## Short-Term Effects of Cannabinoids in Patients with HIV-1 Infection

A Randomized, Placebo-Controlled Clinical Trial

Donald I. Abrams, MD; Joan F. Hilton, DSc; Roslyn J. Leiser, RN; Starley B. Shade, MPH; Tarek A. Elbeik, PhD; Francesca T. Aweeka, PharmD; Neal L. Benowitz, MD; Barry M. Bredt, MA; Bradley Kosel, PharmD; Judith A. Aberg, MD; Steven G. Deeks, MD; Thomas F. Mitchell, MPH; Kathleen MhaTigan, PhD; Peter Bacchetti, PhD; Joseph M. McCune, MD, PhD; and Morris Schambelan, MD

Background: Cannabinoid use could potentially alter HIV RNA levels by two mechanisms: immune modulation or cannabinoid-protease inhibitor interactions (because both share cytochrome

The identification of a CB2 receptor, found predominantly

Research Design and Procedures

Study clinicians admitted study participants to the General Clinical Research Center for a 4-day lead-in pe-

counts was additionally adjusted for baseline CD8 counts and vice versa. We added 10 to the cell counts to reduce the influence of very small values and then transformed to the  $\log_{10}$  scale to ensure model validity. These models estimate multiplicative effects on geometric means, which we described as percentage effects by converting the effect on the original log scale with the formula  $(10^{\rm effect}, 1)$  100%. For example, an effect of 0.05 is a 12% greater increase

increases in viral load of  $0.3\ log_{10}\ copies/mL$  (100%), our a priori threshold for concern.

Change in CD4<sup>+</sup> and CD8<sup>+</sup> Cell Subsets Figure 2

35. Kosel BW, Aweeka FT, Benowitz NL, Shade SB, Hilton JF, Lizak PS, et al. The effects of cannabinoids on the pharmacokinetics of indinavir and nel

C rr n A hor Addr ss s Drs. Abrams and Deeks: University of California, San Francisco, Positive Health Program, Ward 84, 995 Potrero Avenue, San Francisco, CA 94110.

Dr. Hilton: 500 Parnassus Avenue, San Francisco, CA 94143-0560.

Ms. Leiser: University of California, San Francisco, 143 Stillings Avenue, San Francisco, CA 94131.

Mr. Shade and Mr. Mitchell: University of California, San Francisco, 3180 18th Street, Suite 201, San Francisco, CA 94110.

Drs. Elbeik and Benowitz and Mr. Bredt: University of California, San Francisco, 1001 Potrero Avenue, San Francisco, CA 94110.

Dr. Aweeka: University of California, San Francisco, 521 Parnassus Avenue, San Francisco, CA 94143-0622.

Dr. Kosel: University of Washington, 325 9th Avenue, Seattle, WA 98104.

Dr. Aberg: Washington University, 4511 Forest Park, St. Louis, MO 63108.

Dr. Mulligan: San Francisco General Hospital, 1001 Potrero Avenue, Building 30, R3501D, San Francisco, CA 94110.

Dr. Bacchetti: University of California, San Francisco, 500 Parnassus Avenue, Room 423A West, San Francisco, CA 94143-0560.

Dr. McCune: Gladstone Institute, PO Box 419100, San Francisco, CA 94141-9100.

Dr. Schambelan: San Francisco General Hospital, Building 5, 5B6, San Francisco, CA 94110.

## A hor Con rib ions