



## Council for Responsible Nutrition

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February 10, 2017

The Honorable Linda Rosenthal  
New York State Assembly  
Legislative Office Building, Suite 627  
Albany, NY 12247

**RE: AB 4712 – prohibiting the sale or distribution of creatine to minors**

Dear Assemblywoman Rosenthal:

The Council for Responsible Nutrition (CRN)<sup>1</sup>, a national trade association representing manufacturers and ingredient suppliers of dietary supplements and functional foods, is concerned with AB 4712, legislation you recently introduced that would prohibit the sale of the dietary supplement creatine to minors.

We are troubled that you are singling out a dietary supplement product with a strong and proven safety record. It would appear that this legislation may be based on recommendations from an old report via New Jersey's *Governor's Task Force on Steroid Use and Prevention*. We believe that report over-reached its mandate on illegal-steroid use and prevention and unfairly focused on legal dietary supplements.

Creatine is a naturally occurring amino acid-like compound made in the liver, kidneys and pancreas and is a substance which is readily available in the food supply—found mostly in red meat, fish and poultry. This popular dietary supplement was introduced to the U.S. market in 1993 and has a large body of evidence demonstrating benefit with no serious adverse effects. The overwhelming majority of the published clinical trials have been positive, with a general consensus showing the safe and beneficial effects from creatine supplementation, particularly during short, repeated bursts of high-intensity activity. Recent studies have also focused on the potential benefits of creatine use in individuals with certain neuromuscular conditions. The overall safety and efficacy of creatine supplements, especially the most widely studied creatine monohydrate form, were affirmed by the European Food Safety Authority in 2004 and in a 2007 position stand from the International Society of Sports Nutrition (ISSN).

The New Jersey Governor's Task Force report refers to creatine being linked to kidney damage. This assertion is based on a total of two published case reports in which the affected individuals were suffering from existing underlying renal disease—the serious limitations of individual case studies were addressed in the ISSN position stand. In fact, other, more reliable (i.e. double-blind, randomized, controlled intervention) studies demonstrate the safety of long term creatine use in both healthy individuals and clinical populations, specifically as it relates to renal function. In consideration of this, there is no conclusive evidence whatsoever to support the notion that creatine use may adversely affect kidney function in healthy individuals. Creatine is safe, made to high quality standards and beneficial as shown by the many positive scientific research studies that have been done on this popular performance-enhancing

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<sup>1</sup> The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing 150+ dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety, our manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Visit [www.crnusa.org](http://www.crnusa.org). Follow us on Twitter [@crn\\_supplements](https://twitter.com/crn_supplements) and [@wannabewell](https://twitter.com/wannabewell) and on [Facebook](https://www.facebook.com/crnusa).

The Honorable Linda Rosenthal  
AB 4712

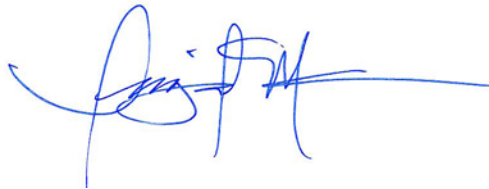
dietary supplement. To paint creatine as a potentially harmful dietary supplement is wrong and unwarranted.

The legislation would place mandatory age restrictions on creatine dietary supplements. Mandatory age restrictions will force many retailers to cease selling the products altogether out of fear of liability from the age restrictions. Those retailers that continue to sell the products will have to closely monitor their inventory which will mean that self-service availability of the products for adults will also diminish. Experience in other consumer products repeatedly demonstrates that when age restrictions are imposed on a product it becomes much harder for even consumers of legal age to purchase the products in a convenient manner.

Please note, the Dietary Supplement Health and Education Act (DSHEA), a federal law enacted in 1994, establishes federal regulatory structure for dietary supplements, and provides FDA with substantial authority to protect consumers and their safety. DSHEA gives FDA the tools to remove dietary supplement products from the market if the product, or any of its ingredients, is adulterated or misbranded, poses an imminent hazard to public health or safety, presents a significant or unreasonable risk of illness or injury, contains new ingredients for which there is not adequate evidence of safety, or was manufactured or packaged under conditions that do not comply with good manufacturing practices. Consumers are also protected under this federal regulatory structure.

CRN would be pleased to speak to you or members of your staff if you would like to discuss this issue in more detail. Please don't hesitate to contact me at [ilebert@crnusa.org](mailto:ilebert@crnusa.org) or 202.204.7699 if you have any questions.

Sincerely,



Ingrid Lebert  
Senior Director, Government Relations

cc: The Honorable Brian Kavanagh  
The Honorable Peter Abbate, Jr.  
The Honorable David Buchwald  
The Honorable Erik Dilan  
The Honorable David McDonough  
The Honorable Tom McKeivitt  
The Honorable Yuh-Line Niou  
The Honorable Anthony H. Palumbo  
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The Honorable Dan Stec  
The Honorable Jaime Williams