



**ADR's Dietary Supplement Survey  
Controlled Substances in Dietary Supplements  
and the Potential Threat to Public Health  
October 2010**

**Current Dietary Supplements May Contain Harmful Ingredients**

According to the U.S. Food & Drug Administration, over-the-counter dietary supplements available today are increasingly unsafe. The FDA recently issued the following warning: "FDA has identified an emerging trend where over-the-counter products, frequently represented as dietary supplements, contain hidden active ingredients that could be harmful. Consumers may unknowingly take products laced with varying quantities of approved prescription drug ingredients, controlled substances, and untested and unstudied pharmaceutically active ingredients. These deceptive products can harm you! Hidden ingredients are increasingly becoming a problem in products promoted for bodybuilding, weight loss and sexual enhancement. Remember, FDA cannot test all products on the market that contain potentially harmful hidden ingredients. Enforcement actions and consumer advisories for tainted products only cover a small fraction of the tainted over-the-counter products on the market."<sup>1</sup>

With more than half the population of the United States consuming dietary supplements, according to a recent Nielsen survey<sup>2</sup>, the current situation represents a serious risk to public health. It also threatens the integrity of sport and the livelihoods of elite professionals and others who are subject to strict drug testing. The Los Angeles-based nonprofit organization Anti-Doping Research, Inc., a leading performance-enhancing drug and toxicology research organization, is moving to help tackle this problem with its Dietary Supplement Survey and is seeking financial assistance to fund its work. Please consider joining ADR in this important effort.

**Background**

The passage of the Dietary Supplement Health and Education Act of 1994 (DSHEA) led to a remarkable expansion of the dietary supplement industry. Today, the industry has reached more than \$25 billion in annual sales with over 29,000 products<sup>3</sup>. DSHEA qualified dietary supplements as a special category excluding them from the stringent requirements for safety or efficacy that the FDA has for food and drugs. Vitamins, minerals, herbs, amino acids, protein powders, weight loss products, muscle building or performance aids, and more are classified as 'dietary supplements'.

It is generally agreed that DSHEA was an important legislative advance, yet ongoing issues remain with interpretation of certain provisions and enforcement. Of greatest importance, as the FDA clearly warns, it does not have the capacity to keep hidden, undeclared active ingredients out of the dietary supplement market. Consequently, some complicated and dangerous issues have become apparent.

**Specific Examples of the Problems**

***Prohormones – Steroid alternatives still widely available over-the-counter today***

Prohormones are a loosely defined group of compounds that are anabolic steroids in disguise or work like anabolic steroids through body metabolism. Androstenedione, which appeared around 1996 and

<sup>1</sup> <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm207647.htm>

<sup>2</sup> [http://en-us.nielsen.com/content/nielsen/en\\_us/insights/consumer\\_insight/issue\\_16/half\\_of\\_americans.html](http://en-us.nielsen.com/content/nielsen/en_us/insights/consumer_insight/issue_16/half_of_americans.html)

<sup>3</sup> <http://www.crnusa.org/CRNRegQandA.html>

was made famous by Mark McGwire, was the first ‘successful’ prohormone. Other options soon followed with names like Madol, Tren, Turinabol, Superdrol, Halodrol 50 and THG, the drug at the center of the infamous BALCO<sup>4</sup> sports scandal. Not surprisingly, these compounds, known under hundreds of synonyms and brand names, became very popular and sales exploded. Finally, in 2004 the government revised the Anabolic Steroid Control Act<sup>5</sup>, officially classifying these drugs and their chemical cousins as controlled substances making them illegal to sell in dietary supplements.

Despite the new legislation, the sports supplement industry continued to sell and create new options. In late 2009, the FDA stepped up efforts to curtail sales by approaching one of the largest retailers, Bodybuilding.com, and informing the company that they were selling 65 products classified as steroids resulting in a voluntary recall<sup>6</sup>. In a laudable step, Bodybuilding.com appears to have adopted a commitment to keep prohormones off its site as none are found on the site currently.

One might think this was the end for these products but a quick Internet search today demonstrates otherwise. Amazon.com is still selling Competitive Edge Labs X-Tren<sup>7</sup> and more like M-Drol and H-Drol. Nutrition Arsenal has Competitive Edge Labs M-Drol and H-Drol today as well as 84 other prohormone options<sup>8</sup>. Another, BuySupps.com has 6 prohormones<sup>9</sup> listed including new clones of old favorites like Halodrol and Superdrol. These are mere examples of the dangerous products that remain widely available and more brands and products appear monthly.

### ***Drug alternatives sold as dietary supplements – Example: Ephedra and other herbal stimulants***

The herbal stimulant craze became widespread with Ephedra, a popular Chinese remedy known also as Ma Huang. FDA started attempts to regulate it around 1995 as it became associated with harmful side effects and health concerns. They were finally successful in 2004, prompted in large part by the death of Major League Baseball pitcher Steve Bechler in February 2003.

Since then, the supplement industry has created a variety of ‘legal ephedra’ alternatives such as bitter orange. Bitter orange, or citrus aurantium, is known to contain octopamine, an analog of ephedrine that is banned in many sports. The National Center for Complementary and Alternative Medicine has found that “there is currently little evidence that bitter orange is safer to use than ephedra.”<sup>10</sup> Nonetheless, it remains a popular ingredient in dietary supplements.

Methylhexanamine is a weak stimulant that has become popular in supplement products. It was first trademarked under the name ‘Forthane’ by Eli Lilly in 1971 as a nasal decongestant and has been used as a ‘party pill’ in New Zealand. In 2009, the use of methylhexanamine caused five Jamaican athletes to return positive drug tests. Although methylhexanamine was not named as a banned substance by the World Anti-Doping Agency (WADA) at the time, it was banned as a “related substance” on [page 7 of the WADA Prohibited List](#), therefore sanctions were imposed. Methylhexanamine is chemically similar to tuaminoheptane, which was banned in 2009. Methylhexanamine was explicitly added to the WADA 2010 List of Banned Substances, largely in response to this situation.

Despite its addition to the list, methylhexanamine continues to cause positive drugs tests, including the recent announcements of nearly a dozen positives among Indian athletes. This is largely due to the confusing network of synonyms and brand names. For example, methylhexanamine is also known as Forthan, Forthane, Floradrene, Jack3d, DMAA, shizandol A, 1-3 dimethylamine, geranamine, geranium

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<sup>4</sup> <http://www.usatoday.com/sports/balco-timeline.htm>

<sup>5</sup> <http://www.govtrack.us/congress/billtext.xpd?bill=s108-2195>

<sup>6</sup> <http://www.fda.gov/Safety/Recalls/ArchiveRecalls/2009/ucm188929.htm>

<sup>7</sup> [http://www.amazon.com/Competitive-Edge-Labs-CEL-tren/dp/B002W2X8BM/ref=pd\\_sim\\_hpc\\_6](http://www.amazon.com/Competitive-Edge-Labs-CEL-tren/dp/B002W2X8BM/ref=pd_sim_hpc_6)

<sup>8</sup> <http://www.nutritionarsenal.com/Prohormones-C33.aspx>

<sup>9</sup> <http://www.buysupps.com/categories/Prohormones/>

<sup>10</sup> <http://nccam.nih.gov/health/bitterorange/>

oil extract and more. This is of primary concern as it results in unknown use of these drugs by consumers and athletes alike.

### ***Purposeful contamination with pharmaceutical drugs – StarCaps***

Sometimes nefarious manufacturers spike their supplements with drugs. Lay persons are at risk for serious adverse reactions while athletes and elite professionals who consume these tainted products may return a positive test jeopardizing their careers.

StarCaps is a weight loss supplement that was proven to contain an undeclared potent diuretic, bumetanide, in amounts indicating that it was not a contaminant but rather was likely added to achieve a desired effect. In 2008, several NFL players tested positive for bumetanide after using the StarCaps product. Unfortunately, StarCaps is not an exception. A survey performed by the FDA in 2009 found that 72 products sold as weight loss supplements contained unlisted pharmaceutical medications<sup>11</sup>. Sexual performance enhancers and testosterone boosters also raise similar concerns.

### ***Raw material impurities and accidental contamination of products - AdvoCare***

During the 2008 Olympic Trials, a swimmer, Jessica Hardy, tested positive for clenbuterol. She alleged that the positive came from a product by AdvoCare, one of her sponsors. ADR's testing showed the presence of clenbuterol in very small amounts. The amount of clenbuterol was so low that it is highly improbable that it was deliberately added to the supplement. The issue was likely due to raw material contamination as opposed to purposeful contamination.

Vitamins too are susceptible to contamination as the Kicker Vencill case demonstrated. Vencill lost a chance at the 2004 Olympics due to a positive drug test, later proven to have come from a multi-vitamin<sup>12</sup>. Amazingly enough there are no requirements to test raw materials for banned or controlled substances prior to their inclusion in supplements. Impurities are often the culprit behind adverse reactions and positive drug tests in sports-persons, police, fire and other elite professionals.

### **Actions**

Through our Dietary Supplement Survey, Anti-Doping Research aims to do more to protect the public and athletes through product testing, research and information dissemination. Our survey encompasses the following objectives:

1. Randomly select products from across the industry and subject them to broad screening for a variety of controlled substances or those banned by sport. We aim to analyze 250-500 products annually to obtain an adequate and representative sampling.
2. Target test for certain compounds in high-risk categories. We will focus on steroids in muscle building products and pharmaceutical drugs in weight loss supplements and sexual performance/testosterone enhancers.
3. Categorize ingredients that are banned in sport or in professional drug testing programs and index the many synonyms and brands that contain them. Distribute the information through searchable databases similar to [ADR's Searchable Database of Banned Stimulants](#).
4. Scan for new ingredients or brands appearing on the market that could be potentially harmful or lead to a positive drug test. Make public service announcements to provide information.
5. In the process of scanning the marketplace and purchasing products, ADR will track where illicit products are promoted in efforts to help audit the current retail environment and assist with enforcement.
6. Operate the 'Dietary Supplement Survey', an interactive website portal that makes results available to the public and athletes, and conveys accurate and up-to-date information.

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<sup>11</sup> <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm136187.htm>

<sup>12</sup> <http://sports.espn.go.com/oly/news/story?id=2059714>

## Needed Resources

We are seeking \$1.5 million dollars annually to support the project. The budget would be used as follows:

<b>Operating Expenses</b>	<b>Annual \$</b>
Laboratory Equipment	\$ 50,000
Equipment Maintenance	\$ 45,000
Laboratory Consumables (Chemicals, Glassware)	\$ 240,000
Supplement Purchases	\$ 30,000
Website Support and Development	\$ 75,000
Consulting/Professional Services	\$ 70,000
Building Operations	\$ 115,000
Office Expenses	\$ 75,000
Scientific Payroll	\$ 565,600
Administration and Office Payroll	\$ 194,400
Miscellaneous	\$ 40,000
<b>TOTAL</b>	<b>\$ 1,500,000</b>

## About Anti-Doping Research, Inc.

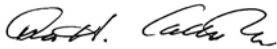
Anti-Doping Research has a great deal of experience working on various sides of these issues. We have worked on medical cases supporting doctors whose teenage patients have suffered liver failure from inadvertent use of powerful designer steroids such as Superdrol or 4,9-Estradiene-3,17-dione, also known as 'Tren.' We have worked on legal cases for athletes whose use of products resulted in a positive drug test severely impacting their career and reputation. We have worked with the media to expose new designer steroids. We also perform testing on behalf of Banned Substances Control Group on a variety of supplement products to determine if they contain banned substances.

Anti-Doping Research, Inc. (ADR) is a non-profit organization founded in 2005 by anti-doping pioneer Don Catlin, M.D., and colleagues as a dynamic new paradigm dedicated to creating novel solutions to modern-day issues related to banned substances in sports, toxicology and public health. Its focus is on research, analytical testing, education, program development and collaboration.

ADR is grateful to the following major contributors whose generous support during the last six years have made ADR's work possible: Amgen, Anti-Doping Sciences Institute, Grayson-Jockey Club Research Foundation's Equine Drug Research Institute, Major League Baseball, the National Football League/National Football League Players Association Research & Education Foundation and the United States Anti-Doping Agency.

Please join us and help support this important public health project with your contribution today.

Sincerely,



Don H. Catlin M.D.  
CEO and President



Oliver Catlin  
Vice President and CFO