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

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

EXPERT REPORT OF CRAIG W. HENDRIX, M.D.

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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 report to provide my expert opinion regarding the U.S. Department of Defense ("DoD") and U.S. Army and Air Force 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 or from remaining in the Air Force.

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, including to combat zones, based solely on the fact they are living with HIV.

4. The opinions I express are my own and do not reflect the official policy of any organization with which I am affiliated.

5. My expertise regarding the subjects discussed below is based upon my own knowledge and experience, as well as my review of various materials cited herein.

A. Professional Background & Qualifications

6. I am currently a Professor of Medicine, Pharmacology and Molecular Sciences, and Epidemiology 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 1997, I joined the full-time faculty at The Johns Hopkins University School of Medicine in the Division of Clinical Pharmacology and

Division of Infectious Diseases and have been Director of the Drug Development Unit since 1998. In 2015, I was appointed as the Wellcome Professor and Director, Division of Clinical Pharmacology. In 2018, I received the Distinguished Investigator Award from the American College of Clinical Pharmacology, and in 2017, I was the recipient of the PhRMA Foundation Award in Excellence in Clinical Pharmacology. I have received the John Hopkins Alumni Association Excellence in Teaching Award, as well as the David M. Levine Faculty Mentoring Award.

7. Before joining the Johns Hopkins medical school faculty, I served on active duty for nearly 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 monitoring the condition of HIV-positive service members, studying behavioral risk factors associated with HIV, and educating service members about the treatment and prevention 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 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. In addition to research and teaching, I have served on several Food and Drug Administration Advisory Committees (Antiviral, Oncology, Arthritis, Drug Safety and Risk Management), the Institute of Medicine's Ad Hoc Advisory Committee, the National Center for Infectious Diseases' Board of Scientific Counselors, as well as in multiple leadership positions, including on the Board of Directors for the American Society for Clinical Pharmacology and Therapeutics and for the American Board of Clinical Pharmacology.

11. I have not testified as an expert at trial or at deposition in during the previous four years.

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

B. Materials Considered

13. In undertaking my analysis, I have considered information from a variety of sources that are identified in Exhibit 2 (Materials Considered), as well as relying on my

[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.

professional judgement and extensive experience in the fields of clinical pharmacology, drug development, and HIV treatment and prevention, both while in the military services and during civilian employment.

14. I reserve the right to make and use demonstratives to help explain my opinions.

C. Compensation

15. I am not receiving any compensation for my work or testimony in this litigation.

II. SUMMARY OF OPINIONS

16. HIV seropositivity is not inconsistent with the demands of military service. Service members living with well-managed HIV do not pose a cognizable danger to the health of other individuals through battlefield transmission, nor do they have a negative impact on military readiness or military blood supplies.

17. Based on the information I have reviewed, Nicholas Harrison was medically fit to be commissioned as an officer, as well as to be deployed or stationed overseas. My review of his medical records shows that his HIV was virally suppressed and has been for a number of years, his immune system is normal, and he received a strong assessment of his physical skills in his most recent Army physical. Sergeant Harrison was medically fit to serve as a JAG officer.

18. In my opinion, based on the information I have reviewed, Roe and Voe were medically fit to be deployed or stationed overseas. My review of their medical records shows that their HIV was virally suppressed, their immune systems are normal, and they faced no work restrictions because of their HIV status.

19. To the extent the regulations of the Department of Defense, Army, Air Force, and any other military branch do not allow for Sgt. Harrison to commission as an officer or Harrison,

Roe or Voe to deploy, they are not consistent with the current state of medical science regarding HIV.

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

20. Being HIV-positive is entirely compatible with military service. The Department of Defense has recognized this for many years by generally permitting people to continue to serve if they seroconvert (i.e., acquire HIV and develop HIV antibodies) after entering service. Moreover, I understand the Navy has allowed service members with HIV to deploy for selected overseas missions since 2012.[2] As I discuss below, the reasons articulated by the DoD, Army and Air Force for the disparate treatment of people living with HIV do not justify excluding them from or restricting their military service.

A. Military Policies Regarding People Living with HIV

1. Accession Ban

21. I understand that, under Department of Defense ("DoD") Instruction 6485.01 (Human Immunodeficiency Virus (HIV) in Military Service Members),[3] it is the U.S. military's policy to deny the "appointment, enlistment, pre-appointment, or initial entry training for military service" to people living with HIV, pursuant to DoD Instruction ("DoDI") 6130.03,

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[2] U.S. Navy, Sec'y of the Navy Instr. 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); U.S. Navy, Secretary of the Navy Instruction 5300.30F (Management of Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection in the Navy and Marine Corps), Encl. 5, ¶ 3 (December 27, 2018).

[3] U.S. Dep't of Def. Instr. 6485.01 (Human Immunodeficiency Virus (HIV) in Military Service Members), ¶ 3.a (June 7, 2013), http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/648501p.pdf.

which sets medical standards for appointment, enlistment, and induction into the military services. In other words, people living with HIV are barred from entering the military or—if they seroconvert after joining the military—from being appointed an officer.

22. 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."[4] According to this regulation, service members with HIV who are determined to be fit for duty may continue to serve.[5]

23. 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.[6] 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) 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.

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[4] *Id.* at Encl. 3, ¶ 2.c.
[5] *Id.* at Encl. 3, ¶ 2.e.
[6] U.S. Dep't of Def. Instr. 6130.03 (Medical Standards for Appointment, Enlistment, or Induction into the Military Sciences) (May 6, 2018), http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/613003p.pdf (hereinafter "DoDI 6130.03").

(5) Medically capable of performing duties without aggravating existing physical defects or medical conditions.[7]

24. Despite the fact that people living with HIV who are adherent to their medication regimen would meet all of the requirements set forth in DoDI 6130.03, HIV is among the "disqualifying conditions" specified under that regulation.[8]

25. I also understand that Army Regulation 600-110 (Identification, Surveillance, and Administration of Personnel Infected with Human Immunodeficiency Virus)[9] 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.[10] 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.[11] Again, however, the Army regulation states that active duty soldiers with HIV who do not demonstrate progressive clinical illness or immunological

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[7] *Id.* at Sec. 1, ¶ 1.2.c.
[8] *Id.* at Sec. 5, ¶ 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).").
[9] U.S. Army Reg. 600-110 (Identification, Surveillance, and Administration of Personnel Infected with Human Immunodeficiency Virus) (Apr. 22, 2014), https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r600_110.pdf.
[10] *Id.* at Ch. 1, Sec. III, ¶ 1-15.
[11] *Id.* at Ch. 1, Sec. III, ¶ 1-16.a.

deficiency during periodic evaluations will not be involuntarily separated solely because they have HIV.[12]

26. I understand that this regulation defines "progressive clinical illness" as follows:

> Development of neurological manifestations; Kaposi's sarcoma; other lymphoreticular malignancies; thrombocytopenia; diffuse, persistent lymphadenopathy; or unexplained weight loss, diarrhea, anorexia, fever, malaise, or fatigue.[13]

27. I also understand that this regulation also defines "immunological deficiency" as follows:

> Persistent reduction in the level of T-helper lymphocytes below 300 cells per cubic millimeter for greater than one month without other demonstrable cause; reduced or absent delayed hypersensitivity, as measured by the standardized battery of skin tests (in association with other significant clinical findings); development of thrush; increased susceptibility to either common or uncommon infections; and more severe episodes of infection than usually seen with a given organism.[14]

28. In my opinion, the definitions of "progressive clinical illness" and "immunological deficiency" contained in AR 600-110 are reasonable.

29. I further understand that Air Force Instruction 44-178 (Human Immunodeficiency Virus Program)[15] implements DoDI 6485.01 and describes policies related to HIV with respect to members of the Air Force. It states that individuals living with HIV are not eligible for

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[12] *Id.* at Ch. 1, Sec. III, ¶ 1-16.e; *see also* Tumminello Dep. at 91:13–92:1 (Deputy State Surgeon for the D.C. Army National Guard, Lt. Col. Paul Tumminello, testified that whether or not a person living with HIV has a progressive clinical illness or immunological deficiency, they cannot obtain an accessions waiver.).
[13] U.S. Army Reg. 600-110, at 54.
[14] *Id.*
[15] Air Force Instr. 44-178 (Human Immunodeficiency Virus Program) (Mar. 4, 2014), https://static.e-publishing.af.mil/production/1/af_sg/publication/afi44-178/afi44-178.pdf.

enlistment or appointment to the Active Duty Air Force or Air Reserve Component.[16] Although HIV seropositivity alone is not grounds for separation,[17] HIV-positive service members must undergo medical evaluation to determine status for continued military service.[18] According to this regulation, they are evaluated for retention or separation in accordance with Air Force Instruction 36-3212.[19] Service members with HIV who are retained are given an assignment limitation code and returned to duty.[20]

2. Conditions for Deployment and Deployment Restrictions

30. 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

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[16] *Id.* at Sec. 2.2.1.
[17] *Id.* at Sec. 2.4.1.
[18] *Id.* at Sec. 2.4.
[19] *Id.* at Sec. A9.2.1.
[20] *Id.* at Sec. A9.2.2. I understand that in another case, the same entity that ordered the discharge or Roe and Voe, the Secretary of the Air Force Personnel Council ("SAFPC"), returned to duty an Air Force service member living with HIV. (Roe Declaration at Ex. A6.) The letter by SAF Personnel Council Director Col. Lisa M. Craig cited AFI 48-178 as providing for retention of Air Force service members with HIV. *Id.* In its decision, the letter cites the service member's "current health status and no requirement for medications requiring special handling . . . ." *Id.* Based on the information that I have reviewed, it is my opinion that the Air Force should have made the same decision in Roe and Voe's cases.

> 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.)[21]

31. Again, despite the fact that service members with well-controlled HIV would meet all of the requirements set forth in DoDI 6490.07, the regulation specifically identifies HIV as a medical condition that could preclude a service member's deployment outside of the United States.[22] DoDI 6490.07 provides that a 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..[23] Though the first sentence of provision (e)(2) of Enclosure 3 attached to DoDI 6490.07 contemplates the need for a waiver only if the individual has 'progressive clinical illness' or 'immunological deficiency,' Defendants appear to interpret the second sentence as requiring a waiver in all instances of HIV seropositivity.[24]

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[21] Dep't of Def. Instr. 6490.07 (Medical Conditions Usually Precluding Contingency Deployment), Encl. 3, ¶ 4.b (Feb. 5, 2010), http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/649007p.pdf.

[22] *Id.* at Encl. 3, ¶ e.2.

[23] *Id.* at ¶ 4.c ("Individuals with the conditions in Enclosure 3, based on medical assessments in accordance with Enclosure 2 and Reference (l), shall not deploy unless a waiver can be granted according to the procedures in section 3 of Enclosure 2."); *id. at* Encl. 2, ¶ 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.").

[24] Among others, I understand that the DoD designee on the topic of DoDI 6490.07 interprets that regulation to require a waiver for all people living with HIV engaging in a contingency deployment. *See* Wiesen Dep. at 121:4-123:7 ("Q: Isn't it essentially saying that a waiver is required regardless of

3. "Deploy or Get Out" Policy

32. I understand that on February 14, 2018, the DoD issued the "Retention Policy for Non-Deployable Service Members," often referred to as the "Deploy or Get Out" or "DOGO" policy.[25] This policy states that "[s]ervice members who have been non-deployable for more than 12 consecutive months, for any reason, will be processed for administrative separation."[26]

33. This policy was replaced by DoDI 1332.45 (Retention Determinations for Non-Deployable Service Members) (the "DOGO Instruction"), which classifies individuals with any medical condition listed in DoDI 6490.07 (which includes HIV) as "deployable with limitations."[27] At his deposition, the Department of Defense's 30(b)(6) designee regarding the DOGO Instruction, Michael Melillo, testified that the DoD agrees that persons with asymptomatic HIV should be classified as "deployable with limitations" under DoDI 1332.45 (Melillo Dep. 61:15-24), and that persons classified as "deployable with limitations" should not be subject to retention determinations under DoDI 1332.45 § 1.2 (Melillo Dep. 63:9-64:9).

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whether there is clinical progressive -- I'm sorry -- progressive clinical illness or immunological deficiency?" A: Yes."); *see also* Blaylock Dep. at 194:20-23 ("Q: And all people living with HIV must obtain a waiver to deploy in the Army; is that right? A: Yes."); *id.* at 195:6-10; Lute Dep. 219:2-221:21 (Army's designee on AR 600-110 discussing the Army's policy that all members with HIV must obtain a waiver to be able to engage in a contingency deployment); Soper Dep. at 107:7-108:1 (Air Force designee regarding Air Force personnel policies discussing the Air Force policy that all members with HIV must obtain a waiver to be able to engage in a contingency deployment).

[25] U.S. Dep't of Def. Mem. (Retention Policy for Non-Deployable Service Members*)* (Feb. 14, 2018) (hereinafter "DOGO Policy"), https://dod.defense.gov/Portals/1/Documents/pubs/DoD-Universal-Retention-Policy.PDF; *see also* Dep't of Def. Instr. 1332.45 (Retention Determination for Non-Deployable Service Members) (July 30, 2018), https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/133245p.pdf?ver=2018-08-01-143025-053 (hereinafter "DoDI 1332.45").

[26] DOGO Policy at 1; DoDI 1332.45, at Sec. 1, ¶ 1.2.b.

[27] DoDI 1332.45, at Sec 3., ¶ 3.3.

DoDI 1332.45 also gives the secretary of each military department discretion to retain nondeployable service members if their retention would be "in the best interest of the Military Service."[28]

34. On November 8, 2018, the Army published a memo titled "Army Directive 2018-22 (Retention Policy for Non-Deployable Soldiers)," contemplating that some soldiers will be found "deployable with limitations."[29] On February 19, 2019, the Air Force published a memo titled "Air Force Guidance Memorandum Establishing Guidance for Implementing Department of Defense Instruction (DoDI) 1332.45, Retention Determinations for Non-Deployable Service Members."[30] This guidance memorandum does not use the term "deployable with limitations." Instead, this memorandum states that "every Airman is personally responsible to be fit for duty and to maintain a wartime mission-capable status."[31] Under this regulation, this requirement is achieved by accomplishing the following:

> (a) meet[ing] individual medical readiness standards, to include medical, dental, and physical components,
> (b) be[ing] able to execute the wartime mission requirements of their respective career fields, to include technical, educational, and physical proficiency,
> (c) be[ing] current on the Physical Fitness Assessment, and
> (d) be[ing] considered a satisfactory participant in Air Force Reserve and Air National Guard duties, as applicable.[32]

4. "MOD 13"

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[28] *Id.* at Sec. 2, ¶ 4.b.1.
[29] U.S. Army Mem. 2018-22 (Retention Policy for Non-Deployable Soldiers) p. 2 (Nov. 8, 2018).
[30] Air Force Mem. AFGM2019-36-01 (Air Force Guidance Memorandum for Implementing Department of Defense Instruction (DoDI) 1332.45, Retention Determinations for Non-Deployable Service Members) (February 19, 2019).
[31] *Id.* at ¶ 1.c.(1).
[32] *Id.* at ¶ 1.c.(1)(a)-(d).

35. I understand that Modification Thirteen to USCENTCOM Individual Protection and Individual-Unit Deployment Policy ("MOD 13") was published by the United States Central Command in March 2017 and provides medical screening standards for deployment to Central Command ("CENTCOM").[33] Tab A accompanied MOD 13 and "provides amplification of the minimal standards of fitness for deployment to the CENTCOM area of responsibility (AOR)."[34] Tab A lists conditions that require a waiver for deployment, including HIV. Specifically, it states that "confirmed HIV infection is disqualifying for deployment."[35]

5. Disability Evaluation System

36. I understand that Department of Defense Instruction 1332.18 (Disability Evaluation System ("DES")) establishes procedures for the separation or retirement of service members for disability.[36] The Medical Evaluation Board ("MEB") consists of two or more physicians that "confirm the medical diagnosis for and document the full clinical information" of a Service Member with medical conditions that may "prevent the Service member from performing the duties of his office, grade, rank, or rating and state."[37] The MEB then determines if the medical condition warrants a referral to a Physical Evaluation Board.[38]

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[33] U.S. Cent. Command Doc. 231245Z (Modification Thirteen to USCENTCOM Individual Protection and Individual Unit Deployment Policy) (Mar. 2017).
[34] U.S. Cent. Command Doc. PPG-TAB A (Amplification of the Minimal Standards of Fitness for Deployment to the CENTCOM AOR; To Accompany Mod Thirteen to USCENTCOM Individual Protection and Individual/Unit Deployment Policy) (March 2017), https://www.express-scripts.com/TRICARE/tools/USCENTCOM-MOD-13_TAB-A.pdf (Hereinafter "Modification Thirteen, Tab A").
[35] *Id.* at ¶ 7.c.2.
[36] Dep't of Def. Instr. 1332.18 (Disability Evaluation System (DES)) (August 5, 2014), https://warriorcare.dodlive.mil/files/2016/03/DoDI_1332.18.pdf (hereinafter "DoDI 1332.18").
[37] *Id.* at Encl. 3, ¶¶ 2.b, 2.f.(2).
[38] *Id.* at Encl. 3, ¶ 2.f.(2).

37. The Informal Physical Evaluation Board ("IPEB") is made up of two or three military personnel, and makes the "initial findings and recommendations" regarding the Service Members retirement or separation.[39] The Formal Physical Evaluation Board ("FPEB") is comprised of a military officer, a medical officer and a line officer (at minimum), and conducts a formal hearing if the service member challenges the IPEB's determinations.[40]

6. Additional Air Force Guidance

38. The Air Force published several guidance memoranda that provided additional information about how the Air Force's HIV policies would be implemented. On October 11, 2017, the Air Force published a memorandum titled "Retention of Airmen with Asymptomatic HIV," which stated that airmen with laboratory evidence of HIV and without progressive clinical illness or immunological deficiency will be referred to the Air Force Personnel Center Medical Standards Branch for Case Review.[41] However, it also stated that "asymptomatic HIV alone is not unfitting for continued service."[42]

39. On June 6, 2018 the Air Force published a memo titled "Appropriate Evaluation of Fitness for Continued Service for Airmen with Asymptomatic Human Immunodeficiency Virus (HIV)."[43] This memo reiterates that asymptomatic HIV would be evaluated in the same manner as "any Airman with a chronic and/or progressive disease,"[44] and that referral to the DES required the airman to meet the following criteria from DoDI 1332.18:

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[39] *Id.* at Encl. 3, ¶¶ 3.b,3.d(1).
[40] *Id.* at Encl. 3, ¶¶ 3.c 3.d.(2).
[41] Air Force Mem. A-00341 (Retention of Airmen with Asymptomatic HIV) (Oct. 11, 2017).
[42] *Id.*
[43] Air Force Mem. A-00338 (Appropriate Evaluation of Fitness for Continued Service for Airmen with Asymptomatic Human Immunodeficiency Virus (HIV)) (June 6, 2018).
[44] *Id.*

> (1) Have one or more medical conditions that may, individually or collectively, prevent the Service member from reasonably performing the duties of their office, grade, rank, or rating . . . ;
> (2) Have a medical condition that represents an obvious medical risk to the health of the member or the health or safety of other members; or
> (3) Have a medical condition that imposes unreasonable requirements on the military to maintain or protect the Service member.[45]

40. The Memorandum states that "[a]symptomatic HIV alone is not unfitting for continued service."[46]

41. On September 26, 2018 the Air Force published a memo titled "Airmen with Asymptomatic Human Immunodeficiency Virus (HIV) Disposition."[47] This memo stated that the decision authority or boards will use the criteria in DoDI 1332.18, Enclosure 3, Appendices 1 and 2, *as well as an assessment of the current career point of the Airman*, to evaluate if the Airman should be retained or separated.[48] The memo also clarified that the statement "'asymptomatic HIV alone is not unfitting for continued service' . . . is not a policy statement that asymptomatic HIV Airmen are not to be referred into DES."[49]

7. Department of Defense 2018 Report to Congress

42. I have reviewed Defendants' responses to Interrogatories Nos. 17 and 18 of Plaintiff's First Set of Interrogatories to Defendants (Nos. 1-23) in *Harrison v. Shanahan*, which pose the following questions:

> INTERROGATORY NO. 17: Explain in detail each of the reasons underlying DoD's policies that, absent a medical waiver or exception to policy, prohibit HIV-positive persons from enlisting in the Military Services, being inducted into the Military Services, or being appointed as an officer in the Military Services as set forth in, *inter alia*, DoDI 6485.01 and DoDI 6130.03.

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[45] DoDI 1332.18, at App. 1 to Encl. 3, ¶ 2.a.(1)–(3).
[46] Air Force Mem. A-00338, at 1.
[47] Air Force Mem. A-00339 (Airmen with Asymptomatic Human Immunodeficiency Virus (HIV) Disposition) (Sep. 26, 2018).
[48] *Id.*
[49] *Id.*

> INTERROGATORY NO. 18: Explain in detail each of the reasons underlying DoD's policies that, absent a medical waiver or exception to policy, prohibit HIV-positive persons from deploying to regular operations or contingency operations areas, as set forth in, *inter alia*, DoDI [6490.07].

After lodging their objections, Defendants respond that the DoD set forth its complete reasoning underlying the policies referenced in these interrogatories in the 2014 and 2018 reports to Congress.

43. I understand that in August 2018, at the request of Congress, the DoD submitted a report titled *Department of Defense Personnel Policies Regarding Members of the Armed Forces Infected with Human Immunodeficiency Virus* ("2018 Report").[50] This report provides "[a] description of policies addressing the enlistment or commissioning, retention, deployment, discharge, and disciplinary policies regarding individuals with this condition [HIV]."[51]

44. The 2018 Report discusses the regulations set forth above, including the aforementioned policies underlying the accession and deployment of individuals living with HIV.[52] The 2018 Report also includes a "MEDICAL ASSESSMENT OF POLICIES."[53] Below, I endeavor to address all of the purported medical justifications for the policies as set forth in the 2018 Report. (While also older, the 2014 Report is less detailed and contains no justifications not reiterated in the 2018 Report.)

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[50] Dep't of Def., *Department of Defense Personnel Policies Regarding Members of the Armed Forced Infected with Human Immunodeficiency Virus: Report to the Committees on the Armed Services of the Senate and House of Representatives* (Aug. 2018) (hereinafter "2018 Report").
[51] *Id.* at 1.
[52] *Id.* at 7–18.
[53] *Id.* at 19–23.

45. Regarding the "Deploy or Get Out" policy, the 2018 Report explains, "[t]he overarching policy is that to maximize the lethality and readiness of the Joint Force, all Service members are expected to be deployable."[54] The 2018 Report clarifies that "'non-deployable' and 'deployable with limitations' are two separate categories . . . [and] [t]he Military Departments have authority to determine the specific dividing line between the two categories most appropriate for the operational circumstances applicable to their respective Services."[55]

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

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

46. 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. As stated above, the Navy has already taken steps to allow service members living with HIV to serve overseas on a case-by-case

[54] *Id.* at 4.
[55] *Id.*

basis.[56] That decision was based on the explicit recognition that: "There is no demonstrated risk of transmission of disease in normal daily activities."[57]

47. Similarly, there is no medical basis for any service member to refuse to serve with people living with HIV. 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."[58]

48. 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" (which also occur occasionally in the health care setting) or those experienced while a wounded soldier with HIV is receiving or providing care to another wounded soldier (i.e., "wound-to-wound contact," which may occur occasionally in some civilian settings, such as after a car accident or in some sporting activities, such as boxing or sports causing occasional compound fractures)—are not documented routes of transmission. The risk of an exposure that could result in transmission under such circumstances is at most a theoretical risk. For example, in his deposition, Lt. Jason Blaylock, service chief of infectious diseases at Walter Reed National Military Medical Center and the Army's designee regarding the

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[56] NAVSECINS 5300.30E, at ¶ 3.c.(2) ("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."); 2018 Report, at 17.

[57] NAVSECINS 5300.30E, at ¶ 9.b.1.

[58] U.S. Army Reg. 600-110, *supra* note 9, at Ch.1, Sect. III, ¶ 1-16(p).

purported medical bases for the Army's HIV-related personnel policies, described the risk of transmission of HIV via blood splash or wound-to-wound contact as "negligible" and said he was not aware of there ever being a documented case of transmission of HIV via blood splash, nor was he aware of there ever being a documented instance of HIV transmission on the battlefield.[59]

49. 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.[60] In his deposition, Lt. Col. Blaylock also agreed that the risk of transmission of HIV through sexual exposure with someone with an undetectable viral load is "approximately zero."[61]

50. It is reasonable to conclude the risk of transmission through battlefield activities that present at most a theoretical risk of transmission in the absence of treatment is also effectively zero if the person with HIV has a suppressed or undetectable viral load. In his deposition testimony, Col. Andrew Wiesen, Director of Preventive Medicine in the office of the Deputy Assistant Secretary of Defense for Health Readiness Policy and Oversight and the DoD's designee regarding the deployment restrictions placed on service members living with HIV, testified that DoDI 6130.03's criteria preventing accession based on the existence of a contagious

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[59] Blaylock Dep. at 37:7–21; 122:13–15; Lute Dep. at 51:3–8 (testifying that she is not aware of any documented cases of battlefield transmission of HIV); *see also* Wiesen Dep. at 37:5–9 (testifying that he is not aware of a documented case of transmission of HIV via blood splash).
[60] *See* U.S. Centers for Disease Control and Prevention, *HIV Risk Behaviors: Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act* (Dec. 2015), www.cdc.gov/hiv/risk/estimates/riskbehaviors.html.
[61] Blaylock Dep. at 56:25; *see also* Lute Dep. at 45:22–46:1 ("[I]f the individual was on medication and they're — they were less than 200 [viral load] count, then there would be no — there would be a negligible risk to any of the population.").

disease that may endanger the health of other personnel requires at least a 1 percent chance (annually) of disease transmission.[62] The chances of transmission of HIV are far less than 1 in 100 through the type of exposures contemplated in a combat setting, and no service member is likely to have multiple such exposure incidents in a year, much less the thousands that would be required to bring the risk, if any exists at all, to 1 percent.

51. 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 ("PEP") 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. The Health Care of an Individual with HIV Does Not Involve Excessive Time or Significant Additional Costs

52. Adherence to an effective ART regimen does not require much time at all—it is as simple as taking medication every day. As Kevin Cron, the DoD's designee on the topic of waivers to deploy despite the existence of a deployment-limiting condition, testified: "It's challenging to find an individual these days who's not on some kind of medication for something[.]"[63] 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.

53. 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

[62] Wiesen Dep. at 61:6–10.
[63] Cron Dep. 111:14-16.

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.[64] I understand that Sgt. Harrison, for example, took a daily dose of doxycycline when he was deployed in Afghanistan. Furthermore, based on my review of DoD regulations and policies, I have learned there are other medical conditions requiring daily medication, such as dyslipidemia and hypothyroidism, that are not considered incompatible with military service or world-wide deployment.[65] A service member could bring sufficient supplies of medication based on the duration of the deployment.[66]

54. I also understand that certain witnesses have testified that people living with HIV cannot receive certain live vaccines.[67] However, I am not aware of any live vaccines that are absolutely contraindicated for individuals with HIV who have a suppressed viral load and normal immune function. Some public health authorities recommend specific live virus vaccines if medically indicated. To the extent an individual's HIV might prevent that individual from receiving certain live vaccines, I further note that Col. Wiesen testified regarding the smallpox

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

[65] *See* DoDI 6130.03, at Sec. 5, ¶ 5.24.k (hypothyroidism); *id.* at 5.24.n (dyslipidemia); DoDI 6490.07, at Encl. 3, ¶ g(1) (hypertension); *id.* at Encl. 3, ¶ d (asthma).

[66] *See* Tumminello Dep. at 152:8–17 (stating that patients who take medication for high cholesterol may deploy without a waiver); *id.* at 153:11–154:18 (stating that patients who taking blood pressure medication would likely be permitted to deploy even though they could face health ramifications immediately upon stopping the medications).

[67] Lute Dep. at 67:9–12.

vaccine that "we do have other people with valid reasons to not take that vaccine as well."[68] He also described any interactions between antimalarial drugs and HIV medications as "minimal."[69]

55. The medical monitoring required for a person living with HIV is also limited. According to U.S. HIV treatment guidelines, viral load should be measured every six months for individuals with well-controlled HIV (i.e., those whose viral load has been suppressed for more than two years and whose clinical and immunologic status is stable).[70] Those who have not yet met this threshold typically should have their viral load measured every four months (approx. 120 day intervals).[71] I note that even this frequency falls within the parameters of MOD 13, Tab A, which considers 90-day intervals between clinical testing to monitor a health condition to be a "reasonable timeframe."[72]

56. It is my understanding that Sgt. Harrison currently has his viral load tested approximately twice a year.[73] This is a standard testing frequency for people living with HIV. Furthermore, according to Dr. Jason Okulicz, Chief of the Infectious Disease Service at the San Antonio Military Medical Center, Roe will only require laboratory testing twice a year and a once-yearly evaluation.[74] In fact, Col. Wiesen testified that a person living with HIV who is in

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[68] Wiesen Dep. at 141:14–22.
[69] *Id*. at 142:16–17.
[70] *See* U.S. Department of Health and Human Services, *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV* (May 1, 2014), https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/458/plasma-hiv-1-rna--viral-load--and-cd4-count-monitoring.
[71] *Id*.
[72] *See* Modification Thirteen, Tab A, at ¶¶ 1.D.3, 6.B.2; *see also* Cron Dep. at 113:17-22 ("So, quarterly is where we drew a line in the sand, because it's just convenient to do so. That's once every three months. That's also for controlled substances, the period they need to maintain in order to refill those prescriptions. So, it is an arbitrary standard.").
[73] Decl. of Nicholas Harrison at ¶ 13 (July 19, 2018), Dkt. 26-3.
[74] Decl. of Roe at Ex. A3 (July 18, 2018), ROE-000092.

treatment and has a suppressed viral load would not result in excessive time lost from duties.[75] It is also my opinion that this twice-annual testing does not need to take place at strict six-month intervals. Because these evaluations are monitoring "check-ins" and clinical deterioration is relatively rare once a patient has achieved a suppressed viral load, it is not imperative that this testing occur at exactly six-month intervals.

57. 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. In his deposition, Lt. Col. Jason Blaylock, service chief of infectious diseases at Walter Reed National Military Medical Center, testified that combat support hospitals, which are available "at major hubs of military bases in the deployed setting," such as in Afghanistan, can conduct the twice-annual blood testing required for a service member living with HIV.[76]

58. When viral load testing is done, routine blood tests are conducted to monitor the effects, if any, of the person's ART regimen on the functioning of the person's organs and other bodily systems. Only a very small percentage of people who start HIV treatment regimens with single daily pill fixed dose combinations discontinue the regimen due to adverse effects. It is even more rare for a person who has already achieved viral suppression on a particular ART regimen to need to change regimens based on side effects the medication is having on the functioning of other organs or bodily systems.

[75] Wiesen Dep. at 82:15–83:9.
[76] Blaylock Dep. at 68:7–15.

59. General practitioner physicians are capable of engaging in the type of medical monitoring and care required for people living with HIV.[77] In the United States, 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. I disagree with Defendants to the extent they argue that treatment of other medical conditions, such as common infections, would require a full evaluation of a patient's HIV status to ensure proper treatment. For the most part, HIV-related immune deficiency begins slowly after many years of declining CD4+ cells and then is mainly cell mediated immunity. The occurrence of symptoms and signs of infections, consistent with those commonly occurring in daily life, do not automatically indicate a need to do a medical work-up for decline in immune function as they are also common in uninfected persons who have normal immune systems. Therefore, there is no special concern to work-up the HIV condition if an intercurrent infection occurs. It may be routine to check CD4+ cell count as assurance, but such testing is not necessary to make treatment decisions for another infection, assuming the individual's status prior to deployment is a suppressed viral load and normal CD4+ cells.

60. 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

[77] *See* Wiesen Dep. at 171:17–19 ("[A]n internal medicine physician or other specialist should be able to do that evaluation without evacuating the individual out of theater.").

qualified infectious disease doctors employed by the Armed Services or a telemedicine session could be arranged between an infectious disease specialist and the service member with HIV.

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

61. 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. There should be no effect on the physical fitness and capabilities of any person with HIV who is adhering to their prescribed ART regimen. As Col. Stephen J. Thomas, U.S. Army Infectious Diseases Consultant, wrote in an email exchange between members of the Department of the Army regarding Sgt. Harrison's application for an exception to policy, "From a purely medical standpoint it is possible for someone with HIV to have a normal life expectancy, experience a high quality of life and health, and be productive."[78] 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."[79]

62. As far back as 2004, the DoD's Armed Forces Epidemiology Board explained that "[t]here is no evidence that HIV infection, per se, affects physical fitness."[80] The same

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[78] Email from Marguerite Lawrence, Chief Health Promotions Policy, U.S. Army, to Laurie Fontaine and Stephen Thomas, re a medical recommendation concerning Nicholas Harrison, at US0002430 (Dec. 23, 2015, 8:42 EST).

[79] J. Brundage et al., *Durations of Military Service after Diagnoses of HIV-1 Infections Among Active Component Members of the U.S. Armed Forces 1990-2013*, Medical Surveillance Monthly Report, Aug. 2015, at 9, 9–12, https://health.mil/Reference-Center/Reports/2015/01/01/Medical-Surveillance-Monthly-Report-Volume-22-Number-8.

[80] Office of the Assistant Secretary of Defense, Health Affairs Mem. (Policy Memorandum – Human Immunodeficiency Virus Interval Testing) (Mar. 29, 2004),

remains true today. In fact, there is evidence that by some measures the physical fitness of service members increases after they learn they are living with HIV.[81] One retrospective study conducted by, among others, Dr. Okulicz, Chief of the Infectious Disease Service of the Air Force and Director of the HIV Medical Evaluation Unit at the San Antonio Military Medical Center, found that composite fitness scores, mean push-up, and sit-up scores for Airmen living with HIV were higher post-HIV than pre-HIV.[82] I understand that Mr. Harrison, who was diagnosed with HIV in 2012, received a PULHES[83] 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).[84] In addition, I understand Mr. Harrison received strong scores on his army physical fitness test (92/100 for pushups, 88/100 for sit ups and 88/100 for a two-mile run) in 2014.[85] In his deposition, Lt. Col. Paul Tumminello, Deputy State Surgeon for the D.C. Army National Guard, testified that his review of Sgt. Harrison's medical evaluations showed that Sgt. Harrison did not exhibit either progressive clinical illness or immunological deficiency.[86]

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https://www.health.mil/Reference-Center/Policies/2004/03/29/Policy-Memorandum---Human-Immunodeficiency-Virus-Interval-Testing.

[81] Asha De et al., *Physical fitness characteristics of active duty US Air Force members with HIV infection*, Medicine 95:44 (2016).

[82] J. Okulicz et al., *Review of the U.S. Military's Human Immunodeficiency Virus Program: A Legacy of Progress and a Future of Promise*, Medical Surveillance Monthly Report, Sept. 2017, at 2, 2–7, https://health.mil/Reference-Center/Reports/2017/01/01/Medical-Surveillance-Monthly-Report-Volume-24-Number-9.

[83] U.S. Army Reg. 40-501 (Standards of Medical Fitness) Glossary, Sec. 1, p. 136 (June 14, 2017) (defining PULHES as an acronym for Physical stamina, Upper extremities, Lower extremities, Hearing/ears, Eyes, and Psychiatric).

[84] *Id.* at Ch. 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.").

[85] N. Harrison, Army Physical Fitness Test Scorecard (Dec. 6, 2014), US00000323.

[86] Tumminello Dep. at 87: 7–11.

63. I also understand that Dr. Okulicz, Chief of the Infectious Disease Service for the Air Force and Director of the HIV Medical Evaluation Unit at the San Antonio Military Medical Center, stated that Roe "has no physical limitation that would prevent him from conducting his duties."[87] I have reviewed Roe's Member Individual Fitness Report, which evaluates the following fitness metrics: (1) height, (2) weight, (3) body mass index, (4) aerobic time, (5) abs score, (6) push-ups score, and (7) sit-ups score. From this review, I understand that Roe has passed all his fitness evaluations from August 2012 to March 2018, and received a score of 98.25 out of 100 on his most recent evaluation.[88] I further understand that the Physical Evaluation Board found Voe's "HIV condition well controlled and [that] he is currently asymptomatic." Additionally, they acknowledged that Voe "exhibited no evidence of infection related to his HIV diagnosis" and "does not have evidence of immune compromise."[89] I understand Voe has passed all physical fitness assessments during his time in the military, and received a score of 84.2 out of 100 on his most recent evaluation.[90]

64. 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 are very unlikely to experience any HIV-related symptoms or complications of any kind related to their HIV. Evidence of essentially normal immune function is indicated by a normal CD4+ cell count. Provided they are able to continue taking their medications, inhospitable environmental conditions and/or challenging work conditions should have no effect

[87] Decl. of Roe at Ex. A3 (July 18, 2018), ROE-000092
[88] Roe, Air Force Individual Fitness Report (Apr. 2, 2018), ROE-000089.
[89] Decl. of Voe at Ex. B2 (July 18, 2018), VOE-000021–23.
[90] Memorandum from Voe, Appeal of Findings of the Formal Physical Evaluation Board (FPEB) (Dec. 20, 2017), VOE-000033.

on the person living with HIV's health or their ability to serve. Col. Wiesen agreed that individuals taking their medication during their military duty would be capable of performing their duties without aggravating their HIV.[91]

65. The 2018 Report contains a section on "Recent Findings Signifying Impairments Despite Viral Suppression and Asymptomatic HIV."[92] Specifically, the Report suggests that people living with HIV on ART may develop certain types of neuro-cognitive impairment ("NCI").[93] I understand that Dr. Hardy is addressing neurocognitive impairments in his report; however, I wish to note several things about their effect—or lack thereof—on a service member's ability to perform their duties: 1) though limited in number in the age of antiretroviral therapy, particularly among younger individuals who have not lived with HIV for an extended period of time, those with the most serious form of HIV-associated neurocognitive impairments should be relatively easy to identify and restrict to certain types of duties or to discharge if disabled by NCI's; 2) by definition, asymptomatic NCI's will have no noticeable effect on the service members ability to perform their duties; and 3) the medical fitness standards for service members are designed to weed out individuals who have symptomatic neurocognitive impairments that will affect their ability to perform their duties.[94] Dr. Jason Okulicz, Chief of the Infectious Disease Service for the Air Force and Director of the HIV Medical Evaluation Unit testified that he does not test his HIV patients for neurocognitive impairments because he does "not have a clinical perception that HIV impacts their neurocognition to the point that it affects either their day-to-day life or their job doing their - - doing [their] duties." Okulicz Dep.

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[91] Wiesen Dep. at 92:13–21.
[91] 2018 Report at 20.
[92] *Id*.
[94] DoDI 6130.03, Sec. 5, ¶ 5.26 (Neurologic Conditions).

(rough draft) at 116:23-117:1. Furthermore, for those with highly specialized duties (such as fighter pilots), additional testing could be conducted to ensure that neurocognitive function is at the level necessary to perform in these elite roles.[95] The relative infrequent incidence of NCI's among people living with HIV certainly does not justify the group-wide restrictions on their accession or deployment.

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

66. 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. 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. People living with HIV, particularly those with well-controlled HIV, are not more susceptible to the vicissitudes of heat, cold, humidity, dryness, etc. or conditions of moderate dehydration than those who are not living with HIV. For individuals with reconstituted immune systems as a result of treatment, concerns regarding "immune system dysregulation," as described in the 2018 Report,[96] are overblown and overly protective to the point of patronization. All service members are subject to the stressors of the military environment, and there is no reason to believe that

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[95] Okulicz Dep. (rough draft) at 58:17-19 ("There [is] testing available to assess whether or not a person may have neurocognitive impairment whether it's symptomatic or asymptomatic."); *id.* at 59:2-6 ("If it is felt that a person on flying status should be assessed for neurocognition, then I think there are testing available that could help answer that question for jobs that would require a neurocognitive assessment.")

[96] 2018 Report at 9.

service members with HIV will be any less able to tolerate these environmental conditions than other service members who are not living with HIV. Again, I understand the Navy has already adopted policies to allow service members living with HIV to serve outside of the continental United States. 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.[97] 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 Danger to the Safety of Military Blood Supplies

67. 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.[98] People who have been diagnosed with HIV are informed that they can no longer donate blood, and service members newly-diagnosed with HIV are instructed that they are not to donate blood. In addition, along with blood type, it could be indicated on a service member's "dog tags" that they are ineligible to donate blood.

68. The 2018 Report suggests that "in emergency battlefield circumstances it is impossible to eliminate all risk of communicability through blood transfusion."[99] This is undoubtedly true (in part because it is impossible to eliminate *all* risk in any setting), but it is

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[97] J. Okulicz et al., *Review of the U.S. Military's Human Immunodeficiency Virus Program: A Legacy of Progress and a Future of Promise*, Medical Surveillance Monthly Report, Sept. 2017, at 2, 2–7, https://health.mil/Reference-Center/Reports/2017/01/01/Medical-Surveillance-Monthly-Report-Volume-24-Number-9.
[98] Armed Services Blood Program, *About Us*, http://www.militaryblood.dod.mil/About/default.aspx (last visited Mar. 21, 2019).
[99] 2018 Report at 22.

also undoubtedly true that the primary risk to the blood supply in terms of HIV transmission arises from those who are unaware they are living with HIV. However, the military 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.[100] These efforts have 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 2001–07, "[n]one were emergency blood transfusion donors or recipients."[101] Indeed, for 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."[102] 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.

69. Furthermore, there are various other factors that often disqualify or severely limit individuals as emergency blood donors, such as blood type[103] or same-sex sexual activity between men—making people living with HIV no different in this respect from these other groups who are allowed to serve and deploy. Under the Armed Services Blood Program Medical

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[100] J. Okulicz et al., at 2–7.
[101] P. Scott et al., *Short Communication: Investigation of Incident HIV Infections Among U.S. Army Soldiers Deployed to Afghanistan and Iraq, 2001-2007*, 28 AIDS Research and Human Retroviruses 1308, 1308–1312 (2012).
[102] U.S. Department of Health & Human Services, National Heart, Lung, and Blood Institute, *Blood Transfusion*, https://www.nhlbi.nih.gov/health-topics/blood-transfusion (last visited Mar. 22, 2019).
[103] Borden Institute, *Emergency War Surgery*, 467–488 (4th ed. 2014), http://www.cs.amedd.army.mil/FileDownloadpublic.aspx?docid=189c4a13-522f-4d91-9236-a109d7b5ee4d.

Conditions List, conditions such as Addison's Disease, Hepatitis B or C, even receiving a blood transfusion in the UK or France since 1980 or a tattoo in certain states, can limit or prevent an individual from being a blood donor.[104] 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 any individuals who test HIV-positive that they cannot act as emergency blood transfusion donors. Allowing service members with HIV to deploy into combat zones will have no effect on the safety of the military's blood supply, and the inability of service members with HIV to donate blood will have negligible impact on the availability of blood for battlefield transfusions. Not only are battlefield transfusions relatively rare,[105] the percentage of service members living with HIV is and would continue to be relatively low (i.e., people living with HIV comprise approximately one-third of one percent of the population of the United States, and currently just 0.027% of active duty service members).[106]

7. The Other Requirements of DoDI 6490.07(b) Are Met

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[104] Armed Services Blood Program Medical Conditions List (February 2019), Taylor Dep. at Ex. 4, pp. 1, 5, 16, 31.

[105] *See* T. Ballard et al., *Transfusion-Transmissible Infections Among U.S. Military Recipients of Emergently Transfused Blood Products, June 2006-December 2012*, Medical Surveillance Monthly Report, November 2014, at 2, 2–7 (stating that "[a]ccording 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).

[106] United States Census Bureau, *American Factfinder: Monthly Population Estimates for the United States: April 1, 2010 to December 1, 2016* (December 2017) https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=PEP_2017_PEPMONTHN&prodType=table; 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, at 2, 2-8.

70. According to DoDI 6490.07(b), a service member may deploy if their medical condition: (1) is not subject to unexpected worsening, and physical trauma is not likely to have a grave medical outcome or negative impact on mission execution; (2) is stable and not expected to worsen during deployment; (3) is not reliant on health care unavailable in theater or medication with special handling or storage requirements, and (4) will not require routine evacuation out of theater for diagnostics or evaluation.

71. As discussed above in § II.B.3, controlled HIV will not unexpectedly worsen during deployment, leading to a grave medical outcome or negative impact on mission execution. Also, as I discussed above in § III.B.2, the health care and medicinal requirements of service members living with HIV are available in theater and can be satisfied for the duration of deployment. Therefore, there is also no need for routine evacuation for diagnostics or evaluation, and therefore, there should not be excessive time lost from duty for follow-up medical monitoring. My review of Harrison, Roe and Voe's records also does not reveal any sign of progressive clinical illness or immunological deficiency, which would not be present in an individual with well-controlled HIV.

8. CENTCOM's Interpretation of MOD 13 Is Not Supported by the State of Medical Science Regarding HIV

72. In my opinion, CENTCOM's implementation of MOD 13 is not supported by medical science and the current state of HIV treatment. MOD 13 explicitly requires a waiver for individuals living with HIV to deploy to CENTCOM.[107] I understand that Lt. Col. Kevin Cron, who currently serves as the primary waiver action officer for CENTCOM, has never "granted a

[107] U.S. Cent. Command Doc. 231245Z (Modification Thirteen to USCENTCOM Individual Protection and Individual Unit Deployment Policy) (Mar. 2017).

deployment waiver for a HIV-positive Service member" and is not aware that such a waiver has ever been granted.[108] Therefore, as implemented, MOD 13 entirely precludes service members from being able to deploy to CENTCOM, which therefore prevents service members from being designated worldwide deployable. For the reasons discussed above, it is my opinion that a categorical CENTCOM deployment bar for service members with HIV has no basis in medical science. Certainly, this categorical bar should not be the basis for discharging members of the service who are permitted to deploy elsewhere.

73. Even in the unusual circumstance that a service member with HIV no longer had access to their HIV medications, I understand it would take multiple weeks for their viral load to increase to levels above a suppressed viral load, longer for the viral load to reach a level at which a genotype of that person's virus could be performed, and years, typically, before the person's immune system is likely to deteriorate to a point which could result in an opportunistic infection or irreversible damage to their immune system. MOD 13 provides that "personnel who require medication and who are deploying to the CENTCOM [or] will deploy with no less a 180 day supply (or appropriate amount for shorter deployments) of their maintenance medications with arrangements to obtain a sufficient supply to cover the remainder of the deployment using a follow-on refill prescription."[109] The risks associated with not taking medications is no greater for patients with HIV than for patients with other conditions, such as dyslipidemia, hypertension, and asthma.

IV. MEDICAL JUSTIFICATIONS FOR DENYING MR. HARRISON'S EXCEPTION TO POLICY ARE UNFOUNDED

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[108] Decl. of Cron at ¶ 11; Cron Dep. 60:5-61:22.
[109] U.S. Cent. Command Doc. 231245Z (Modification Thirteen to USCENTCOM Individual Protection and Individual Unit Deployment Policy) (Mar. 2017).

74. Sgt. Harrison meets the accessions medical standards, and there is no medical justification for not allowing Sgt. Harrison to become an officer. I understand that when Sgt. Harrison requested an exception to policy to AR 600-110, the Army Reserve National Guard, Office of the Chief Surgeon ("OTSG") provided a Medical Opinion regarding his request.[110] The Chief Surgeon made the following "observations:" (1) "Due to the risks from blood borne transmission, SGT Harrison is not deployable into a combat zone; waivers are not possible[;]" and (2) "The medications required to control the primary condition do not allow individuals to be stationed overseas where these medications cannot be guaranteed."[111] The Chief Surgeon further stated that "advances in medical treatments allow SGT Harrison's primary condition to meet retention standards. However, medical advances have not been made yet that would allow this Soldier to be deployable, or stationed overseas."[112]

75. It is worth noting that prior to issuance of this opinion, the OTSG had first been informed that "The OTSG Infectious Disease Consultant has reviewed the submitted documentation. The Consultant noted that there is ***no medical restriction related to the Service Member accepting the position being offered within the parameters outlined in AR 600-110***."[113] Eight months later, however, just a month prior to the issuance of the OTSG medical opinion, the Consultant appears to have had a change of opinion. Specifically, the Consultant provided an updated recommendation to deny Mr. Harrison's exception to policy request based

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[110] National Guard Bureau Mem. ARNG-CSG (Request for a Medical Opinion, Roe) (Feb. 29, 2016), US00001135.
[111] *Id.* at ¶ 2.
[112] *Id.* at ¶ 3.
[113] Dep't of the Army Mem. DASG-HCO (Request for Medical Opinion, Roe) ¶ 2 (Apr. 30, 2015) (emphasis added), US00001136.

on "an increased risk of associated medical conditions and side effects of lifelong medication treatment, as well as deployment limitations."[114]

76. For the reasons set forth above, I disagree with the OTSG assessment. Medical advances have been made that would allow Mr. Harrison to deploy to a combat zone. There are no demonstrable risks of HIV transmission through consensual sexual contact for someone who is virally suppressed, as explained above. There is only a theoretical, vanishingly small risk of transmission through battlefield activities (e.g., via "blood splash" or wound-to-wound contact in the provision of "buddy aid"), which is also further reduced if a person with HIV has an undetectable viral load. In fact, Defendants' witnesses admitted at their depositions that they are not aware of such a transmission ever occurring. Moreover, the medications for service members living with HIV and monitoring for health effects can be as easily provided overseas as any other deployable condition needing medications, such as malaria prophylaxis or treatment for dyslipidemia or hypothyroidism.

77. Furthermore, as described above in Section III.B.3, under current treatment regimens, the side effects of HIV medication are limited. For example, in an email exchange, Col. Thomas, wrote that "[I]t is possible for someone with HIV to have a normal life expectancy, experience a high quality of life and health, and be productive."[115] I also understand that Dr. Hardy is addressing the advances in HIV treatment in the past few decades. There is no medical rationale for categorically not allowing people with HIV to deploy. Therefore, there is no

[114] Dep't of the Army Mem. DASG-HCZ (Request for Medical Opinion, Roe) ¶ 2 (Jan. 12, 2016), US00001137.
[115] Email from Marguerite Lawrence, at US00002430.

medical or scientific basis for denying Sgt. Harrison's request for an exception to policy and allowing him to accede.

V. ROE AND VOE'S SEPARATIONS ARE NOT MEDICALLY JUSTIFIED

78. I understand both Roe and Voe were scheduled to be separated based on Defendants' contention that they are not worldwide deployable because of their HIV status. In my opinion, the current state of the medical science regarding HIV does not support this decision. Based on my review of their medical records and other documents involving Roe and Voe, they are deployable without any limitation.

79. Roe's commanding officer, Lt. Col. Kenneth Beebe III, recommended Roe be retained, and his primary care doctor, Captain Daniel Cieslak, recommended he be returned to duty.[116] Since Roe began antiretroviral treatment following his October 2017 diagnosis, his viral load remained undetectable.[117] I also understand he has continued to serve as a specialist in logistics without any work restrictions due to his HIV.[118] As, Dr. Okulicz wrote, Roe "will require continuation of his 1 pill daily treatment with laboratory testing approximately every 6 months and once yearly evaluation for HIV infection at the [USAF HIV Medical Evaluation Unit]."[119] Dr. Okulicz's "assessment [] did not reveal a medical reason to explain why he would not be returned to duty . . . ."[120]

80. However, the Informal Physical Evaluation Board found that although Roe was able to perform his duties and his commander recommended retention, his "medical condition is

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[116] Kenneth Beebe III and Daniel Cieslak Mem. (Commander's Impact Statement for Medical Evaluation Board) 3–4 (Dec. 2017-Jan. 2018), ROE000014.
[117] Decl. of Roe at ¶ 8 (July 18, 2018), Dkt. 31.
[118] *Id.* at ¶¶ 20–21.
[119] *Id.* at Ex. A3, Roe000092.
[120] *Id.*

subject to sudden and unpredictable progression" and "will result in deployment restrictions that prevent him from being fully worldwide qualified."[121] While the formal PEB affirmed the informal PEB's decision, it also found that Roe "is asymptomatic" and that "[h]is commander reports he is able to perform all in-garrison duties of his AFSC and recommends his retention."[122] The PEB's decision appears to have been based on an assumption that Roe could not be deployed worldwide.[123]

81. In fact, the letter sent on behalf of the Secretary of the Air Force ordering Roe's discharge stated that while the Air Force Personnel Board ("AFPB") found no medical reasons to deny Roe's retention, "the Board noted the member's condition precludes him from being able to deploy world-wide without a waiver and renders him ineligible for deployment to [CENTCOM] . . . ."[124] The letter based the decision on "his inability to deploy . . . ."[125]

82. However, there is no medical justification to support that decision. There is no reason to believe that Roe's medical condition will suddenly or unpredictably progress. I agree with Dr. Okulicz's assessment of May 29, 2018 — "there is no physical limitation that would prevent [Roe] from conducting his duties."[126] Given Roe has had a suppressed viral load since he first began ART treatment, he is unlikely to "be subject to sudden and unpredictable progression."

83. As in the case of Roe, I understand Voe's HIV has been stable and well-managed, and is unlikely to be subject to sudden regression. After Voe's diagnosis in March 2017, I

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[121] *Id*. at Ex. A2, Roe000003–4.
[122] *Id*. at Ex. A4, Roe000001–2.
[123] *Id.*
[124] *Id.* at Ex. A5, Roe000005–8.
[125] *Id.*
[126] *Id*. at Ex. A3, Roe000092.

understand he began antiretroviral therapy, and by August 2017, he had an undetectable viral load, which he has maintained since that time. I also understand that none of Voe's physicians recommended restricting his work as a result of his HIV.[127]

84. The IPEB found that although Voe was able to perform his duties and his commander recommended retention, "[Voe's] medical condition prevents him from reasonably performing the duties of his office. . . represents a medical risk to the health of the SM [Voe] or the health/safety of others with continued service; is subject to progression; requires frequent follow-up with a medical specialist; and limits the SM's ability to meet mobility requirements."[128] As discussed previously, a service member living with HIV but with a suppressed viral load—like Voe—is entirely capable of performing his duties and does not represent a threat to the health of others, including when deployed to any location in the world. In fact, the formal PEB decision states that Voe "has exhibited no evidence of infection related to his HIV diagnosis."[129]

85. In addition, the Air Force Personnel Board, which made the final retention decision, initially voted unanimously on May 4, 2018, to retain Voe, finding that he "meets criteria for retention." *See* A01074. However, without explanation, another AFPB voted unanimously on October 28, 2018 to separate Voe, though that AFPB also found that Voe "[met] criteria for retention . . . ." A01072. The letter on behalf of the Secretary of the Air Force discharging Voe does not base the decision on any medical reasoning. The letter states that "the

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[127] *Id.* at ¶ 11, Dkt. 31.
[128] Decl. of Voe at Ex. B1 (July 18, 2018), Dkt. 30, Voe000025–27.
[129] *Id.* at Ex. B2, Voe000021–23.

member's condition precludes him from being able to deploy world-wide without a waiver and renders him ineligible for deployment to [CENTCOM] . . . ."[130]

86. In short, based on my review of the records available to me, Roe and Voe were fit for duty when they were separated. Both had undetectable viral loads and their doctors have never suggested they needed to restrict their work.[131] My review of the facts in this case, including Roe's and Voe's medical records, shows they are able to meet the requirements of DoDI 6490.07 in that their conditions meet the requirements of ¶ 4.b(1)–(4) and their diagnoses obviously do not include "the presence of progressive clinical illness or immunological deficiency." *Id.* at Enclosure 3(e)(2).

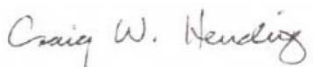
[130] *Id*. at Ex. B3, Voe000031–32.
[131] Decl. of Roe at ¶ 9 (July 18, 2018), Dkt. 31; Decl. of Voe at ¶ 11 (July 18, 2018), Dkt. 30.

VI. CONCLUSION

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

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

Executed this 22th day of March, 2019.



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Craig W. Hendrix, M.D.

EXHIBIT 1

CURRICULUM VITAE

The Johns Hopkins University School of Medicine

20 MAR 2019

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

Hospital

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

Personal Data

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EDUCATION AND TRAINING

Year	*Degree/Cert.*	*Institution*	*Discipline*
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

Dates	*Position*	*Institutions*
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

Dates	*Position*	*Institutions*
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

Dates	*Position*	*Institutions*
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

Dates	*Position*	*Institutions*
2009-present	Professor	Department of Epidemiology Johns Hopkins University Bloomberg School of Public Health Baltimore, MD
2012-2014	Co-Director	Behavioral Science Core
2014-present	Director	Laboratory Core
2014-present	Member	Executive Committee 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	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
2018-present	Director	Precision Medicine Center of Excellence Division of Clinical Pharmacology

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Original Research

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195. 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

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197. Heffron R, McClelland RS, Balkus JE, Celum C, Cohen CR, Mugo N, Bukusi E, Donnell D, Lingappa J, Kiarie J, Fiedler T, Munch M, Fredricks DN, Baeten JM; **Partners PrEP Study Team**. Efficacy of oral pre-exposure prophylaxis (PrEP) for HIV among women with abnormal vaginal microbiota: a post-hoc analysis of the randomised, placebo-controlled Partners PrEP Study. Lancet HIV. 2017 Oct;4(10):e449-e456. PMC5649365

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205. 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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218. Vincent KL, Moss JA, Marzinke MA, **Hendrix CW**, Anton PA, Gunawardana M, Dawson L, Olive TJ, Pyles RB, Baum MM. Phase I Trial of Pod-intravaginal Rings Delivering Antiretroviral Agents for HIV-1 Prevention: Rectal Drug Exposure from Vaginal Dosing with Tenofovir Disoproxil Fumarate, Emtricitabine, and Maraviroc. PLOS One 2018 Aug 22;13(8):e0201952. PMC6104940

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Invited 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. PMCID: 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

7. **Hendrix CW**. HIV Antiretroviral Pre-Exposure Prophylaxis: Development Challenges and Pipeline Promise. Clin Pharmacol Ther. 2018 Dec;104(6):1082-1097 *PMCID Pending*

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Case Reports

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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, Zwerski 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

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)

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Letters, Correspondence (continued)

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.

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 Pharamcokinetic 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%

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:	02/0l/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:	07/0l/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:	01/0l/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 jornal club 2012-2015
Tutorial "My Favorite Drug (Drug Develolpment)" 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 rthe Clinical Investigator – Short Course 2017-present
- Coruse 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, Obsetetrics & Gynecology, Johns Hopkins University 2014-present

Ethel Weld, MD, 2013-2016
Joint Clinical Pharmacology –Infectious Diseases Fellow
Graduate Training Program in Clinical Investigation, PhD 2019
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
Assocaite Professor, University of California, San Diego
HIV Prevention Trials Network Scholar
Research in Progress: Impact of staff-particpant 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: Quantiative assessment of White Coart 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

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, pharmacokinietics mentor

Kattayoun Kordy MD, 2014-2016
Clinical Pharmacology UCLA, F32, Pharmacokinetics mentor
Current Position: Assistant Professor, Medicine (Gastroenterology) University of Southern California (2016-present)

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.

EDUCATIONAL ACTIVITIES

Mentoring

*Thesis/*Oral Examination *Committees – continued*

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.

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.

Moira McMahon, Ph.D. Candidate, Department of Pharmacology, School of Medicine, Preliminary Oral Exam Committee Member, 2006.

EDUCATIONAL ACTIVITIES

Mentoring

Thesis/Oral Examination Committees – continued

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.

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.

EDUCATIONAL ACTIVITIES

Mentoring

Thesis/Oral Examination Committees – continued

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.

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, 2015-2019

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

EDUCATIONAL ACTIVITIES

Mentoring

Thesis/Oral Examination Committees – continued

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

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 coruse)
- Initial Course developer 2017
- Designed to provide an overview to clinical post-doctoral fellows and junior faculty planning clinical research studiesthat 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 director1991-1999
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 Pharamcology (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
Arthritis Advisory Committee 2018
Drug Safety and Risk Management Advisory Committee 2018

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
- Member 2018
- Fellow 2019

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 (ACCP), Distinguished Investigator Award 2018

American Socity of Clinical Pharmacology & Therapeutics (ASCPT) – Food and Drug Administration (FDA) William F. Abrams Award 2019

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 Antimicrobical 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 webnar talk. Sponsored by AIDS Vacine Advocacy Coalition (AVAC) and International Rectal Microbicide Advocates (iRMA). August 2017.

122. "Rectal Microbicides: Where We're Heading". Invited webinar talk. Sponsored by AIDS Vacine 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 Vacine 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 Vacine Advocacy Coalition (AVAC) and International Rectal Microbicide Advocates (iRMA). June 2018.

141. "Rectal Microbicide Protocol Status". Invited webinar talk. Sponsored by AIDS Vacine Advocacy Coalition (AVAC) and International Rectal Microbicide Advocates (iRMA). Septemebr 2018.

142. "On Demand Topical Agents for HIV Pre-exposure Prophylaxis." Invited plenary talk. HIV Research for Prevention (HIV R4P). Madrid, Spain. October 2018.

143. "Estrogen Decreases Tenofovir & Emtricitabine Concentrations in Transgender Women Taking Estrogen". Invited talk. HIV Research for Prevention (HIV R4P). Madrid, Spain. October 2018.

144. "Tenofovir/Emtricitabine and Estrogen Drug-Drug Interactions". Invited webinar talk. NIAID Transgender Research Working Group. January 2019.

145. "The Winding Road to On Demand, Topical, Behaviorally-Congruent HIV Pre-Exposure Prophylaxis. " Medical Grand Rounds, Bayview Medical Center, Baltimore, MD. January 2019.

EXHIBIT 2

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DOCUMENT	**BATES NUMBER**
U.S. Army Regulation 600-110 (Apr. 22, 2014), at https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r600_110.pdf	NH-000023 - 85
U.S. Department of Defense Retention Policy for Non-Deployable Service Members (Feb. 14, 2018), at https://dod.defense.gov/Portals/1/Documents/pubs/DoD-Universal-Retention-Policy.PDF	NH-000086 - 87
Department of Defense Instruction 6490.07 (Feb. 5, 2010), at http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/649007p.pdf	NH-000088 - 101
Department of Defense Instruction 1332.45 (Retention Determination for Non-Deployable Service Members) (July 30, 2018), at https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/133245p.pdf?ver=2018-08-01-143025-053	NH-000102 - 121
Department of Defense, *Department of Defense Personnel Policies Regarding Members of the Armed Forced Infected with Human Immunodeficiency Virus: Report to the Committees on the Armed Services of the Senate and House of Representatives* (August 2018)	NH-000122 - 156
U.S. Department of Defense Instruction 6485.01 (June 7, 2013), at http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/648501p.pdf	NH-000157 – 164
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) (Aug. 13, 2012)	NH-000165 - 187
Army Public Health Center, *Malaria Field Guide: The Prevention, Diagnosis and Treatment of Malaria in U.S. Africa Command* (May 2016), at https://phc.amedd.army.mil/PHC%20Resource%20Library/TG336_MalariaFieldGuide_May2016.pdf	NH-000188 – 254

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DOCUMENT	**BATES NUMBER**
U.S. Department of Health and Human Services, *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV* (May 1, 2014), https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/458/plasma-hiv-1-rna--viral-load--and-cd4-count-monitoring	NH-000255 – 262
Declaration of Nicholas Harrison (DKT 26-3) (July 19, 2018)	NH-000263 - 299
U.S. Department of Health and Human Services, *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV* (May 1, 2014), https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/459/cost-considerations-and-antiretroviral-therapy	NH-000300 - 309
Office of the Assistant Secretary of Defense, Health Affairs Mem. (Policy Memorandum – Human Immunodeficiency Virus Interval Testing) (Mar. 29, 2004), https://www.health.mil/Reference-Center/Policies/2004/03/29/Policy-Memorandum---Human-Immunodeficiency-Virus-Interval-Testing	NH-000310 – 324
J. Brundage et al., *Durations of Military Service after Diagnoses of HIV-1 Infections Among Active Component Members of the U.S. Armed Forces 1990-2013*, Vol. 22 No. 8 Medical Surveillance Monthly Report, pp. 9–12 (Aug. 2015), https://health.mil/Reference-Center/Reports/2015/01/01/Medical-Surveillance-Monthly-Report-Volume-22-Number-8	NH-000325 - 348
U.S. Army Regulation 40-501 (Standards of Medical Fitness) (June 14, 2017)	NH-000349 - 499
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), https://health.mil/Reference-Center/Reports/2017/01/01/Medical-Surveillance-Monthly-Report-Volume-24-Number-9	NH-000500 - 523
U.S. Department of Defense Instruction 6025.19 (Individual Medical Readiness), (June 9, 2014), http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/602519p.pdf	NH-000524 - 538

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DOCUMENT	**BATES NUMBER**
Armed Services Blood Program, About Us, at http://www.militaryblood.dod.mil/About/default.aspx	NH-000539 - 540
P. Scott et al., *Short Communication: Investigation of Incident HIV Infections Among U.S. Army Soldiers Deployed to Afghanistan and Iraq, 2001-2007*	NH-000541 – 545
U.S. Department of Health & Human Services, National Heart, Lung, and Blood Institute, Blood Transfusion, at https://www.nhlbi.nih.gov/health-topics/blood-transfusion	NH-000546 – 552
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)	NH-000553 – 572
United States Census Bureau. *American Factfinder: Monthly Population Estimates for the United States: April 1, 2010 to December 1, 2016* (last visited July 18, 2018), at https://factfinder.census.gov/faces/tableservices/jsf/pages/productionview.xhtml?pid=PEP+2017_PEPMONTHN&prodType=table	NH-000573 - 575
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	NH-000576 - 603
U.S. Department of Defense Instruction 6130.03 (May 6, 2018), at http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/613003p.pdf	NH-000604 - 652
Emergency War Surgery, 4th ed. (2014), Chapter 33 (Battlefield Transfusions), at http://www.cs.amedd.army.mil/FileDownloadpublic.aspx?docid=189c4a13-522f-4d91-9236-a109d7b5ee4d	NH-000653 - 674
U.S. Centers for Disease Control and Prevention, *HIV Risk Behaviors: Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act* (Dec. 2015), at www.cdc.gov/hiv/risk/estimates/riskbehaviors.html.	OutServe_RV-000138

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DOCUMENT	**BATES NUMBER**
Asha De et al., *Physical fitness characteristics of active duty US Air Force members with HIV infection*, Medicine (2016) 95:44	OutServe_RV-000219 - 226
Air Force Mem. AFGM2019-36-01 (Air Force Guidance Memorandum for Implementing Department of Defense Instruction (DoDI) 1332.45, Retention Determinations for Non-Deployable Service Members) (February 19, 2019)	OutServe_RV-000275 - 281
Air Force Instruction 36-3212 (February 2, 2006, incorporating through change 2, November 27, 2009)	OutServe_RV-000618 - 715
Air Force Instruction 44-178, Human Immunodeficiency Virus Program, March 4, 2014 (Certified Current June 28, 2016)	OutServe_RV-000716 - 759
Air Force Mem. AFGM2019-36-01 (Air Force Guidance Memorandum for Impletmenting Department of Defense Instruction (DoDI) 1332.45, Retention Determinations for Non-Deployable Service Members) (February 19, 2019)	OutServe_RV-000275-281
Dep't of Def. Instr. 1332.18 (Disability Evaluation System (DES)) (August 5, 2014), https://warriorcare.dodlive.mil/files/2016/03/DoDI_1332.18.pdf	OutServe_RV-000900-907
Commander's Impact Statement for Medical Evaluation Board regarding Mitchell D. Burge (12/08/17), Addendum (01/16/18), Fitness & Job Performance Report, Consultation Summary, Ancillary Study Summary, History of Present Illness, and Memorandum for Medical Evaluation Board (01/15/18)	ROE-000014 - 22
Air Force Individual Fitness Report for Mitchell David Burge (April 2, 2018)	ROE-000089 - 90
N. Harrison, Army Physical Fitness Test Scorecard (Dec. 6, 2014)	US00000323
Information Paper, Accession Qualification Standards for Human Immunodeficiency Virus (HIV) Infection (Sept. 2015)	US00000656 - 657
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* (July 30, 2014)	US00000659 - 674

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DOCUMENT	**BATES NUMBER**
Memorandum for the Directorate of Military Personnel Management (Feb. 29, 2016)	US00001135
Dep't of the Army Mem. DASG-HCO (Request for Medical Opinion, Roe) (Apr. 30, 2015)	US00001136
Dep't of the Army Mem. DASG-HCZ (Request for Medical Opinion, Roe) ¶ 2 (Jan. 12, 2016)	US00001137
January 5, 2016 Email from Laurie Fontaine (CIV) to Marguerite Anne Lawrence LTC, GS re a medical recommendation concerning Nicholas Harrison	US00002428 - 433
Antinori, A. et al., *Updated research nosology for HIV-associated neurocognitive disorders*, Neurology. 2007 October 30; 69(18): 1789–1799	US00003666 - 386
Consensus Statement: Rick of Sexual Transmission of HIV from a Person Living with HIV who has an Undetectable Viral Load, U.S. Prevention Access Campaign (issued July 21, 2016)	US00004410 - 417
Grant, I. et al., *Asymptomatic HIV-associated neurocognitive impairment increases risk for symptomatic decline*, Neurology 82, June 10, 2014, 2055-2062	US00004418 - 425
Kuhar, D. et al., *Updated US Public Health Service Guidelines for the Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Postexposure Prophylaxis, Infection Control and Hospital Epidemiology*, September 2013, Vol. 34, No. 9, 875-893	US00004426 - 445
Crum-Cianflone, N. et al., *Low prevalence of neurocognitive impairment in early diagnosed and managed HIV-infected persons*, Neurology 80, January 22, 2013, 371-379	US00004446 - 454
Patel, P. et al., *Estimating per-act HIV transmission risk: a systematic review*, AIDS 2014, 28:000-000	US00004565 - 582
De Souza, E. et al., *Risk factors for neurocognitive impairment in HIV-infected patients and comparison of different screening tools*, Dement Neuropsychol 2016 March; 10(1):42-46	US00004960 - 964

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DOCUMENT	**BATES NUMBER**
Price, R., *HIV-associated neurocognitive disorders: Epidemiology, clinical manifestations, and diagnosis – UpToDate*, last updated February 14, 2017, literature review current through October 2018, https://www.uptodate.com/contents/hiv-associated-neurocognitive-disorders-epidemiology-clinical-manifestations-and-diagnosis	US00005269 - 291
Military Infectious Diseases Research Program (MIDRP) (Last Modified Date: March 22, 2010)	US00005292 - 295
Joint Trauma System Clinical Practice Guideline (JTS CPG): Whole Blood Transfusion (CPG ID:21) (May 15, 2018)	US00005296-334
Department of Defense Instruction 1332.18 (Disability Evaluation System (DES)) (August 5, 2014), https://warriorcare.dodlive.mil/files/2016/03/DoDI_1332.18.pdf	US00007238 - 7292
U.S. Cent. Command Doc. 231245Z (Modification Thirteen to USCENTCOM Individual Protection and Individual Unit Deployment Policy) (March 2017)	US00009910 - 931
U.S. Cent. Command Doc. PPG-TAB A (Amplification of the Minimal Standards of Fitness for Deployment to the CENTCOM AOR; To Accompany Mod Thirteen to USCENTCOM Individual Protection and Individual/Unit Deployment Policy) (March 2017), https://www.express-scripts.com/TRICARE/tools/USCENTCOM-MOD-13_TAB-A.pdf	US00010225 - 234
U.S. Navy, Secretary of the Navy Instruction 5300.30F (Management of Human Immunodeficiency Virus, Hepatitus B Virus, and Hepatitis C Virus Infection in the Navy and Marine Corps) (December 27, 2018)	US00031478 - 513
Memorandum for SAF/MRBP regarding the Appeal of the Findings of the Formal Physical Evaluation Board (FPEB) for Michael B, Bell (Dec. 20, 2017)	VOE-000033 - 34
Air Force Mem. A-00338 (Appropriate Evaluation of Fitness for Continued Service for Airmen with Asymptomatic Human Immunodeficiency Virus (HIV)) (June 6, 2018) (1:18-cv-01565, DKT 50-2)	US00031051

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DOCUMENT	BATES NUMBER
Air Force Mem. A-00339 (Airmen with Asymptomatic Human Immunodeficiency Virus (HIV) Disposition) (Sep. 26, 2018) (1:18-cv-01565, DKT 50-2)	US00031049-50
Air Force Mem. A-00341 (Retention of Airmen with Asymptomatic HIV) (Oct. 11, 2017) (1:18-cv-01565, DKT 50-2)	US00031061
Chronological Record of Medical Care of Michael Brian Bell (1:18-cv-01565, DKT 57, pp. 55-70)	N/A
Chronological Record of Medical Care of Mitchell David Burge (1:18-cv-01565, DKT 56, pp. 40-47)	N/A
U.S. Army Mem. 2018-22 (Retention Policy for Non-Deployable Soldiers) (Nov. 8, 2018)	N/A
Declaration of Senior Airman Michael Bell in Support of Motion for Preliminary Injunction with exhibits (01/11/18) (1:18-cv-01565) (Filed Under Seal Pursuant to 1/11/19 Motion) ("Voe Declaration")	N/A
Declaration of Staff Sergeant Mitchell Burge in Support of Plaintiff's Motion for Preliminary Injunction with exhibits (1:18-cv-00641) (07/18/18) (Filed Under Seal Pursuant to 1/11/19 Motion) ("Roe Declaration")	N/A
Declaration of Staff Sergeant Mitchell Burge in Support of Plaintiff's Motion for Preliminary Injunction with exhibits (1:18-cv-00641) (01/11/18) (1:18-cv-01565) (Filed Under Seal Pursuant to 1/11/19 Motion)	N/A
Declaration of Kevin Cron in Support of Plaintiff's Motion for Preliminary Injunction (January 25, 2019)	N/A
Expert Declaration of Carlos Del Rio, M.D. in Support of Plaintiffs' Motion for Preliminary Injunction (1:18-cv-00641, DKT 0026-2) (July 19, 2018)	N/A
Expert Declaration of Craig W. Hendrix, M.D. in Support of Plaintiffs' Motion for Preliminary Injunction (1:18-cv-00641, DKT 0026-5) (July 19, 2018)	N/A

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DOCUMENT	**BATES NUMBER**
Sacktor, N., Changing clinical phenotypes of HIV-associated neurorocognitive disorders, J. Neurovirol. (2018) 24:141–145	N/A
Supplemental Administrative Record (02/22/19) (1:18-cv-01565) (Sealed Version)	N/A
Deposition of Lt. Col. Lisa M. Lute with Exhibits (January 9, 2019)	N/A
30(b)(6) Deposition of United States Army Given By Dr. Jason Blaylock with Exhibits (February 27, 2019)	N/A
Deposition of Lt. Col. Paul Tumminello with Exhibits (February 13, 2019)	N/A
30(b)(6) Deposition of Defendants Given By Andrew Wiesen with Exhibits (February 22, 2019)	N/A
30(b)(6) Deposition of Defendants Given By Audra L. Taylor with Exhibits (March 1, 2019)	N/A
Deposition of Kevin Cron and Exhibits (March 15, 2019)	N/A
Expert Report of W. David Hardy, M.D. (March 22, 2019)	N/A