
American Journal of Clinical Nutrition, Vol 68, 1431S-1435S, "Effects of soy-protein supplementation on epithelial proliferation in the histologically normal human breast" - Study showed that short-term use of dietary soy stimulated breast cell proliferation, which can increase the risk of breast cancer.

Anti-thyroid isoflavones from soybean -- November 1997 article from *Biochem Pharmacol* in which "it was observed that an ... extract of soybeans contains compounds that inhibit thyroid peroxidase- (TPO) catalyzed reactions essential to thyroid hormone synthesis."

Breast and soy-formula feedings in early infancy and the prevalence of autoimmune thyroid disease in children. -- April 1998 article from the *J Am Coll Nutr.* that documents the association of soy formula feedings in infancy and autoimmune thyroid disease.

In the bestselling book *Living Well With Hypothyroidism: What Your Doctor Doesn't Tell You ... That You Need to Know*, leading soy expert Dr. Mike Fitzpatrick was profiled.

Sirtori CR (2001). "Risks and benefits of soy phytoestrogens in cardiovascular diseases, cancer, climacteric symptoms and osteoporosis". *Drug safety : an international journal of medical toxicology and drug experience* **24** (9): 665–82. PMID 11522120.

Hogervorst E, Sadjimim T, Yesufu A, Kreager P, Rahardjo TB (2008). "High tofu intake is associated with worse memory in elderly Indonesian men and women". *Dement Geriatr Cogn Disord* **26** (1): 50–7. doi:10.1159/000141484. PMID 18583909.

Chavarro JE, Toth TL, Sadio SM, Hauser R (Nov 2008). "Soy food and isoflavone intake in relation to semen quality parameters among men from an infertility clinic". *Hum Reprod.* **23** (11): 2584–90. doi:10.1093/humrep/den243. PMID 18650557.

White LR, Petrovitch H, Ross GW, *et al* (2000). "Brain aging and midlife tofu consumption". *J Am Coll Nutr* **19** (2): 242–55. PMID 10763906.

Roebuck BD, Kaplita PV, Edwards BR, Praissman M (1987). "Effects of dietary fats and soybean protein on azaserine-induced pancreatic carcinogenesis and plasma cholecystokinin in the rat". *Cancer Res.* **47** (5): 1333–8. PMID 3815341.

de Lemos ML (2001). "Effects of soy phytoestrogens genistein and daidzein on breast cancer growth". *Ann Pharmacother* **35** (9): 1118–21. doi:10.1345/aph.10257. PMID 11573864.

Rackis, J. J., " Biological and physiological factors in soybeans," *Journal of the American Oil Chemists' Society*, 51: 161A-170A, January 1974.

Lepkovsky, S., "Antivitamins in Foods," Chapter 11 in *Toxicants Occurring Naturally in Foods*, Publication 1354: 98-104, National Academy of Sciences/National Research Council, Washington, DC, 1966.

Tait, S., *et al*, "The availability of minerals in food, with particular reference to iron," *Journal of Research in Society & Health*, 103(2):74-7, April 1983.

Sandstrom, B., *et al*, "Effects of protein level and protein source in zinc absorption in humans," *Journal of Nutrition*, 119: 48-53, January 1989.

Liener, I. E., "Hemagglutinins in Foods," Chapter 6 in *Toxicants Occurring Naturally in Foods*, Publication 1354: 51-7, National Academy of Sciences/National Research Council, Washington, DC, 1966.

Ikeda, T., *et al*, "Dramatic synergism between excess soybean intake and iodine deficiency on the development of rat thyroid hyperplasia," *Carcinogenesis*, 4: 707-13, April 21, 2000.

Divi, R. L., *et al*, "Anti-thyroid isoflavones from soybean," *Biochemical Pharmacology*, 54: 1087-96, November 15, 1997.

Hilakivi-Clarke, L., *et al*, "Maternal genistein exposure mimics the effects of estrogen in mammary gland development in female mouse offspring," *Oncology Report*, 5(3): 609-16, May-June 1998.

Hilakivi-Clarke, L., *et al*, "Maternal exposure to genistein during pregnancy increases carcinogenic-induced mammary tumorigenesis in female rat offspring," *Oncology Report*, 6:1089-95, September-October 1999.

Matone, G., *et al*, "Effects of genistein on growth and development of the male mouse," *Journal of Nutrition*, 86: 235-40, 1956.

Petrakis, N. L., *et al*, "Stimulatory influence of soy protein isolate on breast secretion in pre- and post-menopausal women," *Cancer Epidemiology and Biological Previews*, 5: 785-94, 1996.

McGuinness, J., *et al*, "The effects of long-term feeding of soya flour on the rat pancreas," *Scandinavian Journal of Gastroenterology*, 15: 497-502, 1980.

Murphy, P. A., "Phytoestrogen content of processed soybean foods," *Food Technology*, 36: 50-4, 1982.

Torum, B., "Nutritional quality of soybean protein isolates studies in children of preschool age," Chapter in *Soy Protein and Human Nutrition*, Harold L. Wicke, *et al*, (eds.), Academic Press, New York, 1979.

Stob, M., "Estrogens in Foods," Chapter 2 in *Toxicants Occurring Naturally in Foods*, Publication 1354: 18-23, National Academy of Sciences/National Research Council, Washington, DC, 1966.

¹Constantinou, A., "Interaction between genistein and estrogen receptors may enhance mammary tumor growth," American Association for Cancer Research, April 2000, reported in "The Power of Soy," Guterman, L., *Today's Chemist at Work* (publication of the American Chemical Society), June 2000, page 47.

Dees, C., *et al*, "Dietary estrogens stimulate human breast cells to enter the cell cycle," *Environmental Health Perspectives*, 105 (Supplement 3): 633-6, 1997.

Wallace, G. M. "Studies on the processing and properties of soy milk," *Journal of Science & Food Agriculture*, 22: 526-35, October 1971.

Fort, P., *et al*, "Breast and soy-formula feeding in early infants and the prevalence of autoimmune thyroid disease in children," *Journal of the American College of Nutrition*, 9:164-7, September 1990.

Setchell, K. D. R., *et al*, "Exposure of infants to phyto-oestrogens from soy-based infant formula," *Lancet*, 350: 23-7, 1997.

Setchell, K. D. R., *et al*, "Isoflavone content of infant formulas and the metabolic fate of these phytoestrogens in early life," *American Journal of Clinical Nutrition*, 68 (Supplement): 1453S-61S, 1998.

Setchell, K. D. R., "Phytoestrogens: the biochemistry, physiology, and implications for human health of soy isoflavones," *American Journal of Clinical Nutrition*, 68 (Supplement): 1333S-46S, 1998.

Irvine, C., *et al*, "The potential adverse effect of soybean phytoestrogens in infant feeding," *New Zealand Medical Journal*, 108: 318, May 24, 1995.

James, V., "Comments on isoflavones in soy-based infant formulas," *Journal of Agricultural Food Chemistry*, 46: 3395, 1998; also, Fitzpatrick, M. G., "Comments," 3396-7.

Food & Drug Administration, "Food labeling; health claims: soy protein and coronary heart disease," FDA 21CFR, Part 101; Docket No. 98P-0683, October 26, 1999

Studies Showing Adverse Effects of Dietary Soy, 1971-2003

1971

Wallace, GM. Studies on the Processing and Properties of Soymilk. *J Sci Food Agri* 1971 Oct;22:526-535. In order to neutralize the protease inhibitors (enzymes that inhibit the digestion of protein) in soy, it must be heated to very high temperatures under pressure and for considerable time. This process unfortunately denatures the overall protein content of soy, rendering it largely ineffective.

1974

Joseph, JR. Biological and physiological Factors in Soybeans. *JOACS*, 1974 Jan;51:161A-170A. In feeding experiments, use of soy protein isolate (SPI) increased requirements for vitamins E, K, D and B12 and created deficiency symptoms of calcium, magnesium, manganese, molybdenum, copper, iron and zinc.

1975

Nutrition during Pregnancy and Lactation. California Department of Health, 1975. Soy is listed as a minor source of protein in Japanese and Chinese diets. Major sources of protein listed were meat including organ meats, poultry, fish and eggs.

1976

Searle CE, ed, *Chemical Carcinogens*, ACS Monograph 173, American Chemical Society, Washington, DC, 1976. Asians throughout the world have high rates of thyroid cancer.

1977

Chang KC, ed, *Food in Chinese Culture: Anthropological and Historical Perspectives*, New Haven, 1977. This survey found that soy foods accounted for only 1.5 percent of calories in the Chinese diet, compared with 65 percent of calories from pork.

1978

FDA ref 72/104, Report FDABF GRAS - 258. In 1972, the Nixon administration directed a reexamination of substances believed to be GRAS in the light of any scientific information then available. This reexamination included casein protein which became codified as GRAS in 1978. In 1974, the FDA obtained a literature review of soy protein because, as soy protein had not been used in food until 1959 and was not even in common use in the early 1970s, it was not eligible to have its GRAS status grandfathered under the provisions of the Food, Drug and Cosmetic Act.

1979

Evaluation of the Health Aspects of Soy Protein Isolates as Food Ingredients. Prepared for FDA by Life Sciences Research Office, *Federation of American Societies for Experimental Biology*, 9650 Rockville Pike, Bethesda, MD 20014, Contract No, FDA 223-75-2004, 1979. In this document, the FDA expresses concern about nitrites and lysinoalanine in processed soy. Even at low levels of consumption--averaging one-third of a gram per day at the time--the presence of these carcinogens was considered too great a threat to public health to allow GRAS status. Soy protein did have approval for use as a binder in cardboard boxes and this approval was allowed to continue because researchers considered that migration of nitrites from the box into the food contents would be too small to constitute a cancer risk. FDA officials called for safety specifications and monitoring procedures before granting of GRAS status for food. These were never performed. To this day, use of soy protein is codified as GRAS only for limited industrial use as a cardboard binder.

1979

Torum, B. Nutritional Quality of Soybean Protein Isolates: Studies in Children of Preschool Age. *Soy*

Protein and Human Nutrition, Harold L Wilcke and others, eds, Academic Press, New York, 1979. A group of Central American children suffering from malnutrition was first stabilized and brought into better health by feeding them native foods, including meat and dairy products. Then for a two-week period these traditional foods were replaced by a drink made of soy protein isolate and sugar. All nitrogen taken in and all nitrogen excreted were measured. The researchers found that the children retained nitrogen and that their growth was "adequate," so the experiment was declared a success. However, the researchers noted that the children vomited "occasionally," usually after finishing a meal; over half suffered from periods of moderate diarrhea; some had upper respiratory infections; and others suffered from rash and fever. It should be noted that the researchers did not dare to use soy products to help children recover from malnutrition, and were obliged to supplement the soy?sugar mixture with nutrients largely absent in soy products, notably vitamins A, D, B12, iron, iodine and zinc.

1981

Casey CE and others . Availability of zinc: loading tests with human milk, cow's milk, and infant formulas. *Pediatrics* 1981;68(3):394-6. Female subjects consumed 25 mg of zinc with milk or formula, the amount of which was calculated to provide 5 gm of protein, after an eight-hour fast. Blood samples were taken prior to (base line) and at 30-minute intervals for three hours after consumption of zinc. The plasma response with human milk was significantly greater than with cow's milk and all the formulas. The response with cow's milk and a cow's milk-based formula was one third that with human milk; responses with a soy-based and two casein hydrolysate-based formulas were even lower.

1981

Lebenthal E and others. The development of pancreatic function in premature infants after milk-based and soy-based formulas. *Pediatr Res* 1981 Sep;15(9):1240-1244. Soy formula fed to premature babies caused an increase in digestive enzymes compared to milk-fed babies, indicating low digestibility of soy formula.

1982

Murphy PA. Phytoestrogen Content of Processed Soybean Foods. *Food Technology*. 1982:50-54. One hundred grams of soy protein, the maximum suggested cholesterol-lowering dose in the FDA-sanctioned health claim, can contain almost 600 mg of isoflavones.

1983

Wenk GL and Stemmer KL. Suboptimal dietary zinc intake increases aluminum accumulation into the rat brain. *Brain Res* 1983;288:393-395. Zinc deficiency will cause more aluminum to be absorbed into the body in general, and into the brain in particular. Aluminum will be absorbed by competing for binding sites on a zinc-containing ligand. Fluoride and phytates in soy formula will induce zinc deficiency.

1983

Poley JR and Klein AW. Scanning electron microscopy of soy protein-induced damage of small bowel mucosa in infants. *J Pediatr Gastroenterol Nutr* 1983 May;2(2):271-87. Soy feeding caused damage to small bowel mucosa in 2 infants. The damage was similar to that of celiac disease and consistent with a lectin-induced toxicity.

1983

Tait S and others. The availability of minerals in food, with particular reference to iron. *Journal of Research in Society and Health*, April 1983;103(2):74?77. When precipitated soy products like tofu are consumed with meat, the mineral blocking effects of the phytates are reduced. The Japanese

traditionally eat a small amount of tofu or miso as part of a mineral-rich fish broth, followed by a serving of meat or fish.

1983

Ross RK. Effect of in-utero exposure to diethylstilbesterol on age at onset of puberty and on post-pubertal hormone levels in boys," *Canadian Medical Association Journal* 1983, May 15;128(10):1197-8. Male children exposed during gestation to diethylstilbesterol (DES), a synthetic estrogen that has effects on animals similar to those of phytoestrogens from soy, had testes smaller than normal on maturation.

1984

Ologhobo AD and others. Distribution of phosphorus and phytate in some Nigerian varieties of legumes and some effects of processing. *Journal of Food Science*. January/February 1984;49(1):199-201. The phytic acid in soy is highly resistant to normal phytate-reducing techniques, such as soaking or long, slow cooking.

1994

Hawkins NM and others. Potential aluminium toxicity in infants fed special infant formula. *J Pediatr Gastroenterol Nutr* 1994;19(4):377-81 (1994). Researchers found aluminum concentrations of 534 micrograms/L in soy formula, as compared to 9.2 micrograms/L in breast milk. The authors concluded that infants may be at risk from aluminium toxicity when consuming formula containing more than 300 micrograms/L.

1985

Rackis JJ and others. The USDA trypsin inhibitor study. I. Background, objectives and procedural details. *Qualification of Plant Foods in Human Nutrition*, 1985;35. Diets of soy protein isolate high in trypsin inhibitors caused depressed growth and enlargement and pathological conditions of the pancreas, including cancer, and enlarged thyroid glands in rats. Analyses for this study showed that trypsin inhibitor content of soy protein isolate can vary as much as fivefold. Even low-level-trypsin-inhibitor SPI feeding resulted in reduced weight gain compared to controls. Soy protein isolate and textured vegetable protein made from soy protein isolate are used extensively in school lunch programs, imitation foods, commercial baked goods, diet beverages, meal replacements and fast food products. They are heavily promoted in Third World countries and form the basis of many food giveaway programs.

1986

McGraw MD and others. Aluminum content in milk formulae and intravenous fluids used in infants. *Lancet* 1:157 (1986). Carefully collected human breast milk contained 5 to 20 micrograms aluminum per liter; concentrations were 10 to 20 fold greater in most cow's milk-based formulas and 100-fold greater in soy-based formulas.

1986

Fort P and others. Breast feeding and insulin-dependent diabetes mellitus in children. *J Am Coll Nutr* 1986;5(5):439-441. Twice as many soy-fed children developed diabetes as those in a control group that was breast fed or received milk-based formula. It was based on this study that the American Academy of Pediatrics took a position of opposition to the use of soy infant formula. This objection was later dropped after the AAP received substantial grants from the Infant Formula Council.

1986

Freni-Titulaer LW and others. *Am J Dis Child* 1986 Dec;140(12):1263-1267. Soy infant feeding was

associated with higher rates of early development in girls, including breast development and pubic hair before the age of eight, sometimes before the age of three.

1987

Dabeka RW and McKenzie AD. Lead, cadmium, and fluoride levels in market milk and infant formulas in Canada. *J Assoc Off Anal Chem* 1987;70(4):754-7 (1987). Soy based or milk-free formulas contained about 8-15 times more cadmium than milk-based formulas as well as high amounts of fluoride.

1987

Katz SH. Food and Biocultural Evolution: A Model for the Investigation of Modern Nutritional Problems. *Nutritional Anthropology*, Alan R. Liss Inc., 1987, p 50. During the Chou Dynasty (1134 - 246 BC) the soybean was designated one of the five sacred grains, along with barley, wheat, millet and rice. However, the pictograph for the soybean, which dates from earlier times, indicates that it was not first used as a food; for whereas the pictographs for the other four grains show the seed and stem structure of the plant, the pictograph for the soybean emphasizes the root structure. Agricultural literature of the period speaks frequently of the soybean and its use in crop rotation. Apparently the soy plant was initially used as a method of fixing nitrogen. The soybean did not serve as a food until the discovery of fermentation techniques, sometime during the Chou Dynasty. Katz speculates that the rise of liver cancer in Africa is caused by the introduction of soy foods into the African diet.

1989

El Tiney A. Proximate Composition and Mineral and Phytate Contents of Legumes Grown in Sudan. *Journal of Food Composition and Analysis* 1989;2:67-68. Soybeans are listed as having some of the highest levels of phytic acid of all legumes. Phytic acid blocks the absorption of zinc, iron, copper and magnesium.

1989

Sandstrom and others. Effect of protein level and protein source on zinc absorption in humans. *J Nutr* 1989 Jan;119(1):48-53. When precipitated soy products like tofu are consumed with meat, the mineral blocking effects of the phytates are reduced. The Japanese traditionally eat a small amount of tofu or miso as part of a mineral-rich fish broth, followed by a serving of meat or fish.

1990

Campbell TC. *The Cornell-China-Oxford Project on Nutrition, Health and Environment*. 1990; Chen J and others. *Diet, Lifestyle and Mortality in China. A study of the characteristics of 65 counties*. Monograph, joint publication of Oxford University Press, Cornell University Press, China People's Medical Publishing House. 1990. This exhaustive study of Chinese diets found that legume consumption ranged from 0 to 58 grams per day, with an average of 13 grams. Assuming that two-thirds of this is from soy beans, then consumption averages about 9 grams of soy products per day. Isoflavone content would probably be about 10 mg/day.

1990

Fort P and others. Breast and soy-formula feedings in early infancy and the prevalence of autoimmune thyroid disease in children. *J Am Coll Nutr* 1990;9:164-167. This study documents the association of soy formula feeding in infancy with autoimmune thyroid problems.

1990

Dabeka RW and McKenzie AD. Aluminium levels in Canadian infant formulae and estimation of aluminium intakes from formulae by infants 0-3 months old. *Food Addit Contam* 1990;7(2):275-82. Researchers found that aluminum content in soy formula for 1-3 month old infants could result in an

intake of 363 micrograms/kg/day (2088 micrograms/day) alone, not including potential contribution from other foods or water.

1991

Hagger C and Bachevalier J. Visual habit formation in 3-month-old monkeys (*Macaca mulatta*): reversal of sex difference following neonatal manipulations of androgen. *Behavior and Brain Research* 1991, 45:57-63. Male infants undergo a "testosterone surge" during the first few months of life, when testosterone levels may be as high as those of an adult male. During this period, the infant is programmed to express male characteristics after puberty, not only in the development of his sexual organs and other masculine physical traits, but also in setting patterns in the brain characteristic of male behavior. In monkeys, deficiency of male hormones impairs the development of spatial perception (which, in humans, is normally more acute in men than in women), of learning ability and of visual discrimination tasks (such as would be required for reading.)

1994

Messina MJ and others. Soy Intake and Cancer Risk: A Review of the In Vitro and In Vivo Data," *Nutrition and Cancer*, 1994, 21:(2):113-131. This study fueled speculation on soy's anticarcinogenic properties. The authors noted that in 26 animal studies, 65 percent reported protective effects from soy. At least one study was left out, in which soy feeding caused pancreatic cancer, the 1985 study by Rackis. In the human studies listed, the results were mixed. A few showed some protective effect but most showed no correlation at all between soy consumption and cancer rates. ". . . the data in this review cannot be used as a basis for claiming that soy intake decreases cancer risk." In a subsequent book, *The Simple Soybean and Your Health*, Messina recommends 1 cup or 230 grams of soy products per day in his "optimal" diet as a way to prevent cancer.

1995

Chorazy PA and others. Persistent hypothyroidism in an infant receiving a soy formula: case report and review of the literature. *Pediatrics* 1995 Jul;96(1 Pt 1):148-50. the study describes a case of persistent hypothyroidism in an infant who had received soy formula.

1995

Anderson JW and others. Meta-analysis of the Effects of Soy Protein Intake on Serum Lipids. *New England Journal of Medicine*, 1995 333:(5):276-82. The FDA's allowance of a health claim for soy protein is based largely on this meta-analysis, sponsored by Protein Technologies International. However, the study authors discarded eight studies for various reasons, leaving a remainder of 29. The published report suggested that individuals with cholesterol levels over 250 mg/dl would experience a "significant" reduction of 7 to 20 percent in levels of serum cholesterol if they substituted soy protein for animal protein. Cholesterol reduction was insignificant for individuals whose cholesterol was lower than 250 mg/dl. In other words, for most of the population, the substitution of meat with soy will not bring blood cholesterol levels down.

1996

Harris A, ed. *Cancer Rates and Risks*, 4th Edition, 1996, National Institutes of Health, National Cancer Institute. This report shows that the Japanese, and Asians in general, have lower rates of breast and prostate cancer but much higher rates of other types of cancer, particularly cancer of the esophagus, stomach, pancreas and liver.

1996

Fukutake M and others. Quantification of genistein and genistin in soybeans and soybean products.

Food Chem Toxicol 1996;34:457-461. Average isoflavone consumption in Japan was found to be about 10 mg per day.

1997

IEH assessment on Phytoestrogens in the Human Diet, Final Report to the Ministry of Agriculture, Fisheries and Food, UK, November 1997. This exhaustive report on phytoestrogens, prepared by the British government, failed to find much evidence of benefit and warned against potential adverse effects.

1997

Herman-Giddens ME and others. Secondary Sexual Characteristics and Menses in Young Girls Seen in Office Practice: A Study from the Pediatric Research in Office Settings Network. *Pediatrics*, 1997 Apr;99(4):505-512. Investigators found that one percent of all girls now show signs of puberty, such as breast development or pubic hair, before the age of three; by age eight, 14.7 percent of white girls and almost 50 percent of African-American girls had one or both of these characteristics. Our Comment: The widespread use of soy-based formula, beginning in the 1970s, is a likely explanation for the increase in early maturation in girls.

1998

Nagata C and others. Decreased serum total cholesterol concentration is associated with high intake of soy products in Japanese men and women. *J Nutr* 1998 Feb;128(2):209-13. This study included a survey of soy consumption among Japanese men and women. Consumption of soy products was about 54 grams per day for women and 64 grams per day for men. The total amount of soy protein from these products was 7-8 grams providing about 25 mg isoflavones.

1998

Irvine CH and others. Phytoestrogens in soy-based infant foods: concentrations, daily intake and possible biological effects. *Proc Soc Exp Biol Med* 1998 Mar;217(3):247-53. Researchers found that soy formulas provide infants with a daily dose rate of 3 mg/kg body weight total isoflavones, "which is maintained at a fairly constant level between 0-4 months of age. . . . This rate of isoflavone intake is much greater than that shown in adult humans to alter reproductive hormones."

1998

Yaffe K and others. Serum estrogen levels, cognitive performance, and risk of cognitive decline in older community women. *J Am Geriatr Soc* 1998 Jul;46(7):918-20. Women in the higher estrone quartiles had lower performance on two cognitive tests.

1998

Irvine CH and others. Daily intake and urinary excretion of genistein and daidzein by infants fed soy- or dairy-based infant formulas. *Am J Clin Nutr* 1998 Dec;68(6 Suppl):1462S-1465S. Researchers found that "young infants are able to digest, absorb, and excrete genistein and daidzein from soy-based formulas as efficiently as do adults consuming soy products.

1999

Eklund G and Oskarsson A. Exposure of cadmium from infant formulas and weaning foods. *Food Addit Contam* 16(12):509-19 (1999). Cadmium was 6 times higher in soy formulas than cow's milk formulas.

1999

Olguin MC and others. Intestinal alterations and reduction of growth in prepuberal rats fed with soybean [Article in Spanish]. *Medicina* (B Aires) 1999;59:747-752. Rats fed soy-based chow had reduced growth and an increase in gastrointestinal problems compared to controls.

1999

Nilhausen K and Meinertz H. Lipoprotein(a) and dietary proteins: casein lowers lipoprotein(a) concentrations as compared with soy protein. *Am J Clin Nutr* 1999;69:419-25. Many studies have shown that soy consumption can lower serum cholesterol levels. These studies have led to claims that soy can prevent heart disease. However, the theory that high cholesterol levels cause heart disease is becoming more and more untenable. Cholesterol levels are not a good marker for proneness to heart disease. However Lipoprotein(a) or Lp(a), does serve as a good marker for heart disease. This study indicates that soy raises Lp(a), meaning that it is likely to contribute to heart disease.

1999

Food Labeling: Health Claims: Soy Protein and Coronary Heart Disease, Food and Drug Administration 21 CFR Part 101 (Docket No. 98P-0683). This US government document allows a health claim for foods containing 6.25 grams of soy protein per serving. The original petition, submitted by Protein Technologies International (a division of Dupont), requested a health claim for isoflavones, the estrogen-like compounds found plentifully in soybeans, based on assertions that "only soy protein that has been processed in a manner in which isoflavones are retained will result in cholesterol-lowering." In 1998, the FDA made the unprecedented move of rewriting PTI's petition, removing any reference to the phytoestrogens and substituting a claim for soy protein, a move that was in direct contradiction to the agency's regulations. The FDA is authorized to make rulings only on substances presented by petition. The abrupt change in direction was no doubt due to the fact that a number of researchers, including scientists employed by the US government, submitted documents indicating that isoflavones are toxic. The regulations stipulate that 25 grams of soy protein per day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. Twenty-five grams soy protein can contain from 24-125 mg isoflavones, depending on processing methods. Many letters were written in protest, expressing concerns about mineral blocking effects, enzyme inhibitors, goitrogenicity, endocrine disruption, reproductive problems and increased allergic reactions from consumption of soy products.

1999

Sheehan DM and Doerge DR, Letter to Dockets Management Branch (HFA-305) February 18, 1999. A strong letter of protest from two government researchers at the National Center for Toxicological Research urging that soy protein carry a warning label rather than a health claim.

1999

Ginsburg J and Prelevic GM. Is there a proven place for phytoestrogens in the menopause?" *Climacteric*, 1999;2:75-78. Quantification of discomfort from hot flashes is extremely subjective and most studies show that control subjects report reduction in discomfort in amounts equal to subjects given soy.

1999

White L. Association of High Midlife Tofu Consumption with Accelerated Brain Aging. Plenary Session #8: Cognitive Function, The Third International Soy Symposium, Program, November 1999, page 26. An ongoing study of Japanese Americans living in Hawaii found a significant statistical relationship between two or more servings of tofu per week and "accelerated brain aging." Those participants who consumed tofu in mid life had lower cognitive function in late life and a greater incidence of Alzheimer's and dementia.

2000

Clarkson TB. Soy phytoestrogens: what will be their role in postmenopausal hormone replacement

therapy? *Menopause* 2000 Mar-Apr;7(2):71-5. Soy did not prevent bone loss when measured at autopsy in female monkeys who had had their reproductive organs removed.

2000

Vincent A and Fitzpatrick LA. Soy isoflavones: are they useful in menopause? *Mayo Clin Proc* 2000;75:1174-84. "Current data are insufficient to draw definitive conclusions regarding the use of isoflavones as an alternative to estrogen for hormone replacement in postmenopausal women."

2000

North K and Golding J. A maternal vegetarian diet in pregnancy is associated with hypospadias. The ALSPAC Study Team. Avon Longitudinal Study of Pregnancy and Childhood. *BJU Int* 2000 Jan;85(1):107-113. Vegetarian women are more likely consume more soy than the general population. Incidence of hypospadias was twice as great in vegetarian mothers than in nonvegetarian mothers. Hypospadias is a birth defect due to interrupted development of the penis.

2000

Nakamura Y and others. Determination of the levels of isoflavonoids in soybeans and soy-derived foods and estimation of isoflavonoids in the Japanese daily intake. *J AOAC Int* 2000;83:635-650. This survey found that average isoflavone consumption in Japan is about 28 mg per day.

2000

Bee G. Dietary Conjugated Linoleic Acids Alter Adipose Tissue and Milk Lipids of Pregnant and Lactating Sows. *J Nutr* 2000;130:2292-2298. Dietary mixtures for pigs, which are carefully formulated to promote reproduction and growth, allow approximately 1 percent of the ration as soy in a diet based on grains and supplements. (Pigs have a digestive system similar to humans.) The Central Soya Company, Inc. website gives a range of 2.5 percent to 17.5 percent soy in the diet of pigs, citing a number of anti-nutritional components that "have been documented to cause gastrointestinal disturbance, intestinal damage, increased disease susceptibility and reduced performance in pigs."

2000

Nagata C. Ecological study of the association between soy product intake and mortality from cancer and heart disease in Japan. *International Journal of Epidemiology* Oct 2000; 29(5):832-6. This study contained the following official conclusion: "The present study provides modest support for the preventive role of soy against stomach cancer and heart disease death." However, only the association with lower heart disease death is correct. What the study actually found was that "Soy protein intake was significantly correlated with stomach cancer mortality rate in men" and "soy product intake estimated as total amount as well as isoflavone and soy protein intake were significantly positively correlated with colorectal cancer mortality rates in both sexes." In other words, men who consumed lots of soy had more stomach cancer and men and women who consumed lots of soy had more colorectal cancer. These results are especially interesting as soy proponents often claim that Asians have lower rates of colorectal cancer because they eat more soy.

2001

Strom BL and others. Exposure to soy-based formula in infancy and endocrinological and reproductive outcomes in young adulthood. *JAMA* 2001 Nov 21;286(19):2402-3. Although reported in the media as a vindication of soy infant formula, the study actually found that soy-fed infants had more reproductive problems and more asthma as adults.

2001

Massey LK and others. Oxalate content of soybean seeds (*Glycine max*: Leguminosae), soyfoods,

and other edible legumes. *J Agric Food Chem* 2001 Sep;49(9):4262-6. Soy foods were found to be high in oxalates and likely to contribute to kidney stones.

2002

Khalil DA and others. Soy protein supplementation increases serum insulin-like growth factor-I in young and old men but does not affect markers of bone metabolism. *J Nutr* 2002 Sep;132(9):2605-8. Men consuming soy protein had higher levels of insulin-like growth factor-I (IGF-I) than those consuming milk protein. According to many other studies (but not stated in the report), high levels of IGF-I are also found in rBGH milk and have been implicated in causing hormonal cancers.

2003

Lack G and others. Factors associates with the development of peanut allergy in childhood. *N Engl J Med* 2003 Mar 13;348(11):977-85. The number of children with life-threatening peanut allergies has tripled during the last decade. This study suggests a link between consumption of soy-based formula and the development of peanut allergies. Scientists at the University of Bristol monitored 14,000 babies in the southwest of England. Among the 49 children who developed a peanut allergy, almost a quarter had consumed soy milk during their first two years. (Less than 5 percent of babies overall receive soy formula in the UK.) According to lead researcher Gideon Lack, "These results suggest that sensitization to peanut may possibly occur. . . as a result of soya exposure."