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Testimony of Tod Cooperman, MD, President, ConsumerLab.com to
Senate Special Committee on Aging – Subcommittee on Dietary Supplements

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Dear Senator Kohl and Members of the Committee,

I am Dr. Tod Cooperman, the President of ConsumerLab.com, a company that I founded eleven years ago to help consumers identify better quality health and nutrition products based on independent testing. I am accompanied by Dr. William Obermeyer, our Vice President for Research, who spent nine years at the FDA testing food and dietary supplements in the Center for Food Safety and Applied Nutrition.

We appreciate this opportunity to present findings that are particularly relevant to the aging population.

ConsumerLab.com Background:
ConsumerLab.com's testing is funded by over 40,000 individual and institutional subscribers to our website (www.consumerlab.com). We also provide a Voluntary Certification Program and test products for clinical researchers (many funded by the NIH).

Use of Supplements by Seniors:
A recent survey of people who receive our free e-newsletter revealed that that among those aged 65 and older, 32% use 10 or more supplements daily (Reference 1).

A senior citizen in a vitamin store is a bit like a kid a candy store. However, while the FDA recommends a strict limit on lead contamination in candy, it has not set a limit for supplements. Our tests show that this policy has created a "buyer beware" situation.

General Findings from Supplement Testing:
Based on tests of over 2,000 dietary supplements representing over 300 different brands, we find that one out of four has a quality problem. Problems have been found in products from every size of manufacturer and are most common in herbal supplements, multivitamins, and products with ingredients that are newer to the market.

The most common problem is a lack of ingredient or substandard ingredient.
Our most recent tests of herbal supplements show that 46% contained less than their expected amounts of key compounds. For example, an "Extra Strength" ginseng product provided less than 10% of the claimed amount of expected "ginsenoside" compounds. We reported a similar problem with the same product when purchased three years earlier (Reference 2).

Herbal supplements failing to contain claimed or expected amounts of marker compounds (among products selected in recent reviews):

- Echinacea: 5 of 6 failed to contain expected amounts of specific phenolic compounds (Reference 3).
- Garlic: 6 of 14 supplements had too little of the key compound allicin (Reference 4).
- Ginkgo: 4 of 7 supplements failed to contain the expected amounts of individual flavonol compounds, suggesting adulteration to enhance the apparent quality of the ginkgo material (Reference 5).
- Ginseng: 3 out of 13 failed to contain the expected amount of marker ginsenosides (Reference 2).
- Milk thistle: 7 of 10 failed to meet claims of silymarin standardization (Reference 6).
- St. John's wort: 3 of 10 contained only 23% to 36% of the expected amounts of hypericin or hyperforin (Reference 7).
- Turmeric: 2 of 9 were low in curcuminoids (Reference 8).
- Valerian: 8 of 14 were low in valerenic acids (Reference 9).
- A similar problem exists with certain non-herbal supplements, such as chondroitin (Reference 10).

A major cause of these problems is the reliance by some manufacturers on cheap, non-specific tests which overstate the amount of actual ingredient in raw materials and supplements. More specific tests show the actual amounts to be much lower.

The next most common problem is contamination with lead and other heavy metals.
The FDA professes a policy of reducing lead levels to the lowest amount that can be practicably obtained in manufacturing, yet the FDA has neither set nor suggested limits on heavy metals in supplements. The only official limit on lead in supplements is in the State of California. That limit, 0.5 mcg per daily serving typically works out to be slightly higher than the FDA candy limit, but is still very conservative and meaningful. Products sold in California exceeding this limit must carry a warning label (Reference 11). ConsumerLab.com has found that 11% of herbal supplements exceed the California limit for lead.

Cadmium, a toxin and carcinogen, also occurs in certain herbal supplements, but the FDA has not set a limit on cadmium in supplements. ConsumerLab.com has found 40% of St. John's wort supplements and 14% of valerian supplements to exceed World Health Organization guidelines for cadmium contamination.

Herbal supplements found to exceed California Prop 65 lead limit or the WHO cadmium guidelines:

- Echinacea: 1 of 6 failed for lead (Reference 3).
- Garlic: 2 of 14 failed for lead (Reference 4).
- Ginkgo: 1 of 7 failed for lead (Reference 5).

- Ginseng: 1 out of 13 failed for lead (Reference 2).

- Milk thistle: None of 10 failed for lead (Reference 6).

- St. John's wort: Out of 10 products, 1 failed for lead and 4 failed for cadmium (including the product contaminated with lead) (Reference 7).

- Turmeric: 2 of 9 failed for lead (Reference 8).

- Valerian: Out of 14 products, 1 failed for lead and 2 for cadmium (Reference 9).

- The highest levels found by ConsumerLab.com are 16 mcg and 19 mcg of lead, respectively, in daily servings of ginkgo and turmeric supplements (References 5, 8).

- Some chromium supplements are contaminated with a carcinogenic form of chromium, known at hexavalent chromium. The FDA has not established limits for hexavalent chromium in supplements. California has proposed a limit on hexavalent chromium in its water supplies, which equates to 0.12 mcg in a normal daily intake of water. We recently found much higher amounts (1.6 to 26.4 mcg of hexavalent chromium) in three chromium supplements (Reference 12).

While individual products with elevated levels of lead and cadmium are generally not toxic in themselves, they unnecessarily expose Americans to toxins and the effects are cumulative. As noted earlier, many seniors take ten or more supplements daily and additional exposure comes from foods, beverages, and the environment. It would be dangerous to suggest that a single supplement needs to contain a toxic amount of heavy metal to be a threat to health. However, a 2007 report by the FDA on lead contamination in multivitamins made this faulty assumption and has been criticized for doing so (Reference 13).

Unfortunately, the USP may soon adopt an industry proposal permitting 10 micrograms of lead per daily serving of a supplement – twenty times higher than the California limit. We think such a lax standard would be a terrible mistake, permitting an individual supplement to exceed the total amount of lead that a child can tolerate (6 mcg), and just a few supplements to surpass the daily threshold for adults (Reference 11).

Other problems:

- Tablets that won't break apart properly to release all of their ingredients (References 5, 10, 14, 15, 16).

- A lack of proper labeling to indicate the parts of the plants used (References 5, 8) and deceptive labeling suggesting more ingredients than actually provided (References 10, 17).

- A lack of voluntary warnings which could help consumers avoid potential problems, such ingredients in excess of known tolerable intake levels (References 18, 19).

- Faulty products left on the market due to inaction by manufacturers or "quiet" recalls announced to retailers but not to the public. (Reference 2)

- Spiking of supplements with prescription drugs, particularly those for erectile dysfunction. (Reference 20)

- Lack of public access to adverse event reports filed by manufacturers with the FDA.

Will Good Manufacturing Practices (GMPs) Help?
Good Manufacturing Practices (GMPs) are now required of most supplement manufacturers to help ensure batch-to-batch uniformity. However, "bad" products can, and are, being made under these "good" practices because the GMPs do not include standards for purity and ingredient identity. These standards, and the selection of tests used to measure against them, are left to each manufacturer to determine for itself.

Conclusion
Nearly eleven years of product reviews by ConsumerLab.com have shown consistent problems with a significant percentage of dietary supplements, particularly herbal supplements. However, in nearly every supplement category that we test, we do find products that meet high quality standards, showing that this is achievable. If we want our supplements to be the best and safest in the world, we will need better guidance from government establishing rigorous standards and test methods, greater enforcement of current regulations, and more self-regulation from the industry.

In my written testimony, you will find additional statistics, information, and references.

References:

1. ConsumerLab.com Survey of Supplement Users, 2010 Report. February 1, 2010 news release.
http://www.consumerlab.com/news/Supplement_Survey_Report/1_31_2010/

2. ConsumerLab.com Product Review of Ginseng Supplements (2006)
https://www.consumerlab.com/reviews/Ginseng_Supplements/ginseng/

3. ConsumerLab.com Product Review of Echinacea Supplements (2004)
http://www.consumerlab.com/reviews/Echinacea/Echinacea/

4. ConsumerLab.com Product Review of Garlic Supplements (2006)
http://www.consumerlab.com/reviews/Garlic_Supplements/garlic/

5. ConsumerLab.com Product Review of Memory & Cognition Enhancement Supplements (Ginkgo, Huperzine-A, and Acetyl-L-Carnitine)
http://www.consumerlab.com/reviews/Memory_Supplements_Ginkgo_Huperzine_Acetyl-L-Carnitine/GinkgoBiloba/

6. ConsumerLab.com Product Review of Milk Thistle Supplements (2009)
http://www.consumerlab.com/reviews/Milk_Thistle_Supplements/milkthistle/

7. ConsumerLab.com Product Review of St. John's Wort Supplements (2010)
http://www.consumerlab.com/reviews/St_Johns_Wort/stjohnswort/

8. ConsumerLab.com Product Review of Turmeric Supplements (2008)
http://www.consumerlab.com/reviews/Turmeric_Curcumin_Supplements/turmeric/

9. ConsumerLab.com Product Review of Valerian Supplements (2006)
http://www.consumerlab.com/reviews/Valerian_Supplements/valerian/

10. ConsumerLab.com Product Review of Joint Health Supplements with Glucosamine, Chondroitin, and/or MSM (2009)
http://www.consumerlab.com/reviews/Joint_Supplements_Glucosamine_Chondroitin_and_MSM/jointsupplements/

11. ConsumerLab.com Asks USP to Adopt Safer Lead Limit for Drugs and Supplements, December 8, 2008 news release.
http://www.consumerlab.com/news/USP_Lead_Limit/12_08_2008/

12. ConsumerLab.com Product Review of Chromium Supplements (2010)
http://www.consumerlab.com/reviews/Chromium/chromium/

13. Miodovnik, et al, The U.S. Food and Drug Administration Risk Assessment on Lead in Women's and Children's Vitamins Is Based on Outdated Assumptions. Environ Health Perspect. July 2009, 117(7): 1021-1022.
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2717124/

14. ConsumerLab.com Product Review of Cholesterol-lowering Supplements (2010)
http://www.consumerlab.com/reviews/Cholesterol-Lowering_Supplements_Review_Sterols_Policosanol/cholesterol/

15. ConsumerLab.com Product Review of Supplements for Cancer Prevention (Green Tea, Lycopene and Selenium) (2009)
http://www.consumerlab.com/reviews/Supplements_for_Cancer_Prevention_Green_Tea_review_Lycopene_and_Selenium_reviews/cancerprevention/

16. ConsumerLab.com Product Review of Muscular Enhancement Supplements (Creatine, HMB, Glutamine, BCAAs) (2006)
http://www.consumerlab.com/reviews/Muscular_Enhancement_Supplements-Creatine_HMB_Gluatamine_and_BCAAs/creatine/

17. ConsumerLab.com Product Review of Resveratrol Supplements (2007)
http://www.consumerlab.com/reviews/Resveratrol_Supplements_Including_Red_Wine_Grape_and_Polygonum_Sources/Resveratrol_Red_Wine/

18. ConsumerLab.com Product Review of Multivitamin and Multimineral Supplements (2009)
http://www.consumerlab.com/reviews/Multivitamin_Multimineral_Supplements/multivitamins/

19. ConsumerLab.com Product Review of B Vitamins (2007)
http://www.consumerlab.com/reviews/B_Vitamins_B-Complexes_Thiamin_Niacin_B-6_B-12_Biotin_and_Folic_Acid/bvitamins/

20. ConsumerLab.com Archive of Recalls and Warnings
http://www.consumerlab.com/recalls.asp#Past

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