IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

WHITMAN-WALKER CLINIC, INC., et al.,

Plaintiffs,

v.

Case No. 1:20-cv-1630

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

DECLARATION OF DR. ROBERT BOLAN, MD CHIEF MEDICAL OFFICER, LOS ANGELES LGBT CENTER

- I, Robert Bolan, declare as follows:
- 1. I am the Chief Medical Officer and Director of Clinical Research for the Los Angeles LGBT Center (the "Center" or "LA LGBT Center").
- 2. I oversee all medical care related services at the LA LGBT Center, as well as maintain a panel of patients for whom I provide direct care. In addition, I oversee the LA LGBT Center's Research Department, am the principal investigator for multiple HIV treatment and prevention trials, and have written and presented extensively on various matters related to the care and treatment of people living with or at risk of acquiring HIV and other sexually transmitted infections (STIs).
- 3. I am also Clinical Associate Professor of Family Medicine at the University of Southern California (USC) Keck School of Medicine, and an Adjunct Clinical Professor of Pharmacy Practice at the Western University of Health Sciences. I received my medical degree from the University of Michigan Medical School, interned at St. Mary's Hospital Medical Center, and completed my residency at St. Michael Family Practice Residency. I was the Director of HIV Services in the Department of Family Medicine at the USC Keck School of

Medicine, and I have been honored with the Leadership Award from the San Francisco AIDS Foundation. I maintain active board certification with the American Board of Family Physicians and specialty certification with the American Academy of HIV Medicine. A copy of my curriculum vitae is attached as **Exhibit A**.

- 4. I am submitting this declaration in support of Plaintiffs' Motion for Preliminary Injunction to prevent the revised regulation under Section 1557 of the Affordable Care Act ("ACA"), published by the U.S. Department of Health and Human Services ("HHS") on June 19, 2020 (the "Revised Rule"), from taking effect. The Revised Rule eliminates explicit regulatory protections for LGBT people in health care that were included in the 2016 Final Rule, which was promulgated under Section 1557 in May 2016.
- 5. As the Chief Medical Officer, I oversee the delivery of health care for approximately 32,000 patients who come to the LA LGBT Center and have a panel of approximately 250 patients for whom I personally provide medical care. Over 90% of my patients identify as LGBTQ. My patient population is also disproportionately low-income and experiences high rates of chronic conditions, homelessness, unstable housing, trauma history, and discrimination and stigmatization in health care services. Many of these patients come to me from different areas of California, other states, and even other nations to seek services in a safe and affirming environment.
- 6. Our health care services span the full spectrum of primary health care services, including, but not limited to, HIV treatment and testing, treatment and prevention of sexually transmitted infections, as well as treatment for gender dysphoria, mental-health disorders, and substance-use disorders.

- 7. Many if not most of the individuals in our very diverse patient population face considerable stigma and discrimination as people living with HIV, as sexual or gender minority people, and/or as people of color. In addition, there is a very high incidence of other social determinants of poor health outcomes among the patient population that we serve. These include homelessness, food insecurity, lack of access to transportation, and lack of employment opportunities.
- 8. There is every reason to believe that the Revised Rule will encourage health care providers to claim a right to discriminate, refuse care or opt out of serving patients with particular needs, which will result in more discrimination against LGBT patients and patients living with HIV at other clinics, doctors' offices, hospitals, pharmacies, and other health care facilities outside of the LA LGBT Center. I, and the other providers whom I supervise at the Center, treat patients who have experienced traumatic stigma and discrimination based on their sexual orientation, gender identity, transgender status, HIV status, and/or other factors even before the Revised Rule was proposed or finalized. Based on the stories that my patients have shared with me, this discrimination, mistreatment, and denial of health care services has on many occasions been motivated by the moral or religious beliefs of other health care providers and staff outside of the Center.
- 9. In the more than twenty years that I have been at the Center, I have listened to the stories of countless individuals who have suffered overtly homophobic remarks from health care providers and who were either refused care or given clearly inadequate and inappropriate care because of their sexual orientation or gender identity. One of the most egregious examples was a transgender woman who needed extensive surgery to repair diffuse damage done by silicone injections into her breasts several years earlier. In 2009, she was turned away from an academic

plastic surgery center in Los Angeles after the surgeon said her problem was caused by her own poor decision-making and she would therefore not be considered for treatment.

- 10. Incidents like this reveal that many health care providers and other staff harbor explicit or implicit biases against LGBTQ people. Because of legal requirements, health care facility nondiscrimination policies, and professional norms, many of them have kept their personal biases and feelings in check. By empowering health care staff to think that they have the legal right to act on their personal beliefs, even at the expense of patient needs, the Revised Rule will result in many more incidents of discrimination and greater harm to LGBTQ individuals struggling with mental-health or substance-use issues, including the patients whom I treat and whose treatment I supervise.
- 11. Such experiences are not only insulting and demoralizing for the patient, but can jeopardize the patient's health, especially, for example, when a screening or treatment is denied or postponed, or the patient is discouraged from seeking medical care out of fear of repeated discrimination. Many, if not most, of my transgender patients and the LA LGBT Center's transgender patients express strong distrust of the health care system generally and are reluctant to seek care outside the Center unless they are in a crisis or suffer from severe physical or mental stress. This is because they want to avoid discrimination or belittlement. Such incentives to avoid regular check-ups and other medical care can result in disease processes that are more advanced at diagnosis, less responsive to treatment, or even no longer curable in the case of some cancers.
- 12. In the case of the transgender woman I described above, her general medical condition gradually deteriorated over the several years it took for me to finally identify a surgeon who would take her case. She was suffering from systemic metabolic complications from the

chronic inflammation and skin breakdown caused by the hardened subcutaneous silicone injections. I feared for her survival. Fortunately, the surgeon who cared for her did so with kindness, respect, and compassion, and the patient has had an excellent result. The affirming surgeon saved her life. Nevertheless, the ultimate tragedy in my patient's case was that after the humiliating and callous abuse to which she was subjected by the academic center's specialists, she was completely unwilling to even consider seeing another surgeon for the next six-and-a-half years. Her suffering during that time was completely avoidable had she been treated with basic human respect from the beginning.

- 13. With existing health and health care disparities affecting the LGBTQ community particularly the shortage of LGBTQ/HIV culturally competent providers confusion and chaos resulting from the Revised Rule will further exacerbate existing barriers to health care and result in negative community health outcomes. The Revised Rule will remove any expectation that a provider will approach LGBTQ patients with compassion and respect for their dignity. Good medical care is based on trust as well as frank and full communication between the patient and their provider. Such communication will not happen if the patient is made to feel like a supplicant. It is the providers' responsibility to non-judgmentally elicit the patient's relevant health history, sexual history, substance-use history, lifestyle, and gender identity in order to provide appropriate care for the patients' health, both physical and mental. Incomplete communication, or miscommunication, can have dangerous consequences.
- 14. For instance, a patient who conceals or fails to disclose a same-sex sexual history may not be screened for HIV or other infections or cancers; and a patient who fails to fully disclose their gender identity and sex assigned at birth may not undergo medically-indicated tests or screenings (e.g., some transgender men may require tests for cervical or breast cancer, and

some transgender women may require tests for testicular or prostate cancer). Patients need to be encouraged to fully disclose all information relevant to their health care and potential treatment, and they are unlikely to do so unless they are assured that the information they provide will be treated confidentially and with respect. The Revised Rule endangers the provider-patient relationship, and is likely to harm many patients' health, by discouraging patients from full disclosure, and by encouraging providers to discriminate and avoid topics that may offend their personal moral or religious beliefs in their encounters with patients.

Patients often receive delayed care or misdiagnoses when patients are reluctant to 15. reveal their LGBTQ identity to health care providers out of fear of discrimination or disapproval. Another example of this involved a patient who suffered from a respiratory cough and increasing shortness of breath, which developed over several weeks. The patient was reluctant to go to the emergency room because of distrust of health care providers. After two weeks of suffering from severe symptoms at home, he was persuaded by his boyfriend to go the ER. When he arrived at the ER, the providers were so focused on COVID-19 that they failed to even consider the possibility of HIV-related illness. Had they asked about his health history, sexual history, or sexual orientation, they would have suspected HIV as a cause for his symptoms. Instead, the patient received an incorrect diagnosis and treatment. After two weeks of further decline, he presented at another LGBTQ-affirming clinic where they saw that he had a classic presentation of HIV-related pneumonia. Tragically, even though he was rushed immediately to another hospital where proper treatment was started, it was too late and he died shortly after admission. The nature of a health crisis like COVID-19 is that it inherently creates additional barriers to care for patients. The Revised Rule increases those barriers to treatment.

- 16. Not only is the Revised Rule discriminatory and harmful to my patients and to public health, but the timing of publication of the Revised Rule makes it especially egregious. We cannot afford additional discrimination in health care when patients are in their most desperate times of need for proper and nondiscriminatory health care. We need people to trust their health care providers, especially when their lives and the lives of those around them are at stake. In order to beat this virus, public health requires that all patients seek medical treatment and testing without hesitation or delay should they experience symptoms of COVID-19. By inviting discrimination against LGBTQ patients, the Revised Rule does the exact opposite, harming both patients and the general public.
- 17. The Revised Rule will cause LGBTQ patients and patients living with HIV to lose trust in their health care providers. The Rule will cause LGBTQ patients to attempt to hide their LGBTQ identities to an even greater degree when seeking health care services, especially from religiously-affiliated health care organizations, in order to avoid discrimination. The Revised Rule endangers the provider-patient relationship and is likely to harm many patients' health by discouraging patients from full disclosure about their gender identity, sexual orientation, or related medical histories. Patients will avoid raising any topics, questions, facts that they fear could possibly offend their health care providers' personal beliefs, resulting in harm to patients.
- 18. The Revised Rule is also likely to cause an increase in demand for my health care services. I have seen a spike in behavioral and mental-health issues resulting from discrimination and denials of health care services, and I will undoubtedly see an uptick in requests for my services and the services of the providers that I oversee at the LA LGBT Center because patients will come to us seeking affirming health care out of fear of discrimination elsewhere or because they were already discriminated against elsewhere. The Revised Rule

invites discriminatory behavior that is in direct conflict with the oath I swore as a doctor and many of the federal, state, and insurance rules, regulations, and statutes that I and other health care providers are required to follow.

- 19. Additionally, the Rule's removal of language access protections for Limited English Proficiency (LEP) patients will make it increasingly difficult for the LA LGBT Center and its health care providers, including me, to find appropriate referrals for our LEP clients. Without requiring accommodations for our limited English proficiency clients, our clients are at an increased risk of receiving inferior care and improper testing and delayed diagnoses when they seek health care services from outside providers. In addition, as discussed above, LGBTQ people already fear discrimination from their medical providers and have immense distrust of the health system. That distrust increases for LEP patients who are not provided with necessary translation services to communicate with their health care providers. Without necessary translations services, LEP patients tend to remain silent during consultations because they either cannot articulate the problems that they are experiencing, cannot comprehend what is being asked of them, or fear being open and honest with their providers about their difficulty understanding the providers' English. Patients may be reticent or worried about asking for a translation or articulating that they do not understand because they may want to present as and feel self-sufficient. One's ability to communicate subtly and precisely is hampered by the Revised Rule's removal of LEP accommodations. Health care is highly personal and has emotional impacts. This is heightened for LEP patients who as a result of the Revised Rule will be left navigating the system and care without the assistance of a translator.
- 20. The removal of LEP accommodations also will likely result in family members and friends of patients accompanying the LEP patients to their appointments. Many people think that

a family member or friend translating for a patient is sufficient, but that could not be further from the truth. There are a whole host of problems with having friends or family accompany a patient into the examining room, including, but not limited to, confidentiality issues, concerns about potential domestic violence, and concerns that patients, especially youth, may not be out about their LGBTQ identities to their family and friends. Relying on family or friends for translations is particularly dangerous for non-affirming families of transgender patients who would then create a barrier to health care. The end result is misdiagnoses, improper testing, and delay in treatments. In order to provide proper care to patients, there must be open lines of communication between physicians and their patients. The Revised Rule cuts off the line of communication and trust between providers and their patients.

- 21. These issues are amplified by COVID-19. It is hard enough for LEP patients or LGBTQ patients who fear discrimination in health care to communicate with their providers in person, let alone via telehealth. Each time a patient has their first telehealth visit, there is a learning curve. It is much more difficult for people to feel comfortable sharing information over the phone or video as opposed to in person consultations. The Revised Rule exacerbates these issues by inviting discrimination against LGBTQ patients and decreasing resources for LEP patients. The result is inferior medical care to patients and additional costs to the system, especially during a public health crisis like COVID-19.
- 22. The Revised Rule also adversely impacts the Center and its individual health care providers by necessitating the diversion and reallocation of resources to address the increase in the numbers of referral requests resulting from the Revised Rule. As a result of the Revised Rule's invitation to discriminate against LGBTQ patients, the LA LGBT Center is and will continue to be flooded with referral requests for LGBTQ-affirming services that the Center does not have

sufficient resources to provide. The Center will also have more difficulty finding LGBTQ-affirming health care providers, especially those with niche specialties, given that the Revised Rule emboldens health care providers to discriminate against and refuse services to LGBTQ patients in complete contradiction to medical and ethical standards of care.

- 23. For example, just a few weeks ago we received a call from a transgender patient whom we referred to an outside surgeon for an ear/nose/throat (ENT) issue because we do not provide those services at the Center. The patient later notified us that the physician conducted a breast exam on the transgender woman when the patient was very clear that she was only there for ENT-related issues. There was no reason for the physician to remove the patient's shirt and check her breasts. Such inappropriate professional behavior will increase because the Revised Rule sends a message to the medical field that LGBTQ people are unworthy of protections and quality care in accordance with medical and ethical standards of care. For that reason, we will have to divert our time and resources to vetting potential referrals to ensure that we are not sending our patients to outside health care providers that will discriminate or behave inappropriately and do more harm to our patients.
- 24. The Revised Rule is inherently demeaning and codifies our government's belief that the health care needs of LGBTQ people are unimportant. This proposed rule is shameful. As LA LGBT Center's Chief Medical Officer and Director of Clinical Research, my responsibility includes enforcing our nondiscrimination mandate with respect to all of our providers and staff. The Revised Rule is in direct contradiction with our obligations as physicians and health care providers. We have an obligation to treat all patients in a manner consistent with their best interests to achieve the best possible health results for our patients. The Revised Rule invites health care

providers to do the exact opposite. The increased discrimination resulting from the Revised Rule will harm our patients' health and public health at large.

[Signature on next page.]

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated this 6th day of July, 2020.

Dr. Kohurt Bolan 505159E12051406... Robert Bolan, MD

EXHIBIT A

Curriculum Vitae of Robert K. Bolan, MD

1/13/2020 CURRICULUM VITAE

A. PERSONAL INFORMATION

Name Robert Key Bolan, M.D., AAHIVS

Business Address Los Angeles LGBT Center

1625 N. Schrader Blvd. Los Angeles, CA 90028

Business Phone (323) 993-7577

B. EDUCATION

College or University University of Detroit

Detroit, Michigan B.S. Biology 1968 With Honors

Medical School University of Michigan Medical School

Ann Arbor, Michigan

M.D. 1972

Internship St. Mary's Hospital Medical Center

Madison, Wisconsin

1972-1973

Residency St. Michael Family Practice Residency

Milwaukee, Wisconsin

1975-1977

Honors and Awards Leadership Award, San Francisco A2IDS Foundation May 1992

Licensure California G39301

Board Certification American Board of Family Physicians

1978, 1983, 1990, 1997, 2005, 2012

Specialty Certification American Academy of HIV Medicine (AAHIVS)

C. PROFESSIONAL BACKGROUND

TEACHING RESPONSIBILITIES and ACADEMIC APPOINTMENTS:

Clinical Associate Professor of Family Medicine

University of Southern California (USC) - Keck School of Medicine

September 1995 – Present

Adjunct Clinical Professor of Pharmacy Practice

Western University of Health Sciences

February 2008 - Present

Assistant Clinical Professor

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University of California San Francisco Department of Family and Community Medicine June 1981 - December 1996

Course Organizer and Clinical Faculty "Clinical Approach to Gay and Lesbian Health Care" An elective two hour credit course offered by the University of California, San Francisco Medical School June 1979 - April 1982

ADMINISTRATIVE RESPONSIBILITIES:

Acting (administrative) Director of Health & Mental Health Services LA Gay & Lesbian Center 1625 N. Schrader Blvd.
Los Angeles, CA 90028
July 2001 – September 2002

Chief Medical Officer and Director of Clinical Research Los Angeles LGBT Center 1625 N. Schrader Blvd. Los Angeles, CA 90028 May 1996-Present

Director of HIV Services USC School of Medicine Department of Family Medicine September 1995-December 2004

Acting Chair Department of Family Practice California Pacific Medical Center, San Francisco January 1991-November1992

Medical Director Gay Health Clinic Presbyterian Medical Center, San Francisco March 1982 – June 1983

Attending Physician Presbyterian Medical Center Clinic, San Francisco October 1979- August 1980

HOSPITAL AFFILIATIONS

Queen of Angeles/Hollywood Presbyterian Hospital, Los Angeles January 1999- 2006

Cedars-Sinai Medical Center, Los Angeles July 1999-Present

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USC University Hospital, Los Angeles September 1995- 2004

North Hollywood Medical Center, North Hollywood May 1996-August 1998

California Pacific Medical Center, San Francisco 1979-1996

OTHER ACTIVITIES

Family Practice Pacific Family Practice Medical Group San Francisco, California 1979-September 1995

Family Practice Hartland Clinic, S.C. Hartland, Wisconsin August 1977-July 1979

Emergency Medicine Madison General Hospital Madison, Wisconsin June 1974-June 1975

Three-week intensive post-graduate course in Emergency Medicine Philadelphia, Pennsylvania April 1974

General Practice Dells Clinic Wisconsin Dells, Wisconsin September 1973-June1974

Emergency Medicine St. Clare Hospital Baraboo, Wisconsin June 1973-September1973

D. <u>SOCIETY MEMBERSHIPS</u>

NATIONAL AND INTERNATIONAL American Academy of Family Physicians

American Academy of HIV Medicine Member of Board for California/Hawaii Chapter 2004- Present

E. ACTIVIES IN AREA OF INTEREST

Core Curriculum Committee, American Academy of HIV Medicine 2001-2009

CME Committee, L.A. HIV Inter-City Rounds

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2000 - Present

Organizer and Supervisor, HIV Medicine Fellowship, a Post-Residency one-year training program LA Gay & Lesbian Center, Jeffrey Goodman Special Care Program.

December 1998 – 2005

Chair, Research Committee, Los Angeles LGBT Center Los Angeles, California March 1998 – Present

Chair, Peer Review, LA Gay & Lesbian Center Los Angeles, California March 1998 - Present

Member, Mayor's AIDS Advisory Task Force San Francisco, California January 1985-April 1988

President and Chairman of the Board, San Francisco AIDS Foundation San Francisco, California June 1983-January 1986

Member, AIDS Advisory Task Force of the Director San Francisco Department of Public Health San Francisco, California April 1983-January 1986

Member, Board of Directors, San Francisco AIDS Foundation San Francisco, California June 1983-June 1986

President – Elect, Bay Area Physicians for Human Rights (BAPHR) July 1983-June 1984

Chair, BAPHR Research Committee March 1983-1983

Chair, BAPHR Task Force on Kaposi's Sarcoma June 1981-June 1983

Secretary, BAPHR San Francisco, California June 1980-June 1981

Director and Organizer, "Current Aspects of Sexually Transmitted Diseases II", a Symposium, San Francisco State University
San Francisco, California
June 1980

Medical Director, Gay People's Union Venereal Disease Clinic Milwaukee, Wisconsin September 1977-July1979

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F. RESEARCH ACTIVITIES

Site Principal Investigator, ATN 147, 148, 149: A Comprehensive Community-Based Strategy to Optimize the HIV Prevention and Treatment Continuum for Youth at HIV Risk, Acutely Infected, and with Established Infection. PI: Mary Jane Rotheram-Borus. Sponsor: ATN/NICHD 2017 - 2021

Site Principal Investigator, Performance Evaluation of the DPP HIV Syphilis Assay in the Intended User Setting. Protocol CP-HIV-SYPH03. Funder: Chembio. 2018 – 2019.

Co-Investigator, Four Corners: TGNC Health Research Advisory Network. Funder: Patient Centered Outcomes Research Institute. PI: Andie Baker, Howard Brown University. 2019 – 2021.

Co-Investigator, Understanding tobacco and cannabis use among LGBT emerging adults. PI: Ian Holloway, UCLA. Funder: Tobacco Related Diseases Research Program. 2018 – 2020.

Site Principal Investigator, Performance of Nucleic Acid Amplification Tests for the Detection of Neisseria gonorrhoeae and Chlamydia trachomatis in Extragenital Sites. Antibacterial Resistance Leadership Group Protocol ARLG_pNAAT-Yr3. PI: Jeffrey Klausner. Sponsor: National Institute of Allergy and Infectious Disease.2016-2018.

Site Principal Investigator, Randomized Trial to Prevent Vascular Events in HIV (REPREIVE) – ACTG Protocol A5332. PI (Grinspoon) AIDS Clinical Trial Group Investigators (Overton/Fichenbaum/Aberg/Zanni) Sponsor: National Heart, Lung, and Blood Institute, National Institute of Allergy and Infectious Diseases, National Institute of Diabetes and Digestive and Kidney Diseases. 2015-2022

Site Investigator, Men Who Have Sex with men & Substance Use Cohort at UCLA, Linking Infections, Noting Effects (mSTUDY). PI: Shoptaw/Gorbach. Sponsor: National Institute on Drug Abuse, National Institutes of Health. 2012-2023

Site Principal Investigator, Gilead 2920112. A Phase 3 Open-Label Safety Study of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide Sintle-Table Regimen in HIV-1 Postitive Patients with Mild to Moderate Renal Impairment. 2013 – 2015.

Site Principal Investigator, Gilead 2920109. A Phase 3, Open-Label Study to Evaluate Switching from a TDF-Containing Regimen to a TAF-Containing Combination Single Tablet Regimen (STR) in Virologically-Suppressed, HIV-1 Positive Subjects. 2012 - 2016

Site Investigator, Protocol DMID 15-0090: Clinical Validation of Molecular Test for Ciprofloxacin-Susceptibility in *Neisseria gonorrhoeae*. PI Jeffrey Klausner Sponsor: Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health.. 2015-2019.

Site Investigator, CCTG 603: Randomized Controlled Trial of iTAB plus Motivational Interviewing for PrEP Adherence in Transgender Individuals: A Multicenter Trial of the California Collaborative Treatment Group. Funded by California HIV Research Program. 2015-2020.

A Phase 2b Randomized, Double-Blind, Double-Dummy Trial of 100 or 200 mg Once-Daily Doses of Cenicriviroc (CVC, TBR-652) or Once-Daily EFV, Each With Open-Label FTC/TDF, in HIV-1-Infected, Antiretroviral Treatment-Naïve, Adult Patients With Only CCR5-Tropic Virus. Funded by Tobira. 2011 – 2012.

Site Investigator, Los Angeles County PATH: PrEP and TLC+ for HIV Prevention. A California HIV Research Program (CHRP) Epidemic Interventions Demonstration Research Award. 4/2012 – 3/2016

Sub-investigator, Gilead 263-0110. A phase 3b 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 fumurate in HIV-1 infected, ARV-naïve adults. 2010 – present.

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Sub-investigator, Gilead 264-0106. A phase 3 randomized, open label study to evaluate switching from regimens consisting of a ritonavir boosted protease inhibitor and two nucleoside reverse transcriptase inhibitors to emtricitabine/rilpivirine/tenofovir disoproxil fumurate fixed dose regimen in virologically suppressed HIV-1 infected patients. 2010 – present.

Co-Principal Investigator, Doxycycline Prophylaxis or Incentive Payments to Reduce Incident Syphilis among HIV-infected MSM who Continue to Engage in High Risk Sex: A Pilot Study funded by UCLA Center for HIV Identification, Prevention, and Treatment Services (CHIPTS) 2011. 8/1/2011 – present.

Principal Investigator, A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of GS-9350-boosted Atazanavir Versus Ritonavir-boosted Atazanavir Each Administered with Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1Infected, Antiretroviral Treatment-Naïve Adults. (GS-US-216-0114). Funded by Gilead, 5/2010 – present.

Principal Investigator, A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Emtricitabine/Tenofovir Disoproxil Fumarate/GS-9350 Versus Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults. (GS-US-236-0102). Funded by Gilead, 6/2010 – present.

Principal Investigator, A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Emtricitabine/Tenofovir Disoproxil Fumarate/GS-9350 Versus Ritonavir-Boosted Atazanavir Plus Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults (GS-US-236-0103). Funded by Gilead, 4/2010 – present.

Site Investigator, Project AWARE: HIV Rapid Testing and Counseling in STD Clinics in the U.S.—an Adaptation of CTN 0032. Funded by NIDA, 12/2009 – 8/2011.

Principal Investigator, Evaluation of the Clinical Performance of the Determine® HIV- 1/2 Ag/Ab Combo Test (Clinical Protocol Number 0924401. Funded by Inverness Medical Innovations, Inc. Scarborough, ME, 9/2010 – 6/2011

Co-Investigator, Metromates: Transmission Behavior in Partnerships of Newly HIV Infected Southern Californians. Funded by NIH. 2008-present.

Principal Investigator, Correlation of Short-term Response of Viral Load to Maraviroc Added to a Failing Regimen, with Tropism Assay (A4001060). Funded by Pfizer, 2008 - present

Principal Investigator, A Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Antiretroviral Activity of MK-0518 in Combination With an Optimized Background Therapy (OBT), Versus Optimized Background Therapy Alone, in HIV-Infected Patients With Documented Resistance to at Least 1 Drug in Each of the 3 Classes of Licensed Oral Antiretroviral Therapies (019-00). Funded by Merck. 2006 - present

Principal Investigator, A Randomized, Multicenter, Double Blinded, Phase IV Study Comparing the Safety and Efficacy of Pegasys® 180µg plus Copegus® 1000 or 1200 mg to the Currently Approved Combination of Pegasys® 180µg plus Copegus® 800 mg in Interferon-naïve Patients with Chronic Hepatitis C Genotype 1 virus infection coinfected with human immunodeficiency virus (HIV-1) (PARADIGM). Funded by Roche. 2006 - 2008

Principal Investigator, A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of A Novel CCR5 Antagonist, UK427,857, In Combination With Optimized Background Therapy Versus Optimized Background Therapy Alone For The Treatment of Antiretroviral-Experienced HIV-1 Infected Subjects (A4001027). Funded by Pfizer. 2004 – 2007

Co-Investigator, MWCCS (MACS/WIHS Combined Cohort Study) Funded by NIH/NHLBI, 2001 - present

Principal Investigator, Early Access of TMC125 in combination with other antiretrovirals in treatment-

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experienced HIV-1 infected subjects with limited treatment options (TMC125-C214). Funded by Tibotec, 2007 - 2008

Principal Investigator, Early access of MK-0518 in Combination with an Optimized Background Antiretroviral Therapy (OBT) in Highly Treatment Experienced HIV-1 Infected Patients with Limited to No Treatment Options (023-00). Funded by Merck, 2007 - 2008

Principal Investigator, A Multi-center, Open-Label, Expanded Access Trial of Maraviroc (A4001050). Funded by Pfizer, 2007 - 2008

Principal Investigator, A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multi-center Trial of Pregabalin Versus Placebo in the Treatment of Neuropathic Pain Associated with HIV Neuropathy (A0081066). Funded by Pfizer, 2006 - 2008

Principal Investigator, An Open-label, Extension Safety and Efficacy Trial of Pregabalin in Subjects with Neuropathic Pain Associated with HIV Neuropathy (A0081095). Funded by Pfizer, 2006 - 2008

Principal Investigator, A Phase 3, Randomized, Open-label Study of Lopinavir/ritonavir Tablets 800/200 mg Oncedaily Versus 400/100 mg Twice-daily when Coadministered with Nucleoside/Nucleotide Reverse Transcriptase Inhibitors in Antiretroviral-experienced, HIV-1 Infected Subjects (M06-802). Funded by Abbott, 2007 - 2008

Principal Investigator, Utilization of HIV Drug Resistance Testing in Treatment Experienced Patients (Utilize Study 1182.116). Funded by Boehringer Ingelheim, 2007

Principal Investigator, A Comparative Randomized, Double-Blind, Double-Dummy, Multicenter Study of the Efficacy and Safety of miconazole Lauriad® 50 mg Administered Once a Day and Mycelex® Troches (clotrimazole 10 mg) Administered Five Times a Day in the Treatment of Oropharyngeal Candidiasis in Immunocompromised Patients (SMiLES BA2004/01/04). Funded by BioAlliance Pharma, 2006 - 2007

Principal Investigator, A Multicenter, Open-Label Study Evaluating the Safety and Efficacy of a New Investigational Protease Inhibitor (PI) With FUZEON® (Enfuvirtide) Plus Optimized Background in HIV-1 Infected Triple-Class Treatment-Experienced, Enfuvirtide-Naïve Patients (BLQ Study, ML 19712). Funded by Roche. 2006 – 2007

Principal Investigator, Early access of TMC114 in combination with low-dose ritonavir (RTV) and other antiretrovirals (ARVs) in highly treatment experienced HIV-1 infected subjects with limited to no treatment options (TMC114-C226). Funded by Tibotec. 2006

Co-Principal Investigator, Open-Label, Multiple-Dose, Drug Interaction Study to Assess the Effect of Nevirapine on the Pharmacokinetics of Atazanavir in HIV-Infected Individuals (ANDI). Funded by Bristol-Myers Squibb. 2006

Principal Investigator, A Phase III randomized, double-blinded, placebo-controlled trial to investigate the efficacy, tolerability and safety of TMC125 as part of an ART including TMC114/RTV and an investigator-selected OBR in HIV-1 infected subjects with limited to no treatment options (TMC125-C206). Funded by Tibotec. 2006 - 2008

Principal Investigator, A 48-Week, Randomized, Open-Label, 2-Arm Study to Compare the Efficacy of Saquinavir/Ritonavir BID Plus Emtricitabine/Tenofovir QD Versus Lopinavir/Ritonavir BID Plus Emtricitabine/Tenofovir QD in Treatment-Naïve HIV-1 Infected Patients (Gemini ML18413). Funded by Roche. 2005 - 2007

Principal Investigator, A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of A Novel CCR5 Antagonist, UK427,857, In Combination With Optimized Background Therapy Versus Optimized Background Therapy Alone For The Treatment of Antiretroviral-Experienced, Non CCR5-Tropic HIV-1 Infected Subjects (A4001029). Funded by Pfizer. 2004 – 2008

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Co-Principal Investigator, A 48-week prospective study comparing the safety and efficacy of switching from a Combivir (Zidovudine/ZDV + Lamivudine/3TC) based HAART regimen to a Viread (Tenofovir DF/TDF) + Emtriva (Emtricitabine/FTC) based HAART regimen in HIV-infected adults with HIV RNA < 50copies/ml (COMET). Funded by Gilead. 2004 - 2005

Principal Investigator, Tipranavir Open Label Safety Study (Trial # 1182.58). Funded by Boehringer Ingelheim. 2004 - 2005

Principal Investigator, A Large, Simple Trial Comparing Two Strategies for Management of Anti-Retroviral Therapy (SMART). Funded by NIH, DAIDS number CPCRA 065. 2003 - 2008

Principal Investigator, A Phase III, 48-week, open label, randomized, multicenter study of the safety and efficacy of the Abacavir/Lamivudine fixed-dose combination tablet administered QD versus Abacavir + Lamivudine administered BID in combination with a PI or NNRTI in antiretroviral experienced patients (ESS 30008). Funded by GlaxoSmithKline, 2002

Principal Investigator, Post exposure prophylaxis as a biobehavioral HIV intervention (PEP). Funded by City of Los Angeles, 2002 - 2004

Co-Investigator, Short cycle intermittent versus continuous HAART for the treatment of chronic HIV infection (M77). Funded by FAIR Foundation, 2002

Principal Investigator, Genotype assisted initial Nelfinavir study (GAIN). Funded by Agouran, 2001

Co-Investigator, A double blind, phase III extension study of SGN-00101 in the treatment of high grade anal intraepithelial neoplasia (AIN 0002). Funded by StressGen, 2001 - 2002

Co-Investigator, A randomized, placebo-controlled, phase III trial of SGN-00101 in the treatment of high grade anal intraepithelial neoplasia (AIN 0001). Funded by StressGen, 2000 – 2001

Co-Investigator, The impact of a prescriptive barriers-to-adherence questionnaire on HIV patients' adherence to HAART medications. Funded through University of Nevada at Reno, 2000

Co-Principal Investigator, Exploratory investigation of medical literacy: meaning of illness, information-seeking, and medical knowledge among people living with HIV/AIDS. Sponsored by University of Southern California, 2001 - 2002

Co-Investigator, A randomized, open-label, two arm trial to compare the safety and antiviral efficacy of GW 433908/Ritonavir QD to Nelfinavir BID when used in combination with Abacavir and Lamivudine BID for 48 weeks in antiretroviral therapy naïve HIV-1 infected subjects (APV 30002). Funded by GlaxoSmithKline, 2001 - 2002

Co-Investigator, Tenofovir DF (tenofovir disoproxil fumarate) Expanded Access Program. Funded by Gilead, April - October 2001

Principal Investigator, A phase II, open-label randomized study to compare the efficacy and safety of Epivir/Ziagen/Zerit versus Epivir/Ziagen/Sustiva versus Epivir/Ziagen/GW433908/Norvir for 96 weeks in the treatment of HIV-1 infected subjects who are antiretroviral therapy naïve (ESS 40001). Funded by Glaxo Wellcome, 2000 - 2002

Principal Investigator, A phase III randomized placebo controlled and double blinded study of IM862 for patients with muco-cutaneous AIDS associated Kaposi's Sarcoma (AMC 013). Funded by Cytran, 2000 - 2001

Principal Investigator, The prevalence of anemia in HIV infected patients (Anemia). Funded by OrthoBiotech, 2000 - 2001

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Co-Investigator, Ziagen optimal regimen and resistance observational study (ESS 40009, ZORRO). Funded by Glaxo Wellcome, 1999 - 2000

Co-Investigator, A 96 week, randomized, open-label, multi-center trial to evaluate the safety and tolerability of the antiretroviral activity of Stavudine (40mg BID) + 3TC (150mg BID) + Nelfinavir (1250mg BID) versus Abacavir (300mg BID) + Combivir (150mg/300mg BID) versus Combivir (150mg/300mg) + Nelfinavir (1250mg BID) in HIV-1 infected female subjects (ESS 40002). Funded by Glaxo Wellcome, 1999 - 2000

Co-Investigator, ABT 378/ritonavir Early Access Program. Funded by Abbott, 1999 - 2000

Principal Investigator, A randomized, controlled, open-label comparison of continuing Indinavir vs switching to Norvir/Indinavir 400mg/400mg BID (NICE). Funded by Abbott, 1999 - 2000

Co-Investigator, Preveon (adefovir dipivoxil) Expanded Access Program. Funded by Gilead, 1998 – 2000

Co-Investigator, Role of the oral environment in HIV transmission and pathogenesis (HOT). Funded by NIH/NIDR through UCSF, 1998-2000

Principal Investigator, Brief safer sex intervention for HIV outpatient clinics (Partnership for Health Study). Funded by NIMH through USC, 1997 - 2001

G. PUBLICATIONS

ABSTRACTS, POSTERS, ORAL PRESENTATIONS

Beymer MR, Weiss RE, Sugar CA, Bourque LB, Gee GC, Morisky DE, et al. Are CDC Guidelines for Pre-Exposure Prophylaxis Specific Enough? Formulation of a Personalized HIV Risk Score for Pre-Exposure Prophylaxis Initiation. *Presented at the International AIDS Society Conference, Durban, South Africa* (2016).

Beymer MR, Bolan RK, Flynn RP. It's Not Just Black and White: Determining Within Group Differences for HIV Infection among African-American Gay and Bisexual Men. *Presented at the American Public Health Association Conference, New Orleans, Louisiana* (2014).

Hernandez W, Beymer MR, Flynn RP, Carpenter W, Bolan RK. Elucidating Reasons for PEP Use among Transgender Women at a Community-Based Clinic in Los Angeles, California. *Presented at the Transgender Health Summit, San Francisco, California* (2015).

Landovitz RJ, Amico KR, Psaros C, et al. Real-time Biomarkers of TFV/FTC adherence support a staged-intensity adherence support intervention in a Pre-Exposure Prophylaxis demonstration Project. Abstract, National HIV Prevention Conference, 2015, Atlanta.

Beymer MR, Bolan RK, Flynn RP. Differential Rates in Diagnosis of Acute HIV Infection by Race. *Presented at the National STD Prevention Conference, Atlanta, Georgia* (2014).

Beymer MR, Weiss RE, Bolan RK, Rudy ET, Bourque LB, Rodriguez JP, Morisky DE. Sex On-Demand: Geosocial Networking Phone Apps and Risk of Sexually Transmitted Infections among a Sample of Men who have Sex with Men in Los Angeles County. *Sexually Transmitted Infections* (2doi: 10.1136/sextrans-2013-051494.

Beymer MR, Bolan RK, Flynn RP, Kerrone DR, Pieribone DL, Kulkarni, SP, Stitt JC, Mejia E, Landovitz RJ. Uptake and repeat use of post-exposure prophylaxis in a community-based clinic in Los Angeles, California. *AIDS Research and Human Retroviruses* (2014) doi: pending.

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Beymer MR, Llata E, Stirland AM, Weinstock HS, Wigen CL, Guerry SL, Mejia E, Bolan RK. Evaluation of Gonorrhea Test of Cure at One Week for Men who have Sex with Men in a Community-Based Clinic in Los Angeles, California. *Sexually Transmitted Diseases* (2014) doi: pending.

Bolan RK, Beymer M, Weiss RE, Flynn R, Leibowitz A, Klausner JD. Doxycycline Prophylaxis or Incentive Payments to Reduce Incident Syphilis among HIV-infected MSM who Continue to Engage in High Risk Sex: A Pilot Study. Oral Poster Presentation, STI & AIDS World Congress 2013. Vienna. July 14-17, 2013.

Bolan RK, Beymer M, Flynn R, Mejia E, Rizzo M. Crystal Meth: Still Speeding Out of Control with Sexual Partners Along for the Ride. Poster Presentation, 2012 National STD Prevention Conference, Minneapolis, Minnesota, March 12-15, 2012.

RK Bolan, M Beymer, R Flynn, D Prock. Experience at a Community-based LGBT Organization with Integrated HIV/STI Testing and HIV Care. Oral Presentation, 6th International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention, Rome, Italy, July 17-20, 2011

Robert K Bolan, Ellen T Rudy, Kai-Jen Cheng, Swanand Tilekar, Christine Wigen, Peter Kerndt. Sexually Transmitted Infections among HIV Positive Persons Before and After Entry into HIV Care: the Need for Priority Interventions. Oral Presentation, National HIV Prevention Conference, Atlanta, August 23-26, 2009

Robert K. Bolan, MD, Ellen T. Rudy, PhD, Swanand D. Tilekar, MSc, MPH, Christine Wigen, MD, MPH, Peter R. Kerndt, MD, MPH. Collaboration between Health Departments and Community-Based Healthcare Organizations: A Case Study of Success. Oral Presentation, National HIV Prevention Conference, Atlanta, August 23-26, 2009

Shin SM, Scott JD, Bolan RK. Pharmacy refill rates of HAART as predictor of CD4 and VL values. 4th International Conference on HIV Treatment Adherence, Miami, FL, April 5-7, 2009, Abstr 0155.

Bolan RK, Tilekar S, Clay E, Uniyal A, Chein M, Kerndt PR. Increased Risk for Acute HIV Infection from Non-ulcerative STI's in MSM: Aggressive STI Eradication Programs Needed for Reduction in HIV Incidence. Poster Presentation, Ninth International Congress on Drug Therapy in HIV Infection. November, 2008: Glasgow, UK. J Int AIDS Soc. 2008, 11 (Suppl 1):P303

Tilekar SD, Bolan RK, Stallworth P, Clay E, Hall MJ. Racial/Ethnic Disparities in HIV Incidence among the LGBT Community. Oral Presentation at APHA 136th Annual Meeting and Expo. San Diego, October 2008

Bolan RK, Hall MJ, Tilekar S, Clay E, Wigen C, Rudy ET, Kerndt P. Rectal Neisseria gonorrhea and Chlamydia trachomatis among Men Who Have Sex With Men: High Incidence of Co-infections and Implications for Treatment. Poster Presentation, 2008 National STD Prevention Conference. Chicago, March 2008.

Wigen, CL, Rudy E, Clay E, Bolan R, Guerry S, Kerndt PR. Provider-collected versus Self-collected Rectal Screening for Gonorrhea and Chlamydia in Men who have Sex with Men. Poster Presentation at the 2008 National STD Prevention Conference. Chicago, March 2008.

MW Chien, A Stirland, A Uniyal, LA Borenstein, R Bolan, J Hall, T Horton, J Samson, K Cheng, Z Zeng, and PR Kerndt. Acute HIV Infection among Patients Seen in a Sexually Transmitted Disease (STD) Clinic in Los Angeles County, USA. International Society for Sexually Transmitted Diseases Research (ISSTDR) July 29 - August 1, 2007, Seattle, Washington, USA.

James D. Scott, Pharm.D., Robert K. Bolan, M.D. Factors Associated with Poor Follow-up To HIV Post-Exposure Prophylaxis. Poster, 4th IAS Conference on HIV Pathogenesis, Treatment and Prevention Sydney, Australia, 22-25 July 2007.

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Scott J, Wolfe P, Chow L, Bolan R. Rare Occurrence of Renal Impairment when Retrospectively Evaluating the Use of TDF in Two Clinical Practices. Poster P-448E, 38th ASHP Midyear Clinical Meeting, New Orleans, December 7-11, 2003.

Scott JD, Guyer B, Bethel J, Anderson D, Bolan RK. 48-week Results of a Stable Switch Study: Changing Combivir to Tenofovir/Emtricitabine. Poster: 41, ACCP Spring Practice and Research Forum, Memphis, TN. April 21-25, 2007

Dybul M, Bolan R, Condoluci D, Cox-Iyamu R, Redfield R, Hallahan C, Sathasivam K, Folino M, Weisberg M, Andrews M, Hidalgo B, Vasquez J, Fauci AS. Initial CD4+ T-Cell counts in patients with newly diagnosed HIV infection indicate that a substantial proportion of these patients have advanced disease regardless of gender, race or socio-economic status. Abstract at the 9th Conference on Retroviruses and Opportunistic Infections, Seattle, WA., February 2002.

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LETTERS TO THE EDITOR

Joseph Davey DL, Beymer MR, Roberts C, et al. Regarding Suthar et al.'s article Programmatic Implications of Acute and Early HIV Infection. J Infec Dis. 2015 Nov1;212(9):1351-60.

Marks GS, Richardson JL. Milam JE, Bolan R., Stoyanoff S, McCutchan A. Use of Erectile Dysfunction Medication and Unsafe Sex Among HIV+ MSM in Care. Int J STD AIDS. 2005 Mar;16(3):271-2

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Bolan RK. Sexual transmission of hepatitis A in homosexual men. New England Journal of Medicine, 303: 282, July 31, 1980.

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H. <u>SCIENTIFIC MEETINGS AND PRESENTATIONS</u>

PARTIAL AND REPRESENTATIVE ONLY (Guest lecturer, numerous speaking engagements concerning clinical and educational AIDS issues)

Lecture: Anal Dysplasia, Community Forum; December 15, 2005. The Village at Ed Gould Plaza.

LA Department of Health Services STD Grand Rounds: Lymphogranuloma venereum; June 15, 2005.

Grand Rounds: LA HIV Intercity Rounds: HIV and Hepatitis B, May 20, 2005.

Lecture: 10th Conference on Retroviruses and Opportunistic Infections, Community Update; March 3, 2003. The Village at Ed Gould Plaza.

Lecture: Conference on Retroviruses and Opportunistic Infections, Clinical Provider Update, Jeffrey Goodman Clinic, March 7, 2003.

Lecture: "HIV Dynamics" USC Keck School of Medicine, to first year medical students; October 1999, 2000

Grand Rounds: LA HIV Intercity Rounds- Primary Pulmonary Hypertension; August 4, 2000

Lecture: "HIV Update" USC Family Medicine Board Review Course; June 26, 1999

Lecture: "HIV 1999: An Update" USC Family Medicine Primary Care Review Course; March 23, 1999

Lecture: "Anemia and HIV Disease" USC Family Medicine Grand Rounds; December 6, 1998

Lecture: "Sexually Transmitted Diseases" USC Family Medicine Board Review Course; June 13, 1998

Symposium Organizer and Speaker: "HIV Treatment Adherence: Toward an Understanding of Harmful Intrusions into Effective HIV Treatment Strategies." November 1, 1997; USC School of Medicine.

Lecture: "The Challenge of Medication in the Age of Anti-HIV Combination Therapy in the Mentally Ill Client" North Hollywood Medical Center Continuing Education Series; June 18, 1997

Lecture: "Primary HIV Infection" North Hollywood Medical Center Continuing Education Series; March 19,1997

Faculty Advisor and lecturer: "HIV/AIDS: What They're Not Teaching You in School" Student Organization for Medical AIDS Awareness and Los Angeles AIDS Forum, Saturday January 6, 1996. USC School of Medicine.

Workshop: "Automated Medical Records, HIV managed care, and Clinical Outcomes Analysis": 6th Annual Symposium: Clinical Care Options for HIV; May 2, 1996; Scottsdale

Workshop: "Managed Care and AETC Training": Faculty Development Conference, AIDS Education and Training Centers; April 16, 1996; Asilomar

Workshop: "HIV Risk Reduction and Test Counseling": Common Problems in Primary Care: 22nd Annual Review Course, April 2, 1996

Lecture: "HIV: Early Care" USC Student Health Clinic, February 16,1996.

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Bolan RK. Health Education Planning for AIDS Risk Reduction in the Gay/Bisexual Male Community: Use of the PRECEDE Framework. Poster session, International Conference on Acquired Immune Deficiency Syndrome. Atlanta, Georgia, April 14-17, 1985.

Guidelines Recommendations for Healthful Sexual Activity. Robert K. Bolan, M.D., Editor. National Coalition of Gay Sexually Transmitted Disease Services, ©1981.