

## PRESS RELEASE

### Contact:

Kaayla T. Daniel PhD  
(505) 984-2093  
wholenutritionist@earthlink.net  
www.wholesoystory.com

Bill Sanda  
Director of Public Affairs  
Weston A. Price Foundation  
(202) 333-4325  
westonaprice\_contact@msn.com  
www.westonaprice.org

## Health Experts Urge FDA To Deny Soy Protein Cancer Prevention Health Claim

*Scientists say Solae petition omits many studies indicating soy may cause cancer*

July 5, 2004, WASHINGTON, DC: Researchers at a non-profit nutrition education foundation in Washington, DC are urging the Food and Drug Administration to deny a petition that would clear the way for soy products to claim they prevent cancer. The Weston A. Price Foundation says a petition by Solae, a manufacturer of soy protein and other processed soy products, for a FDA health claim is based on misleading research.

Approved health claims can be used in product labeling and packaging to influence consumers in making dietary choices. The FDA will make a decision later this year.

Kaayla T. Daniel, PhD, author of *The Whole Soy Story* (to be released Fall 2004), noted that "Solae was highly selective in its choice of evidence and biased in its interpretations. It omitted many studies that show soy to be ineffective in preventing cancer, emphasized favorable outcome in studies when results were mixed and excused results of a few unfavorable studies that they included to give the illusion of balance. Most seriously, Solae omitted many well-designed studies that have suggested that soy protein can contribute to, cause and accelerate the growth of cancer."

Solae, a joint venture of Dupont and Bunge, applied for a Soy Protein and Cancer Health Claim in March 2004. Sally Fallon, President of the Weston A. Price Foundation, points out that Solae has a strong financial interest in winning a cancer health claim. "In their petition," notes Fallon, "Solae states that since the FDA authorized the Soy Protein and Coronary Heart Disease Health Claim, per capita consumption of soy protein increased from 0.78 g/day in 1998 to 2.23 g/day in 2002. Solae predicts that consumption of soy protein will double with a cancer health claim. Solae stands to reap tremendous financial gain at the expense of the public."

"Numerous experts – including scientists from the FDA's own National Laboratory for Toxicological Research – have warned of soy protein's carcinogenic potential and of the health dangers of excess soy-food consumption," says Bill Sanda, Director of Public Affairs for the Weston A. Price Foundation. "Yet in its petition, Solae contends that their data 'establish that there is scientific agreement among experts qualified by scientific training and experience to evaluate such claims regarding the relationship between soy protein products and a reduced risk of cancers.' No such consensus exists. The British Committee on Toxicity (COT) reviewed much of the evidence and found the results to be both 'inconsistent and contradictory.'"

The British Committee on Toxicity (COT) has stated that “the epidemiological data on soy intake and prostate cancer are inconsistent” and that concentrations used in animal experiments are “very high compared with the likely dietary exposure levels in humans.” These studies not only show that soy foods are not protective against prostate cancer or less effective than other dietary agents, but also that soy protein – and its constituent isoflavones – have been linked to increased prostate cancer risk. In addition, they have caused undesirable side effects, including changes to the brain.

According to the Weston A. Price Foundation, Solae also failed to present theories about why soy might be protective against the development of prostate cancer. “Prostate cancer is generally thought to be dependent on exposure to male reproductive hormone. If soy confers protection, it does so by altering endogenous hormone concentrations – by decreasing testosterone and androgen levels and feminizing men,” said Fallon. “While this might have valid pharmaceutical applications for cancer treatment, it seems inadvisable as a preventive treatment for our entire population of men and boys.”

Solae’s claim that soy protein prevents gastrointestinal cancer is contradicted by numerous studies, including one that links soy protein with a lowered risk of stomach cancer but a higher risk of colorectal cancer. Dr. Daniel adds that “Solae also omitted key studies that link the soy lectin – a component of soy protein – to precancerous conditions in the small intestines, including shortened villi, a diminished capacity for digestion and absorption, cell proliferation in the crypt cells, interference with hormone and growth factor signaling and unfavorable population shifts among the microbial flora.”

Solae states that “the totality” of the evidence supports a soy protein/cancer claim, a conclusion that Solae's consultants were able to reach only through a series of statistical studies known as meta-analyses. “Meta-analyses serve researchers – and their industry sponsors – when they wish to draw specific conclusions,” explains Fallon. “Meta-analysts have been criticized by many in the scientific and statistical communities for making faulty assumptions, indulging in creative accounting and for leaving out studies that contradict or dilute the conclusions desired. Solae has left out many such studies.”

Experts were also concerned about Solae’s summaries of the body of evidence concerning soy and other cancers. Solae chose to minimize a large-scale study linking soy protein to bladder cancer and it omitted evidence linking soy protein to thyroid and pancreatic cancers and to childhood leukemia. Solae also failed to address soy protein’s well-documented risks to the digestive, immune and neuroendocrine systems of the body, including strong evidence that dietary soy has contributed to rising rates of infertility and hypothyroidism. Soy is also highly allergenic. Most experts now place soy protein among the top eight allergens, and some rate it in the top six or even top four. Allergic reactions to soy range from mild to life threatening and fatalities have been reported in medical journals.

The full request to the FDA for denial is posted at [www.westonaprice.org](http://www.westonaprice.org).