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

SUF ¶ 55	16:6-7	Ex. 33, Hendrix Dep. 157:11-159:14	Ex. 33, Hardy Dep. 157:11-159:14
SUF ¶ 61	17:12	Ex. 33, Hendrix Dep. 159:24-160:17	Ex. 33, Hardy Dep. 159:24-160:17
SUF ¶ 62	17:18	Ex. 33, Hendrix Dep. 174:6-10, 174:19-175:17	Ex. 33, Hardy Dep. 174:6-10, 174:19-175:17
SUF ¶ 64	17:23-24	Ex. 33, Hendrix Dep. 142:17-144:15, 156:21-157:3	Ex. 32, Hendrix Dep. 142:17-144:15, 156:21-157:3; Ex. 33, Hardy Dep. 175:3-176:10
SUF ¶ 67	18:16	Ex. 33, Hendrix Dep. 311:1-10	Ex. 32, Hendrix Dep. 311:1-10; Ex. 33, Hardy Dep. 161:11-16
RSUF ¶ 25	29:4	Ex. 33, Hendrix Dep. 144:5-9, 152:21-153:5	Ex. 32, Hendrix Dep. 144:5-9, 152:21-153:5; Ex. 33, Hardy Dep. 80:23-81:25
RSUF ¶ 26	29:8-9	Ex. 33, Hendrix Dep. 64:18-65:8	Ex. 33, Hardy Dep. 64:18-65:8
RSUF ¶ 37	31:8	Ex. 12, Aswell Dep. 59:10-18	Ex. 17, Aswell Dep. 59:10-18
RSUF ¶ 61	33:19	Ex. 12, Aswell Dep. 119:11-121:17	Ex. 17, Aswell Dep. 119:11-121:17
Soper Decl. (Under Seal)	Cover Sheet	Exhibit 22	Exhibit 25
Mot. to Exclude Memorandum	Pgs. 9-10	Nat'l Science Foundation, *Science & Technology: Public Attitudes and Understanding*, WWW.NSF.GOV (in 2016, 27% of survey respondents reporting that the Earth revolves around the sun).	Nat'l Science Foundation, *Science & Technology: Public Attitudes and Understanding*, WWW.NSF.GOV (in 2016, 26% of survey respondents reporting that the sun revolves around the Earth)

DATE: June 11, 2020

Respectfully submitted,

G. ZACHARY TERWILLIGER
United States Attorney

/s/
DENNIS C. BARGHAAN, JR.
Deputy Chief, Civil Division
2100 Jamieson Avenue
Alexandria, Virginia 22314
Tel: (703) 299-3891

JOSEPH H. HUNT
Assistant Attorney General
Civil Division

ANTHONY J. COPPOLINO
Deputy Director
Federal Programs Branch

JOSHUA C. ABBUHL

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

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

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

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.

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.

EXAMINATION INDEX

	PAGE
EXAMINATION BY MR. SCHOETTES	5, 353
EXAMINATION BY MR. NORWAY	304

E X H I B I T S

EXHIBIT	DESCRIPTION	PAGE
Exhibit 1	Notice of Deposition	8
Exhibit 2	Defendants' Disclosure Pursuant to Rule 26(a)(2)(C)	10
Exhibit 3	DoD's 2018 Report to Congress . .	27
Exhibit 4	PowerPoint presentation entitled "HIV Update: Current Status, Policy & Deployment Considerations" . .	90
Exhibit 5	U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV, Bates us00004426	295
Exhibit 6	DoD Instruction 6130.03	299
Exhibit 7	Active Duty ART Outcomes V2.0, Bates USX00000012	312

things such as diarrhea aren't, aren't capable of being used as a biological warfare agent. So you can see scenarios where someone could potentially use HIV as an instrument to deliver biological warfare agent on the battlefield.

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

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

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

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

MR. NORWAY: Objection. Vague.

You may answer to the extent that you know.

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

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

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

BY MR. SCHOETTES:

Q But in terms of a found needle --

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

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

A Correct.

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

You may answer.

THE WITNESS: Correct.

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

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

BY MR. SCHOETTES:

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

MR. NORWAY: Objection. Form.

You may answer.

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

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

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

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

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

BY MR. SCHOETTES:

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

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

BY MR. SCHOETTES:

Q They are unlikely?

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

Q But they do use gloves?

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

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

Q What do they use for antimicrobial protection?

A Correct. The recommended battlefield

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

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

MR. NORWAY: Objection. Form.

You may answer.

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

BY MR. SCHOETTES:

Q Do they attempt to sanitize their hands?

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

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

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

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

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

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

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

asking for something that is defined by the Army.

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

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

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

Q For a particular theater?

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

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

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

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

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

Q Got it.

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

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

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

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

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

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

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

You may have -- from a medical

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

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

BY MR. SCHOETTES:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

referring to.

BY MR. SCHOETTES:

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

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

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

A Correct.

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

MR. NORWAY: Objection. Form. Mischaracterizes his testimony.

You may answer.

THE WITNESS: Is there a question?
BY MR. SCHOETTES:
Q Yes. Does that 99.8 percent indicate that we're talking about only two out of 1,000 individuals would not have achieved viral suppression?
A Correct.
Q The next column is "Viral Suppression Within Six Months of ART Initiation."
Can you just tell us what "ART" stands for?
A Antiretroviral therapy.
Q And this shows that approximately 75 percent of people diagnosed with HIV between 2012 and 2016 achieved viral suppression within six months; is that correct?
A Correct.
MR. NORWAY: Objection.
Foundation.
You may answer.
THE WITNESS: Correct.
BY MR. SCHOETTES:
Q It says here at the bottom, "Viral suppression has occurred with 90 plus percent of service members becoming virally suppressed ever

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

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

MR. NORWAY: Objection. Form.

You may answer.

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

BY MR. SCHOETTES:

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

What does that mean?

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

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

group being followed for three.

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

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

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

A Correct.

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

A That's my addition.

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

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

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

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

MR. NORWAY: Objection. Form.

You may answer.

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

BY MR. SCHOETTES:

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

MR. NORWAY: Objection. Form.

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

five percent is a reasonable area to move.
BY MR. SCHOETTES:
Q If you go now to the next slide again, there are zeros in the last column at approximately one year, it looks like.
What do those zeros indicate?
A So again, I don't know if that is sitting before or after 12 months. I can't actually tell you if those are all those time points.
Q For whatever time point it's at, let's say it's at 12, what do those zeros indicate?
A Those indicate viral suppression.
Q Meaning that everyone had achieved viral suppression from the various cohorts described?
A So as evident on the previous slide, 99.8 ever, 98.8 and 97.1, so three percent to .2 percent. That would be an assumption that could be made. I would like to see the absolute data to be able to say that for sure, which is why I wrote this statement "90 plus percent," because I think that's not overstating the facts.
Q If you go to slide 27, which has "Mortality and Morbidity" at the top, does this slide indicate that essentially no one in the

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

MR. NORWAY: Objection.

There's no question pending.

Sorry.

BY MR. SCHOETTES:

Q How do you know that to be the situation?

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

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

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

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

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

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

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

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

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

Did the Army know that this individual had HCV?

MR. NORWAY: Objection. Form.

You may answer.

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

BY MR. SCHOETTES:

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

A However, they don't screen for hepatitis

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

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

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

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

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

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

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

MR. NORWAY: Objection. Form. Objection. Foundation. Objection. Mischaracterizes the testimony.

You may answer.

THE WITNESS: I would disagree with

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

BY MR. SCHOETTES:

Q Hold up just one record. All recorded?

A Mm-hmm.

Q So these are all instances that --

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

Q Okay.

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

Q Continue.

A Okay.

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

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

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

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

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

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

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

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

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

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

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

Q You said that there is a recommended

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

MR. NORWAY: Objection. Form. Objection. Foundation.

BY MR. SCHOETTES:

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

MR. NORWAY: Objection. Form. Foundation.

You may answer.

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

BY MR. SCHOETTES:

Q Why not?

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

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

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

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

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

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

level of risk?

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

Q When is that CDC guidance from?

A What do you mean "from"?

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

MR. NORWAY: Objection. Form.

You may answer.

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

BY MR. SCHOETTES:

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

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

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

A When they're giving descriptions of what

that surgeon does with the needlestick.

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

MR. NORWAY: Objection. Form.

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

What they don't come out and say is

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

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

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

BY MR. SCHOETTES:

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

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

MR. NORWAY: Objection. Form. Foundation.

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

BY MR. SCHOETTES:

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

MR. NORWAY: Objection. Form. Foundation.

trying to have with the command surgeons.
BY MR. SCHOETTES:
Q So let me break this down a little bit further.
Where does the two in 1,000 for needlestick come from?
A So if you look at the site where I pulled this from, it was on there.
Q I'm sorry. The site from the page before, the slide before?
A Yeah, the Google site or the hyperlink. It's a New York City discussion of "undetectable, untransmittable," which I thought they did a very nice job of capturing really the four studies, with some subtleties within those studies, and I think they did a nice job of walking through the sharps exposure and the pregnancy discussion.
I think they were trying to do the same thing that I'm trying to do tomorrow, which is paint this broader discussion of how science, medicine, HIV is improving in the environment of a constrained or austere environment or the challenges downrange.
Q But can you now tell me what, what is the two in 1,000 or .2 percent number referring

to?

A Oh, that's transmission.

Q Transmission through needlestick in the absence of treatment?

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

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

MR. NORWAY: Objection. Form.

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

anything. No one has come out and said that.
BY MR. SCHOETTES:
Q Right, and no one is ever going to do a study, right, that's going to come up with those -- you can't do a prospective study. That would be completely unethical, right, to --
A Correct. I agree with you.
Q So how do you expect to obtain data to get to the point where you would be comfortable saying the person doesn't need to use PEP after an exposure to a person with -- a needlestick exposure to a person with an undetectable viral load?
MR. NORWAY: Objection. Form.
You may answer.
THE WITNESS: So I think there's a couple of things that are going to play into that. One is: Will the various organizations out there come out and say that? So will IDSA, HIV organization, the CDC, Public Health Service, are they all going to come out and say this? Because I'm going to have to then say this is the standard across the country now, right? We have not done that. They have shifted.

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

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

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

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

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

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

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

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

MR. NORWAY: Objection.

Foundation. Form.

You can answer.

THE WITNESS: Can you rephrase that?

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

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

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

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

(Whereupon, a short recess was taken.)

BY MR. SCHOETTES:

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

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

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

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

So I think there's criteria for them to

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Q Which one?

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

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

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

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

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

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

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

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

Q Can you explain to me --

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

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

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

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

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

So my unit is at Aberdeen Proving

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

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

MR. NORWAY: Objection. Foundation. Objection. Form.

You may answer.

THE WITNESS: Yeah, I don't know.

BY MR. SCHOETTES:

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

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

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

blew up our mail truck more than once, so --
BY MR. SCHOETTES:
Q I'm asking a slightly different question. I was asking about someone, before going on deployment, obtaining their medication through a mail-order pharmacy.
A I don't know that the mail-order pharmacy will be allowed to give them 180 days worth of medicine. That may be a contract issue.
Q You think they might be limited to 90 days?
MR. NORWAY: Objection. Form. Speculation.
You can answer.
THE WITNESS: I've never used it, so I can't answer that question, but I'm not convinced they get 180 days as patients.
BY MR. SCHOETTES:
Q And you said that's by contract, you think?
A It is a DoD contract, but I can't speak much more than that.
Q But you're saying they would be able to get the 180-day supply from an actual base that had their prescription, their medications?

MR. NORWAY: Objection. Form.
You may answer.
THE WITNESS: Maybe.
BY MR. SCHOETTES:
Q So then let's go ahead and talk about the capabilities for delivery to a deployed area. Is there anything that would prevent a person with HIV from refilling, seeking a prescription refill with a large amount of cushion, if you will, so while they still have 60 days left in their medication?
MR. NORWAY: Objection. Form. Objection. Vague. Objection. Foundation.
You may answer.
THE WITNESS: So there's scenarios we're working through right now where that would not be possible for extended periods of time.
BY MR. SCHOETTES:
Q Explain what would not be possible.
A Flights of nonmilitary specific equipment into a combat zone, so --
Q For more than 60 days?
A Mail would not be being delivered for over 30 days, correct.

Q Over 30 days?
A I'm, I'm hesitant to go much further than that for other reasons. It goes back to the, the near-peer conversation of earlier.
Q But for the purposes of the hypothetical that I posed, which is could a person seek to refill their prescription with 60 days of medication left, can you explain why the potential for a 30-day delay would --
A Because we don't know what's going to happen in the next 30 days.
MR. NORWAY: Objection. Form. Speculation.
If you would just, sir, please allow me to --
THE WITNESS: Sorry.
BY MR. SCHOETTES:
Q I'm sorry. Did you finish your response?
A So the windows of time that we're discussing is -- there are certain events that have to occur that allow follow-on, less-priority supplies to get into a theater. So if the gates aren't reached in 30 days, they still may not get that after 30 days. That's what I'm saying. I

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

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

MR. NORWAY: Objection. Vague. Objection. Form.

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

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

BY MR. SCHOETTES:

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

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

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

MR. NORWAY: Objection. Form.

THE WITNESS: Correct.

BY MR. SCHOETTES:

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

MR. NORWAY: Objection. Form. Objection. Foundation. Objection. Vague.

You may answer if you can, sir.

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

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

As you move off that and try to

taking care of people on the battlefield.

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

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

BY MR. SCHOETTES:

Q What does "MD DO" stand for?

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

Q But I was asking a slightly different

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

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

MR. NORWAY: Objection. Form. Objection. Vague, ambiguous.

You may answer if you can, sir.

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

BY MR. SCHOETTES:

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

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

Is that, is that true?

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

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

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

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

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

THE WITNESS: Can you, can you rephrase that?

BY MR. SCHOETTES:

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

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

You may answer.

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

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

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

BY MR. SCHOETTES:

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

MR. NORWAY: Objection. Form.

You may answer.

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

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

BY MR. SCHOETTES:

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

MR. NORWAY: Objection. Form. Objection. Speculation.

You may answer if you can.

THE WITNESS: Yes.

BY MR. SCHOETTES:

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

A Correct.

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

MR. NORWAY: Objection. Form. Objection. Mischaracterizes former testimony.

You may answer, sir.

THE WITNESS: No. What I'm saying

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

BY MR. SCHOETTES:

Q What prevents that system from existing?

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

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

MR. NORWAY: Objection. Form. Objection. Foundation. Improper hypothetical.

You may answer if you can.

THE WITNESS: So as we've talked

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

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

BY MR. SCHOETTES:

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

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

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

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

MR. NORWAY: Objection. Form. Foundation. Mischaracterizes the testimony.

You may answer.

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

BY MR. SCHOETTES:

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

MR. NORWAY: Objection. Vague. Objection. Foundation.

You may answer.

THE WITNESS: Not that I know of.

BY MR. SCHOETTES:

Q What does a unit that has one-deep

capability do when one person is killed?
MR. NORWAY: Objection. Form. Speculation.
You may answer.
THE WITNESS: They go non-mission-capable and ask for a replacement.
BY MR. SCHOETTES:
Q What was the first part of that?
A They go non-mission-capable, meaning they can't carry out their mission, and they ask for a replacement.
Q For how long could that be the situation where they are non-mission-capable?
MR. NORWAY: Objection. Speculation. Form.
THE WITNESS: Depends on the capability of the person that was lost.
BY MR. SCHOETTES:
Q How many units are one deep in capability?
MR. NORWAY: Objection. Foundation, form, speculation.
You may answer if you can.
THE WITNESS: So the small surgical

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

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

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

BY MR. SCHOETTES:

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

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

You may answer if you can.

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

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

So those are examples of how replacements would occur.

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

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

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

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

MR. NORWAY: Objection. Vague. Speculation.

You may answer.

THE WITNESS: Could you describe "contingency deployment"?

BY MR. SCHOETTES:

Q Probably not better than you can.

So in DoDI 6490.07, it describes conditions that are, well, that essentially require a waiver, and those deployments are called "contingency deployments." So I believe that a non-fixed medical facility is part of the description.

MR. NORWAY: Objection. Form.

Do we have a question pending?

BY MR. SCHOETTES:

Q And maybe this is a little bit better.

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

MR. NORWAY: Is there a question pending?

BY MR. SCHOETTES:

Q There was.

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

MR. NORWAY: Objection. Form.

You may answer.

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

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

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

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

BY MR. SCHOETTES:

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

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

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

Q Is mail moved into all units?

A Not all the time.

Q Is mail moved into all units eventually?

MR. NORWAY: Objection.
Speculation.
THE WITNESS: So I've seen it take four plus weeks getting mail to Ramadi, and then mail trucks get blown up, so that mail did not make it far. Let's put it that way.
BY MR. SCHOETTES:
Q Right.
A And I think that's what folks don't absolutely appreciate is the best laid plans in RPG changes. RPG changes the best laid plans by blowing up something.
Q Well, and there was a driver driving that mail truck?
A Or two.
Q Or two, and there was some decision made that the mail needed to move forward, so that risk was worth taking, correct?
MR. NORWAY: Objection.
Foundation. Form.
You may answer.
THE WITNESS: So every decision in a combat zone is buying risk. You have to always decide which side of that conversation you want to go on, and I can tell you we quit

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

BY MR. SCHOETTES:

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

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

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

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

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

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

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

absolute constraints of that potential future fight.

BY MR. SCHOETTES:

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

MR. NORWAY: Objection. Form. Vague.

You may answer.

THE WITNESS: Can you say that a little differently?

BY MR. SCHOETTES:

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

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

MR. NORWAY: Objection. Form. Foundation. Vague.

You may answer.

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

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

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

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

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

BY MR. SCHOETTES:

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

MR. NORWAY: Objection. Form,

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

BY MR. SCHOETTES:

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

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

Q Yes, yes.

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

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

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

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

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

BY MR. SCHOETTES:

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

MR. NORWAY: Objection. Form. Speculation. Mischaracterizes.

Go ahead.

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

BY MR. SCHOETTES:

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

MR. NORWAY: Objection. Speculation.

You can answer.

THE WITNESS: So I think we're,

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

BY MR. SCHOETTES:

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

MR. NORWAY: Objection. Form. Foundation.

You may answer.

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

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

MR. SCHOETTES: All right.

MR. NORWAY: Let's take a break.

(Whereupon, a short recess was taken.)

BY MR. SCHOETTES:

Q Let's go back on the record.

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

BY MR. SCHOETTES:

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

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

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

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

station. Then what supplies are we talking about?

MR. NORWAY: Objection. Form. Foundation. Improper hypothetical.

You may answer if you can.

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

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

BY MR. SCHOETTES:

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

MR. NORWAY: Objection. Form. Foundation.

You may answer if you can.

THE WITNESS: Some do. Some don't.

BY MR. SCHOETTES:

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

MR. NORWAY: Objection. Form. Foundation.

You may answer.

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

BY MR. SCHOETTES:

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

MR. NORWAY: Objection. Foundation. Speculation.

THE WITNESS: Some have gone 15 months.

BY MR. SCHOETTES:

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

MR. NORWAY: Objection. Form. Foundation. Mischaracterizes former testimony.

You may answer.

THE WITNESS: Correct.

BY MR. SCHOETTES:

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

MR. NORWAY: Objection. Form. Foundation. Improper hypothetical.

You may answer if you can.

THE WITNESS: It can, yes.

BY MR. SCHOETTES:

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

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

You may answer if you can.

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

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

BY MR. SCHOETTES:

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

MR. NORWAY: Objection. Form.

THE WITNESS: Even with extended times.

BY MR. SCHOETTES:

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

A Correct.

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

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

MR. NORWAY: Objection. Form. Objection. Foundation. Objection to the extent it mischaracterizes the prior testimony.

You may answer.

THE WITNESS: So there's something

BY MR. SCHOETTES:

Q Yes.

A Yes.

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

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

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

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

A The way you asked the question, absolutely.

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

MR. NORWAY: Objection. Form. Foundation.

You can answer if you can.

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

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

BY MR. SCHOETTES:

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

MR. NORWAY: Objection. Form. Foundation. Improper hypothetical.

You can answer.

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

BY MR. SCHOETTES:

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

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

You may answer if you can.

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

BY MR. SCHOETTES:

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

MR. NORWAY: Same objection.

BY MR. SCHOETTES:

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

MR. NORWAY: Objection. Form. Foundation. Improper hypothetical.

You may answer if you can.

BY MR. SCHOETTES:

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

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

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

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

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

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

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

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

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

Q And what kind of impact is it?

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

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

MR. SCHOETTES: Objection to the

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

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

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

Q And below that, you have "tyranny of

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

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

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

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

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

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

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

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

Q So there are space and weight requirements?

A Correct.

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

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

A To include a capability and capacity conversation.

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

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

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

A If it's a special operations, it will be special operations command for that region, so, for example, if it's Africa, it's special operations command Africa. If they work outside of that, then they would have to go to the African combatant commander, so elevating it up to a four-star. Typically that can be delegated down to a two-star, and if it's small enough operations, down to an 06, but it's still a very high-level discussion.

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

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

Q Thank you.

I think it's time to take a break.

(Whereupon, a short recess was taken.)

BY MR. NORWAY:

Q Let's go back on the record.

Sir, do you remember when you were

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

Do you recall that testimony?

A I do, mm-hmm.

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

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

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

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

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

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

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

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

A Correct. I used to teach that course.

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

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

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

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

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

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

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

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

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

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

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

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

start resupplying.

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

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

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

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

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

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

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

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

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

downrange is not better than that.

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

A Correct.

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

A None.

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

MR. SCHOETTES: Objection. Form.

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

What happens is within TRADOC,

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

BY MR. NORWAY:

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

MR. SCHOETTES: Objection. Form. Go ahead.

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

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

FURTHER EXAM BY COUNSEL FOR PLAINTIFFS

BY MR. SCHOETTES:

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

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

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

Q Why would that be?

A Because I get to say what my blood type

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

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

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

You may answer.

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

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

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

BY MR. SCHOETTES:

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

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

You may answer.

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

done.

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

MR. SCHOETTES: Thank you.

MR. NORWAY: We will read and sign.

THE REPORTER: Do you want a rough draft?

MR. NORWAY: Yes, please.

MR. SCHOETTES: Yes, please.

THE REPORTER: Normal turnaround? Two weeks?

MR. NORWAY: Yes.

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

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 _____ (DATE)

(SIGNATURE)

ACKNOWLEDGED before me
this 28 day of MAY 2019
by _____
KIRK LAMONT KNOCKETT
NOTARY PUBLIC STATE OF MARYLAND
My Commission Expires 9/26/2020

Job #3308250

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

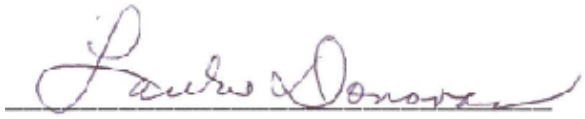
Job #3308250

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

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

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.)

APPEARANCES (continued):

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

STUART C. SPARKER, ESQUIRE
U.S. Department of Defense
Office of the General Counsel
1600 Defense Pentagon
Room 3B688
Washington, D.C. 20301
(703) 571-0802
stuart.c.sparker.civ@mail.mil

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

MAJOR W. CASEY BIGGERSTAFF, ESQUIRE
U.S. Army Legal Services Agency
9275 Gunston Road
Suite 3018
Fort Belvoir, Virginia 22060
(703) 693-1040
william.c.biggerstaff.mil@mail.mil

ALSO PRESENT: Solomon Francis, Videographer

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

BLAYLOCK DEPOSITION EXHIBITS:	PAGE:
Exhibit 1 - Plaintiffs' Notice of Deposition of Defendants Pursuant to FED.R.CIV.P. 30(B)(6)	11
Exhibit 2 - Bates US00005454-5487	48
Exhibit 3 - Bates US00025970-25973	122
Exhibit 4 - Bates US00025671-25673	126
Exhibit 5 - Army Directive 2018-22	131
Exhibit 6 - Bates 00025695-25697	137
Exhibit 7 - Bates 00005451-5452	142
Exhibit 8 - Interim Procedures Memorandum 18-020	147

(*Exhibits attached to the transcript.)

years.

Q Not a bad posting.

A Not bad at all.

Q And then prior to that?

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

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

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

Q And did you have a specialty at that point?

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

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

A Correct.

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

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

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

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

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

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

Q What about breast milk?

A Okay. Breast milk, yes.

Q Should be on that list as well?

A Yes, it should.

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

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

Q And so those two things are related --

A Yes.

Q -- viral load is related to medication adherence?

A Correct.

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

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

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

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

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

Q What is the risk of transmission via oral sex?

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

Q Is it possible to transmit HIV by biting someone?

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

their oral pharynx somewhere that was bleeding.

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

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

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

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

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

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

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

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

Q How is HIV treated?

MS. BERMAN: Objection. Vague.

BY MR. SCHOETTES:

Q What is the common treatment for HIV?

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

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

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

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

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

Q Okay.

(Discussion held off the record.)

THE WITNESS: Twice daily dosing, BID.

BY MR. SCHOETTES:

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

A So pre-exposure prophylaxis for HIV

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

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

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

BY MR. SCHOETTES:

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

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

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

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

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

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

A No.

Q Have you heard the treatment as prevention?

A I have.

Q Can you tell us what treatment as prevention is?

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

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

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

A Correct.

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

A Correct.

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

A To -- to some extent, yes.

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

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

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

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

A Potentially, yes.

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

MS. BERMAN: Objection. Mischaracterizes the testimony.

You can answer.

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

BY MR. SCHOETTES:

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

A Okay.

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

MS. BERMAN: Objection. Lack of

foundation.

You can answer.

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

BY MR. SCHOETTES:

Q Yes.

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

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

A Via sexual transmission is the other most likely.

Q Anything else?

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

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

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

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

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

Q But approximately zero, correct?

A Approximately zero, correct.

their home duty station.

Q So you referred to appointments every six months --

A Correct.

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

A Uh-huh.

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

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

Q Yes. Within a theater of operations.

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

Q And where -- sorry.

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

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

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

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

A Right.

Q -- to do that --

A Correct.

Q -- right now?

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

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

BY MR. SCHOETTES:

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

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

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

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

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

Q So --

A It depends on what you're testing for.

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

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

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

A Yes.

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

A Correct.

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

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

Q Sure.

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

Q Yes.

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

typically has little to no lab testing capability at all.

So the next level of care --

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

A Yes.

Q You said lab testing capability.

A Correct.

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

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

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

A Oh, you're saying --

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

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

Q The processing capabilities --

A Correct.

Q -- for the draw?

A Yes.

Q Okay. Go ahead. You were going to talk

about, I think, role two.

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

BY MR. SCHOETTES:

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

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

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

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

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

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

Q Can you talk about the next level of care?

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

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

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

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

A Correct, yeah.

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

MS. BERMAN: Objection. Calls for speculation.

You can answer.

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

BY MR. SCHOETTES:

Q Yeah. So --
A I just want to make sure we're talking about the same --
Q Yeah.
A -- scenario.
Q Yeah. Let's assume a person who has been diagnosed with HIV and they're on a regimen and they've been virally suppressed for some period of time and relatively stable, and they're going in to get their six-month evaluation. Doctor does follow-up. You referred to the fact that it takes a while to get the results back. Does that in any way impact the validity of those results or the ability to monitor that relatively stable person in the deployed setting?
MS. BERMAN: Objection. Calls for speculation and compound.
Go ahead.
THE WITNESS: So we're assuming that there's a lot of variables that fall into place here too. So we're assuming that that individual can get to a role three facility fairly easily to -- which also depends on the combat environment in a deployed setting. We're assuming that, once that blood test, the lab work is drawn, we would

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

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

BY MR. SCHOETTES:

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

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

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

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

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

Q Presumably --

A -- algorithm.

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

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

Go ahead.

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

BY MR. SCHOETTES:

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

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

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

A Sure.

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

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

Go ahead.

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

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

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

BY MR. SCHOETTES:

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

MS. BERMAN: Same objections.

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

A Yes.

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

A Correct.

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

MS. BERMAN: Same objections and asked and answered.

You can answer.

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

BY MR. SCHOETTES:

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

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

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

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

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

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

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

A Currently, yes.

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

need at a role three facility?

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

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

A Yes.

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

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

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

MS. BERMAN: Objection. Mischaracterizes the testimony.

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

BY MR. SCHOETTES:

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

MS. BERMAN: Objection. Calls for speculation.

You can answer.

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

BY MR. SCHOETTES:

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

MS. BERMAN: Objection. Calls for speculation.

THE WITNESS: Currently, no.

BY MR. SCHOETTES:

Q And why is that?

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

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

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

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

MS. BERMAN: Objection. Vague.

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

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

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

BY MR. SCHOETTES:

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

MS. BERMAN: Objection. Vague.

You can answer.

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

You can answer.

THE WITNESS: To clarify, this is assuming on a deployment?

BY MR. SCHOETTES:

Q Yes, I'm sorry.

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

Q How long are the longest deployments?

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

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

A Yes.

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

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

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

A Sure.

Q Okay.

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

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

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

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

MS. BERMAN: Objection. Vague.

You can answer if you know.

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

BY MR. SCHOETTES:

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

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

But you can answer.

THE WITNESS: Yes.

BY MR. SCHOETTES:

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

MS. BERMAN: Can you clarify which question?

BY MR. SCHOETTES:

Q Yeah. So we were talking about how a

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

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

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

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

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

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

A Correct.

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

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

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

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

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

MS. BERMAN: Objection. Calls for speculation.

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

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

BY MR. SCHOETTES:

Q It could be more than two months?

A Sure.

Q It could be more than three months?

A Potentially. Unlikely, but potentially.

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

MS. BERMAN: Objection. Mischaracterizes the testimony.

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

BY MR. SCHOETTES:

Q But more than three months is unlikely?

A Correct.

Q Is more than two months unlikely?

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

Q Do antiretroviral medications have any storage or handling restrictions?

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

requirements. And antiretrovirals are no exclusion to that.

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

MS. BERMAN: Objection. Vague.

You can answer.

THE WITNESS: Not to my knowledge.

BY MR. SCHOETTES:

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

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

Q Do they tolerate heat relatively well?

MS. BERMAN: Objection. Vague.

You can answer.

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

BY MR. SCHOETTES:

Q Do they tolerate cold very well?

MS. BERMAN: Same objection.

THE WITNESS: Same response.

BY MR. SCHOETTES:

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

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

A Yes.

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

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

individual donating blood, obviously.

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

A Uh-huh.

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

A Correct.

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

A Correct.

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

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

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

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

A Correct.

MS. BERMAN: Objection. Calls for speculation.

THE WITNESS: Correct.

BY MR. SCHOETTES:

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

A Correct.

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

bank?

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

Q And can -- why is that?

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

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

MS. BERMAN: Objection. Calls for speculation.

You can answer.

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

BY MR. SCHOETTES:

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

A No.

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

MS. BERMAN: Objection. Calls for speculation.

You can answer.

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

BY MR. SCHOETTES:

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

A Yes.

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

A Correct.

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

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

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

MS. BERMAN: Objection. Form. And compound.

But you can answer.

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

BY MR. SCHOETTES:

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

A Yes.

A Correct.

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

Do you know that to be true?

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

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

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

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

A No, it's very variable.

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

A Again, it's variable on several factors.
Q Can you tell me what those factors are?
A So if somebody is taking their ART regularly, is probably the biggest factor, how well controlled their HIV is. However, on the flip side, there's also bodies of literature that express concern about certain ART regimens and their effects on the cardiovascular system as well.
Q So I just want to pause for a moment and say --
A And osteoporosis. I'm sorry.
Q -- that in the sentence, though, it talks about someone virally suppressed.
A Okay.
Q So wouldn't that indicate that that person is regularly taking their HIV medications?
A Yes.
Q So that wouldn't be a factor for that individual.
A Correct.
Q But now I heard you say the regimen they're on could affect when we might see the possibility of illnesses associated with premature aging, correct?

A Yes, that's correct. But even --
Q What other --
A Even in virally suppressed patients there is evidence to show that HIV-infected persons, even with suppressed viral loads, still have -- whether it's related to an increased inflammatory state in their body or their immune system, for lack of a better term, is ramped up to control the HIV virus, that that has effects on the cardiovascular system and other organ systems as well.
Q Which is indeed what this sentence says, "Some HIV-infected virally suppressed patients on ART will develop illnesses associated with premature aging."
A Yes.
Q So what I'm trying to understand is, are there factors -- what the factors are that you described that would influence if that happened? One thing you said would be the treatment regimen that they were on. Are there other factors that would influence when we might see that?
MS. BERMAN: Objection. Form.
You can answer.
THE WITNESS: So I had mentioned the

body's own kind of inflammatory state. So there's various inflammatory chemicals in the body, cytokines in particular and interleukins and these different factors that -- a lot of research has looked at their role in inducing conditions like cardiovascular disease, renal disease, osteoporosis in the setting of HIV infection.

So even with a suppressed viral load, perhaps, the thought is -- and some of the research is showing that these -- this ramp-up of these inflammatory factors are affecting an individual's cardiovascular system or bone system or renal system.

BY MR. SCHOETTES:

Q Am I -- is it correct that those response -- the level of those responses may vary from individual to individual?

A Yes, correct.

Q So that would be another factor is how -- a particular person's response, immune system response in terms of these inflammatory conditions?

A Yes.

Q Is there other factors that would influence how rapidly one might see the onset of

these illnesses associated with premature aging?

A So the other, you know, very common comorbid factors to a lot of Americans: Smoking, alcohol use, lifestyle habits. Those, combined with HIV infection, might portend a higher likelihood of development of cardiovascular disease and osteoporosis.

Q Anything else?

A Not that I can think of right now.

Q Further down, it talks about, "Some patients may experience a fluctuating course of neurocognitive impairments over time, including symptom normalization; however, it is unknown whether these changes reflect biological alterations induced by responses to (or failures) of ART, or occur independently of viral load and changes to ART regimens."

So we're still figuring this all out. Is that an accurate statement?

A Yes. That's very accurate.

Q And some of this is speculative as to how these things are associated?

MS. BERMAN: Objection. Vague.

THE WITNESS: Some of it is -- could be speculative, but a lot of it is based on studies

that have been done as well. So it's -- I think there's data on both sides of the spectrum so far, and we're waiting for more data to make firmer -- firmer conclusions from this.

BY MR. SCHOETTES:

Q Actually, I'm going to go back to the factors. You did not identify length of time that the person has been infected with HIV. Is that not a factor in whether we -- you would see illnesses associated with premature aging in that individual?

A There are studies that have shown length of time on ART is -- more likelihood of development of cardiovascular disease. And the issue is, is it due to the HIV itself or is it due to a bunch of regimens that that person had seen over the course of their HIV illness, and is it an ART-related issue or is it both? I mean, there's...

Q Is it also possible that the onset of the illnesses associated with premature aging could be affected by the regimen used on a particular individual?

MS. BERMAN: Objection. Asked and answered.

You can answer.

THE WITNESS: Yes.

BY MR. SCHOETTES:

Q Are some of the people that are now aging with HIV, did they take regimens that are no longer used?

MS. BERMAN: Objection. Calls for speculation.

You can answer.

THE WITNESS: Yes.

BY MR. SCHOETTES:

Q And we have newer medications to treat HIV on a fairly regular basis, correct?

MS. BERMAN: Objection. Calls for speculation.

You can answer.

THE WITNESS: Correct.

BY MR. SCHOETTES:

Q And because we're not sure exactly what the cause of this is, no one can say whether the newer regimens will have the same types of effect as some of the older regimens, correct?

A Correct. The newer regimens have not been around long enough either for us to have that body of data to show. So I think time will tell

any potential long-term side effects of our newer regimens.

Q How many regimens, if you know, have been phased out of use over the course of the 35 years of the HIV epidemic?

A So there have been a handful of antiretroviral medications that are no longer being produced and have certainly been taken off of our formulary within the military health care system. A couple of them -- like didanosine and stavudine are two that come to the top of my mind.

Q And, before, you talked about first-line regimens and second-line regimens. Are there third-line regimens?

A So I believe I would have to refresh my memory of the DHHS guidelines for ART treatment, but I believe they list them as first-line and then alternative regimens, there's a category for. And that includes, I think, all of the -- and then there are -- there is a not recommended category as well for ART.

Q And the two medications that you just identified would fall into the not recommended category at this point?

A They would, yes.

Q And how many medications are in the not recommended category at this point?

A I would be speculating off the top of my head, but I'm sure it's a handful.

Q Okay. There's a sentence here that says, "A longitudinal cohort observation study found that numerous patients with asymptomatic neurocognitive impairment (ANI), even with a suppressed plasma viral load, eventually developed symptomatic neurocognitive impairment."

Are you familiar with the longitudinal cohort observation study referenced there?

A Perhaps not this exact study, but I am aware of different studies that have looked at this and have shown that this is to be the case, that even HIV-infected service -- or personnel with suppressed viral loads can still demonstrate asymptomatic neurocognitive impairment.

Q Would you look to page 30 and it's -- the longitudinal study is identified there.

A Reference 8.

Q Yes. Is this one with which you are familiar?

A Again, I'd have to see the exact -- I'd have to see the article to -- to really confirm

that I have seen this individual study.

Q Okay. The next sentence admits that, "The impact of these potential neurocognitive impairments on a service member's readiness, resilience and/or retention is currently unknown."

Would you agree with that statement?

A Yes.

Q The next sentence talks about the HIV-positive population on -- "As the HIV-positive population on ART ages" -- ART is capitalized, A-R-T -- "there is greater recognition that cerebrovascular disease risk factors such as hypertension, diabetes and hypercholesterolemia may become risk factors for cognitive impairment."

Are those also risk factors for cognitive impairment for people who are not HIV-positive?

A Yes. They certainly are.

Q So right now, we're not sure the extent to which HIV-positive service members will be disproportionately impacted with neurocognitive impairments; is that correct?

MS. BERMAN: Objection. Again, he's -- the scope of his testimony will only be for the Army. And also this calls for speculation.

But you can answer.

THE WITNESS: Yes, I would say that's correct.

BY MR. SCHOETTES:

Q Is there any reason the Army would not be able to identify and address neurocognitive impairments in HIV-positive people just as it would in the population not living with HIV?

A So the diagnosis of HAND, HIV-associated neurocognitive disorder, is fairly complicated. It's actually -- by definition, it's a clinical diagnosis. We don't have MRI imaging or electroencephalogram -- EEG -- readouts that say, yes, based on this study, this person definitively has HIV-associated neurocognitive disorder.

It's based on more of what's called neuro -- neuropsychiatric testing or neuropsychological testing profiles that are pretty complex and have a lot of different variables to them. So it's more of a clinical diagnosis based on that testing. And we use brain imaging, like MRIs and EEGs and lumbar punctures, to rule out other infections, to make sure we're not missing another diagnosis.

So it's very -- bottom line, it's very -- it's a very unique testing panel that goes into

formal diagnoses of HAND.

Q So that's specific with respect to HAND, which is HIV-associated neurocognitive disorder, which, I'm assuming, a person who is not living with HIV would not have -- could not have. So what I actually am asking is just neurocognitive impairments as they occur in the general population, is there any reason why the neurocognitive impairments that might be the result of HAND could not be addressed in the same way as neurocognitive impairments that occur in the general population?

MS. BERMAN: Objection. Assumes facts not in evidence.

You can answer the question.

THE WITNESS: I don't think so. I'm a little confused, though, at what you're trying to ask.

BY MR. SCHOETTES:

Q Well, I'm assuming that the Army has some way of identifying and addressing neurocognitive impairments that might occur to service members in general. Correct?

A I mean, we do -- neuropsychologic testing is our battery that is performed for most cases of

neurocognitive impairment, whether it's HIV-related or not. So -- so in answer to your question, yes, there is a way to identify that.

Q And what I'm asking is, is there any reason that HIV-associated neurocognitive impairment would not be diagnosed using those tests in the same way?

A The only issue is that there's a lot of unknowns, as this is stating, regarding, you know, the extent of neurocognitive impairment and, you know, further details of exactly the pathophysiology and the mechanism of what's causing this neurocognitive impairment.

So I think -- I think that's what you're -- I mean, so that's the issue that I have, I guess, is that --

Q Yeah.

A -- based on what they are saying in here as well, that there's -- there's a lot of unknowns regarding this. So giving everybody a formal diagnosis of, yes, you have neurocognitive impairment or, no, you do not, I don't think it's as -- it's not black and white because of all these unknowns.

Q And I understand, in terms of a diagnosis

and being able to say it is HIV-associated or not and -- I guess what I'm asking is, to the extent that it's having an impact on a person's memory, concentration, attention, motor skills, it seems to me that that could be diagnosed in a person with HIV or without HIV in the same manner. Am I correct?

MS. BERMAN: Objection. Form.

You can answer.

THE WITNESS: I don't know how to best answer that, to be honest with you. I mean, I -- a service member without HIV infection who had these similar symptoms would undergo similar testing, if that answers your question.

BY MR. SCHOETTES:

Q Yeah. So I guess what I'm asking is, you offered neurocognitive impairments as a reason why HIV-positive individuals should not be deployed or are not fit to serve. And I'm asking why, given its relatively low occurrence in all populations, why wouldn't it just be diagnosed as if the person didn't have HIV, and addressed as a neurocognitive impairment separately from the fact that the person has HIV?

MS. BERMAN: Objection. Mischaracterizes

the testimony. And form.

THE WITNESS: I see what you're -- I think I see what you're saying. The issue with -- regardless of HIV infection, if we take that even out of the picture here, whether somebody has HIV infection or not, it's still a clinical diagnosis. So it's fairly subjective based on the results of testing.

So there's certainly potential for some people to get diagnosed, some people not to get diagnosed formally. Right? So I guess in that setting, it's not -- again, it's not a black or white, like, you obviously have neurocognitive impairment, we're not going to deploy you, versus you're cleared -- you're cleared to deploy, if that's what you're...

BY MR. SCHOETTES:

Q Do you know what the current prevalence of HIV-associated neurocognitive disorder is among the population in the military living with HIV?

A In the military living with HIV overall, no, I don't know that. So when you talk about HIV-associated neurocognitive disorder, it's a spectrum, so everything from asymptomatic neurocognitive disorder to HIV-associated

dementia. So every -- and there's a couple, you know, gray areas between there.

So I mean, it's kind of -- obviously, you can see that if somebody has asymptomatic neurocognitive disorder, it's very hard to calculate that because they're not demonstrating any obvious symptoms or signs to suggest that. So it's --

Q And is that the reason why you don't have an estimate of prevalence within the military or is that why you don't have an estimate across the general population?

MS. BERMAN: Objection. Compound. Lack of foundation.

You can answer.

THE WITNESS: Exactly the latter, that we don't have a good estimate of that nationwide, let alone within the military.

BY MR. SCHOETTES:

Q And do you have an estimate of the percentage of the population with HIV in the military who are exhibiting symptoms in a way that has impacted their ability to perform their duties?

MS. BERMAN: Objection. Vague.

"Pharmaceutical supplies intended for emergency nPEP will not be compromised for PrEP."

So nPEP is, as you said, nonoccupational exposures. So nPEP is kept on hand for potential sexual exposures?

A So I think this could classify as nPEP or PEP, you know, in general, needle stick exposures. Like I had mentioned before, we do keep -- currently the pharmacies that are in OCONUS settings keep a short supply of antiretrovirals -- and it's typically Truvada plus another antiretroviral -- for use as PEP and -- or nPEP if needed --

Q Okay. And nPEP --

A -- for these situations.

Q So -- I guess I'm wondering how nPEP is used in the military. I'm imagining potentially after a sexual assault?

A Correct.

Q Is it ever used for someone who comes in and says, I think I may have been exposed sexually to HIV?

A Yes.

Q Okay. But you're saying that really this sentence, the "n" could be taken off of PEP there?

A Yes. That's what I'm saying.
Q Okay. I think I'm good there. You can put that document aside. Give me a second. I need to find this document to do this part of my outline.
(Pause.)
BY MR. SCHOETTES:
Q We're going to continue on and I will come back to this after we've taken a break.
I'm going to talk about topic 23 which is accessions and deployment policies for other conditions requiring daily medication. Are you familiar with the medical condition of dyslipidemia?
A Yes, I am.
Q What kind of treatment does dyslipidemia generally require?
A Generally, it requires a cholesterol-lowering medication, typically from a class we call statins.
Q Taken daily?
A Yes.
Q Generally one pill?
A Yes.
Q Once a day?

A Yes.

Q What is the accession policy for individuals with dyslipidemia?

A I don't believe it specifically mentions dyslipidemia as a limiting restriction to joining the military.

Q And if it's not listed specifically, then it would not be a bar to enlisting or commissioning?

A I believe there's a line in our accessions policy that says every medication can be looked at on an individual basis for consideration for whether it merits accessioning or not.

MS. BERMAN: Counsel, I just want to reiterate that this witness is here to provide medical testimony as it applies to these questions. We did offer someone to talk about accessions in a more policy-specific way. And deployment as well.

MR. SCHOETTES: Okay.

MS. BERMAN: But you --

MR. SCHOETTES: I just want to try to understand what portion of the topic -- I mean, I don't want to waste our time if he's not

testifying on the topic. So...

MS. BERMAN: As we discussed earlier, it's just -- he's going to talk about these conditions and how they might be different than HIV, might be treated same or different than HIV. But I think it's fine. You can --

MR. SCHOETTES: Okay.

MS. BERMAN: -- continue your questioning.

BY MR. SCHOETTES:

Q All right. So if a soldier is diagnosed with dyslipidemia after enlisting or commissioning, are they discharged?

A No.

Q If a soldier is required to start taking daily medication for dyslipidemia, are they discharged?

A No.

Q What is the deployment policy for individuals with dyslipidemia?

A So I don't know exactly what the deployment policy is with [sic] somebody with dyslipidemia, but if it is very well controlled on a once-daily statin regimen, they would be allowed to deploy.

Q And are individuals with dyslipidemia supplied with their medication during deployment -- well, let me go back.

How are individuals living with dyslipidemia supplied with their medication during deployment?

A So if they don't already bring a 270-day or whatever duration their deployment is, supply with them, they can sign up via TRICARE Express Scripts to have it mailed to them throughout their deployment.

Q If they go with 180-day supply on a 270-day deployment, how long into their deployment before they can request a refill of their prescription?

A I don't know the exact time frame that TRICARE would -- mandates for you before you can get a refill of a medication.

Q Would it take into account the fact that it might take some time for that refill to get to the individual who is deployed?

A I would hope so, but I can't tell you definitively.

Q And if the medication of a person with dyslipidemia was lost, stolen or destroyed while

deployed, would they be resupplied in the manner that we discussed earlier for all of their medications?

A Yes.

Q Besides for [sic] receiving treatment, are soldiers handled -- are soldiers with dyslipidemia handled differently in any respect?

MS. BERMAN: Objection. Vague.

BY MR. SCHOETTES:

Q I can ask a more specific question. Are individuals living with dyslipidemia referred into the DES under 1332.18?

A I don't know -- I don't know how to exactly address that, because I would imagine it would -- if they have very uncontrolled dyslipidemia that -- despite being on appropriate statins or other agents to reduce cholesterol, then they very well may be referred to the DES.

Q And to clarify, the DES is the Disability Evaluation System?

A Correct.

MS. BERMAN: And I want to reiterate that this witness is not being offered to talk about retentions, so...

MR. SCHOETTES: Right.

BY MR. SCHOETTES:

Q And they're certainly not referred into the DES automatically upon diagnosis?

A No.

Q Are you familiar with the medical condition of hypothyroidism?

A Yes.

Q What kind of treatment does hypothyroidism generally require?

A It generally requires a pill called levothyroxine. It's a -- it's a synthetic thyroid replacement medication taken once daily.

Q I'm going to go back for a moment. What are the consequences of not taking one's dyslipidemia medication?

A So the consequences of not taking that daily, it depends on the duration of time that you go without it, but your cholesterol levels increase and, over time, you may be at higher risk of heart disease, stroke, all the other complications of dyslipidemia that goes untreated.

Q Including some potentially fatal conditions?

A Yes.

Q So what are the consequences of untreated

hypothyroidism?

A So if it goes untreated, then you develop -- in many cases, you can develop symptomatic hypothyroidism which is manifested by a number of symptoms to include extreme fatigue, weight gain, cold intolerance, constipation.

Q All things that could affect one's ability to perform one's duties as a soldier, correct?

A Correct.

Q What is the accession policy for individuals with hypothyroidism?

A Individuals with hypothyroidism are, if it's well controlled, are allowed to accession.

Q And if a service member is diagnosed with hypothyroidism after enlisting or commissioning, are they discharged?

A No.

Q If they're required to start taking daily medication for their hypothyroidism, are they discharged?

A No.

Q Do you know what the deployment policy is for individuals with hypothyroidism?

A As long as it's well controlled, then

they are allowed to deploy.

Q And are they supplied with their medication during that deployment and -- if it is lost or stolen in the same manner as people with dyslipidemia or any other condition?

MS. BERMAN: Objection. Compound.

You can answer.

THE WITNESS: Yes.

BY MR. SCHOETTES:

Q Are you familiar with any conditions requiring hormone replacement therapy?

A I mean, there's a number of different reasons people go on hormone replacement therapy, whether it even be oral contraceptive pills versus premature menopause or -- you know, for our active duty population in particular.

Q What is the -- is there one that's most common that creates a need for hormone replacement therapy?

A You mean as far as what I just mentioned there? I mean, oral contraceptive pills are probably the most commonly used by females in the military.

Q Are you familiar with the condition called dysmenorrhea?

noticeable symptoms as a result of that loss of medication?

MS. BERMAN: Objection. Calls for speculation.

You can answer.

THE WITNESS: So that time frame is very variable. It depends on a lot of factors that we've already discussed, in particular, the environment that that person is working in with regards to their potential exposure to environment stimulants that affect the immune system.

Also, what that person's baseline CD4 count was at the time they stopped taking the medication. And that person's individual immune system, how it reacts to not being on antiretroviral therapy for a period of time.

BY MR. SCHOETTES:

Q Is there a -- are you able to provide what the average time would be before you would see a significant increase in the person's viral load assuming they were -- had a suppressed viral load before the loss of medication?

A So there are studies that have looked at this before, kind of what's called viral load rebound, or rebound viremia, after stopping

antiretroviral therapy. The majority of the studies seem to show that within even as early as nine days, you can see evidence of viral load, significant viral load rebound after stopping antiretroviral therapy.

There is some data to show that the earlier somebody is started on antiretroviral therapy shortly after their diagnosis, if they do stop it later on, that rebound may not occur for outwards of 50 days or so. But the -- most of the studies have shown what I've seen to be an average of about nine days.

Q And when you say significant viral rebound, do you have a demarcation point at which you are setting significant viral --

A No, I don't. I'd have to look closer at those studies to see what the actual viral loads are that they're depicting.

Q Are you familiar with genotype testing to identify resistance in the HIV virus?

A Yes.

Q Do you have a sense -- or can you tell us how long it would take before there was enough virus in the blood to do genotype testing after stopping treatment?

their HIV as a result of stopping medication?

MS. BERMAN: Objection. Vague.

You can answer.

THE WITNESS: I mean, again, that -- it depends on what you're categorizing as symptoms and then also it depends on that person's baseline immune status. And there's a very broad range of time period between symptom onset after stopping -- or when having uncontrolled HIV infection.

BY MR. SCHOETTES:

Q If HIV is left untreated, for how long after infection does it remain asymptomatic? Again, it would have to be an average, because I understand everyone is different --

A Yes.

Q -- but what's the average amount of time?

MS. BERMAN: Objection. Vague.

Go ahead.

THE WITNESS: So average amount of time in our early studies of HIV infection prior to treatment were anywhere from two years to ten years. So on average, maybe around five years, you could say. But typically, again, those studies were conducted prior to combination

antiretroviral therapy and those -- we're talking pretty severe symptoms, like opportunistic infections, malignancy, to include lymphoma, Kaposi's sarcoma, so pretty significant infections and disease processes that occur with untreated for that long.

Q The things that could actually lead to a person being disabled by their HIV?

A Yes.

Q What is the course of treatment after treatment interruption? What would the normal plan be for such an individual?

A To restart your antiretroviral therapy as soon as possible.

Q To restart the regimen you were on?

A Correct. And then hope to obtain a genotype on -- after being on that therapy for typically three weeks to a month, because that would be our best assessment of if you've developed any resistance to that regimen after stopping it for periods of time.

Q You would do a genotype at that point or would a viral load test indicate whether the same regimen was being -- was still effective?

A So you can't do a genotype without

getting a viral load. So they kind of go hand in hand, because you get the genotype based on that viral load, if that makes sense.

Q So the individual who goes back on treatment would be on treatment for some period of time, the same treatment?

A Yes.

Q And you would see if the viral load went back to suppressed or undetectable?

A Correct. So you would assess that at the three to four-week period after they restart that regimen. You would want to get a viral load with a genotype at three to four weeks after being back on that regimen.

Q What if they didn't have enough viral -- virus at that point to do a genotype?

A Then that would be great. Then we wouldn't need a genotype.

Q Right.

A The goal is to see that they've either suppressed their viral load again or, if not, we're going to try to get a genotype to see if they've developed resistance.

Q Got it. Is it possible that they would have -- that it would have been reduced, but they

maybe had not gotten all the way back down to suppressed at that point, in which case what do you do?

A We would still --

MS. BERMAN: Objection. Form.

THE WITNESS: We -- can I still answer?

MS. BERMAN: Yes.

THE WITNESS: We would still want to check a genotype because it might give us a glimpse into a new resistance panel and it may prompt us to switch that regimen.

BY MR. SCHOETTES:

Q But that would require at least a thousand copies if you used the one test?

A Right, 1,000 to 2,000 copies, yes.

Q Okay. What concerns, if any, is there around -- well, I guess we were just talking about this. Do you know what the likelihood is of resistance after treatment interruption?

MS. BERMAN: Objection. Vague and calls for speculation.

You can answer.

THE WITNESS: Yeah. I mean, it depends on a lot of different variables. So it's -- you are more likely to acquire resistance if you're

intermittently taking your medications. So one thing that we always try to couch [sic] our patients about is when you're -- sometimes what our patients do -- because, for various reasons, they may not come back in to get refills of their medications or run out of their meds -- sometimes what they do is they start spacing out the dosing of their medication. So they'll say, oh, I'll take it every other day or every third day to make it last longer. That's exactly how you develop resistance. So it's actually better to stop it cold turkey and then restart it up later. That's your best option for not developing resistance.

So it depends on if somebody is taking their meds intermittently to space them to -- or stops it altogether.

BY MR. SCHOETTES:

Q So in the context of lost medication, and it's a sustained stop, that would be less likely to develop resistance than someone intermittently taking their medication?

A Correct. The other thing that you have to take into account is the half life of the particular drug in the body. So there's different antiretroviral regimens that have longer half

lives or shorter half lives. So missing one or two medications of one drug might be not as -- might be less forgiving than missing one or two days of another drug.

Q And that's more of a concern in that intermittent drug-taking scenario --

A Yes.

Q -- than it would be in a full stop?

A Yes.

Q Because the half life on all of them is going to sort of run out relatively quickly and then there won't be anything that the virus could mutate around, because there's only one of the medications left, right?

A Correct.

MR. SCHOETTES: I think I'm done.

MS. BERMAN: Okay. I think we want to talk for a minute about whether I have any follow-up questions. And -- so if we want to go off the record for a minute, I may have a few more.

MR. SCHOETTES: Sounds good.

THE VIDEOGRAPHER: The time is 3:28 p.m. We are going off the record.

(Whereupon, a short recess was taken.)

THE VIDEOGRAPHER: The time is 3:35 p.m. We are back on the record. Please proceed, Counsel.

EXAMINATION BY COUNSEL FOR THE U.S. DEPARTMENT OF JUSTICE

BY MS. BERMAN:

Q Colonel Blaylock, I just want to clarify a few things. You and counsel were talking about the CDC guidelines earlier about -- that state there's essentially zero risk, or approximately zero risk, of transmission of HIV from a person with a suppressed viral load. Does that guideline specifically concern sexual transmission?

A Yes. That guideline does concern sexual transmission only.

Q Is there any similar statement about transmission by blood transfusion from the CDC?

A No, there is not.

Q Okay. And I think this is in the record, but before, when you were talking about the risk of transmission by blood transfusion, I believe you and counsel were talking about the scenario of someone with an increased viral load, someone who was not fully suppressed. Is there also a significant risk of transmission from a person

with a suppressed viral load by blood transfusion?

A Yes. There would still be a significant risk, even if the viral load was suppressed under 20 copies because, again, that's not zero copies; that's -- could be ten copies per milliliter of blood.

So when you're looking at a total of 250 to 300 milliliters of blood in a whole unit of blood, that risk becomes more substantial.

Q Okay. Do you have any estimate of the percentage risk of transmission in both of those scenarios, both the suppressed viral load scenario and the unsuppressed viral load scenario?

A So, unfortunately, the only solid data that we have is pretty old CDC data from -- I believe it was 1990 when it was published that talked about the risk via blood transfusion. And they did not separate it out into folks who had very low viral loads, or even undetectable viral load, and those that had high viral load.

We just know across the board, across everybody with HIV, there was upwards of 90 percent transmission rate from somebody who was HIV-infected donating blood.

Q Okay. And we talked about this somewhat,

between a person with a high viral load and one with a suppressed viral load?

A I think it's -- I don't think there are studies that have looked at somebody with an undetectable viral load, their ability to transmit virus to a seronegative person. That would be a very unethical study.

Q Right.

MR. SCHOETTES: Okay. That's all I have.

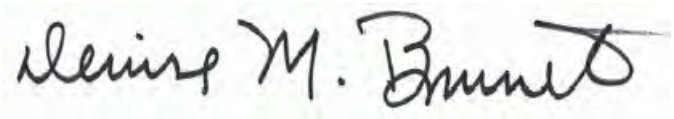
MS. BERMAN: Okay. We're done, then.

THE VIDEOGRAPHER: The time is 3:54 p.m. This concludes today's testimony given by the United States Army and Dr. Jason Blaylock. We are now off the record.

(Whereupon, at 3:54 p.m., the deposition of JASON BLAYLOCK was concluded.)

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

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

NO NOTARY REQUIRED IN CA

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

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

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