

# National Athletic Trainers' Association Position Statement: Evaluation of Dietary Supplements for Performance Nutrition



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**Objectives:** To help athletic trainers promote a “food-first” philosophy to support health and performance, understand federal and sport governing body rules and regulations regarding dietary supplements and banned substances, and become familiar with reliable resources for evaluating the safety, purity, and efficacy of dietary supplements.

**Background:** The dietary supplement industry is poorly regulated and takes in billions of dollars per year. Uneducated athletes need to gain a better understanding of the safety, eligibility, and efficacy concerns associated with choosing to take dietary supplements. The athletic trainer is a valuable athletic team member who can help in the educational process. In many cases, athletic trainers are asked to help evaluate the legality, safety, and efficacy of dietary supplements. For this

position statement, our mission is to provide the athletic trainer with the necessary resources for these tasks.

**Recommendations:** Proper nutrition and changes in the athlete's habitual diet should be considered first when improved performance is the goal. Athletes need to understand the level of regulation (or lack thereof) governing the dietary supplement industry at the international, federal, state, and individual sport-participation levels. Athletes should not assume a product is safe simply because it is marketed over the counter. All products athletes are considering using should be evaluated for purity (ie, truth in labeling), safety, and efficacy.

**Key Words:** ergogenics, Dietary Supplement and Health Education Act, World Anti-Doping Agency

Foods and dietary supplements have been used to enhance health and athletic performance (ergogenics) since the early Olympic Games. Today, athletes at all levels of competition continually work to improve performance, and many consider the use of dietary supplements or engineered foods to gain an additional performance edge or health benefit. This may concern health care professionals because athletes may receive advice and feel pressure from many well-meaning supporters and advocates. However, athletes can be vulnerable to misinformation and risk in terms of the safety, legality, and efficacy of dietary supplements.

Although determining overall rates of supplement use among athletes is difficult, estimates of use by collegiate, high school, and middle school athletes have been reported

in the literature.<sup>1–6</sup> In a 2004 study by Burns et al,<sup>1</sup> 88% of the collegiate athletes surveyed used 1 or more nutritional supplements, yet the perceived efficacy of those supplements was only moderate. Athletic trainers (ATs) were their primary sources of nutrition information and were perceived to have significant nutrition knowledge. The 2012 “Substance Use” report compiled by the National Collegiate Athletic Association (NCAA) presented survey data from 20 474 US athletes and compared those data with 2005 outcomes.<sup>7</sup> Although survey data are limited by the perceived anonymity of the results, they can be useful to better understand trends and potential risk factors.

The overwhelming industry presence and advertising appeal likely has strong influence on athlete choices. According to the 2011 “Sports Nutrition and Weight Loss

Report,<sup>18</sup> 9% annual sales growth and \$22.7 billion in total sales were noted for sports nutrition and weight-loss products in 2010. Energy drinks and shots (small containers of concentrated product) were the primary product category (\$12 million) and were purchased through mass channels. A December 2010 press release from the US Food and Drug Administration (FDA) regarding methylhexanamine, which has been identified as the “new ephedra” (stimulant), anticipated continued reports of adverse events, failed drug tests, and product recalls. The release also cited consumer-trust issues in the supplement industry and the joining of forces by the FDA and major trade organizations to “clean up” the industry. Obviously, health care practitioners need to be aware of the trends in supplement use and the risks the supplements may carry for athletes’ health and sport eligibility.

As health care professionals, ATs must be knowledgeable regarding basic nutrition and supplement use and must be able to educate their athletes regarding the efficacy, safety, and legal issues associated with the use of supplements. If they are not knowledgeable in these areas, ATs must be aware of resources for education and proper referral, so they can provide guidance for those within the athletic community. This position statement provides suggested resources to help ATs stay current in the ever-changing landscape of dietary supplements.

To formalize the position statement objectives into recommendations, we used (where appropriate) evidence-based review and the Strength of Recommendation Taxonomy (SORT) criterion scale (Table) proposed by the American Academy of Family Physicians<sup>9</sup> and adopted by the National Athletic Trainers’ Association. Some of the educational materials regarding dietary supplements are found in federal law; these are noted in the recommendations.

## Recommendations

Evaluation of the literature associated with performance nutrition and dietary supplements resulted in the following evidence-based recommendations:

1. Performance can be enhanced using an intentional performance diet. When attempting to improve an athlete’s performance, we should consider proper nutrition, and changes in the athlete’s habitual diet should be considered first. The AT should be knowledgeable in the area of performance nutrition and aware of resources for nutritional information. If he or she is not knowledgeable, the AT should establish a support team that includes a registered dietitian or other health care professional with expertise in nutrition.<sup>10–18</sup> *Evidence Category: A.*
2. Athletes need to understand the level of regulation (or lack thereof) governing the supplement industry at the international, federal, state, and individual sport-participation levels. Athletes should not assume a product is safe simply because it is marketed over the counter.
  - a. Athletes and ATs should be aware that dietary supplement labels do not require third-party verification; purity (truth in labeling), and noncontamination cannot be assumed.<sup>19–22</sup> *Evidence Category: A.*
  - b. All ATs should be prepared to educate athletes that dietary supplements are not well regulated and may contain banned substances. Sport governing bodies

**Table. Strength of Recommendation Taxonomy (SORT)<sup>a</sup>**

Strength of Recommendation	Definition
A	Recommendation based on consistent and good-quality, patient-oriented evidence <sup>a</sup>
B	Recommendation based on inconsistent or limited-quality, experimental evidence <sup>a</sup>
C	Recommendation based on consensus, usual practice, opinion, disease-oriented evidence, <sup>b</sup> or case series for studies of diagnosis, treatment, prevention, or screening

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<sup>b</sup> Patient-oriented evidence measures outcomes that matter to patients: morbidity, mortality, symptom improvement, cost reduction, quality of life. Disease-oriented evidence measures intermediate, physiologic, or surrogate end points that may or may not reflect improvements in patient outcomes (ie, blood pressure, blood chemistry, physiological function, and pathological findings).

provide athletes and other personnel with the rules regarding banned substances and their philosophies regarding supplementation.<sup>23,24</sup> *Evidence Category: C.*

3. Products athletes are considering ingesting should be evaluated for purity (ie, truth in labeling), safety, and efficacy. *Current federal law does not require manufacturers or distributors to provide evidence of purity, safety, or efficacy before products are distributed or sold.*
  - a. Labeling requirements for dietary supplements are similar to those for food products.<sup>22,25</sup> Because ATs cannot be expected to perform a direct analysis of supplement purity, they should be aware of resources to help identify companies or products known to have a history of problems with labeling, adulteration, or contamination. *Evidence Category: C.*
  - b. Federal regulations do not require supplement manufacturers to provide evidence of safety.<sup>22,25</sup> Therefore, ATs should be aware of resources to identify products associated with adverse effects. Athletes should also be educated about the lack of regulation, because they are ultimately responsible for the health and eligibility risks resulting from use.<sup>26</sup> *Evidence Category: C.*
  - c. Dietary supplement manufacturers are not required to provide evidence of efficacy.<sup>22,25</sup> As a result, ATs should be aware of resources to identify supplements (or individual components), the quantity of active ingredients, and the mixture of active and inactive ingredients supported by peer-reviewed scientific evidence relating to product efficacy. *Evidence Category: C.*

## BACKGROUND

### A Food-First Philosophy

Before we consider adding a supplement to the athlete’s diet, it is appropriate to ensure an adequate training diet and routine. Whole foods should be emphasized over dietary supplements for a number of reasons.<sup>27</sup> Whole foods have greater nutritional content than their pill- or powder-form counterparts. In most cases, the vitamins and minerals in food products are better absorbed than those found in

supplements. Ingredients added to conventional foods are required to appear on the FDA generally recognized-as-safe (GRAS; proven safe for human consumption) list, and new ingredients must be FDA approved before marketing<sup>28</sup>; dietary supplements (and ingredients) do not require FDA approval as long as all ingredients are not considered new and fit the criteria of DHSEA.<sup>29</sup> One of the major differences between foods and supplements is that all ingredients in foods must be on the GRAS list, indicating prior FDA approval as safe. Dietary supplements and individual supplement ingredients are not required to appear on the GRAS list, which means that safety studies have not necessarily been conducted on all ingredients. Additionally, without specific product research, the variety of components present in many dietary supplements makes it impossible to predict the chemical interactions, absorptive issues, and metabolism in the body or the possible competition or interaction with medicines the athlete may need. Athletes should realize that nutrient overconsumption is possible when using supplements<sup>30</sup> or highly fortified foods,<sup>31</sup> and the risk of overconsumption was the driving force behind adding a safe upper limit to the dietary recommended intakes.<sup>32</sup> During intense training protocols, athletes may forget to prioritize a healthful diet over dietary supplements to support performance, and they need to be aware of potential problems with supplements.

The AT should be knowledgeable in the area of performance nutrition and aware of reliable resources for this information (Appendix 1). In March 2009, a joint position statement<sup>10</sup> of the American College of Sports Medicine and American Dietetic Association (ADA; now recognized as the Academy of Nutrition and Dietetics) outlined the current status of the evidence-based literature in helping athletes with training diets. In April 2010, the Gatorade Sports Science Institute<sup>33</sup> supported the translation of those guidelines into practical advice using food and fluids. The position statement and guidelines translation have been endorsed by the National Athletic Trainers' Association as reliable sources of athlete nutrition guidance<sup>33</sup> and include examples of how to use food and drinks to improve performance. The International Olympic Committee regularly convenes sports-nutrition experts to provide nutritional guidance to athletes and makes the information available digitally.<sup>34</sup> These resources are peer reviewed, credible, and available to the public.

The Sports, Cardiovascular, and Wellness Nutrition (SCAN) dietary practice group of the ADA has developed a specialty-practice credential for registered dietitians called the Certified Specialist in Sports Dietetics (CSSD).<sup>35</sup> The purpose of this credential is to ensure that the professional has the knowledge and experience needed to educate and assist athletes with their specialized dietary needs. The Sports Dietetics subunit of the SCAN dietary practice group provides health care professionals with open access to their group-compiled and peer-reviewed fact sheets.<sup>36</sup> Athletic trainers can use these resources when educating or referring athletes for proper nutrition counseling and sport performance. The Collegiate and Professional Sports Dietitians Association (CPSDA) was created to provide an educational forum for and resources specific to professionals engaged in the nutrition counseling and dietary interests of athletes. Athletic trainers are welcome in that group as associate members ([org\). Many sports dietitians participate in both SCAN and CPSDA to hone their skills and knowledge. Many academic institutions employ registered dietitians, for whom specialty-practice experience, knowledge, and credentialing are beneficial when working with athletes.](http://www.sportsrd.</a></p></div><div data-bbox=)

### Practice Application: Food First

For example, a male athlete who wishes to gain lean mass might decide to use a muscle-building supplement such as creatine. Based on company claims and testimonies, a product such as JackD 3d (USPlabs, Dallas, TX) may seem appealing. Discussing the athlete's nutrition habits might reveal infrequent eating or inadequate caloric support for gaining lean-muscle mass. Correcting these habits will favor lean-muscle accretion. In addition to a healthy diet, performance nutrition guidelines will ensure that the muscles are adequately fueled to work hard, that hydration during activity is sufficient, and that good muscle recovery practices are followed. The current recommendation is a carbohydrate intake of at least 6 g/kg and a maximal protein intake of 1.7 g/kg.<sup>10</sup>

### Dietary Supplement Regulations

The regulatory issues associated with the use of dietary supplements are complex, challenging, and constantly evolving at many levels. The term *dietary supplement* represents a wide spectrum of products, including some fortified whole foods, herbal products, and ergogenic aids and products designed to improve work or performance. No universal regulations for dietary supplements are currently accepted, and consumers are often naïve to the lack of regulation and associated risks. However, resources are available at the international, federal, and sport-organization levels for the consumer and health care professional. Although individual sport or organization governing bodies regulate supplement use among their athletes, international and federal Web sites (Appendix 2) provide education and guidance that athletes and health care professionals might find helpful.

The Codex Alimentarius Commission was first developed in 1963 by the Food and Agriculture Organization of the United Nations and the World Health Organization to foster international guidelines for the protection of consumers in broader food safety (ie, safety of the food supply). A subcommittee of the Commission is responsible for publishing and updating the Codex Alimentarius, which is "a collection of standards, codes of practice, guidelines and other recommendations" as they pertain to foods, including ingredients such as dietary supplements ([http://www.codexalimentarius.net/web/index\\_en.jsp](http://www.codexalimentarius.net/web/index_en.jsp)).<sup>37</sup> The German Commission E monographs are considered the standard for safety and efficacy in herbal therapy.<sup>38</sup> The investigations of safety and efficacy of more than 400 herbs are available as monographs compiled from the literature, clinical studies, and anecdotal reports. The monographs were translated by the American Botanical Council and are available on the Web (<http://cms.herbalgram.org/commissione/index.html>) and in book form for those wishing to learn more about herbal supplements.<sup>38</sup> These international resources may be helpful in evaluating safety and efficacy, but they carry no regulatory value in the United States.

In the United States, dietary supplements are regulated by the FDA through the Federal Food, Drug, and Cosmetic Act according to the intended use. In 1994, the Dietary Supplement Health and Education Act (DSHEA) amended the Federal Food, Drug, and Cosmetic Act to establish new standards for dietary supplements.<sup>19</sup> This act defined a *dietary supplement* as “a product (other than tobacco) intended to supplement the diet that contains one or more of the following dietary ingredients: vitamin; mineral; herb or other botanical; amino acid; dietary substance to supplement the diet by increasing the total dietary intake; concentrate, metabolite, constituent, extract or combination of any of the aforementioned ingredients.”<sup>19</sup> This act also broadened the regulatory definition of dietary supplements, allowing them to be considered with foods instead of adhering to the more stringent regulations for drug products. Ingredients and packaging of foods and dietary supplements are controlled through the FDA with the guidance provided by Title 21 of the Code of Federal Regulations, and this resource is available as the Electronic Code of Federal Regulations (e-CFR).<sup>39</sup>

Not all supplements or ingredients are manufactured in the United States, but for products distributed in this country, manufacturers and distributors are required to provide labels consistent with US supplement-labeling laws.<sup>40</sup> Ingredients added to conventional foods are required to appear on the GRAS list, and *new* food ingredients must be FDA approved before marketing.<sup>28</sup> In contrast, DSHEA holds the manufacturers and distributors of dietary supplements responsible for ensuring that their products are safe before they are marketed; no third-party screening ensures this has happened. According to DSHEA, safety only needs to be proven for new ingredients because products containing ingredients that were marketed before 1994 do not require premarketing approval. Unfortunately, no authoritative list of dietary ingredients that were marketed before 1994 is available. Therefore, manufacturers and distributors are free to determine whether a dietary ingredient is new or contains ingredients that were marketed in the United States before 1994. Under DSHEA, once the product is marketed, the FDA has the responsibility for showing that a dietary supplement is unsafe or illegal before it can take action to restrict the product’s use or remove it from the marketplace. Unlike the FDA approval process for drugs, the supplement manufacturer or distributor does not have to prove that the supplement is effective. If the manufacturer does provide a nutritional support statement on the label, it must be accompanied by “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”<sup>41</sup> A similarly worded disclaimer suggests the manufacturer is making a claim that the supplement affects structure or function, which may or may not have been properly evaluated. The Federal Food, Drug, and Cosmetic Act is available online (<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDAAct/default.htm>)<sup>25</sup>; the digital format allows the public to view changes and updates immediately.

Athletes participating in sports at various levels of competition may use supplements or other ergogenic aids in an attempt to enhance health<sup>42,43</sup> or performance<sup>44</sup> (or both). Ironically, some athletes use dietary supplements

when they are concerned about the safety of the food supply.<sup>45</sup> Coaches, ATs, team physicians, and administrators are responsible for knowing, educating, and encouraging athletes to follow the code of ethics dictated by their governing body. Following are descriptions of commonly acknowledged governing bodies, but the list is by no means exhaustive.

The World Anti-Doping Agency (WADA) was established in November 1999.<sup>23</sup> Four years later, at the 2003 World Conference on Doping in Sport, all major sports federations and nearly 80 countries supported a resolution that accepts the WADA Code as the basis for their stance against doping in sports. The Code provides a framework for antidoping policies and rules and regulations for sport organizations and public authorities to level the global playing field. Athletes are held to a code of “strict liability,” which means they are ultimately and solely responsible for any prohibited substance or method identified during testing. It is the athlete’s responsibility to know which substances are banned and which substances can result in a doping violation. This Code acts as the regulating document for Olympic athletes worldwide. The United States also has information regarding doping on the US Olympic Committee’s Web site under the auspices of the US Anti-Doping Agency (USADA). It is common for other countries to have a code of behavior specific to their athletes. Country-level guidelines, such as those of the USADA, are usually similar to or more stringent than those of WADA in an attempt to ensure that athletes do not test positive at international competitions, including the Olympic Games.

In February 2012, USADA released a significant online educational tool for athletes.<sup>46</sup> Supplement 411 leads the athlete through the risks and challenges of using dietary supplements. The Web site also shares professional and personal testimonial videos to help athletes understand the risks. The site provides a running news section to update all sports personnel on current press releases and topics and additional resources about high-risk dietary supplements. This call to action and education by USADA is an exemplary tool, free for use by all who wish to learn and remain informed about the topic.

On the amateur level in the United States and not necessarily affiliated with academia are many sport governing bodies, including the Amateur Softball Association of America, US Soccer, US Volleyball, USA Baseball, USA Basketball, USA Track & Field, USA Wrestling, United States Aquatic Sports, and United States Tennis Association. Each body determines the regulations for athletes competing under their umbrella, and such governing bodies typically have easily accessible Web sites.

The NCAA is the governing body for collegiate student-athletes at member institutions. The NCAA guidelines regulate what can and cannot be provided to a student-athlete in accordance with the Restrictions By-Laws (16.5.2) through the “permissible” and “non-permissible” lists.<sup>47</sup> The legislation was intended to permit institutions to assist student-athletes with calorie and fluid replacement by defining which classes of supplement products schools were allowed to give their student-athletes (permissible). According to the 2011–2012 Bylaws, “An institution may provide permissible nutritional supplements to a student athlete for the purpose of providing additional calories and electrolytes.

Permissible nutritional supplements do not contain any NCAA banned substances and are identified according to the following classes: carbohydrate/electrolyte drinks, energy bars, carbohydrate boosters and vitamins and minerals.” The intent of the ruling was that it be applied to dietary supplements only, but some compliance interpretations applied this rule to foods and did not allow some schools to provide simple foods, such as bagels and nuts. The rule was clarified in 2005 to include these foods; a formal rule change in 2009 allowed open provision of fruit, nuts, and bagels at any time.<sup>48</sup> It is easy to understand the confusion about legislation meant for foods versus dietary supplements within the ever-changing landscape of available products and the murky line between foods and supplements. However, it is important to note that a permissible supplement product contains no more than 30% of total calories from whole protein sources, as identified in the ingredients. Supplements that do not fall under the permissible categories are *nonpermissible*, simply meaning that institutions cannot provide them to student-athletes. Yet *nonpermissible* is not synonymous with *banned*. The NCAA also provides lists of banned substance classes to guide student-athletes for drug-testing purposes. Student-athletes may ingest supplements on the nonpermissible list at their own risk as long as they do not contain an ingredient on the NCAA banned-substance list. However, nonpermissible supplements cannot be provided by the institution.

To further assist student-athletes in making decisions regarding supplement use, the NCAA recently adopted legislation that each Division I member institution appoint 1 resource person responsible for answering student-athlete and staff questions regarding banned substances and dietary supplements.<sup>47</sup> Although CSSDs or ATs are likely to be involved in this program, the resource person need not possess or develop any particular level of expertise related to NCAA-banned substances or nutritional supplements. Instead, the resource person has access to the Resource Exchange Center, which is a subscription-based service of the NCAA-affiliate National Center for Drug Free Sport, Inc. Student-athletes are advised to check with the designated staff member before consuming any substance other than food. In addition, institutions are obligated to educate athletics-department staff members that any nutritional supplement use may endanger the student-athlete’s health and eligibility. This new policy likely increases the value of these educational resources for the AT.

The National Association of Intercollegiate Athletics (NAIA) institutions also have guidelines pertaining to student-athlete regulations.<sup>49</sup> Each institution must file an annual report describing the results of a substance abuse education and evaluation program and must have an NAIA Substance Abuse Certificate of Compliance form on file with the NAIA national office to participate in postseason play. However, these guidelines focus on drugs, alcohol, tobacco, and smokeless tobacco; dietary supplements are not mentioned.

Most state high school athletic associations have a position or policy on doping for athletes under their jurisdiction. The easiest way to find a state’s code is to visit the state’s high school athletics Web site and then search for *banned substances*, *doping policy*, or *dietary supplements*. The National Federation of State High School

Associations (NFHS) Web site<sup>50</sup> is useful for finding each state’s site. Similar to many professional organizations, the NFHS posts position statements on sports medicine, supplements, ergogenic aids, anabolic steroids, use of energy drinks, and hydration.<sup>51</sup>

Professional sport organizations are responsible for their own by-laws and sanctions regarding banned substances. Although American football and baseball have advanced greatly in this respect, positive drug tests after dietary supplement use have been a source of controversy. As a result, a number of organizations such as Major League Baseball and the Professional Golfers’ Association of America have adopted the NSF Certified for Sport program. Collective bargaining agreements are also an important consideration in how the rules pertain to professional athletes. For example, as part of the collective bargaining agreement signed by the National Football League and National Football League Players Association in 2011, teams will also use the NSF Certified for Sport program to guide athletes who wish to use dietary supplements.

### **Practice Application: Is the Supplement Legal According to the Sport Governing Body?**

National Collegiate Athletic Association athletes who wish to use products such as JackD 3d should check the organization’s list of banned substances. An athlete who is also involved in an Olympic sport such as swimming should check the supplement’s ingredients against the USADA prohibited list. On doing so, the athlete learns that JackD 3d contains methylhexanamine, which is a prohibited substance that will yield a positive drug test.

### **Safety, Purity, and Labeling**

Reliable resources and a stepwise process are critical in the evaluation of dietary supplements. For consumers to believe that supplements are safe or pure just because they are available for purchase over the counter is naïve. The Food and Nutrition Information Center of the US Department of Agriculture Natural Agricultural Library provides multiple consumer resources for food safety, food labeling, dietary supplements, and supplement safety.<sup>52</sup>

Many resources specific to product safety are available. The FDA offers a valuable reporting and warning tool, MedWatch, which monitors adverse events and recalls of drugs, foods, and supplements.<sup>53</sup> The National Center for Drug Free Sport was founded in 1999 as a nationwide resource for the NCAA drug-testing and education program.<sup>54</sup> This organization discourages the use of drugs and dietary supplements in sports and is dedicated solely to drug and supplement education and testing programs. The Resource Exchange Center<sup>54</sup> contains valuable resources for athletes, coaches, and health care practitioners, including an online drug-education program with accurate and confidential information about dietary supplements and banned substances. Appendix 3A provides information on Web-based safety resources for identifying potentially harmful supplements and ingredients, along with manufacturers and distributors.

## Practice Application: Does Evidence Exist of Safety or Harm?

If any well-controlled product trials have been conducted, they will likely be listed on the company Web site. Other safety resources (Appendix 3A) are used to see if any negative or adverse reports have been filed for any of the ingredients. Using the JackD 3d example, the company Web site boasts of the safety and efficacy of the product.<sup>55</sup> A search of FDA resources reveals both a warning letter to USPlabs dated April 24, 2012, that the dimethylamylamine (DMAA; the same as methylhexaneamine) in the product is not legal for inclusion in a supplement<sup>56</sup> and a news release challenging the ingredient's marketing due to a lack of safety evidence.<sup>57</sup>

The manufacturer or distributor of a dietary supplement decides whether to invest in third-party product evaluation and assurance to demonstrate purity and truth in labeling. Governmental regulation regarding consumer-product availability is usually based solely on the postmarket safety of the product, with no truth in labeling oversight. However, consumers should be concerned about the purity of the product and truth in labeling, because these are not assured in many products. The DSHEA granted the FDA the authority to establish Current Good Manufacturing Practices to ensure quality, and the final rule establishing these practices was released in June 2007.<sup>58</sup> Large, medium, and small dietary supplement companies (as defined by number of employees) were expected to comply with these guidelines in 2008, 2009, and 2010, respectively. The desired outcome of this law was to improve the quality assurance of dietary supplement products.

Consumers generally expect that the list of ingredients on a supplement label is accurate and the supplement is free of impurities and undeclared substances. Cases of dangerous contamination and adulteration are well documented; these may be intentional or unintentional.<sup>59,60</sup> Gregory Kutz, who was then managing director of forensic audits and special investigations for the Government Accountability Office, testified before the Senate Special Committee on Aging on the magnitude of this problem relative to herbal products.<sup>61</sup> (Consumers might consider a similar risk in nonherbal dietary supplements.) His report identified herbal products contaminated with arsenic, lead, mercury, and pesticide residues. A product that is contaminated with harmful substances may be dangerous to the athlete's health. Similarly, if a product is adulterated with an illegal or banned substance, the athlete's eligibility and reputation might be at risk. In a landmark study performed by the International Olympic Committee in Cologne, Germany, to define the hormonal adulteration of popular muscle-building (supposedly nonhormonal) supplements,<sup>62</sup> 18.8% of the muscle-building supplements purchased from US companies were adulterated with banned substances. Adulteration and contamination are risks to the athlete's health and eligibility because they may lead to unfavorable health outcomes and positive drug tests.

Dietary supplements are not always screened for truth in labeling, and this can result in more or less active ingredient in the particular product than declared on the label. For example, in 2001, Green et al<sup>20</sup> reported that only 1 in 12 hormonal supplements contained 90% to 110% of the labeled active ingredients. In an analysis of 9 brands of androstenedione (classified as a supplement in 2000), Catlin

et al<sup>63</sup> found that 6 contained less than 90% of the amount stated on the label; 1 contained no androstenedione at all, and 1 contained 10 mg of testosterone. In the same study, 20 of 24 men ingesting androstenedione (100 or 300 mg) would have tested positive for the banned steroid nandrolone based on urinary levels of 19-norandrosterone (a metabolite of nandrolone). Ephedra-containing supplements were also problematic because documented dosages were much higher than stated on the labels.<sup>64</sup> When label amounts are inaccurate, unintentional overconsumption can pose a significant health risk, whereas underconsumption likely affects efficacy.

In 2010, the FDA issued a letter of concern to the supplement industry citing 300 tainted product alerts in recent years.<sup>26</sup> Because drug testing is a strict liability in competitive athletics, athletes and health care practitioners should be aware of questions about product purity and labeling. *Strict liability* means that the athlete is responsible for the presence of the banned supplement in his or her system, regardless of how it got there. Athletes risk eligibility if they test positive for a banned substance, even if it was unknowingly consumed in adulterated supplements. Although many organizations, educators, and sport professionals advocate abstinence, educational efforts should focus on minimizing the risk of consuming a tainted supplement in an athlete who is choosing to use dietary supplements.

Unbiased third-party laboratories may serve to validate truth in labeling by product certification or verification. Certification or third-party assurance typically tests for product dissolution, accuracy of active ingredients as described on the label, and detectable (tested) impurities or contaminants. Third-party testing does not assure safety or efficacy but assures truth in labeling and good manufacturing practices for the batch of product tested. A third-party certified or verified product is not necessarily a better or more effective product. Conversely, a product without such verification may have an accurate label, but no rigorous, unbiased third party has evaluated it. Appendix 3B provides several resources to help identify products with verification.

Third-party verifications are also available to screen for the presence of banned substances, confirm the ingredient list, and recognize adulteration. As previously mentioned in the "Dietary Supplement Regulations" section, many professional sport organizations have adopted the NSF Certified for Sport designation to ensure product quality and purity. This third-party verification program was created for athletes concerned about banned substances in dietary supplements and designed to minimize the risk that a dietary supplement contains banned substances. The program's objective is to certify that participating sport-supplement manufacturers have met NSF's stringent independent certification process guidelines for certified products. A key component of this program is an NSF mark on each product label to show athletes, health care professionals, and consumers that a supplement has met NSF's comprehensive Certified for Sport program guidelines. Appendix 3C provides the third-party verifications and a brief synopsis of the process for each.

Products that have been third-party verified will likely carry a stamp on the label, which improves marketability from the manufacturer's perspective. The verification

laboratory Web site will often offer a current list of verified products. Consumers should also realize that different third-party laboratories test for different substances and quality assurance, and it may be helpful for athletes to consider the comparison standards. Looking for third-party verification is a reasonable step toward assuring purity and truth in labeling.

### **Practice Application: Is There Evidence of Third-Party Verification?**

The JackD 3d product marketed by USPlabs is potentially deceiving. The name of the company is USPlabs, which should not be confused with the US Pharmacopeia. Further exploration of the product's Web site does not reveal third-party verification, and the product is not found on a search of third-party verification Web sites (Appendix 3C).

### **Efficacy**

Efficacy studies of various performance-enhancing substances are regularly published, and outcomes are often equivocal, making the use of the substance controversial and confusing. Having the ability to evaluate these studies helps the AT better assist athletes with supplementation questions and choices. The health care professional should understand the proposed mechanism, likely efficacy, and suggested use of common dietary supplements athletes are taking. Unfortunately, this is a daunting task in an ever-changing landscape of product development, choices, and research. Many ergogenic supplements have only anecdotal or manufacturers' claims of efficacy, and determining whether adequate scientific evidence exists to support these claims often becomes the health care professional's responsibility.

The scientific evidence should be critically evaluated. For example, boron is a marketed mineral that became extremely popular as an anabolic agent because it was proposed to enhance the body's natural testosterone production. The manufacturers' anecdotal claims were also supported by scientific evidence.<sup>65</sup> However, critical evaluation of this scientific evidence revealed that the investigated population consisted of postmenopausal women instead of the young, healthy men the product targeted. Boron ingestion did increase testosterone levels in the postmenopausal women, but measurements were only taken under boron-deficient and normal diet conditions. These results could not be reproduced in a young, healthy male population. Manufacturers often use deficiency models or animal studies and generalize the results to a young, healthy population. Poor research design or inappropriate extrapolation of results should be recognized as poor scientific evidence. Although athletic trainers are exposed to research and design principles within approved curriculums, a review of the desirable qualities of well-documented research provides a reasonable checklist of criteria to consider in judging the quality of research (see <http://www.vtpi.org/resqual.pdf> for more information).

For the health care professional who must research a particular supplement or substance, it might be best to form an algorithm of resources to yield a well-rounded opinion from peer-reviewed research. For instance, it is common for dietetics practitioners to begin with a search of the National Institutes of Health Office of Dietary Supplements when looking for peer-reviewed research and information.<sup>66</sup> Similar compiled results can be found using the Natural

Medicines Comprehensive Database,<sup>67</sup> to which many academic institutions or professional groups subscribe. Another useful strategy is a formal review service such as the Cochrane Collaboration.<sup>68</sup> There seems to be no shortage of organizations and companies that offer information in a clearinghouse format, where brief fact sheets might be available free of charge. Several major academic health care institutions provide patients with links to various resources on nutrition and dietary supplementation. Although these tools may be quite valuable, they are too numerous to list in this document. The Internet also offers a plethora of nutrition information; Appendix 3D is a compilation of trustworthy Web resources. The FDA Web site includes a resource page to help consumers become more savvy.<sup>69</sup> However, using the resources compiled by others means trusting the training, research, and opinions of those others. One must be ready to evaluate both the evidence base of the materials and the credentialing of the contributors. The Figure, as supplemented by the appendices, offers an algorithm to help the AT navigate the concerns discussed in this position statement.

### **Practice Application: Is There Evidence of Product Efficacy?**

When evaluating a product such as JackD 3d for efficacy, we should evaluate each ingredient using the resources cited in Appendix 3D. For instance, searching for evidence of efficacy for the ingredients creatine,  $\beta$ -alanine, and caffeine yields many studies. Conversely, the DMAA in the product is the source of safety concerns. Proprietary blends can be difficult to evaluate due to their complex matrices.

### **CONCLUSIONS**

The keys to good health and successful athletic performance are a carefully designed, healthful, and nutritionally balanced diet and well-developed training program; there is no "quick fix" or shortcut to success. When an athlete is considering use of a dietary supplement, several questions should be investigated: Is it safe, is it legal, and will it work? As allied health professionals, ATs must be ready to educate athletes in the areas of safety, efficacy, and regulation. This is especially true when the AT is asked to serve as the primary evaluator in accordance with NCAA regulations.<sup>47</sup> Athletes may count on health care practitioners such as ATs to help them, and ATs need to be familiar with the appropriate resources when this important opportunity arises.

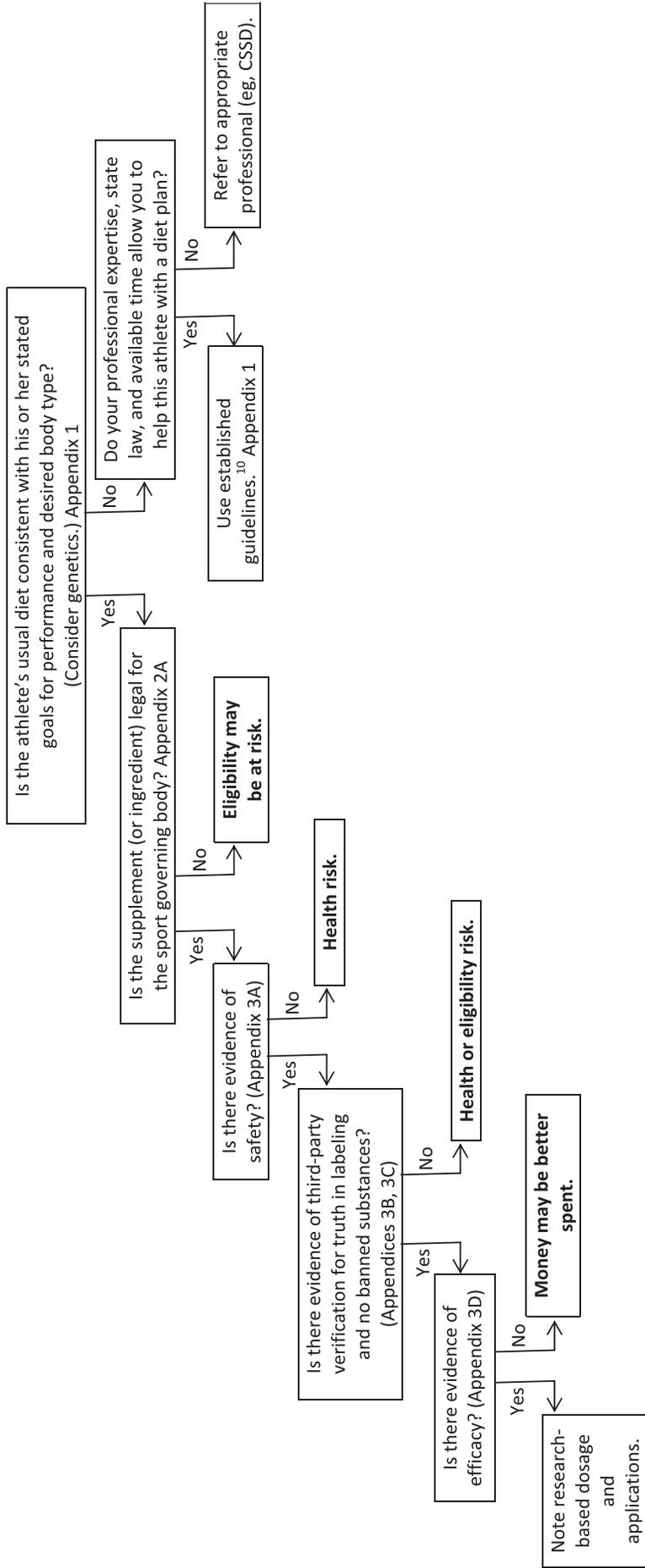
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### **DISCLAIMER**

The NATA and NATA Foundation publish their position statements as a service to promote the awareness of certain issues to its members. The information contained in the position statement is neither exhaustive nor exclusive to all circumstances or individuals. Variables such as institutional human resource

**So your athlete wants to use a dietary supplement....  
How to avoid the risks and harms**



**Figure.** Algorithm for providing guidance to an athlete who wants to use a dietary supplement.

guidelines, state or federal statutes, rules, or regulations, as well as regional environmental conditions, may impact the relevance and implementation of these recommendations. The NATA and NATA Foundation advise members and others to carefully and independently consider each of the recommendations (including the applicability of same to any particular circumstance or individual). The position statement should not be relied upon as an independent basis for care but rather as a resource available to NATA members or others. Moreover, no opinion is expressed herein regarding the quality of care that adheres to or differs from the NATA and NATA Foundation position statements. The NATA and NATA Foundation reserve the right to rescind or modify position statements at any time.

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## Appendix 1. Food Resources

- Nutrient recommendations and general diet guidance: dietary reference intakes and recommended dietary allowances: [http://ods.od.nih.gov/health\\_information/Dietary\\_Reference\\_Intakes.aspx](http://ods.od.nih.gov/health_information/Dietary_Reference_Intakes.aspx) <http://www.choosemyplate.gov>
- Sports, Cardiovascular, and Wellness Nutrition practice group of the American Dietetic Association: <http://www.scandpg.org> and <http://www.scandpg.org/sports-nutrition/sports-nutrition-fact-sheets>
- Professionals in Nutrition for Exercise and Sport (PINES): <http://www.pinesnutrition.org>
- International Olympic Committee Medical Commission 2010 consensus statement <http://www.olympic.org/Documents/Reports/EN/CONSENSUS-FINAL-v8-en.pdf>
- Australian Institute of Sport: <http://www.ausport.gov.au/ais/nutrition>
- Food and Nutrition Information Center of the U.S. Department of Agriculture: [http://fnic.nal.usda.gov/nal\\_display/index.php?info\\_center=4&tax\\_level=1](http://fnic.nal.usda.gov/nal_display/index.php?info_center=4&tax_level=1)
- Sportsoracle Web site, particularly the International Association of Athletics Federations document: <http://www.sportsoracle.com/resources?id=2039>
- Select food and supplement companies develop and maintain educational Web sites for public access, but it is not the intention of this paper to promote companies or products

## Appendix 2. Regulatory Resources

- Codex Alimentarius: [http://www.codexalimentarius.net/web/index\\_en.jsp](http://www.codexalimentarius.net/web/index_en.jsp)
- American Botanical Council access to Commission E monographs for herbal therapies: <http://cms.herbalgram.org/commissione/index.html>
- Consumer information from the Federal Trade Commission: <http://www.ftc.gov/bcp/menus/consumer/health/drugs.shtm>
- Council for Responsible Nutrition (leading trade association represents ingredient suppliers and manufacturers): <http://www.crnusa.org>

- World Anti-Doping Agency, *The Guide*, 4th edition: <http://www.wada-ama.org>; Adopted code: <http://www.wada-ama.org/en/World-Anti-Doping-Program/Sports-and-Anti-Doping-Organizations/The-Code/Code-Acceptance>
- United States Anti-Doping Agency: <http://www.usantidoping.org>
- National Collegiate Athletic Association Drug-Testing Program and exceptions procedures: <http://www.ncaa.org/health-safety> and banned substance list <http://www.ncaa.org/wps/wcm/connect/public/NCAA/Student-Athlete+Experience/NCAA+banned+drugs+list>
- National Association of Intercollegiate Athletics: <http://naia.cstv.com>
- National Federation of State High Schools Associations Sports Medicine Advisory Committee position statements: <http://www.nfhs.org/content.aspx?id=5786&terms=position%20statements>
- The International Olympic Committee: <http://www.olympic.org>
- The National Center for Drug Free Sport and Resource Exchange Center: <http://www.drugfreesport.com>

## Appendix 3A. Safety Resources

- MedWatch: <http://www.fda.gov/Safety/MedWatch/default.htm>
- Quackwatch: <http://quackwatch.org>
- Dietary warnings and safety information from the US Food and Drug Administration: <http://www.fda.gov/Food/DietarySupplements/Alerts/default.htm>
- Recall of products: <http://www.fda.gov/Safety/Recalls/default.htm>
- Center for Drug Evaluation and Research: <http://www.fda.gov/Drugs/default.htm>
- United States Anti-Doping Agency: <http://www.supplementsafetynow.com>
- Reporting of dietary supplements: <http://www.oig.hhs.gov/oei/reports/oei-01-00-00180.pdf>
- US Department of Agriculture Food and Nutrition Information Center, dietary supplements (regulations, reports, and warnings): [http://fnic.nal.usda.gov/nal\\_display/index.php?info\\_center=4&tax\\_level=2&tax\\_subject=274&topic\\_id=1328](http://fnic.nal.usda.gov/nal_display/index.php?info_center=4&tax_level=2&tax_subject=274&topic_id=1328)

## Appendix 3B. Purity Resources<sup>a</sup>

Resource	Description
U.S. Pharmacopeia Dietary Supplement Verification Program <sup>70</sup> 	Voluntary program for manufacturers that “verifies” the quality of a product’s ingredients and manufacturing processes. The USP mark identifies products that <ul style="list-style-type: none"> <li>• contain the ingredients on the label in the declared potency and amount</li> <li>• do not contain harmful levels of specified contaminants (eg, heavy metals, pesticides, dioxins, polychlorinated biphenyls, microbes)</li> <li>• will break down and release into the body in a specified amount of time</li> <li>• have been made according to the Food and Drug Administration’s Good Manufacturing Process</li> </ul>

**Appendix 3B. Continued**

Resource	Description
<p>ConsumerLab.com Quality Evaluation<sup>21</sup></p> 	<p>For a product to use the ConsumerLab symbol, the product must be tested every 12 months based on a random sample purchased on the open market. The ConsumerLab symbol indicates that products were tested for</p> <ul style="list-style-type: none"> <li>• identity: label accuracy</li> <li>• strength: product contains the amount of the ingredient claimed on the label</li> <li>• purity: product is free of specified contaminants</li> <li>• disintegration: product breaks down properly, so it can be used by the body</li> </ul>
<p>NSF International Dietary Supplements Certification Program<sup>71</sup></p> 	<p>Independent, not-for-profit testing organization offers dietary supplement verification with 5 main components:</p> <ol style="list-style-type: none"> <li>1. Verification that the contents of the supplement match the label</li> <li>2. Assurance that no ingredients are present in the supplement that are not openly disclosed on the label</li> <li>3. Assurance of no unacceptable levels of contaminants</li> <li>4. Auditing of the manufacturing process to ensure no cross-contamination</li> <li>5. Verification that suggested dosing would not cause toxicity</li> </ol>

<sup>a</sup> These organizations do not screen for banned substances.

**Appendix 3C. Verification Programs for Purity and Banned Substances**

Resource	Description
<p>NSF Certified for Sport<sup>72</sup></p> 	<p>Includes supplement verification:</p> <ul style="list-style-type: none"> <li>• Product testing for banned substances and confirmation of label contents</li> <li>• Formulation and label review</li> <li>• Production facility and supplier inspections</li> <li>• Ongoing monitoring</li> </ul> <p>In addition, tests are performed against 164 analytes that could act as banned substances. The process includes 2 facility audits per year, including the other raw ingredients a company has on site and other finished products it manufactures to help ensure no cross-contamination. Product formulation and dosing are also evaluated to avoid any toxicity problems. This certification process includes unannounced plant inspections and ongoing product monitoring.</p> <p>NSF certifies products and inspects facilities for a range of substances identified by leading sports organizations, such as the National Football League, National Football League Players Association, Major League Baseball, Major League Baseball Players Association, Professional Golf Association, Ladies Professional Golf Association, and Canadian Centre for Ethics in Sport. Tested products include stimulants, narcotics, steroids, diuretics, <math>\beta_2</math>-agonists, masking agents, and other substances.</p>
<p>Banned Substances Control Group partnered with Anti-Doping Research Laboratory<sup>73</sup></p> 	<p>Process includes</p> <ul style="list-style-type: none"> <li>• Familiarization with the company history, facilities, and prior concerns and determining whether motivation for seeking approval is true product development or marketing</li> <li>• Ingredient review of formula sheet, looking for overt banned substances, including alternative names of banned substances</li> <li>• Unique product validation process in which the product is intentionally spiked with each analyte of interest and tested to identify the substance in the unique matrix of each supplement. This ensures high performance standards and sensitivity of each assay. Product performance varies widely in this step of the process; validation determines the threshold of banned substance the assay can identify</li> <li>• Product validation is performed once and used for future batch or lot certification; updated only if formula for product changes</li> </ul> <p>Menu of substances includes steroids and stimulants with development of prohormones and search for 56 banned substances. Ingredient competition in the matrix drives the menu of products that can be evaluated accurately, so menu development is unique for each product. New development underway includes <math>\beta_2</math>-agonists and diuretic testing for an additional 30 substances.</p>

**Appendix 3C. Continued**

Resource	Description
Informed-Choice program <sup>74</sup> partnered with UK-based HFL Sport Science Testing Laboratory <sup>75</sup>	<p>Informed-Sport (HFL) tests products or specific ingredients for more than 200 banned substances that are prohibited by Major League Baseball, National Collegiate Athletic Association, National Football League, and the World Anti-Doping Agency. The substance list is reviewed regularly against current knowledge and updated as necessary.</p> <p>The facility is reviewed for</p> <ul style="list-style-type: none"> <li>• Product/ingredient evaluation</li> <li>• Raw material evaluation at each production or packing site</li> <li>• Raw material supplier assessment procedures</li> <li>• Certificate and standard operating procedure review for all production, packing, and storage areas</li> <li>• Label claim, purity, and contaminant testing review</li> <li>• Third-party manufacturer</li> </ul> <p>Before a product or ingredient can be registered with Informed-Choice, 5 samples (from 3 batches) are tested and must be free of prohibited substances. Informed-Choice independently purchases and samples registered products.</p>



**Appendix 3D. Efficacy Resources and Fact Sheets**

- National Institutes of Health Fact sheets on dietary supplements: <http://ods.od.nih.gov/factsheets/list-all>
- Nutrient Recommendations: Dietary Reference Intakes (DRI), and Recommended Dietary Allowances (RDA): [http://ods.od.nih.gov/health\\_information/Dietary\\_Reference\\_Intakes.aspx](http://ods.od.nih.gov/health_information/Dietary_Reference_Intakes.aspx)
- National Institutes of Health, Office of Dietary Supplements fact sheets: [http://ods.od.nih.gov/Research/PubMed\\_Dietary\\_Supplement\\_Subset.aspx](http://ods.od.nih.gov/Research/PubMed_Dietary_Supplement_Subset.aspx)
- Natural Medicines database: <http://naturaldatabase.therapeuticresearch.com/home.aspx?cs=osu&s=ND>
- The Natural Pharmacist partners with ConsumerLab: <http://www.consumerlab.com/tnp.asp>
- Sports, Cardiovascular, and Wellness Nutritionists Practice Group of the American Dietetic Association: <http://www.scandpg.org>, <http://www.scandpg.org/sports-nutrition/sports-nutrition-fact-sheets>
- Professionals in Nutrition for Exercise and Sport (PINES): <http://www.sportsoracle.com/pines/pines-home>
- Australian Institute of Sport: <http://www.ausport.gov.au/ais/nutrition>
- *British Journal of Sports Medicine* series “A-Z of Nutritional Supplements: Dietary Supplements, Sports Nutrition Foods and Ergogenic Aids for Health and Performance” as published by sports nutrition experts<sup>44</sup>: [bjsm.bmj.com/content](http://bjsm.bmj.com/content)

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