SUMMARY

Background: Green tea extract, a common herbal supplement, is consumed as a weight loss and dietary supplement and is used as an ingredient in sunblock, cream rinses, and other cosmetics. Many studies have investigated the potential therapeutic uses of green tea extract, but few studies have evaluated the long-term safety of consumption at high doses. The effects of oral administration of green tea extract in male and female rats and mice were studied to identify potential toxicity or cancer-related outcomes.

Methods: Groups of 50–60 male and 50–60 female rats were orally administered 100, 300, or 1,000 milligrams (mg) of green tea extract per kilogram (kg) per day in water via oral gavage for 5 days per week for 2 years; similar groups of 50 male and female mice were administered 30, 100, or 300 mg/kg. Control animals received 0 mg/kg (water with no chemical added). Additional 3-month studies were conducted to set appropriate doses and identify target organs for subsequent studies. Tests were conducted to evaluate the potential for green tree extract to cause DNA damage. At the end of the study, tissues from more than 40 sites from every animal were examined for signs of disease.

Results: There was decreased survival in male and female rats at the highest dose administered compared to the control rats. Decreased body weights were also observed in male rats at the highest dose administered as well as in female rats and male and female mice at the two highest doses administered. No increases in the rates of neoplasms (which can include benign or malignant growths) in male or female rats or mice were attributed to the oral administration of green tea extract. Rates of noncancerous tissue abnormalities were increased in the liver, glandular stomach, small intestine, nose, lung, heart, and spleen of male and female rats; in the bone marrow of female rats; in the nose, mandibular lymph node, and bone marrow of male and female mice; and in the liver of male mice. Tests to evaluate the potential for green tea extract to damage DNA were negative.

Conclusions: *The NTP four-point scale rates the level of evidence that a substance has the ability to cause cancer in laboratory animals. Under the conditions of these 2-year gavage studies, there was no evidence that green tea extract administration causes cancer in male and female rats and mice. Oral administration of green tea extract caused increased incidences of noncancerous tissue abnormalities in the liver, glandular stomach (a tissue that secretes gastric acid), small intestine, bone marrow (female only), nose, lung, heart, and spleen of male and female rats and in the nose, liver (male only), mandibular lymph node, and bone marrow of male and female mice.*