

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

NICHOLAS HARRISON, *et al.*,

Plaintiffs,

v.

MARK ESPER, Secretary of Defense, *et al.*,

Defendants.

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

RICHARD ROE, *et al.*,

Plaintiffs,

v.

MARK ESPER, Secretary of Defense, *et al.*,

Defendants.

No. 1:18-cv-1565 (LMB/IDD)

NOTICE OF ERRATA

It has come to Defendants' attention that their Memorandum in Support of Defendants' Cross Motions for Summary Judgment and in Opposition to Plaintiffs' Motions for Summary Judgment, as well as their Memorandum in Support of Defendants' Motions to Exclude, contained certain errors warranting correction. *See Harrison* ECF Nos. 264, 272, 275; *Roe* ECF Nos. 276, 284, 287. Importantly, none of these errors – or the correction of those errors in this paper – in any way modifies any of the substantive arguments that Defendants asserted in their timely-filed summary judgment papers.

With respect to Defendants' summary judgment memorandum, *first*, Exhibit 22 is missing pages 58, 59, and 125, and Exhibit 35 is missing page 183. Both exhibits are re-filed accompanying this errata with the missing pages now included. These exhibits each also had

two pages out of order; this mistake has been corrected in the re-filed versions. *Second*, Defendants incorrectly cited the Deposition of Paul Aswell (“Aswell Dep.”) as Exhibit 12, but it can be found at Exhibit 17. *Third*, in one instance the Declaration of Paul Ciminera was cited as Exhibit 18, but it can be found at Exhibit 19; and in one instance DoDI 6485.01 was cited as Exhibit 6, but it can be found at Exhibit 2. *Fourth*, Defendants incorrectly cited Exhibit 33 as the Deposition of Dr. Craig Hendrix (“Hendrix Dep.”). Exhibit 33 is the Deposition of Dr. W. David Hardy (“Hardy Dep.”). The Deposition of Dr. Hendrix can be found at Exhibit 32. Because of this incorrect citation, several of the pin cites are in error. *Fifth*, the confidential version of the Declaration of Martha P. Soper (“Soper Decl.”) which was filed under seal as “Exhibit 25” contains an incorrect cover sheet identifying it as Exhibit 22, but it is Exhibit 25. *Finally*, with respect to Defendants’ motion to exclude memorandum, Defendants inaccurately reported one statistic.

Defendants apologize for these oversights and correct the record as follows:

Para. No.	Page: Line	Citation	Corrected Citation
SUF ¶ 6	4:23-24	Ex. 12, Aswell Dep. 67:1-16	Ex. 17, Aswell Dep. 67:1-16
SUF ¶ 21	8:15	Ex. 6, DoDI 6485.01 Enc. 2, §§ 1(b), 3(c).	Ex. 2, DoDI 6485.01 Enc. 2, §§ 1(b), 3(c).
SUF ¶ 44	13:22-23	Ex. 33, Hendrix Dep. 149:4-151:11; 270:15-271:22	Ex. 32, Hendrix Dep. 149:4-151:11; 270:15-271:22; Ex. 33, Hardy Dep. 131:20-132:2, 238:24-239:7
SUF ¶ 45	13:24-25	Ex. 33, Hendrix Dep. 86:16-89:4	Ex. 32, Hendrix Dep. 86:16-89:4; Ex. 33, Hardy Dep. 84:1-85:22
SUF ¶ 47	14:4	Ex. 33, Hendrix Dep. 159:14-161:19	Ex. 32, Hendrix Dep. 159:14-161:19; Ex. 33, Hardy Dep. 138:13-23
SUF ¶ 53	15:19	Ex. 33, Hendrix Dep. 143:19-147:18	Ex. 33, Hardy Dep. 143:19-147:18
SUF ¶ 54	16:2	Ex. 18, Ciminera Decl. ¶ 41	Ex. 19, Ciminera Decl. ¶ 41

Fax: (703) 299-3983
dennis.barghaan@usdoj.gov

KERI L. BERMAN
REBECCA CUTRI-KOHART
STEPHEN M. PEZZI
Trial Attorneys
U.S. Department of Justice
Civil Division
Federal Programs Branch
1100 L Street, N.W.
Washington, D.C. 20530
Telephone: (202) 514-0265
Facsimile: (202) 616-8460
rebecca.cutri-kohart@usdoj.gov

Counsel for the Government

EXHIBIT 22

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

RICHARD ROE, et al.

Plaintiffs

vs.

PATRICK M. SHANAHAN, et al.

Defendants

Civil Action No.:

1:18-cv-01565

NICHOLAS HARRISON, et al.

Plaintiffs

vs.

PATRICK M. SHANAHAN, et al.

Defendants

Civil Action No.:

1:18-cv-00641

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Deposition of
COLONEL CLINTON K. MURRAY, M.D.
Washington, D.C.
Tuesday, April 30, 2019
9:30 a.m.

Reported by: Laurie Donovan, RPR, CRR, CLR

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Deposition of
COLONEL CLINTON K. MURRAY, M.D.

Held at the offices of:

Winston & Strawn
1700 K Street, NW
Washington, D.C. 20006
(202)282-5000

Taken pursuant to notice, before
Laurie Donovan, Registered Professional
Reporter, Certified Realtime Reporter, and
notary public for the District of Columbia.

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A P P E A R A N C E S

ON BEHALF OF THE PLAINTIFFS:

Lambda Legal

105 West Adams Street

Suite 2600

Chicago, Illinois 60603

(312)663-4413

By: Scott A. Schoettes, Esq.

sschoettes@lambdalegal.org

Kylee Reynolds, Esq. (DC office)

kreynolds@lambdalegal.org

ON BEHALF OF THE DEFENDANTS:

U.S. Department of Justice

Civil Division

1100 L Street, NW

Washington, D.C. 20001

(202)305-7667

By: Robert M. Norway, Esq.

robert.m.norway@usdoj.gov

ALSO PRESENT: Major S. Casey Biggerstaff, Esq.

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E X H I B I T S

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Exhibit 3	DoD's 2018 Report to Congress	27
Exhibit 4	PowerPoint presentation entitled "HIV Update: Current Status, Policy & Deployment Considerations"	90
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1 things such as diarrhea aren't, aren't capable of
2 being used as a biological warfare agent. So you
3 can see scenarios where someone could potentially
4 use HIV as an instrument to deliver biological
5 warfare agent on the battlefield.

6 So, for example, if I load an IED with
7 discarded needles and blow up that roadside bomb,
8 and the needles all fly through -- whoever is in
9 those vehicles will get hit with those. If you're
10 obtaining those needles from an HIV clinic, then
11 if that's all purposefully done, then it can be
12 used as a biological weapon.

13 Q To your knowledge, has it ever been used
14 in that way?

15 A So IEDs loaded with needles have been
16 used. Loaded with HIV? Not that I know of.

17 Q And has there ever been a documented
18 case of HIV transmission from a found needle?

19 MR. NORWAY: Objection. Vague.

20 You may answer to the extent that
21 you know.

22 THE WITNESS: So it's a little bit
23 more complicated than that. Just a needle
24 sitting there, no. A needle sitting there
25 with, with blood that's not contaminated with

1 HIV, no, but if you transition from that
2 needle, large quantity of HIV goes straight
3 from one person to another, then you're
4 starting to get the higher and higher risk of
5 transmitting.

6 So it really is where are you on
7 that continuum of nothing in the needle to a
8 very, very fresh sample goes straight from
9 one person to the next.

10 BY MR. SCHOETTES:

11 Q But in terms of a found needle --

12 A A found needle? I'd have to pull the
13 literature to say absolutely no, but I feel
14 comfortable the current post-exposure prophylaxis
15 guidelines do not recommend post-exposure
16 prophylaxis for a found needle, which just means
17 the risk is very low.

18 Q And you said that HIV would not be in
19 the top tiers of biological warfare agents; is
20 that correct?

21 A Correct.

22 MR. NORWAY: Objection to the
23 extent it mischaracterizes the testimony.

24 You may answer.

25 THE WITNESS: Correct.

1 had a fair bit of liver test abnormalities,
2 so again, a quick referral to GI, make sure
3 everything is okay. Do all the labs, which
4 is not inconsequential, because it takes a
5 couple weeks for most of them to come back.

6 If that's all stable and nothing
7 changes, then the next time they come back,
8 they don't have to do a follow-up, but I am
9 continually impressed that there's just
10 enough lab abnormalities that you have to
11 spend some time at least thinking about it
12 when they come there.

13 BY MR. SCHOETTES:

14 Q Would those occur at the beginning of a
15 person's time on a particular regimen?

16 MR. NORWAY: Objection. Form.

17 You may answer.

18 THE WITNESS: So typically, yes,
19 but life happens, and then all of a sudden
20 someone just changes their life events. I've
21 had folks go from non-drinkers to substantial
22 drinkers a year into their diagnosis for lots
23 of reasons, and we would not have picked that
24 up.

25 So I think there's, there's -- as a

1 doctor, I sort of treat each encounter as a
2 brand new encounter. I'm going to give you
3 the credit that I'm not biased by yesterday.
4 I'm going to give you a brand new bill of
5 health when you leave here.

6 So I think it's on us to be as
7 observant as possible to make sure we're
8 giving the best care, but no, I would agree
9 with you. Overall, most of this toxicity is
10 early on.

11 The thing that I do struggle with
12 is we continue to come out with new regimens
13 that we're not necessarily completely
14 familiar with that are absolute long-term
15 safety and toxicity, and drugs that have come
16 out in the last couple of years, now there's
17 more information coming out about their lipid
18 profiles being abnormal, so I just think we
19 have to maintain that sort of emphasis.

20 BY MR. SCHOETTES:

21 Q How long do you get to spend with
22 someone in a one-on-one encounter?

23 A So what we -- as a subspecialty clinic,
24 what the Army says you can have is 30 minutes.
25 What most of us do is take about an hour, unless

1 BY MR. SCHOETTES:

2 Q They are unlikely?

3 A Correct. So these folks would set up in
4 a tent, in an old, abandoned building. They would
5 not be using any environment that someone would
6 associate with a normal operating room.

7 Q But they do use gloves?

8 A Correct, but you have as many gloves as
9 you have, so in contrast to a combat support
10 hospital or a normal forward surgical team where
11 your supplies on the shelf are reasonable --
12 limited, but reasonable -- they're going to have
13 very limited options.

14 So more than one case becomes an issue.
15 Any destruction of a glove becomes a substantial
16 issue, because you're not going to have six and
17 seven extra pair, and then typically you hope
18 you're using sterile gloves. That's the goal.
19 Those team members frequently do not all wear the
20 same sizes, so you really are just sort of losing
21 weight and cube again as you expand those teams
22 out.

23 Q What do they use for antimicrobial
24 protection?

25 A Correct. The recommended battlefield

1 antibiotic is ancef, cefazolin, and ertapenem.
2 One of those is a once-a-day, so you're pretty
3 good. The other one can be infused every eight
4 hours. So you have enough time to work within
5 that, and they come in incredibly small
6 (inaudible).

7 Q And so those are provided to the
8 patient, correct?

9 MR. NORWAY: Objection. Form.
10 You may answer.

11 THE WITNESS: They're brought in
12 the kits at the time the patient arrives for
13 care. They will put in an IV and infuse the
14 antibiotics, correct, and those antibiotics
15 are the field antibiotics, so everyone,
16 whether you're at a forward surgical team or
17 a combat support hospital or in these
18 incredibly small teams, are all using the
19 same antibiotic choices.

20 BY MR. SCHOETTES:

21 Q Do they attempt to sanitize their hands?

22 A They would use alcohol hand gel, but
23 they would not have the sink where you can wash
24 your hands for two, three minutes, which is sort
25 of recommended pre-OR, or if you get splash on you

1 or a needlestick, that would not be available at
2 all in that environment.

3 Q And what was your job during this two
4 weeks of overseeing the work that was -- that you
5 just described?

6 A So the Army works upon this concept
7 called "doctrinally-based." Everything we do in
8 the Army is doctrine-based, so the CSH is a
9 doctrine-based organization. The forward surgical
10 team is a doctrinally-based organization. So it's
11 a combat support hospital forward hospital team.

12 This team is non-doctrinally-based, so
13 the assessment was to see if it could be
14 incorporated into a doctrinally-based program, and
15 what were the constraints, limitations, strengths,
16 weaknesses of this team was my marching orders
17 from the two-star who told me to go to
18 Afghanistan.

19 Q Can you explain to me what it means to
20 be doctrinally-based?

21 A Correct. So large documents say a CSH
22 has 498 people, it has four ORs, it has this type
23 of equipment, it has this type of medicines, it
24 has this many ICU nurses, so it's very regimented.
25 When the Army says I want a CSH, they get a CSH,

1 asking for something that is defined by the Army.

2 Q Does every doctrinally-based entity,
3 medical entity have the same formulary as the
4 other entities within that category?

5 A So every area support medical company
6 would have the same sets and kits with the same
7 things in them. Every battalion aid station would
8 have the same kits and the same thing in them.
9 Every combat support hospital would have the same
10 kits.

11 When you get to theater, you can ask for
12 something unique. So, for example, the kits do
13 not have certain anti-malarial medicine, so if I'm
14 going to send you to Africa, there's got to be a
15 specific plan of how I'm going to get you that
16 drug, and how I'm going to train you on that drug,
17 and how I'm going to train all these other folks
18 that are going to support that event. So then it
19 becomes that one-off conversation that we have.

20 Q For a particular theater?

21 A For a, for a specific threat or a
22 specific capability, right. So if, if we're going
23 to Liberia, that is a very different threat
24 problem than to go to Kenya. The medicines are a
25 little bit different, HIV-1 versus HIV-2, so, you

1 know, little subtle differences are important to
2 recognize between those two theaters.

3 So if it's doctrinally-based, I can't
4 answer both of those. Those would have to be
5 special engagements, special requests, special
6 logistics, special training, that whole
7 man/train/equip/develop/sustain. So all of those
8 pieces we talked about that commanders are
9 responsible for go into all of these requirements
10 that are not standard.

11 Q So I'm just trying to make sure I
12 understand this, but a battalion aid station is
13 going to have the same thing, whether it's in Iraq
14 or Africa?

15 A The kit they show up with would be the
16 same, and then I augment it with anything that is
17 specific for that either theater, region, patient
18 population, risk factors --

19 Q Got it.

20 A -- which in a, in a very mature
21 environment like Iraq and Afghanistan, that's easy
22 to do. In a very immature theater, just the words
23 we use, injury ops, just going in like I did in
24 Ramadi -- I mean we ran out of Motrin for six
25 weeks and couldn't get resupplied. That's the

1 candy for soldiers, and we couldn't get
2 resupplied.

3 It just gives you a picture contrasting
4 what we see in Iraq and Afghanistan, absolutely
5 not what you see early on in a fight or really in
6 a near-peer fight, which is not what Iraq and
7 Afghanistan are, where you really are logistically
8 constrained. So if it's not in that kit, you may
9 struggle actually getting it into that kit at a
10 later date.

11 Q Can you explain to me the term
12 "near-peer"?

13 A So near-peer currently is being referred
14 to as Russia, China, Korea.

15 Q So I think I have a sense from those
16 examples, but can you describe what you -- what
17 the term "near-peer" means?

18 A So their weapon systems, their
19 personnel, their training, their equipment is par,
20 potentially better, potentially a little less than
21 our training, equipping, manning, so that if there
22 is a fight, you might not have air superiority,
23 you may not have sea superiority, you may not have
24 ground superiority.

25 You may have -- from a medical

1 forgot to take my malaria drugs for basically
2 four days. So I'm an ID doctor. I should
3 never forget to do that.

4 So, you know, just that environment
5 of care just showed you what a challenge it
6 can be to actually remember to do all the
7 things you're supposed to do, so . . .

8 BY MR. SCHOETTES:

9 Q And that was a result of specifically
10 the circumstance with the coup?

11 A Correct, to the point -- we had a dugout
12 pool area with a fence above it, so we sat by the
13 pool. The AK-47 rounds were going above your
14 head, and the pool was dug out low enough that you
15 weren't going to get shot. If you went up to your
16 room, the AK-47s and the RPGs were flying through
17 our windows. So you weren't necessarily going
18 back up to your room to get anything, and there
19 was a fair bit of stress. You just forget to sort
20 of do things.

21 And then I could talk if you'd like --
22 so a lot of combat-related injury/infection
23 research, which not only does it just talk about
24 point-of-injury care and antibiotics, and then as
25 the casualties move back to the evacuation system,

1 Iraq and Afghanistan to Germany, and then back to
2 the States, what complications they had, part of
3 all of that research was ensuring that we looked
4 at other modalities to improve survival rate, so
5 don't let your patient get too cold. Bad
6 outcomes. Don't let them get too acidotic. Bad
7 outcomes.

8 When I was deployed and when I came
9 back, one of the big conversations we were having
10 was all about fresh whole blood and the walking
11 blood bank, so really before '03/'04, the blood
12 bankers were -- you get component therapy, which
13 means packed red blood cells or platelets or FFP.
14 When we went downrange, you could get packed red
15 blood cells. They have a shelf life of about 42
16 days. You want them within 14 days. That's the
17 best for delivering oxygen. We couldn't get the
18 packed red blood cells within 14 days, so we were
19 trying to figure that out.

20 You can't actually collect -- you can't
21 ship platelets in theater. You have to collect
22 them locally. They didn't have a machine to
23 collect them. So now all of a sudden, you have
24 old packed red blood cells, you have platelets not
25 available, and then the last part at the top that

1 helps mortality, because this is all bleeding out,
2 there's something called fresh frozen plasma,
3 which are all the clotting factors that sort of
4 fit between the platelets so you don't bleed out.
5 And it's frozen, so it's got to get to you frozen.

6 So it's got to go from Germany to these
7 logistical hubs, from these logistical hubs, push
8 forward to combat support hospitals, push forward
9 from combat support hospitals down to forward
10 surgical teams. As part of that continuum of
11 care, we were ineffective at getting probably the
12 right packed red blood cells, we were ineffective
13 at getting platelets at all, and we were not
14 getting fresh frozen plasma frozen.

15 So there's lots of historical literature
16 from really The Great War, World War II-ish, where
17 in the sense of The Great War of learning for
18 combat casual care and then some experiences in
19 Viet Nam with fresh whole blood was really good on
20 the battlefield, plasma and fresh whole blood.

21 So a couple surgeons started using a lot
22 of fresh whole blood, and they started doing
23 studies that showed it was safer, better
24 outcomes -- all retrospective studies, you can't
25 do controlled trials here. So either you do

1 component therapy, which is one unit of packed red
2 blood cells and a six-pack of platelets, which is
3 six units put together, and then a unit of FFP.
4 If you have all of that, that's really good, but
5 fresh whole blood is probably still better.

6 So as all of that was growing and
7 maturing, we were engaging me because of lots of
8 trauma experience on the battlefield, lots of the
9 surgeons that were doing the research, we were
10 trying to figure out what do we do to make sure
11 this is safe as possible.

12 So they had started using rapid
13 diagnostic kits in the CSH in Baghdad. They just
14 ordered them off the street, brought them back and
15 said do these work, and Robert O'Connell, one of
16 the infectious disease doctors, assessed those
17 kits for hepatitis B, hepatitis C, and HIV, and
18 showed they had sensitivities and specificities of
19 20 to 40 percent. So we're ineffective picking up
20 those pathogens in a blood bank.

21 So lots of effort went into trying to
22 find the right rapid diagnostic for hepatitis B,
23 hepatitis C, to go along with building the process
24 of fresh whole blood collection and then infusion.
25 So you're eventually able to find a rapid kit for

1 each of those, at least for HIV. It is not
2 FDA-approved for screening of personnel for
3 transfusion, so even today it's not FDA-approved
4 for collecting blood for donor, so it's not there.

5 In addition, there was lots of studies
6 that this doctor was doing, along with other folks
7 in the States that were showing someone that may
8 be freshly infected and freshly initiated on
9 therapy, but probably definitely anyone that had
10 been on multiple regimens of HIV, those rapid kits
11 were giving a false negative result.

12 So someone known to be infected with
13 HIV, known to be on medicines, when their blood
14 was tested, it gave a false negative. So even the
15 current OraQuick HIV test that we use now has that
16 same restrictions that someone that is
17 HIV-infected, if they're on therapy, can result in
18 false negative results.

19 Q From that -- I'm just going to pause you
20 here. That's from that kit that is not
21 FDA-approved?

22 A So it's FDA-approved for these things.
23 What it's not approved for, blood donors.

24 Q And maybe we can pause there, because I
25 may have some questions that I want to ask

1 referring to.

2 BY MR. SCHOETTES:

3 Q And so you're saying "Ever Viral
4 Suppression" means that the people within that
5 category have achieved viral suppression at some
6 point after their diagnosis and being on
7 treatment, correct?

8 A So there are elite controllers that
9 might be able to suppress their virus. I can't
10 tell you if they are in that mix or not, but yes,
11 on the vast majority of cases, it would be
12 diagnosed with HIV, therapy initiated, and when
13 did their viral load get below the lower limit of
14 detection for the assay being used.

15 Q And for the cohort with an HIV diagnosis
16 between 2012 and 2016, the percentage of people
17 who have ever achieved viral suppression is
18 99.8 percent; is that correct?

19 A Correct.

20 Q That means 998 out of 1,000 people who
21 have been diagnosed with HIV during that time
22 period would have achieved viral suppression?

23 MR. NORWAY: Objection. Form.

24 Mischaracterizes his testimony.

25 You may answer.

1 THE WITNESS: Is there a question?

2 BY MR. SCHOETTES:

3 Q Yes. Does that 99.8 percent indicate
4 that we're talking about only two out of 1,000
5 individuals would not have achieved viral
6 suppression?

7 A Correct.

8 Q The next column is "Viral Suppression
9 Within Six Months of ART Initiation."

10 Can you just tell us what "ART" stands
11 for?

12 A Antiretroviral therapy.

13 Q And this shows that approximately
14 75 percent of people diagnosed with HIV between
15 2012 and 2016 achieved viral suppression within
16 six months; is that correct?

17 A Correct.

18 MR. NORWAY: Objection.

19 Foundation.

20 You may answer.

21 THE WITNESS: Correct.

22 BY MR. SCHOETTES:

23 Q It says here at the bottom, "Viral
24 suppression has occurred with 90 plus percent of
25 service members becoming virally suppressed ever

1 and by one year, accounting for newer ART
2 regimens."

3 First of all, did you create this entire
4 slide, or is this data pulled from another source?

5 MR. NORWAY: Objection. Form.

6 You may answer.

7 THE WITNESS: So the infectious
8 disease clinical research program is a USUHS
9 NIH, NIAID program that looks at the care of
10 HIV service members in our facilities. The
11 director of that program is Dr. Agan, who
12 provided this information to us.

13 BY MR. SCHOETTES:

14 Q And this slide says that it's "data
15 censored February 22, 2019."

16 What does that mean?

17 A So, for example, someone that enrolled
18 in 2002 would have 17 years' worth of data through
19 2019. Someone enrolled in 2016 would only have
20 three years of data in 2019.

21 So when you look at outcomes,
22 complications, errors, errors like time windows of
23 therapy, time windows of diagnosis, you have to
24 incorporate the bias associated with the group
25 being followed for 17 years versus the bias of the

1 group being followed for three.

2 Q And so does that indicate that all of
3 the people covered by this slide as having been
4 diagnosed with HIV are still in the Army?

5 A No. What it means is if you were still
6 enrolled in the study, still being followed up,
7 then we stopped at 2019. If, on the other hand,
8 you enrolled in the study in 2002 and you decided
9 to not be in the study in 2011, your individual
10 data would have nine years' worth of information
11 in it. The "you" is the individual that got out
12 after nine years, censored yourself at nine years.

13 Q So that data is still included for
14 people who exited the study after whatever period
15 of time, say nine years?

16 A Correct.

17 Q Did you add this statement to the bottom
18 of this slide, or was this provided by Dr. Agan?

19 A That's my addition.

20 Q So can you tell me where the data for
21 the "and by one year" comes from in that
22 statement?

23 A So I think if you look on the next
24 slide, the bottom right figure, if you look at the
25 time course in months, you can see that marches

1 out to 12 and a half months, and you can see the
2 various time-depicted lines for all basically at a
3 one or close to 100 percent by one year.

4 Q So going back to the slide previous, is
5 it true that not only is viral suppression at 90
6 plus percent for people at one year, but indeed it
7 is almost 100 percent by first year?

8 MR. NORWAY: Objection. Form.

9 You may answer.

10 THE WITNESS: I would use the
11 caveat almost as you did, so plus or minus
12 five percent, yes.

13 BY MR. SCHOETTES:

14 Q And I don't think I heard me use "plus
15 or minus five percent," so I'll ask you why that
16 is the interval -- well, obviously, it couldn't be
17 plus five percent, but why that is the interval
18 you would use to describe it as "almost
19 100 percent."

20 MR. NORWAY: Objection. Form.

21 THE WITNESS: Because I can't see
22 the data, so I, I give it a statistical error
23 of .05 percent, which is five percent, which
24 is my sort of pat answer for a question when
25 you're starting to look at numbers. I think

1 five percent is a reasonable area to move.

2 BY MR. SCHOETTES:

3 Q If you go now to the next slide again,
4 there are zeros in the last column at
5 approximately one year, it looks like.

6 What do those zeros indicate?

7 A So again, I don't know if that is
8 sitting before or after 12 months. I can't
9 actually tell you if those are all those time
10 points.

11 Q For whatever time point it's at, let's
12 say it's at 12, what do those zeros indicate?

13 A Those indicate viral suppression.

14 Q Meaning that everyone had achieved viral
15 suppression from the various cohorts described?

16 A So as evident on the previous slide,
17 99.8 ever, 98.8 and 97.1, so three percent to
18 .2 percent. That would be an assumption that
19 could be made. I would like to see the absolute
20 data to be able to say that for sure, which is why
21 I wrote this statement "90 plus percent," because
22 I think that's not overstating the facts.

23 Q If you go to slide 27, which has
24 "Mortality and Morbidity" at the top, does this
25 slide indicate that essentially no one in the

1 Q If you flip to slide 30, which is the
2 one labeled "Walking Blood Bank," there's a
3 reference to a known transmission of HCV and one
4 of HTLV, and then in the box at the bottom, you
5 stated that "the HCV case was from a known
6 HCV-infected service member who donated anyway."

7 MR. NORWAY: Objection.

8 There's no question pending.

9 Sorry.

10 BY MR. SCHOETTES:

11 Q How do you know that to be the
12 situation?

13 A So both the hepatitis C transmission and
14 the HTLV transmission were associated with an
15 epidemiological look-back to figure out how that
16 occurred. The patient -- let me pause for a
17 second.

18 When that unit of blood is obtained from
19 a soldier in a walking blood bank, it's labeled.
20 Tubes are obtained. The unit is still given to
21 the patient, but the tubes are sent back to a
22 testing center in the U.S. to validate if they
23 have the classic transfusion-transmitted
24 complications of a unit, because you can't do that
25 downrange.

1 When they sent that blood back, it was
2 identified as hepatitis C. Occasionally those
3 tubes of blood don't make it back, so we follow
4 folks who get a non-FDA-approved unit of blood,
5 which means they didn't go through the standard
6 testing. Those patients are then monitored, and
7 it moves a little bit, but it's mostly at three,
8 six and 12 months after coming back.

9 They draw their blood, they test them
10 for hepatitis B and C and HIV, and based upon
11 their epidemiological risk factors, that patient
12 may be tested for malaria, may be tested for
13 syphilis.

14 So the hepatitis C patient's blood was
15 identified as positive, the donor. The person who
16 received it did develop hepatitis C infection.
17 That hepatitis C soldier, when his boss -- I don't
18 remember if it was a platoon leader or a company
19 commander -- was injured, he was taken to a remote
20 forward surgical team. He absolutely needed
21 blood. They did not have enough on the shelf, so
22 they asked for an emergency walking blood bank.

23 This soldier is one of his soldiers that
24 was out with him when he had his severely
25 traumatic injury. He and other soldiers with him

1 that were part of this leader's unit all donated
2 blood.

3 This soldier actually knew he had
4 hepatitis C. Somewhere it got lost in translation
5 that you don't donate blood with hepatitis C, what
6 hepatitis C is. The person that was receiving the
7 unit didn't understand what was going on. So
8 somewhere there was a break in that understanding
9 of what hepatitis C is.

10 Q So let me ask a follow-up question.
11 Does the Army knowingly deploy individuals -- let
12 me back up.

13 Did the Army know that this individual
14 had HCV?

15 MR. NORWAY: Objection. Form.
16 You may answer.

17 THE WITNESS: I don't know that
18 specific question. Army regulation says no
19 one with hepatitis B or hepatitis C can
20 deploy without a waiver.

21 BY MR. SCHOETTES:

22 Q So that was my next question. So the
23 Army does not deploy, without a waiver, an
24 individual who has hepatitis C?

25 A However, they don't screen for hepatitis

1 to 95 percent are protected, so pretty much all
2 babies get immunized against hepatitis B and have
3 been for, gosh, a couple decades now. Soldiers
4 entering the Army have been immunized against
5 hepatitis B since 2002. So 95 percent, 90 to
6 95 percent effective vaccine, right?

7 If I -- say I'm not protected, vaccine
8 didn't take, I'm part of that five to ten percent,
9 and I get exposed to hepatitis B, 95 percent of
10 the time I will clear it and it will not be a
11 chronic infection.

12 Hepatitis C, its infection rate is
13 higher, 30 to 70 percent. Hepatitis C is not --
14 hepatitis C, there's genotype 1, there's genotype
15 2, genotype 1b, so there's lots of subtleties.
16 These are different across ethnicities and race.
17 They're different across exposures.

18 So in addition is the infection rate is
19 potentially different. There's now a therapy,
20 based upon genotypes, that's 70 to 90-plus percent
21 effective, which, again, contrasting with HIV,
22 there is no cure, there is no vaccine. There is
23 incredibly effective therapy, incredibly effective
24 therapy, but the problem sets across a B to a C to
25 an HIV are different.

1 So in a place like Iraq where I got my
2 needlesticks, and I'm inside a guy's chest cavity
3 with my hand, and there's blood everywhere, so I
4 feel very comfortable that there's blood now in my
5 finger. As I look at my patient, I go I know I'm
6 immunized against B, I'm safe. If this guy has
7 hepatitis C, I can probably treat myself and cure
8 myself 90 percent of the time, and if they have
9 HIV or I'm not sure, that's the last scenario that
10 I play in my mind before I say I'm scrubbing out,
11 I'm going to move on, or I'm going to keep driving
12 on.

13 So those were those sort of thought
14 processes think through, either at a transfusion
15 point, a needlestick point kind of standpoint.

16 Q So while we're here, what role does PEP
17 play in your thinking in terms of the risk of HIV
18 transmission after this relatively rare
19 circumstance of a needlestick inside somebody's
20 body cavity?

21 MR. NORWAY: Objection. Form.

22 Objection. Foundation. Objection.

23 Mischaracterizes the testimony.

24 You may answer.

25 THE WITNESS: I would disagree with

1 "rare" as a person would personally got
2 needlesticks in a combat zone. Studies show
3 that surgeons get sticks, nurses get sticks,
4 large populations get needlesticks, so it
5 is a -- I would have to define "rare," but I
6 do not think it's rare.

7 BY MR. SCHOETTES:

8 Q Hold up just one record. All recorded?

9 A Mm-hmm.

10 Q So these are all instances that --

11 A No, no. I didn't tell anyone. I told
12 no one.

13 Q Okay.

14 A And I think when you sit down and ask a
15 surgeon, they go I rarely tell anyone I had a
16 needlestick today.

17 Q Continue.

18 A Okay.

19 So yes, PEP absolutely plays a part. So
20 if that person is there and I just got a
21 needlestick, and I think my HIV risk is zero or
22 close to zero, I'm going to keep going. If that
23 risk is not zero or really close to zero, I then
24 have to decide can I break and have someone else
25 suture that person up.

1 Where I was, there was no one else to do
2 it but me. I'm one deep. So if you're one deep,
3 there is no capacity and you got a capability. So
4 that becomes an issue when you're trying to make
5 those decisions.

6 If the risk is high enough, the CDC says
7 if you're a surgeon, you get a needlestick, you
8 should break surgery, you should wash vigorously,
9 you should start PEP. It also says you should
10 call an expert in PEP, an infectious disease
11 doctor or equivalent, for recommendations on
12 current PEP recommendations or protocols.

13 What is currently recommended in the PEP
14 system is Truvada and raltegravir, and Truvada is
15 once a day, raltegravir is twice a day.

16 So now I have to know do I have those,
17 do I have a kit that I could test this soldier
18 that's on the table for HIV. It takes 20 minutes.
19 Post-exposure prophylaxis says don't wait for
20 tests. Take the drug now if you have it.

21 What we struggle with and historically
22 have always struggled with is should I take the
23 regimen of the person that I got stuck with, if
24 their viral load is zero, then I'm likely going to
25 keep protecting myself. Close to zero. If they

1 are resistant, I probably shouldn't take their
2 regimen. I should take someone else's.

3 So having an idea of what their regimen
4 is, what their viral load is, probably what the
5 CD4 count was, how much blood there was,
6 hollow-bore needle, when you put all of those
7 scenarios into the mix, you start making a
8 decision for post-exposure prophylaxis.

9 And to add, so that's easy to do when
10 you're an infectious disease doctor. That's not
11 easy to do if you're a combat medic or a PA,
12 because they have none of that training.

13 So all of these conversations we're
14 having are very, very high-level conversations.
15 For example, the PA, in their entire training, two
16 years of training, gets three hours of infectious
17 disease lectures, and that's meningitis and
18 pneumonia, urinary tract infections, and malaria
19 and dengue. It's not HIV.

20 So as you think about this problem set
21 as an ID doctor, and then you move it off to
22 remote units that are, that are supported by
23 medics, these conversations are incredibly
24 difficult and different.

25 Q You said that there is a recommended

1 course for PEP, which is Truvada and raltegravir.
2 Isn't that the PEP regimen that's going to be used
3 by a particular unit if it has that stocked as its
4 PEP protocol?

5 MR. NORWAY: Objection. Form.

6 Objection. Foundation.

7 BY MR. SCHOETTES:

8 Q I guess my question is: Where is the
9 decision if there is already in place a protocol
10 for PEP?

11 MR. NORWAY: Objection. Form.

12 Foundation.

13 You may answer.

14 THE WITNESS: So that's a CDC
15 public health recommendation. That has not
16 been codified in Army doctrine. It wouldn't
17 be codified in doctrine. It is not
18 consistently codified at the facilities when
19 you meet them and when you visit them.

20 BY MR. SCHOETTES:

21 Q Why not?

22 A So if the risk in your environment is
23 low enough, that may not make it to the top of the
24 list. Where there are so many other things you
25 struggle with, you don't have the time to

1 necessarily get to everything, and it's a
2 risk/benefit ratio.

3 So, for example, the four-person
4 surgical team we talked about earlier in eastern
5 Afghanistan, if you're going to tell them to take
6 two bottles of medicines and be able to take them
7 until they come home, and coming home could be two
8 to three weeks.

9 Where you have a needlestick and you
10 didn't bring the medicine or a diagnostic kit, and
11 I can't bring you home for two to three weeks,
12 you're buying risk. If it's a low prevalence or
13 low area with HIV, that's a different
14 conversation. If it becomes a higher prevalence
15 or a known patient with HIV, then I think that
16 conversation markedly changes.

17 So now I have to consider the entire
18 logistical support, the training support, the
19 educational support of all of those folks to make
20 sure we do the right thing, understanding east and
21 west Africa are different than Honduras, which is
22 different than the Middle East.

23 Q And how does the viral load of the
24 patient in this situation of potential exposure to
25 a healthcare worker affect the analysis as to the

1 level of risk?

2 A The CDC does not talk about viral load
3 as part of the equation for the needlestick from a
4 known HIV-infected person.

5 Q When is that CDC guidance from?

6 A What do you mean "from"?

7 Q Well, you said the CDC doesn't talk
8 about this, so in whatever you're discussing that
9 they are talking about this in general, when is
10 that guidance dated?

11 MR. NORWAY: Objection. Form.

12 You may answer.

13 THE WITNESS: So it's the most
14 recent post-exposure prophylaxis guidelines
15 from the CDC. I don't remember the date off
16 the top of my head.

17 BY MR. SCHOETTES:

18 Q Is it the CDC or is it the U.S. Public
19 Health Service?

20 A I think it's the U.S. Public Health
21 Service.

22 Q And you say they don't talk about viral
23 load in that document from the U.S. Public Health
24 Service?

25 A When they're giving descriptions of what

1 that surgeon does with the needlestick.

2 Q But I was asking you a slightly
3 different question. You have described all of
4 these considerations of things that affect the
5 risk and the analysis as to whether it is
6 sufficient to, to warrant PEP, and I'm asking you,
7 as the expert, how the undetectable viral load or
8 suppressed viral load on the part of the HIV
9 positive patient in this case would affect the
10 risk.

11 MR. NORWAY: Objection. Form.

12 THE WITNESS: So I think we're
13 moving through an interesting era of HIV
14 therapy, HIV prophylaxis, HIV prevention. So
15 if you look at the "undetectable,
16 untransmittable" recommendation from the CDC
17 a couple years old now, that basically said
18 if you have someone taking their medicines as
19 prescribed, they achieve a suppressed viral
20 load, they maintain a suppressed viral load,
21 then they effectively have no risk of sexual
22 transmission of the virus to an HIV-negative
23 partner. So huge number of caveats in that
24 sentence.

25 What they don't come out and say is

1 for blood and body fluid, that that same
2 conversation is applicable. So it is, it is
3 very specific as to what the CDC's statement
4 was in September 2017.

5 As such, I feel uncomfortable
6 saying that an undetectable viral load, and
7 even if we use the best test today, that the
8 risk approaches zero enough not to do
9 something with a needlestick from a known
10 HIV-infected person; no different than sort
11 of the pregnancy discussion of an unmeasured
12 suppressed viral load, you're still going to
13 get the -- the kid is still going to get
14 treated, you're still going to maximize
15 everything you can not to have transmission.

16 So I think we're in an era of the
17 data is moving closer and closer to the
18 transmissibility of HIV getting really
19 unlikely in the vast majority of scenarios,
20 but I just don't think we're there yet.

21 BY MR. SCHOETTES:

22 Q And in the case of providing PEP, it
23 seems to me part of the calculus is the side
24 effects are not so intolerable that it is not --
25 that it makes sense to provide that prevention

1 tool, that intervention, even if the risk is very,
2 very, very low.

3 MR. NORWAY: Objection. Form.
4 Foundation.

5 THE WITNESS: So there's more than
6 just saying I put a bottle on a shelf or two
7 bottles on a shelf to be used. You have to
8 train folks to be able to use them, you have
9 to maintain them, you have to sustain them,
10 and then you have to be able to resupply
11 them. There's an entire system --

12 BY MR. SCHOETTES:

13 Q I understand, but I'm asking a more
14 rudimentary question, which is what you were
15 getting to in terms of the guidance as to why you
16 would provide PEP to someone, and your assessment
17 that the risk isn't low enough yet to issue use of
18 PEP. It seems to me what you're saying is, well,
19 even if the risk is low, it may be -- you said
20 it's approaching very, very low, we just don't
21 know yet if it's at zero, but it seems wise to use
22 the precaution in the meantime.

23 MR. NORWAY: Objection. Form.
24 Foundation.

25

1 trying to have with the command surgeons.

2 BY MR. SCHOETTES:

3 Q So let me break this down a little bit
4 further.

5 Where does the two in 1,000 for
6 needlestick come from?

7 A So if you look at the site where I
8 pulled this from, it was on there.

9 Q I'm sorry. The site from the page
10 before, the slide before?

11 A Yeah, the Google site or the hyperlink.
12 It's a New York City discussion of "undetactable,
13 untransmittable," which I thought they did a very
14 nice job of capturing really the four studies,
15 with some subtleties within those studies, and I
16 think they did a nice job of walking through the
17 sharps exposure and the pregnancy discussion.

18 I think they were trying to do the same
19 thing that I'm trying to do tomorrow, which is
20 paint this broader discussion of how science,
21 medicine, HIV is improving in the environment of a
22 constrained or austere environment or the
23 challenges downrange.

24 Q But can you now tell me what, what is
25 the two in 1,000 or .2 percent number referring

1 to?

2 A Oh, that's transmission.

3 Q Transmission through needlestick in the
4 absence of treatment?

5 A So the .2/.3 percent is the historical
6 number we quote for needlestick transmission of
7 HIV, so that's what I'm saying. So historically
8 it's .3. Some of those folks are on therapies.
9 Some of those folks are not on therapy. That data
10 is very old data, '90s, so it's not been
11 replicated. That's where that number sits.

12 Q Right. So then I guess what I think
13 you're saying here is that then you would expect
14 there to be an effect of someone on therapy and
15 having a suppressed viral load, that would drop
16 that to somewhere, something lower than that two
17 in 1,000, as you've listed here?

18 MR. NORWAY: Objection. Form.

19 THE WITNESS: So that's the
20 discussion we have. There's not enough data
21 that backs that up. There's not enough
22 information that backs that up. No one has
23 gone out and said we are going to do this.
24 You get a needlestick from a known HIV-
25 suppressed patient. You don't have to do

1 anything. No one has come out and said that.

2 BY MR. SCHOETTES:

3 Q Right, and no one is ever going to do a
4 study, right, that's going to come up with
5 those -- you can't do a prospective study. That
6 would be completely unethical, right, to --

7 A Correct. I agree with you.

8 Q So how do you expect to obtain data to
9 get to the point where you would be comfortable
10 saying the person doesn't need to use PEP after an
11 exposure to a person with -- a needlestick
12 exposure to a person with an undetectable viral
13 load?

14 MR. NORWAY: Objection. Form.

15 You may answer.

16 THE WITNESS: So I think there's a
17 couple of things that are going to play into
18 that. One is: Will the various
19 organizations out there come out and say
20 that? So will IDSA, HIV organization, the
21 CDC, Public Health Service, are they all
22 going to come out and say this? Because I'm
23 going to have to then say this is the
24 standard across the country now, right? We
25 have not done that. They have shifted.

1 broken up into this category 1 and category 2.
2 That sort of reflects how the categories were
3 broken up back then.

4 We have actually had -- I've read
5 debates, had debates within sort of a smaller ID
6 community of many of us who started post-exposure
7 prophylaxis in this era, watched our patients who
8 had a needlestick, low risk, have lots of adverse
9 events from medicines, where those folks who were
10 infected with HIV did not have lots of side
11 effects with that medicine. That's been described
12 in the literature.

13 So what I don't know is, as you progress
14 forward and as you've alluded to, the drugs are
15 less number of times per day, easier to take, less
16 side effects, would you potentially modify this,
17 knowing the regimens are safer than they were,
18 easier than they were, than they were back in '08
19 with the regimens that were recommended.

20 So there's been discussions on would
21 this get shifted today, and then you have to put
22 on top the U equals U conversation. That's why
23 this is, this is an incredibly complicated piece,
24 and this is expert opinion, because we didn't walk
25 around with blast fragments flying into folks and

1 randomize them into groups, so most of it ended up
2 being expert opinion.

3 I will say that the casualties that we
4 frequently see in bombings, so the Boston
5 marathon, so a couple amputees, mostly unilateral.
6 Our folks in Afghanistan are triple amputees.
7 They get 250 units of blood product support within
8 the first 24 hours, so we really are talking
9 drastically different levels of trauma. We really
10 are talking drastically different levels of his
11 catastrophic injury, bone fragments flying into
12 me. It is really different.

13 If you watch the images of the blast in
14 Afghanistan or Iraq, it's truly sobering that
15 folks live through those, but it just gives you an
16 insight into what we're talking about from a
17 fragment exposure issue.

18 Q And is there, is there the same concern
19 around civilian populations that might blow
20 themselves up and be of unknown HIV status?

21 MR. NORWAY: Objection.

22 Foundation. Form.

23 You can answer.

24 THE WITNESS: Can you rephrase
25 that?

1 carry two bottles of HIV medicines in their
2 pocket, so it is a very different problem set
3 out there.

4 If the expectation is that because
5 that soldier is now identified as
6 HIV-positive, and he's out on the maneuvers,
7 that the medic -- because the medic is not
8 always in the same vehicle they are, they can
9 be four vehicles back, you blow up the middle
10 vehicle, the medic can't get forward for
11 hours, then you're buying delay, and that's
12 not the goal. The goal is immediate.

13 So that's what I'm saying. This is
14 a very complicated issue versus I have a
15 needlestick in an OR, I walk downstairs, or I
16 have a bombing at a marathon, and I go to two
17 or three local trauma centers, and someone
18 took blood from that person and it screens
19 positive for HIV. I think those scenarios
20 are fairly different, because the system of
21 health in Boston is drastically different
22 than the system of health in Ramadi.

23 MR. SCHOETTES: Okay. Should we
24 take a short break?

25

1 (Whereupon, a short recess was
2 taken.)

3 BY MR. SCHOETTES:

4 Q You can set aside what we were just
5 looking at. I believe it's Exhibit 4, but if you
6 would please pull out Exhibit 2, which was your
7 expert disclosures. I'm going to ask you some
8 questions about the topics you've identified here
9 and what your opinions are.

10 The first is: What is your opinion
11 regarding the effect of remote or austere deployed
12 environments on the potential deployment of
13 service members with HIV?

14 A I think there's some substantial
15 constraints that impact the care of HIV-infected
16 personnel, not only their individual care, but the
17 system of care that supports them.

18 So, for example, you have to ensure that
19 that soldier is on a regimen, is on a stable
20 regimen, who's virally suppressed, immunologically
21 stable, not in a window where you're still doing
22 frequent lab follow-ups or complications
23 associated with either the disease or medicines or
24 behavioral health or anything else.

25 So I think there's criteria for them to

1 be successful downrange. I think there are
2 challenges getting them downrange in the sense of
3 ensuring they have right medicines, they have the
4 right -- if it's a 12- or 15-month deployment,
5 they have the right follow-up plan, whether that's
6 follow-up personally by blood, if there's the
7 bandwidth for communication, remote follow-up, so
8 I think those are variable issues in the system.

9 And then once they're there, how do they
10 effectively develop a similar process that allows
11 them to be successful managing their life like
12 they were back home, meaning it's really easy to
13 leave your medicine next to your toothbrush so
14 when you brush your teeth every morning, you
15 remember to take your medicine. It's in a
16 controlled, air-conditioned/heated room that if
17 you run out of medicines, either you can get them
18 back at the pharmacy you're in or they will just
19 call them in to Walgreens, and you'll get them
20 next door.

21 You've learned that your wake/sleep
22 cycles -- when you do PT, when you go to work --
23 are mostly regimented until you go downrange. All
24 those things I just described down exist
25 downrange. So you don't have a private bath. I

1 literally took showers with two one-and-a-half-
2 liter bottles for 12 months. So that system is
3 really different, so you have to make sure they're
4 able to manage and understand the challenges in
5 that environment.

6 At the same time, they have to be able
7 to manage their individual issues. The system has
8 to support them. So not only does there have to
9 be a conversation as to who is going to know their
10 HIV status downrange, because, back home, it's
11 their commander and probably their ID doctor and
12 maybe no one else.

13 Downrange, you're going to have to
14 decide does their immediate healthcare system
15 support them? Do they know? Because if so, they
16 need to have the right medicines and the right
17 diagnostics. If it's more than their system, so
18 the doctor and PA, is it the medic, because I'll
19 push folks from a forward operating base to a
20 combat outpost to something more remote to that.

21 So as I go down even further in the
22 system, I go from maybe a PA to maybe a combat
23 medic or a corpsman to no one. So what is that
24 system of health that's going to support them? If
25 that soldier that has HIV has any issues, who is

1 their reach-back system, and are they informed
2 enough to be able to manage that care?

3 So whatever question comes up, can I
4 train that -- we call them 68 whiskeys, combat
5 medics. Can I train that 68 whiskey to manage a
6 disease that I can tell you is barely mentioned in
7 my internal medicine recertification book that I'm
8 studying right now as an internist. So now I have
9 to translate from an ID doctor to an internist to
10 a PA to a medic.

11 As I'm dealing with that system, these
12 places I've mentioned don't have electronic health
13 records, so all of it is paper, and you don't
14 really bring your records with you. So now
15 there's another layer of care that is taken away,
16 and that medic may not know what questions to ask
17 about with Truvada and the potential renal issues
18 with one of those drugs, in an environment where
19 you may have two canteens a day, and that's all
20 the water you're afforded. So in that system, he
21 or she may not know enough to be able to
22 effectively ask the right questions.

23 If I need to bring that soldier out for
24 care, if it's a one-deep capability, someone's
25 going to have to replace them, so now I've put

1 someone in the air or ground to go replace them,
2 and someone has to wait until they come back.
3 Same thing with the blood. You've still got to
4 move a helicopter.

5 If they're a casualty, how do I
6 communicate that they actually have HIV? That
7 system is not there. And then each of those
8 things I talked about are actually much more
9 complicated. I'll give you an example.

10 In Ramadi, I had one soldier whose
11 tympanic membranes were blown out because of a
12 overpressure injury from an explosive device, and
13 I had another soldier punch a wall because his
14 buddy died and had a massive break in his hand.
15 So they come and pick him up, only at night,
16 because they wouldn't fly during the day.

17 Q Which one?

18 A Both. So two helicopters land. Both of
19 them get into one helicopter. The other one is
20 just there. They both take off from Ramadi, land
21 in Fallujah. They wait there ten minutes. One
22 takes off. It gets blown out of the sky. So
23 you're sitting there going. The guy with the
24 fractured hand had to leave. The person with
25 tympanic membranes that have been blown could have

1 just let them heal by scarring over the next six
2 months. Did I put someone's life at risk to move
3 them for a non-lethal event?

4 So there are challenges downrange to
5 move people or move blood that are not consistent
6 with the U.S., and then expand that out a bit; if
7 it's a near-peer scenario, you're not necessarily
8 going to have air superiority, so then that whole
9 conversation adjusts again. How would you move
10 someone if you needed to, and how are you going to
11 share that information across systems?

12 Q The last part, "share that information
13 across systems," could you better explain that?

14 A So as I move those folks, I have to be
15 able to articulate what's more important; moving
16 this person or moving those bullets or that food,
17 and where in that system does that priority need
18 to be? Because it's not like I just order up an
19 ambulance. Everything is based upon a global
20 movement, and in Iraq and Afghanistan, global
21 movements are okay.

22 So let's move off of sort of those
23 scenarios and move to a scenario like Africa. So
24 we have incredibly small teams that are flying
25 across large parts of Africa, and to give you a

1 picture of what "large" means, so the Congo, three
2 and a half Texas fit in the Congo, and there is
3 no road system, so how you move in systems like
4 that -- and because it's not Iraq and Afghanistan,
5 they don't have the air assets that these other
6 places do, and their resupply is measured in
7 10-to-14-day windows, not three to five.

8 So I think you just have to look at this
9 from all of these different perspectives. You can
10 describe similar stories for the Andes in Peru or
11 the jungles of different countries where there's
12 triple canopies. If there's a casualty there, how
13 do you get them in and out of triple canopies?

14 Q Can you explain to me --

15 A Some jungles have sort of layers of
16 craziness, and to penetrate three layers of
17 jungles is almost impossible, so you have to sort
18 of hike them out of a triple-canopy jungle to get
19 them to an evacuation place. So jungles or places
20 like this in Kenya, places like this in Congo,
21 when you're out there walking around, trying to
22 figure out what you're going to do with a
23 casualty, that is a different problem set than
24 wide open sand, a helicopter lands wherever it
25 feels like it. I think you have to sort of put

1 theater, so Germany back to the States is role 4.
2 So that's why it can be confusing.

3 From a hospital standpoint, the Army,
4 the Air Force and the Navy do this a bit
5 different. So the Army has things that are called
6 medical centers. These are larger MTFs, typically
7 with subspecialists, not necessarily all the
8 subspecialists, but a pretty reasonable number of
9 them.

10 And then they have something called
11 MEDACs, and then they have large clinics and they
12 have small clinics, so all of those systems are
13 involved. So, for example, Walter Reed is a
14 medical center large referral tertiary care
15 facility. Fort Meade, 45 miles northeast of here,
16 does outpatient surgery but no inpatient care,
17 they have no subspecialty care, mostly primary
18 care.

19 And if you go up to Aberdeen Proving
20 Grounds, which is just north of Baltimore,
21 90 miles from here, a two-hour drive, they have no
22 same-day surgery, they have limited number of
23 personnel in uniform, and they are mostly PAs and
24 family practitioners, with a very small pharmacy.

25 So my unit is at Aberdeen Proving

1 Grounds, so the systems of care even in the U.S.
2 are almost sort of tiered, if we want to use that
3 term, so sort of smaller, bigger, bigger, biggest,
4 which is why we refer folks back to those major
5 medical centers for their HIV follow-up every six
6 months.

7 Q What percentage of service members
8 living with HIV obtain their medications via
9 mail-order pharmacy?

10 MR. NORWAY: Objection.

11 Foundation. Objection. Form.

12 You may answer.

13 THE WITNESS: Yeah, I don't know.

14 BY MR. SCHOETTES:

15 Q Is there any reason you know of why a
16 person who was going to deploy wouldn't be able to
17 obtain the medications they need via mail-order
18 pharmacy?

19 MR. NORWAY: Objection. Form.

20 Foundation. Speculation.

21 THE WITNESS: So it depends on when
22 you're talking about a combat zone, so for
23 when I was there, considered entry ops, no
24 DHL, no FedEx. We literally had mail arrive,
25 if we were lucky, every two weeks, and they

1 blew up our mail truck more than once, so --

2 BY MR. SCHOETTES:

3 Q I'm asking a slightly different
4 question. I was asking about someone, before
5 going on deployment, obtaining their medication
6 through a mail-order pharmacy.

7 A I don't know that the mail-order
8 pharmacy will be allowed to give them 180 days
9 worth of medicine. That may be a contract issue.

10 Q You think they might be limited to 90
11 days?

12 MR. NORWAY: Objection. Form.
13 Speculation.

14 You can answer.

15 THE WITNESS: I've never used it,
16 so I can't answer that question, but I'm not
17 convinced they get 180 days as patients.

18 BY MR. SCHOETTES:

19 Q And you said that's by contract, you
20 think?

21 A It is a DoD contract, but I can't speak
22 much more than that.

23 Q But you're saying they would be able to
24 get the 180-day supply from an actual base that
25 had their prescription, their medications?

1 MR. NORWAY: Objection. Form.

2 You may answer.

3 THE WITNESS: Maybe.

4 BY MR. SCHOETTES:

5 Q So then let's go ahead and talk about
6 the capabilities for delivery to a deployed area.
7 Is there anything that would prevent a person with
8 HIV from refilling, seeking a prescription refill
9 with a large amount of cushion, if you will, so
10 while they still have 60 days left in their
11 medication?

12 MR. NORWAY: Objection. Form.

13 Objection. Vague. Objection. Foundation.

14 You may answer.

15 THE WITNESS: So there's scenarios
16 we're working through right now where that
17 would not be possible for extended periods of
18 time.

19 BY MR. SCHOETTES:

20 Q Explain what would not be possible.

21 A Flights of nonmilitary specific
22 equipment into a combat zone, so --

23 Q For more than 60 days?

24 A Mail would not be being delivered for
25 over 30 days, correct.

1 Q Over 30 days?

2 A I'm, I'm hesitant to go much further
3 than that for other reasons. It goes back to the,
4 the near-peer conversation of earlier.

5 Q But for the purposes of the hypothetical
6 that I posed, which is could a person seek to
7 refill their prescription with 60 days of
8 medication left, can you explain why the potential
9 for a 30-day delay would --

10 A Because we don't know what's going to
11 happen in the next 30 days.

12 MR. NORWAY: Objection. Form.
13 Speculation.

14 If you would just, sir, please
15 allow me to --

16 THE WITNESS: Sorry.

17 BY MR. SCHOETTES:

18 Q I'm sorry. Did you finish your
19 response?

20 A So the windows of time that we're
21 discussing is -- there are certain events that
22 have to occur that allow follow-on, less-priority
23 supplies to get into a theater. So if the gates
24 aren't reached in 30 days, they still may not get
25 that after 30 days. That's what I'm saying. I

1 can, I can clearly describe scenarios -- not in
2 this room -- that we're walking through that
3 that's not an option.

4 Q And what is the longest period of time
5 for which a, a delay or the lack of a flight with
6 such supplies would be acceptable in the eyes of
7 the military?

8 MR. NORWAY: Objection. Vague.
9 Objection. Form.

10 I'm also going to object to the
11 extent that you're asking him to disclose, in
12 an unclassified environment, classified
13 information.

14 THE WITNESS: So it's the same
15 answer I gave, which is there are scenarios
16 that we're working through for near-peer
17 fights that would impact windows of time that
18 medication can, as you describe, medication
19 could be delivered, and I can't give you a
20 far end of those days.

21 BY MR. SCHOETTES:

22 Q Because that information is classified
23 or for some other reason?

24 A So classified and unknown, so it could
25 be both.

1 Q So you can't put any kind of time limit
2 on how long that delay could be?

3 MR. NORWAY: Objection. Form.

4 THE WITNESS: Correct.

5 BY MR. SCHOETTES:

6 Q Does a role 2 medical facility in a
7 deployed environment have the capability to
8 collect the specimens in an appropriate manner for
9 them to be shipped elsewhere for the testing, for
10 tests that are required by HIV follow-up care?

11 MR. NORWAY: Objection. Form.

12 Objection. Foundation. Objection. Vague.

13 You may answer if you can, sir.

14 THE WITNESS: So certain tests
15 could be done at the area support medical
16 company, so they have, as I mentioned
17 earlier, an ISTAT, which is sort of a
18 hand-held device that has cartridges that
19 could do sodium and potassium and creatinine.

20 There's not a good CBC test at an
21 area support medical company. There is a
22 dipstick for a urine, but no one would be
23 able to sort of spin it and look at it, and
24 they would not do lipids.

25 As you move off that and try to

1 taking care of people on the battlefield.

2 I mentioned earlier that if you
3 look at what I'm reading right now to
4 recertify in internal medicine, there is next
5 to nothing on HIV care, current diagnosis,
6 current therapy. The new undetectable-
7 untransmittable, that is not in anything that
8 I'm reading for the tests I'm taking Friday.

9 So to make an assumption that that
10 knowledge is inherent in our training
11 platforms or our sustainment platforms at an
12 MD DO level is not currently true, because
13 I'm living it, and as I move off where I
14 might get a little bit of knowledge about HIV
15 in medical school, I get even less as I move
16 into residency, even less as I move down.
17 The transition from MD DOs to PAs, it really
18 starts to hit zero, and when I hit the
19 medics, combat medics, corpsman, it really is
20 zero.

21 BY MR. SCHOETTES:

22 Q What does "MD DO" stand for?

23 A Medical doctor, MD degree or a doctor of
24 osteopathic medicine.

25 Q But I was asking a slightly different

1 question. I wasn't clear. I was talking about
2 providing that six-month follow-up visit, which I
3 don't think we would be asking PAs to do, or
4 medics.

5 I'm talking about: Could a doctor at a
6 role 3 medical facility who was not an infectious
7 disease specialist provide the kind of visit
8 necessary for that six-month follow-up?

9 MR. NORWAY: Objection. Form.

10 Objection. Vague, ambiguous.

11 You may answer if you can, sir.

12 THE WITNESS: So there's no role 3
13 where some of our units are in Africa.
14 There's no PA where some of our units are in
15 Africa. There is just a medic.

16 BY MR. SCHOETTES:

17 Q I understand where some of the units
18 are. I'm suggesting that a person could be
19 transported to a role 3 medical facility.

20 Now, maybe you can tell me that there
21 are theaters of operation in which we don't have a
22 role 3 medical facility.

23 Is that, is that true?

24 A It is true. In addition, many of these
25 small units are one deep, so that capability is

1 one deep. If that person has to be removed, that
2 team becomes non-mission-capable and can't carry
3 out their mission.

4 Q Again, I want to ask questions about
5 that, but I guess first I just want to try to
6 establish: Does the follow-up care -- this is a
7 better way to ask it. Does the six-month
8 follow-up visit require an infectious disease
9 doctor?

10 MR. NORWAY: Objection. Form.

11 You may answer.

12 THE WITNESS: I think it requires
13 someone that is well-informed of the
14 medicines, the side effects of the medicines,
15 the laboratory assessments, the
16 interpretation of the laboratory assessments,
17 the issues -- you know, we can discuss
18 neurocognition, we can discuss transmission.
19 So all of those are part of that conversation
20 that occurs at the six-month follow-up. It's
21 not just let me check your labs, you're good.
22 There's an awful lot into full body health
23 that is involved in those follow-up
24 appointments.

25

1 THE WITNESS: Can you, can you
2 rephrase that?

3 BY MR. SCHOETTES:

4 Q Yeah. This helps potentially for the
5 fact that the person is living with HIV. What
6 type of care would you expect a medic or a PA to
7 provide or to need to provide that they wouldn't
8 be already equipped for?

9 MR. NORWAY: Objection. Form.
10 Objection. Asked and answered.

11 You may answer.

12 THE WITNESS: So I think the PA or
13 the medic is going to have to understand a
14 little bit of the post-exposure prophylaxis
15 discussion we've had, he's going to have to
16 understand the needlestick conversation, he's
17 going to have to understand the blood and
18 body fluid conversation.

19 I think he needs to understand
20 sexual transmission in a theater. I think he
21 needs to understand that there can be
22 complications from the medicines they're on
23 that they have to maintain and monitor. I
24 think they need to understand that there's
25 follow-up requirements and why.

1 I think they need to understand if
2 they have subtle lab abnormalities that go
3 with that, and you have to put all of that
4 together, because it's related to
5 understanding the disease to be able to be
6 successful.

7 BY MR. SCHOETTES:

8 Q So I understand the pieces about
9 post-exposure prophylaxis. It's a little unclear
10 to me the level at which they need to engage on
11 that issue, but here's -- but I'm not sure. What
12 do they need to know about the sexual transmission
13 to provide care to this individual?

14 MR. NORWAY: Objection. Form.
15 You may answer.

16 THE WITNESS: So there is ongoing
17 sexual activity downrange. We actually saw
18 higher rates of GC and Chlamydia downrange
19 than we did back in the States. Clearly
20 there's pregnancy occurring downrange. We
21 talk about this U versus U or U equals U.

22 If the leadership understands that
23 there's an HIV service member downrange,
24 there's going to be questions about all of
25 these things, and someone is going to have to

1 BY MR. SCHOETTES:

2 Q So can you give me an example here? Are
3 you saying that there would be sexual activity on
4 the part of the person living with HIV, and then
5 questions would be asked of the medic regarding
6 whether or not he was putting other people at
7 risk? I'm not sure I understand.

8 MR. NORWAY: Objection. Form.
9 Objection. Speculation.

10 You may answer if you can.

11 THE WITNESS: Yes.

12 BY MR. SCHOETTES:

13 Q And your concern is that the medics
14 would not understand that a person who is virally
15 suppressed was not putting someone else at risk of
16 HIV?

17 A Correct.

18 Q And you're saying that's a reason that
19 you can't provide the care necessary to a person
20 living with HIV in a deployed environment?

21 MR. NORWAY: Objection. Form.
22 Objection. Mischaracterizes former
23 testimony.

24 You may answer, sir.

25 THE WITNESS: No. What I'm saying

1 is there has to be a system developed that
2 has to teach that medic and that corpsman all
3 of the things we've been talking about.
4 Currently that system doesn't exist.

5 BY MR. SCHOETTES:

6 Q What prevents that system from existing?

7 A So going back to what we talked about
8 earlier, there has to be priorities. There's not
9 enough time in a course to teach everything. You
10 know, we're going to talk about how to put on a
11 tourniquet, we're going to talk about how to do a
12 needle decompression, we're going to talk about
13 malaria. HIV is unlikely to bubble up to the top
14 of that list for education.

15 Q What do they need to know about side
16 effects of medications for people who are already
17 on a viral -- have been stable on a particular
18 regimen for some period of time? What does the --
19 I think you called them 68 whiskeys. What do they
20 need to know in order to provide care?

21 MR. NORWAY: Objection. Form.

22 Objection. Foundation. Improper
23 hypothetical.

24 You may answer if you can.

25 THE WITNESS: So as we've talked

1 about, some of the medicines have liver
2 toxicity, some of the medicines have kidney
3 toxicity, some of them -- not really the ones
4 we're using now, but it can have behavioral
5 health issues, sleep issues, dream issues.

6 So they need to understand that
7 potentially putting them on co-toxins, so a
8 large amount of Tylenol, or putting them in a
9 scenario where they really are having limited
10 access to water, or putting them in
11 incredibly stressful situations where they
12 may not sleep for three or four days, that if
13 that interferes with their health, they not
14 only need to watch out for those
15 complications in the sense of informing the
16 patient or others that are engaged in this,
17 but also making sure that they don't pick up
18 any subtle events.

19 BY MR. SCHOETTES:

20 Q What do you mean when you say "events"?

21 A Where they really are put in a place
22 where they're taking co-toxins that may hurt their
23 kidneys. Dehydration and things like that.

24 Q And aren't the things that you described
25 in terms of liver toxicity, et cetera, designed to

1 be discovered and addressed at that, at those
2 six-month evaluations?

3 MR. NORWAY: Objection. Form.

4 Foundation. Mischaracterizes the testimony.

5 You may answer.

6 THE WITNESS: As I've said, I'm now
7 switching their scenario. Their diet is
8 different, their sleep patterns are
9 different, their water is different, what
10 they drink is different, what they do on the
11 weekend is different. Nothing is the same in
12 a deployed environment, so to think normal in
13 the States is normal in a deployed
14 environment is just not the case.

15 BY MR. SCHOETTES:

16 Q Is the Army currently conducting any of
17 those studies that I hear you saying would be
18 necessary before the Army could deploy service
19 members living with HIV?

20 MR. NORWAY: Objection. Vague.

21 Objection. Foundation.

22 You may answer.

23 THE WITNESS: Not that I know of.

24 BY MR. SCHOETTES:

25 Q What does a unit that has one-deep

1 capability do when one person is killed?

2 MR. NORWAY: Objection. Form.

3 Speculation.

4 You may answer.

5 THE WITNESS: They go
6 non-mission-capable and ask for a
7 replacement.

8 BY MR. SCHOETTES:

9 Q What was the first part of that?

10 A They go non-mission-capable, meaning
11 they can't carry out their mission, and they ask
12 for a replacement.

13 Q For how long could that be the situation
14 where they are non-mission-capable?

15 MR. NORWAY: Objection.

16 Speculation. Form.

17 THE WITNESS: Depends on the
18 capability of the person that was lost.

19 BY MR. SCHOETTES:

20 Q How many units are one deep in
21 capability?

22 MR. NORWAY: Objection.

23 Foundation, form, speculation.

24 You may answer if you can.

25 THE WITNESS: So the small surgical

1 teams that I talked about earlier, every one
2 of those is one deep, so that entire team of
3 three to five folks is one deep. You lose
4 one of them, I don't have a surgical team in
5 Afghanistan.

6 Sniper teams are two deep. If you
7 lose one of those two folks, you're done.
8 EODs, explosive ordnance disposable personnel
9 typically work in very small teams, teams of
10 two to three, and you pull one of those folks
11 out, it becomes non-mission-capable.

12 The special operations community,
13 typically those folks are one deep. Close
14 air support that I've seen used, that's
15 typically one Air Force officer and a large
16 unit. That person is out, it can have a
17 large issue. If you're in a remote post like
18 a combat outpost, you may have one medic. If
19 that medic is out, you've lost your medic.

20 BY MR. SCHOETTES:

21 Q And when there is a need for a
22 replacement into one of these units, from where
23 does that replacement generally come?

24 MR. NORWAY: Objection. Vague,
25 form, speculation.

1 You may answer if you can.

2 THE WITNESS: So, for example, if
3 you need another medic at a combat outpost,
4 you could reach back to a higher level of
5 care, and frequently they have medics. So
6 now you're going to pull one medic, put him
7 in the air, move him over, buy some risk, and
8 then they will do an exchange, and then that
9 person will fly back, and then they do it
10 again.

11 For other assets -- so, for
12 example, a surgical team -- you may have
13 someone that was in Kuwait on a CSH of three
14 or four surgeons. They will pull that
15 surgeon out and fly them, for example, to
16 Syria. This has been a recent example. Lots
17 of issues flying from Kuwait to Syria, as you
18 can imagine, and then flying someone back,
19 lots of issues.

20 So those are examples of how
21 replacements would occur.

22 There's other units, special
23 operations units that truthfully you might be
24 getting backfill from the States, which is
25 even longer.

1 compatible with deployment and may be
2 disqualifying for deployment, absent a waiver.

3 A I don't think there's anything to add
4 there.

5 Q Are there circumstances in which you
6 believe a waiver for a person living with HIV to
7 deploy to, on a contingency deployment, would be
8 appropriate?

9 MR. NORWAY: Objection. Vague.
10 Speculation.

11 You may answer.

12 THE WITNESS: Could you describe
13 "contingency deployment"?

14 BY MR. SCHOETTES:

15 Q Probably not better than you can.
16 So in DoDI 6490.07, it describes
17 conditions that are, well, that essentially
18 require a waiver, and those deployments are called
19 "contingency deployments." So I believe that a
20 non-fixed medical facility is part of the
21 description.

22 MR. NORWAY: Objection. Form.

23 Do we have a question pending?

24 BY MR. SCHOETTES:

25 Q And maybe this is a little bit better.

1 So it's my understanding that all of
2 Iraq and Afghanistan are contingency deployments.
3 That is my understanding.

4 MR. NORWAY: Is there a question
5 pending?

6 BY MR. SCHOETTES:

7 Q There was.

8 Oh, are there instances in which you
9 think it would be appropriate to grant a waiver to
10 a person living with HIV to engage in a
11 contingency deployment?

12 MR. NORWAY: Objection. Form.

13 You may answer.

14 THE WITNESS: So I think as I've,
15 as I've wrestled with this question, knowing
16 that we, as a system, might be able to
17 develop a location that effectively has lab
18 support and medicines, because of how we work
19 in an operational environment, there is no
20 guarantee that that person that has HIV won't
21 be pushed to another location, more remote,
22 without those assets.

23 So as I, as I walk through this,
24 because we work in places, the contingency
25 operations that are associated with moving

1 folks around, there were not scenarios where
2 I couldn't come up with buying, buying risk
3 in all these things we've been talking about
4 because of that potential movement.

5 So even if, if I can walk through
6 an incredibly safe, very, very far in the
7 rear, and I use that term sort of loosely,
8 knowing that folks get moved forward, I just
9 was not able to effectively come to a place
10 that I can put a finger on and say "waivers
11 approved here."

12 BY MR. SCHOETTES:

13 Q I'm going to move to the next topic.

14 Do you have any opinions that you have
15 not yet expressed regarding whether medical
16 evacuations can have significant negative impacts
17 on deployed units?

18 A Yeah, I think we walked through that
19 pretty in-depth, moving folks back and forth,
20 air/ground, lack of air/ground capability in sort
21 of those one-deep conversations, so I think we did
22 a pretty good job on that.

23 Q Is mail moved into all units?

24 A Not all the time.

25 Q Is mail moved into all units eventually?

1 MR. NORWAY: Objection.

2 Speculation.

3 THE WITNESS: So I've seen it take
4 four plus weeks getting mail to Ramadi, and
5 then mail trucks get blown up, so that mail
6 did not make it far. Let's put it that way.

7 BY MR. SCHOETTES:

8 Q Right.

9 A And I think that's what folks don't
10 absolutely appreciate is the best laid plans in
11 RPG changes. RPG changes the best laid plans by
12 blowing up something.

13 Q Well, and there was a driver driving
14 that mail truck?

15 A Or two.

16 Q Or two, and there was some decision made
17 that the mail needed to move forward, so that risk
18 was worth taking, correct?

19 MR. NORWAY: Objection.

20 Foundation. Form.

21 You may answer.

22 THE WITNESS: So every decision in
23 a combat zone is buying risk. You have to
24 always decide which side of that conversation
25 you want to go on, and I can tell you we quit

1 moving mail trucks, just like we quit moving
2 medics for six plus weeks, because the road
3 between Balad and Ramadi was RPG alley, and
4 nothing moved for six plus weeks.

5 BY MR. SCHOETTES:

6 Q Do you have any opinions that you have
7 not yet expressed regarding whether certain
8 medical conditions, including the diagnosis and
9 treatment thereof, may pose significant risks to
10 military interests in the deployed environment,
11 even if they do not require evacuation?

12 A So one of the things that I wrestle with
13 a little bit is if, if you have a, so either that
14 needlestick or that, that foreign body, and now
15 all of a sudden it was from an HIV-infected
16 service member, and I'm started on PEP, and now I
17 don't have CD4 counts and viral loads to follow up
18 within related country, what am I now doing with
19 that PEP scenario?

20 So not only did I have to move the
21 patient out, but now I have to decide for that
22 post-exposure prophylaxis person, what is my plan
23 for them as either an individual, and/or what is
24 my plan with them from a blood standpoint, and
25 knowing that even if in Iraq and Afghanistan, to

1 get a flight to Germany, it's about every seven
2 days if we're sort of thinking about it on a
3 rotational basis.

4 So seven days to get the lab result
5 there, a couple days to run the lab, so you're
6 already sort of looking at four weeks, plus some
7 other time, until you get that viral load back,
8 versus in any hospital in this country, I can
9 pretty much run a viral load every day. We may
10 batch them, but I can turn the machine on and run
11 a viral load.

12 So as you think about the scenario that
13 that individual may have expanded into a
14 completely different conversation for a second
15 individual, and let's say that second individual
16 is your one of two surgeons on a forward surgical
17 team that's in a forward operating base, you have
18 now decreased your capacity -- if you move them
19 out -- by 50 percent, and we don't have enough
20 surgeons to replace them, just generically in
21 Afghanistan right now.

22 So you can just see how the scenario
23 starts to build on itself. So that gives you an
24 example of the things that I've had to sort of
25 think through in this scenario.

1 absolute constraints of that potential future
2 fight.

3 BY MR. SCHOETTES:

4 Q And I think what I'm just trying to get
5 at is: Given that we are talking about policies
6 with respect to people who are already diagnosed
7 with HIV and, in fact, people who have their HIV
8 well-managed and under control, what the delayed
9 presentation of HIV infection due to those
10 considerations you just identified, how that is
11 relevant.

12 MR. NORWAY: Objection. Form.
13 Vague.

14 You may answer.

15 THE WITNESS: Can you say that a
16 little differently?

17 BY MR. SCHOETTES:

18 Q It's listed as a topic here. The topic
19 is that delayed presentation of HIV infection due
20 to prolonged field care or exposure due to ongoing
21 operations is expected.

22 How is the fact that someone is going to
23 present late with their HIV infection a relevant
24 consideration in terms of whether or not you
25 deploy or assess people living in HIV?

1 MR. NORWAY: Objection. Form.

2 Foundation. Vague.

3 You may answer.

4 THE WITNESS: So I think part of
5 the conversation with prolonged field care is
6 this thought process of -- although I think
7 opportunistic infections are relatively not
8 part of the conversation. I think the
9 inflammatory diseases, cancer and heart
10 disease and lung disease, kidney disease are
11 not really the primary part of this function.

12 I do think prolonged field care, if
13 you're having complications from your
14 medicine because of all those events we
15 talked about earlier, kidney issues because
16 of dehydration, on top of Truvada, or liver
17 toxicity from one of the other agents, I
18 think those are all important.

19 And then when, when folks go out
20 for operations, they typically don't take
21 their entire set of pills with them. They
22 will take a couple. If they're only going
23 out for the day, they take none. The fight
24 of the future means they may be out for
25 longer than a day.

1 So now all of a sudden we're
2 starting to miss doses when we're out in the
3 field, and what impact -- and I think it can
4 have substantial impact of what missing two
5 or three doses are doing either during an
6 evacuation chain or waiting for prolonged
7 field care to actually occur, or as simple as
8 just getting someone back to where their
9 medicines are, because they were only going
10 to go out on parole for two hours -- and we
11 had that happen. It was a two-hour parole,
12 and they were in a gunfight for 22 straight
13 hours.

14 Life happens in a combat zone. So
15 I think you just got of sort look through it
16 in a slightly different lens.

17 BY MR. SCHOETTES:

18 Q So I'm going to come back to that in
19 just a second, but I still -- I haven't heard you
20 talk about how delayed presentation of HIV
21 infection, which I assume is in someone who is
22 HIV-uninfected before they present with HIV
23 infection, how that is relevant to the policies at
24 issue in this case.

25 MR. NORWAY: Objection. Form,

1 vague, also asked and answered, but you may
2 answer, sir.

3 BY MR. SCHOETTES:

4 Q And if it's not and you just want to say
5 maybe this wasn't phrased as well as it could have
6 been --

7 A I'm just making sure that there was
8 nothing else I was getting at. It's a long day,
9 as you know.

10 Q Yes, yes.

11 A And I think I addressed it in sort of
12 the framework I thought I meant it in.

13 Q Okay. Given the changing nature of
14 modern warfare, couldn't the problem you just
15 described with potential treatment interruption be
16 solved by requiring a soldier living with HIV to
17 take a three-day supply of their medication or a
18 seven-day supply of their medication on such a
19 patrol?

20 MR. NORWAY: Objection. Form.
21 Foundation. Hypothetical.

22 THE WITNESS: So we can go way back
23 to the early part of everyone minimizing the
24 weight they're carrying going up and down the
25 mountains of Afghanistan. Every ounce you

1 take is another ounce you're taking. So, you
2 know, folks are deliberate in minimizing what
3 they take, and folks really will look at am I
4 taking a bottle and what am I doing, and as
5 much as I can say you're taking three pills,
6 they don't always listen to me. They take no
7 pills. It's just what happens.

8 BY MR. SCHOETTES:

9 Q And they would do that, you're saying,
10 because of the weight?

11 MR. NORWAY: Objection. Form.

12 Speculation. Mischaracterizes.

13 Go ahead.

14 THE WITNESS: Or forget, or "I've
15 done this ten times, I'm not doing it the
16 11th," and the 11th is when it goes bad. I
17 mean the level of complacency you can get
18 downrange is actually impressive.

19 BY MR. SCHOETTES:

20 Q What is the effect of missing a dose of
21 one's HIV medications?

22 MR. NORWAY: Objection.

23 Speculation.

24 You can answer.

25 THE WITNESS: So I think we're,

1 there may be a shift in drugs, they're going
2 to --

3 BY MR. SCHOETTES:

4 Q And you think missing one dose of a
5 single-tablet regimen could lead to resistance?

6 MR. NORWAY: Objection. Form.
7 Foundation.

8 You may answer.

9 THE WITNESS: So I don't think the
10 current primary integrase inhibitors that we
11 use are going to lead to that. I'm not sure
12 we know everyone's genetic profile to say
13 that for sure, and I'm not sure we can say
14 that for older regimens, and some of our
15 patients are still on older regimens.

16 I think you have to be cautious
17 saying "anyone" without just putting the
18 caveats next to it of which regimens we're
19 talking about and their complication history.

20 MR. SCHOETTES: All right.

21 MR. NORWAY: Let's take a break.

22 (Whereupon, a short recess was
23 taken.)

24 BY MR. SCHOETTES:

25 Q Let's go back on the record.

1 them in or out of theater, so the battalion
2 aid station would have a different
3 requirement than an area support medical
4 company, which would have a different
5 requirement than a combat support hospital.

6 BY MR. SCHOETTES:

7 Q I still haven't heard what it is that
8 would need to go -- so let's just start with a
9 battalion aid company.

10 What would need to be in that kit that
11 would potentially displace some other medical
12 supply if a person living with HIV was in the
13 field?

14 A So I would need the medicines, and
15 understanding that it's not a medicine, it's
16 numerous medicines, because there's multiple
17 options, I would have to put multiple options of
18 medicines in kits at a battalion aid station, if
19 we're building this as part of a standard kit that
20 answers the question for all places.

21 Q So let's assume that the person is going
22 to get their medication, as we discussed, by
23 taking it with them and/or obtaining a refill
24 through the supply chain so that you don't have to
25 have every HIV medication and every battalion aid

1 station. Then what supplies are we talking about?

2 MR. NORWAY: Objection. Form.

3 Foundation. Improper hypothetical.

4 You may answer if you can.

5 THE WITNESS: I'm just not sure
6 that's how we would handle it. As I've
7 described, logistical chains may not support
8 what you're describing. I think as a system
9 we would have to decide if we know -- because
10 we prepare these units for entry ops for the
11 first 30 days. That's how we build them for
12 equipment and sets.

13 So if I know that that 30 days is
14 the biggest struggle, and if you have a
15 potential for losing medicines or having
16 complications and I now need to prepare for
17 that contingency, we may need to put that
18 into a battalion aid station kit. Those are
19 the decisions that would need to be made at a
20 combat developer level.

21 BY MR. SCHOETTES:

22 Q Okay. Do units that are one deep tend
23 to have shorter deployment times?

24 MR. NORWAY: Objection. Form.

25 Foundation.

1 You may answer if you can.

2 THE WITNESS: Some do. Some don't.

3 BY MR. SCHOETTES:

4 Q Is the depth of the personnel a
5 consideration as to how long of a deployment a
6 particular unit generally has?

7 MR. NORWAY: Objection. Form.
8 Foundation.

9 You may answer.

10 THE WITNESS: It would be part of
11 the equation, but it's not a sole decision.

12 BY MR. SCHOETTES:

13 Q How -- for those units that are one
14 deep, can you tell me what the longest deployment
15 would be for such a unit?

16 MR. NORWAY: Objection.
17 Foundation. Speculation.

18 THE WITNESS: Some have gone 15
19 months.

20 BY MR. SCHOETTES:

21 Q And they served that entire time without
22 anyone able to replace them in a, in a quick way?

23 MR. NORWAY: Objection. Form.
24 Foundation. Mischaracterizes former

25 testimony.

1 You may answer.

2 THE WITNESS: Correct.

3 BY MR. SCHOETTES:

4 Q If a commander needed to find three days
5 for a service member to be absent from the unit --
6 setting aside the one-deep units, if a commander
7 needed to find three days for a service member to
8 be absent within a four-month period, would that
9 still present a logistical problem?

10 MR. NORWAY: Objection. Form.

11 Foundation. Improper hypothetical.

12 You may answer if you can.

13 THE WITNESS: It can, yes.

14 BY MR. SCHOETTES:

15 Q How -- when you say "it can," how
16 frequently would you say it would present a
17 logistical problem?

18 MR. NORWAY: Objection. Form.

19 Foundation. Speculation.

20 You may answer if you can.

21 THE WITNESS: I think it walks
22 through the scenarios we've talked about.
23 Challenges in Africa are different than the
24 challenges in Iraq and Afghanistan, which
25 would be very different than the challenges

1 in a near-peer entry ops scenario. So based
2 upon which, which scenario you're describing,
3 there could be substantial issues trying to
4 get folks out for windows of time.

5 BY MR. SCHOETTES:

6 Q Even with an extended period of time in
7 which to do that?

8 MR. NORWAY: Objection. Form.

9 THE WITNESS: Even with extended
10 times.

11 BY MR. SCHOETTES:

12 Q But you're not able to quantify that in
13 any way?

14 A Correct.

15 Q Is there -- is the protocol for --
16 withdrawn.

17 Using the walking blood bank is not the
18 ideal way of providing blood to a deployed unit,
19 correct?

20 MR. NORWAY: Objection. Form.

21 Objection. Foundation. Objection to the
22 extent it mischaracterizes the prior
23 testimony.

24 You may answer.

25 THE WITNESS: So there's something

1 BY MR. SCHOETTES:

2 Q Yes.

3 A Yes.

4 Q Do you believe that HIV is a "contagious
5 disease that probably will endanger the health of
6 other personnel"?

7 A So I think we've walked through this in
8 numerous ways today, but yes, it has the potential
9 to impact the health of another person.

10 Q But the question or the criteria is not
11 whether it has the potential; it is whether it
12 "probably will."

13 Do you believe that HIV probably will
14 endanger the health of other personnel?

15 A The way you asked the question,
16 absolutely.

17 Q But you can't quantify that risk in any
18 way?

19 MR. NORWAY: Objection. Form.
20 Foundation.

21 You can answer if you can.

22 THE WITNESS: So you can
23 characterize the contagiousness of a disease,
24 the probability of transmitting, based upon
25 the source of that infection, the route of

1 infection, with variables such as viral load
2 on therapy, all would impact the
3 contagiousness of a disease.

4 BY MR. SCHOETTES:

5 Q And you think that -- it still doesn't
6 give us -- can you tell me what you think the
7 percentage risk is of someone with HIV endangering
8 the health of other personnel? You can even make
9 this a person who does not have a suppressed viral
10 load.

11 MR. NORWAY: Objection. Form.
12 Foundation. Improper hypothetical.
13 You can answer.

14 THE WITNESS: So it's 93 percent
15 transfusion. 23 percent maternal fetal
16 transmission.

17 BY MR. SCHOETTES:

18 Q And how would -- what is the likelihood
19 of there being a transfusion that would endanger
20 the health of other personnel? So it will be
21 92 percent if there was such a transfusion.
22 What's the likelihood of such transfusion
23 occurring?

24 MR. NORWAY: Objection. Form.
25 Foundation. Speculation.

1 You may answer if you can.

2 THE WITNESS: So for your scenario,
3 an HIV person not on medicine, donating a
4 unit of blood downrange, will be 92 percent
5 transmission.

6 BY MR. SCHOETTES:

7 Q And what's the possibility or the
8 probability, I should say, of there being such a
9 transmission?

10 MR. NORWAY: Same objection.

11 BY MR. SCHOETTES:

12 Q You're assuming the -- I'm sorry on such
13 a transfusion, you are assuming that the
14 transfusion has occurred. I'm asking you: What
15 is the probability that such a transfusion would
16 actually occur?

17 MR. NORWAY: Objection. Form.

18 Foundation. Improper hypothetical.

19 You may answer if you can.

20 BY MR. SCHOETTES:

21 Q Wouldn't it require someone who was
22 living with HIV to ignore the order that they have
23 been given, the counseling that they have been
24 given, and choose to donate blood nonetheless, in
25 order for the transfusion to even occur that would

1 complications we see with HIV, whether it be heart
2 disease, cancers. Kidney disease could be part of
3 the drugs or part of the virus.

4 So I think those are interrelated to the
5 point there's ongoing discussions of is HIV an
6 independent risk factor for heart disease,
7 irrespective of diabetes, smoking and cholesterol,
8 and I think that again is likely reflective of
9 inflammation.

10 I don't think HIV is like other
11 pathogens, like Chlamydia, where it actually may
12 be sort of involved in plaque development. I
13 don't know that I've actually read enough to know
14 that answer, but I think that inflammation is sort
15 of going on all the time, because that immune
16 response is continually occurring.

17 Q How well does antiretroviral therapy
18 treat a person's viral load?

19 A I think it's outstanding, truthfully. I
20 think appropriate therapy, especially the
21 integrase inhibitors, are able to maximally
22 virally suppress an incredibly large percentage of
23 folks, and not only do they suppress them, it's
24 also durable, so it's sort of a lasting impact.
25 So if they're adherent with their medicines,

1 they're making good life decisions, they're not
2 getting a lot of comorbidities, they're going to
3 live a very, very long life.

4 Q How well does antiretroviral therapy
5 impact the activation of an individual's immune
6 system by HIV?

7 A So I feel a little uncomfortable being
8 able to clearly state that an integrase inhibitor
9 is going to be responsible for turning on a CD4
10 count which is associated with inflammation.
11 Although the drugs are inside the cell, they're
12 interacting with mitochondria, they're interacting
13 with the DNA, I'm not sure I feel comfortable
14 saying what the impact that has on immune
15 inflammation. The answer is probably out there,
16 but I do think the virus impacts the CD4 count in
17 the CD4 cell, and immune cell CD8, it has an
18 impact there. That's sort of my thoughts.

19 Q And what kind of impact is it?

20 A It increases the immune response and the
21 inflammation that we've been talking about.

22 Q Okay. So the immune response, even in
23 somebody who is taking antiretroviral therapy, is
24 greater than a person who is not?

25 MR. SCHOETTES: Objection to the

1 six or seven folks is O, we could say O negative,
2 but I think that's less relevant, but O-AB low
3 titer is my HIV service member, then I've just
4 lost one out of my universal donor where there
5 would have been one if they were not a soldier
6 with HIV.

7 So when you're, when you're talking
8 about locations where you have relatively large
9 footprints of personnel, you can find probably
10 enough O-AB negatives for your donor pool. As you
11 shrink that pool smaller and smaller, everyone on
12 that team becomes more and more relevant to this
13 conversation.

14 The Rangers have done a really good job
15 of building this program. We are actively
16 building this program in Korea, so this is now
17 going to be a much broader conversation, and this
18 housing of a walking blood bank then starts moving
19 into other databases. So now we know you have O.
20 What other transmitted infections might you have
21 or not have that you have to worry about? So
22 there's just this broad building in this program,
23 but from a operational small-unit standpoint,
24 you're limited by who goes out with you.

25 Q And below that, you have "tyranny of

1 distance." Can you explain to me what that refers
2 to?

3 A I was involved in building a
4 seven-person team for east Africa, and five of
5 those people were positioned in Kenya. Three of
6 those -- the other three were stationed in
7 Djibouti, and what we had to figure out how to do
8 was do damage control surgery as well as movement
9 across Africa.

10 Their operational space went from Kenya
11 all the way through about half of the Congo. As I
12 said earlier, the Congo is three and a half
13 Texas. If you look at a map of Africa, the U.S.
14 doesn't even fill the top section. We're not even
15 talking about sliding it down to where we're
16 talking about.

17 So the distance of moving people is
18 incredibly difficult. The evacuation times for a
19 C130 were, from Djibouti, for where most of the
20 ops, operations were going, was 12 to 15 hours.
21 So if something happened, it was going to take 12
22 to 15 hours for evacuation to occur, presuming you
23 had the bird, the C130 release.

24 So these two teams, the intent, the
25 design was the surgical team would be

1 prepositioned with the special operators who were
2 going to have a mission to, if something happened,
3 they had immediate surgery, so again one surgeon
4 on the team. The other three folks were the ones
5 involved in moving, so they would be on the back
6 of C130, coming to pick them up, and then from
7 there, they would go to Germany.

8 So being able to work in that distance,
9 we really have had to think about blood product
10 support, low titer of blood, what medicines were
11 they going to have on their back, because it
12 really was backpack requirements. To fit folks
13 that are doing the operation into a helicopter,
14 plus five more people, four more people, plus
15 their backpacks is really difficult.

16 So you've pretty much got to bring sort
17 of a fanny pack equivalent of who you are and
18 everything you need, because the rest is a regular
19 backpack with all your surgical instruments, and
20 that's the challenge of those environments.

21 Q So there are space and weight
22 requirements?

23 A Correct.

24 Q The decision to -- is it fair to say the
25 decision of what capabilities and assets to bring

1 at any particular level of the medical system is a
2 combination of medical knowledge and operational
3 experiences rolled together into a risk equation?

4 A To include a capability and capacity
5 conversation.

6 So the constraints environmentally that
7 are built around a capability and capacity to
8 carry out the support that's required of the
9 operator on the battlefield, so the ultimate is
10 who's the one pulling the trigger or knocking down
11 the door. Everyone else is supporting them.
12 You're sharing -- I'll use bandwidth in the sense
13 of logistical support, movement of people,
14 movement of equipment, movement of medical is all
15 moving onto this piece.

16 So that's the constraint that you're
17 dealing with, a very complicated problem set,
18 because someone up here is going to say you get
19 two feet by two feet. That's all the space you
20 get in the back of the bird. Everything else is
21 going to bullets and water and everything else, so
22 they're going to constrain you, and you have to
23 work within that.

24 Q Who is the decision-making authority for
25 constraints in operations like that?

1 A If it's a special operations, it will be
2 special operations command for that region, so,
3 for example, if it's Africa, it's special
4 operations command Africa. If they work outside
5 of that, then they would have to go to the African
6 combatant commander, so elevating it up to a
7 four-star. Typically that can be delegated down
8 to a two-star, and if it's small enough
9 operations, down to an O6, but it's still a very
10 high-level discussion.

11 Q Is it fair to say it's a military
12 decision?

13 A Absolutely. So we are staff officers
14 giving advice, and then they put that into the
15 context of the operation and what risk we hope we
16 have articulated appropriately that they then put
17 into their risk equation and then make a decision
18 from that.

19 Q Thank you.

20 I think it's time to take a break.

21 (Whereupon, a short recess was
22 taken.)

23 BY MR. NORWAY:

24 Q Let's go back on the record.

25 Sir, do you remember when you were

1 testifying earlier about some impacts on like the
2 training environment that HIV might have?

3 Do you recall that testimony?

4 A I do, mm-hmm.

5 Q That training environment you were
6 discussing, was it the initial entry training,
7 basic training?

8 A So most of this type of training would
9 not occur in basic training. This would occur in
10 either what's called AIT or advanced individual
11 training, which is where we train our medics. For
12 PAs, it would be at their PA school, so that's a
13 two-year program. For physicians it would be part
14 of whichever educational program they have if you
15 could fit it into those places.

16 So TRADOC is the governing body for what
17 would go into any enlisted training, which would
18 be the combat medics. What their position is is
19 that you have a block of time you can train with
20 them. You don't get any more, and we can take it
21 away, but we don't want to. If you want to put
22 any new training in there, something has to come
23 out for you to put something new in.

24 So to introduce that into that program,
25 it's just not something the medical community can

1 do. That's something TRADOC -- so big Army
2 four-star level command would be responsible for
3 approval of any changes, so that's substantial.

4 The PA program, their first year is sort
5 of book-learning, and their second year is
6 clinical. They mostly follow the PA curriculum
7 that's driven on high, because they have to pass
8 their boards, understanding they still have to
9 train military unique issues, so they, too, have
10 limited windows of time.

11 So as I alluded to earlier, they have a
12 three-hour total block in that first year to
13 address all of the infectious disease challenges
14 in a, in a routine medical environment, like in
15 the States, as well as all the challenges in
16 Africa, southeast Asia, South and Central America.
17 It's incredibly difficult to do all that, so
18 again, they would have to prioritize the
19 requirement of training something new inside that
20 block of time.

21 Q So that military official would need to
22 make a decision to provide priority training for
23 the treatment of HIV individuals over some other
24 training?

25 A Correct. I used to teach that course.

1 We spent most of our time talking about key
2 infections that they need to recognize at the
3 bedside: Meningitis, pneumonia, malaria, dengue,
4 those kind of diseases. Even the three hours we
5 were given was nowhere adequate to cover the
6 things we just highlighted, so it would be
7 difficult to add much more in there.

8 The other way you can do training is
9 something called "just in time" training, which
10 is, you know, try to figure out how to do this as
11 they go out the door. So for our personnel who
12 went to Liberia, that was me spending about four
13 weeks on the road, and I had to go to Fort Bragg,
14 I had to go to Fort Campbell, I had to go to Fort
15 Benning, I had to go to Fort Hood to train those
16 folks up, and that included delivering sort of the
17 entire challenges from an infectious disease
18 standpoint for Liberia to everything from a
19 whiskey to a PA to a doctor.

20 So that's really difficult to do. It
21 completely took me out of my day job, but a
22 FORSCOM four-star, General Milley, said this is
23 going to happen, so that trickled down to I was
24 there doing it. The commander back at the
25 hospital canceled my clinics. I wasn't training

1 fellows, I wasn't doing substantial research or
2 teaching, because that was my mission set.

3 So that was to get a relatively small
4 number of medical personnel to Liberia. To do
5 that, to scale in quality is really, really
6 difficult. In the Army we have 40 ID doctors, so
7 to be able to spread that out and do everything
8 else we're required to do would be really
9 difficult.

10 So although we can do just-in-time
11 training, it is, it is difficult, because you then
12 also have to work -- so, for example, the Liberia
13 experience, the teams didn't know how to do
14 malaria diagnosis, they didn't actually have the
15 stains to do the diagnosis, so we had to start at
16 the most basic for something that absolutely was
17 lethal and fix that first before we moved on to
18 other things. So not that anything is impossible,
19 but there's constraints that would make this
20 difficult.

21 Q Are there logistical constraints to
22 treating individuals with HIV both in the deployed
23 setting and undeployed setting?

24 A We talked about this a little bit. We
25 talked about the different levels of providers,

1 So as the senior physician, you're correct. The
2 R.P.G. Alley got so bad, we could not get Motrin
3 from the major combat support hospital equivalent.
4 It's an Air Force, different name, but same thing.
5 We could not move Motrin to Ramadi, because it was
6 so unsafe.

7 Q If you -- during that time, were you
8 confronted by any situation where a soldier was
9 presented with an injury that required a
10 medication, a lifesaving medication?

11 A Frequently. We had -- we continued to
12 have casualties during that time. Some of those
13 casualties had to be intubated, so to intubate a
14 patient, you have to sort of paralyze them, put a
15 tube down their throat, and you've got to breathe
16 for them. So the medicine that's involved in a
17 rapid-sequence intubation is required of all of
18 that.

19 In addition, in an area support medical
20 company, although you're logistically pretty well
21 supplied, we had a 43-person MASCAL one day, or
22 42, and the logistical constraints on moving those
23 people, but just the supply demand, was
24 overwhelming. We pretty much ran out of
25 everything, and it took us about two weeks to

1 start resupplying.

2 So we almost -- well, we actually were
3 non-mission-capable for a fair bit of time,
4 because we just couldn't take care of the next
5 patient who walked through the door.

6 Q When you took care of that 43-person
7 mass casualty event, was there time during that
8 event to change your gloves?

9 A No. So we started about at 1:00 on a
10 Sunday afternoon, and it ended at about 8:00 that
11 evening, and about four hours in is when I
12 realized I had the same pair of gloves on, despite
13 putting test tubes in folks, doing central veins
14 to infuse medicine, fluids.

15 As an ID doctor, you sort of cringe at
16 that statement, but it didn't even enter your mind
17 to do that. The constraints in that environment,
18 we were not using blood, for lots of reasons we
19 didn't use blood, but to do what we normally do
20 with trauma, such as X-rays, infusing antibiotics,
21 doing stability labs, all of that stuff stopped,
22 because you were just trying to get to the next
23 patient.

24 So understanding the challenges and the
25 decisions you would make when you're managing

1 42 -- and just to clarify, so there was two convoy
2 briefs (?) occurring, and mortars landed between
3 the two of them, and that's the reason 42
4 casualties happened. So just understanding the
5 constraints and an environment like that, we put
6 mathematical modeling onto scenarios in other
7 near-peer fights that will dwarf what that
8 42-person experience was.

9 Q During that mass-casualty event, were
10 you able to stop and check patients' medical
11 records?

12 A We didn't have electronic health
13 records, so there was nothing you could check. As
14 they were unconscious, you got no information.
15 Dog tags have less than no useful information on
16 it. Despite folks supposedly wearing their
17 allergy either tags or bracelets, most folks take
18 them off and don't wear them.

19 So none of that really happens, and even
20 if you were going to go to the electronic record,
21 trying to find the piece that says what's wrong
22 with them previously, our electronic records
23 struggles at best, so pulling out labs or a key
24 note with a key diagnosis just isn't useful in
25 our, our MTF electronic medical record, and the

1 downrange is not better than that.

2 Q Sir, you're familiar with the pool of
3 infectious disease doctors in the United States
4 Army, correct?

5 A Correct.

6 Q How many individuals would you say who
7 are infectious disease doctors in the United
8 States Army have your level of operational
9 experience?

10 A None.

11 Q Sir, to add a capability to a unit, even
12 at a very low treatment level, would that addition
13 require changes to doctrine, organization,
14 equipment deploying or the array of forces and
15 training?

16 MR. SCHOETTES: Objection. Form.

17 THE WITNESS: So the process for
18 changing an organization's footprint and what
19 that loosely means is personnel, equipment,
20 maintenance, vehicles, training, or use this
21 dot-mil PFP, which is doctrine organization,
22 manpower -- I always have to look it up, but
23 it's all of these different assets to make a
24 unit successful.

25 What happens is within TRADOC,

1 and we think that's a priority, then it is a
2 broader system you have to fix.

3 BY MR. NORWAY:

4 Q So there are many more decisions that
5 need to be made besides just medical decisions?

6 MR. SCHOETTES: Objection. Form.
7 Go ahead.

8 THE WITNESS: Correct. So an ID
9 consultant would not be able to say yes, we
10 absolutely should have this inside a medical
11 kit, let's make it happen tomorrow. Just not
12 going to happen.

13 MR. NORWAY: All right. Thank you,
14 sir. I think I'll turn the witness back
15 over.

16 FURTHER EXAM BY COUNSEL FOR PLAINTIFFS

17 BY MR. SCHOETTES:

18 Q I have a few questions, but we'll get
19 out of here fairly quickly.

20 Going backwards, is a person's blood
21 type on their dog tag?

22 A There is, but studies have shown it's
23 frequently inaccurate.

24 Q Why would that be?

25 A Because I get to say what my blood type

1 is, and then someone types it in wherever they
2 make dog tags. There's no confirmation. No one
3 looks it up in a computer system. No one --
4 literally I go "I'm O negative," and the next
5 thing I know, I get dog tags that say O positive.

6 Q That seems like a risky system to have
7 for such important information. Why would there
8 not be a more sound system for identifying blood
9 type on dog tags?

10 MR. NORWAY: Objection. Form.

11 Objection. Foundation. Speculation.

12 You may answer.

13 THE WITNESS: I can't answer that
14 question. I think many folks have asked the
15 exact same question. I have found dog tags
16 less than helpful. The places that
17 frequently soldiers and Marines put their dog
18 tag is actually the shoestring down at the
19 bottom. The number of folks that have come
20 in without a foot so that I couldn't find a
21 dog tag is not inconsequential. The number
22 of folks that don't like to wear them around
23 their neck or it falls off or when you get
24 blown up in a vehicle and everything is
25 shifting around, you lose it, so it's been

1 infrequent that I've used dog tags to help
2 drive a conversation.

3 Again, I write down whatever -- we
4 now use DoD ID numbers instead of Social
5 Security numbers, so I get to tell you what
6 to write. No one confirms that it's really
7 my DoD ID number. They're just something I
8 struggle trusting. I think you'd get your
9 name right, but I've seen folks add their pet
10 name to their dog tags.

11 BY MR. SCHOETTES:

12 Q I think you said that a person with
13 type B blood can't be a donor?

14 MR. NORWAY: Objection. Form.
15 Objection to the extent it mischaracterizes
16 the testimony.

17 You may answer.

18 THE WITNESS: So for the O, low
19 titer O blood, that's your primary donor, and
20 then A is your next donor. If you have time
21 inside of CSH, and you're B minus and the
22 patient needs B minus, then I can do that,
23 but that adds complexity, and it also is not
24 a universal donor unit, so now it really is
25 the B minus person walks in the door, is

1 done.

2 MR. NORWAY: Great. Thank you very
3 much, Scott.

4 MR. SCHOETTES: Thank you.

5 MR. NORWAY: We will read and sign.

6 THE REPORTER: Do you want a rough
7 draft?

8 MR. NORWAY: Yes, please.

9 MR. SCHOETTES: Yes, please.

10 THE REPORTER: Normal turnaround?
11 Two weeks?

12 MR. NORWAY: Yes.

13 (Signature having not been
14 waived, the deposition of
15 COLONEL CLINTON K. MURRAY, M.D.
16 was concluded at 8:13 p.m.)

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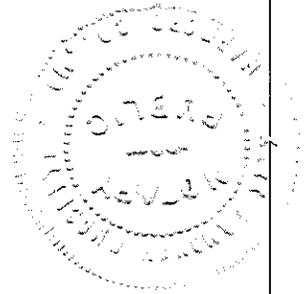
ACKNOWLEDGEMENT OF WITNESS

I, Colonel Clinton K. Murray, M.D.,
do hereby acknowledge that I have read and
examined the foregoing testimony, and the
same is a true, correct and complete
transcription of the testimony given by me,
and any corrections appear on the attached
Errata sheet signed by me.

29 May 2019 [Signature] (DATE)
(SIGNATURE)

ACKNOWLEDGED before me
this 28 day of May 2019
by [Signature]

KIRK LAMONT KNOCKETT
NOTARY PUBLIC STATE OF MARYLAND
My Commission Expires 9/26/2020



Job #3308250

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E R R A T A S H E E T

IN RE: RICHARD ROE, ET AL VS. PATRICK SHANAHAN

WITNESS: COLONEL CLINTON K. MURRAY, M.D.

PAGE LINE CORRECTION AND REASON

15 __1_ __HTLV not HTLP_____

49 __18_ __Medical Corps not W Corps_____

122 __22_ __era(s) not error(s)_____

139 __12__ ___insert chronic before infection

Job #3308250

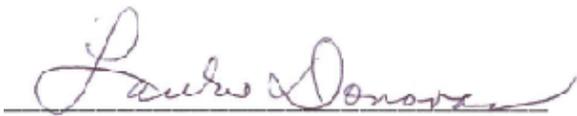
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CERTIFICATE OF SHORTHAND REPORTER -- NOTARY PUBLIC

I, Laurie Donovan, Registered Professional Reporter, Certified Realtime Reporter, and notary public for the District of Columbia, the officer before whom the foregoing deposition was taken, do hereby certify that the foregoing transcript is a true and correct record of the testimony given; that said testimony was taken by me stenographically and thereafter reduced to typewriting under my supervision; and that I am neither counsel for, related to, nor employed by any of the parties to this case and have no interest, financial or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand this 14th day of May, 2019.

My Commission Expires: March 14, 2022



LAURIE DONOVAN
NOTARY PUBLIC IN AND FOR
THE DISTRICT OF COLUMBIA

EXHIBIT 35

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

- - - - - x
NICHOLAS HARRISON and :
OUTSERVE-SLDN, INC., :
Plaintiffs, :
vs. : No. 1:18-cv-00641
JAMES N. MATTIS, In His : LMB-IDD
Official Capacity As Secretary:
of Defense; MARK ESPER, In His:
Official Capacity As the :
Secretary of the Army; and the:
UNITED STATES DEPARTMENT OF :
DEFENSE, :
Defendants. :

- - - - - x
VIDEOTAPED 30(b)(6) DEPOSITION OF
UNITED STATES ARMY
GIVEN BY JASON BLAYLOCK
DATE: Wednesday, February 27, 2019
TIME: 9:04 a.m.
LOCATION: Winston & Strawn
1700 K Street, N.W.
Washington, D.C.
REPORTED BY: Denise M. Brunet, RPR
Reporter/Notary

Veritext Legal Solutions
1250 Eye Street, N.W., Suite 350
Washington, D.C. 20005

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A P P E A R A N C E S

On behalf of the Plaintiffs:

SCOTT A. SCHOETTES, ESQUIRE
Lambda Legal
11 East Adams
Suite 1008
Chicago, Illinois 60603
(312) 663-4413
sschoettes@lambdalegal.org

On behalf of the U.S. Department of Justice:

KERI L. BERMAN, ESQUIRE
JOSHUA ABBUHL, ESQUIRE
U.S. Department of Justice
Civil Division
1100 L Street, Northwest
Washington, D.C. 20005
(202) 353-4537
keri.l.berman@usdoj.gov

(Appearances continued on the next page.)

1 APPEARANCES (continued):

2

3 On behalf of the U.S. Department of Defense:

4 STUART C. SPARKER, ESQUIRE

5 U.S. Department of Defense

6 Office of the General Counsel

7 1600 Defense Pentagon

8 Room 3B688

9 Washington, D.C. 20301

10 (703) 571-0802

11 stuart.c.sparkers.civ@mail.mil

12

13 On behalf of the U.S. Department of the Army:

14 MAJOR W. CASEY BIGGERSTAFF, ESQUIRE

15 U.S. Army Legal Services Agency

16 9275 Gunston Road

17 Suite 3018

18 Fort Belvoir, Virginia 22060

19 (703) 693-1040

20 william.c.biggerstaff.mil@mail.mil

21

22 ALSO PRESENT: Solomon Francis, Videographer

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C O N T E N T S

EXAMINATION BY:	PAGE:
Counsel for Plaintiffs	6
Counsel for U.S. Department of Justice	206
Counsel for Plaintiffs	212

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(*Exhibits attached to the transcript.)

1 years.

2 Q Not a bad posting.

3 A Not bad at all.

4 Q And then prior to that?

5 A Prior to that, I was in medical school
6 for four years at Georgetown University school of
7 medicine.

8 Q Georgetown is also my alma mater, law
9 school. And what year did you obtain your M.D.?

10 A I obtained my M.D. -- it would have been
11 2005.

12 Q And did you have a specialty at that
13 point?

14 A No. So upon obtaining my medical degree,
15 I completed my internal medicine residency at
16 Tripler, so completed that in 2008. And then went
17 to my infectious disease fellowship at the former
18 Walter Reed from 2008 to 2011. Then spent one
19 year in the viral diseases branch right after
20 that, prior to coming to Walter Reed National
21 Military Medical Center.

22 Q Obviously, as a part of your training,
23 you spent some amount of time learning about HIV
24 transmission and diagnosis, correct?

25 A Correct.

1 Q Do you have any training that is specific
2 to service members living with HIV? I'm talking
3 about training that related to that specific
4 context.

5 A I'm not aware that there is any training
6 specific to service members living with HIV.

7 Q So some of these next questions -- we're
8 going to talk a little bit about HIV -- may seem
9 basic to you and -- but it's still important to
10 sort of get down on the record. So what bodily
11 fluids are capable of transmitting HIV?

12 A Some bodily fluids that are capable of
13 transmission include blood, also via sexual
14 exposure, so semen, vaginal fluids. I can tell
15 you that, you know, there's a lot of body fluids
16 that are not found to really be highly
17 transmissible for HIV: Saliva, sweat, tears.

18 Q Any other bodily fluids that do present a
19 significant risk of transmission besides blood,
20 semen, vaginal fluids?

21 A When I say blood, I mean, you know, blood
22 components, you know, as well. So -- but other...

23 Q What about breast milk?

24 A Okay. Breast milk, yes.

25 Q Should be on that list as well?

1 A Yes, it should.

2 Q Okay. What factors influence the risk of
3 HIV transmission?

4 A So the major factors that influence risk
5 include, probably most importantly, the patient's
6 viral load, so number of copies per milliliter of
7 blood. Also, how -- with that, how adherent the
8 patient is to taking their antiretroviral therapy
9 also affects that.

10 Q And so those two things are related --

11 A Yes.

12 Q -- viral load is related to medication
13 adherence?

14 A Correct.

15 Q While we're there, is it true that a
16 patient who adheres to their treatment regimen
17 will obtain an undetectable viral load?

18 A Not in all cases, but to some extent, in
19 the majority of cases, if somebody adheres to what
20 today is considered first-line regimens for
21 antiretroviral therapy, they should be able to
22 attain an undetectable viral load.

23 Q And if someone is unable to reach an
24 undetectable or suppressed viral load on the
25 first-line regimens, are there second-line

1 Q What approximately is the per-act risk of
2 transmission from receptive anal intercourse?

3 A I would have to have the CDC's -- the CDC
4 has a nice table that depicts these different
5 modes of transmission. It's fairly low, but it's
6 not -- I want to say, off the top of my head, like
7 ten out of a hundred thousand, or something close
8 to that. Or maybe it's out of 10,000. I'd have
9 to see the document right in front of me, but...

10 Q What is the risk of transmission via oral
11 sex?

12 A Oral sex is very, very low risk of
13 transmission. I'm not sure if the CDC document
14 says negligible for oral sex, but it's -- as far
15 as modes of sexual transmission, that's the
16 lowest.

17 Q Is it possible to transmit HIV by biting
18 someone?

19 A It is possible. A couple of factors
20 would have to play. You would have to -- it would
21 have to be a decent bite that breaks whatever
22 mucosal surface you're biting. And that person
23 who's biting would typically have to have also a
24 break in their mucosal surface somewhere in their
25 mouth, whether a lesion in their gumline or in

1 their oral pharynx somewhere that was bleeding.

2 Q Has there ever been a documented case of
3 HIV transmission via biting?

4 A I have not reviewed the literature
5 recently on that, so I wouldn't be able to tell
6 you definitively.

7 Q What is the risk of transmission of HIV
8 via blood splash?

9 A Again, assuming an intact mucosal
10 surface, it's negligible.

11 Q And actually, will you define blood
12 splash for us?

13 A When I -- my definition of blood splash
14 is if blood or -- splashed onto a person who --
15 let's say it was a health care provider caring for
16 a patient, and the blood landed on intact skin,
17 then that's a negligible risk of transmission.

18 Q Has there ever been a documented case of
19 transmission via blood splash?

20 A Not to my knowledge, but I have not
21 reviewed the literature on that recently.

22 Q How is HIV treated?

23 MS. BERMAN: Objection. Vague.

24 BY MR. SCHOETTES:

25 Q What is the common treatment for HIV?

1 A So combination antiretroviral therapy is
2 the preferred and first-line treatment regimen for
3 HIV infection. And there's a handful of them. A
4 couple of them are slated as first-line regimens.

5 Q And the first-line treatments today, are
6 those all single-tablet regimens?

7 A The first-line regimens today, there are
8 two single-tablet, one pill one a day, regimens,
9 and then there's a -- it ends up being three,
10 three pills a day regimen that is also still on
11 the first line.

12 Q And are there some individuals who are on
13 a regimen that's two pills once a day?

14 A Two separate pills once a day? Yes, one
15 of those pills being a pill that you do take twice
16 a day, though, as well. I don't know if you're
17 thinking of raltegravir as a BID dosing.

18 Q Okay.

19 (Discussion held off the record.)

20 THE WITNESS: Twice daily dosing, BID.

21 BY MR. SCHOETTES:

22 Q Can you tell us what -- you referred
23 earlier to pre-exposure prophylaxis. Can you tell
24 us how pre-exposure prophylaxis works?

25 A So pre-exposure prophylaxis for HIV

1 involves taking one medication. It's a
2 combination pill of emtricitabine and tenofovir
3 disoproxil fumarate.

4 THE REPORTER: You need to say those
5 slower, please.

6 THE WITNESS: And this pre-exposure
7 prophylaxis for HIV involves taking one pill that
8 is a combination of two drugs, emtricitabine,
9 E-M-T-R-I-C-I-B-I-N-E [sic], and tenofovir,
10 T-E-N-O-F-O-V-I-R, disoproxil, D-I-S-I-P-R-O-X-I-L
11 [sic], fumarate, F-U-M-A-R-A-T-E.

12 BY MR. SCHOETTES:

13 Q I'll try to avoid asking questions that
14 involve medication names in the answers.

15 A Once daily to prevent -- if someone were
16 to get exposed to HIV infection, to prevent that
17 virus from being transmitted to that person.

18 Q And without using medication names, can
19 you explain how post-exposure prophylaxis, or PEP,
20 works?

21 A Yes. So post-exposure prophylaxis for
22 HIV infection is designed in the sense that if a
23 person were to present for medical care after
24 being potentially exposed to somebody with HIV
25 infection or a high suspicion of HIV infection,

1 they would be started on at least a three-drug
2 regimen for HIV empiric treatment within 72 hours,
3 is what the guidance is for that exposure. And
4 you continue on that regimen for 28 days, for four
5 weeks. And during that time, you undergo
6 subsequent follow-up, HIV testing and toxicity
7 testing based on the regimen that you started on
8 to ensure that you're tolerating it well and that
9 you do not acquire HIV infection after that
10 exposure.

11 Q Are the side effects of PEP that is
12 administered currently considered significant?

13 A No.

14 Q Have you heard the treatment as
15 prevention?

16 A I have.

17 Q Can you tell us what treatment as
18 prevention is?

19 A So the idea of treatment as prevention is
20 identifying patients or personnel that are at high
21 risk of HIV infection, identifying them and
22 identifying if they are actively infected with HIV
23 and getting them on treatment as quickly as
24 possible and, by doing that, preventing
25 transmission to other -- other individuals.

1 circumstance, it's -- it depends on a lot of
2 variables that we've already discussed, if they're
3 taking their HIV medications regularly, what kind
4 of environment they're in, what access they have
5 to medications and lab testing. It depends on a
6 lot of different variables, where they are in the
7 world.

8 Q So the risk of transmission in that
9 context would have to take into account all of
10 those different variables?

11 A Correct.

12 Q And the likelihood that each of those
13 circumstances would be occurring at that time?

14 A Correct.

15 Q Is the probability of HIV transmission
16 affected by the role in which the HIV-positive
17 soldier is serving?

18 A To -- to some extent, yes.

19 Q And can you describe how the role affects
20 the risk of transmission?

21 A So based on where a service member may be
22 in the world -- let's say, for example, if a
23 service member is deployed to a combat environment
24 with little to no capabilities for access to
25 pharmacy, access to laboratory testing and medical

1 services in general, and based on the stresses in
2 that combat environment, that would potentially
3 affect a service member's HIV infection -- ability
4 to maintain control of their HIV infection.

5 Q And are both of those factors that you
6 just cited, access to pharmacy/medical services
7 and stressors, are you saying that those things
8 would affect the soldier's ability to adhere to
9 their medications?

10 A Potentially, yes.

11 Q And that that's the mechanism by which
12 there could then be a risk to other personnel?

13 MS. BERMAN: Objection. Mischaracterizes
14 the testimony.

15 You can answer.

16 THE WITNESS: Yes, to other personnel or
17 themselves, yes.

18 BY MR. SCHOETTES:

19 Q So let's just focus on other personnel
20 for a moment.

21 A Okay.

22 Q Can you describe the mechanism by which,
23 then, the increased viral load creates a risk to
24 other personnel?

25 MS. BERMAN: Objection. Lack of

1 foundation.

2 You can answer.

3 THE WITNESS: So an increase in viral
4 load -- you wanted to refer to other personnel,
5 how -- its effects on other personnel first, you
6 said?

7 BY MR. SCHOETTES:

8 Q Yes.

9 A So somebody with an increased viral load
10 in a deployed setting, the biggest concern is the
11 potential need for activation of emergent blood
12 transfusions in the deployed setting. So should
13 that person donate blood in a deployed setting
14 where we don't have the -- oftentimes the
15 appropriate resources to exclude HIV infection
16 prior to blood donation, then that would pose a
17 significant risk to somebody receiving that unit
18 of blood or units of blood.

19 Q Setting aside blood donation, which we
20 will return to, what are the other mechanisms by
21 which a person with a non-suppressed viral load
22 would present a risk to the health of other
23 personnel?

24 A Via sexual transmission is the other most
25 likely.

1 Q Anything else?

2 A No. We don't allow pregnant,
3 breast-feeding women in theater, so it would not
4 include that.

5 Q So if a soldier has an undetectable viral
6 load, what is the probability that that soldier
7 will endanger the health of other personnel?

8 A Again, it depends on the scenario. If we
9 take that previous scenario of an HIV-infected
10 service member in a deployed setting and in the
11 potential setting of an emergent blood transfusion
12 need, there is still a significant risk of
13 transmission of HIV infection.

14 Q Then again, setting aside -- or not even
15 setting aside -- any other potential risk other
16 than the service member donating blood?

17 A So the other risk we didn't mention,
18 other than blood donation, would still be blood
19 exposure, but a needle stick exposure would also
20 be a significant -- could be a significant risk.
21 Sexual exposure with an undetectable viral load
22 would be a very, very low risk, but again, not
23 zero.

24 Q But approximately zero, correct?

25 A Approximately zero, correct.

1 their home duty station.

2 Q So you referred to appointments every six
3 months --

4 A Correct.

5 Q -- at which an evaluation is done and
6 blood is drawn?

7 A Uh-huh.

8 Q Would the time that is required for that
9 care in theater be considered excessive time lost?

10 A When you say "in theater," mean in a
11 deployed setting?

12 Q Yes. Within a theater of operations.

13 A So currently, in a theater of operations,
14 we don't have access to care at a military
15 treatment facility that would include an
16 infectious disease specialist and all of the
17 laboratory testing required that would need to be
18 obtained for somebody's biannual visit with HIV.

19 Q And where -- sorry.

20 Is an infectious disease specialist
21 required to provide the follow-up evaluation for
22 an individual living with HIV in a deployed
23 setting?

24 A So again, in a deployed setting, we --
25 there's no precedent for that. We don't have

1 capabilities to -- you know, as far as lab
2 capabilities and stuff needed. So there has never
3 been an evaluation of an HIV-infected person in a
4 deployed setting. So...

5 Q So because you're not deploying people
6 living with HIV, there are not the mechanisms set
7 up --

8 A Right.

9 Q -- to do that --

10 A Correct.

11 Q -- right now?

12 MS. BERMAN: Objection. Mischaracterizes
13 the testimony. Sorry.

14 THE WITNESS: Correct. Yes. That's what
15 I'm...

16 BY MR. SCHOETTES:

17 Q So let me back up and make my question
18 more general. Is it required that a physician be
19 an infectious disease specialist in order to
20 provide an individual living with HIV with this
21 type of follow-up care?

22 A So by our Army regulation, it is
23 specified that they are followed by an infectious
24 disease provider. On a national level, there are
25 providers that are not infectious disease

1 specialists who still are slated as HIV
2 specialists who do follow patients. And there are
3 a handful of primary care providers in the -- on a
4 national level that do follow HIV patients.

5 Q Can the -- is it possible to do a blood
6 draw within theater?

7 A Yes, it's possible to do a blood draw in
8 theater. However, it depends on what you want to
9 do with that blood draw in theater.

10 Q So --

11 A It depends on what you're testing for.

12 Q Okay. So tell me -- explain that to me.
13 Explain why that makes a difference.

14 A So different tests, depending on what you
15 would like to order in theater, require different
16 processing of the specimen and different ways to
17 preserve that specimen in order to do the
18 appropriate testing based on where you need that
19 specimen to go to get that testing accomplished,
20 if that makes sense.

21 Q I think it does. Let me unpack it a
22 little bit more. So there could be particular
23 ways that you have to conduct the blood draw or
24 preserve the specimen --

25 A Yes.

1 Q -- in order to make it viable for the
2 kind of test that's going to be performed?

3 A Correct.

4 Q And are you saying that, for HIV, there
5 are currently not the capabilities to do those
6 types of preservation of the specimen within
7 theater?

8 A At most levels of care within theater.
9 So if I -- can I explain to you --

10 Q Sure.

11 A -- the different roles of care for
12 patients in theater?

13 Q Yes.

14 A So we have role one capabilities, which
15 is our most minimal capability for care, which is
16 usually at the front line where the unit is in --
17 very near to combat operations. So that
18 essentially is what we typically call it as a
19 battalion aid station. It's a tented facility
20 that really is designed for acute trauma care,
21 life -- lifesaving care to get them to the next
22 level of care. So it's run by, most of the time,
23 a PA, sometimes a medical physician, and a handful
24 of medics, to sometimes include, like, a senior
25 medic. So there's that level of care which really

1 typically has little to no lab testing capability
2 at all.

3 So the next level of care --

4 Q I'm sorry. Follow-up question there.

5 A Yes.

6 Q You said lab testing capability.

7 A Correct.

8 Q Is that differentiated from the actual
9 draw of the blood?

10 A They kind of go hand in hand because you
11 wouldn't draw somebody's blood if you weren't
12 going to be able to test it from there.

13 Q So that's part of my question, is can --

14 A Oh, you're saying --

15 Q Can blood be shipped -- can a specimen be
16 shipped to a different location?

17 A Yes, but you would need to know -- you
18 would need to be able to process that blood at
19 that role one facility. And those capabilities
20 are typically not in place.

21 Q The processing capabilities --

22 A Correct.

23 Q -- for the draw?

24 A Yes.

25 Q Okay. Go ahead. You were going to talk

1 about, I think, role two.

2 A Okay. But if I could also clarify. So
3 processing -- typically what it involves is
4 spinning down the blood to separate it out
5 between -- there's different, you know,
6 compartments of the blood. There's plasma, serum,
7 and there's actually whole, you know, red blood
8 cells. So they separate that out. Then they
9 typically need to freeze it, particularly for HIV
10 testing. They freeze it to minus 20 degrees
11 Celsius. And that capability is not present at
12 role one facilities.

13 BY MR. SCHOETTES:

14 Q Thank you. Let's talk about the next
15 level of care.

16 A Sure. So the next level of care is
17 role two facilities. That is typically run by a
18 medical company, which could be anywhere from, you
19 know, 30 to as many as, like, a hundred personnel
20 in that medical company. It includes essentially
21 the capability maybe to hold somebody for a 24 to
22 maybe 48-hour period, depending on the type of
23 environment you're working in. We also include
24 our forward surgical teams as kind of a role two
25 facility. And that's -- they provide acute

1 surgical care fairly close to the front line. And
2 so they're considered, just because of their
3 surgical capabilities, a role two level of care.

4 Again, at role two facilities, very
5 limited laboratory services as well. Maybe
6 chemistries, like checking somebody's electrolytes
7 or -- I -- I can't speak to the exact lab assets
8 at the role two, but they're fairly limited and --
9 your more, like, benign, day-to-day lab testing
10 capabilities.

11 Q And then -- so they also would not have
12 the capability of processing the blood, spinning
13 it down, as you say?

14 A For the most part. Again, it probably
15 depends on what assets they decide to deploy with
16 in a given circumstance, but typically not.

17 Q Can you talk about the next level of
18 care?

19 A So role three is the next level of care,
20 and that's your combat support hospitals, which
21 are -- in the deployed setting, they're usually at
22 major hubs of military bases in the deployed
23 setting. So, for example, in our current theater
24 in Afghanistan, we've got role three facilities in
25 Bagram and I think also in Kandahar. And that's

1 current theater of operations, their ability to
2 fly aircraft in and out to transport specimen.

3 Historically, and what we've seen, what
4 I've seen over the past, you know, ten years now,
5 is that it's typically at -- the least amount of
6 time we've seen is about 28 days to get a result
7 for an HIV test, an HIV -- and that's an HIV
8 antibody test from theater.

9 Q And you don't have the -- any type of
10 metric by which to measure the other types of
11 testing related to an HIV follow-up because you're
12 not generally currently doing those kinds of
13 tests; is that correct?

14 A Correct, yeah.

15 Q How would a 28-day delay in receiving the
16 results of the test affect the ability to monitor
17 a person's HIV while in a deployed setting?

18 MS. BERMAN: Objection. Calls for
19 speculation.

20 You can answer.

21 THE WITNESS: I just want to make sure I
22 understand. So we're assuming somebody who
23 already has HIV infection in the deployed setting,
24 if they needed to get blood work to --

25 BY MR. SCHOETTES:

1 Q Yeah. So --

2 A I just want to make sure we're talking
3 about the same --

4 Q Yeah.

5 A -- scenario.

6 Q Yeah. Let's assume a person who has been
7 diagnosed with HIV and they're on a regimen and
8 they've been virally suppressed for some period of
9 time and relatively stable, and they're going in
10 to get their six-month evaluation. Doctor does
11 follow-up. You referred to the fact that it takes
12 a while to get the results back. Does that in any
13 way impact the validity of those results or the
14 ability to monitor that relatively stable person
15 in the deployed setting?

16 MS. BERMAN: Objection. Calls for
17 speculation and compound.

18 Go ahead.

19 THE WITNESS: So we're assuming that
20 there's a lot of variables that fall into place
21 here too. So we're assuming that that individual
22 can get to a role three facility fairly easily
23 to -- which also depends on the combat environment
24 in a deployed setting. We're assuming that, once
25 that blood test, the lab work is drawn, we would

1 be sending, in this case, for a viral load, which
2 also requires, you know, spinning down the blood,
3 freezing it to minus 20 -- so this is assuming
4 that the cold chain for this specimen is preserved
5 as the specimen gets all the way back to the
6 United States, which -- we know that there's a
7 handful of times that it's -- lab specimens
8 frequently can get lost in theater or are not
9 usable by the time they get to the lab for
10 processing. So we're assuming that all of these
11 variables occur successfully.

12 Then, in that setting, we're looking
13 about -- anywhere from a month to longer,
14 depending on any hiccups in the travel of the
15 specimen -- because it typically goes through
16 Landstuhl in Germany and then into the United
17 States. It may be processed in Germany, but right
18 now, our -- the algorithm is that it goes to our
19 HIV diagnostics and research laboratory, or HDRL,
20 in Silver Spring and Rockville, Maryland.

21 BY MR. SCHOETTES:

22 Q Can you explain why that is? Why does it
23 come all the way back to the United States if it
24 could be processed in Germany, for instance?

25 A So far as the -- I can't speak to the lab

1 capabilities in Germany. I think they actually
2 may send it out to the civilian sector in Germany
3 for some HIV testing because of their lab
4 capabilities at Landstuhl, but our -- for the
5 Army, and we do -- for the Army, our HIV
6 diagnostics and research lab that has -- there's a
7 few different antibody tests for HIV as well as
8 viral load testing, and those are all processed at
9 our HDRL in Maryland, in Silver Spring.

10 Q I guess I'm still wondering -- I
11 understand that that is what happens. Is there a
12 reason that it needs to be that way as opposed to
13 having this testing done in Germany?

14 A I'm not a lab personnel so I don't want
15 to speak on something that I'm not aware of the
16 nuanced details of, but that is our current Army
17 processing --

18 Q Presumably --

19 A -- algorithm.

20 Q Go ahead. Presumably, other places know
21 how to do this testing that is required for people
22 living with HIV and it could be done in Germany.

23 MS. BERMAN: Objection. Argumentative.
24 Calls for speculation.

25 Go ahead.

1 THE WITNESS: I mean, I'm sure, you know,
2 different European countries are probably very
3 savvy at obtaining a viral load and the
4 appropriate HIV diagnostics, but the Army does not
5 have an agreement with any of these countries,
6 so...

7 BY MR. SCHOETTES:

8 Q And is that what would be required, some
9 type of agreement?

10 A I don't know. That's not my thing.

11 Q Okay. Going back to my original
12 question, which is, let's say the physician who is
13 conducting this follow-up evaluation receives
14 these results 28 days after the blood is drawn, or
15 even 45 days or 60 days --

16 A Sure.

17 Q -- what effect would that lapse of time
18 have on their ability to effectively monitor the
19 individuals with HIV?

20 MS. BERMAN: Objection. Calls for
21 speculation. It's outside the scope of what this
22 witness is being offered to testify about.

23 Go ahead.

24 THE WITNESS: So, I mean, it's -- the
25 effects are -- you know, there are several

1 different, you know, effects that can occur in
2 that span of -- it depends on a lot of variables,
3 too. It depends on was that service member taking
4 his medication regularly. If he had been
5 somewhere where he lost access to his
6 antiretroviral regimen and, say, it took him a
7 month to two months to get back to this role three
8 facility to actually get his labs drawn, I mean,
9 in that span of time, he probably had a fairly
10 high viral load and, in that setting, depending on
11 what's going on in that combat environment, that
12 might affect his ability to perform his job. It
13 certainly would become an issue in an emergent
14 blood transfusion setting.

15 I mean, there's -- it depends on the
16 scenario and it depends on a lot of different
17 variables again.

18 BY MR. SCHOETTES:

19 Q And I want to talk about all those
20 things, but I'm still not hearing -- the doctor
21 who is evaluating this individual, I want to know
22 what effect the delay in receiving those test
23 results has on that doctor's ability to monitor
24 this individual.

25 MS. BERMAN: Same objections.

1 medication, that it would be important to get that
2 individual back on their medication.

3 A Yes.

4 Q And that would not be reliant upon the --
5 getting the test results from that patient,
6 correct?

7 A Correct.

8 Q So I want to know what the effect would
9 be on the doctor's ability to provide the type of
10 monitoring and care that the doctor is being asked
11 to provide if they got the labs back 30 days
12 later, 45 days later?

13 MS. BERMAN: Same objections and asked
14 and answered.

15 You can answer.

16 THE WITNESS: I don't see an effect to
17 the doctor managing the patient in that setting.

18 BY MR. SCHOETTES:

19 Q You talked about -- would it likely
20 result in excessive time lost from duty for an
21 individual with HIV to get to a role three medical
22 facility twice a year?

23 A So again, I think you're mixing up -- so
24 a role three medical facility in our current Army
25 policy does not have an infectious disease

1 specialist there. So they would never go to a --
2 a role three facility, that's only what we talk
3 about in the deployed setting.

4 In the United States, we have role four
5 facilities, which include all of our major medical
6 treatment facilities where, at the -- most of them
7 infectious disease specialists reside.

8 Q Can you tell -- can you describe a
9 role four medical facility?

10 A Yeah. So I can use -- Walter Reed, where
11 I work, for example, is a role four military
12 treatment facility. Has, you know, robust
13 services that you would expect in any other
14 civilian hospital in the United States, great
15 laboratory capabilities, radiology capabilities,
16 primary care and subspecialty care capabilities.

17 Q So does the Army believe that an
18 individual living with HIV must return to the
19 United States from a deployed setting in order to
20 get their six-month follow-up evaluation?

21 A Currently, yes.

22 Q And I understand that that's the current
23 policy, but what I'm asking is, is there any
24 reason why an individual living with HIV would not
25 be able to get the kind of follow-up care they

1 need at a role three facility?

2 A Yes. So again, it depends on what lab
3 capabilities they have at the role three facility.
4 And not every primary care physician is
5 knowledgeable and knows how to treat a patient
6 with HIV infection. So it really is dependent on
7 exactly who is at that role three facility and
8 their comfort and their experience with managing
9 an HIV-infected patient.

10 Q And that includes the type of follow-up
11 care we're talking about for an individual who has
12 well-controlled HIV?

13 A Yes.

14 Q A primary care physician couldn't be
15 expected to handle that type of care?

16 A No, it's not they couldn't be expected.
17 It's just some -- some are more savvy and
18 knowledgeable about our newest HIV regimens and
19 some are not at all, have no experience. So it
20 really depends on the individual experience level
21 of that provider.

22 Q And you're saying that kind of training
23 potentially could be provided to those providers?

24 MS. BERMAN: Objection. Mischaracterizes
25 the testimony.

1 that could be deemed an excessive loss of time for
2 that unit.

3 BY MR. SCHOETTES:

4 Q Are soldiers with HIV medically capable
5 of satisfactorily completing required training?

6 MS. BERMAN: Objection. Calls for
7 speculation.

8 You can answer.

9 THE WITNESS: Yes. Assuming they are
10 well controlled and otherwise asymptomatic
11 HIV-infected service members, yes.

12 BY MR. SCHOETTES:

13 Q Are HIV-positive soldiers -- I'm sorry.
14 Yes. Is an HIV-positive soldier adaptable to the
15 military environment without the necessity of
16 geographic area limitations?

17 MS. BERMAN: Objection. Calls for
18 speculation.

19 THE WITNESS: Currently, no.

20 BY MR. SCHOETTES:

21 Q And why is that?

22 A Currently, because we do not deploy
23 service members into combat operations or
24 contingency operations. They are -- for the
25 various variables that we've already discussed, it

1 depends on the austerity of the environment, the
2 access to laboratory capabilities and medical
3 service capabilities, the access to pharmacy
4 capabilities should that service member require
5 refills of his medications or lose his
6 medications.

7 And I would also add the confidentiality
8 issue that we had already discussed as well.

9 Q So we already talked about the access to
10 care and we talked about the confidentiality
11 provision. Let's talk about the austerity of the
12 environment. What factors influence an individual
13 living with HIV in terms of the austerity of the
14 environment?

15 MS. BERMAN: Objection. Vague.

16 THE WITNESS: So when we talk about
17 austere environments, so -- it depends on, you
18 know, again, the austerity in the environment kind
19 of goes hand in hand with what capabilities are
20 available in that environment.

21 If all -- I guess I'll -- I can use an
22 example from personal experience. Being deployed
23 in the middle of the desert in Afghanistan only
24 next to a role one facility that has essentially
25 no diagnostic laboratory capabilities and no

1 access to pharmaceuticals for treatment of HIV
2 infection at that role one, outside of a short
3 supply of antiretrovirals for use as PEP if
4 needed -- so that's a pretty austere environment
5 where there's a lot of variables that could come
6 into play where an HIV-infected service member
7 might need care at that role one and not be able
8 to receive it.

9 BY MR. SCHOETTES:

10 Q So that's what I -- I -- what I want to
11 know about is what those factors are. So I
12 understand -- and I want to set aside access to
13 care and access to medication. We're going to
14 talk about that in a moment. And I just want to
15 know what the austere environment factors,
16 environmental factors, are that would create a
17 need for more immediate care.

18 MS. BERMAN: Objection. Vague.

19 You can answer.

20 THE WITNESS: I guess -- I mean,
21 that's -- I kind of lump all of this access to
22 austerity, if you get what I'm saying. Are you
23 talking about, like, extremes in temperature,
24 extremes in the -- you know, just maybe staying up
25 for 48 hours straight without sleep?

1 You can answer.

2 THE WITNESS: To clarify, this is

3 assuming on a deployment?

4 BY MR. SCHOETTES:

5 Q Yes, I'm sorry.

6 A If -- on a deployment, the service member
7 would be given whatever number of medications they
8 needed to span that deployment, in most cases.

9 Q How long are the longest deployments?

10 A The longest deployments currently are
11 slated as nine-month deployments, but it varies
12 based on combat operations.

13 Q So for a nine-month deployment, the
14 soldier would be given 270 days' worth of
15 medication, approximately?

16 A Yes.

17 Q If a deployed soldier's medications were
18 lost, stolen or destroyed, how would they be
19 provided with a replacement supply?

20 A That depends on the scenario and where
21 they're located in -- in theater.

22 Q Can we do it for each -- for someone with
23 a role one, someone with a -- a soldier with a
24 role two and then a soldier near a role three?

25 A Sure.

1 Q Okay.

2 A So at a role one facility, there would be
3 no pharmaceutical capability to immediately
4 replenish that medication supply. The role one
5 provider would probably reach out to a role three
6 facility, the closest role three, and ask for
7 their capability to supply an immediate course of
8 that medication until that service member can
9 actually order it through TRICARE Express Scripts
10 and have that new shipment sent out to him.

11 Q How long would it likely take for the
12 supply at the role three to reach a soldier at a
13 role one?

14 A Again, that completely depends on combat
15 operations at the time, whether there's no-fly
16 restrictions, what that unit is doing. If they're
17 out in the field somewhere and not even going back
18 to that role one battalion aid station for a week
19 or so, then it might span anywhere from 48 hours
20 to get that supply to them out to a couple of
21 weeks to a month, depending on what they're doing.

22 Q Are there currently any HIV medications
23 that are stocked or on the formulary within
24 theaters of operations?

25 MS. BERMAN: Objection. Vague.

1 You can answer if you know.

2 THE WITNESS: Yes. There are usually
3 stockpiles for PEP of HIV medications, so for
4 post-exposure prophylaxis, but it usually is as
5 minimal as, like, one course of PEP. So like a
6 28-day supply of an antiretroviral regimen.

7 BY MR. SCHOETTES:

8 Q So a change in the policy that would
9 allow soldiers living with HIV to deploy would
10 require a change to the formularies to include HIV
11 treatment regimens, correct?

12 MS. BERMAN: Objection. Calls for
13 speculation. It's outside the scope of what this
14 witness is being offered to testify about.

15 But you can answer.

16 THE WITNESS: Yes.

17 BY MR. SCHOETTES:

18 Q I didn't let you finish before. We
19 talked about a role one -- a soldier at a role one
20 unit, but what about a soldier in a role two unit
21 or at a role three unit?

22 MS. BERMAN: Can you clarify which
23 question?

24 BY MR. SCHOETTES:

25 Q Yeah. So we were talking about how a

1 soldier who -- living with HIV who had lost --
2 actually, scratch the HIV part. Try again.

3 If a deployed soldier's medications are
4 lost, stolen or destroyed, how are they provided
5 with a replacement supply? You indicated that it
6 would depend in part on the type of medical
7 facility to which they were adjacent. So could
8 you please answer the question with respect to
9 role two and role three facilities?

10 A Yes. So similar to a role one, a
11 role two facility would have to likely reach out
12 to a role three facility and see if that
13 medication was readily available at that pharmacy
14 there. And if -- if so, they would give them a
15 temporary supply, typically like a 30-day supply
16 or so, until Express Scripts can actually deliver
17 a -- that medication to that service member's
18 location.

19 Q And then if they were adjacent to a
20 role three facility, I'm assuming that they would
21 be able to get it readily from that role three
22 facility if they had the medication in stock?

23 A That's correct. So if they had that
24 particular medication at that role three, it would
25 be given to them.

1 Q Until they were able to get their full
2 prescription from Express Scripts?

3 A Correct.

4 Q How long approximately does it take for
5 an Express Scripts prescription medication to
6 reach a soldier at a role one facility, or at a
7 post with a role one medical facility?

8 A So that completely depends on the
9 location of that role one facility. If -- it
10 depends on how remote it is and what the -- what
11 the plane flight route is of Express Scripts. And
12 that could be very variable.

13 Q Can you give us a range? Can you give me
14 a range?

15 A A range would be anywhere from two weeks
16 out to over a month.

17 Q Can you put a top end on -- you say over
18 a month. How much over a month?

19 MS. BERMAN: Objection. Calls for
20 speculation.

21 THE WITNESS: I mean, again, I can't -- I
22 can't give you an upper range because it depends
23 on -- if that unit is hunkered down somewhere and
24 engaged in combat with the enemy, they're not
25 going to fly an Express Scripts shipment in to a

1 service member. So -- I mean, it could be
2 outwards of a month to -- I can't put a top end
3 range to it.

4 BY MR. SCHOETTES:

5 Q It could be more than two months?

6 A Sure.

7 Q It could be more than three months?

8 A Potentially. Unlikely, but potentially.

9 Q So would three months be a top-end range?

10 MS. BERMAN: Objection. Mischaracterizes
11 the testimony.

12 THE WITNESS: I can't definitively give
13 you a top-end range because I don't know -- I
14 can't account for every variable that could occur
15 in that setting.

16 BY MR. SCHOETTES:

17 Q But more than three months is unlikely?

18 A Correct.

19 Q Is more than two months unlikely?

20 A Less likely than more than three months.
21 Less unlikely than more than three months.

22 Q Do antiretroviral medications have any
23 storage or handling restrictions?

24 A So all medications that are FDA-approved
25 come with a package insert that lists storage

1 requirements. And antiretrovirals are no
2 exclusion to that.

3 Q Are they -- do HIV antiretroviral
4 medications have any special storage or handling
5 restrictions that are not -- that are out of the
6 ordinary in some way?

7 MS. BERMAN: Objection. Vague.

8 You can answer.

9 THE WITNESS: Not to my knowledge.

10 BY MR. SCHOETTES:

11 Q Do they tolerate -- do any of them
12 require refrigeration?

13 A Not any of the commonly used regimens
14 that we use today.

15 Q Do they tolerate heat relatively well?

16 MS. BERMAN: Objection. Vague.

17 You can answer.

18 THE WITNESS: As well as antimalarials or
19 other medications we take in a deployed setting.

20 BY MR. SCHOETTES:

21 Q Do they tolerate cold very well?

22 MS. BERMAN: Same objection.

23 THE WITNESS: Same response.

24 BY MR. SCHOETTES:

25 Q I'm going to move on to topics 24 and 25.

1 You described earlier concerns over transmission
2 via the blood supply. Are soldiers who have been
3 diagnosed with HIV told that they are not to
4 donate blood?

5 A Yes.

6 Q Given that soldiers are told not to
7 donate blood, what are the concerns with
8 transmission via a donation from a soldier living
9 with HIV?

10 A So the biggest concern that we've seen
11 actually has been concerns for the soldier
12 breaching confidentiality of his HIV status to
13 fellow service members. And we have seen cases --
14 at least one case that I am aware of -- of a
15 service member who attempted to donate blood
16 within the United States who knew he was
17 HIV-infected and was flagged by the blood bank,
18 because we have very good blood testing
19 capabilities for HIV infection in the United
20 States. And that was brought to the attention of
21 the Army public health -- or the -- I believe this
22 was a marine soldier, so it was a -- whatever
23 public -- the public health service for -- that
24 governs them. And it was also brought to the
25 soldier's attention too. They notified the

1 individual donating blood, obviously.

2 Q And you said that was done in the United
3 States --

4 A Uh-huh.

5 Q -- where the requisite testing is done on
6 the blood to identify a bloodborne pathogen like
7 HIV, correct?

8 A Correct.

9 Q And that's how the blood was flagged and
10 discarded, correct?

11 A Correct.

12 Q In the setting of deployment, what kind
13 of testing is done on the blood that is drawn for
14 transfusion?

15 A So in a deployed setting, in preparation
16 for the potential of a need for emergent blood
17 transfusions, there's kind of two groups of
18 personnel. So there's a blood donor pool, so
19 people who sign up at the start of the deployment
20 or prior to deployment and say, yeah, I'm going to
21 be ready and willing to donate blood if needed.
22 And then there's also an emergent blood donor
23 pool, so folks who are asked on the spot, hey, we
24 need blood, you weren't in the original donor
25 pool, can you emergently give us blood?

1 So there's kind of two separate pools.
2 That first pool is screened, obviously, for HIV,
3 hepatitis B, hepatitis C, all the potential
4 bloodborne transmitted infections at -- when they
5 sign up for that, to be in that donor pool. And
6 then as -- there's -- the guidance says there's
7 attempts to get them rescreened throughout the
8 deployment, but that is typically not possible,
9 so -- but they are, you know, it's a pool that we
10 know at the start of this deployment they are HIV
11 uninfected, or hepatitis B and C uninfected.

12 Q And presumably someone who was diagnosed
13 with HIV would not volunteer to become a part of
14 the blood donor pool, correct?

15 A Correct.

16 MS. BERMAN: Objection. Calls for
17 speculation.

18 THE WITNESS: Correct.

19 BY MR. SCHOETTES:

20 Q The second pool that you talked about, is
21 that sometimes referred to as the walking blood
22 bank?

23 A Correct.

24 Q What kind of testing is done on the blood
25 drawn for the -- as a part of the walking blood

1 bank?

2 A So there are attempts to test for
3 hepatitis B, hepatitis C and HIV in those
4 settings. Those tests are not always run reliably
5 before blood is transfused in the activation of a
6 walking blood bank.

7 Q And can -- why is that?

8 A It's based on the emergence of the need
9 for blood. So each of those tests take
10 approximately 15 minutes to run, to get results,
11 and sometimes you don't have 15 minutes before you
12 need to give somebody blood.

13 Q Now, anyone who is participating in the
14 walking blood bank is presumably asked to consent
15 to giving blood, correct?

16 MS. BERMAN: Objection. Calls for
17 speculation.

18 You can answer.

19 THE WITNESS: To my knowledge, there's no
20 written consent when a walking blood bank is
21 activated.

22 BY MR. SCHOETTES:

23 Q No soldier is asked to donate blood
24 against his will?

25 A No.

1 Q So a soldier has the ability to decline
2 to donate blood?

3 MS. BERMAN: Objection. Calls for
4 speculation.

5 You can answer.

6 THE WITNESS: Yes. But you can imagine
7 how that's perceived by the unit in a setting of a
8 MASCAL if a soldier declines to give blood for a
9 fellow service member.

10 BY MR. SCHOETTES:

11 Q But it is -- my question remains, it is
12 possible for a soldier to decline to give blood.

13 A Yes.

14 Q And then there's a concern that you've
15 expressed with something that happened in the
16 United States, that a soldier, in an effort to
17 maintain confidentiality around his HIV status,
18 might choose to give blood even though he knows he
19 has HIV?

20 A Correct.

21 Q Would there be a method for a soldier to
22 indicate or identify that his blood was not to be
23 used for transfusion even though it had been
24 donated as there is in the United States for
25 people in similar situations?

1 Let me give you an example. They're
2 doing a blood drive at work at a place of
3 employment. And there's a person living with HIV
4 who doesn't want to be seen as not -- who wants
5 his employees [sic] to believe that he is a person
6 who would give blood, but he doesn't want to
7 reveal his HIV status. And lots of blood
8 collection centers have a box you can check that
9 says, don't use this blood.

10 Is there any mechanism or would it be
11 possible for a soldier to indicate that so that
12 their blood would not be used?

13 MS. BERMAN: Objection. Form. And
14 compound.

15 But you can answer.

16 THE WITNESS: To my knowledge, there is
17 no mechanism in place, but that would certainly
18 not be feasible to fill out a checklist to donate
19 blood if it was needed urgently in a MASCAL
20 scenario.

21 BY MR. SCHOETTES:

22 Q Is there -- are there other
23 individuals -- are there other reasons why a
24 person could not donate blood?

25 A Yes.

1 A Correct.

2 Q This sentence says, "Some HIV-infected,
3 virally suppressed patients on ART will develop
4 illnesses associated with premature aging."

5 Do you know that to be true?

6 A Yes. There's quite a bit of literature
7 to demonstrate that HIV-infected service members
8 are more likely to develop cardiovascular disease,
9 osteoporosis, yes.

10 Q Do you know at what -- how long it takes
11 for those illnesses to develop?

12 A It's very variable. It depends on a lot
13 of different factors.

14 Q When it talks about premature aging, is
15 there an age at which we would start to see that
16 kind of premature aging or is it contingent
17 upon -- well, I'll just stop there. Is there a
18 particular age at which we would be likely to see
19 these illnesses associated with premature aging
20 for virally suppressed, HIV-positive people?

21 A No, it's very variable.

22 Q Is there a time from infection, amount of
23 time from infection, that would be an indication
24 of when we might expect to see illnesses
25 associated with premature aging?

1 A Again, it's variable on several factors.

2 Q Can you tell me what those factors are?

3 A So if somebody is taking their ART
4 regularly, is probably the biggest factor, how
5 well controlled their HIV is. However, on the
6 flip side, there's also bodies of literature that
7 express concern about certain ART regimens and
8 their effects on the cardiovascular system as
9 well.

10 Q So I just want to pause for a moment and
11 say --

12 A And osteoporosis. I'm sorry.

13 Q -- that in the sentence, though, it talks
14 about someone virally suppressed.

15 A Okay.

16 Q So wouldn't that indicate that that
17 person is regularly taking their HIV medications?

18 A Yes.

19 Q So that wouldn't be a factor for that
20 individual.

21 A Correct.

22 Q But now I heard you say the regimen
23 they're on could affect when we might see the
24 possibility of illnesses associated with premature
25 aging, correct?

1 A Yes, that's correct. But even --

2 Q What other --

3 A Even in virally suppressed patients there
4 is evidence to show that HIV-infected persons,
5 even with suppressed viral loads, still have --
6 whether it's related to an increased inflammatory
7 state in their body or their immune system, for
8 lack of a better term, is ramped up to control the
9 HIV virus, that that has effects on the
10 cardiovascular system and other organ systems as
11 well.

12 Q Which is indeed what this sentence says,
13 "Some HIV-infected virally suppressed patients on
14 ART will develop illnesses associated with
15 premature aging."

16 A Yes.

17 Q So what I'm trying to understand is, are
18 there factors -- what the factors are that you
19 described that would influence if that happened?
20 One thing you said would be the treatment regimen
21 that they were on. Are there other factors that
22 would influence when we might see that?

23 MS. BERMAN: Objection. Form.

24 You can answer.

25 THE WITNESS: So I had mentioned the

1 body's own kind of inflammatory state. So there's
2 various inflammatory chemicals in the body,
3 cytokines in particular and interleukins and these
4 different factors that -- a lot of research has
5 looked at their role in inducing conditions like
6 cardiovascular disease, renal disease,
7 osteoporosis in the setting of HIV infection.

8 So even with a suppressed viral load,
9 perhaps, the thought is -- and some of the
10 research is showing that these -- this ramp-up of
11 these inflammatory factors are affecting an
12 individual's cardiovascular system or bone system
13 or renal system.

14 BY MR. SCHOETTES:

15 Q Am I -- is it correct that those
16 response -- the level of those responses may vary
17 from individual to individual?

18 A Yes, correct.

19 Q So that would be another factor is how --
20 a particular person's response, immune system
21 response in terms of these inflammatory
22 conditions?

23 A Yes.

24 Q Is there other factors that would
25 influence how rapidly one might see the onset of

1 these illnesses associated with premature aging?

2 A So the other, you know, very common
3 comorbid factors to a lot of Americans: Smoking,
4 alcohol use, lifestyle habits. Those, combined
5 with HIV infection, might portend a higher
6 likelihood of development of cardiovascular
7 disease and osteoporosis.

8 Q Anything else?

9 A Not that I can think of right now.

10 Q Further down, it talks about, "Some
11 patients may experience a fluctuating course of
12 neurocognitive impairments over time, including
13 symptom normalization; however, it is unknown
14 whether these changes reflect biological
15 alterations induced by responses to (or failures)
16 of ART, or occur independently of viral load and
17 changes to ART regimens."

18 So we're still figuring this all out. Is
19 that an accurate statement?

20 A Yes. That's very accurate.

21 Q And some of this is speculative as to how
22 these things are associated?

23 MS. BERMAN: Objection. Vague.

24 THE WITNESS: Some of it is -- could be
25 speculative, but a lot of it is based on studies

1 that have been done as well. So it's -- I think
2 there's data on both sides of the spectrum so far,
3 and we're waiting for more data to make firmer --
4 firmer conclusions from this.

5 BY MR. SCHOETTES:

6 Q Actually, I'm going to go back to the
7 factors. You did not identify length of time that
8 the person has been infected with HIV. Is that
9 not a factor in whether we -- you would see
10 illnesses associated with premature aging in that
11 individual?

12 A There are studies that have shown length
13 of time on ART is -- more likelihood of
14 development of cardiovascular disease. And the
15 issue is, is it due to the HIV itself or is it due
16 to a bunch of regimens that that person had seen
17 over the course of their HIV illness, and is it an
18 ART-related issue or is it both? I mean,
19 there's...

20 Q Is it also possible that the onset of the
21 illnesses associated with premature aging could be
22 affected by the regimen used on a particular
23 individual?

24 MS. BERMAN: Objection. Asked and
25 answered.

1 You can answer.

2 THE WITNESS: Yes.

3 BY MR. SCHOETTES:

4 Q Are some of the people that are now aging
5 with HIV, did they take regimens that are no
6 longer used?

7 MS. BERMAN: Objection. Calls for
8 speculation.

9 You can answer.

10 THE WITNESS: Yes.

11 BY MR. SCHOETTES:

12 Q And we have newer medications to treat
13 HIV on a fairly regular basis, correct?

14 MS. BERMAN: Objection. Calls for
15 speculation.

16 You can answer.

17 THE WITNESS: Correct.

18 BY MR. SCHOETTES:

19 Q And because we're not sure exactly what
20 the cause of this is, no one can say whether the
21 newer regimens will have the same types of effect
22 as some of the older regimens, correct?

23 A Correct. The newer regimens have not
24 been around long enough either for us to have that
25 body of data to show. So I think time will tell

1 any potential long-term side effects of our newer
2 regimens.

3 Q How many regimens, if you know, have been
4 phased out of use over the course of the 35 years
5 of the HIV epidemic?

6 A So there have been a handful of
7 antiretroviral medications that are no longer
8 being produced and have certainly been taken off
9 of our formulary within the military health care
10 system. A couple of them -- like didanosine and
11 stavudine are two that come to the top of my mind.

12 Q And, before, you talked about first-line
13 regimens and second-line regimens. Are there
14 third-line regimens?

15 A So I believe I would have to refresh my
16 memory of the DHHS guidelines for ART treatment,
17 but I believe they list them as first-line and
18 then alternative regimens, there's a category for.
19 And that includes, I think, all of the -- and then
20 there are -- there is a not recommended category
21 as well for ART.

22 Q And the two medications that you just
23 identified would fall into the not recommended
24 category at this point?

25 A They would, yes.

1 Q And how many medications are in the not
2 recommended category at this point?

3 A I would be speculating off the top of my
4 head, but I'm sure it's a handful.

5 Q Okay. There's a sentence here that says,
6 "A longitudinal cohort observation study found
7 that numerous patients with asymptomatic
8 neurocognitive impairment (ANI), even with a
9 suppressed plasma viral load, eventually developed
10 symptomatic neurocognitive impairment."

11 Are you familiar with the longitudinal
12 cohort observation study referenced there?

13 A Perhaps not this exact study, but I am
14 aware of different studies that have looked at
15 this and have shown that this is to be the case,
16 that even HIV-infected service -- or personnel
17 with suppressed viral loads can still demonstrate
18 asymptomatic neurocognitive impairment.

19 Q Would you look to page 30 and it's -- the
20 longitudinal study is identified there.

21 A Reference 8.

22 Q Yes. Is this one with which you are
23 familiar?

24 A Again, I'd have to see the exact -- I'd
25 have to see the article to -- to really confirm

1 that I have seen this individual study.

2 Q Okay. The next sentence admits that,
3 "The impact of these potential neurocognitive
4 impairments on a service member's readiness,
5 resilience and/or retention is currently unknown."

6 Would you agree with that statement?

7 A Yes.

8 Q The next sentence talks about the
9 HIV-positive population on -- "As the HIV-positive
10 population on ART ages" -- ART is capitalized,
11 A-R-T -- "there is greater recognition that
12 cerebrovascular disease risk factors such as
13 hypertension, diabetes and hypercholesterolemia
14 may become risk factors for cognitive impairment."

15 Are those also risk factors for cognitive
16 impairment for people who are not HIV-positive?

17 A Yes. They certainly are.

18 Q So right now, we're not sure the extent
19 to which HIV-positive service members will be
20 disproportionately impacted with neurocognitive
21 impairments; is that correct?

22 MS. BERMAN: Objection. Again, he's --
23 the scope of his testimony will only be for the
24 Army. And also this calls for speculation.

25 But you can answer.

1 THE WITNESS: Yes, I would say that's
2 correct.

3 BY MR. SCHOETTES:

4 Q Is there any reason the Army would not be
5 able to identify and address neurocognitive
6 impairments in HIV-positive people just as it
7 would in the population not living with HIV?

8 A So the diagnosis of HAND, HIV-associated
9 neurocognitive disorder, is fairly complicated.
10 It's actually -- by definition, it's a clinical
11 diagnosis. We don't have MRI imaging or
12 electroencephalogram -- EEG -- readouts that say,
13 yes, based on this study, this person definitively
14 has HIV-associated neurocognitive disorder.

15 It's based on more of what's called
16 neuro -- neuropsychiatric testing or
17 neuropsychological testing profiles that are
18 pretty complex and have a lot of different
19 variables to them. So it's more of a clinical
20 diagnosis based on that testing. And we use brain
21 imaging, like MRIs and EEGs and lumbar punctures,
22 to rule out other infections, to make sure we're
23 not missing another diagnosis.

24 So it's very -- bottom line, it's very --
25 it's a very unique testing panel that goes into

1 formal diagnoses of HAND.

2 Q So that's specific with respect to HAND,
3 which is HIV-associated neurocognitive disorder,
4 which, I'm assuming, a person who is not living
5 with HIV would not have -- could not have. So
6 what I actually am asking is just neurocognitive
7 impairments as they occur in the general
8 population, is there any reason why the
9 neurocognitive impairments that might be the
10 result of HAND could not be addressed in the same
11 way as neurocognitive impairments that occur in
12 the general population?

13 MS. BERMAN: Objection. Assumes facts
14 not in evidence.

15 You can answer the question.

16 THE WITNESS: I don't think so. I'm a
17 little confused, though, at what you're trying to
18 ask.

19 BY MR. SCHOETTES:

20 Q Well, I'm assuming that the Army has some
21 way of identifying and addressing neurocognitive
22 impairments that might occur to service members in
23 general. Correct?

24 A I mean, we do -- neuropsychologic testing
25 is our battery that is performed for most cases of

1 neurocognitive impairment, whether it's
2 HIV-related or not. So -- so in answer to your
3 question, yes, there is a way to identify that.

4 Q And what I'm asking is, is there any
5 reason that HIV-associated neurocognitive
6 impairment would not be diagnosed using those
7 tests in the same way?

8 A The only issue is that there's a lot of
9 unknowns, as this is stating, regarding, you know,
10 the extent of neurocognitive impairment and, you
11 know, further details of exactly the
12 pathophysiology and the mechanism of what's
13 causing this neurocognitive impairment.

14 So I think -- I think that's what
15 you're -- I mean, so that's the issue that I have,
16 I guess, is that --

17 Q Yeah.

18 A -- based on what they are saying in here
19 as well, that there's -- there's a lot of unknowns
20 regarding this. So giving everybody a formal
21 diagnosis of, yes, you have neurocognitive
22 impairment or, no, you do not, I don't think it's
23 as -- it's not black and white because of all
24 these unknowns.

25 Q And I understand, in terms of a diagnosis

1 and being able to say it is HIV-associated or not
2 and -- I guess what I'm asking is, to the extent
3 that it's having an impact on a person's memory,
4 concentration, attention, motor skills, it seems
5 to me that that could be diagnosed in a person
6 with HIV or without HIV in the same manner. Am I
7 correct?

8 MS. BERMAN: Objection. Form.

9 You can answer.

10 THE WITNESS: I don't know how to best
11 answer that, to be honest with you. I mean, I --
12 a service member without HIV infection who had
13 these similar symptoms would undergo similar
14 testing, if that answers your question.

15 BY MR. SCHOETTES:

16 Q Yeah. So I guess what I'm asking is, you
17 offered neurocognitive impairments as a reason why
18 HIV-positive individuals should not be deployed or
19 are not fit to serve. And I'm asking why, given
20 its relatively low occurrence in all populations,
21 why wouldn't it just be diagnosed as if the person
22 didn't have HIV, and addressed as a neurocognitive
23 impairment separately from the fact that the
24 person has HIV?

25 MS. BERMAN: Objection. Mischaracterizes

1 the testimony. And form.

2 THE WITNESS: I see what you're -- I
3 think I see what you're saying. The issue with --
4 regardless of HIV infection, if we take that even
5 out of the picture here, whether somebody has HIV
6 infection or not, it's still a clinical diagnosis.
7 So it's fairly subjective based on the results of
8 testing.

9 So there's certainly potential for some
10 people to get diagnosed, some people not to get
11 diagnosed formally. Right? So I guess in that
12 setting, it's not -- again, it's not a black or
13 white, like, you obviously have neurocognitive
14 impairment, we're not going to deploy you, versus
15 you're cleared -- you're cleared to deploy, if
16 that's what you're...

17 BY MR. SCHOETTES:

18 Q Do you know what the current prevalence
19 of HIV-associated neurocognitive disorder is among
20 the population in the military living with HIV?

21 A In the military living with HIV overall,
22 no, I don't know that. So when you talk about
23 HIV-associated neurocognitive disorder, it's a
24 spectrum, so everything from asymptomatic
25 neurocognitive disorder to HIV-associated

1 dementia. So every -- and there's a couple, you
2 know, gray areas between there.

3 So I mean, it's kind of -- obviously, you
4 can see that if somebody has asymptomatic
5 neurocognitive disorder, it's very hard to
6 calculate that because they're not demonstrating
7 any obvious symptoms or signs to suggest that. So
8 it's --

9 Q And is that the reason why you don't have
10 an estimate of prevalence within the military or
11 is that why you don't have an estimate across the
12 general population?

13 MS. BERMAN: Objection. Compound. Lack
14 of foundation.

15 You can answer.

16 THE WITNESS: Exactly the latter, that we
17 don't have a good estimate of that nationwide, let
18 alone within the military.

19 BY MR. SCHOETTES:

20 Q And do you have an estimate of the
21 percentage of the population with HIV in the
22 military who are exhibiting symptoms in a way that
23 has impacted their ability to perform their
24 duties?

25 MS. BERMAN: Objection. Vague.

1 "Pharmaceutical supplies intended for emergency
2 nPEP will not be compromised for PrEP."

3 So nPEP is, as you said, nonoccupational
4 exposures. So nPEP is kept on hand for potential
5 sexual exposures?

6 A So I think this could classify as nPEP or
7 PEP, you know, in general, needle stick exposures.
8 Like I had mentioned before, we do keep --
9 currently the pharmacies that are in OCONUS
10 settings keep a short supply of antiretrovirals --
11 and it's typically Truvada plus another
12 antiretroviral -- for use as PEP and -- or nPEP if
13 needed --

14 Q Okay. And nPEP --

15 A -- for these situations.

16 Q So -- I guess I'm wondering how nPEP is
17 used in the military. I'm imagining potentially
18 after a sexual assault?

19 A Correct.

20 Q Is it ever used for someone who comes in
21 and says, I think I may have been exposed sexually
22 to HIV?

23 A Yes.

24 Q Okay. But you're saying that really this
25 sentence, the "n" could be taken off of PEP there?

1 A Yes. That's what I'm saying.

2 Q Okay. I think I'm good there. You can
3 put that document aside. Give me a second. I
4 need to find this document to do this part of my
5 outline.

6 (Pause.)

7 BY MR. SCHOETTES:

8 Q We're going to continue on and I will
9 come back to this after we've taken a break.

10 I'm going to talk about topic 23 which is
11 accessions and deployment policies for other
12 conditions requiring daily medication. Are you
13 familiar with the medical condition of
14 dyslipidemia?

15 A Yes, I am.

16 Q What kind of treatment does dyslipidemia
17 generally require?

18 A Generally, it requires a
19 cholesterol-lowering medication, typically from a
20 class we call statins.

21 Q Taken daily?

22 A Yes.

23 Q Generally one pill?

24 A Yes.

25 Q Once a day?

1 A Yes.

2 Q What is the accession policy for
3 individuals with dyslipidemia?

4 A I don't believe it specifically mentions
5 dyslipidemia as a limiting restriction to joining
6 the military.

7 Q And if it's not listed specifically, then
8 it would not be a bar to enlisting or
9 commissioning?

10 A I believe there's a line in our
11 accessions policy that says every medication can
12 be looked at on an individual basis for
13 consideration for whether it merits accessioning
14 or not.

15 MS. BERMAN: Counsel, I just want to
16 reiterate that this witness is here to provide
17 medical testimony as it applies to these
18 questions. We did offer someone to talk about
19 accessions in a more policy-specific way. And
20 deployment as well.

21 MR. SCHOETTES: Okay.

22 MS. BERMAN: But you --

23 MR. SCHOETTES: I just want to try to
24 understand what portion of the topic -- I mean, I
25 don't want to waste our time if he's not

1 testifying on the topic. So...

2 MS. BERMAN: As we discussed earlier,
3 it's just -- he's going to talk about these
4 conditions and how they might be different than
5 HIV, might be treated same or different than HIV.
6 But I think it's fine. You can --

7 MR. SCHOETTES: Okay.

8 MS. BERMAN: -- continue your
9 questioning.

10 BY MR. SCHOETTES:

11 Q All right. So if a soldier is diagnosed
12 with dyslipidemia after enlisting or
13 commissioning, are they discharged?

14 A No.

15 Q If a soldier is required to start taking
16 daily medication for dyslipidemia, are they
17 discharged?

18 A No.

19 Q What is the deployment policy for
20 individuals with dyslipidemia?

21 A So I don't know exactly what the
22 deployment policy is with [sic] somebody with
23 dyslipidemia, but if it is very well controlled on
24 a once-daily statin regimen, they would be allowed
25 to deploy.

1 Q And are individuals with dyslipidemia
2 supplied with their medication during
3 deployment -- well, let me go back.

4 How are individuals living with
5 dyslipidemia supplied with their medication during
6 deployment?

7 A So if they don't already bring a 270-day
8 or whatever duration their deployment is, supply
9 with them, they can sign up via TRICARE Express
10 Scripts to have it mailed to them throughout their
11 deployment.

12 Q If they go with 180-day supply on a
13 270-day deployment, how long into their deployment
14 before they can request a refill of their
15 prescription?

16 A I don't know the exact time frame that
17 TRICARE would -- mandates for you before you can
18 get a refill of a medication.

19 Q Would it take into account the fact that
20 it might take some time for that refill to get to
21 the individual who is deployed?

22 A I would hope so, but I can't tell you
23 definitively.

24 Q And if the medication of a person with
25 dyslipidemia was lost, stolen or destroyed while

1 deployed, would they be resupplied in the manner
2 that we discussed earlier for all of their
3 medications?

4 A Yes.

5 Q Besides for [sic] receiving treatment,
6 are soldiers handled -- are soldiers with
7 dyslipidemia handled differently in any respect?

8 MS. BERMAN: Objection. Vague.

9 BY MR. SCHOETTES:

10 Q I can ask a more specific question. Are
11 individuals living with dyslipidemia referred into
12 the DES under 1332.18?

13 A I don't know -- I don't know how to
14 exactly address that, because I would imagine it
15 would -- if they have very uncontrolled
16 dyslipidemia that -- despite being on appropriate
17 statins or other agents to reduce cholesterol,
18 then they very well may be referred to the DES.

19 Q And to clarify, the DES is the Disability
20 Evaluation System?

21 A Correct.

22 MS. BERMAN: And I want to reiterate that
23 this witness is not being offered to talk about
24 retentions, so...

25 MR. SCHOETTES: Right.

1 BY MR. SCHOETTES:

2 Q And they're certainly not referred into
3 the DES automatically upon diagnosis?

4 A No.

5 Q Are you familiar with the medical
6 condition of hypothyroidism?

7 A Yes.

8 Q What kind of treatment does
9 hypothyroidism generally require?

10 A It generally requires a pill called
11 levothyroxine. It's a -- it's a synthetic thyroid
12 replacement medication taken once daily.

13 Q I'm going to go back for a moment. What
14 are the consequences of not taking one's
15 dyslipidemia medication?

16 A So the consequences of not taking that
17 daily, it depends on the duration of time that you
18 go without it, but your cholesterol levels
19 increase and, over time, you may be at higher risk
20 of heart disease, stroke, all the other
21 complications of dyslipidemia that goes untreated.

22 Q Including some potentially fatal
23 conditions?

24 A Yes.

25 Q So what are the consequences of untreated

1 hypothyroidism?

2 A So if it goes untreated, then you
3 develop -- in many cases, you can develop
4 symptomatic hypothyroidism which is manifested by
5 a number of symptoms to include extreme fatigue,
6 weight gain, cold intolerance, constipation.

7 Q All things that could affect one's
8 ability to perform one's duties as a soldier,
9 correct?

10 A Correct.

11 Q What is the accession policy for
12 individuals with hypothyroidism?

13 A Individuals with hypothyroidism are, if
14 it's well controlled, are allowed to accession.

15 Q And if a service member is diagnosed with
16 hypothyroidism after enlisting or commissioning,
17 are they discharged?

18 A No.

19 Q If they're required to start taking daily
20 medication for their hypothyroidism, are they
21 discharged?

22 A No.

23 Q Do you know what the deployment policy is
24 for individuals with hypothyroidism?

25 A As long as it's well controlled, then

1 they are allowed to deploy.

2 Q And are they supplied with their
3 medication during that deployment and -- if it is
4 lost or stolen in the same manner as people with
5 dyslipidemia or any other condition?

6 MS. BERMAN: Objection. Compound.

7 You can answer.

8 THE WITNESS: Yes.

9 BY MR. SCHOETTES:

10 Q Are you familiar with any conditions
11 requiring hormone replacement therapy?

12 A I mean, there's a number of different
13 reasons people go on hormone replacement therapy,
14 whether it even be oral contraceptive pills versus
15 premature menopause or -- you know, for our active
16 duty population in particular.

17 Q What is the -- is there one that's most
18 common that creates a need for hormone replacement
19 therapy?

20 A You mean as far as what I just mentioned
21 there? I mean, oral contraceptive pills are
22 probably the most commonly used by females in the
23 military.

24 Q Are you familiar with the condition
25 called dysmenorrhea?

1 noticeable symptoms as a result of that loss of
2 medication?

3 MS. BERMAN: Objection. Calls for
4 speculation.

5 You can answer.

6 THE WITNESS: So that time frame is very
7 variable. It depends on a lot of factors that
8 we've already discussed, in particular, the
9 environment that that person is working in with
10 regards to their potential exposure to environment
11 stimulants that affect the immune system.

12 Also, what that person's baseline CD4
13 count was at the time they stopped taking the
14 medication. And that person's individual immune
15 system, how it reacts to not being on
16 antiretroviral therapy for a period of time.

17 BY MR. SCHOETTES:

18 Q Is there a -- are you able to provide
19 what the average time would be before you would
20 see a significant increase in the person's viral
21 load assuming they were -- had a suppressed viral
22 load before the loss of medication?

23 A So there are studies that have looked at
24 this before, kind of what's called viral load
25 rebound, or rebound viremia, after stopping

1 antiretroviral therapy. The majority of the
2 studies seem to show that within even as early as
3 nine days, you can see evidence of viral load,
4 significant viral load rebound after stopping
5 antiretroviral therapy.

6 There is some data to show that the
7 earlier somebody is started on antiretroviral
8 therapy shortly after their diagnosis, if they do
9 stop it later on, that rebound may not occur for
10 outwards of 50 days or so. But the -- most of the
11 studies have shown what I've seen to be an average
12 of about nine days.

13 Q And when you say significant viral
14 rebound, do you have a demarcation point at which
15 you are setting significant viral --

16 A No, I don't. I'd have to look closer at
17 those studies to see what the actual viral loads
18 are that they're depicting.

19 Q Are you familiar with genotype testing to
20 identify resistance in the HIV virus?

21 A Yes.

22 Q Do you have a sense -- or can you tell us
23 how long it would take before there was enough
24 virus in the blood to do genotype testing after
25 stopping treatment?

1 their HIV as a result of stopping medication?

2 MS. BERMAN: Objection. Vague.

3 You can answer.

4 THE WITNESS: I mean, again, that -- it
5 depends on what you're categorizing as symptoms
6 and then also it depends on that person's baseline
7 immune status. And there's a very broad range of
8 time period between symptom onset after
9 stopping -- or when having uncontrolled HIV
10 infection.

11 BY MR. SCHOETTES:

12 Q If HIV is left untreated, for how long
13 after infection does it remain asymptomatic?
14 Again, it would have to be an average, because I
15 understand everyone is different --

16 A Yes.

17 Q -- but what's the average amount of time?

18 MS. BERMAN: Objection. Vague.

19 Go ahead.

20 THE WITNESS: So average amount of time
21 in our early studies of HIV infection prior to
22 treatment were anywhere from two years to ten
23 years. So on average, maybe around five years,
24 you could say. But typically, again, those
25 studies were conducted prior to combination

1 antiretroviral therapy and those -- we're talking
2 pretty severe symptoms, like opportunistic
3 infections, malignancy, to include lymphoma,
4 Kaposi's sarcoma, so pretty significant infections
5 and disease processes that occur with untreated
6 for that long.

7 Q The things that could actually lead to a
8 person being disabled by their HIV?

9 A Yes.

10 Q What is the course of treatment after
11 treatment interruption? What would the normal
12 plan be for such an individual?

13 A To restart your antiretroviral therapy as
14 soon as possible.

15 Q To restart the regimen you were on?

16 A Correct. And then hope to obtain a
17 genotype on -- after being on that therapy for
18 typically three weeks to a month, because that
19 would be our best assessment of if you've
20 developed any resistance to that regimen after
21 stopping it for periods of time.

22 Q You would do a genotype at that point or
23 would a viral load test indicate whether the same
24 regimen was being -- was still effective?

25 A So you can't do a genotype without

1 getting a viral load. So they kind of go hand in
2 hand, because you get the genotype based on that
3 viral load, if that makes sense.

4 Q So the individual who goes back on
5 treatment would be on treatment for some period of
6 time, the same treatment?

7 A Yes.

8 Q And you would see if the viral load went
9 back to suppressed or undetectable?

10 A Correct. So you would assess that at the
11 three to four-week period after they restart that
12 regimen. You would want to get a viral load with
13 a genotype at three to four weeks after being back
14 on that regimen.

15 Q What if they didn't have enough viral --
16 virus at that point to do a genotype?

17 A Then that would be great. Then we
18 wouldn't need a genotype.

19 Q Right.

20 A The goal is to see that they've either
21 suppressed their viral load again or, if not,
22 we're going to try to get a genotype to see if
23 they've developed resistance.

24 Q Got it. Is it possible that they would
25 have -- that it would have been reduced, but they

1 maybe had not gotten all the way back down to
2 suppressed at that point, in which case what do
3 you do?

4 A We would still --

5 MS. BERMAN: Objection. Form.

6 THE WITNESS: We -- can I still answer?

7 MS. BERMAN: Yes.

8 THE WITNESS: We would still want to
9 check a genotype because it might give us a
10 glimpse into a new resistance panel and it may
11 prompt us to switch that regimen.

12 BY MR. SCHOETTES:

13 Q But that would require at least a
14 thousand copies if you used the one test?

15 A Right, 1,000 to 2,000 copies, yes.

16 Q Okay. What concerns, if any, is there
17 around -- well, I guess we were just talking about
18 this. Do you know what the likelihood is of
19 resistance after treatment interruption?

20 MS. BERMAN: Objection. Vague and calls
21 for speculation.

22 You can answer.

23 THE WITNESS: Yeah. I mean, it depends
24 on a lot of different variables. So it's -- you
25 are more likely to acquire resistance if you're

1 intermittently taking your medications. So one
2 thing that we always try to couch [sic] our
3 patients about is when you're -- sometimes what
4 our patients do -- because, for various reasons,
5 they may not come back in to get refills of their
6 medications or run out of their meds -- sometimes
7 what they do is they start spacing out the dosing
8 of their medication. So they'll say, oh, I'll
9 take it every other day or every third day to make
10 it last longer. That's exactly how you develop
11 resistance. So it's actually better to stop it
12 cold turkey and then restart it up later. That's
13 your best option for not developing resistance.

14 So it depends on if somebody is taking
15 their meds intermittently to space them to -- or
16 stops it altogether.

17 BY MR. SCHOETTES:

18 Q So in the context of lost medication, and
19 it's a sustained stop, that would be less likely
20 to develop resistance than someone intermittently
21 taking their medication?

22 A Correct. The other thing that you have
23 to take into account is the half life of the
24 particular drug in the body. So there's different
25 antiretroviral regimens that have longer half

1 lives or shorter half lives. So missing one or
2 two medications of one drug might be not as --
3 might be less forgiving than missing one or two
4 days of another drug.

5 Q And that's more of a concern in that
6 intermittent drug-taking scenario --

7 A Yes.

8 Q -- than it would be in a full stop?

9 A Yes.

10 Q Because the half life on all of them is
11 going to sort of run out relatively quickly and
12 then there won't be anything that the virus could
13 mutate around, because there's only one of the
14 medications left, right?

15 A Correct.

16 MR. SCHOETTES: I think I'm done.

17 MS. BERMAN: Okay. I think we want to
18 talk for a minute about whether I have any
19 follow-up questions. And -- so if we want to go
20 off the record for a minute, I may have a few
21 more.

22 MR. SCHOETTES: Sounds good.

23 THE VIDEOGRAPHER: The time is 3:28 p.m.
24 We are going off the record.

25 (Whereupon, a short recess was taken.)

1 THE VIDEOGRAPHER: The time is 3:35 p.m.
2 We are back on the record. Please proceed,
3 Counsel.

4 EXAMINATION BY COUNSEL FOR THE
5 U.S. DEPARTMENT OF JUSTICE
6 BY MS. BERMAN:

7 Q Colonel Blaylock, I just want to clarify
8 a few things. You and counsel were talking about
9 the CDC guidelines earlier about -- that state
10 there's essentially zero risk, or approximately
11 zero risk, of transmission of HIV from a person
12 with a suppressed viral load. Does that guideline
13 specifically concern sexual transmission?

14 A Yes. That guideline does concern sexual
15 transmission only.

16 Q Is there any similar statement about
17 transmission by blood transfusion from the CDC?

18 A No, there is not.

19 Q Okay. And I think this is in the record,
20 but before, when you were talking about the risk
21 of transmission by blood transfusion, I believe
22 you and counsel were talking about the scenario of
23 someone with an increased viral load, someone who
24 was not fully suppressed. Is there also a
25 significant risk of transmission from a person

1 with a suppressed viral load by blood transfusion?

2 A Yes. There would still be a significant
3 risk, even if the viral load was suppressed under
4 20 copies because, again, that's not zero copies;
5 that's -- could be ten copies per milliliter of
6 blood.

7 So when you're looking at a total of 250
8 to 300 milliliters of blood in a whole unit of
9 blood, that risk becomes more substantial.

10 Q Okay. Do you have any estimate of the
11 percentage risk of transmission in both of those
12 scenarios, both the suppressed viral load scenario
13 and the unsuppressed viral load scenario?

14 A So, unfortunately, the only solid data
15 that we have is pretty old CDC data from -- I
16 believe it was 1990 when it was published that
17 talked about the risk via blood transfusion. And
18 they did not separate it out into folks who had
19 very low viral loads, or even undetectable viral
20 load, and those that had high viral load.

21 We just know across the board, across
22 everybody with HIV, there was upwards of
23 90 percent transmission rate from somebody who was
24 HIV-infected donating blood.

25 Q Okay. And we talked about this somewhat,

1 between a person with a high viral load and one
2 with a suppressed viral load?

3 A I think it's -- I don't think there are
4 studies that have looked at somebody with an
5 undetectable viral load, their ability to transmit
6 virus to a seronegative person. That would be a
7 very unethical study.

8 Q Right.

9 MR. SCHOETTES: Okay. That's all I have.

10 MS. BERMAN: Okay. We're done, then.

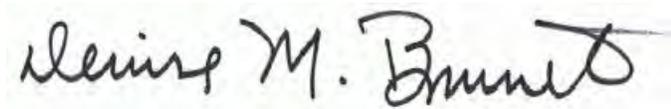
11 THE VIDEOGRAPHER: The time is 3:54 p.m.
12 This concludes today's testimony given by the
13 United States Army and Dr. Jason Blaylock. We are
14 now off the record.

15 (Whereupon, at 3:54 p.m., the deposition
16 of JASON BLAYLOCK was concluded.)
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CERTIFICATE OF NOTARY PUBLIC

I, Denise M. Brunet, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was sworn by me; that the testimony of said witness was taken by me stenographically and thereafter reduced to print by means of computer-assisted transcription by me to the best of my ability; that I am neither counsel for, related to, nor employed by any of the parties to this litigation and have no interest, financial or otherwise, in the outcome of this matter.



Denise M. Brunet
Notary Public in and for
The District of Columbia

My commission expires:
December 14, 2022

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Veritext Legal Solutions
1100 Superior Ave
Suite 1820
Cleveland, Ohio 44114
Phone: 216-523-1313

March 12, 2019

To: Keri L. Berman, Esq.

Case Name: Harrison, Nicholas, et al. v. Mattis, James N., et al.

Veritext Reference Number: 3235700

Witness: Jason Blaylock Deposition Date: 2/27/2019

Dear Sir/Madam:

Enclosed please find a deposition transcript. Please have the witness review the transcript and note any changes or corrections on the included errata sheet, indicating the page, line number, change, and the reason for the change. Have the witness' signature notarized and forward the completed page(s) back to us at the Production address shown above, or email to production-midwest@veritext.com.

If the errata is not returned within thirty days of your receipt of this letter, the reading and signing will be deemed waived.

Sincerely,
Production Department

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DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 3235700
CASE NAME: Harrison, Nicholas, et al. v. Mattis, James N.
DATE OF DEPOSITION: 2/27/2019
WITNESS' NAME: Jason Blaylock

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.

I have made no changes to the testimony as transcribed by the court reporter.

Date Jason Blaylock

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;
They signed the foregoing Sworn Statement; and
Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal
this _____ day of _____, 20____.

Notary Public

Commission Expiration Date

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DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 3235700
CASE NAME: Harrison, Nicholas, et al. v. Mattis, James N.
DATE OF DEPOSITION: 2/27/2019
WITNESS' NAME: Jason Blaylock

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.

I have listed my changes on the attached Errata Sheet, listing page and line numbers as well as the reason(s) for the change(s).

I request that these changes be entered as part of the record of my testimony.

I have executed the Errata Sheet, as well as this Certificate, and request and authorize that both be appended to the transcript of my testimony and be incorporated therein.

Date Jason Blaylock

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

- They have read the transcript;
- They have listed all of their corrections in the appended Errata Sheet;
- They signed the foregoing Sworn Statement; and
- Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal
this _____ day of _____, 20____.

Notary Public

Commission Expiration Date

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ERRATA SHEET
VERITEXT LEGAL SOLUTIONS MIDWEST
ASSIGNMENT NO: 2/27/2019

PAGE/LINE(S) / CHANGE /REASON

Date Jason Blaylock
SUBSCRIBED AND SWORN TO BEFORE ME THIS _____
DAY OF _____, 20_____ .

Notary Public

Commission Expiration Date