

No. 19-1410

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In the  
**United States Court of Appeals**  
for the **Fourth Circuit**

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RICHARD ROE ET AL.,

*Plaintiffs-Appellees,*

v.

UNITED STATES DEPARTMENT OF DEFENSE ET AL.,

*Defendants-Appellants.*

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On Appeal from the United States District Court for the  
Eastern District of Virginia, Case No. 1:18-cv-01565-LMB-IDD  
Hon. Leonie M. Brinkema, *District Judge*

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**BRIEF OF HIV MEDICINE ASSOCIATION,  
AMERICAN ACADEMY OF HIV MEDICINE, GLMA:  
HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, AND  
INFECTIOUS DISEASES SOCIETY OF AMERICA AS AMICI CURIAE  
IN SUPPORT OF APPELLEES AND AFFIRMANCE**

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HIV Medicine, GLMA: Health Professionals Advancing LGBTQ Equality, and  
Infectious Diseases Society of America*



4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation (Local Rule 26.1(a)(2)(B))?  YES  NO  
If yes, identify entity and nature of interest:

5. Is party a trade association? (amici curiae do not complete this question)  YES  NO  
If yes, identify any publicly held member whose stock or equity value could be affected substantially by the outcome of the proceeding or whose claims the trade association is pursuing in a representative capacity, or state that there is no such member:

6. Does this case arise out of a bankruptcy proceeding?  YES  NO  
If yes, identify any trustee and the members of any creditors' committee:

Signature: /s/ Benjamin C. Mizer

Date: July 25, 2019

Counsel for: HIV Medicine Association

**CERTIFICATE OF SERVICE**

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I certify that on July 25, 2019 the foregoing document was served on all parties or their counsel of record through the CM/ECF system if they are registered users or, if they are not, by serving a true and correct copy at the addresses listed below:

/s/ Benjamin C. Mizer  
(signature)

July 25, 2019  
(date)



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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT  
DISCLOSURE OF CORPORATE AFFILIATIONS AND OTHER INTERESTS

Disclosures must be filed on behalf of all parties to a civil, agency, bankruptcy or mandamus case, except that a disclosure statement is **not** required from the United States, from an indigent party, or from a state or local government in a pro se case. In mandamus cases arising from a civil or bankruptcy action, all parties to the action in the district court are considered parties to the mandamus case.

Corporate defendants in a criminal or post-conviction case and corporate amici curiae are required to file disclosure statements.

If counsel is not a registered ECF filer and does not intend to file documents other than the required disclosure statement, counsel may file the disclosure statement in paper rather than electronic form. Counsel has a continuing duty to update this information.

No. 19-1410 Caption: Richard Roe v. U.S. Department of Defense

Pursuant to FRAP 26.1 and Local Rule 26.1,

GLMA: Health Professionals Advancing LGBTQ Equality  
(name of party/amicus)

who is                      amicus                     , makes the following disclosure:  
(appellant/appellee/petitioner/respondent/amicus/intervenor)

1. Is party/amicus a publicly held corporation or other publicly held entity?  YES  NO
  
2. Does party/amicus have any parent corporations?  YES  NO  
If yes, identify all parent corporations, including all generations of parent corporations:
  
3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity?  YES  NO  
If yes, identify all such owners:

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation (Local Rule 26.1(a)(2)(B))?  YES  NO  
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Date: July 25, 2019

Counsel for: GLMA

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Signature: /s/ Benjamin C. Mizer

Date: July 25, 2019

Counsel for: Infectious Diseases Soc'y of America

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## STATEMENT OF IDENTITY AND INTEREST OF AMICI CURIAE

The HIV Medicine Association (HIVMA) is an organization of more than 5,000 physicians, scientists, and other healthcare professionals whose practice and research involve the diagnosis, prevention, and treatment of human immunodeficiency virus (HIV). HIVMA represents the interests of HIV healthcare providers and researchers and their patients by promoting access to quality HIV care and by advocating for policies that ensure a comprehensive and humane response to HIV.<sup>1</sup>

The American Academy of HIV Medicine (AAHIVM) is an organization of HIV care providers who together provide direct care to the majority of HIV patients in the United States. AAHIVM strives to give practitioners the necessary resources to provide optimal care for people living with HIV.<sup>2</sup>

GLMA: Health Professionals Advancing LGBTQ Equality (GLMA) is the largest association of LGBTQ and ally healthcare professionals. Founded

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<sup>1</sup> See HIVMA, *Policy & Advocacy*, <https://www.hivma.org/policy--advocacy/policy--advocacy/>. All websites last visited July 25, 2019.

<sup>2</sup> See AAHIVM, *Who We Are*, <https://aahivm.org/about-us/>.

in 1981 in response to the emerging HIV/AIDS epidemic, GLMA works to ensure health equity for all sexual- and gender-minority individuals.<sup>3</sup>

The Infectious Diseases Society of America (IDSA) represents more than 11,000 physicians, scientists, and public health experts who specialize in infectious diseases. IDSA works to improve the health of individuals, communities, and society by promoting excellence in patient care, education, research, public health, and prevention relating to infectious diseases.<sup>4</sup>

Amici seek to ensure that all people living with HIV, including members of the U.S. Armed Forces, are not subjected to arbitrary or otherwise unlawful treatment because of their HIV diagnosis. Amici are committed to the principle that science should inform government policies respecting people living with HIV, as well as judicial review of those policies.<sup>5</sup>

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<sup>3</sup> See GLMA, *About GLMA*, <http://www.glma.org/index.cfm?fuseaction=Page.viewPage&pageId=532>.

<sup>4</sup> See IDSA, *About IDSA*, <https://www.idsociety.org/about-idsa/about-idsa/>.

<sup>5</sup> Appellees consent to the filing of this brief. Appellants have provided blanket consent to amicus briefs supporting Appellees. No counsel for a party authored this brief in whole or in part, and no such counsel or party, or other person, contributed money intended to fund preparing or submitting this brief.

## SUMMARY OF ARGUMENT

The pace of progress in the understanding and treatment of HIV over the last quarter century has been dramatic. Before the availability of effective treatment, infection with HIV was almost invariably fatal; today, that could not be farther from the truth. But conventional wisdom has not kept up with firmly established scientific consensus. Consequently, some responses to HIV today remain rooted in fear and stigma rather than science and reason.

The indisputable fact is that today, with access to treatment, people living with HIV can lead full lives, with life expectancies as long as if they did not have the virus. And they can lead those lives without any significant symptoms. In most cases, a treatment regimen that can consist of just one pill a day will achieve and sustain viral suppression.

Members of the U.S. Armed Forces have access to the quality healthcare necessary to effectively treat HIV. Even if treatment were temporarily interrupted by a deployment exigency, no immediate symptoms would develop, and with resumption of the same treatment within a reasonable amount of time, the individual generally would re-achieve viral suppression. Nor are the recommended regular check-ups a barrier to deployment. Thus, although HIV is a chronic condition, it is a *manageable* condition

akin to other diagnoses that are not deemed categorically incompatible with military deployment. Indeed, a recent study found that Navy service members living with HIV “remain[ed] fit for duty” “despite the expansion of operational ... assignments” outside the continental United States.<sup>6</sup>

Finally, HIV transmission continues to be misunderstood. The routes of transmission of the virus are in fact more predictable and confined than for many other communicable conditions. And, critically, HIV treatment is HIV prevention: There is effectively no risk that someone who achieves and maintains an undetectable viral load will transmit the virus.

## ARGUMENT

- I. **Scientific understanding and medical treatment of HIV has advanced tremendously since the first combination antiretroviral therapy was developed in 1996**
  - A. **HIV is a virus that attacks the immune-system cells needed to fight off other infections**

A virus is a tiny microbe—a bit of genetic material surrounded by a protective protein coat—that can reproduce only by appropriating the machinery of a “host” cell to replicate its genetic material. There are thousands

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<sup>6</sup> Sarah E. Woodson et al., *Virologic Suppression in U.S. Navy Personnel Living with HIV Infection and Serving in Operational Assignments*, *Military Medicine* (July 11, 2019), <https://academic.oup.com/milmed/advance-article/doi/10.1093/milmed/usz169/5531173>.

of different species of viruses, each with its own way of moving from an infected host organism to a new host organism.

Of the viruses that cause disease in humans, some are much more easily communicable than others. At one end of the spectrum, viruses like rhinovirus (the cause of the common cold), measles, or influenza spread through the air by droplets of moisture emitted when people sneeze or cough.<sup>7</sup> At the other, HIV can spread only if blood or certain other bodily fluids (semen, pre-seminal fluid, rectal fluids, vaginal fluids, or breast milk) of a person living with HIV come into direct contact with the bloodstream of a person without HIV – and even if such contact occurs, transmission is usually quite rare, and rarer still if the person living with HIV has a suppressed viral load. *See infra* pp. 25-33.<sup>8</sup> The possibility of HIV transmission between

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<sup>7</sup> *See* Centers for Disease Control and Prevention (CDC), *Common Colds: Protect Yourself and Others*, <https://www.cdc.gov/features/rhinoviruses/index.html>; CDC, *How Flu Spreads*, <https://www.cdc.gov/flu/about/disease/spread.htm> (“People with flu can spread it to others up to about 6 feet away.”); CDC, *Transmission of Measles*, <https://www.cdc.gov/measles/transmission.html> (“[M]easles virus can live for up to two hours in an air-space where the infected person coughed or sneezed. ... Measles is so contagious that if one person has it, up to 90% of the people close to that person who are not immune will also become infected.”).

<sup>8</sup> *See* CDC, *HIV Transmission*, <https://www.cdc.gov/hiv/basics/transmission.html>; JA599; CDC, *HIV Risk Behaviors*, <https://www.cdc.gov/hiv/risk/estimates/riskbehaviors.html>.

adults outside the context of sexual activity, contaminated needles, and blood transfusion is essentially zero. JA599. HIV cannot reproduce outside a human host, nor can it survive for long outside the human body.<sup>9</sup> Thus, although HIV is communicable, it is communicable *only* in relatively limited and predictable ways. It is *not* communicable through regular interactions in the workplace or home, like sharing dishes or toilets. *See infra* pp. 26. And, as the Centers for Disease Control and Prevention (CDC) explains, transmission of HIV to healthcare workers “is extremely rare,” and “only one confirmed case has been reported since 1999.”<sup>10</sup>

HIV primarily infects cells of the human immune system – in particular, white blood cells known as “CD4 cells” or “T cells.”<sup>11</sup> HIV hijacks those T cells, transcribes its RNA genetic material into strands of DNA (a more durable medium than RNA), and then tricks the cells into “expressing” that

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<sup>9</sup> CDC, *Occupational HIV Transmission and Prevention among Health Care Workers*, <https://www.cdc.gov/hiv/workplace/healthcareworkers.html> (“Health care workers who are exposed to a needlestick involving HIV-infected blood at work have a 0.23% risk of becoming infected,” and the “[r]isk of exposure due to splashes with bodily fluids is thought to be near zero even if the fluids are overtly bloody.”).

<sup>10</sup> *Id.*

<sup>11</sup> CDC, *About HIV/AIDS*, <https://www.cdc.gov/hiv/basics/whatishiv.html>.

DNA, thus producing new copies of the HIV virus.<sup>12</sup> Consequently, HIV is called a “retrovirus” – a “backwards” virus – because most living things, in contrast, store their genetic information as DNA and transcribe DNA into RNA.<sup>13</sup>

More specifically, HIV infects a host cell by attaching itself to receptors on the cell’s surface and then fusing its protein coat with the cell membrane to enter the cell.<sup>14</sup> After it has entered the cell, it releases an enzyme that allows it to transcribe its genetic material – HIV RNA – into HIV DNA. With assistance from a second HIV enzyme, the HIV DNA can be inserted into the DNA of the host cell. Then, the machinery of the host cell can be used to produce new copies of the virus (its proteins and RNA genetic material). These new copies can emerge from the host cell and go on to infect additional

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<sup>12</sup> U.S. Department of Health and Human Services (HHS), *HIV Overview: The HIV Life Cycle*, <https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/19/73/the-hiv-life-cycle>; Scitable (by Nature Education), *Ribonucleic acid/RNA: Definition*, <https://www.nature.com/scitable/definition/ribonucleic-acid-rna-45>.

<sup>13</sup> See HHS, *HIV/AIDS Glossary: Retrovirus*, <https://aidsinfo.nih.gov/understanding-hiv-aids/glossary/634/retrovirus>; Encyclopædia Britannica, *Retrovirus*, <https://www.britannica.com/science/retrovirus>.

<sup>14</sup> HHS, *The HIV Life Cycle*, *supra* p. 7, n.11.

cells. This hijacking process may kill the host cell,<sup>15</sup> or otherwise induce it to self-destruct.<sup>16</sup>

If left untreated for a number of years, HIV will prove fatal. That is because the CD4 T cells that untreated HIV seeks out, infects, and kills are the human immune system's soldiers.<sup>17</sup> Over time, untreated HIV will destroy more and more of these infection-fighting cells.<sup>18</sup> Eventually, the person's immune system becomes so damaged that the body can no longer fight off infections that an uncompromised immune system would easily eliminate. JA597.<sup>19</sup> Once a person acquires such an "opportunistic infection," or

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<sup>15</sup> Nathan W. Cummins & Andrew D. Badley, *Making sense of how HIV kills infected CD4 T cells*, 2 *Molecular & Cellular Therapies* 20 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4452072/>.

<sup>16</sup> Arik Cooper et al., *HIV-1 causes CD4 cell death through DNA-dependent protein kinase during viral integration*, 498 *Nature* 376-79 (2013), <https://www.nature.com/articles/nature12274>.

<sup>17</sup> HHS, *HIV/AIDS Glossary: CD4 T Lymphocyte*, <https://aidsinfo.nih.gov/understanding-hiv-aids/glossary/113/cd4-t-lymphocyte/>.

<sup>18</sup> HHS, *HIV Overview: The Stages of HIV Infection*, <https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/19/46/the-stages-of-hiv-infection>.

<sup>19</sup> See also *id.*

has a CD4 T cell count below a certain threshold, he or she is diagnosed with AIDS, acquired immunodeficiency syndrome.<sup>20</sup>

This process is not immediate. For years, although HIV continues to multiply, a person may not experience any symptoms. *Id.* But before the treatment modern medicine has made possible, *see infra* pp. 16-24, a person diagnosed with HIV was invariably expected to die, usually within eight to ten years. JA794.<sup>21</sup> Thus, if left untreated, HIV leads to serious, fatal complications. In this regard, HIV is no different than many other diagnoses, from acute infections to chronic conditions like diabetes or cardiovascular disease.

**B. Early on, the limited understanding of HIV contributed to the stigma society placed on people living with the virus**

When AIDS was first identified in the early 1980s, scientists did not understand its cause. JA656. As they were guessing at answers, doctors witnessed hundreds and then thousands of otherwise healthy patients become sick and die. *Id.* Because many of the patients were young gay men, AIDS

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<sup>20</sup> *Id.*

<sup>21</sup> The current estimate is that untreated HIV “usually advances to AIDS in 10 years or longer, though in some people it may advance faster,” and “people with AIDS typically survive about 3 years.” *Id.*

was even known at first as “gay cancer” or “gay-related immune deficiency.” *Id.* And before HIV was identified as the cause in 1984, many Americans had come to believe that “a deviant lifestyle” was responsible for AIDS. JA657. Some even “label[ed] AIDS as a punishment from God or ‘God’s cure’ for homosexuality.” *Id.*

In these early years especially, people living with HIV faced frequent discrimination. *Id.* Americans feared contracting HIV from exposures presenting no risk, such as sharing a drinking glass or kissing. JA657-58. Together, the stigma and fear produced punitive HIV-specific laws, most of which ignore science-based transmission risks, especially in light of the powerful effects of modern antiretroviral therapy. JA658-61.<sup>22</sup>

**C. Effective antiretroviral therapy has transformed HIV from a death sentence into a readily manageable condition**

More than two decades ago, medical researchers discovered that combining three or more antiretroviral drugs can stop HIV in its tracks. An-

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<sup>22</sup> See also J. Stan Lehman et al., *Prevalence and Public Health Implications of State Laws that Criminalize Potential HIV Exposure in the United States*, 18 *Aids and Behavior* 997 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4019819/>.

tiretroviral drugs are drugs that prevent retroviruses, like HIV, from carrying out particular steps in their unique reproduction process.<sup>23</sup> *See supra* pp. 6-9. Before this research breakthrough, lasting treatment was elusive because the virus would eventually find ways to mutate around an antiretroviral drug – and once it developed this “resistance,” it could continue reproducing.<sup>24</sup> In 1996, however, researchers discovered that using three or more antiretroviral drugs working in tandem prevents HIV from both reproducing and acquiring resistance to the drugs.<sup>25</sup> JA597. In essence, the virus is unable to mutate around the drugs when three or more types are simultaneously targeting it.<sup>26</sup> This treatment, which for many years has been standard for people living with HIV, is known as antiretroviral therapy (ART).

When a person starts ART, the number of viral particles in the body begins to decrease until the concentration of virus in the bloodstream (“viral

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<sup>23</sup> HHS, *The HIV Life Cycle*, *supra* p. 7 n.11.

<sup>24</sup> Nat’l Inst. of Allergy & Infectious Diseases (NIAID), *Antiretroviral Drug Discovery and Development*, <https://www.niaid.nih.gov/diseases-conditions/antiretroviral-drug-development>.

<sup>25</sup> HHS, *HIV Overview: FDA-Approved HIV Medicines*, <https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/19/58/fda-approved-hiv-medicines>.

<sup>26</sup> NIAID, *Antiretroviral Drug Discovery and Development*, *supra* p. 11 n.24.

load”) is so low that it cannot be detected. And if the individual remains on ART, as discussed further below, the virus remains suppressed and the person can have the same life expectancy as if the virus had never been acquired in the first place. *See infra* pp. 16-18.<sup>27</sup>

HIV remains a chronic condition in the sense that the viral load of a person living with HIV will eventually rebound if he or she ceases ART. That is because ART prevents HIV from replicating, but it cannot wipe out all traces of the virus that linger in cells without replicating.<sup>28</sup> HIV-infected cells

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<sup>27</sup> NIAID, *Starting and Staying on Antiretroviral Treatment*, <https://www.niaid.nih.gov/diseases-conditions/starting-antiretroviral-treatment>. Although more sensitive tests can detect viral loads of as few as 20 copies of virus per milliliter of blood, an “undetectable” load generally means fewer than 50 copies per milliliter. JA597; JA795. By comparison, each milliliter of blood contains four to six *million* red blood cells, nearly half a million platelets, and approximately 10,000 white blood cells. *See* Laura Dean, Nat’l Ctr. for Biotechnology Information, *Blood Groups and Red Cell Antigens*, ch. 1 (2005), <https://www.ncbi.nlm.nih.gov/books/NBK2263/>. A person with a high viral load may have more than 500,000—or even a million—copies of virus per milliliter of blood. *See, e.g.*, Richard M. Selik & Laurie Linley, *Viral Loads Within 6 Weeks After Diagnosis of HIV Infection in Early and Later Stages*, *JMIR Pub. Health & Surveillance* 2018 Oct.-Dec.; 4(4): e10770, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6246969/>.

<sup>28</sup> HHS, *HIV Overview: What is a Latent HIV Reservoir?*, <https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/19/93/what-is-a-latent-hiv-reservoir->; NIAID, *HIV Treatment, the Viral Reservoir, and HIV DNA*, <https://www.niaid.nih.gov/diseases-conditions/hiv-treatment-viral-res->

that are not producing new copies of the virus form what is called a “latent HIV reservoir.”<sup>29</sup> This latent form of the virus retains the potential to reactivate and replicate if ART has ceased. If a person living with HIV stops taking the prescribed medication, the infected cells in the latent reservoir can begin making HIV virus again.

**D. ART can stop transmission of the virus, and pre- and post-exposure prophylaxis can further reduce the risk of HIV transmission**

When people living with HIV achieve and maintain an “undetectable” viral load with ART, it is nearly impossible for them to transmit the virus to anyone else. To be sure, because of the volume of blood involved in a transfusion or transplant, a person living with HIV cannot donate blood or an organ to someone living without HIV.<sup>30</sup> But a person with an undetectable

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[ervoir-hiv-dna](#); see also Jef Vanhamel et al., *Establishment of latent HIV-1 reservoirs: what do we really know?*, 5 J. Virus Eradication 3-9 (2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6362902/pdf/JVE-5-3.pdf>.

<sup>29</sup> Vanhamel, *supra* p. 12 n.28; HHS, *What is a Latent HIV Reservoir?*, *supra* p. 12 n.28.

<sup>30</sup> Under the HIV Organ Policy Equity Act, Pub. L. No. 113-51, 127 Stat. 579 (2013), an individual living with HIV can donate an organ to another individual living with HIV. As of December 2018, more than 100 such organ transplants had been performed. United Network for Organ Sharing, *100 people transplanted thanks to HOPE Act*, <https://unos.org/news/100-people-transplanted-thanks-to-hope-act/>. Amici are aware of no instance in which

viral load has essentially no risk of transmitting the virus to a sexual partner.<sup>31</sup> And the already extremely low risk from needlesticks (0.23%) and needle sharing (0.63%)<sup>32</sup> decreases even more. The government itself has recognized this principle as “firmly established” by “an overwhelming body of clinical evidence.”<sup>33</sup>

Great advances have been made in the efficacy not only of treatment for people living with HIV but also in the biomedical prevention of transmission to those at risk of exposure. A single pill given daily as pre-exposure prophylaxis (PrEP) has proved safe for and effective at preventing HIV transmission, without serious side effects.<sup>34</sup> When taken consistently, PrEP has been shown in randomized clinical trials and large observational studies

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anyone involved in performing such a transplant acquired HIV as a result of the procedure.

<sup>31</sup> CDC, *HIV Treatment as Prevention*, <https://www.cdc.gov/hiv/risk/art/index.html>.

<sup>32</sup> See *supra* p. 6 & n.9; *infra* p. 27.

<sup>33</sup> HHS, *The science is clear: with HIV, undetectable equals untransmittable* (Jan. 10, 2019), <https://www.nih.gov/news-events/news-releases/science-clear-hiv-undetectable-equals-untransmittable>; see also NIAID, *HIV Undetectable=Untransmittable (U=U), or Treatment as Prevention*, <https://www.niaid.nih.gov/diseases-conditions/treatment-prevention>.

<sup>34</sup> James Riddell et al., *HIV Preexposure Prophylaxis: A Review*, 319 JAMA 1261 (2018), <https://jamanetwork.com/journals/jama/fullarticle/2676116>.

to result in a 99% reduction in HIV acquisition.<sup>35</sup> Truvada, the only medication currently approved for PrEP, is a combination of two antiretroviral drugs – that is, two of the drugs that are also used in ART.<sup>36</sup> If these drugs are present in the bloodstream at the time a person is exposed to HIV, they are likely to block the virus from establishing infection.<sup>37</sup> Based on a thorough review of the data, the U.S. Preventive Services Task Force granted PrEP a Grade A rating in June 2019 for its effectiveness in preventing HIV.<sup>38</sup> Additionally, post-exposure prophylaxis has been shown to reduce the risk of transmission fivefold. *See infra* pp. 30-31. Thus, an HIV prevention strategy can rely on biomedical prophylaxis as well as the maintenance of undetectable viral loads through ART.

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<sup>35</sup> *See id.*; CDC, *Pre-Exposure Prophylaxis (PrEP)*, <https://www.cdc.gov/hiv/risk/prep/index.html>.

<sup>36</sup> HIV.gov, *Pre-Exposure Prophylaxis*, <https://www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/pre-exposure-prophylaxis>; *see* Riddell et al, *supra* p. 14 n.34; CDC, *Pre-Exposure Prophylaxis*, *supra* p. 15 n.35.

<sup>37</sup> CDC, *PrEP*, <https://www.cdc.gov/hiv/basics/prep.html>.

<sup>38</sup> U.S. Preventive Services Task Force, *Final Recommendation Statement: Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis*, <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>.

- II. **ART allows people living with HIV to lead full lives, without significant symptoms**
  - A. **With sustained viral suppression, people living with HIV can stay healthy**
    - 1. **ART suppresses HIV to undetectable levels within a short period of time**

Within six months of starting ART, a person living with HIV will almost invariably reach an “undetectable” viral load. JA597-98, JA795; *see supra* p. 12 n.27.<sup>39</sup> Suppression of HIV to undetectable levels means that, while a person will retain latent HIV virus in the body, the virus is controlled. And if all viral load test results are undetectable for at least six months after the first undetectable test result, the person is considered “durably undetectable”: ART has stopped HIV infection from progressing, and the person can expect to remain undetectable by continuing to take ART consistently.<sup>40</sup>

- 2. **People living with HIV can live productive and healthy lives when they achieve and sustain viral suppression**

So long as the person adheres to the prescribed ART treatment regimen, he or she can live a healthy life with a normal life expectancy. JA599,

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<sup>39</sup> NIAID, *10 Things to Know About HIV Suppression*, <https://www.niaid.nih.gov/news-events/10-things-know-about-hiv-suppression>.

<sup>40</sup> *Id.*

JA683.<sup>41</sup> That is because for many people ART causes few side effects, if any, and those side effects are generally well tolerated. JA598.<sup>42</sup> And, in many cases, the treatment regimen imposes no dietary restrictions. JA598.<sup>43</sup> In sum, the prognosis for people living with HIV today is on par with or better than those for many other chronic conditions that the military understands to be consistent with service, such as asthma, high blood pressure, diabetes,

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<sup>41</sup> CDC, *About HIV/AIDS*, <https://www.cdc.gov/hiv/basics/whatishiv.html>.

<sup>42</sup> HIV.gov, *HIV Treatment Overview*, <https://www.hiv.gov/hiv-basics/staying-in-hiv-care/hiv-treatment/hiv-treatment-overview>; HHS, *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV: Adverse Effects of Antiretroviral Agents*, <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/31/adverse-effects-of-arv>.

<sup>43</sup> HHS, *Guidelines: Adherence to the Continuum of Care*, <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/30/adherence> (hereinafter “HHS, *Adherence Guidelines*”).

or rheumatoid arthritis.<sup>44</sup> HIV “is compatible with active service throughout a full career in the U.S. military.”<sup>45</sup>

**B. ART works for just about everyone, and it *keeps* working**

Provided it is accessible, ART makes an undetectable viral load possible for almost everyone living with HIV. JA598, JA795. ART is not always accessible, whether because of limited access to healthcare; substance abuse;

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<sup>44</sup> **Asthma** “preclud[es] contingency deployment” only if the person “has a forced expiratory volume-1 (FEV-1) of less than or equal to 60 percent of predicted FEV-1 despite appropriate therapy and that has required hospitalization at least 2 times in the last 12 months, or that requires daily systemic (not inhalational) steroids.” JA146.

**High blood pressure** precludes deployment only if it is “not controlled with medication or ... requires frequent monitoring.” JA147.

**Diabetes** “preclud[es] contingency deployment” only if it is “diabetes mellitus type I or II treated with insulin or oral hypoglycemic agents,” thereby implying that type II diabetes that does not fit that description does not usually preclude deployment. JA146.

A pilot diagnosed with **rheumatoid arthritis** “was granted military aeromedical waivers for rheumatoid arthritis and chronic medication use.” D.J. Moszyk & D.J. Sulit, *Rheumatoid Arthritis in a Military Aviator*, 78 *Aviation Space Env'tl Med.* 63 (2007), <https://www.ncbi.nlm.nih.gov/pub-med/17225486>; see also JA414-15.

<sup>45</sup> 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*, *Med. Surveillance Monthly Report* (Armed Forces Surveillance Center), vol. 22, no. 8, at 9, 12 (Aug. 2015), <https://health.mil/Military-Health-Topics/Combat-Support/Armed-Forces-Health-Surveillance-Branch/Reports-and-Publications/Medical-Surveillance-Monthly-Report/View-Past-Reports> (click August 2015).

serious mental health problems; unmet housing, food, or transportation needs; lack of financial resources or health insurance; or other such barriers.<sup>46</sup> But the military's infrastructure and rigorous environment eliminate many of those factors. Consequently, service members living with HIV experience exceptionally high rates of sustained viral load suppression.<sup>47</sup>

Development of drug resistance is unlikely in the military context. In almost all cases, resistance to a particular ART regimen develops only if the patient is unable to adhere to the prescribed medications. JA598.<sup>48</sup> Resistance is rare in people who achieve an undetectable viral load and continue taking ART as directed. That is because genetic mutations arise and propagate only through replication, which ART effectively halts.<sup>49</sup> And even where the virus

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<sup>46</sup> HHS, *Guidelines: Limitations to Treatment Safety and Efficacy*, <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/30/adherence>.

<sup>47</sup> See, e.g., JA459 (“The U.S. Air Force (USAF) management of Airmen with HIV is highly structured and achieves viral load suppression in over 90 percent of patients.”).

<sup>48</sup> See, e.g., HHS, *Guidelines: Retention in Care*, *supra* p. 19 n.46 (“Given the potency of contemporary ART, a detectable viral load identified during chronic care for a patient with stable access to ART is most likely the result of poor adherence.”).

<sup>49</sup> Eric J. Arts & Daria J. Hazuda, *HIV-1 Antiretroviral Drug Therapy*, 2 Cold Spring Harbor Perspectives in Med. a007161 (2012), <http://perspectivesinmedicine.cshlp.org/content/2/4/a007161.full>.

has become resistant to a particular treatment regimen – say, because of non-adherence to the prescribed medications – switching to a different combination of antiretroviral drugs can suppress the virus to undetectable levels. JA598.

### **III. Significant advances in drug development and medicine have made HIV treatment easier for many people**

The treatment regimen for a person with HIV is simple. It usually involves only once-daily pills and relatively infrequent checkups. And temporary interruptions in treatment do not generally lead to immediate symptoms or drug resistance.

#### **A. ART is commonly administered as a once-daily pill that has no special handling or storage requirements**

Many people on ART take only one pill a day. JA598, JA796. Each pill contains all three or four of the retroviral medications that person needs. JA598, JA796.<sup>50</sup> These pills have no special storage or handling requirements. JA797. And they can generally tolerate variations in temperature and exposure to sunlight. *Id.*

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<sup>50</sup> HHS, *Adherence Guidelines*, *supra* p. 17 n.43; NIAID, *Starting and Staying on Antiretroviral Treatment*, *supra* p. 12 n.27.

The single-tablet ART regimen is similar to many once-daily pill regimens. Such once-daily treatment regimens are associated with higher levels of adherence.<sup>51</sup> To the extent individuals miss doses of ART, that is not because ART pills are harder to take than other pills. *See* JA681-82.<sup>52</sup> Unsurprisingly, the military has recognized that these treatment regimens are perfectly compatible with deployment. *See* JA136-38. Treatment involves no more effort than is required to take a multivitamin or medicine for elevated cholesterol. JA797. Other once-daily, single-pill regimens include oral contraceptives, drugs to treat high blood cholesterol, and daily malaria prophylaxis. JA681.<sup>53</sup>

**B. The recommended frequency of medical visits can vary from person to person**

Most treatment guidelines recommend semiannual checkups for people living with HIV who maintain a suppressed viral load and good CD4

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<sup>51</sup> HHS, *Adherence Guidelines*, *supra* p. 17 n.43.

<sup>52</sup> *Id.*

<sup>53</sup> *See also* Planned Parenthood, *How do I use the birth control pill?*, <https://www.plannedparenthood.org/learn/birth-control/birth-control-pill/how-do-i-use-the-birth-control-pill>; Mayo Clinic, *Statins: Are these cholesterol-lowering drugs right for you?*, <https://www.mayoclinic.org/diseases-conditions/high-blood-cholesterol/in-depth/statins/art-20045772>.

count.<sup>54</sup> Specifically, the U.S. government suggests that one visit every six months is sufficient once the individual has had a suppressed viral load for more than two years; otherwise, a three- or four-month interval is suggested. JA798.<sup>55</sup> The World Health Organization (WHO), on the other hand, recommends screening at least every 12 months for individuals on consistent treatment for a year,<sup>56</sup> and the military appears to recognize that annual visits suffice, *see* JA456. Indeed, data from the federal government's Ryan White HIV/AIDS Program indicate higher levels of viral suppression (85.9%) than

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<sup>54</sup> HHS, *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV: Tests for Initial Assessment and Follow-up*, <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/3/tests-for-initial-assessment-and-follow-up> (click on Table 3).

<sup>55</sup> *Id.* (Table 3); HHS, *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV: Plasma HIV-1 RNA (Viral Load) and CD4 Count Monitoring*, <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/458/plasma-hiv-1-rna--viral-load--and-cd4-count-monitoring> (hereinafter "HHS, *Viral Load and CD4 Count Monitoring*"); HHS, *Adherence Guidelines*, *supra* p. 17 n.43.

<sup>56</sup> WHO, *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection* 128-30 (2d ed. 2016), [https://apps.who.int/iris/bitstream/handle/10665/208825/9789241549684\\_eng.pdf;jsessionid=5E54F4349F5C47A50D4D829FB7363C42?sequence=1](https://apps.who.int/iris/bitstream/handle/10665/208825/9789241549684_eng.pdf;jsessionid=5E54F4349F5C47A50D4D829FB7363C42?sequence=1) (hereinafter "WHO, *Consolidated Guidelines*").

program retention (80.9%)—confirming that individuals can remain virally suppressed even when they have infrequent checkups.<sup>57</sup>

The goal of these visits is to check that the person’s viral load remains suppressed—as it will, with consistent treatment—and to ensure that the medication is not causing detrimental side effects.<sup>58</sup> Accordingly, visits involve blood testing to check viral load, blood chemistries, and, in response to reports of particular symptoms, any potential side effects from ART.<sup>59</sup> Although visits are usually performed in person,<sup>60</sup> tele-visits are increasingly used for people who cannot access clinics, and would be possible in the military so long as blood can be sent for testing. *See* JA682.<sup>61</sup>

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<sup>57</sup> HHS, *Ryan White HIV/AIDS Program: Annual Client-Level Data Report* 38, 40 (2017), <https://hab.hrsa.gov/sites/default/files/hab/data/data-reports/RWHAP-annual-client-level-data-report-2017.pdf>.

<sup>58</sup> HHS, *Guidelines: Laboratory Testing for Initial Assessment and Monitoring of Patients with HIV Receiving Antiretroviral Therapy*, <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/3/tests-for-initial-assessment-and-follow-up>.

<sup>59</sup> HHS, *Viral Load and CD4 Count Monitoring*, *supra* p. 22 n.54; WHO, *Consolidated Guidelines*, at 136.

<sup>60</sup> *See, e.g.*, HHS, *Adherence Guidelines*, *supra* p. 17 n.43.

<sup>61</sup> *See* M. Ohl et al., *Mixed-Methods Evaluation of a Telehealth Collaborative Care Program for Persons with HIV Infection in a Rural Setting*, 28 *J. Gen. Internal Med.* 1165 (2013) (describing Veterans Affairs telehealth program as “a

**C. A temporary interruption in treatment does not lead to immediate symptoms or drug resistance**

Although an individual living with HIV must remain on ART, a temporary interruption in ART does not lead to immediate symptoms or drug resistance.<sup>62</sup> Most individuals whose first-line ART is interrupted long enough for viral load to rebound are able to achieve re-suppression after resuming treatment.<sup>63</sup> And even where HIV becomes resistant to one ART treatment regimen, others are usually available.<sup>64</sup> Resistance to multiple drugs is increasingly uncommon.<sup>65</sup>

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feasible approach to providing accessible and comprehensive care for persons with HIV in rural settings”), <https://www.ncbi.nlm.nih.gov/pubmed/23475640>.

<sup>62</sup> HHS, *Guidelines: Discontinuation or Interruption of Antiretroviral Therapy*, <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/18/discontinuation-or-interruption-of-antiretroviral-therapy>; see also C. Holkmann Olsen et al., *Interruption of combination antiretroviral therapy and risk of clinical disease progression to AIDS or death*, 8 HIV Med. 96 (2007), <https://doi.org/10.1111/j.1468-1293.2007.00436.x>.

<sup>63</sup> WHO, *Consolidated Guidelines*, at 130.

<sup>64</sup> HHS, *HIV Overview: FDA-Approved Medicines*, *supra* p. 11 n.25.

<sup>65</sup> See HHS, *Guidelines: Drug-Resistance Testing*, <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/6/drug-resistance-testing>; Alison F. Feder et al., *More effective drugs lead to harder selective sweeps in the evolution of drug resistance in HIV-1*, eLife 2016; 5: e10670, <https://elifesciences.org/articles/10670>.

#### **IV. The risk of HIV transmission from a person with an undetectable viral load is vanishingly small**

Absent a blood transfusion, the risk that any person living with HIV will transmit the virus to someone else is low given the virus's limited means of spreading. And the chance of transmission is effectively zero when the person living with HIV has an undetectable viral load. Further, post-exposure prophylaxis is available to help prevent HIV infection in individuals who have been exposed to the virus.

The government nonetheless speculates that "com[ing] into contact with blood" on the battlefield could lead to transmission. Gov't Br. 1, 15. That is highly unlikely. As the CDC notes, transmission from open skin or wound is extremely rare,<sup>66</sup> and amici are aware of no instance of transmission in a scenario resembling the government's hypothetical.

##### **A. HIV can be transmitted only if certain bodily fluids come into contact with an individual's mucous membrane, damaged tissue, or bloodstream**

Unlike some viruses, like the common cold, which can be transmitted by airborne moisture droplets, HIV can be transmitted only in limited ways. Specifically, the virus can be spread only through blood, semen, pre-seminal

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<sup>66</sup> CDC, *HIV Transmission*, *supra* p. 5 n.8.

fluid, rectal and vaginal fluids, and breastmilk. JA599. For these fluids to transmit the virus, they must first come into contact with the bloodstream—and even then, transmission of HIV from any single exposure is unlikely. HIV is not spread through saliva, tears, or sweat. The virus is also not transmitted by hugging, shaking hands, sharing toilets, sharing dishes, or closed-mouth kissing. And the virus is not transmitted by mosquitoes, ticks, or other insects. The virus does not survive long outside the human body; it cannot reproduce outside a human host and it decays on exposure to air. Thus, service members living with HIV pose no cognizable danger to the health of those they work and live alongside in the military. JA679-80.<sup>67</sup>

**B. Transmission rates are very low, leaving aside blood transfusions, and if the person living with HIV has a suppressed viral load, transmission is nearly impossible**

**1. Even when a person living with HIV is not virally suppressed, the chance of transmission through any route of exposure is low**

Even without viral suppression or PrEP, the riskiest sexual exposure, receptive anal intercourse, carries only a 1.38% chance of acquiring HIV per act. Insertive anal intercourse carries a 0.11% risk, and vaginal intercourse is

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<sup>67</sup> The information in this paragraph is available in CDC, *HIV Transmission*, *supra* p. 5 n.8. See also *supra* pp. 5-6.

less risky still. Needle sharing to inject drugs carries a 0.63% risk, and needle-stick a 0.23% risk. For other exposures, the risk is so low that – according to the CDC – it is not possible to put a precise number on it.<sup>68</sup>

A 2006 literature review estimated the rate of transmission via a blood transfusion from an infected source to be 92.5%. *See* JA459.<sup>69</sup> But as an initial matter, the review did not evaluate whether the estimate would differ if the donor had an undetectable viral load.<sup>70</sup> More importantly, individuals living with HIV are not permitted to donate blood. JA685-86. Thus, as the CDC explains, the actual risk of acquiring HIV via blood transfusion is “extremely small because of rigorous testing of the US blood supply”<sup>71</sup> – and that is true in both the civil and military contexts. *See* JA459, JA494-500.<sup>72</sup>

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<sup>68</sup> CDC, *HIV Risk Behaviors*, *supra* p. 5 n.8.

<sup>69</sup> Rebecca F. Baggaley et al., *Risk of HIV-1 transmission for parenteral exposure and blood transfusion*, 20 *AIDS* 805-812 (2006), [https://journals.lww.com/aidsonline/fulltext/2006/04040/Risk\\_of\\_HIV\\_1\\_transmission\\_for\\_parenteral\\_exposure.3.aspx](https://journals.lww.com/aidsonline/fulltext/2006/04040/Risk_of_HIV_1_transmission_for_parenteral_exposure.3.aspx); Pragna Patel et al., *Estimating per-act HIV transmission risk: a systematic review*, 28 *AIDS* 1509-19 & n.5 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6195215/> (citing Baggaley et al., *supra*).

<sup>70</sup> *Id.*

<sup>71</sup> CDC, *HIV Transmission*, *supra* p. 5 n.8.

<sup>72</sup> Noting that service members living with HIV may not donate blood, the government speculates that, because “[t]eams are sometimes composed of just a few soldiers,” “[t]he inability of just one or two soldiers to give blood

**2. Transmission risk depends on viral load, and an undetectable viral load means it is nearly impossible to transmit HIV**

The figures set out above do not account for an undetectable viral load, which greatly reduces the risk of transmission. In fact, individuals living with HIV on consistent ART cannot sexually transmit HIV. *See* JA600.<sup>73</sup> There have been *no* reported cases of transmission of the virus through sex from a partner living with HIV who has an undetectable viral load.<sup>74</sup> These

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may force a wounded soldier to choose between receiving a blood transfusion from an HIV-positive service member and not receiving one at all.” Gov’t Br. 16. But the government does not explain what sort of extreme circumstance could give service members – much less *Airmen* in particular – both cause and opportunity to attempt to give each other such impromptu battlefield transfusions. Nor does the government explain why the presence of HIV in a potential donor’s blood would be any more disabling than if the only potential donor had the wrong blood type. *See* Appellants’ Br. 41-42.

<sup>73</sup> CDC, *Effectiveness of Prevention Strategies to Reduce the Risk of Acquiring or Transmitting HIV*, <https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html> (ART is 100% effective for preventing sexual transmission of HIV); *see also* Robert W. Eisinger, Carl W. Dieffenbach, & Anthony S. Fauci, *HIV Viral Load and Transmissibility of HIV Infection: Undetectable Equals Untransmittable*, 321 JAMA 451-52 (2019), <https://jamanetwork.com/journals/jama/fullarticle/2720997>; Pietro Vernazza & Edwin J. Bernard, *HIV is not transmitted under fully suppressive therapy: The Swiss Statement – eight years later*, *Swiss Med. Weekly* (Jan. 29, 2016), [https://smw.ch/resource/jf/journal/file/view/article/smw/en/smw.2016.14246/6b733cad5240879543cbca8a3809b0c3b8a76087/smw\\_2016\\_14246.pdf/](https://smw.ch/resource/jf/journal/file/view/article/smw/en/smw.2016.14246/6b733cad5240879543cbca8a3809b0c3b8a76087/smw_2016_14246.pdf/).

<sup>74</sup> Myron S. Cohen et al., *Antiretroviral Therapy for the Prevention of HIV-1 Transmission*, 375 *New Eng. J. Med.* 830-39 (2016), <https://www.nejm.org/>

research developments have led jurisdictions like Switzerland, Canada, England, Wales, Scotland, and Sweden to change their approach to criminal prosecutions for HIV exposure.<sup>75</sup>

An individual with an undetectable viral load is also very unlikely to transmit HIV to another person through other means. For instance, more than a decade ago, scientists recognized that the risk of infection from percutaneous accidents depends not only on the amount of blood involved and where the source needle enters the body, but also on the viral load of the individual with the virus.<sup>76</sup> (Controlled studies of such accidents are not possible given ethical constraints.<sup>77</sup>) In fact, given the extremely low risk, the United Kingdom does not recommend post-exposure prophylaxis following percutaneous injury by a needle from a person with an undetectable viral

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[doi/full/10.1056/NEJMoa1600693](https://doi/full/10.1056/NEJMoa1600693); Eisinger et al., *supra* p. 28 n.73; Vernazza & Bernard, *supra* p. 28 n.73.

<sup>75</sup> Vernazza & Bernard, *supra* p. 28 n.73.

<sup>76</sup> Baggaley et al., *supra* p. 27 n.69.

<sup>77</sup> See, e.g., Binta Sultan et al., *Current perspectives in HIV post-exposure prophylaxis*, 6 *HIV/AIDS—Research & Palliative Care* 147-58 (2014), <https://www.dovepress.com/current-perspectives-in-hiv-post-exposure-prophylaxis-peer-reviewed-fulltext-article-HIV>.

load.<sup>78</sup> The U.S. recommendation differs, but recognizes that “the risk of transmission from an occupational exposure to a source patient with an undetectable serum viral load is thought to be very low.”<sup>79</sup>

**C. Individuals exposed to HIV may take post-exposure prophylaxis to further decrease the already low risk of acquiring HIV**

Post-exposure prophylaxis (PEP) is an ART regimen designed to prevent an individual potentially exposed to HIV from becoming infected. PEP

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<sup>78</sup> UK Chief Med. Officers’ Expert Advisory Grp. on AIDS (EAGA), *Updated recommendation for HIV post-exposure prophylaxis (PEP) following occupational exposure to a source with undetectable HIV viral load* (Dec. 2013), [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/275060/EAGA\\_advice\\_on\\_PEP\\_after\\_exposure\\_to\\_UD\\_source\\_Dec13.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/275060/EAGA_advice_on_PEP_after_exposure_to_UD_source_Dec13.pdf); see EAGA, *EAGA guidance on HIV post-exposure prophylaxis*, <https://www.gov.uk/government/publications/eaga-guidance-on-hiv-post-exposure-prophylaxis>; DP Webster, *Is HIV post-exposure prophylaxis required following occupational exposure to a source patient who is virologically suppressed on antiretroviral therapy?*, 16 *HIV Med.* 73-75 (2015), <https://onlinelibrary.wiley.com/doi/full/10.1111/hiv.12187>.

<sup>79</sup> CDC, *Updated US Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis* 10-11 (2013), <https://stacks.cdc.gov/view/cdc/20711>.

operates by preventing the intruding virus from replicating while the original infected cells die off naturally without producing more HIV.<sup>80</sup> Thus, time is of the essence, and PEP should be started within 72 hours of exposure.<sup>81</sup>

PEP has been shown to be effective.<sup>82</sup> In one study of 100 individuals who took a PEP regimen following a higher-risk sexual exposure, for example, no participant became infected with HIV.<sup>83</sup> And in a very early study of individuals who reported needlestick injuries, PEP was shown to reduce the risk of HIV infection by 81%.<sup>84</sup>

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<sup>80</sup> E.g., UC Davis Student Health & Counseling Servs., *Post-exposure Prophylaxis (PEP) for HIV*, <https://shcs.ucdavis.edu/topics/post-exposure-prophylaxis-pep-hiv>; see also CDC, *Updated Guidelines for Antiretroviral Post-exposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV – United States, 2016*, at 30, <https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf>.

<sup>81</sup> CDC, *PEP*, <https://www.cdc.gov/hiv/basics/pep.html>.

<sup>82</sup> See, e.g., Anthony S. Fauci et al., *Ending the HIV Epidemic: A Plan for the United States*, 321 *JAMA* 844-45 (2019), <https://jamanetwork.com/journals/jama/fullarticle/2724455>.

<sup>83</sup> Kenneth H. Mayer et al., *Optimal HIV Postexposure Prophylaxis Regimen Completion With Single Tablet Daily Elvitegravir/Cobicistat/Tenofovir Disoproxil Fumarate/Emtricitabine Compared With More Frequent Dosing Regimens*, 75 *J. Acquired Immune Deficiency Syndromes* 535-39 (2017), [https://journals.lww.com/jaids/fulltext/2017/08150/Optimal\\_HIV\\_Post-exposure\\_Prophylaxis\\_Regimen.6.aspx](https://journals.lww.com/jaids/fulltext/2017/08150/Optimal_HIV_Post-exposure_Prophylaxis_Regimen.6.aspx).

<sup>84</sup> Myron S. Cohen et al., *Narrative Review: Antiretroviral Therapy to Prevent the Sexual Transmission of HIV-1*, 146 *Annals of Internal Med.* 591-601, 595 & n.63 (2007), <https://annals.org/aim/article-abstract/734167/>

**D. HIV transmission through a non-sexual exposure route in a deployed setting has never been observed, and it is not among the very real risks that service members face**

Deployed service members face a number of very real risks to their health and safety. But the possibility of acquiring HIV infection on the battlefield is extremely low. *See* JA679. The government has pointed to no documented instance of HIV transmission on the battlefield, although the military *has* deployed individuals with *undiagnosed* HIV. *See* JA483. Thus, “[i]t is reasonable to conclude [that] 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.” JA680.

In fact, one study conducted by military researchers found that the majority of soldiers who developed HIV while deployed had become infected before their deployment or while on leave for rest and relaxation. *Id.* “None were emergency blood transfusion donors or recipients,” and the researchers found sexual activity to be the most likely cause. JA484. The study further found that “infection while deployed in Afghanistan and Iraq was extremely

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[narrative-review-antiretroviral-therapy-prevent-sexual-transmission-hiv-1?volume=146&issue=8&page=591](#) (cited study was published in 1997).

rare” and that it did “not exceed the rate among nondeploying soldiers.”

JA484-85.

\* \* \*

The clear weight of scientific evidence shows that the risk of HIV transmission from a person with an undetectable viral load—by any realistic exposure route, including exposure routes peculiar to a deployed environment—is vanishingly small. Appropriate deference to military judgment cannot override this scientific consensus.

## CONCLUSION

This Court's judgment, like the District Court's, should be informed by the best possible understanding of HIV science and medicine. In light of that understanding, the Court should affirm.

Dated: July 25, 2019

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

I hereby certify that this amicus brief complies with (1) the type-volume limitation of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7)(B) because, as calculated by Microsoft Word 2016, it contains 6,494 words, excluding the items exempted by Federal Rule of Appellate Procedure 32(f); and (2) the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6), because it has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in a 14-point Book Antiqua font.

Dated: July 25, 2019

/s/ Benjamin C. Mizer  
Benjamin C. Mizer

### CERTIFICATE OF SERVICE

I hereby certify that on July 25, 2019, I filed the foregoing Brief of HIV Medicine Association, American Academy of HIV Medicine, GLMA: Health Professionals Advancing LGBTQ Equality, and Infectious Diseases Society of America as Amici Curiae In Support of Appellees and Affirmance with the Clerk of Court for the United States Court of Appeals for the Fourth Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

Dated: July 25, 2019

/s/ Benjamin C. Mizer  
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