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## Take It with a Grain (or More) of Salt: Why Industry-Backed Dietary Guidelines Fail Americans and How To Fix Them.

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## **TAKE IT WITH A GRAIN (OR MORE) OF SALT: WHY INDUSTRY-BACKED DIETARY GUIDELINES FAIL AMERICANS AND HOW TO FIX THEM**

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Caroline Farrington\*

### ABSTRACT

*The U.S. Dietary Guidelines lack oversight and accountability. The result: Guidelines that reflect food industry interests instead of modern science. This deleterious guidance goes on to govern federally-subsidized food assistance programs and to influence dietary choices throughout the private sector and private life. Ultimately, the Guidelines significantly contribute to the endemic chronic disease they seek to address.*

*The Guidelines Advisory Committee is notoriously rife with conflicts of interest, and thus most Guidelines scholarship has focused on reforming the Committee. But the 2015 and 2020 Guidelines show that these reforms are insufficient and agency-level change is necessary. In 2015, the Committee made several controversial recommendations related to red meat, ultraprocessed foods, sodium, and sustainability. Due to industry backlash, only the sodium recommendation survived in the final Guidelines published by the Secretaries of the U.S. Departments of Agriculture (USDA) and Health and Human Services (HHS). In 2020, the Secretaries, for the first time, predetermined a list of eighty topics that the Committee may consider. Absent from this list are the most contentious topics from previous years. There is little recourse because the Guidelines are not considered an agency action subject to the Administrative Procedure Act (APA), despite their vast impact on food assistance programs, healthcare practices, tort law, and more.*

*This Note proposes two ways to bring the Guidelines within the APA's coverage. The first is a litigation strategy, arguing that the D.C. District Court relied on erroneous reasoning when it held that the Guidelines are not an agency action subject to the APA. Second, this Note describes some ways that Congress could amend the Nutrition Act, the statute governing the Guidelines. Applying the APA to the Guidelines would allow for public participation and public challenge, greater transparency, and greater efficiency across agencies. Evidence-based Guidelines would improve overall health, reduce healthcare costs, and ensure that food assistance beneficiaries can access healthy foods. A robust set of Guidelines would improve public confidence in the recommendations and enable further food law reforms, such as amending the Farm Bill, that would make it easier for people to make healthy choices.*

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## INTRODUCTION

Poor diet is the number one cause of poor health and premature death in America, claiming approximately 700,000 lives annually.<sup>1</sup> The standard American<sup>2</sup> diet (ironically termed “SAD”) is “too high in calories, saturated fat, sodium, and added sugars, and [too low in] fruits, vegetables, whole grains, calcium, and fiber.”<sup>3</sup> These dietary deficiencies contribute to some of the leading causes of death and other diseases that can make Americans’ everyday lives more difficult.<sup>4</sup> Nearly half of all American adults deal with one or more preventable, chronic diseases.<sup>5</sup>

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1. See Christopher J.L. Murray, U.S. Burden of Disease Collaborators, *The State of U.S. Health, 1990-2010: Burden of Diseases, Injuries, and Risk Factors*, 310 JAMA NETWORK 591, 596, 600 fig.3 (2013).

2. For consistency with other nutrition literature, this Note uses “American” to mean relating to the United States or its inhabitants, but acknowledges that the term can denote all of the Americas.

3. *Why Good Nutrition Is Important*, CTR. FOR SCI. IN THE PUB. INT., <https://www.cspinet.org/eating-healthy/why-good-nutrition-important> [https://perma.cc/RVT6-T3ZB].

4. *Id.*

5. U.S. DEP’T OF AGRIC. & U.S. DEP’T OF HEALTH & HUM. SERVS., DIETARY GUIDELINES FOR AMERICANS 2015–2020 xi (8th ed. 2015) [hereinafter DIETARY GUIDELINES 2015–2020].

To address this public health crisis, U.S. nutrition policy focuses on education, labeling, and other forms of information regulation.<sup>6</sup> At the heart of these efforts lie the *Dietary Guidelines for Americans* (the Guidelines). This report, published every five years by the U.S. Departments of Agriculture (USDA) and of Health and Human Services (HHS), contains nutritional information for the general public.<sup>7</sup> The Guidelines have been called “the single most powerful influence on American food choices.”<sup>8</sup> They influence FDA labeling regulations and form the basis of federally subsidized food programs, which serve eighty million beneficiaries each year.<sup>9</sup> They impact food producers who want to participate in those programs.<sup>10</sup> They influence how physicians advise patients.<sup>11</sup> Most importantly, they have a material effect on the health of Americans. For instance, when the 2000 Guidelines targeted trans fatty acids, FDA soon required manufacturers to disclose a product’s trans fat content on its nutrition facts label.<sup>12</sup> This inclusion prompted many manufacturers and restaurants to eliminate trans fats from their products.<sup>13</sup> A Harvard School of Public Health study identifies “lower trans fat consumption as one of the major reasons rates of premature death and disease fell among American adults from 1999 to 2012.”<sup>14</sup>

While the Guidelines have helped achieve improvements in public health, they are deeply flawed, both in substance and methodology. The food and beverage industries have tremendous influence over the Guidelines, leading to recommendations that are often ambiguous, scientifically unsound, and downright harmful. The public has little recourse for challenging this dangerous advice because the Guidelines

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6. Emily M. Broad Leib & Margot J. Pollans, *The New Food Safety*, 107 CALIF. L. REV. 1173, 1187 (2019).

7. DIETARY GUIDELINES 2015–2020, *supra* note 5, at vii.

8. Laura Reiley, *How the Trump Administration Limited the Scope of the USDA’s 2020 Dietary Guidelines*, WASH. POST (Aug. 30, 2019), <https://www.washingtonpost.com/business/2019/08/30/how-trump-administration-limited-scope-usdas-dietary-guidelines/> [<https://perma.cc/PM5P-DFFE>].

9. Brian Secemsky, *Breaking It Down: Controversy over the U.S. Dietary Guidelines*, HUFFINGTON POST (June 24, 2017), [https://www.huffpost.com/entry/breaking-it-down-controve\\_b\\_10622814](https://www.huffpost.com/entry/breaking-it-down-controve_b_10622814) [<https://perma.cc/2BH7-2YTS>]; *see also* DIETARY GUIDELINES 2015–2020, *supra* note 5, at xi, 5–6.

10. Reiley, *supra* note 8.

11. Sandra G. Hassink & Steven J. Stack, *Physician Perspective: Keep Politics out of Dietary Guidelines*, HILL (Oct. 7, 2015), <https://thehill.com/blogs/congress-blog/healthcare/256067-physician-perspective-keep-politics-out-of-dietary-guidelines> [<https://perma.cc/QZA9-3L3A>].

12. Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrition Content Claims, and Health Claims, 68 Fed. Reg. 41434, 41434, 41436–37 (July 11, 2003) (to be codified at 21 C.F.R. pt. 101).

13. Markham Heid, *Experts Say Lobbying Skewed the U.S. Dietary Guidelines*, TIME (Jan. 8, 2016), <https://time.com/4130043/lobbying-politics-dietary-guidelines/> [<https://perma.cc/2C39-WUVJ>].

14. *Id.*; *Improvements in U.S. Diet Lower Premature Deaths*, HARV. T.H. CHAN SCH. OF PUB. HEALTH (Nov. 2, 2015), <https://www.hsph.harvard.edu/news/press-releases/improvements-in-us-diet-lower-premature-deaths/> [<https://perma.cc/539G-8WKF>].

are insulated from any meaningful forms of public participation, such that the agencies responsible have never been held accountable.

This Note proposes to reform the process by which the Guidelines are developed to improve their substance and thus their impact on American health. First, this Note discusses the history of the Guidelines and outlines the legal framework surrounding them. Next, it explores key shortcomings of the Guidelines. Finally, this Note argues that an effective way to address these shortcomings is to bring the Guidelines within the coverage of the Administrative Procedure Act (APA), and puts forth two strategies—one legislative and one judicial—for accomplishing this.

## I. BACKGROUND

### A. *History of the Dietary Guidelines for Americans*

Given the Guidelines' contentious history, their current problems come as no surprise. From the very beginning, the Guidelines have been the epicenter of a hard-fought battle between scientists, politicians, and bureaucrats.

The federal government has been shaping American diets for more than 100 years. USDA's first nutritional guidelines were published as a farmers' bulletin in 1894 by Dr. Wilbur Olin Atwater,<sup>15</sup> who served as a highly-ranked USDA official and is considered the father of modern nutrition research and education.<sup>16</sup> Published sixteen years before the discovery of individual vitamins, these guidelines focused on the overall balance of macronutrients in the diet by encouraging greater consumption of protein and lower consumption of starches and sugars.<sup>17</sup> In 1916, USDA's first food guide<sup>18</sup> introduced the concept of food groups that remains the foundation of nutrition policy today,

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15. W.O. ATWATER, U.S. DEPT OF AGRIC., FARMERS' BULLETIN NO. 23, FOODS: NUTRITIVE VALUE AND COST (1894), <https://ia902506.us.archive.org/14/items/CAT87201446/farmbuloo23.pdf> [<https://perma.cc/49BG-UCZB>].

16. Carole Davis & Etta Saltos, *Dietary Recommendations and How They Have Changed over Time*, in *AMERICA'S EATING HABITS: CHANGES AND CONSEQUENCES* 33, 34 (1999). Abraham Lincoln established USDA in 1862 "to acquire and to diffuse among the people of the United States useful information on subjects connected with agriculture in the most general and comprehensive sense of that word, and to procure, propagate, and distribute among the people new and valuable seeds and plants." An Act to Establish a Department of Agriculture, ch. 72, 12 Stat. 387 (1862). Atwater embraced this broad mission and "initiated the scientific basis for connecting food composition, dietary intake, and health, and emphasized the importance of variety, proportionality, and moderation in healthful eating." Davis & Saltos, *supra*, at 34.

17. Davis & Saltos, *supra* note 16, at 34.

18. CAROLINE L. HUNT, U.S. DEPT OF AGRIC., FARMERS' BULLETIN NO. 717, FOOD FOR YOUNG CHILDREN (1916), <https://digital.library.unt.edu/ark:/67531/metadc96383/m1/1/> [<https://perma.cc/F3JD-RT2D>]; see also Davis & Saltos, *supra* note 16, at 35.

though the number of groups has varied between four and seven.<sup>19</sup> Updated guidelines were published in 1921, 1933, 1943, 1946, and 1956.<sup>20</sup> These voluntary updates generally responded to wartime or financial circumstances, warranting cost-conscious dietary recommendations.<sup>21</sup>

During World War II, the National Academies of Sciences, Engineering, and Medicine (the National Academies) established a committee to advise the federal government on nutrition problems that might affect national defense, such as by reducing the supply of healthy soldiers and workers or creating health crises that take resources away from the war effort.<sup>22</sup> This committee developed the first Recommended Dietary Allowances (RDAs), which listed specific recommended intakes for calories and essential nutrients like iron, calcium, and vitamin C.<sup>23</sup> RDAs have evolved into a broader set of guidelines which are updated periodically by the National Academies at the direction of various governmental entities.<sup>24</sup> These guidelines serve as a basis for the Daily Values found on FDA-mandated “Nutrition Facts” labeling, which are also heavily influenced by the Guidelines.<sup>25</sup>

The modern Guidelines were first released in 1980, in the wake of legislators’ attempts to take food policy into their own hands.<sup>26</sup> Under Senator George McGovern, the Senate Select Committee on Nutrition and Human Needs issued *Dietary Goals for the United States* in 1977.<sup>27</sup> Better known as the McGovern Report, *Dietary Goals* contained a new set of nutritional guidelines for Americans aimed at combatting the “Nation’s major killer diseases.”<sup>28</sup> The Committee recommended eating more fruits, vegetables, and whole grains, and fewer high-fat meat,

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19. Lisa Jahns, Wendy Davis-Shaw, Alice H. Lichtenstein, Suzanne P. Murphy, Zach Conrad & Forrest Nielsen, *The History and Future of Dietary Guidance in America*, 9 ADVANCES NUTRITION 136, 136–37 (2018).

20. Davis & Saltos, *supra* note 16, at 35–36.

21. *See id.*

22. Alfred E. Harper, *Contributions of Women Scientists in the U.S. to the Development of Recommended Dietary Allowances*, 133 J. NUTRITION 3698, 3700 (2003).

23. ELIZABETH FRAZÃO, U.S. DEPT OF AGRIC., AGRICULTURAL INFORMATION BULLETIN NO. 750, AMERICA’S EATING HABITS: CHANGES AND CONSEQUENCES 35 (1999).

24. *See* INST. OF MED. OF THE NAT’L ACADS., DIETARY REFERENCE INTAKES: THE ESSENTIAL GUIDE TO NUTRIENT REQUIREMENTS 6–7 (Jennifer J. Otten, Jennifer Pizzi Hellwig & Linda D. Meyers, eds., 2006).

25. *See infra* note 58.

26. *History of the Dietary Guidelines*, DIETARY GUIDELINES FOR AMs., <https://www.dietaryguidelines.gov/about-dietary-guidelines/history-dietary-guidelines> [<https://perma.cc/48JV-GLCY>] [hereinafter *History*].

27. *Id.*

28. *Summary: History of the Dietary Guidance Development in the United States*, DIETARY GUIDELINES FOR AMs., <https://www.dietaryguidelines.gov/about-dietary-guidelines/history-dietary-guidelines/summary-dietary-guidance-development> [<https://perma.cc/JAJ5-FAN5>] [hereinafter *Summary*]; STAFF OF S. SELECT COMM. ON NUTRITION AND HUM. NEEDS, 95TH CONG., DIETARY GOALS FOR THE UNITED STATES XXI (1977).

egg, and dairy products.<sup>29</sup> The McGovern Report reflected a shift in focus from getting enough nutrients to avoiding excessive intake of food components associated with chronic disease.<sup>30</sup>

The McGovern Report received criticism from many directions.<sup>31</sup> The cattle, dairy, egg, and sugar industries, including those from Senator McGovern's home state of South Dakota, were displeased with the recommendations to limit intake of their products.<sup>32</sup> The American Medical Association expressed its view that dietary guidance should be individualized and come from one's doctor (as opposed to guidance for the general public).<sup>33</sup> The nutrition community largely rejected the advice proffered by the McGovern Report and felt that "a senate committee had no business getting involved in recommendations that ought to be made by the scientific community."<sup>34</sup> In the face of such backlash, the Committee held additional hearings and issued a revised report in late 1977.<sup>35</sup> This second edition tempered the recommendations regarding salt, cholesterol, and meat consumption.<sup>36</sup>

Recognizing the need for authoritative guidance, USDA and HHS (known then as the Department of Health, Education, and Welfare) took on the role of developing dietary recommendations.<sup>37</sup> In 1980, the departments collaboratively released *Nutrition and Your Health: Dietary Guidelines for Americans*.<sup>38</sup> Like the McGovern Report, the 1980 Guidelines encountered controversy, prompting Congress to direct USDA and HHS to use an external advisory committee for future editions of the Guidelines.<sup>39</sup> The 1985 Guidelines did not make many changes to the 1980 Guidelines, but faced much less pushback than their predecessor.<sup>40</sup> 1985 thus marks the beginning of the modern Guidelines era, in which they enjoy widespread acceptance and underpin American nutrition policy.<sup>41</sup>

In 1990, Congress passed the National Nutrition Monitoring and Related Research Act (the Nutrition Act), which for the first time mandated that USDA and HHS publish the Guidelines (the first three

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29. MARION NESTLE, *FOOD POLITICS: HOW THE FOOD INDUSTRY INFLUENCES NUTRITION AND HEALTH* 40 (2d ed. 2007).

30. *Summary*, *supra* note 28.

31. NESTLE, *supra* note 29, at 40.

32. *Id.*

33. *Id.* at 41.

34. Interview by Henry Blackburn with Mark Hegsted 3 (2005), <http://www.foodpolitics.com/wp-content/uploads/Hegsted.pdf> [<https://perma.cc/P4CL-ESSQ>].

35. NESTLE, *supra* note 29, at 41–42.

36. *Id.*

37. *History*, *supra* note 26.

38. *Id.*

39. *Id.*

40. *Id.*

41. *See infra* text accompanying notes 45–57.

editions were voluntary).<sup>42</sup> Under the Nutrition Act, at least every five years, the USDA and HHS Secretaries must publish a report containing “nutritional and dietary information and guidelines for the general public . . . based on the preponderance of the scientific and medical knowledge which is current at the time the report is prepared.”<sup>43</sup> The Nutrition Act also requires that any federal nutrition guidance be reviewed by the USDA and HHS Secretaries before issuance, illustrating lawmakers’ intent for the Guidelines to become the cornerstone of American nutrition policy.<sup>44</sup>

That intent has become a reality. The Healthy Meals for Healthy Americans Act of 1994 required federally subsidized meal programs to provide meals in conformity with the Guidelines.<sup>45</sup> Among the largest of these meal programs, the National School Lunch Program serves around thirty million children daily.<sup>46</sup> The School Breakfast Program serves an additional two billion meals annually,<sup>47</sup> and children consume up to fifty percent of their calories at school.<sup>48</sup> The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) has eight million beneficiaries.<sup>49</sup> Programs funded under the Older Americans Act serve more than 900,000 meals each day.<sup>50</sup> Military meals, Veterans Affairs health facility meals, and many other federally subsidized meal programs are based on the Guidelines.<sup>51</sup> These far-reaching effects extend into the private sector as well. Because federal programs purchase \$100 billion of food each year, manufacturers often formulate (or reformulate) entire product lines around the Guidelines in order to participate in those programs.<sup>52</sup>

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42. *History*, *supra* note 26.

43. 7 U.S.C. § 5341(a)(1)–(2).

44. *Id.* § 5341(a)(1)–(b). Rules or regulations issued by a federal agency are exempt from this review requirement. *Id.* § 5341(b)(3).

45. 42 U.S.C. § 1758(f)(1)(A).

46. *National School Lunch Program*, U.S. DEPT OF AGRIC. ECON. RSCH. SERV., <https://www.ers.usda.gov/topics/food-nutrition-assistance/child-nutrition-programs/national-school-lunch-program/> [<https://perma.cc/3XSZ-85AH>].

47. Nutrition Standards in the National School Lunch and School Breakfast Programs, 77 Fed. Reg. 4088, 4109 (Jan. 26, 2012) (to be codified at 7 C.F.R. pts 210, 220).

48. *Id.*; Jessica Donze Black, *Healthy School Lunches Can Reduce Childhood Obesity and Diabetes*, PEW (Apr. 5, 2016), <https://www.pewtrusts.org/en/research-and-analysis/articles/2016/04/06/healthy-school-lunches-can-reduce-childhood-obesity-and-diabetes> [<https://perma.cc/7H92-TV66>].

49. DIETARY GUIDELINES 2015–2020, *supra* note 5, at 5.

50. *Community Meal Programs*, AGENCY ON AGING S. CENT. CONN., <https://www.aoascc.org/Services/Community-Services-and-Advocacy/Nutrition-Programs> [<https://perma.cc/Q6TB-LDYD>]; *see* 42 U.S.C. § 3030g-21.

51. DIETARY GUIDELINES 2015–2020, *supra* note 5, at 5; *see, e.g.*, DEPT OF VETERAN AFFS., VHA DIRECTIVE 2010-007, HEALTHY DIET GUIDELINES 2 (2010), <https://www.vendorportal.ecms.va.gov/FBODocumentServer/DocumentServer.aspx?DocumentId=1139745&FileName=VA262-14-R-0089-003.pdf> [<https://perma.cc/H74C-EJKR>].

52. Reiley, *supra* note 8.

Nursing homes, hospitals, and universities conform to the Guidelines,<sup>53</sup> and the Guidelines influence the food served in restaurants and cooked at home.<sup>54</sup> Healthcare professionals look to the Guidelines when advising their patients,<sup>55</sup> and the Guidelines shape Americans' idea of a healthy diet.<sup>56</sup> Remarkably, the Guidelines are poised to become even more influential because they recently added recommendations for infants and pregnant individuals, as directed by the 2014 Farm Bill.<sup>57</sup>

The labeling requirements imposed on nearly every packaged food product are also heavily influenced by the Guidelines. FDA regulates food labeling in two major ways. First, FDA requires packaged foods to include a "Nutrition Facts" label detailing the foods' nutrient contents, expressed as % Daily Value (%DV).<sup>58</sup> The Guidelines heavily influence which nutrients are required and how %DVs are calculated.<sup>59</sup> Second, FDA regulates food labeling by defining when packaging may contain various "health claims."<sup>60</sup> These regulations and guidances dictate when a food may be labeled as "low-sodium" or "healthy," and they historically have been consistent with the Guidelines. Furthermore, FDA has responded to past changes in the Guidelines by reconsidering its approach to regulating health claims.<sup>61</sup>

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53. See, e.g., MD. DEPT OF HEALTH & MENTAL HYGIENE, DIET MANUAL FOR LONG-TERM CARE RESIDENTS 5 (2014).

54. See Heid, *supra* note 13.

55. Hassink & Stack, *supra* note 11 ("Physicians routinely provide patients with guidance on how to stay healthy. We rely on the best available scientific evidence to make these recommendations, and fortunately, we have had the Dietary Guidelines for Americans to turn to. Unfortunately, that could all change; there are unprecedented attacks taking place in Congress right now that threaten the scientific integrity of the guidelines.")

56. See Rick Paulas, *Congress Doesn't Think Health and Environmental Issues Are Linked*, KCET (Dec. 18, 2014), <https://www.kcet.org/food-discovery/food/congress-doesnt-think-health-and-environmental-issues-are-linked> [<https://perma.cc/7BFU-P3FB>].

57. Agricultural Act of 2014, Pub. L. No. 113-79, § 4204, 128 Stat. 822–23.

58. 21 C.F.R. § 101.9 (2015).

59. For example, FDA's treatment of added sugar has closely followed the Guidelines. In 2014, FDA issued a Notice of Proposed Rulemaking that would substantially update the requirements of the Nutrition Facts label. One of the most significant (and controversial) was the mandatory declaration of "added sugars" content. Previously, labels did not differentiate between types of sugar. FDA explained that the proposed change was intended to "provide consumers with information they need to implement the dietary recommendations of the *Dietary Guidelines for Americans, 2010*," which warned of the dangers of added sugar. Nutrition and Supplement Facts Labels, 79 Fed. Reg. 11880, 11881 (proposed Mar. 3, 2014) (to be codified at 21 C.F.R. pt. 101). After the 2015 Committee report was published and introduced a quantitative limit on added sugar intake, FDA issued a Supplemental Notice of Proposed Rulemaking, revising its proposed rule to require labels to include a %DV for added sugar based on the limit set by the Guidelines. Nutrition and Supplement Facts Labels, 80 Fed. Reg. 44303 (July 27, 2015) (to be codified at 21 C.F.R. pt. 101).

60. 21 C.F.R. § 101.14 (2015).

61. Prior to 2010, the Guidelines recommended limiting consumption of fat overall, whereas the 2010 Guidelines focused on limiting saturated and trans fats. Compare U.S. DEPT OF AGRIC. & U.S. DEPT OF HEALTH & HUM. SERVS., DIETARY GUIDELINES FOR AMERICANS 2005 at 11 tbl.2 (2005) (recommending numeric limits on all types of fat, including unsaturated fats), with U.S. DEPT OF AGRIC. & U.S. DEPT OF HEALTH & HUM. SERVS., DIETARY GUIDELINES FOR AMERICANS 2010 at 76

### B. Legal Framework of the Dietary Guidelines

This Section outlines the different laws governing the Guidelines. The Nutrition Act is the organic statute for the Dietary Guidelines, delineating Congress's mandate to USDA and HHS. These agencies are governed by the APA, and the Dietary Guidelines Advisory Committee is governed by the Federal Advisory Committee Act (FACA). But these ostensible legal constraints are ineffective, and the Guidelines are subject to few meaningful safeguards.

The Nutrition Act requires USDA and HHS to publish the Guidelines every five years.<sup>62</sup> The Guidelines “shall contain nutritional and dietary information and guidelines for the general public, and shall be promoted by each Federal agency in carrying out any Federal food, nutrition, or health program.”<sup>63</sup> Furthermore, the Guidelines “shall be based on the preponderance of the scientific and medical knowledge which is current at the time the report is prepared.”<sup>64</sup>

The Nutrition Act also provides a process by which “[a]ny Federal agency that proposes to issue any dietary guidance for the general population or identified population subgroups shall submit the text of such guidance to the [USDA and HHS] Secretaries for a sixty-day

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(2010) (recommending numeric limits on only saturated fat and total fat). The 2015 Guidelines reiterated this shift, which reflects the modern scientific understanding that monounsaturated and polyunsaturated fats from whole foods like nuts and avocados contribute to a healthy diet. Citizen Petition from KIND LLC to the FDA 1 (Dec. 1, 2015), <https://s3.amazonaws.com/kind-docs/citizen-petition.pdf> [<https://perma.cc/28PL-2LDD>] (requesting amendment to the FDA Rules regarding food labeling health claims). In 2015, FDA issued a warning letter to snack company KIND regarding the use of “healthy” to market its nutrition bars. Warning Letter from FDA, Center for Food Safety and Applied Nutrition, to KIND LLC (Mar. 17, 2015), <https://wayback.archive-it.org/7993/20201218161031/> <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/kind-llc-03172015> [<https://perma.cc/87XX-6QKN>]. KIND responded by submitting a citizen petition to FDA. Citizen Petition from KIND LLC to the FDA, *supra* (requesting amendment to the FDA Rules regarding food labeling health claims). Frequently citing the 2010 and 2015 Guidelines, KIND urged the agency to revise its labeling regulations to reflect current understandings of healthy eating. *Id.* at 1, 10–14, 17, 19–20, 26. Under FDA's current rule, KIND pointed out, foods like salmon, avocados, and olives could not be labeled healthy while low-fat pudding and sugar cereals met the “healthy” criteria. *Id.* at 1. In response, FDA initiated proceedings to consider amending its regulations and issued guidance expressing the agency's

intent to exercise enforcement discretion relative to foods that use the implied nutrient content claim “healthy” on their labels which: (1) are not low in total fat, but have a fat profile makeup of predominantly mono and polyunsaturated fats; or (2) contain at least ten percent of the Daily Value (DV) per reference amount customarily consumed (RACC) or potassium or vitamin D.

Use of the Term “Healthy” in the Labeling of Human Food Products: Guidance for Industry; Availability, 81 Fed. Reg. 66527 (Sept. 28, 2016) (to be codified at 21 C.F.R. pt. 101), <https://www.govinfo.gov/content/pkg/FR-2016-09-28/pdf/2016-23367.pdf> [<https://perma.cc/G8JW-D8AW>].

62. 7 U.S.C. § 5341(a)(1).

63. *Id.*

64. *Id.* § 5341(a)(2).

review period.”<sup>65</sup> The Secretaries are to review the guidance for consistency with the Guidelines or valid medical or scientific knowledge.<sup>66</sup> If either Secretary finds the guidance inconsistent with the Guidelines, the proposed guidance must be made available for public comment.<sup>67</sup> The final version must address significant comments and must receive approval from either the USDA or HHS Secretary.<sup>68</sup>

Beyond the Nutrition Act’s mandate, the APA and FACA also impact the Guidelines by governing agency activities. The APA governs a broad range of agency actions,<sup>69</sup> while FACA governs the operation of federal advisory committees, including the Dietary Guidelines Advisory Committee.<sup>70</sup> In 2011, the U.S. District Court for the District of Columbia rejected an APA challenge to the 2010 Guidelines, concluding that the Guidelines are not reviewable agency action under the APA.<sup>71</sup> There has been only one subsequent challenge to the Guidelines.<sup>72</sup> In that more recent case, the plaintiffs asserted that USDA and HHS failed to guard against the “inappropriate influence” of “special interests” on the Committee in violation of FACA, rendering the Guidelines “arbitrary, capricious, and contrary to law” in violation of the APA.<sup>73</sup> This case was also unsuccessful: the Northern District of California concluded that FACA did not supply a standard for adjudicating compliance with the Act.<sup>74</sup>

FACA was enacted in response to concerns that federal advisory committees were inefficient and opaque.<sup>75</sup> Since the 1980s, Congress has directed USDA and HHS to convene a Dietary Guidelines Advisory Committee, although the agencies continue to have ultimate responsibility for publishing the Guidelines.<sup>76</sup> The agencies take public

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65. *Id.* § 5341(b)(1); § 5302(9).

66. § 5341(b)(2)(A).

67. *Id.* § 5341(b)(2)(A)(ii)–(iii).

68. *Id.* § 5341(b)(2)(B).

69. 5 U.S.C. § 551(13).

70. U.S. DEP’T OF AGRIC., 2020 DIETARY GUIDELINES ADVISORY COMMITTEE CHARTER para. 2, at 1 (2018), <https://www.dietaryguidelines.gov/sites/default/files/2019-03/DietaryGuidelinesAdvisoryCommitteeCharter-10-05-18.pdf> [<https://perma.cc/29C9-K6NB>] [hereinafter CHARTER].

71. *Physicians Comm. for Responsible Med. v. Vilsack*, 867 F. Supp. 2d 24, 30 (D.D.C. 2011).

72. Both cases were brought by the same public interest group, the Physicians Committee for Responsible Medicine.

73. *Physicians Comm. for Responsible Med. v. Vilsack*, No. 16-cv-00069, 2016 WL 5930585, at \*2 (N.D. Cal. Oct. 12, 2016).

74. *Id.* at \*1, \*3–5.

75. WENDY GINSBURG & CASEY BURGAT, CONG. RSCH. SERV., R44253, FEDERAL ADVISORY COMMITTEES: AN INTRODUCTION AND OVERVIEW (2016), <https://fas.org/sgp/crs/secretary/R44253.pdf> [<https://perma.cc/778T-Q4J4>].

76. CHARTER, *supra* note 70, para. 3, at 1.

nominations before selecting the Committee members,<sup>77</sup> who “are not paid . . . and must report any potential conflicts of interest.”<sup>78</sup> FACA requires that advisory committee meetings be open to the public and records be made publicly available, though agency heads have some discretion to close meetings and withhold records.<sup>79</sup> Under FACA, agency heads who create an advisory committee must develop a charter that clearly defines the committee’s purpose and stipulates that its committee membership be “fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee.”<sup>80</sup> Agency heads must provide assurance “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.”<sup>81</sup>

The 2020 Committee charter carries out this charge by providing that “[s]teps will be taken to encourage fresh points of view, such as establishing a committee in which most members have not served on a previous Dietary Guidelines Advisory Committee and including members with varying points of view on the topics and questions to be examined by the committee.”<sup>82</sup> However, it is difficult to contest the sufficiency of these efforts. As discussed above, the Northern District of California held such claims non-justiciable for lack of a meaningful standard.<sup>83</sup> Unlike the District of Columbia court, the California court apparently presumed that promulgating the Guidelines constitutes

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77. Announcement of Intent to Establish the 2015 Dietary Guidelines Advisory Committee and Solicitation of Nominations for Appointment to the Committee Membership, 77 Fed. Reg. 65384 (Oct. 26, 2012).

78. T.R. Goldman, *Health Policy Brief, Final 2015-20 Dietary Guidelines for Americans. The Federal Government Published Its Latest Recommendations Intended to Shape People’s Diets Based on the Latest Research.*, HEALTH AFFS., at 2 (Mar. 31, 2016), [https://www.healthaffairs.org/doi/10.1377/hpb20160331.683121/full/healthpolicybrief\\_155.pdf](https://www.healthaffairs.org/doi/10.1377/hpb20160331.683121/full/healthpolicybrief_155.pdf) [<https://perma.cc/YP2V-2ZBV>].

79. CHARTER, *supra* note 70, para. 9, at 3.

80. 5 U.S.C. app. 2 §§ 5, 8, 9. FACA does not *directly* mandate that advisory committees be fairly balanced; rather, it sets out requirements for committee charters. *Id.*

81. § 5(b)(3).

82. CHARTER, *supra* note 70, para. 12, at 4.

83. *Physicians Comm. for Responsible Med. v. Vilsack*, No. 16-cv-00069, 2016 WL 5930585, at \*1 (N.D. Cal. Oct. 12, 2016). There is an exception to judicial review under the APA where the action’s authorizing statute is “drawn in such broad terms that in a given case there is no law to apply.” *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971) (quoting S. REP. NO. 752, at 212 (1945)), *abrogated by Califano v. Sanders*, 430 U.S. 99 (1977). Where Congress has used such broad language, the action is considered “committed to agency discretion by law.” *Id.*; 5 U.S.C. § 701(a). This is a very narrow exception which must overcome the “strong presumption that Congress intends judicial review of administrative action.” *Bowen v. Mich. Acad. of Fam. Physicians*, 476 U.S. 667, 670 (1986). Because FACA and the Nutrition Act do not define “inappropriate influence” or “special interest,” the court would not interfere with the agency’s decisions about who to include on the Dietary Guidelines Advisory Committee. *Physicians Comm.*, 2016 WL 5930585, at \*3–8.

agency action. But it nonetheless declined to review them under FACA or the APA, reasoning that neither FACA nor the Nutrition Act provide a sufficiently justiciable standard.<sup>84</sup>

While the APA and FACA may formally govern the Guidelines, their protections are ineffective while judicial review remains unavailable. Without any safeguards against undue influence, the Guidelines have fallen into the hands of the food industry.

## II. PROBLEMS WITH THE DIETARY GUIDELINES FOR AMERICANS

Despite the Guidelines' widespread impact, or perhaps because of it, they have continued to be the subject of criticism. These critiques have centered on conflicts of interest among agency officials and Committee members, the transparency of agency decision-making, and the scientific rigor of the Guidelines' recommendations. On one side, many scientists and scholars believe that the Guidelines are unduly influenced by the food industry and thus do not reflect modern nutrition science.<sup>85</sup> They point to the Guidelines' failure to recommend reduced consumption of red meat and processed foods despite pleas from the scientific community to do so.<sup>86</sup> Other experts—along with meat, dairy, and sugar producers and low-carb diet advocates—argue that the Guidelines meekly adhere to the status quo despite new scientific knowledge.<sup>87</sup> These stakeholders point to the Guidelines' longstanding recommendation to limit saturated fat intake to less than ten percent of total calories.<sup>88</sup> They argue that recent findings contradict the long-held belief that fat is harmful, rendering this guidance outdated.<sup>89</sup> This Part examines the Guidelines' recent history, which illustrates their key shortcomings, and then discusses these shortcomings in more detail.

In 2015, the Guidelines became embroiled in their most heated controversy since their creation. The core advice put forth in the Committee report, which USDA and HHS officials use to develop the Guidelines, was consistent with prior editions: eat more fruit, vegetables, and whole grains, and eat less saturated fat, sodium, and

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84. *Physicians Comm.*, 2016 WL 5930585, at \*3–8.

85. See, e.g., James J. DiNicolantonio, Zoë Harcombe & James H. O'Keefe, *Problems with the 2015 Dietary Guidelines for Americans: An Alternative*, 113 MO. MED. 93 (2016); NESTLE, *supra* note 29; Hassink & Stack, *supra* note 11.

86. See sources cited *supra* note 85.

87. See *The Issue*, NUTRITION COAL., <https://www.nutritioncoalition.us/the-issue> [<https://perma.cc/CKQ3-WX75>].

88. *Dietary Guidelines 101*, NUTRITION COAL., <https://www.nutritioncoalition.us/dietary-guidelines-for-americans-dga-introduction> [<https://perma.cc/78TL-8DMD>].

89. *Id.*

added sugars.<sup>90</sup> But the Committee also made a number of bold recommendations. The report explicitly warned against sugary beverages and artificial sweeteners<sup>91</sup> and recommended a quantitative limit on added sugar—less than ten percent of total calories—as well as a tax on sugar-sweetened beverages.<sup>92</sup> The Committee also advised USDA and HHS to drop the 300 mg cap on cholesterol intake that had been introduced in 2010.<sup>93</sup> And most controversially, the Committee report recommended that Americans eat less red and processed meat, in part to promote better individual health outcomes and in part to promote the long-term health of humankind by shifting to more sustainable food sources.<sup>94</sup>

The Committee's report triggered many negative reactions. Health advocates protested the elimination of a cholesterol cap, arguing that the Committee was improperly influenced by the egg industry.<sup>95</sup> Food and beverage producers bristled at the recommendations to limit sugary beverages and red meat.<sup>96</sup> The meat industry was particularly concerned about sustainability playing a role in the development of the Guidelines.<sup>97</sup> This backlash compelled Agriculture Secretary Tom Vilsack to assuage critics' fears. Secretary Vilsack compared the Committee members to his three- and five-year-old grandchildren, who he described as still learning to color inside the lines.<sup>98</sup> He promised, "I am going to color inside the lines."<sup>99</sup> While sustainability may seem "outside the lines" of the Guidelines, the Committee justified these recommendations with an eye toward food insecurity and long-term health.<sup>100</sup> This was not the first time that the Guidelines considered similarly "marginal" factors. For example, in the 1930s USDA began publishing cost-conscious meal plans.<sup>101</sup> Even physical exercise, which the Guidelines regularly incorporate into

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90. U.S. DEP'T OF AGRIC., SCIENTIFIC REPORT OF THE 2015 DIETARY GUIDELINES ADVISORY COMMITTEE 2 (2015) [hereinafter 2015 SCIENTIFIC REPORT].

91. *See id.* at 342, 346.

92. *Id.* at 28, 347.

93. *Id.* at 58.

94. *See id.* at 3, 5.

95. Marion Nestle, *Perspective: Challenges and Controversial Issues in the Dietary Guidelines for Americans, 1980-2015*, 9 *ADVANCES NUTRITION* 148, 148–49 (2018).

96. *Id.*; see Press Release, Sugar Ass'n, The Sugar Association Responds to 2015 Guidelines (Feb. 19, 2015), <https://www.sugar.org/resources/releases/the-sugar-association-responds-to-2015-dietary-guidelines-advisory-committee-report/> [<https://perma.cc/WRA3-R59M>].

97. Nestle, *supra* note 95, at 149.

98. *Vilsack Likens Dietary Guidelines Committee to 3-Year-Old*, HAGSTROM REP. (Feb. 27, 2015), [https://www.hagstromreport.com/2015news\\_files/2015\\_0227\\_vilsack-likens-dietary-guidelines-committee-3-year-old.html](https://www.hagstromreport.com/2015news_files/2015_0227_vilsack-likens-dietary-guidelines-committee-3-year-old.html) [<https://perma.cc/2UAB-SN38>].

99. *Id.*

100. 2015 SCIENTIFIC REPORT, *supra* note 90, at 5.

101. Davis & Saltos, *supra* note 16, at 35.

recommendations, is arguably outside the bounds of a narrow, literal definition of “nutritional and dietary information.”<sup>102</sup>

Despite these assurances, the industry’s concerns made it all the way to Congress. Members of Congress wrote three bipartisan letters urging the USDA and HHS Secretaries to reconsider the Committee’s guidance on red meat and to extend the public comment period for the guidelines.<sup>103</sup> The Secretaries granted the latter request and extended the forty-five-day comment period to seventy days, ending on May 8, 2015.<sup>104</sup> While the representatives did not hide that meat was the focus of their concerns, they also emphasized the scope of the Committee’s task, saying that the Committee “had neither the expertise, evidence, nor charter” to address issues of sustainability and tax policy.<sup>105</sup> On May 14, representatives wrote to Secretaries Vilsack and Burwell advising them to carefully review the significant number of public comments submitted on the Committee report.<sup>106</sup> In June, in an unprecedented move, Committee members wrote to Congress protesting legislative interference with their scientific process.<sup>107</sup> In July, senators sent another letter to the Secretaries.<sup>108</sup> This time, they urged the agencies to base the Guidelines on “sound scientific evidence and current medical knowledge” and to limit the degree to which recommendations are

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102. See, e.g., U.S. DEP’T OF AGRIC. & U.S. DEP’T OF HEALTH & HUM. SERVS., DIETARY GUIDELINES FOR AMERICANS 2010, at 18 (2010), <https://health.gov/sites/default/files/2020-01/DietaryGuidelines2010.pdf> [<https://perma.cc/3LJW-BNC8>]; U.S. DEP’T OF AGRIC. & U.S. DEP’T OF HEALTH & HUM. SERVS., NUTRITION AND YOUR HEALTH: DIETARY GUIDELINES FOR AMERICANS 15 (1995), <https://www.dietaryguidelines.gov/sites/default/files/2019-05/1995%20Dietary%20Guidelines%20for%20Americans.pdf> [<https://perma.cc/TKT4-MC6T>].

103. E.g., *Senators Roberts, Stabenow, Alexander and Murray Call for Extension of Dietary Guidelines Comment Period*, U.S. SENATE COMM. ON AGRIC., NUTRITION & FORESTRY (Mar. 16, 2015), <https://www.agriculture.senate.gov/newsroom/press/release/senators-roberts-stabenow-alexander-and-murray-call-for-extension-of-dietary-guidelines-comment-period> [<https://perma.cc/4FL7-YX9C>]; see also *Congress Is Concerned*, NUTRITION COAL., <https://www.nutritioncoalition.us/congress-is-concerned#:~:text=HEARING,the%20Guidelines%20are%20not%20working> [<https://perma.cc/QCD5-ZMXX>].

104. Solicitation of Written Comments on the Scientific Report of the 2015 Dietary Guidelines Advisory Committee, 80 Fed. Reg. 18852 (Apr. 8, 2015).

105. Letter from Various Members of Congress to Secretaries Vilsack and Burwell (Mar. 31, 2015), [https://republicans-agriculture.house.gov/uploadedfiles/3.31.15\\_dietary\\_guidelines\\_letter\\_to\\_secs\\_vilsack\\_burwell.pdf](https://republicans-agriculture.house.gov/uploadedfiles/3.31.15_dietary_guidelines_letter_to_secs_vilsack_burwell.pdf) [<https://perma.cc/D7P9-Z8Z7>].

106. Letter from House Agriculture Committee to Secretaries Vilsack and Burwell (May 14, 2015), [https://archives-agriculture.house.gov/sites/republicans.agriculture.house.gov/files/pdf/HAC%20Burwell%20Vilsack%20DGA%20Questions%20051415\\_o.pdf](https://archives-agriculture.house.gov/sites/republicans.agriculture.house.gov/files/pdf/HAC%20Burwell%20Vilsack%20DGA%20Questions%20051415_o.pdf) [<https://perma.cc/LVU6-WUXG>].

107. Letter from 2015 Dietary Guidelines Advisory Comm. to the U.S. House of Representatives Comm. on Appropriations (June 22, 2015), [https://www.foodpolitics.com/wp-content/uploads/dgac\\_appropriations\\_bill\\_response\\_6\\_2015.pdf](https://www.foodpolitics.com/wp-content/uploads/dgac_appropriations_bill_response_6_2015.pdf) [<https://perma.cc/9RNZ-9GCE>].

108. Press Release, U.S. Senate Comm. on Health, Educ., Lab. & Pensions, Chairmen Roberts, Alexander Urge Sound Science in 2015 Dietary Guidelines, (July 7, 2015), <https://www.help.senate.gov/chaire/newsroom/press/-chairmen-roberts-alexander-urge-sound-science-in-2015-dietary-guidelines> [<https://perma.cc/NMS8-G5ZR>].

“agenda-driven.”<sup>109</sup> Ironically, the representatives who signed these letters were accused of having a hidden agenda themselves: promoting the interests of their campaign donors from the food industry.<sup>110</sup> “Every state has cattle and every state has two senators,” said Dr. Marion Nestle, a leading nutrition scholar who served on the 1995 Committee and reviewed the 2015 Guidelines.<sup>111</sup> “So [the food industry is] powerful.”<sup>112</sup>

In October 2015, the House Committee on Agriculture held a hearing to address concerns about the Guidelines.<sup>113</sup> In addition to the issue of whether sustainability should be considered, representatives raised concerns about the methods for selecting and screening evidence; the appropriateness of the Guidelines for children; the lack of transparency with respect to potential conflicts of interest on the Committee; and the overall nutritional sufficiency of USDA-recommended diets.<sup>114</sup> Secretaries Vilsack and Burwell ceded to at least some of these concerns prior to the hearing; in a joint statement, they communicated their view that “we do not believe that the 2015 [Guidelines] are the appropriate vehicle for this important policy conversation about sustainability.”<sup>115</sup>

Unconvinced, Congress took matters into its own hands and put additional safeguards in place. In December, the Consolidated Appropriations Act of 2016 included two riders regarding the Guidelines. First, Congress prohibited USDA and HHS from releasing the Guidelines unless any revisions or new recommendations are “based on significant scientific agreement” and “limited in scope to nutritional and dietary information.”<sup>116</sup> Second, Congress appropriated \$1 million for the Agriculture Secretary to engage the National Academies to conduct a comprehensive review of the entire Guidelines process and provide recommendations for improvement.<sup>117</sup>

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109. *Id.*

110. Laura MacCleery, Opinion, *Leave the Science Alone on Dietary Guidelines 2015*, HILL (July 3, 2015), <https://thehill.com/blogs/congress-blog/246679-leave-the-science-alone-on-dietary-guidelines-2015> [<https://perma.cc/JQ9Z-DHBE>].

111. Helena Bottemiller Evich, *Meat Industry Wins Round in War over Federal Nutrition Advice*, POLITICO (Jan. 7, 2016), <https://www.politico.com/story/2016/01/2015-dietary-guidelines-217438> [<https://perma.cc/GY9H-Y7P>].

112. *Id.*

113. *Congress Is Concerned*, NUTRITION COAL., <https://www.nutritioncoalition.us/congress-is-concerned> [<https://perma.cc/DU6E-86EY>].

114. *Id.*

115. Tom Vilsack & Sylvia Burwell, *2015 Dietary Guidelines: Giving You the Tools You Need to Make Healthy Choices*, U.S. DEPT OF AGRIC. (Feb. 21, 2017), <https://www.usda.gov/media/blog/2015/10/06/2015-dietary-guidelines-giving-you-tools-you-need-make-healthy-choices> [<https://perma.cc/9KJL-JS34>].

116. Consolidated Appropriations Act of 2016, Pub. L. No. 114-113, § 734, 129 Stat. 2241, 2280 (2015).

117. *Id.* § 735.

When USDA and HHS issued the Guidelines in January 2016, they deviated substantially from the Committee's recommendations, but provided little justification. They excluded the Committee's recommendations to cut back on red meat and processed foods.<sup>118</sup> Instead, the 2015 Guidelines included red meat, along with seafood, poultry, and other protein sources as elements of a healthy eating pattern.<sup>119</sup> Yet they also diplomatically noted that "[l]ower intakes of meats . . . have often been identified as characteristics of healthy eating patterns."<sup>120</sup> Additionally, the 2015 Guidelines' recommendations to limit saturated fat to less than 10% of calories and sodium to less than 2300 mg would, in practice, necessarily require limiting intakes of red meat.<sup>121</sup> The agencies also excluded the Committee's recommendations to reduce consumption of sugary beverages but retained the new limit on added sugar. This illustrates a trend in the Guidelines of obfuscating advice by referring to actual foods in the "eat more" recommendations (i.e., eat more vegetables and whole grains), but referring to individual nutrients in the "eat less" recommendations (i.e., eat less saturated fat and added sugar).<sup>122</sup> The Guidelines also retained the Committee's recommendation to eliminate the cholesterol limit, announcing that cholesterol is no longer a "nutrient of concern."<sup>123</sup> Yet at the same time, the Guidelines still advise that "individuals should eat as little dietary cholesterol as possible."<sup>124</sup> This ambiguous advice led to public confusion, exacerbated by a media frenzy,<sup>125</sup> and ultimately sowed distrust in the Guidelines.<sup>126</sup>

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118. Compare 2015 SCIENTIFIC REPORT, *supra* note 90, at 3, 5, with DIETARY GUIDELINES 2015–2020, *supra* note 5, at 35.

119. DIETARY GUIDELINES 2015–2020, *supra* note 5, at 35.

120. *Id.* at 17, 25.

121. Elizabeth Crawford, *2015 Dietary Guidelines Soften Many Controversial Suggestions, but Still Advocate Eating More Plants*, FOOD NAVIGATOR USA (Jan. 7, 2016), <https://www.foodnavigator-usa.com/Article/2016/01/07/2015-Dietary-Guidelines-soften-controversial-suggestions> [<https://perma.cc/944P-UCT8>].

122. See DIETARY GUIDELINES 2015–2020, *supra* note 5, at xiii.

123. 2015 SCIENTIFIC REPORT, *supra* note 90, at 58; DIETARY GUIDELINES 2015–2020, *supra* note 5, at 32.

124. DIETARY GUIDELINES 2015–2020, *supra* note 5, at 32.

125. See, e.g., Editorial, *Scientists Get Egg on Their Faces*, CHI. TRIB. (Feb. 23, 2015), <https://www.chicagotribune.com/opinion/editorials/ct-cholesterol-guidelines-edit-0223-20150220-story.html> [<https://perma.cc/PX9M-RF4F>]; James Hamblin, *The Earnest Simplicity of the New Nutrition Guidelines*, ATLANTIC (Feb. 19, 2015), <https://www.theatlantic.com/health/archive/2015/02/the-new-best-way-to-eat/385659/> [<https://perma.cc/Q373-8N9L>].

126. See, e.g., Goldman, *supra* note 78, at 5 ("Removing previously established nutritional norms, however, comes at a cost, as House Agriculture Committee ranking member Collin Peterson (D-MN) reminded HHS secretary Burwell and USDA secretary Vilsack during an October 7, 2015, hearing on the Committee report. 'From my constituents, most of them don't believe this stuff anymore,' said Peterson. 'You have lost your credibility with a lot of people, and they are just flat out ignoring this stuff.'"); Crawford, *supra* note 121 ("[O]stensibly conflicting interpretations

Pursuant to the 2015 congressional appropriation discussed above, the National Academies released in two reports in 2017 detailing their findings and recommendations with respect to their review of the Dietary Guidelines process. The first report, published early in the year, focused on the Committee selection process.<sup>127</sup> The National Academies recommended third-party nomination and a transparent conflict-of-interest process for Committee members.<sup>128</sup> The second report confirmed those recommendations and also proposed ways to improve the Guidelines' development process as a whole.<sup>129</sup> In response, USDA and HHS promised to incorporate some of the recommendations (or parts of the recommendations), deferred responding to a few recommendations until later in the 2020 Guidelines process, and declined to implement others, citing limited resources, time constraints, and Committee members' privacy.<sup>130</sup> The National Academies recommended an external nomination process for Committee members based on objective criteria developed by USDA and HHS.<sup>131</sup> Citing resource constraints, the agencies did not use a third-party, but did create a list of criteria for selecting Committee members.<sup>132</sup>

The National Academies also suggested redistributing the current functions of the Committee to three separate bodies: a planning and continuity group, to curate evidence and identify and prioritize topics for inclusion in the Guidelines; technical expert panels, to provide content and methodological consultation during evaluation of the

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likely will lead to increased confusion by consumers and trigger additional education campaigns by both sides.”).

127. NAT'L ACADS. OF SCIS., ENG'G & MED., OPTIMIZING THE PROCESS FOR ESTABLISHING THE DIETARY GUIDELINES FOR AMERICANS: THE SELECTION PROCESS (2017) [hereinafter OPTIMIZING THE PROCESS].

128. *Id.* at 3–5.

129. NAT'L ACADS. OF SCIS., ENG'G & MED., REDESIGNING THE PROCESS FOR ESTABLISHING THE DIETARY GUIDELINES FOR AMERICANS 4–15 (2017) [hereinafter REDESIGNING THE PROCESS].

130. DIETARY GUIDELINES FOR AM.S., USDA-HHS RESPONSE TO THE NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, & MEDICINE: SELECTING THE DIETARY GUIDELINES ADVISORY COMMITTEE (2018), <https://www.dietaryguidelines.gov/sites/default/files/2019-12/USDA%20HHS%20Response%20to%20HMD%20Report%201.pdf> [https://perma.cc/94SD-R2Z8] [hereinafter USDA-HHS RESPONSE: SELECTION PROCESS]; Dietary Guidelines for Am.s., *Day 1: Thursday, March 28, 2019, Responding to the National Academies of Sciences, Engineering, and Medicine Study on the Process to Update the Dietary Guidelines for Americans* (Mar. 28, 2019), <https://www.dietaryguidelines.gov/day-1-responding-national-academies-sciences-engineering-and-medicine-study-process-establish> [https://perma.cc/5RJR-ZEAN] (Source: USDA YouTube content) (Speaker: Eve Stoody, Designated Fed. Officer & Lead Nutritionist) [hereinafter Stoody]; see also *Government Rejects Most of National Academies' Recs for Improving the Dietary Guidelines' Advisory Committee*, NUTRITION COAL. (Sept. 25, 2018), <https://www.nutritioncoalition.us/news/2018/9/25/government-rejects-most-of-national-academies-recs-for-improving-the-dietary-guidelines-advisory-Committee> [https://perma.cc/67LV-LH77].

131. OPTIMIZING THE PROCESS, *supra* note 127, at 5–8.

132. USDA-HHS RESPONSE: SELECTION PROCESS, *supra* note 130, at 2.

evidence; and a scientific advisory committee, to interpret the scientific evidence and draw conclusions.<sup>133</sup> USDA and HHS rejected this overall strategy but said that the agencies would, with public input, identify the topics and questions prior to establishing the Committee.<sup>134</sup>

Thus, in 2020, HHS and USDA predetermined for the first time the topics that the Guidelines would address. The eighty questions tasked to the Committee fail to address several of the most controversial issues raised in 2015.<sup>135</sup> For example, the 2020 Committee did not explore the consumption of red meat or processed foods or the appropriate sodium levels for different populations.<sup>136</sup> Dr. Nestle commented: “The cutting-edge issues in dietary advice in 2019 are about eating less meat, avoidance of ultra-processed foods, and sustainable production and consumption. . . . Guidelines that avoid these issues will be years behind the times.”<sup>137</sup> Though focusing the Committee’s inquiry is ostensibly an effort to “promote a deliberate and transparent process,”<sup>138</sup> the result is to prevent the Committee from considering the most important topics in nutrition.

USDA and HHS also limited the research that the 2020 Committee could consider to studies vetted through an opaque process by USDA’s own research team.<sup>139</sup> USDA additionally prohibited the Committee from considering research conducted before 2000 (except in the case of the early childhood subcommittee). Historically, the Committee had latitude to consult with outside experts and draw on research from a variety of sources both inside and outside USDA.<sup>140</sup> Though purportedly in furtherance of the National Academies’ recommendations, these decisions contradicted the National Academies’ conclusion that it

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133. REDESIGNING THE PROCESS, *supra* note 129, at 9.

134. Stoodly, *supra* note 130.

135. Reiley, *supra* note 8.

136. *Id.*

137. *Id.*

138. *Process to Identify the Topics and Questions*, DIETARY GUIDELINES FOR AMs., <https://www.dietaryguidelines.gov/resources/about-process/process-identify-topics-and-questions> [<https://perma.cc/UYT7-CS58>].

139. Reiley, *supra* note 8. USDA’s main research entity for the Guidelines, known as the Nutrition Evidence Systematic Review team, conducts systematic reviews of nutrition literature for each question posed to the Committee. *Systematic Reviews for the 2020 Dietary Guidelines Advisory Committee*, U.S. DEP’T OF AGRIC., <https://nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews> [<https://perma.cc/P8G5-UBZU>]. The process by which studies are screened and reviewed is only facially transparent. Studies are screened primarily using predetermined inclusion and exclusion criteria. *See* U.S. DEP’T OF AGRIC., 2020 DIETARY GUIDELINES ADVISORY COMMITTEE: NUTRITION EVIDENCE SYSTEMATIC REVIEW (NESR) PROCESS FOR CONDUCTING SYSTEMATIC REVIEWS 5 (2020). While USDA publicizes the general categories of these criteria—study design, group size, publication status, etc.—the particular criteria used are unknown. *See id.* at 7. Moreover, USDA’s role in promoting industry-funded research compromises the entire endeavor from the beginning. *See* First Amended Complaint at 3, *Physicians Comm. for Responsible Med. v. Vilsack*, No. 16-cv-00069, 2016 WL 5930585 (N.D. Cal. Oct. 12, 2016).

140. Reiley, *supra* note 8.

would be advantageous for the Guidelines to leverage a variety of existing research.<sup>141</sup>

More than thirty advocacy organizations, including the American Institute for Cancer Research and the American Academy of Pediatrics, petitioned the Committee to cast a wider net.<sup>142</sup> They argued that excluding outside science diminishes the Committee's efficacy given that the 2015 Committee used outside science to answer nearly half of its research questions.<sup>143</sup> Another group of nutrition experts wrote to the Committee expressing concern that USDA's decision to exclude pre-2000 research excludes much of the highest-quality evidence on dietary fats and cardiovascular disease.<sup>144</sup> This approach has a substantial impact on the conclusions drawn from the evidence, particularly given that research in general has become increasingly industry-funded in recent years and is thus more susceptible to bias.<sup>145</sup> For example, a meta-analysis of forty-one studies showed that in 1992, 29% of studies on dietary cholesterol were paid for by industry, mainly the egg industry.<sup>146</sup> In 2013, meta-analysis found that 83% of dietary cholesterol studies published since 2003 were industry-funded.<sup>147</sup>

After these letters and some media buzz, USDA walked back its earlier prohibition on outside data, saying that the "[C]ommittee will review all original, peer-reviewed, published research and data that meets rigorous criteria."<sup>148</sup> However, the 2020 Committee report does not mention using any external data in its methodology.<sup>149</sup> And despite the backlash, USDA continues to tout its topic selection and research vetting as transparency measures, when they in truth represent efforts to constrain the scientific committee and maintain a tight grip on the Guidelines.<sup>150</sup>

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141. REDESIGNING THE PROCESS, *supra* note 129, at 13.

142. Letter from various advocacy groups to Barbara Schneeman, Chair, 2020 Dietary Guidelines Advisory Comm. (July 22, 2019), [https://cspinet.org/sites/default/files/attachment/AICR%20DGAC%20Comments\\_o.pdf](https://cspinet.org/sites/default/files/attachment/AICR%20DGAC%20Comments_o.pdf) [<https://perma.cc/KCM9-5T4P>].

143. *Id.*

144. Letter from Henry Blackburn et al., to Barbara Schneeman, Chair, 2020–2025 Dietary Guidelines Advisory Comm. (July 24, 2019), <https://cspinet.org/sites/default/files/attachment/Scientist%20Comment%20to%20DGAC%20re%20Dietary%20Fats%20and%20CVD%20Protocol%207-24-2019.pdf> [<https://perma.cc/V29D-5TRE>].

145. First Amended Complaint at 2–3, *Physicians Comm. for Responsible Med. v. Vilsack*, No. 16-cv-00069, 2016 WL 5930585 (N.D. Cal. Oct. 12, 2016).

146. Neal D. Barnard, M. Blaire Long, Jennifer M. Ferguson, Rosendo Flores & Hana Kahleova, *Industry Funding and Cholesterol Research: A Systematic Review*, 15 AM. J. LIFESTYLE MED. 165, 171 (2019).

147. *Id.* (finding ten out of twelve studies were industry-funded).

148. Reiley, *supra* note 8.

149. See 2015 SCIENTIFIC REPORT, *supra* note 90, at 2.

150. *Contra* U.S. DEPT OF AGRIC. & U.S. DEPT OF HEALTH & HUM. SERVS., MAKE EVERY BITE COUNT WITH THE DIETARY GUIDELINES 7–10 (2020), [https://www.dietaryguidelines.gov/sites/default/files/2020-12/DGA\\_2020-2025\\_Infographic\\_MakeEveryBiteCount.pdf](https://www.dietaryguidelines.gov/sites/default/files/2020-12/DGA_2020-2025_Infographic_MakeEveryBiteCount.pdf) [<https://perma.cc/TZZ7-HXE6>].

The chaos surrounding the Guidelines in 2015 and 2020 illustrates some of their many shortcomings. The food and beverage industry pressured agencies to overrule—without explanation—the recommendations of an already-captured scientific advisory committee. To prevent further scrutiny, the agencies curtailed future committees by limiting the science that the scientists may consider.

#### A. *Conflicts of Interest*

Perhaps the longest-standing criticism of the Guidelines is that the process of creating them is rife with conflicts of interest, resulting in recommendations that are unduly influenced by industry rather than wholly based in science. This concern focuses largely on the composition of the Committee. At the direction of Congress, the first Committee was established in 1983 in response to concerns that the 1980 Guidelines were not scientifically sound.<sup>151</sup> Typically, the selection process begins with a public notice in the *Federal Register* announcing a call for nominations and describing the role and qualifications sought.<sup>152</sup> Agency officials then make the final selections.<sup>153</sup>

Despite federal requirements and recent efforts to reduce bias, each Committee continues to come under fire.<sup>154</sup> Industry representation has increased steadily over time: three out of eleven members on the 1995 Committee had past or present industry ties; seven out of eleven members on the 2000 Committee; eleven out of thirteen members on the 2005 Committee; and nine out of thirteen members on the 2010 Committee.<sup>155</sup> These ties include trade associations for meat, dairy, eggs, sugar, pharmaceuticals, as well as many individual companies.<sup>156</sup> USDA and HHS faced a lawsuit in 2016 when a scientist who conducted egg industry-funded cholesterol research was appointed Vice Chair of

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151. AGATA DABROWSKA, CONG. RSCH. SERV., R44360, DIETARY GUIDELINES FOR AMERICANS: FREQUENTLY ASKED QUESTIONS 2 (2016) (citing S. REP. NO. 96-1030 (1980)).

152. OPTIMIZING THE PROCESS, *supra* note 127, at 32; *e.g.*, Announcement of Intent to Establish the 2020 Dietary Guidelines Advisory Committee and Solicitation of Nominations for Membership, 83 Fed. Reg. 45206 (Sept. 6, 2018).

153. OPTIMIZING THE PROCESS, *supra* note 127, at 33–34.

154. *See, e.g.*, Brooke Aksnes, Maria Alvim & Sarah Garduño-Díaz, *The Normalization of Conflicts of Interest in the USA and Their Potential Impact on Public Health Nutrition*, 8 WORLD NUTRITION 123 (2017).

155. Linda Carney, *Big Industry's Influence on USDA Food Guidelines*, VEGWORLD MAG. (Nov. 25, 2018), <https://vegworldmag.com/big-industry-s-influence-on-usda-food-guidelines/> [https://perma.cc/AT64-GP4X].

156. *Id.*

the Committee and Chair of the subcommittee that dealt with the issue of dietary cholesterol.<sup>157</sup>

The prevalence of industry ties among the 2020 Committee members may exceed that of any prior Committee.<sup>158</sup> Thirteen of the twenty members have ties to industry.<sup>159</sup> For example:

- Dr. Heather Leidy received funding from the National Pork Board to conduct a 2012 study that found long-term health benefits of pork-based breakfasts—compared to adolescents who normally skip breakfast altogether, but not compared to any other reference groups.<sup>160</sup>
- Dr. Lydia Bazzano was nominated to the Committee by Atkins Nutritionals after her research on the short-term effects of low-carbohydrate diets on weight loss and cardiovascular risk factors helped boost the popularity of the Atkins Diet.<sup>161</sup>
- Dr. Jamy Ard is the Medical Director for Nestlé's Optifast, a food-replacement supplement.<sup>162</sup> He serves on Nestlé's advisory board and has received funding from Nestle to study Optifast.<sup>163</sup>
- Dr. Steven Heymsfield, nominated by the American Beverage Association, has been on the scientific advisory board of Medifast, a weight loss product.<sup>164</sup> He is also the current president of The Obesity Society, an organization that has been criticized for connections to corporate funders such as Coca-Cola and PepsiCo.<sup>165</sup>

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157. First Amended Complaint at 10–11, *Physicians Comm. for Responsible Med. v. Vilsack*, No. 16-cv-00069, 2016 WL 5930585 (N.D. Cal. Oct. 12, 2016).

158. Reiley, *supra* note 8.

159. *Id.*

160. Derrick Z. Jackson, *Food Companies at the Table in Trump Administration's Dietary Guidelines Committee*, EQUATION (Apr. 1, 2019), <https://blog.ucsusa.org/derrick-jackson/trump-administrations-dietary-guidelines-committee/> [<https://perma.cc/YS9F-R6HB>] (citing Heather J. Leidy, Heather A. Hoertel, Steve M. Douglas, Kelly A. Higgins & Rebecca S. Shafer, *A High-Protein Breakfast Prevents Body Fat Gain, Through Reductions in Daily Intake and Hunger*, in *Breakfast Skipping Adolescents*, 23 OBESITY J. 1761 (2015)).

161. *Id.*

162. *Id.*

163. Dr. Ard's Nestlé-funded studies have shown that Optifast diets lead to more weight loss than food-based diets. Jamy D. Ard, Kristina H. Lewis, Amy Rothberg, Anthony Auriemma, Sally L. Coburn, Sarah S. Cohen, Judy Loper, Laura Matarese, Walter J. Pories & Seletha Periman, *Effectiveness of a Total Meal Replacement Program (OPTIFAST Program) on Weight Loss: Results from the OPTIWIN Study*, 27 OBESITY J. 22, 22 (2019). A 2015 study by Johns Hopkins University researchers found that very few commercial weight-loss programs demonstrate long-term benefits, and Optifast is not one of them. Kimberly A. Gudzone, Ruchi S. Doshi, Ambereen K. Mehta, Zoobia W. Chaudhry, David K. Jacobs, Rachit M. Vakil, Clare J. Lee, Sara N. Bleich & Jeanne M. Clark, *Efficacy of Commercial Weight Loss Programs*, 162 ANNALS INTERNAL MED. 501, 508–09 (2016).

164. Jackson, *supra* note 160.

165. *Id.*

Five Committee members are affiliated with the International Life Sciences Institute, an organization founded by a Coca-Cola executive “to unite the food industry.”<sup>166</sup> The organization has repeatedly been criticized for its efforts to manipulate scientific studies on behalf of food companies.<sup>167</sup>

Although these criticisms typically come from commentators who believe that modern science points away from red and processed meats, pro-meat advocates are also displeased. The Nutrition Coalition, a pro-meat organization whose research has been heavily criticized,<sup>168</sup> expressed concern over Committee members who received funding from organizations financially interested in plant consumption, such as the Almond Board of California, the National Peanut Board, and the California Walnut Commission, among other organizations.<sup>169</sup>

Many consider conflicts par for the course when it comes to the Committee, especially given the frequency with which industry funds research and the propensity of experts to serve in a variety of advisory roles. Even the National Academies’ report noted that “the [National Academies] committee does not believe that these influences can be eliminated entirely.”<sup>170</sup> However, these conflicts are particularly troublesome given that the USDA officials who translated the 2020 Committee’s work had unprecedented levels of industry conflicts.<sup>171</sup> The process was entirely devoid of an unconflicted party free of incentive to manipulate the Guidelines to their benefit.<sup>172</sup>

Moreover, inherent institutional conflicts undermine the Guidelines’ declared goal of disseminating evidence-based nutrition policy. The Secretary of Agriculture is specifically mandated by Congress to promote and develop markets for domestic agricultural products.<sup>173</sup> USDA’s duty to promote the agricultural industry is fundamentally at odds with promoting health and preventing chronic

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166. *Id.*

167. *Id.*; Stacy Malkan, *International Life Sciences Institute (ILSI) Is a Food Industry Lobby Group*, U.S. RIGHT TO KNOW (Apr. 19, 2021), <https://usrtk.org/sweeteners/ilsi-wields-stealthy-influence-for-the-food-and-agricultural-industries/> [https://perma.cc/AT64-GP4X].

168. Shannon Palus, *BMJ Corrects Controversial Critique of U.S. Dietary Guidelines Report*, RETRACTION WATCH (Oct. 28, 2015), <https://retractionwatch.com/2015/10/28/bmj-corrects-controversial-critique-of-us-dietary-guidelines-report/> [https://perma.cc/SS4W-MA4M].

169. *Who’s on the Guidelines Committee*, NUTRITION COAL. (Mar. 6, 2019), <https://www.nutritioncoalition.us/news/2020-dietary-guidelines-Committee> [https://perma.cc/49FY-JBN5].

170. OPTIMIZING THE PROCESS, *supra* note 127, at 9.

171. See UNION OF CONCERNED SCIENTISTS, BETRAYAL AT THE USDA: HOW THE TRUMP ADMINISTRATION IS SIDELINING SCIENCE AND FAVORING INDUSTRY OVER FARMERS AND THE PUBLIC 2 (2018), <https://www.ucsusa.org/sites/default/files/attach/2018/04/betrayal-at-the-usda-report-ucs-2018.pdf> [https://perma.cc/SF26-NACH].

172. *See id.*

173. 7 U.S.C. § 1622(e)(1).

diseases.<sup>174</sup> Dr. Nestle says of her time on the Committee: “I was told we could never say ‘eat less meat’ because USDA would not allow it.”<sup>175</sup> Dr. Robert Lustig, co-founder and president of the Institute for Responsible Nutrition, says “tasking the government agency that manages America’s food production with crafting nutrition policy is akin to ‘putting the fox in charge of the hen house.’”<sup>176</sup>

In sum, neither the members of the Committee, the agency officials, nor the agencies as institutions are independent actors committed to developing scientifically sound Dietary Guidelines.

### B. Transparency

The work of the Committee has always been fairly transparent, as required under FACA, and advocacy groups have been able to procure additional records through FOIA requests.<sup>177</sup> But where agency officials become involved, the process becomes opaque because these officials have no obligation to make records publicly available.<sup>178</sup> Prior to 2005, the Committee wrote the actual Guidelines in addition to writing a Committee report.<sup>179</sup> Since 2005, the agencies have written the Guidelines themselves, “separating the science from the actual guidelines and making the process more political.”<sup>180</sup> The National Academies recommended that the agencies explain any deviations from the Committee report in future Guidelines.<sup>181</sup> The agencies agreed to do so, but their candor has yet to be tested by controversial Committee recommendations (and may never truly be tested due to the agencies restricting future Committees to predetermined topics).<sup>182</sup>

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174. *E.g.*, Marya Torrez, *Meatless Monday: Simple Public Health Suggestion or Extremist Plot?*, 28 J. ENV'T L. & LITIG. 515, 516 (2013); Jeff Herman, *Saving U.S. Dietary Advice from Conflicts of Interest*, 65 FOOD DRUG L.J. 285, 285 (2010); Melissa D. Mortazavi, *Are Food Subsidies Making Our Kids Fat? Tensions Between the Healthy Hunger-Free Kids Act and the Farm Bill*, 68 WASH. & LEE L. REV. 1699, 1706 (2011).

175. Heid, *supra* note 13.

176. *Id.*

177. *E.g.*, *Physicians Comm. for Responsible Med. v. Glickman*, 117 F. Supp. 2d 1 (D.D.C. 2000).

178. See REDESIGNING THE PROCESS, *supra* note 129, at 12 (recommending that the agencies provide transparency during this process and explain any deviations from the Committee report).

179. Nestle, *supra* note 95, at 148.

180. *Id.*

181. REDESIGNING THE PROCESS, *supra* note 129, at 12.

182. USDA-HHS Response to the National Academies of Sciences, Engineering, and Medicine: Using the Dietary Guidelines Advisory Committee’s Report to Develop the Dietary Guidelines for Americans, 2020-2025, DIETARY GUIDELINES FOR AM.S., <https://www.dietaryguidelines.gov/about-dietary-guidelines/related-projects/usda-hhs-response-national-academies-sciences-engineering> [<https://perma.cc/8YKP-EZQ8>].

### C. Public Participation & Accountability

There is little accountability built into the Guidelines, as demonstrated by the agencies' complete discretion to accept or reject the National Academies' recommendations without justification. Similarly, although the agencies frequently solicit public input, they are under no obligation to address such contributions.<sup>183</sup> The 2015 Committee report received a record 29,000 comments; 19,000 addressed the issue of sustainability, with 97% of these comments supporting the Guidelines' inclusion of sustainability.<sup>184</sup> Despite clear consensus among public commenters, USDA and HHS excluded sustainability from the final Guidelines.<sup>185</sup> The public is also invited to nominate Committee members and to comment on proposed topics, but agencies do not need to respond to these comments or explain their decision-making in light of the public's concerns.<sup>186</sup> Opportunities for public participation have improved with each iteration of the Guidelines, but opportunities for *meaningful* public participation remain stagnant.<sup>187</sup> Furthermore, the opportunities that do exist can be dominated by industry: 68% of public comments on the 2020 Committee report were submitted by food and beverage industry groups.<sup>188</sup>

The National Academies' review of the Guidelines development process arguably supplies some accountability. But the agencies' ability to cherry-pick which recommendations to adopt rendered the review process relatively superficial. And scraps of accountability should not require million-dollar congressional appropriations.<sup>189</sup> Moreover, because of the pervasive influence of the food industry over congresspeople of a wide range of ideologies,<sup>190</sup> this area requires more

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183. See generally *Public Comments to USDA and HHS*, DIETARY GUIDELINES FOR AM.S., <https://www.dietaryguidelines.gov/public-comments-departments> [<https://perma.cc/CNT6-D7AG>].

184. Margaret Sova McCabe, *Eating for the Environment: The Potential of Dietary Guidelines to Achieve Better Human and Environmental Health Outcomes*, 47 ENV'T L. 741, 751–52 (2017).

185. *Id.* at 752.

186. See *Public Comments to USDA and HHS*, *supra* note 183.

187. For example, for the 2020 edition, the agencies introduced a new process through which the public could submit comments on which topics the Committee should consider when developing the Guidelines. *Process to Identify the Topics and Questions*, *supra* note 138. But as discussed above, because the agencies had no obligation to address these comments, this effort actually allowed the agencies to limit the scope of the Committee's review under the guise of increasing public participation.

188. Laura Reiley, *New U.S. Dietary Guideline Recommendations Take Aim at Sugar for Children and Adults*, WASH. POST (July 11, 2020), <https://www.washingtonpost.com/business/2020/07/11/sugar-2020-dietary-guidelines/> [<https://perma.cc/HBD9-KVUG>].

189. See Consolidated Appropriations Act of 2016, Pub. L. No. 114-113, § 735, 129 Stat. 2242, 2280 (2015).

190. See Evich, *supra* note 111.

direct accountability to the public—which, as of this writing, is nonexistent.

#### D. Coordination Among Agencies

The task of setting American nutrition policy is divided between USDA and HHS.<sup>191</sup> Within HHS, the Office of Disease Prevention and Health Promotion (ODPHP) is responsible for collaborating with USDA to develop the Guidelines.<sup>192</sup> The Guidelines then inform FDA labeling regulations,<sup>193</sup> though such regulations are not required to align with the Guidelines.<sup>194</sup> FDA, housed within HHS, has authority over most food products, but the Food Safety and Inspection Service (FSIS) within USDA is responsible for regulating labels on meat and poultry products.<sup>195</sup> When FDA labeling became mandatory for most foods in 1990, FSIS adopted the policy of conforming to FDA's regulations as much as possible, in the interest of providing consistent regulation for all foods,<sup>196</sup> but the two sets of regulations do differ in some substantial ways.<sup>197</sup>

As previously discussed, FDA has taken steps in recent years to conform its labeling regime to the Guidelines. But FDA's labeling rules are promulgated as agency regulations, not mere guidance, so they are not statutorily required to conform.<sup>198</sup> From 1973 until 2016, FDA's nutrition facts labels used the %DVs determined by the National Academies in 1968.<sup>199</sup> They remained unchanged for more than forty years despite updated understandings of nutrition science that were reflected in the Guidelines.

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191. See, e.g., 7 U.S.C. § 5301 et seq. (establishing the National Nutrition Monitoring and Related Research Program, which is jointly coordinated by USDA and HHS).

192. See *Dietary Guidelines for Americans*, U.S. DEPT OF HEALTH & HUMAN SERVS., <https://health.gov/our-work/food-nutrition> [<https://perma.cc/9DN5-MHA9>].

193. See *supra* notes 59–61 and accompanying text.

194. See 7 U.S.C. § 5341(b)(3) (exempting “any rule or regulation issued by a Federal agency” from the class of dietary guidance requiring review by the USDA and HHS Secretaries).

195. U.S. DEPT OF AGRIC., A GUIDE TO FEDERAL FOOD LABELING REQUIREMENTS FOR MEAT, POULTRY, AND EGG PRODUCTS 4-6 (2007).

196. INST. OF MED. OF THE NAT'L ACADS., FRONT-OF-PACKAGE NUTRITION RATING SYSTEMS AND SYMBOLS: PHASE I REPORT 15 (Ellen A. Wartella, Alice H. Lichtenstein & Caitlin S. Boon, eds., 2010).

197. For example, in 2003, FDA issued a final rule requiring trans fats to be listed separately from total fat; USDA regulations permit but do not require trans fats to be separately declared. *Compare* Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrition Content Claims, and Health Claims, 68 Fed. Reg. 41434, 41434 (July 11, 2003) (to be codified at 21 C.F.R. pt. 101) (requiring that FDA-regulated food labels list trans fat content), with 9 C.F.R. § 317.362 (permitting but not requiring that FSIS-regulated food labels list trans fat content).

198. See 7 U.S.C. § 5341(b)(3) (exempting “any rule or regulation issued by a Federal agency” from the class of dietary guidance requiring review by the USDA and HHS Secretaries).

199. BARBARA A. BREHM, FOOD LABELS: YOUR QUESTIONS ANSWERED 16 (2019).

This more conservative approach has its advantages as well. While the 2015 Guidelines eliminated cholesterol as a nutrient of concern, FDA has chosen to continue requiring cholesterol on nutrition labels.<sup>200</sup> The Guidelines' ambiguous advice—eliminating the cholesterol limit but still recommending consuming as little cholesterol as possible—has caused confusion and created distrust in the Guidelines.<sup>201</sup> But having multiple agencies set inconsistent nutrition policy only furthers those problems.

The current division of duties also creates a concerning dynamic. FDA retains discretion to deviate from the Guidelines as it sees fit. Yet when the recommendations align, FDA uses the Guidelines to justify its regulations, often with little additional reasoning.<sup>202</sup> When FDA sometimes does not trust the Guidelines, why should we trust FDA when it does?

### E. Judicial Review

Despite their far-ranging effects on American diets, the Guidelines are effectively insulated from meaningful judicial review. This exacerbates each of the problems previously discussed by precluding the courts as an avenue for reform. With the courthouse doors closed, the Guidelines' rehabilitation essentially requires an act of Congress.

As discussed earlier in this Part, the D.C. District Court held that the Guidelines are not an agency action subject to the APA,<sup>203</sup> and the Northern District of California held that challenges to the Committee's composition are non-justiciable under both the APA and FACA.<sup>204</sup> While public interest groups have successfully sued USDA for violating FACA's information disclosure requirements, no substantive challenges to the Guidelines have survived the motion to dismiss stage.<sup>205</sup>

The absence of judicial review has severe ramifications, particularly for the approximately eighty million beneficiaries of federally subsidized food programs.<sup>206</sup> The nutrition standards for the National

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200. Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 81 Fed. Reg. 33742, 33791 (2016) (to be codified at 21 C.F.R. pt. 101).

201. See, e.g., Heid, *supra* note 13 ("It's upsetting to see cycles of misinformation coming back over and over again," says Dr. David Heber, founding director of the University of California, Los Angeles, Center for Human Nutrition. "The public has been confused and will remain confused by these guidelines.").

202. Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 79 Fed. Reg. 11880, 11881–82 (Mar. 3, 2014) (to be codified at 21 C.F.R. pt. 101).

203. Physicians Comm. for Responsible Med. v. Vilsack, 867 F. Supp. 2d 24, 29 (D.D.C. 2011).

204. Physicians Comm. for Responsible Med. v. Vilsack, No. 16-cv-00069, 2016 WL 5930585, at \*7 (N.D. Cal. Oct. 12, 2016).

205. See, e.g., Physicians Comm. for Responsible Med. v. Glickman, 117 F. Supp. 2d 1 (2000).

206. Secemsky, *supra* note 9.

School Lunch Program can be challenged under the APA because they are clearly declared agency rules by the language of their authorizing statute.<sup>207</sup> However, the statute only requires that the standards be consistent with the Guidelines; it does not give potential plaintiffs a right to “healthy” or “nutritionally adequate” meals.<sup>208</sup> It does not provide any other standard against which prospective plaintiffs could claim the standards violate the APA as “arbitrary, capricious, or otherwise not in accordance with law.”<sup>209</sup> Thus, because the Guidelines are insulated from review, the school lunch nutrition standards cannot be meaningfully challenged for nutritional inadequacy, only consistency with the Guidelines.<sup>210</sup>

Another barrier to judicial review is standing.<sup>211</sup> Most challenges to the Guidelines have been brought by public interest groups largely unable to establish a particularized injury.<sup>212</sup> Some courts have analyzed such claims, appearing to accept the standing of these organizations—but these outcomes cannot be extrapolated far given that such cases were dismissed on other grounds or did not seek appreciable reform.<sup>213</sup>

Because the Guidelines are insulated from judicial review, their many other flaws—rampant conflicts of interest and paucities of public participation and transparency—remain unchecked.

#### F. Disproportionate Impact

These failures of process and the questionable nutrition standards that result have a disproportionate impact on low-income communities and communities of color. These communities are more directly impacted because they comprise most of the beneficiaries of federally subsidized food assistance programs and can rely on these programs

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207. See 42 U.S.C. § 1758.

208. *Id.* § 1758(f).

209. See *id.*; 5 U.S.C. § 706(2).

210. See generally *Ctr. for Sci. in the Pub. Interest v. Perdue*, 438 F. Supp. 3d 546 (D. Md. 2020) (challenging a Final Rule governing school nutrition standards for inconsistency with the Dietary Guidelines and for failure to adhere to proper rulemaking procedures).

211. Under the standing doctrine, a plaintiff may sue in federal court only if they can allege a “concrete and particularized injury that is: 1) actual or imminent, 2) caused by, or fairly traceable to, an act that [plaintiff] challenges in the instant litigation, and 3) redressable by the court.” *Physicians Comm. for Responsible Med. v. Vilsack*, 867 F. Supp. 2d 24, 28 (D.D.C. 2011) (citation and quotation marks omitted).

212. *E.g., id.* at 29.

213. See, e.g., *Physicians Comm. for Responsible Med. v. Glickman*, 117 F. Supp. 2d 1, 2–3 (D.D.C. 2000) (granting Plaintiffs’ request for declaratory relief under FACA); *Physicians Comm. for Responsible Med. v. Vilsack*, No. 16-cv-00069, 2016 WL 5930585 (N.D. Cal. Oct. 12, 2016) (turning to the merits of Plaintiffs’ claim without discussing standing).

for significant portions of their total daily intake.<sup>214</sup> Although an important tool for addressing food insecurity, these programs often dictate beneficiaries' food choices,<sup>215</sup> taking away their freedom to interpret the nutrition science for themselves. And while lacking such freedom, these communities become those harmed most by the narrative that nutrition is a matter of personal choice.<sup>216</sup> Moreover, poor nutrition causes and compounds chronic disease, exacerbating existing health disparities which stem from systemic oppression.<sup>217</sup>

### III. APPLYING THE APA TO THE DIETARY GUIDELINES

This Note contends that the most effective solution to the concerns outlined above is for the Guidelines to be an agency rule subject to the APA. Rules are subject to procedural requirements and judicial review that can alleviate—though not eliminate—many of the issues discussed in Part II. This change can be accomplished through an amendment to the Nutrition Act or through litigation that challenges the D.C. District Court's holding in *Physicians Committee for Responsible Medicine (PCRM) v. Vilsack* that the Guidelines are not an agency rule.

#### A. Advantages of Applying the APA

The APA would provide much-needed accountability to the Guidelines and the process for their development. The APA's rulemaking procedures ensure that agencies engage in reasoned decision-making that is transparent and considers input from a variety

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214. See, e.g., CONSTANCE NEWMAN & KATHERINE RALSTON, U.S. DEP'T OF AGRIC., PROFILES OF PARTICIPANTS IN THE NATIONAL SCHOOL LUNCH PROGRAM: DATA FROM TWO NATIONAL SURVEYS iii, 10–11, 13–14, 16 tbls.5–8 (2006), [https://www.ers.usda.gov/webdocs/publications/44110/48589\\_eib17.pdf?v=0](https://www.ers.usda.gov/webdocs/publications/44110/48589_eib17.pdf?v=0) [<https://perma.cc/PB45-QXWX>] (showing that National School Lunch Program participants are disproportionately low income and that the Program's free lunch recipients are predominantly non-white, as compared to the overall student population); Mary Story, Guest Editorial, *The Third School Nutrition Dietary Assessment Study: Findings and Policy Implications for Improving the Health of US Children*, 109 J. AM. DIETETIC ASS'N (SUPP.) S7, S8 (2009).

215. See, e.g., *WIC Food Packages – Maximum Monthly Allowances*, U.S. DEP'T OF AGRIC. (Mar. 25, 2021), <https://www.fns.usda.gov/wic/wic-food-packages-maximum-monthly-allowances> [<https://perma.cc/HUL6-89XU>].

216. See Kelli K. Garcia, *The Fat Fight: The Risks and Consequences of the Federal Government's Failing Public Health Campaign*, 112 PA. STATE L. REV. 529, 531, 562–64 (2007).

217. E.g., Jessie A. Satia, *Diet-Related Disparities: Understanding the Problem and Accelerating Solutions*, 109 J. AM. DIETETIC ASS'N 610 (2009); Maria Chiorando, *NBA Champ John Salley Urges U.S. Government to Ditch Racist Dietary Guidelines*, PLANT BASED NEWS (Aug. 12, 2020), <https://plantbasednews.org/lifestyle/john-salley-urges-government-ditch-racist-dietary-guidelines/> [<https://perma.cc/NF7R-TV55>] (“Dairy products are unnecessary and take a disproportionate health toll on people of color.”).

of sources.<sup>218</sup> The APA additionally provides several grounds for challenging inappropriate agency action in the courts.<sup>219</sup>

Rules must follow the APA's rulemaking procedures, which often mandate the notice-and-comment process.<sup>220</sup> This process requires agencies to provide public notice of proposed rules and to allow sufficient time for public comment.<sup>221</sup> These requirements allow the public to have input on rulemaking and help agencies acquire relevant information. The procedural requirements also provide grounds for legal challenges against agency actions that fail to follow the proper procedures.<sup>222</sup> Currently, USDA and HHS voluntarily take public comment on the Committee report but not on the Guidelines themselves.<sup>223</sup>

The APA provides some exceptions to the notice-and-comment rulemaking process. For example, the requirements do not apply to "non-legislative rules," which are "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice."<sup>224</sup> "Legislative rules," on the other hand, are promulgated through the notice-and-comment process and have the force and effect of law.<sup>225</sup> Legislative rules can be exempt from notice-and-comment if the agency has "good cause" to dispense with the procedures.<sup>226</sup> Distinguishing legislative from non-legislative rules requires determining whether an action simply interprets existing law or results in a substantive change to existing law.<sup>227</sup> Under the APA, an injured party may challenge an agency action that did not follow notice-and-comment procedures on the ground that the action was a legislative rule and thus is invalid for failing to comply with procedural requirements.<sup>228</sup> If the Guidelines are deemed a legislative rule, they must undergo notice-and-comment and can be challenged for failure to do so. While non-legislative rules are exempt from the notice-and-comment process, they are still susceptible to judicial scrutiny under the APA.

The statute provides several grounds upon which a court may hold an agency action invalid. These include the procedural grounds

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218. See generally TODD GARVEY, CONG. RSCH. SERV., R41546, A BRIEF OVERVIEW OF RULEMAKING AND JUDICIAL REVIEW 2, 15 (2017).

219. 5 U.S.C. § 706.

220. GARVEY, *supra* note 218, at 1–9.

221. 5 U.S.C. § 553(c).

222. § 706(2)(D).

223. See *Public Comments to USDA and HHS*, *supra* note 183.

224. GARVEY, *supra* note 218, at 1 n.5; § 553(b)(3)(A).

225. GARVEY, *supra* note 218, at 1 n.5.

226. *Id.* at 6–7.

227. *Id.* at 8.

228. See 5 U.S.C. § 706(2)(D).

discussed earlier in this Subsection, like failure to observe notice-and-comment.<sup>229</sup> An injured party can also claim that an action is outside the scope of the agency's statutory authority; that it violates the U.S. Constitution; or, that it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."<sup>230</sup> These grounds can enable meaningful challenges to the Guidelines' content.

Under the "arbitrary and capricious standard," a court may set an agency action aside: if the agency's findings of fact are unsupported by substantial evidence; if the agency's policy decisions are not based on relevant factors; if the agency failed to compile a record sufficient for the court to determine whether these grounds are met; or, if the action reflects a clear error in judgment or is otherwise arbitrary and capricious.<sup>231</sup> An agency's factual determinations must "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'"<sup>232</sup> Under the APA, courts could scrutinize the Guidelines' factual findings, including that cholesterol is no longer a nutrient of concern.<sup>233</sup>

Courts still show a lot of deference to agencies, particularly where a decision relies on complex, often competing, scientific or technical information.<sup>234</sup> But the mere possibility of judicial review would compel USDA and HHS to justify their factfinding. In particular, they would have to explain any deviations between the Guidelines and the Committee report,<sup>235</sup> and reason-giving alone can improve the quality of decisions.<sup>236</sup> An agency action subject to notice-and-comment will also be considered arbitrary and capricious if an agency fails to respond to significant comments.<sup>237</sup> The availability of judicial review renders the public comment process meaningful by giving the public some bargaining power, namely, the threat of litigation that could overturn the agencies' actions. If the Guidelines had been an agency action in 2015, HHS and USDA would have had to address some of the 18,000

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229. § 706(2).

230. *Id.*

231. *Id.*; GARVEY, *supra* note 218, at 13.

232. Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (quoting Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962)).

233. See 2015 SCIENTIFIC REPORT, *supra* note 90, at 58.

234. *E.g.*, Balt. Gas & Elec. Co. v. Nat'l Res. Def. Council, Inc., 462 U.S. 87, 2013 (1983).

235. As discussed above, this was one of the National Academies' recommendations for improving the Guidelines process. See *supra* notes 181–82 and accompanying text. USDA and HHS eventually agreed to implement the recommendation, but notable deviations are unlikely to reoccur given the agencies' tightened grip on the entire process. *Id.*

236. See generally Lawrence Solum, *The Obligation to Give Reasons*, LEGAL THEORY BLOG (July 23, 2006), [https://lsolum.typepad.com/legaltheory/2006/07/the\\_obligation\\_.html](https://lsolum.typepad.com/legaltheory/2006/07/the_obligation_.html) [<https://perma.cc/S7RS-S8J6>] (explaining the benefits of judicial reason-giving); Ashley S. Deeks, *Secret Reason-Giving*, 129 YALE L.J. 612, 620.

237. See *United States v. N.S. Food Prod. Corp.*, 568 F.2d 240, 253 (2d Cir. 1977).

comments supporting the Guidelines' consideration of sustainability, or risk litigation that may invalidate their decision.<sup>238</sup>

An agency action is also arbitrary and capricious if the decision did not consider all the relevant factors or considered irrelevant factors.<sup>239</sup> Which factors are relevant is generally determined by reference to the statute authorizing the agency action in question.<sup>240</sup> The Nutrition Act mandates that the Guidelines contain “nutritional and dietary information and guidelines for the general public” and “shall be based on the preponderance of the scientific and medical knowledge.”<sup>241</sup> APA challenges to the Guidelines could reduce the impermissible influence by the irrelevant factor of USDA's duty to promote domestic agricultural products,<sup>242</sup> as this consideration is not directly relevant to nutrition science. Courts may also invalidate an action where the agencies failed to “exercise sufficiently independent judgment” by deferring to private parties.<sup>243</sup> On this ground, the Guidelines could be challenged for being inappropriately influenced by the food and beverage industries.

In sum, the APA would provide the public with many procedural and substantive safeguards. Notice-and-comment requirements would ensure that the Guidelines themselves would be promulgated with public input. This would sharply contrast the current scheme of voluntary public comment on the Committee report, from which the Guidelines may deviate substantially. The threat of judicial review would compel USDA and HHS to explain their reasoning for any such deviations, as well as justify their factual findings and policy decisions. These agencies would also have to respond to significant comments and compile a record of their decision-making. While the APA would not directly address conflicts of interest among the Committee members or within the agencies, it would limit the influence of these conflicts on the final Guidelines.<sup>244</sup>

Much of the legal scholarship on the Guidelines has focused on reforms to the Committee, paying particular attention to the

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238. See Mary K. Caffrey, *Food Politics Get Heated as Dietary Guidelines Near Approval*, AM. J. MANAGED CARE (Oct. 8, 2015), <https://www.ajmc.com/view/food-politics-get-heated-as-dietary-guidelines-near-approval> [https://perma.cc/DRV2-5JT2].

239. See *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), *abrogated by* *Califano v. Sanders*, 430 U.S. 99 (1977); Cass R. Sunstein, *Reviewing Agency Inaction After Heckler v. Chaney*, 52 U. CHI. L. REV. 653, 668 (1985).

240. See *Overton Park*, 401 U.S. at 416.

241. 7 U.S.C. § 5341(a)(1)–(2).

242. See § 1622; see generally Sunstein, *supra* note 239, at 668.

243. *Tex. Off. of Pub. Util. Couns. v. F.C.C.*, 265 F.3d 313, 327–29 (5th Cir. 2001).

244. Cf. *Tummino v. Hamburg*, 936 F. Supp. 2d 162 (E.D.N.Y. 2013) (invalidating FDA's restrictions on Plan B because impermissible political intrusion made decision arbitrary and capricious under the APA).

Committee's composition.<sup>245</sup> But the 2015 and 2020 Guidelines processes have shown how USDA and HHS can overrule the Committee's recommendations. Judicial review would allow challenges to the substance of the Guidelines, regardless of which body issues them.<sup>246</sup> Both judicial review and notice-and-comment procedures would improve transparency, making it more difficult for the Guidelines to employ misleading language to hide shaky factual underpinnings. A more rigorous Guidelines development process would also reduce concerns about FDA regulations relying on them and could create more consistency and thus greater confidence in the Guidelines.

Perhaps the most important advantage of a single, robust set of Guidelines is that they could serve as the foundation for more sound nutrition policy overall. Federal nutrition policy currently focuses on information regulation, but scholars have called for the government to take a more active role in combating the public health crisis of pervasive diet-related disease and premature death.<sup>247</sup> Healthy foods could be more accessibly priced if they were subsidized by the federal government, for example, by aligning Farm Bill subsidies with authoritative dietary guidance.<sup>248</sup> Concrete nutrition goals could also support calls for a higher minimum wage and other labor reforms that would give people the necessary "leisure" time to make healthy choices. Although detailed discussion of these reforms is beyond the scope of this Note, few of these strategies are viable without sound nutrition guidance as a foundation.

### B. *The Dietary Guidelines Already Resemble a Rule*

Principles of administrative law, as well as policy benefits, favor the Guidelines being a rule. From a functional perspective, the Guidelines

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245. See, e.g., Gabriela Steier, *Dead People Don't Eat: Food Governmentenomics and Conflicts-of-Interest in the USDA and FDA*, 7 PITT. J. ENV'T PUB. HEALTH L. 1, 2 (2012) (proposing statutory amendments to rebalance the composition of the advisory committees and the scientific basis for the dietary recommendations); Herman, *supra* note 174, at 305–08 (proposing statutory amendments to redesignate the Guidelines to a health agency and to prohibit conflicted individuals from serving on the Dietary Guidelines Advisory Committee).

246. It is crucial to create accountability with respect to the substance of the Guidelines in this age of industry-funded research, where unconflicted parties are fewer and farther between, and where conflicts may be the cost of higher-quality experts.

247. See, e.g., Broad Leib & Pollans, *supra* note 6, at 1237–40 (arguing that FDA should use its discretion to increase spending on nutrition, currently only two percent of its budget). In fact, the Guidelines have been criticized for the harmful effects of telling people that they should eat better without modifying their environment to make it easier for them to make healthy choices. Garcia, *supra* note 216, at 564–65.

248. See generally Mortazavi, *supra* note 174.

satisfy the criteria that courts use to determine whether an agency statement is a rule and thus an agency action. Moreover, the circumstances suggest that the Guidelines are not just a rule but a legislative rule subject to the notice-and-comment requirements from which non-legislative rules are exempt.

The APA defines “agency action” fairly broadly, but courts will deny review if the agency’s challenged conduct does not meet the statutory definition, i.e., if it is not a “rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act.”<sup>249</sup> When determining whether an agency statement is a reviewable agency action, courts look to the “actual interpretation and effect” of the statement.<sup>250</sup> Some courts also consider whether the agency statement was disseminated pursuant to a statutory authorization.<sup>251</sup> Generally, an agency statement that establishes legal rights or obligations is reviewable.<sup>252</sup> Accordingly, courts have denied requests for review of agency publications and press releases.<sup>253</sup> For example, *Industrial Safety Equipment Association v. EPA* involved a challenge to a report published jointly by EPA and the National Institute for Occupational Safety and Health titled, “A Guide to Respiratory Protection for the Asbestos Abatement Industry.”<sup>254</sup> The report listed all of the available asbestos respirators that may be used under existing regulations, but encouraged use of only two types of respirators.<sup>255</sup> The plaintiffs, a trade association and respirator manufacturers, alleged that the report effectively revoked certification of some of their respirators, which were not singled out for use in the report.<sup>256</sup> The court held that the report was not an agency action because it did not change the standards necessary to obtain certification, nor did it restrict or revoke existing certification.<sup>257</sup> The report was also consistent with existing regulations and thus did not constitute a new agency interpretation of those regulations.<sup>258</sup> The court concluded that, “where an agency disseminates information in the absence of a specific statutory authorization, and the publication does not bind the agency or alter the rights, liabilities, obligations, or legal relationships of private parties, then no reviewable ‘agency action’

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249. 5 U.S.C. § 551(13).

250. *Indus. Safety Equip. Ass'n v. E.P.A.*, 656 F. Supp. 852, 855 (D.D.C. 1987), *aff'd*, 837 F.2d 1115 (D.C. Cir. 1988).

251. *E.g.*, *Hearst Radio, Inc. v. F.C.C.*, 167 F.2d 225, 227 (D.D.C. 1948) (holding FCC’s report, which exposed plaintiff’s radio station to public controversy, was not a “sanction” and thus not an agency action).

252. GARVEY, *supra* note 218, at 6–7.

253. *See id.* at 7–8.

254. *Indus. Safety Equip. Ass'n*, 656 F. Supp. at 853.

255. *Id.* at 854.

256. *Id.*

257. *Id.* at 855–56.

258. *Id.*

has occurred.”<sup>259</sup> Like the asbestos report, the Guidelines contain guidance and best practices related to a regulatory framework. But unlike the asbestos report, the Guidelines are issued pursuant to a statutory mandate; and, more importantly, they affect legal rights and obligations. Since 1994, USDA has been required to issue school meal nutrition standards that conform with the Guidelines.<sup>260</sup> States that receive federal funding for school meals and other federally subsidized programs must meet these standards.<sup>261</sup> The Guidelines create legal duties governing USDA rulemaking and state policy-setting, and they give program beneficiaries a legal right to Guidelines-compliant meals.<sup>262</sup>

Given their legal consequences, the Guidelines should be considered an agency action subject to judicial review. Moreover, the Guidelines should be considered a legislative rule subject to notice-and-comment procedures and the additional opportunities for judicial review that such procedures provide. Legislative rules are rules that do not meet the definition of “non-legislative rules,” which include agency procedural rules, interpretative rules, and general statements of policy.<sup>263</sup> The Guidelines do not fit any of these exceptions.

Agency procedural rules are the “technical regulation of the form of agency action and proceedings” and they must have an intra-agency impact.<sup>264</sup> The definition excludes any action “which is likely to have considerable impact on ultimate agency decisions” or that “substantially affects the rights of those over whom the agency exercises authority.”<sup>265</sup> The Guidelines are far too impactful to qualify as a procedural rule. As in the case of the school meal nutrition standards, they govern the substance rather than the form of agency decisions. The Guidelines are thus likely to have a considerable impact on those decisions and on the people whose rights are affected by those decisions.

Interpretative rules announce an agency’s interpretation of a statute in a way that “only reminds affected parties of existing duties”

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259. *Id.*

260. 42 U.S.C. § 1758.

261. *Id.*

262. Admittedly, the Guidelines’ bindingness has been somewhat diminished by *CSPI v. Perdue*, which upheld USDA’s interpretation of its obligation as requiring only that the school nutrition standards loosely conform to the overarching goals of the Guidelines. *See* Ctr. for Sci. in the Pub. Interest v. Perdue, 438 F. Supp. 3d 546 (D. Md. 2020). This holding is likely a correct application of the *Chevron* doctrine, but that also means that another administration may interpret its obligation more stringently.

263. GARVEY, *supra* note 218, at 7.

264. *Pickus v. U.S. Bd. of Parole*, 507 F.2d 1107, 1113 (D.C. Cir. 1974).

265. *Id.* at 1113–14.

but do not effect a substantive change in the regulations.<sup>266</sup> Each edition of the Guidelines alters the substantive requirements to which other programs must conform.<sup>267</sup> They do not purport to interpret statutory language.

General statements of policy are “statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power.”<sup>268</sup> Agency guidance documents are a common example of these statements, and their rising use and widespread impact have sparked debate over whether they should in fact be exempt from notice-and-comment.<sup>269</sup> But even under the current framework, the Guidelines do not fit this exemption. Unlike general statements of policy, the Guidelines do not announce an agency’s “tentative intentions for the future in a non-binding manner.”<sup>270</sup> The Guidelines establish binding consequences from the moment they are published. Thus, the Guidelines do not fall into any of the categories of non-legislative rules.

To summarize, the practical effects of the Guidelines suggest that the Guidelines are an agency rule subject to notice-and-comment and judicial review under the APA. When Congress enacted the Nutrition Act in 1990, it may not have intended for the Guidelines to constitute a rule because at the time, the Guidelines contained non-binding advice. But since 1994, the Guidelines have had binding consequences on agency decision making and on the beneficiaries of those decisions. Accordingly, the Guidelines have become a legislative rule and should be treated as such.

### C. Strategy 1: Litigation

Courts are empowered to review agency activities and determine whether they were conducted in accordance with the APA. An aggrieved party could challenge the Guidelines, alleging that they should have undergone notice-and-comment or that their contents do not reflect reasoned agency decision-making. A court could hold that the Guidelines fall within the scope of the APA, subjecting them to all of the procedural and substantive constraints discussed in Section III.A.

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266. *Gen. Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1565 (D.C. Cir. 1984) (quoting *Citizens to Save Spencer Cnty. v. E.P.A.*, 600 F.2d 844, 876 & n.153 (D.C. Cir. 1979)) (internal quotations omitted).

267. *See* 42 U.S.C. § 1758.

268. TOM C. CLARK, U.S. DEP’T OF JUST., ATTORNEY GENERAL’S MANUAL ON THE ADMINISTRATIVE PROCEDURE ACT 30 n.3 (photo. reprt. 1973) (1947).

269. *See, e.g.*, Nina A. Mendelson, *Regulatory Beneficiaries and Informed Agency Policymaking*, 92 CORNELL L. REV. 397, 400–02 (2007).

270. GARVEY, *supra* note 218, at 8 (internal quotations omitted).

The only court that directly faced the question of whether the Guidelines constitute reviewable agency action answered in the negative.<sup>271</sup> In *PCRM v. Vilsack*, as explained below, the D.C. District Court's holding relies on a flawed interpretation of the Nutrition Act and an erroneous account of the Guidelines' effects. Because only one district court case has adopted this flawed interpretation, another court could easily find otherwise, or the D.C. District could diverge from its own prior ruling. In doing so, a court could bring the Guidelines within the scope of the APA, achieving beneficial policy outcomes and adhering more faithfully to principles of administrative law.

In *Physicians Committee for Responsible Medicine v. Vilsack*, the plaintiff argued that the Dietary Guidelines were an agency procedural rule.<sup>272</sup> The court rejected this argument and dismissed the complaint for failure to state a claim, reasoning:<sup>273</sup>

The *Dietary Guidelines*, however, is not an agency statement describing the USDA or HHS organizations or the agencies' procedures or practice requirements. It is, in sum, a report containing "nutritional and dietary information and guidelines for the general public." 7 U.S.C. § 5341(a)(1). As the Nutrition Act makes clear, such dietary guidance "does not include any rule or regulation issued by a Federal agency," and thus, does not constitute an "agency action." *Id.* § 5341(b)(3).<sup>274</sup>

The court seems to have erred by interpreting § 5341(b)(3) as defining the Guidelines themselves, which are established in subsection (a).<sup>275</sup> This provision states that "the term 'dietary guidance for the general population' does not include any rule or regulation issued by a Federal agency."<sup>276</sup> But that provision is, by its own terms, limited to "for purposes of this subsection."<sup>277</sup> Subsection (b), entitled "Approval by Secretaries," describes the process by which "dietary guidance for the general population" proposed by a federal agency must be submitted to the USDA and HHS Secretaries for approval.<sup>278</sup> Section 5341(b)(3) creates an exception to subsection (b)'s approval requirement by

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271. *Physicians Comm. for Responsible Med. v. Vilsack*, 867 F. Supp. 2d 24, 29–30 (D.D.C. 2011).

272. *Id.*

273. *Id.* at 30.

274. *Id.*

275. *Id.*; 7 U.S.C. § 5341.

276. § 5341(b)(3).

277. *Id.*

278. *Id.* § 5341(b).

providing that “dietary guidance for the general population’ does not include any rule or regulation issued by a Federal agency.”<sup>279</sup>

Thus, the provision relied on by the D.C. District Court simply reflects Congress’s intent that agency rules and regulations be exempt from this approval process because their inclusion would be inefficient and redundant. If the Secretaries do not approve of guidance submitted to them, then such guidance must go through the notice-and-comment process prior to publication.<sup>280</sup> This process ensures that any dietary guidance either conforms to the Guidelines or goes through notice-and-comment. Agency rules and regulations already undergo notice-and-comment, so this approval process would not add much benefit. In light of this natural interpretation of the Nutrition Act, it seems that the court erroneously applied the exemption provision of subsection (b) to define the Guidelines themselves, established in subsection (a), rather than solely to define the dietary guidance requiring review under subsection (b).<sup>281</sup>

But the court’s reasoning was vague. It did not clearly explain how it concluded that the Dietary Guidelines are “dietary guidance for the general population” under § 5341(b)(3).<sup>282</sup> Defendant’s motion to dismiss brief provides more specific reasoning in its arguments, which likely formed the basis of the court’s opinion. Defendants argued that “the Dietary Guidelines in no way describe the USDA’s or HHS’s organizations, or the agencies’ procedures or practice requirements. Rather, they are a report that contains nutritional and dietary information and guidelines for the general public.”<sup>283</sup> Defendants further argued that because federal guidance that promote the Guidelines are not rules or regulations (according to § 5341(b)(3)), the Guidelines themselves cannot be a rule or regulation.<sup>284</sup> If the court’s holding was based on Defendants’ arguments, then perhaps it did not mistakenly apply a provision to the wrong subsection. Rather, the court interpreted subsection (b) to necessarily mean that the Guidelines are not a rule or regulation.

But even so, Defendants’ argument is circular. They proposed that because guidance based on the Guidelines does not constitute rules or regulations, the Guidelines themselves cannot be a rule or regulation. Defendants provided no explanation for why this must be the case. To the contrary, the very fact that the Guidelines dictate how agencies may

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279. *Id.* § 5341(b)(3).

280. *Id.* § 5341(b)(2).

281. *See id.* § 5341.

282. *See* Physicians Comm. for Responsible Med. v. Vilsack, 867 F. Supp. 2d 24 (D.D.C. 2011).

283. Defendants’ Response to Plaintiff’s Memorandum in Opposition to Defendants’ Motion to Dismiss at 15, Physicians Comm. for Responsible Med. v. Vilsack, 867 F. Supp. 2d 24 (D.D.C. 2011) (No. 11-0038), 2011 WL 12851056.

284. *Id.* at 15–16.

issue guidance suggests that they should be considered a rule. Moreover, Defendants' arguments ignored the agency rules and regulations that not only promote but incorporate and make binding the Guidelines. For example, USDA nutrition standards governing the School Lunch Program must comply with the Guidelines and are promulgated through notice-and-comment.<sup>285</sup> These regulations were simply excluded from Defendants' narrow analysis because they do not relate to the provision relied upon. The case was dismissed on several other grounds, however, including for lack of standing, so perhaps the court employed faulty reasoning merely because it did not spend much time on this analysis as it would not have changed the outcome.<sup>286</sup>

In sum, courts could, and should, split from *PCRM v. Vilsack* and hold that the Guidelines are an agency action. As described in Section III.B, properly applying the conventional methods for analyzing agency action leads to the conclusion that the Guidelines are a legislative rule. And, as explained earlier in this subsection, the statutory language of the Nutrition Act poses no bar to this conclusion.

Alternatively, a court could hold that the Guidelines are a non-legislative rule. In *PCRM v. Vilsack*, PCRM argued that the Guidelines are an agency procedural rule rather than arguing that they are a legislative rule.<sup>287</sup> PCRM probably did so to appeal to judicial modesty; determining that the Guidelines constitute a legislative rule would have far more ramifications than classifying them as a non-legislative rule. Although, as discussed in Section III.B, the Guidelines do not fit the definition of an agency procedural rule, courts might still classify them as such because of their unique characteristics. The Guidelines are unlike any other agency conduct. In form, they resemble an informational publication, which would not be considered agency action. But few agency publications have such widespread effects, let alone binding consequences, which typify legislative rules.<sup>288</sup> Because the Guidelines are unique and because the agency action doctrines are constantly evolving, courts could categorize the Guidelines as an agency procedural rule. While this would not secure some of the benefits of

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285. 42 U.S.C. § 1758(a)(4).

286. There may be valid arguments that the Guidelines are not an agency action, but these arguments were not discussed by the courts. For example, there's an intentionalist and historical argument. USDA and HHS did not intend for the Guidelines to be a rule or regulation when the agencies voluntarily began publishing this purely informational report in 1980. And if Congress had intended for the Guidelines to be a rule when it enacted the Nutrition Act in 1990, it could have made that intent clear given the Guidelines' history of promulgation without regard to the APA. This Note does not dispute this point but instead emphasizes that the Guidelines effectively became a rule when other statutes made them binding.

287. Plaintiff's Memorandum in Opposition to Defendants' Motion to Dismiss at 9–10, *Physicians Comm. for Responsible Med.*, 867 F. Supp. 2d 24 (D.D.C. 2011) (No. 11-0038), 2011 WL 12851056.

288. GARVEY, *supra* note 218, at 7.

notice-and-comment, such as the requirement that agencies respond to significant comments, classification as a non-legislative rule has some advantages as well. Notice-and-comment procedures are extraordinarily time-intensive, so bypassing them could ensure that the Guidelines are published on time every five years. Congress requires EPA to revise the National Ambient Air Quality Standards (NAAQS) every five years, but they have only been updated four times since they were established in 1971.<sup>289</sup> Thus, both possibilities have benefits and drawbacks, and courts could choose either route.

#### D. *Strategy 2: Legislation*

A straightforward—if politically unlikely—avenue for bringing the Guidelines within the scope of the APA would be for Congress to amend the Nutrition Act to explicitly provide that the Guidelines are a rule. The Nutrition Act is currently silent on how the Guidelines should be characterized. As discussed above, Congress in 1990 likely did not intend for the Guidelines to go through notice-and-comment. But that Congress also did not intend for the Guidelines to have the widespread impact they have today. Since 1990, the Guidelines have grown significantly in impact and acceptance. More importantly, the Guidelines directly define the legal rights and obligations of agencies, states, and the public.

In amending the Nutrition Act, Congress has significantly more flexibility than the courts. Congress could provide that the Guidelines are a legislative rule and subject them to notice-and-comment, or exempt them but still allow for judicial review. Congress could also devise special procedures for the Guidelines, given their unique character, such as requiring that the agencies respond to public comment and providing a private right of action for failure to comply with these procedures. This would not invite substantive challenges, but would still compel the agencies to explain their reasoning, and would make public participation meaningful. Congress could also amend the substantive statutory mandate to be more specific about the Guidelines' objectives and scientific basis, as other scholars have proposed.<sup>290</sup> Finally, as numerous scholars, commentators, and practitioners have urged, Congress could eliminate USDA's role in

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289. EPA, EPA-452/R-20-002, POLICY ASSESSMENT FOR THE REVIEW OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR PARTICULATE MATTER, 1-4, 1-6 (2020), <https://www.epa.gov/system/files/documents/2021-10/final-policy-assessment-for-the-review-of-the-pm-naaqs-01-2020.pdf> [https://perma.cc/8H8G-WYJU].

290. See Garcia, *supra* note 216, at 564–65; Steier, *supra* note 245, at 2, 7.

setting nutrition policy and thereby commit that function to an unconflicted agency dedicated to health.<sup>291</sup>

#### CONCLUSION

The Dietary Guidelines for Americans are scientifically unsound because of defects in their promulgation process. These defects allowed the Dietary Guidelines Advisory Committee to become unduly influenced by industry interests. The Committee's few scientifically sound recommendations can be cast aside by USDA and HHS officials without a word of explanation. When these defects are challenged, courts hold that the Guidelines are unreviewable under the applicable statutes.

But those courts decided incorrectly. The Guidelines do in fact fall within the coverage of the APA, which would be effective in remedying the Guidelines' shortcomings. The APA would require agency officials to explain their decision-making, to support their findings with sufficient evidence, to consider the relevant factors (and not consider irrelevant factors), and to make no arbitrary and capricious decisions. This would help to ensure that the Committee considers all the relevant nutritional science and to protect the promulgation process from political influence. As a result, health outcomes would improve, and Americans would live healthier, happier lives.

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291. See, e.g., Torrez, *supra* note 174; Mortazavi, *supra* note 174; Herman, *supra* note 174.