



PERSONNEL AND
READINESS

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

JAN 13 2023

Chair
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Chair:

The Department's response to House Report 117-118, page 169, accompanying H.R. 4350, the National Defense Authorization Act for Fiscal Year 2022, "Adverse Events Resulting from the Use of Dietary Supplements," which recommends that the Secretary of Defense develop a strategy for including adverse events resulting from the use of dietary supplements within military electronic health records and requests a report to the congressional defense committees on adverse events resulting from the use of dietary supplements, is enclosed.

The report includes a review of the Department of Defense (DoD) systems for health surveillance and detection to ensure situational awareness and provide early warning, and identification of activities to limit adverse events resulting from the use of dietary supplements among members of the Armed Forces and beneficiaries under TRICARE. The DoD is committed to ongoing processes to improve prevention of adverse events resulting from the use of dietary supplements and will continue to focus on supplement identification, education, prevention of adverse events resulting from dietary supplements, and documentation.

Thank you for your continued strong support for our Service members, veterans, and their families. I am sending similar letters to the other congressional defense committees.

Sincerely,

A handwritten signature in black ink, appearing to read "Gilbert R. Cisneros, Jr.", written in a cursive style.

Gilbert R. Cisneros, Jr.

Enclosure:
As stated

cc:
Ranking Member



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Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

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United States Senate
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REPORT TO THE CONGRESSIONAL DEFENSE COMMITTEES



Adverse Events Resulting from the Use of Dietary Supplements

January 2023

The estimated cost of this report or study for the Department of Defense is approximately \$9,220 for the 2022 Fiscal Year. This includes \$25 in expenses and \$9,190 in DoD labor.

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1.0 Purpose

This report is in response to House Report 117–118, page 169, accompanying H.R. 4350, the National Defense Authorization Act for Fiscal Year 2022. This report discusses adverse events resulting from the use of dietary supplements.

2.0 Background

The Department of Defense (DoD) and the Food and Drug Administration (FDA) began collaborating on a nationwide reporting system in 2017. The FDA introduced a revised Center for Food Safety and Applied Nutrition Adverse Event Reporting System (CAERS). CAERS tracks and maintains voluntary and mandatory post-market products complaint reports submitted to FDA for foods, dietary supplements, and cosmetics. FDA staff who oversee the Public Reporting Portal participate in an ongoing process review with the DoD Nutrition Committee, DoD Operation Supplement Safety (OPSS), Dietary Supplements and Other Self-Care Products Subcommittee (DSSC).

Monthly meetings are planned between DoD and FDA for discussion of trending topics.

2.1 Summary of Current Policy

2.1.1 DoD Nutrition Committee

To address policy recommendations for monitoring adverse events resulting from the use of dietary supplements, Department of Defense Instruction (DoDI) 6130.05, “DoD Nutrition Committee,” was originally published in February 2011 and updated in February 2020. The policy established the DoD Nutrition Committee, which is chaired by the Assistant Secretary of Defense for Health Affairs (ASD(HA)). The committee functions as a central oversight body for the DoD and makes decisions regarding overall nutrition based on scientific evidence and proven best practices. It provides guidance and advice from subject matter experts to address issues related to nutrition, health promotion, combat feeding and military food service. The committee reports its findings to the Combat Feeding Research and Engineering Board and the Combat Feeding Program. The chair approves the appointment of the chairs of subcommittees. This policy states that the DoD will:

- a. Provide appropriate nutrition for the Military Services;
- b. Provide appropriate dietary supplements to Service members where indicated;
- c. Provide education and training to Service members to ensure that they are able to make healthy lifestyle choices regarding nutrition and dietary supplements and so achieve and maintain performance and health;
- d. Appoint DoD Nutrition committee and subcommittee members who are full-time or permanent part-time employees of the Federal Government.

The DoDI also assigns responsibility to the Secretaries of the Military Departments to provide military-specific education and training to Service members on the use of and potential harm

from dietary supplements, taking into consideration relevant recommendations of the DoD Nutrition Committee.

2.1.2 Dietary Supplements and Other Self-Care Products Subcommittee

Within the policy, subcommittee operations are delineated and the DSSC is designated as a standing subcommittee to make policy recommendations to the Military Services and other DoD beneficiary groups regarding the use of dietary supplements, where indicated. Other areas for consideration included, but are not limited to:

- a. Dietary supplement education.
- b. Military-specific research.
- c. Adverse events resulting from the use of dietary supplements.
- d. Human performance optimization.
- e. Military Service special operations.
- f. Identification of research gaps and requirements.
- g. Identification of opportunities for resource sharing and cost containment among the Military Services.

The subcommittee completes an annual plan with stated goals and objectives and submits it for approval of the DoD Nutrition Committee. The intent of DSSC is to provide recommendations on doctrine changes and training materials and provide analysis and recommendations on material solutions. The DSSC brings subject matter experts together to discuss issues related to safety investigations wherein dietary supplements may have been involved and providing input to the DoD leadership on military policies in matters addressing the safety and efficacy of dietary supplements. The DSSC provides the DoD Nutrition Committee with a comprehensive integrated joint overview of how dietary supplements are impacting force readiness. Attention to these issues is essential to force health protection because some products may compromise readiness and others may sustain or enhance performance and promote health.

2.1.3 Use of Dietary Supplements in the DoD

Most recently, DoDI 6130.06, "Use of Dietary Supplements in the DoD," was published March 9, 2022. This DoDI establishes policy, assigns responsibilities, and provides procedures for dietary supplement education and use throughout the DoD. The DoDI also formally recognizes the DoD OPSS Program. It establishes policy, assigns responsibilities, and prescribes procedures for administering the OPSS Program and the OPSS Advisory Board.

More specifically, the policy requires mandatory dietary supplement education for all Service members and those who provide health-related services as well as health care providers, including DoD military, civilian, and contract personnel. The policy also requires the Department to establish, host and maintain an OPSS website to provide a list of dietary supplement ingredients prohibited by the DoD (referred to as the DoD Prohibited Dietary Supplement Ingredients List), which will be updated whenever a FDA action occurs, or as new scientific information emerges. Service members are prohibited from using products on the DoD Prohibited Dietary Supplements Ingredients list unless a waiver is requested by a DoD health

care provider. Additionally, within the DoD, contract, appropriated, non-appropriated, and retail facilities (commissary, exchanges) will not sell products containing ingredients on the DoD Prohibited Dietary Supplement Ingredients List on the OPSS website.

2.1.4 Operation Supplement Safety and Advisory Board

The Under Secretary of Defense for Personnel and Readiness established OPSS as a program of the Consortium for Health and Military Performance (CHAMP) at the Uniformed Services University of the Health Sciences (USU).

In support of Total Force Fitness, CHAMP, in collaboration with the OPSS:

- a. Recommends policy and provides procedures for dietary supplement education and use throughout the DoD.
- b. Applies sound and scientific procedures for administering the DoD OPSS Program.
- c. Develops training and education materials with consistent messaging.
- d. Maintains a website capturing current dietary supplement information, resource materials, and updates to the prohibited dietary supplement ingredients list.
- e. Oversees the OPSS Advisory Board meetings and submits recommendations to ASD(HA) on new ingredients that should be added to the List of Dietary Supplement ingredients prohibited by the DoD.
- f. Refers requests for exceptions to the prohibited ingredients list to the DoD Nutrition Committee.
- g. Reviews and answers dietary supplement questions.
- h. Coordinates testing of dietary supplement products.
- i. Serves as advisor to Defense Health Agency (DHA) and Office of the Assistant Secretary of Defense for Health Affairs OASD(HA) on issues related to dietary supplements.

The OPSS Advisory Board, which consists of subject matter experts primarily of pharmaceutical backgrounds from across the Services, is convened quarterly or as needed. The purpose of the OPSS Advisory Board is to review and make recommendations for additions or deletions from the DoD Approved and Prohibited Ingredients Lists located on the OPSS website to OASD(HA), as well as to alert them of emerging issues.

The board is chaired by the Director for the Consortium for Health and Military Performance at USU, which executes OPSS. It consists of at least one subject matter expert at the GS-15 or O6 level from:

- a. U.S. Air Force, Pharmacy Head
- b. U.S. Army, Pharmacy Head
- c. U.S. Army Public Health Center
- d. U.S. Navy / Marine Corps, Pharmacy Head
- e. U.S. Navy Pharmacy Head
- f. U.S. Coast Guard, Pharmacy Head
- g. U.S. Space Force, Pharmacy Head
- h. Office of the Joint Staff Surgeon

- i. Geographic Combatant Commands
- j. DHA Food Safety
- k. DHA Director of Pharmacy
- l. Drug Demand Reduction Program Office
- m. Defense Logistics Agency, Director of Troop Support Medical Directorate
- n. U.S. Anti-Doping Agency
- o. Executive Director, CHAMP
- p. Director, National Institute of Health, Office of Dietary Supplements
- q. U.S. Army Medical Research and Development Command
- r. U.S. Special Operations Command

This board approves revisions and submits recommendations for the dietary supplement ingredients prohibited by the DoD when new scientific information emerges. Additionally, the board provides recommendations on the safety and efficacy of dietary supplements and advises on activities related to dietary supplements and other self-care products, including adverse events, surveillance, provider education and military and community consumer education. Together the OPSS and OPSS Advisory Board work to engage DoD dietary supplement stakeholders to identify, discuss, and resolve issues, and make recommendations to policy owners and appropriate governing bodies for new policies on dietary supplement and other self-care product policies, or changes to dietary supplement policies to support a healthy and fit force, human performance optimization, and healthy communities.

2.2 Reporting on Adverse Events Resulting from the Use of Dietary Supplements.

- Documenting and reporting adverse events resulting from the use of dietary supplements is available from a link on the OPSS website. The link directly opens a new window on the FDA web page's adverse event portal, "The Safety Reporting Portal."

3.0 Conclusion

DoDI 6130.06 explains the requirements for the documentation of dietary supplement use and adverse events in a medical history. Building on past adverse event reporting studies and applications, the DoD is looking to identify and address barriers for the future. DoD will continue:

- Executing an OPSS Advisory Board consisting of subject matter experts from across the Services to evaluate specific ingredients in dietary supplements and make recommendations to OASD(HA) for inclusion of the ingredients on the Dietary Supplements Prohibited Ingredients listed on the OPSS web site.
- Facilitating monthly Operations Supplement Safety meetings to discuss supplement use among use Service members, reviewing the DoD's prohibited supplement list, and making recommendations to the OPSS Advisory Board.
- Holding bi-annual meetings with the military retailers of dietary supplements to highlight updates to the DoD prohibited list.

- Collaborating with the DHA Clinical Communities Practice work group to identify Clinical Quality Management updates, training and education opportunities, Military Health System GENESIS updates, and other topical concerns with dietary supplements.

The DoD is committed to ongoing process improvement that results in improving prevention of adverse events resulting from the use of dietary supplements and safe supplement selection and use by Service members. Building on current momentum, the DoD will continue focusing on the three major sectors of the supplement use: (1) supplement identification; (2) supplement education; and (3) preventing adverse events resulting from the use of dietary supplements.