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10 UNITED STATES DISTRICT COURT  
11 NORTHERN DISTRICT OF CALIFORNIA

12 PHYSICIANS COMMITTEE FOR  
13 RESPONSIBLE MEDICINE,  
14 a nonprofit membership organization,

15 JOHN MCDOUGALL, M.D.,  
16 an individual,

17 ULKA AGARWAL, M.D.,  
18 an individual,

19 DEBRA SHAPIRO, M.D.,  
20 an individual,

21 and

22 DONALD D. FORRESTER, M.D.,  
23 an individual,

24 Plaintiffs

25 v.

26 THOMAS VILSACK, Secretary,  
27 United States Department of Agriculture,

28 and

SYLVIA MATHEWS BURWELL,  
Secretary, Department of Health and Human  
Services,

Defendants.

Case No. \_\_\_\_\_

**COMPLAINT FOR DECLARATORY  
AND INJUNCTIVE RELIEF**

**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

1  
2 1. This is an action under the Federal Advisory Committee Act (“FACA”), 5  
3 U.S.C. App. II, and the Administrative Procedure Act, 5 U.S.C. § 706, to challenge the  
4 operations of an advisory committee, known as the 2015 Dietary Guidelines Advisory  
5 Committee (“DGAC”), formed jointly by the United States Department of Agriculture  
6 (“USDA”) and the United States Department of Health and Human Services (“HHS”). Last  
7 year the DGAC announced, in a widely publicized advisory report submitted to Defendants,  
8 that cholesterol is no longer “a nutrient of concern for overconsumption.” In stark contrast  
9 with the positions taken by the Food and Drug Administration, the Institute of Medicine,  
10 and previous Dietary Guidelines, and contrary to decades of unbiased scientific research,  
11 the new advisory report declared that “available evidence shows no appreciable relationship  
12 between consumption of dietary cholesterol and serum cholesterol.” In a poorly considered  
13 “analysis” consisting of only three sentences, the DGAC recommended that Defendants  
14 drop from the Dietary Guidelines for Americans (“Dietary Guidelines”) Defendants’  
15 longstanding advice that Americans consume no more than 300 milligrams per day of  
16 dietary cholesterol, with stricter limits for individuals at heightened risk of cardiovascular  
17 disease.

18 2. Defendants are now considering formally adopting the DGAC’s  
19 recommendations, which are contrary to the preponderance of scientific and medical  
20 knowledge. Abundant scientific evidence shows that cholesterol is a significant contributor  
21 to cardiovascular disease, the leading killer of Americans. The DGAC’s recommendations  
22 are part of a twenty-year attempt at a cholesterol image makeover based on research funded  
23 by USDA’s egg promotion program and designed specifically to increase egg consumption  
24 regardless of the health risks that may result from unlimited cholesterol ingestion. The  
25 DGAC’s recommendations are disastrous as a matter of public health policy and stem from  
26 a serious violation of FACA by Defendants, who failed to “assure that the advice and  
27 recommendations of the advisory committee *will not be inappropriately influenced by the*  
28

1 *appointing authority or by any special interest*, but will instead be the result of the advisory  
2 committee’s independent judgment.” 5 U.S.C. App. II § 5(b)(3) (emphasis added).

3 3. Defendants allowed the DGAC to ignore the findings from decades of  
4 independent research and instead rely on recent studies funded by the federal egg promotion  
5 program administered by USDA and the views of DGAC members whose institutions  
6 received substantial egg industry funding. As mandated by USDA, these studies were  
7 “directed towards increasing the general demand for eggs, egg products,” and related  
8 products “to the end that the marketing and utilization of” such products would be  
9 “encouraged, expanded, improved, or made more acceptable.” 7 C.F.R. § 1250.341(a)–(b).  
10 Defendants also appointed four members to the DGAC who have held positions with an  
11 institution that requested and received funds from USDA’s egg promotion program for the  
12 sole purpose of overturning Defendants’ recommended limits on dietary cholesterol intake.  
13 As a result, the DGAC’s recommendations on dietary cholesterol are “inappropriately  
14 influenced by the appointing authority or by any special interest,” in violation of FACA.

### 15 **JURISDICTION**

16 4. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331  
17 (federal question jurisdiction).

### 18 **PARTIES**

19 5. Plaintiff Physicians Committee for Responsible Medicine (“Physicians  
20 Committee”) is a nonprofit public health organization that advocates for and educates the  
21 general public about preventive medicine through proper nutrition. Physicians Committee  
22 is a national organization representing 150,000 medical professionals, scientists, and  
23 laypersons, including more than 12,000 physicians. Many members of Physicians  
24 Committee reside in California. On behalf of its members, Physicians Committee monitors  
25 federal nutritional policies, including the Dietary Guidelines and the manner in which the  
26 Dietary Guidelines are developed and implemented. Physicians Committee brings this  
27 action on behalf of its members as well as itself as an organization.

28

1           6.       Physicians Committee members who are laypersons are harmed by the  
2 DGAC's recommendations, and will be further harmed by Defendants' adoption of the  
3 unlawfully developed recommendations as part of the Dietary Guidelines, because these  
4 members and their families are being misled as to the harmful effects of cholesterol, which  
5 in turn has a direct bearing on their health and their families' health. Physicians Committee  
6 members who are physicians are harmed by the DGAC's recommendations, and will be  
7 further harmed by Defendants' adoption of the unlawfully developed recommendations as  
8 part of the Dietary Guidelines, because the recommendations and any Dietary Guidelines  
9 adopting them impair the health of these physicians' patients and interfere with patient  
10 education and care, thus impairing their relationships with patients and making it more  
11 difficult for these physicians to accomplish their professional objectives of keeping their  
12 patients healthy.

13           7.       The unlawfully developed recommendations, and any subsequent adoption by  
14 Defendants as part of the Dietary Guidelines, also harm Physicians Committee by  
15 compelling the organization to expend scarce resources to accomplish Defendants' legally  
16 mandated duties: inform Americans of dietary steps to protect their health. By neglecting  
17 their duty, Defendants have compelled the Physicians Committee to expend resources to  
18 counter misinformation regarding dietary cholesterol's harmful effects. One of Physicians  
19 Committee's principal organizational objectives, to which it has devoted extensive time and  
20 resources, is to publicize, both to its own members and the public at large, the harmful  
21 health effects of a cholesterol-laden diet and the health benefits associated with limiting or  
22 avoiding eggs and other products high in cholesterol. The DGAC's industry-influenced  
23 recommendations, and their potential adoption by Defendants as part of the Dietary  
24 Guidelines, seriously impair the work of Physicians Committee and render it necessary for  
25 Physicians Committee to expend substantial time and resources—time and resources that  
26 normally would be devoted to other organizational initiatives—to inform the public that the  
27 DGAC's recommendations reflect the views and interests of the egg industry rather than  
28 sound public health advice.

1           8.       Plaintiff John McDougall, M.D., has been a citizen and resident of Santa Rosa  
2 in Sonoma County, California, since 1987. Dr. McDougall is a member of Physicians  
3 Committee. Dr. McDougall is certified as an internist by the Board of Internal Medicine  
4 and the National Board of Medical Examiners. Dr. McDougall is a physician and nutrition  
5 expert who has been studying, writing, and speaking about the effects of nutrition on  
6 disease for over thirty years. As a physician, Dr. McDougall is harmed by the DGAC's  
7 recommendations, and will be further harmed by Defendants' adoption of the unlawfully  
8 developed recommendations as part of the Dietary Guidelines, because the  
9 recommendations and any Dietary Guidelines adopting them impair the health of Dr.  
10 McDougall's patients, thereby making it more difficult for Dr. McDougall to accomplish  
11 his professional objectives of keeping his patients healthy.

12           9.       Plaintiff Ulka Agarwal, M.D., is a member of Physicians Committee. Dr.  
13 Agarwal is an integrative medicine physician and board-certified psychiatrist who studies,  
14 writes, and educates the public about the effects of nutrition on disease. As a physician, Dr.  
15 Agarwal is harmed by the DGAC's recommendations, and will be further harmed by  
16 Defendants' adoption of the unlawfully developed recommendations as part of the Dietary  
17 Guidelines, because the recommendations and any Dietary Guidelines adopting them impair  
18 the health of Dr. Agarwal's patients, thereby making it more difficult for Dr. Agarwal to  
19 accomplish her professional objectives of keeping her patients healthy.

20           10.      Plaintiff Debra Shapiro, M.D., has been a citizen and resident of Burlingame,  
21 California, since 1993. Dr. Shapiro is a member of Physicians Committee. Dr. Shapiro is a  
22 board-certified obstetrician/gynecologist. As a physician, Dr. Shapiro is harmed by the  
23 DGAC's recommendations, and will be further harmed by Defendants' adoption of the  
24 unlawfully developed recommendations as part of the Dietary Guidelines, because the  
25 recommendations and any Dietary Guidelines adopting them impair the health of Dr.  
26 Shapiro's patients, thereby making it more difficult for Dr. Shapiro to accomplish her  
27 professional objectives of keeping her patients healthy.

28

1           11. Plaintiff Donald D. Forrester, M.D., has lived in California since 1975. Dr.  
2 Forrester is a member of Physicians Committee. Dr. Forrester is a board-certified family  
3 medicine physician, a Fellow with the American College of Physician Executives, and a  
4 graduate of Intermountain Healthcare's Advanced Training Program in quality  
5 improvement. Dr. Forrester has more than 35 years of clinical experience and is an expert  
6 in the prevention and improvement of chronic diseases through lifestyle interventions.  
7 Current projects include supporting the Right Care Initiative in Northern California and  
8 serving as a board member for NutritionFacts.org. As a physician, Dr. Forrester is harmed  
9 by the DGAC's recommendations, and will be further harmed by Defendants' adoption of  
10 the unlawfully developed recommendations as part of the Dietary Guidelines, because the  
11 recommendations and any Dietary Guidelines adopting them impair the health of Dr.  
12 Forrester's patients, thereby making it more difficult for Dr. Forrester to accomplish his  
13 professional objectives of keeping his patients healthy.

14           12. Defendants are Secretary Thomas Vilsack of USDA and Secretary Sylvia  
15 Mathews Burwell of HHS. USDA and HHS are the two United States agencies to which  
16 the DGAC issued recommendations and which are responsible for establishing and  
17 overseeing the work of the DGAC. USDA regulates matters concerning agriculture and  
18 HHS regulates matters regarding human health in the United States.

### LEGAL FRAMEWORK

#### The Federal Advisory Committee Act

21           13. FACA imposes requirements on all federal agencies that "establish" or  
22 "utilize" advisory committees. 5 U.S.C. App. II, § 3(2). FACA's requirements also apply  
23 to the advisory committees that federal agencies establish.

24           14. In establishing or utilizing an advisory committee, a federal agency must  
25 comply with several requirements. It must ensure that the committee is "fairly balanced in  
26 terms of points of view represented and the function to be performed," *id.* § 5(b)(2), and it  
27 must put in place "appropriate provisions to assure that the advice and recommendations of  
28 the advisory committee will not be inappropriately influenced by the appointing authority or

1 any special interest, but will instead be the result of the advisory committee’s independent  
2 judgment,” *id.* § 5(b)(3).

### 3 STATEMENT OF FACTS

#### 4 USDA Oversees “Research” Designed to Promote Eggs

5 15. USDA created the American Egg Board, pursuant to statute, to administer  
6 USDA’s research and promotion program for eggs. 7 U.S.C. §§ 2701–2718.

7 16. USDA regulations require the American Egg Board to establish “programs or  
8 projects for advertising, sales promotion, and consumer education.” 7 C.F.R. §  
9 1250.341(a). Every “such program or project shall be directed towards increasing the  
10 general demand for eggs, egg products,” and related products. *Id.*

11 17. USDA regulations require the American Egg Board to conduct “research,  
12 marketing, and development projects” regarding eggs “to the end that the marketing and  
13 utilization of eggs, egg products, spent fowl, and products of spent fowl may be encouraged,  
14 expanded, improved, or made more acceptable[.]” 7 C.F.R. § 1250.341(b).

15 18. USDA controls nearly every aspect of the American Egg Board’s activities,  
16 including research funding. *See* 7 C.F.R. §§ 1250.326–1250.336. For example, USDA  
17 must review and approve all of the American Egg Board’s “contracts or agreements with . .  
18 . State, regional, or national egg organizations which administer research, education, or  
19 promotion programs” as well as “public or private research organizations.” 7 C.F.R. §  
20 1250.336(d).

21 19. The American Egg Board is funded by federally mandated assessments  
22 imposed on egg producers. 7 C.F.R. §§ 1250.347–1250.349. By statute, “no funds  
23 collected by the Egg Board . . . shall in any manner be used for the purpose of influencing  
24 governmental policy or action,” other than for the limited purpose of recommending  
25 changes to USDA’s management of the American Egg Board. 7 U.S.C. § 2707(h).

26 20. The American Egg Board’s “research center” is the Egg Nutrition Center.  
27 *About the American Egg Board (AEB)*, AMERICAN EGG BOARD (2015),  
28 <http://www.aeb.org/about-aeb/about>.

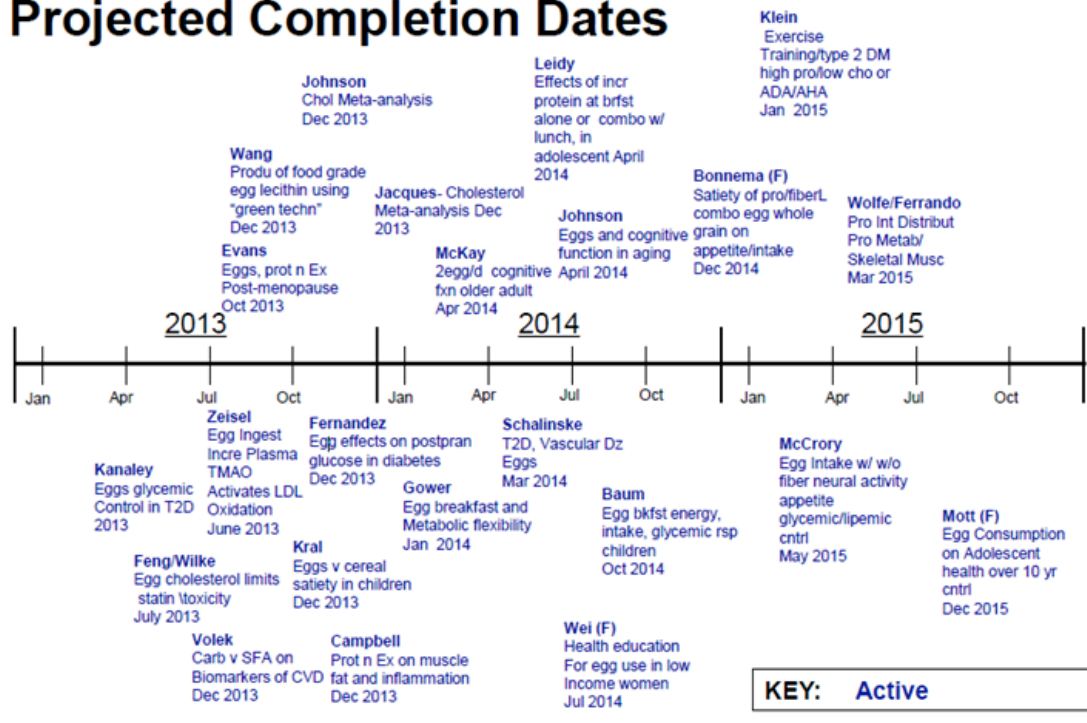
21. The Egg Nutrition Center’s funding establishes financial relationships with key researchers at major universities and supports studies designed to portray eggs in a favorable light. These research funds are not dedicated primarily to elucidating scientific issues or promoting good health. Rather they are used to fund studies designed in pursuit of the American Egg Board’s mission “to increase demand for eggs and egg products.” *See id.*

22. In the past two decades, the American Egg Board and the Egg Nutrition Center have become increasingly active in using research to increase demand for eggs.

23. Of the 41 studies on dietary cholesterol included in a 1992 meta-analysis, 29% were paid for by industry, mainly the egg industry. Nine years later, in a 2001 meta-analysis, that figure had risen to 41%. Two decades later, in a 2013 review, the figure was 92%. This single source now dominates research on dietary cholesterol.

24. In 2013, the Egg Nutrition Center published the following chart showing its aggressive plans for additional egg-promoting research through 2015:

### ENC Funded Research: Projected Completion Dates



*Health Professionals Advisory Call*, EGG NUTRITION CENTER (June 26, 2013),



1 [http://www.eggnutritioncenter.org/wp-content/uploads/2013/10/HPA-Conference-Call-](http://www.eggnutritioncenter.org/wp-content/uploads/2013/10/HPA-Conference-Call-06.26.2013.pdf#page=7)  
2 [06.26.2013.pdf#page=7.](http://www.eggnutritioncenter.org/wp-content/uploads/2013/10/HPA-Conference-Call-06.26.2013.pdf#page=7)

3 25. Studies funded by the American Egg Board and the Egg Nutrition Center use  
4 specific design characteristics to minimize the reported negative health effects of eggs:

- 5 • **Method 1: Compare eggs to other high-cholesterol or high-fat foods.**  
6 Compared to a cholesterol-free egg substitute, eggs raise cholesterol levels.  
7 But when researchers compare eggs to meat, this outcome is less likely,  
8 because meat has cholesterol and saturated fat of its own.
- 9 • **Method 2: Use a mixed diet intervention.** When eggs are added to the diet,  
10 cholesterol levels tend to rise. But if researchers add eggs while also cutting  
11 calories or fat intake, the rise can be blunted or cholesterol levels can even be  
12 made to fall.
- 13 • **Method 3: Claim that dietary cholesterol affects only certain people.**  
14 Some industry-funded researchers have divided research participants into  
15 groups, depending on how large the participants' cholesterol elevations were  
16 after eating eggs or other cholesterol-containing products, and have suggested  
17 that only the “hyper-responders” are at risk.
- 18 • **Method 4: Use a small participant sample.** By using very small participant  
19 samples, researchers increase the statistical likelihood that an observed  
20 effect—such as the cholesterol-raising effect of eggs—can be deemed a  
21 chance finding that is “not statistically significant.” When that happens, many  
22 researchers mistakenly report that there is no effect at all.
- 23 • **Method 5: Call positive studies negative if they are not statistically**  
24 **significant.** As noted above, when an effect, such as a rise in cholesterol in  
25 response to eating eggs, could have been attributed to chance, some  
26 researchers mistakenly report there was no effect at all. Reviewers then carry  
27 this notion forward in summaries of research findings, suggesting that studies  
28 have found no effect.

- 1 • **Method 6: Omit older research studies.** By limiting their reviews to studies  
2 published in recent years—when nearly all studies were industry-funded and  
3 designed to bring about certain outcomes—researchers can make results  
4 appear more favorable for eggs than they would be if the researchers had also  
5 included older, more objectively designed studies. As far back as the 1950s,  
6 researchers linked high blood cholesterol levels to heart disease and other  
7 health problems. Hundreds of experiments thereafter show that dietary  
8 cholesterol boosts blood cholesterol levels. The Institute of Medicine  
9 summarized the evidence through 2001, showing that the addition of 100  
10 milligrams of cholesterol (half the amount in a typical egg) to the daily diet  
11 would boost low-density lipoprotein (LDL or “bad”) cholesterol concentration  
12 by roughly 0.05 mmol/L. INSTITUTE OF MEDICINE, DIETARY REFERENCE  
13 INTAKES FOR ENERGY, CARBOHYDRATE, FIBER, FAT, FATTY ACIDS,  
14 CHOLESTEROL, PROTEIN, AND AMINO ACIDS 560 (2002/2005) (hereinafter  
15 “DIETARY REFERENCE INTAKES”).  
16

17 **USDA and Tufts University Publish “Research” Designed to Promote Eggs**

18 26. Through its Agricultural Research Service (“ARS”), USDA designs,  
19 organizes, and conducts research to address “agricultural problems.” *About Us*, USDA  
20 ARS (2015), <http://www.ars.usda.gov/AboutUs/aboutUs.htm>.

21 27. One ARS research center, the Jean Mayer USDA Human Nutrition Research  
22 Center on Aging, is located at Tufts University (“Tufts/USDA Center”). The center is  
23 financially “supported by the Agricultural Research Service (ARS), the research arm of the  
24 United States Department of Agriculture (USDA). . . . It is run by cooperative agreement  
25 between the ARS and Tufts University.” *About the HNRCA*, TUFTS UNIVERSITY (2015),  
26 <http://hnrc.tufts.edu/about/mission/>.

27  
28

1           28.     In 2013, two Tufts/USDA Center researchers, John Griffin and Alice  
2 Lichtenstein, published a review on dietary cholesterol, which, intentionally or not, used the  
3 methods above to hide the negative effects of cholesterol-containing foods. As noted  
4 below, Dr. Lichtenstein was that same year appointed Vice Chair of the DGAC and  
5 Chair/Vice Chair Representative of the DGAC subcommittee that dealt with the issue of  
6 dietary cholesterol. In these roles, Dr. Lichtenstein was in position of particular influence  
7 with regard to this issue.

8           29.     The Tufts/USDA Center researchers excluded all studies published prior to  
9 2003. Of the 12 studies that they included, eight were funded by the American Egg Board  
10 through the Egg Nutrition Center. Two were funded by British or Australian egg industry  
11 associations, and the eleventh was funded by the fish industry in defense of prawn  
12 consumption. In other words, 11 out of the 12 cited studies were designed to arrive at a  
13 specific pro-industry result.

14           30.     Despite their industry-related funding, nearly every cited study showed that  
15 eggs or other cholesterol-containing foods had an unfavorable effect on blood cholesterol  
16 levels. Nevertheless, Mr. Griffin and Dr. Lichtenstein concluded that the effect of dietary  
17 cholesterol on plasma lipid concentrations “is modest and appears to be limited to  
18 population subgroups.” (Griffin JD, Lichtenstein AH, Dietary cholesterol and plasma  
19 lipoprotein profiles: randomized-controlled trials, *Curr Nutr Rep.* 2013, 2:274-282.)

20           31.     Dr. Lichtenstein also was a coauthor of a 2013 report from the American  
21 Heart Association (“AHA”) and the American College of Cardiology (“ACC”) that touched  
22 on the issue of dietary cholesterol (“AHA/ACC Report”). The report’s authors intentionally  
23 disregarded all cholesterol studies published before 1998, citing a lack of resources and  
24 time. They also specifically disregarded the findings of meta-analyses published in 1992  
25 and 1997, failed to cite other published meta-analyses, failed to cite the Institute of  
26 Medicine findings noted above, and cited no other studies at all regarding the effect of  
27 dietary cholesterol on blood cholesterol concentrations. With little information left to go  
28 on, their conclusion was that more research was needed. (*See* Eckel RH, Jakicic JM, Ard

1 JD, et al, American College of Cardiology/American Heart Association Task Force on  
2 Practice Guidelines, 2013 AHA/ACC guideline on lifestyle management to reduce  
3 cardiovascular risk: a report of the American College of Cardiology/American Heart  
4 Association Task Force on Practice Guidelines, *Circulation*, 2014 Jun 24, 129(25 Suppl  
5 2):S76-99, doi: 10.1161/01.cir.0000437740.48606.d1. Epub 2013 Nov 12.)

6 32. In 2015, Tufts/USDA Center researchers published a new report, citing  
7 funding from the Egg Nutrition Center. As was the case in Dr. Lichtenstein's earlier report,  
8 nearly every study included in the meta-analysis described in the report was funded by the  
9 American Egg Board or other industry-related sources. Specifically, in the analysis of the  
10 effect of dietary cholesterol on LDL cholesterol concentrations, 13 of the 15 included  
11 studies (87%) were industry-funded. (See Berger S, Raman G, Vishwanathan R, Jacques  
12 PF, Johnson EJ, Dietary cholesterol and cardiovascular disease: a systematic review and  
13 meta – analysis, *Am J Clin Nutr*, doi: 10.3945/ajcn.114.100305.)

14 33. Prior to publication, the Tufts/USDA Center researchers requested \$101,268  
15 from the Egg Nutrition Center “to determine if the evidence supports the current  
16 recommendation of limiting cholesterol to < 300 mg/day.” HNRCA Letter of Intent (LOI),  
17 Tufts University (Nov. 16, 2012).

18 34. In other words, the Tufts/USDA Center researchers sought Egg Nutrition  
19 Center funding for the sole purpose of undermining Defendants' prior Dietary Guidelines'  
20 recommendation that Americans limit dietary cholesterol to no more than 300 milligrams  
21 per day. See USDA & HHS, DIETARY GUIDELINES FOR AMERICANS, 2010 at 27 (2010),  
22 <http://www.health.gov/dietaryguidelines/dga2010/DietaryGuidelines2010.pdf#page=40>.

23 35. The limit of 300 milligrams corresponds to a maximum consumption of one  
24 egg per day, a limit that likely frustrates the egg industry.

25 **Defendants Appoint Egg Industry Scientists to the DGAC**

26 36. The National Nutrition Monitoring and Related Research Act requires  
27 Defendants to publish Dietary Guidelines based on “the preponderance of the scientific and  
28 medical knowledge which is current at the time the report is prepared.” 7 U.S.C. § 5341(a).

1           37. In October 2012, Defendants invited the public to submit nominations for the  
2 Dietary Guidelines Advisory Committee. 77 Fed. Reg. 65,384, 65,384–85 (Oct. 26, 2012).

3           38. DGAC members were to be “knowledgeable of current scientific research in  
4 human nutrition and chronic disease and be respected and published experts in their fields.  
5 The prospective members also should be familiar with the purpose, communication, and  
6 application of the Guidelines and have demonstrated interest in the public’s health and well-  
7 being through research and/or educational endeavors.” 77 Fed. Reg. at 65,385.

8           39. Despite the statutory prohibition against using American Egg Board funds to  
9 influence federal policy, the Egg Nutrition Center nominated seven individuals to serve on  
10 the DGAC. *Professionals Advisory Call*, EGG NUTRITION CENTER (June 26, 2013),  
11 [http://www.eggnutritioncenter.org/wp-content/uploads/2013/10/HPA-Conference-Call-  
12 06.26.2013.pdf#page=12](http://www.eggnutritioncenter.org/wp-content/uploads/2013/10/HPA-Conference-Call-06.26.2013.pdf#page=12).

13           40. In mid-2013, Defendants announced the membership of the DGAC.

14           41. The DGAC included one Egg Nutrition Center nominee, Frank Hu.

15           42. The DGAC included Dr. Lichtenstein of the Tufts/USDA Center. Dr.  
16 Lichtenstein was appointed Vice Chair of the DGAC and also served as the “Chair/Vice  
17 Chair Representative” of the subcommittee evaluating the risks of dietary cholesterol.

18           43. The DGAC included Wayne Campbell, Steven Clinton, and Miriam Nelson,  
19 all of whom also held positions with the Tufts/USDA Center.

### 20                           **The DGAC Defers to USDA’s Promotional Research**

21           44. In February 2015, the DGAC submitted its Scientific Report of the 2015  
22 Dietary Guidelines Advisory Committee (“Scientific Report”) to Defendants.

23           45. Contradicting decades of unbiased scientific research, the DGAC reported that  
24 cholesterol is no longer “a nutrient of concern for overconsumption” and that “available  
25 evidence shows no appreciable relationship between consumption of dietary cholesterol and  
26 serum cholesterol.” DGAC, SCIENTIFIC REPORT OF THE 2015 DIETARY GUIDELINES  
27 ADVISORY COMMITTEE D17 (2015), *available at* <http://health.gov/dietaryguidelines/2015->  
28

1 scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-  
2 Committee.pdf#page=90.

3 46. Although Defendants previously recommended limiting dietary cholesterol to  
4 no more than 300 milligrams per day, with further reductions to no more than 200  
5 milligrams per day for persons with or at high risk for cardiovascular disease, the DGAC  
6 recommended that the Dietary Guidelines no longer advise Americans to place any limits  
7 whatsoever on dietary cholesterol. *See id.*

8 47. The DGAC's conclusion sharply contrasts with that of the Institute of  
9 Medicine, which stated that "serum cholesterol concentrations increase with increased  
10 dietary cholesterol, and the relationship of serum cholesterol to CHD risk or mortality  
11 increases progressively. . . . [I]ncreased risk may occur at a very low intake level and at a  
12 level this is exceeded by usual diets." DIETARY REFERENCE INTAKES at 572 (internal  
13 references omitted).

14 48. The DGAC's conclusion also contrasts with that of the Food and Drug  
15 Administration, which retains dietary cholesterol figures on food labels despite pressure  
16 from food manufacturers to remove them, as noted in the Federal Register last year:

17 Current dietary recommendations continue to recognize the well-established  
18 relationship between consumption of cholesterol and its effect on blood  
19 cholesterol levels, which are a surrogate endpoint for CHD risk (Ref. 6). . . .  
20 We are unaware of evidence that would support a change to the requirement  
21 for mandatory declaration of cholesterol on the Nutrition Facts label in §  
22 101.9(c)(3) and, therefore, we are not proposing any changes to the current  
23 requirement for mandatory declaration.

24 79 Fed. Reg. 11,880, 11,889 (Mar. 3, 2014).

25 49. As support for its recommendations, the DGAC cited only two sources, one of  
26 which was the aforementioned AHA/ACC Report, which skewed results by excluding all  
27 research prior to 1998 and ignoring several key studies, cited no studies on the effects of  
28 dietary cholesterol on blood cholesterol concentrations, and did not support the DGAC's  
conclusion.

1           50. In response to the Scientific Report, ACC formally repudiated the DGAC's  
2 reliance on the AHA/ACC Report, stating in a letter to Defendants,

3           The Dietary Guidelines Advisory Committee report of February 19, 2015, did  
4 not reflect our organization's stance on this issue or the article referenced,  
5 leading to misunderstandings in the media and the general public. Left  
6 uncorrected, these misunderstandings are likely to encourage dietary choices  
7 that could prove risky for many Americans.

8           The Dietary Guidelines Advisory Committee reported that there is "no  
9 appreciable relationship between consumption of dietary cholesterol and  
10 serum cholesterol, consistent with the conclusions of the AHA/ACC report,"  
11 referring to a recent report from the American Heart Association (AHA) and  
12 American College of Cardiology (ACC).

13           However, the AHA/ACC report did not reach that conclusion. Rather, it  
14 simply called for more research on certain aspects of this issue. . . .

15           It is important that the Dietary Guidelines remain appropriately cautious and  
16 continue to recommend that dietary cholesterol be limited.

17 Letter from Kim Allan Williams Sr., M.D., President, American College of Cardiology, to  
18 Sylvia Mathews Burwell, Secretary, HHS, & Thomas J. Vilsack, Secretary, USDA (Oct. 7,  
19 2015) (footnotes omitted).

20           51. The second source cited by the DGAC did not relate to the topic of dietary  
21 cholesterol on blood cholesterol concentrations. Rather it was a meta-analysis of the  
22 associations between egg consumption and cardiovascular disease risk, cardiovascular  
23 mortality, and diabetes risk. The meta-analysis found that egg consumption increased the  
24 risk of developing diabetes and also increased the risk of cardiovascular disease among  
25 people with diabetes. The authors cautioned against using their findings to alter nutrition  
26 guidance, stating that "the results of this meta-analysis should be interpreted with caution  
27 and may not justify changes in current dietary advice on egg consumption until more  
28 scientific data become available." (Shin JY, Xun P, Nakamura Y, He K, Egg consumption  
in relation to risk of cardiovascular disease and diabetes: a systematic review and meta-  
analysis, *Am J Clin Nutr*, 2013, 98(1):146-59.)

          52. The DGAC failed to refute or even acknowledge the Institute of Medicine's  
findings regarding dietary cholesterol, even though the DGAC had access to and referenced

1 the Institute of Medicine's report for other purposes. *See, e.g.*, Scientific Report at C17  
2 n.19, D81 n.33.

### 3 The DGAC's Recommendations Mislead the Public

4 53. A Gallup poll of 1,009 American adults conducted July 8–12, 2015 (five  
5 months after the Scientific Report's release) suggests that the public viewed recent reports  
6 suggesting that cholesterol no longer matters to mean that a healthful diet in general does  
7 not matter. Gallup's figures show that, between mid-2014 and mid-2015, the number of  
8 Americans seeking to avoid dietary fat dropped from 56% to 47%, and the number avoiding  
9 excess salt dropped from 46% to 39%. Justin McCarthy, *Americans Not Avoiding Fat and*  
10 *Salt as Much*, GALLUP (July 27, 2015), [http://www.gallup.com/poll/184340/  
11 americans-not-avoiding-fat-salt.aspx](http://www.gallup.com/poll/184340/americans-not-avoiding-fat-salt.aspx).

12 54. Immediately following the Scientific Report's publication, press reports  
13 claimed that scientists had been wrong for decades and that eggs and other cholesterol-  
14 containing foods pose no health risks.

15 55. "It finally says that dietary cholesterol isn't much of a problem; you can  
16 forget counting milligrams. Think of all those eggs you missed!" wrote the *New York*  
17 *Times*. Mark Bittman, *How Should We Eat?*, N.Y. TIMES, Feb. 25, 2015, *available at*  
18 <http://www.nytimes.com/2015/02/25/opinion/how-should-we-eat.html>.

19 56. The *Chicago Tribune* wrote, "The nation's top nutrition advisory panel has  
20 dropped charges against dietary cholesterol, recommending that it can no longer be  
21 considered a 'nutrient of concern.' The new thinking: scarfing down cholesterol-choked  
22 delicacies does not appear to significantly affect the level of cholesterol in the blood for  
23 many people." Editorial, *Scientists Get Egg on Their Faces*, CHI. TRIB., Feb. 23, 2015,  
24 *available at* [http://www.chicagotribune.com/news/opinion/editorials/ct-cholesterol-  
25 guidelines-edit-0223-20150220-story.html](http://www.chicagotribune.com/news/opinion/editorials/ct-cholesterol-guidelines-edit-0223-20150220-story.html).

26 57. "Eggs are back, indeed, as many headlines are celebrating today," wrote *The*  
27 *Atlantic*. James Hamblin, *Eggs Are Back: The Earnest Simplicity of the New Nutrition*  
28 *Guidelines*, ATLANTIC, Feb. 19, 2015, *available at* <http://www.theatlantic.com/health/>



1 archive/2015/02/the-new-best-way-to-eat/385659/.

2 58. Many people likely have adopted a dismissive attitude about healthful diets in  
3 general in response to these media reports resulting from the DGAC recommendations. A  
4 resulting rise in cholesterol of even a few points for an average American would translate  
5 into a major increase in cardiovascular disease and mortality.

6 59. The DGAC confused and misled the general public, the very group the  
7 Dietary Guidelines are supposed to benefit, by appearing to exonerating dietary cholesterol  
8 and by widely publicizing its dangerous recommendations.

9 60. The DGAC's recommendations interfere with the efforts of Physicians  
10 Committee, as well as other independent health authorities and federal agencies, to improve  
11 the public welfare by educating the general public about proper nutrition.

12 **Status of the Dietary Guidelines**

13 61. Defendants have advised that they intend to issue the new Dietary Guidelines  
14 in January 2016.

15 62. On information and belief, Defendants will, contrary to "the preponderance of  
16 the scientific and medical knowledge," incorporate into the Dietary Guidelines the DGAC's  
17 unsubstantiated and biased conclusion that cholesterol is "not a nutrient of concern for  
18 overconsumption," thereby significantly jeopardizing the public health.

19 63. On information and belief, Defendants will, contrary to "the preponderance of  
20 the scientific and medical knowledge," accept the DGAC's recommendation to discontinue  
21 Defendants' longstanding advice that Americans consume no more than 300 milligrams per  
22 day of dietary cholesterol, with further reductions to no more than 200 milligrams per day  
23 for persons with or at high risk for cardiovascular disease, thereby significantly jeopardizing  
24 the public health.

25 64. More than 115 million Americans have diabetes or prediabetes and are at a  
26 heightened risk of cardiovascular disease. Many of these people will be misled or at least  
27 confused by the DGAC recommendations and any subsequent Dietary Guidelines  
28 incorporating them, and their health will suffer significantly as a consequence.

1            65. Physicians Committee notified Defendants of its scientific, medical, and legal  
2 concerns with the DGAC's dietary cholesterol recommendations. Physicians Committee  
3 requested that Defendants disregard the DGAC's dietary cholesterol recommendations and  
4 reiterate prior recommendations that Americans limit their cholesterol intake.

5    **CLAIM FOR RELIEF**

6    **FACA SECTION 5(b)(3)**  
7    **INAPPROPRIATE INFLUENCE**

8            66. Plaintiffs reallege and incorporate by reference each and every allegation of  
9 the preceding paragraphs.

10           67. Defendants established the DGAC as a scientific advisory committee to  
11 provide recommendations on nutritional standards based solely on current scientific and  
12 medical knowledge in the best interests of the American population, not in the best interests  
13 of the egg industry.

14           68. The DGAC purported to base its dietary cholesterol recommendations on only  
15 two sources. The first source, the AHA/ACC Report, skewed results by excluding all  
16 research prior to 1998 and omitting any citations on the effects of dietary cholesterol on  
17 blood cholesterol concentrations. The AHA/ACC Report was coauthored by the DGAC's  
18 influential Vice Chair, Dr. Lichtenstein, and later repudiated by ACC, one of the  
19 institutional publishers.

20           69. The second source did not relate to the topic of dietary cholesterol on blood  
21 cholesterol concentrations. Rather it was a meta-analysis of the associations between egg  
22 consumption and cardiovascular disease risk, cardiovascular mortality, and diabetes risk.  
23 As noted above, the authors cautioned against using their findings to alter nutrition  
24 guidance.

25           70. On information and belief, Dr. Lichtenstein did not disclose to other DGAC  
26 members that her institution, the Tufts/USDA Center, requested and received funds from  
27 USDA's egg promotion program for the sole purpose of overturning Defendants'  
28 recommended limits on dietary cholesterol intake.

1           71. On information and belief, in drafting recommendations on dietary  
2 cholesterol, DGAC members deferred to the expertise of one or more DGAC members  
3 whose institution, the Tufts/USDA Center, requested and received funds from USDA’s egg  
4 promotion program for the sole purpose of overturning Defendants’ recommended limits on  
5 dietary cholesterol intake.

6           72. On information and belief, Dr. Lichtenstein did not disclose to other members  
7 of the DGAC that her 2013 review on the effect of dietary cholesterol on blood cholesterol  
8 concentrations relied heavily on research studies funded by USDA’s egg promotion  
9 program.

10           73. On information and belief, in drafting recommendations on dietary  
11 cholesterol, DGAC members relied heavily on research studies funded by USDA’s egg  
12 promotion program.

13           74. Although FACA required Defendants to put in place “appropriate provisions  
14 to assure that the advice and recommendations of the advisory committee [would] not be  
15 inappropriately influenced by the *appointing authority or any special interest*,” Defendants  
16 failed to maintain such provisions.

17           75. For example, Defendants could have required the DGAC not to rely on  
18 research funded and overseen by commodity programs such as USDA’s egg promotion  
19 program because such research is designed to arrive at a specific biased result.

20           76. Instead Defendants allowed the DGAC to make recommendations favorable  
21 to the federal egg promotion program administered by USDA, an appointing agency.

22           77. This violates the language and purpose of FACA, and constitutes agency  
23 action that is arbitrary, capricious, and contrary to law, in violation of the Administrative  
24 Procedure Act, 5 U.S.C. § 706(2).

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**RELIEF REQUESTED**

WHEREFORE, Physicians Committee respectfully requests that this Court:

A. Preliminarily and permanently enjoin Defendants from relying on the DGAC’s recommendations regarding dietary cholesterol in drafting the Dietary Guidelines for Americans;

B. Enjoin Defendants to maintain, in the Dietary Guidelines, their longstanding recommendation limiting dietary cholesterol to no more than 300 milligrams per day, with further reductions to no more than 200 milligrams per day for persons with or at high risk for cardiovascular disease;

C. Order Defendants to withdraw, from any draft of the Dietary Guidelines, those portions that rely on the DGAC’s dietary cholesterol recommendations and reissue such portions based on the preponderance of current scientific and medical knowledge

D. Declare that Defendants violated FACA, 5 U.S.C. App. II § 5(b)(3), by failing to take appropriate steps to ensure that the DGAC is not inappropriately influenced by an appointing authority or a special interest;

E. Award Physicians Committee’s costs and reasonable attorneys’ fees in this action; and

F. Grant such other and further relief as the Court may deem just and proper.

Dated: January 6, 2016

Respectfully submitted,

**EVANS & PAGE**

By: /s/ Corey Page  
Corey Page  
Attorney for Plaintiffs