

# Exhibit E

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

NICHOLAS HARRISON and  
OUTSERVE-SLDN, INC.

Plaintiffs,

v.

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

Defendants.

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

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

## **I. INTRODUCTION**

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

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

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

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

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

## **II. PROFESSIONAL BACKGROUND & QUALIFICATIONS**

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

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

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

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

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

---

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

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

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

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

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

**A. Military Policies Regarding People Living with HIV**

**1. Accession Ban**

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

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

14. Department of Defense Instruction 6130.03 (Medical Standards for Appointment, Enlistment, and Induction into the Military Services) sets forth guidance regarding the physical and medical standards required for military service.<sup>5</sup> 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.

---

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

<sup>3</sup> *Id.* at Enclosure 3: Procedures, ¶3.c.

<sup>4</sup> *Id.* at Enclosure 3: Procedures, ¶3.e.

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

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

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

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

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

15. HIV is among the specified “disqualifying conditions” under DoDI 6130.03.<sup>7</sup>

16. I also understand that Army Regulation 600-110 (Identification, Surveillance, and Administration of Personnel Infected with Human Immunodeficiency Virus)<sup>8</sup> 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.<sup>9</sup> 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.<sup>10</sup> Again, however, the Army regulation states that active duty soldiers with HIV who do not demonstrate progressive clinical illness or immunological

---

<sup>6</sup> *Id.* at ¶1.2.c.

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

<sup>8</sup> U.S. Army Regulation 600-110 (Apr. 22, 2014), available at [https://armypubs.army.mil/epubs/DR\\_pubs/DR\\_a/pdf/web/r600\\_110.pdf](https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r600_110.pdf).

<sup>9</sup> *Id.* at Section III, ¶1-15.

<sup>10</sup> *Id.* at Section III, ¶1-16.a.

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

## 2. Conditions for Deployment and Deployment Restrictions

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

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

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

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

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

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

---

<sup>11</sup> *Id.* at Section III, ¶1-16.e.

<sup>12</sup> *Id.* at ¶4.b.

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



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

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

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

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

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

---

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

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

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

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

---

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

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

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

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

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

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

---

<sup>18</sup> Army Public Health Center, *Malaria Field Guide: The Prevention, Diagnosis and Treatment of Malaria in U.S. Africa Command* (May 2016), available at [https://phc.amedd.army.mil/PHC%20Resource%20Library/TG336\\_MalariaFieldGuide\\_May2016.pdf](https://phc.amedd.army.mil/PHC%20Resource%20Library/TG336_MalariaFieldGuide_May2016.pdf).

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

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

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

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

---

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

back as 2004, when DoD mandated universal two-year interval HIV testing, the DoD’s Armed Forces Epidemiology Board explained that “There is no evidence that HIV infection, per se, affects physical fitness.”<sup>20</sup> The same remains true today. As explained in a 2015 article in the *Medical Surveillance Monthly Report*: “In the past 30 years, HIV-1 infection has gone from an untreatable disease marked by inexorable clinical progression through extreme debility to death to a treatable disease that is compatible with active service throughout a full career in the U.S. military.”<sup>21</sup> As an example, I understand that Mr. Harrison, who was diagnosed with HIV in 2012, received a PULHES<sup>22</sup> 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).<sup>23</sup> There should be no effect on the physical fitness and capabilities of any person with HIV who is adhering to their prescribed ART regimen

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

---

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

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

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

<sup>23</sup> U.S. Army Regulation 40-501 (Standards of Medical Fitness), Chapter 7, ¶7-3.d(1) (“An individual having a numerical designation of ‘1’ under all factors is considered to possess a high level of medical fitness.”).

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

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

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

**5. There is No Impact on Medical Readiness**

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

---

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

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

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

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

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

---

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

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

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

<sup>27</sup> Armed Services Blood Program, About Us, available at

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

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

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

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

---

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

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

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

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



approximately one-third of one percent of the population of the United States, and just .027% of active duty service members).<sup>32</sup> Furthermore, there are various other factors that often disqualify individuals as emergency blood donors, such as blood type<sup>33</sup>—making people living with HIV no different from these other groups who are allowed to serve and deploy. Finally, the use of blood substitutes is on the rise, which should result in even less need for emergency battlefield transfusions from other service members.

#### IV. CONCLUSION

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

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

Executed this 18th day of July, 2018



Craig W. Hendrix, M.D.

---

<sup>32</sup> United States Census Bureau. *American Factfinder: Monthly Population Estimates for the United States: April 1, 2010 to December 1, 2016*, [https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=PEP\\_2017\\_PEMONTHN&prodType=table](https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=PEP_2017_PEMONTHN&prodType=table) (last visited July 18, 2018); Armed Forces Health Surveillance Center (AFHSC), *Update: Routine Screening for Antibodies to Human Immunodeficiency Virus, Civilian Applicants for U.S. Military Service and U.S. Armed Forces, Active and Reserve Components, January 2010–June 2015*, Medical Surveillance Monthly Report, Aug. 2015, 2-8.

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

# **Attachment**

## CURRICULUM VITAE

The Johns Hopkins University School of Medicine

10 JUL 18

Craig W. Hendrix

(Date of this version)

### DEMOGRAPHIC AND PERSONAL INFORMATION

#### Current Appointments

##### *University*

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

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

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

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

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

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

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

##### *Hospital*

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

#### Personal Data

Blalock 569  
600 North Wolfe Street  
Baltimore, Maryland 21287  
Voice 410-955-9707  
Facsimile 410-955-9708  
E-mail chendrix@jhmi.edu

**EDUCATION AND TRAINING**

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

**PROFESSIONAL EXPERIENCE**

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

**PROFESSIONAL EXPERIENCE**

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

**PROFESSIONAL EXPERIENCE**

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

**PROFESSIONAL EXPERIENCE**

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

## PUBLICATIONS

### Original Research

1. Smith CR, Petty BG, **Hendrix CW**, Kernan WN, Garver PL, Fox K, Beamer A, Carbone K, Threlkeld M, Lietman PS. Ceftriaxone Compared with Cefotaxime for Serious Bacterial Infections. *J Infect Dis* 1989;160(3):442-7.
2. Kornhauser DM, Petty BG, **Hendrix CW**, Woods AS, Nerhood LJ, Bartlett JG, Lietman PS. Probenecid and Zidovudine Metabolism. *Lancet* 1989;2(8661):473-5.
3. Lorentsen KJ, **Hendrix CW**, Collins JM, Kornhauser D, Petty BG, Klecker RW, Flexner C, Eckel RH, Lietman PS. Dextran Sulfate is Poorly Absorbed after Oral Administration. *Ann Intern Med* 1989;111(7):561-6.
4. Lucey DR, **Hendrix CW**, Andrzejewski C, McGlasson D, Ward WW, Melcher GP, Zajac RA, Boswell RN. Hepatitis C Antibody in a Non-Hemophiliac Cohort Infected with the Human Immunodeficiency Virus. *Viral Immunol* 1990;3(4):295-301.
5. Lucey DR, McGuire SA, Clerici M, Hall K, Benton J, Clifford AB, Ward WW, Shearer G, Boswell RN, **Hendrix CW**. Comparison of Spinal Fluid Beta 2-Microglobulin Levels with CD4+ T Lymphocyte Count, In Vitro T Helper Cell Function, and Spinal Fluid IgG Parameters in 163 Neurologically Normal Adults Infected with the Human Immunodeficiency Virus Type 1. *J Infect Dis* 1991;163(5):971-5.
6. **Hendrix CW**, Volberding PA, Chaisson RE. HIV Antigen Variability in ARC/AIDS. *J Acquir Immun Defic Syndr* 1991;4(9):847-850.
7. Lucey DR, Melcher GP, **Hendrix CW**, Zajac RA, Goetz DW, Butzin CA, Clerici M, Warner RD, Abbadessa S, Hall K, Jaso R, Woolford B, Miller S, Stocks NI, Salinas CM, Wolfe WH, Shearer GM, Boswell RN. Human Immunodeficiency Virus (HIV-1) Infection in the U.S. Air Force: Seroconversions, Clinical Staging, and Assessment of a T-Helper Cell Functional Assay to Predict Change in CD4+ T Cell Counts. *J Infect Dis* 1991;164(4): 631-7.
8. De Groot AS, Clerici M, Hosmalin A, Hughes SH, Brand D, **Hendrix CW**, Houghten R, Shearer GM, Berzofsky JA. Human Immunodeficiency Virus Reverse Transcriptase T Helper Epitopes Identified in Mice and Humans: Correlation with a Cytotoxic T Cell Epitope. *J Infect Dis* 1991;164(6):1058-65.
9. Flexner C, Barditch-Crovo PA, Kornhauser DM, Farzadegan H, Nerhood LJ, Chaisson RE, Bell KM, Lorentsen KJ, **Hendrix CW**, Petty BG, Lietman PS. Pharmacokinetics, Toxicity, and Activity of Intravenous Dextran Sulfate in Human Immunodeficiency Virus Infection. *Antimicrob Agents Chemother* 1991;35(12):2544-50.



**PUBLICATIONS****Original Research - continued**

10. Warren RQ, Nkya WM, Shao JF, Anderson SA, Wolf H, **Hendrix CW**, Kanda P, Wabuke M, Boswell RN, Redfield RR, Kennedy RC. Comparison of Antibody Reactivity to Human Immunodeficiency Virus Type 1 (HIV-1) gp160 Epitopes in Sera from HIV-1-Infected Individuals from Tanzania and from the United States. *J Clin Microbiol* 1992;30(1):126-31.
11. Nyka WM, Warren RQ, Wolf H, **Hendrix CW**, Tesha J, Redfield RR, Melcher GP, Burke DS, Kanda P, Kennedy RC. Fine Specificity of the Humoral Immune Response to HIV-1 GP 160 in HIV-1 Infected Individuals from Tanzania. *J Med Virol* 1992;37(1):61-6.
12. Lucey DR, **Hendrix CW**, Andrzejewski C, Melcher GP, Butzin CA, Henry R, Wians F, Boswell RN. Comparison by Race of Total Serum IgG, IgA, IgM with CD4+ T-Cell Counts in North American Persons Infected with the Human Immunodeficiency Virus type 1. *J Acquir Immune Defic Syndr* 1992;5:325-32.
13. Warren RQ, Anderson SA, Nyka WM, Shao JF, **Hendrix CW**, Melcher GP, Redfield RR, Kennedy RC. Examination of Sera from HIV-1 Infected Individuals for Antibodies Reactive with Peptides Corresponding to the Principal Neutralizing Determinant of HIV-1 gp120 and In Vitro Neutralizing Activity. *J Virology* 1992;66(9):5210-5.
14. Blay R, Hernandez D, Betts M, Clerici M, Lucey DR, **Hendrix CW**, Hoffman T, Golding B. *Brucella abortus* Stimulates Human T Cells from Uninfected and HIV-Infected Individuals to Secrete IFN-gamma: Implications for use of *Brucella abortus* as a Carrier in Development of Human Vaccines. *AIDS Res and Human Retroviruses* 1992;8(4):479-86.
15. Clerici M, Landay AL, Kessler HA, Venzon DJ, **Hendrix CW**, Lucey DR, Shearer GM. Reconstitution of Long-Term T Helper Cell Function Following Zidovudine Therapy in HIV-infected Patients. *J Infect Dis* 1992;166(4):723-30.
16. Blatt S, Lucey CR, Butzin CA, **Hendrix CW**, Lucey DP. Total Lymphocyte Count as a Predictor of Absolute CD4+ Count and CD4+ Percentage in HIV-Infected Persons. *JAMA* 1993;269(5):622-6.
17. **Hendrix CW**, Margolick JB, Petty BG, Markham RB, Nerhood L, Farzadegan H, Ts'o POP, Lietman PS. Biologic Effects After Single Dose poly I:poly C12U (Mismatched Double-Stranded RNA, Atvogen) in Healthy Volunteers. *Antimicrob Agents Chemother* 1993;37 (3):429-435.
18. Clerici M, Hakim FT, Venzon DJ, Blatt S, **Hendrix CW**, Shearer GM. Changes in Interleukin-2 and Interleukin-4 Production in Asymptomatic, Human Immunodeficiency Virus-Seropositive Individuals. *J Clin Invest* 1993;91(3):759-65.

**PUBLICATIONS****Original Research – continued**

19. Warner RD, Mathis RE, Weston ME, Bigbee LR, **Hendrix CW**, Lucey DR. Estimates of Human Immunodeficiency Virus (HIV) Incidence and Trends in the US Air Force. *Vaccine* 1993;11(5):534-37.
20. Dolan MJ, Lucey DR, **Hendrix CW**, Melcher GP, Spencer GA, Boswell RN. Early Markers of HIV Infection and Subclinical Disease Progression. *Vaccine* 1993;11(5):548-51.
21. Lucey DR, McCarthy WF, Blatt SP, Melcher GP, **Hendrix CW**. Racial Differences in Serum Beta2- microglobulin in Persons with Human Immunodeficiency Virus Infection. *J Infect Dis* 1993;167(5):1259-60.
22. Blatt SP, **Hendrix CW**, Butzin CA, Freeman TM, Ward WW, Hensley RE, Melcher GP, Donovan DJ, Boswell RN. Delayed-type Hypersensitivity Skin Testing Predicts Progression to AIDS in HIV-Infected Patients. *Ann Intern Med* 1993;119:117-84.
23. Lucey DR, Van Cott TC, Loomis LD, Bethke FR, **Hendrix CW**, Melcher GP, Redfield RR, Birx DL. Measurement of Cerebrospinal Fluid Antibody to the HIV-1 Principal Neutralizing Determinant (V3 Loop). *J Acquir Immune Defic Syndr* 1993;6(9):994-1001.
24. Clerici M, Yarchoan R, Blatt S, **Hendrix CW**, Ammann AJ, Broder S, Shearer GM. Effect of Recombinant CD4-IgG on In Vitro T Helper Cell Function: Data from a Phase I/II Study of Patients with the Acquired Immunodeficiency Syndrome (AIDS). *J Infect Dis* 1993;168(4):1012-6.
25. Wong MT, Warren RQ, Anderson SA, Dolan MJ, **Hendrix CW**, Blatt SP, Melcher GP, Boswell RN, Kennedy RC. Longitudinal Analysis of the Humoral Immune Response to Human Immunodeficiency Virus, Type-1 (HIV-1) gp160 Epitopes in Rapid and Nonprogressing HIV-1-Infected Subjects. *J Infect Dis* 1993;168(6):1523-7.
26. Clerici M, Lucey DR, Berzofsky JA, Pinto LA, Wynn TA, Blatt SP, Dolan MJ, **Hendrix CW**, Wolf SF, Shearer GM. Restoration of HIV-Specific Cell-Mediated Immune Responses by Interleukin-12 In Vitro. *Science* 1993;262(5140):1721-4.
27. Lucey DR, McGuire SA, Abbadessa S, Hall K, Woolford B, Valtier S, Butzin CA, Melcher GP, **Hendrix CW**. Cerebrospinal Fluid Neopterin Levels in 159 Neurologically Asymptomatic Persons Infected with the Human Immunodeficiency Virus (HIV-1). Relationship to Immune Status. *Viral Immunol* 1993;6(4):267-72.
28. Musser JM, Kapur V, Peters JE, **Hendrix CW**, Drehner D, Gackstetter GD, Skalka DR, Fort PL, Maffei JT, Li LL, Melcher GP. Real-time Molecular Epidemiologic Analysis of an Outbreak of *Streptococcus pyogenes* Invasive Disease in US Air Force Trainees. *Arch Pathol Lab Med* 1994;118(2):128-36.

**PUBLICATIONS****Original Research - continued**

29. Clerici M, Wynn TA, Berzofsky JA, Blatt SP, **Hendrix CW**, Sher A, Coffman RL, Shearer GM. Role of Interleukin-10 in T Helper Cell Dysfunction in Asymptomatic Individuals Infected with the Human Immunodeficiency Virus. *J Clin Invest* 1994;93(2):768-75.
30. **Hendrix CW**, Flexner C, Szebeni J, Kuwahara S, Pennypacker S, Weinstein J, Lietman P. Dipyridamole's Effect on Zidovudine Pharmacokinetics and Tolerance in Asymptomatic HIV-Infected Subjects. *Antimicrob Agents Chemother* 1994;38(5):1036-40.
31. Ascher DP, Blatt SP, **Hendrix CW**, Roberts C, Fowler CB. Validation of Post-Acidification P24 Antigen as a Prognostic Marker for HIV Disease Progression. *AIDS Patient Care* 1994;8(5):251-253.
32. Sarin A, Clerici M, Blatt SP, **Hendrix CW**, Shearer GM, Henkart PA. Inhibition of Activation-Induced Programmed Cell Death and Restoration of Defective Immune Responses of HIV+ Donors by Cysteine Protease Inhibitors. *J Immunol* 1994;153(2):862-72.
33. Clerici M, Sarin A, Coffman RL, Wynn TA, Blatt SP, **Hendrix CW**, Wolf SF, Shearer GM, Henkart PA. Type 1/type 2 Cytokine Modulation of T Cell Programmed Cell Death as a Model for HIV Pathogenesis. *Proc Natl Acad Sci USA* 1994;91(25):11811-5.
34. Blatt SP, McCarthy WF, Bucko-Krasnicka B, Melcher GP, Boswell RN, Dolan MJ, Freeman TM, Rusnak JM, Hensley RE, Ward WW, Barnes D, **Hendrix CW**. Multivariate Models for Predicting Progression to AIDS and Survival in HIV-Infected Persons. *J Infect Dis* 1995;171(4):837.
35. Dolan MJ, Clerici M, Blatt SP, **Hendrix CW**, Melcher GP, Boswell RN, Freeman TM, Ward W, Hensley R, Shearer GM. In vitro T cell function, delayed-type hypersensitivity skin testing, and CD4+ T cell subset phenotyping independently predict survival time in patients infected with Human Immunodeficiency Virus. *J Infect Dis* 1995 ;172(1):79-87.
36. Epstein LJ, Strollo PJ, Jr., Donegan RB, Delmar J, **Hendrix CW**, Westbrook PR. Obstructive Sleep Apnea in Patients with Human Immunodeficiency Virus (HIV) Disease. *Sleep* 1995;18(5):368-76.
37. **Hendrix CW**, Petty BG, Woods A, Kuwahara SK, Witter FR, Soo W, Griffin DE, Lietman PS. Modulation of alpha interferon's antiviral and clinical effects by aspirin, acetaminophen, and prednisone in healthy volunteers. *Antiviral Research* 1995;28(2):121-131.
38. Clerici M, Sarin A, Berzofsky, JA, Landay AL, Kessler HA, Hashemi F, **Hendrix CW**, Blatt SP, Rusnak J, Dolan MJ, Coffman RL, Henkart PA, Shearer GM. Antigen-stimulated apoptotic T cell death in HIV infection is selective for CD4+ T cells, modulated by cytokines and lymphotoxin. *AIDS* 1996;10(6):603-611.

**PUBLICATIONS****Original Research - continued**

39. Barditch-Crovo P, Toole J, **Hendrix CW**, Cundy KC, Ebeling D, Jaffe HS, Lietman PS. Anti-human immunodeficiency virus (HIV) activity, safety, and pharmacokinetics of adefovir dipivoxil (9-[2-(bispivaloyloxymethyl) phosphonylmethoxyethyl] adenine) in HIV-infected patients. *J Infect Dis* 1997;176(2):406-413.
40. Chien S-C, Chow AT, Williams R, Wong F, Nayak RK, **Hendrix CW**. The pharmacokinetics and safety of oral levofloxacin in HIV-infected individuals receiving concomitant zidovudine. *Antimicrob Agents Chemother* 1997;41(8):1765-1769.
41. Gardner LI, Harrison SH, **Hendrix CW**, Blatt SP, Wagner KF, Chung RCY, Harris RW, Cohn DL, Burke DS, Mayers DL. Size and duration of zidovudine benefit in 1003 HIV-infected patients: U.S. Army, Navy and Air Force Natural History Data. *J Acq Immundef Synd* 1998 ;17(4):345-53.
42. Barditch-Crovo P, Trapnell CB, Ette E, Zacur H, **Hendrix CW**, Flexner CW. Effects of Rifampin and Rifabutin on Combination Oral Contraceptive Pharmacodynamics. *Clin Pharmacol Ther* 1999;65(4):428-38.
43. Petty B, Black J, **Hendrix CW**, Bassiakos Y, Feinberg J, Hafner R. Escalating Multiple-Dose Safety and Tolerance of WR 6026 in HIV-Infected Subjects. *J Acq Immundef Synd* 1999 ;21(1):26-32.
44. **Hendrix CW**, Daniell FD. HIV Prevention Education: Utilization of Evaluation to Inform Policy Evolution in the Military. *AIDS & Public Policy* 1999;14(2):80-91.
45. Turchin A, Lehmann HP, Flexner CW, **Hendrix CW**, Shatzer JH, Merz WG. Active Learning Center: Potential uses and efficacy of an interactive Internet-based teaching tool. *Medical Teacher*. 2000;22(3):271-275.
46. Yeager RD, **Hendrix CW**, Kingma S. International military human immunodeficiency virus/acquired immunodeficiency syndrome policies and programs: strengths and limitations in current practice. *Mil Med*. 2000;165(2):87-92.
47. Michelson AD, Furman MI, Coleman L, Hamlington J, Goldschmidt-Clermont P, **Hendrix CW**, Mascelli MA, Barnard MR, Kickler T, Christie DJ, Kundu S, Bray PF. Integrin Beta<sub>3</sub> (GPIIIa) Pl<sup>A</sup> Polymorphisms on Platelets Display Different Sensitivity to Agonists and Antagonists. *Circulation* 2000;101(9):1013-8.
48. **Hendrix CW**, Flexner C, MacFarland RT, Giandomenico C, Fuchs EJ, Redpath E, Bridger G, Henson GW. Pharmacokinetics and Safety of AMD-3100, a Novel Antagonist of the CXCR-4 Chemokine Receptor, in Human Volunteers. *Antimicrob Agents Chemother* 2000;44(6):1667-1673.
49. **Collaborative Group** on AIDS Incubation and HIV Survival including the CASCADE EU Concerted Action. Time from HIV-1 seroconversion to AIDS and death before widespread use of highly active antiretroviral therapy: a collaborative reanalysis. *Lancet* 2000;355(9210):1131-1137.

**PUBLICATIONS****Original Research – continued**

50. Pelz RK, Lipsett PA, Swoboda SM, Diener-West M, Powe NR, Brower RG, Perl TM, Hammond JMJ, **Hendrix CW**. Candida Infections: Outcome and Attributable ICU costs in critically ill patients. *J Intensive Care Med* 2000;15:255-261.
51. Pelz RK, Lipsett PA, Swoboda SM, Diener-West M, Hammond JMJ, **Hendrix CW**. The diagnostic value of fungal surveillance cultures in critically ill patients. *Surgical Infections (Larchmt)* 2000;1(4):273-281.
52. **Hendrix CW**, Hammond JMJ, Swoboda SM, Merz WG, Harrington SM, Perl TM, Dick JD, Borschel DM, Halczenko PW, Pelz RK, Rocco LE, Conway JE, Brower RG, Lipsett PA. Surveillance Strategies and Impact of Vancomycin-Resistant Enterococcal (VRE) Colonization and Infection in Critically Ill Patients. *Ann Surg* 2001;233(2):259-265.
53. Dimick JB, Pelz RK, Consunji R, Swoboda SM, **Hendrix CW**, Lipsett PA. Increased Resource Use Associated With Catheter-Related Bloodstream Infection in the Surgical Intensive Care Unit. *Arch Surg.* 2001;136(2):229-234.
54. Pelz R, **Hendrix CW**, Swoboda S, Diener-West M, Merz, W, Hammond JMJ, Lipsett PA. A double blind placebo controlled trial of prophylactic fluconazole to prevent Candida infections in critically ill surgical patients. *Ann Surg* 2001;233(4):542-548.
55. Pelz R, Lipsett PA, Swoboda SM, Merz W, **Hendrix CW**. Enteral fluconazole is well absorbed in critically ill surgical patients. *Surgery* 2002;131(5):534-40.
56. Pelz RK, Lipsett PA, Swoboda SM, Diener-West M, Powe NR, Brower RG, Perl TM, Hammond JMJ, **Hendrix CW**. Vancomycin-sensitive and vancomycin-resistant enterococcal infections in the ICU: attributable costs and outcomes. *Intensive Care Med* 2002;28(6):692-7.
57. Jackson JB, Barnett S, Piwowar-Manning E, Apuzzo L, Raines C, **Hendrix C**, Hamzeh F, Gallant J. A Phase I/II Study To Evaluate The Safety And Efficacy Of Pre-Exposure Nevirapine Prophylaxis For The Prevention Of HIV-1 Transmission In HIV-1 Uninfected Participants At High Risk. *AIDS* 2003;17(4):547-553.
58. Rajagopalan P, Pelz RK, Lipsett PA, Swoboda SS, **Hendrix CW**. Population pharmacokinetics of enteral fluconazole in surgical ICU patients. *Pharmacotherapy* 2003;23(5):592-602.
59. Dimick JB, Swoboda S, Talamini MA, Pelz RK, **Hendrix CW**, Lipsett PA. Risk of colonization of central venous catheters: catheters for total parenteral nutrition vs. other catheters. *Am J Crit Care.* 2003 Jul;12(4):328-35.

**PUBLICATIONS****Original Research - continued**

60. Wire MB, Ballow C, Preston SL, **Hendrix CW**, Piliero PJ, Lou Y, Stein DS. Pharmacokinetics and safety of GW433908 and ritonavir, with and without efavirenz, in healthy volunteers. *AIDS* 2004;18(6):897-907.
61. **Hendrix CW**, Jackson KA, Whitmore E, Guidos A, Kretzer R, Liss CR, Patel-Shah L, McLane J, Trapnell CB. The Effect of Isotretinoin on the Pharmacokinetics and Pharmacodynamics of Ethinyl Estradiol and Norethindrone. *Clin Pharm Ther* 2004;75(5):464-475.
62. Magill S, Puthanakit T, Swoboda S, Carson K, Salvatori R, Lipsett P, **Hendrix CW**. Impact of fluconazole prophylaxis on cortisol levels in critically ill surgical patients. *Antimicrob Agents Chemother* 2004;48(7):2471-2476.
63. **Hendrix CW**, Wakeford J, Wire MB, Bigelow G, Cornell E, Christopher J, Fuchs E, Snidow J. Pharmacokinetics and pharmacodynamics of methadone enantiomers after co-administration with amprenavir in opioid-dependent subjects. *Pharmacotherapy* 2004;24(9):1110-1121.
64. **Hendrix CW**, Collier AC, Lederman MM, Schols D, Pollard RB, Brown S, Jackson JB, Coombs RW, Glesby MJ, Flexner CW, Bridger GJ, Badel K, MacFarland RT, Henson GW, Calandra G, AMD3100 HIV Study Group. Safety, Pharmacokinetics, and Antiviral activity of AMD3100, a selective CXCR4 Receptor Inhibitor, in HIV-1 Infection. *J Acquir Immune Defic Syndr* 2004;37(2):1253-1262.
65. Mayer KH, Maslankowski L, Gai F, El-Sadr W, Justman J, Kwiecien A, Masse B, Eshleman S, **Hendrix CW**, Morrow K, Absalon J, Rooney J, Soto-Torres L. Tenofovir vaginal gel: Safety and tolerability in low-risk HIV-uninfected women and HIV-infected women (HPTN 050). *AIDS* 2006;20(4):543-551.
66. Magill SS, Swoboda S, Johnson E, Merz WG, Pelz RK, Lipsett PA, **Hendrix CW**. The impact of anatomical site of *Candida* colonization on the development of invasive candidiasis and mortality in critically ill surgical patients. *Diagn Microbiol Infect Dis* 2006;55(4):293-301. Epub 2006 May 15.
67. Ndovi TT, Choi L, Caffo B, Parsons T, Baker S, Zhao M, Rohde C, **Hendrix CW**. Quantitative assessment of seminal vesicle and prostate drug concentrations by use of a non-invasive method. *Clin Pharmacol Ther* 2006;80(2):146-158.
68. Ndovi TT, Parsons T, Choi L, Caffo B, Rohde C, **Hendrix CW**. A New Method to Quantitatively Estimate Seminal Vesicle and Prostate Gland Contributions to Ejaculate. *Br J Clin Pharmacol* 2007;63(4):404-20. Epub 2006 Oct 31.

**PUBLICATIONS****Original Research – continued**

69. Fuchs EJ, Lee LA, Torbenson MS, Parsons TL, Bakshi RP, Guidos AM, Wahl RL, **Hendrix CW**. Hyperosmolar Sexual Lubricant Causes Epithelial Damage in the Distal Colon: Potential Implication for HIV Transmission. *J Infect Dis* 2007;195(5):703-710. Epub 2007 Jan 23.
70. Stone, ND, Dunaway, SB, Flexner, CW, Tierney, C, Calandra, GB, Becker, S, Cao, Y, Wiggins, IP, Conley, J, MacFarland, RT, Park, J, Lalama, C, Snyder, S, Kallungal, B, Klingman, K, **Hendrix, CW**. Multiple Dose Escalation Study of the Safety, Pharmacokinetics, and Biologic Activity of Oral AMD070, a selective CXCR4 Receptor Inhibitor, in Human Subjects (ACTG A5191). *Antimicrob Agents Chemother* 2007;51(7):2351-8. Epub 2007 Apr 23.
71. Pham P, **Hendrix CW**, Barditch-Crovo P, Parsons T, Khan W, Parrish M, Radebaugh C, Carson KA, Pakes GE, Qaquish R, Flexner C. Amprenavir and lopinavir pharmacokinetics following coadministration of amprenavir or fosamprenavir with lopinavir/ritonavir, with or without efavirenz. *Antivir Ther* 2007;12(6):963-9.
72. Ndovi TT, Cao YJ, Fuchs EJ, Fletcher CV, Guidos A, **Hendrix CW**. Food affects zidovudine concentration independent of effects on gastrointestinal absorption. *J Clin Pharmacol* 2007;47(11):1366-73.
73. **Hendrix CW**, Fuchs EJ, Macura KJ, Lee LA, Parsons TL, Bakshi RP, Khan WA, Guidos A, Leal JP, Wahl R. Quantitative imaging and sigmoidoscopy to assess distribution of rectal microbicide surrogates. *Clin Pharmacol Ther* 2008 Jan;83(1):97-105. Epub 2007 May 16.
74. Choi L, Caffo BS, Rohde C, Ndovi TT, **Hendrix CW**. A Mechanistic Latent Variable Model for Estimating Drug Concentrations in the Male Genital Tract: A Case Study in Drug Kinetics. *Stat Med* 2008 Jun 30;27(14):2697-714.
75. Cao YJ, Ndovi TT, Parsons TL, Guidos A, Caffo B, **Hendrix CW**. Effect of semen sampling frequency on seminal antiretroviral drug concentration. *Clin Pharmacol Ther*. 2008 Jun;83(6):848-56.
76. Cao YJ, Caffo B, Choi L, Radebaugh C, Fuchs EJ, **Hendrix CW**. Noninvasive quantitation of drug concentration in prostate and seminal vesicles: improvement and validation with desipramine and aspirin. *J Clin Pharmacol*. 2008 Feb;48(2):176-83. Epub 2007 Dec 19.
77. Nyunt M, Becker S, MacFarland R, Everts S, Chee P, Scarborough R, **Hendrix CW**. Pharmacokinetic Interaction between AMD11070 and Substrates of CYP3A4 and 2D6 Enzymes in Healthy Volunteers. *J Acquir Immune Defic Syndr* 2008 Apr 15;47(5):559-565.

**PUBLICATIONS****Original Research – continued**

78. Cao YJ, Smith PF, Wire MB, Lou Y, Lancaster CT, Causon RC, Bigelow G, Martinez E, Fuchs EJ, McCabe S, **Hendrix CW**. Pharmacokinetics and Pharmacodynamics of Methadone Enantiomers Following Coadministration with Fosamprenavir and Ritonavir in Opioid-Dependent Subjects. *Pharmacotherapy* 2008 Jul;28(7):863-74.
79. Cao YJ, Flexner C, Dunaway S, Park JG, Klingman K, Wiggins I, Conley J, Radebaugh C, Kashuba AD, MacFarland R, Becker S, **Hendrix CW**. Effect of Low-dose Ritonavir on the Pharmacokinetics of the CXCR4 Antagonist AMD070 in Healthy Volunteers. *Antimicrob Agents Chemother* 2008 May;52(5):1630-4.
80. Andrade AS, **Hendrix CW**, Parsons TL, Caballero BH, Yuan C, Flexner C, Dobs AS, Brown T. Pharmacokinetic and Metabolic Effects of American Ginseng (*Panax quinquefolius*) in Healthy Volunteers Receiving the HIV Protease Inhibitor Indinavir. *BMC Complementary and Alternative Medicine* 2008, 8:50 (19 Aug 2008).
81. Caffo B, Crainiceanu C, Deng L, **Hendrix CW**. A Case Study in Pharmacologic Imaging Using Principal Curves in Single Photon Emission Computed Tomography. *J American Statistical Assoc* 2008, 103(484):1470-1480. PMC2794148
82. Agthe AG, Kim GR, Mathias KB, **Hendrix CW**, Chavez-Valdez R, Jansson L, Lewis TR, Yaster M, Gauda EB. Clonidine as an adjunct therapy to opioids for neonatal abstinence syndrome: a randomized, controlled trial. *Pediatrics*. 2009 May;123(5):e849-56. PMC2746902
83. Magill SS, Swoboda SM, Shields CE, Johnson EA, Fothergill AW, Merz WG, Lipsett PA, **Hendrix CW**. The epidemiology of *Candida* colonization and invasive candidiasis in critically ill surgical patients before and after implementation of routine fluconazole prophylaxis. *Ann Surg* 2009;249(4):657-665.
84. Nyunt M, **Hendrix CW**, Bakshi R, Kumar N, Shapiro TA. Phase I/II evaluation of the prophylactic antimalarial activity of pafuramidine in healthy volunteers challenged with plasmodium falciparum sporozoites. *Am J Trop Med Hyg* 2009;80(4):528-35. PMC2763313
85. Xie HG, Cao YJ, Gauda EB, Agthe AG, **Hendrix CW**, Lee H. Clonidine Clearance Matures Rapidly during the Early Postnatal Period: A Population Pharmacokinetic Analysis in Newborns with Neonatal Abstinence Syndrome. *J Clin Pharmacol* 2011 51(4):502-511
86. Keller MJ, Madan RP, Torres NM, Fazzari MJ, Cho S, Kalyoussef S, Shust G, Mesquita PM, Louissaint N, Chen J, Cohen HW, Diament EC, Lee AC, Soto-Torres L, **Hendrix CW**, Herold BC. A randomized trial to assess anti-HIV activity in female genital tract secretions and soluble mucosal immunity following application of 1% tenofovir gel. *PLoS One*. 2011 Jan 25;6(1):e16475. PMC3026837



**PUBLICATIONS****Original Research – continued**

87. Goldsmith J, Caffo B, Crainiceanu C, Reich D, Chen Y, **Hendrix CW**. Non-linear Tube Fitting for the Analysis of Anatomical and Functional Structures. *Ann Appl Stat.* 2011 Jan 1;5(1):337-363. PMC3119905
88. Avery LB, Bakshi RP, Cao YJ, **Hendrix CW**. The male genital tract is not a pharmacological sanctuary from efavirenz. *Clin Pharm Ther* 2011 Jul;90(1):151-6. PMC3215581
89. Krauss GL, Davit BM, Caffo B, Palamakula A, Chang YT, **Hendrix CW**, Cheung K. Assessing bioequivalence of generic antiepilepsy drug formulations. *Ann Neuro* 2011 Aug;70(2):221-8.
90. Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, Hakim JG, Kumwenda J, Grinsztejn B, Pilotto JH, Godbole SV, Mehendale S, Chariyalertsak S, Santos BR, Mayer KH, Hoffman IF, Eshleman SH, Piwowar-Manning E, Wang L, Makhema J, Mills LA, de Bruyn G, Sanne I, Eron J, Gallant J, Havlir D, Swindells S, Ribaud H, Elharrar V, Burns D, Taha TE, Nielsen-Saines K, Celentano D, Essex M, Fleming TR; **HPTN 052 Study Team**. Prevention of HIV-1 infection with early antiretroviral therapy. *N Engl J Med.* 2011 Aug 11;365(6):493-505. Epub 2011 Jul 18. PMC3200068
91. Dezzutti CS, **Hendrix CW**, Marrazzo J, Pan Z, Wang L, Louissaint N, Kalyoussef S, Torres NM, Hladik F, Parikh U, Mellors J, Hillier SL, Herold BC Comparing Swabs, Lavage, and Diluents to Quantify Biomarkers of Female Genital Tract Soluble Mucosal Mediators. 2011 *PloS One* 2011;6(8):e23136. PMC3155537
92. Beigi R, Noguchi L, Parsons T, Macio I, Kunjara Na Ayudhya RP, Chen J, **Hendrix CW**, Mâsse B, Valentine M, Piper J, Watts DH. Pharmacokinetics and Placental Transfer of Single Dose Tenofovir 1% Vaginal Gel in Term Pregnancy. *J Infect Dis* 2011 2011 Nov;204(10):1527-31. PMC3192189
93. Louissaint NA, Nimmagadda S, Fuchs EJ, Bakshi RP, Cao Y, Lee L, Goldsmith AJ, Caffo B, Du Y, King KE, Menendez FA, Torbenson MS, **Hendrix CW**. Distribution of Cell-free and Cell-associated HIV surrogates in the Colon Following Simulated Receptive Anal Intercourse in Men. *J Acquir Immune Defic Syndr* 2012 Jan 1;59(1):10-17. PMC3237874
94. Louissaint NA, Fuchs EJ, Bakshi RP, Nimmagadda S, Du Y, Macura K, King KE, Goldsmith AJ, Caffo B, Cao Y, Anderson JR, **Hendrix CW**. Distribution of Cell-free and Cell-associated HIV Surrogates in the Female Genital Tract following Simulated Vaginal Intercourse. *J Infect Dis* 2012 Mar;205(5):725-32. PMC pending

**PUBLICATIONS****Original Research – continued**

95. Lu Y, Celum C, Wald A, Baeten JM, Cowan F, Delany-Moretlwe S, Reid SE, Hughes JP, Wilcox E, Corey L, **Hendrix CW**. Acyclovir achieves lower concentration in African HIV-seronegative, HSV-2 seropositive women compared to non-African populations. *Antimicrob Agents Chemother* 2012 May;56(5): 2777-2779. PMC 3346629
96. Nyunt MM, Lu Y, Yu Q, El-Gasim M, Parsons TL, Petty BG, **Hendrix CW**. Effects of ritonavir-boosted lopinavir on the pharmacokinetics of quinine. *Clin Pharmacol Ther.* 2012 May;91(5):889-95.
97. Baeten JM, Donnell D, Ndase P, Mugo NR, Campbell JD, Wangisi J, Jordan W, Tappero JW, Bukusi EA, Cohen CR, Katabira E, Ronald A, Tumwesigye E, Were E, Fife KH, Kiarie J, Farquhar C, John-Stewart G, Kania A, Odoyo J, Mucunguzi A, Nakku-Joloba E, Twesigye R, Ngure K, Apaka C, Tamoooh H, Gabona F, Mujugira A, Panteleeff D, Thomas KK, Kidoguchi L, Krows M, Revall J, Morrison S, Haugen H, Emmanuel-Ogier M, Ondrejcek L, Coombs RW, Frenkel L, **Hendrix CW**, Bumpus N, Bangsberg D, Haberer J, Stevens WS, Lingappa JR, Celum C. Antiretroviral Prophylaxis for HIV-1 Prevention among Heterosexual Men and Women. *N Engl J Med* 2012 Aug 2;367(5):399-410.
98. Thigpen MC, Kebaabetswe PM, Paxton LA, Smith DK, Segolodi TM, Soud FA, Henderson FL, Pathak SR, Rose CE, Chillag KL, Mutanhaurwa R, Chirwa LI, Kasonde K, Abebe D, Buliva E, Gvetadze RJ, Johnson S, Sukalac T, Thomas VT, Hart C, Johnson JA, Malotte CK, **Hendrix CW**, Brooks JT. Safety and Efficacy of Daily Oral Antiretroviral Use for the Prevention of HIV Infection in Heterosexually Active Young Adults in Botswana: the TDF2 Study. *N Engl J Med* 2012 Aug 2;367(5):423-34.
99. Cao YJ, Caffo BS, Fuchs EJ, Lee LA, Du Y, Li L, Bakshi RP, Macura K, Khan WA, Wahl RL, Grohskopf LA, **Hendrix CW**. Quantification of the Spatial Distribution of Rectally Applied Surrogates for Microbicide and Semen in Colon with SPECT Imaging. *Br J Clin Pharmacol* 2012 Dec;74(6):1013-22 PMC3522815
100. Fogel J, Taha TE, Sun J, Hoover DR, Parsons TL, Kumwenda JJ, Mofenson LM, Fowler MG, **Hendrix CW**, Kumwenda NI, Eshleman SH, Mirochnick M. Stavudine (d4T) concentrations in women receiving post-partum antiretroviral treatment and their breastfeeding infants. *JAIDS* 2012 Aug 15;60(5):462-5. PMC3404155

**PUBLICATIONS****Original Research – continued**

101. Chen J, Flexner C, Liberman RG, Skipper PL, Louissaint NA, Tannenbaum SR, **Hendrix CW**, Fuchs E. Phase 0 Study of Intracellular Drug Concentrations: Accelerator Mass Spectrometry Measurement of Phosphorylated Tenofovir and Zidovudine. *J Acq Immuno Defic Syndr* 2012 Dec 15;61(5):593-9. PMC3509498
102. Lu, Y, **Hendrix CW**, Bumpus NN. Cytochrome P450 3A5 Plays a Prominent Role in the Oxidative Metabolism of the Anti-HIV Drug Maraviroc. *Drug Metabol Disp* 2012 Dec;40(12):2221-30. doi: 10.1124/dmd.112.048298. Epub 2012 Aug 24. PMC3500548
103. Anton PA, Cranston RD, Kashuba A, **Hendrix CW**, Bumpus NN, Richardson-Harman N, Elliott J, Janocko L, Khanukhova E, Dennis R, Cumberland WG, Ju C, Carballo-Diéguez A, Mauck C, McGowan I. RMP-02/MTN-006: A Phase 1 Rectal Safety, Acceptability, Pharmacokinetic and Pharmacodynamic Study of Tenofovir 1% Gel Compared to Oral Tenofovir DF. *AIDS Res Hum Retroviruses*. 2012 Nov;28(11):1412-21. doi: 10.1089/AID.2012.0262. Epub 2012 Oct 9. PMC3484811
104. Minnis AM, Gandham S, Richardson BA, Guddera V, Riddler S, Salata R, Nakabiito C, Hoesley C, Justman J, Soto-Torres L, Patterson K, Gomez K, **Hendrix CW**. Adherence and acceptability in MTN 001: A randomized cross-over trial of daily oral and topical tenofovir for HIV prevention in women. *AIDS Behav* 2012 Feb;17(2):737-47. PMC 3562423
105. Avery LB, VanAusdall JL, **Hendrix CW**, Bumpus NN. Compartmentalization and Antiviral Effect of Efavirenz Metabolites in Blood Plasma, Seminal Plasma and Cerebrospinal Fluid. *Drug Metabo Disp* 2012 Nov 19. [Epub ahead of print] PMID: PMC 3558859
106. **Hendrix CW**, Chen BA, Guddera V, Hoesley C, Justman J, Nakabiito C, Salata R, Soto-Torres L, Patterson K, Minnis AM, Gandham S, Gomez K, Richardson BA, Bumpus N. Pharmacokinetic cross-over study in women comparing tenofovir vaginal gel and oral tablets in vaginal tissue and other anatomic compartments (MTN-001) *PLoS One*. 2013;8(1):e55013. PMC3559346
107. Fuchs EJ, Grohskopf LA, Lee LA, Bakshi RP, **Hendrix CW**. Quantitative Assessment of Altered Rectal Mucosal Permeability Due to Rectally Applied Nonoxynol-9, Biopsy, and Simulated Intercourse. *J Infect Dis* 2013 May 1;207(9):1389-96 PMC3693591
108. Avery LB, Sacktor N, McArthur JC, **Hendrix CW**. Protein-free Efavirenz is Equivalent in Cerebrospinal Fluid & Blood Plasma: Applying the Law of Mass Action to Predict Protein-Free Drug Concentration. *Antimicrob Agents Chemother* 2013 Jan;57(3):1409-1414. Jan 7 [Epub ahead of print]. PMID: PMC3591913

**PUBLICATIONS****Original Research – continued**

109. Louissaint NA, Cao YJ, Skipper PL, Liberman RG, Tannenbaum SR, Nimmagadda S, Anderson JR, Everts S, Bakshi R, Fuchs EJ, **Hendrix CW**. Single Dose Pharmacokinetics of Oral Tenofovir in Plasma, Peripheral Blood Mononuclear Cells, Colonic and Vaginal Tissue. *AIDS Res Hum Retroviruses* 2013 Nov; 29(11): 1443-1450. PMC3809387
110. Avery LB, Zarr M, Bakshi RP, Siliciano R, **Hendrix CW**. Increasing Extracellular Protein Concentration Reduces Intracellular Antiretroviral Drug Concentration and Antiviral Effect. *AIDS Res Hum Retroviruses* 2013 Nov;29(11): 1434-1442. PMC3809607
111. Choopanya K, Martin M, Suntharasamai P, Sangkum U, Mock PA, Leethochawalit M, Chiamwongpaet S, Kitisin P, Natrujirote P, Kittimunkong S, Chuachoowong R, Gvetadze R, McNicholl J, Paxton L, Curlin M, **Hendrix CW**, Vanichseni S, for the Bangkok Tenofovir Study Group. Antiretroviral Prophylaxis for HIV Infection among People Who Inject Drugs in Bangkok, Thailand: a randomized, double-blind, placebo-controlled trial. *Lancet* 2013 Jun 15;381(9883):2083-90.
112. Fogel JM, Wang L, Parsons TL, Ou S-S, Piwowar-Manning E, Chen Y, Mudhune VB, Hosseinipour MC, Kumwenda J, Hakim JG, Chariyalertsak S, Panchia R, Sanne I, Kumarasamy N, Grinsztejn B, Makhema J, Pilotto J, Santos BR, Mayer KH, McCauley M, Gamble T, Bumpus NN, **Hendrix CW**, Cohen MS, and Eshleman SH. Undisclosed antiretroviral drug use in a multi-national clinical trial (HPTN 052). *J Infect Dis* 2013. PMC 3805242
113. Leyva FJ, Bakshi R, Fuchs EJ, Li L, Caffo BS, Goldsmith AJ, Carballo-Diequez A, Ventuneac A, Du Y, Leal J, Lee LA, Torbenson MT, **Hendrix CW**. Iso-osmolar enemas demonstrate preferential gastrointestinal distribution, safety, and acceptability compared with hyper- and hypo-osmolar enemas as a potential delivery vehicle for rectal microbicides. *AIDS Res Hum Retroviruses* 2013 Nov;29(11): 1487-1495. PMC3809953
114. To E, **Hendrix CW**, Bumpus NN. Dissimilarities in the Metabolism of Antiretroviral Drugs used in HIV Pre-exposure Prophylaxis in Colon and Vagina Tissues. *Biochem Pharmacol* 2013 Oct 1;86(7):979-90. PMC3807636.
115. Seserko L, Emory JF, **Hendrix CW**, Marzinke M. The Development and Validation of an Ultra Performance-Liquid Chromatography-Tandem Mass Spectrometric (LC-MS/MS) Method for the Rapid Quantitation of the Antiretroviral Agent Dapivirine in Human Plasma. *Bioanalysis* 2013 Nov;5(22):2771-2783. PMCID in process

**PUBLICATIONS****Original Research – continued**

116. Murnane PM, Celum C, Mugo N, Campbell JD, Donnell D, Bukusi E, Mujugira A, Tappero J, Kahle EM, Thomas KK, Baeten JM; **Partners PrEP Study Team**. Efficacy of preexposure prophylaxis for HIV-1 prevention among high-risk heterosexuals: subgroup analyses from a randomized trial. *AIDS*. 2013 Aug 24;27(13):2155-60.
117. Chaturvedula A, Fossler M, **Hendrix CW**. Estimation of tenofovir's population pharmacokinetic parameters without reliable dosing histories and application to tracing dosing history using simulation strategies. *J Clin Pharmacol* 2013 Nov 6; 54(2): 150-60. PMC5001555
118. Cranston RD, Hoesley C, Carballo-Diéguez A, **Hendrix CW**, Husnik M, Levy L, Hall W, Soto-Torres L, Nel AM. A Randomized Male Tolerance Study of Dapivirine Gel Following Multiple Topical Penile Exposures (MTN 012/IPM 010) *AIDS Res Hum Retroviruses*. 2014 Feb;30(2):184-9. PMC3910451
119. Kayentao K, Guirou EA, Doumbo OK, Venkatesan M, Plowe CV, Parsons TL, **Hendrix CW**, Nyunt MM. Preliminary Study of Quinine Pharmacokinetics in Pregnant Women with Malaria-HIV Co-Infection. *Am J Trop Med Hyg*. 2014 Mar;90(3):530-4. PMC3945700
120. Herold BC, Dezzutti CS, Richardson BA, Marrazzo J, Mesquita PM, Carpenter C, Huber A, Louissaint N, Marzinke MA, Hillier SL, **Hendrix CW**. Antiviral Activity of Genital Tract Secretions following Oral or Topical Tenofovir Pre-exposure Prophylaxis for HIV-1. *J Acquir Immune Defic Syndr*. 2014 May 1; 66(1):65-73. PMC3981887
121. Martin M, Vanichseni S, Suntharasamai P, Sangkum U, Mock PA, Leethochawalit M, Chiamwongpaet S, Gvetadze RJ, Kittimunkong S, Curlin ME, Worrajittanon D, McNicholl JM, Paxton LA, Choopanya K; **Bangkok Tenofovir Study Group**. Risk behaviors and risk factors for HIV infection among participants in the Bangkok tenofovir study, an HIV pre-exposure prophylaxis trial among people who inject drugs. *PLoS One*. 2014 Mar 25;9(3):e92809. PMC3965466
122. Celum C, Morrow RA, Donnell D, Hong T, **Hendrix CW**, Thomas KK, Fife KH, Nakku-Joloba E, Mujugira A, Baeten JM, Partners PrEP Study Team. Daily oral tenofovir and emtricitabine/tenofovir pre-exposure prophylaxis reduces herpes simplex virus type 2 acquisition among heterosexual HIV-1 uninfected men and women: a subgroup analysis of a randomized trial. *Ann In Med* 2014;161:11-19. PMID in progress.
123. Donnell D, Baeten J, Bumpus NN, Brantley J, Bangsberg D, Haberer JE, Mujugira A, **Hendrix CW**, Celum C. HIV Protective Efficacy and correlates of Tenofovir Blood Concentrations in a Clinical Trial of PrEP for HIV Prevention. *J Acquir Immune Defic Syndr*. 2014 Apr 29 [Epub ahead of print]. PMC4059553

**PUBLICATIONS****Original Research – continued**

124. Martin M, Vanichseni S, Suntharasamai P, Sangkum U, Mock PA, Gvetadze RJ, Curlin ME, Leethochawalit M, Chiamwongpaet S, Cherdrakulkiat T, Anekvorapong R, Leelawiwat W, Chantharojwong N, McNicholl JM, Paxton LA, Kittimunkong S, Choopanya K; for the **Bangkok Tenofovir Study Group**. Renal function of participants in the Bangkok Tenofovir Study, Thailand, 2005-2012. *Clin Infect Dis*. 2014 Sep 1;59(5):716-24. PMID in progress.
125. Murnane PM, Heffron R, Ronald A, Bukusi EA, Donnell D, Mugo NR, Were E, Mujugira A, Kiarie J, Celum C, Baeten JM; **Partners PrEP Study Team**. Pre-exposure prophylaxis for HIV-1 prevention does not diminish the pregnancy prevention effectiveness of hormonal contraception. *AIDS*. 2014 Jul 31;28(12):1825-30. PMID in progress.
126. Matthews LT, Heffron R, Mugo NR, Cohen CR, **Hendrix CW**, Celum C, Bangsberg DR, Baeten JM. High medication adherence during periconception periods among HIV-1-uninfected women participating in a clinical trial of antiretroviral pre-exposure prophylaxis. *J Acq Immuno Defic Syndr* 2014 Sep 1;67(1):91-7. PMID4149628
127. Mugo NR, Hong T, Celum C, Donnell D, Bukusi EA, John-Stewart G, Wangisi J, Were E, Heffron R, Matthews LT, Morrison S, Ngure K, Baeten JM; **Partners PrEP Study Team**. Pregnancy incidence and outcomes among women receiving preexposure prophylaxis for HIV prevention: a randomized clinical trial. *JAMA*. 2014 Jul 23-30;312(4):362-71. PMID in progress.
128. Mujugira A, Celum C, Thomas KK, Farquhar C, Mugo N, Katabira E, Bukusi EA, Tumwesigye E, Baeten JM; **Partners PrEP Study Team**. Delay of antiretroviral therapy initiation is common in East African HIV-infected individuals in serodiscordant partnerships. *J Acquir Immune Defic Syndr*. 2014 Aug 1;66(4):436-42. PMID in progress.
129. Lu Y., Fuchs EJ, **Hendrix CW**, Bumpus NN. Cytochrome P450 3A5 Genotype Impacts Maraviroc Concentrations in Healthy Volunteers. *Drug Metabol Disp* 2014 Aug 12. pii: dmd.114.060194. [Epub ahead of print] PMID in progress.
130. Were EO, Heffron R, Mugo NR, Celum C, Mujugira A, Bukusi EA, Baeten JM; **Partners PrEP Study Team**. Pre-exposure prophylaxis does not affect the fertility of HIV-1-uninfected men. *AIDS*. 2014 Aug 24;28(13):1977-82.
131. Nayak SU, Griffiss JM, McKenzie R, Fuchs EJ, Jura RA, An AT, Ahene A, Tomic M, **Hendrix CW**, Zenilman JM. Safety and Pharmacokinetics of XOMA 3AB, a Novel Mixture of Three Monoclonal Antibodies Against Botulinum Neurotoxin A: A Randomized Placebo Controlled Trial in Healthy Subjects. *Antimicrob Agents Chemother* 2014 Sep;58(9):5047-53. PMID4135817

**PUBLICATIONS****Original Research – continued**

132. Baeten JM, Donnell D, Mugo NR, Ndase P, Thomas KK, Campbell JD, Wangisi J, Tappero JW, Bukusi EA, Cohen CR, Katabira E, Ronald A, Tumwesigye E, Were E, Fife KH, Kiarie J, Farquhar C, John-Stewart G, Kidoguchi L, Coombs RW, **Hendrix CW**, Marzinke MA, Frenkel L, Haberer JE, Bangsberg D, Celum C, Partners PrEP Study Team. Single-Agent Tenofovir versus Combination Emtricitabine/Tenofovir for Pre-Exposure Prophylaxis against HIV-1 Acquisition: A Randomized Trial. *Lancet Infectious Diseases* 2014 Oct 6. pii: S1473-3099(14)70937-5.
133. Yang K, **Hendrix CW**, Bumpus N, Elliott J, Tanner K, Mauck C, Cranston R, McGowan I, Richardson-Harman N, Anton PA, Kashuba AD. A Multi-Compartment Single and Multiple Dose Pharmacokinetic Comparison of Rectally Applied Tenofovir 1% Gel and Oral Tenofovir Disoproxil Fumarate. *PLoS One*. 2014 Oct 28;9(10):e106196.
134. Richardson-Harman N, **Hendrix CW**, Bumpus NN, Mauck C, Cranston RD, Yang K, Elliott J, Tanner K, McGowan I, Kashuba ADM, Anton PA. Correlation between compartmental tenofovir concentrations and an ex vivo rectal biopsy model of tissue infectibility in the RMP-02/MTN-006 Phase 1 study. *PLoS One*. 2014 Oct 28;9(10):e111507.
135. Madrasi K, Burns R, **Hendrix CW**, Fossler M, Chaturvedula A. Linking the population pharmacokinetics of tenofovir and its metabolites with its cellular uptake and metabolism. *CPT: Pharmacometrics & Systems Pharmacology* 2014 Nov 12;3:e147.
136. Heffron R, Mugo N, Were E, Kiarie J, Bukusi EA, Mujugira A, Frenkel LM, Donnell D, Ronald A, Celum C, Baeten JM; **Partners PrEP Study Team**. Preexposure prophylaxis is efficacious for HIV-1 prevention among women using depot medroxyprogesterone acetate for contraception. *AIDS*. 2014 Nov 28;28(18):2771-6.
137. Pintye J, Baeten JM, Manhart LE, Celum C, Ronald A, Mugo N, Mujugira A, Cohen C, Were E, Bukusi E, Kiarie J, Heffron R; **Partners PrEP Study Team**. Association between male circumcision and incidence of syphilis in men and women: a prospective study in HIV-1 serodiscordant heterosexual African couples. *Lancet Glob Health*. 2014 Nov;2(11):e664-71. PMC4271270
138. Baxi SM, Liu A, Bacchetti P, Mutua G, Sanders EJ, Kibengo FM, Haberer JE, Rooney J, **Hendrix CW**, Anderson PL, Huang Y, Priddy Y F, Gandhi M. Comparing the Novel Method of Assessing PrEP Adherence/Exposure using Hair Samples to other Pharmacologic and Traditional Measures. *J Acquir Immune Defic Syndr*. Jan 1, 2015; 68(1): 13–20. PMC4262724

**PUBLICATIONS****Original Research – continued**

139. Lehman DA, Baeten JA, McCoy CO, Weis JF, Peterson D, Mbara G, Donnell D, Thomas KK, **Hendrix CW**, Marzinke MA, Frenkel L, Ndase P, Mugo NR, Celum C, Overbaugh JO, Matsen FA, Partners PrEP Study Team. Risk of Drug Resistance Among Persons Acquiring HIV Within a Randomized Clinical Trial of Single- or Dual-Agent Preexposure Prophylaxis. *J Infect Dis* 2015 Apr 15;211:1211–8. PMC4402339
140. Burns RN, **Hendrix CW**, Fossler MJ, Chaturvedula A. Population Pharmacokinetics of Tenofovir and Tenofovir-diphosphate in healthy women. *J Clin Pharmacol* 2015 Jun;55(6):629-38 PMC 5008110
141. Marrazzo JM, Ramjee G, Richardson B, Gomez K, Mgodhi N, Nair G, Palanee T, Nakabito C, van der Straten A, Noguchi L, **Hendrix CW**, Dai JY, Ganesh S, Mkhize B, Taljaard M, ParikhU, Piper J, Mâsse B, Grossman C, Rooney J, Schwartz JL, Watts H, Marzinke M, Hillier SL, McGowan IM, Chirenje ZM, VOICE Study Team. Tenofovir-Based Preexposure Prophylaxis for HIV Infection among African Women. *N Engl J Med* 2015 Feb 5;372(6):509-18. PMC4341965
142. Mugwanya KK, Wyatt C, Celum C, Donnell D, Mugo NR, Tappero J, Kiarie J, Ronald A, Baeten JM; **Partners PrEP Study Team**. Changes in glomerular kidney function among HIV-1-uninfected men and women receiving emtricitabine-tenofovir disoproxil fumarate preexposure prophylaxis: a randomized clinical trial. *JAMA Intern Med.* 2015 Feb;175(2):246-54 PMC4354899
143. Ndase P, Celum C, Kidoguchi L, Ronald A, Fife KH, Bukusi E, Donnell D, Baeten JM; **Partners PrEP Study Team**. Frequency of false positive rapid HIV serologic tests in African men and women receiving PrEP for HIV prevention: implications for programmatic roll-out of biomedical interventions. *PLoS One.* 2015 Apr 17;10(4):e0123005 PMC4401675
144. Gunawardana M, Remedios-Chan M, Miller CS, Fanter R, Yang F, Marzinke MA, **Hendrix CW**, Beliveau M, Moss JA, Smith TJ, Baum MM. Pharmacokinetics of Long-acting Tenofovir Alafenamide (GS-7340) Subdermal Implant for HIV Prophylaxis Antimicrob Agents Chemother 2015 Jul;59(7):3913-9 PMC4468692
145. Kintu A, Hankinson SE, Balasubramanian R, Ertel K, Tumwesigye E, Bangsberg DR, Haberer JE; **Partners Ancillary Adherence Study Team**. Sexual Relationships Outside Primary Partnerships and Abstinence Are Associated With Lower Adherence and Adherence Gaps: Data From the Partners PrEP Ancillary Adherence Study. *J Acquir Immune Defic Syndr.* 2015 May 1;69(1):36-43. PMC4422183
146. Rahn KA, Cao YJ, **Hendrix CW**, Kaplin AI. The role of 5-HT1A receptors in mediating acute negative effects of antidepressants: Implications in pediatric depression. *Nature: Translational Psychiatry* 2015 May 5;5:e563. PMC4471288



**PUBLICATIONS****Original Research – continued**

147. McGowan I, Cranston RD, Duffill K, Siegel A, Engstrom J, Nikiforov A, Jacobson C, Rehman K, Elliott J, Khanukhova E, Abebe A, Mauck C, Spiegel H, Dezzutti C, Rohan L, Marzinke M, Hiruy H, **Hendrix CW**, Richardson-Harman N, Anton P. A Phase 1 Randomized, Open Label, Rectal Safety, Acceptability, Pharmacokinetic, and Pharmacodynamic Study of Three Formulations of Tenofovir 1% Gel (CHARM-01). *PLOS One* 2015 May 5;10(5):e0125363 PMC4420274
148. Maisel K, Chattopadhyay S, Moench T, **Hendrix CW**, Cone R, Ensign LM, Hanes J. Enema ion compositions for enhancing colorectal drug delivery. *J Control Release*. 2015 Apr 30;209:280-287. PMC4458383
149. Lade J, To E, **Hendrix CW**, Bumpus NN. Discovery of Genetic Variants of the Kinases that Activate Tenofovir in a Compartment-Specific Manner. *EBioMedicine* 2015 Jul 9;2(9):1145-52. PMC4588390
150. Murphy K, Richardson BA, Dezzutti CS, Marrazzo J, Hillier SL, **Hendrix CW**, Herold BC. Levels of genital tract defensins and cytokines differ between HIV negative US and African women. *Am J Reprod Immunol* 2015 Oct;74(4):313-22. PMC4573314
151. Chen BA, Panther L, Marzinke MA, **Hendrix CW**, Hoesley CJ, van der Straten A, Husnik MJ, Soto-Torres L, Nel A, Johnson S, Richardson-Harman N, Rabe LK, Dezzutti CS, MTN-013 Protocol Team. Phase 1 safety, pharmacokinetics, and pharmacodynamics of dapivirine and maraviroc vaginal rings: a double-blind randomized trial. *J Acquir Immune Defic Syndr* 2015 Nov 1;70(3):242-249. PMC4607587
152. Zenilman J, Fuchs EJ, **Hendrix CW**, Radebaugh C, Jurao RA, Nayak S, G Hamilton RG, Griffiss M. Phase 1 Clinical Trials of DAS181, an Inhaled Sialidase, in Healthy Adults. *Antimicrob Agents Chemother* 2015 Sep 25;123:114-119. PMC4639451
153. Leyva F, Fuchs EJ, Bakshi R, Carballo-Diequez A, Ventuneac A, Yue C, Caffo B, Du Y, Torbenson M, Li L, Mullin G, Lee L, Rohan L, Anton PA, **Hendrix CW**. Simultaneous evaluation of safety, acceptability, peri-coital kinetics, and ex vivo pharmacodynamics comparing four rectal microbicide vehicle candidates. *AIDS Res Hum Retrovir* 2015 November 31(11):1089-1097. PMC4651043
154. Fuchs EJ, Schwartz J, Memon MA, Bakshi RP, Coleman J, **Hendrix CW**. A Pilot Study to Measure the Distribution and Permeability of a Vaginal HIV Microbicide Gel Vehicle using MRI, SPECT/CT, and Radiolabeled Small Molecule. *AIDS Res Hum Retrovir* 2015 November 31(11):1109-1115. PMC4651045

**PUBLICATIONS****Original Research – continued**

155. Hiruy H, Fuchs EJ, Marzinke MA, Yue C, Caffo B, Spiegel HML, Rohan LC, McGowan I, **Hendrix CW**. A Phase 1 Randomized, Blinded Comparison of the Pharmacokinetics and Colonic Distribution of Three Candidate Rectal Microbicide Formulations of Tenofovir 1% Gel with Simulated Unprotected Sex (CHARM-02). *AIDS Res Hum Retrovir* 2015 November 31(11):1098-1108. PMC4651050
156. Murnane PM, Brown ER, Donnell D, Coley RY, Mugo N, Mujugira A, Celum C, Baeten JM; **Partners PrEP Study Team**. Estimating Efficacy in a Randomized Trial With Product Nonadherence: Application of Multiple Methods to a Trial of Preexposure Prophylaxis for HIV Prevention. *Am J Epidemiol*. 2015 Nov 15;182(10):848-56. PMC4634306
157. Minnis AM, van der Straten A, Salée P, **Hendrix CW**. Pre-exposure Prophylaxis adherence measured by plasma drug level in MTN-001: comparison between vaginal gel and oral tablets in two geographic regions. *AIDS Behav* 2016 Jul;20(7):1541-8. PMC4957649
158. **Hendrix CW**, Andrade A, Bumpus NN, Kashuba AD, Marzinke M, Moore A, Anderson PL, Bushman LR, Fuchs E, Wiggins I, Radebaugh C, Prince HA, Bakshi R, Wang R, Richardson P, Shieh E, McKinstry L, Li X, Donnell D, Elharrar V, Mayer K, Patterson KB. Dose Frequency Ranging Pharmacokinetic Study of Tenofovir-Emtricitabine after Directly Observed Dosing in Healthy Volunteers to establish Adherence Benchmarks (HPTN 066). *AIDS Res Hum Retrovir* 2016 Jan 32(1):32-43. PMC4692123
159. Dai JY, **Hendrix CW**, Richardson BA, Kelly C, Marzinke MA, Chirenje ZM, Marrazzo JM, Brown ER. Pharmacological measures of adherence and risk of HIV acquisition in the VOICE study. *J Infect. Dis* 2016 Feb 1;213(3):335-42. PMC4704663
160. Weis JF, Baeten JM, McCoy CO, Warth C, Donnell D, Thomas KK, **Hendrix CW**, Marzinke MA, Mugo N, Matsen FA, Celum C, Lehman DA, Partners PrEP Study Team. Preexposure prophylaxis-selected drug resistance decays rapidly after drug cessation. *AIDS* 2016, 30:31–35. PMC4704103
161. Herold BC, Chen BA, Salata RA, Marzinke MA, Kelly C, Dezzutti CS, McGowan I, Galaska B, Levy L, Piper JM, Hillier S, **Hendrix CW**; MTN-011 Study Team. Impact of Sex on the Pharmacokinetics and Pharmacodynamics of 1% Tenofovir Gel. *Clin Infect Dis* 2016 Feb 1;62(3):375-382. PMC4706638
162. Keller MJ, Mesquita PM, Marzinke MA, Teller R, Espinoza L, Atrio JM, Lo Y, Frank B, Srinivasan S, Fredricks DN, Rabe L, Anderson PL, **Hendrix CW**, Kiser PF, Herold BC. Phase 1 Randomized Placebo-Controlled Safety and Pharmacokinetic Trial of a Tenofovir Disoproxil Fumarate Vaginal Ring. *AIDS* 2016 Mar 13;30(5):743-51. PMC4767579

**PUBLICATIONS****Original Research – continued**

163. Bunge KE, Dezzutti CS, Rohan LC, **Hendrix CW**, Marzinke MA, Richardson-Harman N, Moncla BJ, Devlin B, Meyn LA, Spiegel HM, Hillier SL. A Phase 1 trial to assess the safety, acceptability, pharmacokinetics and pharmacodynamics of a novel dapivirine vaginal film. *J Acquir Immune Defic Syndr*. 2016 Apr 15;71(5):498-505. PMC5040830
164. van der Straten A, Brown ER, Marrazzo JM, Chirenje MZ, Liu K, Gomez K, Marzinke MA, Piper JM, **Hendrix CW**, MTN-003 VOICE Protocol Team. Divergent Adherence Estimates with Pharmacokinetic and Behavioral Measures in the MTN-003 (VOICE) Study. *J Internat AIDS Soc* 2016 Feb 4;19(1):20642. PMC4744323
165. Musinguzi N, Muganzi CD, Boum Y, Ronald A, Celum C, Baeten J, Bangsberg DR, Haberer JE, **Partners PrEP Ancillary Adherence Study Team**. Comparison of Subjective and Objective Adherence Measures for Pre-Exposure Prophylaxis against HIV Infection among Serodiscordant Couples in East Africa: An Analysis from the Partners PrEP Ancillary Adherence Study. *AIDS* 2016 Apr 24;30(7):1121-9. *PMCID Pending*
166. Coleman J, Fuchs EJ, Aung WS, Marzinke MA, Bakshi RP, Spiegel HML, Robinson JR, **Hendrix CW**. Feasibility of radiolabeled small molecule permeability as a quantitative measure of microbicide candidate toxicity. *Contraception* 2016 Apr;93(4):331-6. PMC4783221
167. Fuchs EJ, Kiser J, **Hendrix CW**, Sulkowski M, Radebaugh C, Bushman L, Ray M, Andrade A. Plasma and Intracellular Ribavirin Concentrations are not Significantly Altered by Abacavir in Hepatitis C Virus-Infected Patients”. *J Antimicrob Chemother* 2016 Feb 10. Jun;71(6):1597-600. PMC4867100
168. Baeten JM, Palanee-Phillips T, Brown ER, Schwartz K, Soto-Torres LE, Govender V, Mgodini NM, Matovu Kiweewa F, Nair G, Mhlanga F, Siva S, Bekker LG, Jeena N, Gaffoor Z, Martinson F, Maman B, Pather A, Naidoo L, Husnik M, Richardson BA, Parikh UM, Mellors JW, Marzinke MA, **Hendrix CW**, van der Straten A, Ramjee G, Chirenje ZM, Nakabiito C, Taha TE, Jones J, Mayo A, Scheckter R, Berthiaume J, Livant E, Jacobson C, Ndase P, White R, Patterson K, Germuga D, Galaska B, Bunge K, Singh D, Szydlo DW, Montgomery ET, Mensch BS, Torjesen K, Grossman CI, Chakhtoura N, Nel A, Rosenberg Z, McGowan I, Hillier S; MTN-020–ASPIRE Study Team. Use of a Vaginal Ring Containing Dapivirine for HIV-1 Prevention in Women. *N Engl J Med*. 2016 Dec 1;375(22):2121-2132. PMC4993693
169. Mugwanya K, Baeten J, Celum C, Donnell D, Nickolas T, Mugo N, Branch A, Tappero J, Kiarie J, Ronald A, Yin M, Wyatt C; **Partners PrEP Study Team**. Low risk of Proximal Tubular Dysfunction Associated with Emtricitabine-Tenofovir Disoproxil Fumarate Pre-Exposure Prophylaxis in Men and Women. *J Infect Dis*. 2016 Oct 1;214(7):1050-7. PMC5021224

**PUBLICATIONS****Original Research – continued**

170. Mujugira A, Coombs RW, Heffron R, Celum C, Ronald A, Mugo N, Baeten JM; **Partners PrEP Study Team**. Seminal HIV-1 RNA Detection in Heterosexual African Men Initiating Antiretroviral Therapy. *J Infect Dis*. 2016 Aug 15;72(5): 465-584. PMC4918825
171. Moss JA, Butkyavichene I, Churchman SA, Gunawardana M, Fanter R, Miller CS, Yang F, Easley JT, Marzinke MA, **Hendrix CW**, Smith TJ, Baum MM. Combination pod-intravaginal ring delivers antiretroviral agents for HIV prophylaxis: pharmacokinetic evaluation in an ovine model. *Antimicrob Agents Chemother* 2016 May 23;60(6):3759-66. PMC4879417
172. Lu Y, Goti V, Chaturvedula A, Haberer J, Fossler M, Sale M, Bangsberg D, Baeten J, Celum C, **Hendrix CW**. Population pharmacokinetics of tenofovir in HIV-1 uninfected members of sero-discordant couples and effect of dose reporting methods" *Antimicrob Agen Chemother* 2016 September 2016 60:5379-5386. PMC4997873
173. Baeten JM, Heffron R, Kidoguchi L, Mugo NR, Katabira E, Bukusi EA, Asimwe S, Haberer JE, Morton J, Ngure K, Bulya N, Odoyo J, Tindimwebna E, **Hendrix CW**, Marzinke MA, Ware N, Wyatt M, Morrison S, Haugen H, Mujugira A, Donnell D, Celum C, Partners Demonstration Project Team. Integrated Delivery of Antiretroviral Treatment and Pre-Exposure Prophylaxis Results in Near Elimination of HIV-1 Transmission among African HIV-1 Serodiscordant Couples: A Prospective Implementation Study. *PLOS Medicine* 2016 Aug 23;13(8):e1002099. PMC4995047
174. Noguchi L, Montgomery E, Biggio J, **Hendrix CW**, Bogen D , Hillier S, Dai J, Piper J, Marzinke M, Dezzutti C, Isaacs S, Schwartz J, Watts DH, Beigi RH. Detectable tenofovir levels in breastfeeding infants of mothers exposed to topical tenofovir. *Antimicrob Agent Chemother* 2016 Aug 22;60(9):5616-9. PMC4997886
175. Beigi, RH, Noguchi LM, Montgomery E, Biggio J, **Hendrix CW**, Marzinke MA, Dai JY, Pan J, Kunjara R, Schwartz JL, Isaacs K, Piper JM, Watts DH. A Randomized Safety and Pharmacokinetic Trial of Daily Tenofovir 1% Gel in Term and Near-Term Pregnancy. *J Internat AIDS Soc*. 2016 Sep 21;19(1):20990. PMC5034095
176. Mugwanya KK, **Hendrix CW**, Mugo N, Marzinke MA, Katabira E, Ngure K, Semiyaga N, John-Stewart G, Muwonge T, Muthuri G, Stergachis A, Celum C, Jared M. Baeten JM. Pre-exposure Prophylaxis Use by Breastfeeding HIV-Uninfected Women: A Prospective Short-Term Study of Antiretroviral Excretion in Breast Milk and Infant Absorption. *PLOS Med* 2016 Sep 27;13(9):e1002132. PMC5038971
177. Heffron R, Parikh UM, Penrose KJ, Mugo N, Donnell D, Celum C, Mellors JW, Baeten JM; **Partners PrEP Study Team**. Objective Measurement of Inaccurate Condom Use Reporting Among Women Using Depot Medroxyprogesterone Acetate for Contraception. *AIDS Behav*. 2016 Oct 3. [Epub ahead of print] PMC5378697

**PUBLICATIONS****Original Research – continued**

178. Irungu EM, Heffron R, Mugo N, Ngure K, Katabira E, Bulya N, Bukusi E, Odoyo J, Asiimwe S, Tindimwebwa E, Celum C, Baeten JM; **Partners Demonstration Project Team**. Use of a risk scoring tool to identify higher-risk HIV-1 serodiscordant couples for an antiretroviral-based HIV-1 prevention intervention. *BMC Infect Dis*. 2016 Oct 17;16(1):571. PMC5067880
179. Dalesio NM, **Hendrix CW**, McMichael DH, Thompson CB, Lee CKK, Pho H, Arias RS, Lynn RR, Galinkin J, Yaster M, Brown RH, Schwartz AR. Effects of Obesity and Leptin Deficiency on Morphine Pharmacokinetics in a Mouse Model. *Anesth Analg*. 2016 Dec;123(6):1611-1617. *PMCID Pending*
180. Madrasi K, Chaturvedula A, Haberer JE, Sale M, Fossler MJ, Bangsberg D, Baeten J, Celum C, **Hendrix CW**. Markov mixed effects modeling using electronic adherence monitoring records identifies influential covariates to HIV pre-exposure prophylaxis. *J Clin Pharm* 2017 May;57(5):606-615. *PMCID pending*
181. Gulick RM, Wilkin TJ, Chen YQ, Landovitz RJ, Amico KR, Young AM, Richardson P, Marzinke MA, **Hendrix CW**, Eshleman SH, McGowan I, Cottle LM, Andrade A, Marcus C, Klingman KL, Chege W, Rinehart AR, Rooney JF, Andrew P, Salata RA, Magnus M, Farley JE, Liu A, Frank I, Ho K, Santana J, Stekler JD, McCauley M, Mayer KH. Phase 2 Study of the Safety and Tolerability of Maraviroc-Containing Regimens to Prevent HIV Infection in Men Who Have Sex with Men (MSM) (HPTN 069/ACTG A5305) *J Infect Dis* 2017 Jan 15; 215 (2): 238-246. *PMCID pending*
182. Robinson JA, Marzinke MA, Bakshi RP, Fuchs EJ, Radebaugh CL, Aung W, Spiegel HML, Coleman JC, Rohan LC, **Hendrix CW**. Comparison of dapivirine vaginal gel and film formulation pharmacokinetics and pharmacodynamics (FAME 02B). *AIDS Res Hum Retrovir* 2017 Apr;33(4):339-346. PMC5372771
183. Weld EW\*, Hiruy H\*, Guthrie KM, Fava JL, Vargas SE, Buckheit K, Buckheit R, Spiegel H, Breakey J, Fuchs EJ, **Hendrix CW**. A Comparative Pre-Phase I Study of the Impact of Gel Vehicle Volume on Distal Colon Distribution, User Experience, and Acceptability. *AIDS Res Hum Retrovir* 2017 May;33(5):440-447. *\*Co-first authors*. PMC5439405
184. Mayer KH, Safren SA, Elsesser SA, Psaros C, Tinsley J, Marzinke MA, Clarke W, **Hendrix CW**, Taylor SW, Haberer J, Mimiaga MJ. Optimizing Pre-Exposure Antiretroviral Prophylaxis Adherence in Men Who Have Sex with Men: Results of a Pilot Randomized Controlled Trial of "Life-Steps for PrEP". *AIDS Behav* 2017 May;21(5):1350-1360. PMC5380582

**PUBLICATIONS****Original Research – continued**

185. Cranston RD, Lama JR, Richardson BA, Carballo-Diéguez A, Kunjara RP, Liu K, Leu C-S, Galaska B, Jacobson CE, Parikh U, Marzinke MA, **Hendrix CW**, Johnson S, Piper JM, Grossman C, Ho KS, Lucas J, Pickett J, Bekker L-G, Chariyalertsak S, Chitwarakorn A, Gonzales P, Holtz TH, Liu AY, Mayer KH, Zorrilla C, McGowan I, and the MTN-017 Protocol Team. MTN-017: A Rectal Phase 2 Extended Safety and Acceptability Study of Tenofovir Reduced-Glycerin 1% Gel. *Clin Infect Dis* 2017 Mar 1;64(5):614-620. PMC5850518
186. Haaland RE, Holder A, Pau CP, Swaims-Kohlmeier A, Dawson C, Smith DK, Segolodi TM, Thigpen MC, Paxton LA, Parsons TL, **Hendrix CW**, Hart CE. Levels of Intracellular Phosphorylated Tenofovir and Emtricitabine Correlate With Natural Substrate Concentrations in Peripheral Blood Mononuclear Cells of Persons Prescribed Daily Oral Truvada for HIV Pre-exposure Prophylaxis. *J Acquir Immune Defic Syndr*. 2017 Jul 1;75(3):e86-e88. PMC5472483
187. Thomson KA, Haberer JE, Marzinke MA, Mujugira A, **Hendrix CW**, Celum C, Ndase P, Ronald A, Bangsberg DR, Baeten JM; Partners PrEP Study Team. Medication Sharing is Rare among African HIV-1 Serodiscordant Couples Using Oral Pre-exposure Prophylaxis (PrEP) for HIV-1 Prevention. *J Acquir Immune Defic Syndr*. 2017 Jun 1;75(2):184-189. PMC5432041
188. Sivay MV, Li M, Piwowar-Manning E, Zhang Y, Hudelson SE, Marzinke MA, Amico RK, Redd A, **Hendrix CW**, Anderson PL, Bokoch K, Bekker LG, van Griensven F, Mannheimer S, Hughes JP, Grant R, Eshleman SH; HPTN 067/ADAPT Study Team. Characterization of HIV Seroconverters in a TDF/FTC PrEP Study: HPTN 067/ADAPT. *J Acquir Immune Defic Syndr*. 2017 Jul 1;75(3):271-279. PMC5472493
189. Bochner AF, Baeten JM, Rustagi AS, Nakku-Joloba E, Lingappa JR, Mugo NR, Bukusi EA, Kapiga S, Delany-Moretlwe S, Celum C, Barnabas RV; Partners in Prevention HSV/HIV Transmission Study and **Partners PrEP Study Teams**. A cross-sectional analysis of *Trichomonas vaginalis* infection among heterosexual HIV-1 serodiscordant African couples. *Sex Transm Infect*. 2017 Nov;93(7):520-529. *PMCID pending*
190. Zhang Y, Clarke W, Marzinke MA, Piwowar-Manning E, Beauchamp G, Breaud A, **Hendrix CW**, Cloherty GA, Emel L, Rose S, Hightow-Weidman L, Siegel M, Shoptaw S, Fields SD, Wheeler D, Eshleman SH. Evaluation of a multi-drug assay for monitoring adherence to a regimen for HIV pre-exposure prophylaxis in a clinical study (HIV Prevention Trials Network 073). *Antimicrob Agents Chemother*. 2017 Apr 24. pii: AAC.02743-16. doi: 10.1128/AAC.02743-16. PMC5487665

**PUBLICATIONS****Original Research – continued**

191. Gulick RM, Wilkin TJ, Chen YQ, Landovitz RJ, Amico KR, Young AM, Richardson P, Marzinke MA, Hendrix CW, Eshleman SH, McGowan I, Cottle LM, Andrade A, Marcus C, Klingman KL, Chege W, Rinehart AR, Rooney JF, Andrew P, Salata RA, Siegel M, Manabe YC, Frank I, Ho K, Santana J, Stekler JD, Swaminathan S, McCauley M, Hodder S, Mayer KH. Safety and Tolerability of Maraviroc-Containing Regimens to Prevent HIV Infection in Women: A Phase 2 Randomized Trial. *Ann Intern Med* 2017 Sep 19;167(6):384-393. PMC5667908
192. Velloza J, Celum C, Haberer JE, Ngure K, Irungu E, Mugo N, Baeten JM, Heffron R; **Partners Demonstration Project Team**. Depression and ART Initiation Among HIV Serodiscordant Couples in Kenya and Uganda. *AIDS Behav.* 2017 Aug;21(8):2509-2518. PMC5552192
193. Shieh EC\*, Weld ED\*, Fuchs EJ, Hiruy H, Buckheit KW, Buckheit RW, Breakey JC, **Hendrix CW**. Lubricant Provides Poor Rectal Mucosal HIV Coverage. *AIDS Res Hum Retroviruses.* 2017 Aug;33(8):784-787. \*Co-First Authors. PMC5564025
194. Husnik MJ, Brown ER, Marzinke M, Livant E, Palanee-Phillips T, **Hendrix CW**, Kiweewa FM, Nair G, Soto-Torres LE, Schwartz K, Hillier SL, Baeten J. Implementation of a Novel Adherence Monitoring Strategy in a Phase III, Blinded, Placebo-Controlled, HIV-1 Prevention Clinical Trial. *J Acquir Immune Defic Syndr.* 2017 Nov 1;76(3):330-337. PMC5634926
195. Heffron R, Parikh UM, Penrose KJ, Mugo N, Donnell D, Celum C, Mellors JW, Baeten JM; **Partners PrEP Study Team**. Objective Measurement of Inaccurate Condom Use Reporting Among Women Using Depot Medroxyprogesterone Acetate for Contraception. *AIDS Behav.* 2017 Jul;21(7):2173-2179. PMC5378697
196. 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
197. Carballo-Diéguez A, Balán IC, Brown W 3rd, Giguere R, Dolezal C, Leu CS, Marzinke MA, **Hendrix CW**, Piper JM, Richardson BA, Grossman C, Johnson S, Gomez K, Horn S, Kunjara Na Ayudhya RP, Patterson K, Jacobson C, Bekker LG, Chariyalertsak S, Chitwarakorn A, Gonzales P, Holtz TH, Liu A, Mayer KH, Zorrilla C, Lama J, McGowan I, Cranston RD. High levels of adherence to a rectal microbicide gel and to oral Pre-Exposure Prophylaxis (PrEP) achieved in MTN-017 among men who have sex with men (MSM) and transgender women. *PLoS One.* 2017 Jul 27;12(7):e0181607. PMC5531503

**PUBLICATIONS****Original Research – continued**

198. Heffron R, Thomson K, Celum C, Haberer J, Ngunjiri K, Mugo N, Bukusi E, Katabira E, Odoyo J, Bulya N, Asimwe S, Tindimwebwa E, Baeten JM; **Partners Demonstration Project Team**. Fertility Intentions, Pregnancy, and Use of PrEP and ART for Safer Conception Among East African HIV Serodiscordant Couples. *AIDS Behav*. 2017 Sep 11. doi: 10.1007/s10461-017-1902-7. PMC5845763
199. Montgomery ET, Noguchi LM, Dai JY, Pan J, Biggio J, **Hendrix CW**, Isaacs K, Watts DH, Schwartz JL, Piper J, Beigi R. Acceptability of and Adherence to an Antiretroviral-Based Vaginal Microbicide among Pregnant Women in the United States. *AIDS Behav* 2018 Feb; 22(2): 402–411. PMC5702586
200. Bekker LG, Roux S, Sebastien E, Yola N, Amico KR, Hughes JP, Marzinke MA, **Hendrix CW**, Anderson PL, Elharrar V, Stirratt M, Rooney JF, Piwowar-Manning E, Eshleman SH, McKinstry L, Li M, Dye BJ, Grant RM, HPTN 067 (ADAPT) study team. Daily and non-daily pre-exposure prophylaxis in African women (HPTN 067/ADAPT Cape Town Trial): a randomised, open-label, phase 2 trial. *Lancet HIV*. 2018 Feb;5(2):e68-e78. doi: 10.1016/S2352-3018(17)30156-X. *PMCID Pending*
201. Robinson JA, Marzinke MA, Fuchs EJ, Bakshi RP, Radebaugh CL, Spiegel HML, Coleman JS, Rohan LC, **Hendrix CW**. Comparison of the pharmacokinetics and pharmacodynamics of single-dose tenofovir vaginal film and gel formulation (FAME-05). *JAIDS* 2018 Feb 1;77(2):175-182. PMC5821271
202. Smith J, Moss J, Srinivasan P, Butkyavichene I, Gunawardana M, Fanter R, Miller C, Sanchez D, Yang F, Ellis S; Zhang J, Marzinke M, **Hendrix CW**, Kapoor A, Baum M. Novel multipurpose pod-intravaginal ring for the prevention of HIV, HSV, and unintended pregnancy: Pharmacokinetic evaluation in a macaque model. *PLOS One* 2017 Oct 5;12(10):e0185946. PMC5628903
203. Xiao P, Gumber S, Marzinke M, Date A, Hoang T, Hanes J, Ensign L, Wang L, Rohan L, Fuchs E, **Hendrix CW**, Villinger F. Hypo-osmolar formulation of TFV enema promotes uptake and metabolism of TFV in tissues leading to prevention of SHIV/SIV infection. *Antimicrob Agents Chemother* 2017 Dec 21;62(1). pii: e01644-17. PMC5740373
204. Abaasa A, **Hendrix CW**, Gandhi M, Anderson P, Kamali A, Kibengo F, Sanders E, Mutua G, Priddy F, Haberer JE. Utility of Different Adherence Measures for Prep: Patterns and Incremental Value. *AIDS Behav* 2018 Apr;22(4):1165-1173. PMC5878836



**PUBLICATIONS****Original Articles (continued)**

205. Balán IC, Giguere R, Brown W 3rd, Carballo-Diéguez A, Horn S, **Hendrix CW**, Marzinke MA, Ayudhya RPKN, Patterson K, Piper JM, McGowan I, Lama JR, Cranston RD; MTN-017 Protocol Team. Brief Participant-Centered Convergence Interviews Integrate Self-Reports, Product Returns, and Pharmacokinetic Results to Improve Adherence Measurement in MTN-017. *AIDS Behav.* 2017 Oct 26. doi: 10.1007/s10461-017-1955-7. *PMCID Pending*
206. Figueroa D, Madeen E, Tillotson J, Richardson P, Cottle L, McCauley M, Landovitz R, Andrade A, **Hendrix CW**, Mayer KH, Wilkin TJ, Gulick R, Bumpus NN. Genetic Variation of the Kinases that Phosphorylate Tenofovir and Emtricitabine in Peripheral Blood Mononuclear Cells. *AIDS Res Hum Retroviruses.* 2018 May;34(5):421-429. *PMCID Pending*
207. Grant RM, Mannheimer S, Hughes JP, Hirsch-Moverman Y, Loquere A, Chitwarakorn A, Curlin ME, Li M, Amico KR, **Hendrix CW**, Anderson PL, Dye BJ, Marzinke MA, Piwowar-Manning E, McKinstry L, Elharrar V, Stirratt M, Rooney JF, Eshleman SH, McNicholl JM, van Griensven F, Holtz TH. Daily and Nondaily Oral Preexposure Prophylaxis in Men and Transgender Women Who Have Sex With Men: The Human Immunodeficiency Virus Prevention Trials Network 067/ADAPT Study. *Clin Infect Dis.* 2018 Feb 6. doi: 10.1093/cid/cix1086. [Epub ahead of print] *PMCID Pending*
208. Figueroa DB, Tillotson J, Li M, Piwowar-Manning E, **Hendrix CW**, Holtz TH, Bokoch K, Bekker LG, van Griensven F, Mannheimer S, Hughes JP, Grant RM, Bumpus NN. Discovery of genetic variants of the kinases that activate tenofovir among individuals in the United States, Thailand, and South Africa: HPTN067. *PLoS One.* 2018 Apr 11;13(4):e0195764. PMC5895070
209. Heffron R, Thomson K, Celum C, Haberer J, Ngure K, Mugo N, Bukusi E, Katabira E, Odoyo J, Bulya N, Asiimwe S, Tindimwebwa E, Baeten JM; **Partners Demonstration Project Team**. Fertility Intentions, Pregnancy, and Use of PrEP and ART for Safer Conception Among East African HIV Serodiscordant Couples. *AIDS Behav.* 2018 Jun;22(6):1758-1765. PMC5845763
210. Justman JE, Nair G, **Hendrix CW**, Piper JM, Marzinke MA, Dai JY, Pan Z, Galaska B, Levy L, Schwartz JL, Balar B, Kunjara Na Ayudhya RP, Mushamiri I, McGowan I, Dezzutti CS, MTN-014 Study Team. Pharmacokinetics and Pharmacodynamics of Tenofovir Reduced-Glycerin 1% Gel in the Rectal and Vaginal Compartments in Women: A Cross-Compartmental Study with Directly Observed Dosing. *J Acquir Immune Defic Syndr.* 2018 Jun 1;78(2):175-182. PMC5963717
211. Hoang T, Date AA, Ortiz JO, Young TW, Bensouda S, Xiao P, Marzinke MA, Rohan LC, Fuchs EJ, **Hendrix CW**, Gumber S, Villinger F, Cone RA, Hanes J, Ensign LM. Development of rectal enema as microbicide (DREAM): Preclinical progressive selection of a tenofovir prodrug enema. *Eur J Pharm Biopharm* 2018 May 23. pii: S0939-6411(18)30476-4. doi: 10.1016/j.ejpb.2018.05.030. [Epub ahead of print] *PMCID Pending*

## PUBLICATIONS

### Original Articles

212. Pyra M, Anderson PL, **Hendrix CW**, Heffron R, Mugwanya K, Haberer JE, Thomas KK, Celum C, Donnell D, Marzinke MA, Bukusi EA, Mugo NR, Asiimwe S, Katabira E, Baeten JM; Partners Demonstration Study Team. Tenofovir and tenofovir-diphosphate concentrations during pregnancy among HIV-uninfected women using oral pre-exposure prophylaxis. *AIDS*. 2018 Jun 11. doi: 10.1097/QAD.0000000000001922. [Epub ahead of print] PMID in progress
213. Bunge KE, Dezzutti CS, **Hendrix CW**, Marzinke MA, Spiegel HML, Moncla BJ, Schwartz JL, Meyn LA, Richardson-Harman N, Rohan LC, Hillier SL. FAME-04: A Phase 1 trial to assess the safety, acceptability, pharmacokinetics and pharmacodynamics of film and gel formulations of tenofovir *J Internat AIDS Soc* 2018 [In Press] PMID pending
214. Aung W, Bakshi RP, Breakey J, Johnson JE, **Hendrix CW**, Weld ED, Fuchs EJ, Marzinke MA. Fecal Coliform Bacterial Detection to Assess Enema Adherence in HIV Prevention Clinical Studies. *AIDS Behav* 2018 Jul 3. doi: 10.1007/s10461-018-2211-5. [Epub ahead of print] PMID pending

### Review Articles

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

### Case Reports

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

## PUBLICATIONS

### Book Chapters, Monographs

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

### Proceedings Reports

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

### Editorials (Invited)

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

### Letters, Correspondence

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

## **PUBLICATIONS**

### **Letters, Correspondence**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



Craig W. Hendrix., MD

Curriculum Vitae

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## **CLINICAL ACTIVITIES**

### **Certification**

#### ***Medical Licensure***

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

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

#### ***Medical Boards or Other Specialty Certification***

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

American Board of Internal Medicine, 9/87

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

American Board of Clinical Pharmacology, 10/2016

#### ***Membership in or Examiner for Specialty Board***

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



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

Physician and Society (medical student curriculum)

“Scientific Misconduct” 2001

Medical Pharmacology (medical student curriculum)

*Lectures*

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

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

“Pharmacokinetics III: Dosing Regimens” 1995-present

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

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

“Introduction to Antibiotics” 1998-present

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

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

“Ribosomal inhibiting antibiotics I: Aminoglycosides” 1998-present

“Ribosomal inhibiting antibiotics II: Others” 1998-present

“Antifungal Drugs” 2001

“Pharmacokinetics of anti-seizure drugs” 1995-1999

“Pharmacology of immunotherapeutics in neurology” 2000

“Aspirin and NSAIDs” 1998-2004, 2017

“Opiates” 1994-2004

“Quinolones” 2007

*Small group/tutorials*

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

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

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

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

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

Metabolism small group 2012-2015

Pharmacology medical student journal club 2012-2015

Tutorial “My Favorite Drug (Drug Development)” 2016

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

“Practical Pharmacokinetics” 1995-2004

“Drug Interactions” 2004

“Rational Use of Antibiotics” 2005-2006

Pharmacology (Pharmacology Graduate Students):

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

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

“Pharmacokinetics III: Mixed Order Kinetics” 2000-present

“Antibiotics” 2000-2006

“Aspirin and NSAIDs” 2000-2004

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

## **EDUCATIONAL ACTIVITIES**

### **Teaching**

#### *Classroom Instruction- continued*

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

“Principles of PK/PD in Drug Development”

“Curve Stripping”

“Non-Compartmental Analysis”

“Compartmental Analysis”

“Pharmacodynamic Studies”

“Pharmacodynamic Data Analysis”

“PK/PD Linkage Analysis”

“Population PK Analysis Overview”

“Clinical Trial Simulation Overview”

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

Course creator and co-director with S. Nimmagadda

Osler House Staff Noon Teaching Conference 2004 - 2012

“Practical Pharmacokinetics for the House Officer” 2004-2012

“Pharmacokinetics in Special Populations” 2004-2012

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

“Making Drugs Safer” 2005-2012

“Aminoglycoside Dosing Strategies” 2007-2012

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

#### School of Nursing

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

#### School of Public Health

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

“Overview of the drug development process” 1999-2003

“Pharmacokinetics for Drug Development” 1999-2003

“Pharmacokinetic and Safety Studies” 1994-2003

“Pharmacokinetic and Safety Studies - practicum” 1999-2003

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

“Learning vs. Confirming Studies” 1999-2003

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

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

“Clinical Trial Simulation” 2001-2003

## **EDUCATIONAL ACTIVITIES**

### **Teaching**

#### *Classroom Instruction - continued*

Analytical Methods in Clinical Investigation (required GTPCI Course),

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

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

Topics in Clinical Investigation (required GTPCI Course)

“Scientific Misconduct” 1995-present

Epidemiology and Natural History of Human Viral Infections

“Antiviral Therapy” 1997 - present

Epidemiology and Public Health Impact of HIV and AIDS

“Antiretroviral Therapy” 2004 - present

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

Advanced Topics on the Control and Prevention of HIV/ AIDS

“HIV Chemoprevention” 2006 - present

Epidemiology of Infectious Disease Journal Club, Faculty discussant, 2007

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

#### *Clinical Instruction*

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

Internal Medicine Inpatient Service, Teaching Attending, 1995-1996

#### *PerdanaUniversity Graduate School of Medicine (Kuala Lumpur, Malaysia)*

*Scientific Foundations of Medicine Course*

*Introduction to Pharmacology Section (2013-present)*

*“Receptors and Enzymes”*

*“Drug Metabolism”*

*“Pharmacokinetics I-IV”*

*“Pharmacokinetic Case Studies – Problem Solving”*

*“Autonomic Pharmacology I-II”*

*“Drug Safety”*

*“Drug Development”*

*“Complementary and Alternative Medicine”*

*“Drug Resistance”*

## **EDUCATIONAL ACTIVITIES**

### **Teaching**

#### ***Continuing Medical Education – Military***

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

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

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

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

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

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

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

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

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

#### ***Continuing Medical Education- Civilian***

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

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

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

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

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

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

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

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

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

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

“Databases and Clinical Research: How to Use and Abuse Them.” Johns Hopkins University School of Medicine, Office of Continuing Medical Education, Baltimore, Maryland. May 2000. JHMI. Clinical faculty and post-doctoral trainees.

“NSAIDs and COX-2 Inhibitors: Current Status.” Conjoint Clinic, Johns Hopkins University School of Medicine, Office of Continuing Medical Education. Baltimore, Maryland. February 2001. JHMI/Regional. Clinical faculty and post-doctoral trainees.

“Databases and Clinical Research: How to Use and Abuse Them.” Johns Hopkins University School of Medicine, Office of Continuing Medical Education, Baltimore, Maryland. April 2001. JHMI. Clinical faculty and post-doctoral trainees.

“Tools for Pre-Approval Drug Safety Evaluation”, Academics to CDER Series: Annual Continuing Medical Education Course May 2003. Regional. FDA Professional Staff Development.

“Aminoglycoside and Vancomycin Therapeutic Drug Monitoring.” Johns Hopkins Distance Learning (Bermuda Site), Office Of Continuing Medical Education, Baltimore, Maryland. May 2005. JHMI/Regional. Clinical faculty and post-doctoral trainees.

“Practical Pharmacokinetics for Primary Care.” Anne Arundel Community College, Physician Assistant Curriculum, Arnold, Maryland, 2005. Regional. Physician Assistant candidates.

## EDUCATIONAL ACTIVITIES

### Teaching

#### *Continuing Medical Education – Civilian continued*

“Relationships between Academia and the Pharmaceutical Industry.” American Medical Student Association (Johns Hopkins University Chapter), November 2006. JHMI. Medical Students.

“Development of Topical HIV Microbicides.” Division of Infectious Diseases, Fellows’ Conference, December 2006. JHMI. Clinical faculty and post-doctoral trainees.

“Clinical Pharmacology of Antiretroviral Drugs.” Curriculum Review Course, American Society of Clinical Pharmacology and Therapeutics, Anaheim, California. March 2007. International. Audience: Clinical Pharmacologists faculty and post-doctoral trainees.

“Pharmacodynamics of Antibiotics.” Division of Infectious Diseases, Fellows’ Conference, November 2007. JHMI. ID faculty and post-doctoral fellows.

“Pharmacological Principles of Antiretroviral Drugs” Curriculum Review Course. ASCPT, March 2009. International. Audience: Clinical Pharmacologists faculty and post-doctoral trainees.

“Pharmacological Principles of Antiretroviral Drugs” Curriculum Review Course. ASCPT, March 2013. International. Audience: Clinical Pharmacologists faculty and post-doctoral trainees.

“Pharmacogenomics: One Aspect of Precision Medicine in Primary Care” Curriculum Review Course. American Medical Forum. Washington, DC. November 2017. National. Audience: Internal Medicine & Primary Care Physicians.

“Pharmacogenomics: One Aspect of Precision Medicine in Primary Care” Curriculum Review Course. American Medical Forum. Washington, DC. June 2018. National. Audience: Internal Medicine & Primary Care Physicians.

“HIV Prevention with Drugs: Pre-Exposure Prophylaxis (PrEP) in Primary Care.” Curriculum Review Course. American Medical Forum. Washington, DC. June 2018. National. Audience: Internal Medicine & Primary Care Physicians.

“HIV Prevention with Drugs: Pre-Exposure Prophylaxis (PrEP) in Primary Care.” Curriculum Review Course. American Medical Forum. Washington, DC. November 2017. National. Audience: Internal Medicine & Primary Care Physicians.

## **EDUCATIONAL ACTIVITIES**

### **Mentoring**

#### ***Principal Mentor***

Stephen P. Blatt, M.D., 1990-1991

Infectious Disease Fellow, Wilford Hall USAF Medical Center  
Current position: Private Practice, Dayton, OH (1994-present)

Janet M. J. Hammond, M.D., Ph.D., 1995-1998

Clinical Pharmacology Fellow; Graduate Training Program in Clinical Investigation,  
Johns Hopkins University School of Hygiene and Public Health  
Thesis "Emerging Pathogens in Intensive Care"; Sc.M. granted 5/25/99.  
Current Position: Vice President of Infectious Diseases Development, AbbVie, Lake  
Forest, IL.

Robert Pelz, M.D., 1997-2000

Infectious Diseases Fellow  
Graduate Training Program in Clinical Investigation, Ph.D. 2000  
Research: Epidemiology and treatment of ICU infections  
Awards: Infectious Diseases Society of America 1998 Fellows Award for Scientific  
Excellence. "Do surveillance cultures predict fungal infection in critically ill pts?"  
Society of Critical Care Medicine 2000 In-training Fellow Award. "A double blind  
placebo controlled trial of prophylactic fluconazole to prevent Candida  
infections in critically ill surgical patients"  
Society of Critical Care Medicine 2000 Educational Scholarship Award  
"Fluconazole blood concentrations after enteral administration in critically ill  
surgical patients exceed most Candida minimal inhibitory concentrations in a  
double-blind, placebo-controlled trial in which fluconazole prevented Candidal  
infections."  
Johns Hopkins University Helen B. Taussig Young Investigators Award.  
"Nosocomial Fungal Infections in the Critically Ill: Dx and Prevention."  
Current Position: Clinical Assistant Professor of Medicine, Oregon Health and Science  
University, School of Medicine, Portland, OR

Thomas Ndovi, M.D., 1999-2005

Clinical Pharmacology Fellow  
Graduate Training Program in Clinical Investigation, 1999-2005, Ph.D. 2005  
Fogarty International Fellow 1999-2001, 2003-2004  
Merck International Fellow in Clinical Pharmacology 2001-2003  
Research: Pharmacology of antiretroviral drugs in genital compartments  
Awards: Department of Medicine Research Retreat Clinical Fellow Poster Finalist 2005  
British Journal of Clinical Pharmacology Prize 2007  
Last Position: Assistant Professor of Medicine, University of Malawi; Director, Johns  
Hopkins-Malawi Clinical Research Unit, Blantyre, Malawi (Deceased 2007)

## **EDUCATIONAL ACTIVITIES**

### **Mentoring**

#### ***Principal Mentor - continued***

Shelley Sylvester Magill, M.D., 2000-2007

Infectious Diseases Fellow/Assistant Professor

Graduate Training Program in Clinical Investigation, Ph.D. 2007

Awards: Pfizer Mycology Fellowship Award Recipient 2001-2003;

Clinical Scientist Award 2003 (Johns Hopkins University, declined)

Research: Ecology and prevention of fungal infections in the ICU

Position: Assistant Professor, Division of Infectious Diseases, Johns Hopkins University School of Medicine 2004 - 2007

Current Position: Medical Officer, Mycotic Diseases Branch, CDC, Atlanta, GA (2007-present)

Lewis Radonovich, M.D., 2000-2002

Clinical Pharmacology Fellow

Graduate Training Program in Clinical Investigation, Ph.D. Candidate

PhRMA Fellowship in Pharmacology 2001-2002

Research: Chemoprophylaxis of adenoviral infections

Previous Position: Assistant Professor of Medicine, University of Florida, Gainesville FL (2002-2015)

Current Position: Centers for Disease Control, NIOSH, Pittsburgh, PA (2015-present)

Thanyawee Puthanakit, M.D., 2001-2002

International Fogarty Fellow; Clinical Pharmacology Fellow

Graduate Training Program in Clinical Investigation; MHS degree 2002

Research: Pharmacokinetics of Antiretroviral Drugs, Drug interactions in the ICU

Assistant Professor, Chiang Mai University Medical Faculty, 2002-2005

Current Position: Associate Professor, Department of Pediatrics, Chulalongkorn University, Bangkok, Thailand; The HIV Netherlands Australia Thailand Research Collaborative.(2002-present)

Nimalie Stone, M.D., 2003-2004

Clinical Pharmacology Fellow

Research: Chemokine receptor inhibition phase I studies; Anti-infective drug utilization

Current Position: Medical Officer, CDC, Atlanta, Georgia

Wasif Khan, M.D., 2003-2005

Clinical Pharmacology Fellow

Graduate Training Program in Clinical Investigation, M.H.S. 2005

Merck International Fellow in Clinical Pharmacology 2003-2005

Research: Pharmacology of antiretroviral drugs, microbicide distribution

Current Position: Research Physician, International Center for Diarrheal Disease Research, Dhaka, Bangladesh. (2005-present)



**EDUCATIONAL ACTIVITIES****Mentoring*****Principal Mentor – continued***

Ying-Jun Cao, M.D., 2004-2007

Clinical Pharmacology Fellow

Graduate Training Program in Clinical Investigation, Ph.D. 2007

Research in Progress: Development of methods to describe pharmacokinetics in the male genital tract; Quantitative methods to assess colon microbicide and HIV distribution

Awards: Department of Medicine Research Retreat Clinical Fellow Poster Finalist 2005;

American Society for Clinical Pharmacology and Therapeutics Young Investigator Award 2006-7;

Conference Retroviruses and Opportunistic Infections, Young Investigator Award 2007

British Journal of Clinical Pharmacology Prize 2012

Positions: Assistant Professor of Medicine, Division of Clinical Pharmacology, Johns Hopkins University School of Medicine. 2007-2008; 2008-present (Adjunct).

Director Science, Global Clinical Pharmacology & Exploratory Development, Astellas Pharmaceuticals, 2008-present.

Sridhar Nimmagadda, Ph.D., 2005-2008

Post-doctoral Fellow in Pharmacology and Radiology (Martin Pomper co-mentor)

Research: Quantitative luminal and tissue distribution of HIV and CD4 cells in the human vagina and colon following simulated receptive intercourse

Positions: Associate Professor of Radiology, Johns Hopkins University School of Medicine, 2009-present.

Kelly Brungardt Stein, MD, 2006-2007

Joint Clinical Pharmacology – Infectious Diseases Fellow

Graduate Training Program in Clinical Investigation, ScM 2009

Research: Protein binding of antiretrovirals in semen; vaginal distribution of HIV & CD4 cells.

Current Position: Instructor, Rush University Medical Center 2008-present

Nicolette Louissaint, PhD, 2006-2013

Pharmacology Training Program, Department of Pharmacology (2006 – 2010)

Ph.D. Candidate (PhD conferred May 2010), Post-doctoral fellow (May 2010-present)

Research in Progress: Quantitative luminal and tissue distribution of HIV and CD4 cells in the human vagina and colon following simulated receptive intercourse

Awards: Keystone Symposia Minority Scholarship, 2008

Department of Medicine Research Retreat Clinical Research Fellow Poster Finalist, 2009

American Society for Clinical Pharmacology and Therapeutics (ASCPT) Presidential Trainee Award 2010

ASPET Integrative Research in Pharmacology Awards 2012

AAAS Fellow – US Department of State 2013-2014

Current Position: Director of Healthcare Ready, AAAS Science and Technology Policy Fellow, Foreign Affairs Officer, US Department of State, 2014 - present

## **EDUCATIONAL ACTIVITIES**

### **Mentoring**

#### ***Principal Mentor - continued***

Lindsay Brooke Avery, BS, 2008-2012

Pharmacology Training Program, Department of Pharmacology

Ph.D. Candidate; PhD conferred August 2012

Research: Efavirenz protein binding, compartmental distribution, and antiviral effect

Awards: American Society for Clinical Pharmacology and Therapeutics (ASCPT) Presidential Trainee Award 2010

Young Investigator Award. 20th Conference on Retroviruses and Opportunistic Infections 2013

Positions: Post-doctoral fellow, Namandje Bumpus Lab, Johns Hopkins University 2012-2014;

Current position: Pharmaceutical Development, Pfizer, Inc. Boston, MA, 2014-present

Liye Li, MD, PhD. 2009-2010

Clinical Pharmacology Fellow

Research: Development of candidate topical rectal microbicides.

Current Position: Nuclear Medicine private practice 2010 - present

Francisco Leyva, Md. PhD, 2009-2013

Clinical Pharmacology Fellow

Graduate Training Program in Clinical Investigation, M.H.S. 2012

Research: Development of candidate topical rectal microbicides.

Current Position: National Institutes of Health, Division of Microbiology and Infectious Diseases

Yanhui Lu, BS, 2010-2014

Pharmacology Training Program, Department of Pharmacology

Ph.D. Candidate; PhD conferred March 2014

Research: Identification of Novel Phase I and Phase II Metabolites of Maraviroc

Awards:

Junghea Park Memorial Travel Award 2012

Scheinberg Travel Award for spring 2011

Graduate Student Travel Award, ASPET Annual Meeting 2012

2012 Chinese Government Award for Outstanding Self-financed Students Abroad (China Scholarship Council)

2014 Bae Gyo Jung Young Investigator Day Award. Johns Hopkins University

Current Position: Office of Clinical Pharmacology, FDA 2015-present

Jenell Fenell Coleman, MD, 2010 – 2014

Assistant Professor, Department of Obstetrics and Gynecology

Harold Amos Medical Faculty Development Award

Research: Contraceptive – Antiretroviral drug interactions

Current Position: Associate Professor, Obstetrics & Gynecology, Johns Hopkins University

## **EDUCATIONAL ACTIVITIES**

### **Mentoring**

#### ***Principal Mentor - continued***

Salee Parichat, MD, M.P.H. 2011-2012

International Fogarty Fellow, Thailand; Epidemiology, Masters of Public Health 2012,  
Bloomberg School of Public Health,

Research: Pre-exposure Prophylaxis adherence measured by plasma drug levels in MTN-001:  
comparison between vaginal gel and oral tablets in two geographic regions.

Current Position: RIHES, Chiang Mai University, Thailand

Hiwot Hiruy, MD, 2011-2015

Joint Clinical Pharmacology – Pediatric Infectious Diseases Fellow

Graduate Training Program in Clinical Investigation, PhD 2015

Research: Gastrointestinal tract pharmacology of topical HIV microbicides

Current Position: Medical Officer, FDA 2015-present

Jenny Robinson, MD, 2012-2014

Clinical Pharmacology Fellow

Graduate Training Program in Clinical Investigation, PhD Candidate

Research in progress: Female Genital tract pharmacology of topical HIV microbicides

Current Position: Assistant Professor, Obstetrics & Gynecology, Johns Hopkins University  
2014-present

Ethel Weld, MD, 2013-2016

Joint Clinical Pharmacology –Infectious Diseases Fellow

Graduate Training Program in Clinical Investigation, PhD Candidate

Research in progress: Gastrointestinal tract pharmacology of topical HIV microbicides

Awards:

The Pearl M. Stetler Research Fund for Women Physicians Award 2015-2016

Research Scholars Junior Faculty Award (KL2) 2017-2018

Current Position: Assistant Professor, Department of Medicine (Clinical Pharmacology), Johns  
Hopkins University, 2016-present

Funding: KL2 NCTS Johns Hopkins ICTR

Jackson Mukonzo, PhD, 2014

Fulbright Faculty Scholar

Research in progress: Polymorphisms uniquely impacting HIV treatment in African populations

Current Position: Director (Acting), Department of Pharmacology & Therapeutics, Makerere  
University, College of Health Science, Kampala, Uganda

Eugenie Shieh, MD, 2014-2017

Joint Clinical Pharmacology–Gastroenterology Fellow

Graduate Training Program in Clinical Investigation, PhD Candidate

Research in progress: Gastrointestinal tract pharmacology of topical HIV microbicides

Private practice gastroenterology, CA 2017-present

## **EDUCATIONAL ACTIVITIES**

### **Mentoring**

#### ***Principal Mentor - continued***

Victoria Ojeda, 2015-present

Associate Professor, University of California, San Diego

HIV Prevention Trials Network Scholar

Research in Progress: Impact of staff-participant relationships on adherence in randomized controlled PrEP trials

Current Position: Associate Professor, University of California at San Diego, School of Public Health, San Diego, CA

Rachel Scott, MD, 2016-present

Assistant Professor, Georgetown University

Mid Atlantic CFAR Mentoring

Research in progress: ARV & PrEP PK in pregnancy and post-partum

Current Position: Assistant Professor of Medicine, Georgetown University, Washington, DC

Funding: K23 NIMH

Zachary Janik, 2016-present

Medical Student, Research Mentor

Research in Progress: Quantitative assessment of White Coat Adherence in HIV Pre-Exposure Prophylaxis.

Katherine Huether, 2017-2018

Medical Student, Drug Development Research Rotation

#### ***Secondary Sub-Specialty Mentoring***

Normalynn Garrett, PhD candidate, Nursing; Pharmacology mentoring, 1998-1999

Andre Agthe, Neonatal Fellow, GTPCI; Pharmacology mentor, 2000-2004

Amy Ginsberg, Infectious Diseases Fellow; Pharmacology mentor, 2002-2003

#### ***Advisor (when not Primary Mentor) – GTPCI - continued***

Rodney Willoughby, MD, Pediatrics Faculty, GTPCI; Pharmacology mentor, 1999-2004

Lawrence Lee, Clinical Pharmacology Fellow; Pharmacokinetics mentor, 2003-2004

Devi Chittineni, Clinical Pharmacology Fellow; Pharmacokinetics mentor, 2004 – 2006

Myaing Nyunt, Clinical Pharmacology Fellow, GTPCI; Pharmacokinetics mentor, 2005 - 2008

Current Position: Assistant Professor of Medicine, University of Maryland Medical Center

## EDUCATIONAL ACTIVITIES

### *Advisor (when not Primary Mentor) – GTPCI - continued*

Kelly Dooley, MD, Joint Clinical Pharmacology – Infectious Diseases Fellow, GTPCI;  
Pharmacokinetics Mentor, 2006 – 2010  
Current Position: Associate Professor of Medicine, Johns Hopkins University

Sofia Perea, Pharm.D., Ph.D., 2002-2004  
Oncology Post-Doctoral Fellow  
Graduate Training Program in Clinical Investigation, Ph.D. Candidate

Kai Zhang, M.D., 2003-2004  
Post-Doctoral Fellow  
Graduate Training Program in Clinical Investigation, Ph.D. Candidate

Victor Crentsil, M.D., 2005 – 2007  
Division of Geriatric Medicine  
Graduate Training Program in Clinical Investigation, M.H.S. Degree 2007  
Current Position: FDA Medical Officer

Romanee Chaiwarith, M.D. 2006 - 2007  
Post-Doctoral Fellow  
Graduate Training Program in Clinical Investigation, M.H.S. Candidate  
Current Position: Assistant Professor, Medicine, Chiang Mai University

Tamorah Lewis, MD, Joint Clinical Pharmacology – Neonatology Fellow, GTPCI;  
Pharmacokinetics Mentor, 2010 – 2014, Fellowship Advisory Committee, 2010-2014  
Current Position: Assistant Professor, Pediatrics, Mercy Children’s Hospital, Kansas City  
(2014-present)

Pranita Tamma, M.D. 2010-2011  
Post-Doctoral Fellow Pediatric Infectious Diseases  
Graduate Training Program in Clinical Investigation, M.H.S. Candidate  
Current Position: Assistant Professor, Pediatrics (Infectious Diseases), Johns Hopkins  
University (2011-present)

Berkley Limketkai MD 2011 – 2017  
Post-Doctoral Fellow Gastroenterology  
Graduate Training Program in Clinical Investigation, Ph.D. 2017  
Current Position: Assistant Professor, Medicine (Gastroenterology) Stanford University  
(2014-present)

Erica Shelton MD 2012 – 2014  
Instructor, Emergency Medicine  
Graduate Training Program in Clinical Investigation, Ph.D. Candidate

Craig W. Hendrix., MD

Curriculum Vitae

Current Position: Assistant Professor, Emergency Medicine, Johns Hopkins University  
(2014-present)

Omamah Alfarisi PharmD 2012 – present

Post-Doctoral Fellow Clinical Pharmacology

Graduate Training Program in Clinical Investigation, Ph.D. Candidate, pharmacokinetics  
mentor

Kattayoun Kordy MD, 2014-2016

Clinical Pharmacology UCLA, F32, Pharmacokinetics mentor

Current Position: Assistant Professor, Medicine (Gastroenterology) University of Southern  
California (2016-present)

**EDUCATIONAL ACTIVITIES*****Mentoring Committees***

Adriana Andrade, MD 2007-2018

Associate Professor of Medicine (Infectious Diseases)

Research in Progress: HIV Clinical Pharmacology, Drug interactions with complementary medicine products and antiretroviral drugs, Adherence to therapeutic regimens.

Myaing Nyunt, MD, PhD 2008-2013

Assistant Professor of International Health (School of Public Health)

Research in Progress: Clinical pharmacology of malaria therapeutics and prevention

Previous Position: Assistant Professor, Medicine, University of Maryland, Baltimore, MD (2014-2017)

Current Position: Assitant Professor, Medicine, Duke University, Durham, NC (2017-present)

**Mentoring*****Thesis/Oral Examination Committees***

Janet Hammond, “Emerging Pathogens in Intensive Care”, M.H.S. thesis, Graduate Training Program in Clinical Investigation, School of Hygiene and Public Health, Thesis advisor, Thesis Committee Member 1996-1999.

Normalynn Garrett, “Effects of LY235959 on surgery-induced immunosuppression and increased metastasis in rats”, Ph.D. thesis, School of Nursing, Thesis Committee Member, 1998-9.

Robert Pelz, “Prophylaxis of invasive fungal infections in the Surgical Intensive Care Unit: Efficacy, Pharmacology, and Cost Analysis”, Ph.D. thesis, Graduate Training Program in Clinical Investigation, School of Hygiene and Public Health, Thesis advisor, Thesis Committee Member, 1997-2001.

Rodney Willoughby, “Developmental Kinetics of Cytokines in Cerebral Palsy”, Ph.D. thesis, Graduate Training Program in Clinical Investigation, School of Hygiene and Public Health, Thesis Committee Member, 1999-2008.

Claudine Woo, “Subgroup analyses in clinical trials”, PhD thesis; Ph.D. 2006, Clinical Trials Program, Department of Epidemiology. School of Public Health, Preliminary Oral Examination Committee Member, 2001; Thesis Committee Member, 2003 - 2006.

Leena Choi, “Modeling biomedical data and the foundations of bioequivalence”, Ph.D. Thesis, Department of Biostatistics, School of Public Health, Preliminary Oral Examination Committee Chairman, 2001; Thesis Committee Chairman, 2005.

Elizabeth Lowe, “Phase I and Pharmacokinetic Study of Liposomal Doxorubicin (TLC D-99) in Pediatric Patients with Refractory Solid Tumors”, M.H.S. thesis, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Reader, 2002.

Melanie Rusch, “Were Sexual Risk Behaviors Changing in Injection Drug Users in the ALIVE Cohort Before HAART was Readily Available in this Population”, M.H.S. Candidate, Department of Epidemiology, School of Public Health, Thesis reader, 2002.

**EDUCATIONAL ACTIVITIES****Mentoring*****Thesis/Oral Examination Committees – continued***

Alex Agthe, “Clonidine and opiates in the treatment of neonatal abstinence syndrome”, Ph.D. candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Examination Committee, 2002 Thesis Committee Member, 2007-2008.

Thomas Ndovi, “Compartmental Kinetics of Antiretroviral Drugs (ARVs) in the human Male Genital Tract”, PhD Thesis, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Examination Committee Member, 2003; Thesis Committee Member, 2003-2005.

Michael Gibson, Ph.D. candidate, Department of Oncology, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2002-2007.

Ricardo Carvalho, “Unidirectional Transscleral Delivery from Episcleral Implants”, Sc.M. Thesis, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2003-2006, Thesis Reader 2006.

Shelley Sylvester Magill, PhD Candidate, Department of Medicine, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Examination Committee Member 2004, Thesis Committee member, 2004-2007.

Courtney Silverthorn, Ph.D. Candidate, Department of Pharmacology, School of Medicine, Preliminary Oral Exam Committee Member, 2004.

Lawrence Soon-U Lee, “Antioxidant and phase 2 enzyme induction activity of ginseng in humans”, PhD Candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Oral Examination Committee, 2005; Thesis Committee, 2007.

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

Ying-Jun Cao, “Antiretroviral Drug Penetration into the Male Genital Tract,” PhD Candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Examination Committee Member, 2006; Thesis Defense Committee, 2007.

Lijuan Deng, “Spline Based Curve Fitting with Application to Kinetic Imaging M.S.” Candidate, Department of Biostatistics, Bloomberg School of Public Health, Thesis Reader 2006.

AeRang Kim, Ph.D. candidate, Department of Oncology, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2006-2009.

Michael Yu, Ph.D. candidate, Department of Oncology, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2006-2010.

Susanna Nazarian, PhD candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2008-2009.



**EDUCATIONAL ACTIVITIES****Mentoring*****Thesis/Oral Examination Committees – continued***

Jean Wang, “Predicting Cancer in Barrett's Esophagus”, PhD candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2008-2009.

Nicolette Louissaint, PhD candidate, Pharmacology and Molecular Sciences, School of Medicine, Thesis Committee Member, 2008-2010.

Benjamin Jilek, PhD candidate, Biochemistry, Cellular and Molecular Biology (BCMB) Graduate Program, School of Medicine, Thesis Committee Member, 2008-2011.

Jonathan Neiswinger, PhD candidate, Pharmacology and Molecular Sciences, School of Medicine, Oral Examination Committee Member, 2009.

Ying-Chun Lo, PhD candidate, Pharmacology and Molecular Sciences, School of Medicine, Oral Examination Committee Member, 2009.

Meng-Jung Chiang, PhD candidate, Pharmacology and Molecular Sciences, School of Medicine, Oral Examination Committee Member (Alternate), 2009.

Jeff Goldsmith, PhD candidate, Biostatistics, Bloomberg School of Public Health, Oral Examination Committee member. 2010. Thesis Committee member, 2011-2012.

Lindsay B. Avery, PhD Candidate. Pharmacology and Molecular Sciences, School of Medicine, Thesis Committee Member, 2011-2012.

Salee Parichat, MD, M.P.H. Candidate. Epidemiology, Bloomberg School of Public Health, Thesis Committee, 2011-2012.

Ryan Westergaard, PhD candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2012.

Melissa Zarr, PhD Candidate. Pharmacology and Molecular Sciences, School of Medicine, Thesis Committee Member, 2012 – 2014. Thesis Reader 2014.

Laura Ensign, PhD candidate, Chemical and Biomolecular Engineering, School of Engineering, Thesis Committee, 2012.

Tamara Lewis, PhD candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2012-2015.

Jenny Robinson, PhD candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2013-present.

Yanhui Lu, PhD Candidate, Pharmacology and Molecular Sciences, School of Medicine, Thesis Committee Member, Thesis Advisor, 2012-2014.

Berkeley Limetkai, PhD candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Exam Committee Member, 2013; Thesis Committee Member, 2013-2017.

**EDUCATIONAL ACTIVITIES****Mentoring*****Thesis/Oral Examination Committees – continued***

Elaine To, PhD candidate, Department of Pharmacology and Molecular Sciences, School of Medicine, Thesis Committee, 2013-2014.

Chen Yue, PhD candidate, Biostatistics, Bloomberg School of Public Health, Oral Examination Committee member. 2013. Thesis Committee member, 2013-2016.

Evelyn Eisele, PhD Candidate, Pharmacology and Molecular Sciences, School of Medicine, Thesis Committee Member, 2013-2016.

Katharina Maisel, PhD Candidate, Biomedical Engineering, School of Engineering, Thesis Committee Member, 2013-2014.

Kai Deng, PhD Candidate, Biochemistry, Cellular and Molecular Biology (BCMB) Graduate Program, Thesis Committee Member, 2013-2014.

Christopher Saeui, PhD candidate, Biomedical Engineering. Oral exam committee. 2014

Julie Lade, PhD Candidate, Pharmacology and Molecular Sciences. Thesis Committee. 2014-2016

Ethel Weld, PhD Candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Exam Committee Member, 2015; Thesis Committee Member, 2015-present

Dominique Figueroa, PhD Candidate, Pharmacology and Molecular Sciences. Thesis Committee. 2015-2016

Clare Ruberman, PhD Candidate, Biostatistics. Oral Examination Committee, Member 2015. Thesis Committee Chair 2015-2018

Hugh Giovinazzo, PhD Candidate, Pharmacology and Molecular Sciences. Oral Examination Committee. 2015

Eugenie Shieh, PhD Candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Exam Committee Member, 2016; Thesis Committee Member, 2015-present

Thuy Huang, PhD Candidate, Pharmacology and Molecular Sciences. Oral Examination Committee. 2015-present

Matthew Ippolito, PhD Candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Exam Committee Member, 2016; Thesis Committee Member, 2017-present

Taarika Babu, PhD Candidate, Pharmacology and Molecular Sciences. Thesis Committee Member. 2017-present

Omamah Alfarisi, PhD Candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2018-present

## **EDUCATIONAL ACTIVITIES**

### **Mentoring**

#### *Thesis/Oral Examination Committees – continued*

Huilei Wang, PhD Candidate, Biomedical Engineering. Oral Exam Committee (Alternate) 2018.

Christy Pickering, PhD Candidate, Biomedical Engineering. Oral Exam Committee Chair 2018.

Inez Lam, PhD Candidate, Biomedical Engineering. Oral Exam Committee Chair 2018.

## **EDUCATIONAL ACTIVITIES**

### **Mentoring**

#### ***Training Grant Participation***

Grant #: 4T32GM066691

Title: Clinical Pharmacology Training Program

Principal Investigator: C. Hendrix (as of 2016 multi-PI with K. Dooley)

Date: 07/01/08-06/30/2023

Award: \$196,485 current year direct costs

Role: Mentor Clinical Pharmacology Fellows in clinical research; pharmacokinetics teaching

Grant #: 1UL1TR001079-01

Title: Institutional Clinical and Translational Science Award

Principal Investigator: D. Ford

Dates: 9/17/07 – 4/30/18

Award: \$\$7,485,218

Role: Mentor post-doctoral fellows in Graduate Training Program in Clinical Investigation

Grant #: 5T32GM08763-14

Title: Pharmacology Training Grant

Principal Investigator: J. Liu

Date: 07/01/00 – 06/30/20

Award: \$312,004

Role: Train graduate students in clinical pharmacology teaching and research.

Grant #: 2T32AI007291-21

Title: Research Training in Microbial Diseases

Principal Investigator: K. Gebo

Date: 08/01/01 – 08/31/16

Award: \$267,125 current year direct costs

Role: Mentor Infectious Diseases Fellows in clinical research

Grant #: 5R25DA021630

Title: Pediatric Training Grant: Immersion in Drug Abuse Research

Principal Investigator: E. Gauda

Dates: 07/01/07-04/30/13

Award: \$301,715

Role: Johns Hopkins/Morgan State University research training aspects of illicit drug use.

Grant #: 5D43TW00010

Title: Fogarty AIDS International Training & Research Program

Principal Investigator: C. Beyrer

Dates: 07/01/07-05/31/13

Award: \$695,000

Role: Mentoring of international post-doctoral clinical research fellows.

## **EDUCATIONAL ACTIVITIES**

### **Educational Program Building / Leadership / Administration**

#### ***School of Medicine***

Educational Policy and Curriculum Committee (EPCC), Student Assessment and Program Evaluation (SAPE) Subcommittee, member 2015-present

Medical Pharmacology (2<sup>nd</sup> year medical school)

Course Co-Director 1997-2001

Sectional Focus Group Leader (Introduction, Infectious Diseases, Rheumatology, Hepatology, Pain) 1997- 2003

Rational Therapeutics (4th year medical school, required course)

Initial Course Developer 1995

Course Director 1995-2004

Sessions jointly taught by experienced clinician and clinical pharmacologist to emphasize rational approach to therapeutic problems; focus on topics of keen interest to soon-to-be interns.

Analytical Methods in Clinical Pharmacology (Fellowship training curriculum, required course)

Initial Course Developer 2000

Course Director 2000-present

Cognitive and skill-based curriculum introduces quantitative aspects of clinical pharmacology in small-group problem-solving sessions.

Laboratory Science for the Clinical Investigator (Fellowship training curriculum, required course)

Initial Course developer 2017

Designed to provide an overview to clinical post-doctoral fellows and junior faculty planning clinical research studies that will rely on laboratory collaboration to support the clinical research. Curriculum covers a broad array of laboratory methods that describe quantitative laboratory methods, process of validation, quality control, and culture of laboratory-clinical interactions.

#### ***School of Public Health***

Principles of Drug Development, (required GTPCI Course)

Course Director 1999-2003

Curriculum oriented around small-group “pharmaceutical team” skill-building exercises supplemented by didactic sessions (course director, industry and FDA medical reviewers) to provide fundamentals of the drug development process. Final exam includes visiting senior leadership from FDA to hear fully developed drug development plans designed by student teams.

## **EDUCATIONAL ACTIVITIES**

### **Educational Program Building / Leadership - continued**

#### ***US Air Force***

US Air Force HIV Force wide Base Level Prevention & Education Program

Initial Program Development 1991

Course director 1991-1999

Lecturer/ Small Group leader 1991-1999

US Air Force wide HIV prevention program implemented based on identification and training of small multi-disciplinary base-level HIV prevention teams comprised of physician, nurse educator, public health officer and other health professionals who develop a local prevention plan tailored to meet local needs. Team building and training carried out initially and sustained over time at annual HIV/AIDS Train-the-trainer Short Course (24 hour CME units).

#### ***National***

“Principles and Practice of Drug Development”

Sanctioned by Institute of Medicine, concept developed at Institute of Medicine Forum

Sponsored by Stanford University, The Burroughs Wellcome Fund, and The Doris Duke Charitable Foundation

2006 - Curriculum development consultant

2006 - Lectures (delivered at Stanford University and internet broadcast to dozens of registered U.S. university campuses via the Stanford University Center for Professional Development)

“Role of pharmacokinetics-pharmacodynamics in drug development”

“Pharmacokinetics bridging process and practice in drug development”

“Pharmacokinetic-Pharmacodynamic models in drug development”

#### ***Food and Drug Administration***

“Academics to CDER” Annual CME Curriculum Development

Jointly developed curriculum between FDA Center for Drug Evaluation and Research Office of Training and Communication staff and Baltimore-Washington area academics

Target audience Baltimore-Washington Clinical Pharmacology Programs and FDA staff

2001-2004 Curriculum Development Committee

2003 “Tools for Pre-Approval Drug Safety Evaluation”, Course Director, Session Moderator, Lecturer

## **RESEARCH ACTIVITIES**

### **Research Program Building / Leadership**

Dates, name of research / basic science program, role

- 1989 – 1994 US Air Force/Henry M. Jackson Foundation HIV Research Program. Transitioned and substantially expanded existing observational database focused research program to integrated interventional clinical research organization collaborating in tri-service military medical consortium. Provided leadership and management of program during growth from initial staff of 4 to over 50 FTEs in clinical research program. Served initially as Research and Evaluation Unit Director (1989-1992), then Program Director (1992-1994).
- 1997 – Present Drug Development Unit (Division of Clinical Pharmacology) Reorganization. Reorganized existing clinical research unit, which focused on internal pharmaceutical industry-funded studies, to expand capacity to support investigator-initiated studies for faculty throughout the School of Medicine and refocused internal research portfolio to a primarily federally-funded clinical research enterprise. Served initially as Clinical Director (1997-1998), then overall Director (1998-Present).

## **ORGANIZATIONAL ACTIVITIES**

### **Institutional Administrative Appointments** (committees, dates)

#### *Johns Hopkins University School of Medicine Committees:*

Johns Hopkins Medicine Institutional Review Board (JHM IRB)

Member 2001- present

Co-Chairman IRB #2 – 2001 - 2007

Pharmacy & Therapeutics Liaison to JHM IRB 2001-present

Selection Committee, David S. Levine Award for Excellence in Mentoring, Department of Medicine, 2008

Department of Medicine, Appointment and Promotion Committee, 2009-present

Student Promotions Committee – Third and Fourth Years, 1996-2004

Student Promotions Committee – Second Year, 2000-2001

Joint Committee on Clinical Investigations, 1998-2001

Subcommittee (Pharmacy & Therapeutics Representative) 1998-2001

Graduate Training Program in Clinical Investigation,

Research Review Committee, 2/00-9/2006

Search Committee, Chief, Division of Infectious Diseases, Department of Medicine, 2004-2005

Search Committee, Clinical Pharmacology Faculty, Department of Medicine, 2004-2005

Search Committee, Pharmacology Faculty, Department of Pharmacology, 2004

#### *The Johns Hopkins Hospital Committees:*

Pharmacy and Therapeutics Committee, 1995-present

Joint Antibiotic Subcommittee, Chairman, 1998-2002

## **Editorial Activities**

### ***Journal Editorial Board***

Clinical Pharmacology and Therapeutics (2005 – 2008)

Clinical and Translational Science (2007 – 2015)

Pharmacology Research & Perspectives (2017-present)



## **ORGANIZATIONAL ACTIVITIES**

### ***Journal Peer Review Activities***

AIDS Research and Human Retroviruses (2006 – present)  
Antiviral Research (2001 – present)  
Clinical Drug Investigation (2006 – present)  
Clinical Infectious Diseases (2006 – present)  
Clinical Pharmacokinetics (2014-present)  
Clinical Pharmacology and Therapeutics (2002 – present)  
Clinical and Translational Science (2007 – present)  
Contraception (2006 – present)  
International Journal of STD & AIDS (2014-present)  
Journal of Acquired Immune Deficiency Syndromes (2003 – present)  
Journal of Antimicrobial Chemotherapy (2014-present)  
Journal of Clinical Pharmacology (2014-present)  
Journal of Infectious Diseases (2006 – present)  
Journal of Pharmacology and Experimental Therapeutics (2002 – present)  
Lancet HIV (2016 – present)  
Medicine (2009 – present)  
Neurology (2011 – present)  
PLOS One (2014 – present)

### **Advisory Committees, Review Groups/Study Sections** (sponsor, role, date)

Office of AIDS Research Advisory Committee, National Institutes of Health, *ex officio* member  
Department of Defense, 1995-1999

AIDS Clinical Trials Group IBT RAC, General Immune Modulation Subcommittee, National  
Institutes of Health, 1997-1998

General Clinical Research Centers, Division of Research Resources, National Institutes of Health;  
Study Section, Site Reviewer, 1998

Therapeutics Research Working Group, Office of AIDS Research Advisory Committee, National  
Institutes of Health, 1999-present

General Clinical Research Centers, Division of Research Resources, National Institutes of Health;  
Study Section, Site Reviewer, 2002

Institute of Medicine, Panel Member, Panel on “Institutional Review Boards: Health Services  
Research Data Privacy Protection”, 2000

U.S. Dept. of Agriculture, National Organic Standards Board, Technology Advisory Panel,  
Reviewer, 2002

## **ORGANIZATIONAL ACTIVITIES**

### **Advisory Committees, Review Groups (sponsor, role, date) – continued**

Centers for Disease Control and Prevention, Chairman, Special Grant Review Panel, PA “Clinical Evaluation and Testing of Vaginal Microbicide Candidates.” August 2003

National Institutes of Health, NIAID special review meeting PAR 03-138 entitled "Novel HIV Therapies: Integrated Preclinical/Clinical Program" March 2004

National Institutes of Health, NIGMS, Clinical Pharmacology Training Grant (T32), Special Emphasis Panel; Site Visit team. July 2004

National Institutes of Health, NIAID Special Emphasis Panel RFA-AI 04-047 "Partnership for Topical Microbicides" Review Committee, April 2005

National Institutes of Health, NIGMS, Clinical Pharmacology Training Grant (T32), Special Emphasis Panel. June 2005

Centers for Disease Control and Prevention (CDC), Board of Scientific Counselors, National Center for Infectious Diseases, March 2005 – 2007

Medical Research Council of Ireland, Clinical Research Infrastructure Grant Reviewer, 2006

American Foundation for AIDS Research (amfAR), Rectal HIV Transmission Targeted RFP, Scientific Reviewer, August 2006

SyNCH Trial (Single and Multiple Dose Escalation Phase I Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Orally Administered Silymarin (Legalon®) in Non-Cirrhotic Subjects with Chronic Hepatitis C or Non-Alcoholic Fatty Liver Disease), Safety Monitor, 2006

Food and Drug Administration (FDA),  
Antiviral Drugs Advisory Committee, 2007 – 2010  
Oncology Drugs Advisory Committee 2017

National Institutes of Health, NIAID Special Emphasis Panel RFA-AI-07-019 "Novel HIV Therapies: Integrated Preclinical/Clinical Program (U19)" Review Committee, October 2007

Population Council Microbicides Scientific Advisory Board, 2009 – present

National Institutes of Health, NIGMS, Clinical Pharmacology Training Grant (T32), Special Emphasis Panel; Study Section, Site Visit team. July 2014, July 2015

PREVENT U19 Program Project Grant, University of Louisville, KY, Scientific Advisory Board (2017-present)

UNC Chapel Hill Center for AIDS Research Scientific Advisory Board (2016-present)

## **ORGANIZATIONAL ACTIVITIES**

### **Professional Societies (membership, committees, dates, role)**

Alpha Omega Alpha Honor Medical Society 1983-present

Infectious Diseases Society of America 1989-1998

Civil-Military Alliance to Combat HIV/AIDS, 1996-2002; Steering Committee, 1999-2002

Armed Forces Infectious Diseases Society, 1997-1999

International Society of Antiviral Research  
Scientific Program Committee Reviewer 2001

International AIDS Society 1997 - present  
Industry Liaison Forum 2005

American Society for Clinical Pharmacology and Therapeutics (ASCPT) 1997 – present  
Board of Directors, 2010 – 2012  
Coordinating Committee on Scientific Sections, 2004-2010  
Chairman 2010-2012  
Vice Chairman 2008 – 2010  
Infectious Diseases and Antimicrobial Agents Section, 1997-present  
Chairman 2005 – 2008  
Vice Chairman 2004 – 2005  
Steering Committee 2018-present  
Scientific Program Committee, 1998-2002, 2005-2008  
ASCPT Nominating Committee, 2004-2005, 2014-2015  
Education Committee-1999-2002, 2015-present  
Social Media Task Force 2014-2015  
Mentor Task Force 2015-present  
Career Development Committee 2016-present  
Webinar Committee 2017

International Society of Pharmacometrics 2011 – 2015

American College of Clinical Pharmacology 2018-present

**ORGANIZATIONAL ACTIVITIES****Conference Organizer, Session Chair** (sponsor, date, role) - continued

Thirty-First International Congress of Military Medicine, “Medical Response to Chemical Warfare”, Beijing, People’s Republic of China, Symposium Co-Chair, December 1996.

Third Congress on AIDS in Asia and the Pacific, “Military AIDS Symposium”, Manila, Philippines, December 1997, Symposium Co-chair.

American Society for Clinical Pharmacology and Therapeutics, “Post-Marketing Surveillance”, San Antonio, Texas March 1999, Symposium Co-Chair.

American Society for Clinical Pharmacology and Therapeutics, “Novel Pharmacokinetic Methods for Developing HIV Chemoprevention Strategies”, Orlando, Florida March 2005, Workshop Organizer, Co-Chair.

American Society for Clinical Pharmacology and Therapeutics, “Pharmacokinetics and Clinical Applications”, Baltimore, Maryland, March 2006, Session Co-Chair.

Microbicides 2012, “Can we determine who uses? Self reports and objective measures of adherence in microbicide & PrEP trials”. Sydney. April 2012. Symposium committee.

American College of Clinical Pharmacology. “Symposium VII: Adherence: Missing Link in the Puzzle of Clinical Pharmacology”. Bethesda, MD. September 2013. Session Co-Chair.

HIV Research for Prevention (HIVR4P). “Long-acting Drug Release Systems for PrEP and Treatment.” Chicago, IL. October 2016. Session Co-Chair.

HIV Research for Prevention (HIVR4P). “Choosing ARVs for Prevention: Ensuring and Measuring Effective Tissue Delivery” Chicago, IL. October 2016. Session Co-Chair.

Conference on Retroviruses and Opportunistic Infections (CROI). “Of Mice, Monkeys, and Men: Prep from Preclinical to Population Level Impact”. Boston, MA. March 2018. Session Co-Chair.

## **RECOGNITION**

### **Awards, Honors**

Distinguished Military Graduate, Massachusetts Institute of Technology, AFROTC, 1978

Air Force Commendation Medal (USAF), 1980

Alpha Omega Alpha Honor Medical Society, 1983

Department of Medicine Award for Outstanding Academic Performance, Georgetown University, School of Medicine, 1984

Cahill Award for Academic Excellence in Surgery, Georgetown Univ., School of Medicine, 1984

*Magna cum Laude* Graduate, Georgetown University, School of Medicine, 1984

Meritorious Service Medal (USAF), 1994

Meritorious Service Medal, First Oak Leaf Cluster (USAF), 1997

Pharmaceutical Research and Manufacturers Association Faculty Development Award, 1997

Outstanding Pharmacology Professor (Basic Sciences), Medical Student Association, 2001-2002

Student Marshal, Medical School Graduation, Class of 2002

Johns Hopkins Alumni Association Excellence in Teaching Award, 2003

David M. Levine Faculty Mentoring Award (Department of Medicine) 2007

PhRMA Foundation Award in Excellence 2017

American College of Clinical Pharmacology, Distinguished Investigator Award 2018

**RECOGNITION****Invited Talks, Panels**

1. “A Risk-Benefit Perspective on Universal HIV Screening in the United States Air Force.” 1991, Buenos Aires, Argentina. Invited Talk, 17th Meeting of the Committee on Medicine in the Air Forces in the Americas. Sponsor: Committee on Medicine in the Air Forces in the Americas.
2. “International Security Impact of the HIV/AIDS Epidemic”. 1995. Kampala, Uganda. Invited Talk, Africa Regional AIDS Conference, Military AIDS Symposium. Sponsor: UNAIDS.
3. “HIV Prevention Policy in Military Organizations”. December 1996. Beijing, People’s Republic of China. Invited Talk, Thirty-First International Congress of Military Medicine, Beijing, China. Sponsor: Peoples Liberation Army, People’s Republic of China.
4. “Planning Effective HIV Prevention Interventions in the Military”. October 1998. St. Petersburg, Russian Federation. Invited Talk, Kirov Military Medical Academy. Sponsor: Russian Federation Ministry of Defense.
5. “Drug Interaction Research Issues in Heavily Treated HIV-infected Patients”. May 1999. Toronto, Canada. Invited Talk, International AIDS Society – Industrial Liaison Forum: The Challenge of Clinical Trial Design in Evaluating HIV Antiretroviral Use in Heavily-Pre-Treated Patients (Conference). Sponsor: International AIDS Society.
6. “Pharmacology of Antiretroviral Drugs in the Genital Tract”. August 1999. Atlanta, Georgia. Invited Talk, National HIV Prevention Conference. Sponsor: CDC.
7. “COX-2 Inhibitors: Evaluation of New NSAIDs”. September 1999. Towson, Maryland. Invited Talk, Arthritis Foundation of Maryland (Sponsor).
8. “Potential Drug Interactions in Antiviral Therapy”. May 2000. Madrid, Spain. Invited Talk, European Congress on Chemotherapy-3 (Sponsor).
9. “Clinical Pharmacology of Rectal Microbicides”. Atlanta, February 2001. Invited Talk, Centers for Disease Control (CDC) Conference on Rectal Microbicides, Sponsor: CDC.
10. “Preventing Fungal Infections”. May 2001. Baltimore. Medical Grand Rounds, Johns Hopkins University School of Medicine. Sponsor: Department of Medicine.
11. “Pharmacologic Studies in the Development of Rectal Microbicides”, June 2001. Baltimore. Invited Talk, Rectal Microbicide Workshop. Sponsor: NIH Office of AIDS Research.
12. “Development of Beta-Cyclodextrin as a Topical HIV Microbicide Candidate”, August 2001. Rockville. Invited Talk, NIH Division of Antiviral Drug Products. Sponsor: FDA.
13. “Drug Interactions in Combined Hepatitis C-HIV Chemotherapy”, April 2002. Aspen. Strategies for the Management of HIV/HCV Coinfection. Sponsor: Perspectives in Medicine.

**RECOGNITION****Invited Talks, Panels – continued**

14. “Quantitative Safety Assessment in Microbicide Development”, May 2002. Antwerp, Belgium. Invited Talk, Microbicides 2002. (Cancelled)
15. “Distribution of Candidate Microbicide Gel and Simulated Ejaculate in the Lower Gastrointestinal Tract”, June 2003. Los Angeles. Invited Talk, UCLA Center for HIV and Digestive Diseases (Sponsor).
16. “Clinical Development of a CXCR4 Chemokine Inhibitor”, June 2003. New York City. Invited Talk, Entry Inhibitor Special Issue Advisory Board. Sponsor: Glaxo-Smith-Kline.
17. "Rational Development of Rectal Microbicides: Pharmacology, Toxicity, and Acceptability", July 2003. Atlanta. Invited Talk, National HIV Prevention Conference. Sponsor: CDC.
18. “Development of a CXCR4 Chemokine Receptor Inhibitor for HIV Infection”, December 2003. Towson. Invited Talk, Towson University. Sponsor: Towson University.
19. “Distribution of Rectal Microbicide Vehicle and Simulated Ejaculate following Simulated Coital Activity” January 2004. New York City. Invited Talk, Columbia University. Sponsor: Columbia University, School of Medicine.
20. “Delivery of Microbicide to “At Risk” Intestinal Mucosa” March 2004. London. Invited Talk, Challenges to Rectal Microbicide Development (Satellite): Microbicides 2004.
21. “Critical Pharmacologic Issues in Vaginal and Rectal Microbicide Development” October 2004. Providence. Visiting Professor. Sponsor: Tufts University - Brown University Center for AIDS Research.
22. “Pharmacologic Issues in HIV Chemoprevention.” February 2005. Boston. Invited Talk, International AIDS Society - Industry Liaison Forum, 12<sup>th</sup> 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. 10<sup>th</sup> HIV Clinical Pharmacology Workshop.
62. “Quantitative Pharmacokinetics of the Male Genital Tract and Applications in Drug Development”. Invited Lecture. Atlanta March 2010. 111<sup>th</sup> 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. 19<sup>th</sup> 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, 54<sup>th</sup> Interscience Conference on Antibiotics and Antimicrobial Therapy. Washington, D.C. September 9, 2014.
99. “HIV Pre-exposure Prophylaxis (PrEP) Trials: Making the Complex Simpler through Clinical Pharmacology”. Invited Talk, Medical Grand Rounds, Western Ontario University, London, Ontario, September 17, 2014.
100. “Combining Pharmacology and Behavioral Science to Develop a Rectal Microbicide for HIV PrEP that People will Enjoy Using”. Invited talk, Columbia University. Sponsor: Columbia University, School of Medicine. December 18, 2014.

**RECOGNITION****Invited Talks, Panels – continued**

101. “HIV Pre-Exposure Prophylaxis: Clinical Pharmacology Enriching Drug Development”. Invited Talk, Dartmouth University, Division of Clinical Pharmacology. Lebanon, NH 23 June 2015.
102. “Pharmacokinetics in Microbicide Development”. Invited Talk. NIH/DAIDS MTN Conference, “The Use of Mucosal Assays in Microbicide Trials” Arlington, VA 25-26 August 2015.
103. “Real-Time” Pharmacologically-based Adherence Testing”. Invited Talk. NIH/DAIDS Conference “Optimizing Adherence Post-VOICE”, Rockville, MD 2-3 September 2015.
104. “HIV Pre-Exposure Prophylaxis (PrEP) & Development of Microbicides”. Invited Talk. American College of Clinical Pharmacology Annual Meeting, “An Update on HIV Treatment, Prevention and Drug Development Symposium”, San Francisco, CA 28 September 2015.
105. “HIV Pre-Exposure Prophylaxis (PrEP) & Development of Microbicides”. Invited Talk. University of California at San Diego Center for AIDS Research, San Diego, CA 23 October 2015.
106. “HIV Pre-Exposure Prophylaxis Drug Development”. Invited Talk. Medical Grand Rounds, General Hospital, Tijuana, Mexico, 26 October 2015.
107. “Pharmacologic Adherence Assessment & Application in PrEP”. Invited Talk. 2015 Center for AIDS Research (CFAR) Social and Behavioral Sciences Research Network Conference, Baltimore, MD 29 October 2015.
108. “Developing Behaviorally-Congruent Rectal Microbicides: A Clinical Pharmacology Approach”. US-Japan Conference USAID, Bethesda, MD. 12 January 2016.
109. “Lessons Learned from Antiretroviral Testing”. Invited Talk . UCLA CFAR-Sponsored Substance Use Meeting: Advancing the Field of Biobehavioral Substance Use Measurement for HIV Positive and At-risk Populations. Los Angeles, CA. 1 February 2016.
110. “Development of HIV Pre-exposure Prophylaxis: A Clinical Pharmacologist’s Inside View”. Invited Talk. University of North Texas Health Science Center. Fort Worth, TX. 8 April 2016
111. “Building on Oral PrEP Success: Rectal Microbicide Development”. Invited Talk. DC Center for AIDS Research, Howard University, Washington, DC. 4 May 2016.
112. “HIV Pre-Exposure Prophylaxis Development: A Clinical Pharmacologist’s Inside View”. Invited Talk. KU Leuven, Leuven, Belgium. 17 May 2016.

**RECOGNITION****Invited Talks, Panels – continued**

113. “PK-PD Data to Advance Topical PrEP Products to Phase III”. Invited Talk. Clinical Trial Evaluation Workshop for MPTs. Initiative for Multipurpose Prevention Technologies (IMPT). Washington, DC. 13 September 2016.
114. “Rectal vs. Vaginal Compartment Pharmacology.” Invited talk. Contribution of Sexual Behaviour in the Global Heterosexual HIV Epidemic Workshop. NIH/DAIDS. Bethesda, MD. 15 September 2016.
115. “Pharmacologic Considerations for HIV Prevention Strategies”. Invited talk. Western New York HIV Prevention Network Meeting. University of Buffalo, Buffalo, NY. 19 September 2016
116. “HIV Pre-exposure Prophylaxis Development: A Clinical Pharmacologist’s Inside View”. Invited talk. Combating HIV/AIDS: Tx, PGx and PrEP Workshop, ACCP Annual Meeting. HIV symposium. San Diego, CA. 24 September 2016.
117. “Quantitative Assessment of Adherence: Experiences in HIV Prevention”. Invited Talk. National Institute of Drug Abuse, Baltimore, MD 20 December 2016.
118. “Rectal Microbicide Development & DREAM Progress”. Invited talk. Tenofovir Development Meeting, MTN Annual Meeting. Bethesda, MD. 20 March 2017.
119. “Developing Alternatives to Oral HIV PrEP: Rectal Microbicides & Long-Acting Formulations”. Invited Talk. University of Texas Health Science Center, Galveston. April 2017.
120. “For Something Completely Different: Development of a Rectal Enema as Microbicide”. Invited Talk. Oak Crest Institute of Science, Monroeville, CA May 2017.
121. “Rectal Microbicide Development: How Did We Get Here? What Have we Learned?” Invited webinar talk. Sponsored by AIDS Vaccine Advocacy Coalition (AVAC) and International Rectal Microbicide Advocates (iRMA). August 2017.
122. “Rectal Microbicides: Where We’re Heading”. Invited webinar talk. Sponsored by AIDS Vaccine Advocacy Coalition (AVAC) and International Rectal Microbicide Advocates (iRMA). August 2017.
123. “Impact of adherence on the development of HIV Pre-exposure Prophylaxis” Invited Symposium Talk (delivered Mark Sales), American College of Clinical Pharmacology Annual Meeting. San Diego, CA. September 2017.

**RECOGNITION****Invited Talks, Panels – continued**

124. “Advances in Formulations in HIV PrEP: Topical Products - Rings, Gels, Implants, etc.”  
Invited Symposium talk (delivered Marc Baum), American College of Clinical Pharmacology Annual Meeting. San Diego, CA. September 2017.
125. “Review of the Current Rectal Microbicide Context”. Invited Talk. Reboot the Booty Think Tank. Sponsored by AIDS Vaccine Advocacy Coalition (AVAC) and International Rectal Microbicide Advocates (iRMA). New York, NY. September 2017.
126. “Lube Safety 101”. Symposium on Lubricant Safety, US Conference on AIDS. Washington, DC. September 2017.
127. “Next Generation PrEP? Injectable & Implantable ARVs”. Plenary Talk. Microbicide Trial Network Regional Meeting, Cape Town, RSA. September 2017.
128. “The Path Ahead for Rectal Microbicides”. Plenary Talk. Microbicide Trials Network Regional Meeting, Cape Town, RSA. September 2017.
129. “DREAM Program for Rectal Microbicide Prevention”. Invited talk. PREVENT Program Project Annual Meeting. Louisville, KY. October 2017.
130. “Promise & Progress of Rectal Microbicides for HIV Pre-Exposure Prophylaxis”. Invited Talk. Center for AIDS Research. University of Alabama, Birmingham, AL. November 2017.
131. “Microbicides: Where We’re Heading” Invited Talk. Second Annual Biomedical HIV Prevention Summit (NMAC). New Orleans, LA. December 2017
132. “Clinical Pharmacology of HIV Pre-Exposure Prophylaxis (PrEP) – Where are we now?”  
Visiting Professor. University of Liverpool. Liverpool, UK. February 2018.
133. “Beyond Oral PrEP: Promise and Challenges of Alternative Antiviral Dosing Methods for PrEP”. Invited Lecture. Office of AIDS Research Brown Bag Seminar. Brockville, MD. February 2018.
134. “Beyond Oral PrEP: Promise and Challenges of Alternative Antiviral Dosing Methods for PrEP” Invited Talk. 8th International Workshop on HIV & Women. Boston, MA. March 2018.
135. “Proof-of-Concept for On Demand, Behaviorally-Congruent Rectal Microbicide Douche”.  
Plenary Lecture. MTN Annual Meeting. Bethesda, MD March 2018.
136. “Success, Disappointment, & *Hope* in the Development of HIV Pre-Exposure Prophylaxis”.  
Invited Talk. Walter Reed Army Institute of Research, Silver Spring, MD. April 2018.



## **RECOGNITION**

### **Invited Talks, Panels – continued**

137. “Rectal Microbicide Product Development”. Invited talk. Oak Crest Institute of Science Program Project Annual Meeting. Monrovia, CA. May 2018.

138. “Pharmacology Lab Contributions to PrEP Product Development”. Invited Talk. HPTN Annual Meeting. Washington, DC. May 2018.

139. “Clinical Pharmacology of HIV Pre-Exposure Prophylaxis (PrEP) – Where are we now?” Invited Talk. International Workshop on Clinical Pharmacology of Antiviral Therapy. Baltimore, MD. May 2018.

140. “DREAM Program: On Demand, Behaviorally-Congruent Rectal Microbicide Douche”. Invited webinar talk. Sponsored by AIDS Vaccine Advocacy Coalition (AVAC) and International Rectal Microbicide Advocates (iRMA). June 2018.