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

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

PLAINTIFFS' SUPPLEMENTAL 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. I also submitted a rebuttal expert report on May 6, 2019.

2. I was asked to review certain documents that I understand the Defendants recently produced or identified on their trial exhibit list. A list of the documents that I reviewed in preparing this report is attached as Appendix A to this report. I was asked to review these documents to determine whether they were relevant to the opinions contained in my expert and rebuttal reports; in particular, whether any of these documents altered the opinions expressed in my expert and rebuttal reports.

3. After reviewing the documents listed in Appendix A, I reached the conclusion that none of those documents change the opinions I have previously provided in my expert and rebuttal reports. However, there were several documents on the list that provided further support for those opinions.

4. In particular, the documents pertaining to the risk of HIV transmission as a result of a suicide bombing were helpful in underscoring just how low (maybe non-existent) that risk actually is. For example, I reviewed DX014 (Kao, R.L. & McAlister, V.C. (2018). Care of victims of suicide bombing. *Can. J. Surg.*, 61(6): S184-87 ("Kao Article")), including references cited in the article, and where necessary, sources cited by those supporting references. This review reinforced my opinion that the risk of a battlefield transmission of HIV from a service member who knows that they are living with HIV is exceedingly low for the following reasons.

5. **First**, the risk of HIV transmission through a suicide bombing is exceedingly low in part because the risk of the bone of an individual with HIV penetrating the skin of another is low. Based on papers that report bone shard injuries resulting from suicide bombing (see footnote 2), I have estimated there is evidence of a bomber's bone shard penetrating the skin—the potential route of exposure to a blood-borne pathogen—in only 2.9%¹ of suicide bombing victims seeking medical care or 1 in 34.² Because I did not include any suicide

¹ As with other risk estimates in my expert opinions in this case, I am using the "worst case scenario" (*i.e.*, highest level of risk supported by the data) in calculating the level of overall risk for transmission. In this instance, the studies on victims of suicide bombings do not appear to take into account that some victims may not seek care in an emergency department, meaning that the denominator in this risk estimate is likely larger than the papers suggest and this risk is therefore lower.

 $^{^{2}}$ I considered 10 people with reported bone shard injuries from five suicide bombings divided by the 343 people recorded as victims of those blasts. In making this assessment, I considered the following papers: Kao Article; Braverman, I., *et al.* (2002). A novel mode of infection with

bombing reports that did not specifically report bone shard injuries and I excluded the largest report (Patel 2012), which has half the rate of studies in the pooled estimate, I am confident the actual number is lower. I am not suggesting, however, that the suicide bomber scenario provides a situation directly analogous to combat; the suicide bomber scenario risk likely represents a much higher estimate. For example, several large mass casualty reports indicate no bone shard injuries after urban terrorist bombings, except when there is a suicide bomber, meaning the 2.9% estimate is a very conservative, worst-case estimate. *See* Turégano-Fuentes, F., *et al.* (2008). Injury patterns from major urban terrorist bombings in trains: The Madrid experience. *World J Surg.*, 32(6):1168-75; *see also* Hadden, W.A., *et al.* (1978) The injuries of terrorist bombing: A study of 1532 consecutive patients. *Br. J. Surg.*, 65(8):525–31.

6. **Second**, as I have previously discussed, the amount of blood to which a person is exposed through percutaneous injury is key to how likely it would be for HIV transmission to result based on. CDC estimates the HIV transmission risk to be 3 per 1,000³ exposures for a

Hepatitis B: penetrating bone fragments due to the explosion of a suicide bomber. *Isr. Med. Assoc. J.*, 4(7):528-29; Eshkol, Z. & Katz, K. (2005). Injuries from biologic material of suicide bombers. *Injury*, 36(2):271-74; Patel, H.D., *et al.* (2012). Human body projectiles implantation in victims of suicide bombings and implications for health and emergency care providers: the 7/7 experience. *Ann. R. Coll. Surg. Engl.*, 94(5):313-17 ("Patel 2012"); Wong, J.M., *et al.* (2006). Biological foreign body implantation in victims of the London July 7th suicide bombings. *J. Trauma*, 60(2):402-4; Wolf, D.G., *et al.* (2000). High rate of candidemia in patients sustaining injuries in a bomb blast at a marketplace: a possible environmental source. *Clin. Infect. Dis.*, 31(3):712-16; de l'Escalopier N., *et al.* (2016). Infectious risk for suicide bomber attack victims: management of penetrative wounds in French Army personnel. *Int. Orthop.*, 40(5):861-64. ³ Again, this is the more conservative risk estimate, and the actual risk may be lower. The current CDC estimate places this risk at .23%. See Centers for Disease Control. (2015). Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act. *HIV Risk Behaviors*, available at https://www.cdc.gov/hiv/risk/estimates/riskbehaviors.html (citing Patel, P., et al. (2014)); Cardo, D.M., *et al.* (1997). A case-control study of HIV seroconversion

deep injury with a hollow bore needle with known HIV-infected blood to be in the same category as a deep penetrating injury with an object soaked in HIV-infected blood. Patel, P., *et al.* (2014). Estimating per-act HIV Transmission risk: a systematic review. *AIDS*, 28(10):1509-19. Considering that risk (0.3%) along with the risk of a penetrating bone fragment as a result of proximity to a suicide bomber (2.9%), the HIV transmission risk *without* viral suppression could be estimated at less than 1 per 10,000.⁴

7. **Third**, I am not aware that there has ever been a documented transmission of HIV as a result of a suicide bombing. The lack of a documented transmission in this manner is at least in part due to the previous two points.

8. **Fourth**, however low the theoretical risk of transmission through this type of exposure may be, it is reduced at least another 100-fold (to roughly 1 in a million) if the person with HIV has a suppressed viral load.

9. **Fifth**, the risk of transmission can be further mitigated by providing postexposure prophylaxis (PEP). Specifically, the risk of transmission is further reduced another 5-fold if the victim of a suicide bombing victim is provided with post-exposure prophylaxis (PEP) for HIV (taking the risk to roughly 1 in 5 million). Cardo, D.M., *et al.* (1997). A casecontrol study of HIV seroconversion in health care workers after percutaneous exposure. Centers for Disease Control and Preventions Needlestick Surveillance Group. *N. Engl. J. of*

in health care workers after percutaneous exposure. Centers for Disease Control and Preventions Needlestick Surveillance Group. *N. Engl. J. of Med.*, 337(21):1485-90.

⁴ And one must keep in mind my first point, which is that the risk of a penetrating bone fragment through a catastrophic injury created by an IED or enemy fire is very likely much lower, if not non-existent when compared to the risk created by a suicide bomber.

Med., 337(21):1485-90. The CDC and several other international bodies recommend PEP in the event of a known exposure to HIV-positive blood or a high-risk exposure during mass-casualty event. British Health Protection Agency. (2005). Post exposure prophylaxis against Hepatitis B for bomb victims and immediate care providers. Consideration of other blood borne viruses (Hepatitis C and HIV) Archived July 14, 2014, available at https://webarchive.nationalarchives.gov.uk/20140714093222/http://www.hpa.org.uk/Topics/EmergencyResponse/ExplosionsAndFires/HealthEffectsOfExplosions/PostExposureProphyla xisAgainstBloodBorneViruses/; Centers for Disease Control (2008). Recommendations for postexposure interventions to prevent HIV infections with Hepatitis B virus, Hepatitis C virus, or Human Immunodeficiency Virus, and Tetanus in Persons Wounded During Bombings and Other Mass-Casualty Events. *Morbidity and Mortality Weekly Report.* 57(RR-6):1-19, available at https://www.cdc.gov/MMWR/preview/mmwrhtml/rr5706a1.htm;
Siegal-Itzkovich, J. (2001). Israeli minister orders Hepatitis B vaccine for survivors of suicide bomb attacks. *Br. Med. J.*, 323(7310):417.

10. **Sixth**, as I have also previously noted, there is a significantly higher risk of transmission of HIV from a person with HIV who is undiagnosed and not in treatment than from a person who is diagnosed and has a suppressed viral load. About one-third of new diagnoses in the military occur while the service member is deployed—meaning there are service members with HIV who are deployed and who present a greater risk than service members like Plaintiffs, who know they are living with HIV and who are receiving treatment.

11. **Seventh**, the risk of battlefield transmission due to battlefield injury of other conditions, like undiagnosed hepatitis C, for which the military does not even test on a regular basis, is higher than the risk of transmission of HIV from a service member who

knows they are living with HIV. Centers for Disease Control. (2001). Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. *Morbidity and Mortality Weekly Report*. 50(RR-11):1-42, available at

https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm. In other words, the risk of transmission of HIV from a service member who knows that they are living with HIV and is receiving treatment is lower than the risk of transmission from someone who is not aware that they are living with HIV or someone living with another condition like hepatitis C.

12. **Finally,** a suicide bombing—where an individual has packed their own body with explosives with the intent to turn their body into an instrument of destruction—is not perfectly analogous to the types of injury experienced by a soldier, even one who triggers an IED or is targeted by an enemy firepower; however, it does provide some relevant data on potential for battlefield infectious disease transmission, described above.

13. I also reviewed the document titled "Active Duty ART Outcomes V2.0" compiled by Seung Hyun Won, using a data cut from February 22, 2019 (DX309). In addition to the "Viral Suppression—Ever" rate of 99.8% for active duty members diagnosed between 2012 and 2016, which is incredibly high and demonstrates just how excellent adherence to HIV medications is in the active duty military, I noted other statistics that support the opinions I have previously presented. *Id.* at 23. In particular, the fact that in the most recent period (2012-16), 75% of active duty service members achieve viral suppression within the first 6 months of starting treatment, 99.8% achieve viral suppression within a year. Fully 92% achieve viral suppression on their first regimen, which increases to 97% with the newest integrase inhibitor class drugs. *Id.*

14. I also reviewed documents titled "Air Force response to HAF242613 (2Ltr) UPR006187-17 - Personnel Policies Regarding Members of the Armed Forces Infected with HIV" (US00021263_0001-05) (PX 381) and "Talking Paper on Retention of Airmen with Human Immunodeficiency Virus (HIV)" (US 00021290_0001-04) (PX 382). These documents contain multiple statements that align with and confirm the opinions I am offering in this case. Of note, many statements in these documents were omitted from the *Department of Defense Personnel Policies Regarding Members of the Armed Forces Infected with Human Immunodeficiency Virus* (PX 040). PX 381 also states that "(AIDS), not asymptomatic HIV, is a medical condition that usually precludes contingency deployment. This is in keeping with current evidence based findings with regards to undetectable viral loads." PX381 at 2.

15. I agree that the evidence shows that asymptomatic HIV should not preclude deployment, including contingency deployments. The document also states service members "with asymptomatic HIV alone do not have a disability" and that they should be evaluated for continued service "via the same process as those without HIV." *Id.* at 3. It continues that "[t]he problem with the current process is that it is now resulting in Airmen with asymptomatic HIV being inappropriately referred into the IDES and discharged from the Air Force." *Id.* at 4.

16. The document compares HIV to conditions like high blood pressure and acid reflux, which also require one daily pill for treatment. *Id.* at 3-4. It also describes the minimal treatment requirements for people living with asymptomatic HIV and states that "[t]hose with asymptomatic HIV who take their medication generally have a life expectancy and quality of life similar to those without HIV." *Id.* at 4. After stating that the risk of

transmission from a person with HIV to others via blood transfusion or another encounter is "minimal," the document states that "[a]irmen with asymptomatic HIV should be deployable. The medical burden for typical deployment durations is no different than for other medical conditions managed with medications. The risk of blood transmission is minimal. This is supported by both DoD and Air Force policy." *Id.* at 5.

17. I have also reviewed the section of this document regarding the feasibility of allowing an enlisted member of the Armed Forces to become a commissioned officer and agree that the medical standards are the same for enlisted members and for officers and that for nearly all officer positions, there is no medical reason that an enlisted person with asymptomatic HIV could not serve as an officer. *See Id.* at 5.

18. This information demonstrates that service members with asymptomatic HIV can serve in the military, including in deployed settings. In fact, the Talking Paper on Retention of Airmen with Human Immunodeficiency Virus (HIV) states that "[a]irmen with asymptomatic HIV are deployable by both DoD and AF policy." PX382 at 3 (citing DoDI 6490.07 and AFI 48-123). The document states, "Airmen with asymptomatic HIV meet this definition of being deployable (they would simply need to bring a supply of their medication with them like someone with high blood pressure or acid reflux)." *Id*.

I have also considered Defendants' production of correspondence, including
 "Email chain from J. Stangle to D. Menendez, *et al.*, (Feb. 7, 2018). RE: Policy Clarification:
 Adjudicating Retainability for Members Identified with Asymptomatic

HIV"(US00040186_0001–12), which is an Air Force email chain regarding clarifying policy regarding retention of members with asymptomatic HIV. Based on my review of this correspondence, it appears that there are no rational medical barriers to deployability. I agree

with the statements made by Col. Patrick Danaher, who explained the Air Force treats HIV differently than other chronic conditions, like well-controlled hypertension. *Id.* at 12. I agree that "Airmen with asymptomatic HIV should be returned to duty without review by the IDES because no such review is medically necessary for similar chronic illnesses which cause no impairment." *Id.* I also agree with the observations that Col. Danaher makes on page 8 of the thread, including that even under existing policy, airmen with asymptomatic HIV should be deployable, even though that does not appear to be the current practice.⁵

20. I have also listened to a portion of an audio recording I understand to be of a meeting regarding accessions policy. I understand the participants in the meeting were representatives of the Defense Department's various service branches. The portion of the audio recording I listened to focused on accessions policy with respect to HIV. I intend to testify regarding my impressions of this recording at trial.

21. Because the accessions policies being discussed in the recording are medical policies, in my opinion, they should be justified based on an understanding of medical science. Policy with respect to the role that individuals with HIV can play should begin with

⁵ It also appears that even if the branches' policies permit service members with HIV to deploy with waivers, they do not appear to permit HIV waivers in practice. The application of those policies is not supported by medical science because, as I have previously stated, the medical science supports allowing individuals with asymptomatic HIV to continue to serve and deploy. These members are in fact medically fit to deploy and do not pose any appreciable risk to themselves or others. For example, I considered the views described by Lt. Col. Len Trout, and I disagree with them to the extent he is declaring his belief that the current "practice" in making deployment decisions for service members with HIV is justified. *Id.* at 6 (stating that even if the regulations define deployability in a certain way, "that's only the PRINCIPLE of deployability. The PRACTICE of deployability is where the decision is made about whether these members actually get approved to deploy. And the practice is, at this point in time, that these members are NOT approved to deploy."). Furthermore, Lt. Col. Trout's comparison of asymptomatic HIV to conditions like rheumatoid arthritis, Crohn's disease, and ulcerative colitis—being treated with injections or infusions and that potentially have an impact on readiness even when treated because they are more complex to treat—is a misleading comparison.

an evidence-based evaluation of the diagnosis, meaning that it should be based on analysis of the facts and current state of medical treatment of HIV. However, my impression of the recording was that the individuals in attendance started with a premise that individuals living with HIV should not be allowed accession into the military and then searched for medical justifications or facts to support that premise. *See, e.g.*, "MP3 Recording of AMSWG Meeting August 5" at 3:18, 3:20, 3:32 (US00012348_0001).

22. I also agree with the statements made during the meeting that many of the military's current justifications for not allowing individuals with HIV to enter active duty are contradicted by science. For example, HIV is not highly infectious, especially when treated, medicines do not require refrigeration or sensitive storage conditions more than other commonly used medications that are all tested within the same environmental constraints, there is not heavy dependence on blood transfusions from all service members, and individuals living with HIV do not require intensive ongoing evaluation.

23. If the various policies are to be brought into alignment with modern medicine, the various branches of the military should base their decisions on current state of medical science by updating their accessions, retentions, and deployment policies, not by searching for new justifications to support the current policy.

24. Finally, I also reviewed a study published in Military Medicine only a few days ago that examined "how an operational or OCONUS assignment impacts the ability of an HIV AD service member[] to receive the standard of care HIV medical treatment and maintain viral suppression." Woodson, S. *et al.* (2019). Virologic Suppression in U.S. Navy Personnel Living with Infection and Serving in Operational Assignments. *Mil. Med.* doi:10.1093/milmed/usz169. In 2012, the Navy began allowing service members living with

HIV to serve OCONUS or on large ship platform tours. *Id.* at 1. The study, which notes that ART "has revolutionized the care of [HIV]," concluded that all of the service members reviewed "were able to maintain viral suppression despite the location of their assignments [suggesting] that care is accessible and the standard HIV care continuum is maintained while deployed or stationed overseas." *Id.* While this study was limited, particularly by its small sample size, the conclusions support my opinion that service members with asymptomatic HIV can safely serve in deployed settings.

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

Executed this 18th day of July, 2019

Craig W. Hending

Craig W. Hendrix, M.D.

APPENDIX A

MATERIALS CONSIDERED

MATERIALS CONSIDERED

Air Force response to HAF242613 (2Ltr) UPR006187-17 - Personnel Policies Regarding Members of the Armed Forces Infected with HIV (US00021263_0001-05 US00021263_0001-05) (PX 381).

Braverman, I., *et al.* (2002). A novel mode of infection with Hepatitis B: penetrating bone fragments due to the explosion of a suicide bomber. *Isr. Med. Assoc. J.*, 4(7):528-29.

British Health Protection Agency. (2005). Post exposure prophylaxis against Hepatitis B for bomb victims and immediate care providers. Consideration of other blood borne viruses (Hepatitis C and HIV). Archived July 14, 2014, available at https://webarchive.nationalarchives.gov.uk/20140714093222/http://www.hpa.org.uk/Topics/Eme rgencyResponse/ExplosionsAndFires/HealthEffectsOfExplosions/PostExposureProphylaxisAgai nstBloodBorneViruses/.

Cardo, D.M., *et al.* (1997). A case-control study of HIV seroconversion in health care workers after percutaneous exposure. Centers for Disease Control and Preventions Needlestick Surveillance Group. *N. Engl. J. of Med.*, 337(21):1485-90.

Centers for Disease Control (2015). Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act. *HIV Risk Behaviors*, available at https://www.cdc.gov/hiv/risk/estimates/riskbehaviors.html.

Centers for Disease Control (2008). Recommendations for postexposure interventions to prevent HIV infections with Hepatitis B virus, Hepatitis C virus, or Human Immunodeficiency Virus, and Tetanus in Persons Wounded During Bombings and Other Mass-Casualty Events. *Morbidity and Mortality Weekly Report.* 57(RR-6):1-19, available at https://www.cdc.gov/MMWR/preview/mmwrhtml/rr5706a1.htm.

Centers for Disease Control. (2001). Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. *Morbidity and Mortality Weekly Report*. 50(RR-11):1-42, available at https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm.

de l'Escalopier N., *et al.* (2016). Infectious risk for suicide bomber attack victims: management of penetrative wounds in French Army personnel. *Int. Orthop.*, 40(5):861-64.

Department of Defense Personnel Policies Regarding Members of the Armed Forces Infected with Human Immunodeficiency Virus (PX 040).

Email chain from J. Stangle to D. Menendez, *et al.*, (Feb. 7, 2018). RE: Policy Clarification: Adjudicating Retainability for Members Identified with Asymptomatic HIV (US00040186–0001–12).

Eshkol, Z. & Katz, K. (2005). Injuries from biologic material of suicide bombers. *Injury*, 36(2):271-74.

Hadden, W.A., *et al.* (1978) The injuries of terrorist bombing: A study of 1532 consecutive patients. *Br. J. Surg.*, 65(8):525–31.

Kao, R.L. & McAlister, V.C. (2018). Care of victims of suicide bombing. *Can. J. Surg.*, 61(6): S184-87. (DX014).

MP3 Recording of AMSWG Meeting August 5. (US00012348_0001).

Patel, H.D., *et al.* (2012). Human body projectiles implantation in victims of suicide bombings and implications for health and emergency care providers: the 7/7 experience. *Ann. R. Coll. Surg. Engl.*, 94(5):313-17.

Patel, P., *et al.* (2014). Estimating per-act HIV Transmission risk: a systematic review. *AIDS*, 28(10):1509-19.

Siegal-Itzkovich, J. (2001). Israeli minister orders Hepatitis B vaccine for survivors of suicide bomb attacks. *Br. Med. J.*, 323(7310):417.

Talking Paper on Retention of Airmen with Human Immunodeficiency Virus (HIV) (US 00021290_0001-04) (PX 382).

Turégano-Fuentes, F., *et al.* (2008). Injury patterns from major urban terrorist bombings in trains: The Madrid experience. *World J Surg.*, 32(6):1168-75.

Wolf, D.G., *et al.* (2000). High rate of candidemia in patients sustaining injuries in a bomb blast at a marketplace: a possible environmental source. *Clin. Infect. Dis.*, 31(3):712-16.

Won, S. (2019). Active Duty ART Outcomes V2.0. (DX309).

Wong, J.M., *et al.* (2006). Biological foreign body implantation in victims of the London July 7th suicide bombings. *J. Trauma*, 60(2):402-4.

Woodson, S. *et al.* (2019). Virologic Suppression in U.S. Navy Personnel Living with Infection and Serving in Operational Assignments. *Mil. Med.* doi: 10.1093/milmed/usz169.