

(b)(6)



Subject: RE: PA re: Animal Tissue Training Studies 3/22 Hill Briefing

Signed By:

(b)(6)



Ok--thank you

(b)(6)



(b)(5) Subject: PA re: Animal Tissue Training Studies 3/22 Hill Briefing


Importance: High

(b)(5)



Hi, (b)(6)

(b)(6), (b)(5)



(b)(6)

Best,

(b)(6)



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Twitter: @DoDIInnovation

<http://www.acq.osd.mil/chieftechнологist/index.html>



Combat Casualty Care Training:

An Information Brief on Three Studies Funded by the Department of Defense

22 March 2016

(b)(6)

VMD

Associate Director, Animal RDT&E Protection Programs
Office of the Assistant Secretary of Defense for Research
and Engineering



Outline



- Briefing Purpose
- Background
- Combat Casualty Care Training Studies
- Findings from the Studies
- Early Implementation of Findings
- Summary

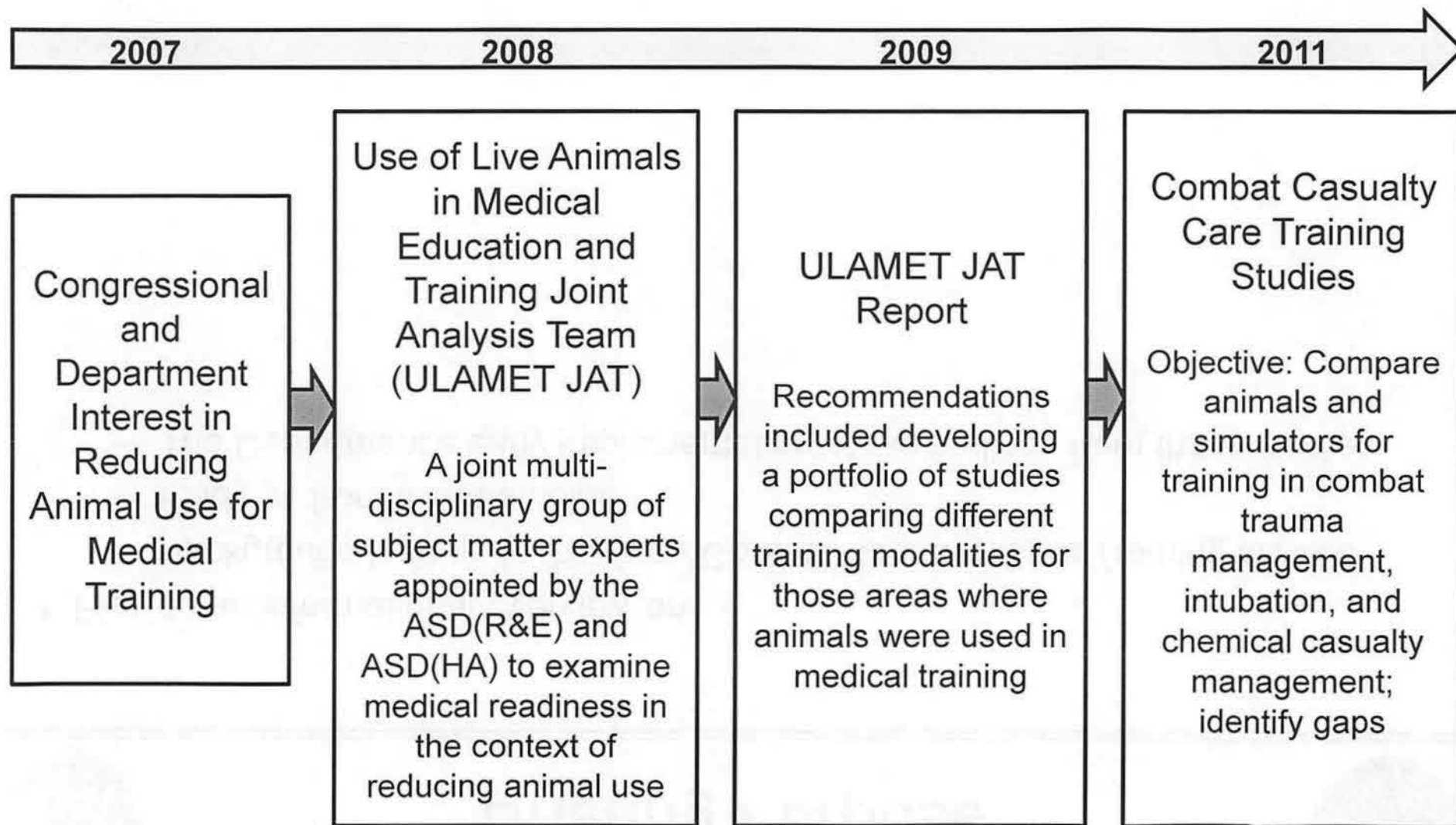


Briefing Purpose

- Provide an informational overview on:
 - Background leading to the three Combat Casualty Care Training studies
 - Findings from these studies
 - The Department's early implementation of the findings from these studies



Background: What Led to the Studies





Background: Combat Casualty Care Training Studies



Based on the ULAMET JAT report and an evaluation of the pre-deployment skills taught to Army general forces combat medics (68Ws) and Army Special Forces combat medics (18Ds), these skills were studied:

Trauma Airway Skills for Medics:

- Nasopharyngeal airway
- Surgical airway
- Chest tube
- Chest seal
- Needle chest decompression

Trauma Hemorrhage Skills for Medics:

- Amputation management
- Application of hemostatic dressing
- Application of tourniquets
- Intravenous fluid resuscitation
- Intraosseous fluid administration

Emergency Medicine Skills for Medical Providers:

- Intubation
- Management of cholinergic crisis



Combat Casualty Care Training Studies



- Dr. Sweet - University of Minnesota
 - Evaluated 68W Combat Medics, in preparatory course prior to deployment. (EXSUM, p.1)
 - Studied tourniquet placement, junctional hemorrhage control, amputation stump management, nasopharyngeal airway placement, surgical cricothyrotomy, chest seal placement, needle chest decompression, bowel evisceration treatment, chest tube placement, and endotracheal intubation. (EXSUM, p. 1)
- Dr. Barnes - University of Missouri
 - Studied 12 skills in the critical research areas (CRA) of hemorrhage, airway trauma, neonatal/pediatric intubation, and management of nerve agent casualty. (EXSUM, p. 4 and Table 1 of EXSUM, p. 7)
 - Determined validity of existing, published peer-reviewed curriculum metrics (EXSUM, p. 4)
 - Determined how to modify existing or develop new training curricula (EXSUM, p. 4)
- Dr. Andreatta - University of Minnesota, started at Michigan
 - Studied management of cholinergic crisis and pediatric/neonatal intubation (EXSUM, p. 4)
 - Developed curricula for management of cholinergic crisis and pediatric/neonatal intubation (EXSUM, p.4)



Findings From the Studies

Dr. Sweet - University of Minnesota

- Surveyed and acquired all available synthetic tissue models (STMs). There were a total of over 300 systems initially considered. (EXSUM, p. 9)
- There wasn't a single commercial system deemed acceptable to go up against the animal model. (EXSUM, p. 9)
- Combined three commercial systems (head/neck/upper extremities; chest/abdomen; pelvis/lower extremities) and added a live, distressed, trained, human scripted actor for the purposes of assessment or culminating event. (EXSUM, p. 9)
- Did not find either the simulator or animal model to be superior for training or assessment of all critical trauma procedures. (EXSUM, p. 19)
- Adding standardized assessment to the curriculum will improve skills and save lives. (EXSUM, p. 19)



Findings From the Studies

Dr. Barnes – University of Missouri

- None of the existing training modalities offers an ideal solution in isolation. (EXSUM, p. 13)
- One universal principle is that multi-modality approaches produce the largest training benefit. Thus, additional investment should occur from a system engineering approach to integrate live, constructive, and virtual models. (EXSUM, p. 8)
- The overarching issues center around animation, realism, dynamic behavior, tactile feedback, and reliability in both facility and field training. (EXSUM, p. 14)
- Live tissue model was perceived to drive a sense of urgency in treatment, with failure leading to loss of life. (EXSUM, p. 7)
- Sedated/anesthetized live tissue models cannot receive appropriate human pharmacological interventions by drug or dose. (EXSUM, p. 8)
- Inanimate simulations had artificial linear responses to treatment, appeared and felt unrealistic, and did not convey wounds of war effectively. (EXSUM, p. 8)



Findings From the Studies



Dr. Andreatta - University of Minnesota

- Cholinergic Crisis Recognition and Management:
 - No significant differences between watching a high-definition video of a nerve agent response experienced by a live animal or human actor. (EXSUM, p. 4 and 10)
 - This study did not directly answer the question of the value regarding the use of live animals for training. (EXSUM, p. 14)
- Neonatal/Pediatric Intubation:
 - Outcomes of this study suggest there is no significant difference between the effectiveness of the live animal and simulated models for training in the clinical performance of pediatric and neonatal intubation. (EXSUM, p. 13)
- Developed evidence-based curricula for the management of cholinergic crisis and the need for pediatric and neonatal intubation, eliminating the use of animals whenever possible. (EXSUM, p. 13)
- Noted that the opportunity for experiential learning is extremely important because knowledge-based training alone may miss the vital mastery of associated skills and affective elements embedded in clinical contexts. (EXSUM, p. 13)



Findings From the Studies

As part of the work, each of the studies assessed the state of technology for synthetic tissue models and provided recommendations regarding where the Department should focus future efforts and resources. The areas below are summarized from the information* within the three reports.

- Anatomical accuracy and realism
- Tissue behavior, feel
- Physiology
- Bleeding, fluid simulations
- Anatomical variations
- Joint articulations
- Embedded metrics, sensor insertion
- Interventional responses with dynamic behaviors
- Simulator reliability, ruggedness

*Dr. Sweet: Summarized in Figure 4-6 of final report

*Dr. Barnes: Content of EXSUM and final report Appendix F, "Technology Roadmap"

*Dr. Andreatta: Pages 119-120 of the final report



Early Implementation of Findings



- In response to the Department's efforts to standardize training combined with findings from these studies, animals are no longer used for training the management of chemical casualties or neonatal/pediatric intubation.
- The Department no longer uses animals in a career progression training course for Army combat medics (68Ws).
- The Department has used the information from these studies to inform research and development efforts, continuing to invest approximately \$15 million per year in the development of alternative technologies.
 - Many of the current commercial simulation tools resulted from these investments (e.g., MATT® Series 1500 Trauma Trainer, AirwayPlus Lifecast (APL) Upper Torso Trainer® (Kforce Government Solutions, Inc.), and TraumaMan®System (Simulab Corporation)).



Summary



- These studies informed the Department of the gaps in training and assessment.
- Ongoing research and development efforts by the Department are continuing to close gaps by advancing simulated tissues, modeling human physiology, and developing training systems that are rugged, open-sourced, and modular.
- In agreement with Dr. Barnes, the Department is pursuing a system engineering approach to integrate live, constructive, and virtual models.

(b)(6)

Subject: RE: Live Tissue Training**Signed By:**

(b)(6)

The topic made the quotes this morning:

MILITARY MEDICAL TRAINING: USE OF ANIMALS

Rep. Ted Lieu: [Former military doctors and veterans called for an end of the practice of using animals for military medical training during a briefing on Capital Hill.

The practice, sometimes referred to as live tissue trauma training, uses injured animals to train military medics to respond to emergency situations on the battlefield, such as injuries caused by improvised explosive devices or in combat.

During the presentation on Capitol Hill, former military doctors suggested the use of human simulators would not only be a more ethical solution, but also provide more accurate and cost-effective training for military medical personnel.]

"First, the vast differences in the anatomy and physiology of humans and other animals make animals poor surrogates for humans," [Rep. Ted W. Lieu, D-Calif., and Israeli Defense Force combat veteran Gideon Raff wrote in an editorial published by USA Today on Tuesday.] "Second, replacing live animals with artificial simulators also benefits the taxpayers."

[The event featured a demonstration by a technician from the Canadian Aviation Engineering Health Care, who used a human simulator to demonstrate various medical scenarios.

The U.S. Department of Defense announced it was scaling back the use of live animals for medical training in November 2014, and plans to use more simulators in place of animals.]

-February 10, 2016; UPI.com

http://www.upi.com/Business_News/Security-Industry/2016/02/10/Former-military-doctors-call-for-end-to-live-tissue-training/6131455136508/

-----Original Message-----

(b)(6)

Subject: FW: Live Tissue Training

FYSA...

(b)(6)

(b)(6)

Subject: RE: Live Tissue Training

H

(b)(6)

There were a series of studies conducted through a consortium. All but one is releasable at this time. R&E and Health Affairs have been working together to develop a briefing for the HASC and SASC that outlines the findings and recommendations. Mr. Welby has provided feedback on these draft briefs but need to check with Dr. Mason's office where we stand.

We also have a request from CM Johnson for the studies. Our goal is brief the HASC and SASC on the findings prior to the studies being released.

The ARMDEC is the release authority for the studies.

Wil get back with you with more info.

Thanks

(b)(6)

(b)(6)

Subject: FW: Live Tissue Training

(b)(6)

Hope your weekend is going well.

Rep Gabbard is asking "if there are any DoD data or studies showing the effectiveness of live tissue training" (see below and attached for entire thread).

Can you see what you come up with? For my own professional development, is this in Dr. Mason's shop (or somewhere else)?

Thanks for the help,

(b)(6)

(b)(6)

Subject: RE: [Non-DoD Source] RE: Live Tissue Training
Signed By: (b)(6)

(b)(6)

We do not have a date yet when the studies will be released but will share once available.

To answer your question if removing live tissue from combat trauma training would impact the competence of medics, yes, it would. Information in the studies on combat casualty care training indicate gaps in simulation technologies. If the animal patients were removed from combat trauma training, the existing simulation systems would leave gaps in tissue fidelity, physiologic responses, hemorrhage, and ruggedness. All of these factor into the Department's capability to provide realistic, scenario-based training to prepare Service members to deliver comprehensive combat casualty care.

The Department has not been able to quantify competence in combat due to the inability to perform controlled studies in the combat environment. The studies do have information where medics report assessing themselves as better prepared for combat trauma when trained using live tissue.

Thank you,

(b)(6)

-----Original Message-----

From: Chovil, Andres [mailto:Andres.Chovil@mail.house.gov]

Sent: Friday, February 05, 2016 3:59 PM

To: (b)(6)

Subject: [Non-DoD Source] RE: Live Tissue Training

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

(b)(6)

Thank you for your help. I did have one additional related question:

Under the 2013 NDAA (Public Law 112-239), the Secretary of Defense was required to submit to congressional defense committees no later than March 1, 2013, a strategy and timeline for a transition from using live animals in training for the treatment of combat trauma injuries. I was also required that DOD specify whether removing animals from training sessions could lead to a "reduction in the competency of combat medical personnel". Has DOD specified in the past whether this transition would lead to such a reduction?

Thank you again for your help.

Andres Chovil

Andres F. Chovil

Legislative Correspondent | Congresswoman Tulsi Gabbard (HI-02)

1609 Longworth House Office Building

(202) 225-4906 | (202) 225-4987 fax

Stay connected with Congresswoman Tulsi Gabbard:

cid:image001.jpg@01CFED3E.E69DCBD0 < Caution-http://gabbard.house.gov/ >

cid:image013.jpg@01CE3126.6ABA5E00 < Caution-https://twitter.com/TulsiPress >

cid:image012.jpg@01CE3126.6ABA5E00 < Caution-https://www.facebook.com/RepTulsiGabbard >

cid:image014.jpg@01CE3126.6ABA5E00 < Caution-https://www.youtube.com/user/tulsipress > Caution-

http://i.yimg.com/g/images/goodies/white-large-chiclet.png < Caution-

https://www.flickr.com/photos/reptulsigabbard/sets > Caution-https://encrypted-

tbn3.gstatic.com/images?q=tbn:ANd9GcTtdNEld2zN69OXXKGd5zQnYmlu1pfGGUJroEvHA9AFm2Qjv1sgx < Caution-

http://gabbard.dcsweb.house.gov/index.php?option=com_content&view=article&id=197&Itemid=133 >

(b)(6)

Subject: RE: Rep Gabbard (D-HI): Live Tissue Training inquiry

Signed By:

(b)(6)

Thanks

(b)(6)

-----Original Message-----

(b)(6)

Subject: FW: Rep Gabbard (D-HI): Live Tissue Training inquiry

Hi

(b)(6)

(b)(5) (b)(5)

Thanks

(b)(6)

(b)(6)

-----Original Message-----

(b)(6)

Subject: Rep Gabbard (D-HI): Live Tissue Training inquiry

Good Morning

(b)(6)

Please coordinate a response for Andres Chovil from Rep Gabbard's on live tissue training. He asked:

"Under the 2013 NDAA (Public Law 112-239), the Secretary of Defense was required to submit to congressional defense committees no later than March 1, 2013, a strategy and timeline for a transition from using live animals in training for the treatment of combat trauma injuries. I was also required that DOD specify whether removing animals from training sessions could lead to a "reduction in the competency of combat medical personnel". Has DOD specified in the past whether this transition would lead to such a reduction?"

He also heard about the pending report and asked for a copy when released.

Thank you,

(b)(6)



(b)(6)

Subject: RE: [Non-DoD Source] FW: DOD Contact for Animal Testing Story
Signed By: (b)(6)

Thank you!

(b)(6)

Subject: FW: [Non-DoD Source] FW: DOD Contact for Animal Testing Story

Once we get through this issue, I told (b)(6) to shift any future inquiries my way so you will only have to deal with one of us. :)

(b)(6)

-----Original Message-----

(b)(6)

Subject: RE: [Non-DoD Source] FW: DOD Contact for Animal Testing Story

Perfect, thanks for the update

-----Original Message-----

(b)(6)

Subject: RE: [Non-DoD Source] FW: DOD Contact for Animal Testing Story

Hi

Yes - it is now going to be in the Pentagon at 3:30.

Thanks

(b)(6)

(b)(6)

Subject: RE: [Non-DoD Source] FW: DOD Contact for Animal Testing Story

Morning (b)(6)

Do you know if (b)(6) is doing the press event referenced below?

Thanks

(b)(6)

Original Message

(b)(6)

Sent: Tuesday, February 09, 2016 4:32 PM

(b)(6)

(b)(6)

Flagg, Melissa L SES OSD OUSD ATL

(US); Mason, Patrick A SES OSD OUSD ATL (US); Ormond, Dale A SES OSD OUSD ATL (US) (b)(6)

(b)(6)

Subject: RE: [Non-DoD Source] FW: DOD Contact for Animal Testing Story

Hi (b)(6)

Just got office the phone with Mr. Welby and he is comfortable with (b)(6) doing the interview. Would you be escorting (b)(6) to the Hill and have you coordinated with LA. I am cc (b)(6) who has live tissue training in his LA portfolio.

Thanks

(b)(6)

(b)(6)

(b)(6)

Subject: Re: [Non-DoD Source] FW: DOD Contact for Animal Testing Story

Ma'am,

Thanks. I'm stuck in a hearing. Can you see if Mr Welby would be amenable to having a SME like (b)(6) doing the interview?

Sent from my BlackBerry 10 smartphone.

Original Message

From (b)(6)

Sent: Tuesday, February 9, 2016 3:48 PM

(b)(6)

Subject: RE: [Non-DoD Source] FW: DOD Contact for Animal Testing Story

(b)(6)

(b)(6)

He has not yet [redacted] s working it. We got a request from SASC too.

v/r

(b)(6)

From: [redacted]

Sent: Tuesday, February 09, 2016 3:47 PM

To: [redacted]
Cc: [redacted]

Subject: Fw: [Non-DoD Source] FW: DOD Contact for Animal Testing Story
Importance: High

Ma'am,

I received the interview request below on live tissue testing. Before I take this further with the reporter, can you tell me if ASD Welby has given the thumbs up on the TPs on this issue?

Thanks.

V/r

(b)(6)

Sent from my BlackBerry 10 smartphone.

Original Message

From: [redacted]

Sent: Tuesday, February 9, 2016 3:20 PM

To: [redacted]

(b)(6)

Subject: Fw: [Non-DoD Source] FW: DOD Contact for Animal Testing Story

(b)(6)

I'm in a hearing and can't escape. Check out the request below.

Do we have someone at this hearing? I will call her when I get out. I don't want to get ahead of anyone who will be testifying to congress.

Sent from my BlackBerry 10 smartphone.

Original Message

From: Walsh, Lynn (NBCUniversal) <Lynn.walsh@nbcuni.com>

Sent: Tuesday, February 9, 2016 3:14 PM

To: [redacted]

Cc: Payton, Mari (NBCUniversal); August, J.W (NBCUniversal); Naso, Bridget (NBCUniversal)

Subject: [Non-DoD Source] FW: DOD Contact for Animal Testing Story

(b)(6)

Hope all is well. I am reaching out on behalf of NBC in San Diego. I know you previously spoke to my colleague here, Mari Payton.

I wanted to let you know we are working on a story airing tomorrow, centered on the congressional briefing being held by PETA tomorrow focusing on the Battlefield Excellence through Superior Training (BEST) Practices Act (S. 587/H.R. 1095).

We will be talking on camera to everyone at the event and would like to know if there is someone from your agency we can speak to about this bill? Specifically we would like to know what the agencies thoughts are on the bill and if it is feasible to stop using animal for medical testing/training? Does eliminating the use of animals put members of the military at risk?

Thank you so much and feel free to call me directly to discuss too: 614-579-7937

Lynn Walsh
NBC 7 Investigative Executive Producer
o 619.578.0578 | c 614.579.7937
@LWalsh
225 Broadway, San Diego CA 92101

MEDIA ALERT - MEDIA ALERT - MEDIA ALERT

'HOMELAND' EXEC PRODUCER GIDEON RAFF TO LEAD PETA'S CONGRESSIONAL BRIEFING ON ANIMAL-FREE MILITARY TRAINING

PETA and Medical Experts Will Demonstrate Life-Like Human Simulators That Talk, Breathe, and Bleed

What: On Wednesday, Gideon Raff-the Emmy Award-winning executive producer of the hit TV show Homeland and a former Israel Defense Forces paratrooper-will join PETA and honorary hosts Reps. Raúl Grijalva (D-Ariz.) and Ted Lieu (D-Calif.) to lead a briefing that will demonstrate to members of Congress how realistic and cost-effective human simulators can replace archaic U.S. military medical training in which thousands of live animals are shot, stabbed, and killed each year.

Where: Rayburn House Office Building, Rm. 2203, 45 Independence Ave. S.W., Washington, DC 20515

When: Wednesday, February 10, 10:30-12 p.m.
****BRUNCH WILL BE SERVED****

Your coverage is invited. RSVP to Tasgola Bruner at 404-907-4172 or TasgolaB@peta.org.

"Shooting, stabbing, and dismembering thousands of live animals is a cruel, wasteful, and inferior way to prepare service members to treat human patients," says PETA Director Justin Goodman. "PETA looks forward to showing Congress firsthand how modern human simulators that talk, breathe, and bleed teach lifesaving skills more effectively, more economically, and far more humanely than maiming pigs and goats."

"Having served in an Israel Defense Forces special combat unit, I have the utmost concern for the health and security of the heroic service members-like those portrayed on my shows-who risk their lives to protect our safety and freedom," says Raff. "Research has proven time and again that the military doesn't need to mutilate animals to save troops' lives." Expert medical panelists speaking at the event will include Anahita Dua, M.D., M.S., M.B.A., and retired Rear Adm. Marion Balsam, M.D. The briefing will also feature a hands-on demonstration of CAE Healthcare's strikingly life-like human-simulation technology designed specifically for military training.

Congress is currently considering the Battlefield Excellence through Superior Training (BEST) Practices Act (S. 587/H.R. 1095)-a bipartisan bill cosponsored by Reps. Grijalva and Lieu-which would phase out the use of animals in military

medical training in favor of the simulation methods used instead of animals by nearly 80 percent of the U.S.' NATO allies and more than 98 percent of civilian facilities in the U.S.

This congressional briefing follows a video exposé by PETA released in 2015 that revealed abuse of animals and soldiers by a leading military medical-training contractor.

Broadcast-quality video footage is available upon request. For more information, please visit PETA.org or [click here](#).

-----Original Message-----

From: (b)(6)
Sent: Thursday, January 14, 2016 8:08 AM
To: Payton, Mari (NBCUniversal)
Subject: RE: [Non-DoD Source] NBC7 Information Request

Dear Mari,

Your query has reached the right place. I'd appreciate it if you could call me at the numbers below so we can talk about your project. Thanks.

Very respectfully,

(b)(6)

-----Original Message-----

From: Payton, Mari (NBCUniversal) [mailto:Mari.Payton@nbcuni.com]
Sent: Wednesday, January 13, 2016 6:03 PM
To: (b)(6)
Subject: [Non-DoD Source] NBC7 Information Request

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

(b)(6)

I am starting to work on a story about the military's use of live animal training or live tissue training. I am just doing some research on the subject, since I have very little knowledge on the subject.

Can you confirm that this is still going on in the military and the military's stance on it?

I have just read the Best Practices Act that was introduced to Congress:

Caution-<https://www.congress.gov/bill/114th-congress/house-bill/1095> < Caution-
<https://www.congress.gov/bill/114th-congress/house-bill/1095> >

How can I get more information on the subject? If you prefer, we can speak by phone.

Thanks.

cid:image001.jpg@01CFDD79.87445F20

Mari Payton

Investigative Reporter/Anchor
o 619.578.0255 c 619.843.0510
225 Broadway, San Diego CA

E:mari.payton@nbcuni.com < Caution-mailto:mari.payton@nbcuni.com >

W:Caution-www.nbc7.com < Caution-http://www.nbc7.com >

(b)(6)

(b)(6)

Subject:

RE: Live Tissue Training - SASC inquiry

Thank you

(b)(6)

V/R

(b)(6)

(b)(6)

Subject: FW: Live Tissue Training - SASC inquiry

I think we all received inquiries from SASC PSM John Quirk on this, so I wanted to share what OSD provided.

Attached are some talking points from the OUSD AT&L R&E office, an article on combat casualty care training, and the DoDI that covers the "Use of Animals in DoD Programs".

Also FYSA, PETA is on the Hill tomorrow, see below

(b)(6)

'HOMELAND' EXEC PRODUCER GIDEON RAFF TO LEAD PETA'S CONGRESSIONAL BRIEFING ON ANIMAL-FREE MILITARY TRAINING

PETA and Medical Experts Will Demonstrate Life-Like Human Simulators That Talk, Breathe, and Bleed

What: On Wednesday, Gideon Raff-the Emmy Award-winning executive producer of the hit TV show Homeland and a former Israel Defense Forces paratrooper-will join PETA and honorary hosts Reps. Raúl Grijalva (D-Ariz.) and Ted Lieu (D-Calif.) to lead a briefing that will demonstrate to members of Congress how realistic and cost-effective human simulators can replace archaic U.S. military medical training in which thousands of live animals are shot, stabbed, and killed each year.

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(b)(6)

(b)(6) Ormond, Dale A SES OSD OUSD ATL (US); Flagg, Melissa L SES OSD OUSD ATL (US); Mason, Patrick A SES OSD OUSD ATL (US); (b)(6) OSD OUSD ATL (US)
Subject: RE: Live Tissue Training - SASC inquiry

H (b)(6)

Here is a set of TPs that can be shared with the SASC in support of Sen Reed's meeting with PETA. Note these TPs were approved by Mr. Welby, ASD(R&E).

Thanks

(b)(6)

(b)(6)

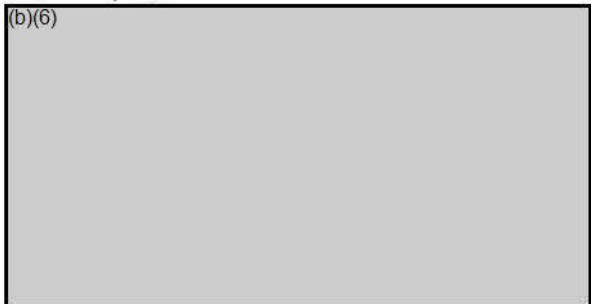
Subject: Live Tissue Training - SASC inquiry

R&E/HA,

SASC PSM John Quirk is prepping SASC Ranking Member SEN Reed (D-RI) for a meeting with People for the Ethical Treatment of Animals (PETA) on live animal training.

Are there any bullet points on the Department's current live tissue training policies and/or direction the department is going on this that we can share with John?

Thank you,



(b)(6)

Subject: FW: Live Tissue Training - SASC inquiry
Attachments: Simulation TPs Feb 2016 VSendUp.docx; Combat Casualty Care Training Extracted from HPT&B Newsletter Issue 3 Fi....pdf; DoDI_321601.pdf
Signed By: (b)(6)

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Your coverage is invited. RSVP to Tasgola Bruner at 404-907-4172 or TasgolaB@peta.org.

"Shooting, stabbing, and dismembering thousands of live animals is a cruel, wasteful, and inferior way to prepare service members to treat human patients," says PETA Director Justin Goodman. "PETA looks forward to showing Congress firsthand how modern human simulators that talk, breathe, and bleed teach lifesaving skills more effectively, more economically, and far more humanely than maiming pigs and goats."

"Having served in an Israel Defense Forces special combat unit, I have the utmost concern for the health and security of the heroic service members-like those portrayed on my shows-who risk their lives to protect our safety and freedom," says Raff. "Research has proven time and again that the military doesn't need to mutilate animals to save troops' lives."

Expert medical panelists speaking at the event will include Anahita Dua, M.D., M.S., M.B.A., and retired Rear Adm. Marion Balsam, M.D. The briefing will also feature a hands-on demonstration of CAE Healthcare's strikingly life-like human-simulation technology designed specifically for military training.

Congress is currently considering the Battlefield Excellence through Superior Training (BEST) Practices Act (S. 587/H.R. 1095)-a bipartisan bill cosponsored by Reps. Grijalva and Lieu-which would phase out the use of animals in military medical training in favor of the simulation methods used instead of animals by nearly 80 percent of the U.S.' NATO allies and more than 98 percent of civilian facilities in the U.S.

This congressional briefing follows a video exposé by PETA released in 2015 that revealed abuse of animals and soldiers by a leading military medical-training contractor.

Broadcast-quality video footage is available upon request. For more information, please visit PETA.org or [click here](#).

(b)(6)

(b)(6)

Ormond, Dale A SES OSD OUSD ATL (US); Flagg, Melissa L SES OSD OUSD ATL

(US); Mason, Patrick A SES OSD OUSD ATL (US);
OSD OUSD ATL (US)

Subject: RE: Live Tissue Training - SASC inquiry

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(b)(6)

Here is a set of TPs that can be shared with the SASC in support of Sen Reed's meeting with PETA. Note these TPs were approved by Mr. Welby, ASD(R&E).

Thanks

(b)(6)

(b)(6)

Subject: Live Tissue Training - SASC inquiry

R&E/HA,

SASC PSM John Quirk is prepping SASC Ranking Member SEN Reed (D-RI) for a meeting with People for the Ethical Treatment of Animals (PETA) on live animal training.

Are there any bullet points on the Department's current live tissue training policies and/or direction the department is going on this that we can share with John?



Simulation for Combat Casualty Care Training Talking Points

The Department of Defense has medical training needs unique from the civilian medical sector due to the types of personnel, missions, and injuries of combat. Access to fully-equipped emergency departments and supporting medical personnel will be determined by the operational environment and may be hours away or longer. Saving lives of Service members depends on the care received at the point of injury and how well-prepared the Department is to deliver and sustain that care until medical evacuation is possible. Combat casualty care training is vital to the success of the Department's missions and in saving the lives of injured Service members.

Training Process:

- Combat casualty care training follows a “crawl, walk, run” approach that begins with classroom learning and ends with realistic scenario-based training. In each of these phases, simulation is the principle system supporting learning.
- Simulation-based systems include: video games to develop cognitive skills; partial manikins to train individual skills such as inserting a chest tube; moulage actors to train medics to interact with the wounded; virtual environments to simulate the sights and sounds of combat; and high fidelity manikins to represent and train some trauma management skills such as application of a tourniquet for lower limb amputation.

Training Gaps in Simulation:

- Each phase of training leverages the technologies developed by the medical simulation industry, however, even the most advanced simulation systems have gaps in capabilities to simulate combat trauma injuries.
- Current simulation-based systems cannot fully replicate physiology, hemorrhage, and structural anatomy that a living system provides nor is there a complete, commercially-available system that models a multiply-wounded combat casualty.

Closing the Gaps in Simulation Systems:

- The “run” phase of training integrates animal patients into realistic, operationally-relevant scenarios that train medics to deliver comprehensive combat casualty care to a living being prior to deployment. These training scenarios are the culminating events that bridge the gaps that simulation-based systems have in modeling a combat trauma casualty with multiple wounds.
- Through the Department's studies into combat casualty care training, the gaps between simulation systems and live tissue have been identified. The Department's investments in these gaps--the characterization of human tissues, development of open-source physiology models, and development of rugged, open-source platforms to integrate manikin parts from various vendors-- facilitate the replacement of animals in combat trauma training.

The Department's Investments:

- Since 2009, the Department has invested approximately \$16 million per year to provide simulation training devices and products that assist combat casualty care training. Many of the current commercial simulation tools resulted from these investments (e.g., MATT® Series 1500 Trauma Trainer, AirwayPlus Lifecast (APL) Upper Torso Trainer® (Kforce Government Solutions, Inc.), and the TraumaMan®System (Simulab Corporation)).
- The Department is continuing to interact with national and international government agencies, industry, and academia to conduct research, development, testing, and validation of technologies for combat casualty care training.

The Department's Commitment to Replacement of Animals:

- Committed to replacing animals in training, the Department no longer uses animals in chemical casualty care training, pediatric and neonatal intubation courses, nor in other courses where patient contact or simulation was adequate. The Department has also fully transitioned to simulation for a course in hospital-based trauma management.


 NEWSLETTER

HPT&B

HUMAN PERFORMANCE, TRAINING, AND BIOSYSTEMS DIRECTORATE



ISSUE 3 JANUARY 2015

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Technology Solutions for Combat Casualty Care Training

By LTC Dawn C. Fitzhugh, VMD, MPH

In combat, enlisted medical personnel (medics) are DoD's first responders, providing care to casualties where they are injured. Depending on the ongoing mission and types of injuries, medics may be responsible for moving combat casualties out of immediate danger, keeping the airway open, ensuring breathing, controlling blood loss, and managing pain all while they may be injured themselves and still in harm's way. When they are not deployed, medics may have limited opportunities to perform lifesaving skills and manage multiple trauma casualties primarily due to the restricted scope of practice for non-licensed providers. Although the DoD partners with civilian hospitals for trauma training, this provides a much different learning experience. Civilian first responders are typically within minutes of sophisticated emergency rooms with highly specialized medical providers and supporting staff. Civilian first responders utilize equipment that is not available on the battlefield and the type of wounds

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HPT&B TECHNOLOGY FOR HUMANS

In the Human Performance, Training, and BioSystems (HPT&B) Directorate, we believe that Department of Defense (DoD) technologies are developed to extend the capabilities of the human, enhance the capabilities of the human, sustain the human, or repair the human.

Visit www.acq.osd.mil/rd/hptb for more information on the HPT&B Directorate.

WELCOME

From the Desk of Dr. Patrick Mason, Director HPT&B



Patrick A. Mason, Ph.D.
Director
Human Performance, Training,
and BioSystems Directorate

My team and I hope you enjoy the third edition of the HPT&B newsletter. Our focus on medical research and development (R&D) in this edition of the HPT&B newsletter is timely, coinciding with DoD's response to the Ebola outbreak in West Africa. As outlined in Dr. David Simon's article, DoD's R&D investment in Ebola and other emerging diseases continues to pay off; providing important capabilities such as rapid diagnostics, vaccines, therapeutics, patient evacuation systems, and personal protective equipment. Many of the DoD organizations executing Ebola-relevant R&D have worked together to coordinate their efforts and expedite the transition of technologies for use in the current Ebola outbreak. As RADM Bruce Doll emphasizes in his article on military medical research, the DoD medical research community is large and diverse and coordination is imperative to developing and transitioning

capabilities. The Armed Services Biomedical Research Evaluation and Management (ASBREM) Community of Interest (COI) provides the necessary venue for DoD medical research community to come together to communicate, coordinate, and collaborate.

This newsletter highlights some of our efforts to bring together the R&D and operational communities. One such effort was the organization of the Autonomous Patient Transport workshop in August. This newsletter also provides the opportunity to highlight some of our visits to see your research efforts and facilities. Finally, we continue to engage at the international level. We provided a summary of the recent India-U.S. Cognitive Sciences/Autonomy Workshop and Directed Energy Workshop.

We look forward and encourage your active participation in our Newsletter. Please send your comments, suggestions and success stories to: Jennifer.r.coughlin.ctr@mail.mil.

Technology Solutions for Combat Casualty Care Training

Continued from the cover

they treat may be very different from those that a medic will manage.

Development of skills for combat casualty care can be viewed as a system of systems working together for optimal training. At the core of the system is the curriculum with learning objectives and desired knowledge that impacts casualty care on the battlefield. This core system includes classroom and distance learning with lectures or other didactic materials to build the cognitive knowledge for medics to perform in accordance with established service-specific doctrine. The next step builds upon the curriculum and cognitive knowledge to obtain proficiency in certain medical techniques by engaging training systems using task trainers, manikins, and other modalities. Task trainers, manikins, browser-based virtual reality, and other simulation systems allow medics to practice procedures repeatedly, such as tourniquet placement, until they achieve competency and then proficiency with individual tasks. Once the cognitive and psychomotor skills have been developed, advanced simulator systems and moulaged actors can be used to integrate multiple skills, improving proficiency, knowledge, and confidence.

The external environment and individual stressors must then be considered in providing optimal training integrated along the training progression and incorporated in many of the culminating events. To that end, DoD trains as it fights; combat trauma training occurs on the ground, in tents, in the rain, snow, or heat using the actual equipment that the medic will take onto the battlefield. In addition to the environmental conditions, additional stressors may be added to training to create realistic scenarios. These stressors include an increased complexity of the combat-relevant injuries, increases in the number of injured, and/or an incorporation of different team dynamics.

In the virtual world, the National Capital Area Medical Simulation Center in Forest Glen, Maryland and the Medical Readiness Training Center at Camp Bullis, Texas both have Wide Area Virtual Environment (WAVE) training systems. In this virtual world, the sights, sounds, smells, and stressors of the battlefield immerse medical personnel in an environment that simulates the fog of war. Together these systems provide the medic with the knowledge and skills to perform their duties.

However, a gap remains between the skills that can be gained using the most advanced simulation systems and the proficiency and confidence that translates to performance and resilience on the battlefield.

In some medic training programs within DoD, animals are used in a capstone, pre-deployment event to build resilience and train for performance on the battlefield. At each institution that uses animals, an animal care committee must assess the use of the animals for training with the associated benefit. The committee's mission is to ensure responsible use of animals, consistent with federal laws and DoD policies, while providing the best medical training possible to save the lives of Service men and women. These committees make decisions within the bounds of regulatory guidance that includes the Animal Welfare Act, the federal law that applies to use of animals, and DoD policies. DoD policies (DoDI 3216.01 and DoDI 1322.24) limit the use of animals in training, allowing their use only when alternatives such as task trainers and manikins are not sufficient to adequately train personnel. Animal care committees review and assess the scientific literature related to the training in order to guide their decisions regarding the use of animals. While the DoD is sponsoring numerous projects to build evidence-based decisions, there is difficulty in designing a scientific study to accurately

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Technology Solutions for Combat Casualty Care Training

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quantify the impact that the animal brings to training. Current medical success on the battlefield, subjective feedback from medics, and guidance from experts in medical training must be considered in the decision to include the use of animals in a comprehensive capstone event prior to deployment. These decisions by animal care committees remain a delicate balance of logic and emotion. Removing the animal from DoD medic training could degrade the quality of combat casualty care on the battlefield, leading to an increase in combat fatality rates.

In order to advance the state of medical science in those areas of most pressing need and relevance to today's battlefield experience, the Assistant Secretary of Defense for Health Affairs (ASD(HA)) established the Defense Medical Research and Development Program (DMRDP). One of the goals of the DMRDP is to discover and explore innovative approaches to accelerate the transition of technologies to ensure the most effective medical training systems for the DoD. Under the DMRDP, the Joint Program Committee-1 (JPC-1) is responsible for Medical Simulation research. The



Photo courtesy of U.S. Air Force

Air Force personnel work with the Tactical Combat Casualty Care Cut Suit. The cut suit can be worn on a human or simulator to simulate severe traumatic situations for medical training environments.

JPC-1 was established in fiscal year 2010 to provide recommendations for research related to medical training and education efforts to advance the development and integration of simulation-based training systems.

The JPC-1 has several ongoing projects to advance simulation-based systems for combat casualty care training. Work in this area began in 2011 by addressing the need for improving knowledge of curricula and simulation modalities. These initial research initiatives were to: identify training gaps when using simulation technologies; determine objective evaluation criteria for trainees; compare current simulation systems (e.g., simulators and animals) with end user needs; identify metrics by skill or procedure; and determine which metrics discriminate between users. As these early studies begin to conclude, this knowledge base will provide an initial means to

compare training effectiveness across a spectrum of modalities to include manikins and animals.

While such projects contribute to knowledge of how to optimize training curricula, research in other areas examines improved material solutions for simulation in combat casualty care training. One such product is the multiple amputation trauma trainer, or MATT® which successfully transitioned from a research effort (U.S. Army Research, Development and Engineering Command, Simulation and Training Technology Center (RDECOM-STTC)) to a product in use today at medical simulation training centers (MSTCs). The MATT® product trains medics to respond to severe lower extremity injuries, managing hemorrhages and amputations. A similar ongoing effort is the development of an

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Technology Solutions for Combat Casualty Care Training

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Photo courtesy of U.S. Air Force photo/Senior Airman

Airmen train Aug. 22 using the Multiple Amputation Trauma Trainer (MATT) at David Grant USAF Medical Center

advanced modular manikin with interchangeable core and peripheral components of varying fidelity that will meet the needs of core and tailored curriculum for the trainees.

Providing products of high fidelity will improve the realism of simulation-based training systems for combat casualty care. In both the virtual and physical world, JPC-1 has recommended studies to understand the complex mechanisms of tissue biomechanics and human physiology. The desired long-term outcome is the development of simulation-based systems that realistically replicate a human response to medical procedures--be that a physical examination, application of a tourniquet, placement of an intravenous catheter with subsequent administration of medications, or all the way to complex multiple injuries where not only does it matter how to treat, but also the order in which to treat. The ideal product will not only look and feel like a human being, but will replicate the complex physiologic responses of a living being, responding to medical interventions with realistic variations in heart rate, blood pressure, breathing, and other parameters all based upon the level of injury. Such high fidelity, physiologically relevant systems

must also be untethered and rugged enough to endure the DoD's training environments. Ongoing research into the training environment will help the DoD train medics in situations that are optimally stressful, providing the right combination of factors external to their "patient" that will prepare them for their roles on the battlefields of the future with the resilience to endure the reality of combat casualty care.

Through ongoing research efforts, the DoD is improving knowledge of how to best assess and compare training platforms for combat casualty care, developing improved materiel solutions for non-animal alternatives in both the physical and virtual world, and creating optimal environments to train ready, resilient medics. Standing alone, each of these systems aids in the overall learning experience. Combining these individual systems into one overarching system creates a robust learning atmosphere, fully engaging the medic mentally, physically, and emotionally. Many of these advancements will likely be applied to medical simulation systems used by other extramural healthcare providers, as well as by other Government organizations, such as the Department of Homeland Security (DHS) or the Federal Emergency Management Agency (FEMA) to prepare for human-made or natural disasters. To this end, the DoD continues its research efforts and is interacting with industry, academia, and international partners to meet the challenges that come with learning in a simulated environment to best prepare medics to care for the combat-wounded warfighter.



Department of Defense INSTRUCTION

NUMBER 3216.01

September 13, 2010

USD(AT&L)

SUBJECT: Use of Animals in DoD Programs

References: See Enclosure 1

1. PURPOSE. This Instruction reissues DoD Directive (DoDD) 3216.1 (Reference (a)) as a DoD Instruction (DoDI) in accordance with the authority in DoDD 5134.01 (Reference (b)) to establish policy and assign responsibilities for the use of animals in DoD programs. The Reference (a) designation of the Secretary of the Army as the DoD Executive Agent to develop and issue Service regulations to implement Reference (a) has been cancelled pursuant to Deputy Secretary of Defense Memorandum (Reference (c)).

2. APPLICABILITY

a. This Instruction applies to:

(1) OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the Department of Defense (hereafter referred to collectively as the "DoD Components").

(2) Research, development, test, and evaluation (RDT&E) or training that is conducted or supported both within the continental United States and outside of the continental United States. (See Glossary, Part II, for definitions.)

(3) Vertebrate animals, alive and dead, including birds, cold-blooded animals, and other designated mammalian species. (See Glossary, Part II, for definitions.)

b. This Instruction does not apply to:

(1) Animals used strictly for ceremonial and/or recreational purposes and working animals, such as military working dogs. However, if ceremonial, recreational, or military

working animals are also used to conduct RDT&E or training, as defined in the Glossary, this Instruction applies.

(2) Farm animals such as but not limited to livestock or poultry used or intended for use as food or fiber, or livestock or poultry used or intended for use improving animal nutrition, breeding, management, or production efficiency; or for improving the quality of food or fiber.

(3) Animals used in disease surveillance, as defined in the Glossary, unless the disease screening procedure harms the animal. If there is no Institutional Animal Care and Use Committee (IACUC) supporting the institution, a DoD veterinarian with demonstrated familiarity with this Instruction and not involved in the activity shall determine if the activity is disease surveillance or if it harms the animal.

(4) Animals involved in field studies, as defined in the Glossary. If there is no IACUC supporting the institution, a DoD veterinarian with demonstrated familiarity with this Instruction and not involved in the activity shall determine if the activity is a field study.

3. DEFINITIONS. See Glossary.

4. POLICY. It is DoD policy that:

a. RDT&E or training conducted or supported by the Department of Defense shall comply with sections 2131-2159 of title 7, United States Code (Reference (d)) and its implementation in parts 1-4 of title 9, Code of Federal Regulations (Reference (e)).

(1) RDT&E or training conducted or supported by the Department of Defense shall also comply with the DoD policy and guidance in DoDDs 6025.21E and 6400.4 (References (f) and (g)) and DoDI 3210.7 (Reference (h)), and shall adopt other Federal policies and guidance, as applicable, that provide national standards for the acquisition, transportation, housing, control, maintenance, handling, treatment, care, use, and disposal of animals. This includes the policies and guidance in References (i) through (u). Federal policies for animal welfare shall be applied as directed in this Instruction.

(2) Activities subject to this Instruction shall also comply with all other applicable Federal, State, and local statutes and regulations, and requirements of non-U.S. entities when the work is conducted outside of the United States.

b. Methods other than animal use and alternatives to animal use (i.e., methods to refine, reduce, or replace the use of animals) shall be considered and used whenever possible to attain the objectives of RDT&E or training if such alternative methods produce scientifically or educationally valid or equivalent results.

c. The purchase or use of dogs or cats for inflicting wounds from any type of weapon(s) to conduct training in surgical or other medical treatment procedures is prohibited in accordance


with section 8019 of Public Law 101-511 (Reference (i)). The purchase or use of nonhuman primates or marine mammals for inflicting wounds from any type of weapon(s) to conduct training in surgical or other medical treatment procedures is also prohibited.

5. RESPONSIBILITIES. See Enclosure 2.

6. PROCEDURES. See Enclosure 3.

7. RELEASABILITY. UNLIMITED. This Instruction is approved for public release and is available on the Internet from the DoD Issuances Website at <http://www.dtic.mil/whs/directives>.

8. EFFECTIVE DATE. This Instruction is effective immediately.


Ashton B. Carter
Under Secretary of Defense
for Acquisition, Technology, and Logistics
ACTING USDP(ATH)

Enclosures

1. References
 2. Responsibilities
 3. Procedures
- Glossary

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ENCLOSURE 1

REFERENCES

- (a) DoD Directive 3216.1, "Use of Animals in DoD Programs," April 17, 1995 (hereby cancelled)
- (b) DoD Directive 5134.01, "Under Secretary of Defense for Acquisition, Technology, and Logistics (USD(AT&L))," December 9, 2005
- (c) Deputy Secretary of Defense Memorandum, "Approval to Rescind the Designation of the DoD Executive (EA) for Use of Animals in DoD Programs," February 12, 2010
- (d) Sections 2131-2159 of title 7, United States Code
- (e) Parts 1-4 of title 9, Code of Federal Regulations
- (f) DoD Directive 6025.21E, "Medical Research for Prevention, Mitigation, and Treatment of Blast Injuries," July 5, 2006
- (g) DoD Directive 6400.4, "DoD Veterinary Services Program," August 22, 2003
- (h) DoD Instruction 3210.7, "Research Integrity and Misconduct," May 14, 2004
- (i) Section 8019 of Public Law 101-511, "The Department of Defense Appropriations Act, 1991," November 5, 1990
- (j) Institute of Laboratory Animal Research, Commission on Life Sciences, and National Research Council, "Guide for the Care and Use of Laboratory Animals," January 2, 1996¹
- (k) Public Law 106-545, "ICCVAM Authorization Act of 2000," December 19, 2000
- (l) Title 21, Code of Federal Regulations
- (m) U.S. Department of Agriculture Policy Manual, Policy 23, "Criteria for Licensing Hoofstock Dealers," August 26, 2002
- (n) Sections 3109 and 3371-3376² of title 5, United States Code
- (o) National Institutes of Health, Office of Laboratory Animal Welfare, "Public Health Service Policy on Humane Care and Use of Laboratory Animals," August 7, 2002
- (p) Defense Federal Acquisition Regulations Supplement, clause 252.235-7002, "Animal Welfare," December 1991
- (q) U.S. Department of Agriculture, "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training," February 15, 2001
- (r) Sections 1361-1384 and 1531-1543 of title 16, United States Code
- (s) Section 42 of title 18, United States Code
- (t) Parts 10-14, 16, 23, and 216-226 of title 50, Code of Federal Regulations
- (u) Federation of Animal Science Societies, "Guide for the Care and Use of Agricultural Animals in Research and Teaching," January 2010
- (v) DoD Instruction 5025.01, "DoD Directives System," October 28, 2007

¹ Available on the Internet at http://www.nap.edu/openbook.php?record_id=5140&page=R1

² Also known as "The Intergovernmental Personnel Act of 1970, as amended"

ENCLOSURE 2

RESPONSIBILITIES

1. DIRECTOR OF DEFENSE RESEARCH AND ENGINEERING (DDR&E). The DDR&E, under the authority, direction, and control of the Under Secretary of Defense for Acquisition, Technology, and Logistics, shall:

a. Be the DoD point of contact for all matters related to DoD compliance with this Instruction, and shall act as the principal DoD liaison with agencies outside the Department of Defense on matters pertaining to animal care and use for RDT&E and training.

b. Provide guidance and policy necessary to implement this Instruction, after consulting with the Assistant Secretary of Defense for Health Affairs (ASD(HA)) for matters affecting medical training, and with the Director, DoD Veterinary Services Activity, for matters affecting animal health and welfare.

c. Exercise the responsibilities and authorities of the Secretary of Defense identified in section 2143(c) of Reference (d) for:

(1) Ensuring corrective action is taken on deficiencies of DoD research facilities (as defined in section 2132(e) of Reference (d)) reported by the DoD IACUC.

(2) Granting exceptions to procedures or requirements in this Instruction based upon an appropriate justification from the Head of an OSD or DoD Component and consistent with law.

d. Establish a process to oversee DoD Component implementation of their respective Component animal use management plan and compliance with this Instruction.

e. Establish policies and procedures to facilitate efficient management, tracking, and reporting of the care and use of animals in DoD-conducted and -supported RDT&E and training.

f. Maintain the:

(1) DoD Standard Animal Use Protocol Format (available at http://www.dtic.mil/biosys/docs/au-DoD_Standard_Animal_Use_Protocol.pdf).

(2) DoD (DD) Form 2856, "DoD Semiannual Program Review/Facility Inspection Checklist" (available at <http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2856.pdf>).

g. Maintain a list of foreign and international standards that are at least equivalent to those in the "Guide for the Care and Use of Laboratory Animals" (Reference (j)) or the United States Department of Agriculture (USDA) and Department of Defense.

h. Designate a DoD representative to the Interagency Coordinating Committee on the Validation of Alternative Methods established under the management of Department of Health and Human Services (DHHS) pursuant to Public Law 106-545 (Reference (k)).

i. Designate a DoD representative to the Interagency Research Animal Committee established by DHHS who is a veterinarian of appropriate rank or grade and experience and a diplomate of the American College of Laboratory Animal Medicine.

j. Establish the Joint Technical Working Group (JTWG) on Animal Use in DoD Programs to act as the central advisory committee to the Armed Services Biomedical Research Evaluation and Management (ASBREM) Committee on all matters regarding the care and use of animals for RDT&E or training pursuant to Reference (f). Membership shall be as described in section 4 of Enclosure 3.

2. ASD(HA). The ASD(HA), under the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness, shall advise the DDR&E on matters related to the necessity to use animals in medical education and training and the appropriate use of alternatives.

3. HEADS OF THE OSD AND DoD COMPONENTS. The Heads of the OSD and DoD Components that use or support the use of animals covered by this Instruction shall:

a. Develop, issue, and monitor the Component animal use management plan that contains the Component implementing policies and procedures to ensure compliance with this Instruction and any other supplementing or implementing issuances.

(1) The Component animal use management plan shall:

(a) Incorporate the procedures set forth in Enclosure 3.

(b) For each action, identify the responsible Component office.

(c) Integrate applicable Federal policy and guidance that provides national standards for the acquisition, transportation, housing, control, maintenance, handling, treatment, care, use, and disposal of animals. This includes References (d) through (u) and other applicable Federal policy and guidance.

(2) The authority and responsibility for implementing and overseeing the Component animal use management plan shall only be delegated to a single, senior official at the general or flag officer, Senior Executive Service, or equivalent level, or higher.

b. Establish and oversee Component policies and procedures for animal use. Component policies may be more restrictive than the requirements in this Instruction, but they may not be less restrictive. They shall include policies and procedures:

(1) For Component headquarters administrative review of DoD-conducted and -supported RDT&E and training (sections 1 and 2 of Enclosure 3) and allegations of noncompliance or misconduct (section 5 of Enclosure 3).

(2) For Component headquarters oversight of the inspections of the institutions' animal care and use program review, including the institutions' facility inspection. Oversight should ensure that the program reviews are appropriately conducted and corrective action is taken in a timely manner (sections 1 and 2 of Enclosure 3).

(3) That support the assignment of responsibilities when performing RDT&E and training in collaboration with another DoD Component, to include establishing written agreements for tasks such as single IACUC approval, single Component headquarters administrative reviews and inspections (section 1 of Enclosure 3), and/or single oversight of extramural RDT&E and training (section 2 of Enclosure 3).

(4) To maintain a list of providers approved by the Component for each training plan and establishing a process to communicate this list with the other DoD Components to allow a Component to rely on the review and inspection of another Component (section 2 of Enclosure 3).

(5) To provide education and training for implementation, management, and oversight of this Instruction (section 3 of Enclosure 3).

c. Coordinate and cooperate in the transfer of Government-owned nonhuman primates within the Department of Defense and with other Governmental agencies to maximize conservation and proper utilization.

d. Ensure prior approval for proposals intending to use chimpanzees by the DHHS Interagency Animal Model Committee, which coordinates national priorities for research utilization of this species.

e. Provide members to intra- and interagency committees and to the JTWG when requested by the DDR&E (section 4 of Enclosure 3).

f. Report in a timely manner to the DDR&E any research misconduct or serious noncompliance issues related to animal use for RDT&E or training (section 5 of Enclosure 3). Report at a minimum annually to the DDR&E any waivers, exemptions, exceptions, or other deviations from requirements granted in accordance with this Instruction.

g. Maintain all records identified in this Instruction or required by References (d) through (u) for at least 3 years beyond the end of the RDT&E or training or the effective date of the record (section 6 of Enclosure 3).

4. SECRETARY OF THE ARMY. The Secretary of the Army, in addition to the responsibilities in section 3 of this enclosure, and as the DoD Executive Agent for the DoD Veterinary Services Program pursuant to Reference (g), shall:

a. Develop and issue, in consultation with the other DoD Components that have an animal use program, a joint Component regulation to implement this Instruction.

b. Designate the Director, DoD Veterinary Services Activity, a Field Operating Agency of the Army under the authority, direction, and control of the Army Surgeon General, to serve as:

(1) A consultant to the ASD(HA) and the DDR&E for technical and professional matters related to this Instruction.

(2) The DoD representative on animal care and use matters for implementing Food and Drug Administration regulatory requirements in accordance with title 21, Code of Federal Regulations (Reference (l)).

ENCLOSURE 3

PROCEDURES

1. DoD-CONDUCTED RDT&E AND TRAINING

a. Acquisition of Animals

(1) When purchasing animals covered by this Instruction, the DoD Components shall ensure that the animals are legally obtained from suppliers licensed by the USDA in accordance with sections 2133-2134 of Reference (d), unless specifically exempted from the licensing requirements in References (d), (e), and Department of Agriculture policy manual (Reference (m)). When a U.S. supplier claims it meets an exemption criterion in References (d), (e), or (m), the Component shall conduct a program review that includes a facility inspection to confirm that the supplier cares for the animals according to accepted U.S. industry standards or practices and meets the exemption criterion. A DoD veterinarian with training or experience in laboratory animal science and medicine shall conduct the review. If the supplier is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC), International, the Component may waive the requirement for on-site inspection. This waiver does not preclude the Component from conducting an inspection at any time.

(2) When conducting RDT&E or training outside of the United States and using foreign suppliers, the DoD Component shall require a program review that includes a facility inspection to confirm that the supplier cares for the animals according to accepted U.S. industry standards or practices. A DoD veterinarian with training or experience in laboratory animal science and medicine shall conduct the review. If the supplier is accredited by AAALAC, or meets the equivalent standards established as directed in paragraph 1.g of Enclosure 2, the Component may waive the requirement for on-site inspection. This waiver does not preclude the Component from conducting an inspection at any time. Foreign suppliers shall also be in compliance with their national policies.

(3) When capturing animals from the wild, institutions shall ensure they have all required capture and use permits approved prior to acquisition.

b. AAALAC Accreditation. ALL DoD institutions housing animals for RDT&E or training shall attain and maintain AAALAC accreditation, with these exceptions:

(1) DoD institutions using or housing animals for RDT&E or training for less than 8 continuous calendar days. However, they shall have the animal facilities inspected and approved by a DoD veterinarian trained or experienced in laboratory animal medicine prior to initiation of any research protocol or training plans involving animals. The inspection shall ensure that the institution has met the requirements in this Instruction. The DoD Component may waive this requirement for an inspection when they have determined a compelling reason exists.

(2) Additional exemptions as the DDR&E determines appropriate.

c. IACUC Membership

(1) The IACUCs of the DoD institutions established in accordance with section 2143 of Reference (d) shall:

(a) Consist of committee members who are Federal employees; individuals covered by sections 3371-3376 of title 5, United States Code (also known as "The Intergovernmental Personnel Act of 1970, as amended" (Reference (n))); or individuals considered as experts or consultants in accordance with section 3109 of Reference (n). IACUCs may consult with subject matter experts who are not members of the committee; these consultants may not vote.

(b) Have at least five members with various backgrounds to promote complete and accurate review of RDT&E and training activities commonly conducted by the institution, in accordance with National Institutes of Health policy (Reference (o)). No more than three members shall be from the same administrative unit of the institution.

(c) Have at least one member who is a doctor of veterinary medicine with training or experience in laboratory animal science and medicine.

(d) Have at least one member who represents the general community interest and is not affiliated with the institution sponsoring the IACUC. The IACUCs must designate an alternate member(s) for the non-affiliated member to ensure community representation at convened IACUC meetings.

(e) Have at least one member who does not have a scientific background. When appropriate, the non-affiliated and the non-scientific member may be the same person.

(2) To have a quorum, at least one veterinarian and one non-affiliated member (or his or her alternate) must be present. When a compelling reason exists, the IACUC may request approval from the Head of the OSD or DoD Component to waive this requirement in order to meet without the non-affiliated member.

d. IACUC Approval and Oversight

(1) All RDT&E and training shall be approved and provided oversight by a duly constituted IACUC in accordance with Reference (d) before the activity can begin.

(2) All proposed RDT&E shall be submitted to the IACUC using the DoD Standard Animal Use Protocol Format. All proposed training plans submitted to the IACUC shall contain the relevant information outlined in the DoD Standard Animal Use Protocol Format.

(3) A veterinarian, working under the authority of the IACUC, shall oversee the animals being used during the RDT&E or training as described either in the protocol approved by the IACUC or in the IACUC policy, which is referenced in the protocol.

(4) When an investigator proposes significant changes to an IACUC-approved protocol, the IACUC must review and approve the changes before they can be implemented.

(5) All RDT&E and training approved by an IACUC must be reviewed by the IACUC at least annually.

e. Program Review. All DoD institutions using or housing animals for RDT&E or training for more than 12 hours shall conduct a program review, including a facility inspection, at least semiannually using DD Form 2856. A majority of the institution's IACUC members shall sign the report to the institutional official, and the report shall include a statement indicating the presence or absence of minority opinions. This review shall also be submitted to the DoD Component headquarters oversight office.

f. DoD Component Headquarters Approval and Oversight

(1) At a minimum, the DoD Component headquarters oversight office must conduct an administrative review and approve all RDT&E and training requiring the use of nonhuman primates, dogs, cats, or marine mammals, and all medical training involving live animals. The review must be conducted to ensure conformance with all applicable regulations and policies.

(2) When an IACUC approves significant changes to an approved protocol that was administratively reviewed by the Component headquarters oversight office as required in subparagraph 1.f.(1) of this enclosure, the Component headquarters oversight office must review and approve the changes to the IACUC-approved protocol before they can be implemented.

(3) The institutional program review conducted by the IACUC (required by paragraph 1.e. of this enclosure) shall be reviewed by the Component headquarters oversight office. Any issues needing corrective action shall be overseen by the Component headquarters oversight office to ensure that actions are completed in a timely manner.

g. Institution Notifications to the DoD Component

(1) When an institution is notified by the USDA that it is under investigation, the institution shall notify their Component headquarters oversight office within 5 business days.

(2) When an institution is notified by AAALAC that it has lost its accreditation status, the institution shall notify their Component headquarters oversight office within 5 business days.

(3) When an institution has experienced any adverse events regarding the RDT&E or training, the institution shall notify their Component headquarters oversight office within 5 business days.

2. DoD-SUPPORTED, BUT NOT -CONDUCTED, RDT&E AND TRAINING

a. Clause in Contracts and Agreements. All contracts for DoD-supported RDT&E or training must contain Defense Federal Acquisition Regulations Supplement (DFARS) clause 252.235-7002 (Reference (p)). Agreements not subject to Reference (p) (e.g., grants and cooperative research and development agreements) must contain language equivalent to that in Reference (p).

b. USDA Registration. Non-Federal institutions conducting DoD-supported RDT&E or training in the United States must be registered with the USDA, unless otherwise exempt from this requirement by meeting the conditions in Reference (d) for the duration of the activity.

c. IACUC Approval and Oversight

(1) DoD-supported RDT&E and training involving animals must be approved by the performing institution's IACUC in accordance with Reference (d) before the activity begins.

(2) A veterinarian, working under the authority of the IACUC, shall oversee the animals being used during the RDT&E or training as described in either the protocol approved by the IACUC or in the IACUC policy, which is referenced in the protocol.

(3) When an investigator proposes significant changes to an IACUC-approved protocol, the IACUC must review and approve the changes before they can be implemented.

(4) All RDT&E and training approved by an IACUC must be reviewed by the IACUC at least annually.

d. DoD Component Headquarters Approval and Oversight

(1) Protocol or Training Plan Approval. At a minimum, the DoD Component headquarters oversight office must conduct an administrative review and approve all DoD-supported RDT&E and training. The review must be conducted to ensure conformance with all applicable regulations and policies. The review shall be conducted by a DoD veterinarian trained or experienced in laboratory animal science and medicine to ensure the activity meets the requirements in this Instruction. This Component review and approval must occur before the performing institution is allowed to begin animal work. Although non-DoD institutions are not required to use the DoD Standard Animal Use Protocol Format, the documents submitted to the Component shall provide all pertinent information contained in the DoD Standard Animal Use Protocol Format. When an IACUC approves significant changes to an approved protocol that has been reviewed by the Component supporting the RDT&E or training, the Component must review and approve the changes before they can be implemented. The Component must ensure the IACUC conducts an appropriate continuing review at least annually.

(2) Veterinary Care Plan. The DoD Component must review and approve the veterinary care plan required by subparagraph 2.c.(2) of this enclosure before the performing institution is allowed to begin animal work.

(3) Acquisition of Animals

(a) Extramural RDT&E and Training Conducted in the United States. The performing institution shall include in the documents submitted to the DoD Component for review a statement that the animals shall be or have been legally obtained from suppliers licensed by the USDA in accordance with sections 2133-2134 of Reference (d), unless the supplier claims to meet the exemption criteria in References (d), (e), or (m). When a supplier claims to meet the exemption criteria, the institution performing the work shall convey the claim of exemption to the supporting Component.

(b) Extramural RDT&E and Training Outside of the United States. The performing institution shall include in the documents submitted to the DoD Component for review a statement that the animals shall be or have been legally obtained from suppliers in accordance with national policy.

(c) Wild Animals. When capturing animals from the wild for the purpose of the DoD-supported RDT&E or training, the performing institution shall include in the documents submitted to the DoD Component for review all required capture and use permits.

(4) USDA Inspection Reports. As part of the DoD approval process, the DoD veterinarian shall also review the most recent USDA inspection reports, unless the institution is exempt from inspection by meeting the criteria in References (d) and (e). The inspection reports must be reviewed annually for the duration of the activity.

(5) On-Site Inspection

(a) For all RDT&E using dogs, cats, nonhuman primates, or marine mammals, and for all medical training using live animals, the contractor must pass an on-site evaluation conducted by a DoD veterinarian trained or experienced in laboratory animal medicine to ensure that the animal care program meets the standards in References (d), (e), and (j). The site visit shall be conducted within 30 days of the signed agreement with the Department of Defense (e.g., contract award) if the animals are already at the institution or training site, or within 30 days of delivery of the animals if they are not. The DoD Component may allow this inspection to occur at a later date if the Component determines that it is in the best interest of the animals. The on-site evaluation shall be repeated annually for the duration of the training agreement, as long as animals are being used. For efficiency, a Component may rely on the evaluation of another Component.

(b) If the institution is accredited by AAALAC or meets equivalent standards referenced in paragraph 1.g. of Enclosure 2 for the duration of the RDT&E or training agreement, the DoD Component may waive the requirement for on-site inspection. This waiver does not preclude the Component from conducting an inspection at any time.

(c) For institutions outside of the United States, if the facility can provide evidence to the DoD Component that it meets either their national standards or standards from an

internationally recognized organization, the Component may waive the requirement for an on-site inspection. In either case, the standards must be determined by the DDR&E to be at least equivalent to the standards referenced in paragraph 1.g. of Enclosure 2. This waiver does not preclude the Component from conducting an inspection at any time.

e. Notifications to the DoD Component

(1) When an institution is notified by the USDA that it is under investigation, the institution shall notify the supporting DoD Component within 5 business days. An institution with AAALAC accreditation shall notify the Component within 5 business days of loss of AAALAC accreditation. Upon either of these notifications and when the issues are relevant to a DoD-supported activity, a DoD veterinarian trained or experienced in laboratory animal medicine shall perform a site inspection within 30 days of the notification. The Component may allow more time for this inspection to occur on a case-by-case basis.

(2) Site inspections for cause shall evaluate and ensure the adequacy of animal care and use in DoD-supported programs, and provide recommendations to the Component about allowing continued DoD support of the research, suspending the research until necessary changes have been made, or terminating the research.

(3) The IACUC must notify the Component in accordance with subparagraph 2.d.(1) of this enclosure when the IACUC approves significant changes to the protocol, and when the IACUC conducts its continuing review.

(4) The Component shall require the contractor to inform the Component of any adverse events regarding the RDT&E or training that might impact DoD continued support of the activity.

3. EDUCATION AND TRAINING. The DoD Components shall ensure that all DoD personnel involved in the conduct, review, or approval of RDT&E and training involving animals, including the non-affiliated members of the DoD IACUCs, receive initial and continuing education and training.

a. Training and education shall integrate Federal policy and guidance that provides national standards for the acquisition, transportation, housing, control, maintenance, handling, treatment, care, use, and disposal of animals.

b. Both initial and continuing education and training shall be commensurate with the duties and responsibilities of the DoD personnel.

c. All training and education of DoD personnel shall be documented.

d. Certification is encouraged for all personnel involved in the care and use of animals in RDT&E or training.

4. **JTWG MEMBERSHIP.** The ASBREM Committee Co-Chairs shall designate the JTWG Chair. At a minimum, the JTWG shall be composed of representatives of the DDR&E, each of the DoD Components with an animal use management plan, and the DoD Veterinary Services Activity.

5. **RESEARCH MISCONDUCT AND NONCOMPLIANCE.** The DoD Components shall comply with the requirements for reviewing allegations of misconduct as required by Reference (h). DoD Component implementing policies and procedures for addressing allegations of noncompliance with animal care and use standards by their Component, or by an institution supported by their Component, shall refer the matter to the next higher management echelon to take deliberate action to resolve. All findings of serious noncompliance shall be reported to the DDR&E.

6. **RECORD KEEPING**

a. The requirement in paragraph 3.g. of Enclosure 2 for the DoD Components to retain records for at least 3 years beyond the end of the RDT&E and training activity or the effective date of the record applies to:

(1) Records from DoD-conducted or -supported RDT&E and training that are created by either the Government or the institution conducting the work.

(2) All records regarding Component waivers, exemptions, and extensions, and all Component requests for exceptions, waivers, exemptions, and extensions submitted to the DDR&E for action.

b. The DoD Components may be required to retain records for longer than specified in paragraph 6.a. of this enclosure. For complete recordkeeping guidance and instruction, the DoD Components shall consult their respective records disposition schedules.

c. Records that document extramural compliance or noncompliance with this Instruction shall be made accessible for inspection and copying by authorized representatives of the Department of Defense at reasonable times and in a reasonable manner as determined by the supporting DoD Component.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

| | |
|---------|---|
| AAALAC | Association for Assessment and Accreditation of Laboratory Animal Care, International |
| ASBREM | Armed Services Biomedical Research Evaluation and Management |
| ASD(HA) | Assistant Secretary of Defense for Health Affairs |
| DDR&E | Director of Defense Research and Engineering |
| DHHS | Department of Health and Human Services |
| DoDD | DoD Directive |
| DoDI | DoD Instruction |
| IACUC | Institutional Animal Care and Use Committee |
| ICCVAM | Interagency Coordinating Committee on the Validation of Alternative Methods |
| JTWG | Joint Technical Working Group |
| RDT&E | research, development, test, and evaluation |
| USDA | United States Department of Agriculture |

PART II. DEFINITIONS

Unless otherwise noted, these terms and their definitions are for the purpose of this Instruction.

administrative review of an RDT&E protocol or training plan. A review of documents related to animal use for RDT&E and training by a Component headquarters-level veterinarian trained or experienced in laboratory animal medicine. This review is not intended to be another IACUC review. The purpose of this review is to ensure that the institution performing the RDT&E or training has met the requirements in all applicable regulations and policies.

alternatives. Alternatives to animal use are characterized by “the three R’s:” replacement, reduction, and refinement. Investigators may replace methods that use animals with those that do not. Reduction refers to the use of fewer animals. Existing procedures may be refined so that animals are subjected to less pain and distress.

animal. Any living or dead vertebrate animal, including birds, cold-blooded animals, rats of the genus “Rattus” and mice of the genus “Mus.” With respect to avians and other egg-laying vertebrate species, their offspring are considered animals only after hatching. With respect to fish and amphibians, their larval offspring are considered animals. Reference (d) governs most

species of vertebrate animals; this Instruction governs all species of vertebrate animals. For the purposes of this definition, “dead” is defined as animals killed for the direct purpose of conducting RDT&E or training. However, it does not include dead animals or parts of dead animals purchased at grocery stores or slaughterhouses.

disease surveillance. A systematic collection, analysis, and interpretation of health data of an animal or animals for the purpose of monitoring the presence of a condition in an individual animal or an animal population. Disease surveillance in animals is not governed by Reference (d) or this Instruction unless the disease screening procedures harm the animal. When the disease surveillance harms the animal, the activity is governed by this Instruction.

DoD-conducted RDT&E or training. RDT&E or training conducted by DoD personnel. DoD-conducted RDT&E or training is also referred to as “intramural” RDT&E or training. The intramural RDT&E or training may be performed in collaboration with a non-DoD institution or supported by a non-DoD institution (which also referred to as an “extramural institution”).

DoD-supported RDT&E or training. The provision of DoD funding, animals, facilities, equipment, or any other resources to an institution other than the Department of Defense that are needed to conduct the RDT&E or training. DoD-supported RDT&E or training is also referred to as “extramural” RDT&E or training.

extramural institution. An institution that is not part of the Department of Defense.

extramural RDT&E or training. RDT&E or training that is conducted by an institution that is not part of the Department of Defense.

field research. An investigation conducted on free-living wild animals in their natural habitat that DOES involve an invasive procedure, harms the animal, or materially alters the behavior of the animal under study. Field research is governed by Reference (d) and this Instruction.

field study. An investigation conducted on free-living wild animals in their natural habitat. A field study excludes any investigation that involves an invasive procedure, harms the animal, or materially alters the behavior of the animal under study. A field study is not governed by Reference (d) or this Instruction. A field study is distinct from field research.

harm. Any procedure that either causes lasting detrimental physical, behavioral, or psychological damage, or exposes an animal to potentially perilous situations (e.g., releasing a nocturnal animal during daylight hours).

IACUC. A board that is charged with evaluating an institution’s care, treatment, housing, and use of animals, and with assuring compliance with Reference (d) and this Instruction. When full committee review of a project is requested, the IACUC shall have a quorum as defined in this Instruction. The board members are appointed by the institution’s commander or the institutional official. The DoD institutional official is, or is appointed by, the institution’s commander and can legally commit the institution to comply with Federal requirements for animal care and use.

marine mammal. Animals belonging to the class mammalia and whose primary habitat is the sea or ocean (e.g., cetaceans and pinnipeds).

non-affiliated IACUC member. A member of the public who represents the interests of the general community in the proper care and use of animals. A public IACUC member should not be involved in animal care and use, be affiliated with the institution(s) supporting or relying on the IACUC, or be an immediate family member of a person who is affiliated with the institution(s).

non-scientific IACUC member. A person whose interests, training, and education are not in a scientific discipline.

OSD Component. Defined in DoDI 5025.01 (Reference (v)).

quorum. A quorum is obtained when a majority of the members of the IACUC are present. At least one veterinarian and one non-affiliated member, or their alternates, must be part of the majority present.

RDT&E. A series of four broad categories of activities beginning with the exploration of a concept and ending with the determination that a product is suitable for its intended use. RDT&E is not defined by budget activity, the DoD institution supporting or conducting the work, the type of extramural institution conducting the work, the program title, or the security classification. The four categories of RDT&E are:

research. A systematic investigation of a scientific question employing a hypothesis, structured methodology, and controlled study design (e.g., a manipulation of variables, an assessment of differences in outcome due to variables) for the purpose of contributing to the generalized body of knowledge.

development. A systematic investigation, structured methodology, or controlled study designed for the purpose of further refining the product and demonstrating its intended use.

test. A systematic analysis of the product to ensure that it meets its intended goals.

evaluation. An analysis of the product's suitability and readiness to be produced and fielded.

serious noncompliance. An activity that is not in accordance with this Instruction and its references and that is currently or has the likelihood to affect the health and well-being of an animal adversely.

training. An activity with the goal of imparting knowledge, skills, and competencies to a human student. Activities conducted solely for the purpose of training animals are covered by Reference (d) but are not covered by this Instruction. Training is covered by Reference (d) and this Instruction if the activity is conducted for the purpose of training personnel about animal care and handling, and when the animals will also be used in support of activities that are

covered by this Instruction. If the training is conducted to teach animal care for animals that will be used in RDT&E, the training is covered by this Instruction. If the training is conducted to teach medical care for humans, the training is covered by this Instruction. However, if the training is conducted to teach animal care and handling for routine veterinary procedures, or for handling of ceremonial, recreational, or working animals (e.g., military working dogs), the training is not covered by this Instruction.

weapon. A device (e.g., a club, knife, gun, or directed energy) used to injure, defeat, or destroy.

wound. An injury or damage usually restricted to those caused by physical means with disruption of normal continuity of the body's structures.

(b)(6)

Subject: RE: Live Tissue Training - SASC inquiry
Signed By: (b)(6)

Team,

Following up on this request SASC PSM John Quirk was told by SOCOM Legislative Affairs (SOLA) that a US Army Medical Research and Materiel Command (USAMRMC) study is pending release that discusses the gap between simulation and Long-term training (LTT).

John realizes that this is not going away and asked for a brief and copy of the study when complete. I believe (b)(6) from the Office of the Assistant Secretary of Defense for Research and Engineering (OUSD ATL) is the POC for this.

Thank you.

(b)(6)

(b)(6)

Subject: RE: Live Tissue Training - SASC inquiry

H (b)(6)

I am checking to see if R&E has a set of approved TPs to share.

Thanks

(b)(6)

-----Original Message-----

(b)(6)

(b)(6)

Subject: Live Tissue Training - SASC inquiry

R&E/HA,

SASC PSM John Quirk is prepping SASC Ranking Member SEN Reed (D-RI) for a meeting with People for the Ethical Treatment of Animals (PETA) on live animal training.

Are there any bullet points on the Department's current live tissue training policies and/or direction the department is going on this that we can share with John?

Thank you,

(b)(6)

(b)(6)

Subject: RE: Live Tissue Training - SASC inquiry
Signed By: (b)(6)

Thank (b)(6)

Sen Reed is meeting with PETA tomorrow (10 Feb)

SASC PSM John Quirk said it would be helpful for the Senator to have the Department's current policy/position prior to the meeting

V/R,
(b)(6)

-----Original Message-----

(b)(6)

Subject: RE: Live Tissue Training - SASC inquiry

Hi (b)(6)

I am checking to see if R&E has a set of approved TPs to share.

Thanks
(b)(6)

(b)(6)

Subject: Live Tissue Training - SASC inquiry

R&E/HA,

SASC PSM John Quirk is prepping SASC Ranking Member SEN Reed (D-RI) for a meeting with People for the Ethical Treatment of Animals (PETA) on live animal training.

Are there any bullet points on the Department's current live tissue training policies and/or direction the department is going on this that we can share with John?

Thank you,

(b)(6)



(b)(6)

Subject:

RE: Live Tissue Training

Signed By:

(b)(6)

Hi

(b)(6)

There were a series of studies conducted through a consortium. All but one is releasable at this time. R&E and Health Affairs have been working together to develop a briefing for the HASC and SASC that outlines the findings and recommendations. Mr. Welby has provided feedback on these draft briefs but need to check with Dr. Mason's office where we stand.

We also have a request from CM Johnson for the studies. Our goal is brief the HASC and SASC on the findings prior to the studies being released.

The ARMDEC is the release authority for the studies.

Will get back with you with more info.

Thanks

(b)(6)

-----Original Message-----

(b)(6)

Subject: FW: Live Tissue Training

(b)(6)

Hope your weekend is going well.

Rep Gabbard is asking "if there are any DoD data or studies showing the effectiveness of live tissue training" (see below and attached for entire thread).

Can you see what you come up with? For my own professional development, is this in Dr. Mason's shop (or somewhere else)?

Thanks for the help.

(b)(6)

(b)(6)



Subject: RE: Live Tissue Training

Thank you Sir,

For reference, attached is the Dear Colleague about live tissue training

V/R,

(b)(6)



(b)(5)

(b)(6)



Subject: RE: Live Tissue Training

(b)(6)



(b)(5)



V/R

(b)(6)



(b)(6)

Subject: FW: Live Tissue Training

Sir,

(b)(6) said this might fall under your portfolio:

Rep Tulsi Gabbard's (D-HI) office asked if there are any DoD data or studies showing the effectiveness of live tissue training?

I suspect this is question resulted from a lunch brief on the Hill last week on this (see below/attached):

Topic: "Saving Soldiers by Sparing Animals"

Date/Time: Tuesday, January 26, 2016, 12-1:30 p.m.

Location: Rayburn House Office Building, Room B-339

V/R,

Jeremy

-----Original Message-----

(b)(6)

Sent: Friday, February 05, 2016 3:37 PM

(b)(6)

Cc: DHA NCR Prog Integ List PI List

Subject: Re: Live Tissue Training

AT&L is lead

(b)(6)

> On Feb 5, 2016, at 3:28 PM, wrote:

>

> Rep Tulsi Gabbard's (D-HI) office asked if there is any DoD data or studies showing the effectiveness of live tissue training?

>

> I suspect this is question resulted from a lunch brief on the Hill last week on this (see below/attached):

>

> Topic: "Saving Soldiers by Sparing Animals"

> Date/Time: Tuesday, January 26, 2016, 12-1:30 p.m.

> Location: Rayburn House Office Building, Room B-339

>

> -----Original Message-----

> From: (b)(6)

> Sent: Friday, February 05, 2016 3:26 PM

> To: 'andres.chovil@mail.house.gov'

> Subject: Live Tissue Training

>

> Hi Andres,

>

> Good talking to you earlier.

>

> Please let me know if you have any questions in addition to if there is data or studies showing the effectiveness of live tissue training.

>

> Thank you,

(b)(6)



>

> <mime-attachment>

(b)(6)

To: DHA NCR Prog Integ List PI List
Subject: FW: [Non-DoD Source] Fw: ArmedServices: Dear Colleague: LUNCH BRIEFING WITH GIDEON RAFF, CREATOR OF TV'S "HOMELAND"
Signed By: (b)(6)

FYSA, Rep Grijalva (D-AZ) is hosting an event on the Hill in support of H.R. 1095, the BEST Practices Act, which has been introduced in Congress this year to phase out so-called "live tissue training" on animals

-----Original Message-----

From: Greene, Craig [mailto:Craig.Greene@mail.house.gov]

Sent: Thursday, January 21, 2016 1:41 PM

(b)(6)

Subject: [Non-DoD Source] Fw: ArmedServices: Dear Colleague: LUNCH BRIEFING WITH GIDEON RAFF, CREATOR OF TV'S "HOMELAND"

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

Fyi

Sent from my BlackBerry 10 smartphone.

From: e-Dear Colleague <e-dearcolleague@housemail.house.gov>

Sent: Thursday, January 21, 2016 10:37 PM

To: E-DEARCOLL_ISSUES_A-F_0000@ls2.house.gov

Reply To: e-Dear Colleague

Subject: ArmedServices: Dear Colleague: LUNCH BRIEFING WITH GIDEON RAFF, CREATOR OF TV'S "HOMELAND"

LUNCH BRIEFING WITH GIDEON RAFF, CREATOR OF TV'S "HOMELAND"

From: The Honorable Raul M. Grijalva

Sent By: david.gellman@mail.house.gov <Caution-mailto:david.gellman@mail.house.gov?subject=RE: LUNCH BRIEFING WITH GIDEON RAFF, CREATOR OF TV'S >

Date: 1/21/2016

Topic: "Saving Soldiers by Sparing Animals"

Date/Time: Tuesday, January 26, 2016, 12-1:30 p.m.

Location: Rayburn House Office Building, Room B-339

LUNCH WILL BE SERVED

Honorary Hosts: Rep. Raul M. Grijalva and Rep. Ted Lieu

Dear Colleague,

By now you should have received an invitation to attend a lunch briefing on live animal medical training. It's critical to get battlefield medicine right, and the medical education that our service members receive is undergoing modernization. Unfortunately, this transition has been needlessly delayed in parts of our military.

All too often, our service members are being forced to practice their surgical skills on live pigs, dogs, and other animals. Many military medical experts agree that the vast differences in anatomy and physiology between humans and other animals make using animals as surrogates for humans a poor choice, which is why most of our military has progressed to the use of high-tech training simulators instead of animals. Training with these human simulators costs four times less than with live animals, offers a superior hands-on training experience, and doesn't involve maiming live animals.

Bipartisan legislation (H.R. 1095, the BEST Practices Act) has been introduced in Congress this year to responsibly phase out so-called "live tissue training" on animals and ensure that soldiers are given a better education that doesn't waste taxpayer dollars and destroy thousands of animals.

Please join us, Emmy Award-winning creator and executive producer of the hit TV show *Homeland* Gideon Raff, PETA, and medical experts to discuss the move away from live tissue training and to see a demonstration of the high-tech medical simulators that can successfully replace the use of animals today.

Speakers:

- * Gideon Raff, creator and executive producer of TV's *Homeland* and former Israel Defense Forces paratrooper
- * Michael P. Murphy, M.D., F.A.C.S., Major, U.S. Army Reserves, award-winning combat surgeon and two-tour Iraq veteran
- * Marion J. Balsam, M.D., Rear Admiral (Ret.), Medical Corps, U.S. Navy, and former commander of Naval Medical Center Portsmouth

Sponsor:

- * People for the Ethical Treatment of Animals

To RSVP, contact Brittney Hopwood at BrittneyH@peta.org < Caution-mailto:BrittneyH@peta.org > .

Sincerely,

RAUL GRIJALVA

TED LIEU

Member of Congress

Member of Congress

Visit the e-Dear Colleague Service < Caution-<http://e-dearcolleague.house.gov/subscribe.aspx> > to manage your subscription to the available Issue and Party list(s).

(b)(6)



Subject:

RE: Deployment Medicine International

(b)(6)



Sorry I'm late in responding; copy all and let me know how we can help in the FO.

VR

(b)(6)




(b)(6)



Subject: FW: Deployment Medicine International

(b)(6),(b)(5)



(b)(6)



-----Original Message-----

From: White, Jennifer (Armed Services) [mailto:Jennifer_White@armed-services.senate.gov]

Sent: Thursday, September 10, 2015 4:38 PM

(b)(6)

Cc: Edwards, Allen (Armed Services)

Subject: Deployment Medicine International

H

(b)(6)

Can you help me track down the following information about the Department's relationship with DMI and Dr. John Hagmann?

- . Reporting has indicated that Dr. Hagmann maintained a "formal and informal relationship" with USUHS, offering free courses prior to his course being added to the formal USUHS curriculum. When was the course first offered as a free elective, how was that done, and how many students attended the class prior to DMI being contracted by USUHS?
- . Please provide the list of all contracts awarded to DMI, both by USUHS and other DOD components, including contract number, contracting agency, date signed and obligated amount
- . Please provide the total number of military members that attended one of Dr. Hagmann's courses
- . According to the Army National Guard, the DMI course was on a list of courses that met a specific training requirement. What is the list, and are courses on the list correctly referred to as certified? If not certified, what is the proper way to characterize the course? When was the course removed from the list?
- . When did the Department officially end its relationship with DMI, and by what process?

And can you let me know if it's possible to receive the information above by next Friday, September 18th?

Thanks,

Jennifer

Jennifer White

Senate Armed Services Committee

202-224-9348

(b)(6)

Subject:

RE: Deployment Medicine International

Signed By:

(b)(6)

(b)(6),(b)(5)

-----Original Message-----

(b)(6)

Sent: Monday, September 21, 2015 4:06 PM

To: Hedger, Stephen C SES OSD OASD LA (US)

Cc: Stella, Michael J SES OSD OASD LA (US); Gilliland, John E SES OSD OASD LA (US)

(b)(6)

(b)(6) Guenov, Tressa S SES (US)

(b)(6)

STARZAK, ALISSA M SES OSD OGC

(b)(6)

Subject: FW: Deployment Medicine International

Mr. Hedger,

(b)(6),(b)(5)

Just wanted to keep you updated.

v/r

(b)(6)

(b)(6)

-----Original Message-----

From: White, Jennifer (Armed Services) [mailto:Jennifer_White@armed-services.senate.gov]

Sent: Thursday, September 10, 2015 4:38 PM

(b)(6)

Cc: Edwards, Allen (Armed Services)

Subject: Deployment Medicine International

Hi

(b)(6)

Can you help me track down the following information about the Department's relationship with DMI and Dr. John Hagmann?

Reporting has indicated that Dr. Hagmann maintained a "formal and informal relationship" with USUHS, offering free courses prior to his course being added to the formal USUHS curriculum. When was the course first offered as a free elective, how was that done, and how many students attended the class prior to DMI being contracted by USUHS?

Please provide the list of all contracts awarded to DMI, both by USUHS and other DOD components, including contract number, contracting agency, date signed and obligated amount

Please provide the total number of military members that attended one of Dr. Hagmann's courses

According to the Army National Guard, the DMI course was on a list of courses that met a specific training requirement. What is the list, and are courses on the list correctly referred to as certified? If not certified, what is the proper way to characterize the course? When was the course removed from the list?

When did the Department officially end its relationship with DMI, and by what process?

And can you let me know if it's possible to receive the information above by next Friday, September 18th?

Thanks,

Jennifer

Jennifer White

Senate Armed Services Committee

202-224-9348

(b)(6)

Subject:
Signed By:

RE: Combat Casualty Training Consortium reports

(b)(6)

(b)(6)

Let's discuss the hand-off when I get a chance later. Thanks! Vr

(b)(6)

-----Original Message-----

(b)(6)

Subject: FW: Combat Casualty Training Consortium reports

(b)(6)

Is we pass off Rep Johnson's office to MRMC, I will most likely use my Army OCLL medical POC to do so.

Perhaps I should just loop them into the email chain, and give them a call to explain.

(b)(6)

(b)(6)

Subject: Re: Combat Casualty Training Consortium reports

Hi

(b)(6)

Yes (b)(6) and I talked to (b)(6) last week. It will take approx. 30 days for the reports to work through the processes to clear them for release.

V/r

(b)(6)

(b)(6)



Subject: RE: Combat Casualty Training Consortium reports

Has anyone from OSD given MRMC a heads up about this request? Sorry catching up from leave.

(b)(6)



(b)(6)



Subject: Re: Combat Casualty Training Consortium reports

H (b)(6)



(b)(5)



V/r,

(b)(6)



----- Original Message -----

(b)(6)



Hi (b)(6)

(b)(6)

(b)(6), (b)(5)

Thanks,

(b)(6)

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports (UNCLASSIFIED)

Classification: UNCLASSIFIED

Caveats: NONE

(b)(6)

(b)(6)

(b)(6)

Sent: Tuesday, August 18, 2015 4:50 PM

(b)(6)

Subject: Re: Combat Casualty Training Consortium reports

Hi

(b)(6)

(b)(5)

V/r,

(b)(6)

----- Original Message -----

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

(b)(6), (b)(5)

Thanks,

(b)(6)

(b)(6)

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports (UNCLASSIFIED)

Signed By:

(b)(6)

Follow Up Flag:

Follow up

Flag Status:

Flagged

Hi

(b)(6)

How does 3:00 work.

Thanks,

(b)(6)

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports (UNCLASSIFIED)

Good Morning

(b)(6)

(b)(6) and I spoke this morning with (b)(6) USAMRAA's Chief of Staff, to discuss the reports. It would be good for us to talk to be sure we're all on the same page. (b)(6) will update (b)(6) regarding the conversation as well.

Do let me know a good time.

v/r.

(b)(6)

(b)(6)

<http://www.acq.osd.mil/rd/hptb/index.html>

Original Message

(b)(6)

Subject: Re: Combat Casualty Training Consortium reports (UNCLASSIFIED)

H (b)(6)

(b)(6), (b)(5)

Vr (b)(6)

(b)(6)

Original Message

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports (UNCLASSIFIED)

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

(b)(5),(b)(6)

Thanks,

(b)(6)

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

Good Morning

(b)(6)

Following up on this, there are several peer-reviewed publications that resulted from the Consortia studies. Attached is a summary that may answer the mail to CM Johnson. I haven't run this past Dr. Mason yet, wanted to get your thoughts first.

v/r.

(b)(6)

<http://www.acq.osd.mil/rd/hptb/index.html>

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

(b)(6),(b)(5)

Thank you both!

Vr (b)(6)

-----Original Message-----

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

H (b)(6)

(b)(6),(b)(5)

Thanks,

(b)(6)

-----Original Message-----

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

H (b)(6)

Looks like we can do that, too, but the reports still need to go through established processes (see attached). If that's the chosen route, we can start working the reports through the processes. Just let me know what you think is the best course of action.

v/r,

(b)(6)

-----Original Message-----

(b)(6)

Sent: Monday, August 10, 2015 8:19 AM

(b)(6)

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

H (b)(6)

(b)(6), (b)(5)

(b)(6)

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

(b)(6)

The determination from the "customer" of the reports, the US Army Medical Research Acquisition Agency/USAMRAA, has determined that the request for the reports by a Congressman (or his staff) must go through FOIA channels. Email is attached.

Your thoughts and recommendations on way ahead?

v/r,

(b)(6)

<http://www.acq.osd.mil/rd/hptb/index.html>

(b)(6)

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Subject: RE: Combat Casualty Training Consortium reports

H (b)(6)

A small rectangular area of the document is redacted with a solid gray fill.

Give me a call so we can map out a plan of action.

Thanks,

(b)(6)

A small rectangular area of the document is redacted with a solid gray fill.

(b)(6)

A large rectangular area of the document is redacted with a solid gray fill.

Subject: RE: Combat Casualty Training Consortium reports

(b)(6),(b)(5)

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(b)(6)

A rectangular area of the document is redacted with a solid gray fill.

(b)(6)

A large rectangular area of the document is redacted with a solid gray fill.

Subject: Re: Combat Casualty Training Consortium reports

H (b)(6)

A small rectangular area of the document is redacted with a solid gray fill.

Yes, tracking on this. We have final reports from 2 of the consortia studies on LTT. They're several hundred pages each. To the best of my knowledge there haven't been scientific publications yet so we have nothing else that I can think of to send.

As the reports to the Department are what they are interested in, please advise of the proper procedures to "release" such documents and the logistics as they're too big to email.

The studies were commissioned through the joint program committee and I've copied in (b)(6) chair of the committee in case she has additional questions.

Thank you,

(b)(6)

-----Original Message-----

(b)(6)

Subject: FW: Combat Casualty Training Consortium reports

(b)(6)

Im getting some feedback from HA that the Combat Casualty Training Consortium is largely related to LTT. Rep Johnson's office is requesting some particular reports.

Are you tracking this this consortium?

Thanks.

(b)(6)

-----Original Message-----

(b)(6)

Cc: DHA NCR Prog Integ List PI List

Subject: RE: Combat Casualty Training Consortium reports

See attached...AT&L is lead.

(b)(6)

[Redacted]

-----Original Message-----

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

"Hi (b)(6) thank you. Mr. Johnson is looking for the 3 you reference but he would like to see the other reports you mention as well. He is interested in the work of the consortium and would like to see what has been produced so far. Thanks."

(b)(6)

-----Original Message-----

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

Is he looking for the peer reviewed open literature scientific publications from this consortium or the required reports to the contracting officer/activity for the 3 cooperative agreements under this consortium?
Why do they want it?

This issue concerns use of live tissue in training - may be AT&Ls

(b)(6)

Subject: Fw: Combat Casualty Training Consortium reports

See below request

(b)(6)

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

(b)(6)

Looping in my colleague (b)(6) who handles the Health Affairs portfolio.

(b)(6)

Can you help (b)(6) out with his questions?

(b)(6)

Thanks

(b)(6)

(b)(6)

-----Original Message-----

From: Goldstein, Scott [mailto:Scott.Goldstein@mail.house.gov]

Sent: Friday, July 31, 2015 3:48 PM

(b)(6)

Subject: Combat Casualty Training Consortium reports

(b)(6)

Mr. Johnson is looking for copies of the reports submitted to the Department of Defense by sections of the Combat Casualty Training Consortium. It is our understanding that such reports have already been reviewed by members of the civilian medical simulation community.

Thank you,

Scott Goldstein

Legislative Director

Office of Congressman Hank Johnson (GA-4) ph (202) 225-1605 / fax (202)

226-0691 Sign up for Congressman Johnson's e-newsletter <<https://hankjohnsonforms.house.gov/enews.shtml>>

Description: fb

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arch&sid=1410163.1977932072..1> Description: twitter <<https://twitter.com/RepHankJohnson>> Description: youtube

<<https://www.youtube.com/user/RepHankJohnson>> Description: flickr <<https://www.flickr.com/photos/hankjohnson/>>

Description: tumblr <<http://rephankjohnson.tumblr.com/>> cid:image006.jpg@01D0BA52.6764AC80

<<https://instagram.com/rephankjohnson/>>

P Please consider the environment before printing this e-mail.

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

Signed By:

(b)(6)

Follow Up Flag:

Follow up

Flag Status:

Flagged

(b)(6),(b)(5)

-----Original Message-----

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

Good Morning

(b)(6)

Following up on this, there are several peer-reviewed publications that resulted from the Consortia studies. Attached is a summary that may answer the mail to CM Johnson. I haven't run this past Dr. Mason yet, wanted to get your thoughts first.

v/r,

(b)(6)

(b)(6)

<http://www.acq.osd.mil/rd/hptb/index.html>

-----Original Message-----

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

Sounds good (b)(6) We should be proactive with PSMs on this given the engagement history, and agree it is preferable to try to address the Member's request via the committee (we'll see how that works).

Thank you both!

v (b)(6)

-----Original Message-----

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

Hi (b)(6)

(b)(6), (b)(5)

Thanks,

(b)(6)

-----Original Message-----

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

H (b)(6)

Looks like we can do that, too, but the reports still need to go through established processes (see attached). If that's the chosen route, we can start working the reports through the processes. Just let me know what you think is the best course of action.

v/r,

(b)(6)

Three studies comprised the “Combat Casualty Care Training Consortia.” Two of the studies were performed by the University of Minnesota, the third by the University of Missouri. These studies aimed to: identify training gaps when using simulation technologies, determine objective evaluation criteria for trainees, compare current simulation systems (e.g., simulators and animals) with end user needs, identify metrics per skill or procedure, and determine which metrics discriminate between users.

1. University of Minnesota:

Purpose: Evaluate the curriculum and use of live tissue for training of first responder medics (specifically Army 68 W Combat Medics) using a methodical series of studies.

Hypotheses: A majority of the trauma-relevant procedures can be trained and assessed using simulation; neither animal tissues nor simulation analogues have mechanical tissue properties similar to human tissue properties for those structures involved in hemorrhage control and trauma airway skills; variation exists in the current delivery and assessment of training for hemorrhage control and trauma airway skills within and between training sites; and there are definable and measureable environmental and human factors that impact individual performance for hemorrhage control and trauma airway skills.

Publications:

Schmitz CC, Chipman JG, Yoshida K, Vogel RI, Sainfort F, Beilman G, Clinton J, Cooper J, Reihisen T, Sweet RM. Reliability and validity of a test designed to assess combat medics' readiness to perform life-saving procedures. *Mil Med.* 2014 Jan;179(1):42-48.

Robert Sweet, MD presentation at NATO SOF headquarters, Chievres, Belgium, "Framework for understanding medical simulation and simulators in healthcare: ensuring learning and measuring effectiveness".

2. University of Missouri:

Purpose: Provide an objective comparison of live tissue training to simulation-based training for trauma hemorrhage, trauma airway, pediatric intubation, and management of a nerve agent casualty. Provide a gap analysis of currently available technology for the respective procedures indicated.

Hypothesis: Statistically significant differences in self-efficacy, cognitive performance, psychomotor performance, and affective response will be demonstrated between subjects trained utilizing simulation vs live tissue models in life-saving combat medic skills.

Publications: none at this time

3. University of Minnesota (originally started at University of Michigan):

Purpose: Evaluate the relative impact of live animals and high-fidelity mannequin simulators for training in the recognition of medical need and consequential clinical management of cholinergic crisis and pediatric and neonatal intubation.

Hypotheses: Cognitive dissonance from affective overload can interfere with application of knowledge and skills in a mass casualty environment; contextually relevant factors improve training transfer to applied performance; live animals provide contextually relevant factors; current training methods lack contextually-based performance assessment; performance assessment will facilitate comparison of training methods.

Publications and Presentations:

1. Klotz JJ, House JB, Dooley-Hash SL, & Andreatta PB. (2014). Pediatric and neonatal intubation training gaps: instruction, assessment, and technology. *Simulation in Healthcare*, 9(6), 377-383. doi:10.1097/SIH.0000000000000057.
2. Andreatta P, Klotz JJ, Madsen JM, Hurst GC, & Talbot TB. Training effects for first-responder competency in cholinergic crisis management. *Interservice/Industry Training, Simulation, and Education Conference (I/ITSEC) Proceedings*, 2014(14241), 1-11. <http://www.iitsecdocs.com/>
3. Andreatta P, Klotz JJ, Dooley-Hash S, & House J. Outcomes from two forms of pediatric and neonatal intubation training. *Interservice/Industry Training, Simulation, and Education Conference (I/ITSEC) Proceedings*, 2014(14240), 1-10. <http://www.iitsecdocs.com/>
4. Andreatta P, Klotz JJ, Madsen JM, Hurst GC, & Talbot TB. Assessment instrument validation for critical clinical competencies: pediatric-neonatal intubation and cholinergic crisis management. *Interservice/Industry Training, Simulation, and Education Conference (I/ITSEC) Proceedings*, 2014(14232), 1-10. <http://www.iitsecdocs.com/>
5. Andreatta P, Klotz JJ, Dooley-Hash S, & House J. Performance-based comparison of neonatal intubation training outcomes: simulator and live animal. *Advances in Neonatal Care*. 2015 Feb;15(1):56-64. doi:10.1097/ANC.0000000000000130.
6. Andreatta PB, Klotz JJ, Madsen JM, Hurst CG, & Talbot TB. Outcomes from two forms of training for first responder competency in cholinergic crisis management. *Mil Med*. 2015 Apr;180(4):468-74.
7. Andreatta PB, Dooley-Hash SL, Klotz JJ, Hauptman J, Biddinger B, & House J. Retention curves for pediatric and neonatal intubation skills after simulation-based training. *Pediatric Emergency Care*. (In Press).
8. Andreatta PB, Klotz JJ, Madsen JM, Hurst CG, & Talbot TB. Retention of training for first-responder competency in cholinergic crisis management. *Military Medicine* (In Review).
9. Andreatta PB, Klotz JJ, Madsen JM, Hurst CG, & Talbot TB. Mixed methods training for first-responder training in cholinergic crisis management. *Simulation in Healthcare* (In Review).

(b)(6)

From: Torreon, Barbara <BTORREON@crs.loc.gov>
Sent: Thursday, August 13, 2015 8:45 AM
To: (b)(6)
Cc: Gilliland, John E SES OSD OASD LA (US) (b)(6)
Subject: RE: Defense Health - use of animals for combat trauma training

Good morning (b)(6)
 Thank you very much for expediting this request. Have a good day. Barbara

-----Original Message-----

From: (b)(6)
Sent: Wednesday, August 12, 2015 4:10 PM
To: Torreon, Barbara
Cc: Gilliland, John E SES OSD OASD LA (US); (b)(6)
Subject: RE: Defense Health - use of animals for combat trauma training

Barbara: Please find the attached FOUO response paper. Best (b)(6)

-----Original Message-----

From: Torreon, Barbara [mailto:BTORREON@crs.loc.gov]
Sent: Tuesday, August 11, 2015 2:41 PM
To: (b)(6)
Cc: Gilliland, John E SES OSD OASD LA (US); (b)(6)
Subject: RE: Defense Health - use of animals for combat trauma training

Great! Thank you (b)(6) I know the office is eager to receive this information. Best, Barbara

-----Original Message-----

From: (b)(6)
Sent: Tuesday, August 11, 2015 2:39 PM
To: Torreon, Barbara
Cc: Gilliland, John E SES OSD OASD LA (US); (b)(6)
Subject: RE: Defense Health - use of animals for combat trauma training

Hello Barbara: We pulled the string on this yesterday, and will follow up with you.

Best,

(b)(6)

-----Original Message-----

From: Gilliland, John E SES OSD OASD LA (US)
Sent: Tuesday, August 11, 2015 11:15 AM
To: Torreon, Barbara
Cc: (b)(6)
Subject: RE: Defense Health - use of animals for combat trauma training

(b)(6)

Barbara,

Our office of the Under Secretary for AT&L is working the response to this query. I cc'd my colleague that supports AT&L (b)(6) He is aware and tracking the response.

Thanks,
John

-----Original Message-----

From: Torreon, Barbara [mailto:BTORREON@crs.loc.gov]
Sent: Monday, August 10, 2015 11:44 AM
To: Gilliland, John E SES OSD OASD LA (US) (b)(6)
Subject: FW: Defense Health - use of animals for combat trauma training

(b)(6)

Good morning Mr. Gilliland and (b)(6)

I received this out of office email from (b)(6) regarding a follow-up to a congressional request. See emails below. Could you please let us know the status of this request. It has been over two months and the office is not happy about a lack of response. Thank you for your attention. Barbara

Barbara Salazar Torreon

Analyst in Defense Budget and Military Manpower

Foreign Affairs, Defense and Trade Division

Congressional Research Service

Library of Congress Washington, DC 20540

Tel: 202-707-8996

btorreon@crs.loc.gov <mailto:btorreon@crs.loc.gov>

DISCLAIMER: The foregoing has not been cleared by CRS review and is not for attribution. This response is provided to help in time limited situations.

DISCLAIMER: This information is intended only for the congressional addressee or other individual to whom it is addressed and may contain confidential and/or privileged material. Any review, retransmission, dissemination or other use of this information is only at the discretion of the intended recipient. If you received this in error, please contact the

(b)(6)

Subject: RE: Liaison for Defense Health - use of animals for combat trauma training

Signed By:

(b)(6)

Follow Up Flag:

Follow up

Flag Status:

Flagged

Thanks

(b)(6)

-----Original Message-----

(b)(6)

Subject: RE: Liaison for Defense Health - use of animals for combat trauma training

H

(b)(6)

Here you go. Let me know if you need anything else.

Thanks,

(b)(6)

-----Original Message-----

(b)(6)

Subject: RE: Liaison for Defense Health - use of animals for combat trauma training

H

(b)(6)

Probably does not hurt to mark it FOUO. I will resend to you.

Thanks,

(b)(6)

-----Original Message-----

(b)(6)

Subject: RE: Liaison for Defense Health - use of animals for combat trauma training

Hey (b)(6) Appreciate you getting this to us. Should it be marked FOUO?

Thanks

(b)(6)

(b)(6)

Subject: FW: Liaison for Defense Health - use of animals for combat trauma training

Hi (b)(6)

The attached is approved to be sent to CRS.

Thanks,

(b)(6)

-----Original Message-----

(b)(6)

Subject: RE: Liaison for Defense Health - use of animals for combat trauma training

(b)(6)

(b)(6) has approved the answers as given in the attached. Please let me know if you need anything else. Thanks!

Cheers,

(b)(6)

(b)(6)

Subject: FW: Liaison for Defense Health - use of animals for combat trauma training

Hi (b)(6)

Would you mind putting the attached in front of (b)(6) for his approval. Apparently this was sent up in June but never received an OK.

(b)(6)

Subject: RE: Liaison for Defense Health - use of animals for combat trauma training

Signed By:

(b)(6)

(b)(5)

-----Original Message-----

(b)(6)

Subject: RE: Liaison for Defense Health - use of animals for combat trauma training

Sounds good, if plausible basis for it. Thanks

(b)(6)

-----Original Message-----

(b)(6)

Subject: RE: Liaison for Defense Health - use of animals for combat trauma training

Hi

(b)(6)

Probably does not hurt to mark it FOUO. I will resend to you.

Thanks,

(b)(6)

-----Original Message-----

(b)(6)

Subject: RE: Liaison for Defense Health - use of animals for combat trauma training

Hey (b)(6) Appreciate you getting this to us. Should it be marked FOUO?

Thanks,

(b)(6)

-----Original Message-----

(b)(6)

Subject: FW: Liaison for Defense Health - use of animals for combat trauma training

Hi (b)(6)

The attached is approved to be sent to CRS.

Thanks,

(b)(6)

-----Original Message-----

(b)(6)

Subject: RE: Liaison for Defense Health - use of animals for combat trauma training

(b)(6)

(b)(6) has approved the answers as given in the attached. Please let me know if you need anything else. Thanks!

Cheers,

(b)(6)

-----Original Message-----

(b)(6)

Subject: FW: Liaison for Defense Health - use of animals for combat trauma training

Hi (b)(6)

Would you mind putting the attached in front of (b)(6) for his approval. Apparently this was sent up in June but never received an OK.

Thanks,

(b)(6)

-----Original Message-----

(b)(6)

(b)(6)

Subject:

RE: Liaison for Defense Health - use of animals for combat trauma training

Attachments:

RE: Liaison for Defense Health - use of animals for combat trauma training (41.0 KB);

Torreon_CRSrequest_LTT_May2015_toFrontOffice.doc

Hi (b)(6)

Not sure what happened on this, but the attached response was sent to Front Office in AT&L back in June for their review and approval (see email traffic). I didn't hear a yes or a no from the front office based on my archived emails.

v/r,

(b)(6)

(b)(6)

Subject: Fw: Liaison for Defense Health - use of animals for combat trauma training

(b)(6)

Are you working this one?

(b)(6)

Subject: RE: Liaison for Defense Health - use of animals for combat trauma training

We kicked this one back to AT&L...they are the lead for this issue...

(b)(6)

(b)(6)

Subject: Fw: Liaison for Defense Health - use of animals for combat trauma training

(b)(6)

can you check this one?

----- Original Message -----

From: Torreon, Barbara [mailto:BTORREON@crs.loc.gov]

Sent: Monday, August 10, 2015 11:33 AM

To: (b)(6)

Cc:

Subject: RE: Liaison for Defense Health - use of animals for combat trauma training

Good morning (b)(6)

The congressional office requesting this information contacted me Friday, 8/7, regarding the status of this request since it has been over two months. Thanks for your attention. Barbara

Barbara Salazar Torreon

Analyst in Defense Budget and Military Manpower Foreign Affairs, Defense and Trade Division Congressional Research Service Library of Congress Washington, DC 20540

Tel: 202-707-8996

btorreon@crs.loc.gov

DISCLAIMER: The foregoing has not been cleared by CRS review and is not for attribution. This response is provided to help in time limited situations.

DISCLAIMER: This information is intended only for the congressional addressee or other individual to whom it is addressed and may contain confidential and/or privileged material. Any review, retransmission, dissemination or other use of this information is only at the discretion of the intended recipient. If you received this in error, please contact the sender and delete the material from any computer. If this message includes any unexpected attachment(s), please contact the sender immediately and delete the attachment(s) from any computer.

-----Original Message-----

From: Torreon, Barbara

Sent: Thursday, July 09, 2015 10:07 AM

To: (b)(6)

Subject: RE: Liaison for Defense Health - use of animals for combat trauma training

Good morning (b)(6)

I had a call this morning from the congressional office about this request. Can you update us on the status? Is there someone there that the office can speak directly? Thanks for your assistance. Barbara

Barbara Salazar Torreon

Analyst in Defense Budget and Military Manpower Foreign Affairs, Defense and Trade Division Congressional Research Service Library of Congress Washington, DC 20540

Tel: 202-707-8996

btorreon@crs.loc.gov

DISCLAIMER: The foregoing has not been cleared by CRS review and is not for attribution. This response is provided to help in time limited situations.

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(b)(5)

(b)(5)

(b)(6)

Subject:

Re: Combat Casualty Training Consortium reports

Follow Up Flag:

Follow up

Flag Status:

Flagged

(b)(6),(b)(5)

V/r,

(b)(6)

----- Original Message -----

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

(b)(6),(b)(5)

-----Original Message-----

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

(b)(6)

The determination from the "customer" of the reports, the US Army Medical Research Acquisition Agency/USAMRAA, has determined that the request for the reports by a Congressman (or his staff) must go through FOIA channels. Email is attached.

Your thoughts and recommendations on way ahead?

v/r,

(b)(6)

(b)(6)

<http://www.acq.osd.mil/rd/hptb/index.html>

-----Original Message-----

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

Hi

(b)(6)

Give me a call so we can map out a plan of action.

Thanks,

(b)(6)

-----Original Message-----

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports**Signed By:**

(b)(6)

(b)(6)

Thanks for stopping by... you're right that we work through this with due diligence. My other note should help in that regard.

(b)(6)

Vr

(b)(6)

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

(b)(6)

I spoke with (b)(6) We will probably have to discuss a way forward on these reports.

Talk more soon.

(b)(6)

(b)(6)

Subject: Re: Combat Casualty Training Consortium reports

Hi

(b)(6)

Repeat

Yes, tracking on this. We have final reports from 2 of the consortia studies on LTT. They're several hundred pages each. To the best of my knowledge there haven't been scientific publications yet so we have nothing else that I can think of to send.

As the reports to the Department are what they are interested in, please advise of the proper procedures to "release" such documents and the logistics as they're too big to email.

The studies were commissioned through the joint program committee and I've copied in (b)(6) chair of the committee in case she has additional questions.

Thank you

(b)(6)

[Redacted]

----- Original Message -----

(b)(6)

[Redacted]

Subject: FW: Combat Casualty Training Consortium reports

(b)(6)

Im getting some feedback from HA that the Combat Casualty Training Consortium is largely related to LTT. Rep Johnson's office is requesting some particular reports.

Are you tracking this this consortium?

Thanks.

(b)(6)

[Redacted]

-----Original Message-----

(b)(6)

[Redacted]

Subject: RE: Combat Casualty Training Consortium reports

See attached...AT&L is lead.

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

Thanks, (b)(6) Appreciate it.

(b)(6)

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

(b)(6),(b)(5)

(b)(6)

(b)(6)

Subject: RE: Combat Casualty Training Consortium reports

Hi (b)(6)

Any new news on this regarding potential for briefing?

Thank you,

(b)(6)

-----Original Message-----

From (b)(6)

Repeat

(b)(6)

Subject: FW: Combat Casualty Training Consortium reports

(b)(6)

Im getting some feedback from HA that the Combat Casualty Training Consortium is largely related to LTT. Rep Johnson's office is requesting some particular reports.

Are you tracking this this consortium?

Thanks.

Report

(b)(6)

-----Original Message-----

(b)(6)

Cc: DHA NCR Prog Integ List PI List

Subject: RE: Combat Casualty Training Consortium reports

See attached...AT&L is lead.

(b)(6)

-----Original Message-----

(b)(6)

Cc: DHA NCR Prog Integ List PI List

Subject: RE: Combat Casualty Training Consortium reports

"H (b)(6) thank you. Mr. Johnson is looking for the 3 you reference but he would like to see the other reports you mention as well. He is interested in the work of the consortium and would like to see what has been produced so far. Thanks."

(b)(6)

(b)(6)

Subject: RE: Live Tissue Training
Attachments: Congress Report 2013.pdf
Signed By: (b)(6)

H (b)(6)

Sorry - here you go.

Thanks

(b)(6)

-----Original Message----- (b)(6)

(b)(6)

Subject: RE: Live Tissue Training

Answer references a report being included, but its not in there.

(b)(6)

-----Original Message-----

(b)(6)

Subject: RE: Live Tissue Training

Thanks (b)(6) Understand R&E approves (b)(6) is going to send it over to CRS.

Good weekend to you! Best (b)(6)

(b)(6)

-----Original Message-----

From (b)(6)

Sent: Friday, July 31, 2015 12:03 PM

(b)(6)

Subject: FW: Live Tissue Training

H (b)(6)

Happy Friday! Dr. Brown has reviewed and approved the responses on LTT

Thanks,

(b)(6)

(b)(6)

Subject: FW: Live Tissue Training

H (b)(6) Would you get R&E front office ok on this, please?

Vr (b)(6) (b)(6)

(b)(6)

-----Original Message-----
(b)(6)

Cc: Mason, Patrick A SES OSD OUSD ATL (US)

Subject: RE: Live Tissue Training

Hi (b)(6)

Response to Mr. Jansen's questions is attached.

v/r
(b)(6)

(b)(6)

<http://www.acq.osd.mil/rd/hptb/index.html>

-----Original Message-----

(b)(6)

Cc: DHA NCR Prog Integ List PI List
Subject: FW: Live Tissue Training

(b)(6)

Can you help with this CRS request? Looks like some similar issues.

(b)(6)

-----Original Message-----

From: Jansen, Don [mailto:DJANSEN@crs.loc.gov]

Sent: Thursday, July 23, 2015 2:12 PM

To

(b)(6)

Subject: Live Tissue Training

Hello again

(b)(6)

Sorry to bother you again today. This Congressional request is for information related to use of animals in medical training. It reads:

"I'm interested in learning more about live-tissue training in the military and the following areas in particular:

- advantages and disadvantages of using live animals in combat training
- effectiveness and cost of using live animals vs. simulators

- where and how often is live tissue training used in U.S. and internationally?

- changes in military policy to stop live tissue training (specifically, are there any branches of military that are particularly opposed to banning practice?)"

My understanding is that live tissue training is no longer being conducted. Is that accurate? Also I understand that an office somewhere in DOD published a report on this topic but I have not been able to find it online. Are you aware of that? Any assistance much appreciated. Thank you,

V/R

Don Jansen

Specialist in Defense Health Care Policy

Foreign Affairs, Defense, & Trade Division

Congressional Research Service, Library of Congress

101 Independence Ave., S.E.

Washington, DC 20540-7460

djansen@crs.loc.gov <<mailto:djansen@crs.loc.gov>>

(202) 707-4769

Report to Congress on the Strategy to Transition to Use of Human-Based Methods for Certain Medical Training



**Office of the Under Secretary of Defense for
Acquisition, Technology and Logistics**

April 2013

The estimated cost of report or study for the Department of Defense is approximately \$21,400 for the 2013 Fiscal Year. This includes \$400 in expenses and \$21,000 in DoD labor.
Cost estimate generated on March 8, 2013 RefID: 3-EBB399D.

EXECUTIVE SUMMARY

This report is prepared in response to Section 736 of the National Defense Authorization Act for Fiscal Year 2013, Pub. L. No. 112-239. The report provides the strategy employed by the Department of Defense (DoD) to refine and, when appropriate, transition to use of human-based training methods (e.g., simulators, partial-task trainers, moulage, simulated combat environments, human cadavers) for certain medical training. The strategy includes a timeline illustrative of the research activities that will drive the development and procurement of simulation products.

The Department's goal is to reduce the use of live animals in medical training and to increase the use of validated simulation training platforms. DoD is actively working to refine, reduce, and, when appropriate, replace the use of live animals in medical education and training. However, until there are validated alternatives, the experience and confidence gained by the use of the live animal model in teaching life-saving procedures cannot be substituted by other training methods. Combat medic training is vital because the medic is the first responder who provides immediate care at the point of wounding. DoD developed a strategy to transition to the use of human-based methods for training but cannot assume the risk to transition fully to human-based methods until simulation devices and measureable outcomes can be scientifically validated with training methods that achieve established combat casualty survival rates.

REQUESTED ELEMENTS OF THE REPORT

The DoD response follows the requested elements of the report.

(A) Required research, development, testing and evaluation investments to validate human-based training methods to refine, reduce, and, when appropriate, transition from the use of live animals in medical education and training.

The total investment required through research, development, testing, and evaluation to transition to human-based training methods from the use of live animals in medical education and training is unknown at this time. The ability to estimate the total investment required will improve with the development of new medical simulation devices by which there will be methods and metrics that link combat medic skill acquisition to survival rate for casualties. In FY 2010, DoD initiated a \$20 million research effort over 3 years, funded within the Defense Health Program (DHP) appropriation, that follows a systematic approach to quantify combat medic skill acquisition and to measure the effect of the animal model in combat casualty training. This work began by defining measureable outcomes of training effectiveness. Developed metrics, once realized, will allow for identification of gaps in medical training simulation. The metrics will be validated and tested against current training curricula.

This nascent plan has been assisted through grants awarded to three multi-center Combat Casualty Care Training Consortia, which comprise academia, industry, and military collaboration. They are led by the University of Michigan, the University of Minnesota, and the University of Missouri, and while each performer's research plan varies slightly, the common objective of their work is to develop tools by which effectiveness of training methodologies can

be measured. This research will have applicability across a range of training methods to help determine whether skill acquisition is degraded when training is accrued via simulation modality.

The attached Figure 1 is the technology roadmap for research to provide mid- and longer-range capabilities to replace live-tissue training with simulation. The near-term requirements identified through the analysis of current training practices and the assessment of current technologies will highlight the technical gaps that require additional research projects. DoD is developing a means to more rapidly assess emerging medical modeling and simulation devices in technical areas relevant to the reduction of live-tissue training. Accelerating these assessments will speed the transition of simulation devices into practice. The programs in Figure 1 include the work of the Combat Casualty Care Training Consortia, as well as the ongoing work on Physiology Software Platforms that seek to produce models to allow simulators to perform in the same manner as real tissue and organs. For example, the Advanced Modular Manikin is a multi-year investment to create a mannequin that can meet multiple training needs through the addition of curriculum-specific add-ons to a core mannequin, such as a specialized throat training device to simultaneously or sequentially do airway management training on a core mannequin used for wound treatment and suturing. In addition, the Department is leveraging the Small Business Innovation Research program to develop and integrate supporting technologies and products into the roadmap. Lastly, existing simulation training devices, such as the Multiple Amputation Trauma Trainer (MATT®) are under investigation to satisfy additional training needs.

Initial validation studies identified gaps in simulation technology that inform future research activities to resolve ruggedness concerns for combat casualty training and to improve parts modularity across simulation tools. The timeline in Figure 1 should not be construed as an absolute. Research must continue to evaluate novel and emerging technologies for efficacy in the training environment.

(B) Phased sustainment and readiness costs to refine, reduce, and when appropriate, replace the use of live animals in medical education and training.

Although there are no DoD programs that currently budget for sustainment and readiness of simulation devices for combat casualty training, DoD is advancing research to develop and transition to technology-based simulations in medical learning environments. Many of today's simulation tools result from prior DoD investments (e.g., MATT® Series 1500 Trauma Trainer, AirwayPlus Lifecast (APL) Upper Torso Trainer® (Kforce Government Solutions, Inc.), and the TraumaMan®System (Simulab Corporation)). These products and others benefited from experience gained by the pre-hospital provider during the last 10 years of military conflicts. Since 2009, DoD has invested approximately \$16 million per year within the operation and maintenance accounts of the Military Services to provide simulation training devices and products that assist combat casualty training. The development and availability of commercial simulation devices remain heavily reliant on commercialization of these technologies across a limited market. DoD has documented the benefits of introducing medical simulation devices in hospital training centers that improve patient safety and team training readiness; however, applying similar technologies in the field training environment continues to lag owing to reliability issues. These factors further limit industry's return on investment and impede DoD's ability to project sustainment and readiness funding.

(C) Any risks associated with transitioning to human-based training methods, including resource availability, anticipated technological development timelines, and potential impact on the present combat trauma training curricula.

Figure 1, as described in section (A) above, addresses the technological development timeline. However, until the Department has a clearer understanding of future technology solutions, programming for development and procurement will lag currently unknown solutions. Until reliable metrics are defined and technology gaps are identified, projecting a timeline and cost for this technology development is premature. It is important that the foundation evolves from transitioning the intermediary results of the Combat Casualty Care Training Consortia studies that have been transitioned into training programs.

(D) An assessment of potential effect of transitioning to human-based training methods on the quality of medical care delivered on the battlefield, including any reduction in competency of combat medical personnel.

Premature removal of the live animal model from combat casualty training programs would likely degrade combat trauma care on the battlefield and would potentially increase Warfighter fatalities from battlefield injuries. Absent high fidelity medical simulators, the medical corps anticipates a diminished capacity to administer battlefield medical care in the short term until experience levels increase. After more than 10 years of war and battlefield deployment, military medical providers have made major advances in combat casualty care. Combat casualty training instructors are able to interject personal experiences that improve the overall training. As both deployments and battlefield casualties decrease, this cadre of experienced medic trainers will likely also shrink. As the opportunities for medics to experience exposure to real-world combat wounds are reduced, other training experiences will become even more critical to the training curriculum.

(E) An assessment of risks to maintaining the level of combat life-saver techniques performed by all members of the Armed Forces.

The risk to the combat life-saver curriculum is low because the majority of courses do not include the live animal training exercise. Combat life-saver courses emphasize the concepts of tactical combat casualty care: care under fire, tactical field care, and casualty evacuation care. These concepts are primarily taught using a combination of didactic lectures, videos, partial-task trainers, and low-fidelity mannequins.

SUMMARY

More than 10 years of conflict have given military medical providers significant experience in the early care of the battlefield wounded, which has contributed to historically high survival rates. Actions of the pre-hospital provider are paramount to survival, and the commensurate training received by the provider is a critical component to the success of initial intervention. A premature transition to alternative methods of training, without a firm basis

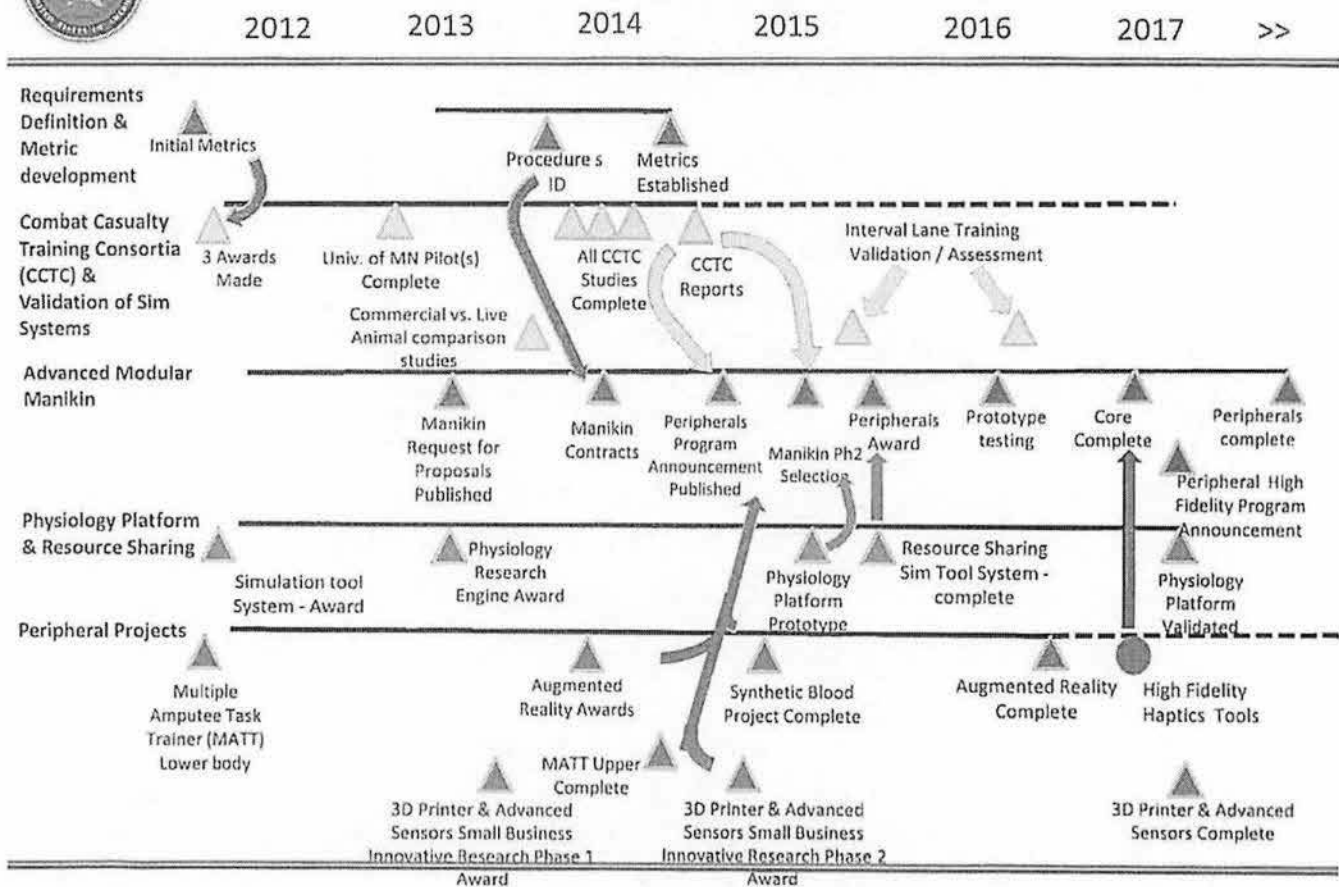
derived from scientific evidence, could unnecessarily lead to a decrease in the combat casualty survival rate.

Attachment:

1. Figure 1 – Timeline of Combat Casualty Training Research Portfolio



Figure 1. Timeline of Combat Casualty Training Research Portfolio



(b)(6)

Subject: FW: Live Tissue Training
Attachments: CRS Jansen Response 30 July 2015 sent.docx
Signed By: (b)(6)

FYI... let's discuss plan to close with requester. Can you do it?

-----Original Message-----

(b)(6)

Subject: FW: Live Tissue Training

Hi (b)(6)

Happy Friday! Dr. Brown has reviewed and approved the responses on LTT

Thanks,

(b)(6)

-----Original Message-----

(b)(6)

(b)(6)

Subject: FW: Live Tissue Training

Hi (b)(6) Would you get R&E front office ok on this, please?

Vr (b)(6)

(b)(6)

(b)(6)

Cc: Mason, Patrick A SES OSD OUSD ATL (US)

Subject: RE: Live Tissue Training

Hi (b)(6)

Response to Mr. Jansen's questions is attached.

v/r

(b)(6)

<http://www.acq.osd.mil/rd/hptb/index.html>

(b)(6)

Cc: DHA NCR Prog Integ List PI List

Subject: FW: Live Tissue Training

(b)(6)

Can you help with this CRS request? Looks like some similar issues.

(b)(6)

-----Original Message-----

From: Jansen, Don [mailto:DJANSEN@crs.loc.gov]

Sent: Thursday, July 23, 2015 2:12 PM

(b)(6)

Subject: Live Tissue Training

Hello again (b)(6)

Sorry to bother you again today. This Congressional request is for information related to use of animals in medical training. It reads:

"I'm interested in learning more about live-tissue training in the military and the following areas in particular:

- advantages and disadvantages of using live animals in combat training
- effectiveness and cost of using live animals vs. simulators
- where and how often is live tissue training used in U.S. and internationally?
- changes in military policy to stop live tissue training (specifically, are there any branches of military that are particularly opposed to banning practice?)"

My understanding is that live tissue training is no longer being conducted. Is that accurate? Also I understand that an office somewhere in DOD published a report on this topic but I have not been able to find it online. Are you aware of that? Any assistance much appreciated. Thank you,

V/R

Don Jansen

Specialist in Defense Health Care Policy

Foreign Affairs, Defense, & Trade Division

Congressional Research Service, Library of Congress

101 Independence Ave., S.E.

Washington, DC 20540-7460

djansen@crs.loc.gov <mailto:djansen@crs.loc.gov>

(202) 707-4769

The following questions were asked in the email from Don Jansen, CRS

1. Advantages and disadvantages of using live animals in combat training; effectiveness and cost of using live animals vs. simulators; where and how often is live tissue training used in U.S. and internationally

Comprehensive training that integrates both simulation and live tissue is used to train military medics to perform lifesaving procedures and manage casualties prior to deployment. There are both advantages and disadvantages to each training modality. Simulators provide the opportunity to learn and repeat psychomotor skills such as the application of a tourniquet. However, simulators lack the feel of real tissue, lack realism in their response to manipulations, and many are not compatible with the military training environment (i.e., large numbers of students training in an outdoor environment). At the current time, there is no single existing technology to comprehensively train military medics to manage trauma casualties without supplementing the training experience with the use of live tissue. The advantage of live tissue is in the realism—the physiological response to injuries, the feel of the tissues, and in the potential loss of life that can result if a medic makes mistakes. This realistic training experience integrates both psychomotor and cognitive skills and contributes to preparedness to manage casualties on the battlefield. In this training experience, the military medic learns not only how to apply a tourniquet, but how to medically manage the other physiological changes that occur. The frequency and location of training depends upon the operational tempo of each unit and the location of deploying medical personnel.

The Department does not routinely collect information on costs of live tissue training or simulation training; both modalities are integrated into the pre-deployment training of medics. However, in July 2014, the Department was asked by Congressional staff to provide Fiscal Year 2013 expenditures for Research, Development, Test, and Evaluation (RDT&E), procurement, and Operation and Maintenance (O&M) for simulation for combat casualty care training. In Fiscal Year 2013, the approximate overall expenditure for RDT&E, procurement, and O&M for simulation for combat casualty care training was \$35 million.

2. Changes in military policy to stop live tissue training (specifically, are there any branches of military that are particularly opposed to banning practice?)

There have been no changes in military policies to stop live tissue training and none of the Components ban the use of animals for such purposes. All branches of the military adhere to Department of Defense Instructions 3216.01 and 1322.24. These policies state that animals shall only be used in training when alternatives are not educationally equivalent or appropriate. Accordingly, the Department continuously seeks opportunities to reduce and replace the use of animals for training. Last year, in an effort to standardize medical education and training programs, several courses stopped using animals.

3. My understanding is that live tissue training is no longer being conducted. Is that accurate? Also I understand that an office somewhere in DOD published a report on this topic but I have not been able to find it online.

Live tissue training does still occur. There was a 2013 Report to Congress on the Strategy to Transition to Use of Human-Based Methods for Certain Training. This report is included.

(b)(5)

(b)(6)

Subject:

FW: Additional recent Dr Hagmann Article

(b)(6)

You probably saw this follow on article, but just in case:

(b)(6)

<http://www.reuters.com/article/2015/07/23/us-usa-doctor-report-exclusive-idUSKCN0PX2L620150723>

> Exclusive: Military school knew of doctor's macabre ways for decades

>

> The president of the U.S. military's medical college said he took swift action after learning in 2013 that John Henry Hagmann, a former Army doctor teaching there, was injecting students with hypnotic drugs, inducing shock by withdrawing their blood, and performing rectal exams in class.

>

> Hagmann was escorted off the Uniformed Services University campus in Maryland, and the college quickly offered students blood tests to determine if they had been exposed to any diseases, school President Charles Rice said. The college also launched an internal investigation into Hagmann's conduct, and it forwarded information to law enforcement authorities and the Virginia Board of Medicine, which revoked Hagmann's license last month.

>

> "We took immediate steps," Rice said.

>

> But records reviewed by Reuters, including the university's own investigation, show that school officials had known of Hagmann's teaching methods for more than 20 years. The records also show that three faculty members sat in on Hagmann's course in 2012 but did not alert their superiors, despite witnessing practices that the school has since banned. One former dean even pushed to have Hagmann court-martialed in 1993 over similar allegations, records show.

>

> "The university's culpability casts a wide net," according to the school's internal review, dated December 2013. The document includes 27 pages of findings and 45 exhibits that total more than 350 pages. It was obtained by Reuters under the Freedom of Information Act.

>

> The Virginia medical board concluded in June that Hagmann, 59, exploited students he trained in 2012 and 2013 at sessions in Virginia, North Carolina, Colorado and Great Britain. Some of those students testified that Hagmann performed penile nerve blocks and instructed them to insert catheters into one another's genitals.

>

> "The evidence is so overwhelming and so bizarre as to almost shock the conscience of a prosecutor who's been doing this for 26 years," Assistant Attorney General Frank Pedrotty told the board in June.

>

> Hagmann's courses in treating battlefield wounds were popular with the U.S. government, however. Since 2007, his company, Deployment Medicine International, has received at least \$10.5 million in federal contracts from government agencies, including the FBI and U.S. Special Forces.

>

- >
- >
- > DR. HAGMANN'S DEFENSE
- >
- > Hagmann has denied any wrongdoing and vowed to appeal the revocation of his license. In an email to Reuters this week, he wrote that "the views of the civilian Board of Medicine and the academic institutions do not match the reality of law enforcement, other military, and special operations medical support training - or real missions." None of the "over 1,000 physicians" who he says have taken his courses "felt the training was dangerous or inappropriate - only one medical student who recruited other students to complain."
- >
- > In June, Hagmann told Reuters that university officials long condoned his teaching techniques, which he says saves lives on the battlefield.
- >
- > "The same institution that is now making a complaint originally supported and encouraged the programs," Hagmann said then.
- >
- > In some ways, the university's internal review reflects Hagmann's claim that the school tacitly supported his approach to teaching battlefield medicine. Rice, who became school president in 2006, acknowledged that "there were flaws and gaps" in the university's oversight.
- >
- > In 1986, during his second year as a professor at the university, Hagmann created a course to give students field experience treating combat wounds, the report says.
- >
- > By the early 1990s, documents show, his techniques were similar to those that cost him his license this year: Students in his class performed procedures on one another and were provided nitrous oxide, also known as laughing gas, as well as a drug to treat insomnia and the antihistamine Benadryl, the report says.
- >
- > In sworn statements that are part of the report, unidentified colleagues offered varied descriptions of Hagmann: "an iconoclast and a cowboy," someone who had "an almost magical spell-like effect on people," and an officer "on a righteous mission ... impatient with government rules."
- >
- > "He has a pied piper mentality," Rice said.
- >
- >
- > A MANAGEMENT PROBLEM
- >
- > Some at the school, including Hagmann's direct supervisor while he was on staff there, found him difficult. "I had to ride herd over him," Colonel Craig Llewellyn told the school's investigator. "He kept toying with things, playing fast and loose..." In a brief interview, Llewellyn said Hagmann repeatedly violated administrative rules.
- >
- > In 1993, the report says, a dean at the school became so alarmed by Hagmann's methods that she told a commandant that Hagmann should be court-martialed. It does not name the dean, who has since died, but the report says an unidentified official at the school determined that Hagmann's conduct was not a military matter but an academic one.
- >
- > The specific steps the university took in 1993 in response to the dean's complaints remain unclear. The school did investigate the concerns and interviewed Hagmann and his supervisors.
- >
- > But the 2013 report takes officials to task for failing to stop Hagmann then. "Despite the dean's grave concerns, the course continued..." the report says. "In any other unit, a troubled course ... would have been discontinued immediately."
- >

> Seven years later, in 2000, Hagmann retired from the university after he received a "less than favorable" performance review, according to the report. Shortly thereafter, Hagmann started his private training company, and the business of training troops to treat battlefield trauma boomed as wars raged in Iraq and Afghanistan.

>

> Then, around 2007, Hagmann returned to the school "unofficially," the report says. He began co-teaching a course, and by 2012, he was teaching a summer class on his own.

>

> The report contends that Hagmann used the university "to subsidize his business." Students provided free labor to help support his consulting company. And because he waived course tuition - about \$2,000 per student - the school allowed him to use its classrooms for his private clients, the report says. Hagmann, in an email to Reuters, disputed the characterization.

>

> Whatever the case, his teaching methods remained controversial. In addition to inducing shock by withdrawing blood from students, Hagmann plied class members with alcohol and had students perform penile nerve blocks on one another and on him, the report says. Two students told the Virginia medical board they have scars on their chests from class demonstrations.

>

>

> "TOO FAR OUT"

>

> One university professor, Patricia Deuster, was "shocked and dumbfounded" to learn Hagmann and his class had returned in 2012, the report says. Deuster, who declined to comment to Reuters, has taught at the school since 1984 and edited The Navy SEAL Physical Fitness Guide. "He was too far out on the edge," Deuster told the school's investigator.

>

> The three doctors who allegedly witnessed Hagmann's teaching but did not report the drug and shock demonstrations in 2012 no longer teach at the university, Rice said. He declined to identify them, and their names are redacted from the records.

>

> The official who handled the school's investigation, Colonel Neil Page, declined to comment. In his report, Page sharply criticizes the three former instructors.

>

> "Medical doctors and educators should have prevented this kind of demonstration, or should have asked serious questions over the purpose and safety," he wrote.

>

> At the time, the medical school did not have a policy against instructors using students as test subjects. Rice said the school has since created one.

>

> Thus, among Hagmann's legacies, is an asterisk in the student handbook with this reminder: "School of Medicine policy prohibits instructors or medical students from requesting medical students from serving as 'patients' for intrusive examinations or procedures, such as a rectal or genitourinary exam."

>

> Rice, who served as trauma surgeon to President George H.W. Bush, said the Hagmann matter is the most bizarre situation he has known in 40 years of government service.

>

> "He shouldn't be a physician," Rice said. "He lost his compass somewhere."

>

>

> (Reporting by John Shiffman. Edited by Blake Morrison)

>

(b)(6)



(b)(6)

From: Jansen, Don <DJANSEN@crs.loc.gov>
Sent: Thursday, July 23, 2015 2:12 PM
To: (b)(6)
Subject: Live Tissue Training

Hello again (b)(6)

Sorry to bother you again today. This Congressional request is for information related to use of animals in medical training. It reads:

"I'm interested in learning more about live-tissue training in the military and the following areas in particular:

- advantages and disadvantages of using live animals in combat training
- effectiveness and cost of using live animals vs. simulators
- where and how often is live tissue training used in U.S. and internationally?
- changes in military policy to stop live tissue training (specifically, are there any branches of military that are particularly opposed to banning practice?)"

My understanding is that live tissue training is no longer being conducted. Is that accurate? Also I understand that an office somewhere in DOD published a report on this topic but I have not been able to find it online. Are you aware of that? Any assistance much appreciated. Thank you,

V/R

Don Jansen

Specialist in Defense Health Care Policy

Foreign Affairs, Defense, & Trade Division

Congressional Research Service, Library of Congress

101 Independence Ave., S.E.

Washington, DC 20540-7460

djansen@crs.loc.gov <<mailto:djansen@crs.loc.gov>>

(202) 707-4769

(b)(6)

Subject:

RE: Arizona National Guard hired suspended doctor for training

(b)(6)

(b)(6)

We'll check and get back to you (b)(6) cc'd) will be the SOLA action officer working this issue.

Sincerely,

(b)(6)

(b)(6)

Subject: FW: Arizona National Guard hired suspended doctor for training

(b)(6)

SASC PSM Al Edwards asked me if the Services and Special ops community has/had a contractual relationship with Dr Hagmann's medical trauma training company. See below article. USUHS and some of the services have had in the past, but evidently we no longer contract with him.

thanks

(b)(6)

(b)(6)

Subject: FW: Arizona National Guard hired suspended doctor for training

Al Edwards wants to know if any of the services have or still contract with Dr Hagmann for trauma training?

USU no longer does.

Thanks.

(b)(6)



-----Original Message-----

From: Edwards, Allen (Armed Services)

[mailto:Allen_Edwards@armed-services.senate.gov]

Sent: Thursday, July 16, 2015 12:25 PM

(b)(6)



Cc: Edwards, Allen (Armed Services)

Subject: Arizona National Guard hired suspended doctor for training

<http://www.azcentral.com/story/news/local/arizona/2015/07/16/arizona-national-guard-suspended-doctor-training/30104133/>

Can I get info on DOD's position of hiring Dr. Hagmann's company for combat trauma training? Thank you.

AI

(b)(6)

Subject:

RE: Arizona National Guard hired suspended doctor for training

Signed By:

(b)(6)

Hi

(b)(6)

AF currently does not have any contracts with Dr. Hagmann. AFSOC has contracted with DMI in the past but all has been through SOCCOM and CENTCOM.

If you have any questions please let me know.

Thanks!

(b)(6)

-----Original Message-----

(b)(6)

Subject: FW: Arizona National Guard hired suspended doctor for training

Al Edwards wants to know if any of the services have or still contract with Dr Hagmann for trauma training?

USU no longer does.

Thanks.

(b)(6)

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[mailto:Allen_Edwards@armed-services.senate.gov]
Sent: Thursday, July 16, 2015 12:25 PM

(b)(6)

Cc: Edwards, Allen (Armed Services)

Subject: Arizona National Guard hired suspended doctor for training

<http://www.azcentral.com/story/news/local/arizona/2015/07/16/arizona-national-guard-suspended-doctor-training/30104133/>

Refused

Can I get info on DOD's position of hiring Dr. Hagmann's company for combat trauma training? Thank you.

AI

(b)(6)

Subject:

Re: Arizona National Guard hired suspended doctor for training

(b)(6)

We cannot speak for the entire Navy, only Navy Medicine. Special Ops might be worth inquiring with.

BL: Navy Medicine has not contracted with Dr. Hagmann (or DMI).

V/R

(b)(6)

----- Original Message -----

(b)(6)

Subject: FW: Arizona National Guard hired suspended doctor for training

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(b)(6)

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Can I get info on DOD's position of hiring Dr. Hagmann's company for combat trauma training? Thank you.

AI

(b)(6)

Subject:

RE: Arizona National Guard hired suspended doctor for training

Good afternoon

(b)(6)

Army medicine previously severed all contracts with Dr Hagmann. I am working to determine the date all ties with him were cut, but I am pretty sure it was 2014.

v/r

(b)(6)

-----Original Message-----

(b)(6)

Subject: FW: Arizona National Guard hired suspended doctor for training

Al Edwards wants to know if any of the services have or still contract with Dr Hagmann for trauma training?

USU no longer does.

Thanks.

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[mailto:Allen_Edwards@armed-services.senate.gov]

Sent: Thursday, July 16, 2015 12:25 PM

(b)(6)

USARMY OSD OASD LA (US)

Cc: Edwards, Allen (Armed Services)

Subject: Arizona National Guard hired suspended doctor for training

<http://www.azcentral.com/story/news/local/arizona/2015/07/16/arizona-national-guard-suspended-doctor-training/30104133/>

Repeat

Can I get info on DOD's position of hiring Dr. Hagmann's company for combat trauma training? Thank you.

AI

(b)(6)

From: Edwards, Allen (Armed Services) <Allen_Edwards@armed-services.senate.gov>
Sent: Monday, July 20, 2015 8:45 AM
To: (b)(6)
Subject: RE: Arizona National Guard hired suspended doctor for training

Please do - thank you.

Al

-----Original Message-----

(b)(6)

Sent: Monday, July 20, 2015 8:44 AM
To: Edwards, Allen (Armed Services)
Subject: RE: Arizona National Guard hired suspended doctor for training

Al, they don't have affiliation with DHA / USU any longer. Would you like me to check with Services and SOCOM?

(b)(6)

-----Original Message-----

From: Edwards, Allen (Armed Services) [mailto:Allen_Edwards@armed-services.senate.gov]
Sent: Thursday, July 16, 2015 12:52 PM

(b)(6)

Subject: RE: Arizona National Guard hired suspended doctor for training

Very helpful - can you let me know if DOD continues to hire this company?

Al

-----Original Message-----

(b)(6)

Sent: Thursday, July 16, 2015 12:37 PM
To: Edwards, Allen (Armed Services); Miller, Andrea C Lt Col USAF OSD OASD LA (US)
Subject: RE: Arizona National Guard hired suspended doctor for training

(b)(5)

(b)(5)

(b)(6)

-----Original Message-----

From: Edwards, Allen (Armed Services) [mailto:Allen_Edwards@armed-services.senate.gov]

Sent: Thursday, July 16, 2015 12:25 PM

To: (b)(6)

Cc: Edwards, Allen (Armed Services)

Subject: Arizona National Guard hired suspended doctor for training

<http://www.azcentral.com/story/news/local/arizona/2015/07/16/arizona-national-guard-suspended-doctor-training/30104133/>

Report

Can I get info on DOD's position of hiring Dr. Hagmann's company for combat trauma training? Thank you.

AI

(b)(6)

Cc: DHA NCR Prog Integ List PI List
Subject: FW: Arizona National Guard hired suspended doctor for training

(b)(6)

You need to check with the Services and SOCOM on this one...not us (they don't have affiliation w USU anymore).

(b)(6)

(b)(6)

----- Original Message -----

(b)(6)

Sent: Thursday, July 16, 2015 04:26 PM
To: DHA NCR Prog Integ List PI List
Subject: FW: Arizona National Guard hired suspended doctor for training

(b)(6)

See below question from AI on Dr Hagmann's company? I think the answer would be no.

(b)(6)

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To: Edwards, Allen (Armed Services); Miller, Andrea C Lt Col USAF OSD OASD LA (US)
Subject: RE: Arizona National Guard hired suspended doctor for training

AI,

(b)(5)



(b)(6)



Refer

-----Original Message-----

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Sent: Thursday, July 16, 2015 12:25 PM

To: (b)(6)

Cc: Edwards, Allen (Armed Services)

Subject: Arizona National Guard hired suspended doctor for training

<http://www.azcentral.com/story/news/local/arizona/2015/07/16/arizona-national-guard-suspended-doctor-training/30104133/>

Can I get info on DOD's position of hiring Dr. Hagmann's company for combat trauma training? Thank you.

AI

Repeat

(b)(6)

Subject:

Re: Arizona National Guard hired suspended doctor for training

I know we can tell you know from USU perspective but we can't answer for all of DoD - you may need to check with Services too - I will do a double-check on our end

----- Original Message -----

From: (b)(6)
Sent: Thursday, July 16, 2015 04:26 PM
To: DHA NCR Prog Integ List PI List
Subject: FW: Arizona National Guard hired suspended doctor for training

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(b)(6)

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From: (b)(6)
Sent: Thursday, July 16, 2015 12:37 PM
To: Edwards, Allen (Armed Services); Miller, Andrea C Lt Col USAF OSD OASD LA (US)
Subject: RE: Arizona National Guard hired suspended doctor for training

Al

(b)(5)

(b)(5)

(b)(6)

Rep

-----Original Message-----

From: Edwards, Allen (Armed Services) [mailto:Allen_Edwards@armed-services.senate.gov]

Sent: Thursday, July 16, 2015 12:25 PM

To: (b)(6)

Cc: Edwards, Allen (Armed Services)

Subject: Arizona National Guard hired suspended doctor for training

<http://www.azcentral.com/story/news/local/arizona/2015/07/16/arizona-national-guard-suspended-doctor-training/30104133/>

Can I get info on DOD's position of hiring Dr. Hagmann's company for combat trauma training? Thank you.

AI

(b)(6)

From: Service Account, CRM Setup <donotreply.crmsetup@mail.mil>
Sent: Thursday, July 02, 2015 3:18 PM
To: (b)(6)
Subject: LA - Request Type: Congressional Incoming, OSD007024-15, CMD Tasking, OPR: LA, Suspense Date: 06/30/15
Attachments: Congressional Incoming-CMD009038-15-2708401-1.pdf
Follow Up Flag: Follow up
Flag Status: Flagged

Notification Type: New ACTION task has been assigned

Importance: High

Control Number: OSD007024-15

Action ID: CMD009038-15 <https://crm.osd.mil/catms1/main.aspx?etn=osd_action&extraqs=id%3d%257b2ceb0f4e-e20d-e511-9fd6-005056aa030f%257d%26&pagetype=entityrecord>

Tasker ID: CATMS26062015CO1RIM

<https://crm.osd.mil/catms1/main.aspx?etn=ava_tasker&extraqs=id%3d%257bdd8585fb-ee20-e511-9830-005056aa5bb4%257d%26&pagetype=entityrecord>

From: MOC JOHNSON, H (b)(6)

To: SECDEF

Task Subject: SEXUAL ASSAULT AND ABUSE BY A CONTRACTOR TO SERVICE MEMBERS DURING LIVE TISSUE TRAINING BY DEPLOYMENT MEDICINE INTERNATIONAL

Request Type: Congressional Incoming

Date of Receipt: 06/08/15

OPR: LA

Response Type: C&R-Comments and Recommendations

OCRs (b)(6)

CCs:

Task Instructions: REWRITTEN AND SUBMITTED FOR RECOORD (b)(6) THEN HOUSE.

Task Suspense Date: 06/30/15

Distribution: RLB DSD UPR

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(b)(6)

(b)(6)

This e-mail is FOUO.

(b)(6)

HENRY C. "HANK" JOHNSON, JR.
9th District, Georgia

COMMITTEES

JUDICIARY

ARMED SERVICES

Congress of the United States
House of Representatives
Washington, DC 20515-1004

SUBCOMMITTEES
REGULATORY REFORM, CONSUMER AFFAIRS,
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INTELLIGENCE, EMERGING TECHNOLOGIES,
AND CYBER-SECURITY
STRATEGIC FORCES

June 5, 2015

Ashton B. Carter
Secretary of Defense
Department of Defense
1000 Defense Pentagon
Washington, DC 20301

Dear Secretary Carter,

Thank you for the work you do in challenging times to protect American interests both at home and abroad. As a member of the House Armed Services Committee, I am well aware of the myriad challenges faced by the Department. It is an honor to serve on this committee, in part because of the opportunity it affords me to offer recommendations for oversight and reform. It is in that spirit that I am writing today. I have been made aware of a series of troubling incidents taking place by various service branches for years. If true, these actions represent serious lapses in judgement and character, as well as oversight by the Department of Defense.

I therefore urge you to carefully review the information and allegations contained in this letter and respond to the questions raised below within 15 days.

Another "Live Tissue" Contractor Cited for Abuse

I was recently made aware that the principal of a longtime Department of Defense (DOD) live tissue training contractor, Deployment Medicine International (DMI) (which also does business with DOD as Deployment Medicine Consultants (DMC)) has recently had his medical license suspended by the state of Virginia.

In a March 12, 2015 order, the Virginia Board of Medicine determined that John Hagmann, MD¹ sexually assaulted and otherwise physically abused service members during live tissue training courses taught by DMI. The Board concluded that Dr. Hagmann is a "*substantial danger to the public health or safety*." The attached documentation outlines the full scope of the charges.

These findings are of particular concern given that the Department of Defense paid Dr. Hagmann and DMI for this work², and continued to pay DMI as recently as contracts awarded for Fiscal

¹ Dr. Hagmann is a retired Lt. Col. and former Uniformed Services University employee.

²

<https://www.usaspending.gov/Pages/AdvancedSearch.aspx?sub=y&ST=C&FY=2013,2012&A=0&SS=US&k=deployment%20medicine%20consultants>

2240 HANBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
PHONE (202) 225-1605
FAX (202) 226-0681

DISTRICT OFFICE
6700 HILLDALE DRIVE, SUITE 120
LITHONIA, GA 30058
PHONE (770) 387-2791
FAX (770) 387-8721



PROVIDED TO YOU BY

OSD007024-15/CMD009038-15

Year 2014.³ DMI had it eligibility to receive federal contracts renewed on May 26, 2015, according to the federal System for Award Management.

Since learning of these abuses, I have also been informed that evidence exists of additional abuses by DMI and Dr. Hagmann during DOD contract work. The evidence in that case reveals DMI instructors and servicemembers inflicting unnecessary pain to animals and reveals a culture of racism, sexual harassment, homophobia, and a celebration of cruelty to animals.

The Culture Surrounding Sexual Assaults

I appreciated your April 22, 2015 remarks to Georgetown University students:

*"One key to prevention is to understand that sexual assaults often occur in environments where crude and offensive behavior, unwanted sexual attention, coercion, and sexual harassment are tolerated, ignored, or condoned."*⁴

I agree fully with your statement, which is why I feel compelled to bring to your attention the allegations of abuse during live tissue trainings appear to be precisely the type of unsafe subculture that DOD wants to eliminate. It's critical to note that this problem is not limited to Dr. Hagmann or to DMI. In 2012, the Department of Defense allowed inappropriate behavior and abuses to take place in controversial live tissue training exercises taught by a separate contractor.⁵

Safer, More Effective Alternatives Not Used

It is also critical to note that live-tissue trainings are not necessary. As you may know, military researchers⁶ and Pentagon officials⁷ have endorsed non-animal medical training alternatives that make live tissue training unnecessary to adequately train military medics. This is precisely why I have introduced the BEST Practices Act.⁸

Sophisticated simulation alternatives allows us to advance beyond controversial live tissue trainings. Phasing out these trainings would eliminate a controversial area of the DOD that is not medically necessary and in which a culture of abuse has now escalated to sexual violence against servicemembers.

Questions

In light of the foregoing concerns, I have several questions that I request that you answer within fifteen (15) days below:

1. When and how did the Department of Defense first become aware of the allegations described in this letter?

³

<https://www.usaspending.gov/Pages/AdvancedSearch.aspx?sub=y&ST=C&FY=2015,2014&A=0&SS=US&k=deployment%20medicine%20consultants>

⁴ <http://www.defense.gov/Speeches/Speech.aspx?SpeechID=1923>

⁵ <http://www.cnn.com/2013/05/03/us/coast-guard-animals/>

⁶ <http://www.ncbi.nlm.nih.gov/pubmed/25975338>

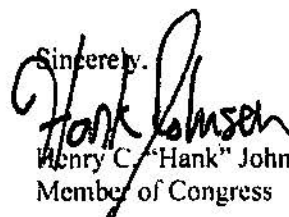
⁷ <http://www.military.com/daily-news/2013/04/02/activists-army-to-limit-live-animal-training.html>

⁸ HR 1095

2. When and how did the Department of Defense first become aware of the facts found by the State of Virginia in its March 12th 2015 order to suspend Dr. Hagmann's medical license?
3. If the Department was aware of these allegations, and the action by the State of Virginia, prior to this letter, what action was taken by the Department in response?
4. Please explain what policies and procedures are in place to facilitate the sharing of allegations of abuse by Department contractors with the Department? If the Department was unaware of these allegations, and the action by the State of Virginia, prior to this letter, please explain how those systems failed to ensure that these allegations were reported? What specific reforms will the Department make to improve its policies and procedures?
5. Please provide specific details on all Department of Defense contracts awarded to companies associated with Dr. Hagmann, including but not limited to. Deployment Medicine International (DMI) and Deployment Medicine Consultants (DMC) since Fiscal Year 2005.
6. How will the Department hold Dr. Hagmann and DMI accountable for their alleged abuses of servicemembers, animals, taxpayer dollars, and the public trust? What process exists, if any, to reclaim taxpayer funds paid to a DOD contractor, such as DMI, that is found to have committed abuses?
7. What reforms were instituted in 2012 following the revelations of misbehavior and animal abuse in a Coast Guard live tissue course, and why did these reforms not adequately address the problem?
8. Since we do not know the total number of service members that were allegedly sexually assaulted and otherwise abused in settings like this in recent years—particularly because of the stigma and risks associated with coming forward—I hope your office will immediately begin a comprehensive investigation into all contractors offering live tissue training to the DOD. That investigation should address questions such as:
 - a. When were the first complaints registered by abused servicemembers against the contractor?
 - b. Was there a senior military official observing these trainings? If not, why not? If so, did that individual raise concerns within the chain of command at how servicemembers were being treated?
 - c. Were any contracts or task orders awarded to DMI or others after any abuse allegations were made?
 - d. Were contracts to DMI sole-source or were they competitively awarded?
 - e. How many servicemembers were exposed to these abuses from DMI since 2012, which is when DOD first issued assurances that these types of trainings were going to be cleaned up?

- f. What is the full dollar amount (in FY15 dollars) any entities owned in whole or part, or managed in whole or part, by Dr. Hagmann have received in the last 10 years, and what percentage of the related contracts were competitively awarded?

I know you are as horrified as I am by what has been revealed here. I look forward to working with you to put an end to these abuses. I look forward to receiving your responses to these questions within fifteen (15) days.

Sincerely,

Henry C. "Hank" Johnson
Member of Congress

CC:

The Hon. Jon T. Rymer, Department of Defense Inspector General
Uniformed Services University
MG Jeffrey J. Snow, DoD Sexual Assault Prevention and Response Office

(b)(6)

Subject:

(US); DHA NCR Prog Integ List PI List
RE: Congressional Ltr to SecDef

I'm pretty sure...they work very closely on all of this together.

(b)(6)

(b)(6)

-----Original Message-----

(b)(6)

Sent: Friday, June 12, 2015 8:34 PM

(b)(6)

DHA NCR Prog Integ List PI List (b)(6)

Subject: Re: Congressional Ltr to SecDef

Does HA plan to let ATL coord on it?

----- Original Message -----

(b)(6)

Sent: Friday, June 12, 2015 10:19 AM

(b)(6)

DHA NCR Prog Integ List PI List (b)(6)

Subject: RE: Congressional Ltr to SecDef

Yes, looks like it was assigned to us in CATMS

v/r

(b)(6)

Please note that the PI group email list has changed. It is now:

(b)(6)

(b)(6)

-----Original Message-----

(b)(6)

Sent: Friday, June 12, 2015 9:49 AM

To: DHA NCR Prog Integ List PI List

(b)(6)

(b)(6)

Subject: FW: Congressional Ltr to SecDef

(b)(6)

Is HA drafting the response on this one? Evidently its assigned to P/R.

Just want to make sure HA and AT&L are linked on this one.

Thanks,

(b)(6)

-----Original Message-----

(b)(6)

Sent: Thursday, June 11, 2015 3:02 PM

(b)(6)

Subject: FW: Congressional Ltr to SecDef

(b)(6)

Hi

Attached is a letter from CM Johnson to SecDef concerning allegations against a live tissue training contractor. Could you tell me what component got tasked to prepare response?

Thanks,

(b)(6)

-----Original Message-----

(b)(6)

Sent: Thursday, June 11, 2015 2:34 PM

(b)(6)

Subject: FW: Congressional Ltr to SecDef

(b)(6)

Hi

Hope you've been well. It's been rather quiet for a week or so on the animal front, but that may be changing. I can't reach (b)(6) but thought you may be able to help. Do you know if a response on this letter from Representative Johnson to Secretary Carter will be tasked to Dr. Mason?

If so, just wanted to get a jump on it since the clock is quickly ticking away to meet the requested 15 day turn-around. It's a very complicated issue, but there are some components involving animals.

Thank you.

v/r,
(b)(6)

[Redacted]

<http://www.acq.osd.mil/rd/hptb/index.html>

-----Original Message-----

(b)(6)

Sent: Thursday, June 11, 2015 1:46 PM

(b)(6)

Subject: FW: Congressional Ltr to SecDef

Good afternoon

(b)(6)

Do you know if there is an action in the tasking system yet for this letter or which office will be tasked to respond?

Thank you,

(b)(6)

[Redacted]

<http://www.acq.osd.mil/rd/hptb/index.html>

-----Original Message-----

From: Mason, Patrick A SES OSD OUSD ATL (US)

Sent: Thursday, June 11, 2015 10:07 AM

(b)(6)

Subject: Fw: Congressional Ltr to SecDef

Patrick Mason, Ph.D., SES

Director, Human Performance, Training, and BioSystems Directorate Office of
the Assistant Secretary of Defense for Research and Engineering
4800 Mark Center Drive, Suite 17E08
Alexandria, VA 22350-3600

(571) 372-6435 Office (DSN 372-6435)

Patrick.a.mason2.civ@mail.mil

<http://www.acq.osd.mil/rd/hptb/index.html>

----- Original Message -----

(b)(6)

Sent: Thursday, June 11, 2015 10:03 AM

To: Mason, Patrick A SES OSD OUSD ATL (US); Ormond, Dale A SES OSD OUSD ATL
(US)

(b)(6)

Subject: Congressional Ltr to SecDef

Gentlemen,

Please see the attached document with a note from Mr. Shaffer that reads,
"Dale Ormond, Patrick Mason, Visibility"

V/r,

(b)(6)

(b)(6)

Sent: Friday, June 12, 2015 1:07 PM

(b)(6)

DHA NCR Prog Integ List PI List

Subject: RE: Article on Trauma Training

Signed By:

(b)(6)

Follow Up Flag:

Follow up

Flag Status:

Flagged

USU did not have any contracts with John Hagmann or his company, Deployment Medicine International (DMI)/Deployment Medicine Consultants Inc. The education and training provided by Dr. Hagmann/DMI during the period in question was gifted to the University. He reportedly has (or had) numerous contracts with the military Services, USCG, DoS, DoE, and other USG entities. Details are available at USAspending.gov for FY 08-14.

(b)(6)

(b)(6)

-----Original Message-----

(b)(6)

Sent: Friday, June 12, 2015 10:15 AM

To: DHA NCR Prog Integ List PI List (b)(6)

Subject: FW: Article on Trauma Training

Follow on question.

(b)(6)

-----Original Message-----

From: Greene, Craig [mailto:Craig.Greene@mail.house.gov]

Sent: Thursday, June 11, 2015 1:08 PM

(b)(6)

Subject: RE: Article on Trauma Training

(b)(6)

I'm assuming the other DOD entities were SOCOM and it sounds like the incidents in the article occurred there more than at USU. Correct?

-----Original Message-----

(b)(6)

Sent: Wednesday, June 10, 2015 9:31 AM

To: James, Jeanette

Cc: Greene, Craig; Bates, Darreisha

Subject: RE: Article on Trauma Training

Statement from Uniformed Services University of the Health Sciences:

In the summer of 2013, a Uniformed Services University of the Health Sciences (USU) student notified the chain of command about inappropriate training methods that had occurred during an offsite "train-the-trainer" course. The course, offered by a private contractor, was in preparation for a larger, on-campus combat medical skills class. The private contractor, an ex-Army officer, alumnus and former faculty member of USU, also served as the lead instructor for the on-campus course.

Once notified by the student, the emergency medical skills course was immediately terminated and the instructor was escorted off campus and barred from the military base. The entire student class was debriefed and given the opportunity to see a health professional and ongoing support has been provided to the students affected.

The reported transgressions were referred to the Defense Criminal Investigative Service, which continues to review the case. Since the contractor was engaged with other Department of Defense entities, those entities were notified of the reported incident. Following a comprehensive USU internal investigation, the findings were forwarded to the Virginia Medical Board where the contractor was licensed and incidents occurred. His license has been suspended, pending a formal hearing before the Board.

The USU investigation determined that several faculty members did not exercise adequate oversight and accountability for the content and teaching methods used during both the pre-course and full course offered to the entire medical school class. Two of these faculty members have been removed from USU and returned to their respective Services and two retired. Following the 2013 revelation, the involved department, School of Medicine, and University have implemented several additional requirements for oversight of courses specifically addressing student travel, accountability, and content.

(b)(6)

-----Original Message-----

From: James, Jeanette [mailto:Jeanette.James@mail.house.gov]

Sent: Tuesday, June 09, 2015 1:34 PM

(b)(6)

Cc: Greene, Craig; Bates, Darreisha

Subject: Article on Trauma Training

Can you get me the facts on this case? Did military students really go through this guys training, did the services ever receive complaints from the students, was the contract terminated and does DOD or the Services have any dealings currently with this contractor? Thanks.

Ex-Army doctor in Virginia accused of grisly training procedures on students

U.S. Army Medical Corps retired Lt. Colonel John Hagmann, left, is presented the William P. Clements, Jr. Outstanding Uniformed Educator Award by Dr. Sam Nixon during the U.S. Military's Uniformed Services University of the Health Sciences 1989 commencement exercises in 1989. (Handout/Reuters)

By John Shiffman June 9 at 12:01 AM

Since retiring from the U.S. Army in 2000, John Henry Hagmann has helped train thousands of soldiers and medical personnel in how to treat battlefield wounds. His company, Deployment Medicine International, has received more than \$10.5 million in business from the federal government.

The taxpayer-funded training has long troubled activists for animal rights, who contend that Hagmann's use of live, wounded pigs to simulate combat injuries is unnecessarily cruel.

But an investigation by Virginia medical authorities alleges that pigs weren't the doctor's only training subjects.

During instructional sessions in 2012 and 2013 for military personnel, Hagmann gave trainees drugs and liquor and directed them to perform macabre medical procedures on one another, according to a report issued by the Virginia Board of Medicine, the state agency that oversees the conduct of doctors.

Hagmann, 59, is accused of inappropriately providing at least 10 students with the hypnotic drug ketamine. The report alleges Hagmann told students to insert catheters into the genitals of other trainees and that two intoxicated students were subjected to penile nerve block procedures. Hagmann also is accused of conducting "shock labs," a process in which he withdrew blood from the students, monitored them for shock, and then transfused the blood back into their systems.

U.S. Army Medical Corps retired Lt. Colonel John Hagmann is seen in a 1980 handout file photo provided by his former employer, the U.S. Military's Uniformed Services. (U.S. Military's Uniformed Services/Reuters)

The report alleges that Hagmann also "exploited, for personal gain and sexual gratification," two participants who attended a July 2013 course at his Virginia farm.

The allegations against Hagmann have not been previously reported. They are administrative in nature, detailed in a 15-page dossier compiled by two assistant attorneys general for the board. The group temporarily suspended Hagmann's license in March. A hearing is set for June 19 before the full medical board, which could revoke Hagmann's medical license. During the hearing, Hagmann and state lawyers are expected to present their respective cases, which may include testimony from students or other witnesses.

In a statement Hagmann provided on Friday to Reuters, he said: "The mechanisms and protocols utilized in the training all comply with standard practices for training medical students and are, in fact, utilized in medical schools in Virginia."

Hagmann said the "claims of sexual misconduct cause me the most anguish. Absolutely no 'sexual gratification' was involved and there is no evidence of such."

Hagmann said "the courses and procedures in question were all reviewed and approved" by officials at the Uniformed Services University of the Health Sciences, a government-run medical school that trains and prepares health professionals to support the military.

The university disputes that. "The procedures used during the training were not authorized by USU faculty," said Sharon Holland, a spokeswoman for the Uniformed Services University.

Holland said a student there raised concerns about Hagmann's training in July 2013. "The moment the department and USU leadership were informed that these events occurred, the institution immediately suspended the relationship with Hagmann, his course, and his company," Holland said.

"We launched an investigation and those findings prompted a report to the Virginia Medical Board."

Holland said the university also alerted the Defense Criminal Investigative Service, a law enforcement agency that oversees the Department of Defense. A spokesman for the service was not immediately available for comment Monday.

Cynthia Smith, a U.S. Army spokeswoman, said she could not comment on the case because the records were not readily accessible. But, she added, "We certainly don't condone that type of behavior."

"Diabolical mad scientist"

Medical health professionals familiar with trauma training say they were stunned to hear about Hagmann's techniques. Virginia state lawyers, investigating complaints by some students who attended the sessions, wrote in the report to the state's medical board that "these procedures were not undertaken or provided in good faith for medicinal or therapeutic purposes."

One doctor who offers trauma training, Harvard Medical School professor David King, said that "some of what is described in these allegations is wildly unheard of and perhaps unsafe."

Dr. Howard Mell, a spokesman for the American College of Emergency Physicians, said he could not comment on any specific case. But speaking generally about "shock labs," Mell said subjecting students to such problems during training would be absurd.

"I treat people in the ER everyday for things I have never experienced," said Mell, a Cleveland doctor who trains emergency medical workers and police officers. "I certainly don't need to experience shock to know how to treat it. If that logic was true, men couldn't be obstetricians."

Hagmann said that the Virginia board is applying the wrong standard in assessing his conduct: He said that his trainees are "students," not "patients" as the board calls them, and therefore he may have them perform procedures on one another as part of the educational process.

He told Reuters the allegations are amplified by "animal rights advocates or those with an anti-military agenda."

Hagmann has drawn fire from animal rights groups for years because he is a leading practitioner of "live-tissue training," which involves teaching students by using wounded live animals as patients. Often, pigs are the subjects.

Under pressure from animal rights groups, the U.S. military has reduced live-tissue training. But groups including People for the Ethical Treatment of Animals have called for an outright ban, long complaining to the Pentagon about DMI's "senseless shooting and stabbing of live animals," said Justin Goodman, PETA's laboratory investigations director.

"We are absolutely disgusted to learn that the company's cruel, violent and abusive behavior apparently targets service members as well," Goodman said.

Earlier today, PETA sent to U.S. Secretary of Defense Ashton Carter a summary of an undercover video it says it took during a 2013 training session by Hagmann's company. The group also asked the Pentagon to cease contracting with DMI. Goodman said the video depicts gratuitous violence against the wounded pigs, and racist and sexist jokes by course instructors.

PETA posted the video, which includes graphic violence, at <http://youtu.be/qXwN8ItF3fE>

U.S. Rep. Hank Johnson, an Armed Services Committee member who has

introduced legislation to ban live-tissue training, said he was disturbed by the video and charges leveled against Hagmann by the Virginia Board of Medicine.

"It seems like this is a renegade contractor visiting abuse on military personnel and live animals," said Johnson, a Georgia Democrat. "It's mind-boggling. It's like a diabolical mad scientist at work in a horror movie."

Among pioneers in trauma

In the Army, Hagmann practiced emergency medicine for two decades. He rose to the rank of lieutenant colonel and co-authored an influential combat treatment manual.

After retiring, Hagmann founded DMI - also known as Deployment Medicine Consultants. It is based in Gig Harbor, Washington. Following the Sept. 11, 2001 terrorist attacks, demand for his courses grew and DMI emerged as a preeminent trauma-response trainer. The majority of DMI's government contracts are with the U.S. military - in particular, Army and Navy special operation units.

"The mission of DMI is to train you to save lives in the combat environment, no one matches our ability to do this," the company says on its website. "We are the single largest trainer of US military forces in operational medicine throughout world, and our record for excellence stands unchallenged."

To demonstrate the positive impact of his training, Hagmann provided to Reuters testimonial emails from two former students. One, deployed in North Africa, wrote last month: "You forever changed my approach to combat medicine. Please know you have made a tremendous impact in countless lives." Reuters could not immediately reach the former students for comment.

Such testimonials stand in stark contrast with the board of medicine's report.

In one case detailed by investigators, Virginia authorities allege that Hagmann boasted to a student "about his proficiency with rectal exams" and took the student to a warehouse on his property. There, the report claims, the two "continued to consume beer" and Hagmann asked the student "about the effect (the student's) uncircumcised penis had on masturbation and sexual intercourse." The student told investigators "that he was inebriated and felt that he could not refuse Dr. Hagmann's request to examine, manipulate and photograph his penis."

In his statement to Reuters, Hagmann connected his comments on circumcision to his live-tissue trauma training course this way: "The debate on the value and impact of circumcision is a current medical and social issue. The historical link between circumcision and masturbation is a fact dating since Victorian England and is still a current topic subject to scientific research."

The Virginia medical board report also says Hagmann conducted what board investigators described as "ketamine labs," "alcohol labs," and "cognition labs." The labs, officials wrote, "involved the dosing of ketamine and consumption of alcohol, at times in combination or in quick succession, so that he (Hagmann) could assess the effects of these substances on their cognition."

During a July 2013 course in North Carolina, authorities say, participants were provided eight shots of rum in 10 minutes. About an hour later, they were allegedly injected with ketamine. Officials allege that one intoxicated participant received a penile nerve block, a type of anesthesia. When other students stepped in to prevent a second intoxicated student from receiving the procedure, the report says, Hagmann volunteered himself, and students performed a penile nerve block on him.

"I have been working in trauma centers for 30 years and I have never done a penile nerve block," said Dr. Mark Brown, an emergency room physician in Lancaster, California. "And why would you ever mix alcohol and drugs? It's very puzzling."

Hagmann told Reuters the medications were all dispensed properly. He also said that procedures performed by students on other students are acceptable.

"For a future or current medical care provider," Hagmann said, "having practice in a safe, controlled, voluntary setting has a huge value and benefit in improving self confidence and self image."

(b)(6)

Sent: Thursday, June 11, 2015 7:18 PM

(b)(6)

Subject: Re: Congressional Ltr to SecDef

Agree (b)(6) should be able to check with P&R, and we will both look for it to come thru LA for coord. (b)(6)

----- Original Message -----

(b)(6)

Sent: Thursday, June 11, 2015 07:08 PM

(b)(6)

Subject: Re: Congressional Ltr to SecDef

Sir,

Thank you. If there's reference to animals in the response, AT&L should receive coord.

V/r,

(b)(6)

----- Original Message -----

(b)(6)

Sent: Thursday, June 11, 2015 06:57 PM

(b)(6)

Subject: RE: Congressional Ltr to SecDef

It was tasked to P&R.

-----Original Message-----

(b)(6)

Sent: Thursday, June 11, 2015 6:33 PM

(b)(6)

Subject: RE: Congressional Ltr to SecDef

Hi (b)(6) Will inquire and let you know.

Thanks.

(b)(6)

(b)(6)

Sent: Thursday, June 11, 2015 3:02 PM

(b)(6)

Subject: FW: Congressional Ltr to SecDef

H (b)(6)

Attached is a letter from CM Johnson to SecDef concerning allegations against a live tissue training contractor. Could you tell me what component got tasked to prepare response?

Thanks,
Beth

-----Original Message-----

(b)(6)

Sent: Thursday, June 11, 2015 2:34 PM

(b)(6)

Subject: FW: Congressional Ltr to SecDef

H (b)(6)

(b)(6) Hope you've been well. It's been rather quiet for a week or so on the animal front, but that may be changing. I can't reach (b)(6) but thought you may be able to help. Do you know if a response on this letter from Representative Johnson to Secretary Carter will be tasked to Dr. Mason? If so, just wanted to get a jump on it since the clock is quickly ticking away to meet the requested 15 day turn-around. It's a very complicated issue, but there are some components involving animals.

Thank you.

v/r,

(b)(6)

-----Original Message-----

(b)(6)

Sent: Thursday, June 11, 2015 1:46 PM

(b)(6)

Subject: FW: Congressional Ltr to SecDef

Good afternoon

(b)(6)

Do you know if there is an action in the tasking system yet for this letter or which office will be tasked to respond?

Thank you,

(b)(6)

<http://www.acq.osd.mil/rd/hptb/index.html>

-----Original Message-----

From: Mason, Patrick A SES OSD OUSD ATL (US)

Sent: Thursday, June 11, 2015 10:07 AM

(b)(6)

Subject: Fw: Congressional Ltr to SecDef

Patrick Mason, Ph.D., SES

Director, Human Performance, Training, and BioSystems Directorate Office of the Assistant Secretary of Defense for Research and Engineering

4800 Mark Center Drive, Suite 17E08

Alexandria, VA 22350-3600

(571) 372-6435 Office (DSN 372-6435)

Patrick.a.mason2.civ@mail.mil

<http://www.acq.osd.mil/rd/hptb/index.html>

----- Original Message -----

(b)(6)

Sent: Thursday, June 11, 2015 10:03 AM

To: Mason, Patrick A SES OSD OUSD ATL (US); Ormond, Dale A SES OSD OUSD ATL (US)

(b)(6)

Subject: Congressional Ltr to SecDef

Gentlemen,

(b)(6)

Please see the attached document with a note from (b)(6) that reads, "Dale Ormond, Patrick Mason, Visibility"

V/r,

(b)(6)

Year 2014.³ DMI had its eligibility to receive federal contracts renewed on May 26, 2015, according to the federal System for Award Management.

Since learning of these abuses, I have also been informed that evidence exists of additional abuses by DMI and Dr. Hagmann during DOD contract work. The evidence in that case reveals DMI instructors and servicemembers inflicting unnecessary pain to animals and reveals a culture of racism, sexual harassment, homophobia, and a celebration of cruelty to animals.

The Culture Surrounding Sexual Assaults

I appreciated your April 22, 2015 remarks to Georgetown University students:

"One key to prevention is to understand that sexual assaults often occur in environments where crude and offensive behavior, unwanted sexual attention, coercion, and sexual harassment are tolerated, ignored, or condoned."⁴

I agree fully with your statement, which is why I feel compelled to bring to your attention the allegations of abuse during live tissue trainings appear to be precisely the type of unsafe subculture that DOD wants to eliminate. It's critical to note that this problem is not limited to Dr. Hagmann or to DMI. In 2012, the Department of Defense allowed inappropriate behavior and abuses to take place in controversial live tissue training exercises taught by a separate contractor.⁵

Safer, More Effective Alternatives Not Used

It is also critical to note that live-tissue trainings are not necessary. As you may know, military researchers⁶ and Pentagon officials⁷ have endorsed non-animal medical training alternatives that make live tissue training unnecessary to adequately train military medics. This is precisely why I have introduced the BEST Practices Act.⁸

Sophisticated simulation alternatives allows us to advance beyond controversial live tissue trainings. Phasing out these trainings would eliminate a controversial area of the DOD that is not medically necessary and in which a culture of abuse has now escalated to sexual violence against servicemembers.

Questions

In light of the foregoing concerns, I have several questions that I request that you answer within fifteen (15) days below:

1. When and how did the Department of Defense first become aware of the allegations described in this letter?

³

<https://www.usaspending.gov/Pages/AdvancedSearch.aspx?sub=y&ST=C&FY=2015,2014&A=0&SS=USA&k=deployment%20medicine%20consultants>

⁴ <http://www.defense.gov/Speeches/Speech.aspx?SpeechID=1923>

⁵ <http://www.cnn.com/2013/05/03/us/coast-guard-animals/>

⁶ <http://www.ncbi.nlm.nih.gov/pubmed/25975338>

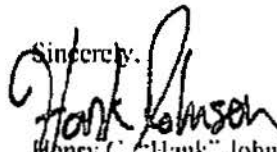
⁷ <http://www.military.com/daily-news/2013/04/02/activists-army-to-limit-live-animal-training.html>

⁸ HR 1095

2. When and how did the Department of Defense first become aware of the facts found by the State of Virginia in its March 12th 2015 order to suspend Dr. Hagmann's medical license?
3. If the Department was aware of these allegations, and the action by the State of Virginia, prior to this letter, what action was taken by the Department in response?
4. Please explain what policies and procedures are in place to facilitate the sharing of allegations of abuse by Department contractors with the Department? If the Department was unaware of these allegations, and the action by the State of Virginia, prior to this letter, please explain how those systems failed to ensure that these allegations were reported? What specific reforms will the Department make to improve its policies and procedures?
5. Please provide specific details on all Department of Defense contracts awarded to companies associated with Dr. Hagmann, including but not limited to, Deployment Medicine International (DMI) and Deployment Medicine Consultants (DMC) since Fiscal Year 2005.
6. How will the Department hold Dr. Hagmann and DMI accountable for their alleged abuses of servicemembers, animals, taxpayer dollars, and the public trust? What process exists, if any, to reclaim taxpayer funds paid to a DOD contractor, such as DMI, that is found to have committed abuses?
7. What reforms were instituted in 2012 following the revelations of misbehavior and animal abuse in a Coast Guard live tissue course, and why did these reforms not adequately address the problem?
8. Since we do not know the total number of service members that were allegedly sexually assaulted and otherwise abused in settings like this in recent years—particularly because of the stigma and risks associated with coming forward—I hope your office will immediately begin a comprehensive investigation into all contractors offering live tissue training to the DOD. That investigation should address questions such as:
 - a. When were the first complaints registered by abused servicemembers against the contractor?
 - b. Was there a senior military official observing these trainings? If not, why not? If so, did that individual raise concerns within the chain of command at how servicemembers were being treated?
 - c. Were any contracts or task orders awarded to DMI or others after any abuse allegations were made?
 - d. Were contracts to DMI sole-source or were they competitively awarded?
 - e. How many servicemembers were exposed to these abuses from DMI since 2012, which is when DOD first issued assurances that these types of trainings were going to be cleaned up?

- f. What is the full dollar amount (in FY15 dollars) any entities owned in whole or part, or managed in whole or part, by Dr. Hagmann have received in the last 10 years, and what percentage of the related contracts were competitively awarded?

I know you are as horrified as I am by what has been revealed here. I look forward to working with you to put an end to these abuses. I look forward to receiving your responses to these questions within fifteen (15) days.

Sincerely,

Henry C. "Hank" Johnson
Member of Congress

CC:

The Hon. Jon T. Rymer, Department of Defense Inspector General
Uniformed Services University
MG Jeffrey J. Snow, DoD Sexual Assault Prevention and Response Office

(b)(6)

Subject:
Signed By:

RE: Article on Trauma Training

(b)(6)

Can you make sure it goes to HASC and SASC please?

Thanks!

(b)(6)

-----Original Message-----

(b)(6)

Subject: RE: Article on Trauma Training

USUHS Statement below...approved by Dr. Woodson to send out.

Statement from Uniformed Services University of the Health Sciences
In the summer of 2013, a Uniformed Services University of the Health Sciences (USU) student notified the chain of command about inappropriate training methods that had occurred during an offsite "train-the-trainer" course. The course, offered by a private contractor, was in preparation for a larger, on-campus combat medical skills class. The private contractor, an ex-Army officer, alumnus and former faculty member of USU, also served as the lead instructor for the on-campus course.

Repeat

Once notified by the student, the emergency medical skills course was immediately terminated and the instructor was escorted off campus and barred from the military base. The entire student class was debriefed and given the opportunity to see a health professional and ongoing support has been provided to the students affected.

The reported transgressions were referred to the Defense Criminal Investigative Service, which continues to review the case. Since the contractor was engaged with other Department of Defense entities, those

entities were notified of the reported incident. Following a comprehensive USU internal investigation, the findings were forwarded to the Virginia Medical Board where the contractor was licensed and incidents occurred. His license has been suspended, pending a formal hearing before the Board.

The USU investigation determined that several faculty members did not exercise adequate oversight and accountability for the content and teaching methods used during both the pre-course and full course offered to the entire medical school class. Two of these faculty members have been removed from USU and returned to their respective Services and two retired. Following the 2013 revelation, the involved department, School of Medicine, and University have implemented several additional requirements for oversight of courses specifically addressing student travel, accountability, and content.

(b)(6)



-----Original Message-----

(b)(6)



Sent: Tuesday, June 09, 2015 3:16 PM

To: DHA NCR Prog Integ List PI List

Subject: FW: Article on Trauma Training

See below.

(b)(6)



-----Original Message-----

From: James, Jeanette [mailto:Jeanette.James@mail.house.gov]

Sent: Tuesday, June 09, 2015 1:34 PM

(b)(6)



Cc: Greene, Craig; Bates, Darreisha

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U.S. Army Medical Corps retired Lt. Colonel John Hagmann, left, is presented the William P. Clements, Jr. Outstanding Uniformed Educator Award by Dr. Sam Nixon during the U.S. Military's Uniformed Services University of the Health Sciences 1989 commencement exercises in 1989. (Handout/Reuters)

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The taxpayer-funded training has long troubled activists for animal rights, who contend that Hagmann's use of live, wounded pigs to simulate combat injuries is unnecessarily cruel.

But an investigation by Virginia medical authorities alleges that pigs weren't the doctor's only training subjects.

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Hagmann, 59, is accused of inappropriately providing at least 10 students with the hypnotic drug ketamine. The report alleges Hagmann told students to insert catheters into the genitals of other trainees and that two intoxicated students were subjected to penile nerve block procedures. Hagmann also is accused of conducting "shock labs," a process in which he withdrew blood from the students, monitored them for shock, and then transfused the blood back into their systems.

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Repeat

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The university disputes that. "The procedures used during the training were not authorized by USU faculty," said Sharon Holland, a spokeswoman for the Uniformed Services University.

Holland said a student there raised concerns about Hagmann's training in July 2013. "The moment the department and USU leadership were informed that these events occurred, the institution immediately suspended the relationship with Hagmann, his course, and his company," Holland said.

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Repeat

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Such testimonials stand in stark contrast with the board of medicine's report.

In one case detailed by investigators, Virginia authorities allege that Hagmann boasted to a student "about his proficiency with rectal exams" and took the student to a warehouse on his property. There, the report claims, the two "continued to consume beer" and Hagmann asked the student "about the effect (the student's) uncircumcised penis had on masturbation and sexual intercourse." The student told investigators "that he was inebriated and felt that he could not refuse Dr. Hagmann's request to examine, manipulate and photograph his penis."

In his statement to Reuters, Hagmann connected his comments on circumcision to his live-tissue trauma training course this way: "The debate on the value and impact of circumcision is a current medical and social issue. The historical link between circumcision and masturbation is a fact dating since Victorian England and is still a current topic subject to scientific research."

The Virginia medical board report also says Hagmann conducted what board investigators described as "ketamine labs," "alcohol labs," and "cognition labs." The labs, officials wrote, "involved the dosing of ketamine and consumption of alcohol, at times in combination or in quick succession, so that he (Hagmann) could assess the effects of these substances on their cognition."

During a July 2013 course in North Carolina, authorities say, participants were provided eight shots of rum in 10 minutes. About an hour later, they were allegedly injected with ketamine. Officials allege that one intoxicated participant received a penile nerve block, a type of anesthesia. When other

students stepped in to prevent a second intoxicated student from receiving the procedure, the report says, Hagmann volunteered himself, and students performed a penile nerve block on him.

"I have been working in trauma centers for 30 years and I have never done a penile nerve block," said Dr. Mark Brown, an emergency room physician in Lancaster, California. "And why would you ever mix alcohol and drugs? It's very puzzling."

Repeat

Hagmann told Reuters the medications were all dispensed properly. He also said that procedures performed by students on other students are acceptable.

"For a future or current medical care provider," Hagmann said, "having practice in a safe, controlled, voluntary setting has a huge value and benefit in improving self confidence and self image."

(b)(6)

Sent: Monday, June 08, 2015 8:51 AM

To: (b)(6)

Cc:

Subject: RE: Informal View: Wyden 1463

Signed By: (b)(6)

FYSA

-----Original Message-----

From: Hedger, Stephen C SES OSD OASD LA (US)

Sent: Sunday, June 07, 2015 7:16 AM

To: Allen_Edwards@armed-services.senate.gov; Gary_Leeling@armed-services.senate.gov

Cc: Stella, Michael J SES OSD OASD LA (US)

Subject: Informal View: Wyden 1463

Gentlemen,

Please find below informal views on Wyden amendment #1463 to require the Secretary of Defense to use only human-based methods of training members of the Armed Forces in the treatment of combat injuries.

The Department of Defense (DoD) objects to the proposed language. Without scientific-based evidence demonstrating the efficacy of training simulators, removing the animal model from the training of DoD medical personnel could degrade combat trauma care on the battlefield. Imposing a deadline to end the use of animals will not advance the knowledge or the material solutions to transition to human-based training techniques any faster than the Department's current research and development efforts and could result in decreasing combat survival rates.

The DoD is committed to replacing animal-based training techniques without adversely affecting the quality of care for injured Service members and, as noted in the language, has made strides in doing so. The DoD's internal working groups, partnerships with industry and academia, and interactions with international allies continuously improves our knowledge and development of training systems appropriate to the DoD's operational environment.

The primary impact of the proposed language would be on combat medic training. The medic is the first responder who provides treatment at the point of wounding. Combat trauma training in the DoD has unique characteristics compared to the training of civilian medical providers. New DoD medics are generally less than 20 years of age and within a short time period must learn and perform complex combat trauma care procedures in chaotic and hostile battlefield environments in which they will not have access to well-equipped surgical suites and highly-trained healthcare professionals.

Simulation technology is currently not feasible, nor has it been validated, for the training of some combat trauma procedures. Limitations of simulation systems include changes in tissue dynamics over time following the onset of injury (e.g., amputation management) and the ability to invoke the response to save the life of an injured patient. Simulation systems are also limited in that they model a known set of injuries. However, injury patterns and the corresponding training vary with the operational environment and anticipated evacuation times. The DoD must maintain the capability of training medical personnel to respond to those threats faced by our Service members.

Although survival in combat is multi-factorial, the experience and confidence gained by the use of the animal model in teaching life-saving procedures has contributed to increased battlefield survival rates. The DoD remains on the path towards replacement of animal models without compromising the quality of medical training.

(b)(6)

Cc: DHA NCR Prog Integ List PI List
Subject: Fw: HASC Testimony
Attachments: 15 06 11, MCRMC HASC Hearing, Dr Woodson, v5.docx

(b)(6)

Cc: DHA NCR Prog Integ List PI List
Subject: HASC Testimony

Good Afternoon

(b)(6)

Please begin clearance of the attached Testimony.

Thank you!

(b)(6)

(b)(6)

Sent: Thursday, June 04, 2015 12:13 PM
To: Hedger, Stephen C SES OSD OASD LA (US)
Cc: Stella, Michael J SES OSD OASD LA (US) (b)(6)
 Gilliland, John E SES OSD OASD LA (US) (b)(6)
 (b)(6)
Subject: INFORMAL VIEW: Amendment to S. 1376 - REQUIREMENT TO USE HUMAN-BASED METHODS (SASC request)
Attachments: Wyden Amdt - 1463.pdf
Signed By: (b)(6)

Mr. Hedger:

SASC staff requested an informal DoD view on the attached proposed amendment from Sen. Wyden, to require the Secretary of Defense to use only human-based methods of training members of the Armed Forces in the treatment of combat injuries.

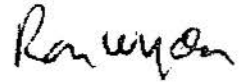
The view proposed below was provided by AT&L/R&E in coordination with P&R/DHA, and it is consistent with previous views provided on very similar/the same proposed language.

SASC points of contact:

Allen_Edwards@armed-services.senate.gov
 Gary_Leeling@armed-services.senate.gov

(b)(5)





ARM15D31

S.L.C.

AMENDMENT NO. _____ Calendar No. _____

Purpose: To require the Secretary of Defense to use only human-based methods for training members of the Armed Forces in the treatment of severe combat injuries.

IN THE SENATE OF THE UNITED STATES—114th Cong., 1st Sess.

H. R. 1735

To authorize appropriations for fiscal year 2016 for military and other purposes, for military and other purposes of the Department of Defense, and for other purposes.

AMENDMENT N° 1531By WydenTo: Amend No 1463 _____ and _____

7
Page(s)

inted

OFFICE 2014 01-623 (00000) WYDEN

Viz:

1 At the end of part II of subtitle D of title V, add
2 the following:

3 **SEC. 540. REQUIREMENT TO USE HUMAN-BASED METHODS**
4 **FOR CERTAIN MEDICAL TRAINING.**

5 (a) FINDINGS.—Congress makes the following find-
6 ings:

7 (1) The Department of Defense has made im-
8 pressive strides in the development and use of meth-
9 ods of medical training and troop protection, such as

1 the use of tourniquets and improvements in body
2 armor, that have led to decreased battlefield fatali-
3 ties.

4 (2) The Department of Defense uses more than
5 8,500 live animals each year to train physicians,
6 medics, corpsmen, and other personnel methods of
7 responding to severe battlefield injuries.

8 (3) The civilian sector has almost exclusively
9 phased in the use of superior human-based training
10 methods for numerous medical procedures currently
11 taught in military courses using animals.

12 (4) Human-based medical training methods
13 such as simulators replicate human anatomy and
14 can allow for repetitive practice and data collection.

15 (5) According to scientific, peer-reviewed lit-
16 erature, medical simulation increases patient safety
17 and decreases errors by healthcare providers.

18 (6) The Army Research, Development and En-
19 gineering Command and other entities of the De-
20 partment of Defense have taken significant steps to
21 develop methods to replace live animal-based train-
22 ing.

23 (7) According to the report by the Department
24 of Defense titled "Final Report on the use of Live

1 Animals in Medical Education and Training Joint
2 Analysis Team", published on July 12, 2009—

3 (A) validated, high-fidelity simulators were
4 to have been available for nearly every high-vol-
5 ume or high-value battlefield medical procedure
6 by the end of 2011, and many were available as
7 of 2009; and

8 (B) validated, high-fidelity simulators were
9 to have been available to teach all other proce-
10 dures to respond to common battlefield injuries
11 by 2014.

12 (8) The Center for Sustainment of Trauma and
13 Readiness Skills of the Air Force exclusively uses
14 human-based training methods in its courses and
15 does not use animals.

16 (9) In 2013, the Army instituted a policy for-
17 bidding non-medical personnel from participating in
18 training courses involving the use of animals.

19 (10) In 2013, the medical school of the Depart-
20 ment of Defense, part of the Uniformed Services
21 University of the Health Sciences, replaced animal
22 use within its medical student curriculum.

23 (11) The Coast Guard announced in 2014 that
24 it would reduce by half the number of animals it
25 uses for combat trauma training courses but stated

1 that animals would continue to be used in courses
2 designed for Department of Defense personnel.

3 (12) Effective January 1, 2015, the Depart-
4 ment of Defense replaced animal use in six areas of
5 medical training, including Advanced Trauma Life
6 Support courses and the development and mainte-
7 nance of surgical and critical care skills for field
8 operational surgery and field assessment and skills
9 tests for international students offered at the De-
10 fense Institute of Medical Operations.

11 (b) REQUIREMENT TO USE HUMAN-BASED METHODS
12 FOR CERTAIN MEDICAL TRAINING.—

13 (1) IN GENERAL.—Chapter 101 of title 10,
14 United States Code, is amended by adding at the
15 end the following new section:

16 **“§ 2017. Use of human-based methods for certain**
17 **medical training**

18 “(a) COMBAT TRAUMA INJURIES.—(1) Not later
19 than October 1, 2018, the Secretary of Defense shall de-
20 velop, test, and validate human-based training methods for
21 the purpose of training members of the armed forces in
22 the treatment of combat trauma injuries with the goal of
23 replacing live animal-based training methods.

24 “(2) Not later than October 1, 2020, the Secretary—

1 “(A) shall only use human-based training meth-
2 ods for the purpose of training members of the
3 armed forces in the treatment of combat trauma in-
4 juries; and

5 “(B) may not use animals for such purpose.

6 “(b) EXCEPTION FOR PARTICULAR COMMANDS AND
7 TRAINING METHODS.—(1) The Secretary may exempt a
8 particular command, particular training method, or both,
9 from the requirement for human-based training methods
10 under subsection (a)(2) if the Secretary determines that
11 human-based training methods will not provide an educa-
12 tionally equivalent or superior substitute for live animal-
13 based training methods for such command or training
14 method, as the case may be.

15 “(2) Any exemption under this subsection shall be for
16 such period, not more than one year, as the Secretary shall
17 specify in granting the exemption. Any exemption may be
18 renewed (subject to the preceding sentence).

19 “(c) ANNUAL REPORTS.—(1) Not later than October
20 1, 2016, and each year thereafter, the Secretary shall sub-
21 mit to the congressional defense committees a report on
22 the development and implementation of human-based
23 training methods for the purpose of training members of
24 the armed forces in the treatment of combat trauma inju-
25 ries under this section.

1 “(2) Each report under this subsection on or after
2 October 1, 2020, shall include a description of any exemp-
3 tion under subsection (b) that is in force as the time of
4 such report, and a current justification for such exemp-
5 tion.

6 “(d) DEFINITIONS.—In this section:

7 “(1) The term ‘combat trauma injuries’ means
8 severe injuries likely to occur during combat, includ-
9 ing—

10 “(A) hemorrhage;

11 “(B) tension pneumothorax;

12 “(C) amputation resulting from blast in-
13 jury;

14 “(D) compromises to the airway; and

15 “(E) other injuries.

16 “(2) The term ‘human-based training methods’
17 means, with respect to training individuals in med-
18 ical treatment, the use of systems and devices that
19 do not use animals, including—

20 “(A) simulators;

21 “(B) partial task trainers;

22 “(C) moulage;

23 “(D) simulated combat environments;

24 “(E) human cadavers; and

1 “(F) rotations in civilian and military trauma
2 centers.

3 “(3) The term ‘partial task trainers’ means
4 training aids that allow individuals to learn or practice
5 specific medical procedures.”.

6 (2) CLERICAL AMENDMENT.—The table of sections
7 at the beginning of chapter 101 of such title
8 is amended by adding at the end the following new
9 item:

“2017. Use of human-based methods for certain medical training.”.

(b)(6)

Sent:
To:
Cc:

Wednesday, June 03, 2015 10:16 PM

(b)(6)

Subject:

(US); Mason, Patrick A SES OSD OUSD ATL (US)
 Re: Need Views

Thanks (b)(6) Think I got it. Will send it up in the morning if no questions. Many thanks for the quick turn!

Vr,

(b)(6)

----- Original Message -----

(b)(6)

(b)(6)

Mason, Patrick A SES OSD OUSD ATL (US)

Subject: RE: Need Views

Sir,

This Wyden language is the same as that introduced in the BEST Practices Act (S.587) that we provided an informal view on a few months back. Attached is the document that I have recorded as the final version on those informal views and the views remain current. Please note that I referred to the language in the informal views as S.1376 based on the word document that we received (attached here, too), but the document itself is HR 1735.

v/r,

(b)(6)

<http://www.acq.osd.mil/rd/hptb/index.html>

-----Original Message-----

(b)(6)

Subject: FW: Need Views

(b)(6)

(b)(6)

Can you prepare an informal view, please?

(b)(6)

-----Original Message-----

(b)(6)

Subject: FW: Need Views

(b)(6)

All,

Below/attached request for informal views from SASC milpers subcommittee on Sen Wyden's live tissue language. Seems like we may have done views in the past on this provision. We can probably dust off but will need a quick look to make sure no changes.

v/r

(b)(6)

-----Original Message-----

(b)(6)

(b)(6) DHA NCR Prog Integ List PI List; (b)(6)

(b)(6)

Subject: RE: Need Views

(b)(6)

per HA, the attached falls to AT&L, they handle animal us in training issues.

-----Original Message-----

(b)(6)

(b)(6) DHA NCR Prog Integ List PI List (b)(6)

(b)(6)

Subject: FW: Need Views

(b)(6)

Requests for informal views on 4 provisions.

1560 - may need AT&L coordination.

(b)(6)

-----Original Message-----

From: Edwards, Allen (Armed Services) [mailto:Allen_Edwards@armed-services.senate.gov]

Sent: Wednesday, June 03, 2015 4:59 PM

(b)(6)

Cc: Edwards, Allen (Armed Services); Leeling, Gary (Armed Services)

Subject: Need Views

Please provide informal views ASAP. Thank you.

AI

Dr. Allen (AI) Edwards

Lead Professional Staff Member

Personnel Subcommittee

U.S. Senate Committee on Armed Services

228 Russell Senate Office Building

Washington, DC 20510-6500

202.224.7151

The Department of Defense (DoD) objects to the proposed language. Without scientific-based evidence demonstrating the efficacy of training simulators, removing the animal model from the training of DoD medical personnel could degrade combat trauma care on the battlefield. Imposing a deadline of October 1, 2020, to end the use of animals will not advance the knowledge or the material solutions to transition to human-based training techniques any faster than the Department's current research and development efforts and could result in decreasing combat survival rates.

The DoD is committed to replacing animal-based training techniques without adversely affecting the quality of care for injured Service members and, as noted in the language of S.1376, has made strides in doing so. The DoD's internal working groups, partnerships with industry and academia, and interactions with international allies continuously improves our knowledge and development of training systems appropriate to the DoD's operational environment.

The primary impact of S.1376 would be on combat medic training. The medic is the first responder who provides treatment at the point of wounding. Combat trauma training in the DoD has unique characteristics compared to the training of civilian medical providers. New DoD medics are generally less than 20 years of age and within a short time period must learn and perform complex combat trauma care procedures in chaotic and hostile battlefield environments in which they will not have access to well-equipped surgical suites and highly-trained healthcare professionals.

Simulation technology is currently not feasible, nor has it been validated, for the training of some combat trauma procedures. Limitations of simulation systems include changes in tissue dynamics over time following the onset of injury (e.g., amputation management) and the ability to invoke the response to save the life of an injured patient. Simulation systems are also limited in that they model a known set of injuries. However, injury patterns and the corresponding training vary with the operational environment and anticipated evacuation times. The DoD must maintain the capability of training medical personnel to respond to those threats faced by our Service members.

Although survival in combat is multi-factorial, the experience and confidence gained by the use of the animal model in teaching life-saving procedures has contributed to increased battlefield survival rates. The DoD remains on the path towards replacement of animal models without compromising the quality of medical training.

Informal views on Amendment to S. 1376 (HEY15678): To require the Secretary of Defense to use only human-based methods of training members of the Armed Forces in the treatment of combat injuries



1531 - Wyden.pdf

Reviewed by: OASD (HA)

DoD Position:

Draft Informal Views:

Approved by:

ARM15D31

*Repeat**Ranney*

S.L.C.

AMENDMENT NO. _____ Calendar No. _____

Purpose: To require the Secretary of Defense to use only human-based methods for training members of the Armed Forces in the treatment of severe combat injuries.

IN THE SENATE OF THE UNITED STATES—114th Cong., 1st Sess.

H. R. 1735

To authorize appropriations for fiscal year 2016 for military

AMENDMENT N^o 1531for military
of the Depart-
ment personnel
for purposes.By *Wyden*To: *Amor No 1463*

_____ and

7

inted

Page(s)

GPO: 2014 01-0257 (HRC)

. WYDEN

Viz:

1 At the end of part II of subtitle D of title V, add
2 the following:

3 **SEC. 540. REQUIREMENT TO USE HUMAN-BASED METHODS**
4 **FOR CERTAIN MEDICAL TRAINING.**

5 (a) FINDINGS.—Congress makes the following find-
6 ings:

7 (1) The Department of Defense has made im-
8 pressive strides in the development and use of meth-
9 ods of medical training and troop protection, such as

1 the use of tourniquets and improvements in body
2 armor, that have led to decreased battlefield fatali-
3 ties.

4 (2) The Department of Defense uses more than
5 8,500 live animals each year to train physicians,
6 medics, corpsmen, and other personnel methods of
7 responding to severe battlefield injuries.

8 (3) The civilian sector has almost exclusively
9 phased in the use of superior human-based training
10 methods for numerous medical procedures currently
11 taught in military courses using animals.

12 (4) Human-based medical training methods
13 such as simulators replicate human anatomy and
14 can allow for repetitive practice and data collection.

15 (5) According to scientific, peer-reviewed lit-
16 erature, medical simulation increases patient safety
17 and decreases errors by healthcare providers.

18 (6) The Army Research, Development and En-
19 gineering Command and other entities of the De-
20 partment of Defense have taken significant steps to
21 develop methods to replace live animal-based train-
22 ing.

23 (7) According to the report by the Department
24 of Defense titled "Final Report on the use of Live

1 Animals in Medical Education and Training Joint
2 Analysis Team”, published on July 12, 2009—

3 (A) validated, high-fidelity simulators were
4 to have been available for nearly every high-vol-
5 ume or high-value battlefield medical procedure
6 by the end of 2011, and many were available as
7 of 2009; and

8 (B) validated, high-fidelity simulators were
9 to have been available to teach all other proce-
10 dures to respond to common battlefield injuries
11 by 2014.

12 (8) The Center for Sustainment of Trauma and
13 Readiness Skills of the Air Force exclusively uses
14 human-based training methods in its courses and
15 does not use animals.

16 (9) In 2013, the Army instituted a policy for-
17 bidding non-medical personnel from participating in
18 training courses involving the use of animals.

19 (10) In 2013, the medical school of the Depart-
20 ment of Defense, part of the Uniformed Services
21 University of the Health Sciences, replaced animal
22 use within its medical student curriculum.

23 (11) The Coast Guard announced in 2014 that
24 it would reduce by half the number of animals it
25 uses for combat trauma training courses but stated

1 that animals would continue to be used in courses
2 designed for Department of Defense personnel.

3 (12) Effective January 1, 2015, the Depart-
4 ment of Defense replaced animal use in six areas of
5 medical training, including Advanced Trauma Life
6 Support courses and the development and mainte-
7 nance of surgical and critical care skills for field
8 operational surgery and field assessment and skills
9 tests for international students offered at the De-
10 fense Institute of Medical Operations.

11 (b) REQUIREMENT TO USE HUMAN-BASED METHODS
12 FOR CERTAIN MEDICAL TRAINING.—

13 (1) IN GENERAL.—Chapter 101 of title 10,
14 United States Code, is amended by adding at the
15 end the following new section:

16 **“§ 2017. Use of human-based methods for certain**
17 **medical training**

18 “(a) COMBAT TRAUMA INJURIES.—(1) Not later
19 than October 1, 2018, the Secretary of Defense shall de-
20 velop, test, and validate human-based training methods for
21 the purpose of training members of the armed forces in
22 the treatment of combat trauma injuries with the goal of
23 replacing live animal-based training methods.

24 “(2) Not later than October 1, 2020, the Secretary—

1 “(A) shall only use human-based training meth-
2 ods for the purpose of training members of the
3 armed forces in the treatment of combat trauma in-
4 juries; and

5 “(B) may not use animals for such purpose.

6 “(b) EXCEPTION FOR PARTICULAR COMMANDS AND
7 TRAINING METHODS.—(1) The Secretary may exempt a
8 particular command, particular training method, or both,
9 from the requirement for human-based training methods
10 under subsection (a)(2) if the Secretary determines that
11 human-based training methods will not provide an educa-
12 tionally equivalent or superior substitute for live animal-
13 based training methods for such command or training
14 method, as the case may be.

15 “(2) Any exemption under this subsection shall be for
16 such period, not more than one year, as the Secretary shall
17 specify in granting the exemption. Any exemption may be
18 renewed (subject to the preceding sentence).

19 “(c) ANNUAL REPORTS.—(1) Not later than October
20 1, 2016, and each year thereafter, the Secretary shall sub-
21 mit to the congressional defense committees a report on
22 the development and implementation of human-based
23 training methods for the purpose of training members of
24 the armed forces in the treatment of combat trauma inju-
25 ries under this section.

1 “(2) Each report under this subsection on or after
2 October 1, 2020, shall include a description of any exemp-
3 tion under subsection (b) that is in force as the time of
4 such report, and a current justification for such exemp-
5 tion.

6 “(d) DEFINITIONS.—In this section:

7 “(1) The term ‘combat trauma injuries’ means
8 severe injuries likely to occur during combat, includ-
9 ing—

10 “(A) hemorrhage;

11 “(B) tension pneumothorax;

12 “(C) amputation resulting from blast in-
13 jury;

14 “(D) compromises to the airway; and

15 “(E) other injuries.

16 “(2) The term ‘human-based training methods’
17 means, with respect to training individuals in med-
18 ical treatment, the use of systems and devices that
19 do not use animals, including—

20 “(A) simulators;

21 “(B) partial task trainers;

22 “(C) moulage;

23 “(D) simulated combat environments;

24 “(E) human cadavers; and

1 “(F) rotations in civilian and military trauma centers.
2 ma centers.

3 “(3) The term ‘partial task trainers’ means
4 training aids that allow individuals to learn or practice specific medical procedures.”.

6 (2) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 101 of such title
7 is amended by adding at the end the following new
8 item:
9 item:

“2017. Use of human-based methods for certain medical training.”.

(b)(6)

Subject: RE: Liaison for Defense Health - use of animals for combat trauma training
Attachments: Torreon_CRSrequest_LTT_May2015_toFrontOffice.doc

Good Morning,

Attached is the proposed response to [Ms. Torreon] ^{(b)(6)} please do let us know if this is acceptable to Mr. Ormond.

v/r,

(b)(6)

<http://www.acq.osd.mil/rd/hptb/index.html>

-----Original Message-----

(b)(6)

Subject: Re: Liaison for Defense Health - use of animals for combat trauma training

Thanks ^{(b)(6)} Think you can consider this the CRS request. Would you be able to have responses ready for R&E approval by mid next week? Or if more time is needed, please let us know. Thanks again.

Vr

(b)(6)

(b)(6)

(b)(6)

(b)(6)

Subject: Re: Liaison for Defense Health - use of animals for combat trauma training

Good Morning,

AT&L takes the lead in responding re animal use. I'll need to cross over to HA as they've done data calls and can help provide some of the requested information.

When do we need to provide and does this come as a more formal tasker or is this the tasker?

V/r,

(b)(6)

(b)(6)

Subject: Fw: Liaison for Defense Health - use of animals for combat trauma training

All,

See below questions from CRS. Let me know who will need to respond. Thanks

(b)(6)

Subject: Re: Liaison for Defense Health - use of animals for combat trauma training

(b)(6)

(b)(6)
handles the HA portfolio.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Torreon, Barbara

Sent: Tuesday, May 26, 2015 4:28 PM

(b)(6)

(b)(6)

Subject: Liaison for Defense Health - use of animals for combat trauma training

(b)(6)

Hello

I hope you had a nice Memorial Day weekend. I received some follow-up questions (below) to a request on the use of animals for combat trauma training in the military. Can you email me the liaison officer who handles these types of defense health questions? This is in response to the May 2014 memo by the Assistant Secretary of Defense for Health Affairs, Dr. Jonathan Woodson, that the Pentagon will scale back its use of live animals in medical training starting Jan. 1, 2015.

- * How many animals were used by DOD for live tissue training for each year 2010-2014?
- * Provide a breakdown of animal use for training by branch of the armed forces, facility and training purpose in 2014.
- * How much does it cost per student for combat trauma training using live animals?
- * How much does it cost per student for combat trauma training using simulators?
- * How much taxpayer money was spent by DOD on live tissue training for combat trauma training in 2014? 2013? 2012? 2011? 2010?
- * Following the full implementation of the May 2014 memorandum "Determination for the use of Animals in Medical Education and Training" issued by Dr. Jonathan Woodson that went into effect January 1, 2015, how many animals are expected to be spared from use each year?
- * Have any waivers been issued to allow animal use to continue in areas identified as being unnecessary in the aforementioned memorandum? If so, how many waivers and for what specific purposes?
- * Are there additional training areas beyond the ones identified in the aforementioned memorandum in which animal use has been reduced or ended by the DOD? If so, what are they?

(b)(6)
Thanks in advance for your assistance. Barbara

Barbara Salazar Torreon

Analyst in Defense Budget and Military Manpower

Foreign Affairs, Defense and Trade Division

Congressional Research Service

Library of Congress Washington, DC 20540

Tel: 202-707-8996

btorreon@crs.loc.gov

(b)(6)

DISCLAIMER: The foregoing has not been cleared by CRS review and is not for attribution. This response is provided to help in time limited situations.

DISCLAIMER: This information is intended only for the congressional addressee or other individual to whom it is addressed and may contain confidential and/or privileged material. Any review, retransmission, dissemination or other use of this information is only at the discretion of the intended recipient. If you received this in error, please contact the sender and delete the material from any computer. If this message includes any unexpected attachment(s), please contact the sender immediately and delete the attachment(s) from any computer.

Response to 26 May 2015 email from Ms. Barbara Salazar Torreon, Analyst in Defense Budget and Military Manpower, Foreign Affairs, Defense and Trade Division, Congressional Research Service

1. How many animals were used by DOD for live tissue training for each year 2010-2014?

The annual number of animals fluctuates with the number of deployments, the frequency and number of deploying medical personnel, and medical skill sustainment requirements. DoD averages approximately 6,000 animals annually for combat trauma training.

2. Provide a breakdown of animal use for training by branch of the armed forces, facility, and training purpose in 2014.

The training purpose is to provide the best trained medical personnel for military operations. These locations are often isolated from medical treatment facilities and may require long evacuation times. The Department's medical personnel are trained to perform lifesaving procedures and to stabilize the patient for follow on treatment. Today's forces operate in a joint environment. Medical personnel may attend joint trauma training regardless of the training sponsor(s) or Service affiliation.

3. How much does it cost per student for combat trauma training using live animals?

4. How much does it cost per student for combat trauma training using simulators?

Combined response to questions 3 and 4:

The Department does not routinely collect this information. The use of live animals in combat trauma training occurs in conjunction with the use of alternatives such as commercial training simulations, manikins, moulaged actors, and cadavers. In July 2014, the Department was asked by Congressional staff to provide Fiscal Year 2013 expenditures for Research, Development, Test, and Evaluation (RDT&E), procurement, and Operation and Maintenance (O&M) for simulation for combat casualty care training. In Fiscal Year 2013, the approximate overall expenditure for RDT&E, procurement, and O&M for simulation for combat casualty care training was \$35 million.

5. How much taxpayer money was spent by DOD on live tissue training for combat trauma training in 2014? 2013? 2012? 2011? 2010?

The DoD does not routinely collect this information".

6. Following the full implementation of the May 2014 memorandum "Determination for the use of Animals in Medical Education and Training" issued by Dr. Jonathan Woodson that went into effect January 1, 2015, how many animals are expected to be spared from use each year?

An annual average of 400 animals.

7. Have any waivers been issued to allow animal use to continue in areas identified as being unnecessary in the aforementioned memorandum? If so, how many waivers and for what specific purposes?

The Air Force requested an exception for the "Development and Maintenance of Surgical and Critical Care Skills for Field Operational Surgery and Field Assessment and Skills" program. This exception was granted by the Assistant Secretary of Defense for Health Affairs.

8. Are there additional training areas beyond the ones identified in the aforementioned memorandum in which animal use has been reduced or ended by the DOD? If so, what are they?

No

(b)(6)

From: Torreon, Barbara <BTORREON@crs.loc.gov>
Sent: Tuesday, June 02, 2015 8:58 AM
To: (b)(6)
Subject: RE: Liaison for Defense Health - use of animals for combat trauma training

That would be appreciated. I will let the office know that the answers to their questions will take some time. Best,
 Barbara (b)(6)

-----Original Message----- (b)(6)

(b)(6)

Sent: Tuesday, June 02, 2015 8:56 AM
 To: Torreon, Barbara; (b)(6)
 Subject: RE: Liaison for Defense Health - use of animals for combat trauma training

I can ask, but I imagine its taking some time considering the questions are fairly in depth, and the answers have to be coordinated with multiple components because this issue crosses a few borders in the building.

Thanks.

(b)(6)

-----Original Message----- (b)(6)

From: Torreon, Barbara [mailto:BTORREON@crs.loc.gov]
Sent: Tuesday, June 02, 2015 8:37 AM

(b)(6)

Subject: RE: Liaison for Defense Health - use of animals for combat trauma training

Good morning (b)(6)

The congressional office called yesterday regarding the status of their follow up questions. Could you let me know when they can expect a reply. Staffer wants to brief the member by the end of the week. Thank you. Barbara (b)(6)

Barbara Salazar Torreon

Analyst in Defense Budget and Military Manpower (b)(6)

Foreign Affairs, Defense and Trade Division

Congressional Research Service

Library of Congress Washington, DC 20540

Tel: 202-707-8996

btorreon@crs.loc.gov

(b)(6)

(b)(6)

From: Torreon, Barbara

Sent: Wednesday, May 27, 2015 7:23 AM

(b)(6)

Subject: RE: Liaison for Defense Health - use of animals for combat trauma training

(b)(6)

Good morning

The office asked if we could get back to them by Friday COB. Let me know if this doable so I can give them a heads up. Thank you for your assistance. Best, Barbara

(b)(6)

(b)(6)

Sent: Tuesday, May 26, 2015 7:26 PM

(b)(6)

Torreon, Barbara

Subject: Re: Liaison for Defense Health - use of animals for combat trauma training

I tasked

(b)(6)

Sent: Tuesday, May 26, 2015 04:35 PM

To: Torreon, Barbara <BTORREON@crs.loc.gov>

(b)(6)

Subject: Re: Liaison for Defense Health - use of animals for combat trauma training

Barbara,

(b)(6)

(b)(6)

handles the HA portfolio.

A

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Torreon, Barbara

Sent: Tuesday, May 26, 2015 4:28 PM

To: (b)(6)

Subject: Liaison for Defense Health - use of animals for combat trauma training

Repeat

Hello (b)(6)

I hope you had a nice Memorial Day weekend. I received some follow-up questions (below) to a request on the use of animals for combat trauma training in the military. Can you email me the liaison officer who handles these types of defense health questions? This is in response to the May 2014 memo by the Assistant Secretary of Defense for Health Affairs, Dr. Jonathan Woodson, that the Pentagon will scale back its use of live animals in medical training starting Jan. 1, 2015.

- * How many animals were used by DOD for live tissue training for each year 2010-2014?
- * Provide a breakdown of animal use for training by branch of the armed forces, facility and training purpose in 2014.
- * How much does it cost per student for combat trauma training using live animals?
- * How much does it cost per student for combat trauma training using simulators?
- * How much taxpayer money was spent by DOD on live tissue training for combat trauma training in 2014? 2013? 2012? 2011? 2010?
- * Following the full implementation of the May 2014 memorandum "Determination for the use of Animals in Medical Education and Training" issued by Dr. Jonathan Woodson that went into effect January 1, 2015, how many animals are expected to be spared from use each year?
- * Have any waivers been issued to allow animal use to continue in areas identified as being unnecessary in the aforementioned memorandum? If so, how many waivers and for what specific purposes?

* Are there additional training areas beyond the ones identified in the aforementioned memorandum in which animal use has been reduced or ended by the DOD? If so, what are they?

Thanks in advance for your assistance. Barbara

Barbara Salazar Torreon

Analyst in Defense Budget and Military Manpower

Foreign Affairs, Defense and Trade Division

Congressional Research Service

Library of Congress Washington, DC 20540

Tel: 202-707-8996

btorreon@crs.loc.gov

Repeat

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(b)(6)

Subject: Re: Liaison for Defense Health - use of animals for combat trauma training

I talked to our guy - he said this needs to go to AT&L

(b)(6)

Subject: Re: Liaison for Defense Health - use of animals for combat trauma training

Yeah but don't think they do anything without coording with your guy.

(b)(6)

Subject: Re: Liaison for Defense Health - use of animals for combat trauma training

I thought AT&L was lead on this issue

(b)(6)

Subject: Fw: Liaison for Defense Health - use of animals for combat trauma training

All,
See below questions from CRS. Let me know who will need to respond. Thanks

(b)(6)

Sent: Tuesday, May 26, 2015 04:35 PM
To: Torreon, Barbara <BTORREON@crs.loc.gov>

(b)(6)

Subject: Re: Liaison for Defense Health - use of animals for combat trauma training

(b)(6)
Barbara,

(b)(6)

handles the HA portfolio.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Torreon, Barbara

Sent: Tuesday, May 26, 2015 4:28 PM

(b)(6)

Subject: Liaison for Defense Health - use of animals for combat trauma training

Refer

Hello (b)(6)

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Thanks in advance for your assistance. Barbara

Barbara Salazar Torreon

Analyst in Defense Budget and Military Manpower

Foreign Affairs, Defense and Trade Division

Congressional Research Service

Library of Congress Washington, DC 20540

Tel: 202-707-8996

btorreon@crs.loc.gov

Repeat

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(b)(6)

Sent: Tuesday, May 26, 2015 12:20 PM
To: Al Edwards (Allen Edwards@armed-services.senate.gov)
Subject: Medical R&D
Attachments: DHP Requirements Overview 2015.ppt

Al -

Here are the slides (b)(6) will refer to in the 1:00pm meeting today.

(b)(6)

(b)(6)

Subject:

FW: DOD use of animals in combat-injuries training (Sen Collins staff RFI)

Signed By:

(b)(6)

H

(b)(6)

(b)(6), (b)(5)

Thanks,

(b)(6)

-----Original Message-----

From: Coleman, Rachel (Collins)

Sent: Thursday, April 16, 2015 12:01 PM

(b)(6)

Subject: DOD use of animals in combat-injuries training

H

(b)(6)

Here's the background:

Senator Wyden has introduced a bill called the BEST Practices Act (Battlefield Excellence through Superior Training), S. 587 which would require the Secretary of Defense to train members of the Armed Forces in the treatment of severe combat injuries by using methods that only involve humans, thereby eliminating the use of animals in combat-injuries training.

Our question:

The FY 2013 National Defense Authorization Act (P.L.112-239) contained a provision that Senator Collins supported requiring the Department of Defense (DOD) to provide Congress with a report on the use of animals in combat training, with the goal of ultimately phasing out the use of animals for this purpose. This report, released in April 2013, stated that the DOD intended to "reduce the use of live animals in medical training and to increase the use of validated simulation training platforms." What steps has the DOD taking to reduce the use of live animals in medical training? More broadly, in the two years since the 2013 report was released, what progress has DOD made on this issue?

Thanks for any information you can send us,

Best,

Rachel

(b)(6)

Rachel Coleman

Office of Senator Susan Collins

Dirksen 413 | Washington, D.C. 20510

Ext. 4-9238

(b)(6)

Subject: Re: SMC staff request - Animal Testing

Got it. Working with (b)(6) will follow up with them tomorrow to see if this is about use of animals for research and/or medical training (e.g. using live tissue), or something else. Much ado about testing shoes may have confused the words in their request.

Vr

(b)(6)

(b)(6)

(b)(6)

Subject: Re: SMC staff request - Animal Testing

Looping in

(b)(6)

(b)(6)

Subject: Fw: SMC staff request - Animal Testing

Gents - Sorry.....this got lost in my frag pattern.

Believe this request re animal testing policy belongs to one of you. Appreciate your help with assisting Sen Collins staff.

Thanks so much

Vr

(b)(6)

From: Carney, Jill (Collins) [mailto:Jill_Carney@collins.senate.gov]

Sent: Monday, April 13, 2015 08:09 AM

(b)(6)

(b)(6)

Subject: Animal Testing

(b)(6)

Hi [redacted] hope you got a chance to relax during recess!

My LC reached out to DoD leg affairs to try to get some information on DoD's animal testing policy, and the person she got said that he wasn't certain who was point on this, but suggested that we reach out to you.

I understand from a couple of press articles that there are some new regulations. Would you be able to provide me with the policy memo or any pertinent information you have on this?

Thanks!

Jill

Jill E. Carney

Senator Collins (R-ME)

4-3913

(b)(6)

From: Clark, Samantha (Armed Services) <Samantha_Clark@armed-services.senate.gov>
Sent: Monday, April 06, 2015 2:41 PM
To: (b)(6); Barney, Steven (Armed Services); Clark, Jonathan (Armed Services); Edwards, Allen (Armed Services); Leeling, Gary (Armed Services); Sawyer, Brendan (Armed Services)
Cc: (b)(6)
Subject: RE: SASC Staffer Due Outs

Thanks (b)(6) your numbering organization just saved me a bunch of time- thank you!

-----Original Message-----

From: (b)(6) (b)(6) (b)(6)
Sent: Monday, March 30, 2015 10:48 AM
To: Barney, Steven (Armed Services); Clark, Jonathan (Armed Services); Clark, Samantha (Armed Services); Edwards, Allen (Armed Services); Leeling, Gary (Armed Services); Sawyer, Brendan (Armed Services)

(b)(6)

Subject: SASC Staffer Due Outs

Attached please find the responses to the due outs from staffer day:

v/r,

(b)(6)

R&FM:

- 1) Cost savings for Compensation PB 16 proposals
- 2) Information paper explaining the indices used to calculate civilian pay raise versus military pay raise. Why the difference

HA:

- 3) Information paper that describes how the TRICARE consolidation proposal addresses the health care findings in the MCRMC report
- 4) Information paper that describes the Department's ongoing and future efforts to improve trauma/casualty care training
- 5) Chart that broke down the savings assumed by the Department for each of its proposals, to include estimated mandatory savings. We would like the info presented by proposal (so for instance, the TFL proposal would be separate from the pharmacy proposal, etc.).

SAPRO:

- 6) Information paper explaining state laws and conflicts regarding restricted reporting

7) Citation from DoD policy/DoDI explaining reporting processes and whether telling a friend eliminates ability to file a restricted report

(b)(6)

Sent:

Tuesday, March 31, 2015 4:45 PM

To:

Stella, Michael J SES OSD OASD LA (US)

Cc:

Gilliland, John E SES OSD OASD LA (US); (b)(6)

(b)(6)

Subject:

INFORMAL VIEW: S. 587 Animal use language (SASC request)

Signed By:

(b)(6)

Mr. Stella:

(b)(5)



(b)(6)



Subject:

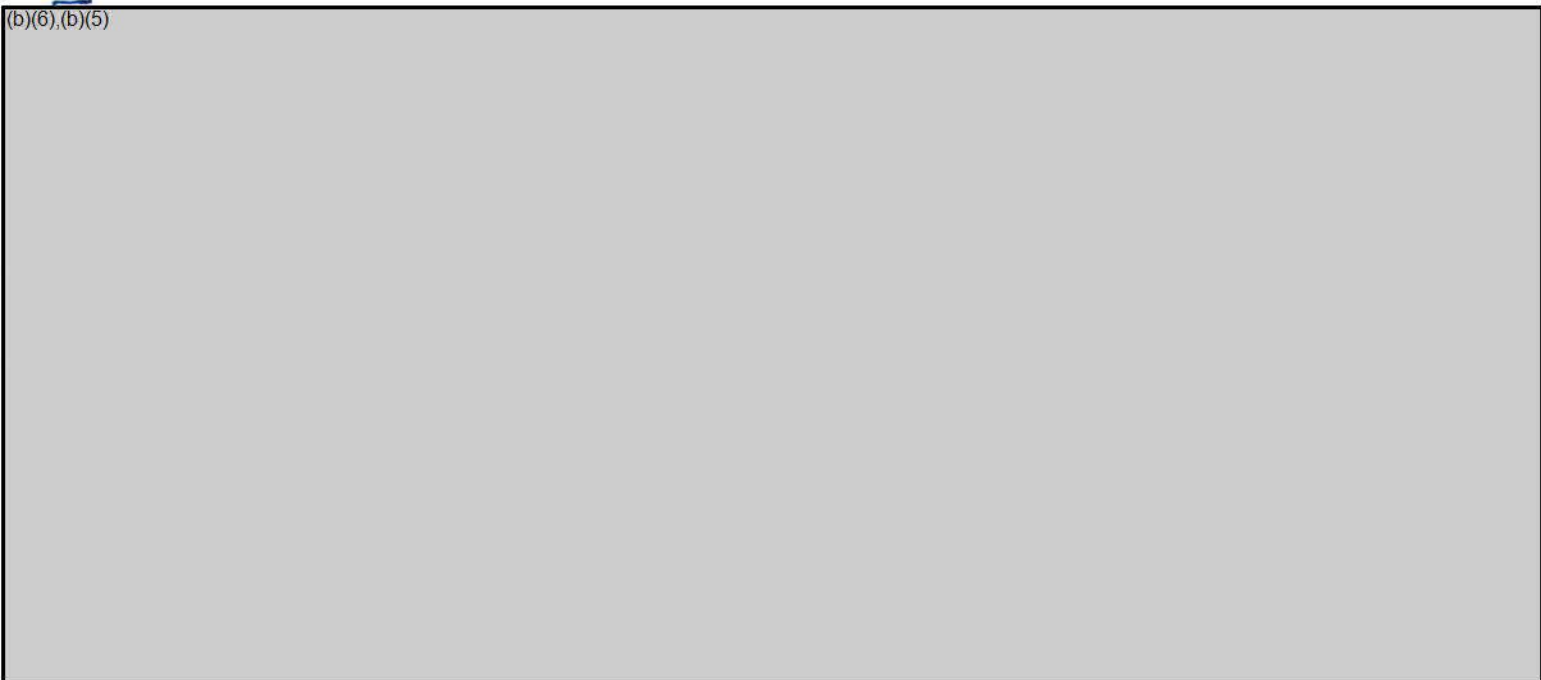
RE: Request informal views - Animal use language

Signed By:

(b)(6)



(b)(6),(b)(5)



Thanks,

(b)(6)



-----Original Message-----

(b)(6)



Subject: Re: Request informal views - Animal use language

Hi

(b)(6)



We can sync tomorrow on this, after our HASC_IETC hearing. I haven't had a chance to review, and want to be sure we have final/approved "view" as well as take care of any needed formatting.

Thanks,

(b)(6)



(b)(6)

----- Original Message -----

(b)(6)

(b)(6) Ormond, Dale A SES OSD OUSD ATL (US) (b)(6)

(b)(6)

Subject: RE: Request informal views - Animal use language

Hi (b)(6)

Thanks for the quick turn.

(b)(6)

-----Original Message-----

(b)(6)

(b)(6) Ormond, Dale A SES OSD OUSD ATL (US) (b)(6)

(b)(6)

Subject: Re: Request informal views - Animal use language

(b)(6)

Attached is our review. It was provided to DHA/P&R. They had no comments or edits.

V/R

(b)(6)

-----Original Message-----

(b)(6)

(b)(6) Ormond, Dale A SES OSD OUSD ATL (US) (b)(6)

(b)(6)

Subject: RE: Request informal views - Animal use language

(b)(6)

Received and understood. Will have a product to you NLT COB tomorrow.

v/r,

(b)(6)

<http://www.acq.osd.mil/rd/hptb/index.html>

-----Original Message-----

(b)(6)

Sent: Tuesday, March 24, 2015 1:34 PM

To: Mason, Patrick A SES OSD OUSD ATL (US)

(b)(6)

(b)(6) Shaffer, Alan R SES OSD OUSD ATL (US) (b)(6)

(b)(6) Ormond, Dale A

SES OSD OUSD ATL (US); (b)(6)

(US)

Subject: FW: Request informal views - Animal use language

Hi Patrick and (b)(6)

We have been asked to provide informal views on the BEST Act. Not sure if last year's paper we provided is still current. If we could have something by COB tomorrow that would be appreciated.

Thanks,

(b)(6)

(b)(6)

Subject: FW: Request informal views - Animal use language

H (b)(6) Can R&E take the lead on this Informal View?

I am running to the Hill, but (b)(6) can provide background as needed.

Thanks,

(b)(6)

(b)(6)

----- Original Message -----

(b)(6)

Subject: FW: Request informal views

(b)(6) see the below for S. 587. Can you assist in having AT&L made the lead for this informal view? Thanks very much.

-----Original Message-----

(b)(6)

Subject: RE: Request informal views

(b)(6)

We believe the official tasking should go to AT&L. All animal use tasking go to AT&L and this one also has an element of simulations. Our folks will begin working with AT&L now.

Thanks!

(b)(6)

-----Original Message-----

(b)(6)

Sent: Monday, March 23, 2015 11:02 AM

To: DHA NCR Prog Integ List PI List

(b)(6)

(b)(6)

Subject: RE: Request informal views

Ladies and Gentlemen, please utilize the attached template in providing informal views on the embedded legislative language (S. 587). Thanks very much.

-----Original Message-----

(b)(6)

(US); DHA NCR Prog Integ List PI List
Subject: FW: Request informal views

Informal views request

(b)(6)

-----Original Message-----

From: Edwards, Allen (Armed Services)
[mailto:Allen_Edwards@armed-services.senate.gov]
Sent: Monday, March 23, 2015 9:56 AM

(b)(6)

Cc: Leeling, Gary (Armed Services); Edwards, Allen (Armed Services)
Subject: Request informal views

(b)(6)

Request informal views on the attached bills. Please get views to us as soon as possible so we can be prepared for potential amendments to our bill.
Thank you.

AI

Dr. Allen (AI) Edwards

Lead Professional Staff Member

Personnel Subcommittee

U.S. Senate Committee on Armed Services

228 Russell Senate Office Building

Washington, DC 20510-6500

(b)(6)

Subject:

RE: SASC Staffer Due Outs

(b)(6),(b)(5)

v/r,

(b)(6)

Original Message

(b)(6)

Subject: SASC Staffer Due Outs

(b)(6)

Please see below for the SASC Staffer Day Due Out questions, and attached are the corresponding answers:

R&FM:

- 1) Cost savings for Compensation PB 16 proposals
- 2) Information paper explaining the indices used to calculate civilian pay raise versus military pay raise. Why the difference

HA:

- 3) Information paper that describes how the TRICARE consolidation proposal addresses the health care findings in the MCRMC report
- 4) Information paper that describes the Department's ongoing and future efforts to improve trauma/casualty care training
- 5) Chart that broke down the savings assumed by the Department for each of its proposals, to include estimated mandatory savings. We would like the info presented by proposal (so for instance, the TFL proposal would be separate from the pharmacy proposal, etc.).

SAPRO:

- 6) Information paper explaining state laws and conflicts regarding restricted reporting
- 7) Citation from DoD policy/DoDI explaining reporting processes and whether telling a friend eliminates ability to file a restricted report

(b)(6)



(b)(6)

From:

(b)(6)

Sent:

Monday, March 30, 2015 10:48 AM

To:

Barney, Steven (Armed Services; Clark, Jonathan (Armed Services; Clark, Samantha (Armed Services; Edwards, Allen (Armed Services; Leeling, Gary (Armed Services; Sawyer, Brendan (Armed Services

Cc:

(b)(6)

Subject:

SASC Staffer Due Outs

Attachments:

#1.docx; #2.docx; #3.doc; #4.doc; #5.xlsx; #6.docx; #7.docx

Attached please find the responses to the due outs from staffer day:

y/r.

(b)(6)

R&FM:

- 1) Cost savings for Compensation PB 16 proposals
- 2) Information paper explaining the indices used to calculate civilian pay raise versus military pay raise. Why the difference

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- 3) Information paper that describes how the TRICARE consolidation proposal addresses the health care findings in the MCRMC report
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Figure 6-3. FY 2016 PB Military Compensation Proposals ^{/1}
(Dollars in billions)

| Proposal | FY 2016 Savings | FY16 – FY20 Savings |
|--|-----------------|---------------------|
| FY 2016 Pay Raise of 1.3% (vice 2.3%) | 0.7 | 4.3 |
| Slow BAH Growth | 0.4 | 3.9 |
| Reduce Commissary Subsidy | 0.3 | 4.4 |
| Consolidated TRICARE Health Plan | -0.1 | 3.1 |
| Pharmacy Co-Pay Adjustments | 0.3 | 2.0 |
| TRICARE-for-Life Enrollment Fee | 0.1 | 0.4 |
| Total Military Compensation Proposal Savings | 1.7 | 18.2 |
| FY17 - FY20 Pay Raises - Additional Risk ^{/1} | -- | 7.2 |
| Total Savings/Risk | 1.7 | 25.4 |

Source: UNITED STATES DEPARTMENT OF DEFENSE FISCAL YEAR 2016 BUDGET REQUEST, OVERVIEW, page 6-6

Question: Does the civil service annual pay raise rely upon a different economic index than the military basic pay increase?

Answer: Both the General Schedule (GS) pay increase (not including the locality pay portion) and the military basic pay increase rely upon the change in same index: the Employment Cost Index for wages and salaries for private industry workers. By operation of law, the GS pay increase is the change in this index minus one-half percentage point. Also by operation of law, the military basic pay increase is the change in this index without any reduction. Both pay adjustments are based upon the change in the ECI measured over the same timeframe (i.e., October through the September ending 15 months in advance of the effective date of the raises).

The Office of Personnel Management (OPM) generates the government-wide civilian pay schedules pursuant to the President's authorization for the pay adjustment or the Federal Employees Pay Comparability Act (FEPCA), as applicable.

Under the FEPCA of 1990, GS pay adjustments, beginning in January 1994, have consisted of two components: (1) a general increase applicable to the GS, which is linked to the Bureau of Labor Statistics (BLS) Employment Cost Index (ECI), and (2) a GS locality adjustment that applies only to specific areas of the United States where non-Federal pay exceeds Federal pay by more than 5 percent.

The BLS uses National Compensation Survey data to derive the ECI used for the general increase. The ECI measures changes in labor costs rather than in the cost of living, as is commonly thought. Pursuant to 5 U.S.C. 5303(a), annual adjustments to the base GS (i.e., GS pay rates not including locality pay) each January are based on the annual change in the ECI for wages and salaries for private industry workers less one-half of one percent. The ECI used for this calculation dates back to the rate established for September, 15 months prior to the January release date.

However, pursuant to 5 U.S.C. 5303(b)(1), the President has the authority to provide an alternative pay adjustment because of national emergency or serious economic conditions affecting the general welfare. Each President has exercised this authority and has authorized a pay adjustment to the GS different than required by FEPCA since it was implemented in 1994.

The pay raise for active duty members is also determined by private sector wage growth measured by the ECI. However, it is not reduced by one-half of one percent as required by FEPCA. The President also has executive authority to make an alternative pay adjustment for military members if he considers it necessary due to national emergency or economic conditions.

Information paper explaining state laws and conflicts regarding restricted reporting.

An Information paper will not capture the complexity required to address the state laws and conflicts regarding restricted reporting. The Office of General Counsel has offered to assign a law clerk to develop a document which provides the detailed state-by-state information regarding state mandatory reporting laws. It is anticipated this product will be available in mid-April 2015. Once completed this review will be provided to the committees.

Citation(s) from DoD policy/DoDI explaining rearing processes and whether telling a friend eliminates the ability to file a restricted report.

Question A. Where does it state in the NDAA that only SARCs, SAPR VAs, and healthcare personnel can receive restricted reports?

Answer: In §581 of NDAA FY 2012.

SEC. 581. ACCESS OF SEXUAL ASSAULT VICTIMS TO LEGAL ASSISTANCE
AND SERVICES OF SEXUAL ASSAULT RESPONSE
COORDINATORS AND SEXUAL ASSAULT VICTIM ADVOCATES. . .

“(b) RESTRICTED REPORTING.—(1) Under regulations prescribed by the Secretary of Defense, a member of the armed forces, or a dependent of a member, who is the victim of a sexual assault may elect to confidentially disclose the details of the assault to an individual specified in paragraph (2) and receive medical treatment, legal assistance under section 1044 of this title, or counseling, without initiating an official investigation of the allegations.

“(2) The individuals specified in this paragraph are the following:

“(A) A Sexual Assault Response Coordinator.

“(B) A Sexual Assault Victim Advocate.

“(C) Healthcare personnel specifically identified in the regulations required by paragraph (1).”.

Question B: If a victim discloses the sexual assault to her/his friend, does s/he lose the ability to file a Restricted report?

Answer: No, Restricted Reporting does not mean anonymous reporting, just confidential. A victim can disclose to a friend, as long as that friend is not law enforcement or in the victim's chain of command. That communication with the friend, however, is not protected under Restricted Reporting. Cite: DoD Instruction 6495.02, March 28, 2013, Incorporating Change 1, Effective February 12, 2014. In Enclosure 4 “Reporting Options and Sexual Assault Reporting Procedures”, p. 28.

“e. Victim Confiding in Another Person. In establishing the Restricted Reporting option, DoD recognizes that a victim may tell someone (e.g., roommate, friend, family member) that a sexual assault has occurred before considering whether to file a Restricted or Unrestricted Report.

(1) A victim's communication with another person (e.g., roommate, friend, family member) does not, in and of itself, prevent the victim from later electing to make a Restricted Report. Restricted Reporting is confidential, not anonymous, reporting. However, if the person to whom the victim confided the information (e.g., roommate, friend, family member) is in the victim's officer or non-commissioned officer chain of command or DoD law enforcement, there can be no Restricted Report.

(2) Communications between the victim and a person other than the SARC, SAPR VA, or healthcare personnel are NOT confidential and do not receive the protections of Restricted Reporting.”

(b)(6)

Subject:

RE: CATMS020320153GVC2R (USE OF LIVE ANIMALS FOR COMBAT TRAUMA TRAINING)

Signed By:

(b)(6)

(b)(6)

Complete. Please route for further/final LA coord. Concur with (b)(6) edits.

Thanks

(b)(6)

(b)(6)

Subject: RE: CATMS020320153GVC2R (USE OF LIVE ANIMALS FOR COMBAT TRAUMA TRAINING)

(b)(6)

Per our discussion, I've added this back to your queue.

CATMS020320153GVC2R

<<https://crm.osd.mil/CATMS1/main.aspx?etc=10022&extraqs=formid%3d58807d59-72ea-4c36-a527-5db33cda40be&id=%7b1caff0d9-51c7-e411-885a-005056aa79f1%7d&pagetype=entityrecord>>

V/r,

(b)(6)

(b)(6)

Subject: CATMS020320153GVC2R (USE OF LIVE ANIMALS FOR COMBAT TRAUMA TRAINING)
Importance: High

**** MISROUTED TASKER / SUSPENSE TOMORROW ****

(b)(6)

I have assigned CATMS020320153GVC2R (USE OF LIVE ANIMALS FOR COMBAT TRAUMA TRAINING) to you for coordination. It was misrouted to (b)(6) because it was originally a P&R item. It was updated, and the response is now coming from (b)(6). Please let us know when you have completed your review.

<<https://crm.osd.mil/CATMS1/main.aspx?etc=10022&extraqs=formid%3d58807d59-72ea-4c36-a527-5db33cda40be&id=%7b1caff0d9-51c7-e411-885a-005056aa79f1%7d&pagetype=entityrecord>>

V/r,

(b)(6)

Congress of the United States

Washington, DC 20510

March 2, 2015

The Honorable Ashton B. Carter
Secretary of Defense
1000 Defense Pentagon
Washington, DC, 20301-1000

Dear Secretary Carter:

First, congratulations on your recent confirmation to serve as the nation's 25th Secretary of Defense. The overwhelming and bipartisan nature of the vote is a testament to your long and distinguished career and the esteem in which you are held.

We are writing today to commend the Department of Defense (DoD) on the steps it has taken to replace the use of live animals for medical training with more advanced training methods and to urge the DoD to take similar steps to modernize combat trauma training.

We welcomed last year's news that the DoD required the replacement of live animal use in six areas of military medical training effective January 1, 2015. This follows a 2013 decision by the DoD medical school that trains new military physicians to replace live animal use in its student curriculum. Taken together, these steps bring the military more in line with the civilian sector, which has overwhelmingly phased out the use of live animals for medical training.

While we commend these steps in the right direction, we were disappointed to see that a May 2014 memo from the Assistant Secretary of Defense for Health Affairs did not address combat trauma training, the largest area of medically unnecessary live animal use. Each year, more than 8,500 goats and pigs are used in combat trauma training courses conducted for U.S. military personnel. We have serious reservations about the killing and maiming of these live animals, particularly when civilian medical centers have all but eliminated this practice and when medical professionals tell us that modern simulations and technology meet or exceed medical training requirements.

The DoD already invests in simulators and owns many, including those that replicate the experience of performing emergency medical procedures – like applying tourniquets and managing collapsed lungs – on a living trauma patient. We know you believe that our military personnel should be taught using the most sophisticated methods, and in that spirit, we urge you to continue transitioning away from the use of live animals in medical training including combat trauma training. We have also reintroduced our bipartisan,



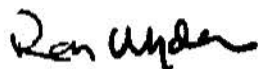
OSD002589-15/CMD003135-15

1503131974

bicameral legislation, the Battlefield Excellence through Superior Training (BEST) Practices Act, to help DoD make this transition.

Thank you for your service to our country. We look forward to timely response to this letter and your plan for continuing the DoD's transition from the use of live animals in combat trauma training.

Sincerely,



Ron Wyden
United States Senator



Henry C. "Hank" Johnson
Member of Congress

CC: Dr. Jonathan Woodson, Assistant Secretary of Defense for Health Affairs



ACQUISITION,
TECHNOLOGY
AND LOGISTICS

THE UNDER SECRETARY OF DEFENSE

3010 DEFENSE PENTAGON
WASHINGTON, DC 20301-3010

The Honorable Henry C. Johnson
U.S. House of Representatives
Washington, DC 20515

MAR 26 2015

Dear Representative Johnson:

Thank you for your March 2, 2015, letter to the Secretary of Defense regarding the Department of Defense's (DoD) use of animals in combat trauma training. I am responding on behalf of Secretary Carter.

The type and complexity of combat trauma wounds experienced today are far more severe than in previous conflicts or as seen in civilian medical centers. While the severity of injury of U.S. Service members in Afghanistan increased from 2005 to 2013, the case fatality rate decreased during that time period (Rasmussen *et al.*, 75:2013, *J. Trauma and Acute Care Surgery*). Although survival in combat is multifactorial, prematurely changing the Department's training practices could result in increased Service member fatalities. As you indicated in your letter, the Department already invests in and owns many simulators for combat casualty training. The Department integrates these simulators and other educational tools such as lectures, video demonstrations, and role play in realistic scenarios to prepare medical providers, from medic to doctor, to care for the combat-wounded. There are, however, gaps between the skills that can be gained using current simulation systems and the proficiency and confidence that translates to performance and resilience on the battlefield. In some DoD programs, animal models fill this gap and are used to prepare medical providers to save the lives of Service members.

Combat trauma training has unique characteristics compared to the training of civilian medical providers. The combat medic is the first responder who provides treatment at the point of wounding. New combat medics are generally less than 20 years of age and, within a short time period, must learn and perform complex combat trauma procedures in chaotic and hostile environments, caring for their patients while awaiting evacuation to well-equipped surgical suites and advanced providers. This is a very stressful environment. Through interactions with medical training subject matter experts in the Department and academia, we have learned that optimal combat trauma training requires the trainees to engage in the experience as though they were on the actual battlefield. To improve the training experience, DoD research and development efforts have focused on training methodologies, synthetic tissues, 3-D printing technologies, high-fidelity task trainers and manikins based on human physiology, and virtual training platforms. These investments have led to training systems with improved realism and reduced our need for animal models; however, without scientific-based evidence demonstrating the efficacy of alternatives, the animal model remains a valuable component of combat trauma training.

The Department of Defense shares your goal of replacing animal models with alternative training solutions. The Department's research and development efforts, working groups focused on alternative training solutions, and interactions with industry, academia, and international partners ensure that we remain on the path to replacement of animal models as quickly as possible without compromising the quality of training. If you would like additional information on the Department's efforts, we will provide a comprehensive briefing on the strategy to reduce and replace the use of animal models in the Department's medical training programs.

An identical letter has been sent to Senator Wyden.

Sincerely,

A handwritten signature in black ink, appearing to read 'Frank Kendall', with a stylized, cursive script.

Frank Kendall



ACQUISITION,
TECHNOLOGY
AND LOGISTICS

THE UNDER SECRETARY OF DEFENSE

3010 DEFENSE PENTAGON
WASHINGTON, DC 20301-3010

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Frank Kendall

(b)(6)

From: Service Account, CRM Setup <donotreply.crmsetup@mail.mil>
Sent: Monday, March 16, 2015 4:00 PM
To: (b)(6)
Subject: LA - Request Type: Congressional Incoming, OSD002589-15, CMD Tasking, OPR: UPR, Suspense Date: 03/16/15
Attachments: OSD002589-15-INCOMING.pdf

Notification Type: New ACTION task has been assigned

Importance: High

Control Number: OSD002589-15

Action ID: CMD003135-15 <https://crm.osd.mil/catms1/main.aspx?etn=osd_action&extraqs=id%3d%257b5dd0cc06-29c1-e411-859a-005056a13529%257d%26&pagetype=entityrecord>

Tasker ID: CATMS020320153GVC2R

<https://crm.osd.mil/catms1/main.aspx?etn=ava_tasker&extraqs=id%3d%257b95962af8-16cc-e411-b0b9-005056a13529%257d%26&pagetype=entityrecord>

From: USS WYDEN, R

To: SECDEF

Task Subject: USE OF LIVE ANIMALS FOR COMBAT TRAUMA TRAINING

Request Type: Congressional Incoming

Date of Receipt: 03/02/15

OPR: UPR

Response Type: RDC-Reply Direct by OSD or DoD Component Head

OCRs: SA GC IA USA-ASDR&F-RESEARCH

CCs: (b)(6) House, and Senate.

Task Suspense Date: 03/16/15

Distribution: RLB DSD UPR

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- * This IS includes security measures (e.g., authentication and access controls) to protect USG interests - not for your personal benefit or privacy.
- * Notwithstanding the above, using this IS does not constitute consent to PM, LE or CI investigative searching or monitoring of the content of privileged communications, or work product, related to personal representation or services

by attorneys, psychotherapists, or clergy, and their assistants. Such communications and work product are private and confidential. See User Agreement for details.

This is an automated message. Please do not replay to this e-mail. These documents may contain sensitive information to include privacy act material - please handle accordingly. Questions concerning this Correspondence can be addressed

(b)(6)



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Washington, DC 20510

March 2, 2015

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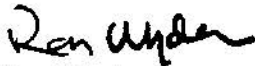


OSD002589-15/CMD003135-15

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Sincerely,



Ron Wyden
United States Senator



Henry C. "Hank" Johnson
Member of Congress

CC: Dr. Jonathan Woodson, Assistant Secretary of Defense for Health Affairs

(b)(6)

Subject: RE: S.587
Attachments: Live Animal Use in Training 03_13_15.doc

Here you go.

v/r

(b)(6)

My email address has changed! You may now reach me at

(b)(6)

-----Original Message-----

From: Edwards, Allen (Armed Services) [mailto:Allen_Edwards@armed-services.senate.gov]

Sent: Wednesday, March 11, 2015 03:40 PM

(b)(6)

(b)(6) Leeling, Gary (Armed Services) <Gary_Leeling@armed-services.senate.gov>; Edwards, Allen (Armed Services) <Allen_Edwards@armed-services.senate.gov>
Subject: S.587

See the attached bill referred to SASC. Can we get an updated info paper on this issue? Thank you.

AI

Live Animals Use in Training

- The Undersecretary of Defense for Acquisition, Logistics, and Technology (USD(AT&L)) is the proponent for policies on the oversight of programs that use live animals, per DoD Instruction (DoDI) 3216.0, "Use of Live Animals in DoD Programs," September 13, 2010.
- The Assistant Secretary of Defense for Health Affairs (ASD(HA)) is the proponent for policies on medical readiness training stipulating that the use of live animals shall occur only when alternatives such as commercial training manikins, mouldaged actors, cadavers, or virtual simulators are not appropriate to the training task, per DoDI 1322.24, "Medical Readiness Training," October 6, 2011.
- DoD policy requires compliance with all applicable laws, directives, regulations, accreditation and approval by the Association for the Assessment and Accreditation of Laboratory Animal Care, International, and also in compliance with 9 Code of Federal Regulations, "Animal Welfare Act."
- The DoD uses live animals for medical education and training for complex and tedious procedures such as microsurgery, and combat trauma training, which are integral to training for medical personnel.
- The Live Animal Use in Medical Education and Training working group, co-chaired by representatives from USD(AT&L) and ASD(HA), brings together subject matter experts from the Services, Joint Staff, United States Special Operations Command, and Uniformed Services University of Health Sciences to identify ways to refine, reduce, or replace the use of live animals in medical training.
- The DoD continues to evaluate emerging alternatives to the use of live animals in medical training, such as models and simulation.
- **Why does the DoD use live animals in medical training?**

The DoD uses live animals for medical education and training because there are no adequate simulators for hemorrhage control/amputations, chest wounds, and cricothyroidotomy that are of equal training effectiveness as live animals. Personnel must be trained to perform in combat situations where Service members frequently have multiple, severe, life-threatening wounds. The live animal model provides realism in tissue handling, and physiological responses to intervention procedures with immediate feedback where no validated simulations exist. Conducting procedures on the live animal model is the culminating step in a series of training modalities that include classroom, textbooks, didactic tests, and simulators. These training methodologies give our combat medical personnel the critical skills they need to save lives. The opportunity to do this training in a clinical setting is relatively rare, especially compared to the number of medics we need to have trained in these procedures.

Live Animals Use in Training

- **What action is the DoD taking to eliminate the use of live animals in medical training?**

USD(AT&L) is the proponent for the use of live animals in DoD programs. The technologies reviewed are either already used extensively in medical training programs or are still in the development phase. DOD maximizes use of non-animal alternatives to limit the use of animals, while assuring the best training for saving lives on the battlefield. Research is underway that explores methods to improve training effectiveness and reduce reliance on animals. DOD is unable to determine how quickly industry can develop and produce the high fidelity, durable technology needed to replace animals in all possible training venues. For the majority of the students, training with live anesthetized animals is the only time they experience treatment of a chest wound, cricothyroidotomy, or severe hemorrhage before performing these procedures without medical assistance under the extreme, adverse conditions of combat. Currently, the integration of simulation technology has not completely replaced the live animal model but has augmented it, reducing the reliance on animals in DoD.

(b)(6)

From: Edwards, Allen (Armed Services) <Allen_Edwards@armed-services.senate.gov>
Sent: Wednesday, March 11, 2015 3:41 PM
To: (b)(6)
Cc: (b)(6); Leeling, Gary (Armed Services); Edwards, Allen (Armed Services)
Subject: S.587
Attachments: BILLS-114s587is.pdf; Live Animal Use in Training.doc

See the attached bill referred to SASC. Can we get an updated info paper on this issue? Thank you.

Al



II

114TH CONGRESS
1ST SESSION

S. 587

To amend title 10, United States Code, to require the Secretary of Defense to use only human-based methods for training members of the Armed Forces in the treatment of severe combat injuries, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 26, 2015

Mr. WYDEN (for himself and Mr. PETERS) introduced the following bill; which was read twice and referred to the Committee on Armed Services

A BILL

To amend title 10, United States Code, to require the Secretary of Defense to use only human-based methods for training members of the Armed Forces in the treatment of severe combat injuries, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Battlefield Excellence
5 through Superior Training Practices Act” or “BEST
6 Practices Act”.

7 **SEC. 2. FINDINGS.**

8 Congress makes the following findings:

1 (1) The Department of Defense has made im-
2 pressive strides in the development and use of meth-
3 ods of medical training and troop protection, such as
4 the use of tourniquets and improvements in body
5 armor, that have led to decreased battlefield fatali-
6 ties.

7 (2) The Department of Defense uses more than
8 8,500 live animals each year to train physicians,
9 medics, corpsmen, and other personnel methods of
10 responding to severe battlefield injuries.

11 (3) The civilian sector has almost exclusively
12 phased in the use of superior human-based training
13 methods for numerous medical procedures currently
14 taught in military courses using animals.

15 (4) Human-based medical training methods
16 such as simulators replicate human anatomy and
17 can allow for repetitive practice and data collection.

18 (5) According to scientific, peer-reviewed lit-
19 erature, medical simulation increases patient safety
20 and decreases errors by healthcare providers.

21 (6) The Army Research, Development and En-
22 gineering Command and other entities of the De-
23 partment of Defense have taken significant steps to
24 develop methods to replace live animal-based train-
25 ing.

1 (7) According to the report by the Department
2 of Defense titled “Final Report on the use of Live
3 Animals in Medical Education and Training Joint
4 Analysis Team”, published on July 12, 2009—

5 (A) validated, high-fidelity simulators were
6 to have been available for nearly every high-vol-
7 ume or high-value battlefield medical procedure
8 by the end of 2011, and many were available as
9 of 2009; and

10 (B) validated, high-fidelity simulators were
11 to have been available to teach all other proce-
12 dures to respond to common battlefield injuries
13 by 2014.

14 (8) The Center for Sustainment of Trauma and
15 Readiness Skills of the Air Force exclusively uses
16 human-based training methods in its courses and
17 does not use animals.

18 (9) In 2013, the Army instituted a policy for-
19 bidding non-medical personnel from participating in
20 training courses involving the use of animals.

21 (10) In 2013, the medical school of the Depart-
22 ment of Defense, part of the Uniformed Services
23 University of the Health Sciences, replaced animal
24 use within its medical student curriculum.

1 (11) The Coast Guard announced in 2014 that
 2 it would reduce by half the number of animals it
 3 uses for combat trauma training courses but stated
 4 that animals would continue to be used in courses
 5 designed for Department of Defense personnel.

6 (12) Effective January 1, 2015, the Depart-
 7 ment of Defense replaced animal use in six areas of
 8 medical training, including Advanced Trauma Life
 9 Support courses and the development and mainte-
 10 nance of surgical and critical care skills for field
 11 operational surgery and field assessment and skills
 12 tests for international students offered at the De-
 13 fense Institute of Medical Operations.

14 **SEC. 3. REQUIREMENT TO USE HUMAN-BASED METHODS**
 15 **FOR CERTAIN MEDICAL TRAINING.**

16 (a) IN GENERAL.—Chapter 101 of title 10, United
 17 States Code, is amended by adding at the end the fol-
 18 lowing new section:

19 **“§ 2017. Use of human-based methods for certain**
 20 **medical training**

21 “(a) COMBAT TRAUMA INJURIES.—(1) Not later
 22 than October 1, 2018, the Secretary of Defense shall de-
 23 velop, test, and validate human-based training methods for
 24 the purpose of training members of the Armed Forces in

1 the treatment of combat trauma injuries with the goal of
2 replacing live animal-based training methods.

3 “(2) Not later than October 1, 2020, the Secretary—

4 “(A) shall only use human-based training meth-
5 ods for the purpose of training members of the
6 Armed Forces in the treatment of combat trauma
7 injuries; and

8 “(B) may not use animals for such purpose.

9 “(b) EXCEPTION FOR PARTICULAR COMMANDS AND
10 TRAINING METHODS.—(1) The Secretary may exempt a
11 particular command, particular training method, or both,
12 from the requirement for human-based training methods
13 under subsection (a)(2) if the Secretary determines that
14 human-based training methods will not provide an educa-
15 tionally equivalent or superior substitute for live animal-
16 based training methods for such command or training
17 method, as the case may be.

18 “(2) Any exemption under this subsection shall be for
19 such period, not more than one year, as the Secretary shall
20 specify in granting the exemption. Any exemption may be
21 renewed (subject to the preceding sentence).

22 “(c) ANNUAL REPORTS.—(1) Not later than October
23 1, 2016, and each year thereafter, the Secretary shall sub-
24 mit to the congressional defense committees a report on
25 the development and implementation of human-based

1 training methods for the purpose of training members of
 2 the Armed Forces in the treatment of combat trauma inju-
 3 ries under this section.

4 “(2) Each report under this subsection on or after
 5 October 1, 2020, shall include a description of any exemp-
 6 tion under subsection (b) that is in force as the time of
 7 such report, and a current justification for such exemp-
 8 tion.

9 “(d) DEFINITIONS.—In this section:

10 “(1) The term ‘combat trauma injuries’ means
 11 severe injuries likely to occur during combat, includ-
 12 ing—

13 “(A) hemorrhage;

14 “(B) tension pneumothorax;

15 “(C) amputation resulting from blast in-
 16 jury;

17 “(D) compromises to the airway; and

18 “(E) other injuries.

19 “(2) The term ‘human-based training methods’
 20 means, with respect to training individuals in med-
 21 ical treatment, the use of systems and devices that
 22 do not use animals, including—

23 “(A) simulators;

24 “(B) partial task trainers;

25 “(C) moulage;

1 “(D) simulated combat environments;
2 “(E) human cadavers; and
3 “(F) rotations in civilian and military trauma centers.
4

5 “(3) The term ‘partial task trainers’ means
6 training aids that allow individuals to learn or practice specific medical procedures.”.

7 (b) CLERICAL AMENDMENT.—The table of sections
8 at the beginning of chapter 101 of such title is amended
9 by adding at the end the following new item:

10 “2017. Use of human-based methods for certain medical training.”.

○

Live Animals Use in Training

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- The DoD uses live animals for medical education and training for complex and tedious procedures such as infant intubation, microsurgery, and combat trauma training, which are integral to training for medical personnel.
- The Live Animal Use in Medical Education and Training working group, co-chaired by representatives from USD(AT&L) and ASD(HA), brings together subject matter experts from the Services, Joint Staff, United States Special Operations Command, and Uniformed Services University of Health Sciences to identify ways to refine, reduce, or replace the use of live animals in medical training.
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(b)(6)

Subject: Re: Live Tissue Training ltr from Chairman Thornberry

Start: Mon 1/5/2015 8:30 PM

End: Mon 1/5/2015 9:30 PM

Recurrence: (none)

Meeting Status: Accepted

Organizer:

(b)(6)

It was signed by Ms. Wright on friday and was to be signed today by Mr. Kendall. I haven't heard for sure that it made today's suspense with his signature. I'll check first thing in the morning. New congress tomorrow?

(b)(6)

From: James, Jeanette <Jeanette.James@mail.house.gov>
Sent: Thursday, May 01, 2014 9:30 AM
To: (b)(6)
Subject: RE: Live Tissue Training

Thanks. What's the answer to me second question?

-----Original Message-----

From: (b)(6)
Sent: Thursday, May 01, 2014 9:07 AM
To: James, Jeanette
Subject: RE: Live Tissue Training

Jeanette,

The University no longer uses live animals for medical education. They have a robust, and growing, simulation program.

(b)(6)

-----Original Message-----

From: James, Jeanette [mailto:Jeanette.James@mail.house.gov]
Sent: Wednesday, April 30, 2014 1:27 PM
To: (b)(6)
Subject: Live Tissue Training

Folks,

I need a quick turn on this ask. Has USUHS totally abandoned any live tissue training? If so, how is it they can accomplish the necessary skill training that the services can't for their combat medics?

Thanks,

Jeanette

(b)(6)

Subject: LTT Meeting with HASC Staff
Location: Room 2216 Rayburn (2nd floor).

Start: Tue 2/25/2014 2:00 PM
End: Tue 2/25/2014 3:00 PM

Recurrence: (none)

Meeting Status: Meeting organizer

Organizer:
Required Attendees:
Optional Attendees:

(b)(6)

Added location.

 All,
 Please forward invite to your briefers.

 Sounds good.

Tom

Dr. Thomas R. Nelson
 Congressional Fellow
 Committee on Armed Services
 U.S. House of Representatives
 202-225-6703

-----Original Message-----

From: (b)(6)
 Sent: Friday, February 07, 2014 4:31 PM
 To: Nelson, Thomas
 Subject: RE: Update on LTT policy & strategy (HASC) CANCELLED!!

Afternoon of 25th is good, say 2:00pm?

(b)(6)

-----Original Message-----

From: Nelson, Thomas [mailto:Thomas.Nelson@mail.house.gov]

Sent: Friday, February 07, 2014 2:23 PM

To: (b)(6)

Subject: RE: Update on LTT policy & strategy (HASC) CANCELLED!!

(b)(6)

It looks like for the most part, our calendars are pretty full until the week of the 24th. It looks right now like we could do something in the afternoon of the 25th, 26th or 28th of February. Let me know how that looks on your end.

Tom

Dr. Thomas R. Nelson
Congressional Fellow
Committee on Armed Services
U.S. House of Representatives
202-225-6703

-----Original Message-----

From: (b)(6)

Sent: Friday, February 07, 2014 2:18 PM

To: Nelson, Thomas

Subject: FW: Update on LTT policy & strategy (HASC) CANCELLED!!

Dr. Nelson,

Can you propose a few dates times over the next few weeks?

(b)(6)

-----Original Message-----

From: Nelson, Thomas [mailto:Thomas.Nelson@mail.house.gov]

Sent: Monday, January 06, 2014 3:58 PM

To: (b)(6)

Subject: Update

(b)(6)

(b)(6)

(b)(6)

and I are interested in getting an update on the current policy and strategy for live tissue training for medical training. I'm not sure who the right person is to ask for. I know that used to be (b)(6) but she's moved on. I

have in one of your old emails that it was (b)(6) Is that still the case? We were hoping sometime in the next few weeks or so would be good to have the discussion. Can we set something up?

Thanks

Tom

Dr. Thomas R. Nelson

Congressional Fellow

Committee on Armed Services

U.S. House of Representatives

202-225-6703



RESEARCH
AND ENGINEERING

ASSISTANT SECRETARY OF DEFENSE

3030 DEFENSE PENTAGON
WASHINGTON, DC 20301-3030

ACTION MEMO

FOR: UNDER SECRETARY OF DEFENSE (ACQUISITION, TECHNOLOGY AND LOGISTICS)

FROM: Alan R. Shaffer, Principal Deputy, Assistant Secretary of Defense (Research and Engineering)

SUBJECT: Response to Senator Wyden and Representative Johnson Regarding the Use of Animals in Combat Trauma Training Programs

- Senator Wyden and Representative Johnson wrote to Secretary Carter regarding their reintroduction of the Battlefield Excellence for Superior Training (BEST) Practices Act and to urge the DoD to take steps to eliminate the use of animals in combat trauma training programs (TAB B).
- The letters at TAB A are the responses to communicate the negative impact the BEST Practices Act would have on trauma training programs as the Department continues its efforts to reduce and replace animals with validated alternatives.

RECOMMENDATION: Sign the letters at TAB A.

COORDINATION: TAB C

Attachments:
As Stated



RESEARCH
AND ENGINEERING

ASSISTANT SECRETARY OF DEFENSE

3030 DEFENSE PENTAGON
WASHINGTON, DC 20301-3030

ACTION MEMO

FOR: PRINCIPAL DEPUTY, ASSISTANT SECRETARY OF DEFENSE (RESEARCH AND ENGINEERING)

FROM: Mr. Dale Ormond, Acting, Principal Deputy, Research

SUBJECT: Response to Senator Wyden and Representative Johnson Regarding the Use of Animals in Combat Trauma Training Programs

- Senator Wyden and Representative Johnson wrote to Secretary Carter regarding their reintroduction of the Battlefield Excellence for Superior Training (BEST) Practices Act and to urge the DoD to take steps to eliminate the use of animals in combat trauma training programs (TAB B).
- The letters at TAB A are the responses to communicate the negative impact the BEST Practices Act would have on trauma training programs as the Department continues its efforts to reduce and replace animals with validated alternatives.

RECOMMENDATION: Submit for Mr. Kendall's signature.

Approve:_____ Disapprove:_____

COORDINATION: TAB C

Attachments:
As Stated

The Department of Defense (DoD) objects to the proposed language. Without scientific-based evidence demonstrating the efficacy of training simulators, removing the animal model from the training of DoD medical personnel could degrade combat trauma care on the battlefield. Imposing a deadline of October 1, 2020, to end the use of animals will not advance the knowledge or the material solutions to transition to human-based training techniques any faster than the Department's current research and development efforts and could result in decreasing combat survival rates.

The DoD is committed to replacing animal-based training techniques without adversely affecting the quality of care for injured Service members and, as noted in the language of S.587, has made strides in doing so. The DoD's internal working groups, partnerships with industry and academia, and interactions with international allies continuously improves our knowledge and development of training systems appropriate to the DoD's operational environment.

The primary impact of S.587 would be on combat medic training. The medic is the first responder who provides treatment at the point of wounding. Combat trauma training in the DoD has unique characteristics compared to the training of civilian medical providers. New DoD medics are generally less than 20 years of age and within a short time period must learn and perform complex combat trauma care procedures in chaotic and hostile battlefield environments in which they will not have access to well-equipped surgical suites and highly-trained healthcare professionals.

Simulation technology is currently not feasible, nor has it been validated, for the training of some combat trauma procedures. Limitations of simulation systems include changes in tissue dynamics over time following the onset of injury (e.g., amputation management) and the ability to invoke the response to save the life of an injured patient. Simulation systems are also limited in that they model a known set of injuries. However, injury patterns and the corresponding training vary with the operational environment and anticipated evacuation times. The DoD must maintain the capability of training medical personnel to respond to those threats faced by our Service members.

Although survival in combat is multi-factorial, the experience and confidence gained by the use of the animal model in teaching life-saving procedures has contributed to increased battlefield survival rates. The DoD remains on the path towards replacement of animal models without compromising the quality of medical training.

Ran Wyden

AMENDMENT NO. _____ Calendar No. _____

Purpose: To require the Secretary of Defense to use only human-based methods for training members of the Armed Forces in the treatment of severe combat injuries.

IN THE SENATE OF THE UNITED STATES—114th Cong., 1st Sess.

H. R. 1735

To authorize appropriations for fiscal year 2016 for military personnel, for military personnel of the Department of Defense, and for other purposes.

AMENDMENT N^o 1531

By Wyden

To: Amst No 1463

7
Page(s)

GPC: 2014 91-623 (mnc)

WYDEN

Viz:

1 At the end of part II of subtitle D of title V, add
2 the following:

3 **SEC. 540. REQUIREMENT TO USE HUMAN-BASED METHODS**
4 **FOR CERTAIN MEDICAL TRAINING.**

5 (a) FINDINGS.—Congress makes the following find-
6 ings:

7 (1) The Department of Defense has made im-
8 pressive strides in the development and use of meth-
9 ods of medical training and troop protection, such as

1 the use of tourniquets and improvements in body
2 armor, that have led to decreased battlefield fatali-
3 ties.

4 (2) The Department of Defense uses more than
5 8,500 live animals each year to train physicians,
6 medics, corpsmen, and other personnel methods of
7 responding to severe battlefield injuries.

8 (3) The civilian sector has almost exclusively
9 phased in the use of superior human-based training
10 methods for numerous medical procedures currently
11 taught in military courses using animals.

12 (4) Human-based medical training methods
13 such as simulators replicate human anatomy and
14 can allow for repetitive practice and data collection.

15 (5) According to scientific, peer-reviewed lit-
16 erature, medical simulation increases patient safety
17 and decreases errors by healthcare providers.

18 (6) The Army Research, Development and En-
19 gineering Command and other entities of the De-
20 partment of Defense have taken significant steps to
21 develop methods to replace live animal-based train-
22 ing.

23 (7) According to the report by the Department
24 of Defense titled "Final Report on the use of Live

1 Animals in Medical Education and Training Joint
2 Analysis Team”, published on July 12, 2009—

3 (A) validated, high-fidelity simulators were
4 to have been available for nearly every high-vol-
5 ume or high-value battlefield medical procedure
6 by the end of 2011, and many were available as
7 of 2009; and

8 (B) validated, high-fidelity simulators were
9 to have been available to teach all other proce-
10 dures to respond to common battlefield injuries
11 by 2014.

12 (8) The Center for Sustainment of Trauma and
13 Readiness Skills of the Air Force exclusively uses
14 human-based training methods in its courses and
15 does not use animals.

16 (9) In 2013, the Army instituted a policy for-
17 bidding non-medical personnel from participating in
18 training courses involving the use of animals.

19 (10) In 2013, the medical school of the Depart-
20 ment of Defense, part of the Uniformed Services
21 University of the Health Sciences, replaced animal
22 use within its medical student curriculum.

23 (11) The Coast Guard announced in 2014 that
24 it would reduce by half the number of animals it
25 uses for combat trauma training courses but stated

1 that animals would continue to be used in courses
2 designed for Department of Defense personnel.

3 (12) Effective January 1, 2015, the Depart-
4 ment of Defense replaced animal use in six areas of
5 medical training, including Advanced Trauma Life
6 Support courses and the development and mainte-
7 nance of surgical and critical care skills for field
8 operational surgery and field assessment and skills
9 tests for international students offered at the De-
10 fense Institute of Medical Operations.

11 (b) REQUIREMENT TO USE HUMAN-BASED METHODS
12 FOR CERTAIN MEDICAL TRAINING.—

13 (1) IN GENERAL.—Chapter 101 of title 10,
14 United States Code, is amended by adding at the
15 end the following new section:

16 **“§2017. Use of human-based methods for certain**
17 **medical training**

18 “(a) COMBAT TRAUMA INJURIES.—(1) Not later
19 than October 1, 2018, the Secretary of Defense shall de-
20 velop, test, and validate human-based training methods for
21 the purpose of training members of the armed forces in
22 the treatment of combat trauma injuries with the goal of
23 replacing live animal-based training methods.

24 “(2) Not later than October 1, 2020, the Secretary—

1 “(A) shall only use human-based training meth-
2 ods for the purpose of training members of the
3 armed forces in the treatment of combat trauma in-
4 juries; and

5 “(B) may not use animals for such purpose.

6 “(b) EXCEPTION FOR PARTICULAR COMMANDS AND
7 TRAINING METHODS.—(1) The Secretary may exempt a
8 particular command, particular training method, or both,
9 from the requirement for human-based training methods
10 under subsection (a)(2) if the Secretary determines that
11 human-based training methods will not provide an educa-
12 tionally equivalent or superior substitute for live animal-
13 based training methods for such command or training
14 method, as the case may be.

15 “(2) Any exemption under this subsection shall be for
16 such period, not more than one year, as the Secretary shall
17 specify in granting the exemption. Any exemption may be
18 renewed (subject to the preceding sentence).

19 “(c) ANNUAL REPORTS.—(1) Not later than October
20 1, 2016, and each year thereafter, the Secretary shall sub-
21 mit to the congressional defense committees a report on
22 the development and implementation of human-based
23 training methods for the purpose of training members of
24 the armed forces in the treatment of combat trauma inju-
25 ries under this section.

1 “(2) Each report under this subsection on or after
2 October 1, 2020, shall include a description of any exemp-
3 tion under subsection (b) that is in force as the time of
4 such report, and a current justification for such exemp-
5 tion.

6 “(d) DEFINITIONS.—In this section:

7 “(1) The term ‘combat trauma injuries’ means
8 severe injuries likely to occur during combat, includ-
9 ing—

10 “(A) hemorrhage;

11 “(B) tension pneumothorax;

12 “(C) amputation resulting from blast in-
13 jury;

14 “(D) compromises to the airway; and

15 “(E) other injuries.

16 “(2) The term ‘human-based training methods’
17 means, with respect to training individuals in med-
18 ical treatment, the use of systems and devices that
19 do not use animals, including—

20 “(A) simulators;

21 “(B) partial task trainers;

22 “(C) moulage;

23 “(D) simulated combat environments;

24 “(E) human cadavers; and

1 “(F) rotations in civilian and military trau-
2 ma centers.

3 “(3) The term ‘partial task trainers’ means
4 training aids that allow individuals to learn or prac-
5 tice specific medical procedures.”.

6 (2) CLERICAL AMENDMENT.—The table of sec-
7 tions at the beginning of chapter 101 of such title
8 is amended by adding at the end the following new
9 item:

“2017. Use of human-based methods for certain medical training.”.

114TH CONGRESS
1ST SESSION

H. R. 1095

To amend title 10, United States Code, to require the Secretary of Defense to use only human-based methods for training members of the Armed Forces in the treatment of severe combat injuries.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 26, 2015

Mr. JOHNSON of Georgia (for himself, Mr. CARSON of Indiana, Mr. POLIS, Mr. HIMES, Mr. HONDA, Mr. GRIJALVA, Mr. CARTWRIGHT, Ms. LEE, Ms. DELAURO, Mr. RANGEL, Mr. COHEN, Ms. CLARKE of New York, Mr. GUTIÉRREZ, Mr. CLAY, Mr. LOWENTHAL, Mr. MCGOVERN, Mr. TONKO, Mr. FITZPATRICK, Ms. SLAUGHTER, Ms. SCHAKOWSKY, Mr. CONNOLLY, Mr. BLUMENAUER, Mr. CONYERS, Ms. LOFGREN, Ms. BROWN of Florida, Ms. NORTON, and Mrs. CAROLYN B. MALONEY of New York) introduced the following bill; which was referred to the Committee on Armed Services

A BILL

To amend title 10, United States Code, to require the Secretary of Defense to use only human-based methods for training members of the Armed Forces in the treatment of severe combat injuries.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Battlefield Excellence
3 through Superior Training Practices Act” or “BEST
4 Practices Act”.

5 **SEC. 2. FINDINGS.**

6 Congress makes the following findings:

7 (1) The Department of Defense has made im-
8 pressive strides in the development and use of meth-
9 ods of medical training and troop protection, such as
10 the use of tourniquets and improvements in body
11 armor, that have led to decreased battlefield fatali-
12 ties.

13 (2) The Department of Defense uses more than
14 8,500 live animals each year to train physicians,
15 medics, corpsmen, and other personnel methods of
16 responding to severe battlefield injuries.

17 (3) The civilian sector has almost exclusively
18 phased in the use of superior human-based training
19 methods for numerous medical procedures currently
20 taught in military courses using animals.

21 (4) Human-based medical training methods
22 such as simulators replicate human anatomy and
23 can allow for repetitive practice and data collection.

24 (5) According to scientific, peer-reviewed lit-
25 erature, medical simulation increases patient safety
26 and decreases errors by healthcare providers.

1 (6) The Army Research, Development and En-
2 gineering Command and other entities of the De-
3 partment of Defense have taken significant steps to
4 develop methods to replace live animal-based train-
5 ing.

6 (7) According to the report by the Department
7 of Defense titled “Final Report on the use of Live
8 Animals in Medical Education and Training Joint
9 Analysis Team”, published on July 12, 2009—

10 (A) validated, high-fidelity simulators were
11 to have been available for nearly every high-vol-
12 ume or high-value battlefield medical procedure
13 by the end of 2011, and many were available as
14 of 2009; and

15 (B) validated, high-fidelity simulators were
16 to have been available to teach all other proce-
17 dures to respond to common battlefield injuries
18 by 2014.

19 (8) The Center for Sustainment of Trauma and
20 Readiness Skills of the Air Force exclusively uses
21 human-based training methods in its courses and
22 does not use animals.

23 (9) In 2013, the Army instituted a policy for-
24 bidding non-medical personnel from participating in
25 training courses involving the use of animals.

1 (10) In 2013, the medical school of the Depart-
2 ment of Defense, part of the Uniformed Services
3 University of the Health Sciences, replaced animal
4 use within its medical student curriculum.

5 (11) The Coast Guard announced in 2014 that
6 it would reduce by half the number of animals it
7 uses for combat trauma training courses but stated
8 that animals would continue to be used in courses
9 designed for Department of Defense personnel.

10 (12) Effective January 1, 2015, the Depart-
11 ment of Defense replaced animal use in six areas of
12 medical training, including Advanced Trauma Life
13 Support courses and the development and mainte-
14 nance of surgical and critical care skills for field
15 operational surgery and field assessment and skills
16 tests for international students offered at the De-
17 fense Institute of Medical Operations.

18 **SEC. 3. REQUIREMENT TO USE HUMAN-BASED METHODS**
19 **FOR CERTAIN MEDICAL TRAINING.**

20 (a) IN GENERAL.—Chapter 101 of title 10, United
21 States Code, is amended by adding at the end the fol-
22 lowing new section:

1 **“§ 2017. Requirement to use human-based methods**
2 **for certain medical training**

3 “(a) COMBAT TRAUMA INJURIES.—(1) Not later
4 than October 1, 2018, the Secretary of Defense shall de-
5 velop, test, and validate human-based training methods for
6 the purpose of training members of the armed forces in
7 the treatment of combat trauma injuries with the goal of
8 replacing live animal-based training methods.

9 “(2) Not later than October 1, 2020, the Secretary—
10 “(A) shall only use human-based training meth-
11 ods for the purpose of training members of the
12 armed forces in the treatment of combat trauma in-
13 juries; and

14 “(B) may not use animals for such purpose.

15 “(b) ANNUAL REPORTS.—Not later than October 1,
16 2016, and each year thereafter, the Secretary shall submit
17 to the congressional defense committees a report on the
18 development and implementation of human-based training
19 methods for the purpose of training members of the armed
20 forces in the treatment of combat trauma injuries under
21 this section.

22 “(c) DEFINITIONS.—In this section:

23 “(1) The term ‘combat trauma injuries’ means
24 severe injuries likely to occur during combat, includ-
25 ing—

26 “(A) hemorrhage;

1 “(B) tension pneumothorax;

2 “(C) amputation resulting from blast in-

3 jury;

4 “(D) compromises to the airway; and

5 “(E) other injuries.

6 “(2) The term ‘human-based training methods’

7 means, with respect to training individuals in med-

8 ical treatment, the use of systems and devices that

9 do not use animals, including—

10 “(A) simulators;

11 “(B) partial task trainers;

12 “(C) moulage;

13 “(D) simulated combat environments;

14 “(E) human cadavers; and

15 “(F) rotations in civilian and military trau-

16 ma centers.

17 “(3) The term ‘partial task trainers’ means

18 training aids that allow individuals to learn or prac-

19 tice specific medical procedures.”.

20 (b) CLERICAL AMENDMENT.—The table of sections

21 at the beginning of chapter 101 of title 10, United States

22 Code, is amended by adding at the end the following new

23 item:

“2017. Requirement to use human-based methods for certain medical training.”.



114TH CONGRESS
1ST SESSION

S. 587

To amend title 10, United States Code, to require the Secretary of Defense to use only human-based methods for training members of the Armed Forces in the treatment of severe combat injuries, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 26, 2015

Mr. WYDEN (for himself and Mr. PETERS) introduced the following bill; which was read twice and referred to the Committee on Armed Services

A BILL

To amend title 10, United States Code, to require the Secretary of Defense to use only human-based methods for training members of the Armed Forces in the treatment of severe combat injuries, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

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5 through Superior Training Practices Act” or “BEST
6 Practices Act”.

7 **SEC. 2. FINDINGS.**

8 Congress makes the following findings:

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2 pressive strides in the development and use of meth-
3 ods of medical training and troop protection, such as
4 the use of tourniquets and improvements in body
5 armor, that have led to decreased battlefield fatali-
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8 8,500 live animals each year to train physicians,
9 medics, corpsmen, and other personnel methods of
10 responding to severe battlefield injuries.

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12 phased in the use of superior human-based training
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16 such as simulators replicate human anatomy and
17 can allow for repetitive practice and data collection.

18 (5) According to scientific, peer-reviewed lit-
19 erature, medical simulation increases patient safety
20 and decreases errors by healthcare providers.

21 (6) The Army Research, Development and En-
22 gineering Command and other entities of the De-
23 partment of Defense have taken significant steps to
24 develop methods to replace live animal-based train-
25 ing.

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2 of Defense titled “Final Report on the use of Live
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4 Analysis Team”, published on July 12, 2009—

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15 Readiness Skills of the Air Force exclusively uses
16 human-based training methods in its courses and
17 does not use animals.

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19 bidding non-medical personnel from participating in
20 training courses involving the use of animals.

21 (10) In 2013, the medical school of the Depart-
22 ment of Defense, part of the Uniformed Services
23 University of the Health Sciences, replaced animal
24 use within its medical student curriculum.

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2 it would reduce by half the number of animals it
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4 that animals would continue to be used in courses
5 designed for Department of Defense personnel.

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7 ment of Defense replaced animal use in six areas of
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9 Support courses and the development and mainte-
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11 operational surgery and field assessment and skills
12 tests for international students offered at the De-
13 fense Institute of Medical Operations.

14 **SEC. 3. REQUIREMENT TO USE HUMAN-BASED METHODS**
15 **FOR CERTAIN MEDICAL TRAINING.**

16 (a) IN GENERAL.—Chapter 101 of title 10, United
17 States Code, is amended by adding at the end the fol-
18 lowing new section:

19 **“§ 2017. Use of human-based methods for certain**
20 **medical training**

21 “(a) COMBAT TRAUMA INJURIES.—(1) Not later
22 than October 1, 2018, the Secretary of Defense shall de-
23 velop, test, and validate human-based training methods for
24 the purpose of training members of the Armed Forces in

1 the treatment of combat trauma injuries with the goal of
2 replacing live animal-based training methods.

3 “(2) Not later than October 1, 2020, the Secretary—

4 “(A) shall only use human-based training meth-
5 ods for the purpose of training members of the
6 Armed Forces in the treatment of combat trauma
7 injuries; and

8 “(B) may not use animals for such purpose.

9 “(b) EXCEPTION FOR PARTICULAR COMMANDS AND
10 TRAINING METHODS.—(1) The Secretary may exempt a
11 particular command, particular training method, or both,
12 from the requirement for human-based training methods
13 under subsection (a)(2) if the Secretary determines that
14 human-based training methods will not provide an educa-
15 tionally equivalent or superior substitute for live animal-
16 based training methods for such command or training
17 method, as the case may be.

18 “(2) Any exemption under this subsection shall be for
19 such period, not more than one year, as the Secretary shall
20 specify in granting the exemption. Any exemption may be
21 renewed (subject to the preceding sentence).

22 “(c) ANNUAL REPORTS.—(1) Not later than October
23 1, 2016, and each year thereafter, the Secretary shall sub-
24 mit to the congressional defense committees a report on
25 the development and implementation of human-based

1 training methods for the purpose of training members of
 2 the Armed Forces in the treatment of combat trauma inju-
 3 ries under this section.

4 “(2) Each report under this subsection on or after
 5 October 1, 2020, shall include a description of any exemp-
 6 tion under subsection (b) that is in force as the time of
 7 such report, and a current justification for such exemp-
 8 tion.

9 “(d) DEFINITIONS.—In this section:

10 “(1) The term ‘combat trauma injuries’ means
 11 severe injuries likely to occur during combat, includ-
 12 ing—

13 “(A) hemorrhage;

14 “(B) tension pneumothorax;

15 “(C) amputation resulting from blast in-
 16 jury;

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 20 means, with respect to training individuals in med-
 21 ical treatment, the use of systems and devices that
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23 “(A) simulators;

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25 “(C) moulage;

1 “(D) simulated combat environments;
2 “(E) human cadavers; and
3 “(F) rotations in civilian and military trauma
4 centers.

5 “(3) The term ‘partial task trainers’ means
6 training aids that allow individuals to learn or practice
7 specific medical procedures.”.

8 (b) CLERICAL AMENDMENT.—The table of sections
9 at the beginning of chapter 101 of such title is amended
10 by adding at the end the following new item:

 “2017. Use of human-based methods for certain medical training.”.



The Department of Defense (DoD) objects to the proposed language. Without scientific-based evidence demonstrating the efficacy of training simulators, removing the animal model from the training of DoD medical personnel could degrade combat trauma care on the battlefield. Imposing a deadline of October 1, 2020, to end the use of animals will not advance the knowledge or the material solutions to transition to human-based training techniques any faster than the Department's current research and development efforts and could result in decreasing combat survival rates.

The DoD is committed to replacing animal-based training techniques without adversely affecting the quality of care for injured Service members and, as noted in the language of S.1376, has made strides in doing so. The DoD's internal working groups, partnerships with industry and academia, and interactions with international allies continuously improves our knowledge and development of training systems appropriate to the DoD's operational environment.

The primary impact of S.1376 would be on combat medic training. The medic is the first responder who provides treatment at the point of wounding. Combat trauma training in the DoD has unique characteristics compared to the training of civilian medical providers. New DoD medics are generally less than 20 years of age and within a short time period must learn and perform complex combat trauma care procedures in chaotic and hostile battlefield environments in which they will not have access to well-equipped surgical suites and highly-trained healthcare professionals.

Simulation technology is currently not feasible, nor has it been validated, for the training of some combat trauma procedures. Limitations of simulation systems include changes in tissue dynamics over time following the onset of injury (e.g., amputation management) and the ability to invoke the response to save the life of an injured patient. Simulation systems are also limited in that they model a known set of injuries. However, injury patterns and the corresponding training vary with the operational environment and anticipated evacuation times. The DoD must maintain the capability of training medical personnel to respond to those threats faced by our Service members.

Although survival in combat is multi-factorial, the experience and confidence gained by the use of the animal model in teaching life-saving procedures has contributed to increased battlefield survival rates. The DoD remains on the path towards replacement of animal models without compromising the quality of medical training.

From: (b)(6)
 To: (b)(6)
 Cc: (b)(6)
 Subject: RE: DoD views on S. 587
 Date: Monday, April 18, 2016 4:27:20 PM

Thanks (b)(6)

(b)(6)

-----Original Message-----

From: (b)(6)
 Sent: Monday, April 18, 2016 3:07 PM
 To: (b)(6) Mason, Patrick A SES OSD OUSD ATL (US)
 Cc: (b)(6)
 Subject: RE: DoD views on S. 587

Good afternoon (b)(6)

The informal view remains the same. Updates are not needed.

v/r,

(b)(6)

(b)(6)

<http://www.acq.osd.mil/rd/hptb/index.html>

-----Original Message-----

From: (b)(6)
 Sent: Friday, April 15, 2016 9:53 AM
 To: (b)(6); Mason, Patrick A SES OSD OUSD ATL (US)
 Cc: Miller, Mary J SES (US); Flagg, Melissa L SES OSD OUSD ATL (US); Ormond, Dale A SES OSD OUSD ATL (US); (b)(6) Nievesortiz, Angel L COL USARMY OSD OUSD ATL (US); Welby, Stephen P HON OSD OUSD ATL (US)
 Subject: FW: DoD views on S. 587

Hi (b)(6)

Sen Booker's office has a constituent that will be visiting his office to discuss S. 587 the BEST Practices Act.

Below is last year's position paper on the BEST Act. Is this still current that can be shared with the Senator's office or should it be updated. Updates are needed by Monday, April 18th.

Thanks

(b)(6)

The Department of Defense (DoD) objects to the proposed language. Without scientific-based evidence demonstrating the efficacy of training simulators, removing the animal model from the training of DoD medical personnel could degrade combat trauma care on the battlefield. Imposing a deadline of October 1, 2020, to end the use of animals will not advance the knowledge or the material solutions to transition to human-based training techniques any faster than the Department's current research and development efforts and could result in decreasing combat survival rates.

The DoD is committed to replacing animal-based training techniques without adversely affecting the quality of care for injured Service members and, as noted in the language of S.587, has made strides in doing so. The DoD's internal working groups, partnerships with industry and academia, and interactions with international allies continuously improves our knowledge and development of training systems appropriate to the DoD's operational environment.

The primary impact of S.587 would be on combat medic training. The medic is the first responder who provides treatment at the point of wounding. Combat trauma training in the DoD has unique characteristics compared to the training of civilian medical providers. New DoD medics are generally less than 20 years of age and within a short time period must learn and perform complex combat trauma care procedures in chaotic and hostile battlefield environments in which they will not have access to well-equipped surgical suites and highly-trained healthcare professionals.

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-----Original Message-----

From: (b)(6)
Sent: Friday, April 15, 2016 9:46 AM
To: (b)(6)
Subject: FW: DoD views on S. 587

Can you see if this is still current?

Thanks,

(b)(6)

(b)(6)

(b)(6)

-----Original Message-----

From: Stella, Michael J SES OSD OASD LA (US)

Sent: Thursday, April 14, 2016 2:45 PM

To: (b)(6)

(US)

Cc: Vitali, Michael R CAPT USN OSD OASD LA (US)

Subject: FW: DoD views on S. 587

Gents,

See request below for views on S. 587. The attached is a view we submitted to SASC last year on the bill. Is this still the current position? Does it need to be updated? Note that Booker's office needs something by April 21.

Thanks,

(b)(6)

-----Original Message-----

From: Rodriguez, John (Booker) [mailto:John_Rodriguez@booker.senate.gov]

Sent: Thursday, April 14, 2016 2:36 PM

To: Stella, Michael J SES OSD OASD LA (US)

Cc: (b)(6)

Subject: [Non-DoD Source] DoD views on S. 587

(b)(6)

Just wanted some clarification as to DoD's opinion of S. 587 the BEST Practices Act. The House Companion bill is H.R. 1095. I am cc'ing our defense LA Sophia Lalani. As I mentioned on the phone we have some constituents coming in on April 21st to discuss this bill and in their emails they have said that DoD is supportive of this measure. Just wanted to confirm that.

Thanks

John

John Rodriguez

Legislative Correspondent | Foreign Policy and Defense U.S. Senator Cory A. Booker (NJ) | 202.224.3224

Congress of the United States

Washington, DC 20510

March 2, 2015

The Honorable Ashton B. Carter
Secretary of Defense
1000 Defense Pentagon
Washington, DC, 20301-1000

Dear Secretary Carter:

First, congratulations on your recent confirmation to serve as the nation's 25th Secretary of Defense. The overwhelming and bipartisan nature of the vote is a testament to your long and distinguished career and the esteem in which you are held.

We are writing today to commend the Department of Defense (DoD) on the steps it has taken to replace the use of live animals for medical training with more advanced training methods and to urge the DoD to take similar steps to modernize combat trauma training.

We welcomed last year's news that the DoD required the replacement of live animal use in six areas of military medical training effective January 1, 2015. This follows a 2013 decision by the DoD medical school that trains new military physicians to replace live animal use in its student curriculum. Taken together, these steps bring the military more in line with the civilian sector, which has overwhelmingly phased out the use of live animals for medical training.

While we commend these steps in the right direction, we were disappointed to see that a May 2014 memo from the Assistant Secretary of Defense for Health Affairs did not address combat trauma training, the largest area of medically unnecessary live animal use. Each year, more than 8,500 goats and pigs are used in combat trauma training courses conducted for U.S. military personnel. We have serious reservations about the killing and maiming of these live animals, particularly when civilian medical centers have all but eliminated this practice and when medical professionals tell us that modern simulations and technology meet or exceed medical training requirements.

The DoD already invests in simulators and owns many, including those that replicate the experience of performing emergency medical procedures – like applying tourniquets and managing collapsed lungs – on a living trauma patient. We know you believe that our military personnel should be taught using the most sophisticated methods, and in that spirit, we urge you to continue transitioning away from the use of live animals in medical training including combat trauma training. We have also reintroduced our bipartisan,



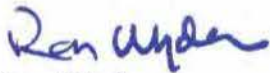
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bicameral legislation, the Battlefield Excellence through Superior Training (BEST) Practices Act, to help DoD make this transition.

Thank you for your service to our country. We look forward to timely response to this letter and your plan for continuing the DoD's transition from the use of live animals in combat trauma training.

Sincerely,



Ron Wyden
United States Senator



Henry C. "Hank" Johnson
Member of Congress

CC: Dr. Jonathan Woodson, Assistant Secretary of Defense for Health Affairs



ACQUISITION,
TECHNOLOGY
AND LOGISTICS

THE UNDER SECRETARY OF DEFENSE

3010 DEFENSE PENTAGON
WASHINGTON, DC 20301-3010

The Honorable Henry C. Johnson
U.S. House of Representatives
Washington, DC 20515

MAR 26 2015

Dear Representative Johnson:

Thank you for your March 2, 2015, letter to the Secretary of Defense regarding the Department of Defense's (DoD) use of animals in combat trauma training. I am responding on behalf of Secretary Carter.

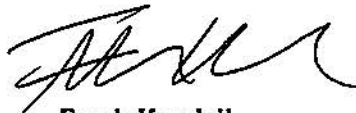
The type and complexity of combat trauma wounds experienced today are far more severe than in previous conflicts or as seen in civilian medical centers. While the severity of injury of U.S. Service members in Afghanistan increased from 2005 to 2013, the case fatality rate decreased during that time period (Rasmussen *et al.*, 75:2013, *J. Trauma and Acute Care Surgery*). Although survival in combat is multifactorial, prematurely changing the Department's training practices could result in increased Service member fatalities. As you indicated in your letter, the Department already invests in and owns many simulators for combat casualty training. The Department integrates these simulators and other educational tools such as lectures, video demonstrations, and role play in realistic scenarios to prepare medical providers, from medic to doctor, to care for the combat-wounded. There are, however, gaps between the skills that can be gained using current simulation systems and the proficiency and confidence that translates to performance and resilience on the battlefield. In some DoD programs, animal models fill this gap and are used to prepare medical providers to save the lives of Service members.

Combat trauma training has unique characteristics compared to the training of civilian medical providers. The combat medic is the first responder who provides treatment at the point of wounding. New combat medics are generally less than 20 years of age and, within a short time period, must learn and perform complex combat trauma procedures in chaotic and hostile environments, caring for their patients while awaiting evacuation to well-equipped surgical suites and advanced providers. This is a very stressful environment. Through interactions with medical training subject matter experts in the Department and academia, we have learned that optimal combat trauma training requires the trainees to engage in the experience as though they were on the actual battlefield. To improve the training experience, DoD research and development efforts have focused on training methodologies, synthetic tissues, 3-D printing technologies, high-fidelity task trainers and manikins based on human physiology, and virtual training platforms. These investments have led to training systems with improved realism and reduced our need for animal models; however, without scientific-based evidence demonstrating the efficacy of alternatives, the animal model remains a valuable component of combat trauma training.

The Department of Defense shares your goal of replacing animal models with alternative training solutions. The Department's research and development efforts, working groups focused on alternative training solutions, and interactions with industry, academia, and international partners ensure that we remain on the path to replacement of animal models as quickly as possible without compromising the quality of training. If you would like additional information on the Department's efforts, we will provide a comprehensive briefing on the strategy to reduce and replace the use of animal models in the Department's medical training programs.

An identical letter has been sent to Senator Wyden.

Sincerely,

A handwritten signature in black ink, appearing to read 'Frank Kendall', with a stylized, cursive script.

Frank Kendall



ACQUISITION,
TECHNOLOGY
AND LOGISTICS

THE UNDER SECRETARY OF DEFENSE

3010 DEFENSE PENTAGON
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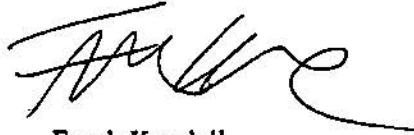
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Frank Kendall

(b)(5)

(b)(5)