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Testimony of Tod Cooperman, MD, President, ConsumerLab.com to Committee on Government Reform – Subcommittee on Dietary Supplements
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Dear Congressman Davis and Members of the Committee,

I am the president of ConsumerLab.com, a company that I founded in 1999 to help consumers identify better quality health and nutrition products based on independent testing. I am accompanied by Dr. William Obermeyer, Vice President for Research, who, prior helping to found ConsumerLab.com spent 9 years at the FDA testing dietary supplements in the Center for Food Safety and Applied Nutrition.

I appreciate this opportunity to present an overview of ConsumerLab.com's findings in order to provide the Committee with insight into the issues that consumers face with dietary supplements.

ConsumerLab.com Background:
ConsumerLab.com's testing of products is funded primarily with revenue from our website (www.consumerlab.com) to which over 25,000 individuals subscribe ($27 per year) and to which over 1.5 million others have access through subscribing institutions, such as colleges and libraries. Free summaries of our reports are also available on our website which receives over 2 million visits per year. We also publish a book and offer a Voluntary Certification Program for manufacturers who wish to have products tested for a fee for certification purposes.

We receive no government funding but, from time to time, are hired by government-funded researchers to test the quality of supplements used in clinical trials.

General Findings from Supplement Testing:
Based on tests of nearly 1,000 dietary supplements selected and purchased by ConsumerLab.com (from approximately 300 different brands), we find:

- One out of four products has a quality problem.
  - The most common problem is a lack of ingredient or substandard ingredient. Example: Pills of a saw palmetto supplement (for prostate health) claiming to be "Guaranteed for Potency" and "Quality Assured" had less than half of the promised amount of saw palmetto.
  - The next most common problem is contamination with lead and other heavy metals and with pesticides. Example: A daily serving a ginkgo supplement (for memory) contained 16 micrograms of lead, far higher than 0.5 microgram limit set by the State of California for the sale without a lead warning.
  - Other problems:
    - Tablets that won't release their contents, i.e., disintegrate;
    - Oils (such as fish oil) that are rancid;
    - Products with *more* ingredient than listed, with the potential for toxicity.

- Herbals and multivitamins are more likely to have problems due to their complexity (about 40% have problems). Supplements made with popular, new ingredients also tend to have more problems, as demand exceeds supply and manufacturers turn to low-quality ingredient.
- Problems have been found in products from every size of manufacturer.

Why Problems Exist:

- **Some manufacturers do not regularly check the quality** of the ingredients used in their products and rely on unverified Certificates of Analysis, nor do they check the quality of finished products.
- **Few manufacturers withdraw products** from market after a problem is identified. When done, recalls are typically "quiet" – announced to retailers but not publicly to consumers.
- **Manufacturers are not required to meet specific standards for ingredient quality/identity, or dosage.** It is up to the manufacturer to use proper ingredients, as well as to suggest an appropriate dose.
- **The federal government has not established standards of *purity*.** We must turn to California, for example, for a limit on lead contamination in supplements.
- **Lack of FDA enforcement.** There is little pro-active monitoring of product quality and little follow-up on reported problems unless life-threatening.
- **Good manufacturing practices (GMPs) have still not been established by the FDA**, although promised for over 10 years. These, if enforced, can help insure batch-to- batch uniformity. (They will not, however, guarantee "good quality" products if they do not include appropriate standards for purity and ingredient identity.)

Other Issues of Concern for Consumers:

- **Uniform labeling** is needed so that consumers can compare products on an "apples to apples" basis. Example: the amount of active "glucosamine" in glucosamine *sulfate* (2KCl) is only about 70% of that in equal weight of glucosamine *hydrochloride (HCl)*. Both may work at the proper dose, but labels should include the amount of active ingredient.
- **Warning labels are voluntary**. Some products exceed tolerable levels of vitamins, minerals, and other ingredients without warning. There are medical uses that may require exceeding these levels, but side effect warnings could help consumers avoid potential problems. (Products that exceed these levels are noted in our reports.)
- **Adverse events reports (AERs) are not required from manufacturers to the government**. Those that are reported are not readily available to consumers or health care professionals.
- **Daily Value (DV) levels of nutrients have not been updated since 1968. As a result,** "Supplement Facts" on labels do not reflect the latest nutrient recommendations proposed by the Institute of Medicine. Children's vitamins, for example, contain far more vitamin A than currently recommended for younger children. Manufacturers understandably will not alter their formulations until the FDA acts, since consumers look for products that contain "100% of the DV."
- **The quality of supplements in government-funded clinical trials have not always been established**, making the results of such studies less meaningful. The NIH should require investigators analyze the quality of supplements prior to clinical study.