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BOTANICAL
COUNCIL

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**FILE: ■St. John's Wort (*Hypericum perforatum*)
■Depression – Mild to Moderate**

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Date: February 16, 2004

RE: Press Conference Reiterates Expert Assessment of Safety and Efficacy of St. John's Wort in Mild to Moderate Depression

Experts reconfirm safety and benefits of St. John's wort for combating mild to moderate symptoms of depression [press release]. *Council for Responsible Nutrition* 2001 June 25.

New study on St. John's wort and depression misleading to consumers and healthcare professionals [press release]. *Council for Responsible Nutrition* 2002 April 9.

The Council for Responsible Nutrition (CRN), in partnership with the American Botanical Council (ABC), has commissioned a panel of experts to review the safety and efficacy of 28 of the best selling botanicals. ABC's Mark Blumenthal joined Lenore Arab, PhD; Dennis Awang PhD; John Beutler, PhD; Mary Chavez, PharmD; Jerry Cott, PhD; Mary Hardy, MD; Thomas James, MD; Richard Kingston, PhD; Thomas Kurt, MD; Tieraona Low Dog, MD; the late Varro Tyler, PhD, MPh; and John Cardellina, PhD (formerly with CRN, now with the National Cancer Institute) in forming the expert panel.

After reviewing over 30 clinical trials on St. John's wort (*Hypericum perforatum*), the committee "reconfirms that it is safe and beneficial for mild to moderate depression, stress, and anxiety." The committee raised concern regarding the National Institute of Health's (NIH) forthcoming study of St. John's wort for severe depression, noting that results may cast doubt on or overshadow St. John's effectiveness for milder forms of depression.

The three-year NIH study was a randomized, double blind, placebo-controlled, multicenter trial comparing St. John's wort and the drug sertraline (Zoloft®) for chronic or severe depression. The trial began in December of 1998, and results from this \$4.3 million study of 336 patients were published in April 2002 in the *Journal of the American Medical Association*.

The NIH estimates that one in 15 Americans is affected by depression each year. The most common forms of depression are: major depression, dysthymia (chronic depression), and bipolar disorder. Depending on the severity of the symptoms of major depression, it can be further classified as mild, moderate, or severe. Symptoms of major depression include: "sad mood, loss of interest or pleasure in activities once enjoyed, change in appetite or weight, difficulty sleeping or oversleeping, physical slowing or agitation, energy loss,

feeling of worthlessness, guilt, difficulty thinking or concentrating, and recurrent thoughts of death or suicide."

On June 25, 2001, CRN covered a press conference to share some of the CRN-ABC expert panel's conclusions about the safety and efficacy of St. John's wort for the treatment of mild to moderate depression. Experts participating in the press conference were Drs. Cott and Low Dog, and Norman Rosenthal, MD, a psychiatrist at Georgetown Medical Center.

CRN reports that the United States spends \$30-44 billion dollars annually on the treatment of depression. The organization notes that St. John's wort is prescribed 20 times more often than Prozac in Germany. One member of the expert panel, Dr. Low Dog, is quoted as following this example, preferring St. John's wort as the first line of treatment for mild to moderate depression, as well as utilizing it in cases of "menopausal irritability or in combination with calcium for premenstrual syndrome (PMS)."

In the April 9th press release, the Council for Responsible Nutrition (CRN) responds to a study of St. John's wort (SJW) published in the April 10 issue of JAMA, calling it "misdirected and inconsequential." SJW is commonly used as an antidepressant in Germany and the United States and has been proven beneficial for mild to moderate depression. This new study, published in JAMA and sponsored by the National Institute of Health, targeted moderate to severe depression. The results of the new study suggest that the patient group was responsive to neither SJW, sertraline (a prescription antidepressant), nor placebo.

The press release states that "the authors [of the study] and the JAMA...downplay the fact that St. John's wort did no worse than a known, effective antidepressant in the two most important primary measures of the study." John Cardellina states that the "new report dismisses the fact that St. John's wort has been proven safe and beneficial for the treatment of mild to moderate depression...based on more than thirty controlled clinical studies and three meta-analyses or systematic reviews." Norman Rosenthal says that the findings "are of limited value, because St. John's wort is not generally used for moderate to severely depressed people."

The press release concludes with an observation by Jerry Cott, former chief of the Psychopharmacology Research Program at the National Institute of Mental Health, that the study "enrolled a population of patients who were too depressed to respond to either sertraline or hypericum...the lack of response in the standard treatment...prevents any valid conclusions from this study regarding the effectiveness of St. John's wort."

–Carolyn William Orlando, MA and Stacy Elliott

Editor's note: For more information on SJW or to read the American Botanical Council's press release regarding the JAMA article, visit www.herbalgram.org.

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