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.

NICHOLAS HARRISON, ET AL.,
    Plaintiffs,
    v.
PATRICK M. SHANAHAN, ET AL.,
    Defendants.

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

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.

\(^2\) 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.”
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.

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.


\(^6\) 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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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

\textsuperscript{9} Fundamentals of HIV Medicine, at Ch.21: HIV-1 Resistance to Antiretroviral Drugs.
\textsuperscript{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. 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. 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

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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

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
16 See CDC Risk Behaviors.
17 See id.
18 See id.
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. 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.” 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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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,

21 The cases referenced in the CDC letter: Myron Cohen et al., Prevention of HIV-1 Infection
(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
retention, deployment, discharge, and disciplinary policies regarding individuals with this condition [HIV].”

28. The 2018 Report contains a section on “Recent Findings Signifying Impairments Despite Viral Suppression and Asymptomatic HIV.” Specifically, the Report suggests that people living with HIV on ART may develop certain types of neuro-cognitive impairment (NCI). 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.” 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.” 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.
25 Id. (emphasis added).
26 Id. at 21 (emphasis added).
27 Id. at 20 (emphasis added).
compared to the individuals without HIV.\textsuperscript{28} Another study found that HIV status had less of an effect on cognition than years of education, age, and reading level.\textsuperscript{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.\textsuperscript{30} In fact, the DHHS guidelines only reference NCIs in older people taking ART and do not recommend testing in any population.\textsuperscript{31}

\textsuperscript{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.

\textbf{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.

\begin{flushright}
\textsuperscript{28} Nancy F. Crum-Cianflone et al., \textit{Low Prevalence of Neurocognitive Impairment in Early Diagnosed and Managed HIV-Infected Persons}, 80 Am. Acad. of Neurology 371, 375 (2013).
\end{flushright}
Executed this 22\textsuperscript{nd} 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
Office Phone: (310) 709-3505
E-MAIL ADDRESS: wdavidhardymd@gmail.com
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)
<table>
<thead>
<tr>
<th>Year Range</th>
<th>Position/Role and Affiliation</th>
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<tbody>
<tr>
<td>1993-1996</td>
<td>Principal Investigator, NIH/NIAID-sponsored, Multidisciplinary HIV/AIDS Training Grant (T32AI07388), UCLA AIDS Institute, University of California – Los Angeles School of Medicine, Los Angeles, California</td>
</tr>
<tr>
<td>1994-1996</td>
<td>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</td>
</tr>
<tr>
<td>1994-1996</td>
<td>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</td>
</tr>
<tr>
<td>1996-2002</td>
<td>Clinical Associate Professor of Medicine, Department of Medicine, University of California - Los Angeles School of Medicine, Los Angeles, California (Volunteer Teaching Faculty)</td>
</tr>
<tr>
<td>1996-2002</td>
<td>Scientific Director of Research, Research Department, Pacific Oaks Medical Group, Beverly Hills, California</td>
</tr>
<tr>
<td>1996-2002</td>
<td>Private Practice Specializing in Infectious Diseases and HIV Medicine, Pacific Oaks Medical Group, Beverly Hills, California</td>
</tr>
<tr>
<td>2002-2009</td>
<td>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)</td>
</tr>
<tr>
<td>2002-2013</td>
<td>Director, Division of Infectious Diseases, Department of Medicine, Cedars-Sinai Medical Center, Los Angeles, California</td>
</tr>
<tr>
<td>2002-2012</td>
<td>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</td>
</tr>
<tr>
<td>2002-2013</td>
<td>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</td>
</tr>
<tr>
<td>2003-2012</td>
<td>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</td>
</tr>
<tr>
<td>2007-2012</td>
<td>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</td>
</tr>
<tr>
<td>2008-2011</td>
<td>Associate Program Director, NIH/NCRR-sponsored General Clinical Research Center (GCRC), Cedars-Sinai Medical Center, Los Angeles, California</td>
</tr>
</tbody>
</table>
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

2002 – 2013 Member, Department of Medicine Performance Improvement Committee, Cedars-Sinai Medical Center, Los Angeles, California

2002 – 2013 Member, Antibiotic Utilization Review Committee, Pharmacy Department, Cedars-Sinai Medical Center, Los Angeles, California

2008 -- 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,


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


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)
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

3. Gilead Sciences
Protocol # GS-US-236-0102
*A Phase 3, 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-formulated 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 GSK1349572 50 mg Once Daily vs Raltegravir 400 mg Twice Daily Both Administered with Fixed-dose Dual Nucleoside Reverse Transcription 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


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 emtricitabine 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: 3/1/12-2/28/14
Cost: $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. K08 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

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-boosted Atazanavir Plus 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 ritonavir-boosted atazanavir plus emtricitabine/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-1 Infected 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 whether 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

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
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
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


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


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


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


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


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.


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


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


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


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


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


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


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


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.


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.


CME-ACCREDITED PROGRAMS:


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


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


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


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


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


PUBLICATIONS / BIBLIOGRAPHY

A. RESEARCH PAPERS (Peer Reviewed)


15. Kahn JO, Lagakos SW, Richman DD, Cross A, Pettinelli C, **Hardy WD**, et al and the NIAID AIDS Clinical Trials Group. A controlled trial comparing...


34. **Studies of the Ocular Complications of AIDS (SOCA) Research Group**


36. **Studies of the Ocular Complications of AIDS (SOCA) Research Group**.


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. MANUSCRIPTS IN PREPARATION**


**RESEARCH PAPERS (NON-PEER REVIEWED)**

None

**TEXT BOOKS EDITED**


**BOOK CHAPTERS**


**EDITORIALS**


**REVIEWS**


2. **Hardy WD.** Lessons learned from HIV pathogenesis and therapy: implications for better management of cytomegalovirus disease. AIDS: Nov: 10 Suppl 1:S3-5, 1996


**CASE REPORTS**


WEBSITE PUBLICATIONS


26. **Hardy WD**: The final nail? What the CD4+ T-cell count-guided treatment interruption strategy has taught us. News and Comment. [www.clinicaloptions.com](http://www.clinicaloptions.com), February 8, 2006


**ABSTRACTS**


27. Hardy WD; Liu C; Xie Y; Folks T; Chen IYS. Foamy virus vectors as potential vaccines against HIV: rationale and preliminary experimental data. Presented at the 5th World Foamy Virus Conference, Wuerzburg, Germany, July 9-11. [Abstract # 32], 2004

28. Hardy WD; Liu C; Xie Y; Folks T; Chen IYS. Foamy viruses (FVs): potential vectors for HIV vaccine. Presented at the 12th Conference on Retroviruses and Opportunistic Infections, Boston, Massachusetts [Abstract # 262].February 22-25, 2005


30. Hardy WD; Liu C; Xie Y; Folks T; Chen IYS. Foamy Virus (FV) Vectors Persistently Express High Levels of HIV-1 gag: Potential for HIV Vaccines. Presented at the 13th Conference on Retroviruses and Opportunistic Infections, Denver, Colorado, [Abstract # 472], February 5-8, 2006


32. Hardy WD; Liu C; Xie Y; Folks T; Chen IYS. Recombinant HIV-1 gag /Foamy Virus Vectors Express p24 Antigen for 6 Months and Process HIV-1gag Similar to
Native Virus. Presented at the 14th Conference on Retroviruses and Opportunistic Infections, Los Angeles, California [Abstract # C-181], February 25-28, 2007


ATTACHMENT 2
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<th>Document or Reference</th>
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<tr>
<td>Department of Defense, <em>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</em> (August 2018)</td>
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<tr>
<td>Expert Declaration of Carlos Del Rio, M.D. in Support of Plaintiffs' Motion for Preliminary Injunction (1:18-cv-00641, DKT 0026-2) (July 19, 2018)</td>
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<td>Expert Declaration of Craig W. Hendrix, M.D. in Support of Plaintiffs' Motion for Preliminary Injunction (1:18-cv-00641, DKT 0026-5) (July 19, 2018)</td>
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<td>Andrew Grulich et al., HIV Transmissions in Male Serodiscordant Couples in Australia, Thailand and Brazil, University of South Wales (Feb 26, 2015), <a href="https://www.croiconference.org/sites/default/files/posters-2015/1019LB.pdf">https://www.croiconference.org/sites/default/files/posters-2015/1019LB.pdf</a></td>
<td></td>
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<td>Li JZ et al., <em>The size of the expressed HIV reservoir predicts timing of viral rebound after treatment interruption</em>, 30 AIDS 343, 343-53 (2016)</td>
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<td>30(b)(6) Deposition of United States Army Given By Dr. Jason Blaylock with Exhibits (February 27, 2019)</td>
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<td>30(b)(6) Deposition of the Department of Defense Given By Donald Shell with Exhibits (March 8, 2019)</td>
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