AIDS TREATMENT NEWS

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California ADAP Alert

by John S. James

Starting September 1, hundreds of California residents on ADAP (the AIDS Drug Assistance Program) are having prescriptions rejected on the grounds that their eligibility for the program has expired. In fact, most of them are still eligible for the services, but they need to re-apply for ADAP, since Federal regulations require that eligibility be re-established each year. Also, through an emergency procedure they can usually get their current prescriptions filled quickly, allowing them 30 days to complete the process of re-entering ADAP.

Unfortunately, few California ADAP recipients have been warned in advance that their eligibility is about to expire. Usually they first learn about this when their pharmacist tells them that their prescription was not approved—and often no one they are working with knows what is going on, or what needs to be done to assure continued drug supply.

If your prescription is rejected on the grounds that you are no longer eligible for California ADAP—even if you have an ADAP card which gives a later expiration date—you should:

1. Make sure that your pharmacist has submitted an emergency authorization form (the PMDC prior authorization form) so that your drug supply is not interrupted. Under a new

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Retroviruses Conference Scholarship Deadline Nov. 3

The 6th Conference on Retroviruses and Opportunistic Infections, January 31 to February 4 at the Sheraton Chicago, may be the most important scientific AIDS conference in 1999. Some scholarships have been made available; the deadline for applying for a scholarship is November 3. Information is available at www.retroconference.org:

> Requirements: Applicants must 1) be affiliated with a local AIDS treatment organization, 2) be involved in community outreach activities, and 3) have a commitment to share what was learned at the conference. Preference will be given to individuals representing diverse and under-represented populations who may not have access to community-based newsletters (community-based press are ineligible for this program) and to individuals who have not been Retroviruses Conference scholarship recipients in the past.
>
> Application Process: Applicants should submit 1) a resume (including applicant's history of volunteerism with any AIDS service organizations, community-based organizations, and/or PWA support groups and a list of any AIDS conferences applicant has attended previously), 2) a letter of application indicating whether the applicant is requesting a full or partial scholarship and including a statement outlining how the applicant would share knowledge acquired during the conference, and 3)

including prices (average wholesale price, per pill); the prices are from the January 1998 edition of the Medi Span *Hospital Formulary Pricing Guide*. This information also appears in print in *1998 Medical Management of HIV Infection*, by John G. Bartlett, M.D. The Web edition, which will be updated more frequently than the printed book, is at http://www.hopkins-AIDS.edu; select "Publications," then "Medical Management of HIV Infection." The prices are in Chapter 6, "Drugs: Guide to Information"; the prices are included with the drug listings, which are alphabetical by generic name.

11th National HIV/AIDS Update Conference; Abstract Submission Deadline November 1

The 11th National HIV/AIDS Update Conference, "Partnering Science and Practice," will be held March 23-26, 1999 at the Bill Graham Civic Auditorium in San Francisco. Abstracts for workshops and poster presentations are being accepted until November 1. The conference is organized in five tracks—prevention, public policy, research and clinical management, mental health, affected communities—and authors can submit proposals for consideration as a 90-minute workshop, 3-hour workshop, or poster presentation. Additional information is available from Cliff Morrison, Program Director, telephone 415-285-8410, fax 415-970-9013, email aidsupdt@aol.com. Abstracts can also be submitted using the World Wide Web at http://www.nauc.org.

Association of Nurses in AIDS Care, November 15-18, San Antonio

The eleventh annual conference of the Association of Nurses in AIDS Care, "Diversity: Walking Together Through the Rivers of Changes/La Diversidad: Caminando Juntos Entre los Rios de Cambios," will take place November 15-18, in San Antonio, Texas. Full registration is $395, and daily registration is $170. Reduced fees are available for members of the Association.

Cultural diversity will be highlighted at this year's conference. Sessions listed in the advance program include: Funding for HIV Care in the Future; Achieving Cultural Competency in HIV/AIDS Nursing; and The Future of HIV Care—Community-Based and Cost-Containment Care Systems. Additionally, the examination to become an AIDS certified registered nurse (ACRN) will be offered on Sunday, November 15. Advance registration on a space-available basis is required; contact the Professional Testing Corporation at 212-356-0660.

For more information contact the Association of Nurses in AIDS Care, 11250 Roger Bacon Drive, Suite 8, Reston, VA 20190. Telephone 703-925-0081, fax 703-435-4390, email AIDSNURSES@aol.com, http://www.anac.org/aids.

San Francisco: Hepatitis C Community Forum, Oct. 20

Community Health Resource Center is sponsoring a community forum about hepatitis C on Tuesday, October 20 at California Pacific Medical Center, 2333 Buchanan, Lobby Level-Conference Room. An information display will begin at 6:30 p.m. with the main program scheduled from 7:00 p.m. to 9:00 p.m. In addition to a patient panel, those scheduled to speak include a medical doctor and a naturopathic doctor/licensed acupuncturist.

Pre-registration is requested, phone 415-923-3155.

A non-profit, physician-directed project, Community Health Resource Center provides free and low cost health and wellness services. An ongoing support group for hepatitis C is available, as well as nutritional counseling, disease and medication management, and a health resource library. For more information: phone 415-923-3155, fax 415-441-5128, email chrcpmc@aol.com, or see http://www.citysearch.com/sfo/chrcatcpmc.

Cannabis and Cannabidiol: Interview with Robert Gorter, M.D.

by Fred Gardner

[Notes: (1) Robert Gorter, M.D., is associate clinical professor at the University of California San Francisco Medical Center (Department of Family and Community Medicine), and also the medical director of the European Institute for Oncological and Immunological Research, a nonprofit with headquarters in Berlin and offices in Milan and Amsterdam. (2) Cannabidiol (CBD) is a non-psychoactive ingredient of the hemp plant which is being studied for potential medical uses including treatment of head injury and certain strokes, as an anti-psychotic, and as an anti-inflammatory. (3) The references to "Anthroposophical" refer to Anthroposophy, a movement founded in 1924 by Rudolph Steiner (1861-1925). JSJ]

Robert Gorter, M.D., is organizing clinical trials of a cannabis extract, hoping to establish that it leads to weight gain in HIV and cancer patients. In July he attended the annual meeting of the International Cannabinoid Research Society, where he apprised colleagues of his progress and

caught up on theirs. We debriefed him in San Francisco in early August.

Fred Gardner: What is your interest in cannabis?

Dr. Gorter: My interest in cannabis goes back to the early 1970s. I studied medicine in Amsterdam in the 1960s and I lived in a commune where almost everybody "blowed" every day—but I never did. And usually in the middle of the night, people would meet in the kitchen and have fried eggs and snacks; they said that when you smoke, it stimulates your appetite.

When I settled down as an Anthroposophical family practitioner in Amsterdam in 1973, I had many cancer patients in my practice. Many had loss of appetite and severe weight loss. Many older people from Holland had never smoked pot. So we made an oral preparation for them. We grew cannabis in a city park, until it was discovered.

We made an alcohol extract of cannabis, and my patients took half a teaspoon a day twice a day, and they loved it. Almost all reported appetite stimulation after about a week. There was a clear mood elevation—they felt better. And many patients who were using opiates for pain control said they needed much less opiates with small amounts of cannabis. Most people gained weight, but not all. If patients were close to dying, weight gain was not seen.

Gardner: For how many years were you treating cancer patients in Amsterdam with cannabis?

From 1973 to 1983. At that time cannabis was also available as an injectable from Weleder, an Anthroposophical company that distributes natural medicines. I've used it as an injectable for backaches and muscle cramps and people with insomnia. But for stimulating appetite the injections did not work well; the patients needed a larger dose, delivered orally.

Gardner: And then you came to UCSF in 1983?

Dr. Gorter: In the Nancy Reagan years, I felt insecure about telling patients about medical effects of cannabis. But if people asked me, of course I would tell them what I knew. Then, in 1986, Marinol® (dronabinol) was developed, so right away I could prescribe Marinol for appetite stimulation. I have also tried it with patients with chronic pain. But many people had side effects. My patients who had experience with both cannabis and Marinol almost always preferred cannabis, because Marinol had more side effects, including headaches and a hung-over feeling. In 1989 I set up an efficacy trial of Marinol as an appetite stimulant in AIDS patients.

Gardner: What happened?

Dr. Gorter: After a delay it was conducted in Texas. In 1991 Marinol received approval of an additional indication for appetite stimulation in HIV infection.

In 1992 I took a sabbatical and went to Europe to conduct a clinical trial of Iscador in HIV patients. To make a long story short, I was offered an opportunity to establish the European Institute for Oncological and Immunological Research in Berlin, and since then I have been flying back and forth.

Gardner: What became of your cannabis-vs.-Marinol study?

Dr. Gorter: We decided to start a clinical trial in Europe to study Marinol against placebo and then compare cannabis against placebo and then cannabis against Marinol for its efficacy, toxicity and so on. It took me about two years of lobbying, but then the German government and the Dutch government agreed that it was time to have these studies done. Both governments have given me an official okay to conduct such a trial in about 800 AIDS and cancer patients. Our institute has developed an oral preparation of cannabis which we have named Cannador—from 'cannabis' plus 'dor/doron' for gift.

Gardner: You will not be testing smoked cannabis?

Dr. Gorter: For the elderly, in a hospital setting or a hospice, smoking raises all kinds of problems. And smoking cannabis is so strongly associated with recreational drug use, that it is not palatable to people in the government. A clean, standardized extract works better. Ours will be a whole-plant extract made from male and female plants, and standardized for its THC and other cannabinoid contents by thin-layer chromatography. We will process it in a fatty medium for packaging in a soft-gel capsule. [Note: THC, or tetrahydrocannabinol, is the main psychoactive ingredient in marijuana.]

Gardner: Do the male and female plants have significantly different components?

Dr. Gorter: Yes. Cannabis contains at least 600 different components; among them 64 different cannabinoids have been identified, and everybody agrees that there are more. And there are 10 times as many other substances. They differ from year to year depending on the soil, the weather, the degree of sexual separation, and other factors. The highest concentration of THC is in the glands of the female plant.

Gardner: Donald Abrams, M.D., told *Synapse* you were planning a study in the U.S. involving cannabis and appetite in HIV patients.

Dr. Gorter: As soon as the German government approved our protocol I sent it to the FDA, and in September of last year they accepted us under the Investigational New Drug program. But one of their pharmacists said "You can never standardize plant extracts." We said, "Maybe not for all the components, but for the main components, we can." They wanted more proof of that, which we have delivered, and they have accepted.

It was decided that we could go straight to a phase III trial, because so much is known already about safety.

But in February of this year we had a conference call from the same FDA committee but with a different chair; she said, "You have to do a phase I trial." We ended agreeing to do a combined phase I/II trial. I am now raising money for that trial and hopefully it will be conducted in the spring of next year. In the late fall we will start with the phase III trial at 18 universities in Germany, the Netherlands, Austria and Switzerland. There will be 360 cancer patients and 360 AIDS patients who have lost at least 5% of their body weight in the last six months, and who are candidates for appetite stimulation, and have been free of cannabis for at least four weeks (so we can test the efficacy of our preparation). So soon we will have both studies

running parallel—a phase III trial in Europe and a phase I/II in the US. [Phase I tests toxicity in humans; phase II tries to determine an optimum dose. Phase III is an efficacy trial against placebo or other medications—the key step in obtaining a license to market the drug. Phase IV trials, conducted after market approval, involve thousands of patients followed over time to assess long-term toxicity.]

Gardner: From what source are you obtaining your cannabis?

Dr. Gorter: The cannabis used in the U.S. will come from NIDA [the National Institute on Drug Abuse, which has authorized Professor Mahmoud ElSohly, a commercial grower employed by the University of Mississippi, to cultivate marijuana on their farmland for sale to the federal government.] The cannabis to be used in Europe will be purchased by the Dutch government, also from NIDA.

Gardner: NIDA's marijuana is reportedly weak and stale.

Dr. Gorter: I trust ElSohly to provide a suitable product. In any case, the concentrations we get in the extraction process are what matters, and we can control that.

We will soon start in Amsterdam and in England trials of Cannador on multiple sclerosis patients.

Gardner: There were references at the International Cannabinoid Research Society meeting to the immunosuppressant activity of THC.

Dr. Gorter: Only in high doses in animal studies that do not correspond to the pattern of human use. After a while you see a drop of blood pressure and immune dysfunction. Animals are generally given 125 milligrams of THC per kilogram body weight. That would be for humans 7 or 8 thousand milligrams per day. The average amount in a joint is about 10-15 milligrams; so 8 thousand milligrams is beyond every form of human use.

Cannabidiol

Dr. Gorter: In Berlin we will develop another form of Cannador with a much higher content of CBD (cannabidiol), and do a pilot project on patients with epilepsy. CBD counters, to some extent, the psychoactive effects of THC.

Gardner: How do you adjust to get a plant heavy on CBD and light on THC?

Dr. Gorter: You grow plants with high content of CBD. No problem.

Gardner: Does ElSohly have that kind of sophistication?

Dr. Gorter: We will collaborate and share our expertise.

For More Information

For more information, you can search the AIDSLINE and MEDLINE databases free through the World Wide Web, at http://igm.nlm.nih.gov. You can contact Dr. Robert Gorter at the European Institute for Oncological and Immunological Research, email robertgorter@compuserve.com, fax +49-30-315-744-44.

California ADAP Alert

(continued from page 1)

system which was started in October 1998, the pharmacist will receive instructions with the rejection notice. You must sign the form, acknowledging that you have been informed that you must re-apply to ADAP within 30 days. Without your signature, ADAP will not pay the pharmacist for the prescription.

2. Within 30 days you need to apply again to ADAP so that your eligibility will be re-established for another year; this cannot be done at the pharmacy, but must be through an ADAP enrollment center in your area. Your doctor may need to provide some medical information, so start early, as there could be delays due to the need for coordination among four different offices—pharmacist, doctor, enrollment center, and PMDC (Professional Management Development Corporation, located in San Leandro, which is the California ADAP contractor).

3. For answers to questions about these procedures, you, your pharmacist, or others can call PMDC toll-free, 888-311-7632 (888-311-PMDC), Monday through Friday 9 a.m. to 7 p.m., Saturday 9 a.m. to 5 p.m., or Sunday 11 a.m. to 4 p.m. Callers can use the voicemail to reach an eligibility worker during these hours.

If necessary, PMDC can refer you to an ADAP enrollment center in your area.

You can also call the same number 24 hours a day to verify your own eligibility electronically, using your ADAP identification number (which is usually the same as your Social Security number). Use the voicemail to select the electronic verification system.

According to the *PMDC Pharmacy Provider Manual*, a pharmacy which gets a "not eligible" message should call PMDC before turning the patient away. But there is no way to know how often this is done.

The rest of this article has background on why the problem has surfaced now, and on the process of applying or re-applying for ADAP.

Background: California ADAP

The Federal ADAP program is run separately by each state, which makes its own rules (subject to Federal regulations). To be eligible to receive prescription drugs under this program, you must have HIV, be a resident of the state, and have income within limits which are set by that state. The drugs which can be covered by ADAP vary tremendously by state. This article applies only to California.

Why Now?

California's current blizzard of prescription rejections started on September 1, and became much worse on October 1. There are likely to be many additional rejection notices in November (although a new procedure may handle them more smoothly). By next year this problem will largely correct itself automatically. Why did it happen now?

About a year ago California fundamentally changed the adminis-

by FRED GARDNER

It was in April, 1968, that I first heard a Vietnam veteran describe a seek-and-destroy mission as "seek-and-avoid." He said that most of the men in his company, an infantry unit stationed near Danang, didn't think the war seemed "worth it" in terms of life, limb and disrupted youth. "On patrol," he explained, "we were [illegible] posed to go a mile and [illegible] right? What we [illegible] yards, find us some heavy foliage, smoke, rap and sack out."

In the past two years, hundreds of thousands of American soldiers have used this tactic. Refusal to take part in combat has grown so widespread that it need no longer be surreptitious. G.I.'s leave their firebases with impunity; commanders fear that court-martialing them will undermine whatever remains of morale. Officers and NCO's who insist on ordering troops into the field are commonly "fragged"—hit by a grenade rolled under their tentflaps. Blatant racists are dealt with similarly. G.I.'s smoke manijuana freely, realizing that a round-up of potheads would deplete the infantry faster than you can say Hatfield-McGovern.

The meaning of the G.I.'s reluctance to fight has not been lost on the Pentagon, where the masterminds are expediting the volunteer Army and planning an ever greater role for the Air Force. But the American people have long been denied the information that it's their boys, not President Nixon, who are cancelling operations. In the Oct. 23 issue of Life there is an illuminating piece by John Saar: "You Can't Just Hand Out Orders," a portrait of a young company commander. We learn that Capt. Brian Utermahlen, West Point '68, enjoys a rapport with the men of his "exceptionally good company" because he hasn't court-martialed those who refuse to go to the field; hasn't persecuted the blacks (whose spokesman sympathizes with the N.L.F. and muses about fighting for liberation back home); hasn't busted the weed blowers; did dismiss a zealous sergeant who tried to enforce certain "less urgent orders"; and managed to lead a 17-day mission in which no one, friend or foe, got seriously hurt. The piece might aptly have been called "You Just Can't Hand Out Orders" and played as the story of a company's refusal—however low-key and unorganized—to fight. The portrait of Capt. Utermahlen, after all, seemed insignificant against the "background" of an Army that will not go into combat.

Perhaps the current mood of the G.I.'s is just too subtle—being neither but [illegible] kid [illegible] ing. This [illegible] at Cu Chi [illegible]

"They [illegible] panics for [illegible] go out to the [illegible] here anymore [illegible] goes visit some buddies at another base camp. Operations have become incredibly rag-tag; vehicles don't work for lack of maintenance; helicopters are just falling to the ground; airfields are falling apart. . . . Many guys don't even put on their uniforms anymore. I am almost always wearing a pair of keds, a blue tie-dye shirt and army pants I made into cut-offs. I put in an appearance at work sometimes to see if I've gotten any mail.

"It used to be they could get a couple of months of work out of new people but that is no longer the case. When new guys come into our company we rap how we've taken over and turn them on. Lately they have been segregating new guys, whom they call 'new meat.' 90th Replacement Battalion, the main processing station for newly arrived personnel is off-limits. They have barbed wire and guards all around it. You have to have a special pass to get in. It is also the outprocessing station for men returning to the states. They have been strictly segregated from the 'new meat.' When we have new men come in, the Sergeant Major personally escorts them from Long Binh. They rush them through processing, give big, lie-filled raps, and quickly send them to the field. . . .

"The American garrisons on the larger bases are virtually unarmed. The lifers have taken our weapons from us and put them under lock and key. Theirs. One black locked and loaded on the battalion CO recently because they were trying to send him into the field. About 10 other blacks backed him up. They just gave the guy a 212 (discharge). They have also been quite a few frag incidents in the battalion. . . ."

President Nixon may claim credit for phasing down the war; Congress may debate a timetable for pulling out; but the fact is that rank-and-file G.I.'s are ending the fighting on their own.

Fred Gardner, author of "The Unlawful Concert," works with the U.S. Servicemen's Fund, which sponsors