



March 3, 2010

The Honorable John McCain
United States Senate
241 Russell Senate Office Building
Washington, DC 20510

Dear Senator McCain:

I'm writing to let you know that Consumers Union, the nonprofit publisher of *Consumer Reports*, strongly supports the Dietary Supplement Safety Act of 2010 (S. 3002). We thank you and Senator Byron Dorgan for introducing important safeguards to these largely unregulated products in the marketplace.

S. 3002 requires dietary supplement manufacturers to list the ingredients of any dietary supplement on the package and to disclose that information to Food and Drug Administration (FDA) before marketing the product. It also requires all dietary supplement manufacturers to register their products with the FDA, to ensure that the FDA knows which products are being sold, and will be in a position to contact the manufacturer if there is a recall. The bill also ensures that the FDA is appropriately notified when products containing New Dietary Ingredients are introduced in the marketplace, and requires supplement companies to establish that products containing steroids are proven safe for their intended use before they are marketed.

Since 2006, manufacturers have been required by federal law to submit serious adverse event reports (AERs) about dietary supplements to FDA. However, S. 3002 further improves adverse event reporting by requiring manufacturers to also forward non-serious AERs to the FDA, to help identify potential safety problems or drug interactions observed in the post-marketing period. Some dietary supplement manufacturers have neglected to notify FDA about serious adverse events experienced by consumers, deeming them non-serious. Finally, the bill would provide the FDA with mandatory recall authority to remove unsafe products from the marketplace if the product is found to be unsafe or adulterated.

As you know, Consumers Union is very concerned about the safety of dietary supplements in the U.S. In 1995, 2004, and 2008, *Consumer Reports* published lists of hazardous supplements that pose serious risks to consumers, and warned readers to avoid them. Many of the hazardous products we identified in these lists are unfortunately still available in the marketplace today. From 2000 to 2004, Consumers Union worked successfully to achieve

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statewide bans on the sale of the dangerous sports supplement, ephedra, in California, Illinois and New York, and advocated for a national ban. We have also testified three times in recent years before the Senate on dietary supplement safety.

The 1994 Dietary Supplement Health and Education Act of 1994 (DSHEA) permitted the entry of literally thousands of new untested products into the marketplace. There are approximately 30,000 different supplement products currently on the market, and an estimated 1,000 new products are introduced every year.

While many dietary supplements are generally safe, and may have important health benefits for consumers, there is a significant number of highly questionable products that would probably not be allowed on the market if they were subject to pre-market safety testing. But because dietary supplements are classified as “foods” instead of “drugs,” they do not undergo the same pre-market safety testing that are required of drugs. New dietary supplement products can be introduced overnight that contain novel, untested ingredients and/or novel combinations of new and/or existing supplement ingredients. Health providers and regulators typically receive little pre-market or post-market information about how such products may affect human health, and interact with medicines that patients are already taking

The contrast with regulatory standards for pharmaceutical drugs is striking. A proposed new drug can only be approved if it is deemed to be safe in multiple human studies, and companies are required to notify the FDA if consumers suffer serious side effects.

Because dietary products are widely available at health food stores, pharmacies, supermarkets and athletic facilities, consumers assume that they are safe. They assume the government is watching and would not let them be sold if they were unsafe. For example, in an October 2002 nationwide Harris poll, 59 percent of respondents said they believed that supplements must be approved by a government agency before they can be sold to the public.

But the reality is that under DSHEA, the FDA’s powers to regulate supplements have been relatively minimal, and the agency is operating without critically needed information and authority to oversee a \$24 billion industry. For example, in April 2001, the Office of Inspector General at the Department of Health and Human Services specifically cited the lack of manufacturer registration as a critical safety gap. As a result of this gap, the FDA does not have a list of supplement products and ingredients when it receives an adverse event report (AER). The Inspector General found that FDA was unable to determine the ingredients for 32 percent of products mentioned in AERs. It also lacked product labels for 77 percent of the products mentioned in the AERs, and product samples for 69 percent of products that it requested. For products referenced in the AERs, the FDA was unable to determine the manufacturer for 32 percent of the products, and the city and state for 71 percent of manufacturers.

In a report issued in January 2009, the U.S. Government Accountability Office (GAO) also noted

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many factors that hinder the FDA from taking prompt action to remove dangerous products from the market, including the lack of information about manufacturers, product ingredients and adverse events, and the lack of mandatory recall authority.

We are very gratified that your legislation would improve the availability of time-urgent, critical information that is needed by FDA to provide effective oversight of the supplement industry. We also applaud the provisions of the bill that will improve scrutiny of New Dietary Ingredients, and products containing steroids, and give FDA mandatory recall authority. We were greatly troubled that it took FDA so long to remove ephedra from the marketplace, even though it had received nearly 17,000 adverse event reports, including serious reports of heart attacks, strokes and fatalities. We continue to be concerned that other products that we have identified as posing serious hazards have not been recalled or removed.

We believe that S. 3002 would be enhanced even more by if all manufacturers were required to adhere to good manufacturing practices (GMPs), and require or encourage them to participate in independent testing and verification programs to ensure that they produce safe, quality products. We would also support more far-reaching measures to appoint an expert panel to review the safety of existing products on the dietary supplement market; pre-market safety testing requirements for certain categories of supplements that pose greater risks, such as sports supplements and steroid-containing supplements; and risk-labeling requirements. Finally, we also urge Congress to provide the FDA with enhanced funding to accomplish these important goals.

In conclusion, Consumers Union believes very strongly there are currently very serious consumer protection gaps in federal law relating to dietary supplements. Consumers turn to dietary supplements because they think these products will promote health and wellness, and often because traditional medicine has failed them. These people should not have to experiment with potentially dangerous products (which they think are safe because the product was sold at the national chain just down the street) that have not been sufficiently tested by their manufacturers prior to coming to market.

S. 3002 contains common-sense reforms that respond to numerous concerns raised in Congressional oversight hearings by health experts and consumer organizations, and watchdog reports issued by the Institute of Medicine, the GAO and the HHS Inspector General. This legislation is very much in the consumer and public interest, and has our enthusiastic support.

Sincerely,



Charles Bell
Programs Director

cc: The Honorable Byron L. Dorgan

