

**COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT**

**WORKING GROUP ON PHYTOESTROGENS**

**Submission from the Weston A. Price Foundation (received 04/07/00)**

**Background**

1. The Weston A. Price Foundation is a non-profit, tax-exempt charity founded in 1999 to disseminate the research of Dr. Weston Price on isolated non-industrialised people. On the basis of this research parameters of human health & nutritionally optimum diets have been developed. The submission includes an article, 'Tragedy and Hype' from The Third International Soy Symposium, Washington November 1999 & a leaflet 'Wise Traditions in Food, Farming and the Healing Arts'.

**Submission**

2. A letter from the President of the Foundation expresses concern over the proliferation of imitation foods based on soya, and in particular, the use of soya infant formula. The Foundation requests that steps be taken to curtail the use of soy in food.
3. The submitted article entitled 'Tragedy and Hope' (published in *Nexus Magazine* 2000) outlines the history of soya use in food, the growth of soya farming and food manufacture & the increase in sales of soya-based products.
4. The article describes how soya has become a major food product consumed by both humans and animals. Advances in processing methods have enabled production of soya-based foods such as oils, margarines and protein isolate. It is suggested the health claims that consumption of soya can help prevent heart disease, cancer, hot flushes and build strong bones, has lead to an increase in sales of soya-based products in the USA.
5. It is suggested that traditionally, raw or unfermented soya beans were not consumed as they contained large quantities of natural toxins such as trypsin inhibitors, hemagglutinins, phytic acid and goitrogens, which disrupt digestive enzymes, affect growth and inhibit uptake of essential vitamins and minerals. Although, the levels of these anutrients are significantly reduced during processing.
6. The article suggests that Eastern & Asian populations, use soy as an ingredient for cooking and hence only consume small quantities in their diet. Soya-based foods such as tofu, tempeh and soy sauce are often added to meat or fish dishes. However, vegetarians who consume tofu and bean curd as a substitute for meat and dairy products, risk severe protein and

mineral deficiencies. Fermentation techniques reduce the levels of nutrients present, the manufacturing process leads to the production of other toxic constituents such as nitrites & aluminium. The article cites a feeding study in schoolchildren (Torum B; 1979) in which a drink made of soya protein isolate and sugar was consumed as a substitute for meat and dairy products for a period of two weeks. Nitrate consumption and excretion, as well as children's weight was monitored. The study found growth was adequate suggesting soya protein isolate was a good substitute for meat and dairy products. However, the article points out that many of the children vomited after meals had stomach upsets, bouts of diarrhoea and suffered from general ill health. The Working Group has not considered this study on the nutritional content of soya.

7. The article reports that the original petition submitted to the FDA by Protein Technologies International (PTI) requesting health claims for isoflavones was based on results from a PTI sponsored study on soy's cholesterol-lowering properties (Anderson *et al*, 1995). It is suggested that the FDA rewrote PTI's petition, removing any reference to phytoestrogens and substituted a claim for soya protein & that this 'unprecedented move' was due to the increasing amount of evidence indicating that isoflavones were toxic. The article goes on to state that the FDA Health claim was approved despite numerous objections and protests from the scientific community (see also Submission PEG/2001/6). Although the FDA ruling does not allow any claims about cancer prevention on food packages, the industry does still promote these chemoprotective effects in their literature. However, soya contains estrogenic compounds and studies have indicated that estrogenic compounds have carcinogenic properties. These studies were included in Working Group papers PEG/2000/16 & PEG/2000/22.
8. The article discusses information suggesting a link between soya consumption and endocrine disruption, thyroid function, menopausal symptoms and osteoporosis. The work done by Mr Richard James (PEG/2001/4) and Dr M Fitzpatrick (PEG/2001/3) is cited. A number of reports are highlighted which indicate that isoflavones have biological effects at commonly encountered consumption levels. These levels are summarised below & were included in the beneficial effects paper (PEG/2000/16):
  - 30 grams of soy beans/day results in a significant increase in thyroid stimulating hormone (Ishizuki *et al*; 1991)
  - 25 grams of soy protein isolate, which is claimed to have cholesterol lowering effects contains approx. 50mg of isoflavones (Cassidy *et al*; 1994)
  - 45 mg isoflavones daily in pre-menopausal women results in significant biological effects (Cassidy *et al*; 1994).
  - 100 grams of soy protein, maximum dose recommended by Protein Technologies for lowering cholesterol contains 600mg isoflavones (Murphy; 1992)

9. The article expresses concern that soya fed infants may be exposed to high levels of estrogens from soya-based infant formulas & receive the estrogenic equivalent of at least five birth control pills per day (Irvine *et al*, 1995).
10. It is suggested that soya protein has not been granted GRAS status and is only approved for limited industrial use as a cardboard binder. The article reports that GRAS status was denied in 1979 as the FDA were concerned about the toxins formed during processing; in particular nitrites and lysinoalanine. Despite this, soy-based foods and ingredients are being widely used by the food industry.
11. The article concludes that there is growing suspicion on the benefits of a soy-rich diet given the emerging evidence that there may be a number of adverse effects on human health.
12. The accompanying leaflet 'Wise Traditions in Food, Farming and the Healing Arts' distributed by the Foundation contains general dietary guidelines for maintaining a healthy nutritionally balanced. The leaflet promotes the benefits of consuming 'a native diet' consisting of freshly farmed food high in nutritional value and warns against converting to a modern diet consisting of highly processed convenience foods low in nutritional value.

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Ms. Jennifer Lamothe, Administrative Secretary  
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Food Standards Agency  
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Dear Ms. Lamothe,

The enclosed article on modern soy products is submitted to the Phytoestrogen Research Programme as evidence for the dangers of soy consumption.

The Weston A. Price Foundation is concerned about the proliferation of imitation foods based on soy and, in particular, the use of soy infant formula. We strongly urge the Food Standards Agency to take the necessary steps to curtail its use in the food supply.

Sincerely yours,

Sally Fallon  
President

Enclosure: "Tragedy and Hype"

# Tragedy and Hype

## The Third International Soy Symposium

by Sally Fallon and Mary G. Enig, PhD

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"Each year, research on the health effects of soy and soybean components seems to increase exponentially. . . Furthermore, research is not just expanding in the primary areas under investigation, such as cancer, heart disease and osteoporosis; new findings suggest that soy has potential benefits that may be more extensive than previously thought." So writes Mark Messina, PhD, General Chairperson of the Third International Soy Symposium, held in Washington, DC in November of 1999.<sup>1</sup>

For four days, well-funded scientists who had gathered in Washington made presentations to an admiring press and to their sponsors—United Soybean Board, American Soybean Association, Monsanto, Protein Technologies International, Central Soya, Cargill Foods, Personal Products Company, SoyLife, Whitehall-Robins Healthcare and the soybean councils of Illinois, Indiana, Kentucky, Michigan, Minnesota, Nebraska, Ohio and South Dakota.

The symposium marked the apogee of a decade-long marketing campaign to gain consumer acceptance of tofu, soy milk, soy ice cream, soy cheese, soy sausage and soy derivatives, particularly soy isoflavones such as genistein and diadzen, the estrogen-like compounds found in soybeans. It coincided with an FDA decision, announced October 25, to allow a health claim for products "low in saturated fat and cholesterol" that contain 6.25 grams of soy protein per serving. Breakfast cereals, baked goods, convenience food, smoothie mixes and meat substitutes could now be sold with labels touting benefits to cardiovascular health as long as these products contained one heaping teaspoon of soy protein per 100-gram serving

### Marketing the Perfect Food

"Just imagine you could grow the perfect food. This food not only would provide affordable nutrition, but also would be delicious and easy to prepare in a variety of ways. It would be a healthful food, with no saturated fat. In fact, you would be growing a virtual fountain of youth on your back forty." The author is Dean Houghton, writing for *The Furrow*<sup>2</sup>, a magazine published in twelve languages by the John Deere tractor company. "This ideal food would help prevent, and perhaps reverse, some of the world's most dreaded diseases. You could grow this miracle crop in a variety of soils and climates. Its cultivation would build up, not deplete, the land. . .

this miracle food already exists. . . It's called soy."

Just imagine. Farmers have been imagining. . . and planting more soy. What was once a minor crop, listed in the 1913 USDA handbook not as a food but as an industrial product, now covers 72 million acres of American farmland. Much of this harvest will be used to feed chickens, turkeys, pigs, cows and salmon. Another large fraction will be squeezed to produce oil for margarine, shortenings and salad dressings.

Advances in technology make it possible to produce isolated soy protein from what was once considered a waste product—the defatted, high-protein soy chips—and then transform something that looks and smells terrible into products that can be consumed by human beings. Flavorings, preservatives, sweeteners, emulsifiers and synthetic nutrients have turned soy protein isolate, the food processors' ugly duckling, into a New Age Cinderella.

Lately, this new fairy-tale food has been marketed not so much for her beauty as for her virtues. Early on, products based on soy protein isolate were sold as extenders and meat substitutes, a strategy that failed to produce the requisite consumer demand. The industry changed its approach. "The quickest way to gain product acceptability in the less affluent society," said an industry spokesman, ". . . is to have the product consumed on its own merit in a more affluent society."<sup>3</sup> So soy is now sold to the upscale consumer, not as a cheap poverty food, but as a miracle substance that will prevent heart disease and cancer, whisk away hot flashes, build strong bones and keep us forever young. The competition—meat, milk, cheese, butter and eggs—has been duly demonized by the appropriate government agencies. Soy serves as meat and milk for a new generation of politically correct vegetarians.

Marketing costs money, especially when it needs to be bolstered with "research," but there's plenty of funds available. All soybean producers pay a mandatory assessment of one-half to one percent of the net market price of soybeans. The total—something like eighty million dollars annually<sup>4</sup>—supports United Soybean's program to "strengthen the position of soybeans in the market place and maintain and expand domestic and foreign markets for uses for soybeans and soybean products." State soybean councils from Maryland, Nebraska, Delaware, Arkansas, Virginia, North Dakota and Michigan provide

another two and one-half million dollars for “research.”<sup>5</sup> Private companies like Archer Daniels Midland also contribute their share. ADM spent \$4.7 million for advertising on “Meet the Press” and \$4.3 million on “Face the Nation” during the course of a year.<sup>6</sup> Public relations firms help convert research projects into newspaper articles and advertising copy; law firms lobby for favorable government regulations; IMF money funds soy processing plants in foreign countries; and free trade policies keep soybean abundance flowing to overseas destinations.

The push for more soy has been relentless and global in its reach. Soy protein is now found in most supermarket breads. It is being used to transform “the humble tortilla, Mexico’s corn-based staple food, into a protein-fortified ‘super-tortilla’ that would give a nutritional boost to the nearly 20 million Mexicans who live in extreme poverty.”<sup>7</sup> Advertising for a new soy-enriched loaf from Allied Bakeries in Britain targets menopausal women seeking relief from hot flashes. Sales are running at a quarter of a million loaves per week.<sup>8</sup>

The soy industry hired Norman Robert Associates, a public relations firm, to “get more soy products onto school menus.”<sup>9</sup> The USDA responded with a proposal to scrap the 30% limit for soy in school lunches. The NuMenu program would allow unlimited use of soy in student meals. With soy added to hamburgers, tacos and lasagna, dieticians can get the total fat content below 30% of calories, thereby conforming to government dictates. “With the soy-enhanced food items, students are receiving better servings of nutrients and less cholesterol and fat.”

Soy milk has posted the biggest gains, soaring from \$2 million in 1980 to \$300 million in the US last year.<sup>10</sup> Recent advances in processing have transformed the gray, thin, bitter, beany-tasting Asian beverage into a product that western consumers will accept—one that tastes like a milk shake, but without the guilt.

Processing miracles, good packaging, massive advertising and a marketing strategy that stresses the products’ possible health benefits account for increasing sales to all age groups. For example, reports that soy helps prevent prostate cancer have made soy milk acceptable to middle-aged men. “You don’t have to twist the arm of a 55- to 60-year-old guy to get him to try soy milk,” says Mark Messina. Michael Milken, former junk bond financier, has helped the industry shed its hippie image with well-publicized efforts to consume 40 grams of soy protein daily. Now it’s OK for stockbrokers to eat soy.

America today, tomorrow the world. Soy milk sales are rising in Canada, even though soy milk there costs twice as much as cow’s milk. Soybean milk processing plants are sprouting up in places like Kenya.<sup>11</sup> Even China, where soy really is a poverty food and whose

people want more meat, not tofu, has opted to build western-style soy factories, rather than develop western grasslands for grazing animals.<sup>12</sup>

### Cinderella’s Dark Side

The propaganda that has created the soy sales miracle is all the more remarkable because only a few decades ago the soybean was considered unfit to eat—even in Asia. 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.<sup>13</sup>

The soybean did not serve as a food until the discovery of fermentation techniques, sometime during the Chou Dynasty. The first soy foods were fermented products like *tempeh*, *natto*, *miso* and soy sauce. At a later date, possibly in the 2nd century B.C., Chinese scientists discovered that a puree of cooked soybeans could be precipitated with calcium sulfate or magnesium sulfate (plaster of Paris or Epsom salts) to make a smooth pale curd—tofu or bean curd. The use of fermented and precipitated soy products soon spread to other parts of the Orient, notably Japan and Indonesia.

The Chinese did not eat unfermented soybeans as they did other legumes such as lentils because the soybean contains large quantities of natural toxins or “antinutrients.” First among them are potent enzyme inhibitors that block the action of trypsin and other enzymes needed for protein digestion. These inhibitors are large, tightly-folded proteins that retain their configuration even when heated for long periods of time. They can produce serious gastric distress, reduced protein digestion and chronic deficiencies in amino acid uptake. In test animals, diets high in trypsin inhibitors cause enlargement and pathological conditions of the pancreas, including cancer.<sup>14</sup>

Soybeans also contain hemagglutinin, a clot promoting substance that causes red blood cells to clump together.

Trypsin inhibitors and hemagglutinin are growth inhibitors—weanling rats fed soy containing these antinutrients fail to grow normally. Growth depressant compounds are deactivated during the process of fermentation, so once the Chinese discovered how to ferment the soybean, they began to incorporate small amounts of soy foods into their diets. In precipitated products, en-

zyme inhibitors concentrate in the soaking liquid rather than in the curd. Thus in tofu and bean curd, growth depressants are reduced in quantity, but not completely eliminated.

Soy also contains goitrogens, substances that depress thyroid function, a fact that has been known for at least 50 years.

Soybeans are high in phytic acid, present in the bran or hulls of all seeds, a substance that can block the uptake of essential minerals—calcium, magnesium, copper, iron and especially zinc—in the intestinal tract. Although not a household word, phytic acid has been extensively studied—there are literally hundreds of articles on the effects of phytic acid in the scientific literature. Researchers are in general agreement that grain- and legume-based diets high in phytates contribute to widespread mineral deficiencies in Third World countries.<sup>15</sup> Analysis shows that calcium, magnesium, iron and zinc are present in the plant foods eaten in these areas, but the high phytate content of soy- and grain-based diets prevents their absorption.

The soybean has one of the highest phytate levels of any grain or legume that has been studied<sup>16</sup> and the phytates in soy are highly resistant to normal phytate-reducing techniques, such as long, slow cooking.<sup>17</sup> Only a long period of fermentation will significantly reduce the phytate content of soybeans. When precipitated soy products like tofu are consumed with meat, the mineral blocking effects of the phytates are reduced.<sup>18</sup> 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.

Vegetarians who consume tofu and bean curd as a substitute for meat and dairy products risk severe mineral deficiencies. The results of calcium, magnesium and iron deficiency are well known, those of zinc are less so. Zinc is called the intelligence mineral because it is needed for optimal development and functioning of the brain and nervous system. It plays a role in protein synthesis and collagen formation; it is involved in the blood sugar control mechanism and thus protects against diabetes; it is needed for a healthy reproductive system. Zinc is a key component in numerous vital enzymes and plays a role in the immune system. Phytates found in soy products interfere with zinc absorption more completely than with other minerals.<sup>19</sup> Zinc deficiency can cause a “spacy” feeling that some vegetarians may mistake for the “high” of spiritual enlightenment.

Milk-drinking is given as the reason second generation Japanese in America grow taller than their native ancestors. Some investigators postulate that the reduced phytate content of the American diet—whatever may be its other deficiencies—is the true explanation, pointing

out that both Asian and Western children who do not get enough meat and fish products to counteract the effects of a high phytate diet frequently suffer rickets, stunting and other growth problems.<sup>20</sup>

### Soy Protein Isolate

Soy processors have worked hard to get these antinutrients out of the finished product, particularly soy protein isolate (SPI), which is the key ingredient in most soy foods that imitate meat and dairy products, including baby formulas and some brands of soy milk. SPI is not something you can make in your own kitchen. Production takes place in industrial factories where a slurry of soy beans is first mixed with an alkaline solution to remove fiber, then precipitated and separated using an acid wash and finally neutralized in an alkaline solution. Acid washing in aluminum tanks leaches high levels of aluminum into the final product. The resultant curds are spray dried at high temperatures to produce a high protein powder. A final indignity to the original soy bean is high-temperature, high-pressure extrusion processing of soy protein isolate to produce textured vegetable protein (TVP).

Much of the trypsin inhibitor content can be removed through high-temperature processing, but not all. Trypsin inhibitor content of soy protein isolate can vary as much as fivefold.<sup>21</sup> (In rats, even low-level-trypsin-inhibitor SPI feeding results in reduced weight gain compared to controls.<sup>22</sup>) But high-temperature processing has the unfortunate side effect of so denaturing the other proteins in soy that they are rendered largely ineffective.<sup>23</sup> That’s why animals on soy feed need lysine supplements for normal growth.

Nitrites, which are potent carcinogens, are formed during spray drying, and a toxin called lysinoalanine is formed during alkaline processing.<sup>24</sup> Numerous artificial flavorings, particularly MSG, are added to soy protein isolate and textured vegetable protein products to mask their strong “beany” taste, and impart the flavor of meat.<sup>25</sup>

In feeding experiments, use of SPI increased requirements for vitamins E, K, D and B12 and created deficiency symptoms of calcium, magnesium, manganese, molybdenum, copper, iron and zinc.<sup>26</sup> Phytic acid remaining in these soy products greatly inhibits zinc and iron absorption; test animals fed SPI develop enlarged organs, particularly the pancreas and thyroid gland, and increased deposition of fatty acids in the liver.<sup>27</sup> Yet soy protein isolate and textured vegetable protein are used extensively in school lunch programs, commercial baked goods, diet beverages and fast food products. They are heavily promoted in Third World countries and form the basis of many food giveaway programs.

In spite of poor results in animal feeding trials, the soy industry has sponsored a number of studies designed to show that soy protein products can be used in *human* diets as a replacement for traditional foods. An example is "Nutritional Quality of Soy Bean Protein Isolates: Studies in Children of Preschool Age" sponsored by the Ralston Purina Company.<sup>28</sup> 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 in truly Orwellian fashion—the children were weighed naked every morning and all excrement and vomit were gathered up for analysis. The researchers found that the children retained nitrogen and that their growth was "adequate," so the experiment was declared a success. Whether the children were actually healthy on such a diet, or could remain so over a long period, is another matter. 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.

### The FDA Health Claim

The best marketing strategy for a product that is inherently unhealthy is, of course, a health claim. "The road to FDA approval was long and demanding," writes a soy apologist, "consisting of a detailed review of human clinical data collected from more than 40 scientific studies conducted over the last 20 years. Soy protein was found to be one of the rare foods that had sufficient scientific evidence not only to qualify for an FDA health claim proposal but to ultimately pass the rigorous approval process."<sup>29</sup>

The "long and demanding" road to FDA approval actually took a few unexpected turns. 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 regu-

lations. 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 FDA had also received, early in 1998, the final British government report on phytoestrogens, which failed to find much evidence of benefit and warned against potential adverse effects.<sup>30</sup>

Even with the change to soy protein isolate, FDA bureaucrats engaged in the "rigorous approval process" were forced to deal nimbly with concerns about mineral blocking effects, enzyme inhibitors, goitrogenicity, endocrine disruption, reproductive problems and increased allergic reactions from consumption of soy products.<sup>31</sup> One of the strongest letters of protest came from Dr. Dan Sheehan and Dr. Daniel Doerge, government researchers at the National Center for Toxicological Research.<sup>32</sup> Their pleas for warning labels were dismissed as unwarranted.

"Sufficient scientific evidence" of soy's cholesterol-lowering properties is drawn largely from a 1995 meta-analysis by Dr. James Anderson, sponsored by Protein Technologies International and published in the *New England Journal of Medicine*.<sup>33</sup> A meta-analysis is a review and summary of the results of many clinical studies on the same subject. Use of meta-analyses to draw general conclusions has come under sharp criticism by members of the scientific community. "Researchers substituting meta-analysis for more rigorous trials risk are making faulty assumptions and indulging in creative accounting," says Sir John Scott, President of the Royal Society of New Zealand. "Like is not being lumped with like. Little lumps and big lumps of data are being gathered together by various groups."<sup>34</sup> There is the added temptation for researchers, particularly researchers funded by a company like Protein Technologies International, to leave out studies that would prevent the desired conclusions. Dr. Anderson 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 seven to twenty 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 us, giving up steak and eating veggieburgers instead will not bring blood cholesterol levels down. The health claim that the FDA approved "after detailed review of human clinical data" fails to inform the consumer about these important details.

Research that ties soy to positive effects on cholesterol levels is "incredibly immature," said Ronald M.

Krauss, MD, head of the Molecular Medical Research Program and Lawrence Berkeley National Laboratory.<sup>35</sup> He might have added that studies in which cholesterol levels were lowered either through diet or drugs have consistently resulted in a greater number of deaths in the treatment groups than in controls, deaths from stroke, cancer, intestinal disorders, accidents and suicide.<sup>36</sup> Cholesterol lowering measures in the US have fueled a sixty-billion-dollar-a-year cholesterol-lowering industry but have not saved us from the ravages of heart disease.

### Soy and Cancer

The new FDA ruling does not allow any claims about cancer prevention on food packages, but that has not restrained the industry and its marketeers from making them in their promotional literature. "In addition to protecting the heart," says a vitamin company brochure, "soy has demonstrated powerful anticancer benefits. . . the Japanese, who eat 30 times as much soy as North Americans, have a lower incidence of cancers of the breast, uterus and prostate."<sup>37</sup>

Indeed they do. But the Japanese, and Asians in general, have much higher rates of other types of cancer, particularly cancer of the esophagus, stomach, pancreas and liver.<sup>38</sup> Asians throughout the world also have high rates of thyroid cancer.<sup>39</sup> The logic that links low rates of reproductive cancers to soy consumption requires attribution of high rates of thyroid and digestive cancers to the same foods, particularly as soy causes these types of cancers in laboratory rats.

Just how much soy do Asians eat? A 1998 survey found that the average daily amount of soy consumed in Japan was about 8 grams for men and 7 for women—less than two teaspoons.<sup>40</sup> The famous Cornell China Study, conducted by Colin T. Campbell, found that legume consumption in China varied from 0 to 58 grams per day, with a mean of about 12.<sup>41</sup> Assuming that two-thirds of legume consumption is soy, then the maximum consumption is about 40 grams or less than 3 tablespoons per day, with an average consumption of about 9 grams, less than two teaspoons. A survey conducted in the 1930s found that soy foods accounted for only 1.5% of calories in the Chinese diet, compared with 65% of calories for pork.<sup>42</sup> (Asians traditionally cooked in lard, not vegetable oil!)

Traditionally fermented soy products make a delicious, natural seasoning that may supply important nutritional factors in the Asian diet. But except in times of famine, Asians consume soy products only in small amounts as condiments, and not as a replacement for animal foods—with one exception. Celibate monks living in monasteries and leading a vegetarian life style find soy foods quite helpful because they dampen libido.

It was a 1994 meta-analysis by Mark Messina, published in *Nutrition and Cancer*, that fueled speculation on soy's anticarcinogenic properties.<sup>43</sup> Messina noted that in 26 animal studies, 65% reported protective effects from soy. He conveniently neglected to include at least one study in which soy feeding caused pancreatic cancer, the 1985 study by Rackis.<sup>44</sup> In the human studies he 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," he concluded. Yet in his subsequent book, *The Simple Soybean and Your Health*, Messina makes just such a claim, recommending 1 cup or 230 grams of soy products per day in his "optimal" diet as a way to prevent cancer.

Thousands of women are now consuming soy in the belief that it protects them against breast cancer. Yet in 1996 researchers found that women consuming soy protein isolate had an increased incidence of epithelial hyperplasia, a condition that presages malignancies.<sup>45</sup> A year later, dietary genistein was found to stimulate breast cells to enter the cell cycle, a discovery that led the study authors to conclude that women should not consume soy products to prevent breast cancer.<sup>46</sup>

### Phytoestrogens—Panacea or Poison?

The male species of tropical birds carries the drab plumage of the female at birth and "colors up" at maturity, somewhere between nine and 24 months. In 1991, Richard and Valerie James, bird breeders in Whangerei, New Zealand, purchased a new kind of feed for their birds, one based largely on soy protein.<sup>47</sup> When soy-based feed was used, their birds "colored up" after just a few months. In fact, one bird food manufacturer claimed that this early development was an advantage imparted by the feed. A 1992 ad for Roudybush feed formula showed a picture of the male crimson rosella, an Australian parrot that acquires beautiful red plumage at 18 to 24 months, already brightly colored at 11 weeks old.

Unfortunately, in the ensuing years, there was decreased fertility in the birds with precocious maturation, deformed, stunted and still-born babies, and premature deaths, especially among females, with the result that the total population in the aviaries went into steady decline. The birds suffered beak and bone deformities, goitre, immune system disorders and pathological aggressive behavior. Autopsy revealed digestive organs in a state of disintegration. The list of problems corresponded with many of the problems the Jameses had encountered in their two children, who had been fed soy-based infant formula.

Startled, aghast, angry. . . the Jameses hired toxicologists.

ologist Mike Fitzpatrick to investigate further. Dr. Fitzpatrick's literature review uncovered evidence that soy consumption has been linked to numerous disorders, including infertility, increased cancer and infantile leukemia; and, in studies dating back to the 1950s<sup>48</sup>, that genistein in soy causes endocrine disruption in animals. Dr. Fitzpatrick also analyzed the bird feed and found that it contained high levels of phytoestrogens, especially genistein. When the Jameses discontinued using soy-based feed, the flock gradually returned to normal breeding habits and behavior.

The Jameses embarked on a private crusade to warn the public and government officials about toxins in soy foods, particularly the endocrine disrupting isoflavones (genistein and diadzen.) Protein Technologies International received their material in 1994.

In 1991, Japanese researchers reported that consumption of as little as 30 grams or 2 tablespoons of soybeans per day for only one month resulted in a significant increase in thyroid stimulating hormone.<sup>49</sup> Diffuse goitre and hypothyroidism appeared in some of the subjects and many complained of constipation, fatigue and lethargy, even though their intake of iodine was adequate. In 1997, researchers from the FDA's National Center for Toxicological Research made the embarrassing discovery that the goitrogenic components of soy were the very same isoflavones.<sup>50</sup>

Twenty-five grams of soy protein isolate, the minimum amount PTI claimed to have cholesterol-lowering effects, contains at least 50 mg of isoflavones. It took only 45 mg daily of isoflavones in premenopausal women to exert significant biological effects including reduction in hormones needed for adequate thyroid function. These effects lingered for three months after soy consumption was discontinued.<sup>51</sup>

One hundred grams of soy protein, the maximum suggested cholesterol-lowering dose (and the amount recommended by Protein Technologies International), can contain almost 600 mg of isoflavones,<sup>52</sup> an amount that is undeniably toxic. In 1992, the Swiss health service estimated that 100 grams of soy protein provided the estrogenic equivalent of the pill.<sup>53</sup>

*In vitro* studies suggest that isoflavones inhibit synthesis of estradiol and other steroid hormones.<sup>54</sup> Reproductive problems, infertility, thyroid disease and liver disease due to dietary intake of isoflavones have been observed for several species of animals including mice, cheetah, quail, pigs, rats, sturgeon and sheep.<sup>55</sup>

It is the isoflavones in soy that are said to have a favorable effect on postmenopausal symptoms, including hot flashes and protection from osteoporosis. 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.<sup>56</sup>

The claim that soy prevents osteoporosis is extraordinary, given that soy foods block calcium and cause vitamin D deficiencies. If Asians indeed have lower rates of osteoporosis than Westerners, it is because their diet provides plenty of vitamin D from shrimp, lard and sea food; and plenty of calcium from bone broths. The reason that Westerners have such high rates of osteoporosis is because they have substituted soy oil for butter, which is a traditional source of vitamin D and other fat-soluble activators needed for calcium absorption.

### **Birth Control Pills for Babies**

But it was the isoflavones in infant formula that gave the Jameses the most cause for concern. In 1998, investigators reported that the daily exposure of infants to isoflavones in soy infant formula is six to eleven times higher on a body weight basis than the dose that has hormonal effects in adults consuming soy foods. Circulating concentrations of isoflavones in infants fed soy-based formula were 13,000 to 22,000 times higher than plasma estradiol concentrations in infants on cows milk formula.<sup>57</sup>

Approximately 25 % of bottle-fed children in the US receive soy-based formula—a much higher percentage than in other parts of the Western world. Fitzpatrick estimated that an infant exclusively fed soy formula receives the estrogenic equivalent (based on body weight) of at least five birth control pills per day.<sup>58</sup> By contrast, almost no phytoestrogens have been detected in dairy-based infant formula or in human milk, even when the mother consumes soy products.

Scientists have known for years that soy-based formula can cause thyroid problems in babies. But what are the effects of soy products on the hormonal development of the infant, both male and female?

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.)<sup>59</sup> It goes without saying that future patterns of sexual orientation may also be influenced by the early hormonal environment. 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.<sup>60</sup>

Learning disabilities and behavioral problems, especially in male children, have reached epidemic proportions. Soy infant feeding—which began in earnest in the early 1970s—cannot be ignored as a probable cause for these tragic developments.

As for girls, an alarming number are entering puberty much earlier than normal, according to a recent study reported in the journal *Pediatrics*.<sup>61</sup> 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. New data indicate that environmental estrogens such as PCBs and DDE (a breakdown product of DDT) may cause early sexual development in girls.<sup>62</sup> In the 1986 Puerto Rico Premature Thelarche study, the most significant dietary association with premature sexual development was not chicken—as reported in the press—but soy infant formula.<sup>63</sup> The Woman, Infants and Children (WIC) program, which supplies free infant formula to welfare mothers, stresses soy formula for African Americans because they are supposedly allergic to milk.

The consequences of truncated childhood are tragic. Young girls with mature bodies must cope with feelings and urges that most children are not well-equipped to handle. And early maturation in girls is frequently a harbinger for problems with the reproductive system later in life including failure to menstruate, infertility and breast cancer.

Parents who have contacted the Jameses recount other problems associated with children of both sexes who were fed soy-based formula including extreme emotional behavior, asthma, immune system problems, pituitary insufficiency, thyroid disorders and irritable bowel syndrome—the same endocrine and digestive havoc that afflicted the Jameses' parrots.

#### **Dissent in the Ranks**

Organizers of the Third International Soy Symposium would be hard pressed to call the conference an unqualified success. On the second day of the conference the London-based Food Commission and the Weston A Price Foundation of Washington, DC held a joint press conference in the same hotel to present concerns about soy infant formula. Industry representatives sat stony faced through the recitation of potential dangers and a plea from concerned scientists and parents to pull soy-based infant formula from the market. Under pressure from the Jameses, the New Zealand government had issued a health warning about soy infant formula in 1998. It was time for the American government to do the same.

On the last day of the conference, presentations on new findings related to toxicity sent a well-oxygenated chill through the industry's giddy helium hype. Dr. Lon White reported on a study of Japanese Americans living in Hawaii. It showed a significant statistical relationship between two or more servings of tofu per week and "accelerated brain aging."<sup>64</sup> Those participants who consumed tofu in mid life had lower cognitive function in late life and a greater incidence of Alzheimers and dementia. "What's more," said Dr. White, "those who ate a lot of tofu, by the time they were 75 or 80, looked five years older."<sup>65</sup> White and his colleagues blamed the negative effects on isoflavones, a finding that supports an earlier study in which post-menopausal women with higher levels of circulating estrogen experienced greater cognitive decline.<sup>66</sup>

Scientists Daniel Sheehan and Daniel Doerge from the National Center for Toxicological Research ruined PTI's day by presenting findings from rat feeding studies indicating that genistein in soy foods causes irreversible damage to enzymes that synthesize thyroid hormones.<sup>67</sup> "The association between soybean consumption and goiter in animals and humans has a long history," wrote Dr. Doerge. "Current evidence for the beneficial effects of soy requires a full understanding of potential adverse effects as well."

Dr. Claude Hughes reported that rats born to mothers fed genistein had decreased birth weights compared to controls and onset of puberty occurred earlier in male offspring.<sup>68</sup> His research suggested that the effects observed in rats "... will be at least somewhat predictive of what occurs in humans. There is no reason to assume that there will be gross malformations of fetuses but there may be subtle changes, such as neurobehavioral attributes, immune function and sex hormone levels." The results, he said "... could be nothing or could be something of great concern... if mom is eating something that can act like sex hormones, it is logical to wonder if that could change the baby's development."<sup>69</sup>

A study of babies born to vegetarian mothers, published in January 2000, indicated just what those changes in baby's development might be. Mothers who ate a vegetarian diet during pregnancy had a fivefold greater risk of delivering a boy with hypospadias, a birth defect of the penis.<sup>70</sup> The authors of the study suggested that the cause was greater exposure to phytoestrogens in soy foods popular with vegetarians. Problems with female offspring of vegetarian mothers are more likely to show up later in life. While soy's estrogenic effect is less than that of diethylstilbestrol (DES), the dose is likely to be higher because it's consumed as a food, not taken as a drug. Daughters of women who took DES during pregnancy suffered from infertility and cancer when they

reached their twenties.

### GRAS Status

Lurking in the background of industry hoop-la for soy is the nagging question of whether it's even legal to add soy protein isolate to food. All food additives not in common use prior to 1958, including casein protein from milk, must have GRAS (Generally Recognized As Safe) status. 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.<sup>71</sup>

The scientific literature up to 1974 recognized many antinutrients in factory-made soy protein, including trypsin inhibitors, phytic acid, and genistein. But the FDA literature review dismissed discussion of adverse impacts with the statement that it was important for "adequate processing" to remove them. Genistein could be removed with an alcohol wash but it was an expensive procedure that processors avoided. Later studies determined that trypsin inhibitor content could be removed only with long periods of heat and pressure, but the FDA has imposed no requirements for manufacturers to do so.

The FDA was more concerned about toxins formed during processing, specifically nitrites and lysinoalanine.<sup>72</sup> 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.

This means that soy protein must be subject to premarket approval procedures each time manufacturers intend to use it as a food or add it to a food. Soy protein was introduced into infant formula in the early 1960s. It was a new product with no history of any use at all. As soy protein did not have GRAS status, premarket approval was required. This was not and still has not been granted. The key ingredient of soy infant formula is not recognized as safe.

### The Next Asbestos?

"Against the backdrop of widespread praise. . . there is growing suspicion that soy—despite its undisputed benefits—may pose some health hazards," writes Marian Burros, a leading food writer for the New York Times. More than any other writer, Ms. Burros' endorsement of a lowfat, largely vegetarian diet has herded Americans into supermarket aisles featuring soy foods. Yet her January 26, 2000 article "Doubts Cloud Rosy News on Soy" contains the following alarming statement: "Not one of the 18 scientists interviewed for this column was willing to say that taking isoflavones was risk free." Ms. Burros did not enumerate the risks, nor did she mention that the recommended 25 daily grams of soy protein contain enough isoflavones to cause problems in sensitive individuals, but it was evident that the industry had recognized the need to cover itself.

Because the industry is extremely exposed. Contingency lawyers will soon discover that the number of potential plaintiffs can be counted in the millions and the pockets are very, very deep. Juries will hear something like the following: "The industry has known for years that soy contains many toxins. At first they told the public that the toxins were removed by processing. When it became apparent that processing could not get rid of them, they claimed that these substances were beneficial. Your government granted a health claim to a substance that is poisonous and the industry lied to the public to sell more soy."

The "industry" includes merchants, manufacturers, scientists, publicists, bureaucrats, former bond financiers, food writers, vitamin companies and retail stores. Farmers will probably escape because they were duped like the rest of us. But they need to find something else to grow before the soy bubble bursts and the market collapses—grass-fed livestock, designer vegetables. . . or hemp to make paper for thousands and thousands of legal briefs.

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