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

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

PLAINTIFFS' REBUTTAL EXPERT REPORT OF CRAIG W. HENDRIX, M.D.

1. I am the same Craig W. Hendrix, M.D. who submitted an expert report on March 22, 2019. My credentials are set forth in that expert report, along with the other disclosures required by the Federal Rules of Civil Procedure.

2. I have been asked to provide testimony rebutting the testimony expected from Colonel Clinton K. Murray, M.D., and Sheila Peel, M.D., who the Defendants have disclosed as non-retained expert witnesses in this case. To provide this rebuttal testimony, I have reviewed the expert disclosures regarding Colonel Clinton K. Murray, M.D. and Sheila Peel, MSPH, Ph.D., the deposition transcripts of Colonel Clinton K. Murray and Sheila Peel, and the materials referenced in the bibliography. I base my testimony on my education, professional experiences, and the materials cited to in this report and in my bibliography.

3. The risk of adverse effects on organs or body systems due to HIV medications — e.g., renal impairment, increased cardiovascular risk and changes in the lipid profile, or increased liver enzymes — has progressively both shifted in type and diminished in overall frequency as the new categories of drugs, particularly with introduction of integrase inhibitors and replacement of an older formulation of tenofovir (tenofovir disoproxil fumarate [TDF]) with a new formulation (tenofovir alafenamide [TAF]).[1] As current HIV treatment guidelines recommend a combination of integrase inhibitors, TAF, and emtricitabine (which has an excellent safety profile), the rate of side effects should decline further.[2] More important for purposes of the potential deployment of service members living with HIV, numerous studies of ARV use in the real world (outside of randomized controlled trials) consistently demonstrate reduced side effects with time on treatment. These studies demonstrate both: (1) reduced side effect-related drug discontinuations year over year after starting ARVs; and (2) dramatically decreasing rates of side effect-related discontinuation rates, correlated with evolution of the most commonly recommended ARVs over larger time periods and populations—from 30% discontinuation rates in the first year (when boosted protease inhibitors were most common) down to less than 5% with current, first-line recommended integrase regimens.[3] The categories of side effects described above most often

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[1] AIDSInfo, *Side Effects of HIV Medicines*, (Aug. 29, 2018), https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/22/63/hiv-medicines-and-side-effects ("[N]ewer HIV regimens cause fewer side effects than regimens used in the past. As HIV treatment options continue to improve, people are less likely to experience side effects from their HIV medicines.").

[2] Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV, AIDSinfo (Oct. 25, 2018), https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/0.

[3] *See*, *e.g.*, Alejandro Gonzalez-Serna et al., *Temporal trends in the discontinuation of first-line antiretroviral therapy*, 69 J. Antimicrob. Chemother. 2202 (2014); Antonio Di Biagio et al., *Discontinuation of Initial Antiretroviral Therapy in Clinical Practice: Moving Toward Individualized Therapy*, 71 J. Acquir. Immune Defic. Syndr. 263 (2016); Judit Penafiel et al.,

occur within the first year of treatment, are diagnosed by periodic laboratory testing, and are usually reversible with change in medication.[4] Because any service member with HIV serving overseas would already be established on a stable, fully-suppressive antiretroviral regimen, the risk of such complications would be slight indeed.

4. By definition, medical care in a deployed setting is less than ideal and will never be at the same level as medical care available in the United States.[5] The realities of medical care in a deployed setting at times require deviation from "best practices" and a marginal diminishment in the standard of care. While the Department of Defense appropriately strives to maintain the highest of standard of care possible for deployed service members, the standard of care currently delivered in deployed settings should have no more significant detrimental effects on service members living with HIV than on service members who are not living with HIV, including those service members living with other chronic and treatable conditions who are regularly permitted to deploy.

5. As pointed out in Dr. Hardy's expert report, development of resistance to an ART regimen does not occur randomly; it generally involves non-adherence to medications, because the development of mutations that lead to resistance becomes impossible if the virus is suppressed. Given the low and declining chance of drug side over time (discussed above), the very high rate of suppression for service members living with HIV, and the extremely low possibility of the development of resistance or viral breakthrough for those who are adherent to their medications, the medical monitoring of service members living with HIV

Tolerability of integrase inhibitors in a real-life setting, 72 J. Antimicrob. Chemother. 1752 (2017).

[4] Id.

[5] Peel Dep. 105:12-18, May 3, 2019.

could be conducted at less frequent intervals and/or scheduled for times when it is most convenient and safe. Current expert panels recommend medical monitoring and laboratory testing for viral load every 6 to 12 months in patents on well tolerated and fully suppressive ART regimens. Providing medical monitoring to deployed HIV-positive service members at approximately 12-month intervals would not be a deviation from the global standard of care,[6] and in the few instances where it could not be accomplished until 14-15 months after the previous medical monitoring appointment, it would not be a significant deviation from the standard of care.

6. The contention that people living with HIV are more susceptible to renal problems as a result of dehydration when compared to persons without HIV infection is not supported by medical literature. Persons with HIV infection, prior to the antiretroviral era, were identified with pre-renal causes of renal dysfunction, but these were causally linked to their HIV infection. Specifically focusing on HIV medications, TDF is most commonly associated with renal dysfunction, usually as a result of renal tubular effects, and the time course is rarely acute as a more chronic pattern of development over many months is most typical. This is usually reversible and the most significant risk factor is pre-existing renal disease, in isolation a likely exclusion for overseas deployment.[7] Dehydration has not been shown to have any particularly detrimental effect on people living with HIV who are taking HIV medications. However, one would expect to observe the same dehydration impact on

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[6] World Health Organization, *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection* 128 (June 2016); *see also* AIDS Map, *CD4, viral load, and other tests* (Feb. 2017), http://www.aidsmap.com/CD4-viral-load-amp-other-tests/page/1327442/; DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents, *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV* (Oct. 25, 2018) https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/0.

[7] Atefeh Jafari et al., *Tenofovir-induced nephrotoxicity: incidence, mechanism, risk factors, prognosis and proposed agents for prevention*, 70 Eur. J. Clin. Pharmacol. 1029 (2014).

renal function and other organ systems for persons living with HIV as for service members who are not taking HIV medications. If environmental conditions and water discipline within the unit result in dehydration, then the dehydration itself and its potentially devastating effects on unit readiness are a much greater immediate concern than an indolent development of renal dysfunction from HIV medications over many months.

7. As noted in Dr. Hardy's initial expert report, a person who stopped taking their HIV medications would continue to have a suppressed viral load for 4-12 weeks; there would be only a rare chance of immediate symptomatic changes (*e.g.*, an acute retroviral syndrome with cessation of ART) and little impact on long-term disease progression.[8] The typical time to clinically important disease progression to susceptibility of opportunistic infections and other AIDS-related conditions takes 8 years. Accounting for the frequency of a few fast-progressors in an HIV-positive population, the risk of progression to 200 CD4 cells is very low (around 5% over one year),[9] and they would not experience symptoms of HIV for several months or years after discontinuing medication. In addition, negative effects of a treatment interruption of less than a year, *e.g.*, loss of CD4 cells, would very likely be reversed after the person is placed back on HIV medications, thus avoiding any significant long-term consequences of such a treatment interruption.

8. The concern with antiretroviral resistance, as noted above, is very low with complete cessation of treatment. By contrast, symptoms and potential impairment of readiness is more acute with cessation of medical treatment for several other chronic medical

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[8] Amy B. Garlin and Paul E. Sax, *Retroviral Rebound Syndrome with Fatal Outcome after Discontinuation of Antiretroviral Therapy*, 41 Clin. Infect. Dis. e83 (2005).
[9] Thierry Buclin et al., *Development and Validation of Decision Rules to Guide Frequency of Monitoring CD4 Cell Count in HIV-1 Infection before Starting Antiretroviral Therapy*, 6 PLOS One 4 e18578 (2011).

conditions allowed to deploy. For example, within approximately a month, a service member with hypothyroidism who is deprived of their daily medication may become lethargic, suffer joint weakness, and have trouble concentrating or remembering.[10] An asthmatic who is prescribed an inhaler and goes without it for even a short period of time, may suffer acute respiratory distress with trouble breathing and weakness while exercising.[11] Though a person with diabetes is allowed to deploy under certain circumstances,[12] the consequences of not having insulin to control one's blood sugar can be severe and even fatal.[13] Active duty women using oral daily contraceptive medications for dysmenorrhea may experience recurrence of severe abdominal pain in the next menstrual cycle with cessation of dosing, [14] and women using them for pregnancy prevention would be at risk of pregnancy within days of stopping those medications, with the potential for readiness impact within weeks if morning sickness occurs prior to pregnancy diagnosis and the service member is relocated out of a combat zone at time of diagnosis. And though a service member is allowed to join the armed services and deploy with vision that must be corrected with glasses (up to a certain level of deficiency), the loss of those glasses would have an immediate effect on that

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[10] Mayo Clinic, *Hypothyroidism (underactive thyroid): symptoms and causes* (Dec. 4, 2018), https://www.mayoclinic.org/diseases-conditions/hypothyroidism/symptoms-causes/syc-20350284.

[11] Mayo Clinic, *Asthma: symptoms and causes* (Sept. 13, 2018), https://www.mayoclinic.org/diseases-conditions/asthma/symptoms-causes/syc-20369653.

[12] *See* AR 40-501, Ch. 5, § 14(f)(1)-(2) (2017).

[13] Mayo Clinic, *Diabetes: Diagnosis and Treatment* (Aug. 8, 2018), https://www.mayoclinic.org/diseases-conditions/diabetes/diagnosis-treatment/drc-20371451 ("People with type 1 diabetes need insulin therapy to survive. Many people with type 2 or gestational diabetes also need insulin therapy").

[14] Mayo Clinic, *Menstrual cramps: diagnosis and treatment* (Apr. 14, 2018), https://www.mayoclinic.org/diseases-conditions/menstrual-cramps/diagnosis-treatment/drc-20374944.

individual's ability to perform their job. In this regard, a different standard is being applied to HIV without a legitimate medical reason for doing so.

9. The concern that deployment will diminish a service member's ability to adhere to their HIV medications is conjectural, not supported by data, and rests on a flawed analogy to malaria prophylaxis. The analogy between a soldier's ability to adhere to HIV treatment and a soldier's ability to adhere to antimalarial prophylaxis in the stress of down range conditions is not an apt one. First, the service member may have trouble remembering to take a daily prophylactic medication, e.g., for malaria prophylaxis, because daily medication adherence is a new behavior that is not well-established prior to deployment and is necessary due to external infection risk factors as a result of the deployment. In contrast, a service member living with HIV taking antiretroviral drugs—and having achieved full viral suppression—must have established a pattern of daily medication adherence through months and months of taking their medications before they deploy. Second, the symptomatic side effects of anti-malarial medications are typically worse than the symptomatic side effects of ART, even upon initiation, and the disparity in terms of side effects profiles is much greater if the person taking ART is already well-established on their regimen. Third, the incentive and motivation to take a daily antiretroviral medication that keeps one healthy and prevents the progression of an already-present, life-threatening disease is much different from the motivation to take a medication, e.g., malaria prophylaxis that *may protect* one from acquiring a life-threatening disease to which one *may* be—but has not yet been—exposed. In fact, the data provided as part of Dr. Murray's disclosures reveals that adherence among service members is extremely high—significantly higher than in the general population—with viral suppression reached by 99.8% of those diagnosed between 2012 and 2016 in a

study conducted by the Department of Defense. By comparison, those receiving medical care through the Ryan White HIV/AIDS Program have only recently reached an 84.9% viral suppression rate—and were at only 75.0% viral suppression as recently as 2012.[15]

10. Service members living with HIV do not require special health-related confidentiality protections in a deployed environment. Though it is true that disclosure of a person's HIV status may subject that person to some forms of stigma and discrimination from other service members, the way to address this problem is to make clear that such conduct will not be permitted—and stigma and discrimination will almost undoubtedly not be reduced by reinforcing the misconceptions and fear that undergird the current policies of HIV exceptionalism, including unwillingness to deploy people living with HIV. As long as personnel in a deployed environment follow the same practices for maintaining patient confidentiality as are currently employed in the United States, which requires disclosure on a "need-to-know" basis, the Department of Defense will meet its obligations to maintain the confidentiality of this health information. Col. Murray's heightened concern for confidentiality notwithstanding, the military has established several practices related to identifying and managing HIV that create numerous opportunities to breach the confidentiality of the service member with HIV. In my own active duty experience leading the periodic HIV medical evaluation program in the Air Force, I heard countless examples in which a service member's HIV status was disclosed to non-medical personnel. These were largely related to informing a non-medical commander of a service member's HIV diagnosis

[15] Ryan White HIV/AIDS Program, *Annual Client-Level Data Report, Ryan White HIV/AIDS Program Services Report (RSR)* (2016), https://hab.hrsa.gov/sites/default/files/hab/data/datareports/RWHAP-annual-client-level-data-report-2016.pdf.

so that the commander could give the so-called "safe sex order" that every service member diagnosed with HIV had to sign. On a need-to-know basis, the commander would then inform a first sergeant and other unit personnel in order to more easily manage periodic evaluations at other medical facilities and to prepare for OCONUS training or military deployment that would preclude travel for the service member with HIV. The safe sex order itself requires HIV-positive service members to disclose their HIV status to all healthcare providers (which may include medical personnel beyond the primary medical practitioners providing care) and to all sexual partners, even if a condom is used or when there is no risk of transmission due to effective virally suppressive HIV treatment.[16]

11. Colonel Murray's concern that service members with HIV will disregard orders to donate blood lacks foundation. Upon being diagnosed, a person living with HIV is informed that they cannot donate blood. Based on my own experience in the military and review of current policies, I know that a newly-diagnosed service member is repeatedly instructed that they cannot donate blood. One of those instructions comes from their commanding officer in the form of an order (colloquially referred to as "safe sex orders," but inclusive of blood donation), the failure of which to obey is prosecutable under the Uniform Code of Military Justice. This warning is repeated by both the physician and public health officer at the initial

[16] *See*, *e.g.*, AR 600-110, Fig. 4-1, 18 (April 2014) ("Condom use does not remove [the] obligation to inform partners of . . . HIV infection before engaging in intimate sexual contact"); *see also*, *e.g.*, Virginia Supervie et al., Per Sex-Act Risk Of HIV Transmission Under Antiretroviral Treatment: A Data-Driven Approach, 79 J. Acquir. Immune. Defic. Syndr. 440 (2018); Benjamin R. Bavinton et al., *Viral Suppression and HIV Transmission in Serodiscordant Male Couples: an International, Prospective, Observational, Cohort Study*. 5 Lancet HIV 8 E438 (2018); Alison J. Rodger et al., *Risk Of HIV Transmission through Condomless Sex in Serodifferent Gay Couples with the HIV-Positive Partner Taking Suppressive Antiretroviral Therapy (Partner): Final Results of a Multicentre, Prospective, Observational Study*. Lancet HIV (May 2, 2019) https://dx.doi.org/10.1016/S0140-6736(19)30418-0.

HIV evaluation. This is repeated at each subsequent periodically mandated HIV evaluation quite apart from routine care and with every change of unit commander. Pointing to evidence of a single transfusion transmitted case of hepatitis C as the result of a "walking blood bank" donation by a service member who knew they had tested positive for hepatitis C (HCV) differs importantly from the case of blood donations by persons with HIV. The service member with HCV who donated blood to the walking blood bank did not know that HCV could be transmitted through blood donation.[17] This individual was diagnosed before entering the service and was not screened for HCV, because the military does not require HCV testing upon entry or at regular intervals, as it does with respect to HIV. Additionally, unlike service members with HIV, service members with HCV are not required to receive preventive counseling or an order instructing them not to donate blood. Finally, for years and years, the general population has received public health messages about preventing HIV transmission, whereas HCV is relatively less well known, understood or feared by the general population. Only recently has the drug company that markets HCV treatment medications been advertising the need for HCV screening in order to increase treatment. It is not surprising that a service member may have been given an HCV diagnosis, but did not understand its implications on his ability to donate blood. Because they do not test for it at regular intervals, the risks the military tolerates with respect to the transmission of HCV are much greater than the risks with respect to HIV. Furthermore, even if a service member with HIV were to accidentally donate blood—*and* it was not tested before being transfused—it is

[17] Shilpa Hakre et al., *Transfusion-transmissible viral infections among U.S. military recipients of whole blood and platelets during Operation Enduring Freedom and Operation Iraqi Freedom*, 51 Transfusion, 473, 480 (2011) ("[the HCV-positive donor] reported that he was never referred for specialty evaluation or care, nor was he ever advised to avoid donating blood").

unclear whether transmission is likely from a person with an undetectable HIV viral load. For example, the reduction in HIV viral load as a result of fully suppressive HIV treatment (regularly achieved in the military) is the same as the difference in the volume and, therefore, viral load associated with an infected unit of blood when compared to the amount of blood associated with transmission of HIV infection through needle sharing or an occupational needlestick injury; this viral load difference accounts for a 150-to-400-fold reduction in HIV transmission risk based on epidemiologic data reviewed by the CDC.[18] If service members with HIV are permitted to deploy, the primary risk to the blood supply in the military will continue to be service members with *undiagnosed* HIV and HCV. In fact, 131 out of 389 (34%) newly diagnosed HIV infections in the US Army between 2001 and 2007 were during deployment to Afghanistan and Iraq; each of these acute infections represents at least a transient viral load 100 times higher as compared to a person with chronic infection without antiretroviral treatment, and 1 million times higher as compared to a person with chronic infection on antiretroviral treatment.[19]

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

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[18] *See*, *e.g.*, Pragna Patel et al., *Estimating per-act HIV transmission risk: a systematic review*, 28 AIDS 10, 1509 (2014); Rebecca Baggaley et al., *Risk of HIV-1 transmission for parenteral exposure and blood transfusion: a systematic review and meta-analysis*. 20 AIDS 6, 805 (2006); Christopher D. Pilcher et al., *Amplified transmission of HIV-1: comparison of HIV-1 concentrations in semen and blood during acute and chronic infection*, 21 AIDS 13, 1723 (2007).

[19] Paul T. Scott et al., *Investigation of Incident HIV infections among US Army Soldiers Deployed to Afghanistan and Iraq, 2001-2007*. 28 AIDS Res. Hum. Retrovir. 10, 1308 (2012).

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

Executed this 6th day of May, 2019

Craig W. Hendrix, M.D.

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