No. 19-1410

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

RICHARD ROE, et al.,

Plaintiffs-Appellees,

v.

UNITED STATES DEPARTMENT OF DEFENSE, et al.,

Defendants-Appellants.

On Appeal from the United States District Court
for the Eastern District of Virginia

JOINT APPENDIX VOLUME 3 OF 5

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

RICHARD ROE et al.,

Plaintiffs,

v.

JAMES N. MATTIS et al.,

Defendants.

Civil Action No. 1:18-cv-01565 (LMB/IDD)

FILED UNDER SEAL

DECLARATION OF STAFF SERGEANT [redacted] IN SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

I, [redacted] declare as follows:

1. Attached as Exhibit A1 is a true and correct copy of the declaration I signed and submitted earlier this year in the case of *Harrison v. Mattis*, currently pending in this Court. All information stated in my original declaration remains accurate.

2. On November 9, 2018, I received a memorandum dated November 7, 2018 from John K. Vallario, Deputy Director of the Secretary of the Air Force Personnel Council, part of the Air Force Personnel Board ("AFPB"). The memorandum is attached to this declaration as Exhibit A5.

3. The memorandum denied my appeal and directed on behalf of the Secretary of the Air Force that I be discharged. The Secretary of the Air Force ("SAF") reached this decision even though, as noted in the memorandum, I have been "compliant with all treatment, [am] currently asymptomatic, and [have] an undetectable human immunodeficiency virus (HIV) viral load," and am "able to perform all in garrison duties, [have] passed [my] most recent fitness assessment without any component exemptions, and [my] commander strongly supports [my] retention." The basis of the decision, as noted in the memorandum, is that my condition

precludes me from being designated world-wide deployable without a waiver, and therefore renders me "unfit for continued military service." According to the memorandum, I am to be discharged with a disability rating of 10 percent.

4. Because of the SAF's decision, I must separate from the Air Force even though I want to continue to serve as I do now—in my regular capacity with no physical limitations. My doctors say that my medical condition does not restrict my ability to do my job. I understand that regulations classify me as non-deployable without a waiver, but I want to be worldwide deployable and I am willing to go anywhere in the world to fulfill my duties.

5. The SAF's decision in my case is different from other recent decisions involving people living with HIV. Exhibit A6 is another memorandum from the SAF involving an appeal by another Airman with HIV. This memorandum was signed by the Director of the SAF Personnel Council (mine was signed by the Deputy Director) and was issued in January 2018 (while mine was in November). Even though this Airman and I both have HIV, the SAF decision in that case resulted in a retention, while mine resulted in a separation. I received Exhibit A6 by email directly from a person who works as a nurse at the San Antonio Military Medical Center, where all Airmen with HIV receive their HIV-related medical care.

6. Before my HIV diagnosis, I intended to apply for retraining in conjunction with re-enlisting for another term of service in the Air Force so that I could continue my military career. The year-long evaluation that I describe above has prevented me from applying for retraining and re-enlisting, however. My term of service has already expired, and my date of separation ("DOS")—which included extensions and terminal leave—kept being extended while this medical evaluation was ongoing. My last extension, approved by AFPC prior to receiving the SAF decision moved my DOS to June 25, 2019.

7. Absent any changes or interventions, I expect to be separated from the Air Force earlier than that, in accordance with the Secretary's decision. On January 3, 2019, I received notice of my formal separation date from my base personnel office. My DOS is now March 28, 2019.

8. After being diagnosed with HIV in October 2017, I began treatment almost immediately and soon after my viral load was undetectable. My current treatment regimen involves taking one pill once a day. The pills are stored in ordinary pill bottles, do not require any special storage conditions, and are refilled every 90 days so that I have a three-month supply. Since being on the medication, my viral load has remained suppressed, and my doctors tell me that it will continue to be suppressed as long as I consistently take my medication as directed.

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

Executed on January 11, 2018.

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

RICHARD ROE et al.,

Plaintiffs,

v.

JAMES N. MATTIS et al.,

Defendants.

Civil Action No. 1:18-cv-01565 (LMB/IDD)

FILED UNDER SEAL

DECLARATION OF SENIOR AIRMAN [redacted] IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

I, [redacted] declare as follows:

1. After graduating from high school in [redacted] I found myself facing a difficult job market in my home state of [redacted] I had heard that the military offered young people like me the ability to further their education through both internal vocational training and financial assistance toward a college education afterward. I was also intrigued by a career in the military because it would afford me the chance to travel to and even live and work in different countries around the world.

2. I enlisted in the United States Air Force in the [redacted] at the age of [redacted] On [redacted] I began eight weeks of Basic Military Training ("BMT"). After completing BMT in [redacted] I reported to [redacted] in [redacted] where I studied to be [redacted] After receiving a broad education that covered [redacted] I left [redacted] in [redacted]

3. In early [redacted] I was stationed with the [redacted] in [redacted] I spent my year-long tour working in the base's [redacted]

4. In [redacted] I began my next tour of duty, this time in [redacted] where [redacted] I worked in the [redacted] where my role consisted mainly of [redacted] I spent nearly [redacted] at [redacted] concluding in [redacted]

5. While stationed at [redacted] I was deployed on two separate occasions to [redacted] The first deployment began in [redacted] and ended in [redacted] At [redacted] I performed largely the same [redacted] role as I had at [redacted]

6. Typically, members of the Air Force who have been deployed begin a period of "dwell time" upon their return, during which they may not be deployed from their home station again. Dwell time is intended to give returning service members the opportunity to rest, recharge, enjoy the comforts of home, and reconnect with family and friends. [redacted]

7. I returned to [redacted] for my second deployment. This time, I was assigned to a different job in the [redacted] There, my

duties consisted of [redacted] After about [redacted] I returned to [redacted] in late [redacted]. I left [redacted] on [redacted]

8. At the end of [redacted] I was assigned to [redacted] at [redacted] I was again placed in [redacted], but this time I worked on [redacted] I was later reassigned to [redacted] similar to the one I had held at [redacted]

9. In early [redacted], I was transferred to the [redacted] This role involves [redacted]

10. In [redacted] I began training to be [redacted] These duties concluded in [redacted] and I returned to [redacted], where I currently serve.

11. On March 1, 2017, I was diagnosed with HIV at [redacted] Within two weeks, I began Antiretroviral Therapy ("ART"). By August 2017, I had an undetectable viral load. It has remained undetectable ever since. My doctors have not recommended restricting my work in any way as a result of my diagnosis.

12. My treatment regimen requires me to take two pills, Tivicay and Descovy. I take them at the same time, once a day. The pills are stored in ordinary pill bottles and do not require any special storage conditions. I refill my prescription every 90 days, just as I would any other long-term medication.

13. In accordance with regulation, after my diagnosis I began a standard medical evaluation process, which was to determine whether I would be retained in or separated from the Air Force. My commanding officer supported my retention, and my doctors offered the opinion that my medical condition, including my HIV status, did not affect my ability to do my job.

14. As part of this process, after what I understand was some review of medical records and other information, in October 2017 I received notification of a recommendation from the Informal Physical Evaluation Board ("IPEB") that I should be separated based on my HIV status. A copy of the IPEB findings and recommendation is attached to this declaration as Exhibit B1.

15. Yet my condition has in fact been well under control since shortly after I was diagnosed and will remain so for as long as I am in treatment, which is required by the Air Force as a condition of my continued service. As I understand it, according to current medical science, the progression of my condition is easily predicted: with my once-daily medication, I understand that it will not progress.

16. I immediately appealed the IPEB's recommendation to the Formal PEB ("FPEB") of the Air Force at Randolph Air Force Base in San Antonio, Texas. My hearing was scheduled for [redacted] During the hearing, which lasted only 20 minutes, I got the impression that the Board was not receptive to my position. After just half an hour of post-hearing deliberation, the FPEB issued its recommendation that I be separated based on my HIV status. A copy of the FPEB's findings and recommendations is attached as Exhibit B2.

17. I appealed the FPEB's recommendation to the Secretary of the Air Force, submitting a memorandum and supporting documents on December 27, 2017. On November 15,

2018, I received a memorandum dated November 7, 2018 from John K. Vallario, Deputy Director of the Secretary of the Air Force Personnel Council.

18. The memorandum denied my appeal and directed on behalf of the Secretary of the Air Force that I be discharged. A copy is attached as Exhibit B3. The Secretary of the Air Force reached this decision even though, as noted in the memorandum, I have been "compliant with all treatment, [am] currently asymptomatic, and [have] an undetectable human immunodeficiency virus (HIV) viral load," and am "able to perform all in garrison duties, [have] passed [my] most recent fitness assessment without any component exemptions, and [my] commander strongly supports [my] retention." The basis of the decision, as noted in the memorandum, is that my condition precludes me from being designated world-wide deployable without a waiver, and therefore renders me "unfit for continued military service." According to the memorandum, I am to be discharged with a disability rating of 10 percent.

19. Consequently, I must separate from the Air Force even though I want to continue to serve as I do at present—in my regular capacity with no physical restrictions. Again, my doctors state that my medical condition does not restrict my ability to do my job. I understand that regulations classify me as non-deployable without a waiver, but I want to be worldwide deployable and I am willing to go anywhere in the world to fulfill my duties.

20. Before my HIV diagnosis, I intended to re-enlist for another term of service in the Air Force so that I could continue the military career that I know and love. But the year-long evaluation process that I describe above has prevented me from re-enlisting. My term of service has already expired, and my date of separation ("DOS")—which includes extensions and terminal leave—keeps being extended while this medical evaluation is ongoing. After three extensions, I would be able to remain in the Air Force until June 2019.

21. I will be separated sooner than that, though. On December 20, 2018, I received notice from the Air Force Personnel Center ("AFPC") of my formal separation date. The notice is attached as Exhibit B4. My DOS is set for February 25, 2019.

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

Executed on January 11, 2018

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

RICHARD ROE et al.,

Plaintiffs,

v.

PATRICK M. SHANAHAN et al.,

Defendants.

Civil Action No. 1:18-cv-01565 (LMB/IDD)

FILED UNDER SEAL

DECLARATION OF STAFF SERGEANT [redacted]
IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

I, [redacted] declare as follows:

1. I have read the government's Memorandum in Support of Defendants' Motion to Dismiss and Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction. I state the following facts in response.

2. The government has stated that I could be denied reenlistment on grounds unrelated to my HIV condition. But that problem does not apply to me. Though my original Date of Separation [redacted] passed when I was put into the DES process, my command supports my reenlistment. I have been informed by my command that I would have been recommended for and selected for reenlistment had I not been on a medical hold for over the past year. My First Sergeant, who would be recommending me for reenlistment, has told me that he does not understand why I was even sent through the DES process. My commander, who would be selecting me for reenlistment, submitted a letter of support for my retention.

3. The government has stated that I am being separated because I am subject to "significant deployment restrictions" in a career field with "high" likelihood of deployment. This is not true based on my own experience.

4. My Air Force Specialty Code (AFSC) is [redacted] which is [redacted] I have held the [redacted] But in the past [redacted] years, I have not been selected for deployment at all. Even with HIV, if I were classified with an Assignment Limitation Code C2, I would be able to PCS, TDY, or deploy to Germany or anywhere else outside the continental United States with a waiver. Air Force bases in Germany are capable of supporting Airmen with HIV, for example. In fact, I am aware that at least one Airman with HIV has been stationed at Ramstein Air Base in Germany for the past two years or more, since his diagnosis.

5. As I said in my first declaration, before my diagnosis, I intended to apply for retraining in conjunction with reenlisting for another term of service in the Air Force. I had hoped to retrain into the legal field, as a [redacted] I am informed that [redacted] deploy at a much lower rate than my current AFSC. In fact, according to the documents that the government submitted in opposition to our Motion for Preliminary Injunction, the [redacted] AFSC deployed at around half as much as my current career field. In addition, the [redacted] especially for people [redacted] is a position of need in the Air Force, according to the On-line Retraining Advisory the Air Force publishes.

6. But I was not allowed the opportunity to retrain into [redacted] AFSC or any other AFSC. The government stated in its brief that in determining whether I can reasonably perform my duties, DoDI 1332.18 directs the Air Force to consider whether reclassification is possible. The Air Force did not consider the feasibility of reclassifying me.

7. The government also implies that Airmen with HIV have rigorous medical monitoring obligations. For example, the government's brief suggests that Airmen with HIV have follow-up evaluations every three months. This is not true: According to regulation,

AFI 44-178 ¶ 1.6, I and other Airmen with HIV are medically monitored as follows: first, upon initial diagnosis for one week; then six months later for three days, then again annually during our birth month. I am sent to San Antonio Military Medical Center (SAMMC) for labs and counseling only once a year. There is no medical monitoring for Airmen with HIV that takes place on a three-month time frame.

8. The government seems to suggest in its brief that all Airmen are referred to a Medical Evaluation Board (MEB) after being diagnosed with HIV. I know of other Airmen with HIV who were not referred to an MEB; rather, they were returned to duty with an Initial Review in Lieu of MEB (IRILO) which, according to regulation (AFI 44-178 ¶ 8.3.2) is done by the HIV Medical Evaluation unit at SAMMC without Commander input due to privacy concerns. When I first went to SAMMC for my initial evaluation and counseling in [redacted] my doctor requested that I be IRILO'd and returned to duty in accordance with AFI 44-178 ¶ 8.3.2. But even though regulations permitted my doctor to make this determination, somebody intervened and overrode it and sent me to a full MEB.

9. In addition, I am aware that military regulation (CENTCOM MOD 13) requires Airmen who deploy to CENTCOM to have no less than a six-month supply of medication. This applies to all conditions, not just HIV. If I were deployed there, the risk of losing adherence to my HIV medication is therefore extremely low. Additionally, all Tricare eligible personnel will obtain any refill prescriptions from the Tricare Mail Order Pharmacy (TMOP), the Deployed Prescription Program (DPP), or Express Scripts; which is the system used by most members to receive their HIV medication currently.

I declare under penalty of perjury that the foregoing is true and correct. Executed on February 01, 2019.

[redacted]

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

RICHARD ROE et al.,

Plaintiffs,

v.

PATRICK M. SHANAHAN et al.,

Defendants.

Civil Action No. 1:18-cv-01565 (LMB/IDD)

FILED UNDER SEAL

DECLARATION OF SENIOR AIRMAN [redacted]
IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

I, [redacted] declare as follows:

1. I have read the government's Memorandum in Support of Defendants' Motion to Dismiss and Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction. I state the following facts in response.

2. The government has stated that I could be denied reenlistment on grounds unrelated to my HIV condition. But that problem does not apply to me. Though my original Date of Separation [redacted] passed when I was put into the DES process, my command supports my reenlistment. I have been informed by both my First Sergeant and my Commander that I would have been recommended and selected for reenlistment had I not been on a medical hold for over the past year. In addition, my Commander submitted a letter in support of my retention.

3. The government has stated that I am being separated because I am subject to "significant deployment restrictions" in a career field with "high" likelihood of deployment. This is not true based on my own experience. Although current regulations prevent me from deploying to CENTCOM or any other location outside the continental United States (OCONUS)

without a waiver, in my current shop—which I've been in since [redacted]—there has never been a shortage of volunteers for deployments, to the point where my shop turns away people in favor of providing deployment experience to younger, newer Airmen. My inability to deploy to CENTCOM (which is a limitation set by regulation, not any issues with my physical ability) has not had an effect on the Air Force.

4. Even with HIV, if I were classified Assignment Limitation Code C2, I would be able to deploy OCONUS with a waiver. Air Force bases in Germany, for example, are capable of supporting Airmen with HIV. In fact, I am aware that at least one Airman with HIV has been stationed at Ramstein Air Base in Germany for the past two years or more, since his diagnosis. [redacted]

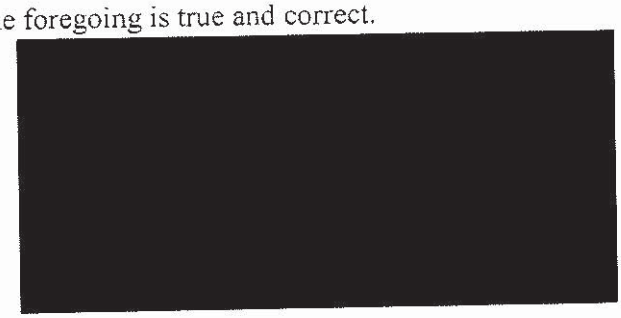
5. Before my diagnosis, I intended to apply for retraining in conjunction with reenlisting for another term of service in the Air Force. I had hoped to retrain into [redacted] I am informed tha[redacted] deploy at a much lower rate than my current AFSC. But I was not allowed the opportunity to retrain into [redacted] or any other AFSC. The government stated in its brief that in determining whether I can reasonably perform my duties, DoDI 1332.18 directs the Air Force to consider whether reclassification is possible. The Air Force did not consider the feasibility of reclassifying me.

6. The government also implies that Airmen with HIV have rigorous medical monitoring obligations. For example, the government's brief suggests that Airmen with HIV have follow-up evaluations every three months. This is not true. From my experience, and others with HIV that I've spoken to, Airmen with HIV are medically monitored as follows: first, upon

initial diagnosis at San Antonio Military Medical Center (SAMMC); then six months later at SAMMC, then again annually during the month of birth. Therefore, I am sent to SAMMC for labs and counseling only once a year. There is no medical monitoring for Airmen with HIV that takes place on a three-month time frame.

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

Executed on February 1, 2019.



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

NICHOLAS HARRISON and OUTSERVE-SLDN, INC. Plaintiffs, v. JAMES N. MATTIS, in his official capacity as Secretary of Defense; MARK ESPER, in his official capacity as the Secretary of the Army; and the UNITED STATES DEPARTMENT OF DEFENSE, Defendants.	Case No. 1:18-cv-00641 (LMB/IDD)

DECLARATION OF STAFF SERGEANT [redacted] IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

I, [redacted] declare as follows:

1. I am a Staff Sergeant in the U.S. Air Force, currently in my [redacted] year of active duty service. I specialize in [redacted] and I am attached to an [redacted] stationed at [redacted]
2. In [redacted] at the age of [redacted] I joined the Air Force out of a desire to serve in the military [redacted] From a young age, I knew I wanted to make the Air Force my lifelong career.
3. Originally, I intended to obtain an undergraduate degree prior to joining the military, so that I would enter as a commissioned officer. Though I was unable to do that, after [redacted] in the military, I continue to aspire to commission.

[redacted]

4. Throughout my career, I have strived to be the best Airman that I can be, and my superiors have recognized my efforts. Along with receiving numerous awards for my conduct, including [redacted] I have been entrusted with enhanced levels of responsibility. For example, while stationed at [redacted] I was placed in charge of a [redacted] Since being promoted to Staff Sergeant—[redacted]—I remained a supervisor of this program.

5. While in the military, I have sought out positions of leadership and responsibility beyond that which is required of me. While stationed at [redacted] I underwent approximately forty hours of training to become [redacted]

6. I truly enjoy the supervisory role in which I find myself as a Staff Sergeant. I am able to encourage my Airmen I supervise to be better airmen and better people, and in turn, my recommendations can help them advance their careers. This mentoring role has become one of the highlights of my military career.

7. Unfortunately, my career is now in jeopardy. In October of 2017, I was diagnosed with HIV while on active duty.

8. Even in the acute stage of infection, I was still healthy. In my initial test results, my T-cell (or "CD4") count was over 500. In keeping with Air Force regulations, I immediately started a course of antiretroviral treatment. The first time I was tested after beginning antiretroviral treatment, my viral load was undetectable. My doctors have

[redacted]

never recommended that my daily work be restricted in any way as a result of my diagnosis.

9. In keeping with Air Force regulations, I have been deemed "non-deployable" because of my HIV status.

10. Because of my diagnosis, my records were reviewed by the local Physical Evaluation Board ("PEB") to determine whether I should be retained for service.

11. On December 7, 2017, my commanding officer, [redacted] wrote an evaluation of my status in light of my condition and recommended that I be retained, because I was fit to serve and was "a valued team member." My primary care doctor, [redacted] also recommended that I be returned to duty.

12. In spite of the recommendations of both my doctor and my commanding officer, the Informal PEB decided on February 22, 2018, that I should nevertheless be discharged. In reaching this conclusion, the Informal PEB determined that my "condition is not compatible with the fundamental expectations of military service," because my condition is "subject to sudden and unpredictable progression and will result in deployment restrictions." See Exh. 1A.

13. This decision was made despite the fact my condition has been well under control since shortly after I was diagnosed and will remain so for as long as I am in treatment, which is required by the Air Force as a condition of my continued service. According to current medical science, the progression of my condition is easily predicted: with my once-daily medication, it will not progress.

14. Given this unsatisfactory result, I decided to appeal to the Formal PEB of the Air Force, which is located at Randolph Air Force Base in Texas. At the same time, I requested

[redacted]

representation from the Judge Advocate General's (JAG) Corps for my appeal to the Formal PEB. [redacted] was assigned as my JAG officer.

15. While waiting for my appeal, I gathered numerous letters of support from my commanding officers and colleagues, in which they all requested I be retained. Among these letters was one from Lt. Col. Jason Okulicz, the Director of the HIV Medical Evaluation Unit at San Antonio Military Medical Center ("SAMMC"), in which he stated that there was "[no] medical reason to explain why [redacted] would not be returned to duty." See Exh. 1B.

16. My hearing before the Formal PEB was scheduled for [redacted] I decided to attend the hearing in person to better answer any specific questions the Board raised about my condition or my record of service.

17. When I arrived for my hearing, however, it had a distinctly *pro forma* feel. The only question they asked was why there had been a delay in the receipt of a particular test result, which had resulted from a medical staffer's logistical error. After traveling from [redacted] to Texas specifically for the hearing, I was dismissed after only a few minutes.

18. Before attending the hearing, I was told that it would take weeks, if not months, for the Formal PEB to reach a decision. Instead, I received a determination approximately three hours after I left the hearing. The Board had determined, despite the recommendations of my doctors, that my condition "place[d an] increased burden on others within [my] career field." This increased burden, in their opinion, was due solely to the fact that I was no longer worldwide deployable. As a result, the Formal PEB upheld the decision of the Informal PEB and recommended that I be discharged. See Exh. 1C.

[redacted]

19. Frustrated with this result as well, I wrote a letter of appeal to the Secretary of the Air Force. I was informed that it would take the Secretary a minimum of six months to reach a decision, if not longer. Thus, I will have to wait until at least October to receive a decision.

20. In the meantime, I continue to serve in my regular capacity with no physical restrictions. In spite of the fact that the Formal PEB described me as a "burden," the Air Force has allowed me to continue my work supporting their overall mission while I await the Secretary's decision on my future.

21. I am not a burden in my role as an Airman. This fact has been recognized by my commanding officers and supervisors on multiple Air Force bases. My doctors do not foresee any daily restrictions on my work as a result of my condition. I am serving with pride at [redacted], and my non-deployable status will not keep me from supporting the Air Force's mission in my current capacity as [redacted]

22. Moreover, my non-deployable designation is not an accurate reflection of my fitness to serve overseas. My condition is well under control; I am virally suppressed; and I likely will remain so for as long as I am in treatment. The non-deployable designation was not a determination by my doctors, but rather a requirement of Air Force regulations.

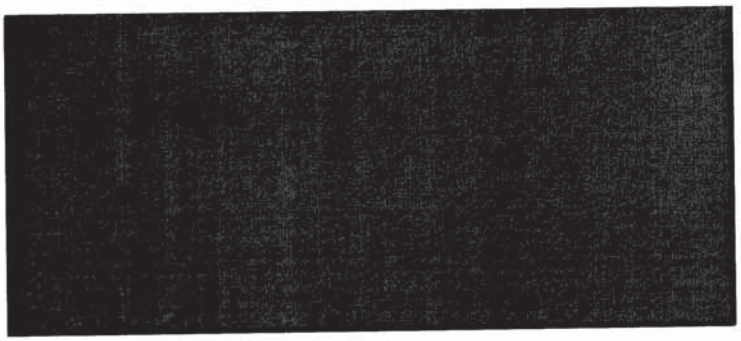
23. My HIV status has not prevented me from serving for approximately the past year. I will continue to serve as I await a final decision in my own case, and I will intently watch this court's adjudication of Sergeant Harrison's case. My career thus far in the Air Force has been a success, and I want to continue that career. The only obstacle in my way is a regulation restricting my deployability that does not accurately reflect my health status or

[redacted]

ability to serve and is preventing thousands of other current and future Air Force service members from serving their country to the full extent of their capabilities.

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

Executed on: July 18, 2018



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

NICHOLAS HARRISON and OUTSERVE-SLDN, INC.

Plaintiffs,

v.

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

Defendants.

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

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

I. INTRODUCTION

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

2. I am offering this declaration to provide my expert opinions regarding HIV—its etiology, the mechanism by which it operates to undermine a person's immune system, the routes and relative risks of transmission, the care and treatment of people living with HIV, the effect of treatment with antiretrovirals on the immunological and overall health of people living with HIV, and the effect of treatment on the risks of transmission.

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

4. I am knowledgeable about the matters set forth below based upon my own knowledge and experience, as well as my review of various materials cited herein.

II. PROFESSIONAL BACKGROUND & QUALIFICATIONS

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

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

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

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

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

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

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

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

III. BACKGROUND ON THE HUMAN IMMUNODEFICIENCY VIRUS

A. An Introduction to HIV

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

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

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

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

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

B. The Treatment of HIV

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

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

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

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

[2] At one time, the testing technologies were not sensitive enough to reliably detect the virus below approximately 50 copies per milliliter. Newer testing technologies are able to detect HIV

18. Every person living with HIV who adheres to their antiretroviral medications will eventually achieve and maintain an undetectable viral load. There is an effective treatment regimen for virtually every person living with HIV, and difficulties in reaching an undetectable viral load are related to a lack of consistent access to the health care and/or other social determinants of health, such as instable housing or food insecurity, that make medication adherence more difficult.

19. Development of resistance to a particular ART regimen does not occur unless the patient is not adherent to their prescribed medications. One of the important features of the ART regimens used today is that if the virus is suppressed the development of mutations that lead to resistance becomes impossible. With three or more medications combatting the virus in different ways at the same time, the virus is not able to mutate around any of those medications. For patients who develop resistance due to non-adherence, switching to a different regimen to which their virus has not developed resistance and to which they are subsequently adherent will return that patient to viral suppression.

20. As drugs have less and less side effected, adherence to ART has grown easier and easier over the past 20 years. Today, most people living with HIV are on a single tablet regimen ("STR")—in which all three or four medications are combined into one pill—that is taken once a day. STRs have no dietary restrictions, and side effects are minimal and generally very well tolerated.

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

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

C. The Transmission of HIV

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

23. Most commonly, HIV is transmitted by engaging in sexual activities or sharing needles or syringes. Outside of the contexts of sexual activity, sharing of injection drug equipment, blood transfusion, needle sticks, or perinatal exposure (including breastfeeding), transmission of HIV is rare. For all other activities—including biting, spitting, and throwing of body fluids—the CDC characterizes the risk as "negligible" and further states that "HIV transmission through these exposure routes is technically possible but unlikely and not well documented."[5]

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

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

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

24. Contrary to popular belief, HIV is not an easily transmitted virus. In the absence of treatment and condom use, the CDC estimates that the per-act risk of transmission for the riskiest sexual activity—receptive anal intercourse—is approximately 1.38% (138 out of 10,000 exposures).[6] The per-act risk of transmission for other sexual activities is between zero and .08%.

25. Furthermore, people living with HIV who are virally suppressed or have an undetectable viral load are incapable of transmitting HIV. Advances in understanding of the preventive effects of ART have led the CDC to declare that "…people who take ART daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to an HIV negative partner. *See* CDC, "Dear Colleague: Information from CDC's Division of HIV/AIDS Prevention," Sept. 27, 2017, *available at* https://www.cdc.gov/hiv/library/dcl/dcl/092717.html (last viewed June 26, 2018).[7]

26. As further stated in the CDC letter, "Across three different studies, including thousands of couples and many thousands of acts of sex without a condom or pre-exposure prophylaxis (PrEP), no HIV transmissions to an HIV-negative partner were observed when the HIV-positive person was virally suppressed"[8] (i.e., a viral load of less than 200 copies/ml).

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

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

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

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

IV. CONCLUSION

HIV is now a relatively easy to manage, chronic condition that, when properly treated, presents no cognizable risk to the health or safety of others through occupational exposures, including exposures that could potentially occur during military service.

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

Executed this 18 day of July, 2018

Carlos del Rio, M.D.

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

Attachment

EMORY UNIVERSITY
CURRICULUM VITAE

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Citizenship: United States of America and Mexico

Websites:
http://medicine.emory.edu/infectious-diseases/faculty-directory/del-rio-carlos.html &
https://sph.emory.edu/faculty/profile/#!cdelrio
ResearcherID:
http://www.researcherid.com/ProfileView.action?returnCode=ROUTER.Success&Init=Yes&SrcApp=CR&queryString=KG0UuZjN5WmP6yAsUHIlBIEGQkwtKoQLBlp0gCLTBbs%253D&SID=7Co6dCuimpqh4njckXt

Current Titles and Affiliations:

a. Academic appointments:

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

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

b. Clinical Appointments:

March 1997 – July 2011: Active Medical Staff, Grady Health System
Oct 1999 – present: Medical Staff member, The Emory Clinic
July 2011 – present: Active-Courtesy staff member, Grady Health System
June 2013 – present: Infectious Diseases Clinical Chief of Service at Emory University Hospital

c. Other administrative appointments:

Jan 16, 2017 – present: Interim Executive Associate Dean for Emory at Grady
Oct 1, 2005 – present: Co-Director, Emory Center for AIDS Research.
Jan. 1, 2007 – present: Clinical Research Site (CRS) Leader at the Ponce de Leon Center for the Emory AIDS Clinical Trials Group (ACTG).

Previous Academic and Professional Appointments:

1990 – 1996: Associate Professor of Medicine, Universidad La Salle, Mexico City, Mexico.
1989 – 1996: Chief of Infectious Diseases and Chairman of the Infection Control Committee, Hospital Angeles del Pedregal, Mexico City, Mexico.

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

Previous Administrative Appointments:

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

Licensures/Boards:

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

Specialty Boards:

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

Education:

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

Postgraduate Training:

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

Executive Training:

Jan 2007: Program for Chiefs of Clinical Services. Department of Health Policy and Management, Harvard School of Public Health.

Jan 2008: Woodruff Health Sciences Center Quality Academy.

Committee Memberships:

a. National and International:

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

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

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

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

b. Regional and State:

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

c. Institutional

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

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

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

Consultantships:

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

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

Editorship and Editorial Boards:

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

Manuscript reviewer

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

Honors and Awards:

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

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

Society Memberships:

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

Organization of National or International Conferences:

a. Administrative positions:

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

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

Grant Support:

a. Active support:

- NIH (2P30 AI 50409). Emory CFAR. (PI: C. del Rio) 08/01/17 – 7/31/22.
- NIH/NIAID (AI069418). Emory-Duke-Orlando-CDC Clinical Trials Unit. (co-PIs: J. Lennox; C. del Rio & M. Mulligan) 12/10/13 – 11/30/20
- NIH/NIDA (1RO1DA037768). Improving Physician Opioid Prescribing for Chronic Pain in HIV-infected Persons (co-PIs: J. Samet & C. del Rio), 09/15/2014 – 08/31/2018.
- NIH/NIDA (1RO1DA032098-03). Project Retain: Providing Integrated Care for HIV-infected crack cocaine users (co-PIs: L. Metsch & C. del Rio), 07/15/2011 – 04/30/2017 (no cost extension).
- CDC (1H25-PS004311). The Emory Atlanta Gonococcal Isolate Surveillance Project - GISP (PI: C. del Rio), 01/01/14 - 12/31/18.
- NIH/NIDA (5U10DA013720). Florida Node of the Drug Abuse Clinical Trials Network (PI: J. Szapocznik & L. Metsch; Emory site PI: C del Rio) 00/30/2000 – 08/31/2020
- CDC (5T01GH001185). Emory Center for Public Health Training in Complex Humanitarian Emergencies (PI: C. del Rio) 9/1/2015 – 08/31/2018
- NIH (D43 TW007124). Emory-Georgia Tuberculosis Research Training Program (PI: H. Blumberg; Co-PI: C. del Rio), 09/30/04 - 06/30/19.
- NIH (D43 TW009127) Emory-Ethiopia Tuberculosis Research Training Program (PI: H. Blumberg; Co-PI: C. del Rio), 07/1/13 - 01/31/18.

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

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

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

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

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

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

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

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

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

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

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

Bibliography:

a. Published and accepted research articles in refereed journals:

1. Gallo S, Marin E, Ramírez A, **del Río C**, Elizondo J, Ramírez J. Colocación Endoscópica de Sondas para Alimentación Enteral. Rev. Gastroenterol Mex. 1984; 49(4): 247-50 [PMID 6442452].
2. Guarner J, **del Río C**, Slade BA. Tuberculosis as a Manifestation of the Acquired Immunodeficiency Syndrome. JAMA 1986; 256(22):3092. [PMID 3783842]
3. **del Río C**, McGowan J. Severe diarrhea in pneumococcal bacteremia: croupous colitis. JAMA 1987; 257(2): 189 [PMID 3795402].
4. Levy D, **del Río C**, Stephens DS. Meningococcemia in identical twins: changes in serum susceptibility after rifampin chemoprophylaxis. J Infect Dis 1988; 157:1064-8 [PMID 3129520].
5. **del Río C**, Guarner J, Honig EG, Slade BA. Sputum examination in the diagnosis of *Pneumocystis carinii* pneumonia in the acquired immune deficiency syndrome. Arch Pathol Lab Med 1988; 112:1229-1232 [PMID 3142440].
6. Mirra SS, **del Río C**. The fine structure of AIDS encephalopathy. Arch Pathol Lab Med 1989; 113:858-65. [PMID 2757485]
7. **del Río C**, Stephens DS, Knapp JS, Rice RJ, Schalla WO. Comparison of isolates of *Neisseria gonorrhoeae* causing meningitis and report of gonococcal meningitis in a patient with C8 deficiency. J Clin Microbiol 1989; 27(5): 1045-49 [PMID 2473091/PMC 267480].
8. Guarner J, **del Río C**, Williams P, McGowan JE. Fungal peritonitis caused by *Curvularia lunata* in a patient undergoing peritoneal dialysis. Am J Med Sci 1989; 298 (5): 320-23 [PMID 26837770].
9. **del Río C**, Soffer O, Widell JL, Judd RL, Slade BA. Acute Human Immunodeficiency virus infection temporally associated with rhabdomyolisis, acute renal failure and nephrosis. Rev. Infect Dis 1990; 12(2): 282-85 [PMID 2330481].
10. Guarner J, **del Río C**, Hendrix L, Unger ER. Composite Hodgkin's and non-Hodgkin's lymphoma in a patient with AIDS. In situ demonstration of Epstein-Barr Virus. Cancer 1990; 66(4): 796-800 [PMID 2167145].
11. Beciewicz PA, **del Río C,** Goncalves MA, Lattouf OM, et al. Catastrophic thrombosis of porcine aortic bioprosthesis. Ann Thorac Surg 1990; 50: 817-9 [PMID 2241350].
12. Guarner J, **del Río C**, Carr D, Hendrix LE, Eley JW, Unger ER. Non-Hodgkin's lymphomas in patients with HIV infection: Presence of Epstein - Barr virus by "in-situ" hybridization. Clinical Presentation and Follow-up. Cancer 1991; 68: 2460-65 [PMID 1657357].
13. Majluf-Cruz AS, Hurtado R, Mijangos C, Souto C, **del Río C**, Simón J. Síndrome Hemofagocítico en Asociación a Histoplasmosis en el Síndrome de Inmunodeficiencia Adquirida: descripción de tres casos y revisión de la literatura. (Haemophagocytic syndrome associated to histoplasmosis in AIDS: report of three cases). Sangre 1993; 38(1): 51-55 [PMID 8470036].
14. **del Río C**, Téllez I. Ganancia de peso con el uso del acetato de megestrol (Megace^{R}) en pacientes con SIDA y pérdida de peso en México. (Weight gain with the use of Megace^{R} in Mexican patients with AIDS). Enf Infecc y Microbiol 1993; 13(5): 249-52.
15. Guarner J, Izazola J, **del Río C**. Los problemas de conteo células T CD4+. (Problems in CD4+ T-cell count). Rev Invest Clin 1994; 46:163-4 [PMID 7914377].

16. Souto-Meriño CA, Simón-Domínguez J, Pulido-Priego MA, Hernández-Pérez A, García-Hernández IC, **del Río C.** Prevalencia de Marcadores para Hepatitis A, B y C en un Hospital de México. (The Prevalence of markers for hepatitis A, B and C in a hospital in Mexico). Salud Públ Mex 1994; 36:257-262 [PMID 7940005].
17. Izazola JA, Valdez M, Sánchez HJ, **del Río C**. Mortalidad por el Síndrome de Inmunodeficiencia Adquirida (SIDA) en México de 1983 a 1992. Tendencias y años perdidos de vida potencial. (AIDS mortality in Mexico, 1983 to 1992. Trends and years of potential life lost). Salud Públ Méx 1995; 37:140-148 [PMID 7618114].
18. **del Rio C**, Muñiz M, Mellado E, et al. Premarital HIV testing: the Case of Mexico. AIDS & Public Policy Journal 1995; 10(2): 104-106.
19. **del Río C**, Guarner J, Izazola JA. The use of oral fluid to determine HIV-1 prevalence rates among men in Mexico City. AIDS 1996; 10(2): 233-235 [PMID 8838717]**.**
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b. Manuscripts published in peer-reviewed journals and acknowledged as a contributor or collaborator

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2. **del Río C** y Uribe P (editores): *Guía para la Atención Psicológica de personas que viven con VIH/SIDA*. CONASIDA 1994. (ISBN 968-811-246-1).
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g. Book reviews:

- Guarner J & **del Río C**. Book review, AIDS Pathology. JAMA 1990; 264:1476.
- **del Río C.** Book Review: Fatal Extraction. Am J Med Sci 1998; 315(5):343-44.

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- **del Rio C** & Lennox J. HIV/AIDS Guideline. In: EBM Solutions (http://www.ebmsolutions.com/)
- **del Rio C.** Human Immunodeficiency Virus. In: Clinical Decision Support: Hospital Infection Control, edited by Wenzel, RW and Bearman, G. 2014. Decision Support in Medicine, LLC. Wilmington, DE

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

NICHOLAS HARRISON and OUTSERVE-SLDN, INC. Plaintiffs, v. JAMES N. MATTIS, in his official capacity as Secretary of Defense; MARK ESPER, in his official capacity as the Secretary of the Army; and the UNITED STATES DEPARTMENT OF DEFENSE, Defendants.	Case No. 1:18-cv-00641 (LMB/IDD)

DECLARATION OF TREVOR HOPPE, MPH, PhD

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

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

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

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

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

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

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

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

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

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

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

[1] "HIV Risk Behaviors," Centers for Disease and Prevention, accessed July 18, 2018. https://www.cdc.gov/hiv/risk/estimates/riskbehaviors.html
[2] Timothy C. Correll, "'You Know about Needle Boy, Right?': Variation in Rumors and Legends about Attacks with HIV-Infected Needles," *Western Folklore* 67 (2008):59-100.

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

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

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

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

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[3] Gregory H. Herek, John P. Capitanio, and Keith F. Widaman, "HIV-Related Stigma and Knowledge in the United States: Prevalence and Trends, 1991–1999," American Journal of Public Health, 92 (2002):371-377.
[4] Gregory H. Herek and Eric K. Glunt, "An Epidemic of Stigma: Public Reactions to AIDS," *American Psychologist* 43 (1988):886-891.

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

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

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

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

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

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

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

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

[8] MCL Annotated § 333.5131.
[9] See pp. 150-151 in Trevor Hoppe. *Punishing Disease: HIV and the Criminalization of Sickness* (Oakland: University of California Press, 2018).
[10] See Chapter 6, "Victim Impact," in Ibid.

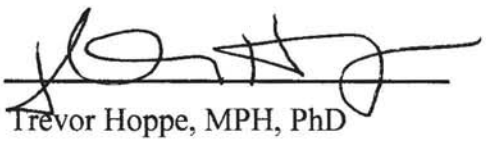
reduces the risk of transmission effectively to zero; there was (of course) no transmission; after pleading guilty, Mr. Rhoades was sentenced to 25 years in prison.[11]

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

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

Executed on: 7/18/2018

Respectfully,



Trevor Hoppe, MPH, PhD

[11] Brian Cox, "Turning the Tide: The Future of HIV Criminalization after *Rhoades v. State* and Legislative Reform in Iowa," *Northwestern Journal of Law and Social Policy* 11 (2016):28-53.
[12] Hasina Samji, et al. "Closing the Gap: Increases in Life Expectancy among Treated HIV-Positive Individuals in the United States and Canada," *PLoS ONE* 8 (2013): e81355.

Exhibit A

Trevor Alexander Hoppe

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EMPLOYMENT

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

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

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

EDUCATION

Ph.D. University of Michigan (2014) — Ann Arbor, MI
Sociology and Women's Studies
Dissertation: *From Sickness to Badness: Michigan HIV Law as a Site of Social Control*
Committee: Renee Anspach & David Halperin (Co-Chairs), Sarah Burgard, Sandra Levitsky
- WINNER: American Sociological Association (ASA), Martin P. Levine Dissertation Fellowship
- WINNER: ASA, Medical Sociology Section, Roberta G. Simmons Outstanding Dissertation Award

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

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

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

PUBLICATIONS

Books:

2018. *Punishing disease: HIV and the criminalization of sickness.* University of California Press.
- WINNER: 2018 Lambda Literary Award for LGBTQ Studies

2017. Hoppe, Trevor and David Halperin (Eds.). *The war on sex*. Duke University Press
- FINALIST: 2018 Lambda Literary Award for LGBTQ Studies

Journal articles:

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

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

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

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

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

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

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

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

- Sociologist AIDS Network Martin Levine Student Essay Award, 2009

Book chapters:

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

Manuscripts in progress or under review:

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

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

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

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

*Authors denoted with an asterisk * are graduate students*

Reviews:

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

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

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

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

Other publications and media appearances:

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

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

Interview. 2018, February 6. "Hepatitis C exposure is a crime in some states; is this the new HIV criminalization?" *The Body*. http://www.thebody.com/content/80840/hepatitis-c-exposure-is-a-crime-in-some-states-is-.html

Interview. 2017, December 12. "What's the future of HIV criminalization activism? An interview with Trevor Hoppe." *The Body*. http://www.thebody.com/content/80680/whats-the-future-of-hiv-criminalization-activism-a.html

Interview. 2017, December 8. "Are we punishing diseases or punishing people? An interview with Trevor Hoppe." *The Body*. http://www.thebody.com/content/80668/are-we-punishing-diseases-or-punishing-people-an-i.html

Hoppe, Trevor. 2017, November 20. "Should we punish the sick?" *Washington Blade*. http://www.washingtonblade.com/2017/11/20/should-we-punish-the-sick/

Interview. 2017, August 14. "Fear and ignorance criminalized HIV. Can science and wisdom undo that?" *Undark*. https://undark.org/article/hiv-criminalization-laws-aids/

Hoppe, Trevor. "Are sex offender registries reinforcing inequality?" *The Conversation*. 2017, August 8. https://theconversation.com/are-sex-offender-registries-reinforcing-inequality-79818

- Reposted in *Newsweek, San Francisco Chronicle*

Hoppe, Trevor, and David Halperin. 2017, June 26. "Two years after SCOTUS gay marriage ruling, the road to sexual freedom remains long." *The Hill*. http://thehill.com/blogs/pundits-blog/civil-rights/337079-two-years-after-scotus-gay-marriage-ruling-long-road-to

Hoppe, Trevor. 2017, May 19. "Lawmakers: Don't give in to the 'stealthing' moral panic." *Advocate*. https://www.advocate.com/commentary/2017/5/19/lawmakers-dont-give-stealthing-moral-panic

Interview. 2016, May 25. "The war on sex offenders is the new war on drugs, which means its about race." *Inverse*. https://www.inverse.com/article/16109-the-war-on-sex-offenders-is-the-new-war-on-drugs-which-means-it-s-about-race

Interview. 2016, April 5. *Stateside*. National Public Radio. http://michiganradio.org/post/stateside-tuesday-april-5-2016

Hoppe, Trevor. 2016, April 3. "The County in Michigan Where HIV is a Crime." *Huffington Post*. http://www.huffingtonpost.com/trevor-hoppe/the-county-in-michigan-wh_b_9602758.html

Hoppe, Trevor. 2015, November 17. "Let's Not Treat Charlie Sheen Like a Criminal." *Huffington Post.* http://www.huffingtonpost.com/trevor-hoppe/lets-not-treat-charlie-sh_b_8583710.html

Interview. 2015, May 29. "The reckless prosecution of 'Tiger Mandingo.' *The Nation*. https://www.thenation.com/article/reckless-prosecution-tiger-mandingo/

Interview. 2013. *More Harm than Good: How Overly Broad HIV Criminalisation is Hurting Public Health*. Documentary Film. Directed by Edwin Bernard, HIV Justice Network. http://www.hivjustice.net/moreharm/

Interview. 2013, March 23. *Strange Fruit*. *89.3 WFPL*. http://wfpl.org/strange-fruit-rob-portman-marriage-equality-trevor-hoppe-criminalization-hiv-0/

AWARDS, GRANTS, SCHOLARSHIPS, AND FELLOWSHIPS

2018 Lambda Literary Award for LGBTQ Studies, Lambda Literary Foundation

2018 Lavender Award for Excellence in LGBTQ+ Scholarship, University at Albany, SUNY

2018 Faculty Research Award Program (FRAP), University at Albany, SUNY ($9850)

2016 Individual Development Award, Campus Professional Development Committee, SUNY-Albany

2015 College of Arts and Sciences Conference Travel Fund Program, SUNY-Albany

2014 American Sociological Association, Sexualities Section, Best Graduate Student Paper

2014 American Sociological Association, Medical Sociology Section, Roberta G. Simmons Outstanding Dissertation Award

2013 American Sociological Association, Sociology of Law Section, Best Graduate Student Paper

2013 University of Michigan Department of Sociology, Mark Chesler Paper Award

2013 Seed Grant, Center for Public Policy in Diverse Societies, Gerald R. Ford School of Public Policy, University of Michigan

2013 American Sociological Association Student Forum, Travel Grant

2013 Lee Student Support Fund Travel Award, Society for the Study of Social Problems

2013 Scholarship, 2nd International Conference for the Social Sciences and Humanities in HIV, Paris, France.

2012 ASA, Martin P. Levine Memorial Dissertation Fellowship

2012 University of Michigan Rackham Predoctoral Fellowship

2012 Scholarship, American Sociological Association Section on Sexualities Mini-Conference

2012 Scholarship, International AIDS Conference, Washington, DC.

2011 Centers for Disease Control and Prevention, Young Innovator Award

2011 Sociologist AIDS Network, Scholarly Activity Award

2011 Community of Scholars Fellowship, Institute for Research on Women and Gender, University of Michigan

2011 Rackham Graduate Student Candidacy Research Grant, University of Michigan

2011 Dissertation Research Grant, Department of Sociology, University of Michigan

2011 Student Research Grant, Center for Education of Women, University of Michigan

2010 Social Science Research Council, Dissertation Proposal Development Fellowship

2009 Sociologist AIDS Network Martin Levine Student Essay Award

2009 Dean's Scholarship, School of Public Health, University of Michigan (Declined)

2008 Rackham Graduate Student Pre-Candidacy Research Grant, University of Michigan

2007 Herbert E. Boynton Scholarship, University of Michigan

2006 SFSU University Scholarship, San Francisco State University

2006 Jim Brogan Teaching Scholarship, San Francisco State University

INVITED LECTURES AND PRESENTATIONS

"Punishing disease: HIV and the criminalization of sickness"

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

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

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

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

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

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

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

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

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

"'Equal time': Gays, media, and the myth of equality." Invited panelist, Indiana University, April 2012, Bloomington, IN

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

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

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

"Historical mobilizations of 'public health' against public sex venues." Summer Institute on Sexuality, San Francisco State University, June 2010, San Francisco, CA.

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

CONFERENCE PRESENTATIONS

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

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

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

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

"Punishing disease: HIV and the criminalization of sickness"

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

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

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

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

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

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

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

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

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

"Controlling sex in the name of 'public health': Social control and Michigan's HIV disclosure law."

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

"Circuits of Power, Circuits of Pleasure: Sexual Scripting in Gay Men's Bottom Narratives"

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

"Resisting Public Health: Working within the Gay Men's Health Movement to Produce Change." LumpenCity: Marginalizing Discourses | Discourses of Marginalization, Toronto, ON, Canada, March 2009.

"Being Gay Post-HAART: Young Gay Men Negotiating Desire, Risk, and Heternormativity."

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

PUBLIC LECTURES AND READINGS

"Punishing disease: HIV and the criminalization of sickness"

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

"Reframing HIV: From 'prevention' to 'management.'" National Gay Men's Health Summit, August 2010, Fort Lauderdale, FL.

"Power and rethinking risk." Gay Men's Health Summit, October 2009, Seattle, WA

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

TEACHING EXPERIENCE

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

- "Global Deviance," Fall 2018
- "Law and Society," Fall 2018

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

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

Primary Instructor, University of Michigan 2009, 2014

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

Graduate Student Instructor, University of Michigan 2008 – 2014

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

Teaching Assistant, San Francisco State University 2006 – 2007

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

REVIEWER FOR THE FOLLOWING PUBLICATIONS

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

PROFESSIONAL SERVICE

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

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

PROFESSIONAL AFFILIATIONS

Member, American Sociological Association (ASA)
- Sections: Medical Sociology; Crime, Law and Deviance; Sex and Gender; Sexualities; Sociology of Law

Member, American Sociology of Criminology (ASC)

Member, Law and Society Association (LSA)

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

Member, International AIDS Society (IAS)

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

NICHOLAS HARRISON and OUTSERVE-SLDN, INC. Plaintiffs, v. JAMES N. MATTIS, in his official capacity as Secretary of Defense; MARK ESPER, in his official capacity as the Secretary of the Army; and the UNITED STATES DEPARTMENT OF DEFENSE, Defendants.	Case No. 1:18-cv-641 (LMB/IDD)

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

I. INTRODUCTION

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

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

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

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

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

II. PROFESSIONAL BACKGROUND & QUALIFICATIONS

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

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

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

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

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

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

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

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

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

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

A. Military Policies Regarding People Living with HIV

1. Accession Ban

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

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

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

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

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[2] U.S. Department of Defense Instruction 6485.01, at ¶3.a. (June 7, 2013), available at http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/648501p.pdf.
[3] *Id.* at Enclosure 3: Procedures, ¶3.c.
[4] *Id.* at Enclosure 3: Procedures, ¶3.e.
[5] U.S. Department of Defense Instruction 6130.03 (May 6, 2018), available at http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/613003p.pdf.

> (2) Free of medical conditions or physical defects that may reasonably be expected to require excessive time lost from duty for necessary treatment or hospitalization, or may result in separation from the Military Service for medical unfitness.
>
> (3) Medically capable of satisfactorily completing required training and initial period of contracted service.
>
> (4) Medically adaptable to the military environment without geographical area limitations.
>
> (5) Medically capable of performing duties without aggravating existing physical defects or medical conditions.[6]

15. HIV is among the specified "disqualifying conditions" under DoDI 6130.03.[7]

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

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[6] *Id.* at ¶1.2.c.
[7] *Id.* at 5.23.b. ("Presence of human immunodeficiency virus or laboratory evidence of infection or false-positive screening test(s) with ambiguous results by supplemental confirmation test(s).").
[8] U.S. Army Regulation 600-110 (Apr. 22, 2014), available at https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r600_110.pdf.
[9] *Id.* at Section III, ¶1-15.
[10] *Id.* at Section III, ¶1-16.a.

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

2. Conditions for Deployment and Deployment Restrictions

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

> (1) The condition is not of such a nature or duration that an unexpected worsening or physical trauma is likely to have a grave medical outcome or negative impact on mission execution.
>
> (2) The condition is stable and reasonably anticipated by the pre-deployment medical evaluator not to worsen during the deployment in light of physical, physiological, psychological, and nutritional effects of the duties and location.
>
> (3) Any required, ongoing health care or medications anticipated to be needed for the duration of the deployment are available in theater within the Military Health System. Medication must have no special handling, storage, or other requirements (e.g., refrigeration, cold chain, or electrical power requirements). Medication must be well tolerated within hard environmental conditions (e.g. heat or cold stress, sunlight) and should not cause significant side effects in the setting of moderate dehydration.
>
> (4) There is no need for routine evacuation out of theater for continuing diagnostics or other evaluations. (All such evaluations should be accomplished before deployment.)[12]

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

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[11] *Id.* at Section III, ¶1-16.e.
[12] *Id.* at ¶4.b.
[13] Department of Defense Instruction 6490.07, Encl. 3 (Medical Conditions Usually Precluding Contingency Deployment) at ¶e(2) (Feb. 5, 2010), available at http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/649007p.pdf.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

back as 2004, when DoD mandated universal two-year interval HIV testing, the DoD's Armed Forces Epidemiology Board explained that "There is no evidence that HIV infection, per se, affects physical fitness."[20] The same remains true today. As explained in a 2015 article in the *Medical Surveillance Monthly Report*: "In the past 30 years, HIV-1 infection has gone from an untreatable disease marked by inexorable clinical progression through extreme debility to death to a treatable disease that is compatible with active service throughout a full career in the U.S. military."[21] As an example, I understand that Mr. Harrison, who was diagnosed with HIV in 2012, received a PULHES[22] score in 2014 of 1 for each of the six factors that are considered, reflecting a "high level of medical fitness" under Army Regulation 40-501 (Standards of Medical Fitness).[23] There should be no effect on the physical fitness and capabilities of any person with HIV who is adhering to their prescribed ART regimen

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

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

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

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

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

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

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

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

5. There is No Impact on Medical Readiness

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

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

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

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

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

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

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

[26] U.S. Department of Defense Instruction 6025.19 (Individual Medical Readiness), Encl. 3 (June 9, 2014), available at http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/602519p.pdf.

[27] Armed Services Blood Program, About Us, available at http://www.militaryblood.dod.mil/About/default.aspx

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

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

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

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

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

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

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

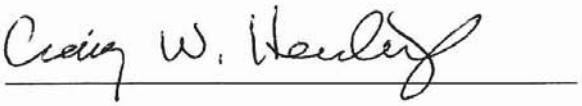
approximately one-third of one percent of the population of the United States, and just .027% of active duty service members).[32] Furthermore, there are various other factors that often disqualify individuals as emergency blood donors, such as blood type[33]—making people living with HIV no different 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.

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[32] United States Census Bureau. *American Factfinder: Monthly Population Estimates for the United States: April 1, 2010 to December 1, 2016*, https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=PEP_2017_PEPMONTHN&prodType=table (last visited July 18, 2018); Armed Forces Health Surveillance Center (AFHSC), *Update: Routine Screening for Antibodies to Human Immunodeficiency Virus, Civilian Applicants for U.S. Military Service and U.S. Armed Forces, Active and Reserve Components, January 2010–June 2015*, Medical Surveillance Monthly Report, Aug. 2015, 2-8.

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

Attachment

CURRICULUM VITAE

The Johns Hopkins University School of Medicine

10 JUL 18

Craig W. Hendrix (Date of this version)

DEMOGRAPHIC AND PERSONAL INFORMATION

Current Appointments

University

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

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

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

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

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

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

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

Hospital

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

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EDUCATION AND TRAINING

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

PROFESSIONAL EXPERIENCE

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

PROFESSIONAL EXPERIENCE

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

PROFESSIONAL EXPERIENCE

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

PROFESSIONAL EXPERIENCE

Dates	*Position*	*Institutions*
2009-present	Professor	Department of Epidemiology Johns Hopkins University Bloomberg School of Public Health Baltimore, MD
2012-2014	Co-Director	Behavioral Science Core 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

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Original Research

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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.

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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

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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

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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

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Original Research – continued

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204. Abaasa A, **Hendrix CW**, Gandhi M, Anderson P, Kamali A, Kibengo F, Sanders E, Mutua G, Priddy F, Haberer JE. Utility of Different Adherence Measures for Prep: Patterns and Incremental Value. AIDS Behav 2018 Apr;22(4):1165-1173. PMC5878836

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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

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210. Justman JE, Nair G, **Hendrix CW**, Piper JM, Marzinke MA, Dai JY, Pan Z, Galaska B, Levy L, Schwartz JL, Balar B, Kunjara Na Ayudhya RP, Mushamiri I, McGowan I, Dezzutti CS, MTN-014 Study Team. Pharmacokinetics and Pharmacodynamics of Tenofovir Reduced-Glycerin 1% Gel in the Rectal and Vaginal Compartments in Women: A Cross-Compartmental Study with Directly Observed Dosing. J Acquir Immune Defic Syndr. 2018 Jun 1;78(2):175-182. PMC5963717

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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] PMCID 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] PMCID pending

Review Articles

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2. **Hendrix CW**, Cao YJ, Fuchs EJ. Topical Microbicides to Prevent HIV: Clinical Drug Development Challenges. Ann Rev Pharmacol Toxicol 2009; 49:349–75.

3. Morrow KM, **Hendrix CW**. Clinical evaluation of microbicide formulations. J Antiviral Res 2010;88S:S40-S46. PMCID: PMC3053029

4. **Hendrix CW**. The Clinical Pharmacology of Antiretrovirals for HIV Prevention. Curr Opin HIV AIDS 2012 Nov;7(6):498-504.

5. **Hendrix CW**. Exploring concentration-response in HIV Pre-Exposure Prophylaxis to optimize clinical care and trial design. Cell 2013 Oct 24;155(3):515-8.

6. Carballo-Diéguez A, Lentz C, Giguere R, Fuchs EJ, **Hendrix CW**. Rectal Douching Associated with Receptive Anal Intercourse: A Literature Review. AIDS Behav. 2017 Nov 2. doi: 10.1007/s10461-017-1959-3. PMC5878987

Case Reports

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

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Book Chapters, Monographs

1. Flexner CF and **Hendrix CW**. Pharmacology of Antiretroviral Agents. In: DeVita VT, Hellman S, Rosenberg SA, AIDS: biology, diagnosis, treatment and prevention. 4th ed. Philadelphia: Lippincott-Raven, 1997.

2. **Hendrix CW**, Sulkowski MS. Hepatotoxicity of antiretroviral therapy and drug-drug interactions with antiviral therapies for hepatitis C infection. In: Strategies for the Management of HIV/HCV Co-infection. Seacaucus: Projects in Knowledge, 2002.

Proceedings Reports

1. Committee on the role of institutional review boards in health services research data privacy protection. Institutional Review Boards and Health Services Research Data Privacy. A Workshop Summary. Institute of Medicine, Washington, D.C. May 2000.

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3. Veronese F, Anton P, Fletcher CV, DeGruttola V, McGowan I, Becker S, Zwerski S, Burns D; **Workshop Organizing Committee**. Implications of HIV PrEP trials results. AIDS Res Hum Retroviruses. 2011 Jan;27(1):81-90.

Editorials (Invited)

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

Letters, Correspondence

1. Blatt SP, **Hendrix CW**. Delayed-Type Hypersensitivity and AIDS. Ann Intern Med 1994;120(4):343-44. (Letter)

2. **Hendrix CW**. Consideration of the prevalence of CMV retinitis alters the assessment of a serum cytomegalovirus DNA test. J Infect Dis 1995;171(6):1688. (Letter)

3. Bray PF, Goldschmidt-Clermont P, Furman MI, Michelson AD, Barnard MR, Mascelli MA, **Hendrix CW**, Coleman L, Hamlington J, Kickler T, Christie DJ, Kundu S. Platelet glycoprotein IIIa PIA polymorphism and effects of aspirin on thrombin generation - Response Circulation 103(6):E33-E34 FEB 13 2001 (Letter)

4. **Hendrix CW**. Seizing the Opportunity. HIV Prevention in Military Communities. Civil-Military Alliance Newsletter. 1995;1(4):9.

5. Kingma SJ, **Hendrix CW**, Yeager R, Miller NN, D'Amelio R, Wouters R, "Analysis of global questionnaire on HIV/AIDS prevention, testing and care in current military medical practice." Occasional Paper, Civil-Military Alliance to Combat HIV and AIDS, 1996.

6. Yeager R, **Hendrix CW**. Global survey of military HIV/AIDS policies and programs. Civil-Military Alliance Newsletter. 1997;3(1): S1.

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Letters, Correspondence

7. **Hendrix CW**. Behavioral surveillance and intervention in the military environment. Civil-Military Alliance Newsletter. 1997;3(4):5.

8. **Hendrix CW**. AIDS in the Public Eye: AIDS Fatigue or Healthy Maturation. Lutheran AIDS Network Newsletter. 9(2);4-5;2000.

9. Lu Y, Fuchs EJ, **Hendrix CW**, Bumpus NN. Response to "Clinical Relevance of CYP3A5 Genotype on Maraviroc Exposures". Drug Metab Dispos. 2015 May;43(5):773

10. Dalesio NM, Lee CKK, **Hendrix CW**. In Response. Anesth Analg. 2017 Jul;125(1):362-363

FUNDING

Extramural Funding (current, pending, previous)

Current

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

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

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

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

FUNDING

Extramural Funding (current, pending, previous)

Current

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

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

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

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

FUNDING

Extramural Funding (current, pending, previous)

Current

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

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

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

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

FUNDING

Extramural Funding (current, pending, previous)

Previous

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

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

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

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

FUNDING

Extramural Funding (current, pending, previous)

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

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

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

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

FUNDING

Extramural Funding (current, pending, previous)

Previous

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

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

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

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

FUNDING

Extramural Funding (current, pending, previous)

Previous

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

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

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

FUNDING

Extramural Funding (current, pending, previous)

Previous

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

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

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

FUNDING

Extramural Funding (current, pending, previous)

Previous

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

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

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

FUNDING

Extramural Funding (current, pending, previous)

Previous

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

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

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

FUNDING

Extramural Funding (current, pending, previous)

Previous

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

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

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

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

FUNDING

Extramural Funding (current, pending, previous)

Previous

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

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

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

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

FUNDING

Extramural Funding (current, pending, previous)

Previous

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

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

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

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

FUNDING

Extramural Funding (current, pending, previous)

Previous

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

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

Dates:	02/01/99 - 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 jornal club 2012-2015
Tutorial "My Favorite Drug (Drug Develolpment)" 2016

Rational Therapeutics (created course; required 4th year medical student course)
"Practical Pharmacokinetics" 1995-2004
"Drug Interactions" 2004
"Rational Use of Antibiotics" 2005-2006

Pharmacology (Pharmacology Graduate Students):
"Pharmacokinetics I: Introduction, Membranes, Bioavailability" 2000-present
"Pharmacokinetics II: Volume, Clearance, Half-life" 2000-present
"Pharmacokinetics III: Mixed Order Kinetics" 2000-present
"Antibiotics" 2000-2006
"Aspirin and NSAIDs" 2000-2004
Pharmacology tutorial "Clinical Investigation" (5, 2-hour sessions) 2010-present

EDUCATIONAL ACTIVITIES

Teaching

Classroom Instruction- continued

Analytical Methods of Clinical Pharmacology (Fellowship 24-hour curriculum) 2000-present
- "Principles of PK/PD in Drug Development"
- "Curve Stripping"
- "Non-Compartmental Analysis"
- "Compartmental Analysis"
- "Pharmacodynamic Studies"
- "Pharmacodynamic Data Analysis"
- "PK/PD Linkage Analysis"
- "Population PK Analysis Overview"
- "Clinical Trial Simulation Overview"

Laboratory Science of rthe Clinical Investigator – Short Course 2017-present
- Coruse creator and co-director with S. Nimmagadda

Osler House Staff Noon Teaching Conference 2004 - 2012
- "Practical Pharmacokinetics for the House Officer" 2004-2012
- "Pharmacokinetics in Special Populations" 2004-2012
- "Rational Therapeutics of COX-2 Selective and Non-selective NSAIDs" 2004-2010
- "Making Drugs Safer" 2005-2012
- "Aminoglycoside Dosing Strategies" 2007-2012
- "Integrating HIV Prevention into an Internal Medicine Practice", 2011-2012

School of Nursing

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

School of Public Health

Principles of Drug Development, (required GTPCI Course) 1994-2003
- "Overview of the drug development process" 1999-2003
- "Pharmacokinetics for Drug Development" 1999-2003
- "Pharmacokinetic and Safety Studies" 1994-2003
- "Pharmacokinetic and Safety Studies - practicum" 1999-2003
- "Pharmacokinetic and Safety Studies – student project critique" 1999-2003
- "Learning vs. Confirming Studies" 1999-2003
- "Learning vs. Confirming Studies - practicum" 1999-2003
- "Learning vs. Confirming Studies - student project critique" 1999-2003
- "Clinical Trial Simulation" 2001-2003

EDUCATIONAL ACTIVITIES

Teaching

Classroom Instruction - continued

Analytical Methods in Clinical Investigation (required GTPCI Course),
"Databases: How to use and abuse them I: Principles" 1997-2002
"Databases: How to use and abuse them II: Applications" 1997-2002

Topics in Clinical Investigation (required GTPCI Course)
"Scientific Misconduct" 1995-present

Epidemiology and Natural History of Human Viral Infections
"Antiviral Therapy" 1997 - present

Epidemiology and Public Health Impact of HIV and AIDS
"Antiretroviral Therapy" 2004 - present

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

Advanced Topics on the Control and Prevention of HIV/ AIDS
"HIV Chemoprevention" 2006 - present

Epidemiology of Infectious Disease Journal Club, Faculty discussant, 2007

Doctoral Seminar in International Health, "Pharmacology in Public Health", 2009-2011

Clinical Instruction

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

Internal Medicine Inpatient Service, Teaching Attending, 1995-1996

PerdanaUniversity Graduate School of Medicine (Kuala Lumpur, Malaysia)

Scientific Foundations of Medicine Course
Introduction to Pharmacology Section (2013-present)
"Receptors and Enzymes"
"Drug Metabolism"
"Pharmacokinetics I-IV"
"Pharmacokinetic Case Studies – Problem Solving"
"Autonomic Pharmacology I-II"
"Drug Safety"
"Drug Development"
"Complementary and Alternative Medicine"
"Drug Resistance"

EDUCATIONAL ACTIVITIES

Teaching

Continuing Medical Education – Military

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

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

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

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

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

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

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

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

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

Continuing Medical Education- Civilian

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

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

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

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

EDUCATIONAL ACTIVITIES

Teaching

Continuing Medical Education – Civilian continued

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

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

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

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

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

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

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

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

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

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

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

EDUCATIONAL ACTIVITIES

Teaching

Continuing Medical Education – Civilian continued

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

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

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

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

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

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

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

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

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

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

EDUCATIONAL ACTIVITIES

Mentoring

Principal Mentor

Stephen P. Blatt, M.D., 1990-1991
Infectious Disease Fellow, Wilford Hall USAF Medical Center
Current position: Private Practice, Dayton, OH (1994-present)

Janet M. J. Hammond, M.D., Ph.D., 1995-1998
Clinical Pharmacology Fellow; Graduate Training Program in Clinical Investigation, Johns Hopkins University School of Hygiene and Public Health
Thesis "Emerging Pathogens in Intensive Care"; Sc.M. granted 5/25/99.
Current Position: Vice President of Infectious Diseases Development, AbbVie, Lake Forest, IL.

Robert Pelz, M.D., 1997-2000
Infectious Diseases Fellow
Graduate Training Program in Clinical Investigation, Ph.D. 2000
Research: Epidemiology and treatment of ICU infections
Awards: Infectious Diseases Society of America 1998 Fellows Award for Scientific Excellence. "Do surveillance cultures predict fungal infection in critically ill pts?"
Society of Critical Care Medicine 2000 In-training Fellow Award. "A double blind placebo controlled trial of prophylactic fluconazole to prevent Candida infections in critically ill surgical patients"
Society of Critical Care Medicine 2000 Educational Scholarship Award "Fluconazole blood concentrations after enteral administration in critically ill surgical patients exceed most Candida minimal inhibitory concentrations in a double-blind, placebo-controlled trial in which fluconazole prevented Candidal infections."
Johns Hopkins University Helen B. Taussig Young Investigators Award. "Nosocomial Fungal Infections in the Critically Ill: Dx and Prevention."
Current Position: Clinical Assistant Professor of Medicine, Oregon Health and Science University, School of Medicine, Portland, OR

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

EDUCATIONAL ACTIVITIES

Mentoring

Principal Mentor - continued

Shelley Sylvester Magill, M.D., 2000-2007
Infectious Diseases Fellow/Assistant Professor
Graduate Training Program in Clinical Investigation, Ph.D. 2007
Awards: Pfizer Mycology Fellowship Award Recipient 2001-2003;
Clinical Scientist Award 2003 (Johns Hopkins University, declined)
Research: Ecology and prevention of fungal infections in the ICU
Position: Assistant Professor, Division of Infectious Diseases, Johns Hopkins University School of Medicine 2004 - 2007
Current Position: Medical Officer, Mycotic Diseases Branch, CDC, Atlanta, GA (2007-present)

Lewis Radonovich, M.D., 2000-2002
Clinical Pharmacology Fellow
Graduate Training Program in Clinical Investigation, Ph.D. Candidate
PhRMA Fellowship in Pharmacology 2001-2002
Research: Chemoprophylaxis of adenoviral infections
Previous Position: Assistant Professor of Medicine, University of Florida, Gainesville FL (2002-2015
Current Position: Centers for Disease Control, NIOSH, Pittsburgh, PA (2015-present)

Thanyawee Puthanakit, M.D., 2001-2002
International Fogarty Fellow; Clinical Pharmacology Fellow
Graduate Training Program in Clinical Investigation; MHS degree 2002
Research: Pharmacokinetics of Antiretroviral Drugs, Drug interactions in the ICU
Assistant Professor, Chiang Mai University Medical Faculty, 2002-2005
Current Position: Associate Professor, Department of Pediatrics, Chulalongkorn University, Bangkok, Thailand; The HIV Netherlands Australia Thailand Research Collaborative.(2002-present)

Nimalie Stone, M.D., 2003-2004
Clinical Pharmacology Fellow
Research: Chemokine receptor inhibition phase I studies; Anti-infective drug utilization
Current Position: Medical Officer, CDC, Atlanta, Georgia

Wasif Khan, M.D., 2003-2005
Clinical Pharmacology Fellow
Graduate Training Program in Clinical Investigation, M.H.S. 2005
Merck International Fellow in Clinical Pharmacology 2003-2005
Research: Pharmacology of antiretroviral drugs, microbicide distribution
Current Position: Research Physician, International Center for Diarrheal Disease Research, Dhaka, Bangladesh. (2005-present)

EDUCATIONAL ACTIVITIES

Mentoring

Principal Mentor – continued

Ying-Jun Cao, M.D., 2004-2007
Clinical Pharmacology Fellow
Graduate Training Program in Clinical Investigation, Ph.D. 2007
Research in Progress: Development of methods to describe pharmacokinetics in the male genital tract; Quantitative methods to assess colon microbicide and HIV distribution
Awards: Department of Medicine Research Retreat Clinical Fellow Poster Finalist 2005;
American Society for Clinical Pharmacology and Therapeutics Young Investigator Award 2006-7;
Conference Retroviruses and Opportunistic Infections, Young Investigator Award 2007
British Journal of Clinical Pharmacology Prize 2012
Positions: Assistant Professor of Medicine, Division of Clinical Pharmacology, Johns Hopkins University School of Medicine. 2007-2008; 2008-present (Adjunct).
Director Science, Global Clinical Pharmacology & Exploratory Development, Astellas Pharmaceuticals, 2008-present.

Sridhar Nimmagadda, Ph.D., 2005-2008
Post-doctoral Fellow in Pharmacology and Radiology (Martin Pomper co-mentor)
Research: Quantitative luminal and tissue distribution of HIV and CD4 cells in the human vagina and colon following simulated receptive intercourse
Positions: Associate Professor of Radiology, Johns Hopkins University School of Medicine, 2009-present.

Kelly Brungardt Stein, MD, 2006-2007
Joint Clinical Pharmacology – Infectious Diseases Fellow
Graduate Training Program in Clinical Investigation, ScM 2009
Research: Protein binding of antiretrovirals in semen; vaginal distribution of HIV & CD4 cells.
Current Position: Instructor, Rush University Medical Center 2008-present

Nicolette Louissaint, PhD, 2006-2013
Pharmacology Training Program, Department of Pharmacology (2006 – 2010)
Ph.D. Candidate (PhD conferred May 2010), Post-doctoral fellow (May 2010-present)
Research in Progress: Quantitative luminal and tissue distribution of HIV and CD4 cells in the human vagina and colon following simulated receptive intercourse
Awards: Keystone Symposia Minority Scholarship, 2008
Department of Medicine Research Retreat Clinical Research Fellow Poster Finalist, 2009
American Society for Clinical Pharmacology and Therapeutics (ASCPT) Presidential Trainee Award 2010
ASPET Integrative Research in Pharmacology Awards 2012
AAAS Fellow – US Department of State 2013-2014
Current Position: Director of Healthcare Ready, AAAS Science and Technology Policy Fellow, Foreign Affairs Officer, US Department of State, 2014 - present

EDUCATIONAL ACTIVITIES

Mentoring

Principal Mentor - continued

Lindsay Brooke Avery, BS, 2008-2012
Pharmacology Training Program, Department of Pharmacology
Ph.D. Candidate; PhD conferred August 2012
Research: Efavirenz protein binding, compartmental distribution, and antiviral effect
Awards: American Society for Clinical Pharmacology and Therapeutics (ASCPT) Presidential Trainee Award 2010
Young Investigator Award. 20th Conference on Retroviruses and Opportunistic Infections 2013
Positions: Post-doctoral fellow, Namandje Bumpus Lab, Johns Hopkins University 2012-2014;
Current position: Pharmaceutical Development, Pfizer, Inc. Boston, MA, 2014-present

Liye Li, MD, PhD. 2009-2010
Clinical Pharmacology Fellow
Research: Development of candidate topical rectal microbicides.
Current Position: Nuclear Medicine private practice 2010 - present

Francisco Leyva, Md. PhD, 2009-2013
Clinical Pharmacology Fellow
Graduate Training Program in Clinical Investigation, M.H.S. 2012
Research: Development of candidate topical rectal microbicides.
Current Position: National Institutes of Health, Division of Microbiology and Infectious Diseases

Yanhui Lu, BS, 2010-2014
Pharmacology Training Program, Department of Pharmacology
Ph.D. Candidate; PhD conferred March 2014
Research: Identification of Novel Phase I and Phase II Metabolites of Maraviroc
Awards:
Junghea Park Memorial Travel Award 2012
Scheinberg Travel Award for spring 2011
Graduate Student Travel Award, ASPET Annual Meeting 2012
2012 Chinese Government Award for Outstanding Self-financed Students Abroad (China Scholarship Council)
2014 Bae Gyo Jung Young Investigator Day Award. Johns Hopkins University
Current Position: Office of Clinical Pharmacology, FDA 2015-present

Jenell Fenell Coleman, MD, 2010 – 2014
Assistant Professor, Department of Obstetrics and Gynecology
Harold Amos Medical Faculty Development Award
Research: Contraceptive – Antiretroviral drug interactions
Current Position: Associate Professor, Obstetrics & Gynecology, Johns Hopkins University

EDUCATIONAL ACTIVITIES

Mentoring

Principal Mentor - continued

Salee Parichat, MD, M.P.H. 2011-2012
International Fogarty Fellow, Thailand; Epidemiology, Masters of Public Health 2012, Bloomberg School of Public Health,
Research: Pre-exposure Prophylaxis adherence measured by plasma drug levels in MTN-001: comparison between vaginal gel and oral tablets in two geographic regions.
Current Position: RIHES, Chiang Mai University, Thailand

Hiwot Hiruy, MD, 2011-2015
Joint Clinical Pharmacology – Pediatric Infectious Diseases Fellow
Graduate Training Program in Clinical Investigation, PhD 2015
Research: Gastrointestinal tract pharmacology of topical HIV microbicides
Current Position: Medical Officer, FDA 2015-present

Jenny Robinson, MD, 2012-2014
Clinical Pharmacology Fellow
Graduate Training Program in Clinical Investigation, PhD Candidate
Research in progress: Female Genital tract pharmacology of topical HIV microbicides
Current Position: Assistant Professor, Obsetetrics & Gynecology, Johns Hopkins University 2014-present

Ethel Weld, MD, 2013-2016
Joint Clinical Pharmacology –Infectious Diseases Fellow
Graduate Training Program in Clinical Investigation, PhD 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
Assocaite Professor, University of California, San Diego
HIV Prevention Trials Network Scholar
Research in Progress: Impact of staff-particpant relationships on adherence in randomized controlled PrEP trials
Current Position: Associate Professor, University of California at San Diego, School of Public Health, San Diego, CA

Rachel Scott, MD, 2016-present
Assistant Professor, Georgetown University
Mid Atlantic CFAR Mentoring
Research in progress: ARV & PrEP PK in pregnancy and post-partum
Current Position: Assistant Professor of Medicine, Georgetown University, Washington, DC
Funding: K23 NIMH

Zachary Janik, 2016-present
Medical Student, Research Mentor
Research in Progress: Quantiative assessment of White Coart Adherence in HIV Pre-Exposure Prophylaxis.

Katherine Huether, 2017-2018
Medical Student, Drug Development Research Rotation

Secondary Sub-Specialty Mentoring

Normalynn Garrett, PhD candidate, Nursing; Pharmacology mentoring, 1998-1999
Andre Agthe, Neonatal Fellow, GTPCI; Pharmacology mentor, 2000-2004
Amy Ginsberg, Infectious Diseases Fellow; Pharmacology mentor, 2002-2003

Advisor (when not Primary Mentor) – GTPCI - continued

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

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

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

Myaing Nyunt, Clinical Pharmacology Fellow, GTPCI; Pharmacokinetics mentor, 2005 - 2008
Current Position: Assistant Professor of Medicine, University of Maryland Medical Center

EDUCATIONAL ACTIVITIES

Advisor (when not Primary Mentor) – GTPCI - continued

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

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

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

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

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

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

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

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

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

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

Omamah Alfarisi PharmD 2012 – present
Post-Doctoral Fellow Clinical Pharmacology
Graduate Training Program in Clinical Investigation, Ph.D. Candidate, pharmacokinietics mentor

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

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.

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

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

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

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

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

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

EDUCATIONAL ACTIVITIES

Mentoring

Thesis/Oral Examination Committees – continued

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EDUCATIONAL ACTIVITIES

Mentoring

Thesis/Oral Examination Committees – continued

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EDUCATIONAL ACTIVITIES

Mentoring

Thesis/Oral Examination Committees – continued

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

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

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

EDUCATIONAL ACTIVITIES

Mentoring

Training Grant Participation

Grant #: 4T32GM066691
Title: Clinical Pharmacology Training Program
Principal Investigator: C. Hendrix (as of 2016 multi-PI with K. Dooley)
Date: 07/01/08-06/30/2023
Award: $196,485 current year direct costs
Role: Mentor Clinical Pharmacology Fellows in clinical research; pharmacokinetics teaching

Grant #: 1UL1TR001079-01
Title: Institutional Clinical and Translational Science Award
Principal Investigator: D. Ford
Dates: 9/17/07 – 4/30/18
Award: $$7,485,218
Role: Mentor post-doctoral fellows in Graduate Training Program in Clinical Investigation

Grant #: 5T32GM08763-14
Title: Pharmacology Training Grant
Principal Investigator: J. Liu
Date: 07/01/00 – 06/30/20
Award: $312,004
Role: Train graduate students in clinical pharmacology teaching and research.

Grant #: 2T32AI007291-21
Title: Research Training in Microbial Diseases
Principal Investigator: K. Gebo
Date: 08/01/01 – 08/31/16
Award: $267,125 current year direct costs
Role: Mentor Infectious Diseases Fellows in clinical research

Grant #: 5R25DA021630
Title: Pediatric Training Grant: Immersion in Drug Abuse Research
Principal Investigator: E. Gauda
Dates: 07/01/07-04/30/13
Award: $301,715
Role: Johns Hopkins/Morgan State University research training aspects of illicit drug use.

Grant #: 5D43TW00010
Title: Fogarty AIDS International Training & Research Program
Principal Investigator: C. Beyrer
Dates: 07/01/07-05/31/13
Award: $695,000
Role: Mentoring of international post-doctoral clinical research fellows.

EDUCATIONAL ACTIVITIES

Educational Program Building / Leadership / Administration

School of Medicine

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

Medical Pharmacology (2nd year medical school)
- Course Co-Director 1997-2001
- Sectional Focus Group Leader (Introduction, Infectious Diseases, Rheumatology, Hepatology, Pain) 1997- 2003

Rational Therapeutics (4th year medical school, required course)
- Initial Course Developer 1995
- Course Director 1995-2004
- Sessions jointly taught by experienced clinician and clinical pharmacologist to emphasize rational approach to therapeutic problems; focus on topics of keen interest to soon-to-be interns.

Analytical Methods in Clinical Pharmacology (Fellowship training curriculum, required course)
- Initial Course Developer 2000
- Course Director 2000-present
- Cognitive and skill-based curriculum introduces quantitative aspects of clinical pharmacology in small-group problem-solving sessions.

Laboratory Science for the Clinical Investigator (Fellowship training curriculum, required coruse)
- Initial Course developer 2017
- Designed to provide an overview to clinical post-doctoral fellows and junior faculty planning clinical research studiesthat will rely on laboratory collaboration to support the clinical research. Curriculum covers a broad array of laboratory methods that describe quantitative laboratory methods, process of validation, quality control, and culture of laboratory-clinical interactions.

School of Public Health

Principles of Drug Development, (required GTPCI Course)
- Course Director 1999-2003
- Curriculum oriented around small-group “pharmaceutical team” skill-building exercises supplemented by didactic sessions (course director, industry and FDA medical reviewers) to provide fundamentals of the drug development process. Final exam includes visiting senior leadership from FDA to hear fully developed drug development plans designed by student teams.

EDUCATIONAL ACTIVITIES

Educational Program Building / Leadership - continued

US Air Force

US Air Force HIV Force wide Base Level Prevention & Education Program
Initial Program Development 1991
Course director1991-1999
Lecturer/ Small Group leader 1991-1999
US Air Force wide HIV prevention program implemented based on identification and training of small multi-disciplinary base-level HIV prevention teams comprised of physician, nurse educator, public health officer and other health professionals who develop a local prevention plan tailored to meet local needs. Team building and training carried out initially and sustained over time at annual HIV/AIDS Train-the-trainer Short Course (24 hour CME units).

National

"Principles and Practice of Drug Development"
Sanctioned by Institute of Medicine, concept developed at Institute of Medicine Forum
Sponsored by Stanford University, The Burroughs Wellcome Fund, and The Doris Duke Charitable Foundation
2006 - Curriculum development consultant
2006 - Lectures (delivered at Stanford University and internet broadcast to dozens of registered U.S. university campuses via the Stanford University Center for Professional Development)
"Role of pharmacokinetics-pharmacodynamics in drug development"
"Pharmacokinetics bridging process and practice in drug development"
"Pharmacokinetic-Pharmacodynamic models in drug development"

Food and Drug Administration

"Academics to CDER" Annual CME Curriculum Development
Jointly developed curriculum between FDA Center for Drug Evaluation and Research Office of Training and Communication staff and Baltimore-Washington area academics
Target audience Baltimore-Washington Clinical Pharmacology Programs and FDA staff
2001-2004 Curriculum Development Committee
2003 "Tools for Pre-Approval Drug Safety Evaluation", Course Director, Session Moderator, Lecturer

RESEARCH ACTIVITIES

Research Program Building / Leadership

Dates, name of research / basic science program, role

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

ORGANIZATIONAL ACTIVITIES

Institutional Administrative Appointments (committees, dates)

Johns Hopkins University School of Medicine Committees:

Johns Hopkins Medicine Institutional Review Board (JHM IRB)
Member 2001- present
Co-Chairman IRB #2 – 2001 - 2007
Pharmacy & Therapeutics Liaison to JHM IRB 2001-present

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

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

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

Student Promotions Committee – Second Year, 2000-2001

Joint Committee on Clinical Investigations, 1998-2001
Subcommittee (Pharmacy & Therapeutics Representative) 1998-2001

Graduate Training Program in Clinical Investigation,
Research Review Committee, 2/00-9/2006

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

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

Search Committee, Pharmacology Faculty, Department of Pharmacology, 2004

The Johns Hopkins Hospital Committees:

Pharmacy and Therapeutics Committee, 1995-present
Joint Antibiotic Subcommittee, Chairman, 1998-2002

Editorial Activities

Journal Editorial Board
Clinical Pharmacology and Therapeutics (2005 – 2008)

Clinical and Translational Science (2007 – 2015)

Pharmacology Research & Perspectives (2017-present)

ORGANIZATIONAL ACTIVITIES

Journal Peer Review Activities

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

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

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

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

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

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

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

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

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

ORGANIZATIONAL ACTIVITIES

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

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

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

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

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

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

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

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

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

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

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

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

Ammerican College of Clinical Pharmacology, Distinguished Investigator Award 2018

RECOGNITION

Invited Talks, Panels

1. "A Risk-Benefit Perspective on Universal HIV Screening in the United States Air Force." 1991, Buenos Aires, Argentina. Invited Talk, 17th Meeting of the Committee on Medicine in the Air Forces in the Americas. Sponsor: Committee on Medicine in the Air Forces in the Americas.

2. "International Security Impact of the HIV/AIDS Epidemic". 1995. Kampala, Uganda. Invited Talk, Africa Regional AIDS Conference, Military AIDS Symposium. Sponsor: UNAIDS.

3. "HIV Prevention Policy in Military Organizations". December 1996. Beijing, People's Republic of China. Invited Talk, Thirty-First International Congress of Military Medicine, Beijing, China. Sponsor: Peoples Liberation Army, People's Republic of China.

4. "Planning Effective HIV Prevention Interventions in the Military". October 1998. St. Petersburg, Russian Federation. Invited Talk, Kirov Military Medical Academy. Sponsor: Russian Federation Ministry of Defense.

5. "Drug Interaction Research Issues in Heavily Treated HIV-infected Patients". May 1999. Toronto, Canada. Invited Talk, International AIDS Society – Industrial Liaison Forum: The Challenge of Clinical Trial Design in Evaluating HIV Antiretroviral Use in Heavily-Pre-Treated Patients (Conference). Sponsor: International AIDS Society.

6. "Pharmacology of Antiretroviral Drugs in the Genital Tract". August 1999. Atlanta, Georgia. Invited Talk, National HIV Prevention Conference. Sponsor: CDC.

7. "COX-2 Inhibitors: Evaluation of New NSAIDs". September 1999. Towson, Maryland. Invited Talk, Arthritis Foundation of Maryland (Sponsor).

8. "Potential Drug Interactions in Antiviral Therapy". May 2000. Madrid, Spain. Invited Talk, European Congress on Chemotherapy-3 (Sponsor).

9. "Clinical Pharmacology of Rectal Microbicides". Atlanta, February 2001. Invited Talk, Centers for Disease Control (CDC) Conference on Rectal Microbicides, Sponsor: CDC.

10. "Preventing Fungal Infections". May 2001. Baltimore. Medical Grand Rounds, Johns Hopkins University School of Medicine. Sponsor: Department of Medicine.

11. "Pharmacologic Studies in the Development of Rectal Microbicides", June 2001. Baltimore. Invited Talk, Rectal Microbicide Workshop. Sponsor: NIH Office of AIDS Research.

12. "Development of Beta-Cyclodextrin as a Topical HIV Microbicide Candidate", August 2001. Rockville. Invited Talk, NIH Division of Antiviral Drug Products. Sponsor: FDA.

13. "Drug Interactions in Combined Hepatitis C-HIV Chemotherapy", April 2002. Aspen. Strategies for the Management of HIV/HCV Coinfection. Sponsor: Perspectives in Medicine.

RECOGNITION

Invited Talks, Panels – continued

14. "Quantitative Safety Assessment in Microbicide Development", May 2002. Antwerp, Belgium. Invited Talk, Microbicides 2002. (Cancelled)

15. "Distribution of Candidate Microbicide Gel and Simulated Ejaculate in the Lower Gastrointestinal Tract", June 2003. Los Angeles. Invited Talk, UCLA Center for HIV and Digestive Diseases (Sponsor).

16. "Clinical Development of a CXCR4 Chemokine Inhibitor", June 2003. New York City. Invited Talk, Entry Inhibitor Special Issue Advisory Board. Sponsor: Glaxo-Smith-Kline.

17. "Rational Development of Rectal Microbicides: Pharmacology, Toxicity, and Acceptability", July 2003. Atlanta. Invited Talk, National HIV Prevention Conference. Sponsor: CDC.

18. "Development of a CXCR4 Chemokine Receptor Inhibitor for HIV Infection", December 2003. Towson. Invited Talk, Towson University. Sponsor: Towson University.

19. "Distribution of Rectal Microbicide Vehicle and Simulated Ejaculate following Simulated Coital Activity" January 2004. New York City. Invited Talk, Columbia University. Sponsor: Columbia University, School of Medicine.

20. "Delivery of Microbicide to "At Risk" Intestinal Mucosa" March 2004. London. Invited Talk, Challenges to Rectal Microbicide Development (Satellite): Microbicides 2004.

21. "Critical Pharmacologic Issues in Vaginal and Rectal Microbicide Development" October 2004. Providence. Visiting Professor. Sponsor: Tufts University - Brown University Center for AIDS Research.

22. "Pharmacologic Issues in HIV Chemoprevention." February 2005. Boston. Invited Talk, International AIDS Society - Industry Liaison Forum, 12th National Conference on Retroviruses and Opportunistic Infections. Sponsor: International AIDS Society.

23. "Clinical Pharmacokinetics and Pharmacodynamics of Chemokine Inhibitors." February 2005. Boston. Invited Talk, 12th National Conference on Retroviruses and Opportunistic Infections. Sponsor: International AIDS Society.

24. "Adaptations of Radiologic Methods With Coital Simulations To Assess The Pharmacokinetics Of Topical Microbicides In The Vagina And Rectum", March 2005. Orlando. Invited Talk, Workshop on "Novel Pharmacokinetic Methods for Developing HIV Chemoprevention Strategies" Sponsor: American Society for Clinical Pharmacology and Therapeutics.

25. "Microbicides for HIV Prevention: Development Challenges for Clinical Pharmacology". April 2005. Quebec City. Invited Talk, 6th International Workshop on Clinical Pharmacology of HIV Therapy (Sponsor).

RECOGNITION

Invited Talks, Panels – continued

26. "Pharmacological Aspects of Microbicide Development". July 2005. Rio de Janeiro. Invited Talk, Challenges in HIV Microbicide Development. UCLA AIDS Institute and Brazilian STD/AIDS Program (Satellite Meeting): 3rd International AIDS Society Conference on HIV Pathogenesis and Treatment. Sponsor: International AIDS Society

27. "Clinical Pharmacology Challenges in Topical HIV Microbicide Development". September 2005. Buffalo. Visiting Professor. University of Buffalo School of Pharmacy and Pharmaceutical Sciences and School of Medicine/VA Medical Center.

28. "Making Drugs Safer" November 2005. Baltimore. Invited Talk, A Woman's Journey. Sponsor: Johns Hopkins University.

29. "HIV Chemoprevention: Evolving Approaches to Prevent HIV Infection with Drugs" Baltimore, January 2006. Invited Talk, Department of Medicine Grand Rounds (Sponsor).

30. "Rectal Microbicide Development: Measuring Gel & Virus Distribution" Web-Cast Teleconference, March 2006. Invited Talk, International Rectal Microbicides Working Group

31. "Drug Distribution & Formulation Issues in Rectal Microbicide Development" Cape Town, April 2006. Invited Talk, Rectal Microbicide Satellite Meeting. Microbicides 2006. Sponsor: UCLA AIDS Institute.

32. "Role of pharmacokinetics-pharmacodynamics in drug development"; "Pharmacokinetics bridging process and practice in drug development"; "Pharmacokinetic-Pharmacodynamic models in drug development". Palo Alto, National Webcast, April 2006. Invited talks, Principles and Practice of Drug Development Course. Sponsor: Stanford University and Institute of Medicine

33. "Rectal Microbicide Development: Contrasts to Traditional Drug and Vaginal Microbicide Development", Washington, D.C., May 2006. Invited Talk, Department of Health Policy, School of Public Health, George Washington University (Sponsor)

34. "Rectal HIV Microbicide Pharmacology & Drug Development" Raleigh-Durham, June 2006. Visiting Professor, Duke University Pratt School of Engineering, Department of Biomedical Engineering (Sponsor).

35. "Debate: Why Microbicides Will Fail" Arlington, September 2006. Invited Talk, Biomedical Interventions for HIV Prevention Working Group Meeting. Sponsor: Forum for Collaborative HIV Research Workshop.

36. "Topical HIV Microbicide Development: Evolving Challenges", Baltimore, November 2006. Invited Talk, Department of Pathology Grand Rounds (Sponsor).

RECOGNITION

Invited Talks, Panels – continued

37. "A Phase I, Dose-Rising Study of AMD11070 in HIV-Seronegative Men to Assess the Safety and Pharmacokinetics after Single or Multiple Doses," Baltimore, December 2006. Invited Talk, Plenary session, AIDS Clinical Trials Group. Sponsor: NIH.

38. "Reporting Scientific Misconduct – Deciding When and How to Act." Washington, D.C., December 2006. Invited Talk, Panel Member. Compliance and Investigator Fraud in Clinical Trials. Sponsor: CBI.

39. "Topical HIV Microbicide Development." Philadelphia. March 2007. Visiting Professor, Thomas Jefferson University, Division of Clinical Pharmacology (Sponsor).

40. "How Does Clinical Pharmacology Enhance HIV Microbicide Development?" Boston. April 2007. Visiting Professor, Tufts University, Division of Infectious Diseases (Sponsor).

41. "Pharmacology and Comparative Properties of NSAIDs." Miami, May 2007. Invited Talk, Panel member, Osteoarthritis and NSAIDs: Scientific Expert Panel Meeting. Sponsor: MDG

43. "HIV Microbicide Development from a Clinical Pharmacology Perspective." Seattle, July 2007. Invited Talk. Center for AIDS Research Pathogenesis Seminar Series, University of Washington.

44. "Clinical Study Design in Drug Development." Chicago, September 2007. Invited Talk. Science for Managers, Kellogg School of Management, Northwestern University.

45. "Distribution of Microbicide and HIV Surrogates in the Rectum and Distal Colon to Inform Rational Rectal Microbicide Development". Durban, South Africa., October 2007. Invited Talk. Nelson R. Mandela School of Medicine, University of KwaZulu-Natal, South Africa.

46. "Sparse Sampling Strategies in the Development of Vaginal Microbicide Candidates to Relationships Between Drug Exposure and Seroconversion Outcomes". Durban, South Africa, October 2007. Invited Talk: South Africa Medical Research Council, HIV/AIDS Lead Programme and HIV Prevention Research Unit.

47. "Pharmacokinetic Issues in ARV Microbicide Resistance". New Delhi, February 2008. Invited Talk, Microbicides 2008.

48. "Methods to Develop a Rectal-Specific Microbicide". New Delhi, February 2008. Invited Talk. Microbicides 2008.

49. "New Methods in Prevention of HIV Infection". Ames, March 2008. Invited Talk. Stupka Symposium, Iowa State University.

RECOGNITION

Invited Talks, Panels – continued

50. "Antiretroviral -based Microbicides Pharmacokinetics-Pharmacodynamics and Resistance". Cape Town, September 2008. Invited Talk. International Partnership for Microbicides Annual Meeting.

51. "Unique Contributions of MTN-001 to Microbicide Development Methodology". Cape Town, September 2008. Invited Talk. Microbicide Trial Network, Regional Investigator's Meeting.

52. "Pharmacokinetics & Future Pharmacodynamic Links". Cape Town, September 2008. Invited Talk. Microbicide Trial Network, Regional Investigator's Meeting.

53. "Microbicide Development Pipeline: Candidates, Mechanisms, Formulations, Clinical Phase" Cape Town September 2008. International Partnership for Microbicides Annual Meeting.

54. "Clinical Study Design in Drug Development" Chicago, September 2007. Invited Talk. Science for Managers, Kellogg School of Management, Northwestern University.

55. "Academic Contributions to Translational Drug Development". Shanghai, September 2008. International Clinical Research and Translational Medicine Symposium, Fudan University.

56. "Clinical Pharmacology Approach to HIV Chemoprevention Drug Development". Rochester, MN, October 2008. Invited Talk. Mayo Clinic.

57. "PK-PD in HIV Chemoprevention Studies" Atlanta. December 2008. AIDS Vaccine Advocacy Coalition (AVAC) sponsored meeting on Intermittent PrEP Development.

58. "Three-dimensional Problems in Imaging Drugs for HIV Chemoprevention" Baltimore 2008. Department of Biostatistics Grand Rounds, Johns Hopkins University School of Public Health.

59. "Drug Concentrations as an adherence biomarker in HIV prevention" New York January 2009. Quick Clinical Trials Working Group meeting on measuring adherence in HIV prevention trials.

60. "HIV Prevention with Drugs: Using Clinical Pharmacology to Put "Rational "Back in Drug Development." Baltimore March 2009. Department of Medicine, Grand Rounds.

61. "HIV Prevention with Topical Microbicides: Using Clinical Pharmacology to Put 'Rational' Back in Drug Development" Amsterdam April 2009. 10th HIV Clinical Pharmacology Workshop.

62. "Quantitative Pharmacokinetics of the Male Genital Tract and Applications in Drug Development". Invited Lecture. Atlanta March 2010. 111th Annual meeting of the American Society for Clinical Pharmacology and Therapeutics.

RECOGNITION

Invited Talks, Panels – continued

63. "HIV Prevention with Drugs". Invited plenary speaker. Hopkins-Brazil HIV Conference, Rio de Janeiro, April 2010.

64. "Pharmacology methods in prevention trials: assessing compartments and adherence". Invited talk, Laboratory Plenary Session, HIV Prevention Trials Network Annual Meeting. Washington, DC. April 2010.

65. "Pharmacokinetic Assessment of Adherence". Invited Talk. Microbicides 2010, May 2010, Pittsburgh.

66. "What Role Pharmacokinetics-Pharmacodynamics?" Invited Talk. Cape Town October 2010. Africa Regional Meeting of Microbicide Trial Network.

67. "Pharmacokinetics and Adherence in PrEP Development". Invited Talk. San Francisco. November 12, 2011 Forum for Collaborative HIV Research: 5th PrEP Working Group.

68. "The Role of Clinical Pharmacology in the Development of Topical HIV Microbicides" Visiting Professor. Pittsburgh. January 2011.University of Pittsburgh.

69. "MTN-001 Phase 2 Adherence and Pharmacokinetic Study of Oral and Vaginal Preparations of Tenofovir." Invited Talk. Microbicide Trial Network Annual Meeting. Arlington. March 2011.

70. "Use of Pharmacokinetics for Understanding Outcomes in HIV Prevention Trials" Invited Talk. Lab Plenary HIV Prevention Trials Network Annual Meeting, Washington, DC. June 2011.

71. Pharmacological assessment of medication adherence – Oral PrEP and Microbicides". Invited Talk. 19th International Society for STD Research. Quebec City. July 2011.

72. "Pharmacokinetics and Tissue Concentrations of Tenofovir and Emtricitabine: What is Needed to Prevent Transmission?" Invited Talk. Plenary HIV Vaccine Trials Network Annual Meeting. Seattle. November 2011.

73. "Clinical Pharmacology in HIV Pre-Exposure Prophylaxis Drug Development: Developing and Applying Tools when the Train has left the Station." Invited Talk. FDA Office of Translational Science. Silver Spring. January 2012.

74. "Attempts to Improve the Rational Development of HIV Pre-Exposure Prophylaxis through Clinical Pharmacology". Invited Talk. Mercer University. School of Pharmacy. Atlanta. February 2012

RECOGNITION

Invited Talks, Panels – continued

75. "Clinical Pharmacology in PrEP Development: Can small intensive studies inform RCTs?" Invited Talk. Microbicide Trials Network Annual Meeting. Bethesda, February 2012.

76. "Exploring Outcome Variability Across HIV Pre-Exposure Prophylaxis (PrEP) Trials", Anti-infective Section, ASCPT Annual Meeting. National Harbor, MD March 2012.

77. "Antiretroviral Pharmacology for PrEP: Enhancing RCT Understanding with Small Intensive Studies", Treatment as Prevention/Pre-Exposure Prophylaxis Summit. London, June 2012.

78. "Making Sense of Oral PrEP trials: Little Studies Informing Big Studies", Plenary Session, HPTN Annual Meeting. Washington, DC, June 2012.

79. "Oral & Topical PrEP: Unifying RCT Outcomes", Invited Talk, 7th HIV Transmission Workshop, Washington, DC. June 2012.

80. "Pharmacokinetic Assessment of PrEP Adherence", Invited talk, NIH DAIDS Behavioral Science Working Group Data Capture Technologies Focus Group, 11 October 2012.

81. "A Pharmacological Perspective on HIV Explant Challenge", invited talk, Biopsy Challenge meeting, NIH-Bill and Melinda Gates Foundation, Washington, DC, 29 November 2012.

82. "Genital and Anal Tract PrEP Pharmacokinetics", Office of AIDS Research Advisory Council Annual Meeting, Washington, DC, 8 November 2012.

83. "Measuring PK & Adherence in PrEP Trials: Explanation & Prediction", invited talk, RIHES, Chiang Mai University, Chiang Mai, Thailand, 7 January 2013.

84. "Clinical Pharmacology Approach to Rational Rectal Microbicide Development", Invited talk, Thai Red Cross/HIV-NAT, Chulalongkorn Univ, Bangkok, Thailand, 10 January 2013.

85. "Measuring PK & Adherence in PrEP Trials: Explanation & Prediction", Invited talk, Department of Medicine, University of Malaya, Kuala Lumpur, Malaysia, 15 January 2013.

86. "Pharmacological Approach to Monitoring Drug Adherence", Plenary Lecture, Microbicide Trials Network Annual Meeting. Bethesda, MD. February 2013.

87. "Enriching the design of clinical PK/PD studies of novel drug delivery systems", Invited Talk, Bill & Melinda Gates Foundation – NIH Think Tank on HIV Prevention Drug Delivery Systems. Washington, DC. February 2013.

88. "PK Assessment of Adherence in PrEP Trials" Pharmacometrics in Antiviral Drug Development Symposium, Annual Meeting of ASCPT, Indianapolis, 8 March 2013.

RECOGNITION

Invited Talks, Panels – continued

89. "Pharmacometric approaches to adherence assessment in HIV prevention trials." Mercer University Invited talk. Atlanta, 5 March 2013.

90. "How PK (could) inform PrEP Trials". Invited Talk, NIH, Division of AIDS Seminar, Bethesda, 15 March 2013.

91. "Pharmacological Aspects of PrEP", Invited Talk, Hopkins-Brazil HIV conference, Rio de Janeiro, Brazil 19 April 2013.

92. "Pharmacological Challenges for Next Generation PrEP", Invited Talk, 14th International Workshop on Clinical Pharmacology of HIV Therapy, Amsterdam, Netherlands, 23 APR 2013.

93. "Making sense out of oral and topical PrEP trials: Using little studies to understand big studies," Invited Talk, Annual Meeting of HIV Prevention Trials Network, Washington, DC, 6 May 2013.

94. "Scientific Misconduct". Invited Talk. FDA Office of Criminal Investigations. Charleston, SC, 18 June 2013.

95. "Exploring concentration-response in HIV Pre-Exposure Prophylaxis to optimize clinical care and trial design." Cell-Lancet Conference "What will it take for an AIDS Free World". San Francisco, 4 November 2013.

96. "HIV Pre-Exposure Prophylaxis: Clinical Pharmacology Insights". Invited Talk, 21st Conference on Retroviruses and Opportunistic Infections, Boston, Mar 4, 2014.

97. "Adherence : Impact on Study Results" CONRAD/AVAC Adaptive Trial Designs Conference. Washington, DC. June 23, 2014.

98. "The Role of Pharmacokinetics in selecting PrEP strategies". Invited Talk, 54th Interscience Conference on Antibiotics and Antimicrobical Therapy. Washington, D.C. September 9, 2014.

99. "HIV Pre-exposure Prophylaxis (PrEP) Trials: Making the Complex Simpler through Clinical Pharmacology". Invited Talk, Medical Grand Rounds, Western Ontario University, London, Ontario, September 17, 2014.

100. "Combining Pharmacology and Behavioral Science to Develop a Rectal Microbicide for HIV PrEP that People will Enjoy Using". Invited talk, Columbia University. Sponsor: Columbia University, School of Medicine. December 18, 2014.

RECOGNITION

Invited Talks, Panels – continued

101. "HIV Pre-Exposure Prophylaxis: Clinical Pharmacology Enriching Drug Development". Invited Talk, Dartmouth University, Division of Clinical Pharmacology. Lebanon, NH 23 June 2015.

102. "Pharmacokinetics in Microbicide Development". Invited Talk. NIH/DAIDS MTN Conference, "The Use of Mucosal Assays in Microbicide Trials" Arlington, VA 25-26 August 2015.

103. "Real-Time" Pharmacologically-based Adherence Testing". Invited Talk. NIH/DAIDS Conference "Optimizing Adherence Post-VOICE", Rockville, MD 2-3 September 2015.

104. "HIV Pre-Exposure Prophylaxis (PrEP) & Development of Microbicides". Invited Talk. American College of Clinical Pharmacology Annual Meeting, "An Update on HIV Treatment, Prevention and Drug Development Symposium", San Francisco, CA 28 September 2015.

105. "HIV Pre-Exposure Prophylaxis (PrEP) & Development of Microbicides". Invited Talk. University of California at San Diego Center for AIDS Research, San Diego, CA 23 October 2015.

106. "HIV Pre-Exposure Prophylaxis Drug Development". Invited Talk. Medical Grand Rounds, General Hospital, Tijuana, Mexico, 26 October 2015.

107. "Pharmacologic Adherence Assessment & Application in PrEP". Invited Talk. 2015 Center for AIDS Research (CFAR) Social and Behavioral Sciences Research Network Conference, Baltimore, MD 29 October 2015.

108. "Developing Behaviorally-Congruent Rectal Microbicides: A Clinical Pharmacology Approach". US-Japan Conference USAID, Bethesda, MD. 12 January 2016.

109. "Lessons Learned from Antiretroviral Testing". Invited Talk . UCLA CFAR-Sponsored Substance Use Meeting: Advancing the Field of Biobehavioral Substance Use Measurement for HIV Positive and At-risk Populations. Los Angeles, CA. 1 February 2016.

110. "Development of HIV Pre-exposure Prophylaxis: A Clinical Pharmacologist's Inside View". Invited Talk. University of North Texas Health Science Center. Fort Worth, TX. 8 April 2016

111. "Building on Oral PrEP Success: Rectal Microbicide Development". Invited Talk. DC Center for AIDS Research, Howard University, Washington, DC. 4 May 2016.

112. "HIV Pre-Exposure Prophylaxis Development: A Clinical Pharmacologist's Inside View". Invited Talk. KU Leuven, Leuven, Belgium. 17 May 2016.

RECOGNITION

Invited Talks, Panels – continued

113. "PK-PD Data to Advance Topical PrEP Products to Phase III". Invited Talk. Clinical Trial Evaluation Workshop for MPTs. Initiative for Multipurpose Prevention Technologies (IMPT). Washington, DC. 13 September 2016.

114. "Rectal vs. Vaginal Compartment Pharmacology." Invited talk. Contribution of Sexual Behaviour in the Global Heterosexual HIV Epidemic Workshop. NIH/DAIDS. Bethesda, MD. 15 September 2016.

115. "Pharmacologic Considerations for HIV Prevention Strategies". Invited talk.Western New York HIV Prevention Network Meeting. University of Buffalo, Buffalo, NY. 19 September 2016

116. "HIV Pre-exposure Prophylaxis Development:
A Clinical Pharmacologist's Inside View". Invited talk. Combating HIV/AIDS: Tx, PGx and PrEP Workshop, ACCP Annual Meeting. HIV symposium. San Diego, CA. 24 September 2016.

117. "Quantitative Assessment of Adherence: Experiences in HIV Prevention". Invited Talk. National Institute of Drug Abuse, Baltimore, MD 20 December 2016.

118. "Rectal Microbicide Development & DREAM Progress". Invited talk. Tenofovir Development Meeting, MTN Annual Meeting. Bethesda, MD. 20 March 2017.

119. "Developing Alternatives to Oral HIV PrEP: Rectal Microbicides & Long-Acting Formulations". Invited Talk. University of Texas Health Science Center, Galveston. April 2017.

120. "For Something Completely Different: Development of a Rectal Enema as Microbicide". Invited Talk. Oak Crest Institute of Science, Monroeville, CA May 2017.

121. "Rectal Microbicide Development: How Did We Get Here? What Have we Learned?" Invited webnar talk. Sponsored by AIDS Vacine Advocacy Coalition (AVAC) and International Rectal Microbicide Advocates (iRMA). August 2017.

122. "Rectal Microbicides: Where We're Heading". Invited webinar talk. Sponsored by AIDS Vacine Advocacy Coalition (AVAC) and International Rectal Microbicide Advocates (iRMA). August 2017.

123. "Impact of adherence on the development of HIV Pre-exposure Prophylaxis" Invited Symposium Talk (delivered Mark Sales), American College of Clinical Pharmacology Annual Meeting. San Diego, CA. September 2017.

RECOGNITION

Invited Talks, Panels – continued

124. "Advances in Formulations in HIV PrEP: Topical Products - Rings, Gels, Implants, etc." Invited Symposium talk (delivered Marc Baum), American College of Clinical Pharmacology Annual Meeting. San Diego, CA. September 2017.

125. "Review of the Current Rectal Microbicide Context". Invited Talk. Reboot the Booty Think Tank. Sponsored by AIDS Vacine Advocacy Coalition (AVAC) and International Rectal Microbicide Advocates (iRMA). New York, NY. September 2017.

126. "Lube Safety 101". Symposium on Lubricant Safety, US Conference on AIDS. Washington, DC. September 2017.

127. "Next Generation PrEP? Injectable & Implantable ARVs". Plenary Talk. Microbicide Trial Network Regional Meeting, Cape Town, RSA. September 2017.

128. "The Path Ahead for Rectal Microbicides". Plenary Talk. Microbicide Trials Network Regional Meeting, Cape Town, RSA. September 2017.

129. "DREAM Program for Rectal Microbicide Prevention". Invited talk. PREVENT Program Project Annual Meeting. Louisville, KY. October 2017.

130. "Promise & Progress of Rectal Microbicides for HIV Pre-Exposure Prophylaxis". Invited Talk. Center for AIDS Research. University of Alabama, Birmingham, AL. November 2017.

131. "Microbicides: Where We're Heading" Invited Talk. Second Annual Biomedical HIV Prevention Summit (NMAC). New Orleans, LA. December 2017

132. "Clinical Pharmacology of HIV Pre-Exposure Prophylaxis (PrEP) – Where are we now?" Visiting Professor. University of Liverpool. Liverpool, UK. February 2018.

133. "Beyond Oral PrEP: Promise and Challenges of Alternative Antiviral Dosing Methods for PrEP". Invited Lecture. Office of AIDS Research Brown Bag Seminar. Brockville, MD. February 2018.

134. "Beyond Oral PrEP: Promise and Challenges of Alternative Antiviral Dosing Methods for PrEP" Invited Talk. 8th International Workshop on HIV & Women. Boston, MA. March 2018.

135. "Proof-of-Concept for On Demand, Behaviorally-Congruent Rectal Microbicide Douche". Plenary Lecture. MTN Annual Meeting. Bethesda, MD March 2018.

136. "Success, Disappointment, *& Hope* in the Development of HIV Pre-Exposure Prophylaxis". Invited Talk. Walter Reed Army Institute of Research, Silver Spring, MD. April 2018.

RECOGNITION

Invited Talks, Panels – continued

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

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

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

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

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

RICHARD ROE et al., Plaintiffs, v. PATRICK M. SHANAHAN et al., Defendants.	Case No. 1:18-cv-01565 (LMB/IDD)

DECLARATION OF PETER PERKOWSKI IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

1. My name is Peter Perkowski. I am the Legal & Policy Director of Plaintiff OutServe-SLDN, Inc.

2. I am over 18 years of age, am competent to testify about the information contained in this declaration if needed, and offer this declaration based on my own actual, personal knowledge.

3. OutServe-SLDN is a non-partisan, non-profit, legal services, watchdog, and policy organization that represents the U.S. LGBTQ+ military community—service members, veterans, civilian Department of Defense, and their spouses and families—worldwide. The organization's mission is to address and end—through litigation, policy advocacy, and education—all forms of unequal or unfair treatment against members of its community based on sexual orientation, gender identity, or HIV status.

4. OutServe-SLDN is in part a membership organization, or the functional equivalent of a membership organization. It has well over 7,000 members—veterans, active-duty

and reserve-component service members, and civilian Department of Defense workers throughout the world who identify as LGBTQ or are living with HIV—and more than 54,000 supporters. OutServe-SLDN also has more than 54 chapters worldwide, including 35 in the United States, and 20 additional special group forums, one of which is the "Positive Forum" for people living with HIV. These chapters are not just social groups: because service members who are LGBTQ+ and/or living with HIV are minority groups that are still sometimes marginalized, stigmatized, or ostracized in the military, the chapters allow these service members to establish emotional support networks and to exchange information that is important for career advancement and professional growth. The chapters also provide a direct link for service members to access services and programs that OutServe-SLDN offers.

5. OutServe-SLDN provides pro-bono advocacy and legal services for members of the military living with HIV. Advocacy work includes working with Congress to change or approve legislation and regulations affecting service members with HIV, as well as working directly with the Department of Defense, the Secretary of Defense, and the service Secretaries on the same issues. Legal services work includes writing and submitting amicus briefs in cases involving HIV-related issues (e.g., *United States v. Forbes*, Court of Appeals for the Armed Forces Case No. 18-0304/NA); filing and litigating impact litigation to change Department of Defense policies; directly representing servicemembers with HIV in administrative-separation and court-martial proceedings; and providing cultural-competency assistance, education and information, and training to Judge Advocate General defense lawyers in all service branches.

6. As Legal & Policy Director, my duties include supervising OutServe-SLDN's legal department and overseeing its legal-services function. I am therefore familiar with the inquiries that the organization receives from members requesting legal assistance.

7. Since the filing of the Complaint in this matter, OutServe-SLDN's legal department has received numerous calls and emails from service members with HIV who are going through a process like plaintiffs Staff Sergeant (SSgt) Roe and Senior Airman (SrA) Voe in this matter. Many of these service members are currently facing separation. OutServe-SLDN's legal staff, including myself, have spoken to these service members and collected relevant documents from them. The facts set forth below are based on those documents and conversations.

8. K.R. is a Senior Airman who joined the Air Force in 2014 and is currently stationed at an Air Force base outside the United States. SrA K.R. was diagnosed with HIV in late 2016 and was immediately put into the Integrated Disability Evaluation System (IDES) to determine whether he would be returned to duty or instead would be separated because of his medical condition. As with plaintiffs, the boards evaluating SrA K.R. determined that he was not worldwide deployable and therefore unfit for duty, and he was recommended for separation.

9. SrA K.R. appealed to the Secretary of the Air Force (SAF). On November 7, 2018, the SAF's designee—John Vallario, Deputy Director of the SAF Personnel Council—issued a memorandum decision stating: "On behalf of the Secretary of the Air Force, it is directed that Senior Airman [K.R.] be discharged." A copy of this memorandum is attached to this declaration as Exhibit C1. (To avoid potential stigma and discrimination based on his HIV status, personal identifying information has been redacted to protect SrA K.R.'s anonymity.)

10. The memorandum to SrA K.R. is almost identical to those received by plaintiffs, and it was issued the same day. As a basis for the decision, it states: "[T]he member's condition precludes him from being able to deploy world-wide without a waiver and renders him ineligible for deployment to the Central Command (CENTCOM) Area of Responsibility (AOR)[.] …

Therefore, based on his inability to deploy and considering his current career point, the Board determined he is unfit for continued military service and shall be discharged with severance pay."

11. SrA K.R. has received orders stating that his Date of Separation (DOS) is March 28, 2019. (Because of the large amount of personal identifying information in the separation orders, I have not attached it to this declaration.) SrA K.R. wants to continue serving in the Air Force, and he has the support of his command, who favor his retention. But without an injunction from this Court he will be separated on March 28.

12. SrA K.R. is also a member of OutServe-SLDN's "Positive Forum," a secret Facebook group for service members, veterans, and others in the military community who are living with HIV. By virtue of this, and by availing himself of OutServe-SLDN's legal services, SrA K.R. is a member of OutServe-SLDN.

13. S.H. is a Senior Airman who joined the Air Force in 2016 and is currently stationed at an Air Force base in the southern United States. SrA S.H. was diagnosed with HIV in early 2018 and was immediately put into the IDES to determine whether he would be returned to duty or instead would be separated because of his medical condition. As with plaintiffs, the boards evaluating SrA S.H. determined that he was not worldwide deployable and therefore unfit for duty, and he was recommended for separation.

14. SrA S.H. appealed to the SAF. On December 4, 2018, the SAF's designee—John Vallario, Deputy Director of the SAF Personnel Council—issued a memorandum decision stating: "On behalf of the Secretary of the Air Force, it is directed that [Airman First Class] [S.H.] be discharged." (SrA S.H. was promoted from Airman First Class (A1C) to Senior Airman while his appeal was pending.) A copy of this memorandum is attached to this

declaration as Exhibit C2. (To avoid potential stigma and discrimination based on his HIV status, personal identifying information has been redacted to protect SrA S.H.'s anonymity.)

15. The memorandum to SrA S.H. is almost identical to those received by plaintiffs, and by SrA K.R. As a basis for the decision, it states: "[T]he member's condition precludes him from being able to deploy world-wide without a waiver and renders him ineligible for deployment to the Central Command (CENTCOM) Area of Responsibility (AOR)[.] … Therefore, based on his inability to deploy and considering his current career point, the [Board] determined he is unfit for continued military service and shall be discharged with severance pay."

16. SrA S.H. has received orders stating that his DOS is March 28, 2019. (Because of the large amount of personal identifying information in the separation orders, I have not attached it to this declaration.) SrA S.H. wants to continue serving in the Air Force, and he has the support of his command, who favor his retention. But without an injunction from this Court he will be separated on March 28.

17. SrA S.H. is also a member of OutServe-SLDN's "Positive Forum." By virtue of this, and by availing himself of OutServe-SLDN's legal services, SrA S.H. is a member of OutServe-SLDN.

18. D.N. is a Senior Airman who joined the Air Force in 2016 and is currently stationed at an Air Force base in the Midwest United States. SrA D.N. was diagnosed with HIV in early 2018 and was immediately put into the IDES to determine whether he would be returned to duty or instead would be separated because of his medical condition. As with plaintiffs, the boards evaluating SrA D.N. determined that he was not worldwide deployable and therefore unfit for duty, and he was recommended for separation.

19. SrA D.N. appealed to the SAF. On December 5, 2018, the SAF's designee—Shane Prater, Director of the SAF Personnel Council—issued a memorandum decision stating: "On behalf of the Secretary of the Air Force, it is directed that SrA [D.N.] be discharged." A copy of this memorandum is attached to this declaration as Exhibit C3. (To avoid potential stigma and discrimination based on his HIV status, personal identifying information has been redacted to protect SrA D.N.'s anonymity.)

20. The memorandum to SrA D.N. is almost identical to that received by plaintiffs and by SrA K.R. and SrA S.H. As a basis for the decision, it states: "[T]he member's condition precludes him from being able to deploy world-wide without a waiver and renders him ineligible for deployment to the Central Command (CENTCOM) Area of Responsibility (AOR)[.] … Therefore, based on his inability to deploy and considering his current career point, the [Board] determined he is unfit for continued military service and shall be discharged with severance pay."

21. SrA D.N. has not yet received orders informing him of his DOS. He wants to continue serving in the Air Force, and he has the support of his command, who favor his retention. But without an injunction from this Court, SrA D.N. will be discharged.

22. SrA D.N. is also a member of OutServe-SLDN's "Positive Forum." By virtue of this, and by availing himself of OutServe-SLDN's legal services, SrA D.N. is a member of OutServe-SLDN.

23. J.B. is a Staff Sergeant who joined the Air Force in 2014 and is currently stationed at an Air Force base in southern United States. SSgt J.B. was diagnosed with HIV in late 2017 and was put into the IDES to determine whether he would be returned to duty or instead would be separated because of his medical condition. As with plaintiffs, the boards

evaluating SSgt J.B. determined that he was not worldwide deployable and therefore unfit for duty, and he was recommended for separation.

24. SSgt J.B. appealed to the SAF. On November 7, 2018, the SECAF's designee—John Vallario, Deputy Director of the SAF Personnel Council—issued a memorandum decision stating: "On behalf of the Secretary of the Air Force, it is directed that Senior Airman [J.B.] be placed on the Temporary Disability Retired List (TDRL) with a disability rating of 60 percent … ." (SSgt J.B. was a Senior Airman at the time but was subsequently promoted to Staff Sergeant.) A copy of this memorandum is attached to this declaration as Exhibit C4. (To avoid potential stigma and discrimination based on his HIV status, personal identifying information has been redacted to protect SSgt J.B.'s anonymity.)

25. The SAF memorandum to SSgt J.B. is almost identical to those received by plaintiffs, and by SrA K.R., SrA S.H., and SrA D.N, and it was issued the same day as plaintiffs'. As a basis for the decision, it states: "[T]he member's condition precludes him from being able to deploy world-wide without a waiver and renders him ineligible for deployment to the Central Command (CENTCOM) Area of Responsibility (AOR)[.] … Therefore, based on his inability to deploy and considering his current career point, the Board determined he is unfit for continued military service and shall be placed on the Temporary Disability Retired List (TDRL) … ."

26. SSgt J.B. has received orders stating that the date he will be relieved of duty is February 25, 2019. (Because of the large amount of personal identifying information in the separation orders, I have not attached it to this declaration.)

27. SSgt J.B. is also a member of OutServe-SLDN's "Positive Forum." By virtue of this, and by availing himself of OutServe-SLDN's legal services, SSgt J.B. is a member of OutServe-SLDN.

28. OutServe-SLDN has also heard from members of the Air National Guard (ANG) who are facing separation because their HIV status makes them not worldwide deployable. Q.S. is a Senior Airman in the ANG of a state in the Midwest. SrA Q.S. enlisted in 2011 and was diagnosed with HIV in June 2018. SrA Q.S.'s current enlistment period expires on February 18, 2019, and he wants to re-enlist.

29. But SrA Q.S. is not being allowed to re-enlist. Instead, on January 10, 2019, his command presented SrA Q.S. with Form AF 418—by which commanders may "select" or "non-select" enlisted personnel for re-enlistment—stating that SrA Q.S. was "not selected for reenlistment." The reason given for non-selecting SrA Q.S. was that his HIV status renders him non-deployable.

30. Without an injunction from this Court, SrA Q.S. will be separated from the ANG as of his Expiration Term of Service (ETS) date of February 18.

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

Executed on this 10th day of January, 2019.

Peter Perkowski

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

RICHARD ROE, ET AL.,

Plaintiffs,

v.

PATRICK M. SHANAHAN, ET AL.,

Defendants.

Case No. 1:18-cv-10565

EXPERT DECLARATION OF W. DAVID HARDY, M.D., IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

I. INTRODUCTION

1. My name is W. David Hardy, MD. 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 opinion on HIV – its pathology, the routes and relative risks of transmission, the care and treatment of people living with HIV, the effect of antiretroviral treatment on the immunological and overall health of people living with HIV, the effect of treatment on the risks of transmission, and best clinical practices for administering both antiretroviral therapy and preexposure prophylaxis ("PrEP").

3. As detailed below, it is my opinion that providing PrEP to members of the Armed Services is more logistically and medically demanding than providing antiretroviral medications to service members living with HIV would be.

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

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.

6. I am currently the Chairman of the Board ("Chair") of the HIV Medicine Association and an Adjunct Professor of Medicine at the Johns Hopkins University School of Medicine. I have 36 years of experience in the care and treatment of people living with HIV, including 34 years of experience researching opportunistic infections, antiretroviral agents, immunotherapies, retroviral vector research, and gene therapy.

7. While serving as Board Chair of the HIV Medicine Association, I also served as Senior Director of Research at Whitman-Walker Health in Washington, DC from 2015 to 2018. From 2013 to 2015, I was the Chief Medical Officer of Calimmune, a translational science

company investigating gene-modified cellular therapies as a potential cure for HIV. Prior to that, I was the Director of the Division of Infectious Diseases at Cedars-Sinai Medical Center and a Professor of Medicine at the David Geffen School of Medicine at UCLA from 2002 to 2013.

8. I received my medical degree from Baylor College of Medicine. I completed my residency in internal medicine at Harbor-UCLA Medical Center, and completed a clinical fellowship in infectious diseases/immunology and clinical research at the UCLA School of Medicine from 1984 to 1986 under the direction of Dr. Michael Gottlieb, the physician who recognized and reported the first cases of AIDS. I later completed a post-doctoral fellowship at UCLA with Irvin Chen, PhD, focusing on molecular retrovirology.

9. For over 30 years, I have been dedicated to the treatment of people living with HIV. In addition to research and teaching, I have served as editor-in-chief of *Fundamentals of HIV Medicine for the HIV Specialist*, the comprehensive textbook of the American Academy of HIV Medicine, and currently serve on that organization's Board of Directors as the Chair of the Education Committee. I also have a long history of working with a number of community-based, organizations that provided critical services for persons living with HIV, including AIDS Research Alliance, Alliance for Housing and Healing, Being Alive-Empowering People with HIV/AIDS, Project Angel Food, and AIDS Project Los Angeles.

10. Once considered invariably fatal within approximately eight to ten years, HIV is now considered a chronic, treatable condition. Those diagnosed in a timely manner and promptly provided with appropriate care and treatment with antiretroviral medications experience few, if any, noticeable effects on their physical health and enjoy a life expectancy approaching that of those who do not have HIV.

11. HIV, which is an acronym for human immunodeficiency virus, attacks the body's immune system. The initial stage of infection, in which the virus is first introduced and gains a foothold in the body over a period of days to weeks, is known as the acute stage of infection. After the acute stage of infection, a person enters a period of clinical latency that can last years. During this period of latency, an individual living with HIV may not display any symptoms or negative health outcomes.

12. At almost any point during infection with HIV, initiation and continuous treatment with antiretroviral therapy (ART) will halt and reverse the downward slope in immune function and restore the person to good health.

13. With consistent adherence to ART, the amount of HIV in a person's body or viral load drops dramatically and their immune system cells or CD4+ T cells rebounds. Within several months, the person's HIV infection will become "virally suppressed," defined as less than 200 copies of the virus per milliliter of blood, and shortly after that, they would have an "undetectable" viral load, which is generally defined as less than 50 copies per milliliter of blood.

14. Greater than 90% of persons living with HIV who adhere to their antiretroviral medications will eventually achieve an undetectable viral load. A person who experiences a lapse in their ART will not immediately suffer negative health outcomes. It often takes weeks for an individual's viral load to reach a level that would not be considered "suppressed." If the lapse in treatment continues, the individual will progress to clinical latency, which, as described above, can last for years, and which can be reversed by restarting ART.

15. After initiating ART, patients are generally evaluated every two to four weeks to assess initial viral load, and check for any possible side effects. After these initial evaluations,

follow-up testing becomes quarterly until the patient reaches an undetectable viral load, at which point evaluations are done three times a year. After a patient's viral load has been undetectable for two years, they need only go to the doctor twice a year for follow-ups.

16. Adherence to ART has grown easier and easier. Today, 75% to 80% of people living with HIV are on a single tablet regimen ("STR")—in which all three or four medications are combined into one pill—that is taken once a day. Most STRs have no dietary restrictions, and side effects are self-limited and minimal to mild with infrequent discontinuation of treatment.

17. People living with HIV who are virally suppressed or have an undetectable viral load are incapable of transmitting HIV. Advances in understanding of the preventive effects of ART have led the CDC to declare that "…people who take ART daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to an HIV negative partner. *See* CDC, "Dear Colleague: Information from CDC's Division of HIV/AIDS Prevention," Sept. 27, 2017, *available at* https://www.cdc.gov/hiv/library/dcl/dcl/092717.html (last viewed June 26, 2018).[1] As further stated in the CDC letter, "[a]cross three different studies, including thousands of couples and many thousands of acts of sex without a condom or pre-exposure prophylaxis (PrEP), no HIV

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

transmissions to an HIV-negative partner were observed when the HIV-positive person was virally suppressed"[2] (i.e., a viral load of less than 200 copies/ml).

18. Adherence to an effective ART regimen does not require much time—in the majority of cases, it is as simple as taking one tablet of medication every day. The HIV medications commonly prescribed today have no special handling, storage or other requirements. These medications generally tolerate extreme external conditions, such as hot or cold temperatures and sunlight, well. Taking medication primarily once or sometimes 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 tablet taken once a day. The time and effort required is similar to that expended by individuals who are prescribed daily medication for elevated cholesterol or those taking a multivitamin.

19. One groundbreaking discovery in the field of HIV prevention is the discovery that certain antiretroviral medications, when taken regularly by an individual not living with HIV, can effectively avert the transmission of HIV to that individual. This treatment is known as "pre-exposure prophylaxis ("PrEP"). Truvada, a tablet containing two HIV medications, is the only medication currently approved for use as PrEP by the U.S. Food and Drug Administration. As the understanding of PrEP has increased in the medical community, more and more doctors are prescribing PrEP to patients who are at higher risk for HIV acquisition.

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[2] The referenced scientific studies: The HIV Prevention Treatment Network Study No. 052 as published in the New England Journal of Medicine 08/11/11, *available at* https://www.nejm.org/doi/full/10.1056/NEJMoa1105243?query=recirc_curatedRelated_article; PARTNER Study, published in the Journal of the American Medical Association (JAMA) July 12, 2016, *available at* https://ncbi.nlm.nih.gov/pubmed/27404185: and Opposites Attract study reported at the Conference on Retroviruses and Opportunistic Infections (CROI) in 2015, *available at* https://www.croiconference.org/sites/default/files/posters-2015/1019LB.pdf and the International AIDS Conference in 2017.

20. Recently, the Defense Health Agency ordered that all medical treatment facilities across the Armed Services "[p]rovide a pathway for access to HIV PrEP and equal access for military and non-military beneficiaries who are high risk for HIV [acquisition]."[3] The Navy and Marine Corps Public Health Center has stressed that "PrEP use does not affect accession eligibility, reenlistment eligibility or readiness status."[4]

21. As per 2017 CDC Guidelines[5], individuals taking PrEP are only prescribed their medications in a 90-day supply; they are required to undergo follow-up evaluations – including blood tests to ensure that they have not acquired HIV – every three months. By contrast, people living with HIV with an undetectable viral load are only required to undergo follow-up evaluations and blood tests every six months.

22. Again, as per CDC Guidelines, individuals taking PrEP are also subjected to a more rigorous protocol for screening for STIs. Extragenital testing for STIs such as gonorrhea and chlamydia— otherwise known as "three-site" testing—is conducted for individuals taking PrEP. Extragenital testing involves checking for the presence of STIs in the rectum and throat in addition to the urine test that demonstrates the presence of a urethral STI. Extragenital testing is important for individuals taking PrEP because the presence of these STIs can increase the chance that an individual could acquire HIV. It is important that a person who is taking PrEP and acquires HIV cease taking PrEP as soon as possible, because taking PrEP while newly infected

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[3] DHA-IPM 18-020, Attach. 2.1.a (November 2018).
[4] Navy and Marine Corps Public Health Center, *HIV Pre-Exposure Prophylaxis (PrEP)* 1 (Nov. 19, 2018) (available at http://www.med.navy.mil/sites/nmcphc/health-promotion/reproductive-sexual-health/Pages/reproductive-and-sexual-health.aspx).
[5] U.S. Public Health Service, *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2017 Update – A Clinical Practice Guideline* (March 2018) (available at https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf).

with HIV can result in resistance to the classes of ART medications contained in Truvada. Because of the increased complexity involved, some clinical settings lack capacity to administer extragenital testing. By contrast, people living with HIV are not required to undergo extragenital testing on a regular basis, and are instead subjected to the same testing protocols as members of the general population based on an STI risk profile.

23. Despite the increased burden of testing and monitoring service members taking PrEP, the military does not consider such a prescription to be a bar to deployment. The DHA has stated that a prescription for PrEP should not prohibit service members from deploying to many places overseas.[6] The Navy and Marine Corps Public Health Center notes that "continuation of PrEP during deployment should be explored and, if possible, accommodated."[7]

II. CONCLUSION

In my opinion, providing health care and treatment to service members living with HIV deployed overseas would be logistically simpler, less costly and less complex than providing care to service members deployed overseas who are prescribed and are taking Truvada as PrEP.

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

Executed this 1st day of February, 2019

David Hardy, MD
W. David Hardy, M.D.

[6] DHA-IPM 18-020, Attach. 3.b (November 2018).
[7] Navy and Marine Corps Public Health Center, *HIV Pre-Exposure Prophylaxis (PrEP)* 3 (Nov. 19, 2018).

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

RICHARD ROE; VICTOR VOE; and OUTSERVE-SLDN, INC., Plaintiffs, vs. PATRICK M. SHANAHAN, in his official capacity as Acting Secretary of Defense; HEATHER A. WILSON, in her official capacity as Secretary of the Air Force; and the UNITED STATES DEPARTMENT OF DEFENSE, Defendants.	Civil Action No. 1:18cv1565 Alexandria, Virginia February 15, 2019 10:21 a.m.

TRANSCRIPT OF MOTIONS HEARING
BEFORE THE HONORABLE LEONIE M. BRINKEMA
UNITED STATES DISTRICT JUDGE

APPEARANCES:

FOR THE PLAINTIFFS:

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(APPEARANCES CONT'D. ON PAGE 2)

COMPUTERIZED TRANSCRIPTION OF STENOGRAPHIC NOTES

APPEARANCES: (Cont'd.)

FOR THE DEFENDANTS:	R. TRENT McCOTTER, AUSA United States Attorney's Office 2100 Jamieson Avenue Alexandria, VA 22314 and ROBERT M. NORWAY, ESQ. U.S. Department of Justice Civil Division Federal Programs Branch 1100 L Street, N.W. Washington, D.C. 20530
ALSO PRESENT:	VICTOR VOE
OFFICIAL COURT REPORTER:	ANNELIESE J. THOMSON, RDR, CRR U.S. District Court, Third Floor 401 Courthouse Square Alexandria, VA 22314 (703)299-8595

P R O C E E D I N G S

THE CLERK: Civil Action 18-1565, Richard Roe, et al. v. United States Department of Defense, et al. Would counsel please note their appearances for the record.

MR. McCOTTER: Good morning, Your Honor. Trent McCotter, Assistant United States Attorney, on behalf of defendants, and with me is Robert Norway from the Federal Programs Branch, and Mr. Norway will be arguing.

THE COURT: And, Mr. Norway, is it like the country, your last name?

MR. NORWAY: Yes, Your Honor.

THE COURT: Very good. Good morning.

And for the plaintiffs?

MS. COOLEY: Good morning, Your Honor. Laura Cooley for the plaintiffs. I'll be introducing several people today. Scott Schoettes of Lambda Legal will be presenting our argument. We have one of our plaintiffs with us today, Victor Voe, as well as Peter Perkowski on behalf of OutServe-SLDN.

MR. PERKOWSKI: Good morning, Your Honor.

THE COURT: Good morning.

All right. Well, we have before us two motions. We have the defendants' motion to dismiss the complaint, and we have the plaintiffs' motion for a preliminary injunction. You-all have submitted extensive paperwork, which we have read very carefully in chambers.

I did want to make sure that we are 100 percent clear on certain things, and so, Mr. Norway, let me ask you a couple of questions. In your brief, you refer to the, I'm going to call it the large black volume, as the administrative record --

MR. NORWAY: Yes, Your Honor.

THE COURT: -- but that's really not an accurate description of that volume, is it?

I mean, traditionally, when I look at an administrative record, my understanding is those are the actual materials that were before the administrative body when it made whatever decisions are at issue. For example, a Social Security case, when I get the administrative record, what I'm getting are all the documents which the Social Security Administration looked at in reaching its decision to, let's say, deny disability, right?

MR. NORWAY: (Nodding head.)

THE COURT: And then if there are additional -- normally there wouldn't be anything additional that the Court would be looking at in that kind of an administrative review, all right?

MR. NORWAY: (Nodding head.)

THE COURT: As I looked at the black volume, it has things other than the administrative, what I would call the administrative record that you are nevertheless calling administrative record items.

MR. NORWAY: So, Your Honor, I'm trying to understand --

THE COURT: Yeah.

MR. NORWAY: -- what you're referring to when you say the "black volume."

We had -- we filed a public appendix with our combined motion and an appendix -- or, I'm sorry, combined motion in opposition and then also a sealed portion, and that sealed portion contained two what we were calling the administrative records for the two --

THE COURT: Individual plaintiffs.

MR. NORWAY: -- Disability Evaluation System proceedings, one for Roe and one for Voe.

That's what we're referring to when we call it the administrative record.

THE COURT: Okay. All right. Then I think we are clear about that, all right.

I want to know then in terms of motion to dismiss, if there's anything that you want to add to the papers you've submitted to the Court.

MR. NORWAY: No, Your Honor.

THE COURT: All right, let me hear from the plaintiffs then. Is there anything that you feel was not adequately focused on in your responses that you want to highlight for the Court?

MR. SCHOETTES: No, Your Honor.

THE COURT: Okay. So you're relying on your briefs on that, okay.

Then in terms of the motion for preliminary injunction, let me ask the plaintiffs on this, you've really asked for two sets of relief. You first of all have asked for an injunction that basically keeps the status quo as to Mr. Voe and Mr. Roe and also as to the four, at least the four individuals within OutServe, if not others, but you've also asked that the Court also enjoin any denial of training or assignments or whatever, and I want you to talk to me a little bit more about that aspect.

Is there any concern that you have that if the Court were to grant the preliminary injunction, that there might be some problems in that respect for any of the plaintiffs?

MR. SCHOETTES: Our concern, Your Honor, is that during the pendency of the case, that the plaintiffs will not be permitted to engage in the activities that they would have been allowed to engage in had they simply not been separated or engaged in the process of separation based on their HIV status.

THE COURT: Can you give me an example of what you think one of the plaintiffs might be on the verge of getting, like training in, you know, I don't know, some sort of computer system or some sort of whatever?

MR. SCHOETTES: Yes. So there are things that, as

you are noting, kind of are held in limbo. One of those things has been their -- the process of reenlistment. They have not been permitted to engage in that process during -- since they've been placed in the DES, the Disability Evaluation System.

So -- and then as a part of that, at least one of them has agreed to -- has requested retraining into a different position, so that's the type of thing that we would be concerned would not be allowed to proceed in the process.

THE COURT: Now, if -- is that Mr. Roe or Mr. Voe who wants the retraining?

MR. SCHOETTES: I'm sorry, I have misstated. So both of them --

THE COURT: Both of them.

MR. SCHOETTES: -- are seeking retraining.

THE COURT: And the positions for which they would be retrained, would they become less likely to be deployed to CENTCOM?

MR. SCHOETTES: Yes, Your Honor.

THE COURT: That's my understanding. I thought there was just one, but now it's both plaintiffs.

Now, I know we're talking about the Air Force, and my understanding from some of the defendants' papers is that there are some HIV-positive members of the Air Force, and make sure I'm correct about this, who have been found to be in positions

that are so unlikely to be deployed to CENTCOM that they have not been put in a position of being directed to be removed from the service.

Is that a correct understanding of the record?

MR. SCHOETTES: That is my understanding as well, Your Honor.

THE COURT: Okay.

MR. SCHOETTES: And I think that our claim in part is based on that difference in the way that they are treating -- this inconsistent way in which they are treating people who have the same limitations on their deployment who just happen to be in a position that is more likely to deploy versus a position that is less likely to deploy, but it has nothing actually to do with that person's abilities to perform their duties. It's just completely contingent on which position they happen to be in.

THE COURT: All right. Mr. Norway, it's rather clear from the -- some of the exhibits you've actually included in your, in your filings, including what appear to be communications with members of Congress about how HIV-positive service people are being treated by the military, first of all, is that an annual report that has to be made, or is it made every couple of years? I know there was one in 2014, and I think there's a 2018 one that I saw in the record as well.

MR. NORWAY: Yes, Your Honor. My understanding is,

is that one of the National Defense Authorization Acts required the submission of the 2014 report, and then subsequently, Congress asked for an additional report, and that resulted in the 2018 report. So it is not an annual report. It was a part of the, the NDAAs.

THE COURT: All right. And is it correct, have I adequately looked at this record in this respect, it looks to the Court as though the plaintiffs submitted a fair amount of relatively current medical evidence in the form of declarations from at least two very, very experienced doctors from Johns Hopkins specializing in the area of infectious diseases, and HIV in particular, and I didn't see any type of medical evidence in the record that you-all submitted.

Did you -- did I miss something? I mean, there were a couple of articles, but they were first of all just articles, and they were fairly old compared to what the current declarations were, but did you have any declarations from medical people in your record?

MR. NORWAY: Yes, Your Honor. There were two declarations in our record. One was from a Ms. Martie Soper, who is not a medical doctor.

THE COURT: That's right.

MR. NORWAY: And then immediately after that, and I think it's at about 420, maybe 421 in the record, there is a declaration from Dr. Cron.

THE COURT: Yeah, but, I mean, neither of those people are what we would call, you know, current practitioners specializing in infectious medicine or HIV.

MR. NORWAY: No, but Dr. Cron is the waiver authority, so he is the medical doctor who, who makes the decision about who can --

THE COURT: What's his background? I don't think that was in -- I didn't, I didn't recall seeing a CV for him. Is that in the record?

MR. NORWAY: That is not in the record, Your Honor, and I don't recall off the top of my head.

THE COURT: All right. You know, I mean, obviously, in this record, there's a significant amount of information from the plaintiffs that would seem to throw doubt on the medical and scientific accuracy of many of the statements in Mr. Cron's affidavit -- in Dr. Cron's affidavit.

MR. NORWAY: The, the key point, Your Honor, is that the military, when it makes its decisions, don't -- they don't make -- they make a risk decision that is based on, on what would happen in the worst case scenario, and the worst case scenario with these individuals is if those individuals are not compliant with their medications.

So if they don't have their medications, if they lose them, if they're destroyed, or if they're separated from their medications, then as the Mr. -- as the Dr. Fauci article that

you referred to states, that if somebody who has -- who is taking therapy who ceases the therapy will, will have HIV come back.

THE COURT: But it takes -- but I think that evidence was it doesn't happen overnight. It takes at least a couple of weeks before the viral load begins to become a bit more noticeable, and it's apparently several weeks if not a couple of months before there's actually any symptoms that might start to arise.

MR. NORWAY: So that's, that's, I think -- it varies individually. It varies depending on the medication that's used. That article itself, I think the earliest had nine days. The article mentioned that it was -- that some of the, some of the individual patients had a much longer time period before viremia came back, but the point is is that viremia comes back, and that is the concern and the risk that the military is taking into account.

THE COURT: And certainly, I mean, people who have chronic medical conditions being put in a battlefield situation in the most extreme forms of, you know, military service, there's no question the military has genuine -- it's absolutely correct that they can -- should be concerned about that.

The problem in this case, though, is whether there's special treatment being done with HIV people different from any other group of medically impaired folks, for example,

asthmatics. Now, my understanding is asthmatics can serve in CENTCOM regions. Is that correct?

MR. NORWAY: I am not sure about asthma, Your Honor. There's another example that I can think of: sleep apnea. If an individual has sleep apnea to the extent where they actually need a machine at night, because CENTCOM can't guarantee a constant supply of electricity to that machine, those individuals wouldn't be granted a waiver, so they might be able to stay in the military even though they have sleep apnea, and that can be resolved using that particular device. They wouldn't be allowed to go to CENTCOM area of operations.

THE COURT: But you just said they could be allowed to stay in the military. I mean, isn't the problem again that our plaintiffs are facing is that because of the deployability restrictions, they have been told they cannot stay in the military?

That's the only reason from this record that I have before me why either Roe or Voe or the four individuals who've been -- who I understand are in the exact same position from OutServe are facing being removed from the military.

MR. NORWAY: Your Honor, the, the Air Force has consistently treated the individuals with HIV just as any other individual with a chronic medical condition. In those circumstances, those individuals are directed to the DES system, the Disability Evaluation System.

That system looks at four particular standards. One of them is military tasks. Another one would be the ability to take the physical examination -- or the physical test. The third is deployability, and the fourth is whether or not there are any special requirements to their jobs.

And as the declaration -- as Martie Soper, Ms. Soper says in her declaration, for individuals who have asymptomatic HIV infections, generally that DES system will -- looks at the deployability aspect of them, of that individual, or whether they have any special duties, so whether their job has special duties that would be -- they would be disqualified from performing.

THE COURT: All right. But in the case of the people we're talking about, the actual individuals anyway, I didn't see any discussion about their job duties being a problem.

MR. NORWAY: And that is correct. So the --

THE COURT: The only issue for these plaintiffs is deployability.

MR. NORWAY: For Roe and Voe, their decisions were based on the deployability.

THE COURT: Wasn't it for the other four, who I'm told are in exactly the same position from OutServe?

MR. NORWAY: So there were -- there were, I believe, six individuals who went all the way through the process, through the Secretary of the Air Force Personnel Committee --

sorry, ten. Four of them were returned to duty. One individual had, had an uncontrolled medical condition, so he was released for that reason; one individual had special duties; and then four individuals are sort of in this bucket.

THE COURT: From, from OutServe?

MR. NORWAY: Correct. That they were, they were -- there was a decision to discharge them based on their inability to deploy to CENTCOM and their particular job duties. And I think that's the point that's, that's worth focusing on here, Your Honor. It's not just that they can't deploy. It's where are the individuals, what does the individual do, what is their job description, is that job likely to require a deployment into a CENTCOM area of operations, and where are they in their career progression. Because as -- and this is in the declaration of Martie Soper as well -- the airmen who are earlier in their career are more likely to deploy than airmen who are later in their careers.

So there were -- I think there's more consideration and analysis other than just they're HIV-positive; they can't deploy. There are other factors that boards consider.

THE COURT: All right. Does the plaintiff -- counsel, do you want to respond to any of that argument?

MR. SCHOETTES: I would, Your Honor. So I want to make clear on this last point that when you cannot deploy only because you have HIV and you are being separated because you

can't deploy, you are being separated solely because you have HIV. That is the point that we are making. That is what is squarely against the Air Force regulations, and whatever semantic jumps we want to do around that, it's the piece that the government really can't get around.

I want to let the Court know that what the government is representing is the way that they're handling people living with HIV today, treating it the same as any other chronic or manageable condition, as they say, is actually different and changed, and this is in the declaration of Martha Soper, as of 2016, and there has been a progression of the way that the government is handling people living with HIV.

As it also says in that declaration, under these exact same policies, all people living with asymptomatic HIV have been returned to duty up until this change in their policy.

At first, that policy stated that people were living with HIV who were asymptomatic or people living with HIV who are servicemembers would only be referred to the DES, Disability Evaluation System, if it was medically necessary. Now, under the policy that they recently iterated in September of this past year, they're actually encouraging the evaluators to use other criteria other than the medical necessity to refer these people to DES and to therefore end up discharging them from the military service.

THE COURT: So part of your argument has also been that just referring asymptomatic HIV-positive servicemembers to the DES process is itself possibly arbitrary and capricious.

MR. SCHOETTES: That is correct, Your Honor. Because there's nothing in the regulations that calls for that kind of evaluation to be made for someone who has no disability. And it really throws us into this very strange space where we have boards that are designed to assess medical situations and a person's health are then apparently assessing this, this piece about deployability, which was never articulated as a separate reason why people living with HIV could be separated.

And as I said, those are one and the same thing. Every airman living with HIV has limited deployability. They're all the same in that regard.

So applying this criteria that they call upon from 1332.18, DoDI 1332.18, actually if you were evaluating airmen using that criteria, which is you either have limited deployment or you do not, they would all fall into the same boat. So it doesn't justify the differential treatment that was just described that they are imposing on these ten individuals that were before the board deciding that.

And then I just want to also point out that I think you've hit on an important point, that the government is not, as far as we know, discharging people with sleep apnea or other conditions that make it difficult to deploy to the CENTCOM

region. As far as we know, this is -- has solely been all of these individuals living with HIV who are being separated because they have limited deployment, and the CENTCOM area, while it may also be difficult for people with sleep apnea or asthma to deploy to that area, they may have to get a waiver, they're not being separated based on that.

THE COURT: And this is the type of evidence that down the road through the discovery process would give us the full record to see whether or not, you know, ultimately there is a basis to grant final judgment in your favor or not.

MR. SCHOETTES: Yes, Your Honor.

THE COURT: All right. All right, I did want to ask the government -- Mr. Norway, you're back in the hot seat -- what changed from 2016? Why was there this change in approach to asymptomatic HIV-positive servicemembers?

MR. NORWAY: So the -- I think the change itself only occurred in the Air Force, Your Honor, and that's the only information that I have.

THE COURT: All right. Well, we're only dealing with the Air Force right now, yeah.

MR. NORWAY: The, the short answer is I don't know. There was a, an evaluation of how -- and this is in Ms. Soper's declaration -- beginning about -- and I could have the dates slightly off -- 2016 or 2017, there was an evaluation of how the DES system, how the Air Force was processing these

individuals.

There are thousands and thousands of DES cases each year, and I think Ms. Soper refers to those in her, in her declaration. So this is not just something that happens just for this one medical condition. It happens for many medical conditions.

THE COURT: All right. Well, we'll obviously look at this case with some care, but I -- I mean, I have been looking at it for some time. I'm going to tell you that I'm going to deny the motion to dismiss the complaint. The Court is going to be issuing an injunction that will protect the plaintiffs from any imminent change in their status because, in fact, this is a situation, as I understand it, Mr. Voe faces a February 25 deadline and Mr. Roe faces a March 29 deadline.

When a party asks for, you know, injunctive relief, one of the things you look at is, you know, the likelihood of success on the merits. I think that the plaintiffs have at this point with the evidence that's in the record, in my view, satisfied me that there is sufficient evidence at this point that there is a likelihood of success on the merits as to the fact that this could be a violation of the APA in terms of an arbitrary and irrational policy that is not soundly based on medical findings.

One of the things that concerns me about -- and I'll go into detail on this in my opinion -- but I looked at the

Cron affidavit, which I think is very significant since he is the decision-maker, he's the man who gives the waivers, and he says in paragraph -- I mean, he makes various statements characterizing, you know, complex medical needs and all this sort of thing, and then I've got counterevidence from the plaintiffs that, you know, HIV-positive people who have their conditions under control as these plaintiffs do take one pill a day.

There are all kinds of chronic diseases that take one pill a day: high blood pressure, diabetes actually probably takes a lot more, so we're not talking about highly specialized medical personnel. Again, the evidence from the plaintiffs -- and again, down the road, there may be evidence that contradicts that, but I don't have that in this record -- talk about the fact that it's just a simple blood test to keep monitoring the, the viral loads of these folks. So we're not talking about anything complicated, in fact, probably less complicated than the sleep apnea business.

But what concerned me the most was paragraph 11 of the Cron affidavit, where he says in his tenure, "I have not granted a deployment waiver for an HIV-positive servicemember." I mean, that's a very categorical statement. And again, my understanding if you read the regulations that everyone's supposed to be operating under, these are supposed to be individualized assessments.

You know, servicepeople are valuable assets. Both of the named plaintiffs, because they're the only two I really know a lot about from the papers, are men who want to make their careers out of the military. They've already served honorably, and there's no other, from what I've got in the record before me, no other problems with their status. Their commanders both recommended that they be retained. One of the plaintiffs actually has served in the Middle East and volunteered to go back there. These are the kind of people that the military, it seems to me, you know, do want to keep in the service.

And so my job is not, of course, to make military decisions. My job as a judge is to make sure that in making their decisions, the military has complied with the law, that the Armed Forces are still part of the U.S. government, and there are still, although they get special treatment, you know, certain principles, including, you know, the APA rules do apply, and at least on the record that's before me, I'm satisfied that the plaintiffs have made a sufficient showing of likelihood of success on the merits.

In terms of irreparable injury to the plaintiffs, it's very significant. They would lose their careers, and they would also have, as they've pointed out, because society still looks upon people who are HIV-positive with a certain degree of negativity, that they would have that on their records because

part of the findings by the military is that they're unfit for medical -- for military service.

I don't see any real harm to the government or to the defendants in a preliminary injunction, which is just a status quo. It holds these people in the position that they're currently in, and certainly public policy is well served by keeping qualified people in the service and also by ensuring that all branches of government function appropriately and in compliance with the law.

So I'm going to grant that relief. We're going to try to get this out today because time is a little bit tight for you-all, but that's my ruling.

So with that being the case now, we're going to move into the discovery phase of this case. I also always even in a complex case like this recommend that wise counsel see if there's any way of resolving the case, and that's something that everybody ought to think about as well, but especially if the class of individuals we're talking about is that small. I mean, I've heard the number ten. I don't know how many are actually in OutServe, and there may be a larger group there, and that's an issue that down the road we're going to have to address, I suspect, but if it's only a group of ten, then it might be much easier to work it out; I don't know.

But in any case, I don't think -- have we issued a discovery order in this case yet?

MR. SCHOETTES: We have, Your Honor.

THE COURT: All right. Have you started discovery?

MR. SCHOETTES: We combined it with the Harrison case, and so --

THE COURT: That's right. That's right.

MR. SCHOETTES: -- we're proceeding through discovery in both cases.

THE COURT: All right, that's fine. And I have the same counsel on both cases; is that correct?

MR. NORWAY: Yes, Your Honor.

THE COURT: All right. Well, maybe -- again, that's right, we want to try to keep that as economical as possible. All right. That's the Court's ruling, all right? Very good, we'll recess court for the day.

MR. NORWAY: Thank you, Your Honor.

(Which were all the proceedings had at this time.)

CERTIFICATE OF THE REPORTER

I certify that the foregoing is a correct transcript of the record of proceedings in the above-entitled matter.

/s/
Anneliese J. Thomson

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

RICHARD ROE, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	1:18-cv-1565 (LMB/IDD)
PATRICK M. SHANAHAN, in his official capacity as Acting Secretary of Defense, et al.,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION

Plaintiffs Richard Roe ("Roe") and Victor Voe ("Voe")[1] are members of the United States Air Force who have been diagnosed with the human immunodeficiency virus ("HIV") and who face imminent separation from service. Roe and Voe—together with plaintiff OutServe-SLDN, Inc. ("OutServe"), an organization representing the interests of veterans, active-duty servicemembers, and civilian employees of the U.S. Department of Defense ("DoD") who are LGBTQ+ or HIV positive—bring this action for declaratory and injunctive relief against the Secretary of Defense, the Secretary of the Air Force, and the DoD. Plaintiffs' complaint contains five counts. Count I, asserted against all defendants, alleges that defendants' policies with respect to the deployment and separation of HIV-positive servicemembers, on their face and as applied to Roe and Voe, violate the equal protection component of the Fifth Amendment's Due Process Clause. Counts II and III, which are asserted only against the Secretary of the Air Force, allege that the decisions to separate Roe and Voe were arbitrary and capricious, an abuse of discretion,

[1] Roe and Voe are proceeding pseudonymously. To protect their identities, all documents containing identifying information have been filed under seal, and redacted versions have been made part of the public record.

and contrary to law in violation of the Administrative Procedure Act ("APA"). Finally, Counts IV and V allege that several of defendants' policies "are based on outdated thinking that does not comport with the current state of HIV medical science" and that defendants' failure to update those policies amounts to an independent violation of the APA.[2]

Plaintiffs have moved for a preliminary injunction preventing Roe and Voe, along with similarly situated servicemembers, from being discharged[3] because of deployment restrictions due to their HIV status. Plaintiffs argue that injunctive relief is necessary to preserve the status quo pending final disposition of their constitutional and administrative law claims. Defendants oppose plaintiffs' motion and have moved to dismiss the complaint for lack of subject matter jurisdiction, arguing that plaintiffs' claims are premature and nonjusticiable; that plaintiffs are not entitled to injunctive relief; and that the scope of any relief granted must be limited to Roe and Voe.[4] The parties have fully briefed and argued their motions.[5] For the reasons stated below,

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[2] Count IV is asserted against the DoD and the Secretary of Defense; Count V is asserted against the Secretary of the Air Force.

[3] The terms "discharge" and "separation" are used interchangeably throughout this Opinion.

[4] Defendants' memoranda have mostly focused on the named plaintiffs and have not devoted significant attention to OutServe, the institutional plaintiff asserting the interests of its HIV-positive members who, like Roe and Voe, face imminent separation. Plaintiffs, too, have blurred the lines between Roe's and Voe's claims on the one hand and OutServe's on the other. For the most part, the parties' motions may be resolved by focusing on Roe and Voe; however, where appropriate, reference is also made to similarly situated members of OutServe.

[5] The parties' substantive written submissions consist of the Memorandum in Support of Plaintiffs' Motion for a Preliminary Injunction [Dkt. No. 34] ("Pls.' Memo."); the Memorandum in Support of Defendants' Motion to Dismiss and Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction [Dkt. No. 50] ("Defs.' Memo. & Opp'n"); Plaintiffs' Opposition to the Motion to Dismiss and Reply in Support of Their Motion for a Preliminary Injunction [Dkt. No. 60] ("Pls.' Opp'n & Reply"); and the Reply in Support of Defendants' Motion to Dismiss [Dkt. No. 70] (Defs.' Reply."). Oral argument was held on February 15, 2019.

defendants' motion to dismiss will be denied, and plaintiffs' motion for a preliminary injunction will be granted in part and denied in part.

I. BACKGROUND

A. Factual Background[6]

1. Richard Roe

Roe enlisted in the Air Force in 2012. Compl. for Declaratory & Injunctive Relief [Dkt. No. 1] ("Compl.") ¶ 57. He enjoyed early signs of success, including being promoted to Senior Airman ahead of schedule and successfully testing for Staff Sergeant, a noncommissioned officer rank, on his first try. Id. ¶ 58. Roe hoped to make the Air Force his lifelong career and one day commission as an officer. Id. ¶ 74.

Roe's upward trajectory was halted in October 2017, when he was diagnosed with HIV while on active duty. Compl. ¶ 59. He began antiretroviral treatment immediately. Id. That treatment requires him to take one pill per day; the pills are stored in an ordinary pill bottle, and his prescription is refilled every 90 days. Id. Ever since he began treatment, Roe's "viral load"—the number of copies of the HIV virus per milliliter of his blood—has registered as "undetectable."[7] Id. ¶¶ 51, 59. He alleges that because of his successful treatment, he remains physically and mentally capable of continuing to serve in the Air Force. See id. ¶¶ 72-75.

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[6] The following facts are drawn from the allegations in the complaint and from official documents appended to the parties' memoranda, which the Court may consider without converting defendants' motion to dismiss into one for summary judgment. Kerns v. United States, 585 F.3d 187, 192-93 (4th Cir. 2009).

[7] An untreated person with HIV may have a viral load in the thousands or even above one million. A viral load under 200 is classified as "virally suppressed"; a load under 48 to 50 is considered "undetectable." See Compl. ¶ 51.

Because Roe had tested positive for HIV, Air Force regulations required that he "undergo [a] medical evaluation for the purpose of determining [his] status for continued military service." Air Force Instruction ("AFI") 44-178, § 2.4, at A298-99.[8] In late November 2017, he received a Duty Limiting Condition Report restricting his deployability pending a Medical Evaluation Board's ("MEB") determination of his fitness for duty. A568. The MEB was convened in January 2018. A554. Roe's commanding officer submitted an impact statement to the MEB affirming that despite Roe's diagnosis, he could "perform all duties without work-arounds, restrictions or limitations." A556. The commanding officer's recommendation was unambiguous: "[Roe] is a valued team member. Recommend retention." A557. The commanding officer made clear that his recommendation would not change even if Roe were to be put on an assignment limitation code that could restrict his deployability. Id. Several other servicemembers likewise submitted letters on Roe's behalf. A562-66. Also before the MEB was a physician assistant's report prepared in January 2018 after a physical examination of Roe. The physician assistant wrote that although Roe would require ongoing antiretroviral treatment, he was asymptomatic and complication-free. A586-88. In response to a question asking whether "any of [Roe's] HIV-related illnesses or complications affect his . . . ability to work," the physician assistant selected "No." A588. An earlier report by an Air Force physician, also part of the record before the MEB, recommended that Roe be returned to active duty. A574.

The MEB did not order Roe retained and returned to duty. Instead, it opted to refer Roe's case to an Informal Physical Evaluation Board ("IPEB"). A554. The IPEB issued its findings and

[8] References in the form "A___" are to the documents attached to defendants' motion to dismiss. Some of those documents were filed under seal [Dkt. Nos. 55-58], and publicly available redacted versions have been filed as well [Dkt. No. 67].

recommendation on February 22, 2018. A549. Although the IPEB's report "acknowledge[d] the commander's recommendation for retention and statement that [Roe] is able to perform his daily in-garrison duties," it also asserted that Roe's condition "is subject to sudden and unpredictable progression"[9] and would "result in deployment restrictions that prevent him from being fully worldwide qualified." A550. As a result, the IPEB concluded that Roe's HIV status was "unfitting" and "[in]compatible with the fundamental expectations of military service." Id. The IPEB recommended that Roe be discharged from the Air Force. A549.

Roe appealed the IPEB's decision to the Formal Physical Evaluation Board ("FPEB"). Compl. ¶ 65. As part of the formal record of his appeal, Roe submitted a letter from the director of the HIV medical evaluation unit and infectious disease service at a military medical center. In the letter, the director opined that Roe "has no physical limitation that would prevent him from conducting his duties" and recommended that he be returned to active duty. A484. Roe also submitted letters from fellow servicemembers in support of his retention, a recent fitness report reflecting good scores, and commendations he had received during his time in service. See A482-548. A formal hearing was held before the FPEB in early April 2018. A481. The hearing lasted less than 30 minutes, and the FPEB affirmed the IPEB's decision roughly three hours later. Compl. ¶¶ 66-67. The FPEB, like the IPEB before it, recognized that Roe was successfully being treated and was asymptomatic. A481. It also acknowledged the commanding officer's recommendation that Roe be retained as well as Roe's "record of performance during his five years of military service and the numerous letters of support for his retention." Id. Nonetheless, the FPEB stated that under military regulations, Roe's HIV status was "disqualifying for

[9] The IPEB did not point to any evidence or documents in the record before it to support this assertion.

deployment" to the Central Command ("CENTCOM") area of responsibility,[10] which "would have [a] significant effect on his career progression and place [an] increased burden on others within his career field." Id. Accordingly, the FPEB concluded that Roe's condition "is unfitting for continued military service" and reaffirmed that he should be discharged. A480-81 (emphasis in original).

Roe appealed the FPEB's findings and recommendation to the Secretary of the Air Force, arguing that his condition "is simple to manage and does not place an undue burden on the Air Force." A471. He also argued that the FPEB's analysis was inconsistent with applicable Air Force regulations, which provide that "HIV seropositivity alone is not grounds for medical separation" and that HIV-positive servicemembers "who are able to perform the duties of their office, grade, rank and/or rating . . . may not be separated solely on the basis of laboratory evidence of HIV infection."[11] Id. Finally, he challenged the assertion that his condition rendered him nondeployable, asserting that under the applicable regulations, HIV renders a servicemember nondeployable only "with the presence of progressive clinical illness or immunological deficiency"[12]—both of which he claimed were absent in his case. A471-72. Counsel was also appointed to represent Roe before the Secretary. Roe's counsel argued that the IPEB and the FPEB were "feign[ing] fealty to the DoD (and by extension Air Force) policy on retaining HIV[-]infected members, but us[ing] the bludgeon of world-wide qualification to effectively bash the policy aside." A465.

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[10] CENTCOM is "a theater-level Unified Combatant Command with responsibility for military operations across North Africa, Central Asia, and the Middle East, including Iraq and Afghanistan, within the Department of Defense." A423.

[11] See AFI 44-178, § 2.4.1, at A299; id. § A9.1.1, at A329.

[12] See Department of Defense Instruction ("DoDI") 6490.07, enclosure 3, § e(2), at A97.

The deputy director of the Secretary of the Air Force Personnel Council ("SAFPC"), acting on authority delegated by the Secretary of the Air Force, rejected Roe's appeal on November 7, 2018. The decision, which refers to Roe as "the member," states in relevant part:

> [Roe's] case was considered by the Air Force Personnel Board (AFPB), which made a recommendation regarding its disposition. The following rationale is provided for the final decision in this case. The Board considered the member's contention that he is fit and should be returned to duty. The Board noted the member has been compliant with all treatment, is currently asymptomatic, and has an undetectable [HIV] viral load. Additionally, he is able to perform all in[-]garrison duties, has passed his most recent fitness assessment without any component exemptions, and his commander strongly supports his retention. However, the Board noted the member's condition precludes him from being able to deploy world-wide without a waiver and renders him ineligible for deployment to the [CENTCOM] Area . . . , where the majority of Air Force members are expected to deploy. Deployability is a key factor in determining fitness for duty and the Board recognized the member belongs to a career field with a comparatively high deployment rate/tempo. Therefore, based on his inability to deploy and considering his current career point, the Board determined he is unfit for continued military service and shall be discharged with severance pay.

A460. Roe was advised that he had the "right to pursue further appeal" by applying to the Air Force Board for Correction of Military Records ("AFBCMR"). A462. He has not done so.

Roe is scheduled to be discharged from the Air Force on March 28, 2019. Pls.' Memo. Ex. A [Dkt. No. 44] ¶ 7. His term of service had been set to expire in mid-2018 but was twice extended as he underwent the medical evaluation and administrative appeals process. Compl. ¶ 74. But for his impending discharge date, Roe's term of service (considering the extensions he received) would have expired on June 25, 2019. Pls.' Memo. Ex. A [Dkt. No. 44] ¶ 6. He alleges that he intended to reenlist for an additional term of service but was prevented from doing so because of the separation process. Id.

2. Victor Voe

Voe enlisted in the Air Force in 2011. Compl. ¶ 77. He has served in several countries overseas and in 2014 was deployed to the Middle East. Id. ¶ 78. Like Roe, Voe is dedicated to

service in the Air Force. Indeed, after his first period of service in the Middle East, Voe voluntarily cut short the "dwell time" between deployments so that he could return for a second tour ahead of schedule. Id.

Voe was diagnosed with HIV in March 2017. Compl. ¶ 79. He immediately began antiretroviral treatment, and since August 2017 his viral load has remained undetectable. Id. Voe takes two pills, at the same time, per day; those pills are stored in ordinary pill bottles and are refilled every 90 days. Id. ¶ 80. Voe claims that because of the treatment, he is asymptomatic and wishes to continue serving.

After his diagnosis, Voe's case proceeded in lockstep with Roe's. Voe's deployability was restricted, and his case was referred to an MEB for initial evaluation. See A768. Voe's commanding officer prepared an impact statement for the MEB in which she stated that Voe was "fully capable of performing any activity/function" necessary for his career field. A763. The commanding officer endorsed Voe unreservedly: "Member superiorly performs all primary duties and has also volunteered with enthusiasm for several on/off base organizations/ function[s]. He is overall a valuable [Air Force] asset. Retain." A764. The commanding officer indicated that her recommendation would not change even if Voe were to be placed on an assignment limitation code that could limit his deployability. Id.

The MEB found that Voe's HIV status made his "qualifications . . . for worldwide duty questionable" and referred his case to an IPEB. A761. The IPEB acknowledged the recommendation of Voe's commanding officer but found that Voe's

> medical condition prevents him from reasonably performing the duties of his office, grade, rank or rating; represents a medical risk to the health of [Voe] or the health/safety of others with continued service; is subject to progression; requires frequent follow-up with a medical specialist; and limits [Voe's] ability to meet mobility requirements.

A758.[13] Accordingly, the IPEB concluded that Voe's condition was "unfitting" and "incompatible with the rigors of military service" and recommended that he be discharged. A757-58.

Voe appealed to an FPEB. His formal hearing before the FPEB lasted only twenty minutes. Compl. ¶ 84. Less than an hour after the hearing had concluded, the FPEB affirmed the IPEB's recommendation that Voe be discharged. Id. The FPEB acknowledged that Voe's "condition is welled [sic] controlled" and that he was asymptomatic. A756. But the FPEB found that because Voe would need "frequent follow-up[s] with a specialist"[14] and had been classified as nondeployable, his HIV condition made him "unfitting for continued military service." Id. (emphasis in original).

Voe appealed to the SAFPC, which (acting on authority delegated by the Secretary of the Air Force) rejected the appeal on November 7, 2018—the same day Roe's appeal was rejected.[15] A748. The reasons given for denying Voe's appeal were identical to those provided in Roe's case:

> [Voe's] case was considered by the Air Force Personnel Board (AFPB), which made a recommendation regarding its disposition. The following rationale is provided for the final decision in this case. The Board considered the member's contention that he is fit and should be returned to duty. The Board noted the member has been compliant with all treatment, is currently asymptomatic, and has an undetectable [HIV] viral load. Additionally, he is able to perform all in[-]garrison duties, has passed his most recent fitness assessment without any component exemptions, and his commander strongly supports his retention. However, the Board noted the member's condition precludes him from being able to deploy world-wide without a waiver and renders him ineligible for deployment to the

[13] The IPEB did not identify any scientific evidence or documents in the record before it to support these conclusions.

[14] Again, the FPEB did not cite evidence in the record before it supporting this assertion.

[15] It appears the SAFPC disposed of many HIV-positive servicemembers' appeals on the same day and with virtually identical statements of reasons. In addition to Roe and Voe, at least two other members of OutServe had their appeals rejected that day. See Pls.' Memo. Ex. C1 [Dkt. No. 40-1]; id. Ex. C4 [Dkt. No. 40-4].

> [CENTCOM] Area . . . , where the majority of Air Force members are expected to deploy. Deployability is a key factor in determining fitness for duty and the Board recognized the member belongs to a career field with a comparatively high deployment rate/tempo. Therefore, based on his inability to deploy and considering his current career point, the Board determined he is unfit for continued military service and shall be discharged with severance pay.

A747. Voe was advised of the right to appeal to the AFBCMR, A749, but has not done so.

Voe's term of service was set to expire in early 2018 but was extended during the pendency of his physical evaluation and administrative appeals process. Compl. ¶ 88. Voe has been unable to apply for reenlistment for another term of service, id., and is set to be discharged from the Air Force on February 25, 2019, Pls.' Memo. Ex. B [Dkt. No. 44-7] ¶¶ 20-21. But for Voe's impending discharge, his term of service (taking into account the extensions he received) would extend until June 2019. Id. ¶ 20.

3. The Human Immunodeficiency Virus (HIV)

HIV epidemiology has undergone drastic changes since the disease first came to the public's attention in the 1980s. Compl. ¶ 49. The first sea change involved the means of treatment. Beginning in the mid-1990s, antiretroviral medications were developed that, if taken consistently, can effectively reduce a patient's viral load to zero. Id. ¶¶ 50-51. Those medications have negligible side effects and can prevent the type of immunological deficiencies and opportunistic infections typically associated with HIV and the Acquired Immunodeficiency Syndrome ("AIDS"). Id. ¶¶ 51-52. HIV remains incurable but is no longer a death sentence. When diagnosed promptly and treated appropriately, it "is a chronic, manageable condition" that does not substantially reduce a person's life expectancy. Id. ¶ 53.

Another major development in the science and study of HIV relates to methods of transmission. HIV is not as easily transmitted as many people believe. For example, the highest-risk sexual activity—engaging in an act of receptive anal sex with an untreated HIV-positive

person without using a condom or other means of prophylaxis—carries a risk of transmission of only 1.38%. Compl. ¶ 54. Other sexual activities pose transmission risks ranging from 0% to 0.08%. Id. Apart from sexual activities, only sharing needles, blood transfusions, and perinatal exposure pose a nonnegligible risk of transmission. Id. ¶ 55. According to the Centers for Disease Control and Prevention ("CDC"), HIV transmission through other means such as biting or accidental contact with bodily fluids "is technically possible but unlikely and not well documented." Id. Moreover, when an individual's viral load has been effectively suppressed by antiretroviral treatment, the risk of transmission is essentially reduced to zero. Id. ¶¶ 54-55.

B. Regulatory and Administrative Background

An intricate web of regulations, policies, and procedures govern the Armed Forces's treatment of servicemembers diagnosed with HIV. Understanding how those sources interact is crucial to analyzing the parties' arguments in this litigation.

1. DoD Regulations

Department of Defense Instruction ("DoDI") 6490.07 is designed to ensure that servicemembers "are medically able to accomplish their duties in deployed environments." DoDI 6490.07, § 1, at A87. The instruction sets out standards governing under what circumstances a medical condition will restrict a servicemember's deployability:

> DoD personnel with existing medical conditions may deploy . . . if all of these 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 harsh 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.) . . .

Id. § 4(b), at A89. A trained healthcare provider, in assessing whether a servicemember is deployable under these guidelines, must consider whether the condition "would put the individual at increased risk of injury or illness" or would be "likely to significantly worsen in the deployed environment." Id. enclosure 2, § 2, at A93.

DoDI 6490.07 also identifies certain medical conditions that categorically prevent individuals from deploying unless a waiver is granted. DoDI 6490.07, § 4(c), at A89. The listed conditions are divided into several types, including those that affect a servicemember's ability to receive immunizations or wear protective equipment, id. enclosure 3, § a, at A96; those that would require ongoing care or impair duty performance in a manner inconsistent with the nature or duration of the deployment, id. § b, at A96-97; those that cause sudden incapacitation, id. § c, at A97; pulmonary, sensory, cardiovascular, and mental-health disorders, id. §§ d, f-h, at A97-98; and infectious diseases, which are defined to include "[a]ctive tuberculosis or known blood-borne diseases that may be transmitted to others in a deployed environment" and "[a] diagnosis of human immunodeficiency (HIV) antibody positive with the presence of progressive clinical illness or immunological deficiency." Id. § e, at A97.

DoDI 6485.01 establishes the DoD's policies and procedures for "the identification, surveillance, and management of members of the Military Services infected with HIV." DoDI

6485.01, § 1, at A79. HIV-positive individuals are ineligible "for appointment, enlistment, pre-appointment, or initial entry training for military service." Id. § 3(a). Each military department must screen servicemembers periodically for evidence of HIV infection. Id. § 3(b). Active-duty servicemembers who test positive for HIV must be "referred for appropriate treatment and a medical evaluation of fitness for continued service in the same manner as a Service member with other chronic or progressive illnesses," and anyone "determined to be fit for duty will be allowed to serve in a manner that ensures access to appropriate medical care." Id. enclosure 3, § 2(c), at A85. Those found to be unfit for duty must be "separated or retired" pursuant to the Disability Evaluation System ("DES"). See id. § 2(e).

DoDI 1332.18 governs the DES, which is a multilevel system under the supervision of the secretary of each of the military departments. DoDI 1332.18, enclosure 3, § 1(a), at A15. The DES comprises (i) the MEB, a board of two or more physicians responsible for reviewing "all available medical evidence" and referring servicemembers with conditions "that will prevent them from reasonably performing the duties of their office, grade, rank, or rating" to the physical evaluation board process, id. § 2(a)-(b), (d), at A16; (ii) the IPEB, which is composed of two to three military personnel and which is responsible for making "initial findings and recommendations," id. § 3(a)-(b), (d)(1), at A18-19; and (iii) the FPEB, which is composed of (at minimum) a military officer, a medical officer, and a line officer, and which is responsible for conducting a formal hearing[16] in the event a servicemember challenges the IPEB's

[16] Servicemembers appearing before the FPEB have a number of rights, among which are the right to be represented by appointed counsel; the right to introduce witnesses, conduct cross-examination, and present evidence; and the right to access all records received by the FPEB before, during, and after the hearing. DoDI 1332.18, enclosure 3, § 3(h), at A19-20.

determinations, id. § 3(c), (d)(2). The instruction also requires each military department to provide appellate review of the FPEB's findings and recommendation. Id. § 3(*l*), at A21.

Finally, DoDI 1332.45—sometimes referred to as the "deploy or get out," or "DOGO," instruction,[17] e.g., Compl. ¶ 41—establishes the Armed Forces-wide policy that "[t]o maximize the lethality and readiness of the joint force, all Service members are expected to be deployable." DoDI 1332.45, § 1.2(a), at A62. Servicemembers who are deemed nondeployable for more than 12 consecutive months will be evaluated for retention, referral into the DES, or processing for administrative separation. Id. § 1.2(b). DoDI 1332.45 tempers this seemingly categorical rule in several ways. It gives the secretary of each military department the discretion to retain nondeployable servicemembers if doing so is found to be "in the best interest of the Military Service." Id. § 2.4(b)(1), at A64.[18] Additionally, "Service members with a medical condition that requires additional medical screening, or Combatant Command approval prior to deployment outside the continental United States, will be categorized as Deployable with Limitations." Id. § 3.3, at A66. Medical conditions triggering the "deployable with limitations" classification include those "referred to in DoDI 6490.07," id.—which, as discussed above, identifies conditions, including HIV under certain circumstances, that preclude deployment without a waiver.[19]

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[17] DoDI 1332.45 cancelled and replaced an earlier memorandum issued in February 2018 by the Office of the Under Secretary of Defense for Personnel and Readiness. See A59. Many felt that under the terms of the February 2018 memorandum, all servicemembers living with HIV would be classified as nondeployable and subject to automatic separation. See Compl. ¶ 12.

[18] The secretary also has discretion to initiate immediate separation processing, even if the servicemember in question has not been nondeployable for 12 consecutive months, if "the Military Service determines there is a reasonable expectation that . . . the Service member will not become deployable" in that time period. DoDI 1332.45, § 2.4(b)(3), at A64.

[19] DoDI 1332.45 does not otherwise define or explain the significance of the classification "deployable with limitations." An August 2018 report prepared by the Office of the Under Secretary of Defense and sent to Congress clarifies that "members with HIV infection may be considered deployable with limitations" because "[a]ll Services currently permit HIV positive

2. Air Force Regulations

Each military department has its own set of regulations and policies with respect to the treatment of HIV-positive servicemembers. The Air Force's main policy is set out in AFI 44-178, which implements DoDI 6485.01 with respect to the "identification, surveillance, and administration" of Air Force members diagnosed with HIV. A294. HIV-positive individuals may not enlist in the Air Force. AFI 44-178, § 2.2.1, at A298. Active-duty servicemembers who contract HIV after enlisting "must undergo medical evaluation for the purpose of determining status for continued military service." Id. § 2.4. Testing positive for HIV does not automatically trigger discharge: "HIV seropositivity alone is not grounds for medical separation or retirement." Id. § 2.4.1, at A299. But servicemembers living with HIV are limited to assignment within the continental United States, Alaska, Hawaii, or Puerto Rico, and may not be deployed beyond those territorial limits absent a waiver. See id. § 2.4.2.

Attachment 9 to AFI 44-178 sets out the Air Force's policy on the retention or separation of servicemembers diagnosed with HIV. It echoes the instruction's clear mandate, providing that servicemembers "who are able to perform the duties of their office, grade, rank and/or rating . . . may not be separated solely on the basis of laboratory evidence of HIV infection." Id. § A9.1.1, at A329. Instead, HIV-positive servicemembers are evaluated for retention or separation in accordance with the Air Force's DES. See id. § A9.2.1. Those who are retained are given an appropriate assignment limitation code and are returned to duty. Id. § A9.1.2.

The Air Force has released additional guidance documents on the treatment of HIV-positive servicemembers. For years, "nearly all cases of asymptomatic HIV resulted in a return to

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Service members to deploy for purposes other than combat or a contingency operation, or to be assigned for duty in certain overseas locations, subject to receipt of a waiver." A385.

duty." A416. That changed in 2017, when the Air Force issued a memorandum stating that any asymptomatic HIV-positive servicemember would be medically evaluated and possibly referred to the DES. A341. The memorandum reiterates AFI 44-178's policy that "[a]symptomatic HIV alone is not unfitting for continued service." Id. The Air Force reaffirmed that policy in a memorandum issued in June 2018, A338, and provided that all HIV-positive members would be evaluated for continued service in the same manner "as any Airman with a chronic and/or progressive disease," id. Under the terms of the 2018 memorandum, no servicemember may be referred into the DES unless specific criteria are met. Id. Those criteria are set out in DoDI 1332.18:

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

DoDI 1332.18, enclosure 3, app. 1, § 2(a), at A26. Most recently, in September 2018, the Air Force reemphasized that servicemembers with asymptomatic HIV are to be "retained or separated on a case by case basis" based on the factors listed in DoDI 1332.18. A339.

II. DEFENDANTS' MOTION TO DISMISS

Defendants have moved to dismiss plaintiffs' complaint on the ground that subject matter jurisdiction is lacking. First, they argue that plaintiffs have failed to exhaust administrative remedies, rendering this lawsuit premature. Second, they contend that plaintiffs' claims raise nonjusticiable questions of military policymaking committed solely to the discretion of the executive branch. Finally, they argue that the plaintiffs lack standing to seek relief.

Under Rule 12(b)(1) of the Federal Rules of Civil Procedure, an action must be dismissed if the court lacks subject matter jurisdiction. The plaintiff, as the party asserting jurisdiction, bears the ultimate burden of proving such jurisdiction. Adams v. Bain, 697 F.2d 1213, 1219 (4th Cir. 1982). If "a complaint simply fails to allege facts upon which subject matter jurisdiction can be based[,] . . . all the facts alleged in the complaint are assumed to be true and the plaintiff, in effect, is afforded the same procedural protection as he would receive under a Rule 12(b)(6) consideration." Id. But in the event of a factual dispute over the jurisdictional allegations in the complaint, the court may consider evidence outside the complaint "without converting the proceeding to one for summary judgment," id., and "the presumption of truthfulness normally accorded a complaint's allegations does not apply," Beck v. McDonald, 848 F.3d 262, 270 (4th Cir. 2017) (citation omitted).

A. Exhaustion of Remedies

Defendants first argue that in failing to appeal to the AFBCMR before filing their complaint, plaintiffs have attempted to "bypass" intraservice remedies "to obtain premature review in federal court." Defs.' Memo. & Opp'n 7. Generally, plaintiffs seeking to challenge military policy or decisions must exhaust "available intraservice corrective measures." Williams v. Wilson, 762 F.2d 357, 359 (4th Cir. 1985) (quoting Mindes v. Seaman, 453 F.2d 197, 201 (5th Cir. 1971)). Like all exhaustion requirements, this rule helps to avoid "premature interruption of the administrative process," McKart v. United States, 395 U.S. 185, 194 (1969), and allows "interested parties [to] obtain notice of the claims and have the potential to resolve disputes more quickly and inexpensively than may typically be accomplished through litigation," United States v. Unisys Corp., 178 F. Supp. 3d 358, 374 (E.D. Va. 2016) (citing Sydnor v. Fairfax County, 681 F.3d 591, 593 (4th Cir. 2012)). Plaintiffs respond by arguing that they are

not required to pursue any additional administrative remedies, that an appeal to the AFBCMR would be futile, and that the burdens of requiring further exhaustion here would far outweigh the benefits. Plaintiffs have the better argument.

At the outset, it must be emphasized that defendants do not rely on an explicit statutory exhaustion requirement.[20] Instead, they rely on a judge-made doctrine developed in response to the unique nature of claims involving military policy. That distinction is significant. Where Congress has adopted an explicit exhaustion regime, courts may not "add unwritten limits onto the[] rigorous textual requirements." Ross v. Blake, 136 S. Ct. 1850, 1857 (2016). But "judge-made exhaustion doctrines, even if flatly stated at first, remain amenable to judge-made exceptions." Id.; see McKart, 395 U.S. at 193 ("The doctrine of exhaustion of administrative remedies . . . is, like most judicial doctrines, subject to numerous exceptions."). Deciding whether to enforce a judicially created exhaustion requirement is a highly fact-sensitive inquiry,

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[20] Plaintiffs seek declaratory and injunctive relief against defendants for what they allege are violations of the Constitution and the APA. Because the APA waives the federal government's sovereign immunity with respect to claims for prospective relief, see 5 U.S.C. § 702, and authorizes courts to set aside agency action that is "contrary to constitutional right, power, privilege, or immunity," id. § 706(2)(B), plaintiffs' constitutional claims may be subsumed within the APA framework. But cf. John F. Preis, In Defense of Implied Injunction Relief in Constitutional Cases, 22 Wm. & Mary Bill Rts. J. 1, 52-53 (2013) (arguing that federal courts retain equitable powers "to imply injunctive relief in constitutional cases" even where the APA "fails to provide a plaintiff with a remedy" (citation omitted)). And "where the APA applies, an appeal to 'superior agency authority' is a prerequisite to judicial review only when expressly required by statute or when an agency rule requires appeal before review and the administrative action is made inoperative pending that review." Darby v. Cisneros, 509 U.S. 137, 154 (1993) (emphasis omitted).

Although it is a statute that empowers the AFBCMR to correct military records, see 10 U.S.C. § 1552(a)(1) ("The Secretary of a military department may correct any military record of the Secretary's department when the Secretary considers it necessary to correct an error or remove an injustice."), that provision's language is purely permissive and does not evince a congressional intent to make appeal to the AFBCMR a mandatory precursor to judicial review. Cf. Ross v. Blake, 136 S. Ct. 1850, 1856-57 (2016) (discussing the mandatory language requiring exhaustion in 42 U.S.C. § 1997e(a)).

"requir[ing] an understanding of its purposes and of the particular administrative scheme involved." McKart, 395 U.S. at 193. If the burdens of enforcing an exhaustion requirement seriously outweigh the benefits in a particular case, that requirement may be excused.[21]

Although defendants cite several cases to support their exhaustion argument, plaintiffs correctly point out that those cases are distinguishable insofar as they involved parties who sought access to federal court at the first sign of disagreement with a military decision. See Guerra v. Scruggs, 942 F.2d 270, 272-73 (4th Cir. 1991) (involving a plaintiff who sued to prevent his discharge for cocaine use and intoxication without having availed himself of either of the available administrative review mechanisms); Williams, 762 F.2d at 358-59 (involving a plaintiff who after receiving a notice that he would be evaluated for separation filed suit in federal court "[b]efore any administrative follow-up on the notice of review had occurred"). In both cases, the lawsuit posed a genuine risk of preempting the agency's deliberative processes and wasting crucial resources, and accordingly the policy concerns underlying the exhaustion doctrine were at their apex.

Those concerns are diminished to the vanishing point in this case. Roe and Voe did not seek judicial review without having given the Air Force a meaningful opportunity to examine its policies and decisions. To the contrary, they presented their claims to a complex, tiered administrative review process—one that involved medical evaluations, written submissions, and formal hearings—culminating in an extensive administrative record and final written decisions by the SAFPC. See A460 ("The following rationale is provided for the final decision in this

[21] In that sense, the exhaustion-of-intraservice-remedies requirement operates as a prudential limitation on the exercise of jurisdiction rather than as a true subject-matter jurisdictional limitation. The Fourth Circuit has described that species of requirement as a matter of "comity." See McDonald v. Centra, Inc., 946 F.2d 1059, 1063 (4th Cir. 1991) (citation omitted).

case."); A747 (same); see also AFI 36-3212, §§ 5.1-.9 (setting out procedures for the SAFPC's "final review and disposition" of a servicemember's appeal (capitalization altered)). Indeed, an official whose affidavit defendants submitted characterized the SAFPC "as the decision authority for a wide array of personnel decisions made by the Air Force" and "as, effectively, the final appeal authority for Airmen evaluated by the DES prior to their separation from Active Duty." A420. Thus, Roe and Voe substantially exhausted the administrative review mechanisms available to them, a fact which undercuts defendants' argument that this lawsuit is premature.

Although Roe and Voe stopped short of applying to the AFBCMR, plaintiffs have persuasively demonstrated that requiring appeals to the AFBCMR as a prerequisite to pursuing this lawsuit would be inappropriate. First, the AFBCMR's ambit is relatively limited; it serves to interpret "the content and effect of military regulations" and decide "whether [a] military tribunal's decision was in error or unjust." Navas v. Gonzalez Vales, 752 F.2d 765, 769-70 (1st Cir. 1985). In accordance with that mission, it can reverse an order of separation, edit a servicemember's military record, and issue back pay, see 10 U.S.C. § 1552(a), (c); however, it cannot adjudicate a claim that the Air Force's policies and regulations themselves are unconstitutional or otherwise unlawful. That an appeal to the AFBCMR could not address the heart of plaintiffs' claims changes the exhaustion calculus. Defendants respond that there is no categorical rule in this circuit exempting constitutional or facial claims from exhaustion requirements. See, e.g., Nationsbank Corp. v. Herman, 174 F.3d 424, 429 (4th Cir. 1999). But "that exhaustion can be useful even where a constitutional issue is presented," Volvo GM Heavy Truck Corp. v. U.S. Dep't of Labor, 118 F.3d 205, 215 (4th Cir. 1997) (emphasis added), does not mean it is automatically required.

Additional considerations weigh in favor of excusing Roe and Voe from having to appeal to the AFBCMR before proceeding in federal court. Parties may be exempt from judicially imposed exhaustion requirements upon showings of futility or irreparable injury. See McDonald v. Centra, Inc., 946 F.2d 1059, 1063 (4th Cir. 1991); see also Shalala v. Ill. Council on Long Term Care, Inc., 529 U.S. 1, 12-13 (2000) ("Doctrines of 'ripeness' and 'exhaustion' contain exceptions, however, which exceptions permit early review when, for example, the legal question is fit for resolution and delay means hardship, . . . or when exhaustion would prove futile" (internal quotation marks and citations omitted)). Although excusal of exhaustion on these grounds is a "high bar," Haramalis v. Lengyel, No. 1:17-cv-946, 2018 WL 476156, at *4 (E.D. Va. Jan. 18, 2018), plaintiffs have cleared that bar. The MEB, IPEB, FPEB, and finally the SAFPC assessed Roe's and Voe's cases in exactly the same way. They recognized that Roe and Voe were being successfully treated, were asymptomatic, and had the support of their commanding officers; nonetheless, they concluded that Roe and Voe could not be deployed to CENTCOM and thus were unfit for continued military service. Because of that consistent and unyielding line of reasoning, Roe and Voe face imminent discharge from the Air Force. Defendants have steadfastly defended that reasoning in this litigation. Nothing suggests that the AFBCMR would depart from the conclusions of multiple Air Force decisionmakers and conclude that Roe's and Voe's discharge determinations contained an "error" to "correct" or an "injustice" to "remove." Exhaustion need not be required where it would constitute an empty formality—particularly where, as here, the plaintiffs face imminent separation from the branch of the armed forces in which they have served honorably and in which they want to continue serving.

Further, under Air Force regulations, the AFBCMR may only issue nonbinding recommendations, AFI 36-2603, §§ 2.1, 4.10, and it is the Secretary of the Air Force (or her

designee) who must decide whether to act, see id. §§ 1.1, 5. Yet the SAFPC's determinations that Roe and Voe should be discharged were expressly made on behalf of the Secretary of the Air Force. See A461, A747. Accordingly, even if the AFBCMR were to agree with Roe's and Voe's arguments, plaintiffs' ability to secure relief would still depend on the same decisionmaker who has already rejected those arguments.

Finally, an appeal to the AFBCMR may take as long as 18 months, see 10 U.S.C. § 1557(b), if not longer, see Pls.' Opp'n & Reply Ex. C [Dkt. No. 60-3] 2-4 (explaining that the boards for correction of military records have experienced notable increases in the time to decision). For example, sergeant Nick Harrison—the plaintiff in a companion case before this Court, see Harrison v. Shanahan, No. 1:18-cv-641—petitioned the Army Board for Correction of Military Records for relief from the decision preventing his commissioning as a JAG officer due to his HIV status. Harrison did not receive the board's decision—a rejection of his appeal—for nearly two years. Pls.' Opp'n & Reply Ex. C [Dkt. No. 60-3] 3-4. The Court may take the decisional timeline into account in deciding whether to require further exhaustion for plaintiffs who, like Roe and Voe, allege imminent and immeasurable harm stemming from the challenged actions.[22]

Deciding whether exhaustion is required is a matter of discretion. It requires a careful balancing between respect for internal administrative decisionmaking processes on the one hand

[22] As is the case with most of their arguments, defendants focus entirely on Roe and Voe and do not address the exhaustion analysis as to OutServe, which has identified four additional active-duty members of the Air Force who face imminent discharge because of HIV-related deployment restrictions. All four of those servicemembers are identically situated to Roe and Voe in that they pursued unsuccessful appeals of those decisions up through the SAFPC. See Pls.' Memo. & Opp'n Ex. C [Dkt. No. 40] 3-8; id. Exs. C-1 to -4. Accordingly, the Court's analysis with respect to Roe and Voe equally applies to the members on whose behalf OutServe is asserting associational standing.

and an individual's ability to protect his rights in federal court on the other. Under the circumstances of this case, no further exhaustion of intraservice remedies is required.

B. Military Controversy

Defendants next argue that plaintiffs' complaint must be dismissed for failure to present a justiciable controversy. Defendants contend that under the balancing framework established by the Fifth Circuit in Mindes, 453 F.2d 197, and adopted by the Fourth Circuit in Williams, 762 F.2d 357, their policies with respect to servicemembers living with HIV—and the application of those policies to Roe and Voe—are altogether immune from judicial scrutiny.

"The military is a specialized society separate from civil society with laws and traditions of its own [developed] during its long history." Schlesinger v. Councilman, 420 U.S. 738, 757 (1975) (alteration in original) (internal quotation marks and citation omitted). The military's separate status and unique institutional interests have often made courts reluctant "to second-guess judgments requiring military expertise" or to "substitute court orders for discretionary military decisions," lest judicial interference "stultify the military in the performance of its vital mission." Mindes, 453 F.2d at 199. Yet neither can the military be wholly free from judicial scrutiny. See id.; see also, e.g., Emory v. Sec'y of the Navy, 819 F.2d 291, 294 (D.C. Cir. 1987) (per curiam) ("The military has not been exempted from constitutional provisions that protect the rights of individuals. It is precisely the role of the courts to determine whether those rights have been violated." (citation omitted)).

To accommodate this tension between deference and judicial review, courts developed a balancing framework designed to capture under what circumstances it is appropriate to adjudicate claims related to military policies. Under that framework, the court must first be satisfied that the plaintiff has appropriately exhausted intraservice remedies and has alleged a

violation of the Constitution, applicable statutes, or military regulations. Mindes, 453 F.2d at 201. If that showing is made, the court must then balance four factors:

> 1. The nature and strength of the plaintiff's challenge to the military determination. . . .
>
> 2. The potential injury to the plaintiff if review is refused.
>
> 3. The type and degree of anticipated interference with the military function. Interference per se is insufficient since there will always be some interference when review is granted, but if the interference would be such as to seriously impede the military in the performance of vital duties, it militates strongly against relief.
>
> 4. The extent to which the exercise of military expertise or discretion is involved. Courts should defer to the superior knowledge and experience of professionals in matters such as promotions or orders directly related to specific military functions.

Guerra, 942 F.2d at 276 (alteration in original) (quoting Mindes, 453 F.2d at 201-02). How those factors should be balanced in each case is left to the trial court's discretion. See Mindes, 453 F.2d at 202.

To begin, it is unclear whether the Mindes balancing test remains good law. In a recent decision, a panel of the Fourth Circuit called its viability into question. See Aikens v. Ingram, 811 F.3d 643, 648 & n.5 (4th Cir. 2016). Since adopting the test in 1985, see Williams, 762 F.2d at 359-60, the Fourth Circuit has applied it only once in a published opinion, in 1991, see Guerra, 942 F.2d at 276.[23] Other courts of appeals have rejected the rule on the theory that it "erroneously 'intertwines the concept of justiciability with the standards to be applied to the merits of the case.'" Knutson v. Wis. Air Nat'l Guard, 995 F.2d 765, 768 (7th Cir. 1993) (quoting Dillard v. Brown, 652 F.2d 316, 323 (3d Cir. 1981)). Those courts that have questioned

[23] The Fourth Circuit has applied the rule in several unpublished opinions. See Downey v. U.S. Dep't of the Army, 685 F. App'x 184, 191-93 (4th Cir. 2017), cert. denied, 138 S. Ct. 645 (2018); Wilt v. Gilmore, 62 F. App'x 484, 487-88 (4th Cir. 2003) (per curiam); Scott v. Rice, No. 92-2463, 1993 WL 375664, at *2 (4th Cir. Sept. 23, 1993) (per curiam).

Mindes have done so for good reason: Its four-factor test, which weighs the plaintiff's case and injuries against military independence and expertise, speaks more to the merits and the appropriate scope of equitable relief than the threshold matter of justiciability.

Nonetheless, even assuming the Mindes test remains good law and applies to this dispute,[24] it does not require dismissal here. To be sure, whether a servicemember is fit for continued military service is a question that implicates military discretion, and one in which courts have little expertise. Yet other factors weigh heavily in favor of finding this dispute to be justiciable. For one, plaintiffs' claims are not weak. At this preliminary stage, they have made a strong showing that defendants' policies are irrational, based on a flawed understanding of HIV epidemiology, and inconsistently applied. Although Roe and Voe advance as-applied claims limited to the application of the military's polices in their cases, they (along with OutServe) also seek relief on behalf of a broader class of HIV-positive servicemembers, all of whom are now confronted with the polices that plaintiffs claim are unlawful. The far-reaching nature of these

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[24] A conceptually distinct issue is whether Mindes applies to all claims related to military policy or only a subset of those claims. When the Fourth Circuit adopted Mindes, it did so in the context of a claim that the West Virginia Army National Guard had failed to follow its own regulations in ordering that the plaintiff be separated after 20 years of service. See Williams, 762 F.2d at 358. Likewise, Guerra involved a challenge to the procedures through which the Army had decided to discharge the plaintiff for cocaine use and alcohol intoxication. See 942 F.2d at 271-72. The Fourth Circuit has suggested that whatever the viability of the test with respect to "internal personnel matters such as challenges to convening of retention boards and military discharge," Mindes is "an ill fit" where the plaintiff has alleged "unconstitutional, ultra vires actions" by the defendant. Aikens, 811 F.3d at 648. Although that distinction has intuitive appeal, it may be difficult to square with Mindes itself, which involved constitutional claims and clearly anticipated its application to constitutional questions, see 453 F.2d at 201-02. In fact, Aikens may have more to do with rejecting Mindes in suits for damages under 42 U.S.C. § 1983 than with any administrative–constitutional distinction.

In any event, it is unclear on which side of Aikens's line this case would fall. Plaintiffs have advanced facial and as-applied claims. Some are constitutional; others are more administrative in nature. And plaintiffs seek equitable relief, not damages. Because at least some of plaintiffs' claims fall within the Guerra and Williams line of cases, the Court will apply the Mindes test.

claims surely counsels in favor of judicial review. For the reasons explained below, plaintiffs have also made a strong demonstration that they face imminent, serious cognizable injuries because of defendants' policies. This is not one servicemember's protest of a technical glitch in the military's decisionmaking process; it is a challenge claiming that HIV-positive servicemembers, who wish to serve their country on equal terms with others, are being irrationally and arbitrarily swept from the ranks. Finally, the gravamen of plaintiffs' complaint is that they have not been evaluated in the personalized, case-by-case manner guaranteed by the applicable regulations, but rather face discharge because of an untailored determination that they are not deployable beyond the continental United States. By requesting only that military decisionmakers evaluate whether they are fit for service with more careful attention to their individual characteristics, plaintiffs give significant breathing space to "the exercise of military expertise [and] discretion," Guerra, 942 F.2d at 276 (citation omitted). For these reasons, this case presents a justiciable controversy properly subject to judicial review.

C. Standing

The federal judicial power extends only to "Cases" and "Controversies." U.S. Const. art. III, § 2. To satisfy the case-or-controversy requirement, a plaintiff must have standing—that is, he must have "alleged such a personal stake in the outcome of the controversy as to warrant his invocation of federal-court jurisdiction and to justify exercise of the court's remedial powers on his behalf." Warth v. Seldin, 422 U.S. 490, 498-99 (1975) (citation omitted). Standing "is built on separation-of-powers principles" and "prevent[s] the judicial process from being used to usurp the powers of the political branches." Clapper v. Amnesty Int'l USA, 568 U.S. 398, 408 (2013). Accordingly, the standing inquiry is "especially rigorous when reaching the merits of the

dispute would force [the court] to decide whether an action taken by one of the other two branches of the Federal Government was unconstitutional." Raines v. Byrd, 521 U.S. 811, 819-20 (1997).

The test for Article III standing is well established:

> Th[e] "irreducible constitutional minimum" of standing requires: (1) that the plaintiff have suffered an "injury in fact"—an invasion of a judicially cognizable interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) that there be a causal connection between the injury and the conduct complained of—the injury must be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court; and (3) that it will be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Bennett v. Spear, 520 U.S. 154, 167 (1997) (quoting Lujan v. Defs. of Wildlife, 504 U.S. 555, 560-61 (1992)). Plaintiffs bear the burden of establishing standing to support each of their claims. South Carolina v. United States, 912 F.3d 720, 726 (4th Cir. 2019). They must satisfy that burden "in the same way as any other matter on which [they] bear[] the burden of proof" during each successive stage of the litigation. Lujan, 504 U.S. at 561.

Defendants' argument that plaintiffs lack standing is, as is often the case, a matter of characterization. In their view, the Article III injury on which plaintiffs rely is that "they have been prevented from continuing to serve in the Air Force." Defs.' Memo. & Opp'n 14. Defendants argue that because "Roe and Voe have both completed their terms of enlistment," both would have to reenlist to continue to serve. Id. at 11, 14. They conclude that this is fatal to plaintiffs' standing, both in terms of injury-in-fact and redressability, because there is no guaranteed right to reenlist in the Air Force and because reenlistment "is a separate process independent of both the medical evaluation and the underlying regulations challenged by" plaintiffs. Id. at 14-15. Plaintiffs label this argument a "Catch-22," arguing that Roe's and Voe's

"terms have expired only because Defendants' illegal policies forced them into the medical discharge process and prevented them from reenlisting." Pls.' Opp'n & Reply 15.[25]

The key fact with respect to Roe's and Voe's standing to sue is that although their terms of service were originally set to expire in 2018, they were extended through June 2019. Compl. ¶¶ 74, 88; see Pls.' Memo. Ex. A [Dkt. No. 44] ¶¶ 6-7; id. Ex. B [Dkt. No. 44-7] ¶¶ 20-21. But as a result of defendants' policies, Voe and Roe are now set to be discharged on February 25 and March 29, 2019, respectively. That both named plaintiffs will be separated—and thus deprived of the economic, medical, and nonpecuniary benefits associated with active-duty service—earlier than as provided by the extensions they received amounts to classic injury-in-fact sufficient to support Article III standing.

Although it is true that if the Court were to grant Roe and Voe the relief they seek,[26] they could conceivably again be ordered discharged for different reasons, that remote possibility does not make their injuries nonredressable. The burden imposed by the redressability requirement "is not onerous," and "[p]laintiffs need not show that a favorable decision will relieve [their] every injury." Deal v. Mercer Cty. Bd. of Educ., 911 F.3d 183, 189 (4th Cir. 2018) (second alteration in original) (internal quotation marks and citation omitted). It is enough to show that a favorable decision would be likely to remedy their injury. Plaintiffs have met that burden.

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[25] Plaintiffs argue as an alternative that they have demonstrated with sufficient certainty that Roe and Voe would have been recommended and selected for reenlistment but for the medical evaluation and separation process. See Pls.' Opp'n & Reply 15 n.2. For the reasons stated below, the Court need not consider that alternative basis for standing.

[26] Plaintiffs have not sought an order preventing Roe and Voe from being separated from service for any reason whatsoever. Instead, they seek an injunction preventing defendants from separating them solely "because of restrictions on deployability due to HIV status" [Dkt. No. 34-1].

Additionally, even if defendants were correct that the expiration of Roe's and Voe's terms of service deprives them of standing, defendants' argument would still fail because OutServe has standing separate from and independent of the named plaintiffs. Although OutServe does not allege any injury to itself qua institutional entity, it may

> bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.

Hunt v. Wash. State Apple Advert. Comm'n, 432 U.S. 333, 343 (1977).

Defendants concede that OutServe meets the requirements for associational standing but argue that because the complaint contains allegations only about Roe and Voe, OutServe's standing must be coterminous with Roe's and Voe's. Defs.' Memo. & Opp'n 16. Yet OutServe has identified several additional members who face imminent separation for similar reasons as Roe and Voe but whose terms of service have not yet expired. Pls.' Opp'n & Reply 17; see Pls.' Memo. Ex. C [Dkt. No. 40] ¶¶ 8-27.

Defendants protest that those OutServe members are not mentioned in the complaint, arguing that "parties cannot amend their complaints through briefing or oral advocacy." Defs.' Memo. & Opp'n 16 n.5 (quoting S. Walk at Broadlands Homeowner's Ass'n v. OpenBand at Broadlands, LLC, 713 F.3d 175, 184 (4th Cir. 2013)).[27] Defendants misstate the law. In adjudicating a factual challenge to subject matter jurisdiction, "the trial court [has] the discretion

[27] Defendants also suggest that OutServe "has not demonstrated that any of the individuals claimed as members are in fact members of the[] organization, an independent jurisdictional flaw." Defs.' Reply 12 n.7. Plaintiffs and their affiants have in fact averred that the four identified servicemembers are OutServe members. See Pls.' Memo. 11; Pls.' Opp'n & Reply Ex. C [Dkt. No. 60-3] 1. In the context of a factual challenge to subject matter jurisdiction at the pleadings stage, no more is required.

to go beyond the allegations of the complaint and . . . determine if there are facts to support the jurisdictional allegations." Beck, 848 F.3d at 270 (internal quotation marks and citation omitted); accord White Tail Park, Inc. v. Stroube, 413 F.3d 451, 459 (4th Cir. 2005) ("When a defendant raises standing as the basis for a motion under Rule 12(b)(1) . . . , the district court may consider evidence outside the pleadings without converting the proceeding to one for summary judgment." (internal quotation marks and citation omitted)).[28] Accordingly, OutServe may assert associational standing on behalf of its members who face imminent separation because of their HIV status, including those whose terms of service have not yet expired.

In sum, plaintiffs filed a timely lawsuit after Roe and Voe, and others like them, had proceeded through a lengthy administrative appeals process culminating in a final decision on behalf of the Secretary of the Air Force; plaintiffs' claims present a justiciable controversy subject to judicial review; and both the named plaintiffs and OutServe have a sufficient Article III stake in the outcome of this litigation to advance those claims. Accordingly, defendants' motion to dismiss under Rule 12(b)(1) will be denied.

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[28] Southern Walk, on which defendants rely, cites two cases for the proposition that "parties cannot amend their complaints through briefing or oral advocacy." See 713 F.3d at 184-85. Both involved motions to dismiss for failure to state a claim under Rule 12(b)(6), not subject-matter jurisdictional challenges under Rule 12(b)(1). See E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc., 637 F.3d 435, 449 (4th Cir. 2011); Car Carriers, Inc. v. Ford Motor Co., 745 F.2d 1101, 1107 (7th Cir. 1984). Moreover, the Fourth Circuit's comment in Southern Walk was just one part of a broader discussion of why the plaintiff's jurisdictional allegations were insufficient, which included that the plaintiff had failed to meaningfully distinguish between "injury in its own right and representational standing based on injury to its members" and had relied on inappropriately vague allegations. See 713 F.3d at 185.

In their reply brief, defendants attempt to recharacterize their motion to dismiss, claiming that it was brought under Rule 12(b)(6) as well as 12(b)(1). See Defs.' Reply 11. This is wholly contrary to how defendants framed their motion in their opening brief. See Defs.' Memo. & Opp'n 6. Because defendants' arguments address only the subject matter jurisdiction of the Court, the standards governing Rule 12(b)(1) apply here.

III. PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

Having resolved defendants' motion to dismiss, the Court now turns to plaintiffs' request for a preliminary injunction preventing Roe and Voe, along with other similarly situated servicemembers, from being separated because of their HIV status. "A preliminary injunction is an extraordinary remedy intended to protect the status quo and prevent irreparable harm during the pendency of a lawsuit." Di Biase v. SPX Corp., 872 F.3d 224, 230 (4th Cir. 2017). To be entitled to such relief, plaintiffs must show "that (1) they are likely to succeed on the merits, (2) they are likely to suffer irreparable harm, (3) the balance of hardships tips in their favor, and (4) the injunction is in the public interest." Metro Reg'l Info. Sys., Inc. v. Am. Home Realty Network, Inc., 722 F.3d 591, 595 (4th Cir. 2013).

In light of the "strong judicial policy against interfering with the internal affairs of the armed forces," courts have generally held that "military discharge proceedings should be enjoined only in exceptional circumstances." Chilcott v. Orr, 747 F.2d 29, 33 (1st Cir. 1984). This case presents such exceptional circumstances. Even bearing in mind the deference owed to the military, the Court concludes that plaintiffs have made a clear showing that a carefully tailored injunction is appropriate and in the public interest.

A. Likelihood of Success on the Merits

A party seeking a preliminary injunction must establish that he is likely to succeed on the merits of at least one claim. Dewhurst v. Century Aluminum Co., 649 F.3d 287, 290 (4th Cir. 2011). To satisfy this requirement, the party must demonstrate more than "a grave or serious question for litigation," Sarsour v. Trump, 245 F. Supp. 3d 719, 729 (E.D. Va. 2017) (emphasis and citation omitted), but need not show "a certainty of success," League of Women Voters of N.C. v. North Carolina, 769 F.3d 224, 247 (4th Cir. 2014) (citation omitted). At least at this

stage, plaintiffs have made a strong and clear showing that defendants' policies are irrational, outdated, and unnecessary and their decisions arbitrary, unreasoned, and inconsistent. As such, they have demonstrated a likelihood of success as to Counts I, II, and III of the complaint.[29]

1. Standards of Review

Count I of plaintiffs' complaint alleges that the decisions to order Roe and Voe discharged, along with the policies that produced those decisions, violate their right to equal protection. "[W]hile the Fifth Amendment contains no equal protection clause, it does forbid discrimination that is 'so unjustifiable as to be violative of due process.'" Schneider v. Rusk, 377 U.S. 163, 168 (1964) (quoting Bolling v. Sharpe, 347 U.S. 497, 499 (1954)). Fifth Amendment equal protection claims are analyzed under the same framework as claims brought under the Fourteenth Amendment's Equal Protection Clause. Weinberger v. Wiesenfeld, 420 U.S. 636, 638 n.2 (1975).

The right to equal protection under the law serves "to secure every person . . . against intentional and arbitrary discrimination." Village of Willowbrook v. Olech, 528 U.S. 562, 564 (2000) (per curiam) (citation omitted). As a baseline, all governmental classifications must be "rationally related to a legitimate governmental interest." U.S. Dep't of Agric. v. Moreno, 413 U.S. 528, 533 (1973).[30] Although classifications need not "be drawn with precise mathematical nicety," id. at 538 (internal quotation marks and citation omitted), rational basis review is not "toothless," Mathews v. Lucas, 427 U.S. 495, 510 (1976). The government "may not rely on a classification whose relationship to an asserted goal is so attenuated as to render the

[29] This conclusion renders it unnecessary to assess whether plaintiffs have demonstrated a likelihood of success as to Counts IV and V.

[30] Plaintiffs do not dispute that maintaining a ready, effective military force and protecting the health and safety of servicemembers are legitimate government interests.

distinction arbitrary or irrational." City of Cleburne v. Cleburne Living Ctr., Inc., 473 U.S. 432, 446 (1985); see Bankers Life & Cas. Co. v. Crenshaw, 486 U.S. 71, 83 (1988) ("[A]rbitrary and irrational discrimination violates the Equal Protection Clause under even our most deferential standard of review."). Nor may a classification be based on "irrational prejudice," City of Cleburne, 473 U.S. at 450, or a "bare . . . desire to harm a politically unpopular group," Moreno, 413 U.S. at 534.[31]

Counts II and III of the complaint invoke the judicial review provisions of the APA, which authorize courts to "hold unlawful and set aside agency action, findings, and conclusions" determined to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Agency action is arbitrary and capricious if

> the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an

[31] Plaintiffs have argued with respect to their equal protection claim that defendants' policies should be subject to more searching judicial scrutiny because HIV status is a suspect or quasi-suspect classification under the four-factor framework outlined in Windsor v. United States, 699 F.3d 169 (2d Cir. 2012), aff'd on other grounds, 570 U.S. 744 (2013). The Windsor framework asks whether the class "has been historically subjected to discrimination," "has a defining characteristic that frequently bears [a] relation to ability to perform or contribute to society," "exhibits obvious, immutable, or distinguishing characteristics that define them as a discrete group," and is "a minority or politically powerless," id. at 181 (alteration in original) (internal quotation marks and citations omitted). Plaintiffs' argument faces an uphill climb. The Supreme Court has not recognized a suspect or quasi-suspect classification since 1977. Kenji Yoshino, The New Equal Protection, 124 Harv. L. Rev. 747, 757 (2011). Moreover, the Fourth Circuit has broadly stated that "classifications based on disability are subject to minimal scrutiny," Constantine v. Rectors & Visitors of George Mason Univ., 411 F.3d 474, 486 (4th Cir. 2005) (citing City of Cleburne, 473 U.S. at 446), as have other federal courts of appeals, see, e.g., Toledo v. Sánchez, 454 F.3d 24, 33 (1st Cir. 2006); Lee v. City of Los Angeles, 250 F.3d 668, 687 (9th Cir. 2001). And the Fourth Circuit has held, albeit in a decades-old opinion, that HIV status is not a suspect classification. Doe v. Univ. of Md. Med. Sys. Corp., 50 F.3d 1261, 1267 (4th Cir. 1995). Whether, given a clean slate, HIV status would qualify as a suspect classification—and, if so, whether Doe would nonetheless require a contrary conclusion—can be left for another day. Plaintiffs are correct that answering those questions "is not necessary here," Pls.' Memo. 12-13, because they have demonstrated a likelihood of success even assuming that rational basis review applies to their equal protection claim.

> explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). Although arbitrary-and-capricious review is necessarily deferential and narrow in scope, the standard "does not reduce judicial review to a rubber stamp." Ergon-W. Va., Inc. v. U.S. EPA, 896 F.3d 600, 609 (4th Cir. 2018) (citation omitted). To the contrary, courts "must conduct a searching and careful review to determine whether the agency's decision was based on a consideration of the relevant factors," whether the agency "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action," and whether the agency committed "a clear error of judgment." Perez v. Cissna, No. 18-1330, 2019 WL 350328, at *3 (4th Cir. Jan. 29, 2019) (alterations in original) (internal quotation marks and citations omitted). The agency's rationale must be "both discernible and defensible," Trans-Pac. Freight Conf. of Japan/Korea v. Fed. Mar. Comm'n, 650 F.2d 1235, 1251 (D.C. Cir. 1980), and the agency "must treat similar cases in a similar manner unless it can provide a legitimate reason for failing to do so," Kreis v. Sec'y of the Air Force, 406 F.3d 684, 687 (D.C. Cir. 2005) (citation omitted).

The standards governing Counts I, II, and III substantially overlap because "rational-basis [r]eview of an equal protection claim in the context of agency action is similar to that under the APA." Cooper Hosp./Univ. Med. Ctr. v. Burwell, 179 F. Supp. 3d 31, 47 (D.D.C. 2016) (alteration in original) (internal quotation marks and citation omitted), aff'd per curiam, 688 F. App'x 11 (D.C. Cir. 2017). Accordingly, in analyzing defendants' policies and decisions, the question is the same for both the equal protection and APA claims: "whether the defendants' treatment of [Roe and Voe] was rational (i.e., not arbitrary and capricious)." Ursack, Inc. v. Sierra Interagency Black Bear Grp., 639 F.3d 949, 955 (9th Cir. 2011). In asking that question,

the Court must defer "to the professional judgment of military authorities concerning the relative importance of a particular military interest." Goldman v. Weinberger, 475 U.S. 503, 507 (1986); see also Winter v. Nat. Resources Def. Council, Inc., 555 U.S. 7, 24 (2008) (requiring deference to "complex, subtle, and professional decisions as to the composition, training, equipping, and control of a military force" (citation omitted)).

2. Analysis

Plaintiffs have challenged the determinations, made as part of the Air Force's retention and disability evaluation system, that Roe and Voe should be separated from service. Those discharge determinations were entirely dependent on the antecedent findings that Roe and Voe were subject to deployment restrictions. Defendants have recognized as much, arguing that Roe and Voe are to be discharged not because they are HIV positive, but rather because their condition makes them ineligible for deployment to an area of operation where servicemembers of their rank and responsibilities are frequently deployed. The deployment policy is thus the driving factor and must be analyzed first.

i. The Deployment Policy

DoDI 6490.07 is the Armed Forces-wide instruction intended to provide "baseline guidance on medical deployability for the DoD." See A424. It states that a servicemember is not subject to deployment restrictions so long as his medical condition is stable, not subject to sudden worsening, not reliant on medication with special handling or storage requirements, and not dependent on routine evacuation for ongoing treatment or evaluation. DoDI 6490.07, § 4(b), at A89. Roe and Voe appear to satisfy all of section 4(b)'s requirements. Defendants do not contest, and no evidence in the record contradicts, plaintiffs' assertions that Roe and Voe are asymptomatic and that their viral loads are suppressed, meaning that their conditions are stable

and not subject to sudden worsening so long as they maintain their course of treatment. Although they require daily medication, there is no evidence in the record contradicting plaintiffs' description of that medication as requiring "no special handling, storage, or other requirements" and causing no "significant side effects," id. § 4(b)(3). Roe and Voe must undergo medical evaluations every few months,[32] but nothing suggests that such a requirement qualifies as a "need for routine evacuation," id. § 4(b)(4). Indeed, that active-duty servicemembers with a high risk of HIV exposure are administered pre-exposure prophylaxis ("PrEP") treatment—which, according to one of plaintiffs' medical experts, Dr. W. David Hardy, gives rise to a need for medical evaluations every three months, see Pls.' Opp'n & Reply Ex. D [Dkt. No. 60-5] ("Hardy Decl.") ¶¶ 19-23[33]—but are nonetheless allowed to deploy suggests the opposite.

Section 4(c) of the instruction identifies certain conditions that bar a servicemember from deploying without a waiver. DoDI 6490.07, § 4(c), at A89. Although HIV is listed, the instruction provides the caveat that a waiver is required for HIV only "with the presence of progressive clinical illness or immunological deficiency." Id. enclosure 3, § e(2), at A97. As the record shows, neither Roe nor Voe falls within the terms of that provision. Because of their successful antiretroviral treatment, their conditions are not "increasing in scope or severity," see Progressive, Dorland's Illustrated Medical Dictionary (26th ed. 1981), and their immune systems are not compromised in the way associated with untreated or advanced-stage HIV or AIDS. At

[32] See Pls.' Memo. Ex. F [Dkt. No. 40-7] 10-11 (explaining that HIV-positive servicemembers generally require screenings every three to four months, a period which may be extended to six months "for individuals whose viral load has been suppressed for more than 2 years and whose clinical and immunologic status is stable").

[33] Hardy is Chair of the HIV Medicine Association and Adjunct Professor of Medicine at the Johns Hopkins University School of Medicine. He has over 30 years' experience in the care and treatment of individuals living with HIV. See Hardy Decl. 2.

least under DoDI 6490.07, it appears Roe and Voe should not have been classified as nondeployable at all.[34]

The Court recognizes that an altogether different standard governs deployment to CENTCOM, the "theater-level Unified Combatant Command with responsibility for military operations across North Africa, Central Asia, and the Middle East." A423. Under Modification Thirteen to USCENTCOM Individual Protection and Individual-Unit Deployment Policy ("MOD 13"), "[c]onfirmed HIV infection is disqualifying for deployment." See A425. Kevin Cron ("Cron"), CENTCOM's primary waiver action officer, submitted a declaration in support of defendants stating that servicemembers who deploy to CENTCOM "must be medically, dentally and psychologically fit" and cannot have medical conditions "requiring highly specialized medical personnel, treatments, or medications." A424-25. Otherwise disqualified servicemembers may deploy to CENTCOM if they secure a waiver; however, Cron has "n[ever] granted a deployment waiver for a[n] HIV-positive Service member," having concluded in every case "that the risks of deploying a[n] HIV-positive Service member were too great to justify waiver approval." A426-27 ("It is highly unlikely that either . . . Roe or Voe would be granted a waiver to deploy to the CENTCOM [area]."). In essence, then, the rule that prohibits HIV-positive servicemembers from deploying to CENTCOM is a categorical one. See A460 (the SAFPC stating that being HIV positive "precludes [a servicemember] from being able to deploy world-wide without a waiver and renders him ineligible for deployment to [CENTCOM]" (emphasis added)).

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[34] This interpretation of DoDI 6490.07 is consistent with guidance that the DoD provided to Congress in 2014, which stated that HIV-positive servicemembers would not be separated or even referred into the DES unless their conditions had "deteriorate[d]" in a way that interfered with the successful performance of their military occupation. A376.

This rule fails to pass muster under even the most deferential form of scrutiny. Because of advances in medicine and science, HIV is no longer a progressive, terminal illness. A study published in 2015 in a peer-reviewed journal under the auspices of the DoD recognized as much, finding that HIV "has gone from an untreatable disease marked by inexorable clinical progression through extreme debility to death to a treatable disease"—one "that is compatible with active service throughout a full career in the U.S. military." Pls.' Memo. 14 (quoting John F. Brundage et al., Durations of Military Service After Diagnoses of HIV-1 Infections Among Active Component Members of the U.S. Armed Forces, 1990-2013, 22 Med. Surveillance Monthly Rep. 9, 12 (2015)). It is thus unsurprising that until very recently, "nearly all cases of asymptomatic HIV resulted in a return to duty." A416. Roe and Voe are cases in point: Their commanding officers have unreservedly supported their retention, stating that despite being HIV positive they are physically and mentally capable of performing all duties required of them.

To be sure, HIV remains incurable, and Roe and Voe must take daily medication to ensure that their viral loads remain suppressed. But that fact does not justify the categorical prohibition at issue here. Although HIV-positive individuals who suddenly stop antiretroviral treatment are vulnerable to "viral rebound," A444, appreciable physical effects are not immediate. According to Dr. Hardy, it "often takes weeks" for an individual's viral load to return to clinically significant levels, and even then, the virus "enters a period of clinical latency that can last years," often with no "symptoms or negative health outcomes." Hardy Decl. ¶¶ 11, 14. What is more, plaintiffs have identified several serious medical conditions treated with daily medication that do not subject servicemembers to the same categorical denial of deployability to

CENTCOM. These include dyslipidemia,[35] which (unlike HIV) does not preclude an individual from enlisting or deploying provided the condition is under "medical management" with "no medication side effects," see DoDI 6130.03, § 5.24(n); hypertension, which is listed as a disqualifying condition only where it is "not controlled with medication" or "requires frequent monitoring," DoDI 6490.07, enclosure 3, § g(1), at A98; and asthma, which does not preclude deployment unless it persists "despite appropriate therapy," requires frequent hospitalization, or requires "daily systemic (not inhalational) steroids," id. § d, at A97. Servicemembers who require daily antimalarial medicine likewise are not barred from deploying to CENTCOM; they are simply instructed to "deploy with either enough medication for their entire deployment or with enough to cover approximately half of the deployment with plans to receive the remainder of their medication in theater." A349-50. More generally, MOD 13 allows "personnel who require medication and who are deploying to the CENTCOM" area to deploy "with no less than a 180[-]day supply (or appropriate amount for shorter deployments)," with provisions made to obtain refill prescriptions through the Armed Forces's Deployment Prescription Program. A349. Thus, although defendants emphasize that deployability determinations must account for "reasonably anticipated contingencies, such as loss, theft, or destruction of medication," Defs.' Memo. & Opp'n 24, there appears to be no reason why asymptomatic HIV is singled out for treatment so different from that given to other chronic conditions, all of which are subject to worsening upon disruption of daily medication.[36]

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[35] "Dyslipidemia is elevation of plasma cholesterol and/or [triglycerides] or a low [high-density lipoprotein] level that contributes to the development of atherosclerosis." The Merck Manual of Diagnosis and Therapy 1295-1309 (Mark H. Beers et al. eds., 18th ed. 2006).

[36] Cron suggests that "features of HIV . . . make it difficult to compare to other conditions" because HIV medications "are highly specialized." A427. Cron does not explain that statement in any way, and as the record reflects, the opposite is true: Antiretroviral treatment requires

Defendants also suggest that their policy is justified by the fact that HIV-positive individuals may require checkups every few months. But as plaintiffs' expert Dr. Craig W. Hendrix explains, those checkups do not require "highly specialized medical personnel," A425, and are consistent with deployment in a forward area; all that is needed is a blood sample, which may be shipped to a laboratory if none is available on site. Pls.' Memo. Ex. F [Dkt. No. 40-7] ("Hendrix Decl.") 11.[37] Dr. Hendrix also explains that point-of-care viral load testing "is becoming increasingly prevalent and cost efficient." Id. Finally, as discussed previously, the Armed Forces's policy of administering PrEP to certain deployed servicemembers undercuts defendants' reliance on the argument that the need for testing every few months bars deployability. See Hardy Decl. 1 ("[P]roviding PrEP to members of the Armed Services is more logistically and medically demanding than providing antiretroviral medications to service members living with HIV would be.").

Nor do other considerations supply the critical missing link in defendants' chain of reasoning. Defendants do not dispute that antiretroviral treatment is highly "effective[] in preventing HIV transmission." A374. Uncontroverted evidence from another of plaintiffs' experts, Dr. Carlos del Rio, demonstrates that when an individual's viral load is suppressed, he cannot transmit the virus to another. Pls.' Memo. Ex. D [Dkt. No. 40-5] ("Del Rio Decl.") 8

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taking one or two pills per day, and those pills are kept in standard pill bottles without special storage requirements. And as plaintiffs' medical expert Dr. Craig W. Hendrix makes clear, "[t]he HIV medications commonly prescribed today have no special handling, storage or other requirements" and "generally tolerate hard conditions, such as hot or cold stress and sunlight, well." Pls.' Memo. Ex. F [Dkt. No. 40-7] 10.

[37] Hendrix is a Professor of Medicine and Pharmacology and Molecular Sciences at the Johns Hopkins University School of Medicine. He also served in the Air Force on active duty for 10 years and previously was Director of the HIV Medical Evaluation Unit and HIV Program at an Air Force medical center. See Hendrix Decl. 2-3.

(citing a 2017 "Dear Colleague" letter from the CDC).[38] The expert evidence presented by plaintiffs supports the conclusion that even in the case of a sustained disruption in treatment long enough for the viral load to rebound to clinically significant levels, an individual's risk of transmitting HIV during military service remains vanishingly low. Defendants have not identified a single recorded case of accidental transmission of HIV on the battlefield, which is unsurprising given the uncontroverted evidence that even without effective treatment, the risk of transmission through nonintimate contact such as blood splash is negligible. See id. at 8-9; see also A375 (describing the Navy's policy allowing HIV-positive servicemembers to deploy on certain vessels in part because there is "no demonstrated risk of transmission of infection in normal daily activities"). And in the extraordinarily unlikely event of accidental or battlefield exposure, advances in PrEP treatment have made it possible to prevent that exposure from leading to infection.

Defendants respond by pointing to another potential risk: that of transmitting HIV through a "battlefield blood transfusion." Defs.' Memo. & Opp'n 25. But defendants' argument compares apples to oranges. The risk they identify is that a servicemember unaware he is HIV positive might donate blood. See A429 (explaining that this possibility was one of the main impetuses for the military's decision to start screening servicemembers for HIV in the 1980s). That concern fades from view after a servicemember has been diagnosed with HIV and thus knows that he cannot give blood, especially if he has been subject to disruptions in his antiretroviral treatment.

[38] Del Rio is the Hubert Professor and Chair of the Development of Global Health, Professor of Epidemiology at the Rollins School of Public Health, and Professor of Medicine in the Division of Infectious Diseases at Emory University School of Medicine, as well as Principal Investigator and co-Director of the Emory Center for AIDS Research. He primarily focuses "on early diagnosis, access to care, engagement in care, compliance with antiretrovirals and prevention of HIV." Del Rio Decl. 2-3.

Defendants have not argued that every deployed servicemember must be able to donate blood. Nor could they: Many servicemembers cannot give blood for various reasons, including blood type and allergies, but are not barred from deploying to CENTCOM or elsewhere. Instead, they are simply issued medical alert tags. Pls.' Memo. 17-18; Pls.' Opp'n & Reply 27.

Defendants have not offered any cogent response to plaintiffs' experienced medical experts, all of whom persuasively explain why the effectively categorical rule declaring all HIV-positive servicemembers ineligible for deployment to CENTCOM is inconsistent with the state of science and medicine and with the way the military treats other chronic but manageable conditions. Indeed, rather than attempting to respond to plaintiffs' experts, defendants rely only on conclusory assertions about their "professional military and medical judgment," Defs.' Memo. & Opp'n 27, and on circular restatements of their policies. For example, defendants argue that "[a]s explained in DoD's 2014 Report to Congress, HIV infection has the potential to undermine a Service member's medical fitness and the readiness of the force." Id. 21 (citing A376). But the portion of the report defendants cite simply does not support their argument. In fact, it amounts to nothing more than a description of the Armed Forces's DES as it relates to HIV-positive servicemembers; it contains no evidence, whether anecdotal or otherwise, of the effect of HIV on a servicemember's medical fitness or the military's readiness. See A376. The same is true for defendants' assertion that the "need for regular treatment and monitoring could impair the ability of an HIV-positive Service member to serve worldwide," Defs.' Memo. & Opp'n 27 (citing A384). The page defendants cite contains no scientific data, evidence, or real-life accounts, but rather is a mere recitation of defendants' policies. In sum, while plaintiffs have presented considerable evidence in support of their arguments, defendants rely on little more than ipse dixit. Based on this record, plaintiffs have made a strong preliminary showing that the

deployment policy applied to asymptomatic HIV-positive servicemembers cannot withstand rational basis review.

ii. The Discharge Decisions

In addition to arguing that the deployment policy is irrational, plaintiffs also argue that the decisions to discharge Roe were arbitrary and capricious. Plaintiffs are likely to succeed on this argument as well.

First, that Roe and Voe were even referred for a separation determination in the first place is arguably inconsistent with defendants' own policies. DoDI 1332.45 establishes that servicemembers classified as "nondeployable" for more than 12 consecutive months—or whose nondeployability would not change within the 12-month period—would be evaluated for retention, referred into the DES, or processed for separation. See DoDI 1332.45, § 1.2(b), at A62; id. § 2.4(b)(3), at A64. But servicemembers with conditions identified in DoDI 6490.07, including HIV (at least with the presence of progressive clinical illness or immunological deficiencies, as discussed above), are classified as "deployable with limitations." Id. § 3.3, at A66. As DoD made clear in a 2018 report to Congress, "nondeployable" and "deployable with limitations" were intended to be meaningfully distinct categories, with "the retention determination process applying to the former but not the latter." A386. As such, DoDI 1332.45 clearly suggests that servicemembers with HIV—even those whose health conditions are much graver than Roe's or Voe's—would not be subject to review for separation. In this respect, plaintiffs are correct that the Air Force's actions with respect to Roe, Voe, and the other HIV-positive servicemembers identified by OutServe seem "not in alignment with DoDI 1332.45." Pls.' Memo. 20.

Defendants concede that "[t]he Air Force did not apply DoDI 1332.45." Defs.' Memo. & Opp'n 22. Instead, they claim to have followed DoDI 6485.01, which states that active-duty servicemembers diagnosed with HIV must be "referred for . . . a medical evaluation for fitness for continued service in the same manner as a Service member with other chronic or progressive illnesses." DoDI 6485.01, enclosure 3, § 2(c), at A85. They claim that under this "case by case" medical evaluation process, A339, Roe and Voe were fairly found to be unfit for duty and therefore must be discharged.

The process to which Roe and Voe were subjected does not comport with even the minimal requirements of the APA. Applicable Air Force regulations make clear that "HIV seropositivity alone is not grounds for medical separation." AFI 44-178, § 2.4.1, at A299; accord id. § A9.1.1, at A329; see also A341 ("Asymptomatic HIV alone is not unfitting for continued service."). To be subject to separation, an HIV-positive individual's condition must (i) prevent him "from reasonably performing the duties of [his] office, grade, rank, or rating"; (ii) "represent[] an obvious medical risk to the health of the member or the health or safety of other members"; or (iii) "impose[] unreasonable requirements on the military to maintain or protect the Service member." DoDI 1332.18, enclosure 3, app. 1, § 2(a), at A26. For the reasons discussed in detail above, the evidence in this record clearly establishes that HIV seropositivity alone is not inconsistent with ongoing military service, does not seriously jeopardize the health or safety of the servicemember or his companions in service, and does not impose unreasonable burdens on the military when compared to similar chronic conditions.[39] Moreover, both named

[39] Indeed, the unjustified different treatment given to HIV as compared to other conditions is itself contrary to the explicit policy demanding that HIV be treated "in the same manner as . . . other chronic or progressive illnesses," DoDI 6485.01, enclosure 3, § 2(c), at A85.

plaintiffs' commanding officers recommended retention, opining that Roe's and Voe's HIV status did not interfere with their ability to perform their duties. The SAFPC recognized as much. See A460 ("[H]e is able to perform all in[-]garrison duties, has passed his most recent fitness assessment without any component exemptions, and his commander strongly supports his retention."); A747 (same). The same is true for the four identified active-duty members of OutServe facing imminent separation. See Pls.' Memo. Exs. C1-C4 [Dkt. Nos. 40-1 to -4].

Nonetheless, Roe and Voe—along with the four OutServe members—were found unfit for duty and ordered discharged. The reason given in all six cases was identical: The servicemember "belongs to a career field with a comparatively high deployment rate/tempo" to the CENTCOM area, but being HIV positive "precludes him from being able to deploy world-wide without a waiver and renders him ineligible for deployment to [CENTCOM]." A460; accord A747; Pls.' Memo. Exs. C1-C4 [Dkt. Nos. 40-1 to -4]; see also Defs.' Memo. & Opp'n 26-27 (stating that Roe and Voe were ordered "discharged for a combination of having HIV and being in a career field where they would have a high deployment tempo to CENTCOM, rendering it impossible for them to fully perform their duties").[40]

The Court has already explained why the policy declaring all HIV-positive servicemembers categorically ineligible for deployment to CENTCOM is irrational and arbitrary.

[40] Defendants have identified four servicemembers who were referred into the DES after being diagnosed with HIV but who were ordered returned to duty rather than separated, assertedly because each "had a much lower likelihood of deployment" to CENTCOM. A421. Two observations are in order. First, at least one servicemember ordered returned to service had a 17.1% likelihood of deployment as measured between fiscal year ("FY") 2015 and FY 2017, whereas those who were ordered separated had "at least a 20% likelihood" over that same period. Id. Because it is unclear by how much any of the servicemembers' likelihoods of deployment exceeded 20%, it is impossible to tell whether defendants' distinction is meaningful. Second, that a few HIV-positive servicemembers were spared from separation does not make the decisions in Roe's and Voe's cases any more acceptable.

Defendants' reliance on that policy renders the decisions to discharge Roe and Voe contrary to the APA for two reasons. First, although the SAFPC purported to engage in an individualized determination as to Roe's and Voe's fitness for duty, in fact its decisions were completely dependent on the across-the-board deployability policy. The failure to consider the issues with that policy or to analyze whether Roe and Voe could in fact be deployable to CENTCOM—let alone to any other location beyond the continental United States—despite their condition renders the decisions to discharge them arbitrary and capricious.[41] Moreover, because the categorical deployment limitation is not rationally related to any legitimate interest, that limitation applies to Roe and Voe solely because they have been diagnosed with HIV. By attempting to discharge them because of that limitation, the SAFPC violated agency policy mandating that HIV status alone is not a permissible ground for separation. A decision in direct conflict with the agency's own standards, and one based on a failure to consider key aspects of the problem, cannot stand under the APA.[42]

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[41] Another aspect of the problem that defendants failed to consider was whether Roe and Voe could be retained in a different capacity. DoDI 1332.18 sets out factors that must be considered in deciding "whether a Service member can reasonably perform his . . . duties," one of which is whether "reclassification or reassignment is feasible." DoDI 1332.18, enclosure 3, app. 2, § 4(a), at A31. Nothing indicates that the SAFPC, or any other Air Force decisionmaker, ever considered that question, even though Roe was hoping to pursue retraining in another field with a lower likelihood of deployment. See Pls.' Opp'n & Reply Ex. A [Dkt. No. 60-1] 2. During oral argument, plaintiffs' counsel stated that Voe also was interested in pursuing retraining.

[42] To show a likelihood of success on their equal protection and APA claims, plaintiffs need only demonstrate that the challenged policies are irrational and arbitrary; they need not endeavor to explain what irrational or unstated forces may be behind those policies. Nonetheless, it bears observing that the history of HIV has largely been one of fear, misinformation, stigma, and moral outrage, see Pls.' Memo. Ex. E [Dkt. No. 40-6] 3-6 (expert declaration of Trevor Hoppe), and the military would hardly be the first American institution to react to HIV in a manner incommensurate with the true nature of the disease and those affected by it.

B. Irreparable Harm

A party seeking a preliminary injunction must make a clear showing of "actual and imminent" irreparable harm in the absence of injunctive relief. Direx Isr., Ltd. v. Breakthrough Med. Corp., 952 F.2d 802, 812 (4th Cir. 1991) (citation omitted). "[I]rreparable harm occurs when the threatened injury impairs the court's ability to grant an effective remedy," Int'l Refugee Assistance Project v. Trump, 883 F.3d 233, 270 (4th Cir.), vacated on other grounds, 138 S. Ct. 2710 (2018), typically when monetary damages "are difficult to ascertain or are inadequate," Handsome Brook Farm, LLC v. Humane Farm Animal Care, Inc., 193 F. Supp. 3d 556, 574 (E.D. Va. 2016) (citation omitted), aff'd, 700 F. App'x 251 (4th Cir. 2017). The impending harm must be likely, not merely possible. Winter, 555 U.S. at 22.

One point of clarification is necessary at the outset. Defendants argue that Sampson v. Murray, 415 U.S. 61 (1974), as applied to military employees in Guerra v. Scruggs, 942 F.2d 270 (4th Cir. 1991), requires plaintiffs "to make a much stronger showing of irreparable harm than [under] the ordinary standard for injunctive relief." Defs.' Memo. & Opp'n 17. Defendants cite Sampson and Guerra out of context. In Sampson, a federal employee sued to prevent herself from being terminated pending her appeal to the Civil Service Commission. 415 U.S. at 62-63. The district court granted an injunction after finding a mere possibility of harm, see id. at 67, and the court of appeals affirmed on similar grounds, see id. at 84-85. The Supreme Court reversed, holding that the court of appeals erred "in suggesting that . . . the District Court need not have concluded that there was actually irreparable injury." Id. at 88. Sampson is thus a relic of the world before Winter's unambiguous rejection of the "possibility" standard, see 555 U.S. at 22 (requiring a showing "that irreparable injury is likely in the absence of an injunction" (emphasis in original)). Likewise, when Guerra applied Sampson in 1991, the Fourth Circuit employed a

flexible sliding-scale approach that permitted a preliminary injunction to issue based only on "possible" irreparable harm. See Guerra, 942 F.2d at 273-74; see also Henderson ex rel. NLRB v. Bluefield Hosp. Co., 902 F.3d 432, 438 n.* (4th Cir. 2018) (discussing the Fourth Circuit's former balancing approach and how that approach was abrogated by Winter). The same was true for the sister-circuit cases on which Guerra relied. See, e.g., Hartikka v. United States, 754 F.2d 1516, 1518 (9th Cir. 1985). Since Winter, the "ordinary standard for injunctive relief," Defs.' Memo. & Opp'n 17, has come into line with what the Court described in Sampson. Accordingly, Guerra does not impose a special, heightened requirement on military-employee plaintiffs.[43] There is but one standard for issuing injunctive relief, in military cases "no less"—and no more—"than in other cases." See eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 394 (2006).

Plaintiffs have made a clear showing that they likely face irreparable, actual harm. Under normal circumstances, termination of employment does not constitute irreparable injury because of the "possibility that adequate compensatory or other corrective relief will be available at a later date." Sampson, 415 U.S. at 90. This may be true for some servicemembers facing discharge, at least absent "unusual actions relating to the discharge itself." Hartikka, 754 F.2d at 1518 (quoting Sampson, 415 U.S. at 92 n.68). But it is not guaranteed to be true in every case. Roe and Voe, along with other similarly situated HIV-positive servicemembers, face a particularly heinous brand of discharge, one based on an irrational application of outmoded policies related to a disease surrounding which there is widespread fear, hostility, and misinformation. In their cases, the "stigma of being removed from active duty . . . and [being]

[43] This is not to suggest that the military context of this litigation is irrelevant. As discussed above, that plaintiffs seek preliminary relief from military discharge orders weighs heavily in the Court's overall analysis of whether relief is appropriate and what form that relief may take.

labeled as unfit for service" is coupled with the indignity suffered because the reason for their discharges bears no relationship to their "ability to perform [their] job[s]." Elzie v. Aspin, 841 F. Supp. 439, 443 (D.D.C. 1993).[44] It is further compounded by the stigma and discrimination facing those living with HIV and the commonsense observation that HIV-positive servicemembers, if discharged under these circumstances, will likely be forced to reveal their condition. In that sense, the discharges with which Roe and Voe are faced are doubly damaging: Not only will they lose the opportunity to "pursue [their] chosen profession," Enyart v. Nat'l Conf. of Bar Exam'rs, Inc., 630 F.3d 1153, 1166 (9th Cir. 2011), but it is likely that they will also face genuine stigmatic injury caused by defendants' decisions, see Karnoski v. Trump, No. 17-cv-1297, 2017 WL 6311305, at *9 (W.D. Wash. Dec. 11, 2017), stay granted, No. 18A625, 2019 WL 271944 (U.S. Jan. 22, 2019).[45] This is precisely the type of harm that back pay or reinstatement cannot remedy and for which status quo-preserving preliminary relief is designed.

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[44] Defendants suggest that Guerra forecloses this reasoning. It does not. Guerra involved an Army private who sought to enjoin his discharge for "cocaine usage and absence from duty due to alcohol intoxication." 942 F.2d at 271-73. Guerra did not dispute his drug and alcohol use; rather, he challenged the procedures through which the discharge recommendation was made. Id. The Fourth Circuit's conclusion that any "damage to [Guerra's] reputation during the interim between his discharge and the decision of the board reviewing his discharge" did not qualify as irreparable harm, id. at 274-75, does not require the same conclusion here. Unlike Guerra, plaintiffs do not simply dispute the procedures used to reach a decision; they also challenge the basic notion that their HIV status makes them in any way unfit for service. Put another way: It was Guerra's behavior, not his impending discharge, that would subject him to stigma, whereas in plaintiffs' case it is the Armed Forces's apparent affirmation that plaintiffs are less valuable by virtue of their HIV status that will cause immeasurable harm.

[45] Defendants suggest that the Supreme Court's decision to stay the injunction in Karnoski, a case involving the ban on military service by openly transgender individuals, rebuts the reasoning in that opinion. Defs. Memo. 19. That argument puts too much weight on the Court's action. Because no reasons were given for granting the stay request, the most that can be intuited is "a reasonable probability that four Members of the Court will consider the issue sufficiently meritorious to grant certiorari." Graves v. Barnes, 405 U.S. 1201, 1203 (Powell, Circuit Justice 1972); cf. Dunn v. Ray, No. 18A815, 2019 WL 488293, at *1 (U.S. Feb. 7, 2019) (vacating a stay and explaining why, in the Court's view, the injunctive relief had been improperly granted).

C. Remaining Equitable Factors

Finally, to be entitled to the preliminary injunctive relief they seek, plaintiffs must show that the balance of equities tips in their favor and that an injunction is in the public interest. Where, as here, the injunctive relief is sought against the federal government and implicates a matter of great public interest, these two factors overlap and may be considered together. Nken v. Holder, 556 U.S. 418, 436 (2009); Int'l Refugee Assistance Project v. Trump, 857 F.3d 554, 602 (4th Cir.), vacated on other grounds, 138 S. Ct. 353 (2017).

The equities weigh heavily in plaintiffs' favor. Although the impact of defendants' policies on servicemembers like Roe and Voe is potentially immense, defendants can scarcely be said to face any serious consequences stemming from the issuance of appropriately tailored injunctive relief, given that HIV-positive individuals make up such a miniscule percentage of active-duty servicemembers—0.027%, by one calculation. Pls.' Memo. 29. Defendants do not attempt to argue that retaining HIV-positive servicemembers would be prohibitively expensive or burdensome. Instead, they focus on a different sort of institutional harm: that granting relief here will encourage a deluge of cases challenging discharge determinations and undermine the principle of military independence. Defendants' concerns are overstated. Plaintiffs' claims are not of the sort that worried the Fourth Circuit in Guerra—namely, individualized or procedural challenges with little or no general applicability. Nor is the relief sought by plaintiffs likely to entangle the Court in "complex, subtle, and professional decisions" in a way that would cause symbolic or actual harm to the Armed Forces. Plaintiffs ask only that defendants adhere to their stated policies and make nonarbitrary, personalized determinations about each individual's fitness for service. That sort of request does not do violence to the notion of military independence, but rather enforces it.

The public interest also decisively favors granting injunctive relief. The military is a branch of the federal government and ultimately bears a responsibility to the American public at large. The public undoubtedly has an interest in seeing its governmental institutions follow the law and treat their employees in reasonable, nonarbitrary ways. More concretely, the public benefits from the security provided by military departments populated with individuals dedicated to the notion of service. Roe and Voe, along with similarly situated HIV-positive members of the Air Force, have been serving—and want to continue serving—their country. They have carried out their responsibilities in a creditable manner, earning trust on the part of their commanding officers and fellow servicemembers. It is in the public interest to prevent their discharge for apparently arbitrary and indefensible reasons, at least until the Court can definitively decide the merits of plaintiffs' claims.

D. Scope of Injunctive Relief

Plaintiffs have demonstrated that they are entitled to injunctive relief. The remaining question is what form that relief should take. "Crafting a preliminary injunction is an exercise of discretion and judgment, often dependent as much on the equities of a given case as the substance of the legal issues it presents." Trump v. Int'l Refugee Assistance Project, 137 S. Ct. 2080, 2087 (2017) (per curiam). Interim equitable relief serves "not to conclusively determine the rights of the parties, but to balance the equities as the litigation moves forward." Id. (citation omitted). In forging such relief, a court must exercise great care to "mold its decree to meet the exigencies of the particular case." Id. (citation omitted); see also North Carolina v. Covington, 137 S. Ct. 1624, 1625 (2017) (per curiam) ("A district court therefore must undertake an equitable weighing process to select a fitting remedy for the legal violations it has identified,

taking account of what is necessary, what is fair, and what is workable." (internal quotation marks and citations omitted)).

First, any relief granted must be "limited to the inadequacy that produced the injury in fact that the plaintiff has established." Lewis v. Casey, 518 U.S. 343, 357 (1996); see Missouri v. Jenkins, 515 U.S. 70, 88 (1995) ("[T]he nature of the . . . remedy is to be determined by the nature and scope of the constitutional violation." (citation omitted)). That requirement respects the separation of powers and keeps courts from entangling themselves in delicate policy matters. Here, the apparent inadequacy giving rise to imminent, irreparable injury is that servicemembers like Roe and Voe face separation based on the arbitrary policy that they are categorically ineligible for deployment to CENTCOM. The solution, then, is the mirror image of that defect: defendants will be prohibited from making or enforcing discharge determinations based on that policy.[46]

Next, defendants have argued that if injunctive relief of any kind is to be granted, it must be limited to Roe and Voe. Such a limitation would be inappropriate for several reasons. For one, plaintiff OutServe has the right to assert associational standing and seek relief on behalf of its members who face imminent and irreparable injury due to defendants' policies. There are at least four active-duty Air Force members who are members of OutServe and who are identically

[46] The order will not address the enlistment of HIV-positive individuals or the reenlistment of HIV-positive servicemembers whose terms of service have expired. Nor will defendants be enjoined at this time "from restricting Roe and Voe and others similarly situated from being promoted, changing duty station, or re-training on the same terms as other service members living with HIV who are not being separated" [Dkt. No. 34-1]. As it currently stands, the preliminary record does not contain information that would allow the Court to evaluate the reasons for, and consequences of, that requested relief. Of course, the Court has "both statutory and equitable authority to modify" an injunctive order, Transp., Inc. v. Mayflower Servs., Inc., 769 F.2d 952, 954 (4th Cir. 1985), and the denial of this aspect of plaintiffs' motion is without prejudice to plaintiffs' ability to seek modification of the order should the need arise.

situated to Roe and Voe. Because of the longstanding stigma and discrimination facing those living with HIV, it may be difficult to identify potential plaintiffs in a case of this nature. Granting relief to all similarly situated servicemembers is thus the only way to ensure uniform, fair, rational treatment of individuals who belong to a vulnerable, and often invisible, class. Moreover, plaintiffs' entitlement to injunctive relief in this civil action is not so much dependent on characteristics peculiar to Roe and Voe; rather, it flows from defendants' reliance on an arbitrary, across-the-board determination that HIV-positive servicemembers must be deemed ineligible to deploy to CENTCOM, regardless of each servicemember's actual physical condition. That determination is flawed, and its uncritical application will be equally flawed no matter whether the servicemember is named Roe or Doe or whether he hails from Portland, Oregon or Portland, Maine. This case deals with national institutions, national policies, and national interests; it is thus unsurprising that the appropriate scope of relief should be national as well. Servicemembers who enlist in the Air Force do so with the expectation that they will fly under one flag and answer to one Department. They serve the country at large, and there are no relevant regional or localized facts that would counsel in favor of limiting the scope of the injunction to the named plaintiffs.[47]

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[47] So-called universal injunctions are the subject of fierce debate. Compare, e.g., Trump v. Hawaii, 138 S. Ct. 2392, 2429 (2018) (Thomas, J., concurring) (labeling universal injunctions "legally and historically dubious"), with, e.g., Amanda Frost, In Defense of Nationwide Injunctions, 93 N.Y.U. L. Rev. 1065, 1090-1104 (2018) (reviewing practical and doctrinal reasons in favor of universal injunctions), and Spencer E. Amdur & David Hausman, Response, Nationwide Injunctions and Nationwide Harm, 131 Harv. L. Rev. F. 49, 52 (2017) ("[W]hen many people face the same genuinely irreparable injury as the plaintiff, a complete injunction of the illegal policy serves an important purpose."). For now, they remain a viable part of a district court's equitable powers and may be used where appropriate. Indeed, in International Refugee Assistance Project, the Supreme Court rejected portions of a district court's injunctive order as overbroad but left in place relief that applied not just to the plaintiffs but also to "similarly situated" individuals. 137 S. Ct. at 2087 (per curiam). That case suggests that there is no categorical rule prohibiting injunctive relief reaching nonparties; rather, what governs the

Although plaintiffs have at times suggested that they seek relief on behalf of all members of the Armed Forces, the relief granted will be limited to active-duty members of the Air Force. The record reveals that there are meaningful differences in the way each military department has approached the issue of HIV-positive servicemembers, and the Court does not discount the possibility that another department's policies could be supported by a rational basis and applied in a manner consistent with the APA. Similarly uncertain is whether the foregoing analysis would apply to HIV-positive servicemembers who are on restricted duty of one kind or another. Without a firmer basis in evidence, any broader relief would be inappropriate.

IV. CONCLUSION

The military is an institution like no other in our system of government. It has unique institutional interests and experience. The decisions it makes are thus entitled to deference from the coordinate branches, and particularly from the judicial branch, whose officers are largely shielded from the exigencies of military life. Nonetheless, the military remains a branch of government and so is bound to follow the Constitution and laws of the United States. And the judiciary's responsibility remains to enforce those laws and protect the rights of individuals vulnerable to arbitrary exercises of governmental authority. Courts must examine questions of military policy with care and humility—but examine them they must.

Here, plaintiffs have made a strong preliminary showing that the Air Force's approach to servicemembers living with HIV is irrational, inconsistent, and at variance with modern science. Accordingly, plaintiffs' motion for a preliminary injunction will be granted in part and denied in

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issuance of equitable relief is, as always, the need to ensure that the relief is carefully tailored to address only those defects giving rise to the specific irreparable injury as demonstrated in the preliminary injunction record.

part, and defendants' motion to dismiss denied, by an appropriate Order to be issued with this Memorandum Opinion.

Entered this 15th day of February, 2019.

Alexandria, Virginia

/s/
Leonie M. Brinkema
United States District Judge

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

RICHARD ROE; VICTOR VOE; and OUTSERVE-SDLN, INC., Plaintiffs, v. PATRICK M. SHANAHAN, in his official capacity as Acting Secretary of Defense; HEATHER A. WILSON, in her official capacity as Secretary of the Air Force; and the UNITED STATES DEPARTMENT OF DEFENSE, Defendants.	)	No. 1:18-cv-1565-LMB-IDD

ORDER

Upon consideration of Defendants' Unopposed Motion to Modify the Preliminary Injunction, the Court hereby

GRANTS Defendants' Motion, and

AMENDS its February 15, 2019 Order, ECF No. 73, to state that it is "ORDERED, ADJUDGED, and DECREED that defendants be and are ENJOINED from separating or discharging from military service Richard Roe, Victor Voe, and any other similarly situated active-duty member of the Air Force because they are classified as ineligible for worldwide deployment or deployment to the United States Central Command ("CENTCOM") area due to their HIV-positive status. If an Airman wishes to be excepted from this Order and be separated or discharged, the Air Force shall provide them a written notice that their consent to separation is not required and that a federal lawsuit may result in his or her retention. After receiving such a notice, the Airman may make a written request to proceed with his or her separation or discharge, and then the Air Force may proceed with the separation or discharge."

/s/
Leonie M. Brinkema
United States District Judge
4/8/19

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

RICHARD ROE; VICTOR VOE; and OUTSERVE-SLDN, INC., Plaintiffs, v. PATRICK M. SHANAHAN, in his official capacity as Acting Secretary of Defense; HEATHER A. WILSON, in her official capacity as Secretary of the Air Force; and the UNITED STATES DEPARTMENT OF DEFENSE, Defendants.	)	No. 1:18-cv-1565-LMB-IDD

DEFENDANTS' NOTICE OF APPEAL

Notice is hereby given that all Defendants appeal to the United States Court of Appeals for the Fourth Circuit from this Court's Order, Dkt. 73, and Memorandum Opinion, Dkt. 72, denying Defendants' motion to dismiss and granting-in-part and denying-in-part, Plaintiffs' motion for a preliminary injunction, and from all other orders, holdings, or rulings merged or incorporated into the Order.

DATE: April 16, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 28, 2019, I electronically filed this joint appendix with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system, except for the following, who will be served (as agreed upon) via email:

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