

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

NICHOLAS HARRISON, ET AL.,

Plaintiffs,

v.

JAMES N. MATTIS, ET AL.,

Defendants.

CIVIL ACTION NO. 1:18-CV-00641

**MEMORANDUM IN SUPPORT OF
PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION**

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| Exhibit | Description |
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| Exhibit A | <i>Department of Defense Retention Policy for Non-Deployable Service Members</i> (Feb. 14, 2018) (hereinafter, “DOGO Policy”), available at https://www.defense.gov/Portals/1/Documents/pubs/DoD-Universal-Retention-Policy.PDF |
| Exhibit B | Expert Declaration of Carlos Del Rio, M.D. |
| Exhibit C | Declaration of Sergeant Nicholas Harrison |
| Exhibit D | Expert Declaration of Trevor Hoppe, MPH, PhD |
| Exhibit E | Expert Declaration of Craig W. Hendrix, M.D. |
| Exhibit F | Declarant 1 Declaration |
| Exhibit G | Declarant 2 Declaration |

I. INTRODUCTION

People living with HIV have served in this nation's armed services with distinction for decades. For much of that time, their service has been unjustifiably restricted based on misconceptions regarding the consequences of an HIV diagnosis. In this action, Plaintiffs Sergeant Nicholas Harrison and OutServe-SLDN are challenging long-standing Department of Defense (DoD) policies that prevent the enlistment, deployment, and commissioning of people living with HIV.

In February 2018, the DoD issued a new policy that will result in the discharge of all service members who are non-deployable for 12-consecutive months (hereinafter the "Deploy or Get Out" or "DOGO Policy").¹ Service members with HIV are, by default, considered non-deployable.² The "Deploy or Get Out" Policy became effective upon issuance³ and provides that "[t]he Military Services have until October 1, 2018, to begin *mandatory processing* of non-deployable Service members . . . [although] they may begin such processing immediately."⁴

Not only is the October 1, 2018 implementation deadline imminent, but Plaintiffs have become aware that several service members living with HIV are being discharged or are having their service restricted as a result of the new DOGO Policy. Because irreparable harm to Sgt. Harrison and to the service members whose interests are represented in this lawsuit by OutServe-SLDN is now imminent, Plaintiffs seek a preliminary injunction to preserve the status quo by

¹ *Department of Defense Retention Policy for Non-Deployable Service Members* (Feb. 14, 2018) (hereinafter, "DOGO Policy"), at <https://www.defense.gov/Portals/1/Documents/pubs/DoD-Universal-Retention-Policy.PDF>. (Ex. A).

² See DoDI 6490.07, Encl. 3, ¶e(2).

³ See L. Ferdinando, *Pentagon Releases New Policy on Nondeployable Members*, U.S. Dep't of Defense (Feb. 16, 2018), at <https://www.defense.gov/News/Article/Article/1443092/pentagon-releases-new-policy-on-nondeployable-members/>.

⁴ Wilkie, DOGO Policy, *supra*, at n.1 (emphasis added).

suspending implementation of the new DOGO Policy as applied to any service member classified as non-deployable based solely on their HIV status.

II. STATEMENT OF FACTS

A. Overview regarding the Human Immunodeficiency Virus (HIV)

Until the mid-1990s, HIV was a universally terminal condition. Del Rio Decl. ¶21 (Ex. B). The virus operates by gaining a foothold in the blood, hijacking the cells of the body's immune system and using them to create copies of itself. *Id.* ¶12. These copies then target for destruction CD4 T-cells, which are critical to the human body's ability to fight infections. *Id.* ¶14. If left untreated, the virus multiplies to levels that allow it to reduce the overall quantity of CD4 cells and the body becomes progressively more prone to "opportunistic infections." *Id.* A person with fewer than 200 CD4 T-cells per milliliter of blood simultaneously with an opportunistic infection has progressed to the third stage of the disease and is diagnosed with Acquired Immune Deficiency Syndrome (AIDS).⁵

In 1996, however, everything changed. New antiretroviral medications that attack the virus and prevent it from replicating transformed the landscape of HIV treatment and radically shifted health outcomes for people living with HIV. Del Rio Decl. ¶16. Antiretrovirals reduce the number of copies of the virus present in a person's blood. *Id.* ¶17. Successful treatment reduces a person's "viral load"—which can measure as high as one million copies per milliliter of blood—to less than fifty copies per milliliter. *Id.* This is referred to as having a suppressed or "undetectable" viral load. *Id.* Today, any person who consistently takes their antiretroviral medications will reach an undetectable viral load. *Id.* ¶18.

⁵ See U.S. Centers for Disease Control and Prevention (CDC), *About HIV/AIDS*, at <https://www.cdc.gov/hiv/basics/whatishiv.html>.

With the reduction in viral load, CD4 T-cells rebound and the immune system recovers, thereby restoring even those with advanced HIV to good health.⁶ Patients with an AIDS diagnosis—sometimes with a CD4 count as low as one—literally have been brought back from the brink of death with antiretroviral combination therapy.⁷ For anyone with access to care, HIV is no longer a terminal condition.⁸ Indeed, someone “who is diagnosed with HIV in a timely manner and adheres to their prescribed antiretroviral therapy has very nearly the same life expectancy as a person who is not living with HIV.”⁹ Del Rio Decl. ¶21.

Over the last twenty-two years, researchers and clinicians have refined the antiretroviral pharmaceuticals to make adherence easier and health outcomes even better. *Id.* ¶20. Three antiretroviral medications were combined into a single pill a person can take once a day, known as a single tablet regimen or “STR,” with no reduction in effectiveness. *Id.* Side effects have been reduced to the point where most people in treatment experience few or no side effects.¹⁰ While still not curable, HIV is now a chronic, manageable condition rather than a terminal diagnosis.¹¹

At the same time, science has made great strides in understanding the transmission of

⁶ Selina Corkery, *Factsheet: Diagnosed with HIV at a low CD4 count*, NAM AIDSMap (March 2016), at <http://www.aidsmap.com/Diagnosed-with-HIV-at-a-low-CD4-count/page/2182215/>.

⁷ *Id.*

⁸ HIV.gov, *What Are HIV and AIDS?* (May 15, 2017), at <https://www.hiv.gov/hiv-basics/overview/about-hiv-and-aids/what-are-hiv-and-aids>.

⁹ Samji et al., *Closing the Gap: Increases in Life Expectancy among Treated HIV-Positive Individuals in the United States and Canada*, 8(12) PLoS ONE (2013), at <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0081355>.

¹⁰ U.S. DHHS, *Fact Sheets: Side Effects of HIV Medicines* (Oct. 9, 2017), at <https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/22/63/hiv-medicines-and-side-effects>.

¹¹ HIV.gov, *What Are HIV and AIDS?* (May 15, 2017).

HIV.¹² Contrary to popular belief, HIV is not easily transmitted. The riskiest sexual activity has only a 1.38% per-act chance of transmitting HIV.¹³ More important, if a person is in consistent treatment and achieves viral suppression, the risk of transmission is essentially zero for any sexual activity. Del Rio Decl. ¶25.

Outside of sexual activity, the only activities that present a measurable risk of HIV transmission are the sharing of injection drug equipment, blood transfusion, needle sticks, and perinatal exposure. For all other activities—including biting, spitting, throwing of body fluids, or blood spatter—the CDC characterizes the risk as negligible, which it defines as “technically possible but unlikely and not well documented.”¹⁴ Access to treatment and the resultant viral suppression eliminates even the theoretical possibility of transmission in these latter contexts. Del Rio Decl. ¶27.

B. The Military’s Policies and Regulations Regarding HIV

The military has had regulations restricting the service of people living with HIV since well before the advent of effective antiretroviral therapy. In 1991, the DoD issued its first version of Instruction 6485.01, which officially made people living with HIV ineligible for appointment, enlistment, pre-appointment, or initial entry training for military service.¹⁵ While this Instruction has been adjusted in minor ways over the years, the underlying bar on enlistment and appointment has remained the same since 1991.¹⁶

¹² See CDC, *Effectiveness of Prevention Strategies to Reduce the Risk of Acquiring or Transmitting HIV*, at <https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html> (updated Mar. 7, 2017).

¹³ See CDC, *HIV Risk Behaviors: Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act*, at www.cdc.gov/hiv/risk/estimates/riskbehaviors.html (updated Dec. 4, 2015). Per-act risk for other sexual activities is between zero and .08%.

¹⁴ See CDC, *HIV Risk Behaviors*, *supra*.

¹⁵ DoDI 6485.01 (1991), ¶ 4.1-4.

¹⁶ DoDI 6485.01 (2013), ¶ 3.a.

Under this Instruction, service members who first test positive for HIV while on active duty are allowed to continue serving “in a manner that ensures access to appropriate medical care.”¹⁷ With the exception of the Navy—which has recently allowed service members to deploy on certain overseas vessels—the various service branches have interpreted this policy to require that people living with HIV be stationed within the continental United States.¹⁸

Further, DoD Instruction 6490.07 specifically identifies HIV as a medical condition that limits a service member’s deployability.¹⁹ Under DoDI 6490.07, a service member living with HIV should not to be deployed outside the continental United States unless a medical waiver is granted after consultation with the Combatant Command surgeon.²⁰

The Army has implemented the policy requirements of DoDI 6485.01 and 6490.07 as AR 600-110, “Identification, Surveillance, and Administration of Personnel Infected with Human Immunodeficiency Virus” (“AR 600-110”). AR 600-110 implements a blanket prohibition on the accession of individuals living with HIV. “Accession” is defined in the regulation as enlistment in either the Army or Reserves, appointment as a West Point cadet, or an initial appointment as a commissioned officer. Under these rules, an enlisted active duty service member who wishes to become a commissioned officer will not be able to receive a commission if they are living with HIV even if they seroconverted (*i.e.*, became HIV-positive) while on active duty.²¹ AR 600-110 also requires that service members living with HIV be stationed only in the continental United States, Alaska, Hawaii, Guam, Puerto Rico, or the U.S. Virgin Islands,

¹⁷ *Id.*, Encl. 3, ¶ 2.c.

¹⁸ SECNAVINST 5300.30E, ¶ 9.b; AFI 44-178, ch. 2.4.2; AR 600-110, ch. 1-16.f.

¹⁹ Dep’t of Def., Instruction No. 6490.07, (Feb. 5, 2010), *at*

<https://www.dcms.uscg.mil/Portals/10/CG->

[1/cg112/cg1121/docs/pdf/MedicalConditionsDeployments.pdf](https://www.dcms.uscg.mil/Portals/10/CG-1/cg112/cg1121/docs/pdf/MedicalConditionsDeployments.pdf) (“DoDI 6490.07”)

²⁰ *See* DoDI 6490.07, Encl. 3, ¶ e(2).

²¹ *See* AR 600-110, ch. 5.2.a.

unless they are granted a medical waiver.²² Such waivers, however, are rarely (if ever) granted.

Service members living with HIV are also required to receive and adhere to treatment for their condition.²³ Each member's condition is monitored regularly, and their vital statistics, such as viral load and CD4 count, are tracked.²⁴ A service member living with HIV can be medically separated if they "demonstrate progressive clinical illness or immunological deficiency as determined by medical authorities."²⁵ Until very recently, they could not be discharged solely because of their HIV status.²⁶

The DoD recently issued a policy of general applicability that makes it effectively impossible for people living with HIV to serve as members of the military. On February 14, 2018, the DoD issued a new policy stating that "[s]ervice members who have been non-deployable for more than 12 consecutive months, for any reason, will be processed for administrative separation."²⁷ As discussed above, all service members living with HIV and currently serving in the military are, by default, considered non-deployable.²⁸ Therefore, the new DOGO Policy, acting in tandem with existing DoD Instructions and Army Regulations, creates a *de facto* prohibition against individuals with HIV serving in the Army.

C. Sergeant Harrison's Military Service

Plaintiff Nicholas Harrison has been serving his country with distinction since 2000. He first joined the U.S. Army eighteen years ago, at the age of 23, and spent three years stationed in Alaska after basic training. Harrison Decl. ¶2 (Ex. C). In 2003, when Sgt. Harrison was

²² See AR 600-110, ch. 1-16.f.

²³ DoDI 6485.01 (2013), Encl. 3, ¶ 2.c.

²⁴ AR 600-110, ch. 1-16.d.

²⁵ AR 600-110, ch. 6-15.

²⁶ AR 600-110, ch. 1-16.e.

²⁷ See Wilkie, DOGO Policy, *supra*, n.1.

²⁸ See DoDI 6485.01; DoDI 6490.07; *see also* AR 600-110.

discharged from active duty, he joined the Army Reserves, returning to his home state of Oklahoma to continue his education while serving in the Oklahoma National Guard. *Id.* ¶3. After receiving a bachelor's degree, he enrolled in law school at Oklahoma City University and was the top student in his class after the first semester. *Id.* ¶4.

Sgt. Harrison's legal education was interrupted, however, by the call of duty. His National Guard deployed to Afghanistan for sixteen months beginning in March 2006 in support of Operation Enduring Freedom. *Id.* ¶5. While deployed, Sgt. Harrison was recognized for his meritorious service with the Army Commendation Medal. *Id.* ¶6. Upon returning to Oklahoma, Sgt. Harrison completed his education, receiving both his J.D. and his M.B.A. from the University of Oklahoma in 2011. *Id.* ¶10. Before sitting for the bar exam, he was called to active duty once more. *Id.* ¶11. Sgt. Harrison deployed for a second tour of duty in 2011, this time to Kuwait, where his unit engaged in security for convoys withdrawing from Iraq. *Id.*

Shortly after returning from his second tour of duty in 2012, Sgt. Harrison was diagnosed with HIV. *Id.* ¶12. In keeping with Army regulations, he was immediately placed on antiretroviral combination therapy. *Id.* Soon thereafter, he had an undetectable viral load. *Id.* His viral load has remained suppressed or undetectable ever since. *Id.* ¶13.

After passing the Oklahoma bar, Sgt. Harrison moved to Washington, DC, to become a Presidential Management Fellow. *Id.* ¶¶14-15. He subsequently was offered a position in the Judge Advocate General (JAG) Corps in the DC National Guard, which required his elevation to officer. *Id.* at 16. Unfortunately, Sgt. Harrison soon discovered that Army policy denied officer status to people living with HIV. Sgt. Harrison requested a medical waiver, but his request was denied. *Id.* ¶¶19-20. Sgt. Harrison then sought an exception to policy (ETP), and many months later, that request also was denied. *Id.* ¶¶24-27. In this lawsuit, Sgt. Harrison seeks relief under

the equal protection guarantees of the U.S. Constitution.

III. LEGAL STANDARD

To obtain a preliminary injunction, a moving party must show: (1) a clear likelihood of success on the merits; (2) a clear likelihood that he or she will suffer irreparable harm in the absence of such relief; (3) that the balance of equities tips in plaintiff's favor; and (4) that an injunction is in the public interest. *United States v. South Carolina*, 720 F.3d 518, 533 (4th Cir. 2013) (citations omitted). "While plaintiffs seeking preliminary injunctions must demonstrate that they are likely to succeed on the merits, they 'need not show a certainty of success.'" *League of Women Voters of N.C. v. North Carolina*, 769 F.3d 224, 247 (4th Cir. 2014) (citation omitted).

Although "constitutional review" of military regulations is often "more deferential than [such] review of similar ... regulations designed for civilian society," *Goldman v. Weinberger*, 475 U.S. 503, 507 (1986), military personnel decisions are subject to equal protection constraints. *See, e.g., Emory v. Sec'y of Navy*, 819 F.2d 291, 294, 260 (D.C. Cir. 1987) ("The military has not been exempted from constitutional provisions that protect the rights of individuals. It is precisely the role of the courts to determine whether those rights have been violated.") (citations omitted); *Crawford v. Cushman*, 531 F.2d 1114, 1120 (2d Cir. 1976) ("[T]he military is subject to the Bill of Rights and its constitutional implications."); *Larsen v. U.S. Navy*, 486 F. Supp. 2d 11, 18-19 (D.D.C. 2007) (rejecting Navy's contention "its personnel decisions are immune from judicial scrutiny where constitutional wrongs are alleged"); *Dahl v. Sec'y of U.S. Navy*, 830 F. Supp. 1319, 1328 (E.D. Cal. 1993) ("the essence of individual constitutional rights ... remain[s] intact" in military).

IV. ARGUMENT

A. Plaintiffs Are Likely to Succeed on the Merits Because the Military’s Policies Regarding HIV-Positive Individuals Violate Equal Protection.

The military’s accessions and deployment policies with respect to people living with HIV violate the equal protection guarantees of the Constitution. As a group, people living with HIV meet all of the criteria defining a suspect or quasi-suspect class. Therefore, regulations and policies that single them out for disparate treatment should be subjected to heightened scrutiny. *Windsor v. United States*, 699 F. 3d 169, 181 (2d Cir. 2012) (holding that heightened scrutiny is warranted where government targets a class that: (1) has been “historically subject to discrimination,” (2) has a defining characteristic bearing no “relation to ability to perform or contribute to society,” (3) has “obvious, immutable, or distinguishing characteristics,” and (4) is “a minority or politically powerless.” (internal quotation marks omitted)), *aff’d*, 133 S. Ct. 2675 (2013). Regardless of the level of scrutiny applied, however, the government’s policies do not pass constitutional muster, because the accessions and deployment policies with respect to people living with HIV lack a rational relationship to a legitimate government interest.

1. Heightened Scrutiny Applies to the Military’s Policies Singling Out People with HIV.

a. The history of stigma and discrimination against people living with HIV is extensive and substantial.

The scope and intensity of stigma and discrimination against people living with HIV is unprecedented for any medical condition in the history of the United States. Hoppe Decl. ¶12 (Ex. D). From the very beginning of the HIV/AIDS epidemic, discrimination was rampant, based largely on the perceived infectiousness of people with this condition and pre-existing stigma against the groups most affected at that time. *Id.* ¶8. Despite all that has been learned about HIV since that time, persistent misconceptions regarding the actual routes and risks of transmission

continue to fuel stigma and discrimination against people living with HIV.²⁹

From the outset, a great number of people feared interacting with people with HIV despite clear evidence that the condition was not communicated through casual contact.³⁰ The demographics of the groups disproportionately reinforced the stigma and discrimination experienced by people living with HIV. As soon as the condition that would later be called “AIDS” appeared on the scene, it was met with a combination of apathy and disapprobation based on the sexual identity of the individuals in whom the condition was first recognized. Hoppe Decl. ¶7. In fact, before it was known that AIDS was caused by a virus, many hypothesized that it was caused by the “deviant lifestyle” of gay men in New York and other major cities in the U.S.³¹ Notably, laws criminalizing intimacy between members of the same sex still existed in many states. *Bowers v. Hardwick*, 478 U.S. 186, 193-94 (1986) (“24 States and the District of Columbia continue to provide criminal penalties for sodomy performed in private and between consenting adults”), *rev’d*, *Lawrence v. Texas*, 539 U.S. 558 (2003).

Religious leaders and others described AIDS as a biblical punishment.³² For example, in 1987, Reverend Jerry Falwell—leader of the Moral Majority—famously said, “God destroyed Sodom and Gomorrah primarily because of the sin of homosexuality. Today He is again bringing

²⁹ *Wash. Post/Kaiser Family Foundation 2012 Survey of Americans on HIV/AIDS* 13 (2012).

³⁰ Diana, Princess of Wales, famously stunned the world in 1987 when she shook the hand of a person living with HIV without wearing gloves. *See How Princess Diana Changed Attitudes to AIDS*, BBC, (Apr. 5, 2017), at <https://www.bbc.com/news/av/magazine-39490507/how-princess-diana-changed-attitudes-to-aids>.

³¹ *See, e.g.*, Lawrence K. Altman, *New Homosexual Disorder Worries Health Officials*, N.Y. Times, May 11, 1982, at <https://www.nytimes.com/1982/05/11/science/new-homosexual-disorder-worries-health-officials.html> (theorizing that AIDS, then referred to as “gay-related immunodeficiency” or GRID, may be caused by a combination of sexual promiscuity, nitrite drugs, and introduction of sperm into the blood through sexual contact).

³² *The Social Impact of AIDS in the United States* 131 (Jonson and Stryker eds., 1993) (quoting evangelical pastors condemning AIDS as the wages of sin).

judgment against this wicked practice through AIDS.”³³ To this day, public figures echo such sentiments and continue to foster perceptions that HIV is a result of immorality.³⁴ As of 2014, approximately one quarter of white evangelical protestants, and 14% percent of Americans overall, continue to believe that HIV is divine punishment for “immoral sexual behavior.”³⁵

Those who publicly condemned people living with HIV often had authority over public policy. In 1988, Jesse Helms, the long-time Senator from North Carolina, opposed funding research and treatment for AIDS because he believed that AIDS was God’s punishment for homosexuals and that “not one single case of AIDS in this country . . . cannot be traced in origin to sodomy.”³⁶ A year before, Helms had successfully included an amendment to an appropriations bill adding HIV to the list of diseases that prevent people from traveling or immigrating to the United States.³⁷ That policy remained in place until 2010.³⁸ In 1995, Helms opposed funding the Ryan White Care Act, saying that people had contracted AIDS due to their “deliberate, disgusting, revolting conduct” and that AIDS was “a disease transmitted by people

³³ Peter L. Allen, *The Wages of Sin: Sex and Disease, Past and Present* 123 (2002).

³⁴ E.g., Michael W. Chapman, CNSNews Blog, Pastor Rick Scarborough: ‘I Believe’ AIDS ‘Was God’s Judgement on a Sinful Generation’ (Jan. 28, 2016), at <https://www.cnsnews.com/blog/michael-w-chapman/pastor-rick-scarborough-i-believe-aids-was-gods-judgment-sinful-generation>.

³⁵ Robert P. Jones, Daniel Cox, and Juhem Navarro-Rivera, *A Shifting Landscape: A Decade of Change in American Attitudes about Same-sex Marriage and LGBT Issues* 44 (2014), at https://www.prii.org/wp-content/uploads/2014/02/2014.LGBT_REPORT-1.pdf.

³⁶ *Former Sen. Jesse Helms dies at 86*, Los Angeles Times, July 5, 2008, at <http://www.latimes.com/news/la-me-helms5-2008jul05-story.html>.

³⁷ David Lauter and Marlene Cimons, *Clinton to Drop Travel Ban on HIV Patients*, L.A. Times, Feb. 5, 1993, at http://articles.latimes.com/1993-02-05/news/mn-1021_1_white-house.

³⁸ Devin Dwyer, *U.S. Ban on HIV-Positive Visitors, Immigrants Expires*, ABC News (Jan. 5, 2010), <https://abcnews.go.com/Politics/united-states-ends-22-year-hiv-travel-ban/story?id=9482817>.

deliberately engaging in unnatural acts.”³⁹

The stigma against people living with HIV was widespread. In 1983, Pat Buchanan—an advisor to President Nixon and a candidate for the Republican presidential nomination in 1992 and 2000—declared that “the poor homosexuals . . . have declared war upon nature, and now nature is exacting an awful retribution.”⁴⁰ Buchanan alleged that there was a liberal conspiracy of silence among doctors regarding the level of threat posed to the American public through “AIDS-carrying homosexuals.” Conservative commentator William F. Buckley famously called for all newly-diagnosed patients to be tattooed as HIV-positive, and countless other leaders called for public health departments to institute quarantine procedures and to criminalize people living with HIV who they viewed as a threat to the health of others. Hoppe Decl. ¶10.

In 1986, political conspiracy theorist Lyndon LaRouche succeeded in adding Proposition 64 to the November ballot in California.⁴¹ The Proposition would have required anyone living with HIV to be reported to state authorities, barred from schools, and, if state officials deemed it appropriate, quarantined.⁴² As recently as 2017, Georgia state representative Betty Price, the wife of former Secretary of Health and Human Services Tom Price, sought to quarantine people living with HIV, arguing that doing so now is necessary because, “in the past, [people living with HIV] died more readily, and then at that point, they are not posing a risk.”⁴³

In 1985, a controversy erupted over Ryan White, who at age 13 was diagnosed with an

³⁹ Katharine Q. Seelye, *Helms Puts the Brakes to a Bill Financing AIDS Treatment*, N.Y. Times (Jul. 5, 1995), at <https://www.nytimes.com/1995/07/05/us/helms-puts-the-brakes-to-a-bill-financing-aids-treatment.html>.

⁴⁰ Patrick Buchanan, *Homosexuals and Retribution*, N.Y. POST, May 24, 1983.

⁴¹ Acquired Immune Deficiency Syndromes (AIDS), California Proposition 64 (1986).

⁴² *Id.*

⁴³ Ben Tinker, *Georgia lawmaker: Can people with HIV be ‘legally’ quarantined?*, CNN (Oct. 22, 2017), at <https://www.cnn.com/2017/10/20/health/betty-price-hiv-aids-quarantine/index.html>.

advanced case of AIDS, the result of a tainted blood product used to treat his hemophilia.⁴⁴

When Ryan attempted to return to his middle school in Kokomo, Indiana, teachers, parents and administrators resisted.⁴⁵ When courts and administrative bodies established that Ryan did not present any type of risk to the health or safety of other students and he was finally allowed to return to school in February 1986,⁴⁶ 151 of 360 students stayed home and seven transferred schools.⁴⁷ Shortly after that, a home school opened in a neighboring town for the express purpose of educating students whose parents did not want them to attend school with Ryan.⁴⁸

Misconceptions about the ways in which HIV is *and is not* transmitted persist and continue to fuel the discrimination experienced by people living with HIV.⁴⁹ Indeed, discrimination against people living with HIV not only continues but has remained stable and

⁴⁴ Dirk Johnson, *Ryan White Dies of AIDS at 18; His Struggle Helped Pierce Myths*, N.Y. TIMES (Apr. 9, 1990) at <https://www.nytimes.com/1990/04/09/obituaries/ryan-white-dies-of-aids-at-18-his-struggle-helped-pierce-myths.html>.

⁴⁵ Christopher M. MacNeil, *School bars door to youth with AIDS*, KOKOMO TRIBUNE, (Aug. 31, 1985, at <http://www.hemophiliafed.org/news-stories/2014/03/1985-ryan-white-banned-from-school-because-of-aids/>).

⁴⁶ *Indiana Judge Allows AIDS Victim Back in School*, N.Y. TIMES (Apr. 11, 1986), at <https://www.nytimes.com/1986/04/11/us/indiana-judge-allows-aids-victim-back-in-school.html>.

⁴⁷ Ryanwhite.com, *A Timeline of Key Events in Ryan's Life*, at <http://web.archive.org/web/20071012032359/www.ryanwhite.com/pages/timeline.html> (archived, last visited Jul. 16, 2018).

⁴⁸ *Id.*

⁴⁹ In 2012, the Kaiser Family Foundation and *The Washington Post* conducted a national survey establishing that approximately one-third (34%) of the public held one or more of the following misconceptions: (1) that HIV can be transmitted by sharing a drinking glass (27%); (2) that HIV can be transmitted by touching a toilet seat (17%); or (3) that HIV can be transmitted by swimming in a pool with someone who is HIV positive (11%). *Washington Post/Kaiser Family Foundation 2012 Survey of Americans on HIV/AIDS* 13 (2012). In the same survey, 20% of respondents said they would be somewhat or very uncomfortable working with someone who has HIV or AIDS; 26% said they would be somewhat or very uncomfortable if their child had an HIV-positive teacher; 33% said they would be somewhat or very uncomfortable having a roommate who was HIV positive; and 44% said they would be somewhat or very uncomfortable if their food was prepared by someone who is HIV positive. *Id.* at 16.

may be on the rise.⁵⁰ From FY 2010 - FY 2017, the U.S. Equal Employment Opportunity Commission (EEOC) reported receiving 1,693 complaints of employment discrimination based on HIV status.⁵¹ This is slightly more than the number of such complaints received in the prior eight-year period.⁵² In 2006, a Williams Institute study of healthcare providers in Los Angeles County revealed that “46% of skilled nursing facilities, 26% of plastic and cosmetic surgeons, and 55% of obstetricians in Los Angeles County would not take any patient who was HIV-positive for any type of service, even when patients were asymptomatic.”⁵³ And in one particularly disturbing throwback to the discrimination experienced by Ryan White, the Milton Hershey School, a private boarding school in Pennsylvania, denied admission in 2011 to a 14-year-old boy after learning that he was living with HIV.⁵⁴

Additionally, after HIV was identified as the cause of AIDS in 1984, state lawmakers around the country began to consider bills to institute disease control programs targeting this new epidemic. Hoppe Decl. ¶11. Along with other more conventional measures, lawmakers in 45

⁵⁰ “Individuals living with HIV have been detrimentally affected in every aspect of life, including experiencing denial and termination of employment; denial of needed medical care; loss of insurance coverage; erosion of social support networks; eviction from homes; disruption of family relationships; social isolation; depression; unwarranted criminal prosecution; and excessive criminal sentences.” Lambda Legal, *HIV Stigma and Discrimination in the U.S.: An Evidence-Based Report* (Nov. 2010), at https://www.lambdalegal.org/sites/default/files/publications/downloads/fs_hiv-stigma-and-discrimination-in-the-us_1.pdf.

⁵¹ U.S. Equal Employment Opportunity Commission (EEOC), *ADA Charge Data by Impairment/Bases – Receipts, FY 1997 – FY 2017*, at <https://www.eeoc.gov/eeoc/statistics/enforcement/ada-receipts.cfm>.

⁵² *Id.*

⁵³ Brad Sears & Deborah Ho, *HIV Discrimination in Health Care Services in Los Angeles County: The Results of Three Testing Studies*, The Williams Institute (Dec. 2006), at <https://williamsinstitute.law.ucla.edu/wp-content/uploads/Sears-Ho-Discrimination-Health-Care-LA-County-Dec-2006.pdf>.

⁵⁴ AIDS Law Project (Jun. 1, 2012), *Milton Hershey School to Pay \$700,000 to End Complaint Over HIV Discrimination*, at <http://www.aidslawpa.org/2012/06/abraham-smith-and-mother-smith-v-milton-hershey-school>.

states introduced legislation that imposed felony level criminal sanctions to control the behavior of people living with HIV. *Id.* No disease in American history has ever been met with a similarly punitive response from lawmakers. *Id.* ¶12.

b. People living with HIV lack relative political power.

As a group, people living with HIV lack sufficient political power to protect themselves from enactment of discriminatory measures. There currently are very few openly HIV-positive elected officials at the state level and none at the federal level of which Plaintiffs are aware.⁵⁵

The HIV/AIDS epidemic and the needs of people living with HIV were largely ignored by those in power for years.⁵⁶ For many of the reasons underlying the stigma and discrimination experienced by people with HIV at the beginning of the epidemic—namely that the disease was associated with already highly stigmatized communities—securing the attention of those who could have marshaled the resources necessary to combat this emerging epidemic was challenging.⁵⁷ Quite infamously, President Reagan did not mention “AIDS” in public until 1985, four years after the first cases were discovered and approximately 5,000 Americans had already died.⁵⁸ By the time Reagan directly addressed the epidemic in a speech in 1987, almost 50,000 Americans had died.⁵⁹ The scant amount of attention and relative inaction of the federal

⁵⁵ *E.g.*, Benjamin Ryan, *HIV-Positive Politicians and HIV Advocates*, POZ MAGAZINE (Sept. 26, 2016), at <https://www.poz.com/article/hivpositive-politicians-hiv-advocates>; Trenton Straube, *NYC Gets Its First Openly HIV-Positive City Council Speaker*, POZ MAGAZINE (Jan. 4, 2018), at <https://www.poz.com/article/nyc-gets-first-openly-hivpositive-city-council-speaker>.

⁵⁶ *E.g.* The Guardian, *The First Lady Who Looked Away: Nancy and the Reagans’ Troubling AIDS Legacy* (Mar. 11, 2016), at <https://www.theguardian.com/us-news/2016/mar/11/nancy-ronald-reagan-aids-crisis-first-lady-legacy>.

⁵⁷ *Id.*

⁵⁸ Richard Lawson, *The Reagan Administration’s Unearthed Response to the AIDS Crisis is Chilling*, Vanity Fair (Dec. 1, 2015), at <https://www.vanityfair.com/news/2015/11/reagan-administration-response-to-aids-crisis>.

⁵⁹ CDC, *HIV and AIDS – United States, 1981-2000*, 50(21) MMWR Weekly 430 (June 1, 2001), at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5021a2.htm#tab1>.

government also played out at state and local levels—even in New York City, which was the epicenter of the epidemic in the United States.⁶⁰ It was that apparent lack of concern and the anemic reaction of government officials that led to the creation of the AIDS Coalition To Unleash Power (ACT UP) in 1987.⁶¹ Over several years, ACT UP engaged in a series of well-publicized civil disobedience actions in an effort to secure the attention of political leaders and to get them to take action in the face of the community’s relative lack of political power.⁶²

While ACT UP was marginally successful in creating some of the changes it sought and funding for HIV/AIDS began to rise—first for research, and eventually for prevention, care and treatment—the domestic epidemic has never received the resources necessary to halt the epidemic. Since 1996, the tools to end the epidemic have been at the disposal of the government.⁶³ It is well established the treatments that became available at that time not only dramatically improve the health of people living with HIV, but also render those taking them non-infectious. Del Rio Decl. ¶25. But the federal program designed to ensure access to treatment is not adequately funded to cover all of those in need of its services and semi-regularly

⁶⁰ David France, *The reinvention of radical protest: life on the frontline of the AIDS epidemic*, The Guardian, November 29, 2016, at <https://www.theguardian.com/society/2016/nov/29/act-up-aids-new-york-spencer-cox> (revealing that it took New York City mayor Ed Koch two years to publicly acknowledge the AIDS crisis).

⁶¹ *Id.*

⁶² See, e.g., Peter Staley, *In Memory of Jesse Helms, and the Condom on His House*, POZ MAGAZINE (July 8, 2008), at <https://www.poz.com/blog/in-memory-of-je> (ACT UP members covered Senator Helms’ house in an inflatable condom reading “Helms is deadlier than a virus”).

⁶³ In 1996, effective antiretroviral treatment became widely available. Del Rio Decl. ¶16. Programs exist at various levels to connect people with HIV to medical care, but those programs are heavily reliant on state and federal funding. See, e.g., Henry J. Kaiser Family Foundation, *The Ryan White HIV/AIDS Program: The Basics* (Feb. 1, 2017), at <https://www.kff.org/hiv/aids/fact-sheet/the-ryan-white-hiv-aids-program-the-basics/> (“[The] Ryan White [Program] is the nation’s safety net for people with HIV providing outpatient HIV care and treatment to those without health insurance and filling in coverage gaps.”).

experiences shortfalls in meeting the needs of those currently enrolled.⁶⁴

Additionally, for more than a decade, advocates have been attempting to change laws criminalizing people living with HIV but have had very limited success in securing change at the state level. They have successfully modified the laws in only three of the 33 states that have HIV-specific criminal laws, thereby doing little to prevent continued unjust prosecutions under these outdated laws.⁶⁵ The limited amount of success people living with HIV have had in this arena is a result of their relative political powerlessness.

Finally, that many people living with HIV choose not to disclose their HIV status publicly reflects the stigma and discrimination that can flow from such a public disclosure and reinforces the insularity of group members. *See United States v. Carolene Prods. Co.*, 304 U.S. 144, 152 n.4 (1938) (allowing that “prejudice against discrete and insular minorities may be a special condition, which tends seriously to curtail the operation of those political processes ordinarily to be relied upon to protect minorities”). That stigma and isolation presents an additional obstacle to exercising political power, as it is hard to organize members of a group unwilling to self-identify.

c. HIV is an immutable characteristic.

Once it has been definitively established that a person is living with HIV, that person

⁶⁴ The most current federal budget proposal would cut funding for the Ryan White Program by a further \$57 million, *See Fiscal Year 2019 Budget in Brief*, Health Res. & Servs. Admin. 2 (2018), at <https://www.hrsa.gov/sites/default/files/hrsa/about/budget/HRSA-fy-2019-budget-in-brief.pdf>.

⁶⁵ For example, people living with HIV in Ohio continue to be prosecuted and convicted for engaging in sexual contact without being able to prove disclosure of their HIV status. Intent to transmit and actual transmission or harm of any kind are not required, and the use of condoms or other prophylaxis is not a defense. *See Ohio Rev. Code Ann. §2903.11* (2016).

never stops having HIV, as there is no available cure.⁶⁶ Contemporary treatments are incredibly effective at neutralizing the detrimental effects of HIV, but they do not eradicate the virus completely from the person's body. If a person with HIV were to stop receiving treatment, the person's HIV would return to detectable levels and eventually deteriorate the person's immune system.⁶⁷ HIV is therefore an immutable characteristic.

d. People living with HIV contribute to society at the same level as others.

There is no relationship between a person's HIV-positive status and their ability to perform and contribute to society. Even before the introduction of antiretroviral therapy, the percentage of people living with HIV whose ability to contribute to society was impaired was confined primarily to people in the most advanced stage of the disease. For people with access to modern treatments, there is no impairment of the ability to perform or contribute in any form.

There is not a job in the world that a person living with HIV cannot perform. Even without taking the effect of antiretroviral therapy on the risk of transmission into account, a person living with HIV can perform in any job without presenting a significant risk to the health or safety of herself or others. In the few contexts where there is a persistent (but false) belief that a person living with HIV would present such a risk—*e.g.*, healthcare workers or first responders—the reality is slowly catching up in the jurisprudence.⁶⁸

⁶⁶ HIV has been eradicated from only one person. See NBC News, *How Many People have been Cured of HIV? One* (July 22, 2014), at <https://www.nbcnews.com/health/health-news/how-many-people-have-been-cured-hiv-one-n161546>.

⁶⁷ Jeffrey Laurence, *Controlling HIV After Stopping Antiretroviral Therapy*, amfAR (Feb. 13, 2013), at <http://www.amfar.org/controlling-hiv-after-stopping-antiretroviral-therapy/>.

⁶⁸ *E.g.*, Consent Decree, *EEOC v. Granite Mesa Health Ctr. Ltd.*, No. 1:16-cv-01113-LY (W.D. Tex. Feb. 18, 2017) (defendant paid nurse \$70,000 for wrongfully terminating his employment after learning of his HIV-positive status); San Diego Gay and Lesbian News, *Atlanta to Pay \$250k to Man Denied Police Officer Job because of HIV Status* (Aug. 22, 2012), at <http://sdgln.com/causes/2012/08/22/atlanta-pay-250k-man-denied-police-officer-job-because-hiv-status>.

Even before the advent of modern treatments for HIV, people with an AIDS diagnosis would be the only group likely to experience the type of physical limitations that could affect their ability to work.⁶⁹ But given the long latency period for HIV, people with an AIDS diagnosis have always been a relatively small part of the overall population living with HIV.⁷⁰ Now that effective HIV treatments are available, significantly fewer people with HIV also have an AIDS diagnosis—and even fewer people with HIV are unable to work.

New scientific technologies have also eliminated limitations on a person’s ability to contribute to society through reproduction while living with HIV. For women, HIV medications provided during childbirth all but eliminate the risk of mother-to-child transmission.⁷¹ For men, a procedure known as “sperm-washing” was developed to allow them to fertilize an egg in an assisted reproduction process.⁷² And today, both men and women living with HIV who have a suppressed viral load are able to engage in reproduction through sexual intercourse.⁷³ There is no longer any significant limitation on a person with HIV’s ability to contribute to society by having

⁶⁹ Even for people with an AIDS diagnosis, physical limitations were due to the debilitating effects of certain opportunistic infections rather than the virus’s presence in the blood. *See, e.g.*, Office of the Assistant Sec’y of Def., Health Affairs Policy Mem. – Human Immunodeficiency Virus Interval Testing (Mar. 29, 2004), at <https://www.health.mil/Reference-Center/Policies/2004/03/29/Policy-Memorandum---Human-Immunodeficiency-Virus-Interval-Testing> (“there is no evidence that HIV infection, per se, affects physical fitness”).

⁷⁰ *See* CDC, *HIV in the United States: At a Glance* (June 26, 2018), at <https://www.cdc.gov/hiv/statistics/overview/ata glance.html> (of over one million people living with HIV in the United States, only 18,000 received an AIDS diagnosis in 2016).

⁷¹ CDC, *Pregnant Women, Infants, and Children*, (August 28, 2017), at <https://www.cdc.gov/hiv/group/gender/pregnantwomen/emct.html>.

⁷² WHO, *How effective and safe is semen washing for HIV-serodiscordant couples?* (last visited July 15, 2018), at <http://www.euro.who.int/en/data-and-evidence/evidence-informed-policy-making/publications/hen-summaries-of-network-members-reports/how-effective-and-safe-is-semen-washing-for-hiv-serodiscordant-couples>.

⁷³ Roger Peabody, *NICE says sperm washing is no safer than effective treatment and timed intercourse*, NAM AIDSMap (May 22, 2012), at <http://www.aidsmap.com/NICE-says-sperm-washing-is-no-safer-than-effective-treatment-and-timed-intercourse/page/2364056/>.

and raising children. People living with HIV are fully contributing members of society.

e. Applying Heightened Scrutiny To Policies Targeting People Living With HIV Is Consistent with *City of Cleburne v. Cleburne Living Center*.

In *City of Cleburne v. Cleburne Living Center*, 473 U.S. 432 (1985), the Supreme Court held that a city’s zoning ordinance impermissibly discriminated against people with mental disabilities. *Cleburne* is often cited for the proposition that regulations targeting people with disabilities, including people living with HIV, are subject only to rational basis review. *See, e.g., Doe v. Univ. of Md. Med. Sys. Corp.*, 50 F.3d 1261, 1267 (4th Cir. 1995). However, *Cleburne*, which determined the appropriate standard of review for classifications based on mental disabilities, should not control the level of scrutiny applied to people living with HIV. The principal factor that led the court to apply rational basis to a mental disability classification in *Cleburne*—the relative inability to perform and contribute to society as others—simply is not present with respect to people living with HIV. In large part for this reason, people living with HIV do not fit easily within any standardized definition of people with disabilities.

In stark contrast to *Cleburne*’s view of the classification at issue in that case, the health status of people living with HIV has no significant impact on their ability to contribute to society. *See* §IV.A(1)(d), *supra*. In *Cleburne*, the Court stated that it was “undeniable . . . that those who are mentally retarded (*sic*) have a reduced ability to cope with and function in the everyday world.” *Cleburne*, 473 U.S. at 442. That is simply not true for people living with HIV. *See* §IV.A(1)(d), *supra*. The *Cleburne* Court’s justification for rejecting rational basis review is not present for the group of people whose rights are at issue here.

Furthermore, in *Cleburne* the Court noted that people with mental disabilities were a “large and diversified group” across a wide spectrum of disability, requiring flexibility for lawmakers adequately to address their varying needs. *See id.* at 442-43. On the other hand,

people living with HIV are, except for a small minority, uniformly capable of contributing to society. *See* §IV.A.(1)(c), *supra*; *see also* *Frontiero v. Richardson*, 411 U.S. 677 (1973) (holding that gender is entitled to heightened scrutiny because it *frequently*—not always—bears no relation to the ability to perform or contribute to society). People with HIV work and live among us unnoticed because their ability to perform in these tasks is not in any way limited by their HIV. They are entitled to heightened scrutiny because of the animus, stigma and discrimination they experience based on other people’s outdated *misperceptions* about HIV. *E.g.*, *Cleburne*, 473 U.S. at 441 (noting that sex-based classifications “very likely reflect outmoded notions of the relative capabilities of men and women”).

Indeed, most people living with HIV do not fit within any common definition of “disabled.” There is not a single legal definition of disability under federal law, much less a definition that has been established for purposes of engaging in an equal protection analysis. For instance, the definition of “disability” that qualifies a person for disability benefits under the Social Security Act is much different—and narrower—than the definition that qualifies a person as an individual with a disability under the Americans with Disabilities Act (“ADA”). *Compare* 42 U.S.C. §1382c(a)(3)(A) *with* 42 U.S.C. §12102(1)(A). Furthermore, successful treatment with antiretroviral therapy moves people with HIV even further away from any traditional definition of a person with a disability.⁷⁴ *See* §§II.A., IV.A.(1)(d), *supra*.

⁷⁴ In fact, when the ADA was amended in 2009, “immune function” was explicitly added to the list of major life activities—the substantial impairment of which would lead to a finding of disability under the ADA—because plaintiffs proceeding under the statute were finding it increasingly difficult to demonstrate that any of the previously recognized major life activities were substantially impaired by their HIV. *See* Andrew J. Gordon, *End Around: HIV Discrimination in the Post-Amendments Act Workplace*, 36 Berkeley J. Emp. & Lab. L. 215, 219 (2015); *see, e.g.*, *Worster v. Carlson Wagon Lit Travel, Inc.*, 353 F.Supp.2d 257, 266 (D. Conn. 2005) (holding that plaintiff was not disabled under the ADA because his HIV status did not substantially impair any major life activities).

For purposes of assessing whether people living with HIV are entitled to heightened scrutiny in an equal protection analysis, it is most appropriate to characterize them as people with a stigmatized health condition—a trait they all share—rather than as people with a disability, a characterization into which only a small percentage of the group may fit depending on the definition applied. Rather than a rote application of *Cleburne* to determine the level of scrutiny,⁷⁵ this Court should evaluate from a clean slate whether people with a stigmatized health condition—and more specifically, people living with HIV—constitute a suspect or quasi-suspect class entitled to heightened scrutiny. In assessing the relevant factors from that perspective, it becomes apparent that people living with HIV are entitled to at least intermediate scrutiny.

2. The Military’s Restrictions on Military Service for People Living with HIV Are Not Even Rationally Related to Military Effectiveness.

Plaintiffs are likely to succeed in demonstrating the military’s restrictions on service for HIV-positive individuals do not survive even rational basis review, much less heightened scrutiny. Under even the lowest level of review, a law must bear a rational relationship to a legitimate government interest to be valid. *See, e.g., U.S. Dep’t of Agric. v. Moreno*, 413 U.S. 528, 534 (1973). This standard is “not a toothless one.” *Mathews v. Lucas*, 427 U.S. 495, 533 (1976). Because of advances in the treatment of HIV, there is no longer a rational relationship between the military’s restrictions on service members with HIV and any legitimate government interest related to military effectiveness, readiness, lethality, or other purported justification.

⁷⁵ *See, e.g., Doe v. City of Chicago*, 883 F.Supp. 1126, 1140-41 (7th Cir. 1994) (applying *Cleburne* with little discussion to hold that classifications based on HIV-positive status are entitled only to rational basis review); *Contractors Ass’n of Eastern Pennsylvania, Inc. v. City of Philadelphia*, 6 F.3d 990, 1001 (3d Cir. 1993) (same); *Leckelt v. Board of Com’rs of Hosp. Dist. No. 1*, 714 F. Supp. 1377, 1390 (E.D. La. 1989) (same).

a. A Soldier’s HIV Diagnosis Bears No Relationship to His or Her Fitness, Military Readiness, Effectiveness, or Lethality.

The military’s restrictions are not rationally related to military effectiveness or readiness,⁷⁶ because a person’s physical capabilities are not affected by an HIV diagnosis. Prior to the availability of antiretroviral therapy in 1996, physical limitations would likely develop once an individual was diagnosed with AIDS. Now, however, someone who receives treatment will not experience physical limitations. *See* Hendrix Decl. ¶¶ 26-27 (Ex. E). As a military publication has explained: “In the past 30 years, HIV-1 infection has gone from an untreatable disease marked by inexorable clinical progression through extreme debility to death to a treatable disease that is compatible with active service throughout a full career in the U.S. military.”⁷⁷ Even the DoD admitted over a decade ago that “[t]here is no evidence that HIV infection, per se, affects physical fitness.”⁷⁸

Sgt. Harrison exemplifies that an HIV diagnosis has no impact on physical abilities. After being diagnosed with HIV, Sgt. Harrison immediately began treatment and shortly thereafter had an undetectable viral load. *See* Harrison Decl. ¶13. Sgt. Harrison has been virally suppressed or had an undetectable viral load since that time. *Id.* ¶14. Three years after his diagnosis, Sgt. Harrison received the highest possible score for “medical fitness” when he underwent his

⁷⁶ AR 600-110 indicates that the Army’s HIV policy reflects “the effect of infected personnel on unit functions and readiness.” AR 600-110 at Ch. 1, § III, ¶1-15.

⁷⁷ J. Brundage, D. Hunt & L. Clark, *Durations of Military Service after Diagnoses of HIV-1 Infections Among Active Component Members of the U.S. Armed Forces 1990-2013*, Armed Forces Health Surveillance Center, *Medical Surveillance Monthly Report*, Vol. 22, No. 8 (Aug. 2015), at <https://health.mil/Reference-Center/Reports/2015/01/01/Medical-Surveillance-Monthly-Report-Volume-22-Number-8>.

⁷⁸ Office of the Assistant Sec’y of Def., Health Affairs Policy Mem. – Human Immunodeficiency Virus Interval Testing (Mar. 29, 2004), at <https://www.health.mil/Reference-Center/Policies/2004/03/29/Policy-Memorandum---Human-Immunodeficiency-Virus-Interval-Testing>.

commissioning medical exam. *Id.* ¶14; Hendrix Decl. ¶26. In other words, Sgt. Harrison’s HIV has not impacted his physical abilities and fitness to serve.

b. Soldiers Living with HIV Who Are Deployed Can Easily Be Provided with Necessary Medical Care.

The military’s purported concerns regarding the risks posed to service members with HIV while deployed are unfounded given current capabilities for medically managing HIV. Medical care for people living with HIV has changed dramatically since the Army first imposed its HIV-related restrictions back in 1988.⁷⁹ Effective treatment became widely-available in 1996, and today HIV medications generally consist of a single tablet regimen (STR), “which is literally one pill taken once a day.” Hendrix Decl. ¶23. This is no different from the prescription medication service members serving overseas must take to prevent malaria, as Sgt. Harrison did when he was deployed in Afghanistan (Harrison Decl. ¶8). Nor is it different from the medication that those with dyslipidemia—who are permitted to enlist and deploy per current military policies—must take daily.⁸⁰

Medical monitoring of HIV-positive individuals has also advanced to the point that there is no longer any HIV-related risk to personnel with HIV serving and deploying. Viral load testing generally is required only 2-3 times per year. *See* Hendrix Decl. ¶24. This testing is routine and entails drawing and testing a blood sample. *Id.* When testing facilities are not available in theater, blood samples may be shipped to a lab. *Id.* But point-of-care viral load testing that is cost-effective and returns results within 90 minutes is also becoming increasingly available. *Id.*

⁷⁹ AR 600-110 (Mar. 11, 1988), at <http://www.whs.mil/library/mildoc/AR%20600-110,%2011%20March%201988.pdf>.

⁸⁰ *See* DoDI 6130.03, *Medical Standards for Appointment, Enlistment, or Induction in the Military Services*, Encl. 4, § 5.24(n), p. 39 (eff. May 6, 2018).

In addition, the on-site care of people living with HIV who have a suppressed viral load is relatively minimal, and physicians in the Armed Forces can provide the requisite level of care for individuals with HIV, regardless of where they are stationed. *Id.* ¶25. In the unusual event that on-site medical personnel do not feel capable of providing the necessary care, an infectious disease specialist may consult via telemedicine. *Id.* In sum, individuals with HIV who receive treatment are not at any greater risk than and can access care in a manner similar to other individuals serving in the military.

The health care costs for individuals with HIV who wish to serve in the Armed Forces are also not a legitimate basis for the military's discriminatory policies. For decades, the military has borne the costs of testing service members and covering the care of service members who have been diagnosed with HIV while on active duty. Moreover, the federal government has the leverage to negotiate the price of medications to keep down costs. Finally, costs alone are an insufficient reason to justify discriminatory policies that otherwise represent a clear violation of equal protection. The government may not "protect the public fisc by drawing an invidious distinction between classes" of persons. *Mem. Hosp. v. Maricopa Cty.*, 415 U.S. 250, 263 (1974).

c. Other Purported Justifications for Restrictions on Military Service for HIV-Positive Individuals Do Not Pass Muster.

If the military maintains that its policies barring individuals from enlisting or deploying overseas are related to preventing battlefield transmissions or protecting the safety of blood supplies,⁸¹ given the current knowledge regarding transmission and treatment of HIV, Plaintiffs are overwhelmingly likely to show that these justifications also lack merit. As an initial matter, to date there is no documented evidence of a battlefield transmission. Hendrix Decl. ¶21.

⁸¹ See AR 600-110 at Ch. 1, § III, ¶1-15.

Moreover, given the known effect of a suppressed or undetectable viral load on sexual transmission risk, there is an “extremely low—and possibly only theoretical—risk of transmission via blood splash and other non-injection activities.” Del Rio Decl. ¶27. In the highly unlikely event that such an exposure occurred, post-exposure prophylaxis could be administered, further decreasing whatever minimal risk of exposure existed. Hendrix Decl. ¶22. As a result, there is no basis to conclude that someone with HIV would present a danger to other military personnel. *Id.*

Allowing individuals with HIV to serve and deploy overseas also does not jeopardize the safety of military blood supplies. People living with HIV are instructed not to act as blood donors and any risk to blood supplies from those who are unaware they have HIV would remain constant. Hendrix Decl. ¶30. Eliminating the military’s discriminatory HIV-related policies will have no impact on the so-called “walking blood bank,” *i.e.*, donations from service members in emergency situations. Emergency battlefield transfusions are relatively rare. *Id.* ¶31 n.31. As it currently stands, not all service members can serve as donors, given that “various other factors that often disqualify individuals as emergency blood donors, such as blood type—making people living with HIV no different from these other groups who are allowed to serve and deploy.” *Id.* Furthermore, in the future, the availability of blood substitutes should also diminish the military’s need to rely on the “walking blood bank.” *Id.*

The fact the military has not only permitted HIV-positive individuals to continue to serve but also has allowed them to serve outside the United States entirely refutes the notion there is any real risk to HIV-positive individuals or others resulting from their service overseas. In 2012, the DoD explained to Congress: “[B]ased on advances in medical treatment which have significantly simplified the disease management of individuals with HIV,” the Navy began

permitting individuals with HIV to deploy outside the United States.⁸² This updated policy was based the Navy's assessment there is "no demonstrated risk" of transmission in normal daily activities and its recognition that an investment had been made in individuals already serving in the military.⁸³ As of September 2017, approximately 55 sailors have been assigned to various overseas and/or operational assignments without any adverse events.⁸⁴

B. Plaintiff and Other HIV-Positive Service Members Will Be Irreparably Harmed Absent a Preliminary Injunction.

Implementation of the new DOGO Policy is likely to result in the discharge of almost all service members living with HIV. This would abruptly end the military careers of hundreds of service members across all branches of the Armed Forces. Without a preliminary injunction, Sgt. Harrison and hundreds of other HIV-positive service members will be irreparably harmed.

The DOGO Policy *requires* the branches of the military to begin processing and discharging members who fall within its parameters by October 2018, but it allows them to start doing so immediately.⁸⁵ Already, multiple individuals with HIV are facing discharge proceedings or service restrictions as a result of the DOGO Policy.⁸⁶

⁸² Dep't of Def., *Report to Congressional Defense Committees on Department of Defense Personnel Policies Regarding Members of the Armed Forces with HIV or Hepatitis B*, at 7 (July 30, 2014), at <https://health.mil/Reference-Center/Reports/2014/09/22/DoD-Personnel-Policies-Regarding-Members-of-the-Armed-Forces-with-HIV-or-Hepatitis-B>

⁸³ SECNAV Instruction 5300.30E, ch. 9.b. (Aug. 13, 2012).

⁸⁴ J. Okulicz, *et al.*, *Review of the U.S. Military's Human Immunodeficiency Virus Program: A Legacy of Progress and a Future of Promise*, Armed Forces Health Surveillance Ctr., *Medical Surveillance Monthly Report*, Vol. 24, No. 9 (Sept. 2017), at <https://health.mil/Reference-Center/Reports/2017/01/01/Medical-Surveillance-Monthly-Report-Volume-24-Number-9>.

⁸⁵ Wilkie, DOGO Policy, *supra*, at n.1.

⁸⁶ See Declarant 2 Decl. ¶ 12 ("In spite of the recommendations of both my doctor and my commanding officer, the informal [Physical Examination Board] decided . . . I should nevertheless be discharged.") (Ex. G); Declarant 1 Decl. ¶¶ 12-13 ("[M]y selection as Commander of the Fifth Brigade had been withdrawn. As justification, my superiors indicated their decision was a result of the Department of Defense Retention [DOGO] Policy for Non-Deployable Service Members . . . , which had been issued on February 14, 2018.") (Ex. F).

Prior to issuance of the DOGO Policy, service members living with HIV who were found to be fit for duty were nonetheless permitted to continue serving “in a manner that ensures access to appropriate medical care.”⁸⁷ Now, due to the DOGO Policy, hundreds of service members living with HIV will be involuntarily separated from the military, where many proudly have served for decades. For example, Sgt. Harrison has served his country for nearly 18 years, earned a law degree, passed a bar examination, and is otherwise qualified to serve as a Judge Advocate General. Yet he is being prevented from doing so by military policies regarding the accession and non-deployability of service members with HIV, and he could be separated from service under the new DOGO Policy before this case is even adjudicated. Hundreds of other service members with HIV would likewise be denied the opportunity to continue and advance their military careers. *See Ariz. Dream Act Coalition v. Brewer*, 855 F.3d 957, 977 (9th Cir. 2017) (“[L]oss of opportunity to pursue one’s chosen profession constitutes irreparable harm”).

Furthermore, “[t]he unconstitutional discharge of even one service member perpetuates a harm to that person that is irreparable.” *Log Cabin Republicans v. United States*, 2012 WL 12952732, at *10 (C.D. Cal. Mar. 15, 2012), *vac’d on other grounds*; Declarant 2 Decl. ¶23. Individuals who are discharged from military service stand to lose medical benefits and a portion of their retirement pay. *See Elzie v. Aspin*, 841 F.Supp. 439, 443 (D.D.C. 1993). The deprivation of medical benefits “is exactly the sort of irreparable harm that preliminary injunctions are designed to address.” *Fishman v. Paolucci*, 628 F. App’x. 797, 801 (2d Cir. 2015).

In addition to the tangible harms discussed above, the stigma suffered by Plaintiffs in being separated from the military is an irreparable harm that warrants a preliminary injunction. Courts have recognized that there is a certain “stigma of being removed from active duty.” *Elzie*

⁸⁷ *See* DoDI 6485.01 (Jun. 7, 2013).

v. Aspin, 841 F.Supp. 439, 443 (D.D.C. 1993); *see also* Declarant 1 Decl. ¶16 (discussing stigma of being denied his promotion at the last minute). This is especially so when that removal is not due to any fault of those being discharged. Additionally, the violation of constitutional rights “unquestionably constitutes irreparable injury.” *See Elrod v. Burns*, 427 U.S. 347, 374 (1976). The DOGO Policy and pre-existing military policies create a regime in which otherwise qualified, HIV-positive service members are prohibited from serving in any capacity in the military. This policy “stigmatizes members of a disfavored group as innately inferior.” *Evancho v. Pine-Richland School District*, 237 F.Supp.3d 267, 294 (W.D. Pa. 2017) (citing *Heckler v. Mathews*, 465 U.S. 728, 739 (1984)).

C. The Balance of Equities Weigh in Favor of Plaintiffs

The balance of equities plainly weighs in favor of granting the requested relief. Government “is in no way harmed by issuance of a preliminary injunction which prevents the state from enforcing restrictions likely to be found unconstitutional. If anything, the system is improved by such an injunction.” *Aziz v. Trump*, 234 F.Supp.3d 724, 737 (E.D. Va. 2017); *see also Centro Tepeyac v. Montgomery Cty.*, 722 F.3d 184, 192 (4th Cir. 2013) (citing *Doran v. Salem Inn., Inc.*, 422 U.S. 922, 934 (1975)). Because Plaintiffs are likely to succeed in the constitutional challenges to the DOGO Policy and the underlying policies regarding HIV, the government cannot claim to be harmed by being forced to cease its unconstitutional actions.

Furthermore, the government cannot point to any significant harm it would suffer from an injunction. As of June 2017, there were 1,194 service members with HIV in the military.⁸⁸ This number accounts for 0.4% of the 286,000 service members who are nondeployable and just

⁸⁸ *See DoD, Update: Routine Screening for Antibodies to Human Immunodeficiency Virus, Civilian Applicants for U.S. Military Service and U.S. Armed Forces, Active and Reserve Components*, (Jan. 2012–Jun. 2017), 24 Med. Surveillance Monthly Rpt. 8, 8–14 (Sept. 2017).

.027% of all active duty service members.⁸⁹ See Hendrix Decl. ¶ 31. Plaintiffs simply ask the Court to return people living with HIV to the status quo that existed prior to issuance of the DOGO Policy. This creates no burden on the government, as the policy of allowing service members with HIV to serve as long as they are fit for duty dates back over two decades to 1993.

D. The Public Interest Favors an Injunction

As this Circuit and Court have made clear, “upholding constitutional rights surely serves the public interest.” *Aziz*, 234 F.Supp.3d at 738; see also *Giovani Carandola, Ltd. v. Bason*, 303 F.3d 507, 521 (4th Cir. 2002). The public interest is also served by preventing discrimination based solely on HIV status as a principle of justice, permitting dedicated soldiers to continue serving their country and receive adequate medical care, while awaiting a decision on the merits.

In addition, there is a significant public health interest in demonstrating to the broader public—particularly those at higher risk for HIV—that they will not face stigma or discrimination if they seek testing and treatment for HIV. The CDC has indicated that “[m]ore than three decades after the first HIV diagnoses were made, stigma remains a barrier to addressing HIV in the United States.”⁹⁰ The issuance of a preliminary injunction to prevent continuing discrimination against people living with HIV will enhance efforts to educate the public about HIV transmission, prevention, and treatment.

V. CONCLUSION

For the reasons set forth above, Plaintiffs are entitled to an injunction maintaining the status quo and suspending implementation of the DOGO Policy against people living with HIV.

⁸⁹ See *Ferdinando*, *supra*.

⁹⁰ See CDC, *Act Against AIDS*, at <https://www.cdc.gov/actagainstaids/campaigns/lsh/index.html>.

Dated: July 19, 2018

/s/ Scott A. Schoettes

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* motion for *pro hac vice* admission pending

CERTIFICATE OF SERVICE

I hereby certify that on the 19th day of July 2018, I served a true and correct copy of the foregoing by first class mail on the following:

James Mattis
Secretary of Defense
1000 Defense Pentagon
Washington, D.C. 20301-1000

Mr. G. Zachary Terwilliger
U.S. Attorney for the Eastern District of Virginia
Justin W. Williams U.S. Attorney Building
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Alexandria, VA 22314

U.S. Department of Defense
1000 Defense Pentagon
Washington, D.C. 20301-1000

Dr. Mark T. Esper
Secretary of the Army
101 Army Pentagon
20310-0101

Mr. Jeff Sessions
Attorney General of the United States
Department of Justice
950 Pennsylvania Ave., N.W.
Washington, D.C. 20530-0001

Dated: July 19, 2018

Respectfully submitted,

/s/ Andrew R. Sommer
Andrew R. Sommer

Exhibit A



PERSONNEL AND
READINESS

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

FEB 14 2018

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
UNDER SECRETARIES OF DEFENSE
DEPUTY CHIEF MANAGEMENT OFFICER
CHIEF, NATIONAL GUARD BUREAU
DIRECTOR OF COST ASSESSMENT AND PROGRAM
EVALUATION

SUBJECT: DoD Retention Policy for Non-Deployable Service Members

In July, the Secretary of Defense directed the Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)) to lead the Department's effort to identify changes to military personnel policies necessary to provide more ready and lethal forces. In his initial memorandum to the Department, Secretary Mattis emphasized, "[e]very action will be designed to ensure our military is ready to fight today and in the future." Given the Secretary's guidance, OUSD(P&R) moved forward from the underlying premise that all Service members are expected to be world-wide deployable. Based on the recommendations of the Military Personnel Policy Working Group, the Deputy Secretary of Defense determined that DoD requires a Department-wide policy establishing standardized criteria for retaining non-deployable Service members. The objective is to both reduce the number of non-deployable Service members and improve personnel readiness across the force.

The Deputy Secretary of Defense directed the following interim policy guidance, which will remain in effect until the Department issues a DoD Instruction on reporting and retention of non-deployable Service members:

- Service members who have been non-deployable for more than 12 consecutive months, for any reason, will be processed for administrative separation in accordance with Department of Defense Instruction (DoDI) 1332.14, *Enlisted Administrative Separations*, or DoD Instruction 1332.30, *Separation of Regular and Reserve Commissioned Officers*, or will be referred into the Disability Evaluation System in accordance with DoDI 1332.18, *Disability Evaluation System (DES)*. Pregnant and post-partum Service members are the only group automatically excepted from this policy.
- The Secretaries of the Military Departments are authorized to grant a waiver to retain in service a Service member whose period of non-deployability exceeds the 12 consecutive months limit. This waiver authority may be delegated in writing to an official at no lower than the Military Service headquarters level.

- The Military Services have until October 1, 2018, to begin mandatory processing of non-deployable Service members for administrative or disability separation under this policy, but they may begin such processing immediately.
- The Military Services may initiate administrative or disability separation upon determination that a Service member will remain non-deployable for more than 12 consecutive months; they are not required to wait until the Service member has been non-deployable for 12 consecutive months.
- The Military Services will continue to provide monthly non-deployable reports to OUSD(P&R) in the format established by the Military Personnel Policy Working Group.

My office will issue a DoDI to provide additional policy guidance and codify non-deployable reporting requirements. Publication of the DoDI will supersede and cancel this policy memorandum.



Robert L. Wilkie

cc:

Assistant Secretary of the Army
for Manpower and Reserve Affairs
Assistant Secretary of the Navy
for Manpower and Reserve Affairs
Assistant Secretary of the Air Force
for Manpower and Reserve Affairs
Senior Enlisted Advisor to the Chairman
of the Joint Chiefs of Staff
Deputy Chief of Staff, G-1, U.S. Army
Chief of Naval Personnel, U.S. Navy
Deputy Chief of Staff for Personnel and Services,
U.S. Air Force
Deputy Commandant for Manpower and Reserve
Affairs, U.S. Marine Corps
Director, Reserve and Military Personnel,
U.S. Coast Guard
Director, Manpower and Personnel, Joint Staff
National Guard Bureau, J-1

Exhibit B

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

NICHOLAS HARRISON and
OUTSERVE-SLDN, INC.

Plaintiffs,

v.

JAMES N. MATTIS, in his official capacity
as Secretary of Defense; MARK ESPER, in
his official capacity as the Secretary of the
Army; and the UNITED STATES
DEPARTMENT OF DEFENSE,

Defendants.

Case No. 1:18-cv-641 (LMB/IDD)

**EXPERT DECLARATION OF CARLOS DEL RIO, M.D., IN SUPPORT OF
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**

I. INTRODUCTION

1. My name is Carlos del Rio. I have been retained by counsel for Plaintiffs as an expert in connection with this litigation.

2. I am offering this declaration 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.

II. PROFESSIONAL BACKGROUND & QUALIFICATIONS

5. I am the Hubert Professor and Chair of the Department of Global Health and Professor of Epidemiology at the Rollins School of Public Health and Professor of Medicine in the Division of Infectious Diseases at Emory University School of Medicine. I am also Principal Investigator and co-Director of the Emory Center for AIDS Research (CFAR).

6. I am a native of Mexico where I attended medical school at Universidad La Salle, graduating in 1983. I did my Internal Medicine and Infectious Diseases residencies at Emory University. In 1989, I returned to Mexico where I was Executive Director of the National AIDS Council of Mexico (CONASIDA, the Federal agency of the Mexican Government responsible for AIDS Policy throughout Mexico) from 1992 through 1996. In November 1996, I returned to Emory where I have been involved in patient care, teaching and research. I was Chief of the

Emory Medical Service at Grady Memorial Hospital from 2001 to 2009 and I am now the interim Executive Associate Dean for Emory at Grady.

7. My research focuses on early diagnosis, access to care, engagement in care, compliance with antiretrovirals and prevention of HIV. I am the co-Primary Investigator of the NIH-funded Emory-CDC HIV Clinical Trials Unit, Clinical Site Leader for the Adult AIDS Clinical Trials Group (ACTG) and the site Primary Investigator for the HIV Prevention Trials Network (HPTN) of the NIAID/NIH. My international work includes collaborations in the following countries: Georgia, Ethiopia, Kenya, Thailand, Vietnam and Mexico. I have also worked on emerging infections, such as pandemic influenza, and was a member of the WHO Influenza A(H1N1) Clinical Advisory Group and of the CDC Influenza A(H1N1) Task Force during the 2009 pandemic.

8. I am a Member of the Board of Directors of the International Antiviral Society-USA (IAS-USA) and was the Chair of the HIVMA of the Infectious Diseases Society of America (IDSA). I was also a member of the Advisory Committee on HIV, Hepatitis and STD Prevention and Treatment of the Centers for Disease Control and Prevention and Health Resources and Services Administration as well as of the Department of Health and Human Services (DHHS) Antiretroviral Treatment Guidelines Panel. I serve as Chief Section Editor for HIV/AIDS for NEJM Journal Watch Infectious Diseases, Associate Editor for Clinical Infectious Diseases and I am a member of the editorial board of the Journal of AIDS and Global Public Health.

9. I have co-authored 30 book chapters and over 300 scientific papers. Among other honors, I received the James H. Nakano Citation in 2001 and was recognized by the Centers for Disease Control and Prevention for an outstanding scientific paper published in 2000; awarded

the Emory University Marion V. Creekmore Achievement Award for Internationalization; selected by the “Atlanta Magazine” as one of the 55 most influential foreign-born Atlantans in 2007. In 2013, I was elected to the Institute of Medicine of the National Academies.

10. My curriculum vitae is attached, which describes my education, work experience, and publications. *See* Attach. 1 (del Rio CV).

III. BACKGROUND ON THE HUMAN IMMUNODEFICIENCY VIRUS

A. An Introduction to HIV

11. Since Acquired Immune Deficiency Syndrome (AIDS) was first identified as a cause of death in the United States in the early 1980s, there has been incredible progress in the treatment of this disease. Once considered invariably fatal within a matter of years, HIV is now considered a chronic, manageable condition. Those diagnosed in a timely manner and provided with appropriate care and treatment with antiretroviral medications experience no noticeable effects on their physical health and enjoy a life expectancy that is nearly the same as those who do not have HIV.

12. HIV, which is an acronym for human immunodeficiency virus, attacks the body’s immune system. Specifically, HIV attacks the body’s CD4 cells, also referred to as T-cells. When HIV takes over a CD4 cell, it forces the cell to produce multiple copies of the virus, which in turn take over other CD4 cells.

13. CD4 cells help the immune systems fight off other types of infections. As HIV reduces the number CD4 cells in the body, it becomes increasingly harder for a person to fend off infections or disease.

14. After the acute stage of infection, a person enters a period of clinical latency that can last years. After time, however, if the person does not receive appropriate treatment, the

amount of virus in their blood (i.e., their “viral load”) will rise and their CD4 count will start to drop. Eventually, an untreated individual’s CD4 count will drop below 200 and/or the person will develop an infection the body would be able to fight off under normal circumstances (i.e., an “opportunistic infection”), at which point that person would have an AIDS diagnosis.

B. The Treatment of HIV

15. At almost any point in the progression of HIV, however, consistent treatment with antiretroviral therapy will halt and reverse the downward slope in immune function and restore the person to good health.

16. In 1996, effective antiretroviral therapy (ART) became widely available. In the mid-1990’s, medical researchers discovered that a combination of three antiretroviral medications (from at least two different subclasses) would not only prevent HIV from reproducing, but would also prevent the virus from mutating and becoming resistant to the medications, as had been the problem with mono and dual therapy approaches. .

17. With adherence to ART, the person’s viral load drops and their CD4 count rebounds. Within several months, the person’s HIV will become “virally suppressed,” defined as less than 200 copies of the virus per milliliter of blood,¹ and shortly after that, they would have an “undetectable”² viral load, which is generally defined as less than 50 copies per milliliter of blood. .

¹ See U.S. Centers for Disease Control and Prevention, *Evidence of HIV Treatment and Viral Suppression in Preventing the Sexual Transmission of HIV* (Dec. 2017), available at <https://www.cdc.gov/hiv/pdf/risk/art/cdc-hiv-art-viral-suppression.pdf>; U.S. Centers for Disease Control and Prevention, *HIV Treatment as Prevention*, available at www.cdc.gov/hiv/risk/art (“[V]iral suppression [is] defined as having less than 200 copies of HIV per milliliter of blood.”).

² 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

18. Every person living with HIV who adheres to their antiretroviral medications will eventually achieve and maintain an undetectable viral load. There is an effective treatment regimen for virtually every person living with HIV, and difficulties in 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 instable housing or food insecurity, that make medication adherence more difficult.

19. Development of resistance to a particular ART regimen does not occur unless the 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 in different ways 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, switching to a different regimen to which their virus has not developed resistance and to which they are subsequently adherent will return that patient to viral suppression.

20. As drugs have less and less side effects, adherence to ART has grown easier and easier over the past 20 years. 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 no dietary restrictions, and side effects are minimal and generally very well tolerated.

below this level, but the term “undetectable” is still used to describe a viral load at or below this level.

21. A person who is diagnosed with HIV in a timely manner and adheres to their prescribed ART has very nearly the same life expectancy as a person who is not living with HIV.³

C. The Transmission of HIV

22. HIV can only be transmitted via certain body fluids—blood, semen, pre-seminal fluid, rectal fluids, vaginal fluids, and breast milk.⁴ For transmission to occur, these fluids from a person who has HIV must either come in contact with a mucous membrane or damaged tissue or be directly injected into the bloodstream (with a needle or syringe). Mucous membranes are found inside the rectum, vagina, penis, and mouth. HIV is not spread through saliva, sweat, tears, urine, or feces.

23. Most commonly, HIV is transmitted by engaging in sexual activities or sharing needles or syringes. Outside of the contexts of sexual activity, sharing of injection drug 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.”⁵

³ See U.S. Centers for Disease Control and Prevention, *About HIV/AIDS*, available at <https://www.cdc.gov/hiv/basics/whatishiv.html>.

⁴ See U.S. Centers for Disease Control and Prevention, *HIV Transmission*, available at <https://www.cdc.gov/hiv/basics/transmission.html>.

⁵ See U.S. Centers for Disease Control and Prevention, *HIV Risk Behaviors: Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act*, available at www.cdc.gov/hiv/risk/estimates/riskbehaviors.html.

24. 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).⁶ The per-act risk of transmission for other sexual activities is between zero and .08%.

25. Furthermore, people living with HIV who are virally suppressed or have an undetectable viral load are incapable of transmitting HIV. Advances in understanding of the preventive 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. See CDC, “Dear Colleague: Information from CDC’s Division of HIV/AIDS Prevention,” Sept. 27, 2017, *available at* <https://www.cdc.gov/hiv/library/dcl/dcl/092717.html> (last viewed June 26, 2018).⁷

26. 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”⁸ (i.e., a viral load of less than 200 copies/ml).

⁶ See U.S. Centers for Disease Control and Prevention, *HIV Risk Behaviors: Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act*, available at www.cdc.gov/hiv/risk/estimates/riskbehaviors.html.

⁷ See U.S. Centers for Disease Control and Prevention, *Treatment as Prevention*, available at www.cdc.gov/hiv/risk/art (“People living with HIV who take HIV medicine as prescribed and get and keep an undetectable viral load have effectively no risk of transmitting HIV to their HIV-negative sexual partners.”).

⁸ The referenced scientific studies: The HIV Prevention Treatment Network Study No. 052 as published in the *New England Journal of Medicine* 08/11/11, *available at* <https://www.nejm.org/doi/full/10.1056/NEJMoa1105243?query=recirc> curated Related article; PARTNER Study, published in the *Journal of the American Medical Association (JAMA)* July

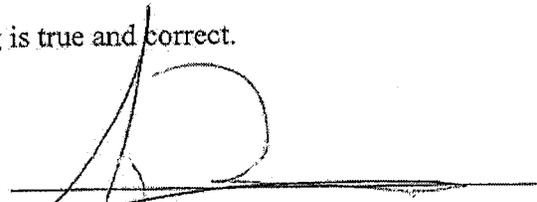
27. Based on these studies regarding the effect of a suppressed or undetectable viral load on sexual transmission risk and the extremely low—and possibly only theoretical—risk of transmission via blood splash and other non-injection activities, I am reasonably certain that it is not possible for a person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

IV. CONCLUSION

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.

Executed this 18 day of July, 2018



Carlos del Rio, M.D.

12, 2016, available at <https://ncbi.nlm.nih.gov/pubmed/27404185>; and Opposites Attract study reported at the Conference on Retroviruses and Opportunistic Infections (CROI) in 2015, available at <https://www.croiconference.org/sites/default/files/posters-2015/1019LB.pdf> and the International AIDS Conference in 2017.

Attachment

**EMORY UNIVERSITY
CURRICULUM VITAE**

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Atlanta GA 30322

E-mail Address: cdelrio@emory.edu

Birth Date and Place: August 28, 1959. Mexico City, Mexico

Citizenship: United States of America and Mexico

Websites:

<http://medicine.emory.edu/infectious-diseases/faculty-directory/del-rio-carlos.html> &
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ResearcherID:

<http://www.researcherid.com/ProfileView.action?returnCode=ROUTER.Success&Init=Yes&SrcApp=CR&queryString=KG0UuZjN5WmP6yAsUHlIBIEGQkwtKoQLBlp0gCLTBbs%253D&SID=7Co6dCuimpqh4njckXt>

Current Titles and Affiliations:

a. Academic appointments:

April 1, 2009 – present: Hubert Professor & Chair, Hubert Dept. of Global Health,
Rollins School of Public Health of Emory University

Sept. 1, 2003 – present: Professor of Medicine (Tenured), Emory University School of
Medicine

b. Clinical Appointments:

March 1997 – July 2011: Active Medical Staff, Grady Health System

Oct 1999 – present: Medical Staff member, The Emory Clinic

July 2011 – present: Active-Courtesy staff member, Grady Health System

June 2013 – present: Infectious Diseases Clinical Chief of Service at Emory University
Hospital

c. Other administrative appointments:

Jan 16, 2017 – present: Interim Executive Associate Dean for Emory at Grady

Oct 1, 2005 – present: Co-Director, Emory Center for AIDS Research.

Jan. 1, 2007 – present: Clinical Research Site (CRS) Leader at the Ponce de Leon Center
for the Emory AIDS Clinical Trials Group (ACTG).

Previous Academic and Professional Appointments:

1990 – 1996: Associate Professor of Medicine, Universidad La Salle, Mexico City, Mexico.

1989 – 1996: Chief of Infectious Diseases and Chairman of the Infection Control
Committee, Hospital Angeles del Pedregal, Mexico City, Mexico.

1993 – 1999: National Investigator, National Research Council (Sistema Nacional de Investigadores), Mexico.
1996 – 1997: Assistant Professor of Medicine (transient appointment), Emory University School of Medicine (EUSM).
1997 – 2001: Associate Director for Clinical Services at the Ponce de Leon Center of the Grady Health System and Director of the Special Immunology Service at Grady Memorial Hospital
September 1, 1997 – August 31, 2003: Associate Professor of Medicine (Infectious Diseases), Emory University School of Medicine
December 18, 1997 – August 31, 2005: Adjunct Associate Professor of International Health, Rollins School of Public Health, Emory University
September 1, 2005 – March 31, 2009: Adjunct Professor of Global Health, Rollins School of Public Health, Emory University.

Previous Administrative Appointments:

1992 – 1994: Executive Director of the National AIDS Council (CONASIDA), Mexico.
1994 – 1996: General Coordinator of the National AIDS Council (CONASIDA), Mexico.
1995 – 1997: Member of the Program Coordinating Board, Joint United Nations Program on HIV/AIDS (UNAIDS)
July 1999 – July 2000: Associate Director of the Internal Medicine Residency Program
January 1998 – July 2001: Director, Clinical Core of the Emory CFAR
July 1, 2000 – March 31, 2001: Program Director, Emory Internal Medicine Residency Program
April 1, 2001 - January 31, 2006: Co-Director, J. Willis Hurst Internal Medicine Program.
April 1, 2001 - March 31, 2009: Chief of Medical Service, Grady Memorial Hospital
February 1, 2006 – February 29, 2008: Director for Resident Scholarly Activities, J. Willis Hurst Internal Medicine Residency Program.
July 1, 2001 – September 30, 2005: Associate Director for Clinical Sciences and International Research, Emory Center for AIDS Research
July 1, 2004 – June 1, 2006: Executive Director, Hope Clinic of the Emory Vaccine Center.
February 1, 2006 – March 31, 2009: Vice Chair for Grady Affairs, Dept. of Medicine, EUSM
March 1, 2008 – May 31, 2010: Program Director, J. Willis Hurst Internal Medicine Residency Program of Emory University.
Sept. 1998 – June 2015: Director and Principal Investigator, AIDS International Training and Research Program (AITRP) of Emory University.

Licensures/Boards:

Georgia Medical License: 027282
1981: ECFMG (Educational Commission for Foreign Medical Graduates)
1982: VQE (Visa Qualifying Examination)
1984: FLEX (Federation Licensing Examination)

Specialty Boards:

- 1986, American Board of Internal Medicine (#108785)
- 1988, American Board of Internal Medicine (Infectious Diseases)

Education:

- 1977-83: Medical School, Universidad La Salle, Mexico City, Mexico
- 1981-82: Pregraduate internship (senior year of medical school), six months at the University of Oregon, Portland, Oregon and six months at Emory University, Atlanta, Georgia
- 1982-83: Social service, Department of Critical Care Medicine, Instituto Nacional de la Nutrición Salvador Zubirán, Mexico City, Mexico

Postgraduate Training:

- 1983-86: Internal Medicine Residency, Emory University School of Medicine, Atlanta, Georgia (five months in JAR year at Johns Hopkins Hospital, Baltimore, MD)
- 1986-88: Infectious Disease Fellowship, Emory University School of Medicine, Atlanta, Georgia
- 1988-89: Chief Resident in Medicine at Crawford Long Hospital of Emory University, Atlanta, Georgia

Executive Training:

- Jan 2007: Program for Chiefs of Clinical Services. Department of Health Policy and Management, Harvard School of Public Health.
- Jan 2008: Woodruff Health Sciences Center Quality Academy.

Committee Memberships:

- a. National and International:
 - Member of the Scientific Advisory Committee of the Latin-American AIDS Initiative (SIDALAC) (1996 – 2000)
 - Member of the Monitoring of the AIDS Pandemic (MAP) Network (1996 – 2000)
 - Chair, Committee on the Status of Minority Microbiologists, Public and Scientific Affairs Board, American Society for Microbiology (June 1997 - June 2003)
 - CDC, Member of the Task Force to develop the “*HIV Prevention Strategic Plan Through 2005*” (February 2000).
 - Member of the CDC Advisory Committee on HIV and STD Prevention (September 2000 – November 2003)
 - Member of the UNAIDS Performance Monitoring and Evaluation Plan Working Group (1997)
 - NIH Office of AIDS Research, Member of the Planning Group on International AIDS Research Priorities (April, 2001 and February 2002)
 - NIH, Chairman of Special Emphasis Panel for NIH NOT AI-01-018 “*Comprehensive International Program of Research on AIDS*” (August, 2001)
 - NIH, Member of Special Emphasis Panel for NH-00-0048 “*Early detection of HIV: Implications for Prevention Research*” (June 2000)
 - NIH, Member of Special Emphasis Panel for NH-00-004 “*Long-term Maintenance of HIV/STD Behavior Change*” (June 2000)
 - Elizabeth Glaser Pediatric AIDS Foundation, Member of Review Panel for “Call for Action Projects” (January 1996 to present)

- Member, Institute of Medicine’s Committee on the Ryan White Care Act: Data for Resource Allocation, Planning and Evaluation. (January 2002 – October 2003).
- NIH, Member of the Outcomes Committee of the Adult AIDS Clinical Trials Group (July 2001 – December 2006)
- Member, International AIDS Society – USA Core Faculty (April 2002 to present)
- NIH, Chairman of Special Emphasis Panel ZAI1-GPJ-A-S2 “*Comprehensive International Program of Research on AIDS - CIPRA*” (May, 2003)
- CDC, Member Special Emphasis Panel 2003-N-008922 “*A US Clinical Trial Site to Conduct Evaluation of Topical Microbicides in Heterosexual Women and Men*” (August, 2003)
- Member, Education Committee, Infectious Diseases Society of America (2003 – 2005)
- NIH, Member of Special Emphasis Panel ICP-2 “*International Bioethics Reviews*” (March 2004)
- NIH, Member of Special Emphasis Panel ZAI1 GP J-M (M1) “*NIAID Enhancement Awards for Underrepresented Minority Scientists*” (June 28 – 30, 2004)
- CDC, Member on Special Emphasis Panel PA 04156, “*Simplified Procedures for Routine HIV Screening in Acute Care Settings*” (August 17, 2004)
- NIH – Charter Member of the AIDS Clinical Studies and Epidemiology Study Section (formerly AARR-6), November 2004 – July 2009.
- Member of the Board of Directors, International AIDS Society – USA (January 2005 – present)
- NIH, Member of Special Emphasis Panel ZAI1 LD-A-J1 “*Unsolicited Research Project Grant Application*” (January 2006)
- NIH, Member of Special Emphasis Panel ZAI1 SV-A (S1) “*TB/HIV Immune Cell Expression*” (August 2006)
- NIH, Chair of Special Emphasis Panel ZAI1QV-1 “*Review of Clinical Trials and Implementation Grants*” (September 2006)
- NIH, Member of Special Emphasis Panel ZRG1 IC2-B (51) “*Phase II Comprehensive ICOHRTA-AIDS/TB (U2R) Review*” (November 2006)
- Representative of HIVMA on the Education Committee of IDSA (2006 – 2010)
- External Reviewer of the draft report by the Committee on the “*President’s Emergency Plan for AIDS [PEPFAR] Implementation Evaluation*”. (November 2006)
- Member, Institute of Medicine’s Committee on Methodological Challenges in HIV Prevention Trials (January 2007 – February 2008).
- Member, DHHS Panel for Antiretroviral Guidelines for Adults and Adolescents (February 2007 – February 2010 and February 2010 – February 2014)
- NIH, Member of Special Emphasis Panel ZAI1 ESB-A (M1) “*HIV Prevention in Men Review*” (April 2007)
- NIH, Member of Special Emphasis Panel ZRG1 BDA-A (52) “*FICRS Resource and Support Center Review*” (April 2007)
- CDC, Member of Special Emphasis Panel ZPS1 FXR (03) “*Minority HIV/AIDS Research Initiative to Build Capacity in Black and Hispanic Communities and Among Black and Hispanic Researchers to Conduct HIV/AIDS Epidemiologic and Prevention Research – MARF*” (May 2007)

- NIH, Member of Special Emphasis Panel ZAI1 SR-M (1) “*NIAID Clinical Trials Planning Grants*” (June 2007)
- Member of the Board of Directors of the HIVMA - HIV Medicine Association of IDSA - (October 2007 – Oct 2017)
 - Chair of the Board (Oct 2015 – Oct 2016)
- Member of the Board of Advisors of HealthSTAT (July 2007 – present)
- NIH, Member of Special Emphasis Panel ZRG1 ICP2-B (51) “*Global Infectious Diseases Training Program*” (February 2008)
- NIH, Member of Special Emphasis Panel ZRG1 ICP2-B (50) “International Research in Infectious Diseases” (February 2008)
- NIH, Member of Special Emphasis Panel ZDA1 NXR-B 13 1, “International Collaborations for HIV and Drug Abuse” (April 2, 2008)
- Member of the OpMAN (Optimization of Co-Infection and Co-Morbidity Committee) of the AIDS Clinical Trials Group (May 2008 – May 2010)
- Member of the Advisory Committee on HIV and STD Prevention and Treatment of the Centers for Disease Control and Prevention and Health Resources and Services Administration (July 1, 2008 – June 30, 2012 and July 1, 2012 – December 30, 2016)
- NIH, Member of Special Emphasis Panel ZDA1 NXR-B 08 1, “Pre-Applications for the Avant-Garde Program” (April 19, 2009)
- NIH, Member of Special Emphasis Panel ZRG1 AARR-C 22 “AIDS Fellowship Review” (July 28-29, 2009)
- Member, Institute of Medicine Committee on HIV Social Security Disability Criteria (Dec 2009 – June 2010)
- Member, WHO Influenza A(H1N1) Clinical Advisory Group (2009)
- Member, CDC Influenza A(H1N1) Task Force (2009)
- NIH, Member of Special Emphasis Panel ZCA1 RTRB-8 M2 R “A Developing Research Capacity in Africa for the Studies of HIV-Associated Malignancies” (March 15, 2010)
- NIH, Member of Special Emphasis Panel ZDA1 NXR-B 08 1, “Pre-Applications for the Avant-Garde Program” (April 23, 2010)
- Member of the ACTG Executive Committee (June 1, 2010 – May 31, 2013)
- Member of the Board of Directors of the Infectious Diseases Society of America (October 2010 – September 2013)
- Member, Institute of Medicine Committee to Review Data Systems for Monitoring HIV Care (February 2011 – September 2012)
- NIH, Member of Special Emphasis Panel ZRG1 IDM-R (50) R, “International Research in Infectious Diseases including AIDS (IRIDA)”. (February 11, 2011)
- NIH, Chair, Special Emphasis Panel ZRG1 F12B-U (20) L, “Fellowships: Psychopathology, Disabilities, Stress and Aging. (February 24, 2011)
- NIH, Member of Special Emphasis Panel ZDA1 NXR-B 15, “Pre-Applications for the 2011 Avant-Garde Program for HIV/AIDS Research” (March 28, 2011)
- NIH/NIAID – Charter Member, Acquired Immunodeficiency Syndrome Research Review Committee (AIDS RRC), (July 1, 2011 – June 30, 2015).
- NIH, Member of Special Emphasis Panel ZRG1 AARR-H (55) “Career Development in International Settings”. (June 29, 2011)

- NIH/FIC – Member, US-India Joint Working Group on Prevention of Sexually Transmitted Diseases and HIV/AIDS (Oct 31, 2011)
- NIH, Member of Special Emphasis Panel ZDA1 NXR-B, “Pre-Applications for the Avant-Garde Program” (Jan 11, 2012)
- NIH, Chair of Special Emphasis Panel ZRG1 AARR-H, “HIV International Research Training” (Oct 31 – Nov 1, 2012)
- Member of the Board of Director, ACTHIV (April 2013 – present)
- Co-Chair, International Antiviral Society-USA Panel on Development of Recommendations for Biomedical Prevention of HIV Infection (2013)
- NIH, member of Special Emphasis Panel ZAI1 BP-A (S4), “Clinical Trials Implementation UO1 Grants” (Aug 26, 2013)
- NIH, member of Special Emphasis Panel ZRG1 AARR-F (52), “Methodologies and Formative Work for Combination HIV Prevention Approaches” (Dec 16, 2013)
- Member, Office of HIV/AIDS Network Coordination (HANC) Behavioral Sciences Consultative Group (Jan 1, 2015 – Dec 31, 2018)
- NIH/NIAID – Chair, Acquired Immunodeficiency Syndrome Research Review Committee (AIDS RRC), (July 1, 2014 – June 30, 2017)
- Member, UNAIDS Scientific and Technical Advisory Committee (Dec 2014 – present)
- Member, Fulton County Task Force on HIV/AIDS (Dec 2014 – Sept 2017)
- Chair, PEPFAR Scientific Advisory Board (March 1, 2015 – present)
- Vice-Chair, ACTG Underrepresented Populations Committee (Dec 1, 2016 – Nov 30, 2018)

b. Regional and State:

- Member of the Scientific Advisory Committee of the AIDS consortium of Atlanta (1996 – 2004)
- Member of the Board, AID Atlanta (1998 – 2004)
- Member of the Board of Trustees, The Paideia School (1998 – 2004)
- Member of the Parent Council of Emory University (2007 – 2010)
- Member of the Board of Directors, Atlanta Symphony Orchestra (2011 – present)

c. Institutional

- LCME Graduate Medical Education/Continuing Education Committee (1998)
- Dean of School of Nursing Search Committee (1999)
- GME Advisory Committee (July 1999 - present)
- Representative of the School of Medicine on the International Affairs Council (November 2000 to 2009)
- Member of the School of Medicine Faculty Committee on Appointments and Promotions (June 2001 – September 2004)
- Member of the Faculty Council of Emory University (2000- 2004)
- Member, Advisory Board of the Center for the Study of Health, Culture and Society (December 2000 – May 2009)
- Internal Medicine House Staff Evaluation Committee (March 1998 - present)
- Orthopedic Chair Search Committee (2001)
- Medical Executive Committee, Grady Health System (April 2001 – March 2009)

- Chair, Education and Training Subcommittee, Woodruff Health Sciences Center Bioterrorism Taskforce (April 2002 – December 2003)
- Representative of the School of Medicine on the Coordinating Committee for University Internationalization (September 2002 – April 2009)
- Chair, Medical Records Committee, Grady Health System (May 2002 – December 2005)
- Member, EMCF Practice Committee (June 2002 – March 2009)
- Member, Emory GCRC Advisory Committee (June 2002 – June 2007)
- Radiology Chair Search Committee (2003-2004)
- Member, Emory University Strategic Planning Committee (Subcommittees on Global Health and Internationalization).
- Co-Chair, Curriculum Planning Steering Committee of Emory University School of Medicine (September 2004 – December 2005)
- GCRC Director Search Committee (2005)
- Member, Faculty Development Committee for the Department of Medicine (2005 – 2009)
- Chair, Department of Medicine Promotions and Tenure Subcommittee (2005 – 2007)
- Member, Honorary Degrees Committee of Emory University (2006 – 2009)
- Member, Global Health Institute Advisory Committee, Emory University (2006 – present)
- Member, Institute for Developing Nations Academic Board, Emory University (2006 – present)
- Co-Chair Task Force on Faculty and Staff Development, Emory University School of Medicine (December 2006 – August 2007)
- Member, Search Advisory Committee for the Senior Vice President for Health Affairs of the Woodruff Health Sciences Center of Emory University (January – July 2007)
- Member, LCME Faculty Subcommittee (2007)
- Member, Presidential Advisory Committee (PAC) of Emory University (September 2007 – August 2009)
- Member, Surgery Chair Search Advisory Committee (2007-08)
- Member, Director of Critical Care for Emory Healthcare Search Advisory Committee (2008-09)
- Member, Research Advisory Committee of the School of Medicine (March 1, 2009 – August 31, 2010)
- Member, Woodruff Health Sciences Center Research Advisory Council (April 2009 – present)
- Chair of the Research Training and Education subcommittee for the WHSC Research Strategic Plan (August 2009 – May 2010)
- Co-Chair, Culture Transformation Group, Woodruff Health Sciences Center (May 2009 – May 2011).
- Member, Task Force on Protest, Dissent and Community (May 2011 – May 2015)
- Member, Emory University Faculty Advisory Committee for Finance and Administration (Oct 2011 – May 2015)
- Member, Family and Preventive Medicine Chair Search Committee (2012)

- Member, Graduate Medical Education Strategic Planning Committee (2013)
- Member, Director of Yerkes National Primate Research Center Search Committee (2013)
- Member, LCME Taskforce (2015)
- Co-Chair, Emory University's Provost Search Advisory Committee (Oct 2016 – 2017)

Consultantships:

- Centers for Disease Control and Prevention, Consultant for the drafting of the "*HIV Prevention Strategic Plan Through 2005*". September 2000.
- Centers for Disease Control and Prevention, External consultant for the "*Control of Neisseria gonorrhoeae infection in the United States*". Oct 10 – 11, 2001.
- Centers for Disease Control and Prevention, Consultant on "*Bioterrorism Education for Clinicians*", August 2002.
- Abbott Laboratories. HOPE Partnership (December 2001 – December 2002)
- Centers for Disease Control and Prevention, Consultant on implementing HIV Testing in Acute Care Settings. March 2004.
- NIH/Harvard Medical School Division of AIDS, Participant in the scientific workshop addressing "*When to Switch HIV Antiviral Therapy in Resource-Limited Settings*". Boston, MA. November 12, 2004.
- Centers for Disease Control and Prevention, Participant in Satellite Broadcast/Web Cast "*Incorporating HIV Prevention into the Medical Care of Persons Living with HIV*". November 13, 2004.
- Centers for Disease Control and Prevention, Consultant in drafting the "*HIV Screening Recommendations for Adults, Adolescents, and Pregnant Women in Health Care Settings*". November 1 – 2, 2005. Published as "*Revised Recommendations for HIV testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*". *MMWR* 2006; 55(RR-14)
- Interagency Task Force on Antimicrobial Resistance, Consultant in drafting "*A Public Health Action Plan to Combat Antimicrobial Resistance*". December 12-13, 2007.
- Centers for Disease Control and Prevention, consultant for the "*External Peer Review of DHAP Surveillance, Research, and HIV Prevention Programs*". April 13 – 15, 2009
- Centers for Disease Control and Prevention, consultant for the "*Consultation on Revised Guidelines for HIV Counseling, Testing, and Referral in non-clinical settings*". June 1 – 2, 2009.
- Centers for Disease Control and Prevention, consultant during a meeting entitled: "*Developing a Rapid Impact Assessment Framework for Pandemic Influenza Response*". August 26, 2010
- Centers for Disease Control and Prevention, consultant for the "*Consultation on Monitoring and Use of Laboratory Data Reported to HIV Surveillance*". Jan 12 – 13, 2011
- Centers for Disease Control and Prevention, consultant for the "*Consultation on MSM Pre-Exposure Prophylaxis (PrEP) Implementation Guidelines*". May 3 – 4, 2011.

- Centers for Disease Control and Prevention, consultant for the “*HIV surveillance Case Definition*”. Feb 7 – 8, 2012.
- Centers for Disease Control and Prevention, consultant for the “*STD Treatment Guidelines 2013*”. April 30 – May 2, 2013.

Editorship and Editorial Boards:

- Chief Editor, HIV/AIDS *Journal Watch Infectious Diseases (2014 – present)*
- Associate Editor for HIV, *Clinical Infectious Diseases (2016 – present)*
- Senior Clinical Editor, *AIDS Research and Human Retroviruses (2007 – 2017)*
- Editorial board, *AIDS Clinical Care (2000 – 2014)*
- Editorial Board, *Journal of AIDS*
- Editorial Board, *Global Public Health*
- Editorial Board, *Women, Children and HIV*
- Editorial board, *Archives of Medical Research*

Manuscript reviewer

- AIDS
- AIDS Research and Human Retroviruses
- AIDS and Behavior
- American Journal of Medicine
- American Journal of Public Health
- American Journal of Preventive Medicine
- American Journal of the Medical Sciences
- Annals of Internal Medicine
- Annals of Emergency Medicine
- Archives of Internal Medicine
- Archives of Medical Research
- Clinical Infectious Diseases
- Emerging Infectious Diseases
- Gaceta Médica de México
- JAMA
- Journal of AIDS
- Journal of General Internal Medicine
- Journal of Infectious Diseases
- Lancet
- New England Journal of Medicine
- PLoS One
- Salud Pública de México
- Sexually Transmitted Infections
- Social Sciences and Medicine
- Vaccine

Honors and Awards:

- 1982 Valedictorian, medical school class of 1982, Universidad La Salle, Mexico
- 1983 Awarded "Los mejores estudiantes de México" (Best students in Mexico)
- 1987 Elected member of A.O.A.
- 1988 Trainee Travel Award, American Federation for Clinical Research
- 1990 Fellow of the American College of Physicians
- 1989, 91, 96 Physician Recognition Award, American Medical Association
- 1992-99 "Investigador Nacional Nivel I" (National Researcher) by the "Sistema Nacional de Investigadores" in Mexico
- 1993 Award "Hermano Miguel" given by the Universidad La Salle in Mexico in recognition of academic achievement
- 1996 Glaxo-Wellcome Foundation Award for Clinical Research. Mexico City, Mexico.
- 1996 Fellow of the Infectious Diseases Society of America
- 2001 James H. Nakano Citation (for an outstanding scientific paper published in 2000)
- 2002 Finalist, Atlanta Business Chronicle "Health-Care Heroes" Award in the

- Physician category
- 2006 Outstanding Achievement Award in the Field of HIV/AIDS awarded by the First Lady of Georgia for “*Personal Contribution in Developing a modern HIV/AIDS Control Program in Georgia*”
 - 2007 Marion V. Creekmore Award for Internationalization, Emory University
 - 2006, 2007, 2009, 2010, 2011, 2012, 2013 and 2017 “Best Conference Award”, as voted by the residents for the most outstanding conference in the Emory Internal Medicine Residency Program.
 - 2007 Selected by “*Atlanta Magazine*” as one of the 55 most influential foreign-born Atlantans (October 2007 issue)
 - 2009 Elected member of the American Clinical and Climatological Association
 - 2011 Elected member of the American Epidemiological Society
 - 2011 Silver Pear Research Mentoring Award, Department of Medicine, Emory Univ.
 - 2013 Fellows Award for Distinguished Educator in Infectious Diseases, University of Pittsburgh Division of Infectious Diseases
 - 2013 Elected to the National Academy of Medicine (formerly the Institute of Medicine)
 - 2014 Winner of the Thomas Jefferson Award at Emory University
 - 2015 Winner of the Department of Medicine R. Wayne Alexander Research Achievement Award
 - 2015 Department of Medicine Research Day, 3rd place winner in the “Clinical, Quality and Health Services Research Poster” category.
 - 2016 Elected to Delta Omega (Honorary Society in Public Health) by the member students of the Phi Chapter at the Rollins School of Public Health
 - 2016 Recipient of the “Ohtli Award” from the Mexican Government for "*distinguished work that benefits the interests of the Mexican community or communities of Mexican origin living in the US*".
 - 2017 John P. McGovern Award Lectureship delivered at the 47th Annual Meeting of the American Osler Society. Atlanta, GA April 10th, 2017.
 - 2017 Distinguished Medical Alumni Achievement Award – Emory University School of Medicine
 - 2017 Inducted to the Emory MilliPub Club (The MilliPub Club honors and recognizes Emory faculty who have published one or more papers that have garnered more than 1,000 citations).
 - 2017 Winner of the Emory University School of Medicine Mentoring Award

Society Memberships:

- American College of Physicians
- Member of the American Society for Microbiology
- Asociación Mexicana de Medicina Interna
- Infectious Diseases Society of America
- Asociación Mexicana de Infectología y Microbiología Clínica
- American Federation for Medical Research
- International AIDS Society

Organization of National or International Conferences:a. Administrative positions:

- Organizing committee of the 8th International Pathogenic *Neisseria* Conference, October 1992, Cuernavaca, Mexico
- Coordinator of the IV National AIDS Conference, October 1993, Mexico City, Mexico
- Organizing committee of the IV International Conference on Travel Medicine, April 1995, Acapulco, Mexico
- Coordinator of the V National AIDS Conference, November 1995, Mexico City, Mexico
- Scientific Committee, 1st IAS Conference on HIV Pathogenesis and Treatment, Buenos Aires, Argentina, July 2001
- Track Co-chair, 2001 National HIV Prevention Conference, Atlanta, GA, August 2001
- Scientific Program Committee Member, 3rd Conference on Global Strategies for the Prevention of HIV Transmission from Mothers to Infants. Kampala, Uganda. September 2001.
- International Scientific Committee, XIV International Conference on AIDS, Barcelona, Spain, July 2002
- Scientific Program Committee, 8th World STI/AIDS Congress, Punta del Este, Uruguay, December 2-5, 2003.
- Joint Program Committee Track Co-chair, XVI International Conference on AIDS, Mexico City, Mexico, August 2008.
- Track Co-chair, 2009 National HIV Prevention Conference, Atlanta, GA, August 2009
- Planning Committee Member, 36th Remington Winter Course in Infectious Diseases. Vail, CO. February 21 - 26, 2010
- Co-Chair, AIDS Vaccine 2010. Atlanta, GA. September 28 – October 1, 2010
- Regional Chair, HIVDART 2010. Los Cabos, Mex. December 7 – 10, 2010
- Planning Committee Member, 37th Remington Winter Course in Infectious Diseases. Snowmass, CO. February 6 – 11, 2011
- Member, Clinical Science Track Committee, XIX International Conference on AIDS, Washington, DC. July 22 – 27, 2012
- Member, Scientific Advisory Committee, 2nd International Treatment as Prevention (TasP) Workshop. Vancouver, BC. April 22 – 25, 2012
- Member, Scientific Advisory Committee, 3rd International Treatment as Prevention (TasP) Workshop. Vancouver, BC. April 22 – 25, 2013
- Co-Chair of Planning Committee, The American Conference for the Treatment of HIV (ACTHIV), Denver, Co. May 8 – 10, 2014
- Scientific Advisory Committee, HIVDART 2014. Key Biscayne, Fla. December 9 – 12, 2014
- Member of the Scientific Program Committee, HIV Drug Therapy in the Americas 2015. Mexico City, Mx. April 16 – 18, 2015.
- Co-Chair of Planning Committee, The American Conference for the Treatment of HIV (ACTHIV), Dallas, Tx. Apr 29 – May 3, 2015
- Member of the Core Committee, HIV & Hepatitis in the Americas 2016. Mexico City, Mx. April 28 – 30, 2016.
- Member of the Core Committee, HIV & Hepatitis in the Americas 2017. Rio de Janeiro, Brazil. April 6 – 8, 2017.

Research focus:

My research efforts focus on access to care, linkage to care and barriers to care among HIV-infected hard to reach populations in the United States and abroad. I also do research on treatment and prevention of HIV/AIDS as well as adherence and the impact of therapy on behavior. I also work on TB and other co-infections like HCV and STI's, in particular gonorrhea. Finally, my research has expanded to include the emerging opioid epidemic and looking for ways to improve opioid prescribing and management of pain in clinical settings.

Grant Support:a. Active support:

- NIH (2P30 AI 50409). Emory CFAR. (PI: C. del Rio) 08/01/17 – 7/31/22.
- NIH/NIAID (AI069418). Emory-Duke-Orlando-CDC Clinical Trials Unit. (co-PIs: J. Lennox; C. del Rio & M. Mulligan) 12/10/13 – 11/30/20
- NIH/NIDA (1R01DA037768). Improving Physician Opioid Prescribing for Chronic Pain in HIV-infected Persons (co-PIs: J. Samet & C. del Rio), 09/15/2014 – 08/31/2018.
- NIH/NIDA (1R01DA032098-03). Project Retain: Providing Integrated Care for HIV-infected crack cocaine users (co-PIs: L. Metsch & C. del Rio), 07/15/2011 – 04/30/2017 (no cost extension).
- CDC (1H25-PS004311). The Emory Atlanta Gonococcal Isolate Surveillance Project - GISP (PI: C. del Rio), 01/01/14 - 12/31/18.
- NIH/NIDA (5U10DA013720). Florida Node of the Drug Abuse Clinical Trials Network (PI: J. Szapocznik & L. Metsch; Emory site PI: C del Rio) 00/30/2000 – 08/31/2020
- CDC (5T01GH001185). Emory Center for Public Health Training in Complex Humanitarian Emergencies (PI: C. del Rio) 9/1/2015 – 08/31/2018
- NIH (D43 TW007124). Emory-Georgia Tuberculosis Research Training Program (PI: H. Blumberg; Co-PI: C. del Rio), 09/30/04 - 06/30/19.
- NIH (D43 TW009127) Emory-Ethiopia Tuberculosis Research Training Program (PI: H. Blumberg; Co-PI: C. del Rio), 07/1/13 - 01/31/18.

Lectureship, Seminar Invitations, and Visiting Professorship: (last ten years)

- * *“Global and regional priorities in Infectious Diseases”*. Opening plenary talk at the XLII Congress of the National Infectious Diseases Society of Mexico. Puebla, Mx. May 24, 2017
- * *“Top 10 in HIV”*. Closing Plenary Speaker at the 11th Annual ACTHIV meeting. Dallas, TX April 20-22, 2017.
- * *“Improving patient outcomes by focusing on the HIV Care Continuum”*. Keynote speaker at the Symposium: Emerging Strategies for HIV and Viral Hepatitis Co-Infection Symposium. Atlanta, GA. Dec 1st, 2016.
- * *“What reviewers look for in your RPG application: perspectives from reviewers”*. Invited talk at the NIAID Research Career (“K”) Development: Fostering Science Leaders Workshop. NIH/NIAID Bethesda, MD. November 29, 2016.
- * *“Health Equity: Improving outcomes in Hard to Reach Populations”*. Invited talk at the 10th Annual Meeting of the CFAR Social and Behavioral Sciences Research Network. Miami, FLA. October 20, 2016.

- * *“The HIV Care Continuum”*. Invited Talk at the Symposium on Clinical and Prevention Care organized by the Fulton County Department of Health and Wellness. Atlanta, Ga. June 20, 2016.
- * *“High Impact Research Transforming Health Policy”*. HIV Grand Rounds organized by the Univ. of Pennsylvania CFAR. Philadelphia, Penn June 16, 2016.
- * *“High Impact Research Transforming Health Policy”*. Invited talk at the 3rd Annual “Advancing Healthcare Quality Research at Emory University: Symposium. Atlanta, Ga. May 18, 2016.
- * *“Improving retention and viral suppression among hard-to-reach HIV-infected populations”*. University of Miami CFAR Visiting Professor. Miami, Fla. May 5th, 2016.
- * *“Sexual Transmission and Mosquitoes: A New Phenomenon in Arbovirology?”* Bridging the Sciences: Zika Virus. Atlanta, GA May 1 – 2, 2016.
- * *“Global Health and US Universities”*, invited speaker at the University of South Carolina Global Health Initiative Workshop. Columbus, SC Oct 22 -23, 2015.
- * *“Becoming an investigator: From Medicine Resident to Professor of Medicine and CFAR co-Director”*, invited lecture at the NIAID/IDSA Infectious Diseases Careers Meeting 2015. Bethesda, MD June 4 – 6, 2015.
- * *“Tactical decision making in Health and Humanitarian Supply Chain Management”*. Invited lecture at the Georgia Tech course “Health & Humanitarian Supply Chain Management”. May 14th, 2015.
- * *“Ebola and other Global Issues of Local Concern”*. Invited talk at the 2015 Infectious Diseases Association of California (IDAC) Spring Symposium. Costa Mesa, CA May 2-3, 2015.
- * *“The Ebola Crisis: Lessons in International Cooperation for Global Health”*. Invited talk at the Association of Academic Health Centers 2015 International Forum. Washington, DC April 20 - 21, 2015.
- * Keynote speaker *“What will it take to end the AIDS epidemic?”*. Invited talk at the HIV Drug Therapy in the Americas Congress 2015. Mexico City, MEX. April 16 – 18, 2015.
- * Keynote Address at the 12th Annual Graduate Division of Biological and Biomedical Sciences Student Research Symposium. Emory University School of Medicine. Jan 15th, 2015.
- * *“How Far We’ve Come and How Far We Still Need to Go: Engagement in HIV Care for our Most Vulnerable Populations of People Living with HIV in Atlanta and the Southern United States”*. Invited talk at the 16th World AIDS Day Symposium organized by the UNC Center for AIDS Research and the Institute for Global Health and Infectious Diseases. Dec 5th, 2014.
- * *“The Past, Present, and Future of Global Health Engagement by Academic Institutions”*. Keynote Lecture at the CFAR HIV Research in International Settings (CHRIS) Meeting hosted by the UCSD CFAR. Oct 1st, 2014.
- * *“Advances in Seek, Test and Treat Strategies/Treatment as Prevention”*. Invited talk at the US-Georgia Program Development Workshop on HIV/AIDS, Tuberculosis and Hepatitis. Tbilisi, Georgia. June 16 – 18, 2014.
- * *“The Diagnosis and Treatment of HIV infection: Translating research into policy and practice”*. Invited talk at the 7th Anniversary of CISIDAT (Consortio de Investigacion sobre VIH/SIDA/TB). Mexico City, Mex. June 5, 2014.

- * *“Can we end the HIV epidemic”*. Life of the Mind Lecture Series organized by the Provost of Emory University. March 26, 2014.
- * *“Linkage and Retention: What works and what doesn’t”*. Invited talk at the 4th International HIV Workshop on Treatment as Prevention. Vancouver, BC. April 1 – 4, 2014.
- * *“Challenges in the HIV Continuum of Care and its Relevance to Treatment as Prevention”*. University of Miami CFAR Visiting Professor. February 28, 2014.
- * *“Current Status of HIV Continuum of Care Research”*, Invited Talk at the 2nd National CFAR/APC HIV Continuum of Care Working Group Meeting: Implementation Science to Address the Challenges of the HIV Continuum of Care. Washington, DC. Feb 3 – 4, 2014.
- * *“The Fight Against AIDS”*, Invited TEDx Talk at Institut LeRosey, Switzerland. Nov 9, 2013 (<http://tedxtalks.ted.com/video/The-Fight-Against-AIDS-Dr-Carlo> & <http://www.youtube.com/watch?v=F2Hz4t66-Ig>)
- * *“Seek, Test, Treat and Retain Among Vulnerable Populations”*, Invited Speaker to the Spring Meeting of the Massachusetts Infectious Diseases Society. Boston, Mass May 14, 2013.
- * *“Treatment is Prevention: novel approaches to HIV therapy”*, Key Note Speaker, AIDS United Access to Care Grantee Meeting, Atlanta, GA April 5, 2012.
- * *“The Future of HIV Prevention”*, Key Note Speaker at the 5th Research Meeting on HIV/AIDS diagnosis, care and prevention among vulnerable populations. Mexico City, Mexico. November 14, 2011
- * *“History of HIV/AIDS in the US”*, Speaker at the 2011 American Conference for the Treatment of HIV (ACTHIV). Denver, CO. April 7, 2011.
- * *“Building on Success”*. Speaker at the CDC World AIDS Day Event. Atlanta, GA. December 1, 2010
- * Invited Keynote speaker: *“Evidence Based Global Health”*. Annual Meeting of the Mexican National Epidemiological Surveillance System (Reunion Nacional del Sistema Nacional de Vigilancia Epidemiologica). Cancun, Mex. November 22, 2010
- * Invited Keynote address: *“Recent Advances in Biomedical HIV Prevention: Translating Research into Practice”*. 5th National Scientific Meeting of the CFAR’s Social and Behavioral Sciences Research Network. Atlanta, GA. October 8, 2010
- * *“14th Annual Paul J. Galkin Lectureship”* Brown University, Providence, RI. September 20-21, 2010.
- * *“University of Massachusetts Center for Global Health Visiting Professor”* University of Massachusetts, Worcester, MA. May 19, 2010
- * *“Facilitators and Barriers to HIV testing in hospital and other ambulatory care settings”*. Presentation to the Institute of Medicine Workshop to identify facilitators and barriers to HIV testing. Washington DC. April 15, 2010.
- * *“Tim Gills Visiting Professorship”* University of Colorado at Denver Center for AIDS Research, Denver CO. March 30-31, 2010.
- * *“Viral Zip Codes: Novel Influenza A (H1N1): what have we learned in the last 6 months?”* Invited speaker at the Fifth Annual National Symposium on Predictive Health “Human Health: Molecules to Mankind”. Atlanta, GA. December 14, 2009
- * *“Public Health and Health Care: Working Together for HIV Prevention”*. Discussant in CDC Panel for World AIDS Day. Atlanta, GA. December 1, 2009

- * *“The Healthcare needs of Migrants*. Key Note Speaker at the Hispanic Health Coalition of Georgia Latino Health Summit. Atlanta, GA. February 27, 2009.
- * *“Challenges in improving the National Response to the HIV/AIDS Epidemic”*. Invited Speaker at the Seminar organized by the Instituto Nacional de Salud Publica and the Secretaria de Salud, Mexico. February 20, 2009
- * *“Challenges and Controversies in Infectious Diseases in the XXI Century”*. Invited Lecture at the XXI Annual Meeting of the Medical Society of Hospital Angeles, Mexico City, Mex. February 19, 2009
- * *“Antiretroviral Therapy: 25 years of Progress”*. Medical Grand Rounds, SUNY Downstate Medical Center, Brooklyn NY. December 11, 2008
- * *“Confronting the Global HIV epidemic: moving forward after Mexico City”*. Invited key note speaker to the Second Annual International; HIV/AIDS Research Day of the UCSD CFAR. San Diego, CA. October 7, 2008
- * *“In the Eye of the Storm: The Emerging Epidemics of HIV, Hepatitis and Tuberculosis in the Former Soviet Republic of the Caucasus”*. Invited Global Health Institute seminar speaker, University of North Carolina, Chapel Hill, NC. December 8, 2007.
- * *“Strategies for Initial Antiretroviral Therapy through Complicated Failure: A Case-Based Discussion”*. Lecture presented at the Annual IAS-USA Course Improving the Management of HIV Disease. New York, NY. October 19, 2007
- * *“New Antiretrovirals”*. Lecture presented at the Annual IAS-USA Course Improving the Management of HIV Disease. Washington, DC. May 23, 2007.
- * *“Antiretroviral Therapy Failure: A case based discussion”*. Lecture presented at the Annual IAS-USA Course Improving the Management of HIV disease. Atlanta, GA. April 27, 2007.
- * *“The Perfect Storm: Emerging Epidemics of HIV, HCV and TB in the Republics of the Former Soviet Union”*. Invited Lecture in the course: AIDS: A Multidisciplinary Approach” at the University of Washington. Seattle, WA. April 2, 2007
- * *“Strategies for Recruitment of Minority Study Participants”*. Invited lecture presented at the symposium “Ethics in Action: Building Trust and Effectiveness in the Clinical Trial Process – Are we doing our best? Organized by the Emory University School of Medicine Clinical Trials Office and the Emory Center for Ethics. Atlanta, GA. March 1, 2006.
- * *“Antiretroviral Therapy in the Treatment Experienced Patient”*. Lecture Presented at the 13th Annual IAS-USA Current challenges in HIV disease. New York, NY. October 17, 2005.
- * *“Update in HIV infection”*. Lecture presented at the Northside Hospital Internal Medicine Conference. Atlanta, GA. September 8, 2005.
- * *“Strategies for Providing Care to Hard to Reach Populations”*. Invited Lecture and visiting Professorship at the University of North Carolina, Chapel Hill, NC. June 9 -10, 2005.

Invitations to National or International Conferences: (last ten years)

- *“Linkage to Care”* Plenary Speaker at ANAC2016. Atlanta, GA. Nov 10 – 12, 2016
- *“What’s Hot in HIV Clinical Research”*. Invited speaker at IDWeek2016. New Orleans, LA. Oct 26 – 30, 2016
- *“What’s New, What’s Next, What’s Ahead?”* Invited Plenary Speaker at AIDS2016.

Durban, South Africa. July 17 – 22, 2016.

- “*Meeting the Health Care Workforce Challenge*”, Invited speaker at the 2016 Pre-Conference UN 90-90-90 Target Workshop. Durban, South Africa. July 17, 2016.
- “*Diagnosis and management of Zika infected and exposed pregnant women*”, Invited talk at the XXI Congreso Mexicano de Especialistas en Ginecología y Obstetricia, A.C. Mexico City, Mex. June 23, 2016.
- “*Interactive Cases: Infectious Diseases in Travelers*”, Invited speaker at the XLI Congress of the Mexican Infectious Diseases Society. Monterrey, Mex. May 25 – 28, 2016.
- “*Optimizing Adherence to Antiretroviral Therapy: Current and Future Options*”, Invited speaker at IDWeek2015. San Diego, Calif. Oct 7 – 11, 2015.
- “*Update on vaccines for HIV-infected Patients*”, Invited speaker at the 54th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC). Washington, DC Sept 5 – 9, 2014.
- “*Infectious Diseases in the context of Global Health*”, Invited Plenary Speaker at the XXXIX Congress of the Mexican Infectious Diseases Society. Acapulco, Mex. May 28 – 31, 2014.
- “*HIV Prevention 2013*”, Invited Plenary Speaker at the 26th Annual Conference of the Association of Nurses in AIDS Care (ANAC). Atlanta, GA November 22, 2013
- “*Vaccines in Immunocompromised patients*”, Invited Speaker at the 4th International Workshop on HIV & Aging. Baltimore, MD Oct 31, 2013
- “*Addressing the Gaps in the HIV Care Cascade*”. Invited talk at the “Treatment as Prevention and Pre-Exposure Prophylaxis Summit”. London, UK. Sept 22 – 24, 2013.
- “*Early Diagnosis and Treatment of HIV Infection*”, Invited talk at the 15th International Symposium on HIV/AIDS of the Mexican Infectious Diseases Society. Queretaro, Mex. Aug 29 – 31, 2013.
- “*Confronting the challenge of infectious diseases among substance abusers*” Invited Conference at the XIII Congress of the Argentinian Society for Infectious Diseases. Mar del Plata, Argentina. June 9 – 11, 2013
- “*Biomedical HIV Prevention*” Invited Conference at the XIII Congress of the Argentinian Society for Infectious Diseases. Mar del Plata, Argentina. June 9 – 11, 2013
- “*Introduction to Global Health*”. Invited Speaker to Lab Medicine 2013. 48th Annual Meeting of the Academy of Clinical Laboratory Physicians & Scientists. Atlanta, GA June 6 – 8, 2013
- “*How Should We Spend our Prevention Dollars?* Invited Speaker to the 20th Conference on Retroviruses and Opportunistic Infections (CROI). Atlanta, GA March 3 – 6, 2013
- “*Opportunistic Infections in Patients with HIV Infection*” and “*The Pregnant Patient with HIV*”. Invited Speaker at the 39th Remington Winter Course in Infectious Diseases. Beaver Creek, CO. February 10 – 15, 2013
- “*The Importance and Implications of Antibiotic Resistance for the Clinician*”. Keynote Speaker at the VII Congreso Grupo Angeles. Mexico City, Mex. Oct 25 – 27, 2012.
- “*Adherence and Retention in Care*”. Invited Speaker to the AWACC (Annual Workshop on Advanced Clinical Care) – AIDS 2012 Conference. Durban, South Africa. October 5, 2012.
- “*Antiretroviral Therapy as Prevention: A Debate on the Role of ART as Prevention in*

Clinical Practice". Open Plenary Speaker at the 2012 American Conference for the Treatment of HIV (ACTHIV), Denver, CO. May 10 -12, 2012,

- “*Aging and HIV: Update from CROI*”. Invited Speaker at the 5th International Course HIV: Pathogenesis, Prevention and Treatment. Lima, Peru. March 23 – 24, 2012.
- “*Neurological Complications of HIV Infection*” and “*Clinical Spectrum of Acute Retrovirus Syndrome*”. Invited Speaker at the 37th Remington Winter Course in Infectious Diseases. Snowmass, CO. February 6 – 11, 2011
- “*Retention in Care*”. Invited Speaker at the 48th Annual Meeting of the Infectious Diseases Society of America Vancouver, Canada. October 21-24, 2010
- “*HIV infection – beginning HAART*” and “*HIV infection – Managing opportunistic infections*”. Invited Speaker at the 36th Remington Winter Course in Infectious Diseases. Vail, CO. February 21 – 26, 2010
- “*HIV Prevention among hard to reach populations*”. United States-Russia Workshop on HIV Prevention Science organized by the Office of AIDS Research. Moscow, Russia. October 28 – 30, 2009.
- “*The role of Integrase inhibitors in the treatment of HIV infection*”. Invited speaker at the 9th International Symposium of the Mexican Association of HIV Providers (AMMVIH). Cancun, Mex. November 22, 2008
- “*Current Issues and Controversies in HIV Infection Management*” Invited panelist to an Interactive Symposium at the 48th Annual ICAAC/46th Annual IDSA. Washington, DC. October 27, 2008
- “*HIV, STDs and the Global AIDS Pandemic: Lethal Synergy 2008*” Invited panelist to an Interactive Symposium at the 48th Annual ICAAC/46th Annual IDSA. Washington, DC. October 28, 2008
- “*Treating Tuberculosis in People Living with HIV*”. Invited Plenary Speaker at the Second Eastern Europe and Central Asia AIDS Conference. Moscow, Russian Federation, May 3 – 5, 2008.
- Poster discussant in the session “*New approaches to HIV testing*” at the 15th Conference on Retroviruses and Opportunistic Infections (CROI). Boston, MA. February 4, 2008.
- “*New drugs and old challenges in AIDS*”. Invited plenary speaker at the X Mexican National HIV/AIDS Meeting. Leon, Mex. December 1, 2007.
- “*The Metamorphosis of the HIV Epidemic*”. Invited lecture presented at the XXIV National Congress of Biomedical Research in Mexico. Monterrey, NL. Mex. Aug 30, 2007
- “*Management of HIV Infection*”. Invited panelist to an Interactive Symposium at the 44th Annual Meeting of the Infectious Diseases Society of America. Toronto, Canada. October 13, 2006
- “*Yellow fever: New Challenges to an Old Scourge*”. Invited lecture presented at the Annual Meeting of the Binford-Dammin Society of Infectious Disease Pathologists. Atlanta, GA. February 12, 2006.
- “*Antiretroviral Therapy and its impact on Public Health*”. Invited speaker at the XI National Public Health Congress. Cuernavaca, Mex. March 2, 2005.
- “*Screening for HIV in Emergency Departments*”. Invited lecture presented at the 2005 National HIV Prevention Conference. Atlanta, GA. June 13, 2005.

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2. Guarner J, **del Río C**, Slade BA. Tuberculosis as a Manifestation of the Acquired Immunodeficiency Syndrome. JAMA 1986; 256(22):3092. [PMID [3783842](#)]
3. **del Río C**, McGowan J. Severe diarrhea in pneumococcal bacteremia: croupous colitis. JAMA 1987; 257(2): 189 [PMID 3795402].
4. Levy D, **del Río C**, Stephens DS. Meningococemia in identical twins: changes in serum susceptibility after rifampin chemoprophylaxis. J Infect Dis 1988; 157:1064-8 [PMID 3129520].
5. **del Río C**, Guarner J, Honig EG, Slade BA. Sputum examination in the diagnosis of *Pneumocystis carinii* pneumonia in the acquired immune deficiency syndrome. Arch Pathol Lab Med 1988; 112:1229-1232 [PMID 3142440].
6. Mirra SS, **del Río C**. The fine structure of AIDS encephalopathy. Arch Pathol Lab Med 1989; 113:858-65. [PMID 2757485]
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12. Guarner J, **del Río C**, Carr D, Hendrix LE, Eley JW, Unger ER. Non-Hodgkin's lymphomas in patients with HIV infection: Presence of Epstein - Barr virus by "in-situ" hybridization. Clinical Presentation and Follow-up. Cancer 1991; 68: 2460-65 [PMID 1657357].
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14. **del Río C**, Téllez I. Ganancia de peso con el uso del acetato de megestrol (Megace^R) en pacientes con SIDA y pérdida de peso en México. (Weight gain with the use of Megace^R in Mexican patients with AIDS). Enf Infecc y Microbiol 1993; 13(5): 249-52.
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- Mexico City. *Amer J Pub Health* 1997; 87(6): 1012-15 [PMID 9224186/PMC 1380940].
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Exhibit C

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

NICHOLAS HARRISON and
OUTSERVE-SLDN, INC.

Plaintiffs,

v.

JAMES N. MATTIS, in his official capacity
as Secretary of Defense; MARK ESPER, in
his official capacity as the Secretary of the
Army; and the UNITED STATES
DEPARTMENT OF DEFENSE,

Defendants.

Case No. 1:18-cv-00641 (LMB/IDD)

**DECLARATION OF NICHOLAS HARRISON IN SUPPORT OF HIS
MOTION FOR PRELIMINARY INJUNCTION**

I, Nicholas Harrison, declare as follows:

1. Originally from Oklahoma, I was raised by a single mother on public assistance.

This experience inspired me to prove myself as I became an adult—working to secure an education, to help others similarly situated, and to serve my country.

2. In 2000, at the age of 23, I joined the U.S. Army in order to gain discipline, a sense of direction, and – as I would come to discover – a sense of purpose. After basic training and airborne school, I was stationed in Alaska with the 1-501st parachute infantry regiment.

3. In 2003, after completing the commitment I had made, I left active duty and joined the Army Reserves, returning to Oklahoma to become a member of the Oklahoma National Guard and to pursue additional education. The Army, in turn, invested in my

education, subsidizing my pursuits through the Army G.I. Bill, tuition assistance, and a yearly stipend based on my participation in Army ROTC.

4. In 2005, I received a bachelor's degree from the University of Central Oklahoma. I was the first in my family to graduate college. My ultimate goal, however, was to become a Judge Advocate General officer ("JAG officer"), so I sat for the LSAT and applied to law school. *See Ex. 1.* I was accepted to Oklahoma City University Law School and began in the fall of 2005. By the end of my first semester, I was the top student in my class.

5. My legal education was interrupted, however, when my National Guard unit deployed to Afghanistan, in the middle of my second semester, for sixteen months in support of Operation Enduring Freedom.

6. In Afghanistan, I was the Non-Commissioned Officer In Charge ("NCOIC") for my brigade Tactical Operations Center ("TOC"). In that role, I successfully operated in a position usually filled by a non-commissioned officer significantly higher in rank than I was at that time. I developed and implemented a new battle tracking system, briefed key leaders on the operation situation, ensured all communications equipment was operational, and trained and supervised all TOC personnel. In recognition of my meritorious service, I was awarded the Army Commendation Medal.

7. I was also selected as the only junior enlisted soldier to lead a security forces team ("SECFOR") at a forward operating base near the border with Pakistan. There, I trained soldiers and officers serving in the Afghan National Army and conducted regular combat patrols. My team took enemy fire on several occasions. As a result, I was awarded the Combat Infantryman's Badge.

8. While deployed in Afghanistan, I was on a pill-a-day doxycycline regime as a precaution to prevent malaria, as were all military personnel in Afghanistan. I was given a 180-day supply and ordered to take it daily, which I did. When our supply ran out, we were provided an additional 180-day supply. Each soldier was responsible for carrying and self-administering his own antimalarial medication. This one-pill-a-day regimen is similar in form to the single-tablet regimen (STR) of antiretroviral medications I use as a person living with HIV.

9. When I returned from active duty, I transferred to the University of Oklahoma College of Law, the most well-respected law school in the state. I had to repeat my entire first year of law school, because my deployment had interrupted my first year at Oklahoma City University Law School.

10. Undeterred by this educational obstacle, I continued to perform well academically. I received both a Juris Doctorate (“J.D.”) and Masters in Business Administration (“MBA”) from the University of Oklahoma in 2011.

11. Before I was able to sit for the Oklahoma bar exam, however, I deployed to Kuwait for a second tour of duty. There, I served as Headquarters Platoon Sergeant for a light reconnaissance cavalry troop. I was responsible for the health and welfare of 21 enlisted soldiers and 9 non-commissioned officers as we engaged in security for convoys withdrawing from Iraq. I was also accountable for over \$3.6 million of military vehicles and equipment in a combat theater.

12. Shortly after returning from my second tour of duty in 2012, I was diagnosed with HIV at an Army medical facility. I was immediately placed on antiretroviral therapy, and soon thereafter, my viral load was undetectable. Undeterred by this new diagnosis, I sat for and passed the Oklahoma bar shortly thereafter.

13. My antiretroviral therapy consists of one pill taken every day. I have not experienced a side effect from my medications in the six years since I started on HIV medications. Every six months, I have a blood test. I may meet with a doctor at the same time, but that is not required. At this point, these exams have become so routine that my doctor often calls me with my test results instead of meeting in person. I have been virally suppressed and generally have had an undetectable viral load since shortly after starting on antiretroviral therapy in 2012.

14. After I passed the Oklahoma bar exam, I applied for and was offered a position as a JAG officer for the Oklahoma National Guard. At nearly the same time, however, I was offered a coveted position as a Presidential Management Fellow in Washington, D.C., which I accepted. I offered to commute to Oklahoma on the weekends in order to perform both roles, but my potential commanding officer in the JAG Corps decided it was not feasible to do both jobs.

15. I moved to Washington, D.C. to begin my work in the Presidential Management Fellow program and transferred to the D.C. National Guard.

16. While living in Washington, D.C. and serving in the Presidential Management Fellow program, I applied for a position in the JAG office for the D.C. National Guard. After interviewing, I was chosen for an open position in the Legal Services Office supporting the Director of the National Guard Bureau in JAG Corps for the D.C. National Guard. At the time, I was told by the recruiters at the D.C. National Guard that my experience stationed in combat zones was a major asset to my application. They informed me that I would be commissioned as a Captain, as opposed to a Second Lieutenant, because of my extensive service record.

17. After receiving the offer, I began the process of assessment and qualification as an officer with the assistance of First Lieutenant Nicole Ono, the Regional Specialty Branch

Recruiter in the recruitment office of the D.C. National Guard. Because I had already been offered the position, this should have been a relatively *pro forma* process.

18. During my commissioning medical exam, I received the top rating in every category: a PULHES score (shorthand for its testing categories: Physical stamina, Upper extremities, Lower extremities, Hearing/ears, Eyes, and Psychiatric) of one on a scale of one to four. This meant that I was at the highest possible level of fitness for service with no duty limitations or restrictions. Nonetheless, I was classified as “non-deployable” based on my HIV status. *See Ex. 2.*

19. First Lt. Ono and I determined that, because of the military’s blanket prohibition on the accession of people living with HIV, I would need to seek a medical waiver to commission as an officer. I provided the necessary materials for the waiver application to First Lt. Ono, who submitted them through the appropriate channels.

20. After approximately five months, my waiver application was denied by the Chief Surgeon of the Army National Guard via a memorandum dated December 30, 2014. *See Ex. 3.*

21. Having been denied a medical waiver, I wrote a memorandum letter to the Under Secretary of Defense for Personnel and Readiness, routed through the Army Deputy Chief of Staff (G-1), seeking a formal exception to policy (“ETP”), which, if granted, would allow me to commission despite the accession ban. *See Ex. 4.*

22. On March 19, 2015, I received a response from the Office of the Assistant Secretary of Defense for Readiness and Force Management, to whom the Under Secretary had delegated the responsibility of responding, identifying the relevant regulations that prohibited me from serving, but not explicitly denying my ETP request. *See Ex. 5.*

23. My ETP request was forwarded to Lt. Col. Conreau Williams, Chief Health Promotions Officer, in the Office of the Deputy Chief of Staff, G-1. In an email dated March 24, 2015, Lt. Col. Williams offered to assist me with my ETP request, noting later in a telephone call that it seemed to her a perfectly reasonable request. *See* Ex. 6.

24. I pulled together all of the necessary materials to support my ETP request, and Lt. Col. Williams submitted the ETP packet for approval to the Office of the Army Surgeon General. In the packet, my physician at the time noted that my HIV was “[v]ery well controlled” and had been since 2013. Ex. 7. She found me “fit for duty” noting that there “should not [be] any limitations placed on [my] service in the military.” *Id.*

25. After I secured the necessary approval from the Office of the Army Surgeon General, I submitted my ETP packet to the Deputy Chief of Staff for the Army (G-1) for approval in the first week of December 2015.

26. On June 29, 2016, the Deputy Chief of Staff for the Army denied my request, giving no explanation other than that the request was “not in the best interest of the Army.” Ex. 8.

27. On July 21, 2016, I elevated my request to the Under Secretary of Defense for Personnel and Readiness. My ETP request was denied by the Under Secretary on July 26, 2016, citing the Department of Defense Instructions and Army Regulations regarding accessions and people living with HIV as the reason for the denial without further explanation. Ex. 9. In other words, the existence of the policy was the reason I was not granted an exception to policy.

28. My HIV status has not prevented me from serving in the National Guard for the past six years. As this case is litigated, I continue to serve in the D.C. National Guard.

29. However, a new Department of Defense policy may completely derail my career. On February 14, 2018, the Department of Defense issued new guidance stating that service members who have been designated as non-deployable for over 12 consecutive months will be discharged. Ex. 10. Under the new policy, discharges are required to begin by October 1, 2018; however, there is nothing to prevent the Army or other branches from discharging service members living with HIV prior to this deadline.

30. I am very concerned about how implementation of this policy will affect me and other service members living with HIV. I have reached out to my congressional representatives, even going so far as to visit their offices on Capitol Hill multiple times, to express my concern. Unfortunately, without action by either Congress or the courts, there is nothing to stop the Army from beginning discharge proceedings at any time and ending my 18-year career in the Armed Services.

31. Since filing this lawsuit, I have learned that actions recently have been taken to separate some service members living with HIV. It is my understanding that the health status of these service members with respect to their HIV is similar to mine and that long-standing military policies related to people living with HIV—policies under which I was retained in the military—should have resulted in their retention as members of the armed services. I am now concerned that the Army and other branches of the Armed Services are not waiting until October 2018 to begin implementing the new directive with respect to “non-deployable” service members and that I could be separated from service at any time. I believe that being the sole named plaintiff in this lawsuit places me in particular jeopardy of having this new policy applied to me while this lawsuit is pending.

32. I have had a long and respected career in the armed services thus far, and I want to continue that career. I am healthy, qualified, and eager to serve as a JAG officer. The only obstacle in my way is a cluster of outdated policies that do not accurately assess or reflect my fitness for duty or ability to serve and that are preventing thousands of other healthy current, former, and aspiring soldiers from serving their country to the full extent of their capabilities.

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

Executed on: July 19, 2018

Nicholas Harrison

Sergeant Nicholas Harrison

EXHIBIT 1

NICHOLAS HARRISON

1417 MAPLE DRIVE
MIDWEST CITY, OKLAHOMA 73110

PHONE: (405) 733-8150
E-MAIL: ALASKAAIRBORNE@YAHOO.COM

Personal Statement

I find myself crammed into an old cargo plane with sixty-three other cocky, athletic guys. I have been on Fort Benning for the past six months and I haven't seen my home or my family for some time. Now, I am finally getting to jump out of a perfectly good aircraft. It seems like a pretty stupid thing to do. However, many of us have been looking forward to this event for quite a while and we're laughing and joking while we wait. Yet, as the aircraft approaches the drop zone, the door is roughly yanked open and a tense silence descends upon the group as everyone turns to stare outside. The young, arrogant, easy-going attitude is suddenly gone and I start to wonder if I've made the right decision.

The first set of jumpers is instructed to stand up and hook up and we reluctantly do as we are told -- moving like a group of condemned prisoners heading toward the gallows. With a sick feeling in my stomach, I anxiously wait for the signal. Thirty seconds seem to drag out for an eternity. Yet, when the green light finally comes on and we start rushing toward the door, it certainly doesn't seem long enough. I reach the exit, take a deep breath, and force myself to leap out into the void -- determined not to be the only guy who refuses to jump. There is a brief moment of weightlessness. Then, I feel myself plummeting toward the ground

To this day, I still have trouble finding the words to explain why anyone would want to become a paratrooper. In August of 2000, part of the reason that I decided that I wanted to enlist in the army was that I realized that I had lost my academic focus and that I had accrued some pretty significant college debts. However, I also felt like I had missed out on something by not

participating in any form of college or high school athletics and I wanted to serve my country in an honorable profession. So, I looked at military service as an opportunity to grow up, to take on real responsibility, and to become a more well rounded person. As it turns out, it is a decision that I have never regretted.

As they apply to law school, I am sure that there are a lot of people who write about their boot camp experiences and argue that the army has given them the drive, discipline, and determination to succeed in the profession. However, I would rather take a different approach and discuss the values that you come to respect and cherish when you serve in an airborne infantry unit. People still sacrifice for one another and live by a code of duty, honor, and country. And, there is a special bond which develops between people when they put their lives in each other's hands -- a sense of friendship, camaraderie, and brotherhood that you will never find anywhere else.

While on active duty, I have served under a lot of good officers and under a lot of bad officers. I have dedicated that last two years of my life to the Army ROTC Program -- aspiring to take on a position which afforded me the opportunity to take care of soldiers and make a real difference in people's lives. I can still remember the look in my comrades' eyes when they found out that my "Green-To-Gold" packet had gone through -- the hope that they would eventually have someone who knew what it was like to be enlisted and who was willing to fight for the common foot soldier. I will never forget my sacred obligation to them.

In the last two months, I have learned that my National Guard unit will deploy to Afghanistan in May of 2006. And, one of the toughest decisions that I will have to face is whether I want to go overseas with them and serve as their platoon leader or whether I want to stay here in the United States and finish law school. When you have the fates of soldiers in your

hands, you are faced with some pretty hard choices. And, as a lieutenant, thirty to forty people will depend on me and the decisions that I make will affect their lives, their families, and their children in the most serious way possible.

It's difficult to turn your back on that obligation. And, part of me wants to go to Afghanistan with my unit when it deploys in May of 2006. However, another part of me also knows that I would only be limiting myself to the people under my direct command. There still needs to be someone who understands what it is like to be enlisted to take care of soldiers when bad officers ignore, abuse, or neglect them. There still needs to be someone who understands what it is like to be an infantryman to protect and defend soldiers who are forced to make tough decisions in intense, combat situations. There still needs to be someone who understands what its like to live by a code of duty, honor, and country to prosecute the terrorists and insurgents who are captured.

Unfortunately, there aren't many attorneys who are willing to give up lucrative jobs in the private sector. So, it is hard to find JAG officers who really care about these issues, who are willing to dedicate their lives to serving those who protect and defend our nation. I can only hope that you will consider my application and allow me to fulfill this role.

EXHIBIT 2

SSN [REDACTED] Name HARRISON NICHOLAS ALEXANDER Rank SGT DOB 1977 [REDACTED] UIC W8AHAA Gender M

Demo Allergies Overall Health Current Health Preventive Health Behavioral Health Family History Evaluation TBIT PULHES

Frequently Asked Questions
Feedback

Current PULHES

| | | | | | |
|---|---|---|---|---|---|
| P | U | L | H | E | S |
| 1 | 1 | 1 | 1 | 1 | 1 |

[Click here](#) to create or modify PULHES or Profile Codes in eProfile.

Profile Codes

| |
|---------------------------------|
| Code V: Deployment Restrictions |
| Code A: No Limitations |

Refresh Pending Profiles

[Show Profiles Pending Approval] [Hide Profiles Pending Approval]

[Show PULHES History] [Hide History]

Height: 75 Weight: 200 Pregnant:

Height and Weight are only required for National Guard and Reserve Soldiers and should not be completed for Active Duty Soldiers

Deployable to an austere environment within next 6 months: Yes

Was the Soldier's e-Profile and/or AHLTA history reviewed to determine the presence of mTBI/Concussion(s) to assess the need for functional limitations or additional evaluation or treatment after this assessment? No

If yes, number of occurrences?

- Source of concussive event?
- eProfile
 - AHLTA
 - Soldier Statement

Additional Comments:

[Empty text area for additional comments]

Form last modified by: craig.w.casella

I certify that this review process has been completed.

AKO authentication passed for: craig.w.casella

previous

EXHIBIT 3



NATIONAL GUARD BUREAU
111 SOUTH GEORGE MASON DRIVE
ARLINGTON VA 22204-1382

ARNG-CSG-C

2014-12-30

MEMORANDUM FOR The Adjutant General, District of Columbia, ATTN: RSID1

SUBJECT: ACCESSION WAIVER COMMISSION

FOR: Prior Service NICHOLAS HARRISON, **REDACTED**

1. After review of this application and supporting documents the following determination has been made:

Waiver Request is DISAPPROVED

With the following comment: For HIV Positive testing.

MOS: 27A

| | | | | | |
|---|---|---|---|---|---|
| P | U | L | H | E | S |
| 3 | 1 | 1 | 1 | 1 | 1 |

2. Points of contact for this action:

Administrative - Mr. Kinney Simpkins at (540) 661-7180 or Mr. Randy Dodson at (601) 826-7344.

Clinical - MAJ Paul D. Tumminello, ARNGUS Medical Standards Officer at (703) 607-9534 or LTC Edith Fraley, M.D., Delegate Waiver Authority at (501) 545-6678.

FOR THE CHIEF SURGEON:

for TUMMINELLO.PAUL.1042104317
ERIC D. MORGAN
Colonel, Medical Corps
Chief Surgeon, Army National Guard

This document contains PHI

EXHIBIT 4

NICHOLAS HARRISON
1530 1/2 R STREET NW
WASHINGTON, D.C. 20009

PHONE: (405) 590-9525

E-MAIL: ALASKAAIRBORNE@YAHOO.COM

23 February 2015

MEMORANDUM THRU MG ERROL SCHWARTZ, Adjutant General, DC National Guard,
2001 East Capitol Street SE, Washington, D.C. 20003

THRU COL ERIC MORAN, Chief Surgeon, Army National Guard, 111 South George Mason
Drive, Arlington, VA 22204

THRU LTG JAMES MCCONVILLE, Deputy Chief of Staff, G-1, United States Army, 300
Army Pentagon, Washington, D.C. 20310

FOR THE HONORABLE JESSICA WRIGHT, Undersecretary of Defense for Personnel and
Readiness, 4000 Defense Pentagon, Washington, D.C. 20301

SUBJECT: Request for Exception to Policy (AR 600-110, DoDI 6485.01)

Executive Summary

1. My name is SGT NICHOLAS HARRISON. I am a member of the DC National Guard and I am writing to request an exception to policy so I can receive a direct commission as a JAG officer.
2. I have been interviewed by the DC National Guard and I have been offered a slot in the legal services office supporting the Director, Army National Guard in Arlington, VA. However, under AR 600-110 and DoDI 6485.01, I am not eligible for a commission because I am HIV positive.
3. I am in receipt of a memorandum from COL ERIC MORAN to MG ERROL SCHWARTZ dated 30 December 2014 denying my request for a medical waiver. This memorandum is going back through them to the proponents of AR 600-110 and DoDI 6485.01 for further review and consideration.
4. Respectfully, I wish to assert that, generally, this policy is outdated and that, specifically, it makes no sense to deny me a direct commission as a JAG officer.

Background

5. I'm a 37-year-old sergeant in the DC National Guard. I've served 3 years on active duty as an airborne paratrooper stationed at Fort Richardson (Anchorage, Alaska). I've served 11 years in the Army National Guard so far with 2 overseas tours of duty in Afghanistan (2006 - 2007) and Kuwait (2011 - 2012).
6. I completed my education by taking advantage of a variety of military benefits – loan repayment program, GI Bill, National Guard kicker, ROTC stipend, and tuition assistance. I graduated with a JD/MBA from the University of Oklahoma in 2011.
7. I was selected as an alternate during the JAG accessions process in 2011 – which carries with it an automatic slot in the National Guard / Reserves if I wanted it. However, I was deployed before I could take the bar exam and I wasn't able to follow through with it until I returned in 2012.
8. I was diagnosed with HIV shortly after I got back from my second deployment in July 2012. And, I am currently undetectable.
9. In 2013, I was selected as a Presidential Management Fellow and I took a job with the U.S. Small Business Administration. Upon relocating to the Washington DC area, I was interviewed by the Legal Services Office which supports the Director of the Army National Guard Bureau in Arlington, VA and I was offered a slot by them.
10. I completed my physical exam at Walter Reed Army Medical Center last year. Although my PULHES code is 111111, I was advised that my HIV status constitutes a disqualifying condition which does not allow me to become a JAG officer. I submitted a medical waiver and it was denied on 30 December 2014.

Argument

11. The current military policy prohibiting HIV positive personnel from becoming commissioned officers is a relic of the 1980s when people were dying of AIDS. Medical technology has evolved considerably over the past thirty-five years and HIV is more easily manageable than many other health conditions.
12. I have no significant duty limitations. HIV positive personnel can work in health care or food service industries. There are no restrictions on taking federal law enforcement, foreign service, or DOD civilian positions. Even the U.S. Navy recently opened up overseas and large-ship platform assignments.
13. The military has already decided that I cannot be discharged for my status. Indeed, current policy affords me with the opportunity to attend NCOES and other MOS-producing courses required for career progression. However, it makes little sense to keep

me where I am. I am of limited use to the service in my current billet. The natural career progression for someone like me (upon graduating from law school and passing the bar exam) is to pursue a direct commission as a JAG officer.

14. I attained my education using military benefits. So, there's a case for giving the military a return on its investment. I also would incur no additional service obligation – having already fulfilled my statutory obligation during the past 15 years as an enlisted soldier.
15. The Legal Services Office supporting the Director of the National Guard Bureau wants me. They've told me that my previous combat experience in a line unit would be a real asset to their office. It suits the needs of the Army.

Conclusion

16. While I respectfully disagree with the military's overall policy, this letter is a request for a narrow exception to that policy. I respectfully assert that AR 600-110 and DoDI 6485.01 should not be a bar to someone:
 - (a) who is already in the service;
 - (b) who has served long enough to fulfill his statutory obligation; and
 - (c) who wishes to receive a direct commission into a specialty support branch for which he is well qualified, to serve out the remainder of his military career.
17. Thus, I ask you to grant my request for an exception to policy so that I can take a direct commission as a JAG officer.
18. When you have time, I respectfully request a meeting under the military's open door policy to discuss this matter further. The point of contact for this memorandum is SGT Nicholas Harrison at (405) 590-9525.

Very Respectfully,

NICHOLAS HARRISON
SGT, DCARNG

CC: The Honorable Eleanor Holmes Norton, Congresswoman, Washington D.C.
The Honorable Eric Fanning, Chief of Staff, United States Department of Defense

EXHIBIT 5

From: Nicholas Harrison
To: [Williams, Conreau L LTC USARMY HQDA \(US\)](#)
Subject: Re: Contact for Exception to Policy (UNCLASSIFIED)
Date: Wednesday, March 25, 2015 10:09:46 AM
Attachments: [dod-letter.pdf](#)

Good morning, ma'am. I'll give you a call here in a few minutes.

I received a letter from the Office of the Assistant Secretary of Defense (Readiness and Force Management) on Monday. And, I've been preparing a response to that letter.

I haven't had the chance to scan in the document I received, but I have typed it out so that you can review:

<Stamped: MAR 19 2015>

*Nicholas Harrison
1530 ½ R Street NW
Washington, DC 20009*

Dear Mr. Harrison:

Thank you for your recent letter to the Under Secretary of Defense, Jessica Wright concerning your medical disqualification to enter the military. Since this matter falls under my purview, this office has been asked to respond.

Each Service establishes its own standards for enlistment under the authority of title 10 of the United States Code, utilizing the specific policies for accession medical standards established by Department of Defense Instruction (DoDI) 6130.03, "Medical Standards for Appointment, Enlistment, or Induction in the Military Service," dated 28 April 2010. Accession criteria are based on Service needs and are designed to ensure that individuals accepted are "qualified, effective, and able-bodied persons" capable of successfully performing military duties.

There is no record of your application for entrance into the Service as an officer. Additionally, the presence of human immunodeficiency virus is disqualifying (DoDI 6130.03 Enclosure 4 Section 24(b)). Applicants with medical conditions which are disqualifying are reviewed on a case-by-case basis by medical professionals from the Service concerned to determine if they will support a waiver. The decision of the Waiver Authority is final.

You may be interested in knowing that approximately 35 percent of individuals desiring to enter the Armed Forces today have some physical condition that is disqualifying. While many of these people have otherwise outstanding qualifications, they are unable to serve. However, the Department of Defense team consists of both military and civilian members. Individuals who are physically disqualified for military duty can and do become civilian members of the team. If you are interested in civilian

employment, you should contact the local government agency where employment consideration is desired. A listing of government job vacancies is available from the U.S. Office of Personnel Management at its website: www.usajobs.opm.gov.

We appreciate your interest and hope that the information provided has been helpful.

Sincerely,

<SIGNATURE>

C.P. Arendt

*Deputy Director, Accession Policy
(Military Personnel Policy)*

The response I am thinking about sending is attached. However, I have several questions.

Very Respectfully,

SGT Harrison

From: "Williams, Conreau L LTC USARMY HQDA (US)" <conreau.l.williams.mil@mail.mil>
To: Nicholas Harrison <alaskaairborne@yahoo.com>
Sent: Wednesday, March 25, 2015 7:14 AM
Subject: RE: Contact for Exception to Policy (UNCLASSIFIED)

Classification: UNCLASSIFIED
Caveats: NONE

Good Morning SGT Harrison,

Thank you for responding. You may reach me anytime today with the exception of the hours of 0900-1015 and 1200-1300.

I look forward to talking with and assisting you today.

V/r
LTC Williams

-----Original Message-----

From: Nicholas Harrison [mailto:alaskaairborne@yahoo.com]
Sent: Tuesday, March 24, 2015 4:24 PM
To: Williams, Conreau L LTC USARMY HQDA (US)
Subject: Re: Contact for Exception to Policy (UNCLASSIFIED)

Good morning, ma'am. Thanks for reaching out to me.

I would definitely appreciate your assistance regarding this request.

Let me know when a good time would be to try to touch base.

Very Respectfully,

SGT Harrison

From: "Williams, Conreau L LTC USARMY HQDA (US)"
<conreau.l.williams.mil@mail.mil>
To: "alaskaairborne@yahoo.com" <alaskaairborne@yahoo.com>
Sent: Tuesday, March 24, 2015 3:24 PM
Subject: Contact for Exception to Policy (UNCLASSIFIED)

Classification: UNCLASSIFIED
Caveats: NONE

Good Afternoon SGT Harrison,

My name is LTC Conreau Williams from HQDA G-1, Army Resiliency Directorate. I received a memorandum that you had written on 23 February 2015, referencing a request for an exception to policy.

I would like to talk with you so that I may assist you with the process of your request. Please contact me at your earliest convenience at (703) 571-7288.

Thank you and have a great day!

V/R,

Conreau L. Williams
LTC, GS
Chief, Health Promotions Officer
Office of the Deputy Chief of Staff, G1
(703) 571-7288
email: conreau.l.williams.mil@mail.mil

Classification: UNCLASSIFIED

Caveats: NONE

Classification: UNCLASSIFIED

Caveats: NONE

EXHIBIT 6

From: Williams, Conreau L LTC USARMY HQDA (US)
To: alaskaairborne@yahoo.com
Subject: Contact for Exception to Policy (UNCLASSIFIED)
Date: Tuesday, March 24, 2015 3:24:48 PM

Classification: UNCLASSIFIED
Caveats: NONE

Good Afternoon SGT Harrison,

My name is LTC Conreau Williams from HQDA G-1, Army Resiliency Directorate. I received a memorandum that you had written on 23 February 2015, referencing a request for an exception to policy.

I would like to talk with you so that I may assist you with the process of your request. Please contact me at your earliest convenience at (703) 571-7288.

Thank you and have a great day!

V/R,

Conreau L. Williams
LTC, GS
Chief, Health Promotions Officer
Office of the Deputy Chief of Staff, G1
(703) 571-7288
email: conreau.l.williams.mil@mail.mil

Classification: UNCLASSIFIED
Caveats: NONE

EXHIBIT 7

MEDICAL RECORD

Progress Notes

NOTE DATED: 03/27/2015 11:00
LOCAL TITLE: ID CLINIC - ESTABLISHED
STANDARD TITLE: INFECTIOUS DISEASE NOTE
VISIT: 03/27/2015 08:30 DC/ID SILVER-CZARNOGORSKI
Age: 38 Sex: MALE Race: WHITE

Allergies: NKDA

Outpatient Meds:

Efavirenz 600/Emtric 200/Tenof 300mg Tab Take 1 Tablet by Mouth Every Day for Infection. (Atripla)

List of Antivirals Ever Prescribed
EFAVIREN7 600/EMTRIC 200/TENOF 300MG TAB

NON-VA MEDS - NONE FOUND

Problem list: (Active & Verified)
Chlamydial infection (Sct 105629000)
Human immunodeficiency virus infection (Sct 86406008)
dc cohort (Icd-9-cm 799.9)

Reason for Visit: this is routine 6 month appointment for HIV (+) follow-up. Pt is in good health with no complaints today.

Vitals:(today's vitals)
HT: WT: 201.9 lb [91.8 kg] T: 97.1 F [36.2 C] P: 78 R: 18
BP: 123/61 PAIN: 0

MEDICATION RECONCILIATION:
The process of medication reconciliation was completed during today's visit. The veteran's current medications (including non-VA medications and any changes made today) were reviewed with the patient and/or caregiver. A written list was offered and/or provided.

Assessment:

1. HIV - Very well controlled - CD4 - 618 and VL < 40 in March 2015. Pt has been well controlled since 2013 under my care. He is fit for duty and should not have any limitations placed on his service in the military. His immune system is as strong as anyone who is not HIV infected and only needs to come to clinic for routine 6 month check-ins only.
2. high triglycerides - will monitor and recommend diet and exercise at this time.
3. HCM - up to date at this time.

RTC in 6 months for routine check in.

Future Appointments:
Dc/Id Silver-czarnogorski - Mar 27, 2015 at 08:30 ()

Signed by: /es/ MAGGIE CZARNOGORSKI, MD
ATTENDING PHYSICIAN (WOC)
03/27/2015 11:06



EXHIBIT 8



DEPARTMENT OF THE ARMY
OFFICE OF THE DEPUTY CHIEF OF STAFF G-1
300 ARMY PENTAGON
WASHINGTON, DC 20310-0300

DAPE-MP

MEMORANDUM THRU Commander, 276th Military Police Company, 2001 East Capitol Street SE, Washington DC 20003-1719

FOR Sergeant Nicholas Harrison, 372nd Military Police Battalion, 2001 East Capitol Street SE, Washington DC 20003-1719

SUBJECT: Request for Exception to Policy (ETP) to Army Regulation 600-110

1. Your request for an ETP to Army Regulation 600-110 was not favorably considered. After thorough review of your arguments in favor of granting an exception, I find that taking such action is not in the best interest of the Army.
2. My point of contact for this action is LTC Lisa M. Lute, (703) 545-1918 or email: lisa.m.lute.mil@mail.mil.

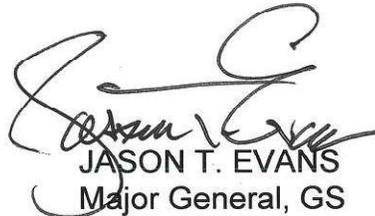

JASON T. EVANS
Major General, GS
Director of Military
Personnel Management

EXHIBIT 9

OFFICE OF THE UNDER SECRETARY OF DEFENSE

4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000



PERSONNEL AND
READINESS

July 26, 2016

Mr. Nicholas A. Harrison
1530 ½ R Street NW
Washington, DC 20009-4156

Dear Mr. Harrison:

Thank you for your letter of July 21, 2016, to Mr. Peter Levine, Acting Under Secretary of Defense for Personnel and Readiness, requesting an exception to the policy set forth in Department of Defense Instruction (DoDI) 6485.01, *Human Immunodeficiency Virus (HIV) in Military Service Members*. We have carefully reviewed your letter and its allied papers and have consulted with the Department of the Army.

The policies enumerated in the DoDI, and in other DoD issuances establishing accession and commissioning standards, were reviewed and revalidated as recently as 2013. Accordingly, we are unable to grant favorable consideration of your request.

Thank you for your service as a member of the D.C. National Guard.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephanie Barna".

Stephanie Barna
Principal Deputy Assistant Secretary of Defense
For Manpower and Reserve Affairs,
Performing the Duties of the Principal
Deputy Under Secretary of Defense for
Personnel and Readiness

EXHIBIT 10



PERSONNEL AND
READINESS

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

FEB 14 2018

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
UNDER SECRETARIES OF DEFENSE
DEPUTY CHIEF MANAGEMENT OFFICER
CHIEF, NATIONAL GUARD BUREAU
DIRECTOR OF COST ASSESSMENT AND PROGRAM
EVALUATION

SUBJECT: DoD Retention Policy for Non-Deployable Service Members

In July, the Secretary of Defense directed the Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)) to lead the Department's effort to identify changes to military personnel policies necessary to provide more ready and lethal forces. In his initial memorandum to the Department, Secretary Mattis emphasized, "[e]very action will be designed to ensure our military is ready to fight today and in the future." Given the Secretary's guidance, OUSD(P&R) moved forward from the underlying premise that all Service members are expected to be world-wide deployable. Based on the recommendations of the Military Personnel Policy Working Group, the Deputy Secretary of Defense determined that DoD requires a Department-wide policy establishing standardized criteria for retaining non-deployable Service members. The objective is to both reduce the number of non-deployable Service members and improve personnel readiness across the force.

The Deputy Secretary of Defense directed the following interim policy guidance, which will remain in effect until the Department issues a DoD Instruction on reporting and retention of non-deployable Service members:

- Service members who have been non-deployable for more than 12 consecutive months, for any reason, will be processed for administrative separation in accordance with Department of Defense Instruction (DoDI) 1332.14, *Enlisted Administrative Separations*, or DoD Instruction 1332.30, *Separation of Regular and Reserve Commissioned Officers*, or will be referred into the Disability Evaluation System in accordance with DoDI 1332.18, *Disability Evaluation System (DES)*. Pregnant and post-partum Service members are the only group automatically excepted from this policy.
- The Secretaries of the Military Departments are authorized to grant a waiver to retain in service a Service member whose period of non-deployability exceeds the 12 consecutive months limit. This waiver authority may be delegated in writing to an official at no lower than the Military Service headquarters level.

- The Military Services have until October 1, 2018, to begin mandatory processing of non-deployable Service members for administrative or disability separation under this policy, but they may begin such processing immediately.
- The Military Services may initiate administrative or disability separation upon determination that a Service member will remain non-deployable for more than 12 consecutive months; they are not required to wait until the Service member has been non-deployable for 12 consecutive months.
- The Military Services will continue to provide monthly non-deployable reports to OUSD(P&R) in the format established by the Military Personnel Policy Working Group.

My office will issue a DoDI to provide additional policy guidance and codify non-deployable reporting requirements. Publication of the DoDI will supersede and cancel this policy memorandum.



Robert L. Wilkie

cc:

Assistant Secretary of the Army
for Manpower and Reserve Affairs
Assistant Secretary of the Navy
for Manpower and Reserve Affairs
Assistant Secretary of the Air Force
for Manpower and Reserve Affairs
Senior Enlisted Advisor to the Chairman
of the Joint Chiefs of Staff
Deputy Chief of Staff, G-1, U.S. Army
Chief of Naval Personnel, U.S. Navy
Deputy Chief of Staff for Personnel and Services,
U.S. Air Force
Deputy Commandant for Manpower and Reserve
Affairs, U.S. Marine Corps
Director, Reserve and Military Personnel,
U.S. Coast Guard
Director, Manpower and Personnel, Joint Staff
National Guard Bureau, J-1

Exhibit D

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

NICHOLAS HARRISON and
OUTSERVE-SLDN, INC.

Plaintiffs,

v.

JAMES N. MATTIS, in his official capacity
as Secretary of Defense; MARK ESPER, in
his official capacity as the Secretary of the
Army; and the UNITED STATES
DEPARTMENT OF DEFENSE,

Defendants.

Case No. 1:18-cv-00641 (LMB/IDD)

DECLARATION OF TREVOR HOPPE, MPH, PhD

1. My name is Trevor Hoppe, PhD. I have been retained by counsel for Plaintiffs in the above-captioned case. I have been asked to provide an expert opinion regarding the history of stigma and discrimination against people living with HIV in the United States and use of the public health system and criminal laws to control the behavior of such persons.

2. Except where otherwise stated, I have actual knowledge of the matters stated and would so testify if called as a witness.

3. I am an assistant professor of sociology at the University at Albany, SUNY. My research examines the rise and application of criminal laws related to HIV and other infectious diseases in the United States. I received my doctoral degree from the University of Michigan in 2014 in Sociology and Women's Studies. I also earned a Master's in Public Health in Health Behavior and Health Education from the University of Michigan in 2011. After my doctoral training, I was awarded a postdoctoral fellowship at the University of California at Irvine in the Department of

Criminology, Law and Society. I subsequently joined the sociology faculty at the University at Albany, SUNY, where I research and teach about crime and deviance.

4. I am an active participant in the global HIV research community, having participated in two International AIDS Conferences. In 2011, the Centers for Disease Control and Prevention awarded me the “Young Innovator Award” at their national HIV prevention conference. I have published extensively on the subject, including four peer-reviewed scientific journal articles and a recently published book, *Punishing Disease: HIV and the Criminalization of Sickness*. I consider myself to be an expert in HIV and infectious disease control, permitting me to give the following expert opinion.

5. A true and accurate copy of my curriculum vitae is attached hereto as Exhibit A, and provides a complete overview of my education, training, work experience, and a full list of my publications.

6. I have not testified as an expert at trial or by deposition in the past four years.

7. When the first outbreak of AIDS (acquired immune deficiency syndrome) was reported in the early 1980s, scientists initially did not understand its cause. Young and otherwise healthy patients became very sick across the country, presenting to healthcare providers with a wide array of rare and often deadly infections, commonly Kaposi’s sarcoma and *pneumocystis pneumonia*. Many died—hundreds at first, and then thousands across the United States. Because many of these patients were gay men, initial reports of the disease described it as “gay cancer” or “gay-related immune deficiency” (or G.R.I.D., for short). At the beginning of the epidemic, in addition to hemophiliacs, those most frequently diagnosed with AIDS were members of marginalized and highly stigmatized communities, leading some to collectively and derisively refer to people with AIDS as the “4-H club” (homosexuals, heroin users, Haitians, and

hemophiliacs). In the summer of 1984, the cause of the disease was finally identified, a retrovirus that became known as human immunodeficiency virus (HIV), which could establish itself in any person sufficiently exposed. However, by that time many Americans already believed the cause of the disease to be a deviant lifestyle, a stigmatizing belief that conservative commentators and politicians promoted by labeling AIDS as a punishment from God or “God’s cure” for homosexuality.

8. During the early years of AIDS, people living with HIV faced frequent discrimination and heightened stigma. Doctors turned away HIV-positive patients. Funeral homes refused to bury people who had died of AIDS-related complications. Even children living with the disease were cast out, as 13-year-old Ryan White experienced in Kokomo, Indiana in 1984. A hemophiliac, Mr. White contracted the disease from tainted blood products. Parents at Mr. White’s school successfully petitioned the school board to expel him from the school based on his diagnosis. To this day, people living with HIV continue to face similar forms of discrimination and, in some cases, even violence.

9. Even when untreated, the per-contact risk of sexually transmitting HIV is relatively low.¹ Nonetheless, many Americans not only feared contracting HIV via exposures it had been established presented no risk, such as kissing or sharing a drinking glass, but also as a result of highly improbable scenarios spread through urban legend tales (such as tainted pins planted in movie theater seat cushions).²For example, beginning in the 1980s—and even in recent years—

¹ “HIV Risk Behaviors,” Centers for Disease and Prevention, accessed July 18, 2018.
<https://www.cdc.gov/hiv/risk/estimates/riskbehaviors.html>

² Timothy C. Correll, “‘You Know about Needle Boy, Right?’: Variation in Rumors and Legends about Attacks with HIV-Infected Needles,” *Western Folklore* 67 (2008):59-100.

polling firms have consistently found that a substantial portion of Americans mistakenly believe that kissing can transmit HIV.³

10. American's fear and ignorance of HIV transmission, coupled with the intense stigma against communities disproportionately impacted by HIV, led to strident calls for invasive measures to control the epidemic. Conservative commentator William F. Buckley famously called for all newly-diagnosed patients to be tattooed as HIV-positive, but there were countless other leaders who called for public health departments to institute quarantine procedures and to criminalize people living with HIV who they viewed as a threat to the health of others.⁴

11. Once HIV was identified, state lawmakers around the country began to consider bills to institute disease control programs targeting this new epidemic. While most of this legislation featured conventional disease control procedures, lawmakers in 45 states also introduced legislation that imposed felony level criminal sanctions in an effort to control the behavior of people living with HIV. Rather than misdemeanor or civil penalties, most HIV-specific criminal legislation enacted in the United States featured felony penalties that carried stiff prison sentences, ranging from 2-3 years to life in prison.

12. No disease in American history has ever been met with a similarly punitive response from lawmakers. The only comparable case is hepatitis C virus (HCV), a viral infection transmitted through blood-to-blood contact (typically needle-sharing) that has been the subject of criminal legislation enacted in a handful of states. Even in states with HCV-specific laws, however, few cases have ever been prosecuted—perhaps because most people who could plausibly file charges are unlikely to do so as it would require reporting criminal drug-using

³ Gregory H. Herek, John P. Capitano, and Keith F. Widaman, "HIV-Related Stigma and Knowledge in the United States: Prevalence and Trends, 1991–1999," *American Journal of Public Health*, 92 (2002):371-377.

⁴ Gregory H. Herek and Eric K. Glunt, "An Epidemic of Stigma: Public Reactions to AIDS," *American Psychologist* 43 (1988):886-891.

behavior to the police. Other diseases that can cause serious health complications and even death have not faced similar criminal penalties. For example, human papillomavirus (HPV) is a highly contagious, sexually transmitted infection that can cause lesions on the skin. Studies now show that it can also cause cervical cancer—sometimes fatal—many years after initial infection.⁵ There have never been campaigns to criminalize HPV exposure. In part, the nonpunitive response to HPV can be credited to two characteristics of the disease that stand in stark contrast to HIV. First, the high prevalence of HPV in adult Americans (upwards of two-thirds of Americans are estimated to be infected) makes criminal sanctions targeting HPV a costly and impractical policy response. Second, the disease is not overwhelmingly concentrated in highly stigmatized communities already viewed as potentially criminal.

13. According to a 2014 report co-authored by staff from the Centers for Disease Control and Prevention and the Department of Justice, 33 states enacted criminal legislation that specifically targets people living with HIV.⁶ Although the federal and state governments do not compile official statistics regarding these prosecutions, research has revealed thousands of criminal cases involving people living with HIV who have been prosecuted under HIV-based criminal laws.⁷

14. Most statutes are construed broadly without regard to transmission or even the risk of transmission from the specific activity in question. In most states with such laws, the crime is defined as failing to disclose one's HIV-positive status before engaging in a range of

⁵ Guglielmo Ronco, et al. "Efficacy of HPV-Based Screening for Prevention of Invasive Cervical Cancer: Follow-up of Four European Randomised Controlled Trials," *The Lancet* 383 (2014):524-532.

⁶ J. Stan Lehman, et al. "Prevalence and Public Health Implications of State Laws That Criminalize Potential HIV Exposure in the United States," *AIDS and Behavior* 18 (2014): 997–1006.

⁷ Amira Hasenbush, *HIV Criminalization in Georgia: Penal Implications for People Living with HIV* (Los Angeles, CA: The Williams Institute at UCLA, 2018); Trevor Hoppe, *Punishing Disease: HIV and the Criminalization of Sickness* (Oakland, CA: University of California Press, 2018); Dini Harsono, Carol L. Galletly, Elaine O'Keefe, and Zita Lazzarini, "Criminalization of HIV Exposure: A Review of Empirical Studies in the United States," *AIDS and Behavior* 21 (2017):27-50; Amira Hasenbush, Ayako Miyashita, and Bianca D. M. Wilson, *HIV Criminalization in California: Penal Implications for People Living with HIV* (Los Angeles, CA: The Williams Institute at UCLA, 2015).

behaviors—typically sexual contacts, however some states also prohibit needle sharing and even spitting, biting, or other nonsexual exposures. Use of a condom or other preventive measures is generally irrelevant. In Michigan, for example, the law prohibits people living with HIV from engaging in “sexual penetration” without first disclosing their HIV status. The law defines sexual penetration as “sexual intercourse, cunnilingus, fellatio, anal intercourse, or any other intrusion, however slight, of any part of a person's body or of any object into the genital or anal openings of another person's body.”⁸ Such imprecise statutory language has facilitated the criminalization of a wide range of practices, including those that are unlikely to transmit the disease and also those that could not conceivably transmit HIV. For example, in a case I review in my book, *Punishing Disease*, a Tennessee man who was admitted to the hospital after attempting suicide was charged in 2010 under that state’s HIV exposure law after he bit a hospital attendant.⁹ Biting has never definitively been established as a route of HIV transmission; nonetheless, the defendant was sentenced to three years in prison.

15. Lengthy prison sentences are common in these cases. In a study I conducted analyzing 431 prosecutions in six U.S. states between 1992 and 2010, I found that more than three-quarters of defendants convicted under HIV-specific criminal laws were sentenced to jail or prison; of those incarcerated, the average prison term was 92 months (nearly eight years).¹⁰ In 2012, an Iowa man, Nick Rhoades, was accused of engaging in a one-time sexual encounter in which he used a condom; he had an undetectable viral load, which the CDC has recently confirmed

⁸ MCL Annotated § 333.5131.

⁹ See pp. 150-151 in Trevor Hoppe. *Punishing Disease: HIV and the Criminalization of Sickness* (Oakland: University of California Press, 2018).

¹⁰ See Chapter 6, “Victim Impact,” in *Ibid.*

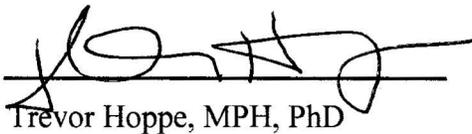
reduces the risk of transmission effectively to zero; there was (of course) no transmission; after pleading guilty, Mr. Rhoades was sentenced to 25 years in prison.¹¹

16. HIV-specific criminal legislation codified the stigma against the epidemic that was (and is) pervasive in the United States. At the time these laws were implemented, HIV was a largely terminal and untreatable infection. Much has changed since that time. In the vast majority of cases, people diagnosed as HIV positive today are prescribed a pill-a-day treatment regimen that carries few side effects. By reducing the amount of virus in a person's bodily fluids, studies now show that modern treatment protocols can render people living with HIV noninfectious. Another recent life expectancy study estimates that a 20-year-old gay man diagnosed as HIV-positive today and prescribed treatment is expected to live several years longer than men in the general population.¹² Despite these dramatic improvements in HIV science, however, the laws of the 1980s largely remain unchanged. To date, only three states—Iowa, Colorado and California—have changed their laws in response to demands from HIV advocates.

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

Executed on: 7/18/2018

Respectfully,



Trevor Hoppe, MPH, PhD

¹¹ Brian Cox, "Turning the Tide: The Future of HIV Criminalization after *Rhoades v. State* and Legislative Reform in Iowa," *Northwestern Journal of Law and Social Policy* 11 (2016):28-53.

¹² Hasina Samji, et al. "Closing the Gap: Increases in Life Expectancy among Treated HIV-Positive Individuals in the United States and Canada," *PLoS ONE* 8 (2013): e81355.

Exhibit A

Trevor Alexander Hoppe

thoppe@albany.edu | <http://www.trevorhoppe.com>

EMPLOYMENT

Assistant Professor, University of North Carolina at Greensboro
Department of Sociology (Beginning Fall 2018) Greensboro, NC

Assistant Professor, University at Albany, SUNY
Department of Sociology (2015-Present) Albany, NY

Postdoctoral Fellow, University of California at Irvine
Department of Criminology, Law and Society (2014-2015) Irvine, CA

EDUCATION

Ph.D. University of Michigan (2014) Ann Arbor, MI
Sociology and Women's Studies
Dissertation: *From Sickness to Badness: Michigan HIV Law as a Site of Social Control*
Committee: Renee Anspach & David Halperin (Co-Chairs), Sarah Burgard, Sandra Levitsky

- WINNER: American Sociological Association (ASA), Martin P. Levine Dissertation Fellowship
- WINNER: ASA, Medical Sociology Section, Roberta G. Simmons Outstanding Dissertation Award

M.P.H. University of Michigan (2011) Ann Arbor, MI
Health Behavior and Health Education, School of Public Health

M.A. San Francisco State University (2007) San Francisco, CA
Human Sexuality Studies

B.A. University of North Carolina at Chapel Hill (2005) Chapel Hill, NC

PUBLICATIONS

Books:

2018. *Punishing disease: HIV and the criminalization of sickness*. University of California Press.

- WINNER: 2018 Lambda Literary Award for LGBTQ Studies

2017. Hoppe, Trevor and David Halperin (Eds.). *The war on sex*. Duke University Press

- FINALIST: 2018 Lambda Literary Award for LGBTQ Studies

Journal articles:

"Punishing sex: Sex offenders and the missing punitive turn in sexuality studies." *Law & Social Inquiry*, 2016, 41(3): 573-94.

"Cruel intentions? HIV prevalence and criminalization during an age of mass incarceration, U.S. 1999-2012." Second author, with Bryan Sykes and Kristen Maziarka. *Medicine*, 2016, 95(16):1-9.

"Social science perspectives on pre-exposure prophylaxis for HIV (PrEP)." Second author, with Judith Auerbach. *Journal of the International AIDS Society*, 2015, 18(S3):19983.

"Disparate risks of conviction under Michigan's felony HIV disclosure law: An observational analysis of convictions and HIV diagnoses, 1992-2010." *Punishment & Society*, 2015. 17:73-93.

- Featured in *Ebony*, *The Nation*, *TheBody.com*

"From sickness to badness: The criminalization of HIV in Michigan." *Social Science & Medicine*, 2014, 101: 139-147.

“Controlling sex in the name of ‘public health’: Social control and Michigan HIV law.” *Social Problems*, 2013, 60: 27-49.

- ASA, Sexualities Section, Best Graduate Student Paper, 2014
- ASA, Sociology of Law Section, Best Graduate Student Paper, 2013
- University of Michigan, Department of Sociology, Mark Chesler Paper Award, 2013

“Circuits of power, circuits of pleasure: Sexual scripting in gay men’s bottom narratives.” *Sexualities*, 2011, 14: 193-217.

- Sociologist AIDS Network Martin Levine Student Essay Award, 2009

Book chapters:

Hoppe, Trevor. “Queer and punishment: Sexual social control and the legacy of ‘nuts, sluts and preverts’” (Book chapter). Forthcoming in Schilt, Kristen, Tey Meadow, and D’Lane Compton (eds.), *Other, Please Specify: _____: Queer Methods in Sociology*. Berkeley, CA: University of California Press.

Manuscripts in progress or under review:

Rebeca Herrero Saenz*, and **Trevor Hoppe**, “Disease on trial: Microbiological responsibility in HIV exposure and disclosure jury trials, 1992-2014.” *Revise and resubmit*.

Hoppe, Trevor, “Othering disease: Spanish flu, Gay-related immunodeficiency, and the stigmatization of infectious disease.” *Revise and resubmit*.

Hoppe, Trevor, Bryan Sykes, and Kyle Maksuta* “Sexual threat: Using group threat theory to explain the rise and spread of American sex offender registries.”

Hoppe, Trevor, and Renee Anspach. “Towards a critical sociology of public health.”

*Authors denoted with an asterisk * are graduate students*

Reviews:

Hoppe, Trevor. Forthcoming. “Review of *Sex Offenders, Stigma, and Social Control*, by Diana Rickard,” *Contemporary Sociology*.

Hoppe, Trevor. 2017. “Review of *The Straight Line: How the Fringe Science of Ex-Gay Therapy Reoriented Sexuality*, by Tom Waidzunus,” *American Journal of Sociology*, 123(1):312-314.

Hoppe, Trevor. 2011. “Review of *Unlimited Intimacy: Reflections on the Subculture of Barebacking*, by Tim Dean.” *Journal of Sex Research*, 48: 506-8.

Hoppe, Trevor. 2009. “Review of *Sexual Inequalities & Social Justice*, N. Teunis & G. Herdt (Eds.), and *The Health of Sexual Minorities*, I. Meyer & M. Northridge (Eds).” *Culture, Health and Sexuality*, 11: 107-10.

Other publications and media appearances:

Interview. 2018, March 26. “How state laws criminalize people with HIV.” *The Crime Report*. <https://thecrimereport.org/2018/03/26/how-state-laws-criminalize-hiv-sufferers/>

Interview and Book Review. 2018, March 2. “Creating criminals: The misguided crackdown on HIV/AIDS.” *Undark*. <https://undark.org/article/book-review-hoppe-punishing-disease/>

- Interview. 2018, February 6. "Hepatitis C exposure is a crime in some states; is this the new HIV criminalization?" *The Body*. <http://www.thebody.com/content/80840/hepatitis-c-exposure-is-a-crime-in-some-states-is-.html>
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- Hoppe, Trevor. 2015, November 17. "Let's Not Treat Charlie Sheen Like a Criminal." *Huffington Post*. http://www.huffingtonpost.com/trevor-hoppe/lets-not-treat-charlie-sh_b_8583710.html
- Interview. 2015, May 29. "The reckless prosecution of 'Tiger Mandingo.'" *The Nation*. <https://www.thenation.com/article/reckless-prosecution-tiger-mandingo/>
- Interview. 2013. *More Harm than Good: How Overly Broad HIV Criminalisation is Hurting Public Health*. Documentary Film. Directed by Edwin Bernard, HIV Justice Network. <http://www.hivjustice.net/moreharm/>
- Interview. 2013, March 23. *Strange Fruit*. 89.3 WFPL. <http://wfpl.org/strange-fruit-rob-portman-marriage-equality-trevor-hoppe-criminalization-hiv-0/>

AWARDS, GRANTS, SCHOLARSHIPS, AND FELLOWSHIPS

- 2018 Lambda Literary Award for LGBTQ Studies, Lambda Literary Foundation
- 2018 Lavender Award for Excellence in LGBTQ+ Scholarship, University at Albany, SUNY

- 2018 Faculty Research Award Program (FRAP), University at Albany, SUNY (\$9850)
- 2016 Individual Development Award, Campus Professional Development Committee, SUNY-Albany
- 2015 College of Arts and Sciences Conference Travel Fund Program, SUNY-Albany
- 2014 American Sociological Association, Sexualities Section, Best Graduate Student Paper
- 2014 American Sociological Association, Medical Sociology Section, Roberta G. Simmons Outstanding Dissertation Award
- 2013 American Sociological Association, Sociology of Law Section, Best Graduate Student Paper
- 2013 University of Michigan Department of Sociology, Mark Chesler Paper Award
- 2013 Seed Grant, Center for Public Policy in Diverse Societies, Gerald R. Ford School of Public Policy, University of Michigan
- 2013 American Sociological Association Student Forum, Travel Grant
- 2013 Lee Student Support Fund Travel Award, Society for the Study of Social Problems
- 2013 Scholarship, 2nd International Conference for the Social Sciences and Humanities in HIV, Paris, France.
- 2012 ASA, Martin P. Levine Memorial Dissertation Fellowship
- 2012 University of Michigan Rackham Predoctoral Fellowship
- 2012 Scholarship, American Sociological Association Section on Sexualities Mini-Conference
- 2012 Scholarship, International AIDS Conference, Washington, DC.
- 2011 Centers for Disease Control and Prevention, Young Innovator Award
- 2011 Sociologist AIDS Network, Scholarly Activity Award
- 2011 Community of Scholars Fellowship, Institute for Research on Women and Gender, University of Michigan
- 2011 Rackham Graduate Student Candidacy Research Grant, University of Michigan
- 2011 Dissertation Research Grant, Department of Sociology, University of Michigan
- 2011 Student Research Grant, Center for Education of Women, University of Michigan
- 2010 Social Science Research Council, Dissertation Proposal Development Fellowship
- 2009 Sociologist AIDS Network Martin Levine Student Essay Award
- 2009 Dean's Scholarship, School of Public Health, University of Michigan (Declined)
- 2008 Rackham Graduate Student Pre-Candidacy Research Grant, University of Michigan
- 2007 Herbert E. Boynton Scholarship, University of Michigan
- 2006 SFSU University Scholarship, San Francisco State University
- 2006 Jim Brogan Teaching Scholarship, San Francisco State University

INVITED LECTURES AND PRESENTATIONS

"Punishing disease: HIV and the criminalization of sickness"

- Department of Women's Studies, University of Michigan, March 2019, Ann Arbor, MI
- Saint Louis University, April 2018, St Louis, MO
- Washington University in St. Louis, April 2018, St Louis, MO

- Middlebury College, April 2018, Middlebury, VT
- Concordia University, March 2018, Montreal, QC, Canada
- Muskegon Community College, March 2018, Muskegon, MI
- Harvard Law School, January 2018, Cambridge, MA
- University of Arizona, January 2018, Tucson, AZ
- HIV is Not a Crime II National Training Academy, May 2016, Huntsville, AL
- HIV Criminalization Working Group, Yale University, April 2016, New Haven, CT
- Department of Sociology, Grand Valley State University, April 2016, Grand Rapids, MI
- Department of Sociomedical Sciences, UCSF, March 2016, San Francisco, CA
- Department of Sociology, UCLA, November 2015, Los Angeles, CA

“Queer and punishment: Sexual social control and the legacy of ‘nuts, sluts and preverts,” Queer Methods in Sociology Conference, Harvard University, April 2016, Cambridge, MA.

“Punishing sex: Sex offenders and the missing punitive turn in sexuality studies,” The Sexualities Project at Northwestern (SPAN) Annual Workshop, April 2015, Chicago, IL

“Surveying the criminalization of HIV in the United States: Preliminary findings.” The Williams Institute, University of California at Los Angeles, October 2013, Los Angeles, CA.

“Making sense of disparate outcomes in Michigan trial court HIV nondisclosure convictions: The modifying impact of the partner’s gender.” York University, April 2013, Toronto, ON.

“The criminalization of HIV.” Invited Lecture, WS 212, “Global HIV/AIDS Epidemic.” April 2013, Ann Arbor, MI.

“HIV criminalization in Michigan: Criminal justice and public health in contest.” Wayne State University, March 2013, Detroit, MI

“The criminalization of HIV/AIDS.” Wayne State University, November 2012, Detroit, MI

“‘Equal time’: Gays, media, and the myth of equality.” Invited panelist, Indiana University, April 2012, Bloomington, IN

“The criminalization of HIV.” Invited lecture, “Global HIV/AIDS Epidemic.” March 2012, Ann Arbor, MI.

“HIV disclosure laws in the United States: Theory, practice, and politics.” Summer Institute on Sexuality, San Francisco State University, June 2011, San Francisco, CA.

“Using sociological theory to understand pleasure and power: Bottom identity among gay men as a case study.” Summer Institute on Sexuality, San Francisco State University, June 2011, San Francisco, CA.

“Historical mobilizations of ‘public health’ against public sex venues.” Summer Institute on Sexuality, San Francisco State University, June 2010, San Francisco, CA.

“Remembering Eric Rofes.” Against Health Conference, University of Michigan, October 2006.

CONFERENCE PRESENTATIONS

“Victim impact: Analyzing disparities by race, gender, and sexuality under state HIV exposure and disclosure laws,”

- American Sociological Association Annual Meeting, August 2017, Montreal, CA.
- International AIDS Conference [Poster presentation], July 2017, Paris, France.

“One million and counting? How policy levers will impact the future of sex offender registries in the United States,” Law & Society Association Annual Meeting, June 2017, Mexico City, MX.

“Punishing HIV: Does race impact sentencing under criminal HIV exposure and disclosure laws in the United States?” [Poster presentation] International AIDS Conference, July 2016, Durban, ZA.

“Punishing disease: HIV and the criminalization of sickness”

- International Sociological Forum, July 2016, Vienna, Austria
- Law and Society Association, June 2016, New Orleans, LA
- American Sociological Association Annual Meeting, August 2015, Chicago, IL

“Punishing sex: Sex offenders and the missing punitive turn in sexuality studies.”

- After Marriage Conference at CUNY, October 2016, New York, NY
- American Sociological Association, August 2016, Seattle, WA
- American Society of Criminology, November 2015, Washington, DC
- Law & Society Association Annual Meeting, May 2015, Seattle, WA
- Pacific Sociological Association Annual Meeting, April 2015, Long Beach, CA

“HIV stops with me: The repolarization of post-AIDS HIV prevention.”

- Association for the Social Sciences and Humanities in HIV, July 2015 Cape Town, ZA
- American Sociological Association Annual Meeting, August 2014, San Francisco, CA.

“Controlling the criminally sick: A systematic analysis of HIV disclosure trial court cases in Michigan.”

- American Sociological Association Annual Meeting, August 2013, New York, NY
- Society for the Study of Social Problems Annual Meeting, August 2013, New York, NY
- 2nd International HIV Social Science and Humanities Conference, July 2013, Paris, France
- 17th Annual Sørensen Memorial Conference, Columbia University, April 2013, New York, NY
- Western Society of Criminology, February 2013, Berkeley, CA
- National Women’s Studies Association Annual Meeting, November 2012, Oakland, CA
- American Sociological Association Section on Sexualities Mini-Conference, August 2012, Denver, CO
- International AIDS Conference, August 2012, Washington, DC

“From sickness to badness: Towards a theory of medical social control beyond medicalization.”

- American Sociology Association Annual Meeting, August 2012, Denver, CO
- Gendered Borders and Queer Frontiers Conference, Madison, WI, March 2012

“Controlling sex in the name of ‘public health’: Social control and Michigan’s HIV disclosure law.”

- Making (In)Appropriate Bodies Conference, Vienna, Austria, December 2011
- American Sociological Association Annual Meeting, Las Vegas, NV, August 2011
- National HIV Prevention Conference, Atlanta, GA, August 2011
- Law & Society Association Annual Meeting, San Francisco, CA, June 2011
- Midwest Sociological Society Annual Meeting, St. Louis, MO, March 2011
- Doing Queer Studies Now: A Graduate Conference, Ann Arbor, MI, October 2010
- Midwest Law & Society Retreat, Madison, WI, October 2010.

“Circuits of Power, Circuits of Pleasure: Sexual Scripting in Gay Men’s Bottom Narratives”

- American Sociological Association Annual Meeting, San Francisco, CA, August 2009
- National Gay Men’s Health Summit, Seattle, WA, October 2008

“Resisting Public Health: Working within the Gay Men’s Health Movement to Produce Change.”

LumpenCity: Marginalizing Discourses | Discourses of Marginalization, Toronto, ON, Canada, March 2009.

“Being Gay Post-HAART: Young Gay Men Negotiating Desire, Risk, and Heteronormativity.”

- AIDS in Culture IV, Mexico City, Mexico, December 2007
- LGBTI Health Summit, Philadelphia, PA, March 2007.

PUBLIC LECTURES AND READINGS

“Punishing disease: HIV and the criminalization of sickness”

- Flyleaf Books, Chapel Hill, NC, March 2018
- LGBT Center of Raleigh, Raleigh, NC, March 2018
- Center on Halsted, Chicago, IL, February 2018
- West Hollywood Library, Los Angeles, CA, January 2018
- Bluestockings, New York, NY, December 2017
- William Way LGBT Center, Philadelphia, PA, November 2017
- Red Emma’s Bookstore, Baltimore, MD, November 2017

“Reframing HIV: From ‘prevention’ to ‘management.’” National Gay Men’s Health Summit, August 2010, Fort Lauderdale, FL.

“Power and rethinking risk.” Gay Men’s Health Summit, October 2009, Seattle, WA

“Bus stops, billboards and you: campaigning for queer health.” San Francisco Lesbian, Gay, Bisexual, and Transgender Community Center, July 2008, San Francisco, CA.

TEACHING EXPERIENCE

Assistant Professor, Department of Sociology, UNC-Greensboro 2018 - Present

- “Global Deviance,” Fall 2018
- “Law and Society,” Fall 2018

Assistant Professor, Department of Sociology, University at Albany, SUNY 2015 - 2018

- “Sociology of Deviant Behavior,” Fall 2015, Fall 2016, Spring 2017, Fall 2017, Spring 2018
- “Sociology of Sexualities,” Spring 2018
- “The Global HIV/AIDS Epidemic,” Fall 2016
- “The Sociology of Law” (Graduate Seminar), Spring 2017

Primary Instructor, University of Michigan 2009, 2014

- “Sociological Analysis of Deviance” (SOC 488), Spring 2014
- “Sociology of Sexuality” (SOC 345), Spring 2009

Graduate Student Instructor, University of Michigan 2008 – 2014

- “Introduction to Sociology” (SOC 100), Fall 2008, Fall 2010, Winter 2011
- “Sociology of Marriage & The Family” (SOC 344), Winter 2009
- “The Global HIV/AIDS Epidemic” (WOMENSTD / ANTHRO 212), Winter 2012, Fall 2013
- “History of Sexuality” (HIST 369), Winter 2010
- “Men’s Health” (WOMENSTD 300), Fall 2009

Teaching Assistant, San Francisco State University 2006 – 2007

- “Variations in Human Sexuality” (SOC 400), Spring 2006, Fall 2006, Spring 2006

REVIEWER FOR THE FOLLOWING PUBLICATIONS

Social Problems, Sociological Forum, Sexualities, Law & Social Inquiry, PLOS One, Theoretical Criminology, Contemporary Sociology, Culture, Health & Sexuality, Men and Masculinities, AIDS & Behavior, Journal of Homosexuality, Archives of Sexual Behavior, Sexuality Research & Social Policy, Women's Studies Quarterly, Studies in Law, Politics & Society, Oxford Bibliographies

PROFESSIONAL SERVICE

- 2018 – 2021 Council Member-Elect, American Sociological Association Section on Sociology of Law
- 2018 – 2021 Editorial Board, *Social Problems*
- 2016 – 2019 Council Member-Elect, American Sociological Association Section on Sexualities
- 2017 – 2018 Member, Undergraduate Committee, University at Albany Department of Sociology
- 2017 Member, Distinguished Book Award Committee, ASA Section on Sex and Gender
- 2016 – 2017 Member, Executive Committee, University at Albany Department of Sociology
- 2016 – 2017 Chair, Advancement Committee, University at Albany Department of Sociology
- 2015 – 2016 Member, Advancement Committee, University at Albany Department of Sociology
- 2014 – 2015 Member, Selection Committee, Roberta G. Simmons Outstanding Dissertation Award, American Sociology Association Section on Medical Sociology
- 2014 – 2015 Member, Selection Committee, Best Graduate Student Paper Award, American Sociology Association Section on Sexualities
- 2013 – 2014 Member, Nominations Committee, American Sociology Association Section on Sex and Gender
- 2013 – Member, Criminalization of HIV Transmission and Exposure Working Group Law, Policy and Ethics (LPE) Core, Center for Interdisciplinary Research on AIDS (CIRA), Yale University
- 2013 Co-chair with Eric Mykhalovskiy of “Social Science, Criminal Law and HIV Transmission Risks: Novel Research” and “Viral Politics: HIV Criminalization & Social Inquiry” Panels, 2nd International HIV Social Sciences and Humanities Conference
- 2012 – Invited Abstract Reviewer, International AIDS Conference
- 2012 “Sex and Justice” Thematic Panel Organizer, American Sociological Association Section on Sexualities Mini-Conference
- 2012 Roundtable Discussant, American Sociological Association Section on Sexualities Mini-Conference
- 2011 – Martin Levine Paper Prize Committee, Sociologist AIDS Network
- 2011 – 2012 Graduate Student Representative-Elect, Section on Sexualities, American Sociological Association
- 2011 – 2012 Organizer, “Sex and Justice” Conference, University of Michigan
- 2011 – 2012 Graduate Admissions Committee, Department of Sociology, University of Michigan
- 2010 – 2011 Personnel Committee, Department of Sociology, University of Michigan
- 2010 Martin Levine Paper Prize Committee, Sociologist AIDS Network

Curriculum vitae: Trevor Hoppe

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- 2009 – 2010 Search Committee, HIV/AIDS Cluster Hire, Department of Women’s Studies, University of Michigan
- 2009 – 2010 HIV/AIDS Survey Course Development Committee, Department of Women’s Studies, University of Michigan
- 2009 – 2010 Organizer, “Doing Queer Studies Now” Graduate Conference, University of Michigan

PROFESSIONAL AFFILIATIONS

Member, American Sociological Association (ASA)

- Sections: Medical Sociology; Crime, Law and Deviance; Sex and Gender; Sexualities; Sociology of Law

Member, American Sociology of Criminology (ASC)

Member, Law and Society Association (LSA)

Member, Society for the Study of Social Problems (SSSP)

Member, International AIDS Society (IAS)

Exhibit E

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

NICHOLAS HARRISON and
OUTSERVE-SLDN, INC.

Plaintiffs,

v.

JAMES N. MATTIS, in his official capacity
as Secretary of Defense; MARK ESPER, in
his official capacity as the Secretary of the
Army; and the UNITED STATES
DEPARTMENT OF DEFENSE,

Defendants.

Case No. 1:18-cv-641 (LMB/IDD)

**EXPERT DECLARATION OF CRAIG W. HENDRIX, M.D., IN SUPPORT OF
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**

I. INTRODUCTION

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

2. I am offering this declaration to provide my expert opinions regarding the U.S. Department of Defense and U.S. Army policies with respect to people living with HIV, including the purported medical justifications for preventing individuals living with HIV from joining the United States military, from being commissioned as officers, and—if already in the military—from deploying outside the United States.

3. As detailed below, it is my opinion that there are no medical justifications for excluding individuals from serving in any capacity in the military or from being deployed outside of the United States based solely on their HIV-positive status.

4. 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.

5. I am knowledgeable about the matters set forth below based upon my own knowledge and experience, as well as my review of various materials that are cited herein. I have reviewed and concur with the opinions expressed by Dr. Carlos del Rio in the declaration he has submitted in support of this motion.

II. PROFESSIONAL BACKGROUND & QUALIFICATIONS

6. Currently, I am a Professor of Medicine and Pharmacology and Molecular Sciences at the Johns Hopkins University School of Medicine. I have 28 years of experience in the design and conduct of translational clinical pharmacology studies, mostly of antiretroviral drugs for HIV treatment and prevention. In 2015, I was appointed as the Wellcome Professor

and Director, Division of Clinical Pharmacology and Director of the Drug Development Unit in the Division.

7. Before joining the Johns Hopkins medical school faculty, I served on active duty for 10 years in the U.S. Air Force (USAF). During that time, after completing my medical training, I was the Director of the HIV Medical Evaluation Unit (MEU) and HIV Program at the Wilford Hall USAF Medical Center in San Antonio, Texas, from July 1989 to June 1994. As Director of the HIV MEU, my responsibilities included screening service members for HIV, monitoring the condition of HIV-positive service members, studying behavioral risk factors associated with HIV, and educating service members about the prevention and treatment of HIV.

8. I received my undergraduate degree in Applied Biology at the Massachusetts Institute of Technology in 1978, and I received my medical degree from Georgetown University, *magna cum laude*, in 1984. I completed internship and residency in internal medicine on the Osler Medical Service, and fellowships in Infectious Diseases and Clinical Pharmacology at The Johns Hopkins Hospital.

9. For nearly 30 years, I have evaluated, treated, and/or conducted research with thousands of individuals living with HIV. I have authored or co-authored over 190 papers in peer-reviewed journals on topics related to HIV treatment, prevention, and education. My current research focuses on development of antiretroviral drugs to prevent HIV infection. This involves oral, topical, and injectable HIV microbicide development. I conduct small, intensive sampling studies of pharmacokinetics (PK)¹ and pharmacodynamics (PD) of drugs for HIV

¹ Pharmacokinetics describes the drug concentration-time courses in body fluids resulting from administration of a certain drug dose, while pharmacodynamics describes the observed effect resulting from a certain drug concentration.

prevention with a focus on developing methods to better understand HIV and drug distribution in the male genital tract, female genital tract, and lower gastrointestinal tract. I also support numerous HIV pre-exposure prophylaxis development studies from phase I to phase III, largely as the leader of the Pharmacology Core Laboratory of both the Microbicide Trial Network and HIV Prevention Trials Network.

10. My curriculum vitae is attached, which describes my education, work experience, and publications. *See* Attach. 1 (Hendrix CV).

III. MEDICAL JUSTIFICATIONS FOR EXCLUDING PEOPLE LIVING WITH HIV FROM MILITARY SERVICE, INCLUDING DEPLOYMENT OUTSIDE THE UNITED STATES, ARE UNFOUNDED

11. Being HIV positive is entirely compatible with military service. The Department of Defense has recognized this for many years by permitting people who seroconvert (i.e., acquire HIV and develop HIV antibodies) after entering service to continue to serve. Moreover, I understand the Navy has allowed service members with HIV to deploy for selected overseas missions since 2012, while the Air Force has granted some waivers for overseas assignments for its members living with HIV who are otherwise medically fit for deployment. As I discuss below, the articulated reasons the DoD and Army have advanced for the disparate treatment of people living with HIV simply do not justify excluding them from or restricting their military service.

A. Military Policies Regarding People Living with HIV

1. Accession Ban

12. I understand that, under Department of Defense (DoD) Instruction 6485.01 (Human Immunodeficiency Virus (HIV) in Military Service Members),² it is the U.S. military's policy to deny eligibility for military service to persons with HIV for "appointment, enlistment, pre-appointment, or initial entry training for military service" pursuant to DoD Instruction ("DoDI") 6130.03. In other words, people living with HIV are barred from entering the military or from being appointed an officer if they seroconvert after joining the military, as Mr. Harrison did.

13. Despite this general policy prohibiting people living with HIV from joining the military or being appointed as an officer, DoDI 6485.01 states that an active duty service member with HIV who it has been determined is otherwise "fit for duty will be allowed to serve in a manner that ensures appropriate medical care."³ Only service members with HIV who are determined to be unfit for duty are to be separated.⁴

14. Department of Defense Instruction 6130.03 (Medical Standards for Appointment, Enlistment, and Induction into the Military Services) sets forth guidance regarding the physical and medical standards required for military service.⁵ These standards state that individuals who are considered for appointment, enlistment, or induction into the Medical Services must be:

- (1) Free of contagious diseases that may endanger the health of other personnel.

² U.S. Department of Defense Instruction 6485.01, at ¶3.a. (June 7, 2013), available at <http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/648501p.pdf>.

³ *Id.* at Enclosure 3: Procedures, ¶3.c.

⁴ *Id.* at Enclosure 3: Procedures, ¶3.e.

⁵ U.S. Department of Defense Instruction 6130.03 (May 6, 2018), available at <http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/613003p.pdf>.

(2) Free of medical conditions or physical defects that may reasonably be expected to require excessive time lost from duty for necessary treatment or hospitalization, or may result in separation from the Military Service for medical unfitness.

(3) Medically capable of satisfactorily completing required training and initial period of contracted service.

(4) Medically adaptable to the military environment without geographical area limitations.

(5) Medically capable of performing duties without aggravating existing physical defects or medical conditions.⁶

15. HIV is among the specified “disqualifying conditions” under DoDI 6130.03.⁷

16. I also understand that Army Regulation 600-110 (Identification, Surveillance, and Administration of Personnel Infected with Human Immunodeficiency Virus)⁸ implements DoDI 6485.01 and describes various policies and responsibilities related to HIV with respect to Army personnel. Specifically, the Army indicates its policies are meant to reflect: [1] the risks incident to military service for the person with HIV; [2] the risk of transmission to other personnel; [3] the overall impact of people living with HIV in Army units and on readiness posture; and [4] the safety of military blood supplies.⁹ Similar to DoDI 6485.01, AR 600-110 states that personnel with HIV are not eligible for appointment on enlistment into the active Army, the Army National Guard, or the U.S. Active Reserve.¹⁰ Again, however, the Army regulation states that active duty soldiers with HIV who do not demonstrate progressive clinical illness or immunological

⁶ *Id.* at ¶1.2.c.

⁷ *Id.* at 5.23.b. (“Presence of human immunodeficiency virus or laboratory evidence of infection or false-positive screening test(s) with ambiguous results by supplemental confirmation test(s).”).

⁸ U.S. Army Regulation 600-110 (Apr. 22, 2014), available at https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r600_110.pdf.

⁹ *Id.* at Section III, ¶1-15.

¹⁰ *Id.* at Section III, ¶1-16.a.

deficiency during periodic evaluations will not be involuntarily separated solely because they have HIV.¹¹

2. Conditions for Deployment and Deployment Restrictions

17. I further understand that Department of Defense Instruction 6490.07 (Deployment-Limiting Medical Conditions for Service Members and DoD Civilian Employees) provides guidance on medical conditions that limit deployment. DoDI 6490.07 indicates that it is DOD policy that service members with existing medical conditions may deploy only when the following conditions are met:

(1) The condition is not of such a nature or duration that an unexpected worsening or physical trauma is likely to have a grave medical outcome or negative impact on mission execution.

(2) The condition is stable and reasonably anticipated by the pre-deployment medical evaluator not to worsen during the deployment in light of physical, physiological, psychological, and nutritional effects of the duties and location.

(3) Any required, ongoing health care or medications anticipated to be needed for the duration of the deployment are available in theater within the Military Health System. Medication must have no special handling, storage, or other requirements (e.g., refrigeration, cold chain, or electrical power requirements). Medication must be well tolerated within hard environmental conditions (e.g. heat or cold stress, sunlight) and should not cause significant side effects in the setting of moderate dehydration.

(4) There is no need for routine evacuation out of theater for continuing diagnostics or other evaluations. (All such evaluations should be accomplished before deployment.)¹²

18. DoDI 6490.07 specifically identifies HIV as a medical condition that precludes a service member's deployment outside of the United States.¹³ DoDI 6490.07 provides that a

¹¹ *Id.* at Section III, ¶1-16.e.

¹² *Id.* at ¶4.b.

¹³ Department of Defense Instruction 6490.07, Encl. 3 (Medical Conditions Usually Precluding Contingency Deployment) at ¶e(2) (Feb. 5, 2010), available at <http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/649007p.pdf>.

service member living with HIV shall not be deployed on a “contingency deployment” (*i.e.*, a deployment of over 30 days located outside the continental United States in a location with medical support from only temporary military medical treatment facilities) unless a medical waiver is granted.¹⁴

B. Policies Underlying the Physical and Medical Standards for Military Service and Deployment Do Not Justify the Exclusion of People Living with HIV

1. There is No Danger to the Health of Other Personnel

19. People living with HIV in the military pose no cognizable danger to the health of other personnel in the military. HIV cannot be transmitted by working alongside or having casual contact with someone who is living with HIV, including sharing bathroom facilities; sharing equipment, utensils, and tableware; or exercising or engaging in physical activities. This fact is borne out by the military’s policy that allows people living with HIV to continue to serve in the military, as long as they are medically fit for duty. AR 600-110 explicitly acknowledges that “[t]here is no basis for civilian employees to refuse to work with fellow employees, Soldiers, or agency clients who have . . . HIV or AIDS. The concerns of such employees will be addressed with education and counseling.”¹⁵

20. Similarly, there is no basis for any service member to refuse to serve with people living with HIV. As stated above, the Navy has already taken steps to allow service members

¹⁴ *Id.* at ¶4.c (“Individuals with the conditions in Enclosure 3, based on medical assessments in accordance with Enclosure 2 and Reference (1), shall not deploy unless a waiver can be granted according to the procedures in section 3 of Enclosure 2.”); *id.*, Encl. 2 (Procedures) at ¶2.a (“In general, DoD personnel with any of the medical conditions in Enclosure 3, and based on a medical assessment, shall not deploy unless a waiver is granted. Consideration should be made for the nature of the disability and if it would put the individual at increased risk of injury or illness, or if the condition is likely to significantly worsen in the deployed environment.”).

¹⁵ U.S. Army Regulation 600-110, Section III, at ¶1-16.p.

living with HIV to serve overseas on a case-by-case basis.¹⁶ That decision was based on the explicit recognition that: “There is no demonstrated risk of transmission of infection in normal daily activities.”¹⁷

21. Furthermore, there is no risk—beyond a hypothetical one—of battlefield transmission of HIV. Transmission via the types of exposure that may take place on the battlefield—such as “blood splashes” or those experienced while one soldier is providing care to a wounded soldier with HIV—are not well documented routes of transmission. The risk of an exposure that could result in transmission under such circumstances is at most a theoretical risk. In addition, recent research has established that a person with HIV who is adherent to their medications, and therefore has a suppressed or undetectable viral load, is incapable of transmitting HIV through the most intimate forms of contact. It is reasonable to conclude the risk of transmission through battlefield activities that present at most a theoretical risk of transmission is also effectively zero if the person with HIV has a suppressed or undetectable viral load.

¹⁶ U.S. Navy, Secretary of the Navy Instruction 5300.30E (Management of Human Immunodeficiency Virus, Hepatitis B Virus and Hepatitis C Virus Infection in the Navy and Marine Corps), ¶ 3.c.(2) (Aug. 13, 2012) (“Selected AC members on a case-by-case basis in consultation with the treating HIV Evaluation and Treatment Unit (HETU), Navy Bloodborne Infection Management Center (NBIMC), and PERS-82 (for sailors) or United States Marine Corp (USMC) Manpower & Reserve Affairs (M&RA) (for Marines) may be assigned to selected ships and Outside the contiguous United States (OCUNUS) commands, as agreed on by all three consultants and the receiving command; the receiving command has the final say on acceptance.”).

¹⁷ Department of Defense, *Report to Congressional Defense Committees on Department of Defense Personnel Policies Regarding Members of the Armed Forces with HIV or Hepatitis B*, at 7 (Sept. 2014), available at <https://health.mil/Reference-Center/Reports/2014/09/22/DoD-Personnel-Policies-Regarding-Members-of-the-Armed-Forces-with-HIV-or-Hepatitis-B>.

22. Finally, in the exceedingly rare event that a battlefield exposure were to occur that presented anything more than a theoretical risk of transmission, post-exposure prophylaxis could be provided to the person exposed, thereby further decreasing whatever minimal hypothetical risk of transmission existed. There is simply no support for the idea that a soldier living with HIV would present a danger to the health and safety of other military personnel, including comrades on the battlefield.

2. Adhering to an ART Regimen Does Not Require “Excessive Time”

23. Adherence to an effective ART regimen does not require much time—it is as simple as taking medication every day. The HIV medications commonly prescribed today have no special handling, storage or other requirements. These medications generally tolerate hard conditions, such as hot or cold stress and sunlight, well. Taking medication once or twice a day, as people living with HIV do, requires very minimal time, especially if that person is on a single tablet regimen (STR), which is literally one pill taken once a day. The time and effort required is similar to that expended by service members deployed overseas who are prescribed daily medication for prophylaxis of malaria.¹⁸ I understand that Mr. Harrison, for example, took a daily dose of doxycycline when he was deployed in Afghanistan.

24. The medical monitoring of a person living with HIV is also limited. According to U.S. HIV treatment guidelines, viral load typically should be measured every 3-4 months, although that period may be extended to once every 6 months for individuals whose viral load

¹⁸ Army Public Health Center, *Malaria Field Guide: The Prevention, Diagnosis and Treatment of Malaria in U.S. Africa Command* (May 2016), available at https://phc.amedd.army.mil/PHC%20Resource%20Library/TG336_MalariaFieldGuide_May2016.pdf.

has been suppressed for more than 2 years and whose clinical and immunologic status is stable.¹⁹ Viral load testing is routine and requires only drawing and testing a blood sample. Where such testing is not immediately available in theater, a blood sample may easily be shipped to a lab that engages in the type of testing required. Moreover, point-of-care viral load testing that returns results within 90 minutes is becoming increasingly prevalent and cost efficient.

25. General practitioner physicians are capable of engaging in the type of medical monitoring and care required for people living with HIV. In the U.S., primary care physicians are expected and often called upon to provide care to a person living with HIV. In fact, physicians' assistants and nurse practitioners also often provide HIV-related care in the United States. The physicians of the Armed Forces are more than capable of providing necessary care to a person living with HIV, alongside other types of health care provided to all members of the military, regardless of where they are stationed. If additional provider training is required in some instances, such training would be easy for the Armed Services to provide to its healthcare professionals. In the rare event that the expertise of an infectious disease doctor was required to care for a deployed service member, the on-site medical staff could consult with the many qualified infectious disease doctors employed by the Armed Services or a telemedicine session could be arranged between the infectious disease specialist and the service member with HIV.

3. People with HIV Can Complete Training and Serve Full Terms

26. People living with HIV who adhere to their prescribed ART regimen are physically able to complete training and serve full contract terms in the Armed Forces. As far

¹⁹ See U.S. Department of Health and Human Services, *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV*, , available at <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/458/plasma-hiv-1-rna--viral-load--and-cd4-count-monitoring>.

back as 2004, when DoD mandated universal two-year interval HIV testing, the DoD's Armed Forces Epidemiology Board explained that "There is no evidence that HIV infection, per se, affects physical fitness."²⁰ The same remains true today. As explained in a 2015 article in the *Medical Surveillance Monthly Report*: "In the past 30 years, HIV-1 infection has gone from an untreatable disease marked by inexorable clinical progression through extreme debility to death to a treatable disease that is compatible with active service throughout a full career in the U.S. military."²¹ As an example, I understand that Mr. Harrison, who was diagnosed with HIV in 2012, received a PULHES²² score in 2014 of 1 for each of the six factors that are considered, reflecting a "high level of medical fitness" under Army Regulation 40-501 (Standards of Medical Fitness).²³ There should be no effect on the physical fitness and capabilities of any person with HIV who is adhering to their prescribed ART regimen

27. Similarly, any person with HIV who is adhering to their prescribed ART regimen will be able to serve without aggravating their condition. People living with HIV who are virally suppressed should not experience any HIV-related symptoms or complications of any kind related to their HIV. Provided they are able to continue taking their medications, inhospitable

²⁰ Office of the Assistant Secretary of Defense, Health Affairs Policy Memorandum – Human Immunodeficiency Virus Interval Testing (Mar. 29, 2004), available at <https://www.health.mil/Reference-Center/Policies/2004/03/29/Policy-Memorandum---Human-Immunodeficiency-Virus-Interval-Testing>.

²¹ J. Brundage, D. Hunt & L. Clark, *Durations of Military Service after Diagnoses of HIV-1 Infections Among Active Component Members of the U.S. Armed Forces 1990-2013*, Armed Forces Health Surveillance Center, *Medical Surveillance Monthly Report*, Vol. 22, No. 8 (Aug. 2015), available at <https://health.mil/Reference-Center/Reports/2015/01/01/Medical-Surveillance-Monthly-Report-Volume-22-Number-8>.

²² PULHES is an acronym for Physical stamina, Upper extremities, Lower extremities, Hearing/ears, Eyes, and Psychiatric.

²³ U.S. Army Regulation 40-501 (Standards of Medical Fitness), Chapter 7, ¶7-3.d(1) ("An individual having a numerical designation of '1' under all factors is considered to possess a high level of medical fitness.").

environmental conditions and/or challenging work conditions should have no effect on the person living with HIV's health or their ability to serve.

4. People with HIV Are Adaptable to the Military Environment Without Geographical Area Limitations

28. People living with HIV are adaptable to the military environment and can deploy worldwide without geographical limitations. As described above, the military environment—regardless of the geographic specifics of that environment—should have no effect on a person with HIV's health or ability to serve. And because it is relatively easy to provide the health care necessary to a person living with HIV (also described in detail above)—and has been for more than a decade—there should be no geographic limitations on an HIV-positive person's service. Again, I understand the Navy has already adopted policies to allow service members living with HIV to serve overseas. Due to this policy, as of September 2017, approximately 55 sailors have been assigned to various overseas and/or operational assignments without any adverse events.²⁴ There are no geographic locations that would pose an issue for a person living with HIV, as long as that individual adheres to their ART regimen.

5. There is No Impact on Medical Readiness

29. Individuals living with HIV can serve without any adverse impact on medical readiness.²⁵ In the medical context, Department of Defense Instruction 6025.19 (Individual

²⁴ J. Okulicz, C. Beckett, J. Blaylock, S. Hakre, B. Agan, N. Michael, S. Peel, P. Scott, and S. Cersovsky, *Review of the U.S. Military's Human Immunodeficiency Virus Program: A Legacy of Progress and a Future of Promise*, Armed Forces Health Surveillance Center, *Medical Surveillance Monthly Report*, Vol. 24, No. 9 (Sept. 2017), available at <https://health.mil/Reference-Center/Reports/2017/01/01/Medical-Surveillance-Monthly-Report-Volume-24-Number-9>.

²⁵ U.S. Department of Defense Instruction 6025.19 (Individual Medical Readiness), at ¶ 3 (June 9, 2014), available at <http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/602519p.pdf> (explaining that

Medical Readiness) establishes medical readiness standards for deployment for individuals as follows: (1) a current periodic health assessment (every 12 months); (2) the absence of deployment-limiting medical conditions; (3) dental readiness to specified standards; (4) immunization standards germane to the theater of operation; (5) current medical readiness laboratory tests; and (6) possession of appropriate individual medical equipment.²⁶ As discussed above, there is no basis for including HIV as a deployment-limiting medical condition, and individuals living with HIV can otherwise satisfy the other elements of medical readiness.

6. There is No Danger to the Safety of Military Blood Supplies

30. Allowing people living with HIV to serve poses no danger to the safety of military blood supplies. Since 1962, the Armed Services Blood Program has provided blood products for all service members, working to collect, process, store, distribute, and transfuse blood worldwide.²⁷ People who have been diagnosed with HIV are informed that they can no longer donate blood—and there is no evidence that they attempt to do so. Any risk to the blood supply would arise from those who are unaware they are living with HIV. The military, however, has protocols in place to prevent donations from those who are unaware they are HIV positive, has screened service members for decades and closely monitors which service members are living with HIV as part of its plan to protect the battlefield blood supply.²⁸ These efforts have

it is DoD policy “to promote a healthy and fit fighting force that is medically prepared to provide the Military Departments with the maximum ability to accomplish their deployment missions throughout the spectrum of military operation.).

²⁶ U.S. Department of Defense Instruction 6025.19 (Individual Medical Readiness), Encl. 3 (June 9, 2014), available at

<http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/602519p.pdf>.

²⁷ Armed Services Blood Program, About Us, available at

<http://www.militaryblood.dod.mil/About/default.aspx>

²⁸ J. Okulicz, C. Beckett, J. Blaylock, S. Hakre, B. Agan, N. Michael, S. Peel, P. Scott, and S. Cersovsky, *Review of the U.S. Military’s Human Immunodeficiency Virus Program: A Legacy of*

been successful. For example, one study of HIV among U.S. Army soldiers found that, of service members who seroconverted while deployed in Afghanistan or Iraq over the period 2001-2007, “[n]one were emergency blood transfusion donors or recipients.”²⁹ Indeed, in the general public, the National Institute of Health has stated: “Your risk of getting HIV from a blood transfusion is lower than your risk of getting killed by lightning. Only 1 in 2 million donations might carry HIV and transmit HIV if given to a patient.”³⁰ Allowing people living with HIV to serve will not change the screening measures already in place to protect the blood supply, which are primarily aimed at preventing transmission from those who are undiagnosed.

31. In the context of battlefield emergency transfusions, i.e., the “walking blood bank,” the safety of the blood supply may be ensured by continuing to screen service members for HIV and informing individuals who test HIV positive that they cannot act as emergency blood transfusion donors. This will have negligible impact on the overall blood supply. Not only are battlefield transfusions relatively rare,³¹ the percentage of service members living with HIV is and would continue to be relatively low (i.e., people living with HIV comprise

Progress and a Future of Promise, Armed Forces Health Surveillance Center, *Medical Surveillance Monthly Report*, Vol. 24, No. 9 (Sept. 2017), available at <https://health.mil/Reference-Center/Reports/2017/01/01/Medical-Surveillance-Monthly-Report-Volume-24-Number-9>

²⁹ P. Scott et al., *Short Communication: Investigation of Incident HIV Infections Among U.S. Army Soldiers Deployed to Afghanistan and Iraq, 2001-2007*,

³⁰ U.S. Department of Health & Human Services, National Heart, Lung, and Blood Institute, *Blood Transfusion*, available at <https://www.nhlbi.nih.gov/health-topics/blood-transfusion>.

³¹ See T. Ballard, P. Rohrbeck, M. Kania, & L. Johnson, *Transfusion-Transmissible Infections Among U.S. Military Recipients of Emergently Transfused Blood Products, June 2006-December 2012*, *Medical Surveillance Monthly Report*, Vol. 21, No. 11 (Nov. 2014) (stating that “According to the Armed Services Blood Program (AFBP), the U.S. military transfused 237,100 units of blood products between June 2006 and December 2012. Thus, the 4,857 non-FDA-compliant units represented approximately 2% of the total blood products” and indicating that “[n]o cases of HIV” resulted from these transfusions).

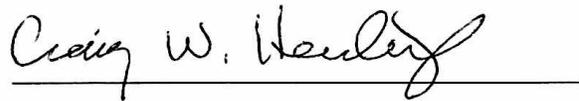
approximately one-third of one percent of the population of the United States, and just .027% of active duty service members).³² Furthermore, there are various other factors that often disqualify individuals as emergency blood donors, such as blood type³³—making people living with HIV no different from these other groups who are allowed to serve and deploy. Finally, the use of blood substitutes is on the rise, which should result in even less need for emergency battlefield transfusions from other service members.

IV. CONCLUSION

In my opinion, there is no medical justification for preventing or restricting the military service and overseas deployment of people living with HIV.

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

Executed this 18th day of July, 2018



Craig W. Hendrix, M.D.

³² United States Census Bureau. *American Factfinder: Monthly Population Estimates for the United States: April 1, 2010 to December 1, 2016*, https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=PEP_2017_PEMONTHN&prodType=table (last visited July 18, 2018); Armed Forces Health Surveillance Center (AFHSC), *Update: Routine Screening for Antibodies to Human Immunodeficiency Virus, Civilian Applicants for U.S. Military Service and U.S. Armed Forces, Active and Reserve Components, January 2010–June 2015*, Medical Surveillance Monthly Report, Aug. 2015, 2-8.

³³ *Emergency War Surgery*, 4th ed. (2014), Chapter 33 (Blood Transfusions), available at <http://www.cs.amedd.army.mil/FileDownloadpublic.aspx?docid=189c4a13-522f-4d91-9236-a109d7b5ee4d>.

Attachment

CURRICULUM VITAE

The Johns Hopkins University School of Medicine

10 JUL 18

Craig W. Hendrix

(Date of this version)

DEMOGRAPHIC AND PERSONAL INFORMATION

Current Appointments

University

Wellcome Professor and Director, Division of Clinical Pharmacology
Appointment effective 1/1/2015

Professor of Medicine, Division of Clinical Pharmacology (Primary)
Appointment effective 1/1/2009

Professor of Medicine, Division of Infectious Diseases (Secondary)
Appointment effective 1/1/2009

Professor of Pharmacology and Molecular Sciences (Secondary)
Appointment effective 1/1/2009

Professor of Epidemiology (Secondary)
Appointment effective 1/1/2009

Director, Drug Development Unit, Division of Clinical Pharmacology
Appointment effective 7/1/1998

Director, Division of Clinical Pharmacology
Appointment effective 1/1/2015

Hospital

Medical Staff, The Johns Hopkins Hospital
Appointment effective 8/1/1994.

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EDUCATION AND TRAINING

| <i>Year</i> | <i>Degree/Cert.</i> | <i>Institution</i> | <i>Discipline</i> |
|-------------|----------------------|---------------------------------------|--|
| 1978 | S.B. | Massachusetts Institute of Technology | Applied Biology |
| 1984 | M.D. | Georgetown University | Medicine |
| 7/84-6/85 | Intern | The Johns Hopkins Hospital | Internal Medicine |
| 7/85-6/87 | Resident | The Johns Hopkins Hospital | Internal Medicine |
| 9/86-7/89 | Post-Doctoral Fellow | Johns Hopkins University | Infectious Diseases |
| 7/87-7/89 | Post-Doctoral Fellow | Johns Hopkins University | Clinical Pharmacology Mentor: Paul S. Lietman |

PROFESSIONAL EXPERIENCE

| <i>Dates</i> | <i>Position</i> | <i>Institutions</i> |
|--------------|------------------------------|---|
| 1989-1994 | Clinical Assistant Professor | Department of Medicine University of Texas Health Sciences Center San Antonio, TX |
| 1989-1994 | Staff Physician | Department of Infectious Diseases Division of Medicine Wilford Hall USAF Medical Center Lackland AFB, TX |
| 1989-1994 | Director | Human Immunodeficiency Virus Unit Department of Infectious Diseases Wilford Hall USAF Medical Center Lackland AFB, TX |
| 1993-1994 | Director | Human Immunodeficiency Virus Research & Education Program Department of Infectious Diseases Wilford Hall USAF Medical Center Lackland AFB, TX |
| 1990-1993 | Assistant Professor | Department of Medicine Uniformed Services University of Health Sciences Bethesda, MD |

PROFESSIONAL EXPERIENCE

| <i>Dates</i> | <i>Position</i> | <i>Institutions</i> |
|--------------|---------------------------------|--|
| 1992-1994 | Associate Scientist (Adjunct) | Southwest Foundation for Biomedical Research and Education San Antonio, TX |
| 1993-1996 | Associate Professor | Department of Medicine Uniformed Services University of Health Sciences Bethesda, MD |
| 1994-2000 | Senior Scientist | Department of Prevention Research, Division of Retrovirology Walter Reed Army Institute of Research Rockville, MD |
| 1994-1996 | Associate Professor (Part-Time) | Division of Clinical Pharmacology, Department of Medicine Johns Hopkins University School of Medicine (JHUSOM) Baltimore, MD |
| 1997-1999 | Ind. Mobilization Augmentee | U.S. Air Force Reserve Preventive Medicine Division Office of the Surgeon General Bolling AFB, DC |
| 1997- 2008 | Associate Professor | Division of Clinical Pharmacology Department of Medicine, JHUSOM Baltimore, MD |
| 1997-1998 | Clinical Director | Drug Development Unit Division of Clinical Pharmacology Department of Medicine, JHUSOM Baltimore, MD |
| 1998-2001 | Director (Acting) | Division of Clinical Pharmacology Department of Medicine, JHUSOM Baltimore, MD |
| 1998-2008 | Associate Professor | Division of Infectious Diseases Department of Medicine, JHUSOM Baltimore, MD |

PROFESSIONAL EXPERIENCE

| <i>Dates</i> | <i>Position</i> | <i>Institutions</i> |
|--------------|---------------------|---|
| 1998-present | Director | Drug Development Unit Division of Clinical Pharmacology Department of Medicine, JHUSOM Baltimore, MD |
| 1999-2008 | Associate Professor | Department of Pharmacology and Molecular Sciences, JHUSOM Baltimore, MD |
| 1999-2008 | Associate Professor | Department of Epidemiology Johns Hopkins University Bloomberg School of Public Health Baltimore, MD |
| 1998-2008 | Associate Professor | Division of Infectious Diseases Department of Medicine, JHUSOM Baltimore, MD |
| 2007-2013 | Co-Director | Drug Development Core Institute for Clinical and Translational Research Johns Hopkins University Baltimore, MD |
| 2007-2014 | Director (Interim) | Division of Clinical Pharmacology Department of Medicine, JHUSOM Baltimore, MD |
| 2007-2014 | Director (Interim) | Clinical Pharmacology Analytical Laboratory Division of Clinical Pharmacology Department of Medicine, JHUSOM Baltimore, MD |
| 2009-present | Professor | Division of Clinical Pharmacology Department of Medicine Johns Hopkins University School of Medicine Baltimore, MD |
| 2009-present | Professor | Department of Pharmacology and Molecular Sciences Johns Hopkins University School of Medicine Baltimore, MD |

PROFESSIONAL EXPERIENCE

| <i>Dates</i> | <i>Position</i> | <i>Institutions</i> |
|--------------|-----------------------------|--|
| 2009-present | Professor | Department of Epidemiology Johns Hopkins University Bloomberg School of Public Health Baltimore, MD |
| 2012-2014 | Co-Director | Behavioral Science Core Center for AIDS Research Johns Hopkins University Baltimore, MD |
| 2014-present | Deputy Director Director | Institute for Clinical and Translational Research Translational Sciences Core Johns Hopkins University School of Medicine Baltimore, MD |
| 2014-present | Director Member | Laboratory Core Executive Committee Center for AIDS Research Johns Hopkins University Baltimore, MD |
| 2014-present | Affiliated Faculty Member | Center for Nanomedicine Wilmer Eye Institute, JHUSOM Baltimore, MD |
| 2015-present | Director | Division of Clinical Pharmacology Wellcome Professor of Clinical Pharmacology Department of Medicine, JHUSOM Baltimore, MD |
| 2016-present | Director (Contact) | Clinical Pharmacology Training Program Division of Clinical Pharmacology, JHUSOM Baltimore, MD |

PUBLICATIONS

Original Research

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10. Warren RQ, Nkya WM, Shao JF, Anderson SA, Wolf H, **Hendrix CW**, Kanda P, Wabuke M, Boswell RN, Redfield RR, Kennedy RC. Comparison of Antibody Reactivity to Human Immunodeficiency Virus Type 1 (HIV-1) gp160 Epitopes in Sera from HIV-1-Infected Individuals from Tanzania and from the United States. *J Clin Microbiol* 1992;30(1):126-31.
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16. Blatt S, Lucey CR, Butzin CA, **Hendrix CW**, Lucey DP. Total Lymphocyte Count as a Predictor of Absolute CD4+ Count and CD4+ Percentage in HIV-Infected Persons. *JAMA* 1993;269(5):622-6.
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19. Warner RD, Mathis RE, Weston ME, Bigbee LR, **Hendrix CW**, Lucey DR. Estimates of Human Immunodeficiency Virus (HIV) Incidence and Trends in the US Air Force. *Vaccine* 1993;11(5):534-37.
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21. Lucey DR, McCarthy WF, Blatt SP, Melcher GP, **Hendrix CW**. Racial Differences in Serum Beta2- microglobulin in Persons with Human Immunodeficiency Virus Infection. *J Infect Dis* 1993;167(5):1259-60.
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29. Clerici M, Wynn TA, Berzofsky JA, Blatt SP, **Hendrix CW**, Sher A, Coffman RL, Shearer GM. Role of Interleukin-10 in T Helper Cell Dysfunction in Asymptomatic Individuals Infected with the Human Immunodeficiency Virus. *J Clin Invest* 1994;93(2):768-75.
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183. Weld EW*, Hiruy H*, Guthrie KM, Fava JL, Vargas SE, Buckheit K, Buckheit R, Spiegel H, Breakey J, Fuchs EJ, **Hendrix CW**. A Comparative Pre-Phase I Study of the Impact of Gel Vehicle Volume on Distal Colon Distribution, User Experience, and Acceptability. *AIDS Res Hum Retrovir* 2017 May;33(5):440-447. **Co-first authors*. PMC5439405
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186. Haaland RE, Holder A, Pau CP, Swaims-Kohlmeier A, Dawson C, Smith DK, Segolodi TM, Thigpen MC, Paxton LA, Parsons TL, **Hendrix CW**, Hart CE. Levels of Intracellular Phosphorylated Tenofovir and Emtricitabine Correlate With Natural Substrate Concentrations in Peripheral Blood Mononuclear Cells of Persons Prescribed Daily Oral Truvada for HIV Pre-exposure Prophylaxis. *J Acquir Immune Defic Syndr*. 2017 Jul 1;75(3):e86-e88. PMC5472483
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193. Shieh EC*, Weld ED*, Fuchs EJ, Hiruy H, Buckheit KW, Buckheit RW, Breakey JC, **Hendrix CW**. Lubricant Provides Poor Rectal Mucosal HIV Coverage. *AIDS Res Hum Retroviruses.* 2017 Aug;33(8):784-787. *Co-First Authors. PMC5564025
194. Husnik MJ, Brown ER, Marzinke M, Livant E, Palanee-Phillips T, **Hendrix CW**, Kiweewa FM, Nair G, Soto-Torres LE, Schwartz K, Hillier SL, Baeten J. Implementation of a Novel Adherence Monitoring Strategy in a Phase III, Blinded, Placebo-Controlled, HIV-1 Prevention Clinical Trial. *J Acquir Immune Defic Syndr.* 2017 Nov 1;76(3):330-337. PMC5634926
195. Heffron R, Parikh UM, Penrose KJ, Mugo N, Donnell D, Celum C, Mellors JW, Baeten JM; **Partners PrEP Study Team**. Objective Measurement of Inaccurate Condom Use Reporting Among Women Using Depot Medroxyprogesterone Acetate for Contraception. *AIDS Behav.* 2017 Jul;21(7):2173-2179. PMC5378697
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PUBLICATIONS**Original Research – continued**

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203. Xiao P, Gumber S, Marzinke M, Date A, Hoang T, Hanes J, Ensign L, Wang L, Rohan L, Fuchs E, **Hendrix CW**, Villinger F. Hypo-osmolar formulation of TFV enema promotes uptake and metabolism of TFV in tissues leading to prevention of SHIV/SIV infection. *Antimicrob Agents Chemother* 2017 Dec 21;62(1). pii: e01644-17. PMC5740373
204. Abaasa A, **Hendrix CW**, Gandhi M, Anderson P, Kamali A, Kibengo F, Sanders E, Mutua G, Priddy F, Haberer JE. Utility of Different Adherence Measures for Prep: Patterns and Incremental Value. *AIDS Behav* 2018 Apr;22(4):1165-1173. PMC5878836

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207. Grant RM, Mannheimer S, Hughes JP, Hirsch-Moverman Y, Loquere A, Chitwarakorn A, Curlin ME, Li M, Amico KR, **Hendrix CW**, Anderson PL, Dye BJ, Marzinke MA, Piwowar-Manning E, McKinstry L, Elharrar V, Stirratt M, Rooney JF, Eshleman SH, McNicholl JM, van Griensven F, Holtz TH. Daily and Nondaily Oral Preexposure Prophylaxis in Men and Transgender Women Who Have Sex With Men: The Human Immunodeficiency Virus Prevention Trials Network 067/ADAPT Study. *Clin Infect Dis.* 2018 Feb 6. doi: 10.1093/cid/cix1086. [Epub ahead of print] *PMCID Pending*
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209. Heffron R, Thomson K, Celum C, Haberer J, Ngure K, Mugo N, Bukusi E, Katabira E, Odoyo J, Bulya N, Asiimwe S, Tindimwebwa E, Baeten JM; **Partners Demonstration Project Team**. Fertility Intentions, Pregnancy, and Use of PrEP and ART for Safer Conception Among East African HIV Serodiscordant Couples. *AIDS Behav.* 2018 Jun;22(6):1758-1765. PMC5845763
210. Justman JE, Nair G, **Hendrix CW**, Piper JM, Marzinke MA, Dai JY, Pan Z, Galaska B, Levy L, Schwartz JL, Balar B, Kunjara Na Ayudhya RP, Mushamiri I, McGowan I, Dezzutti CS, MTN-014 Study Team. Pharmacokinetics and Pharmacodynamics of Tenofovir Reduced-Glycerin 1% Gel in the Rectal and Vaginal Compartments in Women: A Cross-Compartmental Study with Directly Observed Dosing. *J Acquir Immune Defic Syndr.* 2018 Jun 1;78(2):175-182. PMC5963717
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Original Articles

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213. Bunge KE, Dezzutti CS, **Hendrix CW**, Marzinke MA, Spiegel HML, Moncla BJ, Schwartz JL, Meyn LA, Richardson-Harman N, Rohan LC, Hillier SL. FAME-04: A Phase 1 trial to assess the safety, acceptability, pharmacokinetics and pharmacodynamics of film and gel formulations of tenofovir *J Internat AIDS Soc* 2018 [In Press] PMID pending
214. Aung W, Bakshi RP, Breakey J, Johnson JE, **Hendrix CW**, Weld ED, Fuchs EJ, Marzinke MA. Fecal Coliform Bacterial Detection to Assess Enema Adherence in HIV Prevention Clinical Studies. *AIDS Behav* 2018 Jul 3. doi: 10.1007/s10461-018-2211-5. [Epub ahead of print] PMID pending

Review Articles

1. Cao Y-J, **Hendrix CW**. Male Genital Tract Pharmacology: Developments in Quantitative Methods to Better Understand a Complex Peripheral Compartment. *Clin Pharmacol Ther* . 2008 Mar;83(3):401-12.
2. **Hendrix CW**, Cao YJ, Fuchs EJ. Topical Microbicides to Prevent HIV: Clinical Drug Development Challenges. *Ann Rev Pharmacol Toxicol* 2009; 49:349–75.
3. Morrow KM, **Hendrix CW**. Clinical evaluation of microbicide formulations. *J Antiviral Res* 2010;88S:S40-S46. PMID: PMC3053029
4. **Hendrix CW**. The Clinical Pharmacology of Antiretrovirals for HIV Prevention. *Curr Opin HIV AIDS* 2012 Nov;7(6):498-504.
5. **Hendrix CW**. Exploring concentration-response in HIV Pre-Exposure Prophylaxis to optimize clinical care and trial design. *Cell* 2013 Oct 24;155(3):515-8.
6. Carballo-Diéguez A, Lentz C, Giguere R, Fuchs EJ, **Hendrix CW**. Rectal Douching Associated with Receptive Anal Intercourse: A Literature Review. *AIDS Behav*. 2017 Nov 2. doi: 10.1007/s10461-017-1959-3. PMC5878987

Case Reports

1. Blatt SP, Dolan MJ, **Hendrix CW**, Melcher GP. Legionnaires' Disease in HIV-Infected Patients - 8 Cases and Review. *Clin Infect Dis* 1994;18(2):227-32.

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Book Chapters, Monographs

1. Flexner CF and **Hendrix CW**. Pharmacology of Antiretroviral Agents. In: DeVita VT, Hellman S, Rosenberg SA, AIDS: biology, diagnosis, treatment and prevention. 4th ed. Philadelphia: Lippincott-Raven, 1997.
2. **Hendrix CW**, Sulkowski MS. Hepatotoxicity of antiretroviral therapy and drug-drug interactions with antiviral therapies for hepatitis C infection. In: Strategies for the Management of HIV/HCV Co-infection. Seacaucus: Projects in Knowledge, 2002.

Proceedings Reports

1. Committee on the role of institutional review boards in health services research data privacy protection. Institutional Review Boards and Health Services Research Data Privacy. A Workshop Summary. Institute of Medicine, Washington, D.C. May 2000.
2. Committee on the Role of institutional review boards in health services research data privacy protection. Protecting Data Privacy in Health Services Research. A Workshop Summary. Division of Health Care Services. Institute of Medicine, National Academy Press. Washington, D.C. 2000.
3. Veronese F, Anton P, Fletcher CV, DeGruttola V, McGowan I, Becker S, Zwierski S, Burns D; **Workshop Organizing Committee**. Implications of HIV PrEP trials results. AIDS Res Hum Retroviruses. 2011 Jan;27(1):81-90.

Editorials (Invited)

1. **Hendrix CW**. When is a PrEP candidate ready for phase 3? Lancet HIV DOI: [http://dx.doi.org/10.1016/S2352-3018\(16\)30162-X](http://dx.doi.org/10.1016/S2352-3018(16)30162-X)

Letters, Correspondence

1. **Blatt SP, Hendrix CW**. Delayed-Type Hypersensitivity and AIDS. Ann Intern Med 1994;120(4):343-44. (Letter)
2. **Hendrix CW**. Consideration of the prevalence of CMV retinitis alters the assessment of a serum cytomegalovirus DNA test. J Infect Dis 1995;171(6):1688. (Letter)
3. Bray PF, Goldschmidt-Clermont P, Furman MI, Michelson AD, Barnard MR, Mascelli MA, **Hendrix CW**, Coleman L, Hamlington J, Kickler T, Christie DJ, Kundu S. Platelet glycoprotein IIIa PIA polymorphism and effects of aspirin on thrombin generation - Response Circulation 103(6):E33-E34 FEB 13 2001 (Letter)
4. **Hendrix CW**. Seizing the Opportunity. HIV Prevention in Military Communities. Civil-Military Alliance Newsletter. 1995;1(4):9.
5. Kingma SJ, **Hendrix CW**, Yeager R, Miller NN, D'Amelio R, Wouters R, "Analysis of global questionnaire on HIV/AIDS prevention, testing and care in current military medical practice." Occasional Paper, Civil-Military Alliance to Combat HIV and AIDS, 1996.
6. Yeager R, **Hendrix CW**. Global survey of military HIV/AIDS policies and programs. Civil-Military Alliance Newsletter. 1997;3(1): S1.

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Letters, Correspondence

7. **Hendrix CW**. Behavioral surveillance and intervention in the military environment. Civil-Military Alliance Newsletter. 1997;3(4):5.
8. **Hendrix CW**. AIDS in the Public Eye: AIDS Fatigue or Healthy Maturation. Lutheran AIDS Network Newsletter. 9(2);4-5;2000.
9. Lu Y, Fuchs EJ, **Hendrix CW**, Bumpus NN. Response to "Clinical Relevance of CYP3A5 Genotype on Maraviroc Exposures". Drug Metab Dispos. 2015 May;43(5):773
10. Dalesio NM, Lee CKK, **Hendrix CW**. In Response. Anesth Analg. 2017 Jul;125(1):362-363

FUNDING**Extramural Funding (current, pending, previous)*****Current***

Dates: 01/09/2017-01/01/2019
 Title: A Phase I Multi-Compartment Pharmacokinetic Study of Cabotegravir Long-Acting in Healthy Adult Volunteers
 Grant Number: GSK Protocol 201767
 Sponsor: ViiV/GSK
 Total Direct Costs: \$729,798
 Principal Investigator: **C. Hendrix**
 Role: **PI.** Provide protocol development/execution and PK/PD data analysis and interpretation for clinical development of long-acting implantable HIV prevention strategy.
 Effort: 10%

Dates: 07/07/2015-06/30/2020
 Title: Sustained Long Acting Prevention Against HIV Program Operation
 Grant Number: UM1 AI120184-01 (Program Project Grant)
 Sponsor: NIH
 Total Direct Costs: \$72,770
 Principal Investigator: Thomas Hope (Northwestern University)
 Role: **Project Co-Leader, Site PI.** Provide protocol development/execution and PK/PD data analysis and interpretation for clinical development of long-acting implantable HIV prevention strategy.
 Effort: 20%

Dates: 07/01/2014 - 06/30/2019
 Title: Development of Rectal Enema As Microbicide (DREAM)
 Grant Number: U19 AI113127-01 (Program Project Grant)
 Sponsor: NIH
 Total Direct Costs: \$ 16,323,328
 Total Costs: \$ 20,677,877
 Principal Investigator: **C. Hendrix**
 Effort: 20%

Dates: 07/01/2014 - 06/30/2019
 Title: Systemic development of microbicide Intravaginal rings for HIV prevention
 Grant Number: U19AI113048-01
 Sponsor: NIH
 Total Direct Costs: \$ 16,662,549
 Principal Investigator: Marc Baum (Oak Crest Institute of Science)
 Effort: 5%
 Role: **Project PI.** Design, conduct, and data analysis of clinical studies to develop a combination vaginal microbicide ring.

FUNDING**Extramural Funding (current, pending, previous)***Current*

Dates: 04/01/2014-03/31/2019
 Title: HIV-1 reservoir dynamics in the female genital tract
 Grant Number: R01 AI08538091-02
 Sponsor: NIH
 Total Direct Costs: \$43,580
 Principal Investigator: Athe Tsibris (University of Washington)
 Role: Pharmacologist. Relationship between antiretroviral (ARV) drug concentrations in the blood and female genital tract is a key component of understanding HIV persistence and decay in anatomic reservoirs.
 Effort: 2%

Dates: 01/01/2014-11/30/2020
 Title: Pharmacology Network Lab, HIV Prevention Trials Network (HPTN)
 Grant Number: UM1AI068613-08
 Sponsor: NIH
 Total Direct Costs: \$ 2,577,018 (Pharmacology Network Lab)
 Principal Investigator: **C. Hendrix**
 Role: Principal Investigator Pharmacology Group. Design and analysis of pharmacology studies and coordination of analytical laboratory to support HPTN clinical studies of HIV pre-exp[osure prophylaxis].
 Effort: 10%

Dates: 01/01/2014-11/30/2020
 Title: Pharmacology Network Laboratory, Microbicide Trials Network (MTN)
 Grant Number: UM1AI106707 (Laboratory Center [LC]), UM1AI068633 (Leadership & Operations Center [LOC])
 Sponsor: NIH
 Total Direct Costs: \$1,832,004 (Pharmacology Network Lab)
 Principal Investigator: **C. Hendrix**
 Role: Director, Rectal Microbicide Program (LOC), Pharmacology Core Leader Laboratory Center; Principal Investigator for design, execution, and analysis of MTN clinical trials.
 Effort: 15%

Dates: 07/01/2013 - 06/30/2018 (NCE)
 Title: The effect of Depo-Provera on HIV susceptibility, immune activation, and PrEP PK
 Grant Number: 1R01HD077887-01
 Sponsor: NIH
 Total Direct Costs: 1,749,106
 Principal Investigator: **C. Hendrix** (Multi-PI with Jenell Coleman). Clinical studies to describe interaction between tenofovir and depo-medroxyprogesteron and impact on pharamcology, immunology, endocrinology, and virology.
 Effort: 20%

FUNDING**Extramural Funding (current, pending, previous)*****Current***

Dates: 07/01/2011-06/30/2018 (NCE)
 Title: Mucus Penetrating Particles For Rectal Microbicides
 Grant Number: R33 AI094519-03
 Sponsor: NIH
 Total Direct Costs: \$ 282,000
 Principal Investigator: Justin Hanes
 Role: Pharmacologist. This project will develop mucus penetrating particles for colorectal drug delivery of rectal microbicides for protection against HIV and other STDs. Role is to provide clinical pharmacology for product development to maintain feasibility for future human use of the products.
 Effort: 5%

Dates: 09/17/2007-05/31/2018
 Title: Institutional Clinical and Translational Science Award (CTSA)
 Grant Number: NCATS 1UL1TR001079-01
 Sponsor: NIH
 Total Direct Costs: \$ 7,485,218
 Principal Investigator: D. Ford
 Role: **Deputy Director ICTR, Translational Science Core Director**
 Effort: 10%

Dates: 08/01/2012-07/31/2019 (NCE)
 Title: Development and Evaluation of Dual Compartment Microbicides
 Grant Number: 1U19AI101961
 Sponsor: NIH/NIAID
 Total Direct Costs: \$3,224,012
 Principal Investigator: Buckheit (ImQuest Pharmaceuticals, Inc.)
 Role: **Project PI.** Design, conduct, and analysis of clinical studies to develop a combination rectal microbicide IQP-0528/tenofovir.
 Effort: 21%

Dates: 09/01/2012-08/31/2018 (NCE)
 Title: Efficacy & Safety of Multitargeted Combination Microbicides to Prevent HIV & HSV
 Grant Number: 5U19AI076980
 Sponsor: NIH/NIAID
 Total Direct Costs: \$ 2,874,915
 Principal Investigator: Herold (Albert Einstein College of Medicine)
 Role: **Core PI.** Design, sample analysis, PK/PD analysis, vaginal microbicide
 Effort: 5%

FUNDING**Extramural Funding (current, pending, previous)***Previous*

Dates: 04/01/2014 - 03/31/2018
Title: Pharmacostatistical Modeling and Simulation of Randomized Clinical PrEP Trials
Grant Number: ID OPP1099837
Sponsor: Bill and Melinda Gates Foundation
Total Direct Costs: \$925,281
Principal Investigator: **C. Hendrix.** Pooled data from 5 RCTs to estimate concentration-response within and among PrEP RCTS. Development and integration of PK, PD, and disease response models to perform clinical trial simulation.
Effort: 5%

Dates: 07/01/10-05/31/15 (NCE)
Title: Exploratory pharmacokinetics of UC781 and Tenofovir vaginal microbicide gel v film
Grant Number: 1U19AI082639
Sponsor: NIH
Total Direct Costs: \$1,599,703
Principal Investigator: Hillier (Magee Women's – University of Pittsburgh)
Role: **Project PI.** Develop combination antiretroviral vaginal microbicide formulation, in both a gel and film formulation.
Effort: 18%

Dates: 9/23/09-8/31/14 (NCE)
Title: Combination HIV Antiretroviral Rectal Microbicide Program (CHARM)
Grant Number: 1U19AI082637
Sponsor: NIH/NIAID
Total Direct Costs: \$2,240,713 year 1
Principal Investigator: McGowan (Magee Women's Research Institute, Univ Pittsburgh)
Role: **Site PI.** Design, conduct, and analysis of clinical studies and laboratory operations to develop a combination rectal microbicide.
Effort: 18%

Dates: 06/04/08-06/03/15
Title: Provision and management of a Phase 1 Clinical Trial Unit for Therapeutics Against Infectious Diseases.
Grant Number: HHSN272200800026C
Sponsor: NIH-NIAID-DMID
Total Direct costs: \$886,965
Principal Investigator: Zenilman
Role: **Site PI.** Management of Johns Hopkins East Baltimore Phase I site; study design, execution, data analysis
Effort : 10%

Craig W. Hendrix., MD

Curriculum Vitae

FUNDING**Extramural Funding (current, pending, previous)**

Dates: 07/01/06 - 12/31/13
 Title: Pharmacology Network Lab, HIV Prevention Trials Network (HPTN)
 Grant Number: UM1 AI 068613
 Sponsor: NIH
 Total Direct Costs: \$ 1,599,150 (Pharmacology Network Lab)
 Principal Investigator: **C. Hendrix**
 Role: Principal Investigator Pharmacology Core Lab. Design and analysis of pharmacology studies and co-supervision of analytical laboratory to support HPTN clinical studies to investigate the use of anti-retroviral drugs for the prevention of transmission of HIV.
 Effort: 5%

Dates: 07/01/06 - 12/31/13
 Title: Pharmacology Network Laboratory, Microbicide Trials Network (MTN)
 Grant Number: U01 AI 068633 subaward 26-3301-4221
 Sponsor: NIH
 Total Direct Costs: \$1,777,370 (Pharmacology Network Lab)
 Principal Investigator: **C. Hendrix**
 Role: Principal Investigator for design, execution, and analysis of MTN clinical trials; Supervision of Pharmacology Network Laboratory providing analytical support to the MTN; Scientific leadership at the Executive Committee and Biomedical Science Committee
 Effort: 20%

Dates: 02/01/10-01/31/14
 Title: Impact of maternal HAART on HIV-infected breastfeeding infants: Malawi
 Grant Number: 1R01AI087139-01A1
 Sponsor: NIH/NIAID/DAIDS
 Total Direct Costs: \$373,102
 Principal Investigator: Eshleman
 Role: Co-Investigator – Pharmacologist responsible for PK data analysis
 Effort: 1%

Dates: 12/01/09-11/30/13
 Title: Origin and evolution of HIV-1 drug resistance in the RT-SHIVmne Macaque Model
 Grant Number: 1R01AI080290-01A2
 Sponsor: NIH
 Total Direct Costs: \$42,684(total direct, JHU project)
 Principal Investigator: Ambrose (Univ of Pittsburgh)
 Role: Site PI. Pharmacology design, assay development, and PK data analysis
 Effort: 3%

FUNDING**Extramural Funding (current, pending, previous)***Previous*

Dates: 09/01/09-08/31/13
 Title: Safety, Efficacy, Mechanisms of Ginseng in HIV-related Fatigue
 Grant Number: R01 AT005526-01
 Sponsor: NCCAM
 Total Direct Costs: \$1,330,311
 Principal Investigator: Andrade
 Role: Director of clinical research unit, PK data analysis.
 Effort: 4%

Dates: 09/01/09-12/31/12
 Title: Pre-exposure HIV prophylaxis adherence in rural Uganda
 Grant Number: Partners PrEP Study (Bangsberg at MGH)-JHU subaward
 Sponsor: Bill and Melinda Gates Foundation
 Total Direct costs: \$400,000
 Principal Investigator: Bangsberg
 Role: Design/analysis of the pharmacokinetic aspects of the study and laboratory assays to examine the relationship between drug level, adherence, and product sharing.
 Effort: 5%

Dates: 09/01/09-12/31/12
 Title: Pre-exposure HIV prophylaxis adherence in rural Uganda
 Grant Number: Partners PrEP Study (Bangsberg at MGH)-JHU subaward
 Sponsor: Bill and Melinda Gates Foundation
 Total Direct costs: \$400,000
 Principal Investigator: Bangsberg
 Role: Design/analysis of the pharmacokinetic aspects of the study and laboratory assays to examine the relationship between drug level, adherence, and product sharing.
 Effort: 5%

Dates: 11/01/09-04/30/12
 Title: A pilot study of Pre-Exposure Prophylaxis (PrEP) to evaluate safety, acceptability, and adherence in at-risk populations in Kenya, Africa
 Grant Number: JHURSA0901
 Sponsor: International AIDS Vaccine Initiative
 Total Direct Costs: \$72,326
 Principal Investigator: **Hendrix**
 Role: Pharmacological sub-study design and analysis. Supervision of lab assay of samples for drug concentration.
 Effort: 2%

FUNDING**Extramural Funding (current, pending, previous)***Previous*

Dates: 09/01/09-08/28/11
 Title: Pharmacokinetic interactions of Ribavirin and Abacavir in healthy volunteers
 Grant Number: Contract
 Sponsor: GlaxoSmithKline
 Total Direct costs: \$367,185
 Principal Investigator: Andrade
 Role: **Pharmacologist.** Support in design and analysis of investigator initiated Ribavirin-Abacavir drug-drug interaction study.
 Effort: 1%

Dates: 05/01/09-04/30/10
 Title: Distribution of orally-administered Tenofovir into colon and vaginal tissue for the prevention of sexual HIV transmission.
 Grant Number: Contract
 Sponsor: Gilead
 Total Direct costs: \$78,358
 Principal Investigator: **C. Hendrix**
 Role: Design, execution, analysis of study of tenofovir to evaluate the PK of the drug and phosphorylated moieties in blood, tissue (colon and vaginal) and cells using LC/MS/MS and accelerator mass spectrometry.
 Effort: 1%

Dates: 01/01/07 – 12/31/08
 Title: Epithelial Injury and HIV Penetration after Simulated Ejaculation
 Grant Number: 106755-41-RGMT
 Sponsor: amfAR (American Foundation for AIDS Research)
 Total Direct Costs: \$ 100,000
 Principal Investigator: **C. Hendrix**
 Role: Principal Investigator (design, execution, and analysis) of study is to evaluate the effect of anal sexual practices on the rectum and distal colon which might affect the study and development of effective HIV microbicides for rectal use.
 Effort: 4%

FUNDING**Extramural Funding (current, pending, previous)***Previous*

Dates: 09/01/06-09/01/07
 Title: Prophylactic Antimalarial Activity of DB289 in Volunteers Challenged with *Plasmodium falciparum*
 Grant Number: C06-015
 Sponsor: Immtech Pharmaceuticals
 Total Direct Costs: \$ 466,548
 Principal Investigator: T. Shapiro
 Role: Contribute to design and pharmacokinetics data analysis. Investigator-initiated prophylactic antimalarial activity of DB289 in volunteers challenged with plasmodium falciparum.
 Effort: 10%

Dates: 8/01/06 - 7/31/09
 Title: Microbicide Development Program.
 Grant Number: NIH U19 AI060614
 Sponsor: NIH
 Total Direct Costs: \$ 1,429,670
 Principal Investigator: P. Anton (UCLA)
 Role: Project PI. Project 5 to evaluate pharmacokinetics, toxicity, and acceptability of enema and gel as drug delivery device for UC781, a non-nucleoside reverse transcriptase inhibitor, as topical HIV microbicides.
 Effort: 30%

Dates: 04/01/06 – 03/31/07
 Title: CV-N Microbicide Program: A Phase I Study to Determine the Safety, Tolerance, and Acceptability of the Vaginal Distribution of Cyanovirin.
 Grant Number: U19 AI051650 Program Project Grant (R. Bax, Biosyn, PI)
 Sponsor: NIH
 Total Direct Costs: \$ 237,747
 Principal Investigator: **C. Hendrix** (Project)
 Role: Project PI responsible for design, execution, analysis of phase I Cyanovirin vaginal microbicide safety and pharmacokinetics.
 Effort: 10%

FUNDING**Extramural Funding (current, pending, previous)***Previous*

Dates: 1/1/06-12/31/07
Title: The Distribution of CD4 Cells and HIV-sized Particles Following Simulated Vaginal Intercourse.
Grant Number: GPOA 0005004100
Sponsor: US Agency for International Development (through International Partnership for Microbicides)
Total Direct Costs: \$ 157,896
Principal Investigator: **C. Hendrix**
Role: Principal investigator for design and conduct of a clinical study to image T-cell and HIV-sized particle migration in the female genital tract lumen and tissue following exogenous administration of radiolabeled autologous lymphocytes using simulated coitus.
Effort: 5%

Dates: 01/18/06-01/17/07
Title: Correlation of Free and Total Indinavir Concentrations in Seminal Plasma with the Concentrations in Blood Plasma in HIV-Infected Patients
Grant Number: Medical School Project
Sponsor: Merck Pharmaceuticals
Total Direct Costs: \$ 20,816
Principal Investigator: **C. Hendrix**
Role: Phase I study of HIV infected and healthy volunteers to explore the exposure of protein free indinavir in blood and semen. Principal investigator supervising post-doctoral fellow on the project.
Effort: 1%

Dates: 11/04/05-11/03/06
Title: A Study of the Pharmacokinetic Interaction between AMD11070 and Substrates of CYP 3A4 and 2D6 Enzymes in Healthy Volunteers
Grant Number: C-308 CTA
Sponsor: AnorMED
Total Direct Costs: \$ 211,050
Principal Investigator: **C. Hendrix**
Role: An investigator-initiated phase I study of the pharmacokinetic interaction of AMD11070 and two CYP 450 probe drugs, midazolam (CYP 3A4) and dextromethorphan (CYP 2D6). Principal investigator responsible for protocol design, execution, data analysis.
Effort: 10%

FUNDING**Extramural Funding (current, pending, previous)***Previous*

Dates: 07/1/05-06/30/08
Title: Safety and Efficacy of Tenofovir as Pre-Exposure Prophylaxis of HIV infection in Heterosexually Active Young Adults in Botswana and Injection Drug Using Adults in Thailand.
Grant Number: GAB-05-C-0459
Sponsor: Centers for Disease Control
Total Direct Costs: \$ 178,565
Principal Investigator: **C. Hendrix**
Role: Design and analysis of pharmacokinetic-pharmacodynamic sub-study of daily Tenofovir Disoproxil Fumarate for the prevention of HIV infection in heterosexually active young adults in Botswana; supervision of laboratory sample analysis for tenofovir drug levels in study.
Effort: 5%

Dates: 04/01/05-03/31/08
Title: Distribution of HIV in the Distal Gastrointestinal Tract
Grant Number: P30 AI042855
Sponsor: NIH (Hopkins Center for AIDS Research [CFAR])
Project Direct: \$ 59,792
Principal Investigator: **C. Hendrix** (Project)
Role: Principal Investigator of Developmental Pilot Grant from CFAR to describe the distribution of HIV and CD4 cells in the distal gastrointestinal tract following simulated coitus in order to establish the distribution of infectious material following receptive anal intercourse.
Effort: 1%

Dates: 12/04/04-12/03/06
Title: A Phase I, drug interaction study to assess steady-state plasma methadone enantiomer pharmacokinetics following co-administration of methadone qd with Fosamprenavir 700 mg bid + RTV 100 mg bid in opiate-dependent, HIV-adult subjects.
Grant Number: COL 012577 CTA
Sponsor: GlaxoSmithKline
Total Direct Costs: \$ 383,729
Principal Investigator: **C. Hendrix**
Role: PI, design, execution, data analysis of investigator-initiated phase II study of the PK/PD methadone and fosamprenavir.
Effort: 1%

FUNDING**Extramural Funding (current, pending, previous)***Previous*

Dates: 7/23/04-4/23/07
 Title: Pharmacokinetics of Efavirenz during treatment of HIV-1 infected subjects with hepatic impairment.
 Grant Number: M01 RR000052; AI266-917
 Sponsor: NIH; Bristol Myers Squibb
 Total Direct Costs: \$ 128,843
 Principal Investigator: **C. Hendrix**
 Role: Site principal investigator, a multi-center phase I study of the pharmacokinetics of Efavirenz in HIV infected persons.
 Effort: 1%

Dates: 11/01/02 – 04/30/07
 Title: Candida Ecology in the Intensive Care Unit.
 Grant Number: M01 RR00052
 Sponsor: NIH
 Total Direct Costs: GCRC Clinical Study Support
 Principal Investigator: **C. Hendrix**
 Role: Study Candida in ICU following several years of antifungal prophylaxis.
 Effort: 1%

Dates: 11/01/02 – 10/30/03
 Title: Sampling Frequency Limitations of Drugs in Whole Semen Ejaculates.
 Grant Number: M01 RR00052
 Sponsor: NIH
 Total Direct Costs: GCRC Clinical Study Support
 Principal Investigator: **C. Hendrix**
 Role: Design/execution of study to determine the sampling interval for semen that does not interfere with local drug permeability.
 Effort: 1%

Dates: 1/1/02 – 06/30/06
 Title: A Phase I First in Human Dose Escalation Study of the Pharmacokinetics and Safety of AMD070 in Healthy Volunteers
 Grant Number: U01AI 27668-18S1 Adult AIDS Clinical Trials Unit (Flexner, PI)
 Sponsor: NIH
 Total Direct Costs: \$ 4,527,600 (full U19, not project)
 Principal Investigator: **C. Hendrix** (Project)
 Role: Protocol Chair for Multi-center phase I first-in-human, pharmacokinetic study, responsible for protocol design and coordinating study execution.
 Effort: 10%

FUNDING**Extramural Funding (current, pending, previous)***Previous*

Dates: 10/01/01 – 12/31/07
 Title: A U.S. Clinical Trial Site to Conduct Evaluations of Topical Microbicides in Men Who Have Sex with Men (MSM).
 Grant Number: 200-2001-08015
 Sponsor: Centers for Disease Control
 Total Direct Costs: \$ 1,748,272
 Principal Investigator: **C. Hendrix**
 Role: Design and execution of clinical studies to develop methods for the assessment of distribution and clearance of candidate microbicides.
 Effort: 10%

Dates: 10/01/01- 9/30/03
 Title: Prevention of Adenoviral Infection in Basic Military Trainees
 Grant Number: DAMD17-02-1-0213
 Sponsor: US Army Medical Research and Materiel Command
 Total Direct Costs: \$243,452
 Principal Investigator: **C. Hendrix**
 Role: Design, execution, and analysis of In vitro and clinical evaluation of nucleoside analogues to prevent adenoviral infection in military trainees.
 Effort: 10%

Dates: 07/01/01 – 06/30/02
 Title: The Ecological Impact of Antifungal Prophylaxis in the ICU.
 Grant Number: M01 RR00052
 Sponsor: NIH
 Total Direct Costs: GCRC Clinical Trial Support
 Principal Investigator: **C. Hendrix**
 Role: PI, epidemiology of SICU Candida following fluconazole prophylaxis.
 Effort: 1%

Dates: 02/01/01-01/01/02.
 Title: Antiretroviral pharmacodynamics in the male genital tract.
 (Developmental Pilot Project) Hopkins Center for AIDS Research
 Grant Number: P30 AI042855 (Bartlett, PI)
 Sponsor: NIH (Hopkins Center for AIDS Research [CFAR])
 Total Direct Costs: \$ 55,000.
 Principal Investigator: **C. Hendrix** (Project)
 Role: Design, execution, and analysis of clinical studies to localize drugs within the male genital tract.
 Effort: 10%

FUNDING**Extramural Funding (current, pending, previous)***Previous*

Dates: 09/01/00-06/30/05
 Title: Pharmacology of Antiretroviral Drugs in the Genital Tract to prevent HIV Transmission.
 Total Direct Costs: \$ 533,040.
 Grant Number: K24 AI 01825
 Sponsor: NIH
 Principal Investigator: **C. Hendrix**
 Role: Midcareer Investigator Award for Patient-Oriented Research is to support academic career development and mentoring of fellows
 Effort: 50%

Dates: 09/29/00 – 02/28/04
 Title: HIV-HCV Coinfection: Antiviral therapy and fibrosis.
 Grant Number: R01 DA13806-01
 Sponsor: NIH
 Total Direct Costs: \$ 1,696,615
 Principal Investigator: D. Thomas
 Role: Pharmacokinetic/pharmacodynamic study of HIV/HCV treatment.
 Effort: 10%

Dates: 10/01/99 – 09/30/02
 Title: Tuberculosis Treatment Consortium Grant.
 Sponsor: CDC
 Principal Investigator: R. Chaisson
 Role: Site investigator; development of clinical protocols for pharmacokinetic studies of anti-TB drugs.
 Effort: 10%

Dates: 06/1/99 – 08/31/04
 Title: Graduate Training Program in Clinical Investigation.
 Grant Number: T32 HL04141
 Sponsor: NIH
 Principal Investigator: F. Adkinson
 Role: Course director, lecturer “Principles of Drug Development”; Research Committee.
 Effort: 3%

FUNDING**Extramural Funding (current, pending, previous)***Previous*

Dates: 03/01/99 - 02/28/06
Title: Pharmacology Core Laboratory, HIV Prevention Treatment Network (HPTN)
Grant Number: U01AI46745-05
Sponsor: NIH
Total Direct Costs: \$ 627,980
Principal Investigator: **C. Hendrix** (B. Jackson, HPTN Laboratory, PI)
Role: Pharmacologist for HPTN drug studies. Develop of novel methods to assess pharmacology of drugs in the male genital tract.
Effort: 10%

Dates: 02/01/99-01/31/02
Title: Effect of AMD-3100 on HIV positive Patients.
Grant Number: M01 RR000052; AMD3100-2001
Sponsor: NIH; AnorMED
Total Direct Costs: \$ 207,659
Principal Investigator: **C. Hendrix**
Role: PI, design and analysis for 6-site phase II PK-PD study of novel antiretroviral chemokine receptor blocker.
Effort: 10%

Dates: 02/01/99 - 01/31/00
Title: The Effect of Accutane on the Pharmacokinetics and Pharmacodynamics of Oral Contraceptive Tablets in Healthy Pre-menopausal Women with Severe Recalcitrant Nodular Acne.
Grant Number: M01 RR000052; NR15888/M01508
Sponsor: NIH; Roche
Total Direct Costs: \$ 328,832
Principal Investigator: **C. Hendrix**
Role: Principal investigator of investigator-initiated single site pharmacokinetic-pharmacodynamic drug interaction study; developed protocol collaboratively with sponsor; responsible execution, analysis.
Effort: 10%

FUNDING**Extramural Funding (current, pending, previous)*****Previous***

Dates: 02/01/99-01/31/00
Title: Methadone in combination with amprenavir in opiate abusers.
Grant Number: M01 RR000052; COL30330
Sponsor: NIH; Glaxo
Total Direct Costs: \$ 252,561
Principal Investigator: **C. Hendrix**
Role: Protocol design, single site principal investigator, and data analysis for investigator-initiated drug interaction study with pharmacokinetic and pharmacodynamic endpoints.
Effort: 10%

Dates: 09/01/98-08/31/99
Title: Phase I/II study of the pharmacokinetic of efavirenz when added to a ritonavir-saquinavir-containing an antiretroviral regimen in HIV.
Grant Number: NIH M01 RR000052; DMP 266-046
Sponsor: NIH; DuPont-Merck
Total Direct Costs: \$ 284,618
Principal Investigator: **C. Hendrix**
Role: Principal investigator, protocol design, execution, and data analysis of investigator-initiated single site of antiretroviral drug interactions.
Effort: 10%

Dates: 09/01/98-07/01/99
Title: Safety, pharmacokinetics, and tolerability of intravenously administered AMD 3100 in normal healthy volunteers.
Grant Number: M01 RR000052; 98-01
Sponsor: NIH; AnorMED
Total Direct Costs: \$ 72,644
Principal Investigator: **C. Hendrix**
Role: Principal investigator responsible for study design, execution, and data analysis of first-in-human study of novel CXCR-4 receptor inhibitor.
Effort: 10%

Dates: 07/01/98 – 06/30/99
Title: Phosphorylation of Nucleoside Analogs: Treatment-Experienced
Total Direct Costs: \$ 259,211
Grant Number: M01 RR000052; Glaxo Contract
Sponsor: NIH; Glaxo
Principal Investigator: C. Flexner
Role: Analysis for clinical study of antiretroviral intracellular phosphorylation.
Effort: 5%

FUNDING**Extramural Funding (current, pending, previous)***Previous*

Dates: 06/01/98-12/31/98
 Title: Safety of orally administered SP303 for the treatment of AIDS diarrhea.
 Grant Number: M01 RR000052; 37,554-210
 Sponsor: NIH; Shaman Pharmaceuticals
 Total Direct Costs: \$ 173,995
 Principal Investigator: **C. Hendrix**
 Role: Site principal investigator of multi-center, industry-sponsored study of novel natural product to reduce AIDS-related diarrhea.
 Effort: 1%

Dates: 01/01/98-06/30/99
 Title: Fluconazole prophylaxis in the surgical intensive care unit.
 Grant Number: Unrestricted Educational Grant
 Sponsor: Pfizer
 Total Direct Costs: \$ 825,104
 Principal Investigator: **C. Hendrix**
 Role: Principal investigator, clinical trial design, study management, execution, data analysis for phase III randomized clinical trial.
 Effort: 35%

Dates: 01/01/98 – 02/28/99
 Title: A Phase I/II Study of the Potential Interaction Between S-1153 and the Protease Inhibitors Nelfinavir and Indinavir in HIV-1 Infected Adults Treated with 3TC and ZDV or D4T.
 Grant Number: M01 RR000052; AG1549-535
 Sponsor: NIH; Agouron Pharmaceuticals
 Total Direct Costs: \$ 186,127
 Principal Investigator: **C. Hendrix**
 Role: Protocol development and site principal investigator for 3 site dose escalation study of novel antiretroviral agent (capravirine).
 Effort: 10%

Dates: 01/01/98-12/31/98
 Title: A phase I trial to evaluate the intravitreal penetration of 1263W94 after multiple-dose oral administration in AIDS patients with CMV retinitis
 Grant Number: M01 RR000052; CMAA1004
 Sponsor: NIH; Glaxo
 Total Direct Costs: \$ 56,651
 Principal Investigator: **C. Hendrix**
 Role: Protocol design assistance, site principal investigator, data analysis, intravitreal and blood pharmacokinetics of anti-CMV drug.
 Effort: 10%

FUNDING**Extramural Funding (current, pending, previous)***Previous*

Dates: 01/01/98-02/28/98
 Title: Utilization of PK/PD model to optimize 1263W94 dosing against CMV.
 Grant Number: Contract
 Sponsor: Glaxo
 Total Direct Costs: \$ 33,714
 Principal Investigator: F. Hamzeh
 Role: Surrogates of blood contamination of sampling in vitrectomy.
 Effort: 1%

Dates: 07/01/97-06/30/00
 Title: Faculty Development Award
 Sponsor: Pharmaceutical Research and Manufacturer's Association.
 Total Direct Costs: \$ 120,000
 Principal Investigator: **C. Hendrix**
 Role: Leadership and management of reorganized Drug Development Unit to provide complete phase I study services as a core faculty resource.
 Effort: 10%

Dates: 01/01/97-12/31/01
 Title: International Military Prevention Research.
 Grant Number: Contract
 Sponsor: Department of Defense (through Henry M. Jackson Foundation)
 Total Direct Costs: \$ 191,000
 Principal Investigator: **C. Hendrix**
 Role: HIV prevention program development and process research among foreign military leadership in coordination with the UNAIDS, UNDPKO, and the Civil-Military Alliance to Combat HIV/AIDS.
 Effort: 35%

Dates: 01/01/97 - 12/31/00
 Title: AIDS Clinical Trials Group Advanced Technology Laboratory, Pharmacology Research Resource Unit.
 Grant Number: U01 AI27668-PP003
 Sponsor: NIH
 Total Direct Costs: \$ 66,964
 Principal Investigator: C. Flexner
 Role: Clinical trial design, execution, and data analysis for antiretroviral drug development studies, principal investigator for multi-center studies.
 Effort: 10%

FUNDING**Extramural Funding (current, pending, previous)***Previous*

Dates: 01/01/97-12/31/97
 Title: Candida/VRE Surveillance in the Intensive Care Unit.
 Grant Number: Unrestricted Educational Grant.
 Sponsor: Pfizer
 Total Direct Costs: \$ 100,000
 Principal Investigator: **C. Hendrix**
 Role: Principal Investigator, study management, data analysis of pilot study to develop sample size estimates for prophylactic interventions in the ICU
 Effort: 10%

Dates: 01/01/97-12/31/97
 Title: Pharmacokinetics and safety of lobucavir in subjects with hepatic impairment.
 Grant Number: M01 RR000052
 Sponsor: NIH; Bristol-Myers Squibb
 Total Direct Costs: \$ 400,319
 Principal Investigator: **C. Hendrix**
 Role: Site principal investigator of multi-center pharmacokinetic study.
 Effort: 10%

Dates: 01/01/97 - 12/31/97
 Title: Phase I/II randomized double blind placebo controlled study of the safety, tolerance and pharmacokinetics and antiretroviral activity of PMPA Prodrug in HIV-infected patients.
 Grant Number: NIH M01 RR000052; Gilead contract
 Sponsor: NIH; Gilead Pharmaceuticals
 Total Direct Costs: \$ 268,239
 Principal Investigator: P. Barditch-Crovo
 Role: Data analysis of single center antiretroviral pharmacokinetic study.
 Effort: 1%

Dates: 01/01/97 - 10/30/97
 Title: Clinical Pharmacology of generic and antiviral drugs.
 Grant Number: Cooperative Agreement
 Sponsor: FDA
 Total Direct Costs: \$ 1,981,673
 Principal Investigator: P. Lietman
 Role: Data analysis of several investigator-initiated clinical studies of drug interactions and toxicity.
 Effort: 10%

CLINICAL ACTIVITIES

Certification

Medical Licensure

State of Maryland, issued 10/1/94, # D46682 (current)

Commonwealth of Pennsylvania, issued 12/2/92, MD 043514 L, (inactive 12/31/94)

Medical Boards or Other Specialty Certification

National Board of Medical Examiners, Parts I-III, 6/85

American Board of Internal Medicine, 9/87

American Board of Internal Medicine, Infectious Diseases, 11/1990-11/2000, #116631

American Board of Clinical Pharmacology, 10/2016

Membership in or Examiner for Specialty Board

2018-present Board of Directors, American Board of Clinical Pharmacology

EDUCATIONAL ACTIVITIES**Teaching***Classroom Instruction*School of Medicine

Physician and Society (medical student curriculum)

“Scientific Misconduct” 2001

Medical Pharmacology (medical student curriculum)

Lectures

“Pharmacokinetics I: Introduction, Membranes, Bioavailability” 1995-present

“Pharmacokinetics II: Volume, Clearance, Half-life” 1995-present

“Pharmacokinetics III: Dosing Regimens” 1995-present

“Pharmacokinetics IV: Mixed Order Kinetics, Applications” 2000-present

“Pharmacokinetic Clinical Problem Solving I and II” eLectures 2015-present

“Introduction to Antibiotics” 1998-present

“Cell wall active antibiotics I: Penicillins” 1998-present

“Cell wall active antibiotics I: Cephalosporins, Vancomycin” 1998-present

“Ribosomal inhibiting antibiotics I: Aminoglycosides” 1998-present

“Ribosomal inhibiting antibiotics II: Others” 1998-present

“Antifungal Drugs” 2001

“Pharmacokinetics of anti-seizure drugs” 1995-1999

“Pharmacology of immunotherapeutics in neurology” 2000

“Aspirin and NSAIDs” 1998-2004, 2017

“Opiates” 1994-2004

“Quinolones” 2007

Small group/tutorials

Intersession Small Group Co-Leader (Clinical-Basic Science correlations) 2011-present

Pharmacokinetics problem-solving (2, 2-hour sessions) 1995-present

Infectious Diseases small group discussion (4, 2-hour sessions) 1994-2003

Pharmacology tutorial “Clinical Investigation” (5, 2-hour sessions) 1994-2012

Vaccine small group discussion (1, 2-hour session) 1997-2000

Metabolism small group 2012-2015

Pharmacology medical student journal club 2012-2015

Tutorial “My Favorite Drug (Drug Development)” 2016

Rational Therapeutics (created course; required 4th year medical student course)

“Practical Pharmacokinetics” 1995-2004

“Drug Interactions” 2004

“Rational Use of Antibiotics” 2005-2006

Pharmacology (Pharmacology Graduate Students):

“Pharmacokinetics I: Introduction, Membranes, Bioavailability” 2000-present

“Pharmacokinetics II: Volume, Clearance, Half-life” 2000-present

“Pharmacokinetics III: Mixed Order Kinetics” 2000-present

“Antibiotics” 2000-2006

“Aspirin and NSAIDs” 2000-2004

Pharmacology tutorial “Clinical Investigation” (5, 2-hour sessions) 2010-present

EDUCATIONAL ACTIVITIES

Teaching

Classroom Instruction- continued

Analytical Methods of Clinical Pharmacology (Fellowship 24-hour curriculum) 2000-present

“Principles of PK/PD in Drug Development”

“Curve Stripping”

“Non-Compartmental Analysis”

“Compartmental Analysis”

“Pharmacodynamic Studies”

“Pharmacodynamic Data Analysis”

“PK/PD Linkage Analysis”

“Population PK Analysis Overview”

“Clinical Trial Simulation Overview”

Laboratory Science of the Clinical Investigator – Short Course 2017-present

Course creator and co-director with S. Nimmagadda

Osler House Staff Noon Teaching Conference 2004 - 2012

“Practical Pharmacokinetics for the House Officer” 2004-2012

“Pharmacokinetics in Special Populations” 2004-2012

“Rational Therapeutics of COX-2 Selective and Non-selective NSAIDs” 2004-2010

“Making Drugs Safer” 2005-2012

“Aminoglycoside Dosing Strategies” 2007-2012

“Integrating HIV Prevention into an Internal Medicine Practice”, 2011-2012

School of Nursing

“Pharmacology of Immune Suppressive Drugs”, Graduate Student Curriculum, 1998-9

School of Public Health

Principles of Drug Development, (required GTPCI Course) 1994-2003

“Overview of the drug development process” 1999-2003

“Pharmacokinetics for Drug Development” 1999-2003

“Pharmacokinetic and Safety Studies” 1994-2003

“Pharmacokinetic and Safety Studies - practicum” 1999-2003

“Pharmacokinetic and Safety Studies – student project critique” 1999-2003

“Learning vs. Confirming Studies” 1999-2003

“Learning vs. Confirming Studies - practicum” 1999-2003

“Learning vs. Confirming Studies - student project critique” 1999-2003

“Clinical Trial Simulation” 2001-2003

EDUCATIONAL ACTIVITIES

Teaching

Classroom Instruction - continued

Analytical Methods in Clinical Investigation (required GTPCI Course),

“Databases: How to use and abuse them I: Principles” 1997-2002

“Databases: How to use and abuse them II: Applications” 1997-2002

Topics in Clinical Investigation (required GTPCI Course)

“Scientific Misconduct” 1995-present

Epidemiology and Natural History of Human Viral Infections

“Antiviral Therapy” 1997 - present

Epidemiology and Public Health Impact of HIV and AIDS

“Antiretroviral Therapy” 2004 - present

Graduate Summer Institute of Epidemiology and Biostatistics, Advanced Issues in HIV/AIDS Course, “HIV Chemoprevention Drug Development Issues”, 2005 – present

Advanced Topics on the Control and Prevention of HIV/ AIDS

“HIV Chemoprevention” 2006 - present

Epidemiology of Infectious Disease Journal Club, Faculty discussant, 2007

Doctoral Seminar in International Health, “Pharmacology in Public Health”, 2009-2011

Clinical Instruction

Clinical Skills (required 2nd year Course), Preceptor, 1997

Internal Medicine Inpatient Service, Teaching Attending, 1995-1996

PerdanaUniversity Graduate School of Medicine (Kuala Lumpur, Malaysia)

Scientific Foundations of Medicine Course

Introduction to Pharmacology Section (2013-present)

“Receptors and Enzymes”

“Drug Metabolism”

“Pharmacokinetics I-IV”

“Pharmacokinetic Case Studies – Problem Solving”

“Autonomic Pharmacology I-II”

“Drug Safety”

“Drug Development”

“Complementary and Alternative Medicine”

“Drug Resistance”

EDUCATIONAL ACTIVITIES

Teaching

Continuing Medical Education – Military

US Air Force Annual HIV/AIDS Train-the-trainer Short Course 1991-1999
Course Director, Instructor 1991-1999

International Military HIV/AIDS Education (in collaboration with UNAIDS)

Harare, Zimbabwe, Regional Training Seminar, 6 East and Southern African National Delegations, Speaker/Facilitator, 1995

Cha-Am, Thailand, Regional Training Seminar, 7 South and Southeast Asian National Delegations, Speaker/Facilitator, 1995

Kampala, Uganda, Regional Training Seminar, West African National Delegations, Presentation provided, 1996

Windhoek, Namibia, Regional Training Seminar, 14 East and Southern African National Delegations, Speaker/Facilitator, 1997

Hanoi, Republic of Vietnam, Country Site Visit Team, Speaker, Military Consultant, 1998

Moscow/Saint Petersburg, Russian Federation, Country Site Visit, Speaker, Military Consultant, 1998

“HIV Military Threat Assessment and Response.” Annual HIV Prevention Education Train-the-Trainer Course, San Antonio, Texas. May 1999.

Continuing Medical Education- Civilian

“Clinical Pharmacology of Antiretroviral Drugs.” Curriculum Review Course, American Society of Clinical Pharmacology and Therapeutics, New Orleans, Louisiana. March 1998. International. Audience: Clinical Pharmacologists faculty and post-doctoral trainees.

“Clinical Pharmacology of Antiretroviral Drugs.” Curriculum Review Course, American Society of Clinical Pharmacology and Therapeutics, San Antonio, Texas. March 1999. International. Audience: Clinical Pharmacologists faculty and post-doctoral trainees.

“New Antibacterial Drugs.” Pediatric Trends Course, Johns Hopkins University School of Medicine, Office of Continuing Medical Education. Baltimore, Maryland. April 1999. JHMI. Clinical faculty and post-doctoral trainees.

“New Antiviral Drugs”. Pediatric Trends Course. Johns Hopkins University School of Medicine, Office of Continuing Medical Education. Baltimore, Maryland. April 1999. JHMI. Clinical faculty and post-doctoral trainees.

EDUCATIONAL ACTIVITIES**Teaching*****Continuing Medical Education – Civilian continued***

“COX-2 Inhibitors: New NSAIDs on the Block.” Conjoint Clinic, Johns Hopkins University School of Medicine, Office of Continuing Medical Education. Baltimore, Maryland. May 1999. JHMI. Clinical faculty and post-doctoral trainees.

“New Drugs for HIV Infection.” Clinical Care of the Patient with HIV Infection. Baltimore, Maryland. April 1999. JHMI. Clinical faculty and post-doctoral trainees.

“New Drugs for HIV.” The Johns Hopkins AIDS Service HIV Management Preceptorship Program, Baltimore, Maryland. April 1999. JHMI. Clinical faculty and post-doctoral trainees.

“Databases and Clinical Research: How to Use and Abuse Them.” Johns Hopkins University School of Medicine, Office of Continuing Medical Education, Baltimore, Maryland. May 1999. JHMI. Clinical faculty and post-doctoral trainees.

“New Drugs for HIV Infection.” Clinical Care of the Patient with HIV Infection. Baltimore, Maryland. April 2000. JHMI. Clinical faculty and post-doctoral trainees.

“Databases and Clinical Research: How to Use and Abuse Them.” Johns Hopkins University School of Medicine, Office of Continuing Medical Education, Baltimore, Maryland. May 2000. JHMI. Clinical faculty and post-doctoral trainees.

“NSAIDs and COX-2 Inhibitors: Current Status.” Conjoint Clinic, Johns Hopkins University School of Medicine, Office of Continuing Medical Education. Baltimore, Maryland. February 2001. JHMI/Regional. Clinical faculty and post-doctoral trainees.

“Databases and Clinical Research: How to Use and Abuse Them.” Johns Hopkins University School of Medicine, Office of Continuing Medical Education, Baltimore, Maryland. April 2001. JHMI. Clinical faculty and post-doctoral trainees.

“Tools for Pre-Approval Drug Safety Evaluation”, Academics to CDER Series: Annual Continuing Medical Education Course May 2003. Regional. FDA Professional Staff Development.

“Aminoglycoside and Vancomycin Therapeutic Drug Monitoring.” Johns Hopkins Distance Learning (Bermuda Site), Office Of Continuing Medical Education, Baltimore, Maryland. May 2005. JHMI/Regional. Clinical faculty and post-doctoral trainees.

“Practical Pharmacokinetics for Primary Care.” Anne Arundel Community College, Physician Assistant Curriculum, Arnold, Maryland, 2005. Regional. Physician Assistant candidates.

EDUCATIONAL ACTIVITIES

Teaching

Continuing Medical Education – Civilian continued

“Relationships between Academia and the Pharmaceutical Industry.” American Medical Student Association (Johns Hopkins University Chapter), November 2006. JHMI. Medical Students.

“Development of Topical HIV Microbicides.” Division of Infectious Diseases, Fellows’ Conference, December 2006. JHMI. Clinical faculty and post-doctoral trainees.

“Clinical Pharmacology of Antiretroviral Drugs.” Curriculum Review Course, American Society of Clinical Pharmacology and Therapeutics, Anaheim, California. March 2007. International. Audience: Clinical Pharmacologists faculty and post-doctoral trainees.

“Pharmacodynamics of Antibiotics.” Division of Infectious Diseases, Fellows’ Conference, November 2007. JHMI. ID faculty and post-doctoral fellows.

“Pharmacological Principles of Antiretroviral Drugs” Curriculum Review Course. ASCPT, March 2009. International. Audience: Clinical Pharmacologists faculty and post-doctoral trainees.

“Pharmacological Principles of Antiretroviral Drugs” Curriculum Review Course. ASCPT, March 2013. International. Audience: Clinical Pharmacologists faculty and post-doctoral trainees.

“Pharmacogenomics: One Aspect of Precision Medicine in Primary Care” Curriculum Review Course. American Medical Forum. Washington, DC. November 2017. National. Audience: Internal Medicine & Primary Care Physicians.

“Pharmacogenomics: One Aspect of Precision Medicine in Primary Care” Curriculum Review Course. American Medical Forum. Washington, DC. June 2018. National. Audience: Internal Medicine & Primary Care Physicians.

“HIV Prevention with Drugs: Pre-Exposure Prophylaxis (PrEP) in Primary Care.” Curriculum Review Course. American Medical Forum. Washington, DC. June 2018. National. Audience: Internal Medicine & Primary Care Physicians.

“HIV Prevention with Drugs: Pre-Exposure Prophylaxis (PrEP) in Primary Care.” Curriculum Review Course. American Medical Forum. Washington, DC. November 2017. National. Audience: Internal Medicine & Primary Care Physicians.

EDUCATIONAL ACTIVITIES

Mentoring

Principal Mentor

Stephen P. Blatt, M.D., 1990-1991

Infectious Disease Fellow, Wilford Hall USAF Medical Center
Current position: Private Practice, Dayton, OH (1994-present)

Janet M. J. Hammond, M.D., Ph.D., 1995-1998

Clinical Pharmacology Fellow; Graduate Training Program in Clinical Investigation,
Johns Hopkins University School of Hygiene and Public Health
Thesis "Emerging Pathogens in Intensive Care"; Sc.M. granted 5/25/99.
Current Position: Vice President of Infectious Diseases Development, AbbVie, Lake
Forest, IL.

Robert Pelz, M.D., 1997-2000

Infectious Diseases Fellow
Graduate Training Program in Clinical Investigation, Ph.D. 2000
Research: Epidemiology and treatment of ICU infections
Awards: Infectious Diseases Society of America 1998 Fellows Award for Scientific
Excellence. "Do surveillance cultures predict fungal infection in critically ill pts?"
Society of Critical Care Medicine 2000 In-training Fellow Award. "A double blind
placebo controlled trial of prophylactic fluconazole to prevent Candida
infections in critically ill surgical patients"
Society of Critical Care Medicine 2000 Educational Scholarship Award
"Fluconazole blood concentrations after enteral administration in critically ill
surgical patients exceed most Candida minimal inhibitory concentrations in a
double-blind, placebo-controlled trial in which fluconazole prevented Candidal
infections."
Johns Hopkins University Helen B. Taussig Young Investigators Award.
"Nosocomial Fungal Infections in the Critically Ill: Dx and Prevention."
Current Position: Clinical Assistant Professor of Medicine, Oregon Health and Science
University, School of Medicine, Portland, OR

Thomas Ndovi, M.D., 1999-2005

Clinical Pharmacology Fellow
Graduate Training Program in Clinical Investigation, 1999-2005, Ph.D. 2005
Fogarty International Fellow 1999-2001, 2003-2004
Merck International Fellow in Clinical Pharmacology 2001-2003
Research: Pharmacology of antiretroviral drugs in genital compartments
Awards: Department of Medicine Research Retreat Clinical Fellow Poster Finalist 2005
British Journal of Clinical Pharmacology Prize 2007
Last Position: Assistant Professor of Medicine, University of Malawi; Director, Johns
Hopkins-Malawi Clinical Research Unit, Blantyre, Malawi (Deceased 2007)

EDUCATIONAL ACTIVITIES

Mentoring

Principal Mentor - continued

Shelley Sylvester Magill, M.D., 2000-2007

Infectious Diseases Fellow/Assistant Professor

Graduate Training Program in Clinical Investigation, Ph.D. 2007

Awards: Pfizer Mycology Fellowship Award Recipient 2001-2003;

Clinical Scientist Award 2003 (Johns Hopkins University, declined)

Research: Ecology and prevention of fungal infections in the ICU

Position: Assistant Professor, Division of Infectious Diseases, Johns Hopkins University School of Medicine 2004 - 2007

Current Position: Medical Officer, Mycotic Diseases Branch, CDC, Atlanta, GA (2007-present)

Lewis Radonovich, M.D., 2000-2002

Clinical Pharmacology Fellow

Graduate Training Program in Clinical Investigation, Ph.D. Candidate

PhRMA Fellowship in Pharmacology 2001-2002

Research: Chemoprophylaxis of adenoviral infections

Previous Position: Assistant Professor of Medicine, University of Florida, Gainesville FL (2002-2015)

Current Position: Centers for Disease Control, NIOSH, Pittsburgh, PA (2015-present)

Thanyawee Puthanakit, M.D., 2001-2002

International Fogarty Fellow; Clinical Pharmacology Fellow

Graduate Training Program in Clinical Investigation; MHS degree 2002

Research: Pharmacokinetics of Antiretroviral Drugs, Drug interactions in the ICU

Assistant Professor, Chiang Mai University Medical Faculty, 2002-2005

Current Position: Associate Professor, Department of Pediatrics, Chulalongkorn University, Bangkok, Thailand; The HIV Netherlands Australia Thailand Research Collaborative.(2002-present)

Nimalie Stone, M.D., 2003-2004

Clinical Pharmacology Fellow

Research: Chemokine receptor inhibition phase I studies; Anti-infective drug utilization

Current Position: Medical Officer, CDC, Atlanta, Georgia

Wasif Khan, M.D., 2003-2005

Clinical Pharmacology Fellow

Graduate Training Program in Clinical Investigation, M.H.S. 2005

Merck International Fellow in Clinical Pharmacology 2003-2005

Research: Pharmacology of antiretroviral drugs, microbicide distribution

Current Position: Research Physician, International Center for Diarrheal Disease Research, Dhaka, Bangladesh. (2005-present)

EDUCATIONAL ACTIVITIES**Mentoring*****Principal Mentor – continued***

Ying-Jun Cao, M.D., 2004-2007

Clinical Pharmacology Fellow

Graduate Training Program in Clinical Investigation, Ph.D. 2007

Research in Progress: Development of methods to describe pharmacokinetics in the male genital tract; Quantitative methods to assess colon microbicide and HIV distribution

Awards: Department of Medicine Research Retreat Clinical Fellow Poster Finalist 2005;

American Society for Clinical Pharmacology and Therapeutics Young Investigator Award 2006-7;

Conference Retroviruses and Opportunistic Infections, Young Investigator Award 2007

British Journal of Clinical Pharmacology Prize 2012

Positions: Assistant Professor of Medicine, Division of Clinical Pharmacology, Johns Hopkins University School of Medicine. 2007-2008; 2008-present (Adjunct).

Director Science, Global Clinical Pharmacology & Exploratory Development, Astellas Pharmaceuticals, 2008-present.

Sridhar Nimmagadda, Ph.D., 2005-2008

Post-doctoral Fellow in Pharmacology and Radiology (Martin Pomper co-mentor)

Research: Quantitative luminal and tissue distribution of HIV and CD4 cells in the human vagina and colon following simulated receptive intercourse

Positions: Associate Professor of Radiology, Johns Hopkins University School of Medicine, 2009-present.

Kelly Brungardt Stein, MD, 2006-2007

Joint Clinical Pharmacology – Infectious Diseases Fellow

Graduate Training Program in Clinical Investigation, ScM 2009

Research: Protein binding of antiretrovirals in semen; vaginal distribution of HIV & CD4 cells.

Current Position: Instructor, Rush University Medical Center 2008-present

Nicolette Louissaint, PhD, 2006-2013

Pharmacology Training Program, Department of Pharmacology (2006 – 2010)

Ph.D. Candidate (PhD conferred May 2010), Post-doctoral fellow (May 2010-present)

Research in Progress: Quantitative luminal and tissue distribution of HIV and CD4 cells in the human vagina and colon following simulated receptive intercourse

Awards: Keystone Symposia Minority Scholarship, 2008

Department of Medicine Research Retreat Clinical Research Fellow Poster Finalist, 2009

American Society for Clinical Pharmacology and Therapeutics (ASCPT) Presidential Trainee Award 2010

ASPET Integrative Research in Pharmacology Awards 2012

AAAS Fellow – US Department of State 2013-2014

Current Position: Director of Healthcare Ready, AAAS Science and Technology Policy Fellow, Foreign Affairs Officer, US Department of State, 2014 - present

EDUCATIONAL ACTIVITIES

Mentoring

Principal Mentor - continued

Lindsay Brooke Avery, BS, 2008-2012

Pharmacology Training Program, Department of Pharmacology

Ph.D. Candidate; PhD conferred August 2012

Research: Efavirenz protein binding, compartmental distribution, and antiviral effect

Awards: American Society for Clinical Pharmacology and Therapeutics (ASCPT) Presidential Trainee Award 2010

Young Investigator Award. 20th Conference on Retroviruses and Opportunistic Infections 2013

Positions: Post-doctoral fellow, Namandje Bumpus Lab, Johns Hopkins University 2012-2014;

Current position: Pharmaceutical Development, Pfizer, Inc. Boston, MA, 2014-present

Liye Li, MD, PhD. 2009-2010

Clinical Pharmacology Fellow

Research: Development of candidate topical rectal microbicides.

Current Position: Nuclear Medicine private practice 2010 - present

Francisco Leyva, Md. PhD, 2009-2013

Clinical Pharmacology Fellow

Graduate Training Program in Clinical Investigation, M.H.S. 2012

Research: Development of candidate topical rectal microbicides.

Current Position: National Institutes of Health, Division of Microbiology and Infectious Diseases

Yanhui Lu, BS, 2010-2014

Pharmacology Training Program, Department of Pharmacology

Ph.D. Candidate; PhD conferred March 2014

Research: Identification of Novel Phase I and Phase II Metabolites of Maraviroc

Awards:

Junghea Park Memorial Travel Award 2012

Scheinberg Travel Award for spring 2011

Graduate Student Travel Award, ASPET Annual Meeting 2012

2012 Chinese Government Award for Outstanding Self-financed Students Abroad (China Scholarship Council)

2014 Bae Gyo Jung Young Investigator Day Award. Johns Hopkins University

Current Position: Office of Clinical Pharmacology, FDA 2015-present

Jenell Fenell Coleman, MD, 2010 – 2014

Assistant Professor, Department of Obstetrics and Gynecology

Harold Amos Medical Faculty Development Award

Research: Contraceptive – Antiretroviral drug interactions

Current Position: Associate Professor, Obstetrics & Gynecology, Johns Hopkins University

EDUCATIONAL ACTIVITIES

Mentoring

Principal Mentor - continued

Salee Parichat, MD, M.P.H. 2011-2012

International Fogarty Fellow, Thailand; Epidemiology, Masters of Public Health 2012,
Bloomberg School of Public Health,

Research: Pre-exposure Prophylaxis adherence measured by plasma drug levels in MTN-001:
comparison between vaginal gel and oral tablets in two geographic regions.

Current Position: RIHES, Chiang Mai University, Thailand

Hiwot Hiruy, MD, 2011-2015

Joint Clinical Pharmacology – Pediatric Infectious Diseases Fellow

Graduate Training Program in Clinical Investigation, PhD 2015

Research: Gastrointestinal tract pharmacology of topical HIV microbicides

Current Position: Medical Officer, FDA 2015-present

Jenny Robinson, MD, 2012-2014

Clinical Pharmacology Fellow

Graduate Training Program in Clinical Investigation, PhD Candidate

Research in progress: Female Genital tract pharmacology of topical HIV microbicides

Current Position: Assistant Professor, Obstetrics & Gynecology, Johns Hopkins University
2014-present

Ethel Weld, MD, 2013-2016

Joint Clinical Pharmacology –Infectious Diseases Fellow

Graduate Training Program in Clinical Investigation, PhD Candidate

Research in progress: Gastrointestinal tract pharmacology of topical HIV microbicides

Awards:

The Pearl M. Stetler Research Fund for Women Physicians Award 2015-2016

Research Scholars Junior Faculty Award (KL2) 2017-2018

Current Position: Assistant Professor, Department of Medicine (Clinical Pharmacology), Johns
Hopkins University, 2016-present

Funding: KL2 NCTS Johns Hopkins ICTR

Jackson Mukonzo, PhD, 2014

Fulbright Faculty Scholar

Research in progress: Polymorphisms uniquely impacting HIV treatment in African populations

Current Position: Director (Acting), Department of Pharmacology & Therapeutics, Makerere
University, College of Health Science, Kampala, Uganda

Eugenie Shieh, MD, 2014-2017

Joint Clinical Pharmacology–Gastroenterology Fellow

Graduate Training Program in Clinical Investigation, PhD Candidate

Research in progress: Gastrointestinal tract pharmacology of topical HIV microbicides

Private practice gastroenterology, CA 2017-present

EDUCATIONAL ACTIVITIES

Mentoring

Principal Mentor - continued

Victoria Ojeda, 2015-present

Associate Professor, University of California, San Diego

HIV Prevention Trials Network Scholar

Research in Progress: Impact of staff-participant relationships on adherence in randomized controlled PrEP trials

Current Position: Associate Professor, University of California at San Diego, School of Public Health, San Diego, CA

Rachel Scott, MD, 2016-present

Assistant Professor, Georgetown University

Mid Atlantic CFAR Mentoring

Research in progress: ARV & PrEP PK in pregnancy and post-partum

Current Position: Assistant Professor of Medicine, Georgetown University, Washington, DC

Funding: K23 NIMH

Zachary Janik, 2016-present

Medical Student, Research Mentor

Research in Progress: Quantitative assessment of White Coat Adherence in HIV Pre-Exposure Prophylaxis.

Katherine Huether, 2017-2018

Medical Student, Drug Development Research Rotation

Secondary Sub-Specialty Mentoring

Normalynn Garrett, PhD candidate, Nursing; Pharmacology mentoring, 1998-1999

Andre Agthe, Neonatal Fellow, GTPCI; Pharmacology mentor, 2000-2004

Amy Ginsberg, Infectious Diseases Fellow; Pharmacology mentor, 2002-2003

Advisor (when not Primary Mentor) – GTPCI - continued

Rodney Willoughby, MD, Pediatrics Faculty, GTPCI; Pharmacology mentor, 1999-2004

Lawrence Lee, Clinical Pharmacology Fellow; Pharmacokinetics mentor, 2003-2004

Devi Chittineni, Clinical Pharmacology Fellow; Pharmacokinetics mentor, 2004 – 2006

Myaing Nyunt, Clinical Pharmacology Fellow, GTPCI; Pharmacokinetics mentor, 2005 - 2008

Current Position: Assistant Professor of Medicine, University of Maryland Medical Center

EDUCATIONAL ACTIVITIES

Advisor (when not Primary Mentor) – GTPCI - continued

Kelly Dooley, MD, Joint Clinical Pharmacology – Infectious Diseases Fellow, GTPCI;
Pharmacokinetics Mentor, 2006 – 2010
Current Position: Associate Professor of Medicine, Johns Hopkins University

Sofia Perea, Pharm.D., Ph.D., 2002-2004
Oncology Post-Doctoral Fellow
Graduate Training Program in Clinical Investigation, Ph.D. Candidate

Kai Zhang, M.D., 2003-2004
Post-Doctoral Fellow
Graduate Training Program in Clinical Investigation, Ph.D. Candidate

Victor Crentsil, M.D., 2005 – 2007
Division of Geriatric Medicine
Graduate Training Program in Clinical Investigation, M.H.S. Degree 2007
Current Position: FDA Medical Officer

Romanee Chaiwarith, M.D. 2006 - 2007
Post-Doctoral Fellow
Graduate Training Program in Clinical Investigation, M.H.S. Candidate
Current Position: Assistant Professor, Medicine, Chiang Mai University

Tamorah Lewis, MD, Joint Clinical Pharmacology – Neonatology Fellow, GTPCI;
Pharmacokinetics Mentor, 2010 – 2014, Fellowship Advisory Committee, 2010-2014
Current Position: Assistant Professor, Pediatrics, Mercy Children’s Hospital, Kansas City
(2014-present)

Pranita Tamma, M.D. 2010-2011
Post-Doctoral Fellow Pediatric Infectious Diseases
Graduate Training Program in Clinical Investigation, M.H.S. Candidate
Current Position: Assistant Professor, Pediatrics (Infectious Diseases), Johns Hopkins
University (2011-present)

Berkley Limketkai MD 2011 – 2017
Post-Doctoral Fellow Gastroenterology
Graduate Training Program in Clinical Investigation, Ph.D. 2017
Current Position: Assistant Professor, Medicine (Gastroenterology) Stanford University
(2014-present)

Erica Shelton MD 2012 – 2014
Instructor, Emergency Medicine
Graduate Training Program in Clinical Investigation, Ph.D. Candidate

Craig W. Hendrix., MD

Curriculum Vitae

Current Position: Assistant Professor, Emergency Medicine, Johns Hopkins University
(2014-present)

Omamah Alfarisi PharmD 2012 – present

Post-Doctoral Fellow Clinical Pharmacology

Graduate Training Program in Clinical Investigation, Ph.D. Candidate, pharmacokinetics
mentor

Kattayoun Kordy MD, 2014-2016

Clinical Pharmacology UCLA, F32, Pharmacokinetics mentor

Current Position: Assistant Professor, Medicine (Gastroenterology) University of Southern
California (2016-present)

EDUCATIONAL ACTIVITIES***Mentoring Committees***

Adriana Andrade, MD 2007-2018

Associate Professor of Medicine (Infectious Diseases)

Research in Progress: HIV Clinical Pharmacology, Drug interactions with complementary medicine products and antiretroviral drugs, Adherence to therapeutic regimens.

Myaing Nyunt, MD, PhD 2008-2013

Assistant Professor of International Health (School of Public Health)

Research in Progress: Clinical pharmacology of malaria therapeutics and prevention

Previous Position: Assistant Professor, Medicine, University of Maryland, Baltimore, MD (2014-2017)

Current Position: Assitant Professor, Medicine, Duke University, Durham, NC (2017-present)

Mentoring***Thesis/Oral Examination Committees***

Janet Hammond, “Emerging Pathogens in Intensive Care”, M.H.S. thesis, Graduate Training Program in Clinical Investigation, School of Hygiene and Public Health, Thesis advisor, Thesis Committee Member 1996-1999.

Normalynn Garrett, “Effects of LY235959 on surgery-induced immunosuppression and increased metastasis in rats”, Ph.D. thesis, School of Nursing, Thesis Committee Member, 1998-9.

Robert Pelz, “Prophylaxis of invasive fungal infections in the Surgical Intensive Care Unit: Efficacy, Pharmacology, and Cost Analysis”, Ph.D. thesis, Graduate Training Program in Clinical Investigation, School of Hygiene and Public Health, Thesis advisor, Thesis Committee Member, 1997-2001.

Rodney Willoughby, “Developmental Kinetics of Cytokines in Cerebral Palsy”, Ph.D. thesis, Graduate Training Program in Clinical Investigation, School of Hygiene and Public Health, Thesis Committee Member, 1999-2008.

Claudine Woo, “Subgroup analyses in clinical trials”, PhD thesis; Ph.D. 2006, Clinical Trials Program, Department of Epidemiology. School of Public Health, Preliminary Oral Examination Committee Member, 2001; Thesis Committee Member, 2003 - 2006.

Leena Choi, “Modeling biomedical data and the foundations of bioequivalence”, Ph.D. Thesis, Department of Biostatistics, School of Public Health, Preliminary Oral Examination Committee Chairman, 2001; Thesis Committee Chairman, 2005.

Elizabeth Lowe, “Phase I and Pharmacokinetic Study of Liposomal Doxorubicin (TLC D-99) in Pediatric Patients with Refractory Solid Tumors”, M.H.S. thesis, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Reader, 2002.

Melanie Rusch, “Were Sexual Risk Behaviors Changing in Injection Drug Users in the ALIVE Cohort Before HAART was Readily Available in this Population”, M.H.S. Candidate, Department of Epidemiology, School of Public Health, Thesis reader, 2002.

EDUCATIONAL ACTIVITIES**Mentoring*****Thesis/Oral Examination Committees – continued***

Alex Agthe, “Clonidine and opiates in the treatment of neonatal abstinence syndrome”, Ph.D. candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Examination Committee, 2002 Thesis Committee Member, 2007-2008.

Thomas Ndovi, “Compartmental Kinetics of Antiretroviral Drugs (ARVs) in the human Male Genital Tract”, PhD Thesis, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Examination Committee Member, 2003; Thesis Committee Member, 2003-2005.

Michael Gibson, Ph.D. candidate, Department of Oncology, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2002-2007.

Ricardo Carvalho, “Unidirectional Transscleral Delivery from Episcleral Implants”, Sc.M. Thesis, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2003-2006, Thesis Reader 2006.

Shelley Sylvester Magill, PhD Candidate, Department of Medicine, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Examination Committee Member 2004, Thesis Committee member, 2004-2007.

Courtney Silverthorn, Ph.D. Candidate, Department of Pharmacology, School of Medicine, Preliminary Oral Exam Committee Member, 2004.

Lawrence Soon-U Lee, “Antioxidant and phase 2 enzyme induction activity of ginseng in humans”, PhD Candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Oral Examination Committee, 2005; Thesis Committee, 2007.

Moirá McMahon, Ph.D. Candidate, Department of Pharmacology, School of Medicine, Preliminary Oral Exam Committee Member, 2006.

Ying-Jun Cao, “Antiretroviral Drug Penetration into the Male Genital Tract,” PhD Candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Examination Committee Member, 2006; Thesis Defense Committee, 2007.

Lijuan Deng, “Spline Based Curve Fitting with Application to Kinetic Imaging M.S.” Candidate, Department of Biostatistics, Bloomberg School of Public Health, Thesis Reader 2006.

AeRang Kim, Ph.D. candidate, Department of Oncology, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2006-2009.

Michael Yu, Ph.D. candidate, Department of Oncology, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2006-2010.

Susanna Nazarian, PhD candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2008-2009.

EDUCATIONAL ACTIVITIES**Mentoring*****Thesis/Oral Examination Committees – continued***

Jean Wang, “Predicting Cancer in Barrett's Esophagus”, PhD candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2008-2009.

Nicolette Louissaint, PhD candidate, Pharmacology and Molecular Sciences, School of Medicine, Thesis Committee Member, 2008-2010.

Benjamin Jilek, PhD candidate, Biochemistry, Cellular and Molecular Biology (BCMB) Graduate Program, School of Medicine, Thesis Committee Member, 2008-2011.

Jonathan Neiswinger, PhD candidate, Pharmacology and Molecular Sciences, School of Medicine, Oral Examination Committee Member, 2009.

Ying-Chun Lo, PhD candidate, Pharmacology and Molecular Sciences, School of Medicine, Oral Examination Committee Member, 2009.

Meng-Jung Chiang, PhD candidate, Pharmacology and Molecular Sciences, School of Medicine, Oral Examination Committee Member (Alternate), 2009.

Jeff Goldsmith, PhD candidate, Biostatistics, Bloomberg School of Public Health, Oral Examination Committee member. 2010. Thesis Committee member, 2011-2012.

Lindsay B. Avery, PhD Candidate. Pharmacology and Molecular Sciences, School of Medicine, Thesis Committee Member, 2011-2012.

Salee Parichat, MD, M.P.H. Candidate. Epidemiology, Bloomberg School of Public Health, Thesis Committee, 2011-2012.

Ryan Westergaard, PhD candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2012.

Melissa Zarr, PhD Candidate. Pharmacology and Molecular Sciences, School of Medicine, Thesis Committee Member, 2012 – 2014. Thesis Reader 2014.

Laura Ensign, PhD candidate, Chemical and Biomolecular Engineering, School of Engineering, Thesis Committee, 2012.

Tamara Lewis, PhD candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2012-2015.

Jenny Robinson, PhD candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2013-present.

Yanhui Lu, PhD Candidate, Pharmacology and Molecular Sciences, School of Medicine, Thesis Committee Member, Thesis Advisor, 2012-2014.

Berkeley Limetkai, PhD candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Exam Committee Member, 2013; Thesis Committee Member, 2013-2017.

EDUCATIONAL ACTIVITIES**Mentoring*****Thesis/Oral Examination Committees – continued***

Elaine To, PhD candidate, Department of Pharmacology and Molecular Sciences, School of Medicine, Thesis Committee, 2013-2014.

Chen Yue, PhD candidate, Biostatistics, Bloomberg School of Public Health, Oral Examination Committee member. 2013. Thesis Committee member, 2013-2016.

Evelyn Eisele, PhD Candidate, Pharmacology and Molecular Sciences, School of Medicine, Thesis Committee Member, 2013-2016.

Katharina Maisel, PhD Candidate, Biomedical Engineering, School of Engineering, Thesis Committee Member, 2013-2014.

Kai Deng, PhD Candidate, Biochemistry, Cellular and Molecular Biology (BCMB) Graduate Program, Thesis Committee Member, 2013-2014.

Christopher Saeui, PhD candidate, Biomedical Engineering. Oral exam committee. 2014

Julie Lade, PhD Candidate, Pharmacology and Molecular Sciences. Thesis Committee. 2014-2016

Ethel Weld, PhD Candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Exam Committee Member, 2015; Thesis Committee Member, 2015-present

Dominique Figueroa, PhD Candidate, Pharmacology and Molecular Sciences. Thesis Committee. 2015-2016

Clare Ruberman, PhD Candidate, Biostatistics. Oral Examination Committee, Member 2015. Thesis Committee Chair 2015-2018

Hugh Giovinazzo, PhD Candidate, Pharmacology and Molecular Sciences. Oral Examination Committee. 2015

Eugenie Shieh, PhD Candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Exam Committee Member, 2016; Thesis Committee Member, 2015-present

Thuy Huang, PhD Candidate, Pharmacology and Molecular Sciences. Oral Examination Committee. 2015-present

Matthew Ippolito, PhD Candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Exam Committee Member, 2016; Thesis Committee Member, 2017-present

Taarika Babu, PhD Candidate, Pharmacology and Molecular Sciences. Thesis Committee Member. 2017-present

Omamah Alfarisi, PhD Candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2018-present

EDUCATIONAL ACTIVITIES

Mentoring

Thesis/Oral Examination Committees – continued

Huilei Wang, PhD Candidate, Biomedical Engineering. Oral Exam Committee (Alternate) 2018.

Christy Pickering, PhD Candidate, Biomedical Engineering. Oral Exam Committee Chair 2018.

Inez Lam, PhD Candidate, Biomedical Engineering. Oral Exam Committee Chair 2018.

EDUCATIONAL ACTIVITIES

Mentoring

Training Grant Participation

Grant #: 4T32GM066691

Title: Clinical Pharmacology Training Program

Principal Investigator: C. Hendrix (as of 2016 multi-PI with K. Dooley)

Date: 07/01/08-06/30/2023

Award: \$196,485 current year direct costs

Role: Mentor Clinical Pharmacology Fellows in clinical research; pharmacokinetics teaching

Grant #: 1UL1TR001079-01

Title: Institutional Clinical and Translational Science Award

Principal Investigator: D. Ford

Dates: 9/17/07 – 4/30/18

Award: \$\$7,485,218

Role: Mentor post-doctoral fellows in Graduate Training Program in Clinical Investigation

Grant #: 5T32GM08763-14

Title: Pharmacology Training Grant

Principal Investigator: J. Liu

Date: 07/01/00 – 06/30/20

Award: \$312,004

Role: Train graduate students in clinical pharmacology teaching and research.

Grant #: 2T32AI007291-21

Title: Research Training in Microbial Diseases

Principal Investigator: K. Gebo

Date: 08/01/01 – 08/31/16

Award: \$267,125 current year direct costs

Role: Mentor Infectious Diseases Fellows in clinical research

Grant #: 5R25DA021630

Title: Pediatric Training Grant: Immersion in Drug Abuse Research

Principal Investigator: E. Gauda

Dates: 07/01/07-04/30/13

Award: \$301,715

Role: Johns Hopkins/Morgan State University research training aspects of illicit drug use.

Grant #: 5D43TW00010

Title: Fogarty AIDS International Training & Research Program

Principal Investigator: C. Beyrer

Dates: 07/01/07-05/31/13

Award: \$695,000

Role: Mentoring of international post-doctoral clinical research fellows.

EDUCATIONAL ACTIVITIES

Educational Program Building / Leadership / Administration

School of Medicine

Educational Policy and Curriculum Committee (EPCC), Student Assessment and Program Evaluation (SAPE) Subcommittee, member 2015-present

Medical Pharmacology (2nd year medical school)

Course Co-Director 1997-2001

Sectional Focus Group Leader (Introduction, Infectious Diseases, Rheumatology, Hepatology, Pain) 1997- 2003

Rational Therapeutics (4th year medical school, required course)

Initial Course Developer 1995

Course Director 1995-2004

Sessions jointly taught by experienced clinician and clinical pharmacologist to emphasize rational approach to therapeutic problems; focus on topics of keen interest to soon-to-be interns.

Analytical Methods in Clinical Pharmacology (Fellowship training curriculum, required course)

Initial Course Developer 2000

Course Director 2000-present

Cognitive and skill-based curriculum introduces quantitative aspects of clinical pharmacology in small-group problem-solving sessions.

Laboratory Science for the Clinical Investigator (Fellowship training curriculum, required course)

Initial Course developer 2017

Designed to provide an overview to clinical post-doctoral fellows and junior faculty planning clinical research studies that will rely on laboratory collaboration to support the clinical research. Curriculum covers a broad array of laboratory methods that describe quantitative laboratory methods, process of validation, quality control, and culture of laboratory-clinical interactions.

School of Public Health

Principles of Drug Development, (required GTPCI Course)

Course Director 1999-2003

Curriculum oriented around small-group “pharmaceutical team” skill-building exercises supplemented by didactic sessions (course director, industry and FDA medical reviewers) to provide fundamentals of the drug development process. Final exam includes visiting senior leadership from FDA to hear fully developed drug development plans designed by student teams.

EDUCATIONAL ACTIVITIES

Educational Program Building / Leadership - continued

US Air Force

US Air Force HIV Force wide Base Level Prevention & Education Program

Initial Program Development 1991

Course director 1991-1999

Lecturer/ Small Group leader 1991-1999

US Air Force wide HIV prevention program implemented based on identification and training of small multi-disciplinary base-level HIV prevention teams comprised of physician, nurse educator, public health officer and other health professionals who develop a local prevention plan tailored to meet local needs. Team building and training carried out initially and sustained over time at annual HIV/AIDS Train-the-trainer Short Course (24 hour CME units).

National

“Principles and Practice of Drug Development”

Sanctioned by Institute of Medicine, concept developed at Institute of Medicine Forum

Sponsored by Stanford University, The Burroughs Wellcome Fund, and The Doris Duke Charitable Foundation

2006 - Curriculum development consultant

2006 - Lectures (delivered at Stanford University and internet broadcast to dozens of registered U.S. university campuses via the Stanford University Center for Professional Development)

“Role of pharmacokinetics-pharmacodynamics in drug development”

“Pharmacokinetics bridging process and practice in drug development”

“Pharmacokinetic-Pharmacodynamic models in drug development”

Food and Drug Administration

“Academics to CDER” Annual CME Curriculum Development

Jointly developed curriculum between FDA Center for Drug Evaluation and Research Office of Training and Communication staff and Baltimore-Washington area academics

Target audience Baltimore-Washington Clinical Pharmacology Programs and FDA staff

2001-2004 Curriculum Development Committee

2003 “Tools for Pre-Approval Drug Safety Evaluation”, Course Director, Session Moderator, Lecturer

RESEARCH ACTIVITIES

Research Program Building / Leadership

Dates, name of research / basic science program, role

- 1989 – 1994 US Air Force/Henry M. Jackson Foundation HIV Research Program. Transitioned and substantially expanded existing observational database focused research program to integrated interventional clinical research organization collaborating in tri-service military medical consortium. Provided leadership and management of program during growth from initial staff of 4 to over 50 FTEs in clinical research program. Served initially as Research and Evaluation Unit Director (1989-1992), then Program Director (1992-1994).
- 1997 – Present Drug Development Unit (Division of Clinical Pharmacology) Reorganization. Reorganized existing clinical research unit, which focused on internal pharmaceutical industry-funded studies, to expand capacity to support investigator-initiated studies for faculty throughout the School of Medicine and refocused internal research portfolio to a primarily federally-funded clinical research enterprise. Served initially as Clinical Director (1997-1998), then overall Director (1998-Present).

ORGANIZATIONAL ACTIVITIES

Institutional Administrative Appointments (committees, dates)

Johns Hopkins University School of Medicine Committees:

Johns Hopkins Medicine Institutional Review Board (JHM IRB)

Member 2001- present

Co-Chairman IRB #2 – 2001 - 2007

Pharmacy & Therapeutics Liaison to JHM IRB 2001-present

Selection Committee, David S. Levine Award for Excellence in Mentoring, Department of Medicine, 2008

Department of Medicine, Appointment and Promotion Committee, 2009-present

Student Promotions Committee – Third and Fourth Years, 1996-2004

Student Promotions Committee – Second Year, 2000-2001

Joint Committee on Clinical Investigations, 1998-2001

Subcommittee (Pharmacy & Therapeutics Representative) 1998-2001

Graduate Training Program in Clinical Investigation,

Research Review Committee, 2/00-9/2006

Search Committee, Chief, Division of Infectious Diseases, Department of Medicine, 2004-2005

Search Committee, Clinical Pharmacology Faculty, Department of Medicine, 2004-2005

Search Committee, Pharmacology Faculty, Department of Pharmacology, 2004

The Johns Hopkins Hospital Committees:

Pharmacy and Therapeutics Committee, 1995-present

Joint Antibiotic Subcommittee, Chairman, 1998-2002

Editorial Activities

Journal Editorial Board

Clinical Pharmacology and Therapeutics (2005 – 2008)

Clinical and Translational Science (2007 – 2015)

Pharmacology Research & Perspectives (2017-present)

ORGANIZATIONAL ACTIVITIES

Journal Peer Review Activities

AIDS Research and Human Retroviruses (2006 – present)
Antiviral Research (2001 – present)
Clinical Drug Investigation (2006 – present)
Clinical Infectious Diseases (2006 – present)
Clinical Pharmacokinetics (2014-present)
Clinical Pharmacology and Therapeutics (2002 – present)
Clinical and Translational Science (2007 – present)
Contraception (2006 – present)
International Journal of STD & AIDS (2014-present)
Journal of Acquired Immune Deficiency Syndromes (2003 – present)
Journal of Antimicrobial Chemotherapy (2014-present)
Journal of Clinical Pharmacology (2014-present)
Journal of Infectious Diseases (2006 – present)
Journal of Pharmacology and Experimental Therapeutics (2002 – present)
Lancet HIV (2016 – present)
Medicine (2009 – present)
Neurology (2011 – present)
PLOS One (2014 – present)

Advisory Committees, Review Groups/Study Sections (sponsor, role, date)

Office of AIDS Research Advisory Committee, National Institutes of Health, *ex officio* member
Department of Defense, 1995-1999

AIDS Clinical Trials Group IBT RAC, General Immune Modulation Subcommittee, National
Institutes of Health, 1997-1998

General Clinical Research Centers, Division of Research Resources, National Institutes of Health;
Study Section, Site Reviewer, 1998

Therapeutics Research Working Group, Office of AIDS Research Advisory Committee, National
Institutes of Health, 1999-present

General Clinical Research Centers, Division of Research Resources, National Institutes of Health;
Study Section, Site Reviewer, 2002

Institute of Medicine, Panel Member, Panel on “Institutional Review Boards: Health Services
Research Data Privacy Protection”, 2000

U.S. Dept. of Agriculture, National Organic Standards Board, Technology Advisory Panel,
Reviewer, 2002

ORGANIZATIONAL ACTIVITIES

Advisory Committees, Review Groups (sponsor, role, date) – continued

Centers for Disease Control and Prevention, Chairman, Special Grant Review Panel, PA “Clinical Evaluation and Testing of Vaginal Microbicide Candidates.” August 2003

National Institutes of Health, NIAID special review meeting PAR 03-138 entitled "Novel HIV Therapies: Integrated Preclinical/Clinical Program" March 2004

National Institutes of Health, NIGMS, Clinical Pharmacology Training Grant (T32), Special Emphasis Panel; Site Visit team. July 2004

National Institutes of Health, NIAID Special Emphasis Panel RFA-AI 04-047 "Partnership for Topical Microbicides” Review Committee, April 2005

National Institutes of Health, NIGMS, Clinical Pharmacology Training Grant (T32), Special Emphasis Panel. June 2005

Centers for Disease Control and Prevention (CDC), Board of Scientific Counselors, National Center for Infectious Diseases, March 2005 – 2007

Medical Research Council of Ireland, Clinical Research Infrastructure Grant Reviewer, 2006

American Foundation for AIDS Research (amfAR), Rectal HIV Transmission Targeted RFP, Scientific Reviewer, August 2006

SyNCH Trial (Single and Multiple Dose Escalation Phase I Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Orally Administered Silymarin (Legalon®) in Non-Cirrhotic Subjects with Chronic Hepatitis C or Non-Alcoholic Fatty Liver Disease), Safety Monitor, 2006

Food and Drug Administration (FDA),
Antiviral Drugs Advisory Committee, 2007 – 2010
Oncology Drugs Advisory Committee 2017

National Institutes of Health, NIAID Special Emphasis Panel RFA-AI-07-019 "Novel HIV Therapies: Integrated Preclinical/Clinical Program (U19)” Review Committee, October 2007

Population Council Microbicides Scientific Advisory Board, 2009 – present

National Institutes of Health, NIGMS, Clinical Pharmacology Training Grant (T32), Special Emphasis Panel; Study Section, Site Visit team. July 2014, July 2015

PREVENT U19 Program Project Grant, University of Louisville, KY, Scientific Advisory Board (2017-present)

UNC Chapel Hill Center for AIDS Research Scientific Advisory Board (2016-present)

ORGANIZATIONAL ACTIVITIES

Professional Societies (membership, committees, dates, role)

Alpha Omega Alpha Honor Medical Society 1983-present

Infectious Diseases Society of America 1989-1998

Civil-Military Alliance to Combat HIV/AIDS, 1996-2002; Steering Committee, 1999-2002

Armed Forces Infectious Diseases Society, 1997-1999

International Society of Antiviral Research
Scientific Program Committee Reviewer 2001

International AIDS Society 1997 - present
Industry Liaison Forum 2005

American Society for Clinical Pharmacology and Therapeutics (ASCPT) 1997 – present
Board of Directors, 2010 – 2012
Coordinating Committee on Scientific Sections, 2004-2010
Chairman 2010-2012
Vice Chairman 2008 – 2010
Infectious Diseases and Antimicrobial Agents Section, 1997-present
Chairman 2005 – 2008
Vice Chairman 2004 – 2005
Steering Committee 2018-present
Scientific Program Committee, 1998-2002, 2005-2008
ASCPT Nominating Committee, 2004-2005, 2014-2015
Education Committee-1999-2002, 2015-present
Social Media Task Force 2014-2015
Mentor Task Force 2015-present
Career Development Committee 2016-present
Webinar Committee 2017

International Society of Pharmacometrics 2011 – 2015

American College of Clinical Pharmacology 2018-present

ORGANIZATIONAL ACTIVITIES

Conference Organizer, Session Chair (sponsor, date, role) - continued

Thirty-First International Congress of Military Medicine, “Medical Response to Chemical Warfare”, Beijing, People’s Republic of China, Symposium Co-Chair, December 1996.

Third Congress on AIDS in Asia and the Pacific, “Military AIDS Symposium”, Manila, Philippines, December 1997, Symposium Co-chair.

American Society for Clinical Pharmacology and Therapeutics, “Post-Marketing Surveillance”, San Antonio, Texas March 1999, Symposium Co-Chair.

American Society for Clinical Pharmacology and Therapeutics, “Novel Pharmacokinetic Methods for Developing HIV Chemoprevention Strategies”, Orlando, Florida March 2005, Workshop Organizer, Co-Chair.

American Society for Clinical Pharmacology and Therapeutics, “Pharmacokinetics and Clinical Applications”, Baltimore, Maryland, March 2006, Session Co-Chair.

Microbicides 2012, “Can we determine who uses? Self reports and objective measures of adherence in microbicide & PrEP trials”. Sydney. April 2012. Symposium committee.

American College of Clinical Pharmacology. “Symposium VII: Adherence: Missing Link in the Puzzle of Clinical Pharmacology”. Bethesda, MD. September 2013. Session Co-Chair.

HIV Research for Prevention (HIVR4P). “Long-acting Drug Release Systems for PrEP and Treatment.” Chicago, IL. October 2016. Session Co-Chair.

HIV Research for Prevention (HIVR4P). “Choosing ARVs for Prevention: Ensuring and Measuring Effective Tissue Delivery” Chicago, IL. October 2016. Session Co-Chair.

Conference on Retroviruses and Opportunistic Infections (CROI). “Of Mice, Monkeys, and Men: Prep from Preclinical to Population Level Impact”. Boston, MA. March 2018. Session Co-Chair.

RECOGNITION

Awards, Honors

Distinguished Military Graduate, Massachusetts Institute of Technology, AFROTC, 1978

Air Force Commendation Medal (USAF), 1980

Alpha Omega Alpha Honor Medical Society, 1983

Department of Medicine Award for Outstanding Academic Performance, Georgetown University, School of Medicine, 1984

Cahill Award for Academic Excellence in Surgery, Georgetown Univ., School of Medicine, 1984

Magna cum Laude Graduate, Georgetown University, School of Medicine, 1984

Meritorious Service Medal (USAF), 1994

Meritorious Service Medal, First Oak Leaf Cluster (USAF), 1997

Pharmaceutical Research and Manufacturers Association Faculty Development Award, 1997

Outstanding Pharmacology Professor (Basic Sciences), Medical Student Association, 2001-2002

Student Marshal, Medical School Graduation, Class of 2002

Johns Hopkins Alumni Association Excellence in Teaching Award, 2003

David M. Levine Faculty Mentoring Award (Department of Medicine) 2007

PhRMA Foundation Award in Excellence 2017

American College of Clinical Pharmacology, Distinguished Investigator Award 2018

RECOGNITION**Invited Talks, Panels**

1. “A Risk-Benefit Perspective on Universal HIV Screening in the United States Air Force.” 1991, Buenos Aires, Argentina. Invited Talk, 17th Meeting of the Committee on Medicine in the Air Forces in the Americas. Sponsor: Committee on Medicine in the Air Forces in the Americas.
2. “International Security Impact of the HIV/AIDS Epidemic”. 1995. Kampala, Uganda. Invited Talk, Africa Regional AIDS Conference, Military AIDS Symposium. Sponsor: UNAIDS.
3. “HIV Prevention Policy in Military Organizations”. December 1996. Beijing, People’s Republic of China. Invited Talk, Thirty-First International Congress of Military Medicine, Beijing, China. Sponsor: Peoples Liberation Army, People’s Republic of China.
4. “Planning Effective HIV Prevention Interventions in the Military”. October 1998. St. Petersburg, Russian Federation. Invited Talk, Kirov Military Medical Academy. Sponsor: Russian Federation Ministry of Defense.
5. “Drug Interaction Research Issues in Heavily Treated HIV-infected Patients”. May 1999. Toronto, Canada. Invited Talk, International AIDS Society – Industrial Liaison Forum: The Challenge of Clinical Trial Design in Evaluating HIV Antiretroviral Use in Heavily-Pre-Treated Patients (Conference). Sponsor: International AIDS Society.
6. “Pharmacology of Antiretroviral Drugs in the Genital Tract”. August 1999. Atlanta, Georgia. Invited Talk, National HIV Prevention Conference. Sponsor: CDC.
7. “COX-2 Inhibitors: Evaluation of New NSAIDs”. September 1999. Towson, Maryland. Invited Talk, Arthritis Foundation of Maryland (Sponsor).
8. “Potential Drug Interactions in Antiviral Therapy”. May 2000. Madrid, Spain. Invited Talk, European Congress on Chemotherapy-3 (Sponsor).
9. “Clinical Pharmacology of Rectal Microbicides”. Atlanta, February 2001. Invited Talk, Centers for Disease Control (CDC) Conference on Rectal Microbicides, Sponsor: CDC.
10. “Preventing Fungal Infections”. May 2001. Baltimore. Medical Grand Rounds, Johns Hopkins University School of Medicine. Sponsor: Department of Medicine.
11. “Pharmacologic Studies in the Development of Rectal Microbicides”, June 2001. Baltimore. Invited Talk, Rectal Microbicide Workshop. Sponsor: NIH Office of AIDS Research.
12. “Development of Beta-Cyclodextrin as a Topical HIV Microbicide Candidate”, August 2001. Rockville. Invited Talk, NIH Division of Antiviral Drug Products. Sponsor: FDA.
13. “Drug Interactions in Combined Hepatitis C-HIV Chemotherapy”, April 2002. Aspen. Strategies for the Management of HIV/HCV Coinfection. Sponsor: Perspectives in Medicine.

RECOGNITION**Invited Talks, Panels – continued**

14. “Quantitative Safety Assessment in Microbicide Development”, May 2002. Antwerp, Belgium. Invited Talk, Microbicides 2002. (Cancelled)
15. “Distribution of Candidate Microbicide Gel and Simulated Ejaculate in the Lower Gastrointestinal Tract”, June 2003. Los Angeles. Invited Talk, UCLA Center for HIV and Digestive Diseases (Sponsor).
16. “Clinical Development of a CXCR4 Chemokine Inhibitor”, June 2003. New York City. Invited Talk, Entry Inhibitor Special Issue Advisory Board. Sponsor: Glaxo-Smith-Kline.
17. "Rational Development of Rectal Microbicides: Pharmacology, Toxicity, and Acceptability", July 2003. Atlanta. Invited Talk, National HIV Prevention Conference. Sponsor: CDC.
18. “Development of a CXCR4 Chemokine Receptor Inhibitor for HIV Infection”, December 2003. Towson. Invited Talk, Towson University. Sponsor: Towson University.
19. “Distribution of Rectal Microbicide Vehicle and Simulated Ejaculate following Simulated Coital Activity” January 2004. New York City. Invited Talk, Columbia University. Sponsor: Columbia University, School of Medicine.
20. “Delivery of Microbicide to “At Risk” Intestinal Mucosa” March 2004. London. Invited Talk, Challenges to Rectal Microbicide Development (Satellite): Microbicides 2004.
21. “Critical Pharmacologic Issues in Vaginal and Rectal Microbicide Development” October 2004. Providence. Visiting Professor. Sponsor: Tufts University - Brown University Center for AIDS Research.
22. “Pharmacologic Issues in HIV Chemoprevention.” February 2005. Boston. Invited Talk, International AIDS Society - Industry Liaison Forum, 12th National Conference on Retroviruses and Opportunistic Infections. Sponsor: International AIDS Society.
23. “Clinical Pharmacokinetics and Pharmacodynamics of Chemokine Inhibitors.” February 2005. Boston. Invited Talk, 12th National Conference on Retroviruses and Opportunistic Infections. Sponsor: International AIDS Society.
24. “Adaptations of Radiologic Methods With Coital Simulations To Assess The Pharmacokinetics Of Topical Microbicides In The Vagina And Rectum”, March 2005. Orlando. Invited Talk, Workshop on “Novel Pharmacokinetic Methods for Developing HIV Chemoprevention Strategies” Sponsor: American Society for Clinical Pharmacology and Therapeutics.
25. "Microbicides for HIV Prevention: Development Challenges for Clinical Pharmacology". April 2005. Quebec City. Invited Talk, 6th International Workshop on Clinical Pharmacology of HIV Therapy (Sponsor).

RECOGNITION**Invited Talks, Panels – continued**

26. “Pharmacological Aspects of Microbicide Development”. July 2005. Rio de Janeiro. Invited Talk, Challenges in HIV Microbicide Development. UCLA AIDS Institute and Brazilian STD/AIDS Program (Satellite Meeting): 3rd International AIDS Society Conference on HIV Pathogenesis and Treatment. Sponsor: International AIDS Society
27. “Clinical Pharmacology Challenges in Topical HIV Microbicide Development”. September 2005. Buffalo. Visiting Professor. University of Buffalo School of Pharmacy and Pharmaceutical Sciences and School of Medicine/VA Medical Center.
28. “Making Drugs Safer” November 2005. Baltimore. Invited Talk, A Woman’s Journey. Sponsor: Johns Hopkins University.
29. “HIV Chemoprevention: Evolving Approaches to Prevent HIV Infection with Drugs” Baltimore, January 2006. Invited Talk, Department of Medicine Grand Rounds (Sponsor).
30. “Rectal Microbicide Development: Measuring Gel & Virus Distribution” Web-Cast Teleconference, March 2006. Invited Talk, International Rectal Microbicides Working Group
31. “Drug Distribution & Formulation Issues in Rectal Microbicide Development” Cape Town, April 2006. Invited Talk, Rectal Microbicide Satellite Meeting. Microbicides 2006. Sponsor: UCLA AIDS Institute.
32. “Role of pharmacokinetics-pharmacodynamics in drug development”; “Pharmacokinetics bridging process and practice in drug development”; “Pharmacokinetic-Pharmacodynamic models in drug development”. Palo Alto, National Webcast, April 2006. Invited talks, Principles and Practice of Drug Development Course. Sponsor: Stanford University and Institute of Medicine
33. “Rectal Microbicide Development: Contrasts to Traditional Drug and Vaginal Microbicide Development”, Washington, D.C., May 2006. Invited Talk, Department of Health Policy, School of Public Health, George Washington University (Sponsor)
34. “Rectal HIV Microbicide Pharmacology & Drug Development” Raleigh-Durham, June 2006. Visiting Professor, Duke University Pratt School of Engineering, Department of Biomedical Engineering (Sponsor).
35. “Debate: Why Microbicides Will Fail” Arlington, September 2006. Invited Talk, Biomedical Interventions for HIV Prevention Working Group Meeting. Sponsor: Forum for Collaborative HIV Research Workshop.
36. “Topical HIV Microbicide Development: Evolving Challenges”, Baltimore, November 2006. Invited Talk, Department of Pathology Grand Rounds (Sponsor).

RECOGNITION**Invited Talks, Panels – continued**

37. "A Phase I, Dose-Rising Study of AMD11070 in HIV-Seronegative Men to Assess the Safety and Pharmacokinetics after Single or Multiple Doses," Baltimore, December 2006. Invited Talk, Plenary session, AIDS Clinical Trials Group. Sponsor: NIH.
38. "Reporting Scientific Misconduct – Deciding When and How to Act." Washington, D.C., December 2006. Invited Talk, Panel Member. Compliance and Investigator Fraud in Clinical Trials. Sponsor: CBI.
39. "Topical HIV Microbicide Development." Philadelphia. March 2007. Visiting Professor, Thomas Jefferson University, Division of Clinical Pharmacology (Sponsor).
40. "How Does Clinical Pharmacology Enhance HIV Microbicide Development?" Boston. April 2007. Visiting Professor, Tufts University, Division of Infectious Diseases (Sponsor).
41. "Pharmacology and Comparative Properties of NSAIDs." Miami, May 2007. Invited Talk, Panel member, Osteoarthritis and NSAIDs: Scientific Expert Panel Meeting. Sponsor: MDG
43. "HIV Microbicide Development from a Clinical Pharmacology Perspective." Seattle, July 2007. Invited Talk. Center for AIDS Research Pathogenesis Seminar Series, University of Washington.
44. "Clinical Study Design in Drug Development." Chicago, September 2007. Invited Talk. Science for Managers, Kellogg School of Management, Northwestern University.
45. "Distribution of Microbicide and HIV Surrogates in the Rectum and Distal Colon to Inform Rational Rectal Microbicide Development". Durban, South Africa., October 2007. Invited Talk. Nelson R. Mandela School of Medicine, University of KwaZulu-Natal, South Africa.
46. "Sparse Sampling Strategies in the Development of Vaginal Microbicide Candidates to Relationships Between Drug Exposure and Seroconversion Outcomes". Durban, South Africa, October 2007. Invited Talk: South Africa Medical Research Council, HIV/AIDS Lead Programme and HIV Prevention Research Unit.
47. "Pharmacokinetic Issues in ARV Microbicide Resistance". New Delhi, February 2008. Invited Talk, Microbicides 2008.
48. "Methods to Develop a Rectal-Specific Microbicide". New Delhi, February 2008. Invited Talk. Microbicides 2008.
49. "New Methods in Prevention of HIV Infection". Ames, March 2008. Invited Talk. Stupka Symposium, Iowa State University.

RECOGNITION**Invited Talks, Panels – continued**

50. “Antiretroviral -based Microbicides Pharmacokinetics-Pharmacodynamics and Resistance”. Cape Town, September 2008. Invited Talk. International Partnership for Microbicides Annual Meeting.
51. “Unique Contributions of MTN-001 to Microbicide Development Methodology”. Cape Town, September 2008. Invited Talk. Microbicide Trial Network, Regional Investigator’s Meeting.
52. “Pharmacokinetics & Future Pharmacodynamic Links”. Cape Town, September 2008. Invited Talk. Microbicide Trial Network, Regional Investigator’s Meeting.
53. “Microbicide Development Pipeline: Candidates, Mechanisms, Formulations, Clinical Phase” Cape Town September 2008. International Partnership for Microbicides Annual Meeting.
54. “Clinical Study Design in Drug Development” Chicago, September 2007. Invited Talk. Science for Managers, Kellogg School of Management, Northwestern University.
55. “Academic Contributions to Translational Drug Development”. Shanghai, September 2008. International Clinical Research and Translational Medicine Symposium, Fudan University.
56. “Clinical Pharmacology Approach to HIV Chemoprevention Drug Development”. Rochester, MN, October 2008. Invited Talk. Mayo Clinic.
57. “PK-PD in HIV Chemoprevention Studies” Atlanta. December 2008. AIDS Vaccine Advocacy Coalition (AVAC) sponsored meeting on Intermittent PrEP Development.
58. “Three-dimensional Problems in Imaging Drugs for HIV Chemoprevention” Baltimore 2008. Department of Biostatistics Grand Rounds, Johns Hopkins University School of Public Health.
59. “Drug Concentrations as an adherence biomarker in HIV prevention” New York January 2009. Quick Clinical Trials Working Group meeting on measuring adherence in HIV prevention trials.
60. “HIV Prevention with Drugs: Using Clinical Pharmacology to Put "Rational “Back in Drug Development.” Baltimore March 2009. Department of Medicine, Grand Rounds.
61. “HIV Prevention with Topical Microbicides: Using Clinical Pharmacology to Put 'Rational' Back in Drug Development” Amsterdam April 2009. 10th HIV Clinical Pharmacology Workshop.
62. “Quantitative Pharmacokinetics of the Male Genital Tract and Applications in Drug Development”. Invited Lecture. Atlanta March 2010. 111th Annual meeting of the American Society for Clinical Pharmacology and Therapeutics.

RECOGNITION**Invited Talks, Panels – continued**

63. “HIV Prevention with Drugs”. Invited plenary speaker. Hopkins-Brazil HIV Conference, Rio de Janeiro, April 2010.
64. “Pharmacology methods in prevention trials: assessing compartments and adherence”. Invited talk, Laboratory Plenary Session, HIV Prevention Trials Network Annual Meeting. Washington, DC. April 2010.
65. “Pharmacokinetic Assessment of Adherence”. Invited Talk. Microbicides 2010, May 2010, Pittsburgh.
66. “What Role Pharmacokinetics-Pharmacodynamics?” Invited Talk. Cape Town October 2010. Africa Regional Meeting of Microbicide Trial Network.
67. “Pharmacokinetics and Adherence in PrEP Development”. Invited Talk. San Francisco. November 12, 2011 Forum for Collaborative HIV Research: 5th PrEP Working Group.
68. “The Role of Clinical Pharmacology in the Development of Topical HIV Microbicides” Visiting Professor. Pittsburgh. January 2011. University of Pittsburgh.
69. “MTN-001 Phase 2 Adherence and Pharmacokinetic Study of Oral and Vaginal Preparations of Tenofovir.” Invited Talk. Microbicide Trial Network Annual Meeting. Arlington. March 2011.
70. “Use of Pharmacokinetics for Understanding Outcomes in HIV Prevention Trials” Invited Talk. Lab Plenary HIV Prevention Trials Network Annual Meeting, Washington, DC. June 2011.
71. Pharmacological assessment of medication adherence – Oral PrEP and Microbicides”. Invited Talk. 19th International Society for STD Research. Quebec City. July 2011.
72. “Pharmacokinetics and Tissue Concentrations of Tenofovir and Emtricitabine: What is Needed to Prevent Transmission?” Invited Talk. Plenary HIV Vaccine Trials Network Annual Meeting. Seattle. November 2011.
73. “Clinical Pharmacology in HIV Pre-Exposure Prophylaxis Drug Development: Developing and Applying Tools when the Train has left the Station.” Invited Talk. FDA Office of Translational Science. Silver Spring. January 2012.
74. “Attempts to Improve the Rational Development of HIV Pre-Exposure Prophylaxis through Clinical Pharmacology”. Invited Talk. Mercer University. School of Pharmacy. Atlanta. February 2012

RECOGNITION**Invited Talks, Panels – continued**

75. “Clinical Pharmacology in PrEP Development: Can small intensive studies inform RCTs?” Invited Talk. Microbicide Trials Network Annual Meeting. Bethesda, February 2012.
76. “Exploring Outcome Variability Across HIV Pre-Exposure Prophylaxis (PrEP) Trials”, Anti-infective Section, ASCPT Annual Meeting. National Harbor, MD March 2012.
77. “Antiretroviral Pharmacology for PrEP: Enhancing RCT Understanding with Small Intensive Studies”, Treatment as Prevention/Pre-Exposure Prophylaxis Summit. London, June 2012.
78. “Making Sense of Oral PrEP trials: Little Studies Informing Big Studies”, Plenary Session, HPTN Annual Meeting. Washington, DC, June 2012.
79. “Oral & Topical PrEP: Unifying RCT Outcomes”, Invited Talk, 7th HIV Transmission Workshop, Washington, DC. June 2012.
80. “Pharmacokinetic Assessment of PrEP Adherence”, Invited talk, NIH DAIDS Behavioral Science Working Group Data Capture Technologies Focus Group, 11 October 2012.
81. “A Pharmacological Perspective on HIV Explant Challenge”, invited talk, Biopsy Challenge meeting, NIH-Bill and Melinda Gates Foundation, Washington, DC, 29 November 2012.
82. “Genital and Anal Tract PrEP Pharmacokinetics”, Office of AIDS Research Advisory Council Annual Meeting, Washington, DC, 8 November 2012.
83. “Measuring PK & Adherence in PrEP Trials: Explanation & Prediction”, invited talk, RIHES, Chiang Mai University, Chiang Mai, Thailand, 7 January 2013.
84. "Clinical Pharmacology Approach to Rational Rectal Microbicide Development", Invited talk, Thai Red Cross/HIV-NAT, Chulalongkorn Univ, Bangkok, Thailand, 10 January 2013.
85. “Measuring PK & Adherence in PrEP Trials: Explanation & Prediction”, Invited talk, Department of Medicine, University of Malaya, Kuala Lumpur, Malaysia, 15 January 2013.
86. “Pharmacological Approach to Monitoring Drug Adherence”, Plenary Lecture, Microbicide Trials Network Annual Meeting. Bethesda, MD. February 2013.
87. “Enriching the design of clinical PK/PD studies of novel drug delivery systems”, Invited Talk, Bill & Melinda Gates Foundation – NIH Think Tank on HIV Prevention Drug Delivery Systems. Washington, DC. February 2013.
88. “PK Assessment of Adherence in PrEP Trials” Pharmacometrics in Antiviral Drug Development Symposium, Annual Meeting of ASCPT, Indianapolis, 8 March 2013.

RECOGNITION**Invited Talks, Panels – continued**

89. “Pharmacometric approaches to adherence assessment in HIV prevention trials.” Mercer University Invited talk. Atlanta, 5 March 2013.
90. “How PK (could) inform PrEP Trials”. Invited Talk, NIH, Division of AIDS Seminar, Bethesda, 15 March 2013.
91. “Pharmacological Aspects of PrEP”, Invited Talk, Hopkins-Brazil HIV conference, Rio de Janeiro, Brazil 19 April 2013.
92. “Pharmacological Challenges for Next Generation PrEP”, Invited Talk, 14th International Workshop on Clinical Pharmacology of HIV Therapy, Amsterdam, Netherlands, 23 APR 2013.
93. “Making sense out of oral and topical PrEP trials: Using little studies to understand big studies,” Invited Talk, Annual Meeting of HIV Prevention Trials Network, Washington, DC, 6 May 2013.
94. “Scientific Misconduct”. Invited Talk. FDA Office of Criminal Investigations. Charleston, SC, 18 June 2013.
95. “Exploring concentration-response in HIV Pre-Exposure Prophylaxis to optimize clinical care and trial design.” Cell-Lancet Conference “What will it take for an AIDS Free World”. San Francisco, 4 November 2013.
96. “HIV Pre-Exposure Prophylaxis: Clinical Pharmacology Insights”. Invited Talk, 21st Conference on Retroviruses and Opportunistic Infections, Boston, Mar 4, 2014.
97. “Adherence : Impact on Study Results” CONRAD/AVAC Adaptive Trial Designs Conference. Washington, DC. June 23, 2014.
98. “The Role of Pharmacokinetics in selecting PrEP strategies”. Invited Talk, 54th Interscience Conference on Antibiotics and Antimicrobial Therapy. Washington, D.C. September 9, 2014.
99. “HIV Pre-exposure Prophylaxis (PrEP) Trials: Making the Complex Simpler through Clinical Pharmacology”. Invited Talk, Medical Grand Rounds, Western Ontario University, London, Ontario, September 17, 2014.
100. “Combining Pharmacology and Behavioral Science to Develop a Rectal Microbicide for HIV PrEP that People will Enjoy Using”. Invited talk, Columbia University. Sponsor: Columbia University, School of Medicine. December 18, 2014.

RECOGNITION**Invited Talks, Panels – continued**

101. “HIV Pre-Exposure Prophylaxis: Clinical Pharmacology Enriching Drug Development”. Invited Talk, Dartmouth University, Division of Clinical Pharmacology. Lebanon, NH 23 June 2015.
102. “Pharmacokinetics in Microbicide Development”. Invited Talk. NIH/DAIDS MTN Conference, “The Use of Mucosal Assays in Microbicide Trials” Arlington, VA 25-26 August 2015.
103. “Real-Time” Pharmacologically-based Adherence Testing”. Invited Talk. NIH/DAIDS Conference “Optimizing Adherence Post-VOICE”, Rockville, MD 2-3 September 2015.
104. “HIV Pre-Exposure Prophylaxis (PrEP) & Development of Microbicides”. Invited Talk. American College of Clinical Pharmacology Annual Meeting, “An Update on HIV Treatment, Prevention and Drug Development Symposium”, San Francisco, CA 28 September 2015.
105. “HIV Pre-Exposure Prophylaxis (PrEP) & Development of Microbicides”. Invited Talk. University of California at San Diego Center for AIDS Research, San Diego, CA 23 October 2015.
106. “HIV Pre-Exposure Prophylaxis Drug Development”. Invited Talk. Medical Grand Rounds, General Hospital, Tijuana, Mexico, 26 October 2015.
107. “Pharmacologic Adherence Assessment & Application in PrEP”. Invited Talk. 2015 Center for AIDS Research (CFAR) Social and Behavioral Sciences Research Network Conference, Baltimore, MD 29 October 2015.
108. “Developing Behaviorally-Congruent Rectal Microbicides: A Clinical Pharmacology Approach”. US-Japan Conference USAID, Bethesda, MD. 12 January 2016.
109. “Lessons Learned from Antiretroviral Testing”. Invited Talk . UCLA CFAR-Sponsored Substance Use Meeting: Advancing the Field of Biobehavioral Substance Use Measurement for HIV Positive and At-risk Populations. Los Angeles, CA. 1 February 2016.
110. “Development of HIV Pre-exposure Prophylaxis: A Clinical Pharmacologist’s Inside View”. Invited Talk. University of North Texas Health Science Center. Fort Worth, TX. 8 April 2016
111. “Building on Oral PrEP Success: Rectal Microbicide Development”. Invited Talk. DC Center for AIDS Research, Howard University, Washington, DC. 4 May 2016.
112. “HIV Pre-Exposure Prophylaxis Development: A Clinical Pharmacologist’s Inside View”. Invited Talk. KU Leuven, Leuven, Belgium. 17 May 2016.

RECOGNITION**Invited Talks, Panels – continued**

113. “PK-PD Data to Advance Topical PrEP Products to Phase III”. Invited Talk. Clinical Trial Evaluation Workshop for MPTs. Initiative for Multipurpose Prevention Technologies (IMPT). Washington, DC. 13 September 2016.
114. “Rectal vs. Vaginal Compartment Pharmacology.” Invited talk. Contribution of Sexual Behaviour in the Global Heterosexual HIV Epidemic Workshop. NIH/DAIDS. Bethesda, MD. 15 September 2016.
115. “Pharmacologic Considerations for HIV Prevention Strategies”. Invited talk. Western New York HIV Prevention Network Meeting. University of Buffalo, Buffalo, NY. 19 September 2016
116. “HIV Pre-exposure Prophylaxis Development: A Clinical Pharmacologist’s Inside View”. Invited talk. Combating HIV/AIDS: Tx, PGx and PrEP Workshop, ACCP Annual Meeting. HIV symposium. San Diego, CA. 24 September 2016.
117. “Quantitative Assessment of Adherence: Experiences in HIV Prevention”. Invited Talk. National Institute of Drug Abuse, Baltimore, MD 20 December 2016.
118. “Rectal Microbicide Development & DREAM Progress”. Invited talk. Tenofovir Development Meeting, MTN Annual Meeting. Bethesda, MD. 20 March 2017.
119. “Developing Alternatives to Oral HIV PrEP: Rectal Microbicides & Long-Acting Formulations”. Invited Talk. University of Texas Health Science Center, Galveston. April 2017.
120. “For Something Completely Different: Development of a Rectal Enema as Microbicide”. Invited Talk. Oak Crest Institute of Science, Monroeville, CA May 2017.
121. “Rectal Microbicide Development: How Did We Get Here? What Have we Learned?” Invited webinar talk. Sponsored by AIDS Vaccine Advocacy Coalition (AVAC) and International Rectal Microbicide Advocates (iRMA). August 2017.
122. “Rectal Microbicides: Where We’re Heading”. Invited webinar talk. Sponsored by AIDS Vaccine Advocacy Coalition (AVAC) and International Rectal Microbicide Advocates (iRMA). August 2017.
123. “Impact of adherence on the development of HIV Pre-exposure Prophylaxis” Invited Symposium Talk (delivered Mark Sales), American College of Clinical Pharmacology Annual Meeting. San Diego, CA. September 2017.

RECOGNITION**Invited Talks, Panels – continued**

124. “Advances in Formulations in HIV PrEP: Topical Products - Rings, Gels, Implants, etc.”
Invited Symposium talk (delivered Marc Baum), American College of Clinical Pharmacology Annual Meeting. San Diego, CA. September 2017.
125. “Review of the Current Rectal Microbicide Context”. Invited Talk. Reboot the Booty Think Tank. Sponsored by AIDS Vaccine Advocacy Coalition (AVAC) and International Rectal Microbicide Advocates (iRMA). New York, NY. September 2017.
126. “Lube Safety 101”. Symposium on Lubricant Safety, US Conference on AIDS. Washington, DC. September 2017.
127. “Next Generation PrEP? Injectable & Implantable ARVs”. Plenary Talk. Microbicide Trial Network Regional Meeting, Cape Town, RSA. September 2017.
128. “The Path Ahead for Rectal Microbicides”. Plenary Talk. Microbicide Trials Network Regional Meeting, Cape Town, RSA. September 2017.
129. “DREAM Program for Rectal Microbicide Prevention”. Invited talk. PREVENT Program Project Annual Meeting. Louisville, KY. October 2017.
130. “Promise & Progress of Rectal Microbicides for HIV Pre-Exposure Prophylaxis”. Invited Talk. Center for AIDS Research. University of Alabama, Birmingham, AL. November 2017.
131. “Microbicides: Where We’re Heading” Invited Talk. Second Annual Biomedical HIV Prevention Summit (NMAC). New Orleans, LA. December 2017
132. “Clinical Pharmacology of HIV Pre-Exposure Prophylaxis (PrEP) – Where are we now?”
Visiting Professor. University of Liverpool. Liverpool, UK. February 2018.
133. “Beyond Oral PrEP: Promise and Challenges of Alternative Antiviral Dosing Methods for PrEP”. Invited Lecture. Office of AIDS Research Brown Bag Seminar. Brockville, MD. February 2018.
134. “Beyond Oral PrEP: Promise and Challenges of Alternative Antiviral Dosing Methods for PrEP” Invited Talk. 8th International Workshop on HIV & Women. Boston, MA. March 2018.
135. “Proof-of-Concept for On Demand, Behaviorally-Congruent Rectal Microbicide Douche”.
Plenary Lecture. MTN Annual Meeting. Bethesda, MD March 2018.
136. “Success, Disappointment, & *Hope* in the Development of HIV Pre-Exposure Prophylaxis”.
Invited Talk. Walter Reed Army Institute of Research, Silver Spring, MD. April 2018.

RECOGNITION

Invited Talks, Panels – continued

137. “Rectal Microbicide Product Development”. Invited talk. Oak Crest Institute of Science Program Project Annual Meeting. Monrovia, CA. May 2018.
138. “Pharmacology Lab Contributions to PrEP Product Development”. Invited Talk. HPTN Annual Meeting. Washington, DC. May 2018.
139. “Clinical Pharmacology of HIV Pre-Exposure Prophylaxis (PrEP) – Where are we now?” Invited Talk. International Workshop on Clinical Pharmacology of Antiviral Therapy. Baltimore, MD. May 2018.
140. “DREAM Program: On Demand, Behaviorally-Congruent Rectal Microbicide Douche”. Invited webinar talk. Sponsored by AIDS Vaccine Advocacy Coalition (AVAC) and International Rectal Microbicide Advocates (iRMA). June 2018.

Exhibit F

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Exhibit G

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