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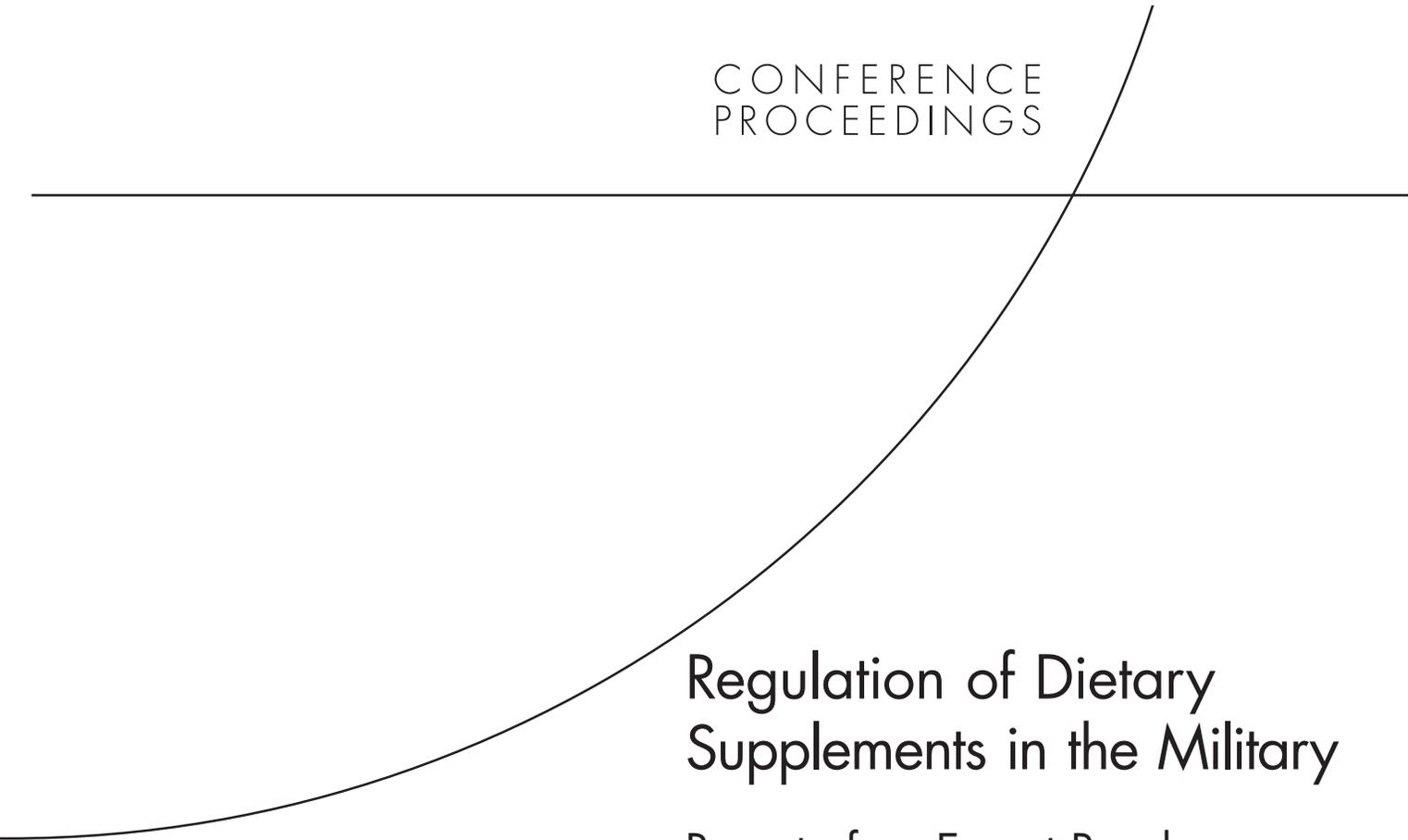
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PROCEEDINGS



Regulation of Dietary Supplements in the *Military*

Report of an Expert Panel

Ian D. Coulter, Sydne Newberry, Lara Hilton

Sponsored by the Samueli Institute



Center for Military Health Policy Research

A JOINT ENDEAVOR OF RAND HEALTH AND THE
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Preface

The U.S. military has had a longstanding interest in the potential for dietary supplements to enhance performance and optimize health, functions that it collectively refers to as “metabolic defense.” However, at the same time, the military is concerned about the potential for misuse of supplements. In 2008, at the request of the Samueli Institute, RAND Health conducted an informal one-day workshop on the use of dietary supplements for performance enhancement and on regulatory issues affecting dietary supplements. The workshop included a panel of experts who considered the following questions:

- What types of policies and regulations currently exist regarding the use of dietary supplements in civilian-sector groups, such as among athletes and those whose jobs demand high levels of physical or cognitive performance?
- What types of policies currently exist in the commercial domain around the point-of-sale for dietary supplements?
- What kind of regulations does the military currently have in place (with respect to the use and purchase of dietary supplements)?
- If it so chose, what could the military do to regulate the use of dietary supplements?

The purpose of this conference proceeding is to summarize the workshop that occurred on September 16, 2008.

The conference proceeding should be of interest to policymakers, human resources and health care personnel who care for individuals in physically or cognitively demanding jobs, and others interested in the use and regulation of use of dietary supplements.

This research was funded by the Samueli Institute and was undertaken within the RAND Center for Military Health Policy Research, a strategic initiative within RAND Health. Ian Coulter was the project leader. Comments and questions can be directed to him at Ian_Coulter@rand.org. Terri Tanielian and Sue Hosek serve as the codirectors of the Center for Military Health Policy Research. More information about RAND is available at www.rand.org/.

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¹ The panel was selected by an advisory committee comprising the following individuals: Ian Coulter, PhD, RAND Corporation (Chair); Rebecca Costello, PhD, National Institutes of Health Office of Dietary Supplements; Patricia Deuster, PhD, MPH, Uniformed Services University of the Health Sciences; Wayne Jonas, MD, Samueli Institute; Joan Walter, JD, Samueli Institute; Sydne Newberry, PhD, RAND; Lara Hilton, MPH, RAND; Andy Young, PhD, Chief, Military Nutrition Research, United States Army Research Institute for Environmental Medicine.

Contents

Preface	iii
Acknowledgments	vii
CHAPTER ONE	
Introduction and Background	1
Introduction	1
Background	2
The Panel	2
CHAPTER TWO	
Panel Discussion	5
What Are the Military’s Concerns Regarding the Use of Supplements?	5
Safety	5
Quality	5
Efficacy and Effectiveness	6
What Is the Prevalence of Supplement Use in the Military?	6
What Are the Current U.S. Military Regulations on Supplement Use and Sales?	7
Regulation of Use	7
Regulation of Supplement Sales	7
What Other Steps Could the Military Take to Regulate or Influence Use?	8
Other Suggestions	10
Provide Targeted Education	10
Conduct Surveillance	11
Other Questions Raised	11
CHAPTER THREE	
Conclusions and Recommendations	15

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Introduction and Background

Introduction

Dietary and nutritional supplements are widely used in the United States. Analysis of data from the 2000–2004 National Health and Nutrition Examination Survey reveals that 52 percent of civilian adults report using supplements.¹ Other recent surveys have shown that as many as seven out of ten Americans take some vitamin, mineral, or other dietary supplement.

For at least the past decade, the Department of Defense (DoD) has had concerns regarding the use of dietary supplements among military personnel and the safety and effectiveness of those supplements. Dietary supplement use among military personnel has been surveyed by several groups. Estimates of the prevalence of supplement use among service personnel vary. One survey showed that the prevalence of over-the-counter supplement use among military Special Forces units may exceed 85 percent.² A 2005 survey that attempted to reach a broad cross section of military personnel estimated that 60 percent of active duty personnel use dietary supplements.³

Not surprising in view of their widespread use by military personnel, dietary supplements are widely available on military bases, where they are sold in the commissaries (supermarkets) and post and base exchanges (retail department stores located at military installations), as well as in GNC shops located on posts and bases. This availability may confer the impression that the military endorses the use of such products or at least believes they are safe and of high quality. The 1994 Dietary Supplement Health and Education Act (DSHEA) defined dietary supplements as products taken by mouth that contain a dietary ingredient intended to supplement the diet. Under DSHEA, the U.S. Food and Drug Administration (FDA) regulates supplements differently from either foods or drugs: Rather, the manufacturer is responsible for ensuring (but does not need to prove) that a supplement is safe before it reaches the market. The FDA's Center for Food Safety and Nutrition monitors after-market safety, labeling, package inserts, and claims, whereas the Federal Trade Commission regulates advertising.

The use of dietary supplements by military personnel raises a number of special concerns. In view of the highly specialized and potentially dangerous mission-related tasks performed by many soldiers, one concern is the possibility that some supplements might interfere with physi-

¹ C. Rock, "Multivitamin-Multimineral Supplements: Who Uses Them?" *American Journal of Clinical Nutrition*, Vol. 85 (suppl), 2007, pp. 277S–279S.

² J. Arsenault and J. Kennedy, "Dietary Supplement Use in US Army Special Operations Candidates," *Military Medicine*, Vol. 164, No. 7, July 1999, pp. 495–501.

³ Based on a personal communication between the authors and Bernadette Marriott, September 16, 2008 (see details on p. 6).

cal or mental performance in as-yet unidentified ways. Another issue concerns the extreme environments in which some soldiers work (for example extremes of temperature, humidity, and altitude coupled with high-intensity exertion) and the potential effects such environments could have on the effectiveness and safety of supplements. These concerns, should they prove legitimate, raise questions regarding the need to regulate the use of at least some supplements among some military personnel.

Background

A 2008 Institute of Medicine (IOM) report aimed to review patterns of dietary supplement use in the military and to recommend a framework for the active monitoring of supplements' use and management of adverse effects.⁴ The IOM report recommended (1) improving monitoring of dietary supplement use by military personnel, (2) using a framework to determine the level of concern for dietary supplements in a military context, (3) implementing a system to report adverse events associated with dietary supplements, and (4) expanding education about dietary supplements.

The paucity of research on the potential for adverse effects of supplement use among soldiers themselves suggests the need for new mechanisms for identifying potentially relevant evidence of harm. This evidence is needed to guide policy on the use of supplements, both for the military and ultimately for the civilian population. To address these issues, the Samueli Institute, with funding from the U.S. Army Medical Research Acquisition Activity, partnered with the RAND Corporation to conduct a review of the published and gray literature and host an expert panel meeting on regulations for selling supplements and issues related to the use and potential regulation of supplements by the military. To help focus the panel's deliberations, RAND prepared a background paper that summarized the findings of the literature review on the prevalence of dietary supplement use by military personnel and the history of dietary supplement regulation, both legislative and nonlegislative. Following up on the 2008 IOM report, these activities further reviewed dietary supplement regulation in the context of the military.

The Panel

The panel met at RAND on September 16, 2008. The members of the panel were individuals identified by the project's advisory board as having special knowledge of this content area. Thus, the panel comprised experts in the biochemistry and physiology of supplements from various fields including the private sector, universities, research institutes, the military and other U.S. government departments. However, no member of the panel was chosen as a representative of an organization or government department, and the final product does not represent the view(s) of such bodies. Furthermore, the focus of the work is not on the regulation of supplement products and does not impinge on the regulations as enforced by the FDA or any other government body.

⁴ Institute of Medicine (IOM) Food and Nutrition Board, Committee on Military Nutrition Research, *Use of Dietary Supplements by Military Personnel*, Washington, D.C.: National Academy of Sciences, 2008.

The panel was asked to focus on two types of supplement regulation—nonlegislative regulation and regulation at the point-of-sale—and to advise on the factors to be considered in developing guidelines and policies for regulating supplement use by military personnel. The types of regulation and assessment to be considered are separate from FDA regulations and in keeping with the framework proposed by the IOM report. The panel’s task was not to develop *specific policies for the military* but to examine how such policies have been developed in other arenas (e.g., by employers—particularly those in high-risk fields such as firefighting, police work, long-distance trucking, and airplane operation), other countries, and athletic organizations and to recommend a process or processes for establishing policy in DoD.

The panel heard a presentation on use of dietary supplements among active duty military personnel in the Army, Air Force, Navy, and Marine Corps globally based on a 2005 DoD survey of health behaviors⁵ and was then asked to consider the following questions:

- What types of policies and regulations currently exist in other [similar] groups?
- What types of policies currently exist in the commercial domain around point-of-sale?
- What kind of regulations does the military currently have?
- If the military so chose to regulate use, what could it do?

The remainder of this document provides a summary of the issues and ideas discussed at the meeting, although not necessarily presented in the order of the questions.

⁵ Bernadette Marriott presented this information to the panel.

Panel Discussion

What Are the Military's Concerns Regarding the Use of Supplements?

The military is committed to optimizing military physical and mental performance. Achievement of this goal is primarily accomplished through training and a healthful diet that is tailored as needed to special environmental extremes and caloric needs of the individual. The military has had a long-standing interest in identifying dietary supplements that might assist service personnel in optimizing their performance. However, at the same time, military officials are concerned about the misuse of supplements. These concerns fall into three general categories: safety, quality, and efficacy and effectiveness. Within each of those categories are some important issues.

Safety

- Taking a supplement may influence physical or cognitive performance.
- Taking a supplement may alter uptake of nutrients from food or beverages or may interact with other supplements or prescription or over-the-counter drugs to alter their effects.
- The extreme environmental or physiological conditions experienced by some troops might modify the physiological effects of a supplement.

The question was raised about whether any actual adverse events had been associated with supplement use among military personnel. Patricia Deuster described incidents that have been reported of soldiers being evacuated from the battlefield because they had collapsed following the use of “stackers,” which are stimulants touted as fat burners, metabolic (thyroid) stimulators, or thermogenic aids. According to other military panel members, such stimulants are the supplements of greatest concern for military personnel. Heightening this concern is that the military encourages the use of particular stimulants, e.g., caffeine, as an ergogenic aid and is actively conducting research to identify the optimal stimulant. However, panel members noted that a number of commercially available caffeine-containing products (so-called energy drinks as well as weight loss products) are reportedly widely used by military personnel, and the potential interaction of their high caffeine content and certain other ingredients with stimulant properties should be a matter of concern.

Quality

The quality of a supplement refers to whether its actual contents match the contents stated on the label (or in the list of ingredients). Supplement quality has two components:

- whether the supplement provides the amount of the “active” ingredient promised (no more and no less)
- whether it is free from contaminants that are toxic, illegal and/or banned, allergenic, or simply not listed.

Concerns about supplement quality are by no means unique to the military.

Efficacy and Effectiveness

The efficacy and effectiveness of a supplement refers to whether it exerts the effect for which it is being used. *Efficacy* specifically refers to the extent to which a substance exerts the desired effect under the conditions of a randomized controlled trial. *Effectiveness* refers to the effect of the supplement under real life conditions, such as its use in the field by soldiers under conditions such as extreme heat. For a high proportion of supplements, particularly herbals, effectiveness is an area of considerable research and controversy. Concerns about the efficacy and effectiveness of particular supplements are also not unique to the military.

What Is the Prevalence of Supplement Use in the Military?

Is supplement use by military personnel (particularly use of supplements whose safety may be in question) of sufficient prevalence to be a concern? The 2008 IOM report recommended continuing to monitor military supplement use and to expand and improve surveys. In 1980, DoD commissioned a survey of supplement use as part of its periodic health survey. The most recent survey had a paper-and-pencil format and was administered in April–August 2005 by Bernadette Marriott and her colleagues at Research Triangle Institute in person to over 16,400 active duty personnel globally (both within and outside the continental United States). Those surveyed were selected to provide a representative sample by service, location, age, gender, pay grade, and other factors. This sample represented a 51 percent response rate (low for this survey, probably because of high deployment), leading to approximately 4,000 responses each in the Army, Navy, Air Force, and Marine Corps.

According to the data of Marriott and her colleagues, some 60 percent of the military respondents reported taking at least one dietary supplement at least once a week over the previous year. This figure is higher than that of the comparable civilian population. Supplement use varied by age and gender. Prevalence of use of any supplement was highest among women 35 and older and men 26–34. Use of weight loss supplements was more prevalent among women than among men; use of body building and performance-enhancing supplements was more prevalent among men than among women. About one-third of respondents stated that they reported use of supplements to a doctor, but only one-fifth had reported it to a physician’s assistant or nurse practitioner. Reporting of supplement use to health professionals was highest among Air Force personnel, possibly because a higher proportion of Air Force personnel are presumed to have flight status. Marriott indicated that each service has detailed regulations that govern supplement use by personnel with flight status.

What Are the Current U.S. Military Regulations on Supplement Use and Sales?

Regulation of Use

As described by Marriott and several other panel members, regulations for supplement use vary among the services and even among job specialties within the same service.

According to Herb Coley, another panel member, the Army Flight Surgeon's office requires all pilots to report *any supplements* they are using. However no measures are taken to assess actual use, such as the random urinalysis that is conducted military-wide for illegal drugs.

U.S. Navy Aeromedical Reference and Waiver Guide divides supplements into three classes (A, B, and C) based on specific limitations of use:

- Class A supplements, which can be used without limit unless a problem is identified during the yearly physical, comprise sports drinks without creatine, ephedra, or other herbal supplements; supplements providing solely protein; vitamins and minerals; and tonic water. The following warnings are provided:
 - Use of tonic water should be limited because of the propensity of quinine, the main ingredient, for causing vestibular disturbances.
 - Vitamins and minerals are best obtained from foods.
 - Products that exceed the Recommended Daily Allowances should generally not be used.
- Class B includes saw palmetto and glucosamine chondroitin. Use of both is limited to individuals who have been cleared for such use by his or her physician.
- Class C comprises substances whose use is banned for aviation personnel, including herbals with known sedative properties, anabolic steroids and their precursors, creatine, glandular extracts, echinacea, and other substances.¹

U.S. Air Force Instruction 48-123 states that “Dietary, herbal, and nutritional supplements can only be used with the approval of a flight surgeon. The flight surgeon should consider aeromedical implications of the supplement as well as the probability the supplement will actually enhance performance.”²

U.S. Marine Corps Order 6200.1E W/CH 1 requires that any soldier taking dietary supplements report it to the medical department.³ Other regulations appear to be in line with those of the Navy.

Regulation of Supplement Sales

The military does not currently regulate which supplements may be sold at the stores on posts and bases (commissaries, exchanges, and GNC). However, regarding the *quality* of supple-

¹ Naval Aerospace Medical Institute, *U.S. Navy Aeromedical Reference and Waiver Guide*, “General Dietary Supplement Advice,” Pensacola, Fla., not dated. As of May 14, 2011: <http://www.med.navy.mil/sites/navmedmpte/nomi/nami/arwg/Pages/AeromedicalReferenceandWaiverGuide.aspx>

² U.S. Air Force, *Physical Examinations and Standards*, “Attachment 7. Medical Standards for Flying Duty,” Washington, D.C.: U.S. Air Force, AFI 48-123, May 22, 2001, Section A7.32.3.8.

³ U.S. Marine Corps, *Heat Injury Prevention Program*, Washington, D.C.: Department of the Navy, Order 6200.1E W/CH 1, June 6, 2002.

ments sold on base, the Defense Commissary Agency (DeCA), which sets policy on the inventory carried by the commissaries, launched a program to establish quality standards for supplements sold at the commissaries. A video prepared by DeCA's chief of the semi-perishables division was shown to the panel. So far, these standards apply only to multinutrient supplements and vitamins (i.e., not herbals and/or botanicals). DeCA is using three sets of quality criteria: Shuster Laboratories' third-party verification (www.strquality.com), the United States Pharmacopeia (USP)/Dietary Supplement Verification Program (which uses a dual certification process—certifying both ingredients and manufacture—and is considered the industry gold standard), validated minimum shelf life, and the FDA Good Manufacturing Process (GMP). The commissaries also limit the sale of dietary supplements to a small number of brands that uphold the standards. Fact sheets explaining this program for quality standards are posted in the commissaries.

In terms of supplement safety, the panel expressed the idea that such a model of standardization is costly but worthwhile. The panel then discussed whether such a program could help with any proposed point-of-sale regulation (aimed at limiting the availability of some supplements to military personnel). The great weakness of such a program, according to the survey findings presented by Marriott, is that *the majority of supplement products used by military personnel are obtained online or from family members*. In addition, according to several panelists, the commissary sells a fairly limited range of the supplements of greatest concern (stimulants). On-base sources of these supplements are other types of stores. Some panelists expressed the opinion that if the commissaries and other on-base stores could use their buying power to compete cost wise with online sources, the military might be able to exert at least some control on the safety and availability of those supplements. However, several panelists raised the issue that current safety standards apply only to single ingredients (not to products with multiple active ingredients) and not at all to herbals.

What Other Steps Could the Military Take to Regulate or Influence Use?

The panelists agreed on the importance of establishing and enforcing supplement efficacy. One panelist cited the example of the Australian Academy of Sport, which has established a four-tiered model regulating supplement use and will pay only for supplements with demonstrated efficacy. Such a policy would be relevant to supplements whose use is encouraged or prescribed by the military as an aid to performance or to promote health. For example, according to Deuster, the Defense Advanced Research Projects Agency worked with a small startup company to produce and test a chewable form of quercetin, a plant flavonoid with antioxidant effects that has been touted to boost immunity and prevent mental and muscle fatigue after physical exertion. The aim is to create a palatable, portable supplement that could be given to all soldiers. Yet little evidence currently exists regarding the efficacy of this substance.

Several panelists then noted that, from the perspective of regulation, efficacy is of secondary importance compared with the issue of safety (lack of effect is of less importance than toxicity).

Returning to the example of quercetin, panelists agreed that even less is known about its safety than about its efficacy.

To address the issue of safety, two questions need to be answered: (1) What supplements cause the most concern among the military services and (2) What actually needs to be regu-

lated? While stimulants are the substances of greatest concern, multivitamins, minerals, and herbals are problematic as well. For example, salvia is an hallucinogenic plant that has been banned by the Navy, but no test exists to detect or screen for it.

Recommendations for Addressing Safety Concerns. Several panelists suggested that it might make sense for the military to conduct its own clinical trials to establish safety (as well as efficacy), as the military has unique needs and concerns. However, clinical trials of supplements are difficult to conduct, and it is difficult to enroll active duty soldiers as participants in supplement studies because of fears of repercussions. Nevertheless, the large size of the active duty population and the presumption of a single, DoD-wide electronic medical record system, combined with the military's interest in performance optimization and the prevalent use of supplements, make it tempting to consider conducting supplement clinical trials with military personnel themselves or at least attempting to track the effects of supplement use in this population.

The 2008 IOM report recommended that the military implement a process to monitor supplement safety by collecting data on adverse events and provided guidance for developing such a monitoring system. According to Deuster, DoD has commissioned development of an online tool to monitor pharmacovigilance; the new database will track adverse events for all drugs, including supplements. However, the challenge is that military physicians do not have time to report or enter information on use or adverse events.

In lieu of collecting data on adverse events, several panelists suggested reviewing the evidence in the literature (particularly that gathered by the National Institutes of Health Office of Dietary Supplements [ODS] and stored in its online database) on adverse events associated with particular supplements and then focusing surveillance efforts and/or policies banning use on these particular supplements. However, one drawback to this suggestion is that, given the military's sometimes unique operational environments and tasks, it is important to consider dose and context. This consideration might necessitate establishing conditions of use (e.g., maximum percentages of the daily value that should not be exceeded) and requesting that DeCA not stock supplements whose contents exceed those values.

Two additional issues are likely to necessitate creating a mechanism for evidence gathering. One is the contaminant issue: Some brands or batches of ostensibly safe substances may be contaminated with toxic or illegal substances. The second issue pertains to new products, that is, new combinations or doses of existing, well-known substances that produce heretofore unobserved outcomes.

Panel members raised several other factors and/or ideas that also need to be considered and that might help shape surveillance policy by providing a classification system:

- The intended use of the supplement, such as pain relief, weight control, disease prevention, alertness and/or physical performance (supplements for each of those indications can have safety issues).
- The existence of at least three communities of users: non-deployed soldiers interested in fitness and/or wellness, warfighters interested in performance in the field, and veterans interested in chronic disease. Each community has different needs, existing health considerations, and use patterns.
- The various health claims made for supplements. There are currently 16 health claims approved by the FDA and an additional 6 qualified claims (those for which evidence is, as yet, limited).

The panelists suggested that DoD could follow a four-phase approach, which recognizes that the military's challenges with respect to dietary supplements simply represent a microcosm of the problems faced by the nation:

1. Conduct generalized, across-the-board quality control of anything sold to military personnel: Is the product what it purports to be?
2. Monitor purchases and conduct a post-marketing surveillance program.
3. Assess the efficacy, safety, and quality of each product.
4. Publicize every adverse reaction as front page news in the *Army Times* and other military media.

Finally, in view of the IOM recommendations on safety monitoring and the fact that the military can draw on the resources of the ODS in determining which substances to monitor, the panel expressed the belief that further recommendations in the safety area are not worth pursuing.

Recommendations for Addressing Quality Concerns. The panel was also asked to consider whether the military needs to develop its own process for establishing quality.

One panel member described the (USP) dual certification process used by the U.S. Olympic committee. The practical result of such extensive certification requirements is that Olympic athletes can use USP-certified products, win, and not fail drug screening tests as a result of having used a contaminated supplement. According to this panelist, DoD could develop a similar set of standards, becoming a model for other organizations. Although these processes are costly, DoD could figure the expense into its costing model. However, as noted earlier, doing so would affect only what commissaries and exchanges sell (i.e., those supplements obtained on base), but most soldiers do not buy their supplements at the commissary, and the commissary certainly does not supply the supplements of greatest concern.

Another panelist raised the point that even assuming the military would undertake a program to procure and sell the highest quality supplements at competitive cost, the most popular supplements are largely multiple ingredient products, whereas USP standards apply only to individual ingredients. And although new GMPs do recommend assessing individual components in a step-wise fashion, it is not possible or appropriate to test individual components of a multicomponent supplement.

Other Suggestions

Aside from the suggestions to develop and enforce quality standards and to monitor safety, the panel had the following suggestions.

Provide Targeted Education

A number of panelists suggested implementing or improving education for soldiers about supplement use. However, panelists questioned whether such education works, what is the best medium to implement it, and when should it be implemented.

The source of the information and how it is presented is especially critical. One military panelist stated that soldiers do not learn by passively reading information on a website (no matter how informative). Another stated that most successful educational campaigns are initi-

ated at the unit commander level, simply by example. If the unit commander tends to use and promote the use of supplements, soldiers will follow the lead. However, the commanders do not always have the appropriate knowledge or information. Such campaigns promote a particular culture, and it is this culture that may need to change or may be a useful vehicle for change.

Panelists suggested that if the military wishes to initiate education programs, one medium to consider, for the Army only, is the Training and Doctrine Command, which is responsible for developing training content and curricula. Education could begin in basic training and continue in advanced individual training (AIT). However, the time spent in basic training and AIT is limited, and many educational topics compete for soldiers' attention. Nevertheless, if the leadership believes that such information is important, then it will be disseminated. One possibility is to implement a center of excellence to promote this issue.

Another suggestion was focused on military health professionals. One panelist suggested holding workshops both to educate military physicians and psychologists about supplement issues (including drug-supplement interactions) and to learn what kinds of problems these professionals have seen in their practices. However, physicians are not likely to exert a strong influence on the users of supplements; rather, peers, (fellow soldiers and, as suggested earlier, immediate commanders) are among the strongest influences and sources of information. Thus, programs aimed at this level are more likely to be effective. One other group of professionals who might be able to influence supplement use, and who possess the appropriate knowledge, is dietitians. Military dietitians could play an important role in soldier education about supplements as well as noting and reporting adverse effects. However, the lack of proximity of dietitians to sites of deployment suggests their role would be limited to providing education stateside; and even within the continental United States, dietitian presence at military sites is sparse. One panelist suggested dietitians should be attached to all basic training sites.

Yet another panelist noted that any educational effort should take note of the media accessed by the current generation of soldiers. This generation tends to get its information from sources like TV and the Internet, rather than from doctors, classes, or books. Thus, the military should consider social marketing efforts using those kinds of sources. Army Knowledge Online and Defense Knowledge Online could be used for this purpose. These are password-protected military-only sites that provide good information, but most soldiers do not access these sites. The U.S. Army Public Health Command (formerly the Center for Health Promotion and Preventive Medicine) site provides a lot of useful information about supplements and is geared toward soldiers. In addition, there are a number of nonmilitary sites whose purpose is to provide soldiers with information they need. Information about supplement use could be posted on these sites as well.

Conduct Surveillance

In addition, panel members suggested that if the military recommends a supplement or implements a policy with respect to a supplement, the committee charged with implementing the pharmacovigilance database should begin tracking the safety and efficacy outcomes. Another approach suggested by one panelist was to identify the 20 most commonly used supplements, either by brand name or by ingredients, and track use patterns and risk profiles.

Other Questions Raised

Can Product Labels Play a Role? The panel discussed the role of product labels and their contents in providing information to soldiers that might influence the use of these products

but disagreed on their importance. Three questions were raised: Is the information on the labels perceived as credible, is the information credible, and do soldiers (or any consumers) read labels?

Some panelists questioned whether the label is perceived to provide information or is regarded as a form of advertising. In the United States, label contents and advertising/marketing are regulated separately (the former by the FDA, the latter by the Federal Trade Commission); in Canada, from a regulatory standpoint, labels and advertising are not distinguished. There, much of the content on dietary supplement labels is tightly regulated. The Supplement Facts panel contents, its layout, and font size of the contents are regulated by the FDA. Claims on the label are also controlled and have to meet specific FDA guidelines. Panelists noted that most consumers do not understand how dietary supplement labeling is regulated and may be skeptical of label statements. At the same time, we know that certain label content (both words and design) increases consumer confidence in the product (whether warranted or not).

The other issue is that purchasers do not always read labels. Several panelists noted research evidence that a small segment of consumers does, in fact, read at least some parts of labels and that labels do provide some education.

What Should the Information Basis Be? Determining what information source should be used by the military as a basis for issuing supplement guidance or regulations is itself a major issue.

For individual-ingredient and some other well-known supplements, ODS has already established a database of the evidence (International Bibliographic Information on Dietary Supplements) and provides fact sheets that the military could link to or distribute. Thus, there is no reason to research and create a new informational database for many of these more commonly used supplements.

New products and multicomponent supplements present the bigger challenge. New supplements appear on the market all the time, and ODS has limited evidence and safety information on these products and on the multicomponent supplements. What is needed is a method to identify the products of greatest concern and a simple flexible process for rapidly assessing the evidence for these supplements.

Ian Coulter (the panel moderator) suggested that a process like the RAND appropriateness panel method⁴ would work in principle but would be time-consuming and resource-intensive. ODS has convened one such meeting to investigate the evidence for performance-enhancing substances but otherwise generally relies on the Food and Nutrition Board and presumably the U.S. Department of Health and Human Services Evidence-Based Practice Centers, which also conduct systematic reviews of supplements.

⁴ The appropriateness panel method is a technique that uses a multistep group process to elicit expert opinion and information about clinical decisionmaking regarding the conditions for which a particular diagnostic or treatment procedure is indicated. The process usually involves the following steps: (1) conducting a systematic review to identify the factors that influence the particular clinical decision as well as the outcomes (efficacy and safety) of the procedure; (2) identifying a group of experts (the panel); (3) providing the panel with a copy of the review, the question(s) of interest, and a matrix of all possible combinations of patient factors and asking the panel members to rate the appropriateness of using the particular procedure under each possible combination of factors; (4) summarizing the results so that each panel member can see (anonymously) how his or her judgments compared with those of the others in the group; (5) holding a face-to-face discussion of the question(s); (6) re-polling the panel members (anonymously) about appropriateness under all possible combinations of factors; (7) summarizing the new results; and (8) sharing the end product. The aim is not to reach consensus but to assess which sets of factors elicit nearly unanimous decisions (treat versus do not treat) and which elicit highly divergent decisions.

Several panelists suggested that for new supplements, particularly those with the potential for interaction with medications or other adverse effects, the military's Dietary Supplement Committee could make a preliminary assessment and recommend a course of action, e.g., that the military track the use of—and events associated with—these products in the military population. The 2008 IOM report recommended tracking supplement use and examining supplements for which use appears to be increasing.

The role of evidence assessment in dietary guideline formation is currently a matter of increasing interest. For evaluating new products, some potentially important evidence, or the only existing evidence, might be dismissed because of the general practice in evidence reviews of excluding studies in laboratory animals, in vitro studies, and human studies with a very small number of human subjects. Although such generally excluded studies might be included if they are the only evidence available, their utility might be questioned. Nevertheless, recent Evidence-Based Practice Center reports on omega-3 fatty acids included an entire report on the mechanism of action of omega-3s for preventing heart disease, and part of another report reviewed the evidence (and proposed mechanisms) for an effect of omega-3 fatty acids on preventing tumor development. For the newer supplements, reliable manufacturer data could serve as a basis.

Conclusions and Recommendations

The purpose of this workshop was to comprehensively assess factors associated with the safety, efficacy, quality, and regulation of dietary supplements in the context of the military.

The panel deliberations resulted in the following suggestions and recommendations:

1. For applications to the military population, any review of safety needs to consider the total content of supplements in the context of the conditions of use.
2. Supplements of particular concern with respect to safety should be identified and subject to a complete review, similar to that of an IOM review or of an evidence-based review.
3. Any assessment of safety requires examining interactions of the substance of interest with pharmaceuticals and other supplements and according to conditions of use.
4. A system that categorizes supplements by both safety/potential risk and intended use would be helpful.
5. Educational media that are likely to be accessed by soldiers should be identified for providing information on supplement safety.