MICHAEL C. BACH, M.D.
F.R.C.P.(C.), F.A.C.P.
INFECTIOUS DISEASES

February 11, 1991

Constance Wofsy, M.D.
Ward 95, Building 90
San Francisco General Hospital
995 Potrero Avenue
San Francisco, CA 94110

Dear Conni:

Just a short note to let you know how much Babette and I enjoyed meeting you and David. We also loved the day with Susan. We thought the whole ambiance of Snow Mass was wonderful and I personally enjoyed participating in the 14th Annual Symposium.

I am enclosing with this letter two reprints of my two articles on aphthous ulcers and I appreciate your including that in your list of topics for your lecture. The other is the Letter to the Editor of the New England Journal that I had published in July documenting clinical failure with AZT. Actually, there are a number of investigators, including Doug Richmond from San Diego, who are seeing the same phenomenon.

I hope we will see each other again if not before Florence, then in Florence.

Best regards and love to Susan.

Sincerely yours,

Michael

Michael C. Bach, M.D.

MCB/sjm
Enclosure

393 SPRING STREET / PORTLAND, MAINE 04102 / TELEPHONE: (207) 775-3064

NEJM
July 26/90

foods. The reductions in dietary cholesterol were made so that both of our low-fat diets also met the recommendations of the National Cholesterol Education Program for cholesterol intake. Our calculated values were unfortunately overestimated because of the use of now outdated tables of the U.S. Department of Agriculture, which list the cholesterol content of a 50-g egg as 275 mg rather than as 213 mg, the corrected value.

In response to Dr. Freudenheim et al., we stand by our statement that our study did not have the statistical power necessary to compare the Step 1 and the monounsaturated fatty acid–enriched diets.

HENRY N. GINSBERG, M.D., SUSAN L. BARR, M.S., R.D., AME GILBERT, B.A., WAHIDA KARMALLY, M.S., R.D., RICHARD DECKELBAUM, M.D., KAREN KAPLAN, M.D., PH.D., RAJASEKHAR RAMAKRISHNAN, SC.D., STEVE HOLLERAN, B.A., AND RALPH DELL, M.D.
Columbia University
New York, NY 10032 College of Physicians and Surgeons

CLINICAL RESPONSE TO DIDEOXYINOSINE IN PATIENTS WITH HIV INFECTION RESISTANT TO ZIDOVUDINE

To the Editor: Recent reports have documented the occurrence of in vitro resistance of strains of the human immunodeficiency virus (HIV) to zidovudine.[1,2] To date, although there has been suspicion of clinical failure during zidovudine therapy,[3] there has been no confirmation of virologic resistance associated with clinical failure.

I report on six patients with the acquired immunodeficiency syndrome (AIDS), all with clinical failure despite standard therapy with zidovudine. In addition, these patients had laboratory evidence of increased viral replication, as defined by rising levels of serum p24 antigen. Virus isolated from the peripheral blood of all six patients demonstrated in vitro resistance to zidovudine. The method used serial dilutions of drug on specimens augmented with fresh peripheral-blood lymphocytes stimulated by phytohemagglutinin and then assayed for reverse transcriptase activity after 14 days of incubation.

Table 1 lists the laboratory and culture data for the six patients. All were not responding to therapy, as evidenced by increasing fatigue, anorexia, weight loss (4 to 13 kg), and sweating. No new opportunistic infections or tumors were evident at the time of evaluation for dideoxyinosine therapy, and CD4 counts were uniformly low.

Therapy with dideoxyinosine (4 mg per kilogram of body weight every 12 hours) was initiated in mid-October 1989 and was well tolerated. The initial clinical response in all patients was noteworthy. Prompt improvement in energy levels and appetite was obvious, and signs of infection, such as low-grade fever, sweating, and diarrhea, disappeared. Weight gains of 5 to 10 kg have been observed. Three patients had significant and sustained falls in p24 antigen levels within the first two months of therapy. It took five months for one patient's antigen level to fall (Patient 2).

Table 1. Virologic and Sensitivity Data in Six Patients Not Responding to Zidovudine Therapy.*

PATIENT NO.	HIV ANTIGEN		β_2-MICROGLOBULIN		AZT IC_{50}†	DDI IC_{50}†
	BEFORE DDI	AFTER DDI	BEFORE DDI	AFTER DDI		
	pg/ml		*mg/liter*		*μmol/liter*	
1	427	174	8.0	6.6	13.9	0.85
2	>500	>500	2.7	2.8	12.0	2.39
3	338	<31	4.7	3.7	13.0	0.3
4	>500	<31	6.4	ND	6.2	0.24
5	102	0	4.1	4.9	16.1	2.0
6	>500	>500	3.8	3.5	10.1	0.71

*DDI denotes dideoxyinosine, AZT zidovudine, and ND not done.

†IC_{50} denotes the concentration of zidovudine (AZT) or dideoxyinosine (DDI) required to inhibit 50 percent of the virus. The IC_{50} of zidovudine for the wild strain is 0.05 to 1.0.

Over the five months of dideoxyinosine therapy, one of the two patients whose p24 antigen levels did not fall began to have clinical deterioration again, with weight loss and fatigue. Patient 2, whose primary problem was neurologic, had grand mal seizures resulting in discontinuation of dideoxyinosine therapy. Full neurologic evaluation failed to reveal another cause, and the seizures have not recurred since the dideoxyinosine therapy was stopped. Patient 6, whose HIV antigen level did not fall with therapy, is clinically stable so far; CD4 counts did not change during the months of therapy.

The observations in these six patients suggest that in vitro resistance of HIV to zidovudine can be correlated with deteriorating clinical status and that treatment with dideoxyinosine, to which the virus remains sensitive, has proved beneficial in some (but not all) patients.

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HODGKIN'S DISEASE IN HIV-INFECTED INTRAVENOUS DRUG ABUSERS

To the Editor: An association between high-grade non-Hodgkin's lymphoma and HIV infection has been demonstrated in several groups at risk for AIDS.[1-3] However, whether Hodgkin's disease is associated with HIV infection is controversial. Hodgkin's disease is not usually associated with other congenital or acquired immunodeficiency states, but several cases have been reported in the context of HIV infection.[4-6] Unfortunately, the diagnosis of Hodgkin's disease in patients with HIV infection is not systematically recorded, since the disease is not a criterion for AIDS according to the Centers for Disease Control.

In January 1987, we set up a registry of HIV-associated tumors.[7] We have since recorded, thanks to the cooperation of 38 university hospitals in France, clinical and epidemiologic data concerning hematologic cancers in patients with HIV infection. As of December 1989, 177 cases of lymphoma had been recorded by the registry. The distribution of non-Hodgkin's lymphoma and Hodgkin's disease in the two major AIDS risk groups is summarized in Table 1.

The ratio of Hodgkin's disease to non-Hodgkin's lymphoma is significantly higher in patients who abused intravenous drugs than in homosexual patients (chi-square = 11.2, P = 0.001). These results for the homosexual group agree with those of a large epidemiologic survey of single men in New York carried out by Biggar et al.,[8] which suggested that non-Hodgkin's lymphoma but not Hodgkin's disease is associated with HIV infection in homosexuals. Until now, there was little information on the risk of Hodgkin's disease in HIV-infected drug abusers. Ahmed et al.,[3] in a study of New York City prison inmates between 1981 and 1984 (a group at risk for AIDS), did not find a significant increase in the incidence of Hodgkin's disease as compared with that in the general population. However, among the prisoners who were intravenous drug abusers, they found that the incidence of Hodgkin's disease was 3 to 10 times higher (the small numbers involved did not permit statistical analysis). In Italy, Tirelli et al.[9,10] also found a high frequency of intravenous drug abuse among patients with HIV infection and Hodgkin's disease, but they correlated this finding with the high frequency of intravenous drug abuse among patients with HIV infection in that country. However, reanalysis of their data reveals that the ratio of Hodgkin's disease to non-Hodgkin's lymphoma was higher in the intravenous drug abusers (0.49) than in the homosexuals (0.06) (Yates' chi-square = 4.3, P = 0.039).

Tumors in patients with HIV infection may occur preferentially in one risk group, as is the case with Kaposi's sarcoma in homosexuals.[11] Our data indicate that Hodgkin's disease occurs preferentially in intravenous drug abusers. Intravenously transmitted factors

Brief Reports

Brief reports of new clinical or laboratory observations, cases of unusual importance, and new developments in medical care will be considered for publication in this section. Manuscripts must be typed double-spaced. Text length must not exceed 750 words; not more than ten references and one figure or table can be used. See "Information for Readers and Authors" for form of references. Manuscripts should include an abstract of not over 150 words. Reports will be reviewed by consultants when, in the opinion of the editors, such review is needed. The Editor reserves the right to shorten reports and to make changes in style.

Aphthous Ulceration of the Gastrointestinal Tract in Patients with the Acquired Immunodeficiency Syndrome (AIDS)

Michael C. Bach, MD; Douglas A. Howell, MD; August J. Valenti, MD; Thomas J. Smith, MD; and Dean L. Winslow, MD

Annals of Internal Medicine. 1990;**112**:465-467.

Patients with steroid-responsive, severe aphthous ulceration involving the mouth, hypopharynx, and esophagus have been described in a previous report (1). In these patients, serious morbidity resulted from the pain and dysphagia associated with the ulcers. Since the publication of this report (1), we have seen another six patients who had giant esophageal ulcers as well as colonic ulcers. In one patient, the colonic ulcers resulted in gastrointestinal hemorrhage. Biopsy specimens from the lesions did not show an underlying recognizable virus or fungus, and five patients responded rapidly to high-dose prednisone therapy. We describe some representative patients and summarize their response to corticosteroid therapy. We also suggest guidelines for diagnosing and treating patients with these lesions.

Case Reports

Patient 1

A 33-year-old intravenous drug user presented with a 2-month history of odynophagia. His temperature at admission was 38 °C, and he had generalized lymphadenopathy on examination. A barium swallow showed discrete ulcers in the distal esophagus; these ulcers were confirmed by endoscopy (Figure 1, *top*). Biopsy specimens and cultures of the lesions failed to show fungus, cytomegalovirus, or herpesvirus. He promptly improved after 3 days of therapy with prednisone, 40 mg daily. The steroid was tapered slowly over the next 3 weeks.

Patient 2

A 23-year-old homosexual man developed *Pneumocystis carinii* pneumonia in 1986. His problems with recurrent oral aphthous ulcers began in October 1986. In April 1987, he developed severe odynophagia without oral lesions. Endoscopy showed a giant esophageal ulcer (Figure 1, *middle*). Biopsy specimens and cultures were unremarkable except for evidence of acute inflammation at the edges of the ulcer. He had a dramatic response to oral prednisone, 40 mg daily, within 48 hours.

Patient 3

A 52-year-old homosexual man with the acquired immunodeficiency syndrome (AIDS) and a long history of irritable bowel syndrome developed bloody diarrhea. Colonoscopy documented extensive superficial ulceration of the colon. Biopsy specimens showed nonspecific inflammation. Cultures were negative (including a test for *Clostridium difficile* toxin). He responded dramatically to prednisone, 40 mg daily; his bleeding stopped within 24 hours.

Patient 4

A 15-year-old boy with hemophilia who was positive for human immunodeficiency virus (HIV) antibody developed lower gastrointestinal bleeding. Colonoscopy showed extensive superficial ulceration of the caecum (Figure 1, *bottom*). Biopsy specimens and cultures did not show the presence of virus or fungus, and the ulcers gradually healed spontaneously during the ensuing 6 weeks. He died of *P. carinii* pneumonia 3 months later.

Discussion

All our patients were symptomatic because of their ulcers. They all had severe CD4-cell depletion, and none had concomitant oral lesions at the time of pre-

From Maine Medical Center, Portland, Maine; Swedish Medical Center, Seattle, Washington; and Medical Center of Delaware, Wilmington, Delaware. For current author addresses, see end of text.

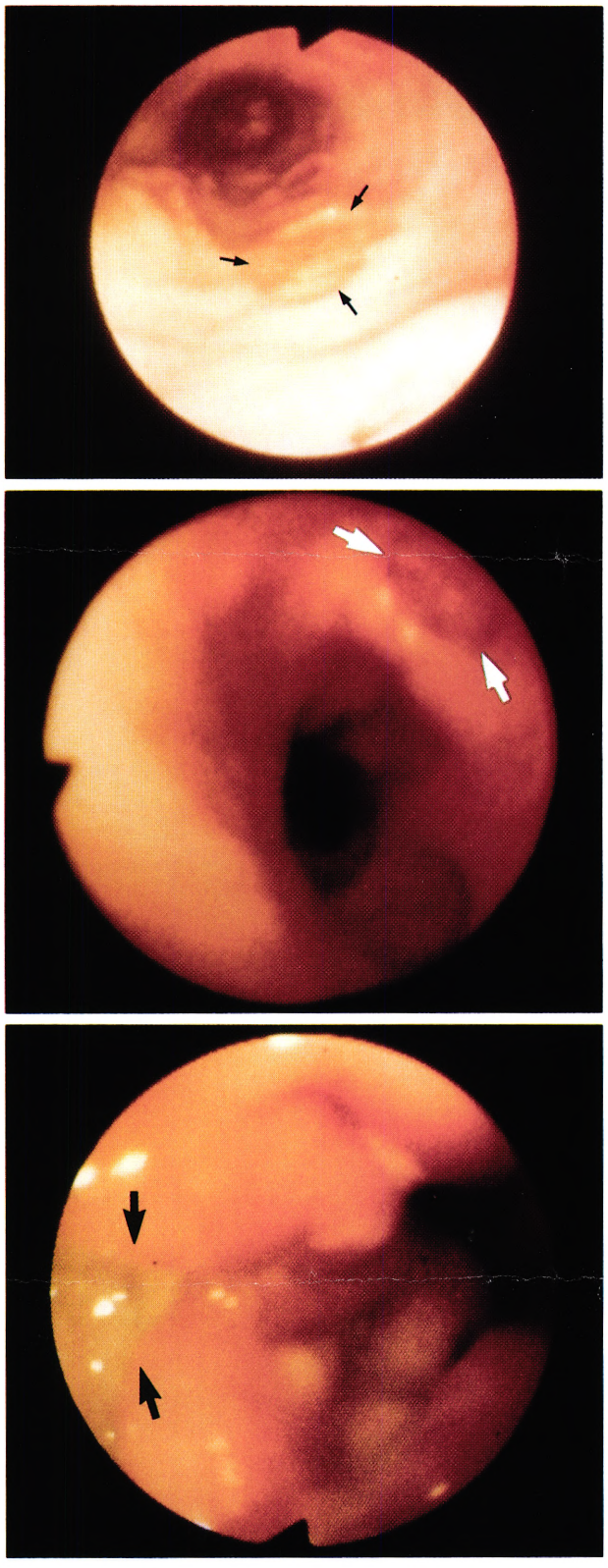

Figure 1. Top. Endoscopic appearance of one of the ulcers (*arrows*) in Patient 1. **Middle.** Endoscopic appearance of the giant esophageal ulcer in Patient 2. **Bottom.** Colonoscopic appearance of the caecum in Patient 4. Several small superficial ulcerations are shown.

sentation. Biopsy specimens showed acute inflammation without inclusions or fungal elements, and cultures were negative for viruses and fungi. Five of the six patients were treated with oral prednisone, 40 mg daily, and their symptoms improved in 48 to 96 hours. The course of treatment was 2 to 3 weeks, during which the corticosteroid was gradually tapered. In two cases, relapses required reinstitution of high-dose prednisone and a more gradual tapering of the dose. Although we cannot be sure that the colonic and esophageal lesions had the same cause, the histologic appearance and response to therapy of both were so similar that a common cause was suggested.

Thus, nonspecific ulceration of the gastrointestinal tract is a new syndrome associated with HIV infection. Although common in the general population and usually found only in the mouth, aphthous ulceration in HIV-infected persons appears to be more severe and more persistent and may involve areas of the gastrointestinal tract as well as the mouth and pharynx.

It is important to identify these ulcers because they may be mistaken for lesions caused by herpes simplex or cytomegalovirus and therefore will not respond to virus-specific therapies. When the lesions are limited to the oral cavity, topical corticosteroid therapy, such as 0.1% dexamethasone solution as a rinse, could be tried before resorting to systemic therapy. There are also anecdotal reports in the literature on other potential treatments for oral aphthous ulcers, including cimetidine (2), thalidomide (3, 4), and colchicine (Slome S. Personal communication). Interestingly, a recent report (5) documented in-vitro inhibition of HIV-1 by colchicine. One other case (6) of a giant esophageal ulcer that responded to prednisone has recently been reported.

Clinicians who see HIV-infected patients should be aware of this syndrome. If endoscopic biopsy specimens and cultures fail to show evidence of infection with herpesvirus, cytomegalovirus, or *Candida* species, empiric corticosteroid therapy is an option that may dramatically improve the condition of patients.

Presented as a poster MBP247 at the Vth International Conference on AIDS, Montreal, Canada, June 4-10, 1989.

Acknowledgments: The authors thank Drs. Marjorie Boyd and Herbert Kaufmann for referring their patients; the Audio-Visual Department, Maine Medical Center, for helping with the photographs; and Sharon Monn for typing the manuscript.

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Dr. Winslow: Medical Center of Delaware, Wilmington, DE 19880.

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Odynophagia from Aphthous Ulcers of the Pharynx and Esophagus in the Acquired Immunodeficiency Syndrome (AIDS)

Michael C. Bach, MD; August J. Valenti, MD; Douglas A. Howell, MD; and Thomas J. Smith, MD

Nonspecific aphthous ulcers of the mouth are common in immunocompetent patients (1). The ulcers are self-limited, rarely progress to involve the hypopharynx or esophagus, and do not usually cause odynophagia. We describe the cases of three patients with the acquired immunodeficiency syndrome (AIDS) who developed severe odynophagia with progressive weight loss, resulting from multiple aphthous ulcers of the hypopharynx and esophagus. No infectious agents could be identified either by biopsy or from culture, and empiric antiviral and antifungal therapy were not effective. Corticosteroid therapy provided prompt and dramatic relief and healing in each patient.

Patient 1

Patient 1, an 18-year-old man with factor VIII deficiency, had severe aphthous ulcers of the mouth recurring for several months. Biopsy in June 1987 showed acute and chronic inflammation. No infectious cause was identified. He was seropositive for human immunodeficiency virus (HIV) antibody, and a CD4 cell count was 12×10^9/L. Therapy with zidovudine (AZT) was begun in November 1987, but was discontinued because of neutropenia. In February 1988 he was hospitalized with a 13.5 kg weight loss, fever, and severe, progressive odynophagia. There were large ulcers of the tongue (Figure 1, top), lips, and gingiva.

Esophagoscopy showed ulcerating lesions of the hypopharynx and esophagus, some of which resembled *Candida* species. Biopsies showed no fungus or virus and there was no response to 1 week of treatment with ketoconazole, 400 mg/d. Within 48 hours after prednisone therapy, 40 mg/d was started, pain decreased dramatically, and the lesions rapidly healed over the next few weeks (Figure 1, middle). He has required maintenance doses of prednisone, 10 mg, because of recurrence as the dosage was tapered.

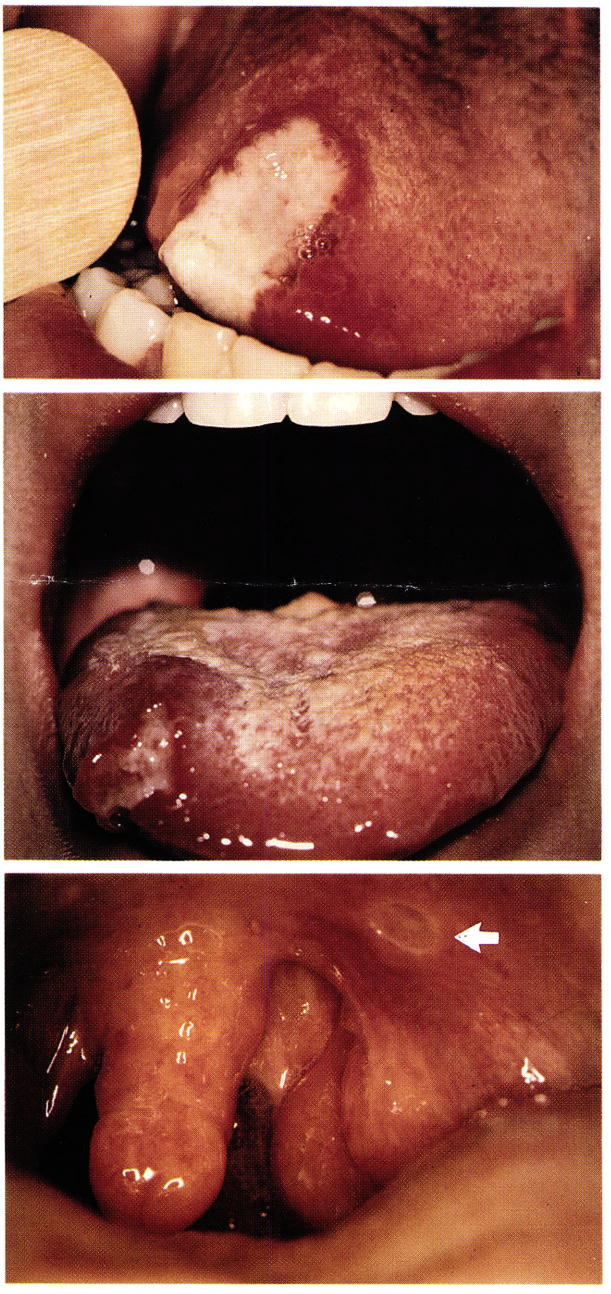

Figure 1. Aphthous ulcer of the tongue of Patient 1 (*top*). Appearance of the tongue lesion after 1 week of prednisone therapy in Patient 1 (*middle*). Aphthous ulcer (*arrow*) on the left anterior fauces in Patient 2 (*bottom*).

Patient 2

Patient 2, a 33-year-old homosexual man, developed cutaneous Kaposi sarcoma in February 1986. He was HIV antibody positive and his CD4 cell count was 383×10^9/L. In December 1987, during month 6 of treatment with zidovudine, 200 mg every 4 hours, he developed slowly progressive odynophagia, which interfered significantly with eating, and he had a weight loss of 2.7 kg over 2 weeks. An empiric trial of treatment with oral ketoconazole was not helpful.

Small aphthous ulcers were noted on his buccal mucosa and palate (Figure 1, bottom). He had aphthous ulcers of the hypopharynx and upper esophagus. Scrapings, biopsy samples, and cultures were negative for fungus, herpes, and cytomegalovirus. He was treated with oral prednisone, 40 mg/d, and his condition improved dramatically within 48 hours. Rapid tapering over 3 weeks resulted in recurrence of the ulcers and the dosage is now being slowly tapered.

From the Maine Medical Center, Portland, Maine; and the Swedish Hospital Medical Center, Seattle, Washington. For current author addresses, see end of text.

repr. ANN INT MED AUG 15 1989

Patient 3

Patient 3, a 40-year-old homosexual man, developed *Pneumocystis carinii* pneumonia in March 1987 and AIDS was diagnosed. He was begun on zidovudine therapy, 200 mg every 4 hours, in May 1987 and required daily ketoconazole for candida esophagitis. A CD4 cell count was 97×10^9/L.

In October 1987, he had a sore throat but findings from oral examination were normal. His symptoms gradually worsened and he had a weight loss of 6.75 kg over the next 3 weeks with increasing odynophagia. Small aphthous ulcers were seen on the posterior pharyngeal wall, hypopharynx, and arytenoid areas. Cultures for fungus, herpes, and cytomegalovirus were negative, and he did not respond to intravenous acyclovir therapy. His condition improved dramatically within 48 hours of treatment with intravenous methylprednisolone, 20 mg every 8 hours, and the dosage of oral steroids was tapered over the subsequent 4 weeks. He has had no recurrence in the intervening 5 months.

Candida species, herpes simplex, and cytomegalovirus are recognized causes of odynophagia and esophageal ulcers in patients with AIDS (2, 3). Cryptosporidia have rarely been found to cause this syndrome (4). Recently, unusual esophageal ulcers were documented in eight homosexual men (5). Biopsies showed enveloped virus-like particles resembling retroviruses.

Our cases were interesting in that two of the three patients were treated with zidovudine chronically and showed no other clinical evidence to suggest HIV activity. An early clue to hypopharyngeal or esophageal involvement was the appearance of oral aphthous ulcers. The dramatic clinical response to corticosteroid therapy in all three patients once opportunistic causes had been eliminated suggests a valuable therapeutic option in the management of this difficult condition.

Acknowledgments: The authors thank Dr. Marjorie Boyd for referring Patient 1; the Audio-Visual Department at Maine Medical Center for the photographs; and Sharon Monn for secretarial assistance.

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March 11, 1991

TO: DR. S.E. EKEID
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REGIONAL OFFICE FOR EUROPE
8 SCHERFIGSVEJ
DK - 2100 KOBENHAVN; DENMARK

FROM: SAM BROYLES
PROGRAM ASSISTANT; APEX (AIDS Provider Education Experience) San Francisco General Hospital

NUMBER OF PAGES INCLUDING COVER: **1**

IF INCOMPLETE TRANSMISSION OCCURS, PLEASE CALL SAM BROYLES AT ABOVE-LISTED NUMBER. THANK YOU.

****

In reference to your fax of March 8, 1991, there would be no change in the basic deposit of $25.00 per person. However, the rooms as previously described at the Hillpoint Inn will need to be reserved by deposit ***by March 15, 1991,*** *at the latest. After that date, it will become quite problematic to ensure housing in any facility for the participants. If at all possible, it would be to our mutual advantage if deposit funds in the amount of $300.00 could be located and forwarded as soon as possible to provide ensured and reserved housing for the participants. Please advise. Thank you.*

Sam Broyles

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TELEFAX 2348

Date: 8 March 1991

Mr Sam Broyles
Program Assistant
AIDS Provider Education Experience
San Francisco General Hospital
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USA

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Notre référence PH/ehj
Unser Zeichen
См. наш номер

Your reference
Votre référence
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На Ваш номер

FAX No.: (415) 476-0341

Number of pages to follow: 0

From: Svein-Erik Ekeid, M.D. Regional Coordinator, Global Programme on AIDS, WHO Regional Office for Europe, Copenhagen

Reserved 3/16/91

Dear Mr Broyles,

Accommodation for WHO/APEX - 29 April - 24 May 1991

Thank you for your communication of 25 February 1991 in which you address the question of accommodations. Since we are asking 6 countries to send 2-person teams, we could end up with odd numbers of each sex. As a result, I think we need to reserve 5 double occupancy, and 2 single occupancy accommodations.

Could you please indicate by return fax what changes this will require in the deposits.

Should it prove possible to accommodate all participants in double rooms, we will investigate the possibility of change at that time.

Yours sincerely,

Svein-Erik Ekeid

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Please address reply to undersigned at
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San Francisco, CA 94110

February 25, 1991

William D. Glenn
Carlotta Del Portillo
Co - Chairpersons
Leadership Recognition Dinner
San Francisco AIDS Foundation
P.O. Box 6182
San Francisco, CA. 94101-6182

Dear William and Carlotta,

Although I initially accepted your invitation to attend the Leadership Recognition Dinner and join other community leaders on the dinner committee, unfortunately I must withdraw my acceptance at this time; a prior pending commitment which has now come to fruition requires my presence in Venezuela on the night of the dinner. It is with great regret that I must decline and I am sure the dinner will be a distinguished gathering of those involved in the fight against AIDS. I will be with you in spirit.

Sincerely,

Connie Wofsy

Constance B. Wofsy, M.D.
Professor of Clinical Medicine

CW:sb

The Atlanta Journal
THE ATLANTA CONSTITUTION

Post Office Box 4689 Atlanta, Georgia 30302 (404) 526-5151

29 March 1991

Dear [redacted]:

Finally, lo these many months after the Snyder Chronicals comes the latest saga of the adventures of People to People's Eastward Ho Team 1!

The delay was partly a result of additional time spent inflicting Chinese (my version of it anyway) on the Chinese (Still a wonderful experience even without the assistance of the lovely, unflappable Miss Wang) and applying for various journalism fellowships for the next academic year (I am happy and slightly stunned to report I'll spend 1991-1992 as a public health fellow at Harvard University).

The story was written with the invaluable assistance of Tim Dondero, who kindly spent several hours of his time with me in Atlanta and contributed the photo shown on the front page; John Peabody, who graciously allowed me to spend about $150 in phone fees calling Manila; and Vince Gil, who again displayed remarkable endurance in reliving his experiences among sexually active Chinese in Chengdu.

I hope that these are not my last words on the subject, and I will, of course, send along any future ruminations on the East. No grades please. Just a postcard every now and then telling me how you're doing.

I apologize for the gang letter, but it seemed the most likely way to reach everyone sometime before my next trip to China in a decade or so.

I hope you're well, and I hope you'll stay in touch.

All my best,

Steve

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MEDICAL SERVICES

March 1, 1991

Dr. Constance B. Wofsy, MD
Ward 95 Bldg. 90
San Francisco General Hospital
995 Potrero Avenue
San Francisco, CA 94110

Dear Dr. Wofsy:

This is to inform you and your co-authors that we are planning to reprint in Syntex Journal Rounds the abstract from the following article:

> Medina I, Mills J, Leoung G, Hopewell PC, Lee B, Modin G, et al: Oral therapy for Pnuemocystis carinii pneumonia in the acquired immunodeficinecy syndrome. N Engl J Med 1990;323:776-782.

Syntex Journal Rounds is a quarterly journal about opportunistic infections in patients with AIDS, distributed as an educational service to physicians and other health-care professionals involved in the care of patients with AIDS.

We have already received permission to reprint the abstract from The New England Journal of Medicine. Would you please be so kind as to inform your co-authors? I am writing this letter to you, as yours was the only author's address appearing in the article.

Sincerely,

Judith H. Windt

Judith H. Windt
Managing Editor, Syntex Journal Rounds

cc to all authors