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FILE: · **Garlic (*Allium sativum*)**
· **Hypercholesterolemia**
· **Cholesterol**

DATE: April 30, 1999 HC 081981

RE: Garlic Oil Study in JAMA Stirs Controversy

Berthold, Heiner, T. Sudhop, K. von Bergmann. Effect of a Garlic Oil Preparation on Serum Lipoproteins and Cholesterol Metabolism. *The Journal of the American Medical Association*, June 17, 1998, Vol. 279, No. 23, pp. 1900-1902.

Duke, James A. perJAMAgame. June 17, 1998 (from email).

Lawson, Larry. Letter to the Editor: Effect of Garlic on Serum Lipid. *JAMA*. Nov. 11, 1998, Vol. 280, No. 18, pp. 1568.

Berthold, Heiner K. Reply to Lawson's Letter to the Editor: Effect of Garlic on Serum Lipid. *JAMA* November 18, 1998, Vol. 280, No. 18, pp. 1568.

Several pharmacognosy researchers in academia and the herb industry found fault with the conclusions drawn in the attached study published in *JAMA*. The study authors conclude that, based on their research using a steam-distilled garlic oil preparation, "there is no evidence to recommend garlic therapy for lowering serum lipid levels." Dr. James Duke responds that he "would expect no hypocholesterolemic activity from a product containing no or negligible hypocholesterolemic compounds."

The JAMA study authors themselves seem to acknowledge that their steam-distilled garlic oil product did not contain the well-known cholesterol-lowering garlic compounds, alliin, allicin, and diallyl ajoene, saying that it "contain[ed] only polysulfides and other volatile thioallyls."

In a letter to JAMA, Dr. Larry Lawson of Murdock Madaus Schwabe explains that when allicin, a water-soluble thiosulfinate, is subjected to steam distillation, it is converted to oil soluble allyl sulfides. In vitro antimicrobial and antithrombotic studies suggest the allyl sulfides are not as therapeutically active as thiosulfinates. Lawson points out that only one other placebo-controlled study of garlic and cholesterol used a steam-distilled oil product, and the dose was nearly twice as high — 18 mg versus Berthold's 10 mg. Reviewing all 440 cholesterol-lowering garlic studies in the literature, Duke

points out that the average cholesterol decrease with alliin-containing fresh garlic was 16 percent; with steam-distilled oil products the average decrease was only 4 percent. Also, in the steam-distilled oil trials, doses were as high as 120 mg daily and the cholesterol-lowering effect was clearly dose-dependent.

The double-blind, randomized, placebo-controlled trial involved 25 patients with “moderate” hypercholesterolemia (some of whom were taking anti-hypertensive medication, hormone replacement drugs and thyroid medication) who were “advised to adhere to their usual diet” as they participated in the study through an outpatient lipid clinic. Divided into two groups, patients received 10 mg daily of the garlic supplement or placebo for 12 weeks. After a four-week “washout period,” the groups were crossed over so that those formerly on placebo received the supplement, and vice versa, for another 12 weeks. Researchers measured serum lipoprotein concentrations, cholesterol absorption, and cholesterol synthesis at the beginning of the study and at the ends of both treatment periods.

Duke finds problems with the JAMA researchers’ assessment of their findings and of other garlic research. The researchers noted “a slight increase in all lipoprotein fractions during active-drug treatment compared with placebo,” but deemed it “statistically [in]significant.” They dismiss the findings of a meta-analysis involving 1,365 individuals, saying some of the underlying studies were of poor quality. Duke points out that in fact, the authors overlooked many other garlic studies. Reuter, Koch, and Lawson assessed 40 clinical garlic studies involving more than 4,000 individuals (of which 12 yielded significant cholesterol-lowering effects) and found an average cholesterol-lowering effect of 10.6 percent. Rates ranged from no effect to a 25 percent decrease, with fresh garlic yielding the best results. Yet, the researchers failed to assess or include citations for many of these studies. Duke points out that Reuter, et al. cite 2,580 references, “two orders of magnitude more references . . . than Berthold and associates cite.”

Finally, Lawson notes that the proprietary product on which the JAMA study was based was a “poor choice,” even among steam-distilled oil products. “Normally, garlic oil pills consist of garlic oil dissolved in a vegetable oil contained in clear soft gelatin capsules that readily dissolve. However, the binding of garlic oil to β-cyclodextrin is unique to the brand used (Tegra®) and may reduce the efficiency of release of the garlic oil.” Lawson obtained two lots of the product and measured its garlic oil release under simulated gastrointestinal dissolution conditions; he found that “only 1.8 mg, rather than 5 mg, of garlic oil was released per tablet” within USP-defined time testing limits. Also, “the tablets did not dissolve or disintegrate well, but remained as large pieces (halves and quarters).” When the researchers administered the product to two individuals and measured exhaled allyl methyl sulfide, they found only “25-40% expected values, compared to garlic oil in gelatin capsules.”

In responding to Lawson’s letter, Dr. Heiner Berthold notes “there are differences between various garlic preparations” and that “ though the conclusions of our study apply only to the preparation we used, we believe

that convincing evidence of lipid-lowering effects of any garlic preparation is still lacking there are differences in various garlic preparations." —*Betsy Levy*

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