Soy Food and Health

Information for Health Care Providers

Medifast®

Medifast is a company dedicated to the achievement of optimal health: striving to provide innovative products, scientifically based recommendations, and clinically proven programs for safe, effective weight loss and the development of lifelong healthy habits. With over 70 different Medifast Meals to choose from, our product line is designed to help meet a wide range of dietary needs and individual preferences.

Many Medifast Meals contain soy protein. Soy protein is recognized by the United States Department of Agriculture (USDA) as equal in quality to animal protein and is considered to be a "complete" protein, as it provides all nine essential amino acids in amounts sufficient to help meet the body's requirements. However, unlike many sources of animal protein, soy is low in saturated fat and naturally cholesterol-free.[1]

In the last 20 years, there has been an impressive amount of research conducted on the health effects of soy. Research shows that soy is a great source of high-quality, low-fat plant protein that may help lower the risk of heart disease,[2] osteoporosis,[3,4] and certain forms of cancer.[5,6] Despite these supportive findings, confusion about the health effects of soy foods and soy isoflavones continues.

At the core of our business is you, our consumer. Medifast believes that an informed consumer is a good consumer, which is why we feel it is our duty to provide you with recent clinical research regarding soy and what it can mean for you, your meal planning, and your health.

The Story of Soy

Soy foods first appeared in China more than 1,000 years ago. Since then, they have become more familiar to consumers worldwide and have become a popular choice of many health-conscious Westerners, valued for their versatility, taste, nutritional content, environmental advantages, and health benefits.

A Truly "GREEN" Bean

Today, European and American governmental agencies recommend that individuals focus on eating more plant-based foods as an eco-friendly way to help decrease the risk of chronic diseases and control weight.[7] *Soy foods fit well within these recommendations:* Compared to animal protein, soy leaves a much smaller carbon footprint, needing less land and natural resources to grow. Soy provides the same high-quality protein as meat, milk, and eggs, often with less saturated fat and "bad" cholesterol. When chosen in place of animal-based proteins, soy offers other health advantages as well.[8,9,10,11]

The Uniqueness of Soybeans: Isoflavones

Soybeans are unique because they are the only commonly eaten food that contains a group of compounds called isoflavones (ahy-soh-FLEY-vohnz or ahy-soh-FLĀ-vōnz). *Evidence suggests that isoflavones are at the heart of many of the proposed benefits of soy foods.*

There are three different isoflavones found in soybeans: genistein, daidzein, and glycitein. Isoflavones are part of a larger group of compounds called phytoestrogens, or plant estrogens, so named because they have a similar chemical structure (though are not the same) as the hormone estrogen.

Providing a more accurate description of their true behavior, isoflavones are also referred to as "SERMS," or selective estrogen receptor modulators. SERMS are compounds with only "selective" estrogenic effects: In some tissues, isoflavones may mimic the behavior of estrogen; in others, isoflavones may have the opposite effect or no effect at all. They can also have their own unique biological activity that is completely unrelated to estrogen.

Misconceptions about isoflavones

The safety concerns about isoflavones come almost exclusively from studies done in rodents. Rodents and

humans differ in many ways, including the way each are able to metabolize isoflavones; therefore, results from most rodent studies provide only a limited amount of relevant information for humans.[12] It is important to note that *results from human studies support the safety and beneficial effects of isoflavones.*

In summary

- Evidence suggests that many of the proposed benefits of soy foods are due to their isoflavone content.
- Isoflavones are a part of a larger group of compounds called phytoestrogens, or plant estrogens, but they are not the same as the hormone estrogen.
- Results from human studies are supportive of the safety and beneficial effects of isoflavones.

Heart Health

Cardiovascular disease (CVD) is the leading cause of death in the United States, killing an average of one American every 37 seconds.[13] Aside from smoking, many of the risk factors for cardiovascular disease, including elevated body weight (being overweight or obese), high cholesterol, and high blood pressure,[14] can often be mitigated or completely eliminated simply with improvements in lifestyle and dietary choices.

Recommendations from the American Heart Association (AHA) to decrease the risk of cardiovascular disease include:

- Reach and maintain a healthy body weight.
- Limit intake of saturated fat by choosing lean meats and plant proteins like soy.
- Increase fiber intake.
- Incorporate omega-3 essential fatty acids, like those from salmon and other types of fish.[15]

Soy for heart health

- Soy foods are a great alternative to meat.
- Soy protein is recognized by the USDA as equal in quality to animal protein. However, unlike many sources of animal protein, soy is low in saturated fat and naturally cholesterol-free.[1]
- Soy protein works to directly lower blood cholesterol levels.
- Studies show that, on average, soy protein lowers low density lipoprotein (LDL, or "bad") cholesterol by 4%.
  - While this may not seem dramatic, over a period of many years this moderate benefit can have a significant impact. Each 1% decrease in LDL is thought to lower the risk of heart disease by 2% to 3%.[16,17]

Soy's beneficial effect on cholesterol was formally recognized by the United States Food and Drug Administration (FDA) in 1999 when it granted approval for a health claim for soy protein and risk of coronary heart disease.[18] This claim states that:

- 25 grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may help to reduce the risk of heart disease.
- To qualify for this claim, a food must contain at least 6.25 grams of soy protein per serving and must be below the specified guidelines for total and saturated fat, cholesterol, and sodium per serving.

The Medifast Connection: Many Medifast Meals meet the requirements to carry the FDA's soy protein and risk of coronary heart disease claim.

A little something extra: The proposed role of soy isoflavones in heart protection

Among Asian populations, those who eat more soy have up to a 70% lower risk of heart disease and stroke compared to those who eat little soy.[19,20,21] While the cholesterol-lowering ability of soy protein is important, it can't fully explain these huge reductions in heart disease risk. Studies suggest that soy foods offer protection against heart disease independent of their effects on cholesterol. Many researchers believe the isoflavones in soy are one big reason why soy foods are so protective against heart disease, and

research has shown that isoflavones may directly improve arterial health.[22,23]

In summary

- Soy foods are high in protein, versatile, and often contain less saturated fat and cholesterol than protein from animal sources.
- Soy protein lowers LDL, or "bad," cholesterol by an average of 4%.
- Soy isoflavones may help reduce the risk of heart disease by improving arterial health.
- Many Medifast Meals meet the criteria to carry the FDA's soy protein and risk of coronary heart disease claim.

Bone Health

According to the National Institutes of Health (NIH) Osteoporosis and Related Bone Disease National Resource Center, 10 million people have osteoporosis and another 34 million have low bone mass, placing them at risk for this disease. Although osteoporosis and concerns over bone health have historically been thought of as a "woman's disease," approximately one in three men are at risk of developing osteoporosis.[24] For women, bone loss is fastest in the first few years after menopause; bones may lose thickness and density, which can dramatically increase the risk of fractures.[25]

General recommendations for promoting bone health include:

- Smoking cessation
- An active lifestyle, including weight-bearing exercise as deemed appropriate by your physician
- Adequate intake of calcium and vitamin D, among others

The Medifast Connection: Medifast Meals not only provide high-quality protein, which is good for building strong, healthy bones,[26] each Medifast Meal is also fortified with vitamins and minerals, including calcium and vitamin D.

Soy for bone health

Long-term population-based studies suggest that soy isoflavones may play a beneficial role in bone health by reducing bone loss in older women.[27] Studies among Asian populations found that women who eat the highest amount of soy were approximately one-third less likely to have a fracture when compared to women who eat soy foods infrequently.[3] However, more research is needed before definitive conclusions can be made about the skeletal benefits of soy isoflavones.

In summary

- Bone health is a concern for both men and women.
- Some studies suggest that isoflavones may play a beneficial role in bone health by reducing bone loss in older women.
- All Medifast Meals contain high-quality protein and are fortified with calcium and vitamin D.

Soy and Cancer Prevention

For decades, scientists have been investigating the role soy may play in decreasing cancer risk. While most studies have concentrated on breast and prostate cancer, evidence exists suggesting that the benefits of soy foods are not limited to just these two types of cancer.

Cancer and weight

According to the American Cancer Society (ACS), obesity is a well-established risk factor for some of the most common cancers. Increased body weight has been associated with increased risk for cancer of the breast, colon, rectum, prostate, and esophagus, among others.[28,29,30,31,32] In addition, research suggests that being overweight also increases the risk of recurrence and reduces the likelihood of survival for many cancers, including breast cancer.[30,33,34,35,36,37,38]

While not yet fully understood, it is believed that what we eat may be a factor in approximately one-third of all cancers.[39] Soy is one dietary factor thought to

help reduce the risk of certain cancers, and may even help improve outcomes in those diagnosed with this disease. Evidence suggests that soy's isoflavones may be behind these proposed effects.[40]

Breast Cancer

Breast cancer is the most common cancer among women in the United States and is the second leading cause of cancer death after lung cancer.[41,42] However, in many other countries outside the United States, breast cancer rates are very low. In fact, the historically low rate of breast cancer in Japan, where soy foods are part of traditional meal plans, is what helped spark researchers' curiosity about whether soy may play a protective role against this particular cancer.[40]

Soy's proposed benefits for breast cancer

In Japan, deaths from breast cancer are only about one-third of those in the United States. Many cultural and dietary differences exist between Asian and Western populations; however, over the last 40 years, as Japanese culture has become more "Westernized," the number of deaths from breast cancer has increased dramatically.[44] Higher rates of cancer are also seen in Japanese-Americans compared to native Japanese[45] and women who migrate from Japan to the United States.[46]

What could be driving these changes in the rates of breast cancer development and death? An analysis by researchers at the University of Southern California suggests that soy may have a protective role: Among Asian women, those who eat the most soy were about 30% less likely to develop breast cancer compared to those who eat little soy.[5]

The protective effects of soy are especially compelling when eaten early in life. Studies show that eating a modest amount of soy as a child and/or teen can help reduce adult breast cancer risk between 28% and 60%.[47,48,49,50] Less certainty exists about whether these protective effects are extended to those who begin eating soy foods in their adult years.

Women with a history of breast cancer can safely eat and may even benefit from choosing soy foods. Recent research, using data from the Women's Healthy Eating and Living (WHEL) study, found that women who eat the highest level of isoflavones (>16.3 mg/day) had a non-significant 54% reduction in risk of death compared to those eating the least.[51] Furthermore, a study published in the *Journal of the American Medical Association* of over 5,000 Chinese breast cancer survivors found that those who eat the highest amount of soy protein (about 2 ½ servings/day) were about 30% less likely to suffer a recurrence or die of their disease. The beneficial effects of soy protein for reducing recurrence and death from breast cancer were seen in both estrogen receptor-positive and estrogen receptor-negative breast cancer and in both users and non-users of the breast cancer drug tamoxifen. A 2009 study of almost 2,000 United States breast cancer survivors reported similar findings.[52,53] Evidence continues to accumulate supporting the safety and possible benefit of choosing soy foods for breast cancer survivors—and is especially important, as this has been an area of much debate.[54]

Although it's probably too soon for physicians to recommend soy foods to breast cancer patients as a way to improve their prognosis, evidence indicates that soy foods can be safely eaten by women with a history of breast cancer.[55] This position is supported by the ACS, which states that moderate amounts of soy foods are safe for breast cancer survivors.[56]

In summary

- Historically low rates of certain cancer types in countries where soy foods are commonly consumed led investigators to study soy's potential cancer benefits.
- Research has shown that Asian women who consume the most soy are about 30% less likely to develop breast cancer than those eating relatively little soy.
- The protective effects of soy foods are most apparent when soy is eaten in early life (as a child and/or teen).
- Soy foods may help reduce the recurrence of breast cancer and/or the risk of death in women

with breast cancer.

- Being overweight or obese, especially if excessive weight is gained after menopause, can increase the risk of certain cancers, including breast cancer.
- Being overweight or obese is associated with an increased risk of recurrence and a lower survival rate.
- The ACS states that breast cancer survivors can safely eat moderate amounts of soy foods.

Prostate Cancer

Among men in the United States, prostate cancer is the most common cancer and the second leading cause of cancer death.[41] As with breast cancer, after observing the historically low rate of prostate cancer in countries where soy foods are commonly eaten,[43] researchers began to investigate the possibility that soy is protective against this prostate cancer.[40]

In Japan, prostate cancer rates are about one-tenth of those in the United States; rates in China are even lower.[57] In these Asian countries, both Western influences and cancer rates have increased greatly in the last few years, and an increase in prostate cancer rates has also been seen when natives of these countries move to Western countries.[46]

Soy's proposed benefits for prostate cancer

In 2009, USDA researchers performed a comprehensive review of several scientific studies and found that men who eat the most soy were about 30% less likely to develop prostate cancer than men eating little soy.[6] Evidence also suggests that one of soy's isoflavones may improve outcomes in prostate cancer by lowering the levels of an enzyme that allows cancer cells to spread throughout the body.[58] Studies have also shown that soy can help slow the rise of elevated PSA (prostate specific antigen) levels.[59] This is a good thing: Lower PSA levels are associated with a lower risk of prostate cancer development and improved outcomes in men with prostate cancer.[60,61,62]

In summary

- Men in countries where soy foods are traditionally eaten have lower levels of prostate cancer occurrence and death.
- Studies show that men who eat the most soy are about 30% less likely to develop prostate cancer than men who eat little soy.
- One of soy's isoflavones may help improve prostate cancer outcomes by lowering the levels of an enzyme that allows cancer cells to spread throughout the body.
- Studies have shown that soy may help decrease the rise of elevated PSA levels; lower PSA levels are associated with a lower risk of prostate cancer development and improved outcomes in those with prostate cancer.

Other Cancers

Studies done in Asia have found that high soy-food consumers are less likely to develop several different types of cancers, including those of the stomach, colon, endometrium, and ovaries.[63,64] Although findings are promising, research in these areas is still too limited to make any definitive conclusions about the beneficial effects of soy on these cancers.

Menopause Symptom Relief

Hot flashes are the most common reason given by women for seeking treatment of menopausal symptoms. For the majority of women who experience them, hot flashes generally begin before menopause and end within six months to two years,[63] though some women report having them for up to 20 years after menopause.[64]

Soy's proposed benefits for relief of hot flashes

While the cause of hot flashes is not yet fully understood, the natural decline in circulating estrogen levels that occurs during the years around menopause is thought to be a factor. The hypothesis that soy foods can help alleviate hot flashes was first proposed in

1992[65] based on the purported effects of isoflavones and the low incidence of hot flashes among Japanese women. Unlike in Western countries where most postmenopausal women report having hot flashes, only 10% of Japanese women report having hot flashes.[66]

To date, over 50 studies have been conducted examining soy's effects on menopause symptoms. A recent comprehensive review of the literature found that supplements using a mix of isoflavones closely matching that found naturally in soybeans consistently alleviated both the frequency and severity of hot flashes. In fact, results from an Italian study, the largest and longest of its kind, found a 50% reduction in hot flash frequency among those receiving one of soy's isoflavones compared to those in the placebo group.[67] These findings are consistent with many other studies that also showed positive results.[68,69,70]

In summary

- Postmenopausal Japanese women are much less likely to report having hot flashes compared to women of Western countries; soy consumption may be one reason.
- In studies where supplements closely matched the natural isoflavone mix found in soybeans, the frequency and severity of hot flashes were consistently reduced.

Thyroid Function

The effect of soy foods on thyroid function has been a topic of research for more than 70 years.[71] Concerns about soy and thyroid function are based primarily on in-vitro ("test tube") research and studies in rodents given isolated isoflavones.[72,73,74]

A comprehensive review of the scientific literature published in *Thyroid*, the official journal of the American Thyroid Association, concluded that there was essentially no evidence that soy had any detrimental effects on thyroid function in healthy individuals.[75] Subsequently published research, including a three-year study conducted in Italy that assessed very sensitive measures of thyroid function, confirmed these findings.[76] Similarly, a very large three-year United States study also showed that soy was without effect on the thyroid.[77]

There is some evidence that soy protein may inhibit the absorption of synthetic thyroid hormone, a type of medication used to treat hypothyroidism.[75,78] However, it is important to note that food, in general, has this effect, which is why it is often recommended that medications of this kind be taken on an empty stomach.[79] Those on thyroid medications do not necessarily need to avoid soy. Medifast recommends that those taking thyroid medications follow the advice of their physician, including any special instructions for soy intake or adjustments to the dosage, timing, or frequency of thyroid medications. General guidelines when taking thyroid medications are to wait one to three hours before or after taking thyroid medication to eat products that contain soy protein,[80] have your labs closely monitored, and make sure you get adequate iodine.

Iodine is an essential mineral needed for thyroid hormone synthesis. Adequate iodine intake is important for those eating soy foods and on thyroid medications. Due to the widespread use of iodized salt, iodine status in the United States is typically quite good.[81]

The Medifast Connection: Each Medifast Meal is fortified with an average 20% of the daily value for iodine, providing approximately 100% of the daily value when five Medifast Meals are eaten, as on the Medifast 5 & 1 Plan.

For those with subclinical hypothyroidism, it may be prudent to monitor thyroid function in response to soy consumption, as only very limited research has been conducted in this group of subjects.[75,82]

Note: Soy lecithin, a common food ingredient, is derived from soybeans, but is not known to affect the absorption of thyroid medications.

In summary

- There is essentially no scientific evidence that soy foods or soy isoflavones adversely affect thyroid

function in healthy individuals.

- For those taking synthetic thyroid hormone (a medication used to treat hypothyroidism), some evidence exists suggesting that eating soy protein may affect the dosage requirement or timing of these medications. This is similar to other common types of food-drug interactions and does not indicate a relationship between soy and thyroid health.
- Patients on thyroid medication should consult with their physician to ensure consistent and effective dosing.
- General guidelines when taking thyroid medications are to wait one to three hours before or after taking thyroid medication to eat products that contain soy protein, have your labs closely monitored, and make sure iodine intake is adequate.

Reproductive Health

Reproductive health for men

Sensationalized media stories and results from some rodent studies[84] have led to concerns, particularly in men, about the impact of soy foods on fertility and reproductive function. Men may be reluctant when it comes to soy foods because of a mistaken belief that soy, or soy isoflavones, will result in feminizing effects. This concern is without credible scientific merit. In fact, research has shown that not only are soy foods safe for men to eat, but men may actually benefit by including soy foods in their meal plan.[85,86]

Comprehensive evaluations of the scientific literature show that neither soy protein nor isoflavones affect levels of testosterone[85] or estrogen[86] in men. Furthermore, clinical intervention studies show that isoflavones do not affect sperm or semen, even when extremely high levels of isoflavones, well beyond the amount typically obtained by eating soy foods, were used.[86] The author of a recent publication in the journal *Fertility and Sterility*, critically examining the clinical evidence of this contentious topic, concluded, "Men can feel confident that making soy a part of their diet will not compromise their virility or reproductive health."[86]

In summary

- There is no meaningful clinical evidence suggesting that soy protein or soy isoflavones lower serum testosterone levels or exert any feminizing effects in men.
- The author of a recent publication in the journal *Fertility and Sterility*, after critically examining the clinical evidence, concluded, "Men can feel confident that making soy a part of their diet will not compromise their virility or reproductive health."

Reproductive health for women

Overall, soy foods appear to have insignificant effects on reproductive hormone levels. Some evidence suggests that soy foods may slightly increase the length of the menstrual cycle in some women, potentially briefly delaying ovulation but not preventing it.[87] Longer menstrual cycles have been associated with a reduction in breast cancer risk.[88,89]

In summary

- Overall, soy foods appear to have no significant effects on reproductive hormone levels in women.
- Some evidence suggests that soy foods may slightly alter the length of a woman's menstrual cycle.

Kidney Stones

Kidney stones, many of which are "calcium oxalate" kidney stones, are a common disorder of the urinary tract. These stones are made up of calcium and oxalate, compounds naturally found in foods and in our own bodies.[90,91] Certain foods, including some soy foods, are high in oxalates.[92] The soy protein used by Medifast contains only a very small amount of oxalate:[93] A Medifast Meal providing 10 grams of soy protein contains approximately five times less oxalate than a single almond.[93,94,95]

In summary

- Medifast's high-quality soy protein contains only a small amount of oxalate.
- A Medifast Meal providing 10 grams of soy protein contains approximately five times less oxalate than one single almond.

Soy Allergies

Despite popular belief, research shows that only between 2% and 10% of the population has a food allergy.[96] In the United States, approximately 90% of all food allergies are thought to be made up of eight major allergens: eggs, peanuts, tree nuts, soy, fish, shellfish, wheat, and milk.[97] The number of people affected and the level of response for each of these individual allergens varies. Soy allergies are believed to be relatively rare. Results from a recent comprehensive study found that only one in 2,500 adults reports being diagnosed with an allergy to soy protein.[98]

Soy in Medifast Meals

While a majority (approximately 67%) of Medifast Meals contain soy protein, the remaining one-third utilize other sources of protein, such as milk or egg, although they may still contain soy lecithin. Soy lecithin is a common ingredient in many foods on the market, used primarily to prevent ingredients from separating, provide stability and texture consistency, and help with the flavoring of foods. Soy lecithin is generally derived from refined soybean oil by a process which is thought to remove most, if not all, of the soy protein that a person with a soy allergy would want to avoid.

Despite the very low allergen concern, government regulations do require food labels to clearly state when any ingredient is derived from soy.[97] While limited in breadth, studies suggest that consuming products that contain soy lecithin is not usually an issue, even for those with a soy allergy.[99,100] Medifast recommends that any consumer who is concerned about an allergy to soy contact their health care provider to determine the best course of action based upon their medical history.

The Medifast Connection: More information about the ingredients in Medifast Meals can be downloaded at our website.

In summary

- Food allergies are much less common than people often suspect—only between 2% and 10% of the population has a food allergy.
- Most food allergies are due to eight major allergens, but these foods are not equally allergenic.
- Soy allergies are believed to be relatively rare: Only one in 2,500 adults reports being diagnosed with an allergy to soy protein.
- Soy lecithin is generally derived from refined soybean oil by a process which is thought to remove most, if not all, of the soy protein that a person with a soy allergy needs to avoid.

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