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Saving U.S. Dietary Advice from Conflicts of Interest

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Saving U.S. Dietary Advice From Conflicts of Interest

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Chronic diseases are the greatest threat to global health in the 21st century. They cause 70 percent of deaths in the United States¹ and 60 percent of deaths worldwide (expected to rise to 73 percent by 2020).² Heart disease is easily the world's deadliest disease.³ In 2005, it killed 864,480 Americans, more than cancer, accidents, chronic lower respiratory disease, and diabetes, *combined*,⁴ and the costs of treating heart disease are a global financial burden.⁵ In 2004, cancer caused 13 percent of all deaths globally, killing 7.4 million people,⁶ and it is the second leading cause of death in the United States.

The Dietary Guidelines for Americans (Guidelines)⁷ are designed to tell the public how to prevent chronic diseases through diet and lifestyle. Unfortunately, they are largely unsuccessful at promoting a healthy diet. Studies show that the Guidelines either cannot reduce a person's risks for chronic diseases, or they are not as effective as other diets. To improve, the Guidelines need to be more consistent with current scientific knowledge.

The Guidelines may be difficult to improve due to conflicts of interest. Conflicts exist at two levels: 1) at the USDA, one of the agencies responsible for creating the Guidelines; and 2) with members of the Dietary Guidelines Advisory Committee (Advisory Committee or Committee), the scientific experts advising the government. As a result of these conflicts, the Guidelines sometimes favor the interests of the food and drug industries over the public's interest in accurate and impartial dietary advice.

Current laws do not protect dietary advice from these conflicts, and thus Congress should consider making two changes. First, the USDA should not have any role in dietary advice, as its duty to promote and support the agricultural industry is fundamentally inconsistent with promoting health and preventing chronic diseases. Second, Congress should make it more difficult for those with ties to the

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¹ CDC—Chronic Diseases and Health Promotion, <http://www.cdc.gov/chronicdisease/overview/index.htm> (last visited Dec. 22, 2009).

² WHO—Integrated Chronic Disease Prevention and Control, http://www.who.int/chp/about/integrated_cd/en/ (last visited Dec. 22, 2009).

³ World Health Organization (WHO): Cardiovascular Diseases Factsheet, <http://www.who.int/mediacentre/factsheets/fs317/en/index.html> (last visited Feb. 24, 2009).

⁴ Donald Lloyd-Jones et al., *Heart Disease and Stroke Statistics 2009 Update: A Report From the American Heart Association Statistics Committee and Stroke Statistics Subcommittee*, 119 *CIRCULATION* e21, e32 (2009).

⁵ See *id.* at e172 (in 2009, cardiovascular diseases are expected to cost the United States \$473.3 billion); EUbusiness.com, *Europe Pays Heavy Price for Heart Disease: Study*, <http://www.eubusiness.com/news-eu/1204036321.87/> (last visited Feb. 24, 2009) (in 2006, heart disease cost the European Union \$285 billion).

⁶ World Health Organization: Cancer Factsheet, <http://www.who.int/mediacentre/factsheets/fs297/en/index.html> (last visited Feb. 24, 2009).

⁷ The following shorthand terms and acronyms are used throughout (they are also defined in the main text where first used): Dietary Guidelines Advisory Committee (Advisory Committee or Committee); Alternate Healthy Eating Index (Alternate Index); Centers for Disease Control and Prevention (CDC); cardiovascular disease (CVD); U.S. Department of Agriculture (USDA) and the Department of Health & Human Services (HHS) (Departments); Dietary Guidelines for Americans (Guidelines); Ethics in Government Act of 1978 (EIGA); Federal Advisory Committee Act (FACA); Freedom of Information Act (FOIA); Healthy Eating Index (Index); National Institutes of Health (NIH); Office of Government Ethics (OGE); Physicians Committee for Responsible Medicine (PCRM); Recommended Food Score (RFS); the Secretaries of USDA and HHS (Secretaries); and World Cancer Research Fund (WCRF).

food and drug industries from serving on the Advisory Committee, as current laws are inadequate to do so. This requires a new prohibition of apparent conflicts of interest and some procedural safeguards.

This article has five sections: I) what the Guidelines are and why they are important; II) how well they actually prevent chronic disease; III) why conflicts of interest may be the reason they perform poorly; IV) whether current law protects dietary advice from these conflicts of interest, and suggestions for how to improve the law; and (V) conclusions.

I. WHAT THE GUIDELINES ARE AND WHY THEY ARE IMPORTANT

The Guidelines are designed to tell the public how to promote health and prevent chronic disease through diet and lifestyle.⁸ They must be published at least every five years by the Secretary of the USDA and the Secretary of the HHS (Departments or Secretaries), they must be based on the preponderance of current scientific and medical knowledge, and they must be promoted by every federal agency when carrying out a food, nutrition or health program.⁹ The Guidelines direct how billions of dollars are spent in programs like the School Lunch Program, the School Breakfast Program, the Food Stamp Program and the Supplemental Nutrition Program for Women, Infants, and Children.¹⁰

U.S. dietary advice is created in three steps. First, the Secretaries form the Advisory Committee, which reviews the science and recommends changes to the Guidelines.¹¹ Second, the Secretaries use the Committee's recommendations to create the Guidelines, which recommend consuming certain amounts of foods and nutrients.¹² Finally, the Secretaries use the new Guidelines to revise MyPyramid, which tells the general public what to eat and how much within each of five food groups: grains, fruits, vegetables, dairy and meat and beans.¹³

⁸ See, e.g., DEP'T OF HEALTH & HUMAN SERVS. & U.S. DEP'T OF AGRIC., DIETARY GUIDELINES FOR AMERICANS 2005 1 (2005), available at <http://www.health.gov/dietaryguidelines/dga2005/document/pdf/DGA2005.pdf> [hereinafter 2005 GUIDELINES] ("provides science-based advice to promote health and to reduce risk for chronic diseases through diet and physical activity").

⁹ National Nutrition Monitoring and Related Research Act of 1990, 7 U.S.C. § 5341(a) (West 2009).

¹⁰ For further discussion of diet and nutrition in the School Lunch Program, see generally J. Amy Dillard, *Sloppy Joe, Slop, Sloppy Joe: How USDA Commodities Dumping Ruined the National School Lunch Program*, 87 OR. L. REV. 221 (2008); Kathryn L. Plemmons, *The National School Lunch Program and USDA Dietary Guidelines: Is There Room for Reconciliation?*, 33 J.L. & EDUC. 181 (2004).

¹¹ See, e.g., DEP'T OF HEALTH & HUMAN SERVS. & U.S. DEP'T OF AGRIC., REPORT OF THE DIETARY GUIDELINES ADVISORY COMMITTEE ON THE DIETARY GUIDELINES FOR AMERICANS, 2005, at section C (2005), available at <http://www.health.gov/dietaryguidelines/dga2005/report/> [hereinafter 2005 COMMITTEE REPORT]. Members of the Committee are selected by the Secretaries, see, e.g., HHS, USDA Designate Experts To The Dietary Guidelines Advisory Committee, <http://www.hhs.gov/news/press/2003pres/20030811.html> (last visited Feb. 23, 2009), after soliciting nominations from the public, see, e.g., Announcement of Intent To Establish the 2010 Dietary Guidelines Advisory Committee and Solicitation of Nominations for Membership, 73 Fed. Reg. 19,454 (Apr. 10, 2008) (soliciting nominations from the public). Members serve without pay except for travel expenses and per diems, see, e.g., 2005 COMMITTEE REPORT, *supra* note 12, at section C; Charter of the 2010 Dietary Guidelines Advisory Committee, <http://www.ocio.usda.gov/directives/doc/DR1042-128> (last visited Feb. 23, 2009) [hereinafter 2010 Charter], and they meet formally only five times, see, e.g., *id.* ("The estimated number of Committee meetings is five over the project duration").

¹² 2005 GUIDELINES, *supra* note 9, at 1-2. For example, the Guidelines recommend: "[c]onsume a variety of nutrient-dense foods and beverages within and among the basic food groups," *id.* at vii; and "[c]onsume a sufficient amount of fruits and vegetables while staying within energy needs," *id.* at viii.

¹³ *Id.* at 2. For technical information on the creation and revision of MyPyramid, see Development of MyPyramid, <http://www.cnpp.usda.gov/MyPyramidDevelopment.htm> (last visited Mar. 7, 2009) (providing or linking to resources). See also Inside the Pyramid, <http://www.mypyramid.gov/pyramid/index.html> (last visited Mar. 18, 2009) (containing information regarding each food category). The previous food groups include the "Basic 7" in the 1940s and the "Basic 4" in the late 1950s. MARION NESTLE, FOOD POLITICS 34-38 (2d ed. 2007).

National dietary advice like the Guidelines is important because it can help save lives. Chronic diseases are the leading causes of death in the world and the United States, but these deaths can largely be prevented through diet and lifestyle.¹⁴ Consider heart disease and cancer.

The World Health Organization (WHO) estimates that 80 percent of deaths from heart disease can be prevented.¹⁵ The INTERHEART Study found that 90 percent of heart attacks in men and 94 percent of heart attacks in women could be predicted based on nine factors, each modifiable through diet and lifestyle.¹⁶ Further, clinical studies have shown that a plant-based diet of primarily whole grains, fruits, vegetables, and legumes can completely prevent heart attacks in those with severe heart disease¹⁷ and even reverse the buildup of plaque in their arteries.¹⁸

About 50 to 75 percent of all cancers can be prevented, according to numerous organizations and scientific studies.¹⁹ Further, clinical studies have shown that the

¹⁴ For further reading on the relationship between diet, nutrition, and the prevention of chronic diseases, see generally WORLD HEALTH ORG., DIET, NUTRITION AND THE PREVENTION OF CHRONIC DISEASES (2003), available at http://whqlibdoc.who.int/trs/WHO_TRS_916.pdf [hereinafter DIET, NUTRITION AND THE PREVENTION OF CHRONIC DISEASES]. See also WORLD HEALTH ORG., 1 COMPARATIVE QUANTIFICATION OF HEALTH RISKS (2003), available at http://www.who.int/healthinfo/global_burden_disease/cra/en/ (quantifying the prevalence and magnitude of health risks from various dietary and lifestyle factors). For further reading specifically on heart disease, see Frank B. Hu & Walter C. Willett, *Optimal Diets for Prevention of Coronary Heart Disease*, 288 JAMA 2569 (2002). For further reading specifically on cancer, see generally AM. INST. FOR CANCER RES., WORLD CANCER RES. FUND, FOOD, NUTRITION, PHYSICAL ACTIVITY, AND THE PREVENTION OF CANCER (2007) (citing and reviewing over 7,000 studies).

¹⁵ WORLD HEALTH ORG., PREVENTING CHRONIC DISEASES 52 (2005), available at http://www.who.int/chp/chronic_disease_report/full_report.pdf [hereinafter WHO, PREVENTING CHRONIC DISEASES].

¹⁶ Salim Yusuf et al., *Effect of Potentially Modifiable Risk Factors Associated with Myocardial Infarction in 52 Countries (the INTERHEART Study): Case-Control Study*, 364 LANCET 937, 942 (2004). The nine factors are: 1) high cholesterol; 2) smoking; 3) high blood pressure; 4) abdominal obesity; 5) psychosocial health; 6) consumption of fruits and vegetables; 7) alcohol consumption; 8) diabetes; and 9) regular exercise. *Id.* at 944.

¹⁷ Caldwell Esselstyn put patients with severe heart disease on a plant-based diet. Caldwell Esselstyn, Jr. et al., *A Strategy to Arrest and Reverse Coronary Artery Disease: A 5-Year Longitudinal Study of a Single Physician's Practice*, 41 J. FAM. PRAC. 560 (1995), http://www.heartattackproof.com/study02_methods.htm. After 5 and 12 years, none of the patients who stuck to the diet experienced a single coronary event, Caldwell Esselstyn, Jr. et al., *A Strategy to Arrest and Reverse Coronary Artery Disease: A 5-Year Longitudinal Study of a Single Physician's Practice*, 41 J. FAM. PRAC. 560 (1995), http://www.heartattackproof.com/study03_results.htm, though they had experienced 49 in the eight years prior to the study, Caldwell Esselstyn, Jr., *Updating a 12-Year Experience with Arrest and Reversal Therapy for Coronary Heart Disease (An Overdue Requiem for Palliative Cardiology)*, 84 AM. J. CARDIOLOGY 339 (1999), <http://www.heartattackproof.com/reversal01.htm>.

¹⁸ Caldwell Esselstyn, Jr., *Updating a 12-Year Experience with Arrest and Reversal Therapy for Coronary Heart Disease (An Overdue Requiem for Palliative Cardiology)*, 84 AM. J. CARDIOLOGY 339 (1999), <http://www.heartattackproof.com/reversal01.htm> (heart disease reversed or unchanged after five years). See also Dean Ornish et al., *Intensive Lifestyle Changes for Reversal of Coronary Heart Disease*, 280 JAMA 2001, 2003-04 (1998) (arteries of patients with severe heart disease on plant-based diet opened by an average of 3.01 percentage points, while arteries of a control group following their regular doctor's advice further closed by an average of 11.72 percentage points).

¹⁹ The World Cancer Research Fund (WCRF) estimates that cancer is a mostly preventable disease. AM. INST. FOR CANCER RES., *supra* note 15, at xxv ("If all factors are taken into account, cancer is mostly a preventable disease"). The National Cancer Institute estimates that 50 to 75 percent of all cancer deaths can be prevented through diet and lifestyle. National Cancer Institute: Cancer Trends Progress Report—2007 Update, <http://progressreport.cancer.gov/doc.asp?pid=1&did=2007&mid=vc0l&chid=71> (last visited Feb. 24, 2009). A 1981 study found that 30% of cancers can be prevented by not smoking, and another 35 percent can be prevented through diet alone. R. Doll & R. Peto, *The Causes of Cancer: Quantitative Estimates of Avoidable Risks of Cancer in the United States Today*, 66 J. NAT'L CANCER INST. 1191, 1191 (1981). A 1995 update put the latter figure at 32%, Walter C. Willett, *Diet, Nutrition, and Avoidable Cancer*, 103 ENVTL. HEALTH PERSP. 165, 168 (1995).

progression of cancer can be slowed by eating a plant-based diet.²⁰ The dietary and lifestyle factors that can prevent cancer have been systematically catalogued by the World Cancer Research Fund (WCRF), which undertook the largest and most comprehensive review of scientific studies to date, looking at all the evidence that existed on preventing cancer through diet and lifestyle.²¹ After five years of research, in 2007 the WCRF made 10 recommendations to substantially reduce the risk of cancer:²² 1) keep body mass index as low as possible without being underweight; 2) be physically active at least 30 minutes every day; 3) limit consumption of energy-dense foods and avoid sugary drinks; 4) eat mostly foods of plant origin; 5) avoid all processed meat and eat less than 18 ounces of red meat a week; 6) limit alcoholic drinks to two a day for men and one for women; 7) consume less than two grams of sodium a day; 8) aim to meet nutritional needs through diet alone, not supplements; 9) mothers should breastfeed exclusively for six months; and 10) cancer survivors should follow the same recommendations.²³

Relying on estimates above, if 90 percent of heart disease deaths and 75 percent of cancer deaths could be prevented, then 11.83 million lives could potentially have been saved in 2002, about 21 percent of all deaths that year.²⁴ By promoting the best diet and lifestyle for preventing chronic diseases (such as the diet advocated by the WCRF), the United States can empower people make healthier choices and reduce needless deaths and suffering.

II. HOW WELL THE GUIDELINES ACTUALLY PREVENT CHRONIC DISEASE

This section discusses: A) how best to evaluate the Guidelines; B) whether the Guidelines are effective; and C) whether people can actually change their diets and lifestyles. It concludes that the Guidelines underperform, as they mostly fail to reduce any person's risk of chronic diseases, and other diets perform much better.

A. How Best to Evaluate the Guidelines

The Guidelines should do two things: they should prevent chronic diseases, and they should do so better than any other recommended diet and lifestyle. If adhering to the Guidelines cannot prevent chronic diseases, then they fail at their most basic purpose. Yet just being able to prevent chronic diseases is not enough. Recall that the Guidelines must be based on the preponderance of current scientific and

²⁰ See Dean Ornish et al., *Intensive Lifestyle Changes May Affect the Progression of Prostate Cancer*, 174 J. UROL. 1065, 1065-1066 (2005) (after one year on plant-based diet, men with low-risk prostate cancer experienced significant decreases in cancerous activity, compared to a control group). *Id.* at 1067. See also Dean Ornish et al., *Changes in Prostate Gene Expression in Men Undergoing an Intensive Nutrition and Lifestyle Intervention*, 105 PROC. NAT'L ACAD. SCI. 8369, 8369 (2008) (the diet decreases the expression of genes in the prostate in men with prostate cancer).

²¹ See Historical Overview, http://www.dietandcancerreport.org/?p=historical_overview (last visited Aug. 25, 2009) ("the largest study ever of its kind"); AM. INST. FOR CANCER RES., *supra* note 15, at xxii ("The first [purpose of the Report] is to summarise, assess, and judge *the most comprehensive body of evidence yet collected and displayed* on the subject of food, nutrition, physical activity, body composition, and the risk of cancer, throughout the life-course") (emphasis added). See also World Cancer Research Fund UK: Our History, http://www.wcrf-uk.org/about_us/our_history.php (last visited Mar. 22, 2009) (from 500,000 studies to 7,000 most relevant).

²² AM. INST. FOR CANCER RES., *supra* note 15, at xv.

²³ *Id.* at xvii-xxi.

²⁴ There were 57.029 million deaths worldwide in 2002. WORLD HEALTH ORG., WORLD HEALTH REPORT 2004, at 120 (2004), available at http://www.who.int/entity/whr/2004/annex/topic/en/annex_2_en.pdf. Cancer caused 7.121 million deaths, and heart disease caused 7.208 million. *Id.* at 122.

medical knowledge.²⁵ Congress clearly wanted the Guidelines to reflect the best science available, for good reason. With incomplete or inaccurate information, the government is unable to appropriately shape nutritional programs and people are deprived of the opportunity to make fully informed choices regarding their health. This creates a risk that people who rely on the Guidelines will make choices they otherwise would not have made, and some may needlessly suffer as a result.

The most practical way to determine whether the Guidelines achieve these goals is by looking at the relationship that emerges between diet and disease in a large group of people over time.²⁶ These studies should show that the more a person adheres to the Guidelines, the less likely he/she is to experience poor health outcomes, such as heart disease, cancer or death. Further, if the Guidelines promote the best diet possible, these risk reductions should be more prevalent and of a greater magnitude when compared to other diets and lifestyles.

B. *Whether the Guidelines Are Effective*

Scientific studies have evaluated the Guidelines using the Healthy Eating Index (Index), which the USDA created to measure adherence to the 1995 Guidelines.²⁷ It has 10 components based on a person's daily intake of grains, vegetables, fruits, milk, meat, total fat, saturated fat, cholesterol and sodium, as well as a measure of the variety of foods consumed.²⁸ The Index has been compared to Harvard's Alternate Healthy Eating Index (Alternate Index),²⁹ the Recommended Food Score (RFS)³⁰ and the Mediterranean diet-score.³¹

²⁵ National Nutrition Monitoring and Related Research Act of 1990, 7 U.S.C. § 5341(a) (West 2009).

²⁶ Walter C. Willett & Marjorie L. McCullough, *Dietary Pattern Analysis for the Evaluation of Dietary Guidelines*, 17 ASIA PAC. J. CLINICAL NUTR. 75, 75 (2008) [hereinafter *Evaluation of Dietary Guidelines*] ("the evaluation of dietary patterns in relation to incidence of major health outcomes in large prospective studies can provide critical information about the value of dietary guidelines").

²⁷ *Id.* at 76. See also Healthy Eating Index, <http://www.cnpp.usda.gov/healthyeatingindex.htm> (last visited Mar. 23, 2010) (providing information on current and past versions of the Index).

²⁸ Marjorie L. McCullough et al., *Adherence to the Dietary Guidelines for Americans and Risk of Major Chronic Disease in Men*, 72 AM. J. CLINICAL NUTR. 1223, 1224 (2000) [hereinafter *Risk in Men*]. Each component has a score from 0 to 10, allowing for total scores between 0 and 100. *Id.*

²⁹ The Alternate Index has nine components, which include fruits and vegetables, and seven components different from the Index: 1) the ratio of white to red meat; 2) nuts and soy products; 3) cereal fiber (a measure of whole grains); 4) ratio of polyunsaturated to saturated fat; 5) low trans fats; 6) moderate alcohol consumption; and 7) vitamin supplements. Marjorie L. McCullough & Walter C. Willett, *Evaluating Adherence to Recommended Diets in Adults: The Alternate Healthy Eating Index*, 9 PUB. HEALTH NUTR. 152, 153 (2006) [hereinafter *The Alternate Index*]. Each component is worth between 0 and 10 points, except for vitamins which receive a score of 2.5 or 7.5 (vitamins receive less weight because diet is considered a more important source of nutrients), allowing total scores between 2.5 and 87.5. *Id.*

³⁰ The RFS includes 23 recommended foods. Marjorie L. McCullough et al., *Diet Quality and Major Chronic Disease Risk in Men and Women: Moving Toward Improved Dietary Guidance*, 76 AM. J. CLINICAL NUTR. 1261, 1262 (2002) [hereinafter *Risk in Men and Women*]. A person receives one point for each food he or she consumes at least weekly. *Id.* Total scores are thus between 0 and 23. *Id.*

³¹ The Mediterranean diet-score reflects the basic principles of a traditional Mediterranean diet: 1) high intakes of fruits, vegetables, legumes, nuts, whole grains, and olive oil; 2) moderately high fish intake; 3) low-to-moderate dairy intake; 4) moderate alcohol intake; and 5) low intakes of meat and poultry. Antonia Trichopoulou et al., *Adherence to a Mediterranean Diet and Survival in a Greek Population*, 348 NEW ENG. J. MED. 2599, 2600 (2003). The diet is evaluated using a Mediterranean diet-score that ranges from zero to nine. The points are distributed as follows: 1) a person can receive up to five points by consuming *more* than the median amounts of fruits, vegetables, whole grains, fish and legumes; 2) a person can receive up to three points by consuming *less* than the median amounts of meat, poultry and dairy; and 3) men and women receive one point for consuming alcohol within a certain range. *Id.* at 2601-2603. The beneficial ranges for alcohol intake are between 10 and 50 grams per day for men, and between 5 and 25 grams per day for women. *Id.* at 2603.

As evaluated using the Index, studies show that adhering to the Guidelines mostly will not reduce a person's risk of chronic diseases. In women, the Index does not reduce the risks of cardiovascular disease (CVD) (defined as fatal or nonfatal heart attacks or strokes), cancer (defined as all confirmed cases of cancer except nonmelanoma skin cancers and situ breast cancers) or death from major chronic diseases (defined as all non-traumatic deaths).³² In men, the Index is associated with a 28 percent reduced risk of CVD, has no significant effect on cancer, and is associated with an 11 percent reduced risk of death from major chronic diseases, due almost entirely to its effect on heart disease.³³ Thus, out of six possible risk reductions in these studies, just two find support, neither of which benefits women.

Other diets perform much better than the Guidelines, especially the Mediterranean diet.³⁴ A two-point increase in a nine-point Mediterranean diet-score is associated with a 9 percent reduced risk of dying from any cause, a 9 percent reduced risk of dying from CVD, a 6 percent reduced risk of developing or dying from cancer, and a 13 percent reduced risk of developing Parkinson's or Alzheimer's disease.³⁵ The results apply to *both* men and women.³⁶ Further, these risk reductions could potentially be *quadrupled* in a person who scores at least 8 on the Mediterranean diet-score (i.e., four two-point increases).³⁷ Further, on the only two outcomes that the Guidelines actually led to reduced risks—heart disease and deaths from major chronic diseases in men—the Mediterranean diet can lead to larger benefits.

Other diets have also performed better than the Guidelines. For example, while the Index does not benefit women at all, the Alternate Index is associated with a 28 percent reduced risk of CVDs³⁸ and an 11 percent reduced risk of death from major chronic diseases.³⁹ While the Index does not predict the risk of breast cancer in women, the Alternate Index, the RFS, and the Mediterranean diet-score are all associated with reduced risks of estrogen receptor negative breast cancer tumors.⁴⁰

³² Marjorie L. McCullough et al., *Adherence to the Dietary Guidelines for Americans and Risk of Major Chronic Disease in Women*, 72 AM. J. CLINICAL NUTR. 1214, 1216, 1218-1219 (2000) [hereinafter *Risk in Women*]. Also, in this section, the Index or the Alternate Index was "ineffective" if there was no statistically significant difference between those scoring in the top and bottom quintiles of the index, based on a 95 percent confidence interval. In contrast, the Index is "associated with a Y percent reduced risk" if a person scoring in the top quintile of the index was Y percent less likely to experience the outcome measure, compared to a person scoring in the bottom quintile.

³³ *Risk in Men*, *supra* note 29, at 1227-1228.

³⁴ This article is not arguing that any of these diets is an optimal diet, or that the United States should adopt any of them, only that they are much more effective than U.S. dietary advice, showing the United States can and should do much better than it currently does.

³⁵ Francesco Sofi et al., *Adherence to a Mediterranean Diet and Health Status: Meta-Analysis*, 337 BMJ a1344, a1347-1348 (2008). This meta-analysis examined the results of 12 studies containing more than 1.57 million total participants, ranging in age from 20 to 90, from 18 countries, who were followed for up to 18 years. *Id.* at a1344, a1346.

³⁶ *Id.* at a1348.

³⁷ See, e.g., Panagiota N. Mitrou et al., *Mediterranean Dietary Pattern and Prediction of All-Cause Mortality in a US Population: Results From the NIH-AARP Diet and Health Study*, 167 ARCH. INTERNAL MED. 2461, 2465 (2007) (a man scoring 4-5 on the Mediterranean diet-score was 6 percent less likely than a person scoring 0-3 to die from a CVD, but a man scoring 6-9 was 24 percent less likely, and woman scoring 4-5 was 12 percent less likely than a person scoring 0-3 to die from all causes, but a woman scoring 6-9 was 22 percent less likely). See also Lluís Serra-Majem et al., *Scientific Evidence of Interventions Using the Mediterranean Diet: A Systematic Review*, 64 NUTR. REVIEWS S27 (2006) (arriving at conclusions similar to the meta-analysis).

³⁸ *The Alternate Index*, *supra* note 30, at 154.

³⁹ *Risk in Men and Women*, *supra* note 31, at 1265, 1267. However, like the Index, the Alternate Index is ineffective at predicting cancers, generally. *The Alternate Index*, *supra* note 30, at 154-155.

⁴⁰ Teresa T. Fung et al., *Diet Quality is Associated with the Risk of Estrogen Receptor-Negative Breast Cancer in Postmenopausal Women*, 136 J. NUTR. 466, 468-469 (2006).

Further, in men, the Alternate Index is associated with a 39 percent reduced risk of CVDs and a 20 percent reduced risk of death from major chronic diseases,⁴¹ each a larger reduction compared to the Index.⁴²

The Guidelines underperform because they fail to distinguish between foods that prevent and cause disease. For example, the 1995 Guidelines make no distinction between refined grains—which have no health benefits—and whole grains—which decrease the risks of heart disease,⁴³ cancer,⁴⁴ and numerous other diseases and conditions.⁴⁵ Also, the Guidelines fail to encourage specific foods and nutrients that reduce the risk of cancer—such as cruciferous vegetables, lycopene, and vitamin D.⁴⁶ They also fail to discourage specific foods that increase the risk of cancer—such as red meat and processed meat.⁴⁷ Further, even when the Guidelines discourage certain foods, the recommendation might not be included in MyPyramid, decreasing the chance the general public will ever know about it, as is the case with sodium intake.⁴⁸

A Mediterranean diet—reflected in the official dietary guidelines of Greece⁴⁹—is much more consistent with current science. A plant-based diet of fruits, vegetables, whole grains, legumes, and no meat reversed heart disease, completely prevented deaths from heart disease, and slowed the progression of cancer,⁵⁰ and an almost identical diet is promoted by the WCRF to prevent cancer, as based on the largest

⁴¹ *The Alternate Index*, *supra* note 30, at 154-155.

⁴² Further, when CVDs are predicted using both the Index and Alternate Index at the same time, only the Alternate Index remains statistically significant, *Risk in Men and Women*, *supra* note 31, at 1266, showing the Index has a much weaker effect on CVDs.

⁴³ See, e.g., Jennifer A. Nettleton et al., *Incident Heart Failure is Associated with Lower Whole-Grain Intake and Greater High-Fat Dairy and Egg Intake in the Atherosclerosis Risk in Communities (ARIC) Study*, 108 J. AM. DIETETIC ASS'N 1881 (2008); Gary E. Fraser et al., *A Possible Protective Effect of Nut Consumption on Risk of Coronary Heart Disease: The Adventist Health Study*, 152 ARCH. INTERNAL MED. 1416 (1992).

⁴⁴ See, e.g., June M. Chan et al., *Whole Grains and Risk of Pancreatic Cancer in a Large Population-Based Case-Control Study in the San Francisco Bay Area, California*, 166 AM. J. EPIDEMIOLOGY 1174 (2007) (pancreatic cancer); Arthur Schatzkin et al., *Dietary Fiber and Whole-Grain Consumption in Relation to Colorectal Cancer in NIH-AARP Diet and Health Study*, 85 AM. J. CLINICAL NUTR. 1353 (2007) (colorectal cancer); Joanne L. Slavin et al., *The Role of Whole Grains in Disease Prevention*, 101 J. AM. DIETETIC ASS'N 780 (2001) (several cancers).

⁴⁵ See, e.g., Jeroen S. L. de Munter et al., *Whole Grain, Bran, and Germ Intake and Risk of Type 2 Diabetes: A Prospective Cohort Study and Systematic Review*, 4 PLoS MED. e261 (2007) (type 2 diabetes); Luc Djousse & J. Michael Gaziano, *Breakfast Cereals and Risk of Heart Failure in the Physicians' Healthy Study I*, 167 ARCH. INTERNAL MED. 2080 (2007) (heart failure); Fraser et al., *supra* note 44 (heart attacks); David R. Jacobs, Jr., et al., *Is Whole Grain Intake Associated with Reduced Total and Cause-Specific Death Rates in Older Women? The Iowa Women's Health Study*, 89 AM. J. PUB. HEALTH 322 (1999) (death from heart disease and cancer); Philip B. Mellen et al., *Whole Grain Intake and Carotid Artery Atherosclerosis in a Multiethnic Cohort: The Insulin Resistance Atherosclerosis Study*, 85 AM. J. CLINICAL NUTR. 1495 (2007) (carotid artery atherosclerosis).

⁴⁶ See *The Alternate Index*, *supra* note 30, at 156; *Risk in Men and Women*, *supra* note 31, at 1267-1268.

⁴⁷ See *supra* note 24 and accompanying text.

⁴⁸ The 2005 Guidelines recommend limits on the daily intake of sodium generally, as well as stricter limits for certain subpopulations. See 2005 GUIDELINES, *supra* note 9, at 39-41. However, these recommendations are not included or represented in MyPyramid, which does not even contain a food group that could encompass a recommendation for sodium. See generally *Inside the Pyramid*, *supra* note 14.

⁴⁹ Ministry of Health and Welfare, Supreme Scientific Health Council, *Dietary Guidelines For Adults In Greece*, 16 ARCH. HELLENIC MED. 516, 519 (1999) (describing the development of Greece's food guidelines and displaying the official food guide pyramid).

⁵⁰ See *supra* notes 18-21 and accompanying text.

review of scientific studies to date.⁵¹ Like these studies—and unlike the Guidelines—Greece discourages the consumption of red meat and poultry, and encourages the consumption of only whole grains. The differences between the two diets can be great. For example, it is consistent with the Guidelines to eat 150 to 195 ounces of red meat a month. In contrast, Greece recommends eating less than 8.5 ounces of red meat a month, roughly 4 percent the amount the United States allows.⁵²

Further, there is little evidence that the Guidelines have improved since 1995, although there are some positive changes.⁵³ The USDA has also created the Healthy Eating Index-2005 (2005 Index), an update of the Index.⁵⁴ However, there is not enough evidence to conclude that the 2005 Guidelines are an improvement, as just one study has evaluated the 2005 Index, and only with respect to colorectal cancer, although it did find some benefits.⁵⁵

Ultimately, all of these studies show that the United States is not providing the public the best information available on diet and health. In contrast, the former Secretaries of USDA and HHS claimed the Guidelines were the “gold standard” of nutrition, and would actually reduce the risks of chronic diseases.⁵⁶ The evidence does not support these claims, but the United States has a great opportunity to make the Guidelines more consistent with current scientific knowledge.

⁵¹ See *supra* note 24 and accompanying text. See also AM. INST. FOR CANCER RES., *supra* note 15, at 68, 378-379 (discussing refined grains); *id.* at 120-121 (discussing dose-response relationship between red meat consumption and risk of colorectal cancer).

⁵² MyPyramid recommends adults eat 5 to 6.5 ounces of meat or alternatives, such as beans and legumes (other sources of protein), a day. Inside the Pyramid: How Much Food from the Meat & Beans Group is Needed Daily, http://www.mypyramid.gov/pyramid/meat_amount_table.html (last visited Mar. 20, 2009). The Mediterranean diet recommends 4 servings of red meat a month and 4 servings of poultry a week. Ministry of Health and Welfare, *supra* note 50, at 519. One serving of lean meat is equal to 60 grams. *Id.* at 521. Sixty grams is equal to 2.12 ounces, rounded up. Grams to Ounces Conversion Calculator, <http://www.metric-conversions.org/weight/grams-to-ounces.htm> (last visited Mar. 20, 2009). Thus, 4 servings of meat is equal to about 8.48 ounces.

⁵³ *Evaluation of Dietary Guidelines*, *supra* note 27, at 77 (arguing that the Guidelines now look more like the Alternate Index). For example, while the 1995 Guidelines made no distinction between whole and refined grains, the 2005 Guidelines recommend that, in general, at least half of grains should be whole. 2005 GUIDELINES, *supra* note 9, at viii.

⁵⁴ See Patricia M. Guenther et al., *Evaluation of the Healthy Eating Index-2005*, 108 J. AM. DIETETIC ASS'N 1854 (2008) (testing validity of the 2005 Index); Patricia M. Guenther et al., *Development of the Healthy Eating Index-2005*, 108 J. AM. DIETETIC ASS'N 1896 (2008) (describing creation of the 2005 Index). The 2005 Index makes the following changes to the Index: 1) it divides fruit into total fruit and whole fruit; 2) it divides vegetables into total vegetables and dark green and orange vegetables and legumes; 3) it divides grains into total grains and whole grains; 4) it adds categories for oils and discretionary calories; and 5) it eliminates a variable measuring the total variety of food consumed in the diet. *Id.* at 1897.

⁵⁵ That study found that the 2005 Index was associated with a reduced risk of colorectal cancer in both men and women, but there were similar reductions using the Alternate Index. J. Reedy et al., *Index-Based Dietary Patterns and Risk of Colorectal Cancer: The NIH-AARP Diet and Health Study*, 168 AM. J. EPIDEMIOLOGY 38, 42-43 (2008). Further, the RFS and the Mediterranean diet-score also reduced the risk of colorectal cancer in men, although not in women; however, the original Index was not examined. *Id.* See also L. Beth Dixon et al., *Adherence to the USDA Food Guide, DASH Eating Plan, and Mediterranean Dietary Pattern Reduces Risk of Colorectal Adenoma*, 137 J. NUTR. 2443 (2007) (creating and tested its own 8-point index based on the 2005 Guidelines, which was associated with reductions in the presence of colorectal adenomas in men and women (colorectal adenomas are common in people over 50, but can be precursors to colorectal cancer); similar reductions were found using the Dietary Approaches to Stop Hypertension Eating Plan and the Mediterranean diet-score). No study appears to have examined the 2005 Index's effect on CVDs or death.

⁵⁶ Updated Dietary Guidelines for Americans, http://www.fcs.okstate.edu/cnep/news/archive/dietary_guidelines.htm (last visited Mar. 12, 2009).

Improving the Guidelines may help more people than just Americans. Many nations have modeled their dietary advice after the Guidelines.⁵⁷ If the United States changes its dietary advice, other countries may either follow the United States by making the same changes, or finally have good reason to conduct an independent and thorough review of the science for themselves.

C. *Whether People Can Change Their Diets and Lifestyles*

Even if the Guidelines promoted an optimal diet for preventing chronic disease, people actually have to follow it to benefit. It is thus crucial to understand how nations can motivate people to do so. This may not be a large obstacle in a nation like Greece, where people are asked to follow a traditional diet. However, this could be a larger obstacle in a nation like the United States, where there may not be any healthy, traditional diets to follow. However, that is an obstacle to better health that can be overcome.

Finland has set an example for the rest of the world. In the early 1970s, Finnish men had the highest rates of heart disease in the world, and life expectancy for both genders was very low due to chronic diseases.⁵⁸ They realized their basic diet was contributing to the problem,⁵⁹ and the government collaborated with the WHO to get people to smoke less, exercise more, eat more fruits and vegetables, and eat less salt and saturated fat, especially from dairy sources.⁶⁰ Schools, supermarkets, the food industry, community leaders, the media, nonprofit organizations and others combined to educate the public and encourage participation in the program.⁶¹ For example, recognizing that dairy farmers might suffer when people changed their eating habits, the government helped many switch to berry farming.⁶²

The results of the program appear extraordinary. From 1969 and 1995, for Finnish men, the mortality rate from CVDs fell 59.7 percent, the mortality rate from heart disease fell 62.4 percent, and the mortality rate from cancer fell 39.9 percent.⁶³ For women, the mortality rate from CVDs fell 68.3 percent, the mortality rate from heart disease fell 65.9 percent, and the mortality rate from cancer fell 15.6 percent.⁶⁴ As a result, life expectancy for men rose 6.4 years, from 66.4 to 72.8, and life expectancy for women rose 5.6 years, from 74.6 to 80.2.⁶⁵

⁵⁷ See James Painter et al., *Comparison of International Food Guide Pictorial Representations*, 102 J. AM. DIETETIC ASS'N 483 (2002) (food pyramids in 11 countries—the U.K., Australia, Canada, China, Germany, Korea, Mexico, the Philippines, Portugal, Puerto Rico and Sweden—virtually identical to U.S. Food Guide Pyramid in terms of food groups and daily recommendations in each food group); Suzanne P. Murphy & Susan I. Barr, *Food Guides Reflect Similarities and Differences in Dietary Guidance in Three Countries (Japan, Canada, and the United States)*, 65 NUTR. REVIEWS 141 (2007) (only notable difference between the guidelines from the United States, Canada and Japan was regarding dairy).

⁵⁸ Puska Pekka et al., *Influencing Public Nutrition for Non-Communicable Disease Prevention: From Community Intervention to National Programme—Experiences from Finland*, 5 PUB. HEALTH NUTR. 245, 246 (2002).

⁵⁹ *Id.*

⁶⁰ *Id.* Despite the positive messages and advice, the government was very slow to update the country's food guides. In 1978, Finland's National Nutrition Council adopted but did not officially implement a food guide pyramid. Liisa M. Valsta, *Food-Based Dietary Guidelines for Finland—A Staged Approach*, 81 BRIT. J. NUTR. S49, S50 (1999). The base of the pyramid—which identifies what to consume the most—included milk, cheese and table fat. *Id.* Currently, however, the food guide has moved milk and dairy products up to the third of four levels in the pyramid, and fats to the fourth level. *Id.*

⁶¹ Pekka et al., *supra* note 59, at 246.

⁶² *Id.*

⁶³ Puska et al., *Changes in Premature Deaths in Finland: Successful Long-Term Prevention of Cardiovascular Diseases*, 76 BULL. WORLD HEALTH ORG. 419, 422 (1998).

⁶⁴ *Id.*

⁶⁵ *Id.* 421.

People can change, but the advice needs to improve before people are encouraged to follow it.⁶⁶ The Guidelines may not be easy to improve, as those who create the Guidelines may appear biased in favor of the food and drug industries. This could limit the extent to which U.S. dietary advice accurately reflects the science.

III. WHY CONFLICTS OF INTEREST MAY BE THE REASON THE GUIDELINES PERFORM POORLY

This section discusses two reasons why the Guidelines may underperform: A) conflicts of interest at the USDA; and B) conflicts of interest on the Advisory Committee. Each participates in creating the Guidelines, and each may be more interested in protecting industry interests than adhering to the science. This section concludes that these conflicts exist and have a strong, negative influence on U.S. dietary advice.

A. *Potential Conflicts of Interest at the USDA*

The USDA basically has three functions: 1) ensure a safe food supply; 2) promote the agricultural industry; and 3) give dietary advice.⁶⁷ Early on, the second and third seemed consistent with each other: millions of American died each year from malnutrition, and it was believed that increasing consumption of agricultural products was the appropriate solution.⁶⁸

A conflict emerged as we realized these foods were contributing to the rise in chronic diseases. Scientists and the government began to encourage people to “eat less” of certain foods, such as animal fat, cholesterol, salt and sugar.⁶⁹ The agricultural industries strongly protested any advice to consume less of their products.⁷⁰ This put the USDA in a tough position: if it followed the science, it would violate its duty to promote the agricultural industry; if it protected the industry, it would violate its duty to issue science-based dietary advice.

The USDA has sometimes responded to this conflict by choosing industry over science.⁷¹ For example, in 1977, the U.S. Senate’s *Dietary Goals for the United States*

⁶⁶ For a discussion of current U.S. efforts to motivate people to choose healthier diets and lifestyles, and how these efforts can improve, see generally Kelli K. Garcia, *The Fat Fight: The Risks and Consequences of the Federal Government’s Failing Public Health Campaign*, 112 PENN. ST. L. REV. 529 (2007).

⁶⁷ See USDA Mission Statement, <http://www.usda.gov> (follow “About USDA” hyperlink) (last visited Feb. 25, 2009) (identifying five strategies to fulfilling its mission: 1) “expanding markets for agricultural products;” 2) “further developing alternative markets for agricultural products;” 3) “providing financing needed to help expand job opportunities ... in rural America;” 4) “enhancing food safety;” and 5) “improving nutrition and health by providing food assistance and nutrition education and promotion”).

⁶⁸ Emily J. Schaffer, *Is the Fox Guarding the Henhouse? Who makes the Rules in American Nutrition Policy?*, 57 FOOD & DRUG L.J. 371, 380 (2002).

⁶⁹ NESTLE, *supra* note 14, at 38-40 (citing WHITE HOUSE CONFERENCE ON FOOD, NUTRITION, AND HEALTH, FINAL REPORT (1970)). See also STAFF OF S. SELECT COMM. ON NUTRITION AND HUMAN NEEDS, 95TH CONG., EXCERPTS FROM THE FIRST EDITION OF “THE DIETARY GOALS FOR THE UNITED STATES” 6 (Comm. Print 1977) [hereinafter DIETARY GOALS FOR THE U.S.], available at http://zerodisease.com/archive/Dietary_Goals_For_The_United_States.pdf (listing dietary goals).

⁷⁰ NESTLE, *supra* note 14, at 40-41 (meat, egg, sugar, and dairy companies criticized 1977 Senate Report calling for Americans to eat less of their products).

⁷¹ See generally Schaffer, *supra* note 69 (arguing that “the government has...supported the interests of the food industry at the expense of individual and public health interests where these two sets of interests have come into conflict”).

recommended that Americans “decrease consumption of meat.”⁷² Over time, the USDA effectively reversed that recommendation; it now advises most Americans to eat 5 to 6.5 ounces of meat or beans a day.⁷³ Also, in 1991 the USDA delayed publishing the Eating Right Pyramid after the meat and dairy industries demanded it be withdrawn.⁷⁴ When finally released in 1992, the Pyramid had 33 changes, including the highest recommended daily intake of meat ever.⁷⁵ Further, the Departments have contradicted basic recommendations in order to protect agricultural products. For example, in the 1990 Guidelines, following advice to reduce consumption of fat, saturated fat, and cholesterol, the Guidelines added that “[s]ome foods that contain fat, saturated fat, and cholesterol, such as meats, milk, cheese, and eggs, also contain high-quality protein and are our best sources of certain vitamins and minerals.”⁷⁶ These statements provide reasons to both consume and not consume agricultural products, resulting in no real advice at all. This is what can happen when the USDA tries to fulfill two conflicting duties.

Personal interests of USDA officials may also play a role in these pro-industry changes. In 2004, nearly every major officeholder at the USDA had previously owned, been employed by, or lobbied for agricultural companies and organizations.⁷⁷ The USDA’s tendency to choose industry over science may also be evident on the Advisory Committee. The Departments could select members who are less likely to threaten agricultural interests.

B. *Potential Conflicts of Interest on the Advisory Committee*

Relationships with the food and drug industries are commonplace on the Advisory Committee: three out of 11 members on the 1995 Committee had past or present industry ties (*see* Table 1);⁷⁸ seven out of 11 members on the 2000 Committee (*see* Table 2); 11 out of 13 members on the 2005 Committee (*see* Table 3); and currently nine out of 13 members on the 2010 Committee (*see* Table 4).⁷⁹ These relationships are substantial. For example, on just the 2000 Committee (*see* Table 2), members

⁷² DIETARY GOALS FOR THE U.S., *supra* note 70.

⁷³ Inside the Pyramid: How much food from the meat & beans group is needed daily?, http://www.mypyramid.gov/pyramid/meat_amount_table.html (last visited Mar. 26, 2010).

⁷⁴ Carole Sugarman & Malcom Gladwell, *U.S. Drops New Food Chart: Meat, Dairy Groups Press Agriculture Dept.*, WASH. POST, (Apr. 27, 1991), at A1, A10.

⁷⁵ NESTLE, *supra* note 14, at 58-64.

⁷⁶ *Id.* at 50 (no objections from the food industries). As another example, the language of advice was changed from “eat less” to the more passive and less threatening “avoid too much.” *Id.* at 46. Also, in the 1970s, the salt allowance was increased from 3 to 5 grams per day. *Id.* at 42.

⁷⁷ Michael F. Jacobson, *Politics 101*, NUTR. ACTION NEWSLETTER, (Sept. 2004), at 2, *available at* http://www.cspinet.org/nah/09_04/cspinews.pdf (including: the Secretary (law and lobbying firms that specialized in food, agriculture, and other issues, including work for Dole Foods and other companies); the Deputy Secretary (owner of hog and feed-grain farm); the Deputy Under Secretary for Farm and Foreign Agricultural Services (International Dairy Foods Association and National Cheese Institute/American Butter Institute); the Under Secretary for Natural Resources and Environment (American Forest and Paper Association); the Under Secretary for Research, Education and Economics (Campbell Soup’s Institute of Research and Technology); the Deputy Under Secretary (National Cattlemen’s Beef Association) and Under Secretary (owner of pesticide aerial application service) for Marketing and Regulatory Programs; the Director of the Center for Nutrition Policy and Promotion (National Pork Board and National Livestock and Meat Board); and the former Deputy Assistant Secretary for Congressional Relations (Ice Cream, Milk and Cheese Political Action Committee)).

⁷⁸ Advisory Committee members’ relationships with industry in 1995, 2000, 2005, and 2010 are presented in the Appendix in Tables 1, 2, 3, and 4, respectively.

⁷⁹ These relationships take five basic forms: 1) receiving research grants; 2) serving on industry boards; 3) consulting industry; 4) publishing in industry-sponsored publications; and 5) lecturing to or for industry. NESTLE, *supra* note 14, at 111-136.

had past or present ties to: two meat associations;⁸⁰ four dairy associations and five dairy companies;⁸¹ one egg association;⁸² one sugar association;⁸³ one grain association;⁸⁴ five other food companies;⁸⁵ six other industry-sponsored associations;⁸⁶ two pharmaceutical associations;⁸⁷ and 28 pharmaceutical companies.⁸⁸

These relationships have the potential to make scientists more likely to favor the industries that support them. If the relationships are current, scientists may not want to upset the industry and jeopardize current sources of jobs, incomes and funding.⁸⁹ The expert may be unable to simultaneously act in the best interests of both the Committee and the industry. Yet even where the expert might act in the best interests of the Committee, his/her ties to industry may create a risk and a perception he/she will not do so. Thus, even if an expert's relationships with industry are all in the past, he/she may appear less likely than other experts to follow the science, as he/she: 1) may feel a sense of duty to represent the interests of his/her former employers and sources of funding; 2) may have developed biased views of the science after serving industry interests; and/or 3) may try to secure new relationships by protecting industry interests. Even if these experts act completely professionally and follow the science, which they may, the public's trust in the process may still be compromised.

Relationships with the drug industry may be just as likely to cause conflicts as those with the food industry. In a sense, drugs are in direct competition with diet and lifestyle for preventing or treating chronic diseases. Pfizer manufactures Lipitor, which is designed to lower cholesterol; it is the best-selling drug in the world by far, with sales of over \$12.9 billion in 2006, more than double its nearest competitor.⁹⁰ The third best-selling drug that year was Plavix, a blood thinner made by Bristol-Myers Squibb.⁹¹ Scientists with ties to the drug industry may feel pressure to not give advice that could have the effect of reducing reliance on these very profitable drugs. They may also not believe that diet or lifestyle is important or even necessary to control risk factors for chronic disease, when people can just take a pill.

⁸⁰ The American Meat Institute and the National Livestock and Beef Board.

⁸¹ The National Dairy Council, the National Dairy Promotion and Research Board, the National Dairy Board, the Wisconsin Milk Marketing Board, Mead Johnson Nutritionals, the Dannon Company, Kraft Foods, Nestle, and Slim-Fast.

⁸² The American Egg Board.

⁸³ The Sugar Association.

⁸⁴ The Grain Foods Foundation.

⁸⁵ The Kellogg Company, Campbell Soup Company, Miller Brewing Company, Health Valley Foods and Weight Watchers.

⁸⁶ The Peanut Institute, the Chocolate Manufacturers Association, the American Council on Science and Health, the International Food Information Council, the International Life Sciences Organization and the Gatorade Life Sciences Institute.

⁸⁷ The American Pharmaceutical Association and the National Association of Chain Drug Stores. The latter may not always share the same interests as pharmaceutical companies.

⁸⁸ GlaxoSmithKline, Bristol-Meyers Squibb, Procter & Gamble, Merck, Hoffman-La Roche, Johnson & Johnson, King Pharmaceuticals, Knoll Pharmaceuticals, Abbott Laboratories, Wyeth Ayerst Laboratories, Eli Lilly, AstraZeneca, BreathQuant, Critical Therapeutics, Warner Lambert, Pharmanex, Dey, Genetech, Janssen, MedImmune, Novartis, Oridion, Pathogen Scientific, Schering-Plough, Verus, Boehringer Ingelheim, Novo Nordisk and Sanofi-Synthelabo.

⁸⁹ In *Physicians Committee for Responsible Medicine's (PCRM's) suit against the USDA and HHS*, the court acknowledged that these ties can make "a Committee member ... financially beholden to a person or entity that had an interest in how the [Guidelines] might be amended," creating a significant public interest in obtaining this information. *Physicians Comm. for Responsible Med. v. Glickman*, 117 F.Supp.2d 1, 6 (D.C. Cir. 2000).

⁹⁰ Matthew Herper & Peter Kang, *The World's Ten Best-Selling Drugs*, http://www.forbes.com/2006/03/21/pfizer-merck-amgen-cx_mh_pk_0321topdrugs.html (last visited Dec. 22, 2009).

⁹¹ *Id.*

The effects of industry ties are very real. Scientists feel pressure to favor industry. For example, in a 1998 survey, 63 percent of scientists conducting clinical studies who received gifts from industry felt that the donor expected acknowledgment in publications, 32 percent felt the donor expected to review articles or reports before publication, and 29 percent felt the donor expected that the gift would not be used for commercial applications that might compete with the company's products.⁹² They may similarly feel pressure to positively frame or even change their results. For example, a 1994 study found that researchers receiving industry money frequently reported the donor's drug was safer than alternatives, a conclusion which was not justified by the data more than half the time.⁹³ Other studies have reached similar findings.⁹⁴

Members of the Advisory Committee are no less susceptible to influence and bias. They can manipulate the Committee's recommendations by selectively relying or not relying on particular science in order to justify their desired outcomes. For example, the 2005 Committee included long and well-cited discussions of the health benefits of eating fruits and vegetables, whole grains and milk products, in attempts to justify the Committee's recommendations for those food groups.⁹⁵ But while the Committee also recommends consuming a variety of foods from the "meat and beans" group on a daily basis, there is oddly *no discussion at all* of the scientific research on the health consequences of eating meat.⁹⁶ If the Committee actually discussed this research, it would be unable to justify its recommendation to eat meat, as the research would show that meat increases the risks of chronic diseases, contrary to the purposes of the Guidelines. Thus, by simply ignoring that research, the Committee is able to reach a conclusion that would otherwise look improper.

The USDA may realize these conflicts look bad, as it unlawfully withheld information about them. In 1999, the PCRM requested information about Committee members, including their financial disclosure forms.⁹⁷ The USDA disclosed most information requested,⁹⁸ but refused to reveal the name of a corporate board one member had sat on, as well as the curricular vitae of nominees not selected to

⁹² Eric G. Campbell et al., *Looking a Gift Horse in the Mouth: Corporate Gifts Supporting Life Sciences Research*, 279 JAMA 995, 997 (1998).

⁹³ Paul A. Rochon, *A Study of Manufacturer-Supported Trials of Nonsteroidal Anti-Inflammatory Drugs in the Treatment of Arthritis*, 154 ARCH. INTERN. MED. 157 (1994).

⁹⁴ See, e.g., Lisa A. Bero et al., *The Publication of Sponsored Symposia in Medical Journals*, 327 NEW ENGL. J. MED. 1135 (1992) (journal articles published in symposia sponsored by pharmaceutical companies more likely to have misleading titles and less likely to be peer-reviewed in the same manner as other articles); Mildred K. Cho & Lisa A. Bero, *The Quality of Drug Studies Published in Symposium Proceedings*, 124 ANN. INTERN. MED. 485 (1996) (journal symposia sponsored by one drug company more likely to have articles without methods sections, and more likely to report outcomes favoring the drug); and H.T. Stelfox et al., *Conflict of Interest in the Debate Over Calcium-Channel Antagonists*, 338 NEW ENGL. J. MED. 101 (1998) (authors supporting use of the drug were more likely than other authors to have financial relationships with the drug manufacturer).

⁹⁵ See 2005 COMMITTEE REPORT, *supra* note 12, at section D(6), available at http://www.health.gov/dietaryguidelines/dga2005/report/PDF/D6_SelectedFood.pdf.

⁹⁶ The Committee's report says that "[t]he other basic food group (meat, poultry, fish and legumes) is covered in Section 1." *Id.* However, Section 1 contains no discussion of the health consequences of eating meat. *Id.* at section D(1), available at http://www.health.gov/dietaryguidelines/dga2005/report/PDF/D1_Adequacy.pdf. Even when the Committee discusses a report by the National Cancer Institute finding that diets high in both red and white meat increase the risk of colorectal cancer, the Committee completely ignores that particular finding. See *id.* at section D(4), available at http://www.health.gov/dietaryguidelines/dga2005/report/PDF/D4_Fats.pdf (quoting the National Cancer Institute: "diets high in . . . meat (both red and white) . . . are associated with an increased incidence of colorectal cancer") (emphasis removed).

⁹⁷ *Physicians Comm. for Responsible Med. v. Glickman*, 117 F.Supp.2d 1, 3 (D.C. Cir. 2000).

⁹⁸ *Id.* The information showed that the Committee members had many more ties to the food industry than had previously been disclosed. See *infra* Table 2.

the Committee.⁹⁹ PCRM sued, and a court held the information had to be disclosed.¹⁰⁰

Ultimately, the best and most accurate dietary advice is only likely to come from those willing to follow the science, even when it is contrary to industry interests.

IV. PROTECTING DIETARY ADVICE FROM CONFLICTS OF INTEREST

The United States needs to protect its dietary advice by ensuring that those who create it have only the public's best interests in mind. This means eliminating or managing conflicts of interest. This section discusses whether current laws are adequate to protect dietary advice from conflicts and then suggests how to improve the law. Section A discusses conflicts at the USDA and concludes that the USDA should be removed from its role in dietary advice. Section B discusses conflicts on the Advisory Committee and concludes that the United States needs a stronger prohibition of apparent conflicts of interest.

A. *The USDA's Conflict*

There is really only one legal protection against the USDA's inherent conflict: HHS has joint responsibility to issue the Guidelines.¹⁰¹ That does not appear to be enough. The Guidelines still underperform and scientists with apparent conflicts of interest are still appointed to the Advisory Committee.¹⁰² The only realistic way to protect the Guidelines from the USDA's conflict is to bar the USDA from having any role in creating U.S. dietary advice, and to give the responsibility to a specific health agency whose duties are most consistent—and not *inconsistent*—with promoting health and preventing chronic disease.¹⁰³

Just as many other nations do,¹⁰⁴ the United States could put an appropriate health agency in charge of dietary advice. The mission of the CDC is to protect the health of people and communities “through health promotion, prevention of

⁹⁹ Glickman, 117 F.Supp.2d at 5-6.

¹⁰⁰ *Id.*

¹⁰¹ National Nutrition Monitoring and Related Research Act of 1990, 7 U.S.C. § 5341(a) (West 2009).

¹⁰² HHS may play a subservient role to the USDA in dietary advice. In PCRM's lawsuit, for example, both Secretaries were named defendants, but the court focused only on the *USDA's* acts, omissions, and arguments, *not* HHS's. See generally *Physicians Comm. for Responsible Med. v. Glickman*, 117 F.Supp.2d 1 (D.C. Cir. 2000) (addressing the USDA's failure to provide information and the USDA's defenses). Also, though the Departments have been jointly issuing national dietary advice since 1980, NESTLE, *supra* note 14, at 46, the Food guide Pyramid was called the *USDA's* Food Guide Pyramid until 1992, *id.* at 65, and the *USDA* is solely responsible for paying travel expenses, per diems, and meeting support for all Committee members, 2010 Charter, *supra* note 12.

¹⁰³ Congress could also eliminate the USDA's other conflicting duty: to promote and protect the agricultural industry. But it would still seem inappropriate for a non-health agency to be giving health advice. Also, it may be more effective for Congress give the responsibility to a specific health agency, rather than to HHS, generally. HHS could assign its responsibility to an agency with conflicting policy objectives, insufficient expertise, or insufficient resources. Congress can obviate the problems that would create by designating a particular agency in advance.

¹⁰⁴ For example, dietary guidelines in Canada, Australia, New Zealand and Greece are created by agencies with missions to promote the health of their citizens. See, e.g., Health Canada—Food and Nutrition, <http://www.hc-sc.gc.ca/fn-an/food-guide-aliment/index-eng.php> (last visited Mar. 12, 2009) (Canada, Health Canada); Dietary Guidelines for All Australians, <http://www.nhmrc.gov.au/publications/synopses/dietsyn.htm> (last visited Mar. 12, 2009) (Australia, National Health and Medical Research Council); Food and Nutrition Guidelines, <http://www.moh.govt.nz/foodandnutrition> (last visited Mar. 12, 2009) (New Zealand, Ministry of Health); Ministry of Health and Welfare, *supra* note 50, at 516 (Greece, Ministry of Health and Social Solidarity).

disease, injury and disability, and preparedness for new health threats.”¹⁰⁵ It has done so for more than 60 years.¹⁰⁶ As a result, it already has many programs that promote and research healthy diets and lifestyle.¹⁰⁷ Thus, the CDC has the knowledge, expertise and resources to develop dietary advice, without the conflict of simultaneously promoting agricultural interests.¹⁰⁸

This is a straightforward solution: have a health agency give health advice. But even if an appropriate health agency takes over, that agency could continue to receive advice from conflicted Committee members.¹⁰⁹ Thus, the Committee must also be protected from conflicts of interest.

B. *Conflicts on the Advisory Committee*

Protecting dietary advice from conflicts of interest on the Committee is not as straightforward as with the USDA, but it can be done. This section shows why current U.S. law is inadequate and suggests one way to improve the law.

1. *Current U.S. Law*

Four existing legal frameworks theoretically could protect the Committee from conflicts of interest: i) mandatory confidential disclosures of interests, pursuant to the Ethics in Government Act of 1978 (EIGA); ii) the criminal prohibition of financial interests in 18 U.S.C. § 208; iii) ethical standards of conduct, pursuant to Executive Orders and regulations by the Office of Government Ethics (OGE); and iv) the Federal Advisory Committee Act (FACA). As each of the following sections show, these laws provide no real protection, and section v) explains why.

i. *Mandatory Confidential Disclosures Apply, but Provide no Protection on Their Own*

Committee members are considered special government employees and are required to file confidential disclosures of certain interests.¹¹⁰ These disclosures are

¹⁰⁵ About CDC, <http://www.cdc.gov/about/> (last visited Mar. 12, 2009).

¹⁰⁶ *Id.*

¹⁰⁷ These programs include the Public Health Action Plan to Prevent Heart Disease, the Skin Cancer Prevention and Education Initiative, the Division of Diabetes Translation, the Healthy Communities Program, the Behavioral Risk Factor Surveillance System, and others. See Healthy Living, <http://www.cdc.gov/HealthyLiving/> (last visited Mar. 12, 2009) (listing CDC’s health resources and programs).

¹⁰⁸ Other appropriate agencies to be in charge of dietary advice might be the National Institutes of Health (NIH) or the Office of the Surgeon General. The mission of NIH is to pursue scientific knowledge in order to “extend healthy life and reduce the burdens of illness and disability.” NIH Mission, <http://www.nih.gov/about/#mission> (last visited Mar. 12, 2009). Like the CDC, the NIH already has programs designed to promote healthy dietary and lifestyle choices in order to prevent diseases. See Disease Prevention, <http://health.nih.gov/search.asp/34> (last visited Mar. 12, 2009) (listing some sub-agencies and programs that address the prevention of cancer, heart attacks, and heart disease). The duties of the Office of the Surgeon General include “[protecting] and advanc[ing] the health of the Nation through educating the public, advocating for effective disease prevention and health promotion programs and activities, and, providing a highly recognized symbol of national commitment to protecting and improving the public’s health.” Duties of the Surgeon General, <http://www.surgeongeneral.gov/about/duties/index.html> (last visited Dec. 22, 2009).

¹⁰⁹ Alternatively, an agency like the CDC could have enough scientific and medical experts on staff that the need for an advisory committee would be reduced or even eliminated.

¹¹⁰ A special government employee includes any officer or employee of the executive branch “who is retained, designated, appointed, or employed to perform, with or without compensation, for not to exceed [130] days during any period of [365] consecutive days, temporary duties either on a full-time or intermittent basis.” Bribery, Graft, and Conflicts of Interest, 18 U.S.C. § 202(a) (West 2009). Here,

designed to elicit information needed to apply civil and criminal ethical standards.¹¹¹ While these disclosures are generally confidential,¹¹² information about a member's financial interests must sometimes be revealed.¹¹³ Specifically, if an agency grants a member a waiver for a criminal financial interest (discussed in section (ii) immediately below), this waiver must be publicly available and will include information about the member's financial interests.¹¹⁴ The waiver can then be obtained by the public via the Freedom of Information Act (FOIA).¹¹⁵ For example, PCRM successfully used FOIA to obtain a court order revealing the source of one Committee member's income.¹¹⁶ Information about other members' financial interests could similarly be revealed.

Alone, however, mandatory confidential disclosures do not protect against conflicts of interest. They do not directly bar conflicts, and the minimal threat of public disclosure is not likely to dissuade many people. But disclosures do allow other ethical standards to be applied, such as the following criminal and civil standards.

Committee members are appointed by agencies in the executive branch, *see* 5 U.S.C. § 105 (West 2009), to perform temporary duties, and they meet just five times within a year, *see supra* note 12.

The EIGA requires special government employees to make *public* disclosures only if they are paid over a certain amount. Ethics in Government Act of 1978, 5 U.S.C. app. 4 § 101(f)(3) (West 2009). Here, however, Committee members are not paid, *see supra* note 12, and thus they need not file public disclosures. The OGE still requires all special government employees in the executive branch to file *confidential* disclosures. 5 C.F.R. §§ 2634.903 (requiring "confidential filers" to make disclosures), 2634.094(a)(2) (defining "confidential filers" to include all special government employees in the executive branch) (West 2009). The OGE is authorized to require special government employees to file confidential disclosures by the EIGA. *See* 5 U.S.C. app. 4 § 107(a).

¹¹¹ 5 C.F.R. § 2634.901(b). For example, Committee members must reveal, subject to possible exceptions, the source of all noninvestment, § 2634.907(b), and investment, § 2634.907(c)(2), income over \$200, all real and personal property valued over \$1,000, § 2634.907(c)(1), all liabilities over \$10,000, § 2634.907(d), and all positions held with non-federal organizations, § 2634.907(e). A Committee member who fails to file or files a false report could be subject to both criminal and civil penalties. 5 U.S.C. app. 4 § 104. The head of each agency is responsible for the day-to-day compliance with ethical requirements, not the OGE. Office of Government Ethics—Agency Ethics Program Administration, http://www.usoge.gov/about/agency_ethics_program_administration.aspx (last visited Dec. 23, 2009). However, each agency appoints a Designated Agency Ethics Official, with whom the OGE communicates regarding the agency's compliance and changes in the law. *Id.*

¹¹² Section 107 of the EIGA exempts confidential disclosures from public reporting requirements, 5 U.S.C. app. 4 § 107(a)(1), states that they shall be confidential and not disclosed to the public, § 107(a)(2), and states that these provisions supersede any general reporting requirements in other conflict of interest laws, § 107(b). Also, the OGE interprets section 107 to require confidential disclosures to be withheld from the public and states that agencies have "no discretion" to decide otherwise. 5 C.F.R. § 2634.901(d). Further, at least three exceptions to the FOIA protect information. *Id.* (FOIA exemptions 3, 4, and 6 apply and will protect "sensitive commercial and financial information").

¹¹³ The OGE recognizes that an agency must reveal confidential information if ordered by a federal court. 5 C.F.R. § 2634.901(d).

¹¹⁴ Bribery, Graft, and Conflicts of Interest, 18 U.S.C. § 208(d)(1) (West 2009).

¹¹⁵ *Id.* However, the agency need not reveal everything; it may withhold from disclosure information falling under a FOIA exemption. *Id.* Further, "the information describing each financial interest shall be no more extensive than that required of the individual in his or her financial disclosure report under the [EIGA] of 1978." *Id.*

¹¹⁶ *Physicians Comm. for Responsible Med. v. Glickman*, 117 F.Supp.2d 1, 5-6 (D.C. Cir. 2000). The USDA argued the information was exempt under FOIA exemption 6, which exempts certain files "the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6). The court found the member's minimal privacy interest in the income's source was outweighed by the public's interest in "learning whether a Committee member was financially beholden to a person or entity that had an interest in how the [Guidelines] might be amended." *Glickman*, 117 F.Supp.2d at 6.

ii. *The Criminal Prohibition in 18 U.S.C. § 208 Does not Apply*

Section 208(a) of title 18 of the U.S. Code prohibits a special government employee from “personally and substantially” participating in a proceeding by giving advice or recommendations, if he/she knows that he/she or certain persons or organizations he/she is affiliated with has a “financial interest” in that proceeding.¹¹⁷ A financial interest is prohibited if the proceeding would have a direct and predictable effect on it.¹¹⁸ An effect is direct if there is a close causal link between the proceeding and the interest.¹¹⁹ An effect is predictable if there is a real, not merely speculative, possibility that the proceeding will affect the interest.¹²⁰

Here, there are no prohibited financial interests. The effects of the Advisory Committee’s proceedings on a Committee member’s financial interests are neither direct nor predictable. They are indirect, as companies independently choose whether to give a member a financial benefit, and they are unpredictable, as there is no certainty that will occur. However, members can also violate the law through their affiliation with organizations that have financial interests in the Committee’s proceedings.¹²¹ The Committee’s effects on these interests are also not direct. Any effect on these companies’ profits depends entirely upon independent events: the Guidelines following the Committee’s advice, and consumers following the Guidelines’ advice.¹²²

Further, even if there were a prohibited financial interest, the Secretaries could easily waive it if they determine it is “not so substantial as to be deemed likely to affect the integrity of the [employee’s] services,”¹²³ or if they certify in writing “that the need for the individual’s services outweighs the potential for a conflict of interest created by the financial interest.”¹²⁴ As a result of these waivers, the criminal statute is a minimal threat.¹²⁵

¹¹⁷ 18 U.S.C. § 208(a).

¹¹⁸ 5 C.F.R. § 2640.103(a). *See also* 5 C.F.R. § 2635.402 (also requiring and defining direct and predictable financial interests for section 208 violations); Keith R. Szeliga, *Watch Your Step: A Contractor’s Guide to Revolving-Door Restrictions*, 36 PUB. CONT. L.J. 519, 527-529 (2007) (arguing that both courts and OGE regulations require there to be a direct causal link between a particular matter and a financial interest).

¹¹⁹ 5 C.F.R. § 2640.103(a)(3)(i).

¹²⁰ § 2640.103(a)(3)(ii).

¹²¹ 18 U.S.C. § 298(a) (imputing to a person the financial interests of any “organization in which he is serving as officer, director, trustee, general partner, or employee, or any person or organization with whom he is negotiating or has any arrangement concerning prospective employment”).

¹²² Also, a proceeding that affects a financial interest “only as a consequence of its effects on the general economy does not have a direct effect.” 5 C.F.R. § 2640.103(a)(3)(i). Ultimately, the companies could only be affected because of changes in consumer spending, which may be an “effect on the general economy.”

¹²³ 18 U.S.C. § 208(b)(1). *See also* 5 C.F.R. § 2640.301(b) (identifying eight factors to determine the substantiality of a prohibited interest). Waiver on either ground likely requires the assent of both Secretaries, rather than merely one or the other, since the waiver must come from the “[g]overnment official responsible for [the employee’s] appointment,” which is technically both Secretaries, as both are responsible for the Guidelines and forming the Committee. *See* 18 U.S.C. §§ 208(b)(1), 208(b)(3).

¹²⁴ 18 U.S.C. § 208(b)(3). *See also* 5 C.F.R. § 2640.302(b) (identifying seven factors to apply when performing the balancing test). In addition to the two exceptions listed here, a third exception applies to financial interests based solely on non-Federal current or prospective employment, provided that “the matter will not have a special or distinct effect on the employee or employer other than as part of a class.” 5 C.F.R. § 2640.203(g) (one of many exemptions that the OGE was authorized to create by 18 U.S.C. § 208(b)(2)). This could exempt certain positions with industry groups during and after service on the Committee.

¹²⁵ Note that although the members’ financial interests almost certainly do not violate the criminal statute, *see supra* notes 122-123 and accompanying text, the Secretaries still granted waivers for many of them. It is likely that the Committee members are insisting on waivers, as they are not willing to take the chance of committing a crime. This has the side effect of making their financial information subject to public disclosure under FOIA. *See supra* notes 114-117 and accompanying text (discussing how this information can be obtained); *see also infra* Table 2 (identifying industry ties of Committee members revealed through FOIA requests).

Thus, the criminal statute does not protect the Advisory Committee from its apparent conflicts. However, ethical standards of conduct not subject to criminal penalties also govern members of the Committee and could provide some protection.

iii. *Ethical Standards of Conduct Are Inapplicable or Irrelevant*

Executive Order 12,731 authorizes the OGE to establish ethical standards for the executive branch.¹²⁶ One standard that could provide some protection bars special government employees from using public office for the private gain of persons, including organizations which the employee is an officer or member of, as well as persons with whom the employee has or seeks employment or business relations.¹²⁷ Here, committee members would violate the law if they used their positions to benefit themselves or their affiliated companies.

However, this standard provides no protection for two reasons. First, a violation would be virtually impossible to prove. So long as members support their recommendations with scientific evidence, it will appear they were motivated by their duty to the Committee and to science, not by a desire for personal or corporate gain.¹²⁸ Second, this standard cannot effectively prevent conflicts from influencing government action, as it actually permits the conflicted member to appear on the Committee; it only bars one particular manifestation of that conflict after his or her appointment. Instead, a preferable ethical standard would prevent individuals with conflicts from ever serving on the Committee.

Remaining standards are all inapplicable or irrelevant. For example, standards governing apparent conflicts only apply to matters involving specific parties, such as, for example, the manufacturer of a particular drug, but the Committee only deals with broad dietary policy, not particular companies.¹²⁹ The bar on accepting gifts from "prohibited sources," given because of the special government employee's official position, is also inapplicable, as it is unlikely any member receives funding or positions from industry sources just because they will appear or have appeared on the Committee.¹³⁰ The standard barring certain employment relationships is inapplicable because it requires a direct and predictable effect on a Committee

¹²⁶ Exec. Order No. 12,731, 55 Fed. Reg. 42,547, 42,548 (Oct. 17, 1990) (section 201(a); modifying Exec. Order No. 12,674, 54 Fed. Reg. 15,159 (Apr. 12, 1989)).

¹²⁷ 5 C.F.R. § 2635.702 (this section then specifies prohibitions, but "[t]he specific prohibitions set forth in paragraphs (a) through (d) ... are not intended to be exclusive or to limit the application of this section").

¹²⁸ However, the failure to provide any scientific evidence supporting the recommendation to eat meat provides some evidence that Committee members are working to promote other interests. *See supra* notes 96-97 and accompanying text.

¹²⁹ For example, an apparent conflict would exist when a matter involving specific parties has a direct and predictable effect on a household member's financial interest, § 2635.502(a), or when a former employer is a party in the matter, and the special government employee received an "extraordinary payment" from the former employer within the last two years, § 2635.503(a).

¹³⁰ § 2635.202(a). Grants and positions are likely gifts. Gifts include most things of monetary value, including things provided in-kind, services, reimbursements, and other items, § 2635.203(b). Grants clearly have monetary value. Positions also likely have monetary value, unless the companies or organizations provide no compensation or reimbursement of any kind. Further, the definition of gift does not exclude those things provided as compensation for services rendered. *See id.* Also, food and drug companies and associations are likely prohibited sources. Prohibited sources include organizations "regulated by the employee's agency," § 2635.203(d)(3), which would include food and drug companies, as they are regulated by the USDA and/or HHS. However, a gift is given because of an official position only if it would not have been given had the person not held the official position. § 2635.203(e). It is possible that Committee members received positions and grants because of their service on the Committee. Even if true, however, this would be virtually impossible to prove. Committee members most likely receive their grants and positions because of their scientific expertise, not because they served on the Committee. Further, there are many exceptions that Committee members could rely upon. *See* § 2635.204.

member's current or prospective employer, which, as discussed above, is not likely true here.¹³¹ Finally, a bar against certain financial interests would only prevent a Committee member from *currently* having a position with the industry; it would not bar past employment or positions.¹³² Other standards are irrelevant, as they would not protect the Committee from conflicts, even if they applied.¹³³ The USDA and HHS have also issued their own ethical regulations, none of which provide any additional protection beyond the OGE's regulations.¹³⁴ Thus, ethical standards similarly do not protect U.S. dietary advice from conflicts on the Advisory Committee. However, FACA could protect against conflicts on the Committee as a whole.

iv. *FACA Could Provide Some Protection, but it is Imprecise*

FACA is a default statute for federal advisory committees.¹³⁵ It imposes two relevant requirements on a committee's composition: a "fair balance" requirement in section 5(b)(2) and an "appropriate provisions" requirement in section 5(b)(3).¹³⁶ The Secretaries have not likely violated the former, but possibly the latter.

The fair balance provision requires a committee's membership to be "fairly balanced in terms of the points of view represented and the functions to be performed."¹³⁷ One court held that a committee can be unfairly balanced only if a group that should be represented is not,¹³⁸ but even if a group is unrepresented, committees that require scientific and technical expertise can exclude those who

¹³¹ See 5 C.F.R. §§ 2635.604(a) (prospective employers), 2635.606(a) (current employers).

¹³² Prohibited financial interests include "service, with or without compensation, as an officer, director, trustee, general partner or employee of any person, including a nonprofit entity." § 2635.403(c)(2). Here, several Committee members served on the board of trustees of industry-sponsored organizations before they were on the Committee. Even if these were prohibited financial interests, the member need only divest the interest within a reasonable period of time. § 2635.403(d).

¹³³ These irrelevant standards include, for example: the bar on financial transactions using non-public information, 5 C.F.R. § 2635.703(a); the bar on the unauthorized use of government property, § 2635.704(a); the requirement that employees expend "honest effort" when performing official duties, § 2635.705(a); and the bar on certain teaching, speaking, and writing activities, § 2635.807(a).

¹³⁴ Agencies are authorized to supplement OGE regulations. § 2635.105. None of the USDA's supplemental regulations apply to special government employees on the Committee, see Supplemental Standards of Ethical Conduct for Employees of the Department of Agriculture, 5 C.F.R. §§ 8301.101-106 (West 2009) (expressly inapplicable to special government employees and/or apply only to specific sub-agencies), and the only supplemental regulation by HHS that applies to special government employees merely expands an exception from conflicts due to teaching, speaking, and writing activities, see Supplemental Standards of Ethical Conduct for Employees of the Department of Health and Human Services, 5 C.F.R. § 5501.107 (West 2009).

¹³⁵ Federal Advisory Committee Act, 5 U.S.C. app. 2 § 4(a) (West 2009) (FACA applies unless another statute specifically provides otherwise).

¹³⁶ The requirements in section 5(b) apply to agency heads creating advisory committees, per section 5(c), which states that "[t]o the extent they are applicable, the guidelines set out in subsection (b) of this section shall be followed by the President, agency heads, or other Federal officials in creating an advisory committee." It has previously been argued that the Departments violated these requirements. In its lawsuit against the Secretaries, PCRM originally alleged section 5(b) was violated. Physicians Comm. for Responsible Med. v. Glickman, 117 F.Supp.2d 1, 3 (D.C. Cir. 2000). In 2003, the Center for Science in the Public Interest (CSPI) told the Secretary of HHS it did not believe the 2005 Committee was meeting FACA's requirements to be "'fairly balanced,' 'impartial,' and free of inappropriate influences of 'any special interest,'" due to conflicts of interest. Letter from Michael F. Jacobson, Executive Director, CSPI, to Tommy Thompson, Secretary, HHS (Aug. 19, 2003), available at <http://cspinet.org/new/pdf/dietaryguidelinethompsonletter.pdf>.

¹³⁷ 5 U.S.C. app. 2 § 5(b)(2).

¹³⁸ See e.g., Pub. Citizen v. Nat'l Advisory Comm. on Microbiological Criteria for Foods, 886 F.2d 419, 423 (D.C. Cir. 1989) (the "legislative history makes clear, [that] the 'fairly balanced' requirement was designed to ensure that persons or groups directly affected by the work of a particular advisory committee would have some representation on the committee") (citing Nat'l Anti-Hunger Coalition v. Exec. Comm. of the President's Private Sector Survey on Cost Control, 711 F.2d 1071, 1074 n.2 (D.C. Cir. 1983)).

lack that expertise.¹³⁹ Here, though the Advisory Committee may lack the viewpoints of enrollees in federal programs directly affected by the Guidelines,¹⁴⁰ these enrollees do not likely have the necessary expertise, as Committee members must be able to analyze scientific and medical research.¹⁴¹ Further, any harm to enrollees is somewhat mitigated, as they can express their views to the Committee through public comments.¹⁴²

FACA also requires “appropriate provisions to assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee’s independent judgment.”¹⁴³ Courts have interpreted 5(b)(3) in two ways, and a violation is possible under either.

The first interpretation requires a court to determine whether the “provisions” that apply to the advisory committee (e.g., laws, rules and internal policies) appropriately safeguard it from the risk of inappropriate influence.¹⁴⁴ Here, there is a risk the Committee will be inappropriately influenced by the food and drug industries. It appears the “provisions” applicable to the Committee are the bare minimum, as required by the ethical standards described in sections i) through iii) above.¹⁴⁵ The Departments would argue that these are sufficient to safeguard the Committee from any risks, yet the above analyses suggest those laws are inadequate to protect the Committee from many apparent conflicts. Thus, a violation is possible.

The second interpretation is really a misinterpretation. It views section 5(b)(3) as a prohibition of inappropriate influences and requires a court to determine if the advisory committee is *actually* inappropriately influenced.¹⁴⁶ This is a misinterpretation because section 5(b)(3) does not *prohibit* anything, but rather imposes an *affirmative duty* on the government body forming the committee to have appropriate safeguards against such influence.¹⁴⁷ The actual presence of an inappropriate influence is relevant but not dispositive of whether this duty has been breached.

¹³⁹ *Nat’l Advisory Comm. on Microbiological Criteria for Foods*, 886 F.2d at 423 (“Since the Committee’s function in this case involves highly technical and scientific studies and recommendations, a ‘fair balance’ of viewpoints can be achieved even though the Committee does not have any members who are consumer advocates or proponents of consumer interests”). See also *id.* at 424 (“The determination of ... ‘fairly balanced’ necessarily lies largely within the discretion of the official who appoints the committee”); Federal Advisory Committee Management, 41 C.F.R. § 102-3.64(c) (West 2009) (“Advisory committees requiring technical expertise should include persons with demonstrated professional or personal qualifications and experience relevant to the functions and tasks to be performed”).

¹⁴⁰ PCRM made this argument in its complaint, but later voluntarily dismissed it. Schaffer, *supra* note 69, at 373-374.

¹⁴¹ 2010 Charter, *supra* note 12, at Officers and Membership, Duties.

¹⁴² See Dietary Guidelines for Americans: Providing Comments to the Committee, <http://www.cnpp.usda.gov/dietaryguidelines.htm> (follow hyperlink “SUBMIT Comments” to submit a comment, or follow hyperlink “VIEW Comments” to view current comments) (last visited Mar. 13, 2009).

¹⁴³ 5 U.S.C. app. 2 § 5(b)(3). The purpose of this requirement is to prevent special interests from unduly influencing committees. *Nat’l Advisory Comm. on Microbiological Criteria for Foods*, 886 F.2d at 425.

¹⁴⁴ See *Cargill, Inc. v. U.S.*, 173 F.3d 323, 338-339 (5th Cir. 1999) (analyzing whether the National Institute for Occupational Safety and Health and the HHS violated FACA by not safeguarding an advisory committee from the risk of inappropriate influence by those two government agencies); but see also *id.* at 339 (affirming the lower court’s finding that section 5(b)(3) was not violated because the interests on the committee were “not strong enough to cause [the Board of Scientific Counselors] to be inappropriately influenced,” suggesting that the court was actually ruling under the second interpretation).

¹⁴⁵ See The USDA Office of Ethics—An Ethics Guide for Special Government Employees of the U.S. Department of Agriculture, <http://www.usda-ethics.net/rules/rule21.htm> (last visited July 26, 2009) (describing the standards applicable to special government employees at the USDA).

¹⁴⁶ See, e.g., *Colo. Envtl. Coalition v. Wenker*, 353 F.3d 1221, 1231-32 (10th Cir. 2004) (“The question is, what does § 5(b)(1)-(3) mean when it prohibits only ‘inappropriate’ influence?”).

¹⁴⁷ See *Cargill*, 173 F.3d at 338-339 (interpreting section 5(b)(3) as imposing a duty to safeguard an advisory committee). This misinterpretation can explain why some courts have found claims under section 5(b)(3) not justiciable. See, e.g., *Wenker*, 353 F.3d at 1231-1232 (“But whether Congress intended that kind of hypothetical future influence to be inappropriate, and hence illegal under § 5(b)(3), is

Even under this standard, a violation is possible. One court held that a majority presence by the food industry, on a committee dealing with food regulations, is not an inappropriate influence so long as the committee legitimately requires industry input.¹⁴⁸ Further, the court held that committee members with academic affiliations can have industry ties so long as they have not overtly acted improperly.¹⁴⁹ Here, however, the Committee does not require industry input, as the Committee's recommendations must be based only on the preponderance of the science.¹⁵⁰ Yet a court could also find that the experts here are not an inappropriate influence because they all have academic affiliations and have not overtly acted improperly. Further, it does not appear that the Departments have inappropriately influenced the Committee, other than choosing its members.

v. *Why Current U.S. Law is Inadequate*

Out of the four legal frameworks, none clearly protects the Advisory Committee from conflicts of interest. There are at least two reasons why. First, U.S. law is focused on current interests and relationships and fails to adequately recognize that a person's past can create conflicts of interest just as likely to corrupt official actions. Second, in an effort to be specific, U.S. law ends up incomplete. It tries to specify in great detail every type of prohibited conflict, and in so doing, it effectively permits all of those it fails to specify.

The gaps created by these legal shortcomings are especially problematic on an advisory committee that deals with complex scientific issues. When a committee deals with science, its members need not openly act improperly to influence the proceedings. Rather, they can selectively rely or not rely on particular science in order to justify an outcome they have predetermined. It would be difficult to discover if anything improper has taken place. That is why it is important individuals with these conflicts never serve on an advisory committee in the first place. The next section discusses how the United States can address its shortcomings.

2. *Suggestions to Protect the Advisory Committee from Conflicts*

The following suggestion has three parts: i) a prohibition; ii) a presumption and a rebuttal; and iii) an exceptions process.

i. *A Prohibition*

To prevent having Committee members with conflicts of interest, U.S. law should at least address its two main shortcomings. This means it should be able to prohibit conflicts based on past relationships, and it should be capable of barring any

something as to which we have absolutely no guidance, guidelines or standards from Congress. Thus, we hold that plaintiffs' claim under § 5(b)(3) is not justiciable." These courts hold that Congress provided no standards for determining whether an influence is "inappropriate." Under a correct interpretation of the requirement imposed by section 5(b)(3), however, a court need not have such standards.

¹⁴⁸ Pub. Citizen v. Nat'l Advisory Comm. on Microbiological Criteria for Foods, 886 F.2d 419, 425-426 (D.C. Cir. 1989). That case dealt with a challenge to a federal advisory committee formed to "provide advice and recommendations to the Secretaries of Agriculture and Health and Human Services ... on the development of microbiological criteria by which the safety and wholesomeness of food could be assessed." *Id.* at 420. Given that the same agencies were involved, and the issue also involved national food policy, this case would likely be highly influential.

¹⁴⁹ *Id.* at 425-426.

¹⁵⁰ See National Nutrition Monitoring and Related Research Act of 1990, 7 U.S.C. § 5341(a) (West 2009) (requiring guidelines and information based on the preponderance of current scientific and medical knowledge).

conflict. Canada uses a standard that achieves both of these goals. Health Canada prohibits real, potential and apparent conflicts of interest that exist before or during an advisory committee member's service.¹⁵¹ An apparent conflict exists when "a well-informed member of the public might have reasonable grounds for concern that the conduct of government is influenced by illegitimate considerations."¹⁵²

If Canada's prohibition applied, many members of the Advisory Committee would seem to have prohibited conflicts. A well-informed member of the American public might reasonably fear that scientists with numerous and substantial ties to food and drug companies may be unwilling to recommend changes in U.S. dietary advice that would damage those ties. Even if those industry ties are all in the past, scientists can have serious conflicts and biases.¹⁵³ The fear of illegitimate considerations influencing the Committee is not only reasonable, it is supported by the Guidelines' underperformance and inconsistency with current science. This is also a flexible standard. Not every past relationship with affected industries will create an apparent conflict of interest. For example, some scientists may have received funding from drug companies with little to no stake in preventing or treating chronic diseases, and only for the purpose of conducting research unrelated to diet, lifestyle, and the prevention of chronic diseases. Similarly, some members' ties may be so minor, so common in the scientific community or have occurred so long ago that it would be unreasonable to expect these ties to affect the members' official actions.

A neutral third party should be in charge of determining whether an apparent conflict exists. The OGE—an independent executive agency whose mission is to prevent and resolve conflicts of interest—is an appropriate choice.¹⁵⁴ An agency should not be the judge in its own cause. Also, this standard would require more extensive disclosures to the OGE of the nominee's industry ties and other relationships, beyond the very specific types of disclosures currently required.¹⁵⁵

However, many if not most members of an advisory committee would have prohibited conflicts under this standard. That is the idea. Congress needs to err on the side most protective of the integrity of national public policy. Plus, as shown below, the existence of a prohibited conflict is not an absolute bar to membership: the individual can still be appointed if the agency shows it cannot do any better (i.e., there are no alternative candidates with no less significant conflicts and equal or better qualifications).

ii. *A Presumption and a Rebuttal*

A prohibition is meaningless if it can be easily avoided by the nominating agency or the reviewing agency. That might happen, for instance, if the administration decided it did not want the standard to get in the way of its policy goals, or if the agencies wanted to spend their resources fighting other battles. A presumption would help by requiring certain procedural and evidentiary burdens to be met before certain people could be appointed to an advisory committee. The presumption should single out the candidates who pose the most harm because of their past relationships, as well as the tendency for their conflicts to be overlooked by the government.

An appropriate presumption here might state that a nominee is presumed to have an apparent conflict of interest if he/she has or has had a substantial relationship with a person who has an interest in the activities of the advisory committee to which he/she is nominated for. A "person" would include individuals as well as

¹⁵¹ Health Canada Policy on Conflict of Interest: Policy Objective, <http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/sci-consult/implant-breast-mammaire/confli-eng.php> (last visited Feb. 10, 2009).

¹⁵² *Id.*

¹⁵³ See discussion *supra* Section III.B. (listing reasons past relationships can create conflicts).

¹⁵⁴ Office of Government Ethics—Background and Mission, http://www.usoge.gov/about/background_mission.aspx (last visited Aug. 25, 2009).

¹⁵⁵ See, e.g., *supra* note 111.

any organization, whether for-profit or nonprofit.¹⁵⁶ A “substantial relationship” would include being employed by, being a consultant to, owning stock or other interests in, receiving research funding from, or receiving any other income from an interested person or other entity, regardless of the amount. A person would “have an interest” if he/she engages in business or advocacy substantially related to, or is otherwise reasonably likely to be directly or indirectly affected by, the activities of the advisory committee. This presumption would automatically recognize apparent conflicts of interest held by Committee members who have served the food and drug industries in the past.

If the presumption applied, it would have to be rebutted in order for the nominee to sit on the advisory committee. There are four important parts to the rebuttal: 1) who has the burden of rebuttal; 2) what must be proved; 3) the quantum of evidence; and 4) who makes the final decision.

First, the agency or agencies seeking to appoint the nominee should have the burden. They should have to weigh the costs of rebuttal when deciding whether to further pursue the nomination. Second, they should have to prove that, in light of all the relevant information about the nominee, her relationships are so insignificant, or her other work or activities are so contrary to the conflict presumed by those relationships, that no well-informed person could reasonably fear the nominee might act based on illegitimate considerations. Third, the basic evidentiary standard should be a preponderance of the evidence, but the decisionmaker should have the freedom to apply a higher standard—e.g., clear and convincing evidence—when the likelihood of illegitimate considerations are particularly high, or when the harm that would occur if the risk materialized is particularly great. Finally, as above, a neutral and impartial decisionmaker should make the final decision. The presumption would be worthless if the agency pursuing the nomination merely had to convince *itself* that it was rebutted, as the agency would be tempted to shortcut the law. That temptation must be countered by relying on a decisionmaker not personally invested in the nomination. Again, an appropriate agency is the OGE.

iii. *An Exceptions Process*

If qualified nominees without apparent conflicts could not be found, the government would be deprived of outside expert advice completely. To prevent this, there must be an exceptions process to allow members with conflicts to serve on a committee, but it must be strictly limited to prevent abuse.¹⁵⁷ Thus, for the exception to

¹⁵⁶ Other entities could also include entities that no longer exist, but would have an interest if they still existed. That way, for example, if a person worked for a company that dissolved or became a new company before the advisory committee was formed, the presumption of an apparent conflict could still apply to that person's nomination, based on employment by the former company.

¹⁵⁷ Even if a person with a conflict survives the exceptions process, his or her participation on the Committee could be limited (or “managed”) in other ways. The literature on managing conflicts generally addresses researchers who are conducting clinical trials, as opposed to experts on advisory committees who are merely reviewing existing studies on behalf of another entity. See, e.g., Elizabeth A. Boyd et al., *Implementation of Financial Disclosure Policies to Manage Conflicts of Interest*, 23 HEALTH AFF. 206 (2004) (describing differences and similarities in conflict of interest policies among seven University of California campuses); Mildred K. Cho et al., *Policies on Faculty Conflicts of Interest at US Universities*, 284 JAMA 2203 (2000) (describing the differences and similarities among conflict of interest policies among 100 research institutions nationwide); Jesse A. Goldner, *Regulating Conflicts of Interest in Research: The Paper Tiger Needs a Real Teeth*, 53 ST. LOUIS L.J. 1211 (2009); Karine Morin et al., *Managing Conflicts of Interest in the Conduct of Clinical Trials*, 287 JAMA 78 (2002) (discussing how to preserve the integrity of clinical trials); and MARC A. RODWIN, *MEDICINE, MONEY, AND MORALS: PHYSICIANS' CONFLICTS OF INTERESTS* (1993) (discussing the history, prevalence, and management of physician conflicts). But participation could be limited on advisory committees, for example, by requiring the conflicts of interest to be disclosed to other committee members, or by imposing a very limited role in the initial selection and review of scientific studies, provided that there are enough other members to adequately complete the other work.

apply, the agency or agencies pursuing the nomination should have to prove to the OGE that, after a reasonably thorough search under the circumstances, alternative committee candidates with equal or greater qualifications, with fewer or no conflicts, and willing and able to serve on the advisory committee, could not be found.

Reasonably thorough searches would likely turn up Committee candidates who are equally- or better-qualified with no or fewer conflicts of interest. For example, the Food and Drug Administration (FDA) authorized a study analyzing whether an advisory committee reporting to the Center for Drug Evaluation and Research (CDER) could theoretically have members without any conflicts requiring waivers.¹⁵⁸ There were 17 members with conflicts requiring waivers on the actual committee.¹⁵⁹ It took researchers 88 hours¹⁶⁰ to identify 30 alternative candidates with equal or greater experience and no conflicts.¹⁶¹ In other words, with a bit more work, FDA could have had a conflict-free committee. The Advisory Committee could similarly find alternative candidates. Like experts dealing with pharmaceutical drugs, there are nutritional experts with no ties to industry. Even the Secretaries were able to find a conflict-free majority in 1995, when eight out of 11 Committee members had no industry ties.¹⁶²

It is possible that most or all of the Committee members would have to go through the exceptions process just for the Committee to form. There is nothing wrong with that. If the government wants to appoint a person with a conflict, it should have to show it cannot do any better. Anything less is a license for government agencies and industry interests to manipulate public policy through advisory committee appointments. The exceptions process would add transparency and accountability to the system and may reveal that federal committees are subject to far too many outside influences and biases than are reasonably necessary.

V. CONCLUSIONS

There is a global pandemic of chronic diseases that is only getting worse. The government can help reduce this burden by educating the public about how to reduce or eliminate the risk of developing chronic diseases through diet and lifestyle. The Dietary Guidelines for Americans, however, significantly underperform when it comes to preventing chronic diseases, though other diets—principally the Mediterranean diet and also Harvard's Alternate Index—perform much better, likely because they are more consistent with current scientific and medical knowledge. The United States thus has a great opportunity to help save lives by improving its dietary advice. To help take advantage of this opportunity, Congress should eliminate conflicts of interest in those who create the advice. This would involve two changes: 1) placing an appropriate health agency in charge of dietary advice, not the USDA; and 2) applying a new standard of apparent conflicts of interest to advisory committee members.

However, management of conflicts should not be the *initial* remedy in place of prohibition, for at least two reasons. First, these experts are far more fungible. Federal advisory committees have a national selection of experts from which to find adequate replacements. If they can be replaced, they should be. Second, these conflicts should be less tolerated given that the work of these advisory committees will have national policy implications. Of course, if the relationship giving rise to an apparent conflict is current, it should have to be ended before the member could serve on the Committee, even in a limited role.

¹⁵⁸ U.S. FOOD & DRUG ADMIN., MEASURING CONFLICTS OF INTEREST AND EXPERTISE ON FDA ADVISORY COMMITTEES 7-1 (2007), available at <http://www.fda.gov/oc/advisory/ERGCORreport.pdf>.

¹⁵⁹ *Id.*

¹⁶⁰ *Id.* at 7-4.

¹⁶¹ *Id.* at 7-8. The study also predicted that "some" of the 30 candidates identified might actually have conflicts requiring waivers. *Id.* at 7-9.

¹⁶² See *supra* note 79 and accompanying text.

APPENDIX

Table 1: Potential Conflicts of Interest on the 1995 Advisory Committee

MEMBER	RELATIONSHIPS WITH INDUSTRY
1. Doris Howes Calloway, Ph.D. (Chair)	Before, during, and after 1995: None.
2. Richard J. Havel, M.D. (Vice-Chair)	Before, during, and after 1995: None.
3. Dennis M. Bier, M.D.	1995 or earlier: None. After 1995: 2005 study funded in part by Mars, Inc. and International Life Sciences Institute (ILSI) (an industry-sponsored research organization). 2003 study also funded in part by Mars, Inc. In 2005, served on advisory board of Shaping America's Youth, funded by Campbell Soup, and McNeil Nutritionals (a Johnson and Johnson company). Chairman of the Kellogg Grain Nutrition Board. Consulted for virtually every major food company. Member of the McDonald's Corp.'s Global Advisory Council on Healthy Lifestyles.
4. William H. Dietz, M.D., Ph.D.	1995 or earlier: None. After 1995: In 2005, serves on Shaping America's Youth, funded by Campbell Soup and McNeil Nutritionals (a Johnson and Johnson company). Consultant to Roche Laboratories and Knoll Pharmaceuticals. In 1997, member of Knoll Pharmaceutical's Weight Risk Investigation Study Council.
5. Cuberto Garza, M.D., Ph.D.	1995 or earlier: In 1987, was a visiting professor with the National Dairy Council. In 1995, organized a research symposium funded by Mead John Nutritionals, a division of Bristol-Myers Squibb. After 1995: In 1996, organized a symposium funded by Nestle. (<i>PCRM v. Glickman</i>) In 1998, he was Vice-President and on the board of directors of the Dannon Institute. Co-authored 2002 article funded in part by the Nestle Foundation. In 2005, member of ILSI's Board of Trustees.
6. Shiriki K. Kumanyika, Ph.D.	1995 or earlier: None. After 1995: In 2008, served as advisory board member for Weight Watchers International.
7. Marion Nestle, Ph.D., M.P.H.	Before, during, and after 1995: None.
8. Irwin H. Rosenberg, M.D.	1995 or earlier: None. After 1995: Current Senior Scientist and Director, Nutrition and Neurocognition Laboratory, Jean Mayer USDA Human Nutrition Research Center on Aging, Tufts University. In 2004, listed as serving on Coca-Cola's Beverage Institute for Health and Wellness.
9. Sachiko T. St. Jeor, R.D., Ph.D.	Before, during, and after 1995: None.
10. Barbara O. Schneeman, Ph.D.	1995 or earlier: In 1989, ILSI public member, Board of Trustees. Authored or co-authored papers funded in part by grants from the National Dairy Board (1989), the California Prune Board (1990 and 1994), the National Dairy Promotion Board (1992), Kraft-General Foods (1993), and Ross Laboratories (1994). After 1995: In 1998, listed as President and member of Board of Directors of Dannon Institute. In 1999, listed as member of ACSH-Advisory Board.
11. John W. Suttie, Ph.D.	1995 or earlier: Consulted for Procter & Gamble on olestra. Wrote letter to FDA on olestra labeling. Presented at the FDA Food Advisory Committee meeting on olestra in Nov. 1995. After 1995: Co-editor of the Procter & Gamble-sponsored Aug. 1997 supplement to J. Nutr. Receives research support from Roche for studies that would help define a dietary requirement for vitamin K.

Sources:

Center for Science in the Public Interest, The Integrity in Science Database, <http://www.cspinet.org/integrity/> (last visited Feb. 21, 2009); DEP'T OF HEALTH & HUMAN SERVS. & U.S. DEP'T OF AGRIC., REPORT OF THE DIETARY GUIDELINES ADVISORY COMMITTEE ON THE DIETARY GUIDELINES FOR AMERICANS, 1995 3-4 (1995), available at <http://www.cnpp.usda.gov/Publications/DietaryGuidelines/1995/1995DGCommitteeReport.pdf> (1995 membership).

Key:

Information for a member following “(*PCRM v. Glickman*)” was revealed only as a result of PCRM’s public information requests and its subsequent lawsuit in *Physicians Comm. for Responsible Med. v. Glickman*, 117 F.Supp.2d 1 (D.C. Cir. 2000).

TABLE 2: Potential Conflicts of Interest on the 2000 Advisory Committee

MEMBER	RELATIONSHIPS WITH INDUSTRY
1. Cutberto Garza, M.D., Ph.D. (Chair)	<p>2000 or earlier: In 1987, was a visiting professor with the National Dairy Council.</p> <p>(<i>PCRM v. Glickman</i>)</p> <p>In 1995, organized a research symposium funded by Mead John Nutritionals, a division of Bristol-Myers Squibb. In 1996, , organized a symposium funded by Nestle. In 1998, he was Vice-President and on the board of directors of the Dannon Institute.</p> <p>After 2000: Co-authored 2002 article funded in part by the Nestle Foundation. In 2005, member of ILSI’s Board of Trustees.</p>
2. Suzanne P. Murphy, Ph.D., R.D. (Vice-Chair)	<p>2000 or earlier: None.</p> <p>After 2000: Received funding from ILSI for a 2003 study on sugar intake.</p>
3. Richard J. Deckelbaum, M.D.	<p>2000 or earlier:</p> <p>(<i>PCRM v. Glickman</i>)</p> <p>Invited lecturer at the Nestle Research Center from 1986-98. Received research grants from the National Dairy Promotion and Research Board (1989-92). Published an invited paper as part of a Nestle Nutrition Workshop Series in 1992. Served as chairman of the board of trustees for the SlimFast Nutrition Institute (1997-Present). Received grant support from the National Live Stock and Meat Board from 1994-95 (now the National Cattlemen’s Beef Association). Received grant from Bristol-Myers Squibb/Mead Johnson in 1998-99. Received a \$500,000 grant from Mead Johnson (date unknown).</p> <p>After 2000: Served as chairman of the board of trustees for the SlimFast Nutrition Institute (1997-Present).</p>
4. Johanna Dwyer, D.Sc., R.D.	<p>2000 or earlier: Edited and reviewed papers on olestra for Procter & Gamble in 1995 or earlier. Co-authored a paper in Procter & Gamble’s 1997 supplement to the J. Nutr. Worked for Procter & Gamble as the company’s Duncan Hines “brand girl” and then as its Crisco brand girl, testing the products in 1990 or earlier.</p> <p>(<i>PCRM v. Glickman</i>)</p> <p>Served on the grant review committee for the American Meat Institute from 1990-93.</p> <p>Served on the scientific advisory board for the National Dairy Promotion and Research Board from 1990-93. Participated in a visiting professorship program sponsored by the National Dairy Council from 1990-95. Co-authored an “Expert Panel Report” on olestra for Procter & Gamble in Aug. 1999, and on mycoprotein (main ingredient Quorn) for Marlow Foods in 1998. Received \$150,000 grant from Gerber Products Company to support the Tufts Roundtable on Nutrition in Pregnancy in 1998. Research on genetic and environmental influences on eating patterns partially funded by RJR Nabisco Corporation and the Gerber Foundation in 2000 or earlier.</p> <p>After 2000: None.</p>

MEMBER	RELATIONSHIPS WITH INDUSTRY
5. Scott M. Grundy, M.D., Ph.D.	<p>2000 or earlier: Received research grant from Procter & Gamble on olestra in 1986.</p> <p><i>(PCRM v. Glickman)</i></p> <p>Served from 1973 to at least 2000 on the American Egg Board grant review committee. Study published in 1997 supported by Merck and Bristol-Myers Squibb. 1996 research on oxidizability of low-density lipoprotein in patients with diabetes mellitus partially supported by the Henkel Corp.</p> <p>After 2000: Received consulting fees from Merck, Merck-Schering-Plough, AstraZeneca, and Pfizer in 2007 or earlier. Received grant support Merck and Abbott in 2007 or earlier. Co-author of “Intensive lipid lowering with atorvastatin in patients with stable coronary disease,” sponsored by Pfizer, in 2005. Received lecture fees from Merck, Pfizer, Kos Pharmaceuticals, Abbott, and AstraZeneca in 2005 or earlier. Received grant support from Merck and Abbott in 2005 or earlier. Received honoraria from Merck, Pfizer, Sankyo, Bayer, Merck/Schering-Plough, Kos, Abbott, Bristol-Myers Squibb, and AstraZeneca. Received research grants from Merck, Abbott, and GlaxoSmithKline in 2004 or earlier.</p>
6. Rachel K. Johnson, Ph.D., M.P.H., R.D.	<p>2000 or earlier:</p> <p><i>(PCRM v. Glickman)</i></p> <p>Received a \$42,000 research grant from Dairy Management, Inc. in 1999 or earlier. Received fellowships from Kraft General Foods in 1988 and 1990.</p> <p>After 2000: In 2005 or earlier: Member of the medical advisory board for the Milk Processor Education Program; speaker’s bureau for the National Dairy Council; received research grants from the New England Dairy Promotion Board and the Vermont Dairy Promotion Council. Research on the nutritional consequences of flavored-milk consumption by school-aged children and adolescents in the U.S. was sponsored by the National Dairy Council, in 2002 or earlier.</p>
7. Shiriki K. Kumanyika, Ph.D.	<p>2000 or earlier: None.</p> <p>After 2000: Served as an advisory board member for Weight Watchers International.</p>
8. Alice H. Lichtenstein, D.Sc.	<p>2000 or earlier: Research for 1994 study partially supported by a grant from the Egg Nutrition Center, which found that diets lower in fat, saturated fat, and cholesterol reduced LDL cholesterol. Research for 1999 study partially supported by the Egg Nutrition Center, which concluded that the possible benefit of higher plasma carotenoid levels due to egg yolks is counterbalanced by increased cholesterol levels.</p> <p>After 2000: None.</p>
9. Meir Stampfer, M.D., Dr.P.H.	<p>2000 or earlier: None.</p> <p>After 2000: Stampfer is the star of a new Anheuser move to publicize the health benefits of beer consumption, according to the Wall Street Journal in 2005. While Stampfer says he receives only travel expenses for speaking, Anheuser donated \$150,000 in doctoral-student scholarship funds to the Harvard School of Public Health where Stampfer teaches.</p>
10. Lesley Fels Tinker, Ph.D., R.D.	<p>2000 or earlier: None.</p> <p>After 2000: None.</p>
11. Roland Weinsier, M.D., Dr.P.H.	<p>2000 or earlier: On the Weight Watchers Advisory Board in 1997 or earlier. Research for a 2000 study on paternal body fat as predictor of changes in body fat partially supported by Knoll Pharmaceutical Company.</p> <p><i>(PCRM v. Glickman)</i></p> <p>Received a \$500,000 grant from Bristol-Myers Squibb/Mead Johnson in 1999 or earlier.</p> <p>After 2000: None.</p>

Sources:

Center for Science in the Public Interest, The Integrity in Science Database, <http://www.cspinet.org/integrity/> (last visited Feb. 21, 2009); DEP'T OF HEALTH & HUMAN SERVS. & U.S. DEP'T OF AGRIC., REPORT OF THE DIETARY GUIDELINES ADVISORY COMMITTEE ON THE DIETARY GUIDELINES FOR AMERICANS, 2000 vii (2000), available at <http://www.cnpp.usda.gov/Publications/DietaryGuidelines/2000/2000DGCommitteeReport.pdf> (2000 membership).

Key:

Information for a member following “(PCRM v. Glickman)” was revealed only as a result of PCRM’s public information requests and its subsequent lawsuit in *Physicians Comm. for Responsible Med. v. Glickman*, 117 F.Supp.2d 1 (D.C. Cir. 2000).

Table 3: Potential Conflicts of Interest on the 2005 Advisory Committee

MEMBER	RELATIONSHIPS WITH INDUSTRY
1. Janet King, Ph.D., R.D. (Chair)	2005 or earlier: Research for 2000 study on zinc absorption partially supported by Mead Johnson Nutritionals, a Bristol-Myers Squibb Company. Research for 1997 study on zinc metabolism in women partially supported by a gift from Bristol-Myers Squibb/Mead Johnson. After 2005: None.
2. Lawrence Appel, M.D., M.P.H.	2005 or earlier: Receives research grants from King Pharmaceuticals in 2003 or earlier. Consultant to Tropicana in 2003 or earlier. After 2005: None.
3. Penny Kris-Etherton, Ph.D.	2005 or earlier: In 2003, was listed as serving as a member of advisory committees to a number of food and pharmaceutical groups and has research support from the food industry. Research for 2000 study on lipid and lipoprotein responses to different diets partially supported by Abbott Laboratories. Research for 2000 study on the effects of folate and vitamins B-12 and B-5 on serum total homocysteine supported by Campbell Soup Company. In 1999, the industry-sponsored International Food Information Council suggested that journalists interested in trans fat call Kris-Etherton. 1999 study on monounsaturated fats was supported by the Peanut Institute. On Nutrition Advisory Panel of the American Egg Board in 1998. 1997 study that compared meal plans and self-selected diet in relation to cardiovascular risk reduction supported by Campbell Soup Company. 1996 study on the benefits of a prepared diet in relation to cardiovascular disease supported by Campbell Soup Company. Consultant to Campbell Soup on “Intelligent Cuisine” product line in 1996. 1994 studies on chocolates and cholesterol levels were supported by the American Cocoa Research Institute, an arm of the Chocolate Manufacturers Association. After 2005: Research for 2007 study on the use of canola oil to meet dietary standards was supported by the U.S. Canola Association.
4. Yvonne Bronner, Sc.D., R.D.	2005 or earlier: None. After 2005: None.
5. Joanne Lupton, Ph.D.	2005 or earlier: Co-authored an “expert Panel Report” on olestra for Procter & Gamble in 1999. Health Valley Foods. Miller Brewing Co. ILSO from 1992-94. Communications consultant to corporations from 1974-80. After 2005: In 2008, disclosed that she was on the M&M Mars’ Scientific Advisory Board.

MEMBER	RELATIONSHIPS WITH INDUSTRY
6. Benjamin Caballero, M.D., Ph.D.	2005 or earlier: None. After 2005: In 2006, listed as a member of the advisory board of the American Council for Fitness & Nutrition, a non-profit organization with over 100 corporate members.
7. Theresa Nicklas, Dr.P.H., M.P.H., L.D.N.	2005 or earlier: In 2005, listed as a member of the Clinical Advisory Board of the Grain Foods Foundation. Study on sugars and nutrient intakes in 10 year old children sponsored by Sugar Association. 1998 study on the sugar intakes of 10 year olds in Bogalus, LA funded in part by the Sugar Association. Research for 1998 study on the nutrient contribution of breakfast and the role of ready-to-eat cereals partially funded by a grant from the Kellogg Company. 1996 study on whether children who consume more carbohydrates are more likely to run short on niacin and zinc was partially funded by the Sugar Association. After: None.
8. Carlos Camargo, M.D., Dr.P.H.	2005 or earlier: In 2005 or earlier, received funding from: AstraZeneca, BreathQuant, Critical Therapeutics, Dey, Genetech, Janssen, MedImmune, Novartis, Oridion, Pathogen Scientific, Schering-Plough and Verus. Co-author of 2005 study on weight and shape in adolescents supported by the Kellogg Company. Co-author of 2003 study on asthma supported by Merck. At least as of 2005, the principal investigator in the Sixteenth Multicenter Airway Research Collaboration (MARC-16), funded by Abbott. 2004 study on children with asthma supported in part by GlaxoSmithKline. 2004 study on COPD sponsored by an unrestricted grant from Boehringer Ingelheim. As of 2002, the medical spokesman for Asthma Action America, a collation made up of the American Pharmaceutical Association and the National Association of Chain Drug Stores and supported by the GlaxoSmithKline Respiratory Institute. After 2005: None.
9. Russell Pate, Ph.D.	2005 or earlier: In 2003, listed as having received a \$200,000 for ongoing studies of physical activity in youth. In 2003, listed as being on the scientific advisory board of Life Fitness, Inc. Published an article on training in cold weather in <i>Coaches Edge</i> , a publication of the Gatorade Life Sciences Institute. In 2003, listed as a scientific advisor to Kidnetic.com, which is funded through the International Food Information Council Foundation (IFIC) by Coca-Cola, Hershey Foods Corp., H.J. Heinz Foundation, Keebler Comp., Kellogg Comp., Kraft Foods, Masterfoods USA, McDonald's, National Confectioners Association, Procter & Gamble, PepsiCo, Sara Lee Corp., and the Snack Food Association. In 2003, listed as a member of the scientific advisory board for the ILSI Center for Health Promotion's Physical Activity and Nutrition Program. In 2003, listed as a member of the Kraft Foods Worldwide Health & Wellness Advisory Board. After 2005: None.
10. Fergus Clydesdale, Ph.D.	2005 or earlier: In 2003, listed as member of the Advisory Board of Tufts' Nutrition Navigator, a website underwritten with a grant from Kraft. From 1990 to at least 2000, was a science advisor and member of the Board of Trustees of the ILSI. In 1997, listed as part of the Strategic Research Alliance at the University of Massachusetts in Amherst. For \$5,000 a year, companies can use the food-science department's pilot plant and consult with the faculty on recent developments. Member of the 2000 Board of Trustees and Treasurer for the International Food Information Council Foundation. In 2003, listed as a member of the Science Advisory Board of the American Council on Science and Health. In 2003, he was listed as being on the board of Sensient Technology Inc., serving on the technical advisory board or consulting for food industry groups, and holding or having held stock in several food and food-related companies. After 2005: None.

MEMBER	RELATIONSHIPS WITH INDUSTRY
11. F. Xavier Pi-Sunyer, M.D.	<p>2005 or earlier: In 2005 listed as being on the advisory boards of Hoffmann-La Roche Inc., Abbott Laboratories, Johnson & Johnson, McNeil Nutritionals and Weight Watchers international Inc. 2004 study supported by funding from Abbott Laboratories Inc., Novo Nordisk, Roche, and Sanofi-Synthelabo. In 2005, listed as having received research funding from Eli Lilly and Company, Merck & Co., Novartis AG, and Sanofi-Aventis. In 2004, listed as being a consultant to Eli Lilly, Roche, and Sanofi-Aventis. In 2005, listed as a member of the Clinical Advisory Board of the Grain Foods Foundation. In 1997, listed as being: on the advisory boards of the American Home Products' Wyeth-Ayerst labs and Knoll Pharmaceuticals; consultant to Lilly Pharmaceuticals, Genentech, Hoffman-La Roche, Knoll, Weight-Watchers International, and Neurogen; on Knoll Pharmaceutical's Weight Risk Investigation Study Council, which provides research grants. In 1999, accepted grants or fees from Warner-Lambert on Rezulin, a diabetes drug. Research for 2000 study on the effects of folate and vitamins B-12 and B-6 on serum total homocysteine supported by Campbell Soup Company. 1997 study that compared meal plans and self-selected diet in relation to cardiovascular risk reduction supported by Campbell Soup Company. 1996 study on the benefits of a prepared diet in relation to cardiovascular disease supported by Campbell Soup Company.</p> <p>After 2005: None.</p>
12. Vay Liang W. Go, M.D.	<p>2005 or earlier: 1999 study on Cholestin funded by Pharmanex.</p> <p>After 2005: None.</p>
13. Connie Weaver, Ph.D.	<p>2005 or earlier: 2000 study on calcium and body weight supported in part by the National Dairy Council. Conducted research supported by the National Dairy Council, National Dairy Board, Wisconsin Milk Marketing Board, and Mead-Johnson Company. Co-authored 1990 study on calcium citrate malate funded in part by Procter & Gamble and the National Dairy Council. In 2000, listed as being on the Board of Trustees for the ILSI. A Kraft Inc. Research Fellow in 1988. 1999 research on calcium supported by the National Dairy Council. In 2000, listed as being available for media interviews via the Tropicana Nutrition Center. Research for 1999 study on milk consumption and bone density in young women partially supported by National Dairy Council.</p> <p>After 2005: None.</p>

Sources:

Center for Science in the Public Interest, The Integrity in Science Database, <http://www.cspinet.org/integrity/> (last visited Feb. 21, 2009); DEP'T OF HEALTH & HUMAN SERVS. & U.S. DEP'T OF AGRIC., REPORT OF THE DIETARY GUIDELINES ADVISORY COMMITTEE ON THE DIETARY GUIDELINES FOR AMERICANS, 2005 (2005), <http://www.health.gov/dietaryguidelines/dga2005/report/HTML/membership.htm> (2005 membership).

Table 4: Potential Conflicts of Interest on the 2010 Advisory Committee

MEMBER	RELATIONSHIPS WITH INDUSTRY UP TO & INCLUDING 2010
1. Linda V. Van Horn, Ph.D., R.D., L.D. (Chair)	2007 study on the impact of intervention of beverage choice of children funded in part by General Mills.
2. Naomi K. Fukagawa, M.D., Ph.D., (Vice-Chair)	None.
3. Cheryl Achterberg, Ph.D.	Scientific advisor to the Dannon Institute in 1998. Received a \$150,538 grant from Kraft General Foods in 1993-94. Received a \$125,000 grant from Campbell's Soup from 1995-97.
4. Lawrence J. Appel, M.D., M.P.H.	In 2003, listed as a consultant to Tropicana. In 2003, listed as receiving research grants from King Pharmaceuticals.
5. Roger A. Clemens, Dr.P.H.	None.
6. Miriam E. Nelson, Ph.D.	In 2007 listed as having received over \$10,000 from Mission Pharmacal (which makes the calcium supplement Citracal, which is sold by Bayer Pharmaceuticals) and over \$10,000 from Luminari (a producer of health-related multi-media content for General Mills, PepsiCo, Stonyfield Farm, Newman's Own, and other companies). In 2003, listed as being a member of the McDonald's Corp. Global Advisory Council on Healthy Lifestyles.
7. Sharon M. Nickols-Richardson, Ph.D., R.D.	None.
8. Thomas A. Pearson, M.D., Ph.D., M.P.H.	1994 study on chocolate's effect on cholesterol levels supported by the American Cocoa Research Institute (an arm of the Chocolate Manufacturers Association). 1999 study on monounsaturated fats was supported by the Peanut Institute. Research for 2000 study on lipid and lipoprotein responses to different diets partially supported by Abbott Laboratories.
9. Rafael Perez-Escamilla, Ph.D.	None.
10. Xavier Pi-Sunyer, M.D., M.P.H.	In 2005 listed as being on the advisory boards of Hoffmann-La Roche Inc., Abbott Laboratories, Johnson & Johnson, McNeil Nutritionals and Weight Watchers international Inc. 2004 study supported by funding from Abbott Laboratories Inc., Novo Nordisk, Roche, and Sanofi-Synthelabo. In 2005, listed as having received research funding from Eli Lilly and Company, Merck & Co., Novartis AG, and Sanofi-Aventis. In 2004, listed as being a consultant to Eli Lilly, Roche, and Sanofi-Aventis. In 2005, listed as a member of the Clinical Advisory Board of the Grain Foods Foundation. In 1997, listed as being: on the advisory boards of the American Home Products' Wyeth-Ayerst labs and Knoll Pharmaceuticals; consultant to Lilly Pharmaceuticals, Genentech, Hoffman-La Roche, Knoll, Weight-Watchers International, and Neurogen; on Knoll Pharmaceutical's Weight Risk Investigation Study Council, which provides research grants. In 1999, accepted grants or fees from Waner-Lambert on Rezulin, a diabetes drug. Research for 2000 study on the effects of folate and vitamins B-12 and B-6 on serum total homocysteine supported by Campbell Soup Company. 1997 study that compared meal plans and self-selected diet in relation to cardiovascular risk reduction supported by Campbell Soup Company. 1996 study on the benefits of a prepared diet in relation to cardiovascular disease supported by Campbell Soup Company.
11. Eric B. Rimm, Sc.D.	In 2008, listed as receiving funding for obesity and diabetes research from Sanofi-Synthelabo and GlaxoSmithKline.

MEMBER	RELATIONSHIPS WITH INDUSTRY UP TO & INCLUDING 2010
12. Joanne L. Slavin, Ph.D., R.D.	Co-author of 2002 study on the “effect of whole grain on insulin sensitivity on overweight hyperinsulinemic adults” funded in part by General Mills. 2001 study on the “effects of dietary arabinogalactan on gastrointestinal and blood parameters in healthy human subjects” sponsored by Larex Inc. In 1999 or earlier, conducted research for General Mills. Research for 1998 study on soybeans supported by the Minnesota Soybean Promotion and Research Council and Minnesota Agricultural Experiment Station. 1997 study on soy-protein supported by the Minnesota Soybean Promotion and Research Council and the Minnesota Agricultural Experiment Station.
13. Christine L. Williams, M.D., M.P.H.	Research for 1999 study on bran fiber in childhood supported in part by Kellogg.

Sources:

Center for Science in the Public Interest, The Integrity in Science Database, <http://www.cspinet.org/integrity/> (last visited Feb. 21, 2009); Announcement of the Second Dietary Guidelines Advisory Committee Meeting, 74 Fed. Reg. 793 (Jan. 8, 2009) (2010 membership).