

# ESSAYS

## REGULATING INHERENTLY SUBJECTIVE FOOD LABELING CLAIMS

BY

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*For many consumers, the modern food label serves as the sole source of information regarding any individual food product. While it may be considered informative in some respects, it is often enigmatic in others. The present debate regarding the creation of a federal regulation to define use of the term “healthy” exemplifies the difficulties associated with seemingly subjective food labeling claims. The law requires manufacturers to include certain facts on food labels. However, they are permitted to include additional voluntary statements related to the healthfulness of the food product, the presence or absence of certain ingredients, and information related to production and growing methods, among other things. These claims have the potential to cause consumers a great deal of confusion, particularly with regard to their veracity. Many scholars have analyzed First Amendment limits on the Food and Drug Administration’s (FDA) ability to restrict specific types of claims, yet few have addressed the issue of whether the agency can and should restrict claims unable to be supported by significant scientific agreement due to the inherent subjectivity of the claim. This Essay proposes FDA adopt such an approach as a means of effectuating the Federal Food, Drug, and Cosmetic Act’s purpose of protecting consumers from false or misleading food product labels. As an alternative, if FDA is unwilling to restrict those claims altogether, this Essay suggests the agency could*

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*require curative disclaimers on labels, as they do for qualified health claims, that are not supported by significant scientific agreement.*

I.	INTRODUCTION.....	544
II.	FOOD AND DRUG ADMINISTRATION’S AUTHORITY TO PROHIBIT MISLEADING LABEL CLAIMS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT .....	548
III.	FIRST AMENDMENT CONCERNS OVER LIMITS TO FOOD LABELING LANGUAGE .....	551
IV.	A BAN ON SUBJECTIVE CLAIMS.....	555

## I. INTRODUCTION

The American food label may be most aptly described as informative in some respects, yet utterly confounding in others. Currently, the debate over how to appropriately craft a federal regulation to define use of the term “healthy” serves as a useful illustration of the potential for difficulty, particularly with regard to seemingly subjective claims.<sup>1</sup> While manufacturers are required to include certain facts on food labels,<sup>2</sup> they are also permitted to include additional voluntary statements regarding the healthfulness of the food product,<sup>3</sup> the presence or absence of certain ingredients,<sup>4</sup> and information related to production methods,<sup>5</sup> among other things. Consequently, marketers include information on labels that can be grouped into a few different categories, including claims about certain product attributes.<sup>6</sup> Research demonstrates that consumers do, in fact, use

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<sup>1</sup> See Use of the Term “Healthy” in the Labeling of Human Food Products; Request for Information and Comments, 81 Fed. Reg. 66,562 (Sept. 28, 2016) (to be codified at 21 C.F.R. pt. 101).

<sup>2</sup> See Food Labeling, 21 C.F.R. §§ 101.1–12 (2016) (specifying information which must be listed on food product packages under the Food and Drug Administration’s jurisdiction to include the statement of identity, net quantity, nutrition facts, ingredient list, manufacturer’s name and address, and in what manner that information is to be included on the package); see also 9 C.F.R. § 317.2 (2016) (specifying mandatory labeling information for meat and poultry products and the manner in which it must be displayed).

<sup>3</sup> See 21 C.F.R. § 101.13 (detailing general requirements for nutrient-content claims such as “healthy,” “good source of,” and “light”).

<sup>4</sup> See *id.* § 101.91 (specifying requirements for labeling foods as “gluten-free” and defining the term); Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants; Guidance for Industry; Availability, 80 Fed. Reg. 73,194 (Nov. 24, 2015) (providing nonbinding guidance regarding use of the terms such as “genetically engineered (GE) free” and “genetically modified organism (GMO) free”).

<sup>5</sup> See, e.g., National Organic Program, 7 C.F.R. pt. 205 (2016); FOOD SAFETY & INSPECTION SERV., U.S. DEP’T OF AGRIC., LABELING GUIDELINE ON DOCUMENTATION NEEDED TO SUBSTANTIATE ANIMAL RAISING CLAIMS FOR LABEL SUBMISSIONS 8–9, 11 (2016), <https://perma.cc/6CMB-DNKZ> (providing guidance regarding the proper use of claims on meat products including “humanely raised,” “raised without antibiotics,” and “grass fed”).

<sup>6</sup> ELLEN A. WARTELLA ET AL., FRONT-OF-PACKAGE NUTRITION RATING SYSTEMS AND SYMBOLS: PROMOTING HEALTHIER CHOICES, at 2-3 tbl.2-1 (2012), <https://perma.cc/AGM6-BW5A>.

this information when making purchasing decisions<sup>7</sup> but may not fully understand or trust the veracity of certain claims.<sup>8</sup> Moreover, consumers may falsely perceive labels as the result of a regulatory process involving significant agency oversight.<sup>9</sup>

In turn, consumers simultaneously drive industry to develop front of the package statements in response to demand for certain food product attributes, yet often lack knowledge or access to evidence about whether those claims actually meet their expectations. This is further complicated by the dearth of political consensus in policy discussions over the propriety of government intervention in labeling—whether to create a uniform federal requirement for the labeling of genetically engineered foods serves as an illustration of this issue.<sup>10</sup> Consequently, the resulting regulatory environment consists largely of inconsistent standards.<sup>11</sup> Because certain claims have specific regulatory definitions whereas others may be influenced by nonbinding agency guidance or subject to agency oversight only when the statement is allegedly misleading, even the most discerning consumers would likely experience difficulty when attempting to assess an individual labeling claim.

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<sup>7</sup> See *id.* at 15–16 (discussing how product packaging influences consumer purchasing decisions); J. Craig Andrews et al., *Consumer Research Needs from the Food and Drug Administration on Front-of-Package Nutritional Labeling*, 33 J. PUB. POL'Y & MARKETING 10, 10 (2014) (“Today, Americans have increasingly busy lifestyles, yet they desire quick and nutritious food choices in addition to considering just taste and price. These conflicts arise in the presence of crowded food labels that often contain textual and graphic labeling statements.” (citation omitted)).

<sup>8</sup> See, e.g., LABEL INSIGHT, THE 2016 LABEL INSIGHT FOOD REVOLUTION STUDY: HOW CONSUMER DEMAND FOR TRANSPARENCY IS SHAPING THE FOOD INDUSTRY 4 (2016), <https://perma.cc/3FSS-CCHA> (“[C]onsumers lack access to the complete set of information they’re looking for in order to make informed purchase decisions . . . . Even when the information is provided, they don’t fully understand what it means due to inconsistency, information overload and misinformation. . . . More than a third of respondents (35 percent) admit they are sometimes confused by what the labels on food packages are actually saying.”); CONSUMER REPORTS NAT’L RESEARCH CTR., FOOD LABELS SURVEY: 2016 NATIONALLY-REPRESENTATIVE PHONE SURVEY 16 (2016), <https://perma.cc/95TF-NHYA> (“Our findings show a clear majority of consumers look to labels when deciding whether to purchase food. Accordingly, many consumers want strong federal standards for a range of food related issues and labels, including feeding drugs to animals, food origin labeling, and genetically engineered food. Survey findings also show consumers want more from a variety of food labels and claims. Many would even pay more to purchase food produced by workers under fair working conditions.”).

<sup>9</sup> Marsha N. Cohen, Commentary, *Can We Talk? About Food and Drug Regulation and the First Amendment*, 58 FOOD & DRUG L.J. 741, 743 (2003).

<sup>10</sup> ELISE GOLAN ET AL., U.S. DEP’T OF AGRIC., AGRICULTURAL ECONOMIC REPORT NO. 793, ECONOMICS OF FOOD LABELING 18 (2000), <https://perma.cc/7YKT-VXDK> (“[L]abeling to avoid political stalemate may provide consumers with no real information. This may particularly be the case when the inability to reach a political consensus arises from a lack of scientific consensus.”).

<sup>11</sup> *Id.* at 35.

Recently, consumer demand for greater food product transparency related to a number of factors has received increasing attention,<sup>12</sup> particularly from industry as it struggles to respond quickly and adapt.<sup>13</sup> Yet this phenomenon is not necessarily new, as demand for accurate and truthful food labels drove consumer advocacy efforts when Congress enacted the Federal Food, Drug, and Cosmetic Act of 1938<sup>14</sup> (the Act).<sup>15</sup> Without question, however, modern consumers have a number of means by which to gain product information beyond the food label.<sup>16</sup> Accordingly, consumers are inundated with statements on the food label, in addition to the myriad sources explaining what those claims mean and whether they may be trusted, creating an uncertain environment.<sup>17</sup>

Fundamentally, FDA is a “science-based regulatory agency”<sup>18</sup> with delegated authority to ensure food labels are not misleading.<sup>19</sup> Yet, the evidence appears to demonstrate consumers are confused, particularly when labeling statements like “healthy” or “natural” remain seemingly subjective even if defined through federal regulation.<sup>20</sup> For the category of

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<sup>12</sup> See, e.g., DELOITTE, CAPITALIZING ON THE SHIFTING CONSUMER FOOD VALUE EQUATION 4 fig.4 (2016), <https://perma.cc/GT3H-2F4G>; LABEL INSIGHT, *supra* note 8, at 4.

<sup>13</sup> See, e.g., Op-Ed, Hans Taparua & Pamela Koch, *Real Food Challenges the Food Industry*, N.Y. TIMES, Nov. 8, 2015, at SR4 (“[F]ood manufacturers are reacting [to changing consumer demand] by cleaning up their ingredient labels, acquiring healthier brands and coming out with a prodigious array of new products.”); Beth Kowitz, *Special Report: The War on Big Food*, FORTUNE (May 21, 2015), <https://perma.cc/3KWN-M2JG> (“We look at our business and say, ‘How can we remake ourselves?’” said Richard Smucker, CEO of [Smuckers].”); Keith Nunes, *The U.S. Consumer Has Changed*, FOOD BUS. NEWS (Jan. 25, 2016), <https://perma.cc/9UFG-H2GK> (according to the Grocery Manufacturer’s Association, the food companies that will survive are those that give consumers the information they want “well beyond what is on the label”).

<sup>14</sup> Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended in scattered sections of 21 U.S.C.).

<sup>15</sup> See Louise G. Baldwin & Florence Kirlin, *Consumers Appraise the Food, Drug, and Cosmetic Act*, 6 L. & CONTEMP. PROBS. 144, 145 (1939) (“‘Informative labeling’ was a rallying cry for consumers. To the consumer[,] informative labeling meant much more than that the label simply be not false.”).

<sup>16</sup> See, e.g., Stephanie Strom, *An App to Deconstruct Your Food*, N.Y. TIMES (July 18, 2016), <https://perma.cc/N6DP-ZCJC> (“Apple’s app store already lists more than three dozen apps offering users information and advice about calories, nutrition data and weight loss.”); see also DELOITTE, *supra* note 12, at 7 (“Empowered by the democratization of information, and the influence and reach of new media, many consumers are taking control of the conversation about food and beverages. This is a departure from when manufacturers could significantly influence consumer preferences through mass marketing—instead, consumers are increasingly relying on social networks, self-proclaimed experts, and web-based media as their sources of information.”).

<sup>17</sup> See DELOITTE, *supra* note 12, at 7; INT’L FOOD INFO. COUNCIL FOUND., 2017 FOOD AND HEALTH SURVEY (2017), <https://perma.cc/4LK6-TYCJ> (noting that Americans rely on a number of different sources beyond the food label when determining what to eat, but the “disconnect between trust and reliance of sources may lead to the glut of conflicting nutrition information”).

<sup>18</sup> FOOD & DRUG ADMIN., FDA FACTS: REGULATORY SCIENCE 1 (2012), <https://perma.cc/BQ7E-7QFL>.

<sup>19</sup> See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 343 to 343-3 (2012).

<sup>20</sup> FDA’s regulation to define the term “healthy” is currently in the process of reconsideration. See 21 C.F.R. § 101.65(d)(2) (2016). The agency has issued a notice soliciting comment on use of the term “natural” but has not formalized a regulation. Use of the Term

labeling claims which FDA has defined, certain claims remain unclear due to the agency's inability to craft an objective definition capable of scientific substantiation. FDA's allowance of labeling claims both capable of and lacking scientific agreement has led to a host of issues with which the agency is presently grappling. Specifically, many of the present issues confronting the agency in the form of lawsuits,<sup>21</sup> petitions, and requests for rulemaking regarding specific and arguably subjective labeling claims could be resolved by a prohibition on statements unable to be substantiated with significant scientific agreement due to their inherent subjectivity.<sup>22</sup>

While many scholars have analyzed First Amendment limits on FDA's ability to restrict specific types of claims,<sup>23</sup> few address the issue of whether the agency should restrict claims that cannot be supported by significant scientific agreement due to the inherent subjectivity of the claim. Likely, this is due to the vastness of the issue. Yet precedent seems far from clear that the agency is constitutionally constrained,<sup>24</sup> and given the increase in petitions for rulemaking regarding specific labeling claims,<sup>25</sup> such a restriction appears to be both a logical and consistent regulatory approach. Consequently, this Essay proposes FDA adopt this approach as a means of effectuating the Act's purpose of protecting consumers from false or misleading food product labels. Alternatively, if FDA is unwilling to restrict those claims altogether, this Essay suggests the agency could require curative disclaimers, as they do for qualified health claims that are not supported by significant scientific agreement. To that end, this Essay proceeds in three Parts. Part II addresses FDA's authority to regulate food labels under the Act, with particular emphasis on the provisions of the statute and accompanying regulations dedicated to misbranding.<sup>26</sup> Part III considers the First Amendment implications of restricting labeling language unsubstantiated by significant scientific agreement, arguing that the courts have not squarely addressed the issue. Finally, Part IV concludes by suggesting that all relevant actors—the agency, industry, and consumers—stand to benefit from a consistently applied approach.

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"Natural" in the Labeling of Human Food Products; Request for Information and Comments, 80 Fed. Reg. 69,905 (Nov. 12, 2015) (to be codified at 21 C.F.R. pt. 101).

<sup>21</sup> See NICOLE E. NEGOWETTI, *FOOD LABELING LITIGATION: EXPOSING GAPS IN THE FDA'S RESOURCES AND REGULATORY AUTHORITY* 1 (2014), <https://perma.cc/4WH2-ULEA> ("[The] 'unprecedented surge' of deceptive labeling and advertising lawsuits against the makers of products such as Naked Juice, Fruit Roll-Ups, Bear Naked Granola, and Wesson Oil, reveals a trend of regulation by litigation—that is, a turning over of food labeling issues to the courts in light of a lax regulatory system. Although [FDA] is charged with regulating food labeling, plaintiffs' attorneys are seeking to fill a void in the FDA's regulatory authority and enforcement of food labeling laws.").

<sup>22</sup> "Significant scientific agreement" is a term of art applied to health claims, which will be discussed later in the Essay. See *infra* Part II.

<sup>23</sup> See, e.g., Gerald Masoudi & Christopher Pruitt, *The Food and Drug Administration v. The First Amendment: A Survey of Recent FDA Enforcement*, 21 HEALTH MATRIX: J.L.-MED. 111, 112 (2011).

<sup>24</sup> See *id.* at 126–28.

<sup>25</sup> *Petitions*, U.S. DEP'T AGRIC., <https://perma.cc/NT5H-F72Y> (last modified May 23, 2017).

<sup>26</sup> See 21 U.S.C. § 343 (2012).

## II. FOOD AND DRUG ADMINISTRATION'S AUTHORITY TO PROHIBIT MISLEADING LABEL CLAIMS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

The history surrounding passage of the Federal Food, Drug, and Cosmetic Act demonstrates that the provisions related to preventing consumer deception through misleading labeling statements are at the core of the statute.<sup>27</sup> During the hearings on various versions of the bill, legislators expressed concern about consumers, with one stating:

The purpose of the bill is to protect the public, to protect the mothers and the children, to protect the citizens; and the fact that regulation is needed is not because the reputable concerns are unwilling to conform to high standards; it is because there are those in the country who are exploiting the public and desirous of imposing their products upon the public for gain.<sup>28</sup>

Debates over how best to protect consumers from unscrupulous manufacturers aided in the creation of a separate definition for "labeling" which includes "labels,"<sup>29</sup> as well as any "other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."<sup>30</sup> By including within the definition of "labeling" any materials that might also accompany the product, the Act included within its reach pamphlets and related materials that might include information intended to induce consumers to purchase the product but might also contain potentially misleading statements.<sup>31</sup> Additionally, the Act acknowledged that while misleading labeling may result from the inclusion of untruths or misrepresentations, a consumer might also be misled due to omissions.<sup>32</sup> To that end, the Act specifies that FDA should consider "the extent to which the labeling or advertising fails to reveal [material] facts" when determining whether the labeling is false or misleading.<sup>33</sup>

Labeling claims on food products are also divided into a few major categories for the purposes of regulation. First, health claims describe a

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<sup>27</sup> Foods are misbranded if the "labeling is false or misleading in any particular." *Id.* § 343(a).

<sup>28</sup> Vincent A. Kleinfeld, *Legislative History of the Federal Food, Drug, and Cosmetic Act*, 50 FOOD & DRUG L.J. (SPECIAL ISSUE) 65, 73 (1995) (quoting Senator Copeland).

<sup>29</sup> "The term 'label' means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper." 21 U.S.C. § 321(k).

<sup>30</sup> *Id.* § 321(m).

<sup>31</sup> See *United States v. Hanafy*, 124 F. Supp. 2d 1016, 1026–27 (N.D. Tex. 2000) (providing case law illustrating the various items to which "labeling" has been applied), *aff'd* 302 F.3d 485 (5th Cir. 2002); Kleinfeld, *supra* note 28, at 69 (quoting Walter G. Campbell, Chief of the Food and Drug Administration).

<sup>32</sup> 21 U.S.C. § 321(n); see also *id.* § 343; David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROBS. 2, 25 (1939) ("[I]nformative labeling is essential to safety from prosecution or seizure.").

<sup>33</sup> 21 U.S.C. § 321(n).

relationship between a food substance and a disease or health-related condition.<sup>34</sup> Health claims are further divided into three subcategories: 1) authorized health claims, which are authorized by regulation once the agency determines that the claim is supported by significant scientific agreement;<sup>35</sup> 2) health claims based on authoritative statements from certain scientific bodies and the National Academy of Sciences;<sup>36</sup> and 3) qualified health claims, which are not supported by significant scientific agreement but may include qualifying language connoting the science is emerging.<sup>37</sup> Second, nutrient-content claims “expressly or implicitly characterize[] the level of a nutrient of the type required to be in nutrition labeling.”<sup>38</sup> The term “healthy” is considered a nutrient-content claim and is defined by federal regulation,<sup>39</sup> yet other common claims include “calorie free,” “low,” “reduced,” and “light.”<sup>40</sup> Finally, structure/function claims may “describe[] the role of a nutrient or dietary ingredient intended to affect the [normal] structure or function in humans” or “characterize[] the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function.”<sup>41</sup> These claims do not require FDA’s pre-approval, but they must be capable of substantiation.<sup>42</sup>

Underlying these provisions, however, is an assumption that there exists some objective means by which to determine whether a statement on a food product is misleading, either due to the presence or absence of information. Precedent suggests that when confronted with challenges to product labels on these grounds, courts traditionally asked “whether the ‘ordinary purchaser’ would be misled by the product in question,” yet there is no commonly accepted approach by which to make this determination.<sup>43</sup> Another method proposes determining whether a significant number of potential consumers at large or in the region where a product is marketed will “probably be misled by the labeling.”<sup>44</sup> However, such an approach necessarily requires the collection and analysis of survey data, which likely serves as a practical constraint in application. The language of the Act itself provides some guidance in the subsection addressing “the prominence of information” on the food product’s label, as it states information should be included in a manner that can be “understood by the ordinary individual

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<sup>34</sup> *Id.* § 343(r); 21 C.F.R. § 101.14(a)(1) (2016).

<sup>35</sup> 21 U.S.C. § 343(r)(3)(B)(ii); 21 C.F.R. § 101.14(c).

<sup>36</sup> 21 U.S.C. § 343(r)(3)(C)(i).

<sup>37</sup> *Label Claims for Conventional Foods and Dietary Supplements*, FOOD & DRUG ADMIN. (Apr. 11, 2016), <https://perma.cc/RL24-TLJ9>.

<sup>38</sup> 21 C.F.R. § 101.13(b).

<sup>39</sup> *Id.* § 101.65(d).

<sup>40</sup> *Id.* § 101.13.

<sup>41</sup> 21 U.S.C. § 343(r)(6); 21 C.F.R. § 101.93(f).

<sup>42</sup> *Label Claims for Conventional Foods and Dietary Supplements*, *supra* note 37.

<sup>43</sup> Wesley E. Forte, *The Ordinary Purchaser and the Federal Food, Drug, and Cosmetic Act*, 52 VA. L. REV. 1467, 1467–68, 1468 n.6 (1966) (noting that the courts use a few different approaches: “the public”; “the ordinary man”; “the average reader of the labeling”; “the ordinary consumer”; and “the ordinary or average purchaser”).

<sup>44</sup> *Id.* at 1502.

under customary conditions of purchase and use.”<sup>45</sup> Finally, in promulgated guidance, the agency stated that it uses a “reasonable consumer” standard when assessing whether food labeling language is misleading.<sup>46</sup>

There are many examples of food product claims that do not fall within the Act’s regulatory framework and are reviewed within the broader context of the Act’s limits on false or misleading labeling language because they lack a specific regulatory definition.<sup>47</sup> Some examples include claims related to the manufacturing or growing processes and the inclusion or exclusion of specific ingredients or substances.<sup>48</sup> The “natural” claim illustrates a claim intended to convey a message to consumers about specific attributes of the manufacturing process, suggesting the absence of artificial ingredients. Yet, given a host of factors, including constantly evolving food production and manufacturing technology, this claim—even if defined by federal regulation—remains inherently subjective depending on the understanding of the consumer. The public comments submitted in response to FDA’s request for information regarding use of the term “natural” provide evidence to this effect. One of the citizen petitions that, in part, led the agency to invite public comment on the issue requested a ban on use of the term due to findings indicating most consumers are misled by the claim.<sup>49</sup> In addition, industry commenters had differing opinions about the proper course of action, with some suggesting the agency should not define the term because of the inability to define it scientifically<sup>50</sup> and others arguing for a regulatory definition given increasing consumer interest and confusion.<sup>51</sup>

Similarly, the “healthy” claim, while falling within the regulatory category of nutrient-content claims and benefitting from a regulatory definition developed by the agency with the input of stakeholders, arguably remains subjective due to differing standards and dietary needs for certain populations and constantly evolving opinions about what makes a food product “healthy.” Moreover, consumers’ perceptions of what constitutes

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<sup>45</sup> 21 U.S.C. § 343(f).

<sup>46</sup> Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements; Availability, 67 Fed. Reg. 78,002, 78,003 (Dec. 20, 2002).

<sup>47</sup> See Sylvia Zarski, *Can You Judge Your Food by Looking at Its Cover? How Courts’ Application of Federal Preemption Allows Misleading Food Labeling to Slip Through the Regulatory Cracks*, 64 DEPAUL L. REV. 1119, 1137–42 (2015) (“[E]very food label feature is subject to the requirement not to be misleading, whether or not it complies with other FDCA requirements.”).

<sup>48</sup> See 21 U.S.C. § 343(r).

<sup>49</sup> See CONSUMERS UNION, CITIZEN PETITION 2 (2014), <https://perma.cc/Q7QZ-YGAH> (“[N]early two-thirds of U.S. consumers are currently misled by the ‘natural’ label on [food], and nearly 90% expect it to mean much more than it does.”). See also Use of the Term “Natural” in the Labeling of Human Food Products; Request for Information and Comments, 80 Fed. Reg. 69,905 (Nov. 12, 2015).

<sup>50</sup> Ebru Basaran-Shull, Sargento Foods, Comment to *Use of the Term “Natural” in the Labeling of Human Food Products*, REGULATIONS.GOV (Nov. 2, 2016), <https://perma.cc/DQ5Z-62GZ>.

<sup>51</sup> Karin F.R. Moore, Grocery Mfr.’s Ass’n, Comment to *Use of the Term “Natural” in the Labeling of Human Food Products*, REGULATIONS.GOV (May 10, 2016), <https://perma.cc/S95E-S6VG>.

healthfulness may include concerns that go beyond the pure nutritional aspects of a specific food product.<sup>52</sup> In the comments submitted in response to FDA's request for information regarding use of the term on food product labels, it was suggested that the agency must account for the goals and purposes driving allowance of this labeling claim given the significant disagreement among stakeholders about how to appropriately define it.<sup>53</sup> Additionally, some commenters suggested the agency disallow continued use of the term rather than craft an amended definition due to scientific consensus that understanding of the term healthy "will continue to evolve, likely in unanticipated ways."<sup>54</sup>

Each of these claims is illustrative of the difficulties presented by inherently subjective claims incapable of scientific agreement. As demonstrated by the public comments and debates surrounding the appropriate role for FDA with respect to these claims, there are no simple answers. Moreover, due to the inherently subjective nature of claims like "natural" and "healthy," it is difficult to conceive of a regulatory definition that would resolve the potential for consumer confusion or deception in the absence of targeted and widespread public education efforts to fully inform consumers of the nuances associated with defining these claims.

### III. FIRST AMENDMENT CONCERNS OVER LIMITS TO FOOD LABELING LANGUAGE

While there have been cases addressing restrictions on labeling language in other contexts, it is far from clear that a restriction on subjective labeling claims incapable of substantiation by significant scientific agreement violates the First Amendment.<sup>55</sup> This Essay does not ignore the significant constitutional concerns intrinsic to restrictions on labeling statements, including the elimination of accurate information that consumers both demand and rely on from the marketplace, as well as the larger issue of authorizing government agency restrictions on speech.<sup>56</sup> On the other hand, Congress delegated authority to FDA to ensure that food

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<sup>52</sup> See, e.g., Nunes, *supra* note 13 ("Health and wellness, for example, is no longer strictly associated with health and nutrition. It includes organic production, natural ingredients and fewer ingredients perceived as artificial, according to the report." (referencing DELOITTE, *supra* note 12, at 14)).

<sup>53</sup> Steven R. Houser, Am. Heart Ass'n, Comment to *Use of the Term "Healthy" in Labeling of Human Food Products*, REGULATIONS.GOV (Apr. 26, 2017), <https://perma.cc/V3MH-9UQ4> (noting that FDA's original approach to the term related to recommended nutrient levels, but that consumers now associate "a broader set of attributes—such as those dealing with a food's production and sourcing" with the term suggesting a "new or different approach" is warranted).

<sup>54</sup> Pamela Schoenfeld, Weston A. Price Found., Comment to *Use of the Term "Healthy" in Labeling of Human Food Products*, REGULATIONS.GOV (Apr. 10, 2017), <https://perma.cc/5KJE-WVMX>.

<sup>55</sup> See, e.g., Timothy D. Lytton, *Signs of Change or Clash of Symbols? FDA Regulation of Nutrient Profile Labeling*, 20 HEALTH MATRIX: J.L.-MED. 93, 114 (2010) ("The application of the First Amendment commercial speech doctrine to FDA labeling restrictions is a relatively new development, and many important questions have yet to be answered by courts.").

<sup>56</sup> Masoudi & Pruitt, *supra* note 23, at 112.

product labels are not misleading.<sup>57</sup> While striking the balance between these competing concerns is difficult, FDA is a science-based, public health agency charged with ensuring food products are safe and accurately labeled.<sup>58</sup>

Many scholars have addressed a variety of First Amendment issues with regard to FDA's compulsion or restriction of speech in a number of different contexts.<sup>59</sup> This Essay does not seek to provide a comprehensive overview of this wide-ranging scholarship but rather focuses on the precedent addressing FDA's attempt to restrict health claims unsupported by significant scientific agreement. Because this Essay proposes a similar restriction, those cases prove most instructive. The seminal case in this context is *Pearson v. Shalala*.<sup>60</sup>

*Pearson* involved two sets of challenges—one focused on impingement of the appellants' First Amendment rights and the other alleged procedural insufficiencies under the Administrative Procedure Act<sup>61</sup>—with regard to FDA's decision not to allow inclusion of a set of proposed health claims that were unsupported by significant scientific agreement on dietary supplement labels.<sup>62</sup> Specifically, a group of dietary supplement manufacturers argued that FDA's final regulation—setting forth the general requirements for health claims<sup>63</sup> and including a definition of “significant scientific agreement”<sup>64</sup>—failed to adequately address the comments suggesting that claims unsupported by significant scientific evidence could be remedied by inclusion of a curative disclaimer on the label explaining the level of scientific evidence supporting the claim.<sup>65</sup> Rather, the agency “unequivocally rejected the notion of requiring disclaimers to cure ‘misleading’ health claims for dietary supplements.”<sup>66</sup>

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<sup>57</sup> 21 U.S.C. § 343(a) (2012).

<sup>58</sup> See *supra* notes 18–19 and accompanying text.

<sup>59</sup> See, e.g., Edward M. Basile & Melanie Gross, *The First Amendment and Federal Court Deference to the Food and Drug Administration: The Times They Are A-Changin'*, 59 FOOD & DRUG L.J. 31, 31 (2004) (arguing that “increased opposition to FDA's policies and their enforcement sheds critical light on FDA and jeopardizes its role as an effective gatekeeper of consumer health and welfare”); Krista Hessler Carver, *A Global View of the First Amendment Constraints on FDA*, 63 FOOD & DRUG L.J. 151, 214–15 (2008); Cohen, *supra* note 9, at 756 (arguing that FDA should “develop[] data to demonstrate how communications are received by consumers” and regulate speech accordingly in the interests of public protection); Lytton, *supra* note 55, at 114; Masoudi & Pruitt, *supra* note 23, at 112; Lars Noah, *The Little Agency That Could (Act with Indifference to Constitutional and Statutory Strictures)*, 93 CORNELL L. REV. 901, 922 (2008) (“The deference that judges historically have shown the FDA, bordering on the position that the agency could do no wrong, did not surface in newer opinions that express some impatience with the FDA's seeming disregard for the First Amendment.”).

<sup>60</sup> 164 F.3d 650 (D.C. Cir.), *reh'g denied*, 172 F.3d 72 (D.C. Cir. 1999).

<sup>61</sup> 5 U.S.C. §§ 551–559, 701–706, 1305, 3105, 3344, 4301, 5335, 5372, 7521 (2012).

<sup>62</sup> *Pearson*, 164 F.3d at 654.

<sup>63</sup> 21 C.F.R. § 101.14 (2016).

<sup>64</sup> 21 U.S.C. § 343(r)(3)(B) (2012).

<sup>65</sup> *Pearson*, 164 F.3d at 654–55.

<sup>66</sup> *Id.* at 655.

Under the Nutrition Labeling and Education Act,<sup>67</sup> enacted as an amendment to the Federal Food, Drug, and Cosmetic Act, health claims are permissible on food labels only when pre-approved by FDA after a determination by the agency that the claim is sound and supported by “significant scientific agreement.”<sup>68</sup> However, the statute did not provide a definition of “significant scientific agreement” but rather delegated authority to the agency to make these determinations.<sup>69</sup>

In *Pearson*, FDA made two arguments in support of its decision: 1) health claims unsupported by significant scientific agreement are “inherently misleading”; and 2), in the alternative, health claims unsupported by significant scientific agreement are “potentially misleading” because consumers would experience difficulty attempting to verify these claims.<sup>70</sup> Using the *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*<sup>71</sup> framework to assess restrictions on commercial speech,<sup>72</sup> the court rejected FDA’s arguments, holding that while the prevention of consumer fraud, particularly with regard to certain products, represents a “substantial state interest,” the means chosen by the agency—outright restriction on health claims unsupported by significant scientific agreement—was unreasonable without the opportunity to include a curative disclaimer approved by the agency.<sup>73</sup>

A few years later, the United States District Court for the District of Columbia, in *Whitaker v. Thompson*,<sup>74</sup> interpreted *Pearson* to stand for the proposition that FDA can reject health claims lacking significant scientific agreement when the agency determines there is no evidence in support of the claim or where the “evidence in support of the claim is qualitatively weaker than evidence against the claim.”<sup>75</sup> However, the court went on to note:

Even in these two situations, a complete ban would only be appropriate when “the government could demonstrate *with empirical evidence* that disclaimers similar to the ones [the Court] suggested above [‘The evidence in support of this claim is inconclusive’ or ‘FDA does not approve this claim’] would bewilder consumers and fail to correct for deceptiveness.”<sup>76</sup>

Following the *Pearson* case, FDA attempted to define “significant scientific agreement” in nonbinding agency guidance as follows: 1) it “refers to the extent of agreement among qualified experts in the field”; 2) “[o]n the

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<sup>67</sup> Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended in scattered sections of 21 U.S.C.).

<sup>68</sup> 21 U.S.C. § 343(r)(1)(B); *id.* § 343(r)(3)(B)

<sup>69</sup> *Id.* § 343(r)(5)(D).

<sup>70</sup> *Pearson*, 164 F.3d at 655.

<sup>71</sup> 447 U.S. 557 (1980).

<sup>72</sup> *Id.* at 564–66.

<sup>73</sup> *Pearson*, 164 F.3d at 656–57, 661.

<sup>74</sup> 248 F. Supp. 2d 1 (D.D.C. 2002).

<sup>75</sup> *Id.* at 10 (quotations omitted) (quoting *Pearson*, 164 F.3d at 659 n.10).

<sup>76</sup> *Id.* (alterations in original) (quoting *Pearson*, 164 F.3d at 659–60).

continuum of scientific evidence that extends from very limited to inconclusive evidence, [significant scientific agreement] lies closer to consensus”; 3) a determination of significant scientific agreement “represents the agency’s best judgment as to whether qualified experts would likely agree that the scientific evidence supports the substance/disease relationship that is the subject of a proposed health claim”; 4) the standard is “intended to be a strong standard that provides a high level of confidence in the validity of the substance/disease relationship”; 5) “[significant scientific agreement] means that the validity of the relationship is not likely to be reversed by new and evolving science, although the exact nature of the relationship may need to be refined”; 6) “[significant scientific agreement] does not require a consensus based on unanimous and incontrovertible scientific opinion [but] occurs well after the stage of emerging science, where data and information permit an inference, [and] before the point of unanimous agreement within the relevant scientific community that the inference is valid.”<sup>77</sup> Ultimately, FDA bears the burden of proving a claim is misleading by demonstrating either a paucity of credible supporting evidence or that the claim conflicts with the weight of the evidence.<sup>78</sup>

Collectively, *Pearson* and *Whitaker* stand for the proposition that FDA cannot suppress potentially misleading label claims without considering whether a curative disclaimer can address the misleading nature of the claims,<sup>79</sup> and FDA would likely fail to successfully defend an outright ban on a health claim completely, assuming the disclaimer could adequately convey the scientific limitations. In other words, when seeking to prohibit labeling language in the interests of consumer protection, the agency must have data to demonstrate the need for the restriction.<sup>80</sup> However, these types of claims, which generally characterize a specific relationship between the food product and a health condition or disease, are very different from inherently subjective label claims. For the latter, it is virtually impossible to conceive of a situation where a manufacturer could support the claim by significant scientific agreement. Using “healthy” and “natural” as examples, it is difficult to imagine a body of scientific evidence able to support such a claim, making the potential for consumer fraud or confusion more than merely speculative.

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<sup>77</sup> *Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims – Final*, FOOD & DRUG ADMIN. (Jan. 2009), <https://perma.cc/NA7L-4DSM>.

<sup>78</sup> Margaret Gilhooley, *The Impact and Limits of the Constitutional Deregulation of Health Claims on Foods and Supplements: From Dementia to Nuts to Chocolate to Saw Palmetto*, 56 MERCER L. REV. 683, 712 (2005).

<sup>79</sup> See Richard A. Samp, *Courts Are Arriving at a Consensus on Food and Drug Administration Speech Regulation*, 58 FOOD & DRUG L.J. 313, 319 (2003).

<sup>80</sup> Cohen, *supra* note 9, at 742.

## IV. A BAN ON SUBJECTIVE CLAIMS

Presently, many advocates press for both the overhaul of existing federal regulations as well as a moratorium on the creation of new ones. While this Essay argues for the development of an agency regulation or policy that serves as a restriction on food product label claims that cannot be supported by significant scientific agreement because they are inherently subjective, such an approach would serve the purpose of reducing the amount of existing and future regulations. If inherently subjective claims are disallowed, the agency would no longer need to engage in extensive rulemaking proceedings to determine how to define an arguably indefinable and constantly evolving term or phrase. However, scholars posit that the agency should be prepared to provide empirical evidence to support a determination that a claim is inherently misleading.<sup>81</sup>

In the alternative, for claims fraught with ambiguity, the agency could use the approach it does now with qualified health claims, which is to require a disclaimer with appropriate language clarifying any ambiguity. Here, that could possibly be achieved by noting that the claim has not been supported by significant scientific evidence, either because reasonable scientists cannot reach agreement with regard to the standard or because insufficient science exists to support the statement. The agency could also simply require manufacturers to include language on the label expressing the operative definition as they understand it.

Studies demonstrate that consumers are, in fact, confused not just by the multitude of claims on labels generally, as previously discussed, but also in the context of health claims which may be supported by varying levels of scientific agreement.<sup>82</sup> Specifically, even when a disclaimer is present, consumers are unable to differentiate between qualified and authorized health claims and experience “similar difficulties understanding the differences among health, structure/function, and other health- and nutrient-related claims.”<sup>83</sup> Some suggest that labeling is appropriate when consumer preferences vary because “information allows consumers to match their individual preferences with their individual purchases.”<sup>84</sup> At the same time, however, information should “focus on concrete facts.”<sup>85</sup> In the context of health, for some nutrient-content claims (excluding “healthy”) and structure-function claims, manufacturers use scientific evidence as the basis of their claims. While some are more substantiated than others, the claims are not inherently subjective in the sense that they make specific assertions about the nutrient content of the product or the product’s effect on the structure or function of the body, or disease and/or health-related conditions. These

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<sup>81</sup> *E.g.*, Carver, *supra* note 59, at 215.

<sup>82</sup> U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-11-102, FOOD LABELING: FDA NEEDS TO REASSESS ITS APPROACH TO PROTECTING CONSUMERS FROM FALSE OR MISLEADING CLAIMS 16 (2011), <https://perma.cc/YG68-BGRN>.

<sup>83</sup> *Id.*

<sup>84</sup> GOLAN ET AL., *supra* note 10.

<sup>85</sup> *Id.* at 18.

claims can be distinguished from those that cannot establish a clearly articulated standard because none exists.

Using “healthy” as an example, the dictionary defines “healthy” as “beneficial to one’s physical, mental, or emotional state; conducive to health.”<sup>86</sup> Yet, FDA’s definition of the term focuses on the product’s fat, cholesterol, and other limited nutrient content.<sup>87</sup> A labeling claim like “healthy” raises many important questions that likely reflect the perceptions of many consumers—healthy *for whom* being one of the most pertinent. In other words, this raises the question whether there are any food products that could be considered healthy for everyone. If not, it remains uncertain whether that ambiguity can be cured through some sort of disclaimer on the product. If it can, the disclaimer may then negate the benefits provided by inclusion of the term on the label.

FDA is currently in the process of considering those questions, in addition to a host of others raising the issue of whether FDA’s actions represent an efficient use of agency resources. Perhaps the agency is better served by restricting claims that cannot be supported by significant scientific agreement due to the inherent subjectivity of the claim. Such an approach would arguably conserve valuable agency resources; better effectuate the Federal Food, Drug, and Cosmetic Act’s purpose of protecting consumers from false or misleading food product labels; and provide consistency for industry.

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<sup>86</sup> *Healthy*, Merriam-Webster Dictionary (11th ed. 2003).

<sup>87</sup> 21 C.F.R. § 101.65(d)(2)(i) (2016).