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Herbal Science Group Says Dosage Too Low In New Echinacea Trial

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(Austin, TX, July 27, 2005). The nonprofit American Botanical Council (ABC), an Austin, Texas-based research and education organization, has reviewed a new clinical trial on the popular herb echinacea for use in a specific kind of induced virus, being published Thursday in the *New England Journal of Medicine*.¹ The study concluded that the echinacea preparations did not prevent or help treat symptoms of a specific virus applied to the test subjects. ABC has found several aspects of the design of the study worthy of clarification, and comments on the potential misinterpretations of the significance of this study.

First, the extracts used were made in a university laboratory and do not correlate with commercial echinacea products currently available to consumers. Second, the dosages used in this trial were probably too low. The echinacea preparations used in the study might have shown activity at more frequent dosing intervals and/or higher dosage levels – as is often the case with contemporary echinacea use.

The new trial utilized extracts made from the roots of a species of echinacea called *Echinacea angustifolia*. The randomized, double-blind, placebo-controlled, seven-arm trial was conducted on 437 college students who had a particular type of rhinovirus inserted into their nostrils (the results were calculated on 399 subjects). In the trial, the echinacea preparations were tested to see if they had a preventive effect or if they could help treat the symptoms caused by the rhinovirus. The students who received the three different echinacea preparations and were sequestered in a hotel room did not experience fewer infections, fewer symptoms, or a reduction in the duration of symptoms, compared with those who received the placebo.

The trial utilized three doses of 1.5 milliliters each of the three laboratory-produced echinacea extracts, presumably equivalent to about 300 milligrams of the dried powdered root in each dose (equivalent to 900 mg per day of the dried root). This level was chosen for the trial because it is the dose recommended by the German government's expert herb panel called the Commission E, which had conducted reviews of the research published on various types of echinacea in the scientific and medical literature in the early 1990s.²

According to ABC various international monographs have acknowledged the generally higher dose used for echinacea root products. The World Health Organization (WHO) monograph for Echinacea root ("Radix Echniaceae") has a dosage for *Echinacea angustifolia* root at the equivalence of 3 gm per day of the dried root.³ This same dosage is also acknowledged in the more recently developed draft monographs on Echinacea from the Canadian Natural Health Products Directorate.⁴

This dosage level is about 330% higher than the dosage of the echinacea preparations given in the NEJM trial. This supports ABC's contention that the preparations may have been under-dosed and that the trial might have shown a potentially positive trend if a higher dosage and/or increased frequency of administration had been followed.

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"It would have been optimal if this trial had tested the echinacea preparations at more frequent and/or higher doses," said Mark Blumenthal, Founder and Executive Director of ABC. "Dosage is one of the most important aspects in assessing any therapeutic agent. Many clinicians who recommend echinacea for treatment of upper respiratory tract infections related to colds and flu normally utilize a frequency of use and/or a total daily dose that is higher than the one used in this trial. This is also true for consumer self-medication with many commercial echinacea preparations according to some label dosage suggestions."

Blumenthal added. "The researchers have previous experience in researching echinacea and have done an admirable job in testing a species of echinacea (i.e., *E. angustifolia*) that has not been adequately researched." But he hastened to add, "The most accurate statement that can be said about this trial is this: These specific laboratory-produced echinacea extracts, at the dose given in the trial, under the specific design of this trial, did not produce any measurable effect."

He emphasized, "This is not a definitive trial on the efficacy of echinacea, nor should the results be generalized to echinacea preparations widely available. Unfortunately, the conclusion that may be drawn by some media who report this study may state that 'echinacea is ineffective,' but this would be an incorrect conclusion based on the design of this study and the evidence in the existing literature."

"Dosing people for rhinovirus in a hotel does not necessarily mimic real life," said Bruce Barrett, MD, PhD, an Assistant Professor of Family Medicine University of Wisconsin School of Medicine and an author of several previous critical reviews on echinacea clinical trials. He noted that the patients were possibly relatively resistant to the echinacea treatment. "College kids are immunocompetent," he stated, referring to the relative health of the test subjects in the trial. "It may have been better to test older people to see how they might have fared."

However, Dr. Barrett was generally complimentary about the trial in general. "This is a very valuable study and quite helpful, although it has some significant limitations, including product, sample, and population," he stated. "In general, you may want to have about 100 people per treatment group for more statistical significance rather than only about 50 per group used in this trial."

In general, products marketed as "Echinacea" are extremely popular in the United States. Echinacea ranked second in sales in mainstream market retail stores in 2004, according to an article in ABC's journal *HerbalGram*.⁵ Total sales of echinacea products in all channels of trade in the United States in 2004 was estimated at about \$155 million, according to data compiled by *Nutrition Business Journal*.

Blumenthal also added that although it was formerly quite popular, there has been a trend away from using *Echinacea angustifolia* root in commercial herbal products based on increased concerns by many responsible members of the herb community regarding conservation and sustainability of wild medicinal plants. *Echinacea angustifolia* is generally more difficult to cultivate commercially than the other two more popular species of echinacea (*E. pallida* and *E. purpurea*), and so more material from these species are found in products on the North American market.

Blumenthal points to a body of clinical evidence that supports the use of various echinacea preparations for treating symptoms associated with colds and flus. A [therapeutic monograph on Echinacea](#) is available in *The ABC Clinical Guide to Herbs*, ABC's reference book and continuing medical education module.⁶ The monograph summarizes 21 clinical trials on various echinacea preparations for colds, flus, upper respiratory tract infections, and other uses. ABC has posted the complete echinacea chapter including this monograph on its website (<http://www.herbalgram.org/>) as an educational service to the public.

The study has generated significant media attention. ABC and Blumenthal have been contacted by a variety of news sources, including: the Associated Press, Bloomberg Business News, CNN, the *Los Angeles Times*, *NBC Nightly News with Brian Williams*, the *New York Times* and *USA Today*.



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About the American Botanical Council

The American Botanical Council is the nation's leading nonprofit organization addressing research and educational issues regarding herbs and medicinal plants. The 17-year-old organization occupies a 2.5 acre site in Austin, Texas, where it publishes *HerbalGram*, a peer-reviewed journal. ABC is also the publisher of *The ABC Clinical Guide to Herbs*, a continuing education and reference book, which contains extensive monographs on the safety and efficacy of 29 popular herbs, including echinacea.⁶ More information on echinacea is available on ABC's extensive website, <http://www.herbalgram.org/>.

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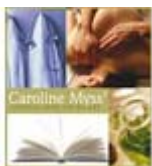
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