

**Questions for the Record**  
**Hearing on Pending Health and Benefits Legislation**  
**Veterans Affairs Committee**  
**United States Senate**  
**May 17, 2017**

**From Senator Bill Cassidy**

In your prepared remarks, you note that the Veterans Administration would like to require the use of ISBT-128 for all biological implants. However, I have several concerns with this position, as noted below. Could you address these in turn?

- 1. The VA defines biological implants to include xenografts (animal-derived grafts) and not just those products of human origin. ISBT-128 (International Standard for Blood and Transplantation) is only suitable for products of human origin. How do you intend to track xenografts that are biological implants? What system will you use for those?**

Response: The VA does not intend to use ISBT-128 for all biological implants. Only those implants of human origin would be required to have a distinct identifier such as provided by ISBT-128. Currently, ISBT-128 is the only available identifier for this purpose. VA would accept a distinct identifier for HCT/P (Human Cell and Tissue Products) from any Food and Drug Administration (FDA) approved source. VA's system will be robust enough to track any biologic implant including both allografts and xenografts. ISBT-128 will only be used for products of human origin. Non-human products will be able to use GS1 (Global Standard One), HIBCC (Health Industry Business Communications Council) or other FDA UDI (Universal Device Identifiers) as appropriate.

- 2. My understanding is that there are only 20 tissue processors within the U.S. that produce Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P's) regulated as devices. According to a recent survey, of those 20, only 2 currently use ISBT-128. Have you checked with your vendors to ensure that you could have access to HCT/Ps if you move forward with your proposal to limit your issuing agency only to ISBT-128?**

Response: VA has checked with its human tissue contractors and has been assured that they can provide ISBT-128 labeled tissue. Those who currently do not use ISBT-128, have indicated that they will be able to do so within a year if requested, at a minimal cost. As a result, VA intends to allow for up to a year for a vendor to come into compliance when it negotiates its contracts if they are not already using ISBT-128. It should be emphasized that a distinct identifier like ISBT-128 is essential to prevent the entry of prohibited tissue sources into the VA supply chain. It allows for the readily auditable trail necessary to ensure that only properly sourced tissue is in use by VA; the underlying intent expressed in the legislation.

While mechanical implants are regulated differently than human or animal derived implants, they could use the same tracking system for blood and biologics. A common

system would also be useful with the emergence of composite devices which combine both mechanical and biologic components.

- 3. Obviously, track and trace efforts should be improved for all implants — not just biological ones. What efforts are you doing to maintain traceability in those areas? My understanding is that the vast majority of medical device companies within the U.S. are opting to use GS1 (barcodes) for labeling their devices. Does the VA have a process for utilizing GS1?**

Response: VA does not have a process for utilizing GS1 at this time. Prosthetic & Sensory Aid Services is currently serving as a member of a VA cross-functional workgroup led by the Office of Strategic Integration (OSI) Veterans Engineering Resource Center (VERC) for implant tracking. This workgroup will identify and develop processes and process requirements that will meet all requirements established by FDA, The Joint Commission, and Congress for the tracking of implantable devices by September 30, 2017.

**SENATOR MAZIE K. HIRONO**

**QUESTIONS FOR THE RECORD  
FOR WITNESS PANEL**

**SENATE VETERANS' AFFAIRS COMMITTEE  
HEARING ON PENDING LEGISLATION (May 17, 2017)**

**Questions for Jennifer S. Lee (VA Deputy Under Secretary)**

***S. 899 VA Veteran Transition Improvement Act***

4. Deputy Under Secretary Lee, could you comment on the VA's current policies related to paid medical leave for your disabled veteran employees and how S.899 would improve on that?

**Response:** Current disabled Veteran employees employed in the Veterans Health Administration (VHA) may request and use leave for medical purposes in accordance with established agency leave procedures. The proposal would require VA to establish a leave transfer program for the benefit of health care professionals appointed under 38 U.S.C. § 7401(1) and authorize the establishment of a leave bank program for the benefit of such health care providers. Inclusion of this provision would ensure that disabled Veteran employees performing health care services in Title 38 occupations have the same opportunity to schedule medical appointments and receive medical care related to their disability without being charged leave as employees in Title 5 and Hybrid Title 38 occupations.

According to January 2017 data from the VA, there are over 13,000 Title 38 critical medical vacancies in the positions not currently subject to the Wounded Warrior Federal Leave Act (these are physicians, physician assistants, registered nurses, chiropractors, podiatrists, optometrists, dentists, and expanded – function dental auxiliaries).

5. Does VA have a goal to hire veterans for these positions and if so, could you comment on the impact of the additional paid medical leave provided in S.899 on efforts hire disabled veterans?

**Response:** VHA continues to encourage the hiring of Veterans for healthcare occupations, as well as other administrative, technical, professional, and clerical occupations. When filling Title 38 positions, VHA also needs to ensure the best qualified individuals are hired to meet the health care needs of our Veteran patients, as well as support our health care mission. The proposed legislation may assist in the hiring of Veterans for Title 38 occupations. Extending the current provisions of 5 United States Code (USC) section 6329, Disabled Veteran Leave, to Title 38 employees appointed under 38 USC § 7401(1) would provide an opportunity for our disabled Veteran employees performing health care services in Title 38 occupations to have the same opportunity to schedule medical appointments and receive medical care related to their disability without being charged leave as employees in Title 5 and Hybrid Title 38

occupations. This will provide disabled Veteran employees an opportunity to undergo medical treatments for their disabilities without having to consider their leave balances or work-life issues to obtain such services outside of scheduled work hours. Although the disabled Veteran employees would be eligible for paid medical leave, the proposal is considered cost neutral as it will not increase VHA full-time employee equivalent levels or salaries of the employees.

### ***S.1094, Department of Veterans Affairs Accountability and Whistleblower Protection Act of 2017***

We all agree that more can be done to increase accountability for those at the VA who have betrayed the trust they have been given to serve our nation's veterans.

While there are some good provisions in S. 1094, I am deeply concerned on the implications of the bill's provision lowering the evidentiary standard for misconduct removals from a "preponderance of the evidence" standard (meaning more than 50% of the evidence) to a "substantial evidence" standard (meaning the agency only needs, among other things, more than a "mere scintilla of the evidence") as the Supreme Court defined in its 1971 decision in *Richardson v. Perales*. This new standard would mean that even when the majority of the evidence supports the employee, he/she will lose.

6. Deputy Under Secretary Lee, can you explain how the VA can ensure due process for its employees under this bill when it says if the majority of the evidence supports the employee, he/she will lose?

**Response:** Employees at VA are entitled to constitutional due process and will continue to be entitled to constitutional due process even if S. 1094 is enacted into law. A change to the burden of proof from preponderant evidence to substantial evidence does not change an employee's right to constitutional due process.

At its simplest, constitutional due process requires that an individual receive notice of an action affecting the individual's interests and a reasonable opportunity to contest that action. Sometimes the notice and opportunity to contest must precede the action (pre-deprivation); sometimes it may come after (post-deprivation), in the form of a post-decisional appeal, whether to a third-party forum like the Merit Systems Protection Board (MSPB) or to the courts. Under S. 1094, this constitutional due process will not be adversely impacted. Under S. 1094, employees will continue to receive notice of a proposed disciplinary action, the ability to respond before a decision is made, and the ability to go to the MSPB or a court.

With regard to the burden of proof, a substantial evidence standard does not mean that an employee will lose, even if the majority of the evidence supports them. The MSPB defines "substantial evidence," the standard proposed under S. 1094, as the "degree of relevant evidence that a reasonable person, considering the record as a whole, might accept as adequate to support a conclusion, even though other reasonable persons might disagree." 5 C.F.R. § 1201.4(p). Substantial evidence is "a lower standard of proof than preponderance of the evidence." *Id.*

The MSPB's definition of "substantial evidence" is echoed in *Richardson v. Perales*, a case that pertains to a social security disability claim rather than the Federal civil service. *Richardson v. Perales*, 402 U.S. 389, 401 (1971) citing *Consol. Edison Co. v. Nat'l Labor Relations Bd.*, 305 U.S. 197, 229 (1938) (substantial evidence is "more than a mere scintilla [of evidence and it] means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion"). But, the MSPB further explains that, in the Federal civil service context, substantial evidence "obliges the presiding official to determine only whether, in light of the relevant and credible evidence[,] a reasonable person could agree with the agency's decision (even though other reasonable persons including the presiding official might disagree with that decision). *Parker v. Def. Logistics Agency*, 1 M.S.P.R. 505, 531 (M.S.P.B. 1980).

The MSPB currently uses the substantial evidence standard to adjudicate agency actions taken based on performance. See 5 U.S.C. § 7701(c)(1); 5 C.F.R. § 1201.56(b)(1)(i). Even with this lower burden of proof, there are numerous cases where the MSPB and its reviewing court have determined that the agency failed to meet this lower burden of proof. See, e.g., *Parkinson v. Dep't of Justice*, 815 F.3d 757, 766 (Fed. Cir. 2016); *Thompson v. Dep't of the Army*, 122 M.S.P.R. 372, 381-82 (M.S.P.B. 2015); *Smith v. Dep't of Veterans Affairs*, 59 M.S.P.R. 340, 342-43 (M.S.P.B. 1993); *Cranwill v. Dep't of Veterans Affairs*, 52 M.S.P.R. 610, 616 (M.S.P.B. 1992). Consequently, it is doubtful that, even with a lower evidentiary burden, the MSPB would always agree with an action taken by VA or that, even if the majority of the evidence supports an employee, he or she will not succeed in a disciplinary appeal before the MSPB.