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**CRN RESPONDS TO SPORTS ILLUSTRATED ARTICLE**

WASHINGTON, D.C., May 19, 2009 – In response to a recent article in the May 18 issue of *Sports Illustrated* magazine, the Council for Responsible Nutrition (CRN), the leading trade association representing the dietary supplement industry, issued the following statement.

**Statement from Steve Mister, president and CEO, CRN:**

“*Sports Illustrated’s* article “What You Don’t Know Might Kill You,” (May 18, 2009) starts by referring to sports nutrition supplements as a “\$20 billion obsession,” portraying the industry as eight times larger than it is. Now it’s true that more than 150 million Americans take dietary supplements annually, and that 72 percent of physicians recommend supplements—products that include vitamins, minerals, botanicals, sports nutrition, weight management, and specialty supplements. The entire dietary supplement industry has U.S. sales of approximately \$24 billion, with vitamin sales alone representing approximately \$10 billion of the total market. But the sports nutrition supplements that are the focus of this article represent sales somewhere closer to \$2.5 billion. While that smaller figure is not nearly as dramatic as the \$20 billion figure which teases the story, it is important, from a factual standpoint, to point out that the estimate in the article for sports nutrition products includes not just dietary supplements, but a whole range of conventional food products and drinks that are marketed for weight loss as well.

Ironically that inflated figure seeks to portray a problem that, if it exists at all, represents only a very small portion of companies in the supplement industry not representative of the mainstream companies that manufacture products that consumers choose to include in their cadre of personal healthcare options.

Further, the article is surprisingly one-sided and suffers from an unfortunate lack of understanding of the Dietary Supplement Health and Education Act (DSHEA)—both in terms of what the law did, and what it allows the Food and Drug Administration (FDA) to do. Contrary to Dr. David Kessler’s statements, and to common misunderstandings about the law, rather than shifting the safety burden to FDA, DSHEA actually provided FDA with new enforcement authority not previously available. Dietary supplements were regulated as a category of food prior to DSHEA and continue to be regulated as a category of food today. Further, FDA never had legal pre-market approval authority for dietary supplements—DSHEA did not change that fact.

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The article inaccurately suggests that dietary supplements are exempted from the entry requirements and regulatory scrutiny that apply to all other FDA-regulated products, including food and drugs. That is simply not so. According to the article, DSHEA “razed virtually every barrier to entry into the marketplace.” With that premise, the extreme examples the article describes appear to be a product of DSHEA, when in fact, they more likely result from FDA’s lack of enforcement of that law over the past 16 years, starting with Dr. Kessler’s decision to allow FDA to turn its back on supplement regulation once DSHEA—a bill he strongly opposed—was enacted.

DSHEA was passed by Congress following an outpouring of letters received from consumers urging the legislative body to keep intact consumers’ freedom of choice when it came to supplements. This consumer activism was fueled consumers’ concerns that FDA was inappropriately looking to stretch its regulatory muscle to the point where it would be impossible for companies to bring new products to market, and could also have pulled products off the shelves without any scientific rationale or safety reason. But consumers made it quite clear that they wanted to play a proactive role in their healthcare regimen, and that FDA’s precautionary principle approach was not going to be tolerated.

Once the law passed, the folklore that the law “took away” FDA’s authority began, but in reality, DSHEA gave the Agency new tools for enforcement. In actuality, FDA chose to sit on its collective hands, refusing to take advantage of the new tools it now had, even ignoring the simplest requirements from Congress to issue new Good Manufacturing Practices (GMPs) specific to dietary supplements.

Whether due to a lack of resources, a lack of interest, or a lack of political will, following the passage of DSHEA, FDA failed to enforce the regulations that DSHEA put on the books. It wasn’t until Dr. Mark McClellan became FDA Commissioner in 2002 that the Agency emerged from its fog of inertia concerning the dietary supplement industry and began to look at and use some of the additional authority provided to it by DSHEA.

Beginning with Dr. McClellan’s tenure, FDA began to open the toolbox, and actively find ways to use the authorities granted it under DSHEA. In the past five years or so, the industry and the Agency have both come a long way: with industry lobbying for GMPs that are supplement-specific and FDA finally issuing these rules; with industry urging for passage of a mandatory reporting system for serious adverse events, and FDA getting the system up and running; and with FDA taking strong enforcement action—ranging from warning letters to significant fines to product seizures against companies that manufacture unapproved drugs masquerading as dietary supplements.

The article’s description is not how we—and responsible companies in the industry—understand the laws and regulations at all. To begin with, because dietary supplements are regulated as a category of food, in every respect they get at least the same levels of scrutiny accorded to any

kinds of food—from breakfast cereals to canned soup—and in many respects they get even more.

Under current law, any facility that manufactures, packages, or processes a dietary supplement must register with FDA before starting operation. Extensive regulations specify that these products carry a “Supplement Facts” box on their labels alerting consumers to the contents of the product, and failure to comply with these rules makes the supplement “adulterated” (in other words, subject to FDA seizure and prosecution). With respect to the claims one can make for these products, there are still more requirements in the law: If you want to make a claim about how the product affects the structure or function of the body, you must provide FDA with the exact wording of those claims within 30 days after beginning marketing of the product; for claims that the product may reduce the risk of certain diseases, you must get FDA approval before using these claims at all; and any claims that a product treats, cures, prevents or mitigates a disease are prohibited altogether. In addition, if you plan to bring a new ingredient to market that was not already sold as a food or dietary supplement prior to 1994, you must notify FDA of the new dietary ingredient and provide evidence that the product can reasonably be expected to be safe at least 75 days *prior* to marketing. Once a company begins manufacturing dietary supplements, it is subject to the GMP regulations that were issued in 2007 and the requirement to report serious adverse events to FDA within 15 days of being notified, a law enacted in 2006. When FDA chooses to enforce these requirements, they offer considerable market barriers to screen out bad actors.

The article also insinuates that anabolic steroids and pro-hormone ingredients are lawfully marketed under the law and that enforcement to remove these products from the market is left to the Drug Enforcement Agency (DEA) to “keep up” with the ever evolving list of new metabolites and analogs of these anabolic steroids. That’s simply not true. Under DSHEA, most of these substances are not even legal dietary ingredients, i.e., they cannot be legally included in dietary supplements, period. DSHEA further provides that a dietary supplement containing a “new dietary ingredient (NDI)” that is marketed without complying with the NDI notification process is adulterated under the Act, and it further provides that any food (including supplements) that is adulterated is subject to a range of penalties including seizure, fines and imprisonment for the manufacturer. Completely independent of DEA’s jurisdiction in this area, FDA has clear and powerful authority to address supplements that contain performance-enhancing drugs or anabolic steroids. These various new chemical cocktails are illegal under DSHEA simply because no NDI has been filed for them or because they are not legal dietary ingredients in the first place. But curiously, we are not aware that FDA has ever initiated an enforcement action because a dietary supplement failed to comply with the NDI notification requirements. Just as the evasion of tax laws were ultimately used to bring down many notorious gangsters of old, the NDI provisions of the law offer a convenient and effective way to get anabolic steroids and human growth hormone and their related analogs out of the supplement aisle once and for all—and this can be accomplished under DSHEA when the FDA chooses to act.

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Unfortunately, readers are left with no way to distinguish legitimate sports nutrition products from the ones without sufficient safety profiles and quality assurance. Every industry has its outliers, the underbelly that ignores the laws, cuts corners in manufacturing and puts profits ahead of long-term confidence of their consumers. This industry is no exception, but that is not the fault of the law itself. No law works unless it is enforced.

The supplement industry, including sports nutrition supplements, has a strong safety profile, and consumers value the benefits these products can provide. The entire supplement industry sells billions of bottles of products in a year, and yet for the first full year that the mandatory serious adverse event reporting system for supplements was in existence, FDA received only 1,080 total adverse event reports, 672 of which were considered serious. Compare these numbers to the pharmaceutical industry where hundreds of thousands of serious adverse events are received each year. In 2008 alone, FDA received over 526,000 adverse event reports related to drugs and biologic products, over 300,000 of which were considered serious, including close to 50,000 deaths. In the period from 1969 through 2002, a total of 75 FDA-approved drugs were removed from the market due to safety concerns. The American Association of Poison Control Centers reported that in 2007 the category of analgesics alone was associated with over 6,300 adverse reactions, compared with just over 3,100 for *all* dietary supplements (including vitamins, minerals, multivitamins, amino acids, botanicals, etc...).

But numbers for serious adverse events must be placed within context, and it should be recognized that while adverse events allow FDA to determine potential patterns or problems with a specific product or product category, they are not necessarily causally related to products. Even with a strong safety record for supplements, consumers would be wise not to buy supplements in back-rooms or ones advertised to be “legal” versions of otherwise illegal substances, and they should be wary of products that make claims that sound too good to be true.

Some critics who call for a revision of DSHEA are cavalier in their approach: suggesting that pre-market approval of all products is the answer. But pre-market approval provides no guarantee of safety, as we’ve seen with pharmaceutical products that have been “approved” only to be later withdrawn due to safety concerns. Further, it is not reasonable to believe that FDA has the resources to manage a pre-market approval system for dietary supplements, nor is it necessary to ask for one: the provisions in place under the law—when enforced—provide the Agency with appropriate authority to protect consumers while still allowing them access to the variety of beneficial products they are requesting.

The article also fails to place any responsibility on the highly-paid professional athletes to know what they put in their bodies and the rules imposed on them by their leagues. Some substances (even caffeine and certain cold medicines) are banned by some professional sports organizations for their potential to provide an artificial “edge” to paid athletes; that doesn’t mean the product is unsafe for everyone else.

Whatever the law, the “burden” for consumer safety should always rest between a combination of industry responsibility and regulatory body enforcement. The article leaves the reader with the misimpression that the industry is suffering from a weak legal framework to govern bad actors and outliers—and that simply is not true. Now that FDA has set its regulatory mind to enforcing the law, it has the ability under the law to weed out bad actors—those who are not abiding by regulations. FDA’s job is to protect the public, and we urge Congress to provide sufficient budgetary funds for the Agency to do its job, rather than wasting time and tax-payers’ money with re-writing laws unnecessarily.”

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**Note to Editor:** The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing dietary supplement manufacturers and ingredient suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements, CRN members also agree to adhere to voluntary guidelines for manufacturing, marketing and CRN’s Code of Ethics. Visit [www.crnusa.org](http://www.crnusa.org).