

Industry has learned that a dietary supplement-related amendment to the National Defense Authorization Act (NDAA) for Fiscal Year 2020 was accepted during the Senate Armed Services Committee mark-up of this bill. As is the practice of this Committee, the markup was closed to the public and the text of the bill and amendments are under a strict embargo until next week. This bill is the primary method of authorizing federal funding for the military for the next fiscal year and may be considered by the full Senate later this month. The House version of this bill may be considered in Armed Services Committee next week. Based on what we know today, we do not believe this issue will come up in the House bill. Industry associations will continue to monitor both the House and Senate situation on this issue.

In the past, Senator Richard Blumenthal (D-CT) has offered amendments in the Senate Armed Services Committee that relate to dietary supplements. It is likely that this year's amendment would be similar to one he offered four years ago. We understand this amendment would direct the military to create a system to record "the use of dietary supplements and adverse events" by all members of the U.S. Armed Forces, and would require the Department of Defense to document and communicate information of "adverse event report data regarding dietary supplement use" to the Food and Drug Administration (FDA). This amendment would require service men and women to report their dietary supplement use to their military healthcare providers—including multivitamins, minerals and energy-boosters—and that information would become part of their individual electronic health records and could be aggregated for further analysis. While industry is confident in our characterization of this amendment, we cannot be certain of the amendment text at this time.

We have several concerns based on what we know. First, consistent with our support of the current reporting system established by Congress and administered by FDA for serious adverse events associated with OTC products and dietary supplements, we would oppose any legislation that would conflict or interfere with current law. Second, when we have the opportunity to review the language, we would look to ensure that neither dietary supplements nor the military personnel who use them are treated differently than would be the case under the existing serious adverse event reporting system for any other product regulated by FDA. Third, while we have not heard what the policy rationale for this amendment is purported to be, we do have concerns that this proposal could actually discourage some military personnel from using beneficial dietary supplements or disclosing such use to their physician.

If the amendment is along the lines of what we describe above, then industry plans to oppose the provision. However, it is important to recognize this amendment is not a direct assault on the industry and over-reacting to it could simply rally the critics of the industry and undermine our objective to have it removed from the bill. We are working to ensure that nothing will undermine the existing AER system which industry supports, nor discourages individuals from the use of beneficial supplements, nor from alerting the FDA to AERs whenever they occur. In the past, the Department of Defense has expressed concerns about amendments of this nature and they may do so again.