

## **Consumer Reports: Creating a Hurricane from a Drop in the Bucket**

**-- CRN Response to an article in the May 2004 issue of *Consumer Reports* --**

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<b>STATEMENT FROM ARTICLE</b>	<b>CRN RESPONSE</b>
<p>“If you can buy it at a clean, well-lighted store, if it’s ‘all-natural,’ it’s not going to do you serious harm, right? That’s what many Americans assume about dietary supplements. But while most supplements are probably fairly benign, CONSUMER REPORTS has identified a dozen that according to government warnings, adverse-event reports, and top experts are too dangerous to be on the market. Yet they are.”</p>	<p>Most supplements are safely used by 150 million American adults each year.</p>
<p>“The potentially dangerous effects of most of these products have been known for more than a decade ...yet until very recently, the U.S. Food and Drug Administration had not managed to remove a single dietary supplement from the market for safety reasons.”</p>	<p>FDA was reluctant to use the full force of regulatory authority provided under DSHEA until Dr. Mark McClellan decided to test the law’s powers, saying that you cannot declare that a law doesn’t work until you try to make it work. FDA’s lack of interest in proving the law can work, rather than an inability under the law to take action, has been one reason that FDA has not until recently removed a single dietary supplement product from the market. The other reason is that the overwhelming majority of dietary supplements are safe.</p>
<p>“Despite these actions against high-profile supplements, whose dangers were so well-known that even industry trade groups had stopped defending them, the agency continues to be hamstrung by [DSHEA].”</p>	<p>Although ephedra had been used without harm by millions of consumers, industry trade groups chose not to challenge FDA’s action, taken under DSHEA, to declare ephedra presents an “unreasonable risk.” As for androstendione, FDA has declared it did not meet the 75-day notice of new ingredient as required under DSHEA and consequently is being illegally marketed as a dietary supplement. That is an action FDA could have taken at any time since DSHEA was passed and could have been taken in response to repeated questioning by Senators Harkin and Hatch as to whether androstendione was a legal dietary</p>

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	<p>supplement. Industry supports legislation to move androstendione to a controlled substance category.</p>
<p>“While drug manufacturers are required to prove that their products are safe before being marketed, DSHEA makes the FDA prove that supplements on the market are <i>unsafe...</i>”</p>	<p>Premarket approval is not a guarantee of safety as witnessed by those drug products that have been approved by FDA, only to be later recalled due to safety concerns. Under DSHEA, FDA can immediately remove a product if it believes that product poses an imminent hazard. In addition, just because there is no premarket approval requirement it does not mean that companies don't do testing, or that the products are unsafe.</p>
<p>“To regulate drugs, annual sales of which are 12 times the amount of supplement sales, the FDA has almost 43 times as much money and almost 48 times as many people.”</p>	<p>It's obvious that drugs require stronger regulation than supplements.</p>
<p>“The law has never been fully funded,” said William Hubbard, FDA associate commissioner for policy and planning. “There's never been the resources to do all the things the law would command us to do.”</p>	<p>At a recent congressional hearing, Robert Brackett, Ph.D., the director of CFSAN, repeatedly asserted that DSHEA provides [FDA] sufficient authority necessary to remove potentially harmful products from the market. Dr. Brackett further specifically assured the committee that FDA and HHS were not seeking additional legislation or modifications to DSHEA at this time. The law could certainly benefit from fuller implementation, something which FDA is now pursuing.</p>
<p>“But critics of DSHEA think the ban illustrates the extremes to which the FDA must go to outlaw a hazardous product.”</p>	<p>DSHEA added enforcement authorities for FDA that were not previously available to the agency. Under DSHEA, FDA has two options for removing unsafe products from the market. One of those options includes immediate removal if the agency believes the product presents an “imminent hazard.” While the agency would then have to make a scientific case for maintaining the ban, it is not unreasonable to expect that FDA's decision be based on sound science, rather than political rhetoric. Products should not be allowed to be removed from the market based solely on bad publicity or a precautionary principle run amok.</p>
<p>“Supplement-industry advocates say the ephedra ban demonstrates that DSHEA gives the FDA enough power to protect consumers from unsafe products. ‘I don't think there's anything wrong except that FDA has only recently begun vigorous and active enforcement of the law,’ said</p>	<p>Industry opposed FDA's proposed action because it was not scientifically based. More importantly, as the article correctly points out, “the General Accounting Office said the FDA ‘did not establish a causal link’ between taking ephedra and deaths or injuries,” and the agency was forced to drop its proposal. The Cantox Report, the report</p>

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<p>Annette Dickinson, Ph.D., president of the Council for Responsible Nutrition, a major trade association for the supplement industry...When the agency initially tried to rein in ephedra use in 1997, after receiving hundreds of reports of adverse events, it sought not an outright ban but dosage restrictions and sterner warning labels. The industry mounted a furious counter attack, including the creation of a public relations group called the Ephedra Education Council and a scientific review from a private consulting firm, commissioned by Dickinson’s trade group, that concluded ephedra was safe.”</p>	<p>commissioned by CRN, did identify conditions of safe use for ephedra, including a specific dose; and, the report also identified subsets of the population that should not use ephedra, reinforcing the label warnings that many companies had already been voluntarily adding to their product.</p>
<p>“...supplement manufacturers can introduce new products without any testing for safety and efficacy.”</p>	<p>If a supplement manufacturer wants to introduce a new ingredient, it must provide FDA with 75 days notice, along with safety information. If FDA has any concerns about the ingredient or the submitted safety profile, the agency can request more information or deny the product’s entry into the marketplace. Since the passage of DSHEA, there have been 138 “unique” New Dietary Ingredient notification (NDI) filings, 65 of which were rejected, indicating FDA’s ability to “turn down” a product it deems questionable.</p>
<p>“While DSHEA gave the FDA authority to impose similar [GMP] standards on supplements, it took until 2003 for the agency to propose regulations—as yet not final—to implement that part of the law.”</p>	<p>The industry proposed GMPs to FDA as early as 1995. Responsible companies did not wait for FDA to issue its GMP rule but instituted their own GMPs, some of which are even more stringent than those for drug companies.</p>
<p>“By law, drug companies are required to tell the FDA about any reports of product-related adverse events that they receive from any source. Almost every year, drugs are removed from the market based on safety risks that first surfaced in those reports.”</p>	<p>Reporting of AERS is mandatory only for prescription drugs and some OTC products. Monographed OTC drugs and food products are not required to report AERS. CRN and other industry trade associations could support mandatory reporting of serious adverse events. That drugs are removed from the market almost every year based on AERS reinforces the fact that premarket approval is not a guarantee of safety.</p>
<p>“Many makers market their supplements as ‘natural,’ exploiting assumptions that such products can’t harm you.”</p>	<p>Many consumers want “natural” products, for a variety of reasons. However, it is insulting to consumers to assume they can be “exploited” into thinking that natural means no harm.</p>
<p>“But...more than two years after the import ban [on Aristolochia] went into effect, CR was able to purchase products online that were labeled as containing Aristolochia.”</p>	<p>This is not the fault of a law ... it is the fault of companies engaging in illegal marketing.</p>

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<p>“Do not take daily doses of vitamins and minerals that exceed the safe upper limits...it’s possible to overdose on some of them [vitamins and minerals].</p>	<p>CRN agrees that safety limits should be observed. CRN’s scientist, John Hathcock, Ph.D., is regarded worldwide as an expert in the field of vitamin and mineral safety. His CRN publication, <i>Vitamin and Mineral Safety</i>, soon to be published in its second edition, is a resource for regulators, government, scientists and industry. While it is possible to overdose on vitamins and minerals, inadequate intakes are a more common problem.</p>
<p>“Stay away from supplements for weight control.”</p>	<p>With obesity such a huge problem in this country, it is irresponsible to suggest that consumers should not have the choice of taking any weight control supplements. However, as with all products, consumers should pay close attention to labeling advice and not exceed the dose. In addition, any weight management products should be used in conjunction with healthy lifestyle choices, not as substitutes for proper eating habits and regular exercise.</p>