
Clinton Presidential Records
National AIDS Policy Office
Kristine Gebbie
OA/Box Number: 3772

FOLDER TITLE:
California Trip, February 1-5, 1994: Living with HIV and AIDS in L.A. {Los Angeles]

2018-0756-F
jp4833

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
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b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

LIVING WITH HIV & AIDS

IN L. A.

NATIONAL AIDS POLICY COORDINATOR

KRISTINE GEBBIE

PAAC L.A. TOUR

TOMORROW'S STANDARD OF HIV AIDS CARE, TODAY.

Chron

SCHEDULE
As of Tuesday 2/2/94

KRISTINE M. GEBBIE
NATIONAL AIDS POLICY COORDINATOR
FEB. 3, 1994

Thursday, February 3, 1994
Traveling with Ms. Gebbe: Dr. Victor Beer, John Gurrola (ONAP), Gordon Nary (PAAC), and Ferd Egan, LA City AIDS Coordinator

6:30 AM	Depart hotel enroute to Fox Studios 5746 Sunset Blvd., LA, CA
7:00 AM	Arrive at Fox Studios for appearance on "Good Day L.A."
7:15 AM to 7:30 AM	**Fox Studios** Appear on "Good Day L.A."
7:30 AM to 8:00 AM	Depart Fox Studios enroute to the BelAge Hotel 1020 N. San Vicente Blvd., West Hollywood, CA
8:00 AM to 9:00 AM	**BelAge Hotel** (Breakfast for 20) Debussy Salon Breakfast meeting to discuss longevity and nutrition with Kristine Gebbie; Gordon Nary, PAAC trustee Victor Beer, MD; Dr. Gary Cohan; the L.A. AIDS IPA co-chair, Jayson Hymes, MD; Councilmember John Heilman; and other members of the coordinating staff. Gay Press: Advocate, Frontiers, Edge, Genre, Lesbian News, Alternatives, APLA newsletter and others are to be invited.
9:00 AM to 9:30 AM	Depart BelAge Hotel enroute to Kraus-Beer Medical Group, 5901 W. Olympic Blvd., #420, Los Angeles, CA
9:30 AM to 10:15 AM	**Kraus-Beer Medical Group** A review of a typical Los Angeles group practice model that contracted directly with pharmaceutical manufacturers to conduct clinical trials.
10:15 AM to 10:30 AM	Depart Kraus-Beer Medical Group enroute to Midway Hospital Medical Center, 5925 Olympic Boulevard, Los Angeles, CA
10:30 AM to 11: 45 AM	**Midway Hospital** Meet and tour the ISU with Dr. Moret; Byran Burlkow, V.P. Summitt; John Fenton, CEO; Dr. Weisman; Dr. Beer; an AIDS patient; and Ruth Pinter. Focus: The ISU is one of the largest in the country and is a prototype facility that is working

	towards significantly reduced the cost of inpatient care. Press will be general: Wall Street Journal, L.A. Times.
11:45 AM to 12:00 PM	**At Midway**, Kristine Gebbie will be interviewed by remote on the **Michael Jackson Talk** show. An ISU patient may be on as well.
12:00 PM to 12:15 PM	Depart Midway Hospital enroute to BelAge Hotel 1020 N. San Vicente Blvd., West Hollywood, CA
12:15 PM to 1:45 PM	**BelAge Hotel** Approximately 200 people. Luncheon meeting with a proposed address by KG to third party payers, hospital administrators, pharmaceutical manufacturers, community leaders and union representatives. This luncheon will also be used as a fund-raiser for L.A./PAAC's IPA project and community standards for care project. Question & Answer Period. Press: Trade, medical, insurance and pharmaceutical.
1:45 PM to 2:00 PM	Depart BelAge Hotel enroute to Pacific Oaks Medical Group 150 N. Robertson Blvd., Suite 300, Beverly Hills, CA
2:00 PM to 3:00 PM	**Pacific Oaks Medical Group** Meet with the Doctors of Pacific Oaks. Focus: The nutritional and clinical research. Dr. Gary Cohan will review the nutritional aspects and its possible link to increase longevity in HIV+/AIDS patients. Press: CNN Nutritional special.
3:00 PM to 3:30 PM	Depart Pacific Oaks Medical Group enroute to Country Villa South, 3515 Overland Avenue, Los Angeles, CA
3:30 PM to 4:30 PM	**Country Villa South** Meet with Steve Reisman, CEO, Country Villa Service Corporation, to examine a facility that will reduce the need for and costs of certain types of hospitalization care by 50-70%. Focus: The transitional support if hospital to home care and its relation to health care reform.
4:30 PM to 5:00 PM	Depart Country Villa South enroute to Century City Hospital, 2070 Century Park East, Los Angeles, CA
5:00 PM to 6:00 PM	**Century City Hospital** Dinner meeting with L.A./PAAC physicians who will be developing a working draft of community of standards for anti-retroviral treatment. There will be an address by KG before the dinner meeting. Press: Wall Street Journal

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VICTOR L. BEER, M.D.

CURRICULUM VITAE

Business Address: Primary
6464 Sunset Blvd. Suite 600
Los Angeles, California 90028
213/ 957-4065 (Fax)213/957-4075

Secondary
5901 W. Olympic Blvd. Suite 420
Los Angeles, California 90036
213/930-2323 (Fax)213/930-2497

(b)(6)

(b)(6)

University:
University of South Carolina; A.A., 1975
California State University, Northridge; B.A., 1977

Medical school: St. George's University, School of Medicine; M.D. 1978-1983

Internship: Wayne State University, School of Medicine; Internal Medicine: Pgy-1 1983

Residency: Kaiser Permanente Medical Center; Internal Medicine Pgy 2 & 3; 1984-1985

[cal]

Employment:

1993-Present	Kraus-Beer Medical Group President.
1986-1993	Keith-Beer Medical Group Vice-president.
1977-1978	Medrad Inc., Radiographic Instrumentation's, West Coast Regional Manager.
1969-1975	US. Navy, Polaris Submarine Division; Nuclear Power and Electronics Specialist.

Hospital Affiliation:
Midway Hospital Medical Center
5925 San Vincente Boulevard
Los Angeles, CA 90019

Hollywood Community Hospital
6245 DeLongpre Avenue
Hollywood, CA 90028

University Affiliation:
Clinical Assistant Professor of Medicine
University of Southern California,
School of Medicine
AIDS Education Training Center
Keith Administration Building
1975 Zonal Avenue
Los Angeles, CA 90033
Phone: (213) 226-7504

Associations:
American Medical Association.
Los Angeles County Medical Association.
California Medical Association.
Los Angeles Physicians AIDS Forum - vice-president.
Physicians Association for AIDS Care.

Professional Committees:
Medical Advisory Committee AIDS Project Los Angeles.
Los Angeles County Medical Association AIDS Committee.

Professional Instruction
AIDS Education and Training Center for University of Southern California - School of Medicine. Providing instruction to primary care providers of HIV-infected patients. Instructor 1991-present.

Continuing Medical Education:
AIDS/ARC Update, University of California, San Francisco, Ca.; July 15-16, 1988.
One Day dermatology Workshop San Diego, Calif
Fifth International AIDS Conference Montreal, Canada; 1989.
Seventh International AIDS Conference Florence, Italy; 1991.
Eighth International AIDS Conference Amsterdam, Netherlands; 1992.
MKSAP VIII.
MKSAP IX.
Intensive Review of Internal Medicine- Harvard Review Course.
Emory University Internal Medicine Review Course.
Continued medical education hours on record with the California Medical Association.
Scientific American "Medicine."

Certifications:
BCLS Instructor Course - 1983, 1988.
Advanced Cardiac Life Support - 1983.

Research Articles & Publications:
The Reliability of Medical Record Abstraction for Assessing the Spectrum of HIV/AIDS Disease in Adults. VII International Conference on AIDS.

Participation in Research as a Co-investigator, LAC-USC Medical Center.

Private Research Protocols as a Co-Investigator:
Stanford University: "ATHOS" Project - A Time Health Oriented Survey & Aids data base acquisition study. Ongoing.

Center for Disease Control: "A Study of the Spectrum of Disease in Persons with Human Immunodeficiency Virus Infection." Ongoing.

Hemacare corporation: - Protocol 312.23
"Passive Immune Therapy in the Treatment of AIDS". Ongoing.

SEARCH ALLIANCE - A community based clinical research organization. Board Member
7461 Beverly Boulevard, Suite 304 Los Angeles; CA. 90036; Phone: (213)930-8820.

Additional Articles and Columns:

LACMA Physician: L.A. County Medical Assn. October 1991, Los Angeles, CA
Cover Story and Interviews, AIDS Awareness Month Issue.

PAAC NOTES: The News journal of the Physicians Association For AIDS Care.
"The Effects of AIDS on Caregivers Spouses." March 1993.

Medical Tribune: "Undetected HIV Spurs lawsuits." September 6, 1990.

Symposiums and Conferences

Speaker: Keith-Beer Medical Group: Los Angeles, California; June 1992;
"VIII International AIDS Conference Review Symposium."

Speaker: American Association for Medical Transcription: Cerritos, Calif.; May 4, 1991
"Aids-Ten Years Old: Where Are We?"

Speaker: California AIDS Statewide surveillance Meeting: March 1991;
"Reporting AIDS within the Private Medical Community"

Speaker: Management of HIV Disease: Beverly Hills, California; October 12, 1990;
"Current Clinical Concepts."

Speaker: University of Oklahoma, Health Sciences Center; June 13, 1990;
"Advances in the Diagnosis and Management of HIV Disease."

Speaker: L.A. County Medical Association Legislative Committee; May 3, 1990;
"Perceived deficits in the Medi-Cal Program."

Speaker: Clinical Partners; Boston, Massachusetts; March 13, 1990;
"Role of Elemental Enteral Nutrition in the Management of HIV-Related Malabsorption and Diarrhea."

Speaker: L.A. County Medical Assn. AIDS Forum; June 15, 1989;
"Fifth International AIDS Conference in Montreal."

Speaker: HIV Disease Management Symposium: Phoenix, Arizona; April 1989;
"Focus on the AIDS management Team."

Guest Lectures:

Glendale Adventist Medical Center
"AIDS Update" April 1, 1992

Santa Monica Hospital Medical Center
"Outpatient Care of HIV Patients"; December 10, 1991

AMI Medical Center of North Hollywood, Calif; October 24, 1990
"New Advances and Researches in AIDS".

Community Health Group of San Ysidro, Calif. March 23, 1989
"Outpatient HIV Management."

Hollywood Community Hospital May 22, 1988
"Update on AIDS Related diseases."

Guest Lectures: (cont)
Westside Hospital
Acquired Immune Deficiency Syndrome.

Verdugo Hills Community Hospital
Acquired Immune Deficiency Syndrome AIDS: An Update.

Century City Hospital
Aids in the Workplace: Digital Equipment Corp.

CIGNA Hospital
Continuing Education "Primary Care of the HIV Patient."

Guest Speaker at the Los Angeles County Medical Association, Los Angeles, CA
Sixth AIDS Update.

Television And Radio Talk Shows:
AIDS UPDATE: Regular guest, Century Cable Television, Host-Bill Rosendahl.

Video:
1992-*Clinical Implications From The Seventh International Conference on Aids.*

SCCIS

SOUTHERN CALIFORNIA CENTER FOR IMMUNE SUPPRESSION AT MIDWAY HOSPITAL MEDICAL CENTER

The Southern California Center for Immune Suppression (SCCIS) at Midway Hospital Medical Center is one of the country's largest immune suppression unit with more than 40 beds.

Services Available: Midway Hospital's Immune Suppression Unit offers the following services:

- Specialized HIV/AIDS care -- High-tech, hi-touch staff training
- High staff-to-patient ratio
- Private rooms -- Every inpatient room in ISU is private with cable television, video movies and selected reading material.
- 24-hour visiting -- All rooms are equipped with sofa beds for friends and loved ones if they wish to spend the night.
- 24-hour food service on each floor
- Social workers -- Clinical social workers to assess the social service needs of all patients, and are available for supportive counseling for patients and their loved ones.
- Physical therapy -- Physical therapy, occupational and speech therapy, are available.
- Convenient admitting
  - Inpatient - Patients can be admitted in the comfort of their private rooms.
  - Outpatient - Patients are admitted on the unit.
- Dietary -- A dietician meets with the patient to plan meals as part of the overall medical plan. Diet aides stop by the rooms each day to collect specific menu orders and to make sure the meals are satisfactory. A food service worker provides snacks several times daily and stocks each room's refrigerator.

History: The Southern California Center for Immune Suppression was founded in 1991 by physicians acknowledged nationally as experts in the field of AIDS care. Their work guides the medical direction and treatment of our patients. The entire fourth floor of Midway Hospital Medical Center is a dedicated care unit of 40 private inpatient rooms, in addition to a full-service outpatient care center.

Address: Midway Hospital Medical Center
5929 San Vicente Blvd.
Los Angeles, CA 90019
213/932-5140

# # #

SCCIS

LOS ANGELES - Kristine Gebbie, President Clinton's National AIDS Policy Coordinator, will visit the Immune Suppression Unit at Midway Hospital today as part of a day-long tour of public and private hospitals across the city.

The 3-year old unit, with centralized services for AIDS patients is considered a possible model for national health care strategies, said John Fenton, the hospital's chief executive officer.

Higher nurse-to-patient ratios, extra quarters for patients relatives and friends, and individually-designed treatment programs are just some of the factors believed to help patients battle the disease and live longer than patients under traditional care.

"When Midway made the decision to add the ISU to the hospital, it made a commitment to more than just adding a new unit," Fenton said.

"Everything else in the hospital had to be upgraded to meet the demands of the ISU," he said. Educational activities for the nursing and care staff are also essential.

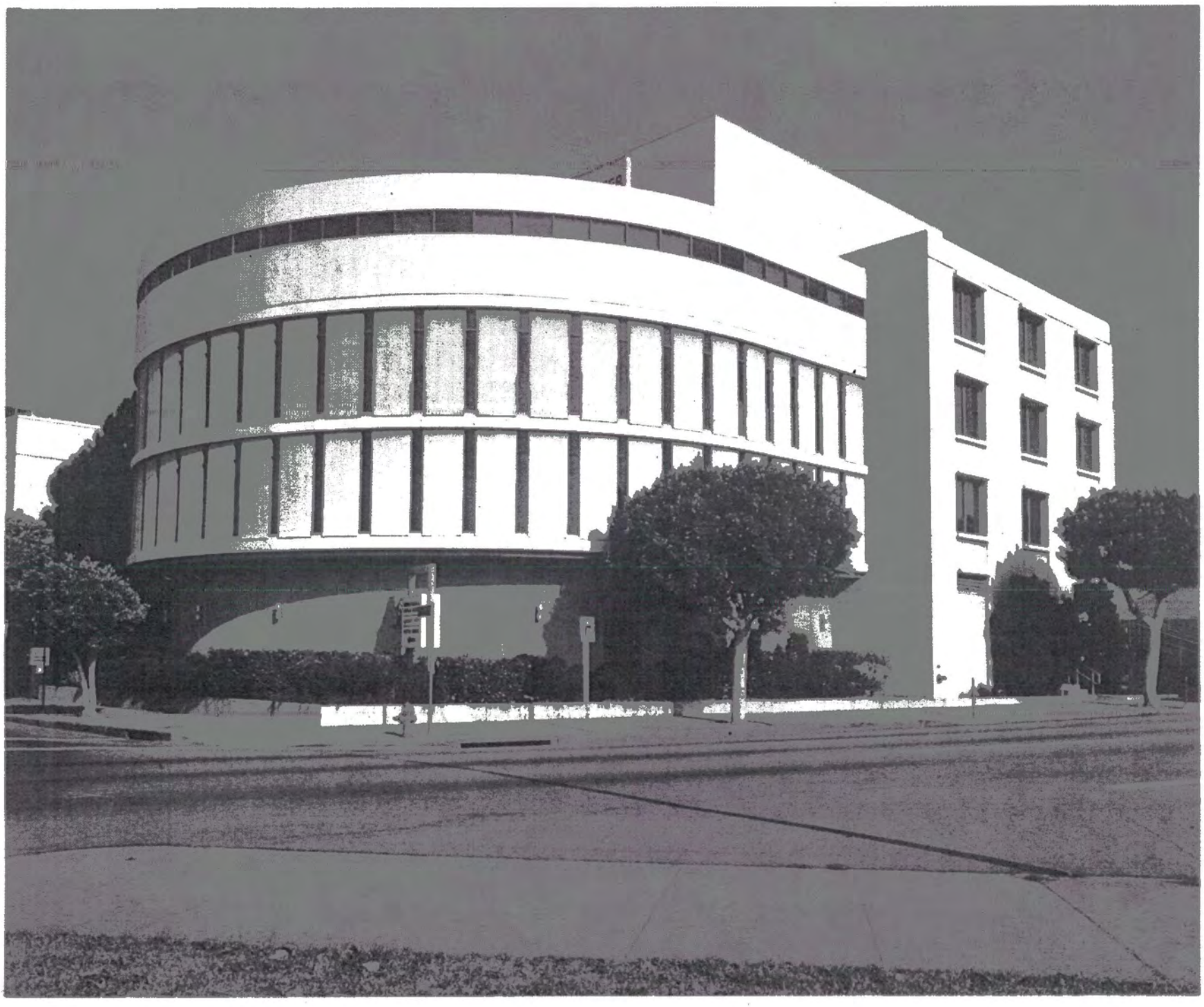
Gebbie will meet with patients, doctors and hospital staff as well as observe medical practices at the 40-bed unit. She will also meet with members of (PAAC), Physicians Association for AIDS Care, to discuss the results of administering "off-label" drugs to battle certain AIDS -related symptoms.

Off-label refers to the use of drugs usually prescribed for different ailments, and not officially endorsed by federal regulatory agencies as treatments for the disease.

Gebbie will meet with Mr. Fenton and Dr. Michael Moret, the unit's Medical Director, attending Physicians and staff and national and local officers of the Physicians Association for AIDS Care, a national association of Physicians who specialize in the treatment of HIV/AIDS.

The group will discuss how the use of off-label drugs and special AIDS facilities like the ISU work towards lowering health costs for AIDS patients, a benefit that has gained the attention of some of the nation's largest health insurance carriers.

The tour also will include stops at the Kraus-Beer Medical Group in West Los Angeles and the Pacific Oaks Medical Group in Beverly Hills two of the largest private practices specializing in AIDS care in the nation.



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SCCIS

Southern California Center for Immune Suppression

at Midway Hospital Medical Center

PACIFIC OAKS

MEDICAL GROUP

Backgrounder

Pacific Oaks Medical Group is the country's largest private medical practice specializing in HIV/AIDS care. Ten physicians work out of two Los Angeles-area offices, which also includes a Department of Research and Scientific Investigations with a full-time research staff. Although a majority of the group's practice is HIV/AIDS related, many of the physicians still maintain a family and general practice.

Pacific Oaks Medical Group was originally founded as a Sherman Oaks family practice called Weisman/Rogolsky Inc., A Medical Group in 1975 by Drs. Eugene Rogolsky and Joel Weisman. In 1980, the practice was renamed Pacific Oaks Medical Group. About the same time as the name change, both physicians began noticing an increased incidence of rare infections in their gay male patients. Little did they know, they were seeing some of the first documented cases of HIV/AIDS. In 1981, Weisman co-authored a report in The New England Journal of Medicine that first identified the syndrome that would eventually be known as AIDS. After the report was published, both physicians found themselves in the national spotlight, becoming medical pioneers and, in the process, becoming activists for not only for AIDS healthcare and research, but for gay civil rights as well.

Today, more than a decade since its founding, POMG has grown to include ten physicians in offices in Sherman Oaks and Beverly Hills. The practice consists of two of the physicians credited with "discovering" HIV/AIDS, and, in addition to primary care, physicians who specialize in research, oncology, pain management, infectious diseases and nutrition.

POMG has been credited with founding the AIDS unit at the Sherman Oaks Hospital and Health Center and co-founding the AIDS unit at Midway Hospital Medical Center in Los Angeles, both ranking among the finest AIDS facilities in the country. POMG physicians also have hospital privileges at Hollywood Community Hospital, Medical Center of North Hollywood and Valley Presbyterian Hospital.

-more-

150 N. Robertson Boulevard, Suite 300 • Beverly Hills, CA 90211 • (310) 652-2562

One of the most unique aspects of POMG is its in-house Department of Research and Scientific Investigations. Dr. Paul Berry is a full-time Research Director, who heads all the practice's drug protocols and clinical trials. The Department was established in response to the urgent need within the community for access to investigational AIDS therapies outside of the traditional academic settings. Currently, all trials are sponsored by pharmaceutical companies who cover the patients' costs of experimental therapies, office visits, laboratory tests and medications related to the trial. The Department of Research and Scientific Investigations again establishes POMG as a leader in its field and makes it one of the few private medical groups in the country to devote a full-time physician to research and clinical drug trials for HIV infection.

Pacific Oaks Medical Group also offers its patients many on-site facilities at both offices including aerosolized pentamidine, chemotherapy, EKG, a fully-licensed respiratory department, home infusion and nursing services, psychotherapy, pulmonary function testing, two outpatient infusion centers and x-rays. POMG also offers 24-hour on-call availability and patient education materials.

Pacific Oaks Medical Group physicians are also leaders in both the HIV/AIDS and gay community. The physicians are affiliated and often donate considerable amounts of time and financial support to the following organizations: AIDS Project Los Angeles (APLA), American Foundation for AIDS Research (AmFAR), Physicians Association with AIDS Care (PAAC), Los Angeles Physicians AIDS Forum, SEARCH Alliance, the Los Angeles Gay & Lesbian Community Services Center, El Proyerto del Barrios, West Hollywood AIDS Clinic, the Human Rights Campaign Fund, GLASS, Lambda Legal Defense, the Gay and Lesbian Victory Fund, the National Gay and Lesbian Task Force (NGLTF) and the Gay and Lesbian Alliance Against Defamation (GLAAD).

Community involvement, state-of-the-art treatment facilities, fast-track access to the latest development in AIDS management and the combined experience of ten front-line AIDS physicians inspire a level of patient confidence and trust in POMG seldom found in modern medical practices. And, although POMG is the country's largest private practice specializing in HIV/AIDS, patients still get personal treatment. Many of the practice's physicians say the people they treat are not only their patients, but oftentimes become their friends.

# # #

PACIFIC OAKS

MEDICAL GROUP

Joel D. Weisman, D.O.

In 1980, when Dr. Joel Weisman first mentioned the strange infections he was seeing in some of his gay male patients, little did he know that in the next decade he would become an acknowledged medical authority and reluctant but effective policy campaigner in the fight against AIDS.

A native of Carteret, N.J., Weisman was first introduced to medicine by a pathologist friend of his family when he was only seven years old and immediately knew that he wanted to be a doctor. After graduating from Upsala College in East Orange, N.J., Weisman went on to the Kansas City College of Osteopathic Medicine and did his internship and Family Practice training at Normandy Hospital in St. Louis. After three years in private practice in Carteret, Weisman moved to Southern California in 1975, where he joined Dr. Eugene Rogolsky in a practice based in Sherman Oaks. In 1980, Weisman/Rogolsky Inc., A Medical Group became the Pacific Oaks Medical Group.

In 1981, Dr. Weisman co-authored a report in The New England Journal of Medicine identifying the immune system failure they were seeing in gay men as a new disease. This was the first published report of the disease that would eventually be know as Acquired Immune Deficiency Syndrome (AIDS).

As AIDS continued to spread and kill more of his patients and some of his closest friends, Dr. Weisman became a front line specialist in management of the syndrome. Once a case was made for sexual transmission of AIDS, Weisman and Rogolsky were among the first to advise their patients to alter their sexual behavior. As ignorance and fear about the new disease spread, Weisman was increasingly called upon as a health educator and lobbyist for social services and research in AIDS.

Dr. Weisman was the first co-chairman of AIDS Project Los Angeles (APLA) when it was founded in 1982 and was instrumental in helping that then-struggling organization find legitimacy and public support. Weisman was also a founding member of the board of the American Foundation for AIDS Research (AmFAR) and served as its chairman from 1988 to 1991. Dr. Weisman has also served on the Medical Advisory Board at the Los Angeles Gay and Lesbian Community Services Center and served on both the Los Angeles City-County Task Force on AIDS and the State of California Task Force on AIDS.

Out of his practice in Sherman Oaks, Dr. Weisman helped start the AIDS unit at Sherman Oaks Community Hospital, the first private hospital AIDS unit in the country and the model for such units worldwide. Weisman and his partners have helped define AIDS management and care in private practice and have lead the way in bringing research to physician offices by conducting clinical trials in-house.

Although Dr. Weisman has known the sadness and constant trial of losing so many patients and friends, he has also been among the first to increase AIDS awareness among professionals and the general public and to introduce new treatments to help manage AIDS and extend the life expectancy of those living with it.

# # #

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PACIFIC OAKS

MEDICAL GROUP

Gary R. Cohan, M.D.

Dr. Gary Cohan is a board certified internist and HIV specialist who is in practice with Pacific Oaks Medical Group -- the largest HIV/AIDS private medical practice in the United States. Dr. Cohan studied at Amherst College, Cambridge University in England, and the University of Pennsylvania School of Medicine. In 1990, he completed special training in HIV care at San Francisco General Hospital. Dr. Cohan relocated to Los Angeles in 1992 from private practice in Philadelphia where he served as Chairman of the HIV Advisory Committee at the Graduate Hospital and was appointed Assistant Clinical Professor of Medicine at the University of Pennsylvania School of Medicine. Dr. Cohan currently serves as a teaching physician at UCLA's HIV Care Clinic.

Dr. Cohan has lectured extensively on AIDS throughout the United States on such topics as novel drug therapies, women, nutrition, and public policy. He co-authored three papers on HIV infection and nutrition which were published at the 8th International AIDS Conference in Amsterdam and he recently created Pacific Oaks' Department of Nutrition and Exercise Physiology. Dr. Cohan served as medical advisor for HBO Pictures' 1993 production of "And The Band Played On," based on Randy Shilts' book chronicling the history of the AIDS epidemic. In August 1993, Dr. Cohan took the task of writing the national monthly HIV/AIDS medical advice and update column -- "AIDSLine" -- for the gay and lesbian magazine, The Advocate.

150 N. Robertson Boulevard, Suite 300 • Beverly Hills, CA 90211 • (310) 652-2562

"The Plague Within The Plague"

Gary R. Cohan, M.D.

People are starving. Right in front of our eyes. We see it in every picture, in every mental image we have of the victims. But you never seem to read about it in the newspapers. Doctors rarely discuss it even though it is the primary cause of death in the majority of their patients. In Africa it is called "Slim Disease". Tom Hanks, for his starring role in the film, *Philadelphia*, had to shed thirty pounds for dramatic accuracy. Yet, while hundreds of thousands perish from the problem, both the medical community and the afflicted, blinded by the lure of "magic bullet" treatments and the search for a "cure", have seemed blandly indifferent. I am referring to the issue of malnutrition and HIV infection.

What if I told you that, today, a treatment already exists that can help to improve the quality of life and to extend the survival of every person with HIV infection ? And do so cheaply, easily, and with minimal technical support ? A treatment that it is not "alternative", "faddism", "quackery", or "pie in the sky"? Well, it does exist. In Los Angeles and throughout the United States. But it has been overlooked and dismissed as tangential, low priority, not high tech modern medicine. The treatment is the prevention of malnutrition. And it works.

NUTRITION AND HIV INFECTION: KEY POINTS

Gary R. Cohan, M.D.

Wasting syndrome -- the involuntary loss of greater than 10% of a person's usual body weight -- is the primary cause of death in more than 20% of persons with HIV infection.

Concept of the combined insults of protein-calorie malnutrition (starvation) and cachexia (abnormal tissue loss).

When a person's lean body (muscle and vital organ) mass falls below a critical point -- usually 54% of normal -- survival of persons with AIDS becomes impossible.

Conclusion: -- it is the *amount* of wasting -- rather than the specific cause of weight loss -- that is the primary determinant of death in AIDS patients.

Nutritional interventions in HIV infected persons are targeted at preserving lean tissue mass.

Primary strategy includes: treating underlying infections and gastrointestinal disorders, nutritional counselling and education, dietary supplements, appetite stimulants, anabolic androgens (steroids), vitamin (antioxidant) supplementation, and exercise.

Simplicity, ease of implementation, cost effectiveness observed by treating physicians. Algorithms for office-based evaluation and treatment have already have been developed by PAAC.

Anecdotal observations in our Los Angeles primary HIV care practice demonstrate that these strategies are extremely effective and well-tolerated by patients.

Need federal funding for formal research for these interventions to be tested and proven both effective and cost efficient. Data likely will be extrapolable to many other chronic debilitating disease processes (e.g. cancer, heart disease, etc).

Nutrition as an integral part of the President's national health carereform program.

THE Silent plague

HIV-ASSOCIATED MALNUTRITION

Gary R. Cohan, MD
Pacific Oaks Medical Group, Beverly Hills, California

We made history today. For the first time, in a presidential inaugural address, a U.S. president listed AIDS as one of his top priorities. I think those of us in the medical community need to change our own priorities. We need to think more about how nutrition, especially malnutrition, affects our patients with HIV infection. My job tonight is to give a brief overview of the problem, how it happens, and what we can do about it.

I have titled my discussion "The Silent Plague" because many healthcare providers tend to overlook the importance of nutrition in HIV infection. In fact, I am sure many people in this room, when asking their doctor for nutritional advice, probably toward the end of the visit, have been met with a blank stare, or "Take some Ensure," or "Eat right, you know what to do."

It has been my observation that most physicians feel pretty impotent regarding nutritional counseling and recommending effective treatment for malnutrition and wasting. They may often fear instituting aggressive therapy because they are already overwhelmed with the details of antivirals and prophylaxis. I recently attended a large seminar that included many of the top AIDS researchers in the United States. I was extremely disappointed that, in a six-hour program, there were no presentations about nutrition, wasting, or malnutrition. I was taught in medical school that when all else fails, look at the patient. Stop looking at the drugs, stop looking at the lab tests, and just look at the patient. We have patients who are wasting right before our eyes, and probably dying from wasting disease, and many of us are doing nothing to stop it. Tonight, we ask four questions: What is the problem? Why is it important? How does it happen? Finally, what can we do about it?

Wasting syndrome

The Centers for Disease Control and Prevention defines wasting as in involuntary weight loss of greater than 10 percent of a person's usual body weight. However, by the time a patient has met this definition, significant and possibly irreversible malnutrition may have already occurred.

In a study of weight changes in persons diagnosed as HIV-positive, symptomatic persons diagnosed with AIDS but without any opportunistic infections, and persons diagnosed with AIDS and secondary infections, Grunfeld et al found that the most dramatic weight loss happens when the person has AIDS but also has a secondary infection, often in the hospital[1]. In the 28 days surrounding the day of study, patients with AIDS and a secondary infection suffered a mean 5 percent weight loss, compared with weight changes of less than one percent in the other two groups.

As weight decreases, quality of life also decreases. Vital organ function is altered, tolerance to treatment is impaired, most persons become more dependent on other caretakers, the durations of hospital stays increase, and in general, patients feel fatigued, and hence, have decreased quality

of life. Most importantly, survival is actually decreased.

ACT UP's moniker for the AIDS epidemic for the first 11 years has been "Silence = Death." For the purpose of this discussion, I suggest we modify that to "Skinny = Death." One of the underground AIDS humor magazines a patient showed me the other day has been addressing it for a while. The DPN, or *Diseased Pariah News*, has a column of recipes entitled "Get Fat, Don't Die." It is kind of sick, dark humor, but it directly underscores one of the most important realities of this disease that most physicians and patients fail to accept.

Chlebowski et al studied survival of patients with AIDS as a function of their baseline nutritional status[2]. They assessed nutritional status with the serum albumin level, which is the measure of a protein that circulates in the blood, and therefore a rough measure of how a person is doing nutritionally. The results showed that of patients with a baseline serum albumin level above 3.5 g/dL (normal), 70 percent were alive after 2½ years. However, of patients whose albumin level was between 2.5 and 3.5 g/dL, only 50 percent were alive at 18 months. Most distressing, of patients with an albumin level of less than 2.5 g/dL, only 20 percent were alive after six months, and all were dead at 14 months.

The fact is that death occurs in AIDS patients with wasting syndrome either when body weight approaches 66 percent of ideal body mass or when the total body cell mass, meaning lean tissue, approaches 54 percent of normal. These statistics come from Kotler et al, who measured the lean body mass and plotted it against survival[3]. Lean body mass is determined by measuring total body potassium with a very special machine. Potassium is a very rough measure of lean body mass because it resides mainly in muscle tissue and is mildly radioactive, so it can be counted. By doing so, Kotler et al found that when the total body potassium approached 54 percent of normal, patients tended to die.

I conclude that the *amount* of wasting, rather than the specific cause of weight loss, is the primary determinant of death. There is a critical level of body cell mass below which survival is impossible.

Intervention

The goals of nutritional intervention in HIV infection are to minimize tissue breakdown, or catabolism; to minimize nutrient losses; to replenish body cell mass, or lean tissue mass; to preserve the function of the bowels and the gut; to improve the host's resistance to infection; to improve the patient's response to medication; and most important, to preserve the quality of life. In their study[2], Chlebowski et al found that the $CD4^+$ T-cell count actually correlated with patients' nutritional status (eg, albumin level). Although this does not mean that if we can improve someone's nutritional status their $CD4^+$ T-cell count will necessarily go up, if a person's nutritional status deteriorates, it is analogous to immunosuppression in and of itself.

In the office, intervention begins with assessment. What measures do we use to determine nutritional status? In addition to the serum albumin level, some rely on total iron-binding capacity, prealbumin, fibronectin, transferrin (other proteins which will not be discussed here); lean body mass; and the percentage of usual body weight. A physician could begin quite simply by asking, "What was your average body weight in the last several years before you got sick?" Sometimes, patients are found to have lost a distressing amount of weight when asked this question.

Mechanisms of malnutrition

How do people get malnourished with HIV infection? There are a number of processes, and I'll go through each one briefly.

There is a final common pathway that serves as an overview. Patients infected with HIV have various metabolic disturbances that predispose them to losing weight. When a person who is HIV infected and also very immunosuppressed gets a secondary infection that causes either diarrhea or loss of appetite, he or she gets debilitated and lose weight, probably at a more accelerated rate than a person with a similar kind of illness who is not HIV infected. Most persons with HIV infection fail to fully recuperate from each insult, resulting in this vicious downward spiral of one illness, weight loss, never fully recover, another illness, and so on.

The first process, which I think is the most important, is called metabolic dysregulation and embodies two complex concepts, namely, protein-calorie malnutrition (also known as protein-energy malnutrition) versus cachexia. Protein-calorie malnutrition is synonymous with starvation. It occurs when the body's need for protein, energy, or both cannot be met by diet. This could be the result of inadequate intake, malabsorption, diarrhea, decreased utilization of nutrients by the body, or some other change in metabolism. The bottom line is that our genetic and evolutionary makeup ensures that when we are in a starvation state, our body will preserve its lean body mass preferentially. Our body will burn fat and other parts of necessary tissue and substance in order to preserve visceral organ function and lean body mass.

Cachexia that happens with HIV infection, however, is a different process. The normal metabolic signals involved with starvation become uncoupled. So, instead of our normal evolutionary adaptations taking place, a marked and almost immediate depletion of lean muscle and vital tissue mass occurs that may not be reversed by traditional nutritional therapies. HIV infection combines this metabolic uncoupling with protein-calorie malnutrition.

The Table compares the immunologic changes associated with protein-calorie malnutrition and AIDS. It can be seen that the immune defects in AIDS are identical to those associated with protein-calorie malnutrition in a non–HIV-infected person. Again, the conclusion to be drawn is that malnutrition, in and of itself, is an immunosuppressed state.

Patients with advanced HIV infection also tend to be hypermetabolic. Their resting energy expenditure, or their basal metabolic rate, the rate at which they burn fuels, is higher. Grunfeld et al found that the mean metabolic rates in a healthy state, in persons with asymptomatic HIV infection, in AIDS, and in AIDS with a secondary infection increase in a stepwise fashion[1].

Certain circulating substances called cytokines are also clearly associated with HIV and wasting. One that has been extensively studied, and is controversial right now, is tumor necrosis factor (TNF), also known as "cachectin," because it causes cachexia, or severe wasting, especially in cancer patients. When otherwise healthy mice were injected with this substance, they would lose muscle mass and weight and become cachectic. Early studies demonstrated an increased level of TNF in patients with AIDS, and this was thought to be directly associated with the wasting process. However, more recent sudies have found TNF levels to be variable and most closely associated with secondary infections.

Other circulating substances, such as interleukin 1 and interferons alpha, beta, and gamma, have also been implicated in this process. There has also been a trial with a substance called pentoxifylline (Trental), which may decrease HIV replication and HIV-associated wasting by decreasing TNF levels. It is currently in active clinical trials.

Anorexia

Anorexia, or the loss of desire to eat, is a significant contributor to malnutrition. What can cause anorexia? Plain old depression, or emotional stress from being sick or having other kinds of problems in one's life, can clearly cause anorexia. Medications like zidovudine (ZDV), didanosine (ddI), and zalcitabine (ddC) can clearly cause loss of appetite, as can any number of secondary infections. Anybody who has just had a fever knows that you do not feel like eating when your body temperature is too high. HIV-infected, very sick patients sometimes run a fever five out of seven days a week. Chemotherapy for AIDS-associated Kaposi's sarcoma (KS) or non-Hodgkin's lymphoma can also cause anorexia.

Again, when caloric intake was studied in controls and patients with asymptomatic HIV infection, AIDS, and AIDS with a secondary infection, counting the calories that patients took in during the course of three days, it was found that the fewest calories were consumed by patients with AIDS and a secondary infection[1].

Immunologic Changes Associated with Protein-Calorie Malnutrition

	AIDS	Protein-Calorie Malnutrition
Cellular immunity		
T cells	Decreased (++)	Decreased (++)
Helper T cells	Decreased (+++)	Decreased (++)
Helper:suppressor T-cell ratio	Inverted	Inverted
Delayed cutaneous hypersensitivity	Anergy (+)	Anergy (++)
Immature T cells	Increased (++)	Increased (++)
Lymphokine production	Decreased (+)	Decreased (+)
Cytotoxic T cells	Decreased (+)	?
Alloreactivity	Decreased	?
Helper T-cell activity	Decreased (+++)	Decreased (+)
Humoral immunity		
Serum immunoglobulins (Igs)	Increased (++)	Increased (++)
Immune complexes in serum	Present (+++)	Present
Primary antibody response	Diminished (++)	Diminished (+)
Circulating Ig-secreting B cells	Increased (+++)	Increased (++)
Antibody affinity	Decreased (++)	Decreased (++)
Miscellaneous		
Thymic hormones	Variable	Variable
Serum complement	Normal	Decreased (++)
Inhibitory factors in serum	Present (++)	Present (++)

Is this anybody's fault? Obviously, a sick patient does not feel like eating. But, when a patient is in the hospital, very often he or she has a test to go to, a CT scan, barium enema, something. They are ordered by their doctors to be "NPO," meaning they cannot eat before the test. A typical scenario arises when the patient has not eaten all morning for an 11:00 a.m. test, the test gets rescheduled for 6:00 p.m., so the patient gets a little Jell-O. This may go on for days and days during a medical workup for an acute illness, just at a time when a patient's metabolic demands are going up and up. I think it is important that patients become their own advocates and start telling their doctors, "Feed me some way, somehow. Don't just give me fluid. Don't give me Jell-O between tests. You know, if I need it, give me nutrition either through my veins, or in my gut, or however is appropriate, but get me some nutrition when I need it most."

Nausea and vomiting are obvious causes of anorexia. Various opportunistic infections can cause these, such as KS or lymphoma of the gastrointestinal tract. Medications, such as zidovudine, especially in the high doses that we used to use, have been associated with this effect. Clearly, chemotherapy for the various kinds of neoplasms associated with HIV can cause nausea and vomiting.

A nastier problem for most patients, especially with advanced HIV infection, is malabsorption, which causes diarrhea. Causes of this are pretty much the same as of nausea and vomiting. Patients can be just plain lactose intolerant, unable to digest milk sugar. This can clearly cause malabsorption and diarrhea. Other infections, such as amoebas, cytomegalovirus,

Cryptosporidium, *Mycobacterium avium* complex, and a newly identified infection of the bowel called *Microsporidium*, have been associated with HIV and diarrhea. "HIV enteropathy" used to account for much of the diarrhea now being attributed to *Microsporidium*. A drug called albendazole actually may be effective for this.

Many of us do not pay attention to good dental care when we have other pressing issues. Gingivitis, periodontitis, and problems with the gums and the bones supporting the teeth and gums are very prevalent, and these processes are accelerated in HIV infection. Good dental care is very important because the mouth is the point of entry for food; pain in chewing and swallowing may limit food intake. Herpes infections, thrush, cytomegalovirus, hairy leukoplakia, KS, and nonspecific esophageal or oral ulcers (that are actually due to either HIV itself or medications) may play a role here. In fact, in the early open-label trials, it was found that ddC sometimes caused nonspecific oral ulcerations that were quite painful and often necessitated discontinuing the drug therapy.

So, some of these wonder drugs may be causing some of the problems themselves. As we test new agents, we do not know every side effect beforehand. If a new symptom occurs during an experimental protocol, it may be advisable to discontinue the drug for a while and see if it is causing the symptom.

Patients with neuropsychiatric impairment, dementia, or infections or cancers of the central nervous system may not be able to take in enough calories to support themselves. Again, under neuropsychiatric impairment, depression can be treated, and not just by a person talking to friends or to a support group. I think depression is a medical illness that needs to be treated with psychotherapy in concert with the appropriate antidepressant agents. I think many people mistakenly attribute depression to an inability to cope with the disease process. Depression is a complex medical illness that may have emotional triggers, but is also neurochemical in origin and augmented by HIV's effect on the central nervous system. It definitely affects a person's desire and ability to eat and needs to be addressed.

In addition to PAAC's excellent symposium on nutrition and HIV/AIDS, there were a few presentations at last year's VIII International Conference on AIDS that involved nutrition and HIV infection, but not nearly enough. One that I published and presented with some of my colleagues (from the Graduate Hospital of the University of Pennsylvania School of Medicine in Philadelphia) tried to relate mortality, or death from HIV infection, to a person's usual body weight and CD4+ T-cell count. The frightening finding was that it did not matter what a person's CD4+ count was; when a person lost enough weight, even with the same number of CD4+ cells, their risk of dying, or even just getting sick from HIV infection, went way up. This underscores the urgent need for more basic clinical research into the causes, treatment, and prevention of HIV-associated wasting so as to stem the tide of this insidious "silent plague."

Later in the program, you will learn more about the PAAC Nutritional Initiative, which includes what I believe to be the most comprehensive model for integrating medical nutrition as a central strategy in the management of HIV disease. I believe that the more physicians take advantage of this model, the better able we in the medical community will be to extend the length and quality of life of patients with HIV disease. □

Editor's note: After the Los Angeles Nutrition Symposium, Dr Cohan was nominated as a member of PAAC's Nutrition Committee, and both Pacific Oaks Medical Group and the Kraus-Beer Medical Group began enrolling their patients in the PAAC Nutritional Model.

References

[Note: the three studies listed below are summarized in PAAC's new publication *Nutrition and HIV/AIDS*, which the author consulted in composing his talk. For ordering information, see the offer on page 81 of this issue.]

1. Grunfeld C, Pang M, Shimizu L, et al. Resting energy expenditure, caloric intake and short-term weight change in human immunodeficiency virus infection and the acquired immunodeficiency syndrome. *Am J Clin Nutr* 1992;55:455-460.
2. Chlebowski RT, Grosvenor MB, Bernhard M, et al. Nutritional status, gastrointestinal dysfunction and survival in patients with AIDS. *Am J Gastroenterol* 1989;84:1288-1293.
3. Kotler DP, Tierney AR, Wang J, Pierson RN Jr. Magnitude of body-cell-mass depletion and the timing of death from wasting in AIDS. *Am J Clin Nutr* 1989;50:444-447.

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Stephen Reissman, President of Country Villa Service Corporation, developed the program after assessing the needs of the community. Country Villa South's 30-bed unit, which is located at 3515 Overland Ave. in West Los Angeles, California, is capable of providing all services offered in a traditional hospital AIDS/HIV unit except extensive diagnostics and invasive surgical procedures. The unit's hospital-trained staff offers technologically advanced therapies. The program also offers a more homelike environment with flexible visiting hours.

This program provides a cost-effective alternative to hospitalization. If you would like more information on this program or our other facilities, please contact Laura Hyatt, V.P. Managed Care at Country Villa's Corporate Offices (310) 390-8049.

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NEWS RELEASE

Century City Hospital

FACT SHEET
SPECIAL CARE CENTER AT CENTURY CITY HOSPITAL

PURPOSE OF CENTER: To provide state-of-the-art treatment, inpatient and outpatient, for people with the HIV virus, AIDS, and other immunosuppressant diseases. Treatment includes medical and psycho-social services.

CENTER FACTS: The first inpatient center of its kind in Los Angeles, the Special Care Center opened in Feb., 1986. Today, the Center has 20 beds.

STAFF: Approximately 20 R.N.s, plus others, staff the Special Care Center. The Center is under the direction of Stephen Gabin, M.D., Medical Director, and Ralph Hansen, M.D., Director of Infectious Disease.

SERVICES OFFERED: Acute inpatient care. Diversified outpatient services including blood transfusions, use of experimental drugs, intravenous medication and chemotherapy. Psycho-social support for patients and loved ones.

UNIQUE FEATURES: The Special Care Center creates a home-like atmosphere for people with AIDS and their loved ones. All day visitation is permitted. The Center's newest emphasis is on treating women with AIDS.

Patients at the Center often dress in street clothes, not hospital gowns. Rooms have a VCR and the Center has a recreation room with a TV, VCR, tape player and refrigerator. The Center also offers 2 daily luncheon buffets which encourage patients to socialize with each other. Century City Hospital provides patients with a supportive environment to enhance both medical treatment and quality of life.

CONTACTS: Andrea Hecht, Hecht Communications, 818/788-9235
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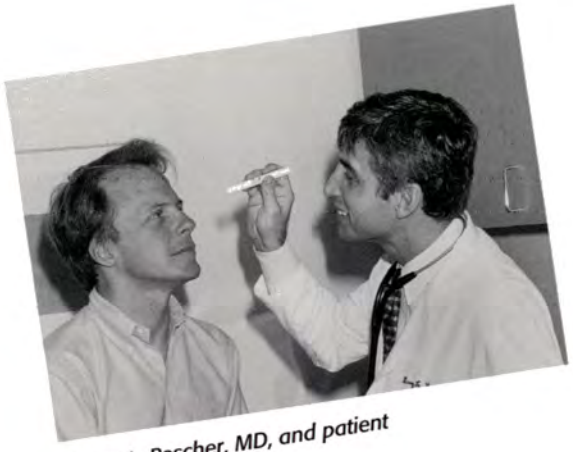
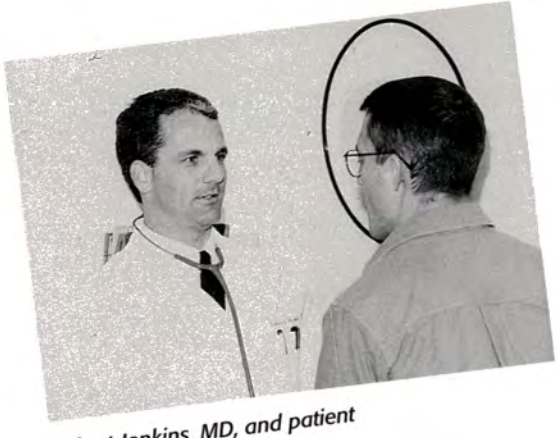


Henry L. Poscher, MD, and patient

Lyssette L. Cardona, MD, and patient



Robert Jenkins, MD, and patient

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You can make a difference in the future of Los Angeles

Physicians Association for AIDS Care

You can make a difference in the future of Los Angeles...

...and the fight against the HIV/AIDS epidemic.

According to some estimates, there could be as many as 80,000 to 100,000 people with HIV disease in greater Los Angeles by the year 2000. The continued spread of this epidemic is having a profound impact on clinical and social services and the economic viability of Los Angeles.

The Los Angeles members of the Physicians Association for AIDS Care (PAAC) are forging a new alliance between the medical, PWA, and corporate communities to develop innovative programs to combat this epidemic and to meet the growing medical needs of people with HIV disease.

Serving the community

PAAC's new Los Angeles regional office provides educational services, clinical support, and advocacy programs for more than 100 Southern California physicians and their patients with HIV disease.

In addition to these services, PAAC has launched three local projects designed to have a major impact on the care of all Southern Californians with HIV disease. These include:

- The development and coordination of HIV clinical trials in Southern California so that all people with HIV disease can have access to the most promising agents that could affect their survival and quality of life.

- The development of community guidelines for the treatment of HIV disease by the physicians treating the majority of people in Los Angeles with HIV/AIDS. These guidelines will help facilitate reimbursement for newer therapies.

- The development of a not-for-profit HIV/AIDS IPA (Independent Practice Association), which will be a group of Los Angeles-area physicians able to contract with employers, unions, managed care organizations, and possibly state agencies, to take over the care of people with HIV disease. This model is designed to implement Los Angeles PAAC community guidelines for the treatment of HIV disease, coupled with significant savings over current care costs.

PAAC is also developing a broad agenda of local HIV projects to support existing community-based organizations in the creation and implementation of innovative programs to reduce the spread of HIV and to improve the length and quality of life of all Southern Californians affected by this disease.

Community support

PAAC needs your support to advance our ambitious goals for local services and to develop a new Los Angeles paradigm of aggressive coordinated medical care and social services to serve as a model for our nation. Your support in any amount can make a difference in the local, national, and global fight against this plague.

For individuals, we recommend an annual contribution of $100, which will include a subscription to ***PAACNOTES***—our monthly newsjournal, and the nation's leading HIV/AIDS publication. Individual contributors will also receive a bimonthly notice of all regional PAAC activities and updates.

For corporations, we recommend an annual contribution of $1,000, which will include five subscriptions to ***PAACNOTES***. We will also develop a custom-designed HIV education program for your personnel and special support services for your employees with HIV disease.

A contribution in any amount is both needed and welcome.

National leadership

Organized in 1988, PAAC is a professional association of physicians, other caregivers, scientists, AIDS activists, pharmaceutical manufacturers, home care companies, and other members of the corporate community who have joined together in a combined effort to improve the care of all people with HIV disease.

PAAC is a principal educational resource for physicians, other caregivers, and people with HIV disease. PAAC is a leading advocate for the rights of people with HIV disease and their caregivers.

PAAC is a federal tax-exempt, nonprofit, 501(c)(3) organization. PAAC's tax FEIN is 36-3588493.
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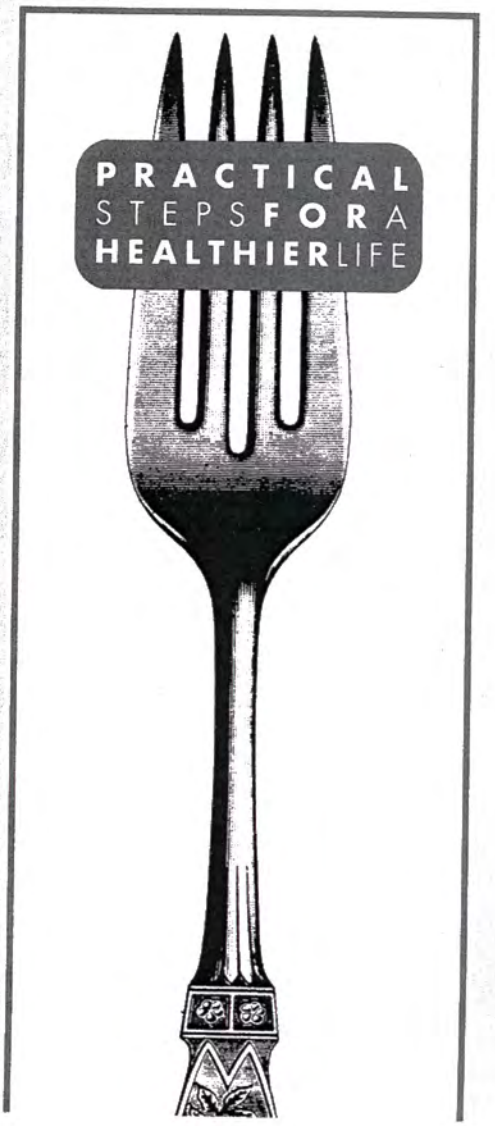

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Backgrounder
Q & A

Q: What is the purpose of Kristine Gebbie's Los Angeles visit of February 3, 1994?

A: 1. Ms. Gebbie's purpose is to learn more about the unique dimensions of HIV/AIDS care by PAAC/LA physicians and institutional members that may be contributing to an increasing number of long-term survivors with HIV/AIDS in this region, and

2. to learn how this care model is being adapted to PAAC/LA's standard of care and managed care initiatives.

Q. Why is the HIV/AIDS Care by PAAC/LA members unique?

A. There are three common factors:

1. Integration of the nutritional support.

   There is increasing evidence that nutritional therapies may play a significant role in long-term survival as some drug therapies. The prevention and reversal of protein-calorie malnutrition as a complication of AIDS may be as significant as the prevention of AIDS opportunistic diseases. Refer to PAACNOTES, February 1993 article *The Silent HIV-Associated Malnutrition Plague* by Gary R. Cohan, MD.

   Nutritional assessment and intervention is a standard of care by many PAAC/LA members and many of the physicians are following the PAAC nutritional algorithm that was published in ***Nutrition & HIV/AIDS.***

2. *Cutting edge therapies are a defining element in the LA care model.*

   An example of cutting edge therapy was the use of

clarithromycin in Los Angeles as a standard of care before it was accepted as a standard in other parts of the country and years before it was approved by the FDA in December of 1993. Refer to PAACNOTES, September 1993 article Bringing a Drug to Market-Again: *Perspectives on Clarithromycin's Approval Process* by Ann Louise Truschel.

3. *The special cooperation between LA physicians and many third-party payers*

   Third-party payers have agreed to reimburse for many experimental and off label therapies used by LA physicians. Reimbursement for cutting edge therapies are essential to the use of these therapies as a strategy for long-term survival. Refer to PAACNOTES, September 1993 article Bringing fa Drug to Market-Again: *Perspectives on Clarithromycin's Approval Process* by Ann Louise Truschel.

Q: What is the PAAC/LA standards of care initiative?

A: The members of PAAC/LA are developing new guidelines for HIV care that reflect the often unique approach provided by the LA medical community. These standards differ from other professional association and federal standards because they are developed by physicians treating the majority of patients with HIV/AIDS in Los Angeles. These standards also differ in the fact that PAAC/LA has standing committees for each standard of care so that the standards can be immediately updated as soon as the community of physicians agree on newer interventions. After these standards are published in PAAC's monthly journal, they will be established as legal guidelines for the reimbursement for new therapies and off-label drugs. Refer to AHA News of November 22, 1993, Special Report, *AIDS/HIV program could lead to national practice guidelines.*

Q: Why are the PAAC/LA standards of care so important?

A: Survival with HIV disease will be affected in great part by small incremental steps in more effective therapies for the prevention and treatment of opportunistic infections. Small and continual advances are important in preventing protein-calorie malnutrition which is a major debilitating complication in later stage HIV disease. Each new intervention with a more effective therapy is expected to increase long-term survival. So our greatest hope until there is a major breakthrough in AIDS treatment is the step by step incremental gains that we will make with more effective prophylaxis and treatment.

Our effectiveness against fighting this disease depends on our ability to immediately approve these incremental advances in care as part of a care plan and to have these therapies reimbursed by third-party payers.

Q: What is the PAAC/LA managed care initiative?

A: PAAC/LA is currently developing an AIDS IPA (Independentt Practice Association) and an AIDS PPO (Preferred Privider Organization) that is planned to contracat with employers a and other third-party payers and state agencies to take over the lifetime care with people with HIV/AIDS in the Los Angeles area. The PAAC/LA managed care model will be based on PAAC/LA standards of care and will provide all participants with the best chance of suvival with their disease. The model is also planned to provide for significant savings over the current cost of HIV/AIDS care. Refer to PAACNOTES, Novemeber 1993, *PAAC Launches Los Angeles Standards of Care and AIDS IPA Projects by Brett Hufziger.*

Q: What is PAAC?

A: PAAC is a not-for profit professional association formed in 1988 to ally physicians, health care providers, the hospital and pharmaceutical industries, the corporate community, and concerned activists to increase awareness and improve care of HIV/AIDS.

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Background Information on the Organization and its Accomplishments

Q: What is the Physicians Association for AIDS Care (PAAC)?

A: The organization is a professional association with over 1000 members comprising of physicians, other healthcare professionals, and concerned individuals and organizations of the HIV community , formed to develop and support innovative programs designed to maximize the length and quality of life of all people with HIV/AIDS.

Q: When was PAAC organized?

A: PAAC was formally organized in 1988. The organization evolved from a group of physicians called the AIDS Medical Resource Center Physicians Association that began in 1986. The Los Angeles Regional Office opened in late 1993.

Q: How is PAAC managed?

A: The association is governed by trustees who represent a broad cross section of physicians and scientists including internationally recognized leaders in clinical research, individuals in private practice and with federal agencies. These dedicated and talented individuals volunteer their time to develop important and resourceful programs which are implemented through the association's staff lead by its executive director, Gordon Nary.

Q: What have been PAAC's principal accomplishments to date?

A: *Communications* - PAAC developed and publishes PAACNOTES, the nation's leading HIV/AIDS publication which provides a unique interdisciplinary focus on the scientific, clinical, ethical, legal and political dimensions of the epidemic. HIV Update is the group's syndicated cable television series featured in 40 US cities on PBS and public access stations.

Nutrition - The association is recognized as the nation's leading advocate in nutritional intervention strategy in HIV disease. PAAC has conducted two international conferences on this topic and has facilitated the distribution of 250,000 of PAAC's first in a series of patient-based booklets on nutrition and AIDS.

Advocacy - PAAC played an instrumental role in developing the new Social Security Administration regulations extending Medicare benefits for tens of thousands of people with HIV/AIDS.

Clinical Trials Support - The association has served as a patient ombudsman for the DDC trials and has assisted several pharmaceutical manufacturers with the implementation of important HIV/AIDS drug trials.

Q: How is PAAC supported?

A: PAAC receives no government funding for its initiatives and has relied on financial support from individuals and corporations.

Q: Who are the physician members of PAAC in Los Angeles?

A: There are more than 100 physician members who treat over 38,000 of the estimated 50,000 people with HIV/AIDS in the greater Los Angeles area. These dedicated physicians were featured in a January 13, 1994, advertisement in the business section of the Los Angeles Times. A copy of the ad is attached.

Q: Who are the corporate members of PAAC?

A: A list of corporate or associate members of PAAC is attached.

Q: How can I help PAAC with it's initiatives here in Los Angeles?

A: Call PAAC's Los Angeles Regional Office at (310) 443-4231 and ask for a membership application or write to the address listed on page one of this fact sheet.

Associate Members of PAAC

02-Feb-94

Abbott Laboratories
Adria Laboratories
Amgen
Astra, USA, Inc.
Barr Laboratories, Inc.
Boehringer Ingelheim Pharmaceuticals
Bristol-Myers Squibb
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THE WHITE HOUSE

WASHINGTON

KRISTINE M. GEBBIE
National AIDS Policy Coordinator
Appointed by President Bill Clinton

Kristine M. Gebbie, R.N., M.N., is President Clinton's National AIDS Policy Coordinator, overseeing the nation's HIV and AIDS agenda in research, services and prevention. Prior to her appointment, Ms. Gebbie served as Secretary of the Department of Health for the State of Washington. She was a member of the Watkins Commission, the first Presidentially-chartered body to make comprehensive recommendations for the national response to HIV and AIDS.

Ms. Gebbie has a lengthy career history in the health field and public policy. She has served as the public health administrator in the State of Oregon, and was the coordinator of ambulatory care for St. Louis University Hospitals. Ms. Gebbie taught health courses at the University of Washington, the Oregon Health Sciences University in Portland, the University of California at Los Angeles, and St. Louis University.

She is active in many professional organizations, and has served as a member of the Executive Board of the American Public Health Association. She has been a member of the HIV Committee of the Association of State and Territorial Health Officials, and has chaired the Centers for Disease Control and Prevention Advisory Committee on the prevention of HIV infection and the Environment, Safety, and Health Advisory Committee of the U.S. Department of Energy. She is a member of the Institute of Medicine, and has served on its AIDS oversight Committee.

Ms. Gebbie has a Bachelor of Science degree in nursing from St. Olaf College, a Masters of Nursing from the University of California at Los Angeles, and is a doctoral candidate at the University of Michigan School of Public Health. She is the mother of three and resides in Washington D.C.

TACNOTES

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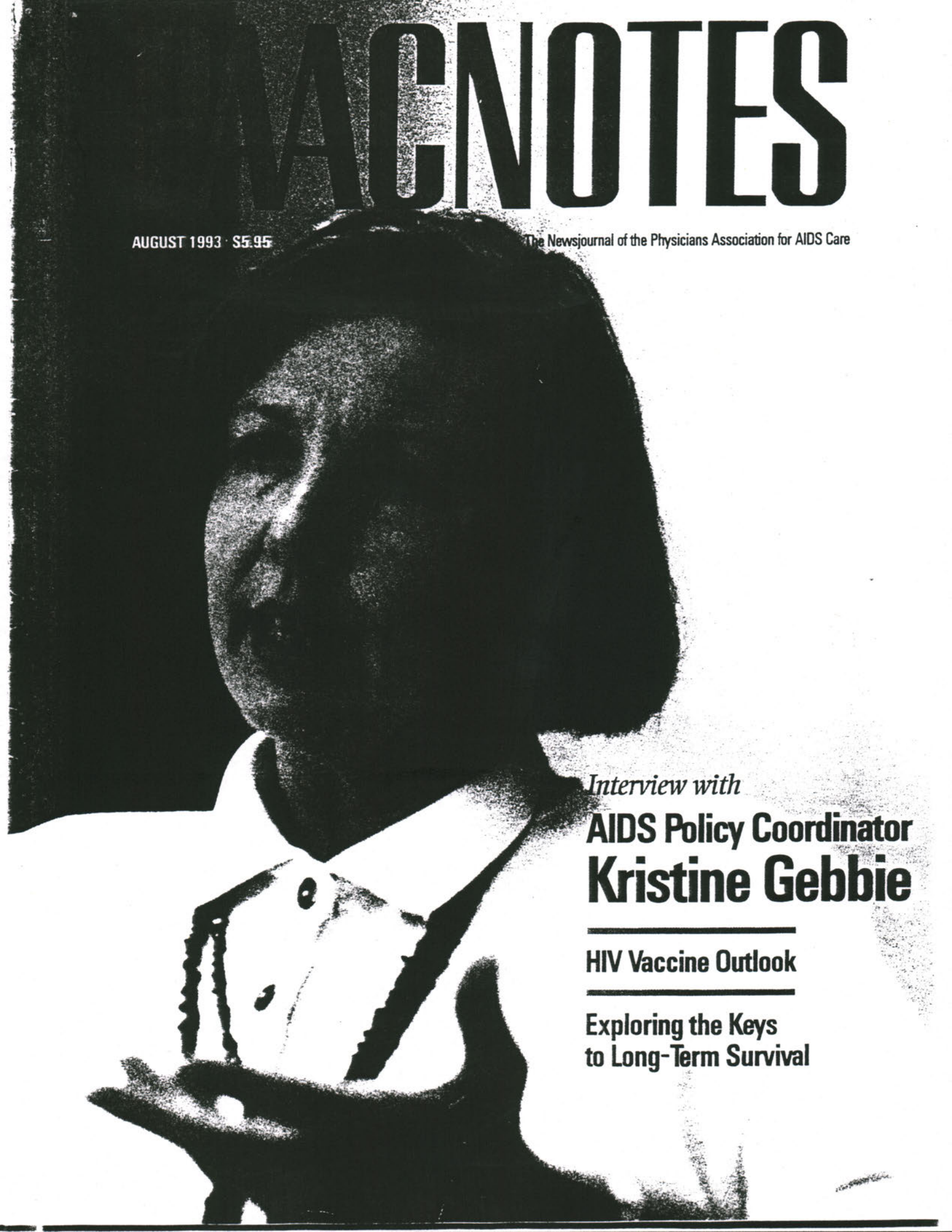
The Newsjournal of the Physicians Association for AIDS Care



Interview with

AIDS Policy Coordinator Kristine Gebbie

HIV Vaccine Outlook

Exploring the Keys to Long-Term Survival

Will the Arrival of a **CZAR** Herald a **REVOLUTION** in AIDS Policy?

An interview with Kristine Gebbie

Marlene Cimons

The phone call came shortly after midnight. "This is Kristine Gebbie," the caller said. "I'm sorry to be returning your call so late, but I just got into town."

She had just arrived in the nation's capital from her home in Washington State, only hours before President Bill Clinton was to name her his new AIDS czar—or czarina, as she likes to point out—in a splashy outdoor White House ceremony attended by a wide range of representatives from AIDS and medical groups, Congress, and the administration. The announcement ended a long and ill-starred search in which at least two others had turned the job down, and AIDS activists had made no secret of their impatience at the delay.

And here it was, almost the middle of the night. The recipient of the call was half asleep, but Gebbie was revved—and admittedly still somewhat puzzled by the rapid turn of events that had brought her to Washington.

"When did all this happen?" she was asked.

"They called me earlier this week and asked if I was still interested," she replied. "I told them I was."

The whole process had been more than a little mystifying—Gebbie's name had been on the White House's short list since the transition, and she had been interviewed by administration officials early in the search.

Yet, the White House had previously offered the post to Dr. Margaret A. Hamburg, New York City's health commissioner, and then to Representative Jim McDermott (D-Washington), both of whom had said no. Hamburg, pregnant with her first child, felt she could not reconcile the demands of new motherhood with those of a new job. McDermott reportedly did not want to give up his seat in Congress.

Those who had been watching the process could not understand why it had taken the White House so long to get to Gebbie. Many have speculated that Clinton wanted to inaugurate the job with someone whose name would spark instant public recognition.

Indeed, Kristine Gebbie's name is not a household word. Nevertheless, she had long been a presence in the AIDS community, where she is well-known and, for the most part, highly regarded.

But that may not be enough. People in the AIDS network remain nervous, hoping that the administration will give Gebbie the resources and the authority to confront the unmet challenges of the epidemic. And everyone will be watching as she begins a newly created job that virtually the entire AIDS community demanded, but that no one, including the Clinton administration, has as yet really been able to define.

It is still too early to assess how she will do. At the moment, the job of the AIDS czar is a work in progress. "I get to make it up as I go along," Gebbie says, with a smile.

Clinton promised quick action on AIDS during his campaign and has proposed increased federal spending both on research and on programs aimed at treating and preventing the disease.

The purpose of the new post is to coordinate the activities of the many federal agencies that currently deal with aspects of the AIDS crisis—from the Centers for Disease Control and Prevention to the National Institutes of Health. This mandate does not necessarily mean that Gebbie will be dabbling internally in any specific agency programs. Rather, she is there to ensure that "everyone is communicating with everyone else," she says.

Her supporters have urged that she focus her efforts on prevention strategies and on working to ensure that Congress implements the president's funding proposals. They also have called on her to implement the recommendations of the two AIDS commissions and to represent the voice of AIDS in all health reform discussions. She says she intends to try to do all of that—and more.

The idea "is to finally make the government responsive to the epidemic, including all the cabinet agencies, and to try to implement all the reports we've been accumulating," she explains, referring to the work of both the National Commission on AIDS and the AIDS commission established by the Ronald Reagan administration, on which she served. "The whole tone of creating this position is that 'we want to do it better. We want to finally do

"Kids have known how to use condoms for water balloons for years—I'd rather they learn to use them for appropriate purposes."

it right.' My job will be to find a way to harness the energy and the commitment that are already there and make them pay off.

"We need to get the system out of people's way and change it so that it works better. How do you make an outpatient program work so that patients can get in, get served, and get out within two hours? All the pieces have to come together. Let's make it easier for people to do the right thing. That's the challenge, and it's what I've been trying to do in public health all along."

For example, "if you're trying to prevent head injuries, it's not enough to make sure there is a trauma hospital available to treat them," she says. "It's making sure that kids know about wearing helmets; it's car seats and seat belts; it's truck safety programs and bicycle lanes. It's not just doctors and nurses doing it differently, and better, but the whole community working together."

Gebbie believes it is critical to beef up prevention efforts, with the federal government providing more resources and technical assistance to states and communities to create such programs. Information should reach everyone, particularly young people before they reach adolescence, from kindergarten on up, she says. "Even kids in kindergarten hear things," she says. "You don't talk to them about safe sex, but you teach them that their bodies are something to take care of and that viruses can mess them up. I believe very strongly that AIDS education has to be part of a comprehensive health education program, not something separate."

As for teenagers, "I think anybody who is sexually active needs to know about the use of condoms," she says. "Kids have known how to use condoms for water balloons for years—I'd rather they learn to use them for appropriate purposes. Does that mean you hand out condoms? That's a community-level decision based on resources. The national role is to give them resources, technical assistance, and good support."

She believes that AIDS clinicians should be concerned about two major areas. "The first is that there should be more of them," she says. "The second is that

On Kristine Gebbie

"She was very tough when there was nonsense coming out of some of the other commissioners. She could carry the day." —*Adm. James Watkins*

"She usually was able to convince me that she was right. We disagreed with the other members of the commission a great deal. My reaction was to get very angry. Hers was to be very gentle and very tactful and to get something accomplished." —*Dr. Frank Lilly*

"She's a very nice person, and the last thing we need for this job is a very nice person." —*Larry Kramer*

"The whole tone of creating this position is, 'We want to do it better. We want to finally do it right.' My job will be to find a way to harness the energy and the commitment that are already there and make them pay off."

they should be able to get the right information [about treatments and so forth] as fast as possible."

A registered nurse and epidemiologist who once taught at the University of California at Los Angeles, Gebbie was chief health officer for the State of Oregon when AIDS first showed its deadly presence. Later, she ran health programs for Washington State.

Her initial reaction to the first AIDS cases in 1981—before the disease even had a name—was like that of the rest of the country: "I remember thinking, gee, those folks in California have a problem," she recalls of her response to reading in the CDC's *Morbidity and Mortality Weekly Report* of the mysterious disease that was killing gay men in Los Angeles. "It took a few months before it sank into my thick head that *we* have a problem."

If that's all it took, Gebbie probably was ahead of the national curve. As a state health official, she became involved early on in tracking the AIDS epidemic. Although Oregon initially did not have a large caseload, Gebbie paid careful attention to the escalating epidemic, studying beyond its public health implications to understand its social and political impact as well.

She served as head of the AIDS task force for the American Association of State and Territorial Health Officials and later was asked to join the AIDS Commission established by the Reagan administration. Having been a foe of Reagan administration AIDS policies, she was reluctant. But Admiral James Watkins, the commission's chairman, was very persistent and persuaded her to join.

"I picked her, and she was a great asset to me, especially since we were greatly outnumbered," Watkins recalls, referring to the commission's many ultraconservative members. "She was very tough when there was nonsense coming out of some of the other commissioners. She could carry the day."

Dr. Frank Lilly, a professor of genetics at Albert Einstein College of Medicine, who was touted as the commission's only gay member, agrees with Watkins: "She knows an awful lot about the epidemic, and her primary interest was in AIDS education and the public health aspects of the epidemic," he says. "She and I agreed on virtually everything of any importance, and the few things we disagreed on, she usually was able to convince me that she was right. We disagreed with the other members of the commission a great deal. My reaction was to get very angry. Hers was to be very gentle and very tactful and to get something accomplished."

Thus it is surprising that she has already had to fend off some vicious attacks from activists who say she is not strong enough for the job, or who dislike some of the things she did while holding state health posts.

"We needed *Jurassic Park*, and we got *Sleepless in Seattle*," comments Larry Kramer, who founded the activist group ACT UP. "My gut reaction tells me she's a very nice person, and the last thing we need for this job is a very nice person," Kramer continues. "We need stormin' Norman—someone who can knock heads together. Having spent 12 years in the trenches, it's hard for me to believe that anything but screaming bloody murder gets anything done."

Gebbie is unfazed. She views her critics as those who simply "never accept anybody at face value and feel they always have to be pushing everyone. I may not have as much flash as some people would like, but I can talk to people, and I can get them to talk to each other," she says. "I can work hard, and I can get others to work hard.

"I think some people expect the person in this job to be a public and loud figure, someone preaching at politicians about

how to do it right," she continues. "I don't think that's as effective as getting people into rooms together to talk. That's not to say I won't speak out, however."

Watkins, who also served as energy secretary in the Bush administration, feels that the activists are underestimating her. Gebbie confronted right-wingers on the Reagan AIDS panel numerous times—and won—when they refused to "get off their ideological box and fight on the facts," he says.

"She's no patsy," Watkins declares.

Gebbie, recalling her work on the Reagan AIDS commission in light of activists' recent attacks on her, laughs. "Some people find it amusing that I defined the radical left fringe of that commission," she says.

ACT UP also has condemned her for supporting Oregon's controversial health rationing scheme when she headed that state's health department. ACT UP also claims that she supported names reporting of HIV-infected individuals when she ran Washington State's health programs.

The latter charge, she insists, is "a distortion, a lie." What she did was to draft a paper on how the issue of reporting should be handled if it should come down as a federal recommendation to the states. "And we had every reason to think it was going to happen under the Bush administration," she says.

Nancy Campbell, executive director of the Northwest AIDS Foundation in Seattle, an AIDS service organization that opposes names reporting, confirms Gebbie's version of the controversy. "She is very protective of confidentiality and the rights of HIV-infected people," Campbell says. "But she's also a pragmatist. What happened was this: she saw some things going on with the Bush administration and thought this was coming. So she went to the governor's council [an AIDS advisory group] and told them to start to plan."

Campbell adds: "I was at those meetings and what I heard was: 'I think this is coming. How do you want to handle it?' I did not hear: 'I think this is a good idea.'"

Gebbie does acknowledge her role in shaping Oregon's controversial health rationing plan but insists that the state has received a bum rap on the issue. As a country, "we already ration," she stresses, dismissing the idea that we currently have a one-level system. The nation rations by economic status and other discriminatory factors.

"Your insurance company rations, and often you don't find out about it until you need something," she says, adding that one of the things rationing does "is get poor people into care" who have not been served by the health system. "With finite resources, we have to make choices about what we invest in," she says. "I support making rationing explicit and involving the whole community in the debate." In the Oregon plan, AIDS and HIV "are in the mainstream" of services, except for end-stage AIDS, "which is rated low," she adds.

Gebbie, who celebrated her 50th birthday the day after her appointment, is a divorced mother of three—her children are 22, 19, and 17—who was born in Sioux City, Iowa, where she lived only five weeks. Her father was a military man, and "I spent most of the war years with my mother and maternal grandparents in Mile City, Montana," she says. She spent her teenage years in Albuquerque, New Mexico, where her mother stills lives. "Rocky Mountain West is what I think of as home," she says. "I lived in the Pacific Northwest for 15 years."

She goes hiking "whenever I can," walks three to four miles every morning, and knits and reads detective novels in her spare time. There isn't much of that these days, since she is also trying to finish her doctoral dissertation, a case study of changes in Washington State statutes and "how and why state governments reorganize themselves."

Gebbie has served as an adviser to the administration's healthcare reform process and has chaired an advisory committee for the CDC, evaluating that agency's AIDS programs. She believes that AIDS can serve as a focal point for a national debate on healthcare and numerous other complex issues confronting society today.

"What does human sexuality mean?" she asks. "What is the balance point between an individual's rights and responsibilities and a community's rights and responsibilities? What is our responsibility to people at the end of life? At what point do we accept the reality of death and not fight it with everything we have?

"AIDS does not involve just the healthcare system—it overlaps into the business and political world as well," she says. "I find that kind of complex puzzle challenging. It leads you into just about every complicated human question that you have to deal with." □

Marlene Cimons, a Washington reporter for the Los Angeles Times *who covers health policy, has written extensively about AIDS since the epidemic's beginnings.*

Bringing a Drug to Market—*Again*

Ann Louise Truschel

The only single therapeutic modality that has been shown to be effective in the treatment of disseminated *Mycobacterium avium* complex (MAC) in patients with AIDS is Abbott Laboratories' clarithromycin (Biaxin). Originally approved in November 1991 for upper and lower respiratory tract bacterial infections, clarithromycin was recommended for accelerated approval for the treatment of MAC at the May meeting of the FDA's Antiviral Drugs Advisory Committee.

"It's still not approved after almost one year. I can't call that accelerated. We anticipated approval sooner than this."—*Andre G. Pernet, PhD*

What led to this accelerated approval recommendation—and not everyone agrees the process has been accelerated—was a lot of effort by Abbott, activist groups, and clinicians. Sometimes working together and sometimes not, all the players have labored to push clarithromycin through the regulatory system.

Did all this effort really shorten the development and approval process for clarithromycin as a treatment for MAC? Does accelerated review and approval really work? How do the activists fit into the process? How do the players view the FDA's role? These questions are important in the analysis of the clarithromycin experience, but there is another part to this story. The clarithromycin story is also a study of relationships—relationships among Abbott, activists, clinicians, and the FDA. All with their own agendas, these groups share the common goal of getting life-sustaining drugs, like clarithromycin, through the regulatory system to the patients who need them.

An untreatable disease

Before the advent of clarithromycin, disseminated MAC in patients with AIDS was essentially untreatable, its symptoms being controlled more or less well by a combination of drugs that sometimes cause intolerable side effects. Symptoms of the disease are nonspecific but debilitating and include fever, drenching night-sweats, fatigue, anemia, weight loss, wasting, and severe diarrhea. Respiratory symptoms and pulmonary involvement, usually seen in immunocompetent patients, are uncommon in AIDS-related MAC.

Left untreated, MAC affects virtually all organs of the body. The effect on patient morbidity is significant, and the most recent data suggest that MAC reduces the life expectancy of patients with AIDS by approximately six months.

Prevalence of MAC increasing

Disseminated MAC is now the second most common AIDS-associated opportunistic infection worldwide. Its prevalence is increasing not only because the incidence of AIDS is increasing, but ironically because antiretroviral therapies are helping HIV-positive patients live long enough to develop the infection. Disseminated MAC is usually a late-onset infection and, in general, is diagnosed about nine months after an AIDS diagnosis has been established.

MAC is now seen in 15 to 24 percent of patients with AIDS in the United States, and an estimated 50 to 80 percent of patients with AIDS in North America will eventually develop some type of *M. avium* infection. The main route of acquisition appears to be gastrointestinal.

Clarithromycin as treatment for MAC

MAC-infected AIDS patients treated with clarithromycin usually experience symptomatic relief within one month as the level of bacteremia is reduced. "Clarithromycin is able to reduce the infection titer in the blood by about 2.7 logs," said Andre G. Pernet, PhD, vice-president of pharmaceutical development at Abbott Laboratories, Abbott Park, Illinois. "Compared to monotherapy with other drugs, it is quite superior, and it's even better than the traditional cocktail of four drugs [ethambutol, amika-

cin, clofazimine, and rifampin], which reduces infection titer only by about 2.4 logs. Most of the side effects of clarithromycin are gastrointestinal and most are mild."

"It's a very good drug; it's one of the best that we have," concurs Lowell S. Young, MD, Director of the Kuzell Institute in San Francisco. Dr. Young, who has the NIH/NIAID contract for the evaluation of new therapies against *M. avium*, conducted screening studies using clarithromycin.

Bringing clarithromycin to the US market

The story of bringing clarithromycin to market is actually the story of bringing the drug to market again. Although originally approved in November 1991 for use against upper and lower respiratory tract bacterial infections, as far back as 1988 the drug had already shown *in vitro* activity against *M. avium*.[1] In 1989, *in vitro* and *in vivo* activities of clarithromycin against *M. avium* were reported,[2] and the following year Dautzenberg, in France, published the results of a double-blind, randomized, placebo-controlled, crossover study demonstrating the efficacy of clarithromycin in MAC infections in patients with AIDS.[3]

Even while the French study was under way, word of the results began to reach activist groups in this country. "We were all really excited about clarithromycin when we first heard even anecdotal data coming from France," said Ben Cheng, information and advocacy associate for San Francisco's Project Inform. "As far as treating *M. avium*, at the time there was nothing except a four- or five-drug combination of fairly toxic drugs. We wanted to get clarithromycin into clinical trials in this country."

Activist groups all over the country began to mobilize to help make clarithromycin available in the U.S. to AIDS patients with MAC. Because the drug was already approved in Italy, the Buyers Club was able to obtain it through Germany and later through Ireland and make it available on the underground. "However, the drug was quite expensive because someone had to fly to Europe to pick up a shipment and bring it back," said Cheng. "Also, nobody knew what dose of the drug was supposed to be used."

Designing the US clinical trials

To answer just that question, Abbott began its first clinical trial, a dose-ranging study, in May 1990. According to Dr. Pernet, placebo trials were not used "because, after the initial observation of activity of the drug, it would have been unethical to use placebo as one arm knowing that MAC is a fatal disease, that people need the drug. All were monotherapy trials because we wanted to study the drug by itself and see its effectiveness." To date, Abbott has conducted five short clinical studies involving some 1,300 patients.

The two trials that provided most of the information for Abbott's New Drug Application were ACTG 157 and the compassionate use trials.

ACTG 157. ACTG 157, begun in May 1990, was a safety and efficacy trial cosponsored by Abbott and led by Richard E. Chaisson, MD, of Johns Hopkins University in Baltimore.[4] Patients enrolled in the study were to receive either 500 mg, 1000 mg, or 2000 mg of clarithromycin twice daily. While the trial was in progress, Abbott asked for and received FDA permission to increase enrollment. The company added three study sites, and ACTG 157 became Abbott's pivotal NDA study.

An interim analysis of the results clearly demonstrated that clarithromycin was highly active against MAC bacteremia. What the results of ACTG 157 also showed was that, as a single agent, clarithromycin induced resistance that usually occurred between weeks eight and 12. Moreover, at the higher doses of clarithromycin, increased toxicity was observed. Clearly more information was needed.

"We have a dialogue with Abbott but it's certainly a rocky relationship."—*Ben Cheng*

The emergence of resistance to clarithromycin was disappointing, but not surprising. "*M. avium* traditionally is almost always resistant to almost all drugs," said Jeffrey Galpin, MD, of the Shared Medical Research Foundation, Tarzana, California. "We need to use a combination of clarithromycin and other drugs. We don't have the optimum treatment yet."

Compassionate use trials. In January 1991, activist groups including Project Inform, ACT UP, ACT UP's Treatment Action Group, and Search Alliance first contacted Dr. Pernet at Abbott to ask for free distribution of clarithromycin to AIDS patients with MAC infection. Abbott agreed and developed a protocol that was approved by the FDA.

However, when the distribution program debuted in July 1991, the company received heavy criticism from the activist community because of the amount of documentation Abbott required from clinicians. According to Cheng, "We had clinicians calling us complaining that, as a result of all the paperwork required by Abbott, they weren't able to put as many patients on compassionate use as they would like. Abbott was essentially running a clinical trial through the compassionate use program. They were using two different dosages and were asking for a lot of laboratory tests. Most compassionate use programs just ask for safety data." Cheng said that the company maintained it needed additional efficacy data. According to PAAC's executive director, Gordon Nary, who was asked by Abbott to monitor the concerns of activists, "There were similar paperwork issues with other pharmaceutical manufacturers with promising new drugs. These concerns mirrored a primary challenge to both the activist and scientific communities to balance good science with the ethical obligation to maximize patients' quality and length of life."

While activist attempts to convince Abbott to decrease the amount of paperwork were largely unsuccessful, Cheng acknowledged that testing clarithromycin at the two dosages yielded valuable information, and that it was partly because of the compassionate use program that Abbott was able to complete its NDA.

Stephen Nightingale, MD, a PAAC trustee from the University of Texas Southwestern Medical School, Dallas, was one of the clinicians involved in the compassionate use trials. "By January of 1992, we knew we had a partial solution to the problem [of treating MAC infections] and that we were going to need second- and third-line drugs [because of the resistance that developed]."

The indigent compassionate use program: a difference of opinion

Following the November 1991 approval of clarithromycin for other indications, Ab-

bott and the activist community clashed again over compassionate distribution of clarithromycin. The disagreement involved Abbott's decision to limit compassionate distribution to those MAC-infected AIDS patients with annual incomes under $26,000.

Abbott's reasoning for this decision was simple. Said Dr. Pernet, "Since the drug was now approved, although for other conditions, anyone could buy it." And, in fact, that is what happened. Physicians began prescribing clarithromycin for their patients with MAC, and use of the drug became widespread.

The activist community remained opposed to the indigent compassionate use program. "Every other company has had an open-ended compassionate use program," said Cheng. "Pfizer has a similar compassionate use program for azithromycin. Their only requirement is a MAC diagnosis. There has never been a compassionate use program in which income determined whether you got the drug or not."

In fact, Abbott's indigent compassionate use program was delayed in the FDA for several months "because it was a precedent for them. It had never been done before," Dr. Pernet said. But the program was ultimately approved and began in July 1992. It now operates worldwide.

According to Nary, who had a preliminary discussion with the FDA about the indigent program before the proposal was submitted by Abbott, "The FDA's approval was a seminal decision because it underscored the obligation of third-party payers to cover the cost of off-label drugs when they have been established as a standard of care." PAAC helped establish the acceptance of clarithromycin as a standard of care for treating MAC by surveying AIDS specialists on their treatment practices. (These findings were published in *PAACNOTES*, volume 3, number 3.)

In October 1992, Abbott filed its NDA.

Accelerated approval recommended

This May, seven months after the filing of the NDA, clarithromycin received an accelerated approval recommendation from the Antiviral Drugs Advisory Committee. As of late September, the drug has not yet been approved for the MAC indication, but approval is expected to come through at any time. Abbott is in the process of negotiating the final labeling for the drug with FDA. The labeling will contain a statement that clarithromycin should be used in combination with other unspecified drugs.

In retrospect

Looking back on the development and approval process for clarithromycin, it would seem a simple task to determine how the process worked. Yet, there is no general agreement as to who or what brought clarithromycin "to market," or even if the drug's passage through the regulatory system has been really accelerated.

"We need to be wise in how we use this drug, or we'll create a population where resistance will emerge much quicker."—*Jeffrey Galpin, MD*

The activists feel they expedited the review process by making their presence felt at the FDA. "We were on the phone with FDA once a week or every two weeks asking about the status of the NDA and about hearing dates," said Cheng. "If FDA hears us asking about a drug, they know we are pushing for approval."

In Dr. Pernet's opinion, however, neither the review nor the approval was expedited. He points out that Abbott filed its NDA in October of last year. "I don't think it was an accelerated approval given the fact that we filed for only one indication, and it's still not approved after almost one year. I can't call that accelerated. We anticipated approval sooner than this."

The situation is further complicated by the fact that the clarithromycin experience is atypical. Clarithromycin is not a "new" drug in the classic sense: it was already approved and on the market for another indication. The question of whether the review and approval were expedited is debatable because it is not clear how much prodding along the regulatory trail the drug really needed.

"My own view is that the drug brought itself to market," said Dr. Nightingale. "After clarithromycin was approved [for upper and lower respiratory infections] and became available by prescription, we began using it to treat MAC. The use was so widespread that the approval [recommendation] pretty much followed medical practice rather than anticipated it."

One can only speculate on who is right. Perhaps everyone is partially correct. What is clear is that the approval process for clarithromycin has not broken any speed records.

Are accelerated review and approval working?

If one accepts the fact that the clarithromycin experience is not typical, then the consensus is that the FDA has made improvements in the regulatory process over the past several years that have resulted in accelerated reviews for AIDS drugs. Dr. Pernet feels that the Agency has been "very responsive." Clinicians involved in screening studies or registration trials also feel that the approval process has been expedited and, in particular, give activists a large share of the credit for getting the FDA bureaucracy to look at new ways of doing things, ways that can speed AIDS drugs through the system.

Dr. Young still labels the FDA "a ponderous bureaucracy," but adds that the Agency has improved greatly over the past three years. He says the activist community had a lot to do with that improvement. "The activists, by accelerating the review process, I think have done the field a favor. And FDA has become more responsive."

In general, Cheng agrees. "FDA is sensitive to the viewpoint of the activist community. Members of the community are always invited as consultants to sit in on the advisory committee meetings. If we support a drug, FDA knows we're pushing for approval. I think that helps in the long run in getting drugs to market." Cheng characterizes the role of activists with FDA as helping the Agency look at its priorities.

By being informed on the issues, activists, many feel, have served a valuable purpose by educating government and helping the FDA recognize that rules can be modified, without losing the protection and benefit of those rules, in order to speed therapeutics through the system.

"I hope this kind of support is a trend that is here to stay," said Dr. Nightingale. "If there is not continuing strong support for accelerated approval of drugs, I think it inevitable that very careful evaluation of drugs for fear of our tort system will return as the dominant force in drug development."

What lies in the future for Abbott and the activists?

There is more discussion ahead for Abbott and the activists: the company has a number of HIV drugs in development. They will continue to talk and to build on the relationship they established during the clarithromycin studies even though they do not agree on just what that relationship is.

Dr. Pernet thinks it is essential to have good relations with the activists not only to avoid their more aggressive actions, but also to make sure they understand Abbott's position. "It's important to keep the activists informed. If they understand what we're doing, and we can reach an acceptable compromise, I think it's in everybody's interest."

For their part, activists want more than information: they want membership in Abbott's scientific advisory board, the committee that designs and plans Abbott's clinical trials. "Abbott doesn't always have the community in mind when it comes to drug development," Cheng said, although he understands that the profit motive has to underlie a lot of Abbott's decisions. "That's not entirely a bad thing," he said, "but it would be better if Abbott would work with the affected community when designing clinical studies. We have a dialogue with Abbott but it's definitely a rocky relationship."

It is not surprising that the relationship between Abbott and the activists is, and probably always will be, somewhat strained. Despite their common purposes, the two represent different constituencies. Activists represent AIDS patients, and Abbott ultimately represents shareholders. "Tension over profits is the reason why I don't see the advocacy groups and the pharmaceutical industry getting too close to each other," said Dr. Nightingale.

Clarithromycin's future

New clinical trials are being planned for clarithromycin, and a number have already started. Because of the emergence of resistance to clarithromycin, combination drug studies are necessary. C. Robert Horsburgh, MD, special assistant for infectious diseases at the Centers for Disease Control and Prevention, reviewed the data for the FDA's Antiviral Drugs Advisory Committee. "Resistance is a serious problem," he said. "It develops in at least half the people and they get sick again. The average time for resistance to develop is three months. Clarithromycin should never be used alone."

Clinical trials are now under way to study clarithromycin in combination with ethambutol, clofazimine, rifabutin, and liposomal gentamicin. Trials with other combination drugs are in the planning stage.

More studies also need to be conducted to resolve the problem of increased toxicity at higher doses. In part, increased toxicity is attributable to gastrointestinal intolerance, mainly stomach pain, which is not an uncommon occurrence with macrolide antibiotics. There were more deaths in the higher dose treatment groups than in the treatment group receiving 500 mg twice per day, but the reason was not obvious, and the number of deaths was not statistically significant when all factors were controlled for.

"It's not clear whether the increased toxicity was the fault of improper study design—that sicker people actually got the higher dose—or whether there's really some toxic effect at the higher doses," said Dr. Horsburgh. "FDA was unwilling to make a decision [on the dose], and I think that was wise." What the FDA finally did decide was to recommend a dose range of 500–1000 mg twice per day until the toxicity question could be resolved by additional studies. (At this dose range, the cost for one year's therapy would range between $1900 and $3800.)

Other indications for clarithromycin are being evaluated. "The emphasis now is on the use of clarithromycin as a prophylactic agent for *M. avium*," said Dr. Pernet, "so we're now doing those studies."

Dr. Galpin thinks such studies are necessary. "We don't know the true effects of prophylaxis. We need to be wise in how we use this drug. We can't use it indiscriminately or we'll create a population where resistance will emerge much quicker."

The clarithromycin experience

Clarithromycin is undergoing additional testing. Combination studies will determine the optimum regimens for long-term treatment of MAC. Prophylactic studies will be conducted, and other trials will try to resolve the toxicity issue.

The relationship between Abbott and the activists will continue and will probably still be uneasy. While appreciating each other's position, they pursue their own agendas. The FDA is viewed more positively by the players, and the activists are given a lot of the credit for bringing about improvement in the regulatory process.

Activists see themselves in a dual role—pressing pharmaceutical companies for early compassionate distribution and for clinical trials that are more community-centered; and lobbying the FDA to expedite the review and approval process. These relationships will also be undergoing additional testing in the future.□

Ann Louise Truschel, a medical communications consultant for Professional Communications in Skokie, Illinois, covers AIDS, public health and healthcare industry issues, and other topics.

"The activists, by accelerating the review process, I think have done the field a favor. And FDA has become more responsive."
—Lowell S. Young, MD

References

1. Nash SF, et al. "The in vitro activity of a new macrolide antibiotic A-56268 (TE-031) against *Mycobacterium avium* complex strain isolated from AIDS patients." Presented at the 88th Annual Meeting of the American Society for Microbiology, 1988.
2. Fernandes P, Hardy D, McDaniel D, et al. "In vitro and in vivo activities of clarithromycin against *Mycobacterium avium*." Antimicrob Agents Chemother 1988;32(9):1531–1534.
3. Dautzenberg B, et al. "Double-blind study of a trial of clarithromycin versus placebo in *Mycobacterium avium* and *Mycobacterium intracellulare* infection in AIDS patients." Am Rev Respir Dis 1992;145:A878.
4. Chaisson RE, Benson C, Dube M, et al. "Clarithromycin therapy for disseminated *Mycobacterium avium* complex (MAC) in AIDS." Program and Abstracts of the 32d Interscience Conference on Antimicrobial Agents and Chemotherapy, Anaheim, Calif., October 1992. Abstract 87.

PAAC Launches Los Angeles Standards of Care and AIDS IPA Projects

Brett Hufziger

On November 10, 1993, the Los Angeles office of the Physicians Association for AIDS Care (LA/PAAC) launched two healthcare reform projects that, according to Gordon Nary, PAAC's executive director, "could have a significant impact on the future of HIV care and on the practice of medicine." Nary referred to the potential impact of the LA PAAC Community Standards of Care Project on the treatment of HIV disease, both locally and nationally, and to the "opportunity for community physicians to standardize third-party reimbursement for off-label use of FDA-approved drugs and other diagnostic and therapeutic procedures that local physicians approve as community standards." In addition, a Los Angeles AIDS IPA (Independent Practice Association) proposal was introduced that is designed to provide medical, social, and financial planning coordination services under the direction of its member physicians.

All accompanying photos by Gary Lester-Weedgard

Physicians, pharmaceutical manufacturers, and members of the hospital and insurance industries attended the November 10 meeting of LA/PAAC to review the organization's Standards of Care project and its Independent Practice Association (IPA) proposal. At center (in blue shirt) is Dr. Ronald Mitsuyasu, head of PAAC's publications committee, and director of UCLA's Center for Clinical AIDS Research and Education (CARE).

Community Standards of Care Project

In his opening remarks in a meeting held at Midway Hospital, Nary explained that Los Angeles was chosen to launch the Community Standards of Care Project because LA/PAAC's physician members have cared for more than 38,000 people with HIV disease, a majority of the 50,000–60,000 estimated cases of HIV in greater Los Angeles. According to Nary, if the physicians treating the majority of patients with HIV disease in Los Angeles could agree on community standards of care, these standards would have a legal basis for reimbursement. Generally, guidelines that have been used to define standards of care have either been (1) developed by recognized specialists in a particular discipline and endorsed by medical organizations, or (2) based on research published in peer-reviewed journals by university researchers.

The LA PAAC Community Standards of Care Project is based on a multi-stage review procedure of 21 protocols, each of which is developed over 90 days and updated regularly. The complete process is scheduled to take 13 months (see Table). There are seven steps in the protocol approval process:

1. A draft of the proposed protocols is developed by PAAC's Standards of Care Committee, based in part on the Standards of Care series of articles in *PAAC-NOTES*. This draft is sent to all PAAC individual and corporate members attending monthly protocol meetings.

2. Any PAAC member attending the meeting can recommend changes in the proposed protocols. These changes are considered by the ad hoc committee for each of the protocols. The committee chairs, with the agreement of the members at the meeting, will prepare a second draft of the protocols based on a consensus of recommendations.

3. The second drafts of the protocols are sent to all LA/PAAC member physicians for final comment.

4. Comments are reviewed by the LA/PAAC Standards of Care Committee chairs and are incorporated into a final draft of the proposed protocols. The final draft is sent out again to all members for their approval.

5. Members can approve the entire protocol or selected sections of the protocol. A member's approval is weighted according to the number of patients (charts) in his or her HIV practice.

6. The final protocols and their approval factors will be published in *PAAC-NOTES*.

7. With appropriate funding, PAAC plans to add an attorney/advocate to the Los Angeles office who will work with third-party payers who fail to reimburse based on the LA/PAAC standards. If, after negotiations, the payer still refuses to base reimbursement on the LA/PAAC standards, a patient advocacy fund will be used to challenge such decisions in the courts.

Schedule: Los Angeles Community Standards of Care Reviews

November 1993	*Mycobacterium avium* complex Cytomegalovirus
December 1993	*Pneumocystis carinii* pneumonia Toxoplasmosis
January 1994	Fungal infections
February 1994	Antiretroviral therapy
March 1994	Kaposi's sarcoma Non-Hodgkin's lymphoma
April 1994	*Cryptosporidium* *Microsporidium* Miscellaneous GI disorders Management of diarrhea
May 1994	Dermatologic disorders
June 1994	Gynecologic disorders
July 1994	Oral complications, excluding fungal and Kaposi's sarcoma
August 1994	Neurologic disorders
September 1994	Endocrinologic disorders Cardiac disorders
October 1994	Pain management
November 1994	Nutrition
December 1994	Pediatric

Protocols submitted for review

Two protocols were reviewed at the November meeting, one for *Mycobacterium avium* complex (MAC) and the other for cytomegalovirus (CMV) disease. The preliminary recommendations discussed at the meeting included:

1. Lowering the current Public Health Service guidelines for the institution of rifabutin (Mycobutin) for prophylaxis against MAC. (This proposal was based in part on Dr. Richard Chaisson's article in the September 1993 issue of *PAAC-NOTES*. Dr. Stephen Nightingale's recommendations presented at the PAAC symposium at the IX International Conference on AIDS in Berlin, and the experience of several of the participating physicians.)

2. The off-label use of filgrastim (Neupogen) for the treatment of leukopenia secondary to drug side effects and isolated decreases in white blood cell counts.

3. The off-label use of ganciclovir (Cytovene) and foscarnet (Foscavir) for the treatment of systemic CMV disease (pulmonary, gastrointestinal, neurologic, etc).

These recommendations were included on the second draft of the protocols distributed to the LA/PAAC membership for final comment.

Budget outlined

Nary projected that the annual budget for the Community Standards of Care Project, which includes adding three staff members to the Los Angeles office, would amount to $250,000. He then outlined LA/PAAC's plan to raise funds.

PAAC will target 250 Los Angeles corporations to contribute $1,000 per year to the project because of the potential value in reducing healthcare costs and improving the length and quality of life of Los Angeles residents. Nary explained that PAAC's message to the corporate community is that the HIV epidemic could have profound social and economic consequences on the Los Angeles business community by the year 2000 unless steps are taken now to control the costs of care without sacrificing the aggressive, comprehensive care that has been a trademark of the Los Angeles community.

The first step for community corporate identification will be a full-page advertisement in the business section of the *Los Angeles Times* outlining LA/PAAC's initiatives. The advertisement is scheduled for early December and is being paid for by a grant from Roche Professional Services. The names of all LA/PAAC member physicians will also be included in the advertisement.

Nary also described an LA/PAAC brochure that was being developed to request both individual and corporate support of the project. The brochure will feature photographs of several local PAAC physicians, including Lysette Cordona, MD, MPH, Henry Poscher, MD, and Robert Jenkins, MD. The brochures will recommend annual corporate support of $1,000 and development of a corporate relationship with LA/PAAC, which would serve as the HIV educational coordinator for that corporation. Individual donations of $100 per year will also be recommended.

Nary also announced the appointment of Rick Nordin as director of develop-

Dr. Jayson Hymes (left) confers with Amber Lindsey of Roche Professional Services, who helped coordinate the LA/PAAC meeting. Jack Brubach of Bon Bon, a payroll management company, looks on.

ment for LA/PAAC. Nordin was the former director of development for AMFAR in Los Angeles. According to Nordin, "It's nice to be a part of this effort, particularly focusing on involving the corporate community. There are lots of details and lots of conversations ahead, but I see elements for success here, namely, the participants in this room, and leadership with some vision and ideas."

AIDS/IPA proposal introduced

Nary also introduced the Los Angeles AIDS/IPA proposal, which was explained in greater detail by Victor Beer, MD, and Jayson Hymes, MD. (Their presentations are featured later in this report.) Nary emphasized that the not-for-profit model was suggested because of the projected millions of dollars in cost analysis, cost benefit, and outcome studies that would be necessary to help compute appropriate annual management fees paid to the IPA by employers and other payors.

Nary also recommended that the LA IPA be based in part on an extension of the landmark AIDS home health, attendant, and hospice care pilot project that was featured in the January/February 1992 issue of *PAACNOTES*. This report (prepared for the California Department of Health Services Office of AIDS) provided critical data on the application of a comprehensive case management model as a central part of HIV care. The proposed LA/PAAC comprehensive case management model involves the coordination of all medical, social, and financial planning services through a case manager working under the direction of the physicians in the IPA. The medical services would be based in part on the LA/PAAC Community Standards of Care.

In outlining the Los Angeles IPA project, Nary also detailed proposals to include two major funds that would be under the direction of a financial planner working with the case manager. The funds could be accessed by patients who might otherwise not be able to pay for specific treatments that are not part of the Standards of Care Project. These funds include:

1. An investigational drug fund. Since many investigational therapies that have become standards of care are off-label uses of FDA-approved drugs, Nary recommended that there be a mechanism to support a physician's investigational use of off-label drugs in a process that could eventually assess whether they proved to be effective community standards.

2. An alternative therapy fund. While traditional third-party payer policies generally do not cover alternative therapies, a growing number of Los Angeles physicians and their patients are incorporating alternative therapies as an adjunct to more traditional therapies. The concept of the alternative therapy fund is to provide money to pay for these alternative therapies approved by the patient's physician on a case-by-case basis.

Other projects introduced

Nary also outlined some of LA/PAAC's other projects designed to reduce the cost of lifetime care, increase long-term survival, and improve quality of life. They include:

1. Expansion of clinical trials. PAAC is currently working with several pharmaceutical manufacturers to bring new clinical trials into the Los Angeles area. Several of these trials are planned to be conducted by some of the major practices, and a program of cross-referrals to the various practices is on the schedule of projects to be considered by the IPA organizing committee.

2. The lifetime care cap on AIDS drugs. PAAC has begun working with several of the leading pharmaceutical manufacturers to determine the feasibility of a trial project in Los Angeles in which companies would assess the impact of a lifetime cap on AIDS drug costs. After the lifetime cap was reached, future drugs would be provided at no cost.

3. Coordinated indigent patient programs. At a December 3 meeting with pharmaceutical manufacturers in Washington, DC, Nary outlined a proposal for a pilot project in Los Angeles that would include common eligibility criteria for free drugs and the coordination of these criteria through a single patient advocate. Based on the success of the pilot project, this function would be assumed by the case manager.

PAAC trustee Dr. Victor Beer, of Kraus-Beer Medical Group, discussed various aspects of the Independent Practice Association

While a schedule of annual management fees will be under consideration for medical care, other services such as hospitalization, transitional care, hospice, and home care could be covered under a separate Preferred Provider Organization (PPO) arrangement with local hospitals, home care companies, and other providers. The savings effected by following the community standards and the special discount negotiated through the PPO are expected to reduce private care costs by 20–30 percent without any sacrifice in quality of care.

Responses to PAAC's proposals

The response by local hospital leaders to PAAC's proposals has been positive. According to Bryan Burklow, Senior Vice President of Summit Health Ltd., "Healthcare reform presents critical challenges to hospitals with specialized AIDS and other disease-specific services. The "centers of excellence" concept provides employers, unions, and third-party payers with the assurance that people with HIV disease will have the most advanced care available by providing that care in its most cost-effective setting."

According to Maxine Cooper, the CEO of Hollywood Community Hospital Medical Center, Inc., "The work of LA/PAAC shows the eagerness of fee-for-service providers to cooperate with and add their expertise to the reorganization of healthcare delivery systems. Healthcare reform will change how everyone receives medical care, but those with HIV disease present a unique challenge to the system for a number of reasons. Chief among them is that HIV disease develops over many years and utilizes the entire health delivery system from testing to hospice. LA/PAAC's input to organizing the system to cost-effectively treat the many facets of HIV disease while preserving top quality is an important contribution."

One of several unions that expressed interest in the IPA applauded the concept of financial planning to help their employees better manage their resources and coordinate access to pharmaceutical company patient assistance programs. According to Tim Trueman, shop steward of the International Association of Machinists, "The financial planner component of the AIDS IPA model provides a pragmatic approach to balance healthcare costs. Our obligation is to help each person with

Victor Beer: Independent Practice Association could benefit physicians, patients, and the healthcare industry

(Excerpted from Dr. Victor Beer's comments to PAAC at Midway Hospital in Los Angeles, November 10, 1993)

What we hope to do is to develop a conglomerate of providers, both from the healthcare industry [pharmaceutical and hospital associations] as well as from the clinicians, to develop a structured IPA which can help to direct the way that care is going to be provided in the future.

We'd like to have input from both the pharmaceutical and the hospital industry, and hope to develop a system that will work effectively for health care in the HIV arena. This will allow us to direct where the care is going to be going, rather than having it thrust upon us in the form of mediocre medicine for the masses—which would only provide less-than-standard care for our patients.

The reality is, there is no community standard at the present time. We hope to develop a rational set of guidelines which will be modified in conjunction with the physicians who are providing the care. Not every one of these guidelines will be a required procedure. Each clinician will have some flexibility within the guidelines.

If we have a series of basic guidelines, I think we'll be able to provide some representation to most of the third party payers, insurance companies, as well as to federal and state agencies. We will then be able to develop the kinds of reimbursements, as well as the subsidized research programs, that we will need to accomplish this whole process.

Medicare and IPAs

We are increasingly involved with the provision of care to the Medicare population. One of the faults of the whole system is that those of us who provide care for Medicare patients, whether it be on a pro bono basis or for whatever reimbursements are provided from Medicare, have difficulty in maintaining continuity with our patient care. Many hospital facilities are not providers under a Medicare of MediCal [Medicaid in California] contract. When the patient requires hospitalization, the physician may be required to hospitalize the patient at a county facility where he or she may not have staff admitting privileges. These circumstances make continuity of care extremely difficult.

From my perspective, that's a very inefficient and undesirable system both from the standpoint of the clinician and the patient. Personally, I would like to be able to maintain continuity with my patients. What we hope to propose with the assistance of Medicare professionals, is a model in which we might be able to obtain special funding from the state and federal governments.

The shape of HIV care in Los Angeles

HIV care in Los Angeles will tend to move toward one or two or three larger medical group-type practices, all devoted to the development of managed care for the HIV population. We hope to integrate in both a horizontal and vertical fashion all areas crucial to the provision of care within this patient population.

I'd like to see that accomplished with the input of the third party payers from the insurance industry, and of the physicians. This could be done in a manner to prevent the development of adversarial relationships. We hope to have direct communication with third party payers, such that it would make all of our lives a lot easier.

The real concept that we have to address is the need to provide quality care for our patients.

Jayson Hymes: Physicians should establish standards of care before the state or national governments do so for us.

(Excerpted from Dr. Jayson Hymes's comments to PAAC at Midway Hospital in Los Angeles, November 10, 1993)

The role of nonprimary-care physicians

Twenty percent of my patient population have HIV as a primary diagnosis. And all I do is pain management and chemical dependency in response in regards to pain problems. As a subspecialist, I see lifestyle-involving complications and ramifications of HIV and seek to augment their care.

I and people in my position tend to interact with most of the larger and some smaller HIV-treating physicians and groups in the area: I'm viewed as somewhat of a neutral because we tend to interact with everybody. And we also interact with our vendors, healthcare corporations, pharmaceutical manufacturers, and hospitals on a somewhat different level than primary care physicians would. And so we'll bring somewhat of a broader perspective to the organizing process.

Caregivers, vendors, laboratories together

What we are proposing—as opposed to a uni-dimensional model of four or five primary care physicians organizing with one or two sub-specialists or sub-specialty groups—is integrating primary care treating physicians, their diagnostic vendors, clinical laboratories, radiology services, sub-specialists, pain management physicians, ophthalmologists, dermatologists, pulmonologists, therapeutic vendors, pharmaceutical manufacturers, DME (dural medical equipment) manufacturers, not only in terms of modalities but in terms of locations.

What's not being proposed is something that's being brought in from outside and we're being invited to join. What we are looking to do at a grass roots level is to organize and establish standards of care on an in-house level because if we don't establish these standards of care ourselves, then they will be mandated, they'll be established and mandated, and we will have to in a backhand measure look to see what we can do to modify them if they don't fit our particular community or practices.

So, when we organize and establish these standards of treating care, it won't come from some national or international law enforcement body, it won't be pushed down on us by the Medical Board of California or the Medicare Administration. But in fact, we can analyze our practices and our patients' needs and establish standards of care proactively. We can track our costs, analyze our outcome data and we can take this information in this vertically integrated model and offer far more to managed care organizations than simply the care of patients with HIV in terms of the medically related aspects.

We are all very much aware as primary care physicians and as sub-specialists of HMOs, PPOs, hospital organizations or indemnity carriers, referring patients to us for a specific thing. And the balance of the care for that patient we have little or no input on. And what we're proposing is an alliance of physicians and corporations to analyze what we are doing, consider our costs, raise funds to perform all these activities and offer a cost-effective, medically efficient superior model to what could be mandated out of Sacramento or out of Washington. And that's why I'm here and we're here.

HIV disease gain access to all the resources available to be a long-term survivor."

LA/PAAC's attention to cost-benefit and outcome studies has also resulted in praise from Gary Wolfe, RN, CCM, president-elect of the Case Management Society of America. According to Mr. Wolfe, "The special balance and cutting-edge therapies and outcome studies, cost-benefit studies, and financial planning that LA/PAAC is addressing in its AIDS IPA model should be of interest to and supported by employers, providers, and third-party payers. The model should become the standard of HIV care throughout the United States."

The proposals were also very well received by several of the Los Angeles physicians. Dr. Anthony Scarsella of Pacific Oaks Medical Group, who serves as LA/PAAC's liaison with the City of Los Angeles, stated, "The entire Los Angeles medical community believes it is time to take a proactive approach to both define and protect the practice guidelines that contribute to our patients' ability to live with HIV disease. The greater emphasis on managed competition and managed care signaled by President Clinton's healthcare reform proposals could mean that even more decisions on what is or what is not appropriate care for people with life-threatening illness will be made by persons other than physicians. This is simply not acceptable to the Los Angeles medical community."

Dr. Victor Beer summed up the LA/PAAC project by stating, "President Clinton's proposal provides the nation with the matrix to implement a much-needed national healthcare system, but cost estimates and political considerations may change critical elements of the proposal to facilitate legislative approval. Our community needs either to be proactive to protect our patients and our practices, or to be passive to an unknown future. There is no question that the Los Angeles medical community will be proactive and will move for a swift implementation of the LA/PAAC initiatives."

For further information concerning the Standards of Care or IPA Projects, contact the LA/PAAC office, 10940 Wilshire, Los Angeles, CA 90024; (310) 443-4231.□

Brett Hufziger is a Los Angeles free-lance writer specializing in financial and management operations.

NUTRITION AND HIV INFECTION: KEY POINTS

Gary R. Cohan, M.D.

Wasting syndrome -- the involuntary loss of greater than 10% of a person's usual body weight -- is the primary cause of death in more than 20% of persons with HIV infection.

Concept of the combined insults of protein-calorie malnutrition (starvation) and cachexia (abnormal tissue loss).

When a person's lean body (muscle and vital organ) mass falls below a critical point -- usually 54% of normal -- survival of persons with AIDS becomes impossible.

Conclusion: -- it is the *amount* of wasting -- rather than the specific cause of weight loss -- that is the primary determinant of death in AIDS patients.

Nutritional interventions in HIV infected persons are targeted at preserving lean tissue mass.

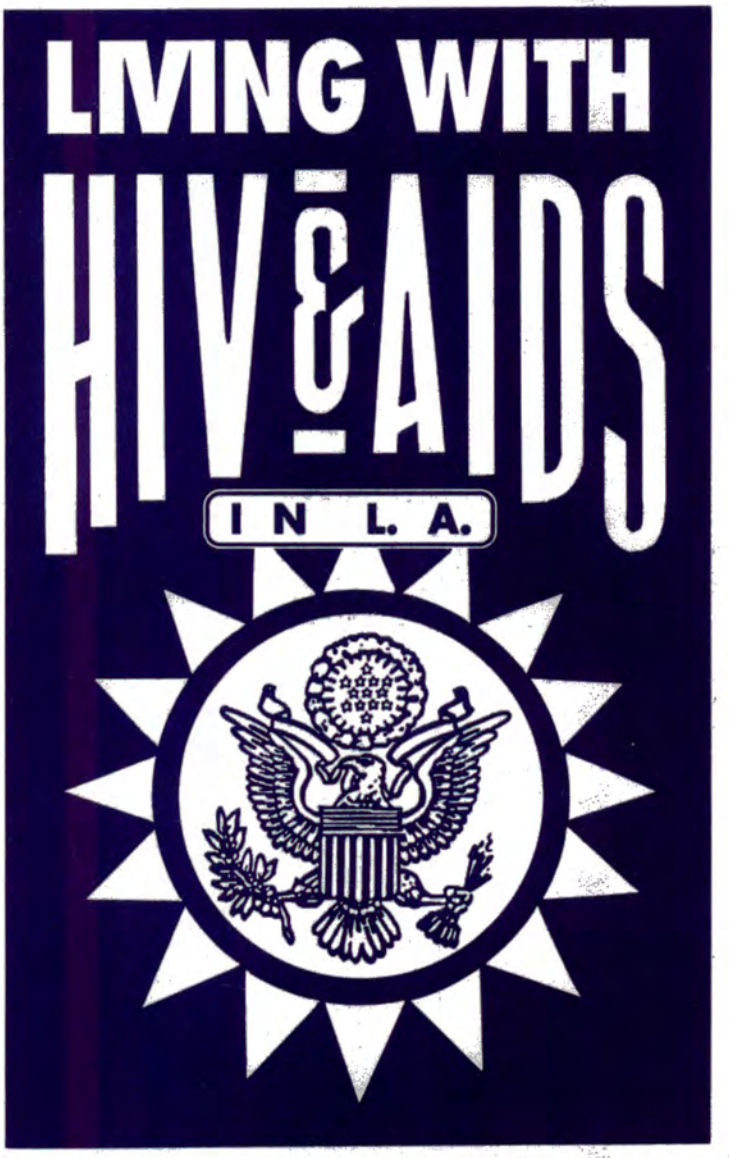
Primary strategy includes: treating underlying infections and gastrointestinal disorders, nutritional counselling and education, dietary supplements, appetite stimulants, anabolic androgens (steroids), vitamin (antioxidant) supplementation, and exercise.

Simplicity, ease of implementation, cost effectiveness observed by treating physicians. Algorithms for office-based evaluation and treatment have already have been developed by PAAC.

Anecdotal observations in our Los Angeles primary HIV care practice demonstrate that these strategies are extremely effective and well-tolerated by patients.

Need federal funding for formal research for these interventions to be tested and proven both effective and cost efficient. Data likely will be extrapolable to many other chronic debilitating disease processes (e.g. cancer, heart disease, etc).

Nutrition as an integral part of the President's national health carereform program.



NATIONAL AIDS POLICY COORDINATOR

KRISTINE GEBBIE

PAAC L.A. TOUR

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b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

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Los Angeles Physicians AIDS Forum - vice-president.
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Professional Committees:
Medical Advisory Committee AIDS Project Los Angeles.
Los Angeles County Medical Association AIDS Committee.

Professional Instruction
AIDS Education and Training Center for University of Southern California - School of Medicine. Providing instruction to primary care providers of HIV-infected patients. Instructor 1991-present.

Continuing Medical Education:
AIDS/ARC Update, University of California, San Francisco, Ca.; July 15-16, 1988.
One Day dermatology Workshop San Diego, Calif
Fifth International AIDS Conference Montreal, Canada; 1989.
Seventh International AIDS Conference Florence, Italy; 1991.
Eighth International AIDS Conference Amsterdam, Netherlands; 1992.
MKSAP VIII.
MKSAP IX.
Intensive Review of Internal Medicine- Harvard Review Course.
Emory University Internal Medicine Review Course.
Continued medical education hours on record with the California Medical Association.
Scientific American "Medicine."

Certifications:
BCLS Instructor Course - 1983, 1988.
Advanced Cardiac Life Support - 1983.

Research Articles & Publications:
The Reliability of Medical Record Abstraction for Assessing the Spectrum of HIV/AIDS Disease in Adults. VII International Conference on AIDS.

Participation in Research as a Co-investigator, LAC-USC Medical Center.

Private Research Protocols as a Co-Investigator:
Stanford University: "ATHOS" Project - A Time Health Oriented Survey & Aids data base acquisition study. Ongoing.

Center for Disease Control: "A Study of the Spectrum of Disease in Persons with Human Immunodeficiency Virus Infection." Ongoing.

Hemacare corporation: - Protocol 312.23
"Passive Immune Therapy in the Treatment of AIDS". Ongoing.

SEARCH ALLIANCE - A community based clinical research organization. Board Member
7461 Beverly Boulevard, Suite 304 Los Angeles; CA. 90036; Phone: (213)930-8820.

Additional Articles and Columns:

LACMA Physician: L.A. County Medical Assn. October 1991, Los Angeles, CA
Cover Story and Interviews, AIDS Awareness Month Issue.

PAAC NOTES: The News journal of the Physicians Association For AIDS Care.
"The Effects of AIDS on Caregivers Spouses." March 1993.

Medical Tribune: "Undetected HIV Spurs lawsuits." September 6, 1990.

Symposiums and Conferences

Speaker: Keith-Beer Medical Group: Los Angeles, California; June 1992;
"VIII International AIDS Conference Review Symposium."

Speaker: American Association for Medical Transcription: Cerritos, Calif.; May 4, 1991
"Aids-Ten Years Old: Where Are We?"

Speaker: California AIDS Statewide surveillance Meeting: March 1991;
"Reporting AIDS within the Private Medical Community"

Speaker: Management of HIV Disease: Beverly Hills, California; October 12, 1990;
"Current Clinical Concepts."

Speaker: University of Oklahoma, Health Sciences Center; June 13, 1990;
"Advances in the Diagnosis and Management of HIV Disease."

Speaker: L.A. County Medical Association Legislative Committee; May 3, 1990;
"Perceived deficits in the Medi-Cal Program."

Speaker: Clinical Partners; Boston, Massachusetts; March 13, 1990;
"Role of Elemental Enteral Nutrition in the Management of HIV-Related Malabsorption and Diarrhea."

Speaker: L.A. County Medical Assn. AIDS Forum; June 15, 1989;
"Fifth International AIDS Conference in Montreal."

Speaker: HIV Disease Management Symposium: Phoenix, Arizona; April 1989;
"Focus on the AIDS management Team."

Guest Lectures:

Glendale Adventist Medical Center
"AIDS Update" April 1, 1992

Santa Monica Hospital Medical Center
"Outpatient Care of HIV Patients"; December 10, 1991

AMI Medical Center of North Hollywood, Calif; October 24, 1990
"New Advances and Researches in AIDS".

Community Health Group of San Ysidro, Calif. March 23, 1989
"Outpatient HIV Management."

Hollywood Community Hospital May 22, 1988
"Update on AIDS Related diseases."

Guest Lectures: (cont)
Westside Hospital
Acquired Immune Deficiency Syndrome.

Verdugo Hills Community Hospital
Acquired Immune Deficiency Syndrome AIDS: An Update.

Century City Hospital
Aids in the Workplace: Digital Equipment Corp.

CIGNA Hospital
Continuing Education "Primary Care of the HIV Patient."

Guest Speaker at the Los Angeles County Medical Association, Los Angeles, CA
Sixth AIDS Update.

Television And Radio Talk Shows:
AIDS UPDATE: Regular guest, Century Cable Television. Host-Bill Rosendahl.

Video:
1992-*Clinical Implications From The Seventh International Conference on Aids.*

SCCIS

SOUTHERN CALIFORNIA CENTER FOR IMMUNE SUPPRESSION AT MIDWAY HOSPITAL MEDICAL CENTER

The Southern California Center for Immune Suppression (SCCIS) at Midway Hospital Medical Center is one of the country's largest immune suppression unit with more than 40 beds.

Services Available: Midway Hospital's Immune Suppression Unit offers the following services:

- Specialized HIV/AIDS care -- High-tech, hi-touch staff training
- High staff-to-patient ratio
- Private rooms -- Every inpatient room in ISU is private with cable television, video movies and selected reading material.
- 24-hour visiting -- All rooms are equipped with sofa beds for friends and loved ones if they wish to spend the night.
- 24-hour food service on each floor
- Social workers -- Clinical social workers to assess the social service needs of all patients, and are available for supportive counseling for patients and their loved ones.
- Physical therapy -- Physical therapy, occupational and speech therapy, are available.
- Convenient admitting
  Inpatient - Patients can be admitted in the comfort of their private rooms.
  Outpatient - Patients are admitted on the unit.
- Dietary -- A dietician meets with the patient to plan meals as part of the overall medical plan. Diet aides stop by the rooms each day to collect specific menu orders and to make sure the meals are satisfactory. A food service worker provides snacks several times daily and stocks each room's refrigerator.

History: The Southern California Center for Immune Suppression was founded in 1991 by physicians acknowledged nationally as experts in the field of AIDS care. Their work guides the medical direction and treatment of our patients. The entire fourth floor of Midway Hospital Medical Center is a dedicated care unit of 40 private inpatient rooms, in addition to a full-service outpatient care center.

Address: Midway Hospital Medical Center
5929 San Vicente Blvd.
Los Angeles, CA 90019
213/932-5140

# # #

SCCIS

LOS ANGELES - Kristine Gebbie, President Clinton's National AIDS Policy Coordinator, will visit the Immune Suppression Unit at Midway Hospital today as part of a day-long tour of public and private hospitals across the city.

The 3-year old unit, with centralized services for AIDS patients is considered a possible model for national health care strategies, said John Fenton, the hospital's chief executive officer.

Higher nurse-to-patient ratios, extra quarters for patients relatives and friends, and individually-designed treatment programs are just some of the factors believed to help patients battle the disease and live longer than patients under traditional care.

"When Midway made the decision to add the ISU to the hospital, it made a commitment to more than just adding a new unit," Fenton said.

"Everything else in the hospital had to be upgraded to meet the demands of the ISU," he said. Educational activities for the nursing and care staff are also essential.

Gebbie will meet with patients, doctors and hospital staff as well as observe medical practices at the 40-bed unit. She will also meet with members of (PAAC), Physicians Association for AIDS Care, to discuss the results of administering "off-label" drugs to battle certain AIDS -related symptoms.

Off-label refers to the use of drugs usually prescribed for different ailments, and not officially endorsed by federal regulatory agencies as treatments for the disease.

Gebbie will meet with Mr. Fenton and Dr. Michael Moret, the unit's Medical Director, attending Physicians and staff and national and local officers of the Physicians Association for AIDS Care, a national association of Physicians who specialize in the treatment of HIV/AIDS.

The group will discuss how the use of off-label drugs and special AIDS facilities like the ISU work towards lowering health costs for AIDS patients, a benefit that has gained the attention of some of the nation's largest health insurance carriers.

The tour also will include stops at the Kraus-Beer Medical Group in West Los Angeles and the Pacific Oaks Medical Group in Beverly Hills two of the largest private practices specializing in AIDS care in the nation.

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SCCIS

Southern California Center for Immune Suppression

at Midway Hospital Medical Center

PACIFIC OAKS

MEDICAL GROUP

Backgrounder

Pacific Oaks Medical Group is the country's largest private medical practice specializing in HIV/AIDS care. Ten physicians work out of two Los Angeles-area offices, which also includes a Department of Research and Scientific Investigations with a full-time research staff. Although a majority of the group's practice is HIV/AIDS related, many of the physicians still maintain a family and general practice.

Pacific Oaks Medical Group was originally founded as a Sherman Oaks family practice called Weisman/Rogolsky Inc., A Medical Group in 1975 by Drs. Eugene Rogolsky and Joel Weisman. In 1980, the practice was renamed Pacific Oaks Medical Group. About the same time as the name change, both physicians began noticing an increased incidence of rare infections in their gay male patients. Little did they know, they were seeing some of the first documented cases of HIV/AIDS. In 1981, Weisman co-authored a report in The New England Journal of Medicine that first identified the syndrome that would eventually be known as AIDS. After the report was published, both physicians found themselves in the national spotlight, becoming medical pioneers and, in the process, becoming activists for not only for AIDS healthcare and research, but for gay civil rights as well.

Today, more than a decade since its founding, POMG has grown to include ten physicians in offices in Sherman Oaks and Beverly Hills. The practice consists of two of the physicians credited with "discovering" HIV/AIDS, and, in addition to primary care, physicians who specialize in research, oncology, pain management, infectious diseases and nutrition.

POMG has been credited with founding the AIDS unit at the Sherman Oaks Hospital and Health Center and co-founding the AIDS unit at Midway Hospital Medical Center in Los Angeles, both ranking among the finest AIDS facilities in the country. POMG physicians also have hospital privileges at Hollywood Community Hospital, Medical Center of North Hollywood and Valley Presbyterian Hospital.

-more-

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One of the most unique aspects of POMG is its in-house Department of Research and Scientific Investigations. Dr. Paul Berry is a full-time Research Director, who heads all the practice's drug protocols and clinical trials. The Department was established in response to the urgent need within the community for access to investigational AIDS therapies outside of the traditional academic settings. Currently, all trials are sponsored by pharmaceutical companies who cover the patients' costs of experimental therapies, office visits, laboratory tests and medications related to the trial. The Department of Research and Scientific Investigations again establishes POMG as a leader in its field and makes it one of the few private medical groups in the country to devote a full-time physician to research and clinical drug trials for HIV infection.

Pacific Oaks Medical Group also offers its patients many on-site facilities at both offices including aerosolized pentamidine, chemotherapy, EKG, a fully-licensed respiratory department, home infusion and nursing services, psychotherapy, pulmonary function testing, two outpatient infusion centers and x-rays. POMG also offers 24-hour on-call availability and patient education materials.

Pacific Oaks Medical Group physicians are also leaders in both the HIV/AIDS and gay community. The physicians are affiliated and often donate considerable amounts of time and financial support to the following organizations: AIDS Project Los Angeles (APLA), American Foundation for AIDS Research (AmFAR), Physicians Association with AIDS Care (PAAC), Los Angeles Physicians AIDS Forum, SEARCH Alliance, the Los Angeles Gay & Lesbian Community Services Center, El Proyerto del Barrios, West Hollywood AIDS Clinic, the Human Rights Campaign Fund, GLASS, Lambda Legal Defense, the Gay and Lesbian Victory Fund, the National Gay and Lesbian Task Force (NGLTF) and the Gay and Lesbian Alliance Against Defamation (GLAAD).

Community involvement, state-of-the-art treatment facilities, fast-track access to the latest development in AIDS management and the combined experience of ten front-line AIDS physicians inspire a level of patient confidence and trust in POMG seldom found in modern medical practices. And, although POMG is the country's largest private practice specializing in HIV/AIDS, patients still get personal treatment. Many of the practice's physicians say the people they treat are not only their patients, but oftentimes become their friends.

# # #

PACIFIC OAKS

MEDICAL GROUP

Joel D. Weisman, D.O.

In 1980, when Dr. Joel Weisman first mentioned the strange infections he was seeing in some of his gay male patients, little did he know that in the next decade he would become an acknowledged medical authority and reluctant but effective policy campaigner in the fight against AIDS.

A native of Carteret, N.J., Weisman was first introduced to medicine by a pathologist friend of his family when he was only seven years old and immediately knew that he wanted to be a doctor. After graduating from Upsala College in East Orange, N.J., Weisman went on to the Kansas City College of Osteopathic Medicine and did his internship and Family Practice training at Normandy Hospital in St. Louis. After three years in private practice in Carteret, Weisman moved to Southern California in 1975, where he joined Dr. Eugene Rogolsky in a practice based in Sherman Oaks. In 1980, Weisman/Rogolsky Inc., A Medical Group became the Pacific Oaks Medical Group.

In 1981, Dr. Weisman co-authored a report in The New England Journal of Medicine identifying the immune system failure they were seeing in gay men as a new disease. This was the first published report of the disease that would eventually be know as Acquired Immune Deficiency Syndrome (AIDS).

As AIDS continued to spread and kill more of his patients and some of his closest friends, Dr. Weisman became a front line specialist in management of the syndrome. Once a case was made for sexual transmission of AIDS, Weisman and Rogolsky were among the first to advise their patients to alter their sexual behavior. As ignorance and fear about the new disease spread, Weisman was increasingly called upon as a health educator and lobbyist for social services and research in AIDS.

Dr. Weisman was the first co-chairman of AIDS Project Los Angeles (APLA) when it was founded in 1982 and was instrumental in helping that then-struggling organization find legitimacy and public support. Weisman was also a founding member of the board of the American Foundation for AIDS Research (AmFAR) and served as its chairman from 1988 to 1991. Dr. Weisman has also served on the Medical Advisory Board at the Los Angeles Gay and Lesbian Community Services Center and served on both the Los Angeles City-County Task Force on AIDS and the State of California Task Force on AIDS.

Out of his practice in Sherman Oaks, Dr. Weisman helped start the AIDS unit at Sherman Oaks Community Hospital, the first private hospital AIDS unit in the country and the model for such units worldwide. Weisman and his partners have helped define AIDS management and care in private practice and have lead the way in bringing research to physician offices by conducting clinical trials in-house.

Although Dr. Weisman has known the sadness and constant trial of losing so many patients and friends, he has also been among the first to increase AIDS awareness among professionals and the general public and to introduce new treatments to help manage AIDS and extend the life expectancy of those living with it.

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PACIFIC OAKS
MEDICAL GROUP

Gary R. Cohan, M.D.

Dr. Gary Cohan is a board certified internist and HIV specialist who is in practice with Pacific Oaks Medical Group -- the largest HIV/AIDS private medical practice in the United States. Dr. Cohan studied at Amherst College, Cambridge University in England, and the University of Pennsylvania School of Medicine. In 1990, he completed special training in HIV care at San Francisco General Hospital. Dr. Cohan relocated to Los Angeles in 1992 from private practice in Philadelphia where he served as Chairman of the HIV Advisory Committee at the Graduate Hospital and was appointed Assistant Clinical Professor of Medicine at the University of Pennsylvania School of Medicine. Dr. Cohan currently serves as a teaching physician at UCLA's HIV Care Clinic.

Dr. Cohan has lectured extensively on AIDS throughout the United States on such topics as novel drug therapies, women, nutrition, and public policy. He co-authored three papers on HIV infection and nutrition which were published at the 8th International AIDS Conference in Amsterdam and he recently created Pacific Oaks' Department of Nutrition and Exercise Physiology. Dr. Cohan served as medical advisor for HBO Pictures' 1993 production of "And The Band Played On," based on Randy Shilts' book chronicling the history of the AIDS epidemic. In August 1993, Dr. Cohan took the task of writing the national monthly HIV/AIDS medical advice and update column -- "AIDSLine" -- for the gay and lesbian magazine, The Advocate.

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"The Plague Within The Plague"

Gary R. Cohan, M.D.

People are starving. Right in front of our eyes. We see it in every picture, in every mental image we have of the victims. But you never seem to read about it in the newspapers. Doctors rarely discuss it even though it is the primary cause of death in the majority of their patients. In Africa it is called "Slim Disease". Tom Hanks, for his starring role in the film, *Philadelphia*, had to shed thirty pounds for dramatic accuracy. Yet, while hundreds of thousands perish from the problem, both the medical community and the afflicted, blinded by the lure of "magic bullet" treatments and the search for a "cure", have seemed blandly indifferent. I am referring to the issue of malnutrition and HIV infection.

What if I told you that, today, a treatment already exists that can help to improve the quality of life and to extend the survival of every person with HIV infection ? And do so cheaply, easily, and with minimal technical support ? A treatment that it is not "alternative", "faddism", "quackery", or "pie in the sky"? Well, it does exist. In Los Angeles and throughout the United States. But it has been overlooked and dismissed as tangential, low priority, not high tech modern medicine. The treatment is the prevention of malnutrition. And it works.

NUTRITION AND HIV INFECTION: KEY POINTS

Gary R. Cohan, M.D.

Wasting syndrome -- the involuntary loss of greater than 10% of a person's usual body weight -- is the primary cause of death in more than 20% of persons with HIV infection.

Concept of the combined insults of protein-calorie malnutrition (starvation) and cachexia (abnormal tissue loss).

When a person's lean body (muscle and vital organ) mass falls below a critical point -- usually 54% of normal -- survival of persons with AIDS becomes impossible.

Conclusion: -- it is the *amount* of wasting -- rather than the specific cause of weight loss -- that is the primary determinant of death in AIDS patients.

Nutritional interventions in HIV infected persons are targeted at preserving lean tissue mass.

Primary strategy includes: treating underlying infections and gastrointestinal disorders, nutritional counselling and education, dietary supplements, appetite stimulants, anabolic androgens (steroids), vitamin (antioxidant) supplementation, and exercise.

Simplicity, ease of implementation, cost effectiveness observed by treating physicians. Algorithms for office-based evaluation and treatment have already have been developed by PAAC.

Anecdotal observations in our Los Angeles primary HIV care practice demonstrate that these strategies are extremely effective and well-tolerated by patients.

Need federal funding for formal research for these interventions to be tested and proven both effective and cost efficient. Data likely will be extrapolable to many other chronic debilitating disease processes (e.g. cancer, heart disease, etc).

Nutrition as an integral part of the President's national health carereform program.

THE Silent plague

HIV-ASSOCIATED MALNUTRITION

Gary R. Cohan, MD
Pacific Oaks Medical Group, Beverly Hills, California

We made history today. For the first time, in a presidential inaugural address, a U.S. president listed AIDS as one of his top priorities. I think those of us in the medical community need to change our own priorities. We need to think more about how nutrition, especially malnutrition, affects our patients with HIV infection. My job tonight is to give a brief overview of the problem, how it happens, and what we can do about it.

I have titled my discussion "The Silent Plague" because many healthcare providers tend to overlook the importance of nutrition in HIV infection. In fact, I am sure many people in this room, when asking their doctor for nutritional advice, probably toward the end of the visit, have been met with a blank stare, or "Take some Ensure," or "Eat right, you know what to do."

It has been my observation that most physicians feel pretty impotent regarding nutritional counseling and recommending effective treatment for malnutrition and wasting. They may often fear instituting aggressive therapy because they are already overwhelmed with the details of antivirals and prophylaxis. I recently attended a large seminar that included many of the top AIDS researchers in the United States. I was extremely disappointed that, in a six-hour program, there were no presentations about nutrition, wasting, or malnutrition. I was taught in medical school that when all else fails, look at the patient. Stop looking at the drugs, stop looking at the lab tests, and just look at the patient. We have patients who are wasting right before our eyes, and probably dying from wasting disease, and many of us are doing nothing to stop it. Tonight, we ask four questions: What is the problem? Why is it important? How does it happen? Finally, what can we do about it?

Wasting syndrome

The Centers for Disease Control and Prevention defines wasting as in involuntary weight loss of greater than 10 percent of a person's usual body weight. However, by the time a patient has met this definition, significant and possibly irreversible malnutrition may have already occurred.

In a study of weight changes in persons diagnosed as HIV-positive, symptomatic persons diagnosed with AIDS but without any opportunistic infections, and persons diagnosed with AIDS and secondary infections, Grunfeld et al found that the most dramatic weight loss happens when the person has AIDS but also has a secondary infection, often in the hospital[1]. In the 28 days surrounding the day of study, patients with AIDS and a secondary infection suffered a mean 5 percent weight loss, compared with weight changes of less than one percent in the other two groups.

As weight decreases, quality of life also decreases. Vital organ function is altered, tolerance to treatment is impaired, most persons become more dependent on other caretakers, the durations of hospital stays increase, and in general, patients feel fatigued, and hence, have decreased quality

of life. Most importantly, survival is actually decreased.

ACT UP's moniker for the AIDS epidemic for the first 11 years has been "Silence = Death." For the purpose of this discussion, I suggest we modify that to "Skinny = Death." One of the underground AIDS humor magazines a patient showed me the other day has been addressing it for a while. The DPN, or *Diseased Pariah News*, has a column of recipes entitled "Get Fat, Don't Die." It is kind of sick, dark humor, but it directly underscores one of the most important realities of this disease that most physicians and patients fail to accept.

Chlebowski et al studied survival of patients with AIDS as a function of their baseline nutritional status[2]. They assessed nutritional status with the serum albumin level, which is the measure of a protein that circulates in the blood, and therefore a rough measure of how a person is doing nutritionally. The results showed that of patients with a baseline serum albumin level above 3.5 g/dL (normal), 70 percent were alive after 2½ years. However, of patients whose albumin level was between 2.5 and 3.5 g/dL, only 50 percent were alive at 18 months. Most distressing, of patients with an albumin level of less than 2.5 g/dL, only 20 percent were alive after six months, and all were dead at 14 months.

The fact is that death occurs in AIDS patients with wasting syndrome either when body weight approaches 66 percent of ideal body mass or when the total body cell mass, meaning lean tissue, approaches 54 percent of normal. These statistics come from Kotler et al, who measured the lean body mass and plotted it against survival[3]. Lean body mass is determined by measuring total body potassium with a very special machine. Potassium is a very rough measure of lean body mass because it resides mainly in muscle tissue and is mildly radioactive, so it can be counted. By doing so, Kotler et al found that when the total body potassium approached 54 percent of normal, patients tended to die.

I conclude that the *amount* of wasting, rather than the specific cause of weight loss, is the primary determinant of death. There is a critical level of body cell mass below which survival is impossible.

Intervention

The goals of nutritional intervention in HIV infection are to minimize tissue breakdown, or catabolism; to minimize nutrient losses; to replenish body cell mass, or lean tissue mass; to preserve the function of the bowels and the gut; to improve the host's resistance to infection; to improve the patient's response to medication; and most important, to preserve the quality of life. In their study[2], Chlebowski et al found that the CD4+ T-cell count actually correlated with patients' nutritional status (eg, albumin level). Although this does not mean that if we can improve someone's nutritional status their CD4+ T-cell count will necessarily go up, if a person's nutritional status deteriorates, it is analogous to immunosuppression in and of itself.

In the office, intervention begins with assessment. What measures do we use to determine nutritional status? In addition to the serum albumin level, some rely on total iron-binding capacity, prealbumin, fibronectin, transferrin (other proteins which will not be discussed here); lean body mass; and the percentage of usual body weight. A physician could begin quite simply by asking, "What was your average body weight in the last several years before you got sick?" Sometimes, patients are found to have lost a distressing amount of weight when asked this question.

Mechanisms of malnutrition

How do people get malnourished with HIV infection? There are a number of processes, and I'll go through each one briefly.

There is a final common pathway that serves as an overview. Patients infected with HIV have various metabolic disturbances that predispose them to losing weight. When a person who is HIV infected and also very immunosuppressed gets a secondary infection that causes either diarrhea or loss of appetite, he or she gets debilitated and lose weight, probably at a more accelerated rate than a person with a similar kind of illness who is not HIV infected. Most persons with HIV infection fail to fully recuperate from each insult, resulting in this vicious downward spiral of one illness, weight loss, never fully recover, another illness, and so on.

The first process, which I think is the most important, is called metabolic dysregulation and embodies two complex concepts, namely, protein-calorie malnutrition (also known as protein-energy malnutrition) versus cachexia. Protein-calorie malnutrition is synonymous with starvation. It occurs when the body's need for protein, energy, or both cannot be met by diet. This could be the result of inadequate intake, malabsorption, diarrhea, decreased utilization of nutrients by the body, or some other change in metabolism. The bottom line is that our genetic and evolutionary makeup ensures that when we are in a starvation state, our body will preserve its lean body mass preferentially. Our body will burn fat and other parts of necessary tissue and substance in order to preserve visceral organ function and lean body mass.

Cachexia that happens with HIV infection, however, is a different process. The normal metabolic signals involved with starvation become uncoupled. So, instead of our normal evolutionary adaptations taking place, a marked and almost immediate depletion of lean muscle and vital tissue mass occurs that may not be reversed by traditional nutritional therapies. HIV infection combines this metabolic uncoupling with protein-calorie malnutrition.

The Table compares the immunologic changes associated with protein-calorie malnutrition and AIDS. It can be seen that the immune defects in AIDS are identical to those associated with protein-calorie malnutrition in a non–HIV-infected person. Again, the conclusion to be drawn is that malnutrition, in and of itself, is an immunosuppressed state.

Patients with advanced HIV infection also tend to be hypermetabolic. Their resting energy expenditure, or their basal metabolic rate, the rate at which they burn fuels, is higher. Grunfeld et al found that the mean metabolic rates in a healthy state, in persons with asymptomatic HIV infection, in AIDS, and in AIDS with a secondary infection increase in a stepwise fashion[1].

Certain circulating substances called cytokines are also clearly associated with HIV and wasting. One that has been extensively studied, and is controversial right now, is tumor necrosis factor (TNF), also known as "cachectin," because it causes cachexia, or severe wasting, especially in cancer patients. When otherwise healthy mice were injected with this substance, they would lose muscle mass and weight and become cachectic. Early studies demonstrated an increased level of TNF in patients with AIDS, and this was thought to be directly associated with the wasting process. However, more recent sudies have found TNF levels to be variable and most closely associated with secondary infections.

Other circulating substances, such as interleukin 1 and interferons alpha, beta, and gamma, have also been implicated in this process. There has also been a trial with a substance called pentoxifylline (Trental), which may decrease HIV replication and HIV-associated wasting by decreasing TNF levels. It is currently in active clinical trials.

Immunologic Changes Associated with Protein-Calorie Malnutrition

	AIDS	Protein-Calorie Malnutrition
Cellular immunity		
T cells	Decreased (++)	Decreased (++)
Helper T cells	Decreased (+++)	Decreased (++)
Helper:suppressor T-cell ratio	Inverted	Inverted
Delayed cutaneous hypersensitivity	Anergy (+)	Anergy (++)
Immature T cells	Increased (++)	Increased (++)
Lymphokine production	Decreased (+)	Decreased (+)
Cytotoxic T cells	Decreased (+)	?
Alloreactivity	Decreased	?
Helper T-cell activity	Decreased (+++)	Decreased (+)
Humoral immunity		
Serum immunoglobulins (Igs)	Increased (++)	Increased (++)
Immune complexes in serum	Present (+++)	Present
Primary antibody response	Diminished (++)	Diminished (+)
Circulating Ig-secreting B cells	Increased (+++)	Increased (++)
Antibody affinity	Decreased (++)	Decreased (++)
Miscellaneous		
Thymic hormones	Variable	Variable
Serum complement	Normal	Decreased (++)
Inhibitory factors in serum	Present (++)	Present (++)

Anorexia

Anorexia, or the loss of desire to eat, is a significant contributor to malnutrition. What can cause anorexia? Plain old depression, or emotional stress from being sick or having other kinds of problems in one's life, can clearly cause anorexia. Medications like zidovudine (ZDV), didanosine (ddI), and zalcitabine (ddC) can clearly cause loss of appetite, as can any number of secondary infections. Anybody who has just had a fever knows that you do not feel like eating when your body temperature is too high. HIV-infected, very sick patients sometimes run a fever five out of seven days a week. Chemotherapy for AIDS-associated Kaposi's sarcoma (KS) or non-Hodgkin's lymphoma can also cause anorexia.

Again, when caloric intake was studied in controls and patients with asymptomatic HIV infection, AIDS, and AIDS with a secondary infection, counting the calories that patients took in during the course of three days, it was found that the fewest calories were consumed by patients with AIDS and a secondary infection[1].

Is this anybody's fault? Obviously, a sick patient does not feel like eating. But, when a patient is in the hospital, very often he or she has a test to go to, a CT scan, barium enema, something. They are ordered by their doctors to be "NPO," meaning they cannot eat before the test. A typical scenario arises when the patient has not eaten all morning for an 11:00 a.m. test, the test gets rescheduled for 6:00 p.m., so the patient gets a little Jell-O. This may go on for days and days during a medical workup for an acute illness, just at a time when a patient's metabolic demands are going up and up. I think it is important that patients become their own advocates and start telling their doctors, "Feed me some way, somehow. Don't just give me fluid. Don't give me Jell-O between tests. You know, if I need it, give me nutrition either through my veins, or in my gut, or however is appropriate, but get me some nutrition when I need it most."

Nausea and vomiting are obvious causes of anorexia. Various opportunistic infections can cause these, such as KS or lymphoma of the gastrointestinal tract. Medications, such as zidovudine, especially in the high doses that we used to use, have been associated with this effect. Clearly, chemotherapy for the various kinds of neoplasms associated with HIV can cause nausea and vomiting.

A nastier problem for most patients, especially with advanced HIV infection, is malabsorption, which causes diarrhea. Causes of this are pretty much the same as of nausea and vomiting. Patients can be just plain lactose intolerant, unable to digest milk sugar. This can clearly cause malabsorption and diarrhea. Other infections, such as amoebas, cytomegalovirus,

Cryptosporidium, *Mycobacterium avium* complex, and a newly identified infection of the bowel called *Microsporidium*, have been associated with HIV and diarrhea. "HIV enteropathy" used to account for much of the diarrhea now being attributed to *Microsporidium*. A drug called albendazole actually may be effective for this.

Many of us do not pay attention to good dental care when we have other pressing issues. Gingivitis, periodontitis, and problems with the gums and the bones supporting the teeth and gums are very prevalent, and these processes are accelerated in HIV infection. Good dental care is very important because the mouth is the point of entry for food; pain in chewing and swallowing may limit food intake. Herpes infections, thrush, cytomegalovirus, hairy leukoplakia, KS, and nonspecific esophageal or oral ulcers (that are actually due to either HIV itself or medications) may play a role here. In fact, in the early open-label trials, it was found that ddC sometimes caused nonspecific oral ulcerations that were quite painful and often necessitated discontinuing the drug therapy.

So, some of these wonder drugs may be causing some of the problems themselves. As we test new agents, we do not know every side effect beforehand. If a new symptom occurs during an experimental protocol, it may be advisable to discontinue the drug for a while and see if it is causing the symptom.

Patients with neuropsychiatric impairment, dementia, or infections or cancers of the central nervous system may not be able to take in enough calories to support themselves. Again, under neuropsychiatric impairment, depression can be treated, and not just by a person talking to friends or to a support group. I think depression is a medical illness that needs to be treated with psychotherapy in concert with the appropriate antidepressant agents. I think many people mistakenly attribute depression to an inability to cope with the disease process. Depression is a complex medical illness that may have emotional triggers, but is also neurochemical in origin and augmented by HIV's effect on the central nervous system. It definitely affects a person's desire and ability to eat and needs to be addressed.

In addition to PAAC's excellent symposium on nutrition and HIV/AIDS, there were a few presentations at last year's VIII International Conference on AIDS that involved nutrition and HIV infection, but not nearly enough. One that I published and presented with some of my colleagues (from the Graduate Hospital of the University of Pennsylvania School of Medicine in Philadelphia) tried to relate mortality, or death from HIV infection, to a person's usual body weight and CD4+ T-cell count. The frightening finding was that it did not matter what a person's CD4+ count was; when a person lost enough weight, even with the same number of CD4+ cells, their risk of dying, or even just getting sick from HIV infection, went way up. This underscores the urgent need for more basic clinical research into the causes, treatment, and prevention of HIV-associated wasting so as to stem the tide of this insidious "silent plague."

Later in the program, you will learn more about the PAAC Nutritional Initiative, which includes what I believe to be the most comprehensive model for integrating medical nutrition as a central strategy in the management of HIV disease. I believe that the more physicians take advantage of this model, the better able we in the medical community will be to extend the length and quality of life of patients with HIV disease. □

Editor's note: After the Los Angeles Nutrition Symposium, Dr Cohan was nominated as a member of PAAC's Nutrition Committee, and both Pacific Oaks Medical Group and the Kraus-Beer Medical Group began enrolling their patients in the PAAC Nutritional Model.

References

[Note: the three studies listed below are summarized in PAAC's new publication *Nutrition and HIV/AIDS*, which the author consulted in composing his talk. For ordering information, see the offer on page 81 of this issue.]

1. Grunfeld C, Pang M, Shimizu L, et al. Resting energy expenditure, caloric intake and short-term weight change in human immunodeficiency virus infection and the acquired immunodeficiency syndrome. *Am J Clin Nutr* 1992;55:455-460.
2. Chlebowski RT, Grosvenor MB, Bernhard M, et al. Nutritional status, gastrointestinal dysfunction and survival in patients with AIDS. *Am J Gastroenterol* 1989;84:1288-1293.
3. Kotler DP, Tierney AR, Wang J, Pierson RN Jr. Magnitude of body-cell-mass depletion and the timing of death from wasting in AIDS. *Am J Clin Nutr* 1989;50:444-447.

Country Villa Service Corporation

Country Villa Service Corporation (CVSC) has been a leading healthcare provider for over 25 years. CVSC manages hospital-based skilled nursing and subacute units, as well as specialty programs, and is the largest operator of free-standing skilled nursing facilities in the City of Los Angeles.

Stephen Reissman, President of Country Villa Service Corporation, developed the program after assessing the needs of the community. Country Villa South's 30-bed unit, which is located at 3515 Overland Ave. in West Los Angeles, California, is capable of providing all services offered in a traditional hospital AIDS/HIV unit except extensive diagnostics and invasive surgical procedures. The unit's hospital-trained staff offers technologically advanced therapies. The program also offers a more homelike environment with flexible visiting hours.

This program provides a cost-effective alternative to hospitalization. If you would like more information on this program or our other facilities, please contact Laura Hyatt, V.P. Managed Care at Country Villa's Corporate Offices (310) 390-8049.

NEWS RELEASE

Century City Hospital

FACT SHEET
SPECIAL CARE CENTER AT CENTURY CITY HOSPITAL

PURPOSE OF CENTER: To provide state-of-the-art treatment, inpatient and outpatient, for people with the HIV virus, AIDS, and other immunosuppressant diseases. Treatment includes medical and psycho-social services.

CENTER FACTS: The first inpatient center of its kind in Los Angeles, the Special Care Center opened in Feb., 1986. Today, the Center has 20 beds.

STAFF: Approximately 20 R.N.s, plus others, staff the Special Care Center. The Center is under the direction of Stephen Gabin, M.D., Medical Director, and Ralph Hansen, M.D., Director of Infectious Disease.

SERVICES OFFERED: Acute inpatient care. Diversified outpatient services including blood transfusions, use of experimental drugs, intravenous medication and chemotherapy. Psycho-social support for patients and loved ones.

UNIQUE FEATURES: The Special Care Center creates a home-like atmosphere for people with AIDS and their loved ones. All day visitation is permitted. The Center's newest emphasis is on treating women with AIDS.

Patients at the Center often dress in street clothes, not hospital gowns. Rooms have a VCR and the Center has a recreation room with a TV, VCR, tape player and refrigerator. The Center also offers 2 daily luncheon buffets which encourage patients to socialize with each other. Century City Hospital provides patients with a supportive environment to enhance both medical treatment and quality of life.

CONTACTS: Andrea Hecht, Hecht Communications, 818/788-9235
Lisa Gaines, Century City Hospital, 310/201-6612

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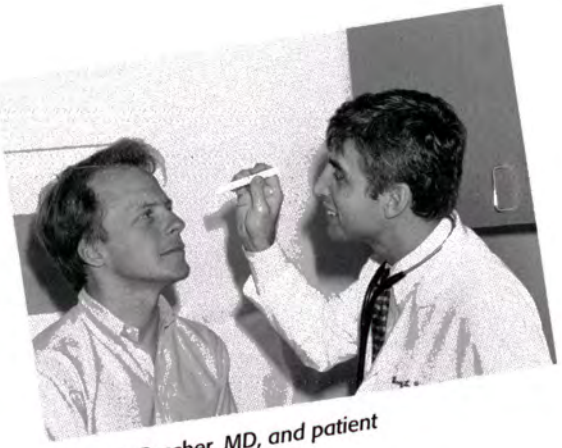
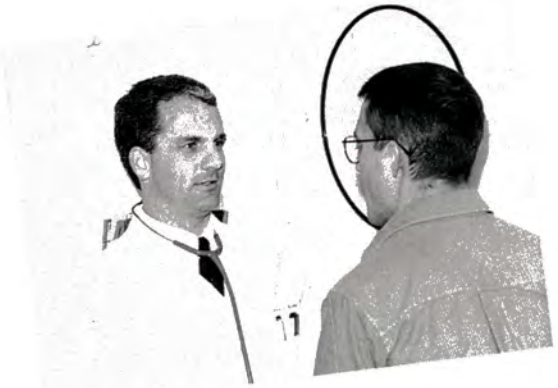


Henry L. Poscher, MD, and patient

Lyssette L. Cardona, MD, and patient



Robert Jenkins, MD, and patient

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You can make a difference in the future of Los Angeles

Physicians Association for AIDS Care

You can make a difference in the future of Los Angeles...

...and the fight against the HIV/AIDS epidemic.

According to some estimates, there could be as many as 80,000 to 100,000 people with HIV disease in greater Los Angeles by the year 2000. The continued spread of this epidemic is having a profound impact on clinical and social services and the economic viability of Los Angeles.

The Los Angeles members of the Physicians Association for AIDS Care (PAAC) are forging a new alliance between the medical, PWA, and corporate communities to develop innovative programs to combat this epidemic and to meet the growing medical needs of people with HIV disease.

Serving the community

PAAC's new Los Angeles regional office provides educational services, clinical support, and advocacy programs for more than 100 Southern California physicians and their patients with HIV disease.

In addition to these services, PAAC has launched three local projects designed to have a major impact on the care of all Southern Californians with HIV disease. These include:

- The development and coordination of HIV clinical trials in Southern California so that all people with HIV disease can have access to the most promising agents that could affect their survival and quality of life.

- The development of community guidelines for the treatment of HIV disease by the physicians treating the majority of people in Los Angeles with HIV/AIDS. These guidelines will help facilitate reimbursement for newer therapies.

- The development of a not-for-profit HIV/AIDS IPA (Independent Practice Association), which will be a group of Los Angeles-area physicians able to contract with employers, unions, managed care organizations, and possibly state agencies, to take over the care of people with HIV disease. This model is designed to implement Los Angeles PAAC community guidelines for the treatment of HIV disease, coupled with significant savings over current care costs.

PAAC is also developing a broad agenda of local HIV projects to support existing community-based organizations in the creation and implementation of innovative programs to reduce the spread of HIV and to improve the length and quality of life of all Southern Californians affected by this disease.

Community support

PAAC needs your support to advance our ambitious goals for local services and to develop a new Los Angeles paradigm of aggressive coordinated medical care and social services to serve as a model for our nation. Your support in any amount can make a difference in the local, national, and global fight against this plague.

For individuals, we recommend an annual contribution of $100, which will include a subscription to ***PAACNOTES***—our monthly newsjournal, and the nation's leading HIV/AIDS publication. Individual contributors will also receive a bimonthly notice of all regional PAAC activities and updates.

For corporations, we recommend an annual contribution of $1,000, which will include five subscriptions to ***PAACNOTES***. We will also develop a custom-designed HIV education program for your personnel and special support services for your employees with HIV disease.

A contribution in any amount is both needed and welcome.

National leadership

Organized in 1988, PAAC is a professional association of physicians, other caregivers, scientists, AIDS activists, pharmaceutical manufacturers, home care companies, and other members of the corporate community who have joined together in a combined effort to improve the care of all people with HIV disease.

PAAC is a principal educational resource for physicians, other caregivers, and people with HIV disease. PAAC is a leading advocate for the rights of people with HIV disease and their caregivers.

PAAC is a federal tax-exempt, nonprofit, 501(c)(3) organization. PAAC's tax FEIN is 36-3588493.
A contribution acknowledgment form is enclosed.
In case the form is missing, please request one from:

Physicians Association for AIDS Care
10940 Wilshire Boulevard, Suite 1600
Los Angeles, California 90024
Phone (310) 443-4231
Fax (310) 443-4238

PAAC

Los Angeles Regional Office

PHYSICIANS ASSOCIATION FOR AIDS CARE

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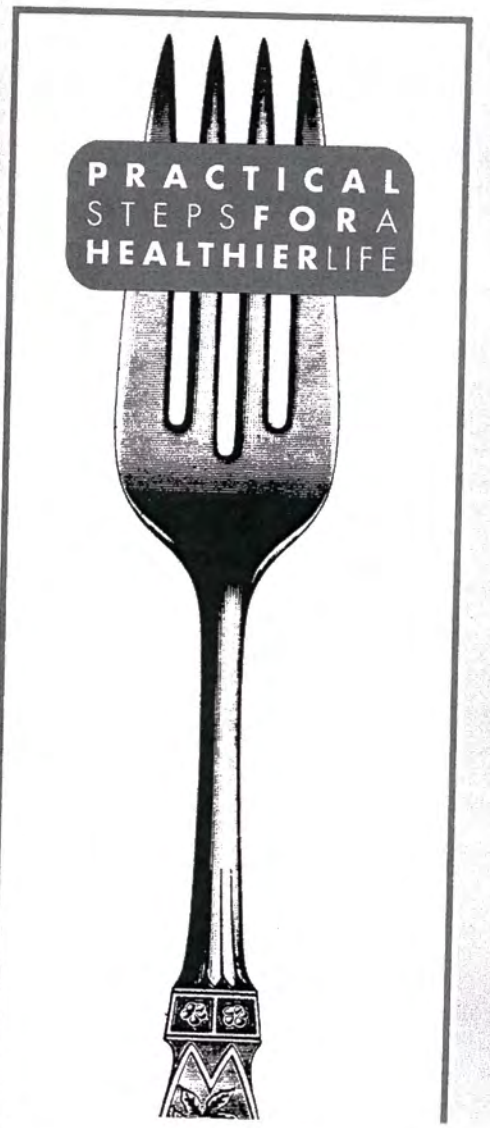
HIV Disease
Nutrition Guide

30 pgs

HIV DISEASE

NUTRITION GUIDELINES



PAAC
PHYSICIANS ASSOCIATION FOR AIDS CARE

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Phone: 310/433-4231
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Backgrounder
Q & A

Q: What is the purpose of Kristine Gebbie's Los Angeles visit of February 3, 1994?

A: 1. Ms. Gebbie's purpose is to learn more about the unique dimensions of HIV/AIDS care by PAAC/LA physicians and institutional members that may be contributing to an increasing number of long-term survivors with HIV/AIDS in this region, and

2. to learn how this care model is being adapted to PAAC/LA's standard of care and managed care initiatives.

Q. Why is the HIV/AIDS Care by PAAC/LA members unique?

A. There are three common factors:

1. Integration of the nutritional support.

   There is increasing evidence that nutritional therapies may play a significant role in long-term survival as some drug therapies. The prevention and reversal of protein-calorie malnutrition as a complication of AIDS may be as significant as the prevention of AIDS opportunistic diseases. Refer to PAACNOTES, February 1993 article *The Silent HIV-Associated Malnutrition Plague* by Gary R. Cohan, MD.

   Nutritional assessment and intervention is a standard of care by many PAAC/LA members and many of the physicians are following the PAAC nutritional algorithm that was published in ***Nutrition & HIV/AIDS.***

2. *Cutting edge therapies are a defining element in the LA care model.*

   An example of cutting edge therapy was the use of

clarithromycin in Los Angeles as a standard of care before it was accepted as a standard in other parts of the country and years before it was approved by the FDA in December of 1993. Refer to PAACNOTES, September 1993 article Bringing a Drug to Market-Again: *Perspectives on Clarithromycin's Approval Process* by Ann Louise Truschel.

3. *The special cooperation between LA physicians and many third-party payers*

   Third-party payers have agreed to reimburse for many experimental and off label therapies used by LA physicians. Reimbursement for cutting edge therapies are essential to the use of these therapies as a strategy for long-term survival. Refer to PAACNOTES, September 1993 article Bringing fa Drug to Market-Again: *Perspectives on Clarithromycin's Approval Process* by Ann Louise Truschel.

Q: What is the PAAC/LA standards of care initiative?

A: The members of PAAC/LA are developing new guidelines for HIV care that reflect the often unique approach provided by the LA medical community. These standards differ from other professional association and federal standards because they are developed by physicians treating the majority of patients with HIV/AIDS in Los Angeles. These standards also differ in the fact that PAAC/LA has standing committees for each standard of care so that the standards can be immediately updated as soon as the community of physicians agree on newer interventions. After these standards are published in PAAC's monthly journal, they will be established as legal guidelines for the reimbursement for new therapies and off-label drugs. Refer to AHA News of November 22, 1993, Special Report, *AIDS/HIV program could lead to national practice guidelines.*

Q: Why are the PAAC/LA standards of care so important?

A: Survival with HIV disease will be affected in great part by small incremental steps in more effective therapies for the prevention and treatment of opportunistic infections. Small and continual advances are important in preventing protein-calorie malnutrition which is a major debilitating complication in later stage HIV disease. Each new intervention with a more effective therapy is expected to increase long-term survival. So our greatest hope until there is a major breakthrough in AIDS treatment is the step by step incremental gains that we will make with more effective prophylaxis and treatment.

Our effectiveness against fighting this disease depends on our ability to immediately approve these incremental advances in care as part of a care plan and to have these therapies reimbursed by third-party payers.

Q: What is the PAAC/LA managed care initiative?

A: PAAC/LA is currently developing an AIDS IPA (Independentt Practice Association) and an AIDS PPO (Preferred Privider Organization) that is planned to contracat with employers a and other third-party payers and state agencies to take over the lifetime care with people with HIV/AIDS in the Los Angeles area. The PAAC/LA managed care model will be based on PAAC/LA standards of care and will provide all participants with the best chance of suvival with their disease. The model is also planned to provide for significant savings over the current cost of HIV/AIDS care. Refer to PAACNOTES, Novemeber 1993, *PAAC Launches Los Angeles Standards of Care and AIDS IPA Projects by Brett Hufziger.*

Q: What is PAAC?

A: PAAC is a not-for profit professional association formed in 1988 to ally physicians, health care providers, the hospital and pharmaceutical industries, the corporate community, and concerned activists to increase awareness and improve care of HIV/AIDS.

PAAC
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Background Information on the Organization and its Accomplishments

Q: What is the Physicians Association for AIDS Care (PAAC)?

A: The organization is a professional association with over 1000 members comprising of physicians, other healthcare professionals, and concerned individuals and organizations of the HIV community , formed to develop and support innovative programs designed to maximize the length and quality of life of all people with HIV/AIDS.

Q: When was PAAC organized?

A: PAAC was formally organized in 1988. The organization evolved from a group of physicians called the AIDS Medical Resource Center Physicians Association that began in 1986. The Los Angeles Regional Office opened in late 1993.

Q: How is PAAC managed?

A: The association is governed by trustees who represent a broad cross section of physicians and scientists including internationally recognized leaders in clinical research, individuals in private practice and with federal agencies. These dedicated and talented individuals volunteer their time to develop important and resourceful programs which are implemented through the association's staff lead by its executive director, Gordon Nary.

Q: What have been PAAC's principal accomplishments to date?

A: *Communications* - PAAC developed and publishes PAACNOTES, the nation's leading HIV/AIDS publication which provides a unique interdisciplinary focus on the scientific, clinical, ethical, legal and political dimensions of the epidemic. HIV Update is the group's syndicated cable television series featured in 40 US cities on PBS and public access stations.

Nutrition - The association is recognized as the nation's leading advocate in nutritional intervention strategy in HIV disease. PAAC has conducted two international conferences on this topic and has facilitated the distribution of 250,000 of PAAC's first in a series of patient-based booklets on nutrition and AIDS.

Advocacy - PAAC played an instrumental role in developing the new Social Security Administration regulations extending Medicare benefits for tens of thousands of people with HIV/AIDS.

Clinical Trials Support - The association has served as a patient ombudsman for the DDC trials and has assisted several pharmaceutical manufacturers with the implementation of important HIV/AIDS drug trials.

Q: How is PAAC supported?

A: PAAC receives no government funding for its initiatives and has relied on financial support from individuals and corporations.

Q: Who are the physician members of PAAC in Los Angeles?

A: There are more than 100 physician members who treat over 38,000 of the estimated 50,000 people with HIV/AIDS in the greater Los Angeles area. These dedicated physicians were featured in a January 13, 1994, advertisement in the business section of the Los Angeles Times. A copy of the ad is attached.

Q: Who are the corporate members of PAAC?

A: A list of corporate or associate members of PAAC is attached.

Q: How can I help PAAC with it's initiatives here in Los Angeles?

A: Call PAAC's Los Angeles Regional Office at (310) 443-4231 and ask for a membership application or write to the address listed on page one of this fact sheet.

Associate Members of PAAC

02-Feb-94

Abbott Laboratories
Adria Laboratories
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Boehringer Ingelheim Pharmaceuticals
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THE WHITE HOUSE

WASHINGTON

KRISTINE M. GEBBIE
National AIDS Policy Coordinator
Appointed by President Bill Clinton

Kristine M. Gebbie, R.N., M.N., is President Clinton's National AIDS Policy Coordinator, overseeing the nation's HIV and AIDS agenda in research, services and prevention. Prior to her appointment, Ms. Gebbie served as Secretary of the Department of Health for the State of Washington. She was a member of the Watkins Commission, the first Presidentially-chartered body to make comprehensive recommendations for the national response to HIV and AIDS.

Ms. Gebbie has a lengthy career history in the health field and public policy. She has served as the public health administrator in the State of Oregon, and was the coordinator of ambulatory care for St. Louis University Hospitals. Ms. Gebbie taught health courses at the University of Washington, the Oregon Health Sciences University in Portland, the University of California at Los Angeles, and St. Louis University.

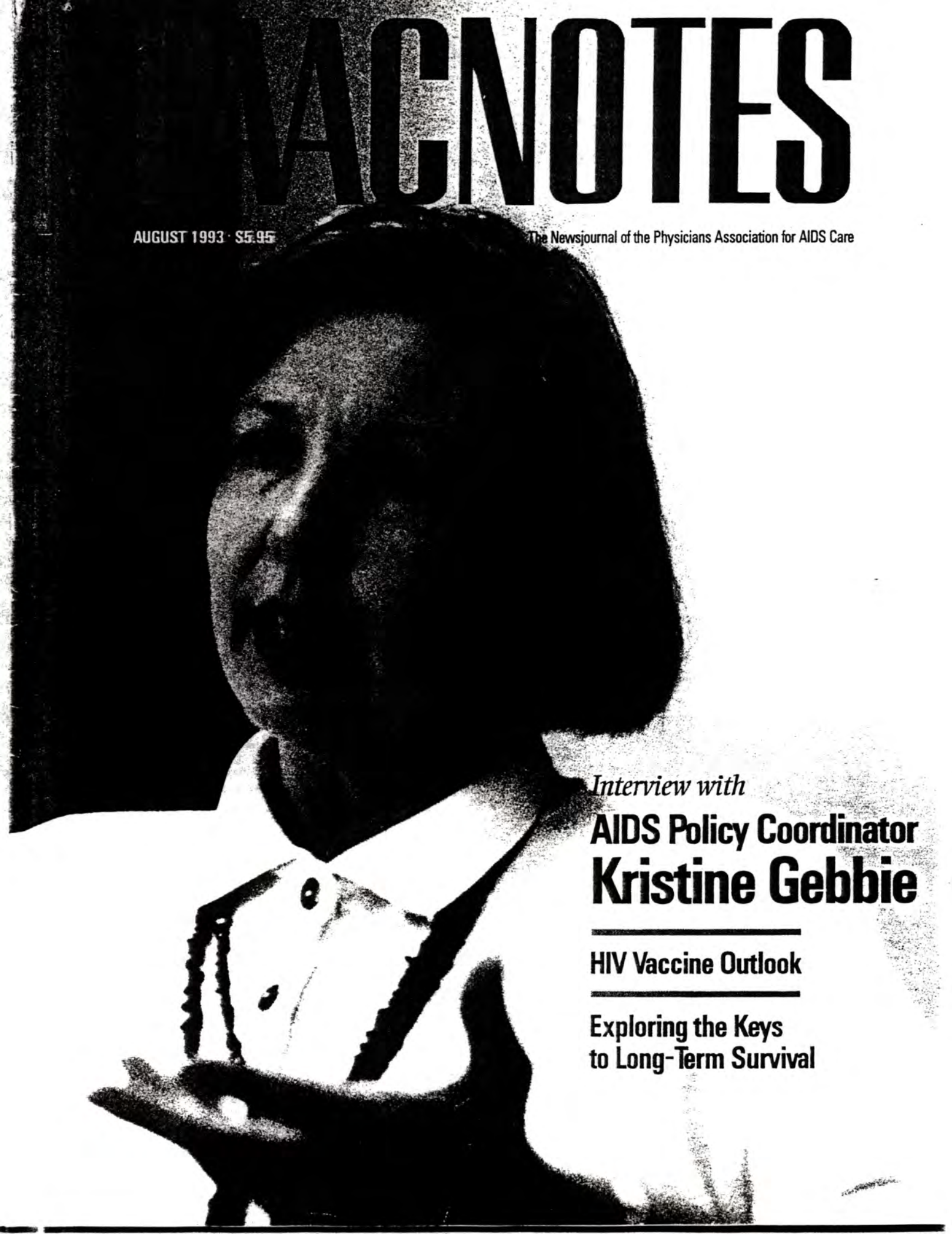
She is active in many professional organizations, and has served as a member of the Executive Board of the American Public Health Association. She has been a member of the HIV Committee of the Association of State and Territorial Health Officials, and has chaired the Centers for Disease Control and Prevention Advisory Committee on the prevention of HIV infection and the Environment, Safety, and Health Advisory Committee of the U.S. Department of Energy. She is a member of the Institute of Medicine, and has served on its AIDS oversight Committee.

Ms. Gebbie has a Bachelor of Science degree in nursing from St. Olaf College, a Masters of Nursing from the University of California at Los Angeles, and is a doctoral candidate at the University of Michigan School of Public Health. She is the mother of three and resides in Washington D.C.

NACNOTES

AUGUST 1993 · $5.95

The Newsjournal of the Physicians Association for AIDS Care



Interview with

AIDS Policy Coordinator Kristine Gebbie

HIV Vaccine Outlook

Exploring the Keys to Long-Term Survival

Will the Arrival of a **CZAR** Herald a **REVOLUTION** in AIDS Policy?

An interview with Kristine Gebbie

Marlene Cimons

The phone call came shortly after midnight. "This is Kristine Gebbie," the caller said. "I'm sorry to be returning your call so late, but I just got into town."

She had just arrived in the nation's capital from her home in Washington State, only hours before President Bill Clinton was to name her his new AIDS czar—or czarina, as she likes to point out—in a splashy outdoor White House ceremony attended by a wide range of representatives from AIDS and medical groups, Congress, and the administration. The announcement ended a long and ill-starred search in which at least two others had turned the job down, and AIDS activists had made no secret of their impatience at the delay.

And here it was, almost the middle of the night. The recipient of the call was half asleep, but Gebbie was revved—and admittedly still somewhat puzzled by the rapid turn of events that had brought her to Washington.

"When did all this happen?" she was asked.

"They called me earlier this week and asked if I was still interested," she replied. "I told them I was."

The whole process had been more than a little mystifying—Gebbie's name had been on the White House's short list since the transition, and she had been interviewed by administration officials early in the search.

Yet, the White House had previously offered the post to Dr. Margaret A. Hamburg, New York City's health commissioner, and then to Representative Jim McDermott (D-Washington), both of whom had said no. Hamburg, pregnant with her first child, felt she could not reconcile the demands of new motherhood with those of a new job. McDermott reportedly did not want to give up his seat in Congress.

Those who had been watching the process could not understand why it had taken the White House so long to get to Gebbie. Many have speculated that Clinton wanted to inaugurate the job with someone whose name would spark instant public recognition.

Indeed, Kristine Gebbie's name is not a household word. Nevertheless, she had long been a presence in the AIDS community, where she is well-known and, for the most part, highly regarded.

But that may not be enough. People in the AIDS network remain nervous, hoping that the administration will give Gebbie the resources and the authority to confront the unmet challenges of the epidemic. And everyone will be watching as she begins a newly created job that virtually the entire AIDS community demanded, but that no one, including the Clinton administration, has as yet really been able to define.

It is still too early to assess how she will do. At the moment, the job of the AIDS czar is a work in progress. "I get to make it up as I go along," Gebbie says, with a smile.

Clinton promised quick action on AIDS during his campaign and has proposed increased federal spending both on research and on programs aimed at treating and preventing the disease.

The purpose of the new post is to coordinate the activities of the many federal agencies that currently deal with aspects of the AIDS crisis—from the Centers for Disease Control and Prevention to the National Institutes of Health. This mandate does not necessarily mean that Gebbie will be dabbling internally in any specific agency programs. Rather, she is there to ensure that "everyone is communicating with everyone else," she says.

Her supporters have urged that she focus her efforts on prevention strategies and on working to ensure that Congress implements the president's funding proposals. They also have called on her to implement the recommendations of the two AIDS commissions and to represent the voice of AIDS in all health reform discussions. She says she intends to try to do all of that—and more.

The idea "is to finally make the government responsive to the epidemic, including all the cabinet agencies, and to try to implement all the reports we've been accumulating," she explains, referring to the work of both the National Commission on AIDS and the AIDS commission established by the Ronald Reagan administration, on which she served. "The whole tone of creating this position is that 'we want to do it better. We want to finally do

"Kids have known how to use condoms for water balloons for years—I'd rather they learn to use them for appropriate purposes."

it right.' My job will be to find a way to harness the energy and the commitment that are already there and make them pay off.

"We need to get the system out of people's way and change it so that it works better. How do you make an outpatient program work so that patients can get in, get served, and get out within two hours? All the pieces have to come together. Let's make it easier for people to do the right thing. That's the challenge, and it's what I've been trying to do in public health all along."

For example, "if you're trying to prevent head injuries, it's not enough to make sure there is a trauma hospital available to treat them," she says. "It's making sure that kids know about wearing helmets; it's car seats and seat belts; it's truck safety programs and bicycle lanes. It's not just doctors and nurses doing it differently, and better, but the whole community working together."

Gebbie believes it is critical to beef up prevention efforts, with the federal government providing more resources and technical assistance to states and communities to create such programs. Information should reach everyone, particularly young people before they reach adolescence, from kindergarten on up, she says. "Even kids in kindergarten hear things," she says. "You don't talk to them about safe sex, but you teach them that their bodies are something to take care of and that viruses can mess them up. I believe very strongly that AIDS education has to be part of a comprehensive health education program, not something separate."

As for teenagers, "I think anybody who is sexually active needs to know about the use of condoms," she says. "Kids have known how to use condoms for water balloons for years—I'd rather they learn to use them for appropriate purposes. Does that mean you hand out condoms? That's a community-level decision based on resources. The national role is to give them resources, technical assistance, and good support."

She believes that AIDS clinicians should be concerned about two major areas. "The first is that there should be more of them," she says. "The second is that

On Kristine Gebbie

"She was very tough when there was nonsense coming out of some of the other commissioners. She could carry the day." — *Adm. James Watkins*

"She usually was able to convince me that she was right. We disagreed with the other members of the commission a great deal. My reaction was to get very angry. Hers was to be very gentle and very tactful and to get something accomplished." — *Dr. Frank Lilly*

"She's a very nice person, and the last thing we need for this job is a very nice person." — *Larry Kramer*

"The whole tone of creating this position is, 'We want to do it better. We want to finally do it right.' My job will be to find a way to harness the energy and the commitment that are already there and make them pay off."

they should be able to get the right information [about treatments and so forth] as fast as possible."

A registered nurse and epidemiologist who once taught at the University of California at Los Angeles, Gebbie was chief health officer for the State of Oregon when AIDS first showed its deadly presence. Later, she ran health programs for Washington State.

Her initial reaction to the first AIDS cases in 1981—before the disease even had a name—was like that of the rest of the country: "I remember thinking, gee, those folks in California have a problem," she recalls of her response to reading in the CDC's *Morbidity and Mortality Weekly Report* of the mysterious disease that was killing gay men in Los Angeles. "It took a few months before it sank into my thick head that *we* have a problem."

If that's all it took, Gebbie probably was ahead of the national curve. As a state health official, she became involved early on in tracking the AIDS epidemic. Although Oregon initially did not have a large caseload, Gebbie paid careful attention to the escalating epidemic, studying beyond its public health implications to understand its social and political impact as well.

She served as head of the AIDS task force for the American Association of State and Territorial Health Officials and later was asked to join the AIDS Commission established by the Reagan administration. Having been a foe of Reagan administration AIDS policies, she was reluctant. But Admiral James Watkins, the commission's chairman, was very persistent and persuaded her to join.

"I picked her, and she was a great asset to me, especially since we were greatly outnumbered," Watkins recalls, referring to the commission's many ultraconservative members. "She was very tough when there was nonsense coming out of some of the other commissioners. She could carry the day."

Dr. Frank Lilly, a professor of genetics at Albert Einstein College of Medicine, who was touted as the commission's only gay member, agrees with Watkins: "She knows an awful lot about the epidemic, and her primary interest was in AIDS education and the public health aspects of the epidemic," he says. "She and I agreed on virtually everything of any importance, and the few things we disagreed on, she usually was able to convince me that she was right. We disagreed with the other members of the commission a great deal. My reaction was to get very angry. Hers was to be very gentle and very tactful and to get something accomplished."

Thus it is surprising that she has already had to fend off some vicious attacks from activists who say she is not strong enough for the job, or who dislike some of the things she did while holding state health posts.

"We needed *Jurassic Park*, and we got *Sleepless in Seattle*," comments Larry Kramer, who founded the activist group ACT UP. "My gut reaction tells me she's a very nice person, and the last thing we need for this job is a very nice person," Kramer continues. "We need stormin' Norman—someone who can knock heads together. Having spent 12 years in the trenches, it's hard for me to believe that anything but screaming bloody murder gets anything done."

Gebbie is unfazed. She views her critics as those who simply "never accept anybody at face value and feel they always have to be pushing everyone. I may not have as much flash as some people would like, but I can talk to people, and I can get them to talk to each other," she says. "I can work hard, and I can get others to work hard.

"I think some people expect the person in this job to be a public and loud figure, someone preaching at politicians about

how to do it right," she continues. "I don't think that's as effective as getting people into rooms together to talk. That's not to say I won't speak out, however."

Watkins, who also served as energy secretary in the Bush administration, feels that the activists are underestimating her. Gebbie confronted right-wingers on the Reagan AIDS panel numerous times—and won—when they refused to "get off their ideological box and fight on the facts," he says.

"She's no patsy," Watkins declares.

Gebbie, recalling her work on the Reagan AIDS commission in light of activists' recent attacks on her, laughs. "Some people find it amusing that I defined the radical left fringe of that commission," she says.

ACT UP also has condemned her for supporting Oregon's controversial health rationing scheme when she headed that state's health department. ACT UP also claims that she supported names reporting of HIV-infected individuals when she ran Washington State's health programs.

The latter charge, she insists, is "a distortion, a lie." What she did was to draft a paper on how the issue of reporting should be handled if it should come down as a federal recommendation to the states. "And we had every reason to think it was going to happen under the Bush administration," she says.

Nancy Campbell, executive director of the Northwest AIDS Foundation in Seattle, an AIDS service organization that opposes names reporting, confirms Gebbie's version of the controversy. "She is very protective of confidentiality and the rights of HIV-infected people," Campbell says. "But she's also a pragmatist. What happened was this: she saw some things going on with the Bush administration and thought this was coming. So she went to the governor's council [an AIDS advisory group] and told them to start to plan."

Campbell adds: "I was at those meetings and what I heard was: 'I think this is coming. How do you want to handle it?' I did not hear: 'I think this is a good idea.'"

Gebbie does acknowledge her role in shaping Oregon's controversial health rationing plan but insists that the state has received a bum rap on the issue. As a country, "we already ration," she stresses, dismissing the idea that we currently have a one-level system. The nation rations by economic status and other discriminatory factors.

"Your insurance company rations, and often you don't find out about it until you need something," she says, adding that one of the things rationing does "is get poor people into care" who have not been served by the health system. "With finite resources, we have to make choices about what we invest in," she says. "I support making rationing explicit and involving the whole community in the debate." In the Oregon plan, AIDS and HIV "are in the mainstream" of services, except for end-stage AIDS, "which is rated low," she adds.

Gebbie, who celebrated her 50th birthday the day after her appointment, is a divorced mother of three—her children are 22, 19, and 17—who was born in Sioux City, Iowa, where she lived only five weeks. Her father was a military man, and "I spent most of the war years with my mother and maternal grandparents in Mile City, Montana," she says. She spent her teenage years in Albuquerque, New Mexico, where her mother stills lives. "Rocky Mountain West is what I think of as home," she says. "I lived in the Pacific Northwest for 15 years."

She goes hiking "whenever I can," walks three to four miles every morning, and knits and reads detective novels in her spare time. There isn't much of that these days, since she is also trying to finish her doctoral dissertation, a case study of changes in Washington State statutes and "how and why state governments reorganize themselves."

Gebbie has served as an adviser to the administration's healthcare reform process and has chaired an advisory committee for the CDC, evaluating that agency's AIDS programs. She believes that AIDS can serve as a focal point for a national debate on healthcare and numerous other complex issues confronting society today.

"What does human sexuality mean?" she asks. "What is the balance point between an individual's rights and responsibilities and a community's rights and responsibilities? What is our responsibility to people at the end of life? At what point do we accept the reality of death and not fight it with everything we have?

"AIDS does not involve just the healthcare system—it overlaps into the business and political world as well," she says. "I find that kind of complex puzzle challenging. It leads you into just about every complicated human question that you have to deal with." □

Marlene Cimons, a Washington reporter for the Los Angeles Times *who covers health policy, has written extensively about AIDS since the epidemic's beginnings.*

Bringing a Drug to Market—*Again*

Ann Louise Truschel

The only single therapeutic modality that has been shown to be effective in the treatment of disseminated *Mycobacterium avium* complex (MAC) in patients with AIDS is Abbott Laboratories' clarithromycin (Biaxin). Originally approved in November 1991 for upper and lower respiratory tract bacterial infections, clarithromycin was recommended for accelerated approval for the treatment of MAC at the May meeting of the FDA's Antiviral Drugs Advisory Committee.

"It's still not approved after almost one year. I can't call that accelerated. We anticipated approval sooner than this."—*Andre G. Pernet, PhD*

What led to this accelerated approval recommendation—and not everyone agrees the process has been accelerated—was a lot of effort by Abbott, activist groups, and clinicians. Sometimes working together and sometimes not, all the players have labored to push clarithromycin through the regulatory system.

Did all this effort really shorten the development and approval process for clarithromycin as a treatment for MAC? Does accelerated review and approval really work? How do the activists fit into the process? How do the players view the FDA's role? These questions are important in the analysis of the clarithromycin experience, but there is another part to this story. The clarithromycin story is also a study of relationships—relationships among Abbott, activists, clinicians, and the FDA. All with their own agendas, these groups share the common goal of getting life-sustaining drugs, like clarithromycin, through the regulatory system to the patients who need them.

An untreatable disease

Before the advent of clarithromycin, disseminated MAC in patients with AIDS was essentially untreatable, its symptoms being controlled more or less well by a combination of drugs that sometimes cause intolerable side effects. Symptoms of the disease are nonspecific but debilitating and include fever, drenching night-sweats, fatigue, anemia, weight loss, wasting, and severe diarrhea. Respiratory symptoms and pulmonary involvement, usually seen in immunocompetent patients, are uncommon in AIDS-related MAC.

Left untreated, MAC affects virtually all organs of the body. The effect on patient morbidity is significant, and the most recent data suggest that MAC reduces the life expectancy of patients with AIDS by approximately six months.

Prevalence of MAC increasing

Disseminated MAC is now the second most common AIDS-associated opportunistic infection worldwide. Its prevalence is increasing not only because the incidence of AIDS is increasing, but ironically because antiretroviral therapies are helping HIV-positive patients live long enough to develop the infection. Disseminated MAC is usually a late-onset infection and, in general, is diagnosed about nine months after an AIDS diagnosis has been established.

MAC is now seen in 15 to 24 percent of patients with AIDS in the United States, and an estimated 50 to 80 percent of patients with AIDS in North America will eventually develop some type of *M. avium* infection. The main route of acquisition appears to be gastrointestinal.

Clarithromycin as treatment for MAC

MAC-infected AIDS patients treated with clarithromycin usually experience symptomatic relief within one month as the level of bacteremia is reduced. "Clarithromycin is able to reduce the infection titer in the blood by about 2.7 logs," said Andre G. Pernet, PhD, vice-president of pharmaceutical development at Abbott Laboratories, Abbott Park, Illinois. "Compared to monotherapy with other drugs, it is quite superior, and it's even better than the traditional cocktail of four drugs [ethambutol, amika-

cin, clofazimine, and rifampin], which reduces infection titer only by about 2.4 logs. Most of the side effects of clarithromycin are gastrointestinal and most are mild."

"It's a very good drug; it's one of the best that we have," concurs Lowell S. Young, MD. Director of the Kuzell Institute in San Francisco. Dr. Young, who has the NIH/NIAID contract for the evaluation of new therapies against *M. avium*, conducted screening studies using clarithromycin.

Bringing clarithromycin to the US market

The story of bringing clarithromycin to market is actually the story of bringing the drug to market again. Although originally approved in November 1991 for use against upper and lower respiratory tract bacterial infections, as far back as 1988 the drug had already shown *in vitro* activity against *M. avium*.[1] In 1989, *in vitro* and *in vivo* activities of clarithromycin against *M. avium* were reported,[2] and the following year Dautzenberg, in France, published the results of a double-blind, randomized, placebo-controlled, crossover study demonstrating the efficacy of clarithromycin in MAC infections in patients with AIDS.[3]

Even while the French study was under way, word of the results began to reach activist groups in this country. "We were all really excited about clarithromycin when we first heard even anecdotal data coming from France," said Ben Cheng, information and advocacy associate for San Francisco's Project Inform. "As far as treating *M. avium*, at the time there was nothing except a four- or five-drug combination of fairly toxic drugs. We wanted to get clarithromycin into clinical trials in this country."

Activist groups all over the country began to mobilize to help make clarithromycin available in the U.S. to AIDS patients with MAC. Because the drug was already approved in Italy, the Buyers Club was able to obtain it through Germany and later through Ireland and make it available on the underground. "However, the drug was quite expensive because someone had to fly to Europe to pick up a shipment and bring it back," said Cheng. "Also, nobody knew what dose of the drug was supposed to be used."

Designing the US clinical trials

To answer just that question, Abbott began its first clinical trial, a dose-ranging study, in May 1990. According to Dr. Pernet, placebo trials were not used "because, after the initial observation of activity of the drug, it would have been unethical to use placebo as one arm knowing that MAC is a fatal disease, that people need the drug. All were monotherapy trials because we wanted to study the drug by itself and see its effectiveness." To date, Abbott has conducted five short clinical studies involving some 1,300 patients.

The two trials that provided most of the information for Abbott's New Drug Application were ACTG 157 and the compassionate use trials.

ACTG 157. ACTG 157, begun in May 1990, was a safety and efficacy trial cosponsored by Abbott and led by Richard E. Chaisson, MD, of Johns Hopkins University in Baltimore.[4] Patients enrolled in the study were to receive either 500 mg, 1000 mg, or 2000 mg of clarithromycin twice daily. While the trial was in progress, Abbott asked for and received FDA permission to increase enrollment. The company added three study sites, and ACTG 157 became Abbott's pivotal NDA study.

An interim analysis of the results clearly demonstrated that clarithromycin was highly active against MAC bacteremia. What the results of ACTG 157 also showed was that, as a single agent, clarithromycin induced resistance that usually occurred between weeks eight and 12. Moreover, at the higher doses of clarithromycin, increased toxicity was observed. Clearly more information was needed.

"We have a dialogue with Abbott but it's certainly a rocky relationship."—*Ben Cheng*

The emergence of resistance to clarithromycin was disappointing, but not surprising. "*M. avium* traditionally is almost always resistant to almost all drugs," said Jeffrey Galpin, MD, of the Shared Medical Research Foundation, Tarzana, California. "We need to use a combination of clarithromycin and other drugs. We don't have the optimum treatment yet."

Compassionate use trials. In January 1991, activist groups including Project Inform, ACT UP, ACT UP's Treatment Action Group, and Search Alliance first contacted Dr. Pernet at Abbott to ask for free distribution of clarithromycin to AIDS patients with MAC infection. Abbott agreed and developed a protocol that was approved by the FDA.

However, when the distribution program debuted in July 1991, the company received heavy criticism from the activist community because of the amount of documentation Abbott required from clinicians. According to Cheng, "We had clinicians calling us complaining that, as a result of all the paperwork required by Abbott, they weren't able to put as many patients on compassionate use as they would like. Abbott was essentially running a clinical trial through the compassionate use program. They were using two different dosages and were asking for a lot of laboratory tests. Most compassionate use programs just ask for safety data." Cheng said that the company maintained it needed additional efficacy data. According to PAAC's executive director, Gordon Nary, who was asked by Abbott to monitor the concerns of activists, "There were similar paperwork issues with other pharmaceutical manufacturers with promising new drugs. These concerns mirrored a primary challenge to both the activist and scientific communities to balance good science with the ethical obligation to maximize patients' quality and length of life."

While activist attempts to convince Abbott to decrease the amount of paperwork were largely unsuccessful, Cheng acknowledged that testing clarithromycin at the two dosages yielded valuable information, and that it was partly because of the compassionate use program that Abbott was able to complete its NDA.

Stephen Nightingale, MD, a PAAC trustee from the University of Texas Southwestern Medical School, Dallas, was one of the clinicians involved in the compassionate use trials. "By January of 1992, we knew we had a partial solution to the problem [of treating MAC infections] and that we were going to need second- and third-line drugs [because of the resistance that developed]."

The indigent compassionate use program: a difference of opinion

Following the November 1991 approval of clarithromycin for other indications, Ab-

bott and the activist community clashed again over compassionate distribution of clarithromycin. The disagreement involved Abbott's decision to limit compassionate distribution to those MAC-infected AIDS patients with annual incomes under $26,000.

Abbott's reasoning for this decision was simple. Said Dr. Pernet, "Since the drug was now approved, although for other conditions, anyone could buy it." And, in fact, that is what happened. Physicians began prescribing clarithromycin for their patients with MAC, and use of the drug became widespread.

The activist community remained opposed to the indigent compassionate use program. "Every other company has had an open-ended compassionate use program," said Cheng. "Pfizer has a similar compassionate use program for azithromycin. Their only requirement is a MAC diagnosis. There has never been a compassionate use program in which income determined whether you got the drug or not."

In fact, Abbott's indigent compassionate use program was delayed in the FDA for several months "because it was a precedent for them. It had never been done before," Dr. Pernet said. But the program was ultimately approved and began in July 1992. It now operates worldwide.

According to Nary, who had a preliminary discussion with the FDA about the indigent program before the proposal was submitted by Abbott, "The FDA's approval was a seminal decision because it underscored the obligation of third-party payers to cover the cost of off-label drugs when they have been established as a standard of care." PAAC helped establish the acceptance of clarithromycin as a standard of care for treating MAC by surveying AIDS specialists on their treatment practices. (These findings were published in *PAACNOTES*, volume 3, number 3.)

In October 1992, Abbott filed its NDA.

Accelerated approval recommended

This May, seven months after the filing of the NDA, clarithromycin received an accelerated approval recommendation from the Antiviral Drugs Advisory Committee. As of late September, the drug has not yet been approved for the MAC indication, but approval is expected to come through at any time. Abbott is in the process of negotiating the final labeling for the drug with FDA. The labeling will contain a statement that clarithromycin should be used in combination with other unspecified drugs.

In retrospect

Looking back on the development and approval process for clarithromycin, it would seem a simple task to determine how the process worked. Yet, there is no general agreement as to who or what brought clarithromycin "to market," or even if the drug's passage through the regulatory system has been really accelerated.

"We need to be wise in how we use this drug, or we'll create a population where resistance will emerge much quicker."—*Jeffrey Galpin, MD*

The activists feel they expedited the review process by making their presence felt at the FDA. "We were on the phone with FDA once a week or every two weeks asking about the status of the NDA and about hearing dates," said Cheng. "If FDA hears us asking about a drug, they know we are pushing for approval."

In Dr. Pernet's opinion, however, neither the review nor the approval was expedited. He points out that Abbott filed its NDA in October of last year. "I don't think it was an accelerated approval given the fact that we filed for only one indication, and it's still not approved after almost one year. I can't call that accelerated. We anticipated approval sooner than this."

The situation is further complicated by the fact that the clarithromycin experience is atypical. Clarithromycin is not a "new" drug in the classic sense: it was already approved and on the market for another indication. The question of whether the review and approval were expedited is debatable because it is not clear how much prodding along the regulatory trail the drug really needed.

"My own view is that the drug brought itself to market," said Dr. Nightingale. "After clarithromycin was approved [for upper and lower respiratory infections] and became available by prescription, we began using it to treat MAC. The use was so widespread that the approval [recommendation] pretty much followed medical practice rather than anticipated it."

One can only speculate on who is right. Perhaps everyone is partially correct. What is clear is that the approval process for clarithromycin has not broken any speed records.

Are accelerated review and approval working?

If one accepts the fact that the clarithromycin experience is not typical, then the consensus is that the FDA has made improvements in the regulatory process over the past several years that have resulted in accelerated reviews for AIDS drugs. Dr. Pernet feels that the Agency has been "very responsive." Clinicians involved in screening studies or registration trials also feel that the approval process has been expedited and, in particular, give activists a large share of the credit for getting the FDA bureaucracy to look at new ways of doing things, ways that can speed AIDS drugs through the system.

Dr. Young still labels the FDA "a ponderous bureaucracy," but adds that the Agency has improved greatly over the past three years. He says the activist community had a lot to do with that improvement. "The activists, by accelerating the review process, I think have done the field a favor. And FDA has become more responsive."

In general, Cheng agrees. "FDA is sensitive to the viewpoint of the activist community. Members of the community are always invited as consultants to sit in on the advisory committee meetings. If we support a drug, FDA knows we're pushing for approval. I think that helps in the long run in getting drugs to market." Cheng characterizes the role of activists with FDA as helping the Agency look at its priorities.

By being informed on the issues, activists, many feel, have served a valuable purpose by educating government and helping the FDA recognize that rules can be modified without losing the protection and benefit of those rules, in order to speed therapeutics through the system.

"I hope this kind of support is a trend that is here to stay," said Dr. Nightingale. "If there is not continuing strong support for accelerated approval of drugs, I think it inevitable that very careful evaluation of drugs for fear of our tort system will return as the dominant force in drug development."

What lies in the future for Abbott and the activists?

There is more discussion ahead for Abbott and the activists: the company has a number of HIV drugs in development. They will continue to talk and to build on the relationship they established during the clarithromycin studies even though they do not agree on just what that relationship is.

Dr. Pernet thinks it is essential to have good relations with the activists not only to avoid their more aggressive actions, but also to make sure they understand Abbott's position. "It's important to keep the activists informed. If they understand what we're doing, and we can reach an acceptable compromise, I think it's in everybody's interest."

For their part, activists want more than information: they want membership in Abbott's scientific advisory board, the committee that designs and plans Abbott's clinical trials. "Abbott doesn't always have the community in mind when it comes to drug development," Cheng said, although he understands that the profit motive has to underlie a lot of Abbott's decisions. "That's not entirely a bad thing," he said, "but it would be better if Abbott would work with the affected community when designing clinical studies. We have a dialogue with Abbott but it's definitely a rocky relationship."

It is not surprising that the relationship between Abbott and the activists is, and probably always will be, somewhat strained. Despite their common purposes, the two represent different constituencies. Activists represent AIDS patients, and Abbott ultimately represents shareholders. "Tension over profits is the reason why I don't see the advocacy groups and the pharmaceutical industry getting too close to each other," said Dr. Nightingale.

Clarithromycin's future

New clinical trials are being planned for clarithromycin, and a number have already started. Because of the emergence of resistance to clarithromycin, combination drug studies are necessary. C. Robert Horsburgh, MD, special assistant for infectious diseases at the Centers for Disease Control and Prevention, reviewed the data for the FDA's Antiviral Drugs Advisory Committee. "Resistance is a serious problem," he said. "It develops in at least half the people and they get sick again. The average time for resistance to develop is three months. Clarithromycin should never be used alone."

Clinical trials are now under way to study clarithromycin in combination with ethambutol, clofazimine, rifabutin, and liposomal gentamicin. Trials with other combination drugs are in the planning stage.

More studies also need to be conducted to resolve the problem of increased toxicity at higher doses. In part, increased toxicity is attributable to gastrointestinal intolerance, mainly stomach pain, which is not an uncommon occurrence with macrolide antibiotics. There were more deaths in the higher dose treatment groups than in the treatment group receiving 500 mg twice per day, but the reason was not obvious, and the number of deaths was not statistically significant when all factors were controlled for.

"It's not clear whether the increased toxicity was the fault of improper study design—that sicker people actually got the higher dose—or whether there's really some toxic effect at the higher doses," said Dr. Horsburgh. "FDA was unwilling to make a decision [on the dose], and I think that was wise." What the FDA finally did decide was to recommend a dose range of 500–1000 mg twice per day until the toxicity question could be resolved by additional studies. (At this dose range, the cost for one year's therapy would range between $1900 and $3800.)

Other indications for clarithromycin are being evaluated. "The emphasis now is on the use of clarithromycin as a prophylactic agent for *M. avium*," said Dr. Pernet, "so we're now doing those studies."

Dr. Galpin thinks such studies are necessary. "We don't know the true effects of prophylaxis. We need to be wise in how we use this drug. We can't use it indiscriminately or we'll create a population where resistance will emerge much quicker."

The clarithromycin experience

Clarithromycin is undergoing additional testing. Combination studies will determine the optimum regimens for long-term treatment of MAC. Prophylactic studies will be conducted, and other trials will try to resolve the toxicity issue.

The relationship between Abbott and the activists will continue and will probably still be uneasy. While appreciating each other's position, they pursue their own agendas. The FDA is viewed more positively by the players, and the activists are given a lot of the credit for bringing about improvement in the regulatory process.

Activists see themselves in a dual role—pressing pharmaceutical companies for early compassionate distribution and for clinical trials that are more community-centered; and lobbying the FDA to expedite the review and approval process. These relationships will also be undergoing additional testing in the future.□

Ann Louise Truschel, a medical communications consultant for Professional Communications in Skokie, Illinois, covers AIDS, public health and healthcare industry issues, and other topics.

"The activists, by accelerating the review process, I think have done the field a favor. And FDA has become more responsive."
—Lowell S. Young, MD

References

1. Nash SF et al. The in vitro activity of a new macrolide antibiotic A-56268 (TE-031) against *Mycobacterium avium* complex strains isolated from AIDS patients. Presented at the 88th Annual Meeting of the American Society for Microbiology, 1988.
2. Fernandes P, Hardy DJ, McDaniel D, et al. In vitro and in vivo activities of clarithromycin against *Mycobacterium avium*. *Antimicrob Agents Chemother* 1988;32(9):1383–1534.
3. Dautzenberg B, et al. Double-blind study of efficacy of clarithromycin versus placebo in *Mycobacterium avium* and *Mycobacterium intracellulare* infection in AIDS patients. *Am Rev Respir Dis* 1990;141:A618.
4. Chaisson RE, Benson C, Dube M, et al. Clarithromycin therapy for disseminated *Mycobacterium avium* complex (MAC) in AIDS. In: Program and Abstracts of the 32d Interscience Conference on Antimicrobial Agents and Chemotherapy, Anaheim, Calif, October 1992. Abstract 69.

PAAC Launches Los Angeles Standards of Care and AIDS IPA Projects

Brett Hufziger

On November 10, 1993, the Los Angeles office of the Physicians Association for AIDS Care (LA/PAAC) launched two healthcare reform projects that, according to Gordon Nary, PAAC's executive director, "could have a significant impact on the future of HIV care and on the practice of medicine." Nary referred to the potential impact of the LA PAAC Community Standards of Care Project on the treatment of HIV disease, both locally and nationally, and to the "opportunity for community physicians to standardize third-party reimbursement for off-label use of FDA-approved drugs and other diagnostic and therapeutic procedures that local physicians approve as community standards." In addition, a Los Angeles AIDS IPA (Independent Practice Association) proposal was introduced that is designed to provide medical, social, and financial planning coordination services under the direction of its member physicians.

All accompanying photos by Gary Irwin/Wordwatch

Physicians, pharmaceutical manufacturers, and members of the hospital and insurance industries attended the November 10 meeting of LA/PAAC to review the organization's Standards of Care project and its Independent Practice Association (IPA) proposal. At center (in blue shirt) is Dr. Ronald Mitsuyasu, head of PAAC's publications committee, and director of UCLA's Center for Clinical AIDS Research and Education (CARE).

Community Standards of Care Project

In his opening remarks in a meeting held at Midway Hospital, Nary explained that Los Angeles was chosen to launch the Community Standards of Care Project because LA/PAAC's physician members have cared for more than 38,000 people with HIV disease, a majority of the 50,000–60,000 estimated cases of HIV in greater Los Angeles. According to Nary, if the physicians treating the majority of patients with HIV disease in Los Angeles could agree on community standards of care, these standards would have a legal basis for reimbursement. Generally, guidelines that have been used to define standards of care have either been (1) developed by recognized specialists in a particular discipline and endorsed by medical organizations, or (2) based on research published in peer-reviewed journals by university researchers.

The LA PAAC Community Standards of Care Project is based on a multi-stage review procedure of 21 protocols, each of which is developed over 90 days and updated regularly. The complete process is scheduled to take 13 months (see Table). There are seven steps in the protocol approval process:

1. A draft of the proposed protocols is developed by PAAC's Standards of Care Committee, based in part on the Standards of Care series of articles in *PAAC-NOTES*. This draft is sent to all PAAC individual and corporate members attending monthly protocol meetings.

2. Any PAAC member attending the meeting can recommend changes in the proposed protocols. These changes are considered by the ad hoc committee for each of the protocols. The committee chairs, with the agreement of the members at the meeting, will prepare a second draft of the protocols based on a consensus of recommendations.

3. The second drafts of the protocols are sent to all LA/PAAC member physicians for final comment.

4. Comments are reviewed by the LA PAAC Standards of Care Committee chairs and are incorporated into a final draft of the proposed protocols. The final draft is sent out again to all members for their approval.

5. Members can approve the entire protocol or selected sections of the protocol. A member's approval is weighted according to the number of patients (charts) in his or her HIV practice.

6. The final protocols and their approval factors will be published in *PAAC-NOTES*.

7. With appropriate funding, PAAC plans to add an attorney/advocate to the Los Angeles office who will work with third-party payers who fail to reimburse based on the LA/PAAC standards. If, after negotiations, the payer still refuses to base reimbursement on the LA/PAAC standards, a patient advocacy fund will be used to challenge such decisions in the courts.

Schedule: Los Angeles Community Standards of Care Reviews

November 1993	*Mycobacterium avium* complex Cytomegalovirus
December 1993	*Pneumocystis carinii* pneumonia Toxoplasmosis
January 1994	Fungal infections
February 1994	Antiretroviral therapy
March 1994	Kaposi's sarcoma Non-Hodgkin's lymphoma
April 1994	*Cryptosporidium* *Microsporidium* Miscellaneous GI disorders Management of diarrhea
May 1994	Dermatologic disorders
June 1994	Gynecologic disorders
July 1994	Oral complications, excluding fungal and Kaposi's sarcoma
August 1994	Neurologic disorders
September 1994	Endocrinologic disorders Cardiac disorders
October 1994	Pain management
November 1994	Nutrition
December 1994	Pediatric

Protocols submitted for review

Two protocols were reviewed at the November meeting, one for *Mycobacterium avium* complex (MAC) and the other for cytomegalovirus (CMV) disease. The preliminary recommendations discussed at the meeting included:

1. Lowering the current Public Health Service guidelines for the institution of rifabutin (Mycobutin) for prophylaxis against MAC. (This proposal was based in part on Dr. Richard Chaisson's article in the September 1993 issue of *PAAC-NOTES*, Dr. Stephen Nightingale's recommendations presented at the PAAC symposium at the IX International Conference on AIDS in Berlin, and the experience of several of the participating physicians.)

2. The off-label use of filgrastim (Neupogen) for the treatment of leukopenia secondary to drug side effects and isolated decreases in white blood cell counts.

3. The off-label use of ganciclovir (Cytovene) and foscarnet (Foscavir) for the treatment of systemic CMV disease (pulmonary, gastrointestinal, neurologic, etc).

These recommendations were included on the second draft of the protocols distributed to the LA/PAAC membership for final comment.

Budget outlined

Nary projected that the annual budget for the Community Standards of Care Project, which includes adding three staff members to the Los Angeles office, would amount to $250,000. He then outlined LA/PAAC's plan to raise funds.

PAAC will target 250 Los Angeles corporations to contribute $1,000 per year to the project because of the potential value in reducing healthcare costs and improving the length and quality of life of Los Angeles residents. Nary explained that PAAC's message to the corporate community is that the HIV epidemic could have profound social and economic consequences on the Los Angeles business community by the year 2000 unless steps are taken now to control the costs of care without sacrificing the aggressive, comprehensive care that has been a trademark of the Los Angeles community.

The first step for community corporate identification will be a full-page advertisement in the business section of the *Los Angeles Times* outlining LA/PAAC's initiatives. The advertisement is scheduled for early December and is being paid for by a grant from Roche Professional Services. The names of all LA/PAAC member physicians will also be included in the advertisement.

Nary also described an LA/PAAC brochure that was being developed to request both individual and corporate support of the project. The brochure will feature photographs of several local PAAC physicians, including Lysette Cordona, MD, MPH, Henry Poscher, MD, and Robert Jenkins, MD. The brochures will recommend annual corporate support of $1,000 and development of a corporate relationship with LA/PAAC, which would serve as the HIV educational coordinator for that corporation. Individual donations of $100 per year will also be recommended.

Nary also announced the appointment of Rick Nordin as director of develop-

Dr. Jayson Hymes (left) confers with Amber Lindsey of Roche Professional Services, who helped coordinate the LA/PAAC meeting. Jack Brubach of Bon Bon, a payroll management company, looks on.

ment for LA/PAAC. Nordin was the former director of development for AMFAR in Los Angeles. According to Nordin, "It's nice to be a part of this effort, particularly focusing on involving the corporate community. There are lots of details and lots of conversations ahead, but I see elements for success here, namely, the participants in this room, and leadership with some vision and ideas."

AIDS/IPA proposal introduced

Nary also introduced the Los Angeles AIDS/IPA proposal, which was explained in greater detail by Victor Beer, MD, and Jayson Hymes, MD. (Their presentations are featured later in this report.) Nary emphasized that the not-for-profit model was suggested because of the projected millions of dollars in cost analysis, cost benefit, and outcome studies that would be necessary to help compute appropriate annual management fees paid to the IPA by employers and other payors.

Nary also recommended that the LA IPA be based in part on an extension of the landmark AIDS home health, attendant, and hospice care pilot project that was featured in the January/February 1992 issue of *PAACNOTES*. This report (prepared for the California Department of Health Services Office of AIDS) provided critical data on the application of a comprehensive case management model as a central part of HIV care. The proposed LA/PAAC comprehensive case management model involves the coordination of all medical, social, and financial planning services through a case manager working under the direction of the physicians in the IPA. The medical services would be based in part on the LA/PAAC Community Standards of Care.

In outlining the Los Angeles IPA project, Nary also detailed proposals to include two major funds that would be under the direction of a financial planner working with the case manager. The funds could be accessed by patients who might otherwise not be able to pay for specific treatments that are not part of the Standards of Care Project. These funds include:

1. An investigational drug fund. Since many investigational therapies that have become standards of care are off-label uses of FDA-approved drugs, Nary recommended that there be a mechanism to support a physician's investigational use of off-label drugs in a process that could eventually assess whether they proved to be effective community standards.

2. An alternative therapy fund. While traditional third-party payer policies generally do not cover alternative therapies, a growing number of Los Angeles physicians and their patients are incorporating alternative therapies as an adjunct to more traditional therapies. The concept of the alternative therapy fund is to provide money to pay for these alternative therapies approved by the patient's physician on a case-by-case basis.

Other projects introduced

Nary also outlined some of LA/PAAC's other projects designed to reduce the cost of lifetime care, increase long-term survival, and improve quality of life. They include:

1. Expansion of clinical trials. PAAC is currently working with several pharmaceutical manufacturers to bring new clinical trials into the Los Angeles area. Several of these trials are planned to be conducted by some of the major practices, and a program of cross-referrals to the various practices is on the schedule of projects to be considered by the IPA organizing committee.

2. The lifetime care cap on AIDS drugs. PAAC has begun working with several of the leading pharmaceutical manufacturers to determine the feasibility of a trial project in Los Angeles in which companies would assess the impact of a lifetime cap on AIDS drug costs. After the lifetime cap was reached, future drugs would be provided at no cost.

3. Coordinated indigent patient programs. At a December 3 meeting with pharmaceutical manufacturers in Washington, DC, Nary outlined a proposal for a pilot project in Los Angeles that would include common eligibility criteria for free drugs and the coordination of these criteria through a single patient advocate. Based on the success of the pilot project, this function would be assumed by the case manager.

PAAC trustee Dr. Victor Beer, of Kraus-Beer Medical Group, discussed various aspects of the Independent Practice Association.

While a schedule of annual management fees will be under consideration for medical care, other services such as hospitalization, transitional care, hospice, and home care could be covered under a separate Preferred Provider Organization (PPO) arrangement with local hospitals, home care companies, and other providers. The savings effected by following the community standards and the special discount negotiated through the PPO are expected to reduce private care costs by 20–30 percent without any sacrifice in quality of care.

Responses to PAAC's proposals

The response by local hospital leaders to PAAC's proposals has been positive. According to Bryan Burklow, Senior Vice President of Summit Health Ltd., "Healthcare reform presents critical challenges to hospitals with specialized AIDS and other disease-specific services. The "centers of excellence" concept provides employers, unions, and third-party payers with the assurance that people with HIV disease will have the most advanced care available by providing that care in its most cost-effective setting."

According to Maxine Cooper, the CEO of Hollywood Community Hospital Medical Center, Inc., "The work of LA/PAAC shows the eagerness of fee-for-service providers to cooperate with and add their expertise to the reorganization of healthcare delivery systems. Healthcare reform will change how everyone receives medical care, but those with HIV disease present a unique challenge to the system for a number of reasons. Chief among them is that HIV disease develops over many years and utilizes the entire health delivery system from testing to hospice. LA/PAAC's input to organizing the system to cost-effectively treat the many facets of HIV disease while preserving top quality is an important contribution."

One of several unions that expressed interest in the IPA applauded the concept of financial planning to help their employees better manage their resources and coordinate access to pharmaceutical company patient assistance programs. According to Tim Trueman, shop steward of the International Association of Machinists, "The financial planner component of the AIDS IPA model provides a pragmatic approach to balance healthcare costs. Our obligation is to help each person with

Victor Beer: Independent Practice Association could benefit physicians, patients, and the healthcare industry

(Excerpted from Dr. Victor Beer's comments to PAAC at Midway Hospital in Los Angeles, November 10, 1993)

What we hope to do is to develop a conglomerate of providers, both from the healthcare industry [pharmaceutical and hospital associations] as well as from the clinicians, to develop a structured IPA which can help to direct the way that care is going to be provided in the future.

We'd like to have input from both the pharmaceutical and the hospital industry, and hope to develop a system that will work effectively for health care in the HIV arena. This will allow us to direct where the care is going to be going, rather than having it thrust upon us in the form of mediocre medicine for the masses—which would only provide less-than-standard care for our patients.

The reality is, there is no community standard at the present time. We hope to develop a rational set of guidelines which will be modified in conjunction with the physicians who are providing the care. Not every one of these guidelines will be a required procedure. Each clinician will have some flexibility within the guidelines.

If we have a series of basic guidelines, I think we'll be able to provide some representation to most of the third party payers, insurance companies, as well as to federal and state agencies. We will then be able to develop the kinds of reimbursements, as well as the subsidized research programs, that we will need to accomplish this whole process.

Medicare and IPAs

We are increasingly involved with the provision of care to the Medicare population. One of the faults of the whole system is that those of us who provide care for Medicare patients, whether it be on a pro bono basis or for whatever reimbursements are provided from Medicare, have difficulty in maintaining continuity with our patient care. Many hospital facilities are not providers under a Medicare of MediCal [Medicaid in California] contract. When the patient requires hospitalization, the physician may be required to hospitalize the patient at a county facility where he or she may not have staff admitting privileges. These circumstances make continuity of care extremely difficult.

From my perspective, that's a very inefficient and undesirable system both from the standpoint of the clinician and the patient. Personally, I would like to be able to maintain continuity with my patients.What we hope to propose with the assistance of Medicare professionals, is a model in which we might be able to obtain special funding from the state and federal governments.

The shape of HIV care in Los Angeles

HIV care in Los Angeles will tend to move toward one or two or three larger medical group-type practices, all devoted to the development of managed care for the HIV population. We hope to integrate in both a horizontal and vertical fashion all areas crucial to the provision of care within this patient population.

I'd like to see that accomplished with the input of the third party payers from the insurance industry, and of the physicians. This could be done in a manner to prevent the development of adversarial relationships. We hope to have direct communication with third party payers, such that it would make all of our lives a lot easier.

The real concept that we have to address is the need to provide quality care for our patients.

Jayson Hymes: Physicians should establish standards of care before the state or national governments do so for us.

(Excerpted from Dr. Jayson Hymes's comments to PAAC at Midway Hospital in Los Angeles, November 10, 1993)

The role of nonprimary-care physicians

Twenty percent of my patient population have HIV as a primary diagnosis. And all I do is pain management and chemical dependency in response in regards to pain problems. As a subspecialist, I see lifestyle-involving complications and ramifications of HIV and seek to augment their care.

I and people in my position tend to interact with most of the larger and some smaller HIV-treating physicians and groups in the area: I'm viewed as somewhat of a neutral because we tend to interact with everybody. And we also interact with our vendors, healthcare corporations, pharmaceutical manufacturers, and hospitals on a somewhat different level than primary care physicians would. And so we'll bring somewhat of a broader perspective to the organizing process.

Caregivers, vendors, laboratories together

What we are proposing—as opposed to a uni-dimensional model of four or five primary care physicians organizing with one or two sub-specialists or sub-specialty groups—is integrating primary care treating physicians, their diagnostic vendors, clinical laboratories, radiology services, sub-specialists, pain management physicians, ophthalmologists, dermatologists, pulmonologists, therapeutic vendors, pharmaceutical manufacturers, DME (dural medical equipment) manufacturers, not only in terms of modalities but in terms of locations.

What's not being proposed is something that's being brought in from outside and we're being invited to join. What we are looking to do at a grass roots level is to organize and establish standards of care on an in-house level because if we don't establish these standards of care ourselves, then they will be mandated, they'll be established and mandated, and we will have to in a backhand measure look to see what we can do to modify them if they don't fit our particular community or practices.

So, when we organize and establish these standards of treating care, it won't come from some national or international law enforcement body, it won't be pushed down on us by the Medical Board of California or the Medicare Administration. But in fact, we can analyze our practices and our patients' needs and establish standards of care proactively. We can track our costs, analyze our outcome data and we can take this information in this vertically integrated model and offer far more to managed care organizations than simply the care of patients with HIV in terms of the medically related aspects.

We are all very much aware as primary care physicians and as sub-specialists of HMOs, PPOs, hospital organizations or indemnity carriers, referring patients to us for a specific thing. And the balance of the care for that patient we have little or no input on. And what we're proposing is an alliance of physicians and corporations to analyze what we are doing, consider our costs, raise funds to perform all these activities and offer a cost-effective, medically efficient superior model to what could be mandated out of Sacramento or out of Washington. And that's why I'm here and we're here.

HIV disease gain access to all the resources available to be a long-term survivor."

LA/PAAC's attention to cost-benefit and outcome studies has also resulted in praise from Gary Wolfe, RN, CCM, president-elect of the Case Management Society of America. According to Mr. Wolfe, "The special balance and cutting-edge therapies and outcome studies, cost-benefit studies, and financial planning that LA/PAAC is addressing in its AIDS IPA model should be of interest to and supported by employers, providers, and third-party payers. The model should become the standard of HIV care throughout the United States."

The proposals were also very well received by several of the Los Angeles physicians. Dr. Anthony Scarsella of Pacific Oaks Medical Group, who serves as LA/PAAC's liaison with the City of Los Angeles, stated, "The entire Los Angeles medical community believes it is time to take a proactive approach to both define and protect the practice guidelines that contribute to our patients' ability to live with HIV disease. The greater emphasis on managed competition and managed care signaled by President Clinton's healthcare reform proposals could mean that even more decisions on what is or what is not appropriate care for people with life-threatening illness will be made by persons other than physicians. This is simply not acceptable to the Los Angeles medical community."

Dr. Victor Beer summed up the LA/PAAC project by stating, "President Clinton's proposal provides the nation with the matrix to implement a much-needed national healthcare system, but cost estimates and political considerations may change critical elements of the proposal to facilitate legislative approval. Our community needs either to be proactive to protect our patients and our practices, or to be passive to an unknown future. There is no question that the Los Angeles medical community will be proactive and will move for a swift implementation of the LA/PAAC initiatives."

For further information concerning the Standards of Care or IPA Projects, contact the LA/PAAC office, 10940 Wilshire, Los Angeles, CA 90024; (310) 443-4231.□

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