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October 20, 2009

BY ELECTRONIC MAIL AND HAND DELIVERY

Sarah Guerrieri
Hearing Clerk
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

Dear Ms. Guerrieri:

This is in response to Senator Specter's letter dated October 6, 2009, and Senator Leahy's letter dated October 7, 2009, which requested answers to supplemental questions in relation to my testimony at the September 29 hearing on "Body Building Products and Hidden Steroids: Enforcement Barriers." My answers are set out in the attachments to this letter.

Please let me know if anything further is required.

Yours sincerely,

Richard Kingham

Attachments

October 20, 2009

Answers from Richard Kingham, Covington & Burling LLP, to Questions from Senator Specter in Relation to the Hearing on "Body Building Products and Hidden Steroids: Enforcement Barriers"

1. How best can we achieve the balance between free and open markets for dietary supplements while keeping all consumers safe from contaminated and unsafe products?

Answer

The current provisions of the Federal Food, Drug, and Cosmetic Act (FDCA) are adequate to achieve this balance. The Act provides the Food and Drug Administration (FDA) and other federal law enforcement authorities with a range of effective remedies against dietary supplements and other products that are unsafe within the meaning of the statute, that contain new dietary ingredients for which required premarket submissions have not been made, or that are deemed to be "new drugs" for which approved new drug applications (NDAs) are required. Enforcement measures available under the FDCA include seizures of unlawful products, injunction proceedings against companies that distribute them, and criminal prosecutions of companies and responsible individuals. Criminal liability does not require proof of intent, negligence, or other *mens rea* and can be imposed on any individual who stands in a responsible relationship to an enterprise that commits a violation. In addition, FDA may take informal measures to enforce the law, including issuance of warning letters and consumer alerts. As was stated in my testimony, products of the type that were the subject of the recent hearing will ordinarily be unlawful under one or more provisions of the FDCA and therefore liable to any or all of the available enforcement measures. The problem is thus not with the provisions of the law, which are more than adequate to protect consumers, but with the enforcement priorities and resources of the federal government. Congress should send a clear message to FDA that it wishes the existing law to be vigorously enforced, and provide FDA with the resources necessary to carry out its statutory duties.

2. Would it help to address the problems raised in this hearing if FDA had recall authority for dietary supplements found to be unsafe?

Answer

Historically, FDA has almost always been able to secure voluntary product withdrawals and recalls, relying in part on the threat of adverse publicity and formal enforcement actions. If the agency vigorously pursues the enforcement measures currently available to it, it should not require formal recall power. I understand, however, that Congress is currently considering including such power in the FDCA in respect of all food products as part of the pending food safety legislation. If such power is granted to FDA, it will presumably apply to dietary supplements that are unsafe or otherwise in violation of the FDCA, in the same manner that it would apply to other foods.

3. Mr. Tygart, in his written statement, suggested some regulatory fixes for the problems addressed in the hearing. Which ones, if any, do you support?

Answer

For the reasons set out in my testimony, I believe the main problem is one of resources and priorities for enforcement of existing legal authority. New legal requirements are unlikely to be effective unless the federal government enforces them. Set out below are responses to Mr. Tygart's proposals, in the order in which they are made on pages 10-11 of his prepared statement:

- It might be feasible to require registration of dietary supplement manufacturers, perhaps coupled with submission of product labels, in a manner similar to the submissions made for drug products under section 510 of the FCDA. As under section 510, these submissions should not require any form of premarket approval, but would provide FDA with current information on products in the marketplace. Such submissions would be in addition to submissions that are already required under bioterrorism legislation and under the FDCA with respect to structure/function claims for dietary supplements.

- There is no reason to require submission of master formulas (which are typically regarded as trade secrets), because appropriate composition information is contained in ingredient declarations that are currently required on product labels.

- There is no need to amend the current provisions relating to premarket submissions for new dietary ingredients to deal with the issues presented by anabolic steroids. Old anabolic steroids will typically be within the list of substances in Schedule III under the Controlled Substances Act, while new anabolic steroids of synthetic origin will require new dietary ingredient submissions under the provisions of the FDCA.

- There is no need to amend the FDCA to create new requirements for data substantiation files for dietary supplements. Current FDA regulations require companies to make submissions to the Agency certifying that the claims about the effects of dietary supplements on the structure or functions of the body are adequately substantiated, and the Federal Trade Commission has long held that it is an unfair practice, in violation of the FTC Act, to make a product performance claim for which prior substantiation does not exist.

- No amendments to the FDCA are needed to hold distributors and retailers of dietary supplements responsible for the products they sell, because the FDCA already imposes such responsibility on these entities.

- Additional rules are not needed for reporting of adverse events associated with dietary supplements. Existing rules require reports of serious adverse events, whether or not they are actually caused by a supplement, and FDA has very limited resources to deal with this small number of reports. If all events were required to be reported, FDA would be swamped, and serious events could be lost in the background noise of minor product

complaints. Under current law, manufacturers are required to keep records of all adverse event complaints, whether serious or not, and make them available to FDA on request, so the agency can obtain full information on all events associated with specific products when it believes that information is required.

- FDA does not need additional authority to deal with marketing of products for which required premarket submissions have not been made. Failure to make such submissions subjects the products to seizure actions and the companies and individuals that market them to injunctions and criminal prosecution (under a strict liability standard). These are the same enforcement powers FDA currently uses to protect against marketing drugs for which required premarket submissions are not made. They give the agency more than adequate power, provided that the power is actually used and the agency commits necessary resources to enforcement.

- There is not currently a case that amendments are required to the scheduling provisions of the Controlled Substances Act (CSA). Congress only recently amended the CSA, at the Drug Enforcement Administration's request, to simplify the findings required for scheduling of anabolic steroids. It does not appear that DEA has committed the resources necessary to make full use of the powers it already possesses. Before any amendments are considered, Congress should make a detailed inquiry to determine why DEA has not made effective use of its existing powers.

- In the absence of effective action by DEA, there is in principle no reason why Congress should not update Schedule III of the CSA to include new anabolic steroids, provided that the listed substances actually meet the scheduling criteria contained in the Act. But it is a matter for considerable concern that DEA rulemaking procedures are so inefficient that Congress can enact amendments to the statute faster than the agency can take administrative action.

- There is no need to enact new provisions relating to advertising claims for anabolic steroids. Under existing law, as interpreted by FDA in warning letters and other enforcement actions, claims of the type with which the hearing was concerned will almost always be "drug" claims within the meaning of the FDCA, subjecting products to enforcement action for lack of an approved new drug application. False or unsubstantiated claims of steroidal effect will also be subject to action under the misbranding provisions of the FDCA and the enforcement provisions of the FTC Act. It would be entirely inappropriate to enact a general prohibition on claims that dietary supplements (or other foods) affect the structure or function of the body. FDA has long permitted such claims for many foods (e.g., "calcium helps build strong bones"), and there is no conceivable reason to deprive consumers of truthful information of this kind.

4. Do you have suggested fixes of your own?

Answer

Existing law is more than adequate to protect consumers against illegal anabolic steroids. The real problem is lack of enforcement. Congress must send a clear message to DEA and FDA to enforce the law, and must give those agencies and other federal law enforcement authorities the resources they need to do their jobs.

October 20, 2009

Answers to Questions from Senator Hatch to Richard Kingham, Covington & Burling LLP, in Relation to Hearing on "Body Building Products and Hidden Steroids: Enforcement Barriers"

1. Does FDA already have the authority to move against dietary supplements contaminated with drugs, including steroids? Please describe the range of enforcement tools available to the agency?

Answer

Yes, FDA has broad powers to act against products marketed as dietary supplements that are contaminated with anabolic steroids and other drugs. If anabolic steroids are not listed in the ingredient declarations, such products will be misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act (FDCA). Contaminated products would also most likely be in violation of FDA regulations establishing requirements for current good manufacturing practice (cGMP) for dietary supplements and thus be deemed to be adulterated under the FDCA. Depending on the circumstances, such products would often be classified as new drugs, for which approved new drug applications (NDAs) are required under the FDCA, or would contain new dietary ingredients for which premarket notifications are required under the law. Failure to comply with the NDA requirement is an offense under the FDCA and also renders the product misbranded for lack of adequate directions for use; failure to comply with the requirement for premarket notification of a new dietary ingredient renders the product adulterated under the FDCA. FDA and the Department of Justice can use a wide range of enforcement measures to punish and prevent violations of the FDCA, including seizures of violative products, injunction actions against companies and individuals that market such products, and criminal prosecutions of companies and responsible individuals. Criminal liability can be imposed under the FDCA on any person who stands in a responsible relation to a violation of the act, without proof of intent, negligence, or other *mens rea.* Federal courts have also used their injunction powers under the FDCA to require disgorgement of profits resulting from sale of violative products. In addition, FDA can take a variety of informal enforcement measures, including issuance of warning letters and other correspondence, as well as consumer alerts and other forms of publicity. Using the threat of adverse publicity and formal enforcement action, FDA can induce companies to recall violative products from the market.

2. Isn't it true that all manufacturers currently have the legal responsibility to list all dietary supplement ingredients on the label?

Answer

Yes, under the FDCA and FDA regulations, the label for a dietary supplement must declare all dietary supplement ingredients. Failure to comply with this requirement renders the product misbranded and subjects the product and persons responsible for selling it to the full range of enforcement measures identified above.

3. Mr. Levy of the FDA states in his testimony that many of these adulterated body-building products may be manufactured without quality controls. This seems to me to be in violation of the Good Manufacturing Practices Regulation. Would you agree, and if so, does FDA have the authority to pursue enforcement actions?

Answer

Yes. FDA's regulations governing current good manufacturing practice for dietary supplements, set out in 21 CFR Part 111, contain detailed requirements for personnel, manufacturing facilities, production and process control systems and quality assurance, control of components, packaging, and labels, master manufacturing records, batch production records, laboratory operations, manufacturing operations, packaging and labeling operations, holding and distributing products, handling of returned products, complaints, and recordkeeping. Products that are not manufactured in accordance with these requirements are deemed to be adulterated under the FDCA, subjecting the products and persons responsible for their manufacture to the full range of legal sanctions identified above.

4. I also welcome your informed viewpoint on food and drug issues. I think you have done a good job in identifying the many tools FDA has to regulate dietary supplements.

   The testimony of FDA's Mr. Levy concludes that there are many regulatory challenges which preclude his agency from being able to identify and remove illegal steroid products from the market.

   Would you care to comment on the challenges Mr. Levy outlined in his testimony in any greater detail for the record? Do you see these as legal challenges or more as administrative challenges?

Answer

In my view, existing law is more than adequate for FDA to take effective action against marketing of unlawful dietary supplement products, including the anabolic steroid products that were the subject of the hearing. As noted in my answer to Question 1, these products will typically violate any of several provisions of the FDCA, subjecting the products and persons responsible for marketing them to a wide range of sanctions, including strict criminal liability. The challenge is therefore a matter of law enforcement resources and priorities rather than lack of legal powers.

In particular, there is no need to adopt additional provisions relating to premarket notification or approval of dietary supplements. Most of the products that were the subject of the hearing appear to have been marketed in violation of existing requirements for approval of NDAs or premarket notification of new dietary ingredients. In the absence of tough enforcement policies, it is unlikely that a new requirement for premarket submissions would be any more effective than the requirements under existing law.

FDA has many resources at its disposal to discover violative products in the marketplace. Investigators can take samples of products sold in retail outlets, and FDA can monitor the Internet and make test purchases of suspicious products. A major source of information is complaints from law-abiding manufacturers, who often submit detailed reports to FDA concerning products that appear to have been introduced to the market in violation of the FDCA. In my experience, FDA has often been slow to act in response to such reports, even when repeated requests are made for enforcement action. In recent years, the agency has also made sparing use of the formal enforcement measures at its disposal, except in the most egregious cases, relying instead on warning letters and other informal communications.

FDA is not entirely to blame for this situation. For many years, Congress has failed to appropriate sufficient funds for enforcement of federal laws governing foods, including dietary supplements. Until recently, the relevant part of FDA's budget actually declined from year to year, after allowing for inflation. The result was a steady decrease in the number of field and headquarters personnel dedicated to enforcement of laws relating to food safety and labeling. In the FY 2009 budget, Congress began to redress this deficiency, responding in part to a substantial effort by coalitions including trade associations of FDA-regulated industries. But more resources are needed, coupled with a clear mandate from Congress for vigorous enforcement of the FDCA.

5. Mr. Kingham, the associations who testified at the hearing indicate that they share the concern we in Congress have shown about the problem of illegal steroid precursor products, many of which could be threatening young athletes.

   Would the association you represent pledge to work with Congress as we consider steps to make these products less available, such as possible amendments to the Controlled Substances Act?

Answer

The Council for Responsible Nutrition (CRN), for which my firm acts as a legal adviser, is fully committed to working with Congress on actions necessary to prevent the sale of illegal anabolic steroid products. The first priority, as outlined above, is effective enforcement of existing law. It is my understanding, however, that CRN would support reasonable amendments to the Controlled Substances Act if they are needed to provide additional power for the federal government to protect consumers, including young athletes, from illegal anabolic steroids.

October 20, 2009

Answers from Richard Kingham, Covington & Burling LLP, to Questions from Senator Hatch for Kingham and Fabricant Relating to Hearing on "Body Building Products and Hidden Steroids: Enforcement Barriers"

1. There has been a lot of discussion about the article appearing in *Sports Illustrated* earlier this year. Mr. Kingham and Mr. Fabricant, could I get your reaction to some of the accusations made in the article? I would appreciate hearing your insights.

Answer

In my view, the article exaggerates the scope of the problem presented by illegal anabolic steroids and misstates the legal status of those products and the enforcement powers available to federal agencies to control their sale. *Any* use of illegal anabolic steroids is a matter for great concern, given the well-known adverse effects of those products. But the article suggests that the sports nutrition industry is much larger than it actually is, and fails to recognize that products containing illegal anabolic steroids comprise a tiny fraction of the products in that sector. The article also wrongly suggests that the Dietary Supplement Health and Education Act of 1994 (DSHEA) effectively deregulated dietary supplements and deprived FDA of enforcement powers. In fact, DSHEA established a detailed and comprehensive regulatory regime that currently includes requirements for premarket notification of new dietary ingredients, full ingredient declarations on product labels, mandatory good manufacturing practice, mandatory notification to FDA about claims that a product or ingredient is intended to affect the structure or function of the body, and more than adequate power for FDA to act against products that are adulterated, misbranded, or unsafe within the meaning of the law. In addition, the statute leaves intact FDA's power to act against products that fall within the provisions of the Federal Food, Drug, and Cosmetic Act (FDCA) governing drugs, including requirements for premarket approval of new drug applications (NDAs). Products of the type that were the subject of the recent hearing will almost always be in violation of one or more provisions of the FDCA. Such products and persons responsible for selling them will be subject to the full range of formal and informal enforcement actions under the statute, including seizures, injunctions, criminal prosecutions, warning letters, and other measures. I am attaching to this submission a detailed response to the *Sports Illustrated* article that was posted on the Internet website of the Council for Responsible Nutrition.

2. What is your response to the concerns raised by both the FDA and the DEA to the difficulties encountered when agencies try to pull products containing steroids off the market?

Answer

My response to Question 4 in the list of questions from Senator Hatch directed specifically to me, which accompanies this submission, contains a detailed answer to this question. In my view, FDA and DEA, working together, have ample authority to control the sale of illegal anabolic

steroids. With respect to products containing ingredients that are listed in Schedule III under the Controlled Substances Act, DEA has extensive enforcement powers, including the potential to seek severe criminal penalties. DEA also has the power to add new substances to Schedule III in accordance with simplified findings established by the Anabolic Steroid Control Act of 2004. As for other products of the type addressed in the hearing, FDA and the Department of Justice have a wide range of enforcement powers at their disposal under the FDCA. The problem is therefore not lack of legal authority but rather lack of effective enforcement of existing laws.

3. Has the federal government, specifically the FDA and the DEA, reached out to the industry to work in a collaborative manner to address issues associated with products containing synthetic steroid ingredients that are marketed as dietary supplements?

Answer

I am not personally aware of such efforts on the part of the federal agencies.

4. In Mr. Tygart's testimony, he makes several suggestions on how to address the problems the Subcommittee is discussing today. Has the industry reviewed his recommendations? Are there any areas of agreement?

Answer

I can offer my personal views as a lawyer to who advises regulated companies. For the reasons set out in my testimony, I believe the main problem is one of resources and priorities for enforcement of existing legal authority. New legal requirements are unlikely to be effective unless the federal government enforces them. Set out below are responses to Mr. Tygart's proposals, in the order in which they are made on pages 10-11 of his prepared statement:

- It might be feasible to require registration of dietary supplement manufacturers, perhaps coupled with submission of product labels, in a manner somewhat similar to the submissions made for drug products under section 510 of the FCDA. As under section 510, these submissions should not require any form of premarket approval, but would provide FDA with current information on products in the marketplace. Such submissions would be in addition to submissions that are already required under bioterrorism legislation and under the FDCA with respect to structure/function claims for dietary supplements.

- There is no reason to require submission of master formulas (which are typically regarded as trade secrets), because necessary information is contained in ingredient declarations that are currently required on product labels.

- There is no need to amend the current provisions relating to premarket submissions for new dietary ingredients to deal with the issues presented by synthetic anabolic steroids. Old anabolic steroids will typically be within the list of substances in Schedule III under the Controlled Substances Act, while new anabolic steroids of synthetic origin will require new dietary ingredient submissions under the provisions of the FDCA.

- There is no need to amend the FDCA to create new requirements for data substantiation files for dietary supplements. Current FDA regulations require companies to make submissions to the Agency certifying that claims about the effects of dietary supplements on the structure or functions of the body are adequately substantiated, and the Federal Trade Commission has long held that it is an unfair practice, in violation of the Federal Trade Commission Act, to make a product performance claim for which prior substantiation does not exist.

- No amendments to the FDCA are needed to hold distributors and retailers of dietary supplements responsible for the products they sell, because the FDCA already imposes such responsibility on these entities.

- Additional rules are not needed for reporting of adverse events associated with dietary supplements. Existing rules require reports of serious adverse events, whether or not they are actually caused by a supplement, and FDA has limited resources even to deal with this relatively small number of reports. If all events were required to be reported, FDA would be swamped, and serious events could be lost in the background noise of minor complaints. Under current law, manufacturers are required to keep records of all adverse event complaints, whether serious or not, and make them available to FDA on request, so the agency can obtain full information on all events associated with specific products whenever it is required.

- FDA does not need additional authority to deal with marketing of products for which required premarket submissions have not been made. Failure to make such submissions subjects the products to seizure actions and the companies and individuals that market them to injunctions and criminal prosecution (under a strict liability standard). These are the same enforcement powers FDA currently uses to protect against the sale of drugs for which required premarket submissions are not made. They give the agency more than adequate power, provided that the power is actually used and the agency commits necessary resources to enforcement.

- There is not currently a case that amendments are required to the scheduling provisions of the Controlled Substances Act (CSA). Congress only recently amended the CSA, at the Drug Enforcement Administration's request, to simplify the findings required for scheduling of anabolic steroids. It does not appear that DEA has committed the resources necessary to make full use of the powers it already possesses. Before any amendments are considered, Congress should make a detailed inquiry to determine why DEA has not made effective use of its existing powers.

- In the absence of effective action by DEA, there is in principle no reason why Congress should not update Schedule III of the CSA to include new anabolic steroids, provided that the listed substances actually meet the scheduling criteria contained in the Act. But it is a matter for considerable concern that DEA rulemaking procedures are so inefficient that Congress can enact amendments to the statute faster than the agency can take administrative action.

- There is no need to enact new provisions relating to advertising claims for anabolic steroids. Under existing law, as interpreted by FDA in warning letters and other enforcement actions, claims of the type with which the hearing was concerned will often be "drug" claims within the meaning of the FDCA, typically subjecting products to enforcement action for lack of an approved new drug application. False or unsubstantiated claims of steroidal effect will also be subject to action under the misbranding provisions of the FDCA and the enforcement provisions of the FTC Act. It would be entirely inappropriate to enact a general prohibition on claims that dietary supplements (or other foods) affect the structure or function of the body. FDA has long permitted such claims for many foods (e.g., "calcium helps build strong bones"), and there is no conceivable reason to deprive consumers of truthful information of this kind.

Attachment

Press Release www.crnusa.org

Council for Responsible Nutrition

The Science Behind the Supplements

FOR IMMEDIATE RELEASE Contact: Season Solorio, 202-204-7682

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.

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.