

III: CONCLUSION

In Section I of this petition, we noted that soy protein isolate has not earned GRAS status and for this reason cannot properly be the subject of a health claim. In Section II, we showed that the totality of publicly available scientific evidence does not support the premise that soy protein prevents heart disease or even that it lowers total or LDL-cholesterol levels. Furthermore, many respected scientists have warned about studies showing that soy protein can contribute to the development of heart disease.

In 1998, scientists from the FDA's Laboratory of Toxicological Research in Jefferson, Arkansas, voiced opposition to the soy protein/heart health claim. Daniel Sheehan, PhD, Director of the Estrogen Base Program, Division of Genetic and Reproductive Technology, and Daniel Doerge, PhD, Division of Biochemical Toxicology, wrote a seven-page letter to the FDA, excerpted below:

We oppose this health claim because there is abundant evidence that some of the isoflavones found in soy, including genistein and equol, a metabolite of daidzein, demonstrate toxicity in estrogen sensitive tissues and in the thyroid. This is true for a number of species, including humans. Additionally, the adverse effects in humans occur in several tissues and, apparently, by several distinct mechanisms. . . .

While isoflavones may have beneficial effects at some ages or circumstances, this cannot be assumed to be true at all ages. Isoflavones are like other estrogens in that they are two-edged swords, conferring both benefits and risks. The health labeling of soy protein isolate for foods needs to be considered just as would the addition of any estrogen or goitrogen to foods, which are bad ideas. . . .

Estrogenic and goitrogenic drugs are regulated by FDA, and are taken under a physician's care. Patients are informed of risks, and are monitored by their physicians for evidence of toxicity. There are no similar safeguards in place for foods, so the public will be put at potential risk from soy isoflavones in soy protein isolate without adequate warning and information.

Irvin E. Liener, PhD, professor emeritus at the University of Minnesota and a leading expert and textbook writer on protease inhibitors and other antinutritional factors in soybeans, also wrote the FDA in 1998 to express his specific concerns about trypsin inhibitors and the FDA's failure to have thoroughly examined USDA and other significant research on this subject. His letter concluded:

Trypsin inhibitors do in fact pose a potential risk to humans when soy protein is incorporated into the diet.

Since 1999, other top US government scientists have published warnings about the dangers of soy protein and its phytoestrogenic constituents. We would particularly like to remind the FDA of work carried out at the molecular toxicology laboratory at the National Institute of Environmental Health Sciences (NIEHS) in Triangle Park, North Carolina. Retha Newbold's team at NIEHS has spent more than 25 years investigating endocrine disruption caused by the soy estrogen genistein, DES and other environmental estrogens and reported on those findings at symposia and in prestigious peer-reviewed journals. After publication of one such study in the January 2006 issue of *Biology of Reproduction*, NIEHS director Dr. David Schwartz commented, "Although we are not entirely certain about how these animal studies on genistein translate to the human population, there is some reason to be cautious."

The findings of scientists at both the FDA's National Laboratory for Toxicological Research and National Institute of Environmental Health Sciences -- which clearly demonstrate the risks of soy protein and its phytoestrogenic constituents genistein and daidzein -- provide a mandate to the FDA to rescind the heart health claim for soy protein.

Finally, we would like to draw the FDA's attention to the health advisories issued by three foreign governments about these and other safety issues surrounding the consumption of soy protein.

In 2005, the Israeli Health Ministry warned its citizens that babies should not receive soy formula, that children age 18 and under should consume soy foods or soy milk no more than once per day to a maximum of three times per week and that adults should exercise caution because of adverse effects on fertility and increased breast cancer risk. The Israeli Ministry based its advice upon the conclusions reached by a 13-member committee of nutritionists, oncologists, toxicologists, pediatricians and other specialists who spent more than a year examining the evidence. The committee concluded that the estrogen-like plant hormones in soy can cause adverse effects on the human body, including cancer promotion and reproductive problems. They strongly urged that consumption of soy foods be minimized until absolutely safety has been proven.

In 2006, the French Food Agency (AFSSA) announced tough new regulations that will soon require manufacturers to improve the safety of soy infant formula and to put warning labels on packages of soy foods and soy milk. The new regulations followed an extensive investigation

culminating in the requirement that manufacturers remove the estrogenic isoflavones from soy infant formula down to 1 ppm and to include warning labels on packages of soy foods and soy milk that will alert consumers of the risks for children under three, children with hypothyroidism and women who have been diagnosed with or have a family history of breast cancer.

In 2007, the German Federal Institute for Risk Assessment warned that babies should not be given soy infant formula without clear, concrete medical reasons and that adults should be wary of excess soy food and soy supplement consumption because soy isoflavones offer no proven health benefits and may pose health risks. Professor Dr. Andreas Hensel, President of the Federal Institute for Risk Assessment (BfR), expressed concerns about the marketing of soy foods and isoflavone supplements to menopausal women and doubts about the claimed advantages of the supplements for heart, bone and breast health.

In conclusion, the precautionary principle mandates that FDA rescind the health claim for soy protein, especially in the light of the Israeli, French and German governments' warning advisories. The FDA, in its mandated role as America's foremost consumer protection agency, has a duty to the American public to amend the Final Rule to disallow the heart disease health claim for soy protein and to require all soy food manufacturers currently using it to cease and desist.

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