Thank you for considering our views on this bill.

Sincerely,

MARILYN PARK,
Legislative Representative.

Mr. TAKANO. Mr. Speaker, I share these concerns and intend to work with my colleagues across the aisle and in the Senate to ensure that if this bill passes into law, the change will not adversely impact whistleblowers, the thousands of veterans employed by the VA, and the VA employees who work hard every day to support the needs of our Nation's veterans.

Whistleblowers and employees who face unlawful retaliation from managers should have the opportunity to clear their names before any proposed admonishments or reprimands are made permanent in their records. I also want to clarify that this bill should not be used to eliminate the VA's ability to enter into clear record settlement agreements with employees or get in the way of resolving personnel matters in an efficient manner.

In our efforts to enhance personnel policies at the VA, it is important that we remember that one-third of VA employees are veterans themselves, and many more have immediate family members who are veterans. Many of these employees are also hardworking doctors and nurses who want to provide quality care for their patients. These Federal civil servants want to do a good job in order to provide veterans the best possible service, and this bill should not be used by managers to intimidate or retaliate against these employees.

This bill simply requires VA to maintain a complete record of a VA employee's personnel file, a practice intended to increase transparency and ultimately improve outcomes for veterans.

Mr. Speaker, I reserve the balance of my time.

Mr. ROE of Tennessee. Mr. Speaker, I yield 3 minutes to the gentleman from Pennsylvania (Mr. COSTELLO), a very active member of the Committee on Veterans' Affairs and my good friend.

Mr. COSTELLO of Pennsylvania. Mr. Speaker, as we all are well aware, today begins a new session of Congress, with a new opportunity to chart a promising path for the future direction of our country.

While many Americans across the country remain very frustrated with what they feel is a giant, unresponsive bureaucracy that is not working for them, all Americans want to see VA care and services implemented properly.

Last session, Mr. Speaker, this Congress did make some reasonable progress legislatively to bring about reforming the VA, but more needs to be done. Some of our legislation which passed the House died in the Senate.

The bill I introduced and rise in support of today, the Ensuring VA Employee Accountability Act, is important for the following reasons: the bill requires the Department of Veterans Affairs to maintain an up-to-date file of employee disciplinary actions throughout each employee's tenure at the VA.

Under current VA policy, disciplinary actions remain in an employee's file for only 3 years before they are deleted, preventing poor performers within the VA from being tracked or held accountable over the long term. This bill will ensure a complete record is kept and evaluated when a VA employee is considered for bonuses, promotions, or other career advancement.

I also want to be clear about this. This bill is fair to all VA employees, and a great many VA employees do very, very good work in caring for our veterans. This bill does not impose any new employee penalties or affect the existing due process rights for a VA employee to appeal a disciplinary action in any manner whatsoever.

The goal is simply to ensure our veterans are receiving the best possible care from our government and that these employees who do wrong or perform poorly do not have it swept under the rug and then disappear after a few years.

I thank the staff on the Committee on Veterans' Affairs for their work on this bill, especially Jon Clark and Kelsey Baron, and look forward to the leadership of Chairman ROE in this session of Congress.

Mr. Speaker, I urge my colleagues to support this bill.

Mr. TAKANO. Mr. Speaker, I have no further speakers.

I yield back the balance of my time.

Mr. ROE of Tennessee. Mr. Speaker, once again, I encourage all Members to support this legislation.

I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Tennessee (Mr. ROE) that the House suspend the rules and pass the bill, H.R. 27.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill was passed.

A motion to reconsider was laid on the table.

BIOLOGICAL IMPLANT TRACKING AND VETERAN SAFETY ACT OF 2017

Mr. ROE of Tennessee. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 28) to amend title 38, United States Code, to direct the Secretary of Veterans Affairs to adopt and implement a standard identification protocol for use in the tracking and procurement of biological implants by the Department of Veterans Affairs, and for other purposes.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 28

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Biological Implant Tracking and Veteran Safety Act of 2017''.

SEC. 2. IDENTIFICATION AND TRACKING OF BIOLOGICAL IMPLANTS USED IN DEPARTMENT OF VETERANS AFFAIRS MEDICAL FACILITIES.

(a) IN GENERAL.—Subchapter II of chapter 73 of title 38, United States Code, is amended by adding at the end the following new section:

''§ 7330C. Identification and tracking of biological implants

''(a) STANDARD IDENTIFICATION SYSTEM FOR BIOLOGICAL IMPLANTS.—(1) The Secretary shall adopt the unique device identification system developed for medical devices by the Food and Drug Administration under section 519(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(f)), or implement a comparable standard identification system, for use in identifying biological implants intended for use in medical procedures conducted in medical facilities of the Department.

''(2) In adopting or implementing a standard identification system for biological implants under paragraph (1), the Secretary shall permit a vendor to use any of the accredited entities identified by the Food and Drug Administration as an issuing agency pursuant to section 830.100 of title 21, Code of Federal Regulations, or any successor regulation.

''(b) BIOLOGICAL IMPLANT TRACKING SYSTEM.—(1) The Secretary shall implement a system for tracking the biological implants described in subsection (a) from human donor or animal source to implantation.

''(2) The tracking system implemented under paragraph (1) shall be compatible with the identification system adopted or implemented under subsection (a).

''(3) The Secretary shall implement inventory controls compatible with the tracking system implemented under paragraph (1) so that all patients who have received, in a medical facility of the Department, a biological implant subject to a recall can be notified of the recall if, based on the evaluation by appropriate medical personnel of the Department of the risks and benefits, the Secretary determines such notification is appropriate.

''(c) CONSISTENCY WITH FOOD AND DRUG ADMINISTRATION REGULATIONS.—To the extent that a conflict arises between this section and a provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or section 351 or 361 of the Public Health Service Act (42 U.S.C. 262 and 264) (including any regulations issued under such provisions), the provision of the Federal Food, Drug, and Cosmetic Act or Public Health Service Act (including any regulations issued under such provisions) shall apply.

''(d) BIOLOGICAL IMPLANT DEFINED.—In this section, the term 'biological implant' means any human cell, tissue, or cellular or tissue-based product or animal product—

''(1) under the meaning given the term 'human cells, tissues, or cellular or tissue-based products' in section 1271.3 of title 21, Code of Federal Regulations, or any successor regulation; or

''(2) that is regulated as a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).''.

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of such chapter is amended by inserting after the item relating to section 7330B the following new item:

''7330C. Identification and tracking of biological implants.''.

(c) IMPLEMENTATION DEADLINES.—

(1) STANDARD IDENTIFICATION SYSTEM.—The Secretary of Veterans Affairs shall adopt or

implement the standard identification system for biological implants required by subsection (a) of section 7330C of title 38, United States Code, as added by subsection (a), with respect to biological implants described in—

(A) subsection (d)(1) of such section, by not later than the date that is 180 days after the date of the enactment of this Act; and

(B) subsection (d)(2) of such section, in compliance with the compliance dates established by the Food and Drug Administration under section 519(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(f)).

(2) TRACKING SYSTEM.—The Secretary of Veterans Affairs shall implement the biological implant tracking system required by section 7330C(b) of title 38, United States Code, as added by subsection (a), by not later than the date that is 180 days after the date of the enactment of this Act.

(d) REPORTING REQUIREMENT.—

(1) IN GENERAL.—If the biological implant tracking system required by section 7330C(b) of title 38, United States Code, as added by subsection (a), is not operational by the date that is 180 days after the date of the enactment of this Act, the Secretary of Veterans Affairs shall submit to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives a report explaining why the system is not operational for each month until such time as the system is operational.

(2) ELEMENTS.—Each report submitted under paragraph (1) shall include a description of the following:

(A) Each impediment to the implementation of the system described in such paragraph.

(B) Steps being taken to remediate each such impediment.

(C) Target dates for a solution to each such impediment.

SEC. 3. PROCUREMENT OF BIOLOGICAL IMPLANTS USED IN DEPARTMENT OF VETERANS AFFAIRS MEDICAL FACILITIES.

(a) PROCUREMENT.—

(1) IN GENERAL.—Subchapter II of chapter 81 of title 38, United States Code, is amended by adding at the end the following new section:

"§ 8129. Procurement of biological implants

''(a) IN GENERAL.—(1) The Secretary may procure biological implants of human origin only from vendors that meet the following conditions:

''(A) The vendor uses the standard identification system adopted or implemented by the Secretary under section 7330C(a) of this title and has safeguards to ensure that a distinct identifier has been in place at each step of distribution of each biological implant from its donor.

''(B) The vendor is registered as required by the Food and Drug Administration under subpart B of part 1271 of title 21, Code of Federal Regulations, or any successor regulation, and in the case of a vendor that uses a tissue distribution intermediary or a tissue processor, the vendor provides assurances that the tissue distribution intermediary or tissue processor is registered as required by the Food and Drug Administration.

''(C) The vendor ensures that donor eligibility determinations and such other records as the Secretary may require accompany each biological implant at all times, regardless of the country of origin of the donor of the biological material.

''(D) The vendor agrees to cooperate with all biological implant recalls conducted on the initiative of the vendor, on the initiative of the original product manufacturer used by the vendor, by the request of the Food and Drug Administration, or by a statutory order of the Food and Drug Administration.

''(E) The vendor agrees to notify the Secretary of any adverse event or reaction report it provides to the Food and Drug Administration, as required by sections 1271.3 and 1271.350 of title 21, Code of Federal Regulations, or any successor regulation, or any warning letter from the Food and Drug Administration issued to the vendor or a tissue processor or tissue distribution intermediary used by the vendor by not later than 60 days after the vendor receives such report or warning letter.

''(F) The vendor agrees to retain all records associated with the procurement of a biological implant by the Department for at least 10 years after the date of the procurement of the biological implant.

''(G) The vendor provides assurances that the biological implants provided by the vendor are acquired only from tissue processors that maintain active accreditation with the American Association of Tissue Banks or a similar national accreditation specific to biological implants.

''(2) The Secretary may procure biological implants of nonhuman origin only from vendors that meet the following conditions:

''(A) The vendor uses the standard identification system adopted or implemented by the Secretary under section 7330C(a) of this title.

''(B) The vendor is registered as an establishment as required by the Food and Drug Administration under sections 807.20 and 807.40 of title 21, Code of Federal Regulations, or any successor regulation (or is not required to register pursuant to section 807.65(a) of such title, or any successor regulation), and in the case of a vendor that is not the original product manufacturer of such implants, the vendor provides assurances that the original product manufacturer is registered as required by the Food and Drug Administration (or is not required to register).

''(C) The vendor agrees to cooperate with all biological implant recalls conducted on the initiative of the vendor, on the initiative of the original product manufacturer used by the vendor, by the request of the Food and Drug Administration, or by a statutory order of the Food and Drug Administration.

''(D) The vendor agrees to notify the Secretary of any adverse event report it provides to the Food and Drug Administration as required under part 803 of title 21, Code of Federal Regulations, or any successor regulation, or any warning letter from the Food and Drug Administration issued to the vendor or the original product manufacturer used by the vendor by not later than 60 days after the vendor receives such report or warning letter.

''(E) The vendor agrees to retain all records associated with the procurement of a biological implant by the Department for at least 10 years after the date of the procurement of the biological implant.

''(3)(A) The Secretary shall procure biological implants under the Federal Supply Schedules of the General Services Administration unless such implants are not available under such Schedules.

''(B) With respect to biological implants listed on the Federal Supply Schedules, the Secretary shall accommodate reasonable vendor requests to undertake outreach efforts to educate medical professionals of the Department about the use and efficacy of such biological implants.

''(C) In the case of biological implants that are unavailable for procurement under the Federal Supply Schedules, the Secretary shall procure such implants using competitive procedures in accordance with applicable law and the Federal Acquisition Regulation, including through the use of a national contract.

''(4) In procuring biological implants under this section, the Secretary shall permit a vendor to use any of the accredited entities identified by the Food and Drug Administration as an issuing agency pursuant to section 830.100 of title 21, Code of Federal Regulations, or any successor regulation.

''(5) Section 8123 of this title shall not apply to the procurement of biological implants.

''(b) PENALTIES.—In addition to any applicable penalty under any other provision of law, any procurement employee of the Department who is found responsible for a biological implant procurement transaction with intent to avoid or with reckless disregard of the requirements of this section shall be ineligible to hold a certificate of appointment as a contracting officer or to serve as the representative of an ordering officer, contracting officer, or purchase card holder.

''(c) DEFINITIONS.—In this section:

''(1) The term 'biological implant' has the meaning given that term in section 7330C(d) of this title.

''(2) The term 'distinct identifier' means a distinct identification code that—

''(A) relates a biological implant to the human donor of the implant and to all records pertaining to the implant;

''(B) includes information designed to facilitate effective tracking, using the distinct identification code, from the donor to the recipient and from the recipient to the donor; and

''(C) satisfies the requirements of section 1271.290(c) of title 21, Code of Federal Regulations, or any successor regulation.

''(3) The term 'tissue distribution intermediary' means an agency that acquires and stores human tissue for further distribution and performs no other tissue banking functions.

''(4) The term 'tissue processor' means an entity processing human tissue for use in biological implants, including activities performed on tissue other than donor screening, donor testing, tissue recovery and collection functions, storage, or distribution.''.

(2) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 81 is amended by inserting after the item relating to section 8128 the following new item:

''8129. Procurement of biological implants.''.

(b) EFFECTIVE DATE.—Section 8129 of title 38, United States Code, as added by subsection (a), shall take effect on the date that is 180 days after the date on which the tracking system required under section 7330C(b) of such title, as added by section 2(a), is implemented.

(c) SPECIAL RULE FOR CRYOPRESERVED PRODUCTS.—During the three-year period beginning on the effective date of section 8129 of title 38, United States Code, as added by subsection (a), biological implants produced and labeled before that effective date may be procured by the Department of Veterans Affairs without relabeling under the standard identification system adopted or implemented under section 7330C of such title, as added by section 2(a).

SEC. 4. FUNDING.

No additional funds are authorized to carry out the requirements of this Act and the amendments made by this Act. Such requirements shall be carried out using amounts otherwise authorized.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Tennessee (Mr. ROE) and the gentleman from California (Mr. TAKANO) each will control 20 minutes.

The Chair recognizes the gentleman from Tennessee.

GENERAL LEAVE

Mr. ROE of Tennessee. Mr. Speaker, I ask unanimous consent that all Members have 5 legislative days in which to revise and extend their remarks.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Tennessee?

There was no objection.

Mr. ROE of Tennessee. I yield myself such time as I may consume.

Mr. Speaker, I rise today in support of my bill, H.R. 28, the Biological Implant Tracking and Veteran Safety Act of 2017.

Two years ago this month, the Government Accountability Office, GAO, released a startling report detailing a failure on the part of the Department of Veterans Affairs to follow requirements for documenting open-market purchases of surgical implants and the lack of a standardized process for tracking biological tissue from cadaver donors to living veteran recipients.

Currently, there is no requirement for VA to systematically identify or track biological implants used in the VA medical facilities. Due to this oversight, if a given biological implant was identified as potentially contaminated or made the subject of a recall, it would be impossible for VA to identify which patients receive the impacted material and, therefore, take steps to inform at-risk patients and address contamination concerns.

That same GAO report also found that VA did not consistently ensure that the vendors that the Department purchases biological implants from are registered with the Food and Drug Administration, and that VA did not maintain an inventory system to prevent expired tissues from remaining in storage alongside unexpired tissues. Needless to say, each of these findings poses a serious and unacceptable risk to veterans' health and safety.

Veterans seeking care through the VA healthcare system deserve a quality standard that is second to none, especially within a system which prides itself on data collection and its electronic health record. The Biological Implant Tracking and Veteran Safety Act would provide a high-quality standard for surgical implants that is now sorely missing.

By requiring VA to implement a standard identification tracking system for biological implants used in the VA medical facilities and requiring VA to procure biological implants only from approved vendors, H.R. 28 would address the deficiencies GAO identified and provide VA a necessary tool to ensure accountability and patient safety. Mr. Speaker, I would say the VA just should do this for quality of care for patients.

I urge all of my colleagues to join me in supporting this important legislation.

Mr. Speaker, I reserve the balance of my time.

Mr. TAKANO. Mr. Speaker, I yield myself such time as I may consume.

I rise today in support of the Biological Implant Tracking and Veteran Safety Act. This bill will require the VA to implement a standard identification system for biological implants that is consistent with the Food and Drug Administration's unique device identification system. This system will allow for the tracking of implants from donor to recipients. This bill will also require VA to procure biological implants only from vendors using the system and only through competitive procurement processes.

The GAO has testified that the Veterans Health Administration is one of the largest purchasers of surgical implants, which include biological implants such as skin and bone grafts, and nonbiological implants such as cardiac pacemakers and artificial joints. The GAO has raised valid concerns regarding VA medical centers complying with VHA requirements for documenting surgical implants purchased from the open market and VHA's ability to identify veterans who received an implant that is being recalled by the manufacturer or the Food and Drug Administration.

Patient safety is our number one concern. We all want to ensure that VA policies are fully followed in this regard. The legislation will continue to protect veterans while they receive the best care available.

Mr. Speaker, before I close, I would like to extend my public congratulations to my good friend, Dr. PHIL ROE, for being named by the majority as the chairman of the Committee on Veterans' Affairs. I can tell you that Members on my side of the aisle are looking very much forward to working with Dr. ROE. He has a splendid reputation.

I don't want to ruin his reputation by saying that we absolutely embrace him because that would make his side of the aisle, I think, a little worried, but the fact is we believe that Chairman ROE is someone that we can work with and who has a genuine, sincere concern for veterans. He is a veteran himself. He is a medical doctor. As we try to gain the trust of veterans and gain the trust of Americans in VA health care and the veterans department, we are very much looking forward to working with him. I offer him my congratulations.

Mr. Speaker, I yield back the balance of my time.

□ 1800

Mr. ROE of Tennessee. Mr. Speaker, I appreciate those kind words. Certainly, Mr. Speaker, this particular committee is a bipartisan committee. For the veterans out there who are watching this and for the American citizens who are watching this, this is truly a committee where we check our political affiliations at the door and try to do what is right and best for America's heroes. I am not talking about the committee, but I am saying in the country that has not always been done. I am a Vietnam-era veteran, and that wasn't done for my generation to begin with.

There is a real commitment on both sides of the aisle, the staffs of both committees and the members of both committees. I am excited to get to work with my friend, Mr. TAKANO. We have been to Afghanistan together and gotten to know each other very well and worked on many issues together. I look forward to doing this. I appreciate his kind comments and also his support for this bill.

Mr. Speaker, I encourage all Members to support this legislation.

I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Tennessee (Mr. ROE) that the House suspend the rules and pass the bill, H.R. 28.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill was passed.

A motion to reconsider was laid on the table.

APPOINTMENT OF MEMBER TO THE JOINT ECONOMIC COMMITTEE

The SPEAKER pro tempore. The Chair announces the Speaker's appointment, pursuant to 15 U.S.C. 1024(a), and the order of the House of today, of the following Member on the part of the House to the Joint Economic Committee:

Mr. TIBERI, Ohio

APPOINTMENT OF MEMBER TO THE PERMANENT SELECT COMMITTEE ON INTELLIGENCE

The SPEAKER pro tempore. The Chair announces the Speaker's appointment, pursuant to clause 11 of rule X, clause 11 of rule I, and the order of the House of today, of the following Member to the Permanent Select Committee on Intelligence:

Mr. NUNES, California, Chairman

APPOINTMENT—HOUSE OFFICE BUILDING COMMISSION

The SPEAKER pro tempore. The Chair announces the Speaker's appointment, pursuant to 2 U.S.C. 2001, and the order of the House of today, of the gentleman from California (Mr. MCCARTHY) and the gentlewoman from California (Ms. PELOSI) as Members of the House Office Building Commission to serve with the Speaker.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. The Chair announces that the Speaker has delivered to the Clerk a letter dated January 3, 2017, listing Members in the order in which each shall act as Speaker pro tempore under clause 8(b)(3) of rule I.