IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

RICHARD ROE, ET AL., Plaintiffs, v. PATRICK M. SHANAHAN, ET AL., Defendants.	CIVIL ACTION NO. 1:18-cv-01565
NICHOLAS HARRISON, ET AL., PLAINTIFFS, V. PATRICK M. SHANAHAN, ET AL., DEFENDANTS.	CIVIL ACTION NO. 1:18-CV-00641

EXPERT REPORT OF W. DAVID HARDY, M.D.

I. INTRODUCTION

1. My name is W. David Hardy. I have been retained by counsel for Plaintiffs as an expert in connection with this litigation.

2. I am offering this report to provide my expert opinions regarding HIV—its etiology, the mechanism by which it operates to undermine a person's immune system, the routes and relative risks of transmission, the care and treatment of people living with HIV, the effect of treatment with antiretrovirals on the immunological and overall health of people living with HIV, and the effect of treatment on the risks of transmission.

3. The opinions I express are my own and do not reflect the official policy of any organization with which I am affiliated. I am not receiving any compensation for my work.

4. I am knowledgeable about the matters set forth below based upon my own knowledge and experience, as well as my review of various materials cited herein.

5. In the past four years, I have not offered testimony at trial or at a deposition.

II. PROFESSIONAL BACKGROUND & QUALIFICATIONS

6. I am currently the Chairman of the Board ("Chair") of the HIV Medicine Association and an Adjunct Professor of Medicine at the Johns Hopkins University School of Medicine. I have 36 years of experience in the care and treatment of people living with HIV, including 34 years of experience researching opportunistic infections, antiretroviral agents, immunotherapies, retroviral vector research, and gene therapy. My curriculum vitae is attached, which describes my education, work experience, and publications. *See* Attach. 1 (Hardy CV).

7. While serving as Chair of the HIV Medicine Association, I also served as Senior Director of Research at Whitman-Walker Health in Washington, DC, from 2015 to 2018. From 2013 to 2015, I was the Chief Medical Officer of Calimmune, a translational science company investigating gene-modified cellular therapies as a potential cure for HIV. Prior to that, I was the Director of the

Division of Infectious Diseases at Cedars-Sinai Medical Center and a Professor of Medicine at the David Geffen School of Medicine at UCLA from 2002 to 2013.

8. I received my medical degree from Baylor College of Medicine. I completed my residency in internal medicine at Harbor-UCLA Medical Center and completed a clinical fellowship in infectious diseases/immunology and clinical research at the UCLA School of Medicine from 1984 to 1986 under the direction of Dr. Michael Gottlieb, the physician who recognized and reported the first cases of AIDS. I later completed a post-doctoral fellowship at UCLA with Irvin Chen, PhD, focusing on molecular retrovirology.

9. For more than 30 years, I have been dedicated to the treatment of people living with HIV. In addition to research and teaching, I have served as Editor-in-Chief of *Fundamentals of HIV Medicine for the HIV Specialist*, the comprehensive textbook of the American Academy of HIV Medicine, and currently serve on that organization's Board of Directors as the Chair of the Education Committee. I also have a long history of working with a number of community-based organizations that provide or provided critical services for persons living with HIV, including AIDS Research Alliance, Alliance for Housing and Healing, Being Alive-Empowering People with HIV/AIDS, Project Angel Food, and AIDS Project Los Angeles.

III. BACKGROUND ON THE HUMAN IMMUNODEFICIENCY VIRUS

A. An Introduction to HIV

10. Since the Acquired Immune Deficiency Syndrome (AIDS) was first identified as a high-mortality disease in the United States in 1981, there has been incredible progress in better understanding its causative agent, the human immunodeficiency virus (HIV), as well as in the development of highly effective treatment of this disease.[1] Once considered invariably fatal

[1] *See generally*, Am. Acad. of HIV Med., *Fundamentals of HIV Medicine* (W. David Hardy ed., CME ed. 2017) (hereinafter "*Fundamentals of HIV Medicine*").

within a matter of years, HIV is now considered a chronic, treatable condition.[2] Today, persons with HIV who are diagnosed in a timely manner and engaged in medical care and treatment with antiretroviral medications experience minimal effects on their physical health and increasingly enjoy the life expectancy of those who do not have HIV.[3]

11. HIV attacks the body's immune system. Specifically, HIV attacks and progressively depletes the body's CD4+ T cells, commonly referred to as T cells. When HIV infects and takes over a CD4+ T cell, it uses the cell's biosynthetic resources to produce multiple copies of itself and then releases them to attack other CD4+ T cells, leaving the previous producer cell to die.

12. CD4+ T cells are an essential component of the human immune system, protecting the body from many types of infections and cancers. As HIV unrelentingly reduces the number of CD4+ T cells in the body, the weakened immune system progressively fails to protect a person from life-threatening infections and cancer.

13. Following the acute stage of infection, a person living with HIV enters a period of clinical latency that can last years. After 4–10 years, however, if the person does not receive appropriate treatment, the amount of virus in their blood (i.e., "viral load") will progressively rise and their CD4+ T cells dwindle away to low levels. Eventually, an untreated individual's CD4+ T cell count will drop below 200/mm^3 and/or the person will develop an opportunistic infection, one to which the body would not be susceptible without HIV-induced immunodeficiency. At this point, that person would be diagnosed as having AIDS.

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[2] *See id.*
[3] *See id.*

B. The Treatment of HIV

14. At almost any point along the course of HIV infection, treatment with modern antiretroviral therapy will halt and reverse the downward slope in immune function and restore the person to good health.

15. The early days of developing treatment for HIV (i.e., 1985–1995) produced dismal or only short-term beneficial results. Finally, in 1996, effective triple-combination antiretroviral therapy (ART) became available. Medical researchers discovered that to fight a rapidly replicating, rapidly mutating, diabolical virus, a combination of at least three antiretroviral medications that hit the virus in at least two vital areas could not only shut down HIV from reproducing and allow the immune system to rebuild, but could also prevent the virus from mutating and becoming resistant to the medications. This had been the major problem with previous mono- and dual-therapy approaches. Since 1996, the development of ART has advanced substantially. Initial triple-combination regimens required a person with HIV to take as many as 24 tablets daily, spread over 2–3 dosages each day, with and without food. These early regimens carried significant side effects, severe enough that fewer than 50% of those who started could tolerate the regimen for more than 6 months. Today, ART development has produced more potent drugs that suppress HIV quicker than before and are extremely well-tolerated and easy to take. These advances have led to the point where, today, multiple single-tablet regimens—combinations of 3 or 4 drugs co-formulated into one tablet—have made it possible to treat HIV with "one pill once a day."

16. With consistent adherence to their ART regimen, a person living with HIV sees their viral load drop and their CD4+ T cell count rebound.[4] Within 4–6 weeks, most people's HIV will become "virally suppressed," defined as fewer than 200 copies of the virus per milliliter of blood,[5] and shortly after that, they would have an "undetectable"[6] viral load, which is generally defined as fewer than 50 copies per milliliter of blood.

17. Persons living with HIV who consistently adhere to their antiretroviral medications will achieve and maintain an undetectable viral load.[7] There is an effective treatment regimen for virtually every person living with HIV. Reasons for not reaching an undetectable viral load are related to a lack of consistent access to the health care and/or other social determinants of health, such as unstable housing or food insecurity, that make medication adherence more difficult. Once a person is consistently taking an effective ART regimen and has achieved an undetectable viral load, their medical care needs become quite simple. The DHHS Guidelines recommend medical monitoring visits only once every 6 months to re-check viral

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[4] *See Fundamentals of HIV Medicine*, at Ch. 17: Overview of ARV Therapy.
[5] *See* U.S. Centers for Disease Control and Prevention, *Evidence of HIV Treatment and Viral Suppression in Preventing the Sexual Transmission of HIV* (Dec. 2018), https://www.cdc.gov/hiv/pdf/risk/art/cdc-hiv-art-viral-suppression.pdf; U.S. Centers for Disease Control and Prevention, *HIV Treatment as Prevention* (Dec. 18, 2018), https://www.cdc.gov/hiv/risk/art ("[V]iral suppression [is] defined as having less than 200 copies of HIV per milliliter of blood.")
[6] At one time, the testing technologies were not sensitive enough to reliably detect the virus below approximately 50 copies per milliliter. Newer testing technologies are able to detect HIV below this level, but the term "undetectable" is still used to describe a viral load at or below this level.
[7] *See Fundamentals of HIV Medicine*, at Ch. 17: Overview of ARV Therapy.

load, sometimes CD4+ T cells and other potential health issues.[8] Increasingly, it is becoming common for physicians to see a well-suppressed, adherent patient once a year.

18. Development of resistance to an ART regimen does not occur randomly. Almost exclusively, resistance occurs because a patient is not adherent to their prescribed medications. One of the important features of the ART regimens used today is that if the virus is suppressed, the development of mutations that lead to resistance becomes impossible. With three or more medications combatting the virus using multiple targets at the same time, the virus is not able to mutate around any of those medications. For patients who develop resistance due to non-adherence, constructing a different regimen to which their virus has not developed resistance and to which they are subsequently adherent will regain viral suppression for that patient.[9] I would not expect a patient to develop viral resistance to medication after abruptly stopping or discontinuing medications. I would expect that someone who stopped taking their medication would continue to have a suppressed viral load for 4–12 weeks.[10] They would not develop symptoms of HIV for several months or years after discontinuing medication.

19. As antiretroviral medications have become increasingly better tolerated over the past 20 years, adherence to ART regimens has grown increasingly easier. Today, most people living with HIV are on a single tablet regimen ("STR")—in which all three or four medications are combined into one pill—that is taken once a day. STRs have few, if any, dietary restrictions and although they contain multiple medications, their side effects are minimal, transient, and

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[8] *See* U.S. Dep't of Health and Human Services, *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV* (Oct. 25, 2018), https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/282.
[9] *Fundamentals of HIV Medicine*, at Ch.21: HIV-1 Resistance to Antiretroviral Drugs.
[10] Li JZ et al., *The size of the expressed HIV reservoir predicts timing of viral rebound after treatment interruption*, 30 AIDS 343, 343-53 (2016).

overall well-tolerated. Long gone is the time when persons living with HIV had to plan their lives around their medications and the attendant side effects.

20. A person who is diagnosed with HIV in a timely manner and adheres to their prescribed ART regimen has nearly the same life expectancy as a person who is not living with HIV.[11] The great majority of previous short-term and medium-term adverse effects associated with ART regimens have almost vanished. Gone are the days of persistent nausea, diarrhea, headaches, dizziness, unpleasant dreams, and body-shape-disfiguring lipodystrophy. Today, with near-normal anticipated lifespans, the majority of persons living with HIV enjoy a renewed and welcomed sense of long-term well-being and hope for an almost medically unblemished life. Some reports of higher prevalence of common medical problems such as cardiac disease, kidney disease, and bone demineralization have appeared, but have not been confirmed as being distinct from the effects of normal aging, a new phenomenon for many persons living with HIV.

C. The Transmission of HIV

21. HIV can be transmitted via only specific body fluids—blood, semen, pre-seminal fluid, rectal fluids, vaginal fluids, and breast milk.[12] For transmission to occur, these fluids from a person living with HIV must either come in contact with a mucous membrane or cut or punctured tissue or be directly injected into the bloodstream (with a needle or syringe). Mucous

[11] *See* U.S. Centers for Disease Control and Prevention, *About HIV/AIDS* (Mar. 9, 2019), https://www.cdc.gov/hiv/basics/whatishiv.html.
[12] *See* U.S. Centers for Disease Control and Prevention, *HIV Transmission* (Oct. 31, 2018), https://www.cdc.gov/hiv/basics/transmission.html

membranes are the moist tissues found inside the rectum, vagina, penis, and mouth. HIV is not spread through saliva, sweat, tears, urine, or feces.[13]

22. Most commonly, HIV is transmitted by engaging in sexual activities or sharing needles or syringes. Outside of the contexts of sexual activity and transmission via routes such as sharing of drug-injection equipment, blood transfusion, needle sticks, or perinatal exposure (including breastfeeding), transmission of HIV is rare. For all other activities—including biting, spitting, and throwing of body fluids—the CDC characterizes the risk as "negligible" and further states that "HIV transmission through these exposure routes is technically possible but unlikely and not well-documented."[14] HIV is approximately 10 times less transmissible than hepatitis C and 100 times less transmissible than hepatitis B.[15] In fact, the CDC estimates the chances of HIV transmission via a blood-filled needle puncture at 0.3%.[16]

23. Contrary to popular belief, HIV is not an easily transmitted virus. In the absence of treatment and condom use, the CDC estimates that the per-act risk of transmission for the riskiest sexual activity—receptive anal intercourse—is approximately 1.38% (138 out of 10,000 exposures).[17] The per-act risk of transmission for other sexual activities is between zero and .08%.[18]

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[13] *See Fundamentals of HIV Medicine*, at Ch. 3: Modes of HIV Transmission; *see also* U.S. Centers for Disease Control and Prevention, *HIV Transmission* (Oct. 31, 2018), https://www.cdc.gov/hiv/basics/transmission.html

[14] *See* U.S. Centers for Disease Control and Prevention, *HIV Risk Behaviors: Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act* (Dec. 4, 2015), www.cdc.gov/hiv/risk/estimates/riskbehaviors.html (hereinafter "CDC Risk Behaviors").

[15] *See* U.S. Centers for Disease Control and Prevention, *Exposure to Blood, What Healthcare Personnel Need to Know* (July 2003), https://www.cdc.gov/hai/pdfs/bbp/exp_to_blood.pdf.

[16] *See* CDC Risk Behaviors.

[17] *See id*.

[18] *See id.*

24. Furthermore, it is now universally accepted by the HIV scientific community that people living with HIV who are virally suppressed or have an undetectable viral load are incapable of transmitting the virus to HIV-negative persons.[19] Advances in our understanding of the transmission-blocking effects of ART have led the CDC to declare that " . . . people who take ART daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to an HIV negative partner."[20] This statement speaks loudly to the high quality of scientific evidence underlying this pronouncement. I personally received this information with great enthusiasm. Having watched this area of research in HIV interpersonal transmission for years, the results of HPTN 052 and the PARTNER 1 and 2 studies tested the question of HIV sexual transmission between MSM (men who have sex with men) as well as heterosexuals with rigorous scientific study design, follow-up, and analysis. The fact that no linked transmissions occurred between any MSM or heterosexual serodiscordant couples after thousands of condomless sex acts provides scientific evidence to confirm the power of ART in preventing HIV transmission. It is not surprising that there have been and will be rare case reports of suspected HIV transmission challenging the CDC's statement (e.g., Case report: Is transmission of HIV-1 in non-viraemic, serodiscordant couples possible?). However, significant limitations in these reports purportedly documenting a new seroconversion frequently invalidates them.

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[19] *See* U.S. Centers for Disease Control and Prevention, *HIV Treatment as Prevention* (Dec. 18, 2018), https://www.cdc.gov/hiv/risk/art

[20] *See* U.S. Centers for Disease Control and Prevention, *Dear Colleague: Information from CDC's Division of HIV/AIDS Prevention* (Sept. 27, 2017), https://www.cdc.gov/hiv/library/dcl/dcl/092717.html; U.S. Centers for Disease Control and Prevention, *Treatment as Prevention* (Dec. 18, 2018), http://www.cdc.gov/hiv/risk/art ("People with HIV who take HIV medicine as prescribed and get and keep an undetectable viral load have effectively no risk of transmitting HIV to their HIV-negative sexual partners.").

25. As further stated in the CDC letter, "Across three different studies, including thousands of couples and many thousands of acts of sex without a condom or pre-exposure prophylaxis (PrEP), no HIV transmissions to an HIV-negative partner were observed when the HIV-positive person was virally suppressed"[21] (i.e., a viral load of fewer than 200 copies/ml).

26. Based on these studies regarding the effect of a suppressed or undetectable viral load on sexual transmission risk, and the extremely low—and possibly only theoretical—risk of transmission via blood splash and other non-injection activities, I am reasonably certain that it is not possible for a person with a suppressed or undetectable viral load to transmit HIV through such exposures.

D. The Risk of Neurocognitive Impairment is Speculative, at Best

27. I understand that in August 2018, at the request of Congress, the Department of Defense ("DoD") submitted a report titled *Department of Defense Personnel Policies Regarding Members of the Armed Forces Infected with Human Immunodeficiency Virus* ("2018 Report").[22] This report provides "[a] description of policies addressing the enlistment or commissioning,

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[21] The cases referenced in the CDC letter: Myron Cohen et al., *Prevention of HIV-1 Infection with Early Antiretroviral Therapy*, 365 New Eng. J. of Med. 493, 493–505 (Aug. 11, 2011) (explaining the results of HIV Prevention Treatment Network Study No. 052); AJ Rodger et al., *Sexual Activity Without Condoms and Risk of HIV Transmission in Serodifferent Couples When the HIV-Positive Partner Is Using Suppressive Antiretroviral Therapy*, 316 J. of the Am. Med. Ass'n 171, 171–181 (2016) (explaining the results of the PARTNER study); Andrew Grulich et al., HIV Transmissions in Male Serodiscordant Couples in Australia, Thailand and Brazil, University of South Wales (Feb 26, 2015), https://www.croiconference.org/sites/default/files/posters-2015/1019LB.pdf (explaining the results of the Opposites Attract study reported at the Conference on Retroviruses and Opportunistic Infections (CROI) in 2015).

[22] Dep't of Def., *Department of Defense Personnel Policies Regarding Members of the Armed Forced Infected with Human Immunodeficiency Virus: Report to the Committees on the Armed Services of the Senate and House of Representatives* (Aug. 2018) (hereinafter "2018 Report").

retention, deployment, discharge, and disciplinary policies regarding individuals with this condition [HIV]."[23]

28. The 2018 Report contains a section on "Recent Findings Signifying Impairments Despite Viral Suppression and Asymptomatic HIV."[24] Specifically, the Report suggests that people living with HIV on ART *may* develop certain types of neuro-cognitive impairment (NCI).[25] But the 2018 Report then indicates the "impact of these *potential* NCI on a Service member's readiness, resilience, and/or retention is currently unknown."[26] In other words, it does not appear that the DoD has determined that the development of NCI is likely, much less that it would have any significant impact on the readiness, resilience, or retention of service members living with HIV. Such possible, but not well-documented, side effects that some researchers are *beginning* to believe *may* occur after long-term infection with HIV can and should be dealt with, if they occur, on a case-by-case basis. The occurrence of NCI as a result of an HIV diagnosis and/or HIV treatments is far too rare and speculative to justify a policy that would prevent all people living with HIV from serving in the military. In fact, the 2018 Report states that "HIV positive patients diagnosed and managed early during the course of HIV infection had a low prevalence of NCI. ***This is comparable to matched HIV-uninfected persons***."[27] In short, the DoD's own report says that the prevalence of NCI is "comparable" to the prevalence of NCI in the general population, which is consistent with my experience. A 2013 study found that people living with HIV who had been diagnosed and managed early had a similar prevalence of NCI

[23] *Id.* at 1.
[24] 2018 Report at 20.
[25] *Id.* (emphasis added).
[26] *Id.* at 21 (emphasis added).
[27] *Id.* at 20 (emphasis added).

compared to the individuals without HIV.[28] Another study found that HIV status had less of an effect on cognition than years of education, age, and reading level.[29] Therefore, there does not appear to be any evidence that NCI would be more likely to affect service members with HIV, especially because those service members would be receiving care for their HIV.[30] In fact, the DHHS guidelines only reference NCIs in older people taking ART and do not recommend testing in any population.[31]

29. To the extent that NCI does occur in service members living with HIV, their onset could be addressed under the general retention or deployment standards and/or the specific retention and deployment standards relating to neurodegenerative disorders.

IV. CONCLUSION

I understand HIV is now a relatively easy-to-manage, chronic condition that, when properly treated, presents no cognizable risk to the health or safety of others through occupational exposures, including exposures that could potentially occur during military service.

I declare under penalty of perjury that the foregoing is true and correct.

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[28] Nancy F. Crum-Cianflone et al., *Low Prevalence of Neurocognitive Impairment in Early Diagnosed and Managed HIV-Infected Persons*, 80 Am. Acad. of Neurology 371, 375 (2013).
[29] Richard W. Price, *HIV-Associated Neurocognitive Disorders: Epidemiology, Clinical Manifestations, and Diagnosis*, Wolters Kluwer (last updated Oct. 2018), https://www.uptodate.com/contents/hiv-associated-neurocognitive-disorders-epidemiology-clinical-manifestations-and-diagnosis.
[30] Blaylock Dep. 147:13–148:1; Shell Dep. 301:22–302:19.
[31] *See* U.S. Dep't of Health and Human Services, *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV* (Oct. 25, 2018), https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/282.

Executed this 22nd day of March, 2019

W. David Hardy, M.D.

ATTACHMENT 1

Curriculum Vitae
W. David Hardy, M.D.

PERSONAL HISTORY:

Title:	Adjunct Professor of Medicine Division of Infectious Diseases Johns Hopkins University School of Medicine
OFFICE ADDRESS:	4627 47th Street, NW, Washington, DC 20016-4436
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Mobile Phone:	(310) 709-3505
PLACE OF BIRTH:	Dallas, Texas
CITIZENSHIP:	U. S. Citizen
PARTNER:	Barry Goldblatt

EDUCATION & TRAINING:

1974-1977	University of Texas at Austin, Texas; (Zoology/Classics) Summa Cum Laude
1977-1981	Baylor College of Medicine, Houston, Texas; Doctor of Medicine with Honors
1981-1982	Internship in Internal Medicine, Department of Medicine, Baylor College of Medicine Affiliated Hospitals, Houston, Texas
1982-1984	Residency in Internal Medicine, Department of Medicine, Harbor-UCLA Medical Center, Torrance, California
1984-1986	Clinical Fellowship in Infectious Diseases and Clinical Immunology (Mentors-Michael S. Gottlieb, MD/Lowell Young, MD), Department of Medicine, University of California - Los Angeles School of Medicine, Los Angeles, CA
1984-1986	Clinical Research Fellowship (Mentor-Michael S. Gottlieb, MD), UCLA AIDS Center, Department of Medicine, University of California – Los Angeles School of Medicine, Los Angeles, California
1998-2002	Laboratory Research Fellowship, Laboratory of Irvin S. Y. Chen, Ph.D., Department of Microbiology, Immunology and Molecular Genetics, David Geffen School of Medicine, UCLA, Los Angeles, CA

LICENSURE:

District of Columbia, #043801
State of California, #C-40623
State of Texas #F-9536

BOARD CERTIFICATION:

1984	Diplomat, American Board of Internal Medicine, Internal Medicine
2015	Diplomat, American Board of Internal Medicine, Infectious Diseases

PROFESSIONAL EXPERIENCE:

1984-1986	Staff Physician, Department of Medicine, UCLA School of Medicine, Los Angeles, California
1986	Visiting Assistant Professor, Division of Clinical Immunology/Allergy, Department of Medicine, University of California-Los Angeles School of Medicine, Los Angeles, California (Full-time Faculty)
1986-1987	Assistant Clinical Professor of Medicine, Division of Infectious Diseases, Department of Medicine, University of California - San Diego School of Medicine, San Diego, California (Full-time Faculty)
1986-1987	Co-Investigator, NIH/ NIAID-sponsored AIDS Clinical Trials Unit (ACTU) University of California - San Diego School of Medicine, San Diego, California
1986-1987	Staff Physician, Owen Clinic (HIV Outpatient Clinical Services), University of California - San Diego School of Medicine, San Diego, California
1987-1993	Assistant Clinical Professor of Medicine, Division of Infectious Diseases, Department of Medicine, University of California - Los Angeles School of Medicine, Los Angeles, California (Full-time Faculty)
1987-1996	Director, Infectious Diseases/Immunology (HIV/AIDS) Clinic, Department of Medicine, UCLA Medical Center, Los Angeles, California
1987-1996	Co-Investigator, NIH/NIAID-sponsored AIDS Clinical Trials Unit (ACTU), University of California – Los Angeles School of Medicine, Los Angeles, California
1988-2010	President and Cofounder, Los Angeles Physicians AIDS Forum (LAPAF), UCLA Center for AIDS Research and Education (CARE; 1988-1996), Independent HIV/AIDS-focused Continuing Medical Education (CME) Provider, Los Angeles, California
1990-1996	Co-Principal Investigator, NIH/NEI-sponsored Studies of the Ocular Complications of AIDS (SOCA), Department of Ophthalmology, University of California - Los Angeles School of Medicine, Los Angeles, California
1993-1996	Associate Clinical Professor of Medicine, Division of Infectious Diseases, Department of Medicine, University of California, Los Angeles, School of Medicine, Los Angeles, California (Accelerated Promotion on Full-time Faculty)

1993-1996	Principal Investigator, NIH/NIAID-sponsored, Multidisciplinary HIV/AIDSTraining Grant (T32AI07388), UCLA AIDS Institute, University of California – Los Angeles School of Medicine, Los Angeles, California
1994-1996	Associate Director for Community Liaison, UCLA Center for AIDS Research (CFAR), UCLA AIDS Institute, University of California - Los Angeles School of Medicine, Los Angeles, California
1994-1996	Program Director, Infectious Diseases Fellowship Training Program, Division of Infectious Diseases, Department of Medicine, University of California – Los Angeles School of Medicine, Los Angeles, California
1996-2002	Clinical Associate Professor of Medicine, Department of Medicine, University of California - Los Angeles School of Medicine, Los Angeles, California (Volunteer Teaching Faculty)
1996-2002	Scientific Director of Research, Research Department, Pacific Oaks Medical Group, Beverly Hills, California
1996-2002	Private Practice Specializing in Infectious Diseases and HIV Medicine, Pacific Oaks Medical Group, Beverly Hills, California
2002-2009	Principal Investigator, NIH/NIAID - K08 AI-49759-01A2, *"Developing Foamy Virus Vectors for HIV-1 Vaccine Applications"*, Cedars-Sinai Medical Center, Los Angeles, California (5-year grant with 2, 1-year no-cost extensions)
2002–2013	Director, Division of Infectious Diseases, Department of Medicine, Cedars-Sinai Medical Center, Los Angeles, California
2002-2012	Associate Professor of Medicine-in-Residence, Division of Infectious Diseases, Department of Medicine, David Geffen School of Medicine, University of California - Los Angeles, Los Angeles, California
2002–2013	Associate Program Director, Cedars-Sinai-UCLA Multi-campus Infectious Diseases Fellowship Training Program (Cedars-Sinai Medical Center, Olive View- UCLA Medical Center, Greater Los Angeles VA Medical Center), Los Angeles, California
2003-2012	Co-Principal Investigator, NIH/ NIAID-funded U01, "*Solid Organ Transplantation in HIV: Multi-site Study,* Departments of Medicine and Surgery, Cedars-Sinai Medical Center, Los Angeles, California
2007-2012	Co-Investigator, NIH/NIMH-funded R01, "*HIV, Aging and Cognition: A Synergism?"*, Department of Psychiatry and Behavioral Medicine, Cedars-Sinai Medical Center, Los Angeles, California
2008-2011	Associate Program Director, NIH/NCRR-sponsored General Clinical Research Center (GCRC), Cedars-Sinai Medical Center, Los Angeles, California

2011–2013 Associate Program Director, NIH/NCATS-sponsored Clinical and Translational Research Center (CTRC), UCLA CTSI, Cedars-Sinai Medical Center site, Los Angeles, California

2012-2015 Clinical Professor of Medicine, Department of Medicine, David Geffen School of Medicine, University of California - Los Angeles, Los Angeles, California [Full-time Faculty (2012-2013), then Volunteer Faculty (2013-2015)]

Medical Officer, State of California Institute of Regenerative Medicine (CIRM)-funded/private (Calimmune) collaborative phase I studies of gene-modified CD4+ T cells and CD34+ hematopoietic stem/progenitor cells to cure HIV infection (NCT01734850).

Chief Medical Officer, State of California Institute for Regenerative Medicine (CIRM)-funded/private (Calimmune) collaborative phase I studies of gene-modified CD4+ T cells and CD34+ hematopoietic stem/progenitor cells to cure HIV infection (NCT01734850).

Senior Director of Evidence-based Practices (Research), Whitman-Walker Health, Washington, DC

ACTG Investigator – Johns Hopkins University CRS, Johns Hopkins University School of Medicine Clinical Trials Unit (CTU), AIDS Clinical Trials Group (ACTG), Baltimore, Maryland

Site Principal Investigator, Multicenter AIDS Cohort Study (MACS), Johns Hopkins University School of Public Health, Baltimore, Maryland (Whitman-Walker – MACS/SHARE expansion site)

Clinical Professor of Medicine, Division of Infectious Diseases, Department of Medicine, George Washington University School of Medicine and Health Sciences, Washington, DC

Investigator and Executive Committee, District of Columbia - Center for AIDS Research (DC CFAR), Washington, DC

Adjunct Professor of Medicine, Johns Hopkins University School of Medicine, Division of Infectious Diseases, Department of Medicine, Baltimore, MA

Investigator, NIH-Martin Delaney HIV Cure Collaboratory- BELIEVE- Multi-site Research HIV Cure Research Project, Washington, DC (P.I.-Doug Nixon, MD, PhD)

PROFESSIONAL ACTIVITIES:

Quality Improvement Committees:

2002 - 2013 Co-Chairman- Pulmonary-Infectious Diseases Performance Improvement Committee, Department of Medicine, Cedars-Sinai Medical Center, Los Angeles, California

22002 – 2013 Member, Department of Medicine Performance Improvement Committee, Cedars-Sinai Medical Center, Los Angeles, California

22002 – 2013 Member, Antibiotic Utilization Review Committee, Pharmacy Department, Cedars-Sinai Medical Center, Los Angeles, California

22008 -- 2013 Member, Hospital-acquired Infection Task Force, Cedars-Sinai Medical Center, Los Angeles, California
Hand Hygiene Working Group
Antibiotic Stewardship

Academic Service Committees

2005 – 2013 Member, Institutional Biosafety Committee (IBC), Burns Research Institute, Cedars-Sinai Medical Center, Los Angeles, California

2006 - 2012 Member, Committee on Academic Appointments and Promotions, Department of Medicine, David Geffen School of Medicine, UCLA, Los Angeles, California

2007 – 2013 Member, Scientific Advisory Committee, General Clinical Research Center, Burns Research Institute, Cedars-Sinai Medical Center, Los Angeles, California

2007 – 2013 Member, Physician Well-Being Committee, Medical Staff Office Cedars-Sinai Medical Center, Los Angeles, California

2009 – 2013 Member, Graduate Medical Education Committee, Academic Affairs,Cedars-Sinai Medical Center, Los Angeles, California

2010 – 2013 Member, Institutional Review Board (IRB), Burns Research Institute,Cedars-Sinai Medical Center, Los Angeles, California

Scientific Committees

1988-1993 NIH/NIAID-AIDS Clinical Trials Group (ACTG) Opportunistic Infection Committee and Protozoan Pathogen Study Group,

1990-1996 NIH/NEI – Steering Committee for Studies of the Ocular Complications of AIDS (SOCA)

1992-2010 Co-Chairman, 2nd, 3rd, 4th, 5th, 6th, 7th, 8th, 9th, 10th ,11th, 12th, 13th, 14th, 17th, 19th and 20th National HIV Clinical Care Options (CCO) for HIV CME Conference.

1993-1996 NIH/NIAID-ACTG Opportunistic Infection Committee – Viral Pathogen Study Group

1993-1996 NIH/NIAID-ACTG Primary Infection, Phase II/III Clinical Trials Working Group

1992, 1994, 2000, 2002 Scientific Organizing Committee, 1st, 2nd, 5th and 6th International Congress on Drug Therapy in HIV Infection, Glasgow, Scotland

2007 *American Academy of HIV Medicine (AAHIVM)/American Heart Association (AHA) Joint Committee on Cardiovascular Complications in HIV-infected Patients, AAHIVM, Washington, DC*
- Prevention strategies for cardiovascular diseases in HIV-infected patients writing subcommittee

2010-present *Centers for Disease Control and Prevention (CDC) Prevention with Positives (PwP) Review Committee and Consultant, CDC, Atlanta, Georgia*

2015-present *Performance Evaluation Committee (PEC), NIH/NIAID-funded AIDS Clinical Trials Group (ACTG)*

2016-present *Investigator-HIV Reservoirs and Viral Eradication (Cure) Transformative Science Group (TSG), NIH/NIAID-funded AIDS Clinical Trials Group (ACTG)*

2017-present Co-chair- ACTG protocol A5370 – "Safety and Immuno-therapeutic Activity of Anti-PD-1 Antibody (REGN2810) in HIV-1-infected Participants on Suppressive cART: A Phase I/II, Double-blind, Placebo-controlled, Multiple Dose Study Ascending Multiple Dose Study"

Community Organization

1989-1996

Community Services Center, Los Angeles, California

1990-1996 Board of Directors, AIDS Project - Los Angeles (APLA), Los Angeles, California

1990-2000 Scientific Advisory Committee, Search Alliance (Community-based clinical research organization), Los Angeles, California

1991-1994 Board of Directors, Southwest Community-based AIDS Trials Group [NIH-sponsored Community Program for Clinical Research on AIDS (CPCRA)], Los Angeles, California

1996 – present Ambassadors Council, AIDS Project - Los Angeles (APLA), Los Angeles, California

1996 - 2007 Medical Advisory Committee, AIDS Healthcare Foundation (AHF; HIV healthcare providing organization), Los Angeles, California

2000 - 2006 Board of Directors, Project Angel Food (home delivery of meals to person with AIDS and other life-threatening illnesses), Los Angeles, California

2008 – 2015	Board of Directors, Aid for AIDS (housing, financial assistance and food for persons and families with AIDS), Los Angeles, California
2012- 2015	Board of Directors, AIDS Research Alliance (community-based, HIV Cure and clinical research organization), Los Angeles, California
2013- 2015	Chairman, Board of Directors, AIDS Research Alliance (community-based, HIV Cure and clinical research organization), Los Angeles, California

PROFESSIONAL ASSOCIATIONS:

1984 – present	American College of Physicians (ACP), Member
1985 – present	American Society for Microbiology (ASM)
1985 – present	Infectious Diseases Society of America (IDSA)
1988 – present	International AIDS Society (IAS)
1988 – 2010	Los Angeles Physicians AIDS Forum (President and Co-founder)
1989 – present	International Society for Antiviral Research
2000 – present	HIV Medicine Association (HIVMA)
2000 – present	American Academy of HIV Medicine (AAHIVM)
2005 – 2010	Board of Directors - California Chapter of the American Academy of HIV Medicine (AAHIVM)
2005 – 2008	Chairman, Board of Directors, California Chapter of the AAHIVM
2005 – present	National Board of Directors, AAHIVM
2008 – present	- Chairman, Education Committee
2008 -- present	- Member, Executive Committee
2010 -- present	HIV Medicine Association (HIVMA) - Research Awards Committee
2011 – 2014	Board of Directors, HIV Medicine Association (HIVMA), Infectious Diseases Representative
2016-2020	Chair-elect (progression to Chair in 2018), Board of Directors, HIV Medicine Association (HIVMA), Infectious Diseases Society of America

HONORS AND SPECIAL AWARDS

1993	Commitment to Service Award from Los Angeles Shanti Foundation (provider of emotional and psychological support for persons with HIV/AIDS; $30,000 Research Award)
2007	Spirit of Hope Award from Being Alive-Empowering People with HIV/AIDS (Community-based HIV/AIDS Service Organization)
2010	Clinical Trial Exceptional Service Award from the Pharmaceutical Researchers and Manufactures Association (PhRMA)

2011 Alliance Humanitarian Award from Alliance for Housing & Healing (Aid for AIDS/Serra Project—provides house and direct financial grants to persons and families with HIV)

2012 Research Achievement Award; AIDS Research Alliance, World AIDS Day Concert Ceremony, Los Angeles, California

RESEARCH GRANTS:

Research Support

NIH-sponsored

2014/04/01 – 2019/03/31
U01 AI035042 Margolick (PI) 2.0 calendar
NIH/NIAID $1,869,107
Subcontract Hardy (PI)
Multicenter AIDS Cohort Study: Natural History Study of HIV-1 in Gay and Bisexual Men

The MACS is an ongoing prospective study of the natural and treated histories of HIV-1 infection in homosexual and bisexual men.

2013/12/01-2020/11/30
UM1AI069465 Flexner/Gupta (PIs) 2.4 calendar
NIH/NIAID

$2,047,780

Subcontract Hardy (PI)
The Johns Hopkins Baltimore-Washington-India Clinical Trials Unit (BWI-CTU)

The goals of this project are to support AIDS research through clinical studies.

2016/07/01-2021/06/30
1UM1AI12661701 (NIAID) $291,076 1.44 calendar
Nixon, Doug (PI)
Subcontract Hardy (PI)
BELIEVE: Bench-to-Bed Enhanced Lymphocyte Infusions to Engineer Viral Eradication
BELIEVE is a new Martin Delaney HIV Cure Collaboratory seeking to create and translate
new technologies aimed at curing HIV infection.
Role: Site PI /Co-Investigator

2017/07/01-2022/06/30

R01DA043089 (Celentano) 0.6 calendar
NIH $429,521
Subcontract Hardy (PI)
Identifying and Engaging Urban HIV-infected and -uninfected Young Black and Latino Men Who Have Sex with Men in Care.

2017/12/01-2022/11/30
UG3AI133669
.42 calendar
NIH (Wirtz) $140,000
Subcontract Hardy (PI)
American Cohort to Study HIV Acquisition among Transgender Women at High Risk

2017/06/01-2018/31/08
5P30Ai117970-03 $12,000
.6 calendar
Greenberg (PI)
Subcontract Hardy (PI)

DC CFAR Membership and Executive Leadership Board

Completed:

2014/04/01-2018/01/10
CDC Foundation
Sustainable Health Center Implementation PrEP Pilot (SHIPP) Study
Subcontract Coleman (PI)
Nationwide study looking at the implementation of PrEP within health centers and adherence.

1. NIH NCATS CTSI – UL1RR033176 (PI-Melmed)
Clinical and Translational Research Institute (CTSI) at UCLA
Clinical and Translational Research Institute (CTSI) is funded by the NIH NCRR to provide an infrastructure to investigators to facilitate their clinical and translational research, in a primarily outpatient and community-based settings and with access to core lab facilities.
Role: Assistant Program Director -
.4 calendar Cost: $72,000 (in salary support)
Duration: 3/01/2011-2/29/16

2. Cedars-Sinai Medical Center Finance Department and Intellectual Property Department, *"East Meets West: In-Vitro Study of Herbal Medicines against Resistant Bacteria"*.
   This project analyzes the antibacterial activity of herbal extracts in *in vitro* experiments alone as well as in combination with synthetic antibiotics against multidrug-resistant(MDR) bacteria. The goal of this research is to identify a specific molecular compound conferring antibacterial properties.
   Role: Principal Investigator – 0.12
   calendar Cost: $391,158
   Duration: 10/1/2009 – 9/30/2010; 10/1/2010 – 9/30/2011; 10/1/2011-9/30/2012,10/1/2012-9/30/2013

3. Gilead Sciences
   Protocol # GS-US-236-0102

A Phase3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Emtricitabine/Tenofovir Disoproxil Fumarate/GS-9350 vs (Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults

The primary objective of this study is to evaluate the safety and efficacy of a regimen containing the quadruple agent co-formulated single tablet of elvitegravir/emtricitabine/tenofovir disoproxil fumarate/cobicistat vs triple agent co-ormulated single tablet of efavirenz/emtricitabine/tenofovir disoproxil fumarate in HIV-1 infected, antiretroviral treatment-naïve adult subjects.
Role: Principal Investigator
Cost: $167,400
Duration: 2/1/2010 – 12/31/2013

4. GSK/ ViiV Healthcare
   GSK- 113086/SPRING2

A Phase III Randomized, Double-blind Study of the Safety and Efficacy of GSK134957250 mg Once Daily vs Raltegravir 400 mg Twice Daily Both Administered with Fixed-dose Dual Nucleoside Reverse Transcriptase Inhibitor Therapy Over 96 Weeks in HIV-1 Infected Antiretroviral Therapy-naïve Adult Subjects

The goal of this study is to compare a new investigational integrase inhibitor drug dolutegravir (GSK 1349572) dosed at 50 mg once daily vs raltegravir 400mg twice daily, currently the only FDA-approved integrase inhibitor and thus the current standard-of-care, both with either abacavir/lamivudine or tenofovir DF/emtricitabine, in treatment-naïve, HIV-1-infected subjects.
Role: Principal Investigator
Duration: 11/1/2010 – 10/31/2013
Cost: $57,425

5. GSK/ViiV Healthcare
   GSK-11762/SAILING

"A Phase III Randomized, Double-blind Study of the Safety and Efficacy of GSK 1349572 50 mg Once Daily vs Raltegravir 400 mg Twice Daily, both Administered with an Investigator-selected Background Regimen Over 48 Weeks in HIV-1 Infected, Integrase Inhibitor-Naïve, Antiretroviral Therapy-Experienced Adults

The goal of this study is to compare the antiviral efficacy of the new investigational integrase inhibitor dolutegravir (GSK 1349572) dosed at 50 mg once daily compared to raltegravir 400 mg twice daily both in combination with a background regimen consisting of one to two fully active agents in HIV-1-infected, integrase inhibitor naïve, therapy-experienced subjects.
Role: Principal Investigator
Duration: 12/6/2010 – 12/5/2013
Cost: $50,088

Gilead Sciences
GS264-0110
"A Phase 3, Randomized, Open-label Study to Evaluate the Safety and Efficacy of a Single Tablet Regimen of Emtricitabine / Rilpivirine / Tenofovir Disoproxil Fumarate Compared with a Single Tablet Regimen of Efavirenz / Emtricitabine / Tenofovir Disoproxil Fumarate in HIV-1 Infected, Antiretroviral Treatment-naïve Adults
The primary objective of this study is to evaluate the efficacy of a single tablet regimen of emtricitabine/rilpivirine/tenofovir disoproxil fumarate (FTC/RPV/TDF) compared with a single tablet regimen of efavirenz/emtricitabine/tenofovir disoproxil fumarate (EFV/FTC/TDF) in HIV-1 infected, antiretroviral treatment-naïve adult subjects.
Role: Principal Investigator
Duration: 3/1/2012 –3/1/2014
Cost: $118,675

P fizer/ViiV A4001095

"A Multicenter, Randomized, Double Blind, Comparative Trial of Maraviroc + Darunavir/Ritonavir versus Emtricitabine/Tenofovir + Darunavir/Ritonavir for Treatment of Antiretorviral-Naive HIV-infected Patients With CCR5 Tropic HIV-1.
The study aims to examine whether or not a once-daily dosing of the new combination of maraviroc (Selzentry®) with darunavir (Prezista®) and ritonavir (Norvir®) will be as safe and effective as another once-daily combination routinely used containing darunavir, ritonavir, and Truvada® (a combination of entricitabine and tenofovir). Maraviroc belongs to a relatively new class of drugs called CCR5 inhibitors which block HIV from entering a target cell.
Role: Principal Investigator
Duration: 12/1/2011-11/30/2013
Cost: $96,000

6. Vertex
VX11-950-115

An Open-Label, Phase 3 Study of Telaprevir in Combination With Peginterferon Alfa-2a (Pegasys®) and Ribavirin (Copegus®) in Subjects Coinfected With Genotype 1 Hepatitis C Virus and Human Immunodeficiency Virus Type 1(HCV/HIV-1).
The proposed study (Vx 11-950-115) is a phase III clinical study to confirm the effectiveness of the new protease inhibitor, telaprevir in HCV treatment in HIV co-infected patients. This study will enroll individuals infected with HIV and HCV genotype 1 who have or have not received prior anti-HCV drug treatment
Role: Principal
Investigator Duration:
3/1/12-2/28/14Cost:
$120,000

7. Gilead
GS 334-0123

*A Phase 3, Open-label Study to Investigate the Efficacy and Safety of GS-7977 (sofosbuvir) plus Ribavirin for 12 Weeks in Chronic Genotype 1, 2 and 3 Hepatitis C Virus (*HCV) and Human Immunodeficiency Virus (HIV) Co-Infected Subjects.*
This is a phase III clinical study to investigate the effectiveness and safety of a new HCV drug, GS-7977 plus Ribavirin for 12 weeks or 24 weeks for HCV treatment in HIV-HCV co-infected patients.
Role: Principal
Investigator Duration:
9/1/12-8/31/2014 Cost:
$130, 000

NIH/NIAID - K08 AI-49759-01A2 (PI-Hardy)
Number: PA-00-003
"*Developing Foamy Virus Vectors for HIV-1 Vaccine Applications"*
The goals of the study are to develop and optimize recombinant HIV-1/Foamy Virus vectors. KO8 Mentored Clinical Scientist Development Award.
Role: Principal Investigator; 75% Effort
Total Direct Costs: $515,000
Duration: 08/01/02 – 04/30/09 (no cost extensions)

NIH/NIAID - 1 U01 AI052748-01A1 (PI-Stock)
"Solid Organ Transplantation in HIV; Multi-Site Study"
The primary aim of this study is to evaluate the safety and efficacy of solid organ transplantation in people with HIV disease by conducting a prospective, multi-center cohort study of HIV-positive (+) patients who undergo kidney or liver transplantation.
Role: Site Co-PI - .012 calendar
Annual Direct Cost: $120,000
Duration: 08/15/03 – 01/31/10; 2/1/2010 – 7/31/2013

NIH/NIMH – 5R01MH058532-10 (PI-Goodkin)
"HIV, Aging and Cognition: A Synergism?"
The goal of this project is to determine if age interacts with HIV infection to result in a higher prevalence and more rapid progression of cognitive-motor impairment, decreases in functional status, decreases in CD4+ cell count, increases in viral load,

progression of CDC stage, and decreased survival time.
Role: Co-investigator – 0.12 calendar
Annual Direct Cost: $436,665
Duration: 01/26/2007 – 11/30/2008; 12/1/2008 – 12/31/2012

NIH/NCRR – M01-RR00425 (PI-Melmed)

General Clinical Research Center

The General Clinical Research Center is funded by the NIH NCRR to provide an infrastructure to investigators to facilitate their clinical research, in a primarily outpatient setting and with access to core lab facilities.
Role: Assistant Program Director - .4 calendar
Cost: $72,000 (in salary support)
Duration: 11/30/2008 – 12/01/2011

UCLA AIDS Institute/Pendelton Trust Seed Grant

"Foamy Virus Vectors for Gene Therapy and Vaccine Studies

The purpose of this study is to optimize foamy virus vectors for future use as HIV vaccine and potential gene therapy applications.
Role: Principal Investigator –
Cost: $50,000
Duration: 05/01/2004 – 04/30/2006

Gilead Sciences

Protocol #GS-US-236-0103

"*A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Emtricitabine/Tenofovir Disoproxil Fumarate/cobicistat vs. Ritonavir-boostedAtazanavir Plus Emitricitabine/Tenofovir Disoproxil Fumarate in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults"*

The primary objective of this study is to evaluate the safety and efficacy of a regimen containing the quadruple agent co-formulated single tablet of elvitegravir/emtricitabine/tenofovir disoproxil fumarate/cobicistat vs ritonavir-boosted atazanavir plus emitricitabine/tenofovir disoproxil fumarate in HIV-1 infected, antiretroviral treatment-naïve adult subjects
Role: Principal Investigator
Duration: 2/1/2010 – 1/31/2013
Cost: $20,125

Bionor Immuno AS

Protocol CT-BI Vacc-4x2007/1: A Phase II, Randomized, Double-Blind, Multicenter, Immunogenicity Study of Vacc-4x versus Placebo in Patients Infected with HIV-1 Who Have Maintained an Adequate Response to ART"

The primary purpose of this study is to evaluate the effect of Vacc-4x immunization versus placebo on CD4+ cell counts, T-cell function and T-cell proliferation, response to treatment interruption of antiretroviral therapy and the proportion of subjects restarting treatment within 24 weeks after stopping ART).

Role: Principal Investigator
05/19/2008 – 04/18/2012
Cost: $108,328

Merck - CSRI #200387; IRB #4066-01
Clinical Trial V520-022 – A phase II, multi-center, double-blind, randomized, placebo-controlled probe study with an additional open-label control arm to evaluate the safety and immunogenicity of a 3-dose regimen of the MRKAd5 HIV-1 gag vaccine in subject with chronic hepatitis C virus infection
Role: Principal Investigator - .06 calendar
Cost: $15,750
Duration: 05/014/04 – 9/30/2005

Boehringer Ingelheim
Protocol No. 1182.12) Phase III, Open-label, Randomized, Parallel Group Pharmacokinetics Trial of Tipranavir (TPV/RTV), Alone or in Combination with Saquinavir (SQV), Amprenavir (APV) or Lopinavir (LPV), Plus an Optimized Background Regimen, in Multiple Antiretroviral (ARV) Experienced Patients.
Role: Principal Investigator
Cost: $51,110
Duration: 6/14/04 – 1/31/07

Boehringer Ingelheim
Clinical Trial 1182.17 - A Long-term Open-label Rollover Trial Assessing the Safety and Tolerability of Combination Tipranavir and Ritonavir use in HIV-1Infected Subjects.
Role: Principal Investigator
Cost: $13,814
Duration: 9/01/04 – 8/31/08

Pfizer, Inc.
Protocol 1029: "A Multi-center, Randomized, Double-blind, Placebo-controlled Trial of a Novel CCR5 Antagonist, UK-427,857, in Combination with Optimized Background Therapy versus Optimized Background Therapy Alone for the Treatment of Antiretroviral- Experienced, non-CCR5-tropic HIV-1 Infected Subjects"
The purpose of this study is to determine wheter the new study drug, UK-427, 857 has effective anti-HIV activity in treatment-experienced patients with few remaining treatment options, who have either mixed tropic (both CCR5 and CXCR4) and non CCR- 5 tropic HIV.
Role: Principal Investigator - .06 calendar
Cost: $12,500
Duration: 01/01/2005 – 12/31/06

International Antiviral Therapy Evaluation Consortium (IATEC)
Protocol #05-IAT-0110: "A Randomized, Controlled, Open-label, 48-week Study to Assess Differences in Changes in Plasma Lipid Profile between Patients on

Saquinavir/Ritonavir or Atazanavir/Ritonavir in Combination with Tenofovir Disoproxil Fumarate and Emtricitabine as a First-line Regimen.
The purpose of this study is to compare several outcomes to two different once-daily protease inhibitor PI-based + Truvada® anti-HIV treatment medication regimens.
Role: Principal Investigator - .012 calendar
Cost: $46,067
Duration: 10/01/2006 – 09/30/2007; 10/01/2007 – 09/30/2009

9. GlaxoSmithKline
GRZ107460): "A Phase 2a, Multicenter, Randomized, Parallel, Double-Blind, Dose Ranging, Placebo-Controlled Study to Compare Antiviral Effect, Safety, Tolerability and Pharmacokinetics of GSK364735 Monotherapy Versus Placebo Over 10 days in HIV-1 Infected Adults"
This study is to evaluate GSK364735 (an integrase inhibitor) for the treatment of HIV infection. Integrase inhibitors are a new class of anti-HIV medications. For HIV to reproduce, its genetic make-up must be spliced into the genetic make-up of the human T-cell (a type of immune cell attacked by HIV). This study is the first of its kind being done in HIV + persons to see if this investigational drug is safe and effective.
Role: Principal Investigator - .06 calendar
Cost: $26,559
Duration: 12/15/06 – 12/15/2007

Pfizer *Protocol #A4001050: "A multi-center, open label, expanded access trial of Maraviroc"* This is an expanded access protocol for Pfizer's investigational anti-HIV medication, maraviroc which makes the drug available to persons needing new treatment options for their HIV infection. Maraviroc is currently in Phase III clinical trials as a new anti-HIV treatment for HIV infection. The study will make maraviroc available for free to HIV+ persons needing treatment and collecting safety and efficacy data..
Role: Principal Investigator - .06 calendar
Cost: $17,580
Duration: 02/01/2007 – 01/30/2008

Tibotec Pharmaceuticals
"A Randomized, Controlled, Open-label Trial to Make TMC114/RTV Available to HIV+ Patients with Limited Treatment Options"
The purpose of this study is to look at the long term safety, tolerability, and effectiveness of TMC114 combined with a low dose of Ritonavir (RTV) compared to Kaletra (the current gold-standard protease inhibitor for HIV treatment) when used in subjects with HIV infection.
Role: Principal Investigator - 1% effort
Cost: $25,350
Duration: 11/11/05 – 12/11/07; 12/12/2007 – 06/11/2008

Pfizer *Protocol 1026: A Multi-center, Randomized, Double-blind, Comparative Trial of a Novel CCR5 Antagonist, UK-427,857, in Combination with Zidovudine/Lamivudine versus Efavirenz in Combination with Zidovudine / Lamivudine for the Treatment of Antiretroviral-naïve HIV-1 Infected Subjects"*

The purpose of this study is to determine the anti-HIV effectiveness of the new anti-HIV drug, UK 427,857 in combination with other anti-HIV medications against HIV infection in HIV+ patients who have never taken HIV medications and whose HIV is CCR5 tropic"

Role: Principal Investigator - .06 calendar
Cost: $43,483
Duration: 01/01/2005 – 09/10/2010

Pfizer, Inc.

Protocol # A400-1078: Phase IIb, Pilot Study of Novel Combination of Maraviroc + Atazanavir/Ritonavir vs Atazanavir/Ritonavir + Tenofovir/Emtricitabine for the Treatment of Naïve HIV-Infected Patients with R5 HIV-1

Role: Principal Investigator
Duration: 4/3/2009 – 4/02/2012
Cost: $32,290

Pfizer

Protocol 1027: A Multi-center, Randomized, Double-blind, Placebo-controlled Trial of a Novel CCR5 Antagonist, Maraviroc, in Combination with Optimized Background Therapy Versus Optimized Background Therapy Alone for the Treatment of Antiretroviral-experienced HIV-1 Infected Subjects

The purpose of this study is to determine the effectiveness of the new anti-HIV drug maraviroc in combination with other anti-HIV medications against HIV infection in treatment-experienced patients whose HIV is CCR5 tropic).
Role: Principal Investigator - .012 calendar
Cost: $142,901
Duration: 01/01/2005 – 12/31/07; 1/01/2008 – 12/31/2010

INVITED LECTURES: (since returning to academic medicine in March 2002)

1. Grand Rounds, Division of Pulmonary/Critical Care Medicine, Department of Medicine, Cedars-Sinai Medical Center, "Update on HIV Research", Cedars-Sinai Medical Center, Los Angeles, CA, August 27, 2002

2. Grand Rounds, Division of Pulmonary/Critical Care Medicine, Department of Medicine, Cedars-Sinai Medical Center, "Update from the XVth World AIDS Conference" Cedars- Sinai Medical Center, Los Angeles, CA, August 18, 2004

3. Second Annual Tough Decisions Made Easier: Clinical Management of Treatment- experienced HIV + Patients, UCLA Center for AIDS Research & Education (CARE), UCLA-Bradley International Hall, Los Angeles, CA, October 22, 2004

4. Grand Rounds, Division of Infectious Diseases, Department of Medicine, Feinberg School of Medicine, Northwestern University "Management of Neurologic Complications in the HAART Era", Chicago, Illinois, October 27, 2004

5. Post ICAAC/Glasgow Conferences Review: "Update on Antiretrovirals Therapy", AIDS Clinical Research Initiative of America (ACRIA), Plaza Hotel, New York, NY, December 2, 2004

6. Los Angeles Gay & Lesbian Center Visiting Faculty Program: "HIV Protease Inhibitor Update", Los Angeles, CA, March 4, 2005

7. Department of Medicine House Staff Noon Conference: "Methicillin-resistant *Staphylococcus aureus*", Department of Graduate Medical Education, Cedars-Sinai Medical Center, Los Angeles, CA, March 28, 2005

8. Grand Rounds, Divisions of Infectious Diseases, Department of Medicine, and Department of Pediatrics, University of Texas at Dallas School of Medicine "Treatment of HIV Infection: New Strategies, New Agents", Dallas, TX, April 8 and 9, 2005.
   (two separate lectures; one emphasizing treatment for adult patients, one for pediatric patients) Grand Rounds, Division of Maternal-Child Health, Department of Pediatrics, Keck School of Medicine, University of Southern California (USC), "Update of HIV Antiretroviral Therapy with Emphasis on Prevention of Mother-to-Child Transmission of HIV", USC School of Medicine/LAC-USC Medical Center, Los Angeles, CA, April 26, 2005

9. Grand Rounds, Department of Psychiatry and Behavioral Sciences, Cedars-Sinai Medical Center, "Update on HIV Treatment and Drug-Drug Interactions", Los Angeles, CA, April 28, 2005

10. Grand Rounds, Genitourinary and HIV Medicine Department, Royal Free Hospital," HIV Treatment Guidelines: An American Perspective", London, UK, August 25, 2005

11. Grand Rounds, Department of Medicine, Royal Free Hospital, "Novel Approach to HIV Vaccine Development", UK, August 29, 2005

12. European AIDS Clinical Society (EACS) Advanced Course on HIV, " "HIV Vaccine Development", Montpelier University, Montpelier, France, August 26-27, 2005

13. Grand Rounds, Department of Medicine, Cedars-Sinai Medical Center "HIV/AIDS: The Global and National Pandemic", Los Angeles, CA, September 16, 2005

14. Grand Rounds, Division of Infectious Diseases, Department of Pediatrics, Keck School of Medicine, University School of Medicine, "HIV as a Chronic Disease and Associated Complications ", Children's Hospital, Los Angeles, CA, October 25, 2005

15. Grand Rounds, Division of Pulmonary/Critical Care Medicine, Department of Medicine, Cedars-Sinai Medical Center, "Progress in HIV Research", Cedars-Sinai Medical Center, Los Angeles, CA, October 26, 2005

16. Didactic Lecture: "HIV Treatment Guidelines", ID Combined Conference, GLAVAMC, Los Angeles, CA, February 14, 2006

17. Los Angeles Physicians AIDS Forum: "Post 13th Conference on Retrovirus & Opportunistic Infections Update", March 7, 2006, Le Meridian Hotel, Los Angeles, CA

18. ID Combined Conference: "Post 13th Conference on Retrovirus & Opportunistic Infections Update", WVAHCS, Los Angeles, CA, March 7, 2006

19. "HIV Treatment: Recent Progress", Physicians from the California Men's Colony at San Luis Obispo, CA, May 30, 2006

20. Invited Lecture for Symposium on Advances in HIV Therapy, "HIV Tropism: Biology of Both Viral and Human Determinants and Therapeutic Applications", Paulista Congress of Infectology, Sao Paulo, Brazil, August 25, 2006

21. Los Angeles Physicians AIDS Forum: "Update from 2006 International AIDS Conference, Hyatt Regency Century Plaza, Los Angeles, CA, September 9, 2006

22. ICAAC Satellite Symposium: Consult with the HIV Experts: "Optimizing HIV Therapy for Treatment-experienced Patients, Moscone Center, San Francisco, CA, September 29, 2006

23. IDSA Satellite Symposium: Emerging Therapies in the Blockade of HIV Binding: "Early Inhibitors: Clinical Progress Thus Far", Sheraton Centre Toronto Hotel, Ontario, Canada, October 11, 2006

24. Continuing Medical Education Program: "Initiating HIV Therapy", Ecotrust Conference Center, Portland, OR, October 24, 2006

25. Infectious Diseases Noon Conference: "New Therapies for HIV Infection", El Rio Community Health Center, Tucson, AZ, February 2, 2007

26. Grand Rounds, Division of Infectious Diseases, Department of Pediatrics, Keck School of Medicine, University of Southern California,, "Long Term Safety & Efficacy of Tenofovir-based Regimens Compared to Thymidine-analog Containing Regimens", Children's Hospital Los Angeles, CA, March 27, 2007.

27. Annual Investigators' Meeting of the NIH-sponsored Multi-Site Solid Organ Transplantation Study in HIV+ Patients, "Novel Therapies for HIV Infection: Use in Solid Organ Transplant Patients", Washington, DC, April 29, 2007

28. Grand Rounds, Division of Infectious Diseases, Department of Medicine, Harbor-UCLA Medical Center, "New Classes of Antiretrovirals: The Potential Clinical Role of Integrase Inhibitors and Entry Inhibitors", Torrance, CA, July 17, 2007

29. CME Dinner Program: "Current Perspectives on HIV-associated Metabolic and Morphologic Abnormalities", Boston, MA, August 17, 2007

30. National Minority AIDS Council (NMAC) Annual Conference, Seminar: Special Issues in HIV Care: "New Therapies and Treatments", Palm Springs, CA, November 8, 2007

31. HIV Grand Rounds, Howard Brown Health Center, "A New Class, A New Option: Understanding CCR5 Antagonists and Maraviroc" , Chicago, IL, January 10, 2008

32. Grand Rounds, Department of Medicine, City of Hope Medical Center, "Strategies for Treatment-Naïve Patients with HIV Infection: When and What to Start?, Duarte, CA, February 19, 2008

33. Grand Rounds, Division of Pediatric Infectious Diseases, University of Nevada School of Medicine, "Optimizing Antiretroviral Therapy for the Treatment-Experienced Patient: A Case-based Approach", Reno, NV, February 21, 2008

34. Los Angeles Physicians AIDS Forum: "Update from the 15th Conference on Retroviruses and Opportunistic Infections (CROI)", InterContinental Hotel, Century City, CA, March 11, 2008

35. HIV Grand Rounds, University Medical Center Wellness Clinic, "Rising to the Challenge: CCR5 Antagonists in Treatment-experienced Patients", Las Vegas, NV, March 21, 2008

36. HIV Conference Program: "CCR5 Antagonists - A New Era in Patient Management", Orange County Public Health, Santa Ana, CA, April 2, 2008

37. Grand Rounds, Division of Infectious Diseases, Department of Medicine, Keck School of Medicine, University of Southern California, "Progress in Antiretroviral Therapy", LAC/USC Medical Center, Los Angeles, CA, May 8, 2008

38. Scientific Meeting on New Trends and New Perspectives for HIV Treatment, Federal University of Rio de Janeiro, "Efficacy and Safety of Maraviroc in HIV+ Patients", Rio de Janeiro, May, 12 2008

39. 16th Annual State of Texas, Department of HIV/STD Conference, "Protease Inhibitor-based HAART: Predictive Factors for Treatment Success", Austin, TX, May 18, 2008

40. HIV Minifellowship Program: Current Challenges in the Clinical Management of HAART: "Side Effect Issues and Management Strategies", Hollywood Roosevelt Hotel, Los Angeles, CA, June 7, 2009

41. Grand Rounds, USC Communicable Diseases Grand Rounds: "HIV in Young Adults: An Often Overlooked Epidemic", USC Medical Center, Los Angeles, July 11, 2008

42. Grand Rounds, Division of Infectious Diseases, Department of Medicine, "A New Era in Patient HIV Treatment", Olive View Medical Center, Sylmar, CA, August 15, 2008

43. UCLA Center for AIDS Research and Education (CARE), 6th Annual HIV Symposium – Tough Decisions Made Easier: "Antiretroviral Therapy in the Current Era: Case-Based Panel Discussion", Renaissance Hotel, Hollywood, CA, October 17, 2008

44. Los Angeles Physicians AIDS Forum, "HIV Highlights of the 2008 ICAAC/IDSA Annual Meeting", InterContinental Hotel, Los Angeles, CA December 2, 2008

45. Infectious Diseases Grand Rounds, "Post CROI Update: Best Practices in HIV Therapy, Kaiser West Los Angeles, CA, March 26, 2009

46. Grand Rounds, Infectious Diseases Section, Sunnybrook Hospital, "HIV-1 Tropism: How We Can Use it to Treat Human Infection", Toronto, Canada, March 30, 2009

47. HIV Rounds Noon Lecture: "Viral Tropism: Epidemiology, Natural History, and Therapeutics", St Michael's Hospital, Toronto, Canada, March 31, 2009

48. Infectious Diseases Morning Rounds, McMaster University School of Medicine, "Progress in Treating HIV Infection: Using Laboratory Technology to Make Therapeutic Decisions", McMaster University, Toronto, Canada, April 1, 2009

49. Ottawa HIV Physicians' Community Consortium, "HIV-1 Tropism: How We Can Use It To Treat Human Infection", Ottawa, Canada, April 1, 2009

50. The New York Course: HIV Management 2009: "HIV Prevention in Clinical Practice", Hudson Theatre, New York, May 15, 2009

51. Cedars-Sinai Department of Pharmacy Conference: "Centers for Disease Control STD Treatment Guidelines", Cedars-Sinai Medical Center, May 27, 2009

52. Grand Rounds, Division of Infectious Diseases, Department of Medicine, SUNY Downstate Medical Center, "A New Era in HIV Patient Management", Brooklyn, NY, June 24, 2009

53. Grand Rounds, Infectious Diseases Section, Department of Medicine, Beth Israel Medical Center, "Rising to the Challenge: CCR5 Antagonists in Treatment-experienced HIV+ Patients", Peter Kruger Clinic, New York, NY, June 25, 2009

54. Grand Rounds, Division of Infectious Diseases and HIV Medicine, New York Hospital of Queens, "Viral Tropism and How it can be Used as Treatment for HIV Infection", Queens, NY, June 26, 2009

55. Grand Rounds, Infectious Diseases Section, Department of Medicine, US Naval Medical Center at Balboa, "Current Considerations for the Management of Patients with HIV Infection", San Diego, CA, August 14, 2009

56. Plenary Session, Session 1, Basic Science, "HIV Infection: An Inflammatory Disease?", HIV Congress 2010, Mumbai, India, January 8, 2010

57. Plenary Session, Session 2, Future Therapies, "Stem Cell Therapy for Treatment of HIV Infection", HIV Congress 2010, Mumbai, India, January 9, 2010

58. Grand Rounds, Division of Infectious Diseases, Department of Medicine, Cedars-Sinai Medical Center, "HIV Infection is an Inflammatory Disease", Cedars-Sinai Medical Center, February 9, 2010

59. 20th Annual Clinical Care Options for HIV Symposium: Current Opportunities and Continuing Challenges in HIV Care: "Missed Opportunities: Practical Strategies for Enhancing Early HIV Diagnosis and Timely Treatment" - Sheraton Wild Horse Pass, Phoenix, AZ – April 8, 2010.

60. Satellite Symposium, XVIII International AIDS Society (IAS) Conference, "The Art of Orchestration: Achieving Treatment Harmony in HIV Patients- Cardiovascular Disease in HIV Infection", Vienna Austria, July 18, 2010.

61. Satellite Symposium, ICAAC-2010, "Asked and Answered: Frontline Providers Challenge the Experts on HIV Management Strategies, Boston, MA, September, 13, 2010.

62. Satellite Symposium, ICAAC-2010, "HIV: Assessing the Long-term Consequences of Therapy and Infection", Boston, MA, September 14, 2010.

63. Seventh Annual St Bernadine Infectious Disease Symposium: "HIV/AIDS: Three Decades of Medical Progress", St Bernadine Medical Center, San Bernardino, CA, March 26, 2011.

64. 20th Annual HIV/AIDS-On the Front Line: "Challenges of Diagnosing and Treating HIV Infection among Latinos", University of California at Irvine School of Medicine, Orange, CA, April 27, 2011.

65. Miami Community HIV Physician Forum, "The Overlooked Epidemic: Beyond the Basics: Meeting the Challenges of Caring for Women with HIV Infection", Miami Beach, FL, September 7, 2011.

66. Los Angeles InterCity HIV Rounds: "Current Clinical Controversies in the Treatment of HIV/AIDS", Hollywood Presbyterian Medical Center, Los Angeles, CA, February 1, 2012

67. Plenary Session: Current Research Questions: "Is HIV Infection a Cardiovascular Disease Risk Equivalent?", International HIV Congress 2012, Mumbai, India, March 15-18, 2012.

68. Plenary Session: HIV Clinical Care: Renal Disease in HIV+ Persons-Diagnosis and Treatment", International HIV Congress 2012, Mumbai, India, March 15-18, 2012.

69. Department of Medicine Grand Rounds: "Emerging Issues in the Management of HIV Infection", WVA Medical Center, Los Angeles, CA, June 6, 2012.

70. Third Annual HIV Latina Forum: "Treating Beyond HIV", Renaissance Sao Paulo Hotel, Sao Paulo, Brazil, June 21 – 23, 2012.

71. Grand Rounds: "Post IAC 2012 Update: Assessing Best Practices in HIV/AIDS Therapy", Health Care Agency of Orange County, Santa Ana, CA, August 15, 2012

72. Department of Medicine Grand Rounds: "Prevention of HIV Infection-Current Research Progress", Cedars-Sinai Medical Center, Los Angeles, CA, September 7, 2012.

73. Department of Medicine Grand Rounds: “Curing HIV Infection: Is It Possible?”, Cedars-Sinai Medical Center, Los Angeles, CA, March 29, 2013.

74. Puerto Rico HIV Physician Forum, “HIV Treatment in Latino Persons: Differences in Adherence, Virologic and Immunologic Response to ART?”, San Juan, Puerto Rico, April 19, 2013.

75. Official Satellite Symposium of 7th International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment and Prevention, “Emerging Issues of Aging HIV-seropositive Persons”, Kuala Lumpur, Malaysia, June 28, 2013.

CME-ACCREDITED PROGRAMS:

76. Foundation for Better Healthcare CME Program: “Fusion Inhibitors: Optimizing Response in Treatment-experienced HIV-infected Patients”, Seattle, WA, January 13, 2004

77. CME Activity: “A New Class, A New Option: Understanding CCR5 Antagonists”, Howard Brown Health Center, Chicago, IL, January 10, 2008

78. CME Activity: “A New Generation of Targets” Understanding Co-Receptor Antagonists”, Milwaukee, WI, January 11, 2008

79. CME Activity for AdvanceMed: HIV Resistance Workshop, Renaissance New York Times Square Hotel, New York, NY, January 25, 2008

80. CME Activity for AdvanceMed: HIV Resistance Workshop, San Francisco, CA, February 22, 2008

81. CME Program: “Current Clinical Controversies in the Treatment of HIV/AIDS”; Case Discussion on Treatment-Experienced Patients: "How many Drugs Does a Patient Need?, Rancho Las Palmas, Rancho Mirage, CA, May 2, 2008

82. CME Program: “Novel Agents for Treatment-Experienced Patients” Faculty Mentoring for Managing Challenging Cases”, Rancho Las Palmas, Rancho Mirage, CA, May 3, 2008

83. CME Program: Simply Speaking HIV – An Expert Educators CME Lecture Series: “Current Clinical Controversies in the Treatment of HIV/AIDS”, Silver Fox, Dallas, TX, May 15, 2008

84. CME Dinner Program: “A New Era in Patient Management”, Simon LA, Los Angeles, CA, May 20, 2008

85. CME Certified Symposium: New Insights into the Use of Protease Inhibitors Across the Treatment Spectrum: Case Scenarios: Participant Polling with Panel Discussion, Inter-Continental Hotel, Los Angeles, CA, June 12, 2008

86. Web-based CME Program: HIV Knowledge Network Study Group, XVII International AIDS Conference: "Highlights of the 2008 IAS", Moderator, August 21, 2008

87. First Care Forums in HIV: "Best Practices Workshops for the Treatment Team", Millennium UN Plaza Hotel, New York, NY, September 6, 2008.

88. CCO CME-Certified Expert Recap from the 17th International AIDS Conference, Mexico City, August 3-8, 2008: "Update on Timing and Choice of First-Line Therapy", October 3, 2008

89. CME Dinner Program: Profiles in HIV: In-Depth Analyses and Case Studies of Unique Populations Living with HIV, Los Angeles, CA, January 15, 2009

90. CME Program: First Care Forums in HIV: Best Practices Workshops for the Treatment Team, Madison Hotel, Washington, DC, January 17, 2009

91. CME Program Simply Speaking HIV, Post ICAAC/IDSA 2008 CME Update: "Assessing Best Practices in HIV/AIDS Therapy", Hollywood Presbyterian Medical Center, Hollywood, CA, January 21, 2009

92. CCO CME Program: Panel Discussion on Management of Antiretroviral Naïve Patients, Loews Hotel Vogue, Montreal, Canada, February 11, 2009

93. CME Program: The HIV Treatment Debate, Renaissance Hotel, Hollywood, CA, March 3, 2009

94. CME Program: "Integrating Resistance Testing into Clinical Practice", Los Angeles, CA, March 18, 2009

95. CCO CME/CE-Certified Video Module: "Planning and Strategizing for Long-term Success With Antiretroviral Therapy", April 6, 2009

96. CCO CME/CE-Certified Treatment Update Video Module: CCO HIV: Stay Tuned Evolving Concepts in Antiretroviral Therapy: "Stem Cell Therapy, SWITCHMRK, and HIV-Associated Inflammation", June 2009

97. CME Harkness Roundtable Program: Current challenges in HIV: Maximizing outcomes Through Case-Based Discussions, West Hollywood, CA, June 17, 2009

98. 5th IAS 2009 Preview from CCO Faculty Experts Audio Preview: "The Impact of Home-Based Compared with Facility-Based HIV Care on Virologic Failure and Mortality: A Cluster Randomized Trial", July 20, 2009

99. 2009 International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment and Prevention, "Highlights and Overview of Progress in Antiretroviral Therapy, July 19, 2009.

100. CME Dinner Program: "The Graying of an Epidemic: Clinical Considerations of HIV and Aging", San Francisco, CA, October 20, 2009

101. CME Dinner Program: "Effect of Resistance and Resistance Barriers on ARV Therapy Efficacy", Beverly Hills, CA, October 21, 2009

102. CME Dinner Program: "The Graying of an Epidemic: Clinical Considerations of HIV and Aging", New York, NY, October 22, 2009.

CEDARS-SINAI MEDICAL CENTER CME CONFERENCES - CHAIRMAN & SPEAKER

103. 5th Annual CSMC World AIDS Day Conference: A Promising Future - Chairman, Cedars-Sinai Medical Center, Hotel Sofitel, Los Angeles, CA, December 4, 2003

104. 6th Annual CSMC HIV/AIDS Update Conference: A Multidisciplinary Approach – Chairman, Cedars-Sinai Medical Center, Le Meridian Hotel, Los Angeles, CA, March 11, 2005

105. 1St CSMC Crystal Methamphetamine Medical Conference (Co-Chair, Organizer & Speaker): "Treatment Options", Cedars-Sinai Medical Center, Los Angeles, CA, June 23, 2006

106. 7th Annual CSMC HIV/AIDS Medical Update Conference: 25 Years of Old Standards and New Frontiers-A Multidisciplinary Approach - Chairman, Cedars-Sinai Medical Center, Le Meridian Hotel, Los Angeles, CA, September 19, 2006

107. 8th Annual CSMC HIV/AIDS Medical Update Conference: Emerging Issues and Challenges - Chairman, InterContinental Hotel-Century City, Los Angeles, CA, September 28, 2007

108. 9th Annual CSMC HIV/AIDS Conference: "New Therapies, New Patient Populations, and New Global Challenges", September 26, 2008.

109. 10th Annual CSMC HIV/AIDS Conference: "HIV Infections – Inflammation, Prevention and Sex Workers", September 25, 2009.

110. 11th Annual HIV/AIDS Conference: Primary Care and ART Optimization in a Changing Healthcare System, Intercontinental Hotel, Los Angeles, CA, September 24, 2010

111. 12th Annual HIV/ AIDS Conference: Hepatitis C Co-infection, Cardiovascular Disease and Promising Gene Therapies", SLS Hotel, Los Angeles, CA, September 23, 2011.

112. 13th Annual HIV/AIDS Conference: "Comparing First-line Antiretroviral Options, Update on Hepatitis C Treatment, Screening for HIV-associated Neurocognitive Disorders, and Prospects for Curing HIV", SLS Hotel, Los Angeles, CA, September 28, 2012

PUBLICATIONS / BIBLIOGRAPHY

A. RESEARCH PAPERS (Peer Reviewed)

1. Ahmed RA, Kaplan RP**, Hardy WD**, Feldman E, Pitt H. Bullous pemphigoid and ulcerative colitis. Int J Dermatol 21:594-598, 1982.

2. Holland GN, Sakamoto MJ, **Hardy WD**, Sidikaro Y, Krieger AE, Frenkel LM. Treatment of cytomegalovirus retinopathy in patients with acquired immunodeficiency syndrome – Use of the experimental drug 9-(2-hydroxyl-1 (hydroxymethyl) ethoxymethyl) guanine (DHPG). Arch Ophthalmol 104:1794-1800, 1986.

3. Holland GN, Sidikaro Y, Kreiger AE, **Hardy WD**, Sakamoto MJ, Frenkel LM, Winston DJ, Gottlieb MS, Bryson YJ, Champlin RE, Ho WG, Winters RE, Wolfe PR, Cherry JD. Treatment of cytomegalovirus retinopathy with ganciclovir. Ophthalmology 94:815-823, 1987.

4. Fay MT, Freeman WR, Wiley CA, **Hardy WD**, Bozzette S. Atypical retinitis in patients with the acquired immunodeficiency syndrome. Am J Ophthalmol 105:483-490, 1988.

5. Fischl MA, Richman DD, Causey DM, Grieco MH and the **AZT Collaborative Working Group-Hardy, WD**. Prolonged zidovudine therapy in patients with AIDS and advanced AIDS-related complex. JAMA 262:2405-2410, 1989.

6. Holland GN, Buhles WC Jr, Mastre B, Kaplan HJ and **UCLA CMV Retinopathy Study Group- Hardy, WD.** A controlled retrospective study of ganciclovir treatment for cytomegalovirus retinopathy. Use of a standardized

system for the assessment of disease outcome. UCLA CMV Retinopathy Study Group. Arch Ophthalmol. Dec;107(12):1759-66, 1989.

7. Volberding PA, Lagakos SW, Koch MA, Pettinelli C, Myers M, Booth D, Balfour HH Jr, Reichman RC, Bartlett JA, Hirsch MS, Murphy RL, **Hardy WD**, et al. Zidovudine in asymptomatic human immunodeficiency virus infection: a controlled trial in persons with fewer than 500 CD4-positive cells per cubic millimeter. N Engl J Med 322:941-949, 1990.

8. Hochster H, Dieterich D, Bozzette S, Reichman RC, Connor JD, Liebes L, Sonke RL, Spector SA, Valentine F, Pettinelli C, Richman DD, **ACTG 004 Investigators-Hardy, WD.** Toxicity of combined ganciclovir and zidovudine for cytomegalovirus disease associated with AIDS. An AIDS Clinical Trials Group Study. Ann Intern Med. Jul 15;113(2):111-7, 1990.

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11. **Hardy WD.** Combined ganciclovir and recombinant human granulocyte-macrophage colony-stimulating factor in the treatment of cytomegalovirus retinitis in AIDS patients. J Acquir Immune Defic Syndr 1:S22-28, 1991.

12. Wu AW, Rubin HR, Mathews WC, Ware JE Jr, Brysk LT, **Hardy WD**, Bozzette SA, Spector SA, Richman DD. A health status questionnaire using 30 items from the Medical Outcomes Study. Preliminary validation in persons with HIV infection. Med Care 29:786-798, 1991.

13. Janoff EN, **Hardy WD**, Smith PD, Wahl SM. Humoral recall responses in HIV infection. Levels, specificity and affinity of antigen-specific IgG. J Immunol 147:2130-2135, 1991.

14. **Studies of the Ocular Complications of AIDS (SOCA) Research Group**. Mortality in patients with the acquired immunodeficiency syndrome treated with either foscarnet or ganciclovir for cytomegalovirus retinitis. Studies of Ocular Complications of AIDS Research Group, in collaboration with the AIDS Clinical Trials Group. N Engl J Med. Jan 23;326(4):213-20, 1992.

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16. **Studies of the Ocular Complications of AIDS (SOCA) Research Group**. Studies of ocular complications of AIDS Foscarnet-Ganciclovir Cytomegalovirus Retinitis Trial: 1. Rationale, design, and methods. AIDS Clinical Trials Group (ACTG). Control Clin Trials. Feb;13(1):22-39, 1992.

17. Bass HZ, **Hardy WD**, Mitsuyasu RT, et al. The effect of zidovudine treatment on serum neopterin and beta 2-microglobulin levels in mildly symptomatic, HIV type 1 seropositive individuals. J Acquir Immune Def Syndr 5:215-221, 1992.

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B. RESEARCH PAPERS – PEER REVIEWED (IN PRESS)

C. MANUSCRIPTS – PEER REVIEWED (SUBMITTED)

1. **Hardy WD,** Ren, S, Liu C, Folks T, Chen I. Recombinant foamy virus (FV) vectors persistently express high levels of HIV-1 p24 antigen: potential for HIV vaccine development. (Submitted to *Retrovirology*).

2. **Hardy WD,** Ren S, Folks T, Chen I: Recombinant foamy virus vectors integrate HIV-1 *gag* into murine PBMCs and elicit immune responses to expressed gag protein. (Submitted to *AIDS Research and Human Retroviruses)*

D. <u>MANUSCRIPTS IN PREPARATION</u>

1. Final Results from: Phase I/II Safety, Immunogenicity and Feasibility Study of a Dual Anti-HIV Gene Transfer Construct to Treat HIV-1 Infection Using an Adaptive Design of Busulfan Pre-conditioning in Viremic HIV-1-Seropositive Persons (NCT01734850)
2. Phase I/II Safety, Immunogenicity and Feasibility Study of a Dual Anti-HIV Gene Transfer Construct to Treat HIV-1 Infection Using and Adaptive Design of Busulfan Pre-conditioning in Viremic HIV-1-Seropositive Persons (NCT01734850): What This Study Teaches the Field of HIV Cure Research.

RESEARCH PAPERS (NON-PEER REVIEWED)

None

<u>TEXT BOOKS EDITED</u>

1. *Fundamentals of HIV Medicine for the HIV Specialist*, 2007 Edition. Washington, DC: American Academy of HIV Medicine. 2007: [pages 1-1163]. **US Core Curriculum Committee**.

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