

# REGULATING INHERENTLY SUBJECTIVE FOOD LABELING CLAIMS

BY

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## 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”<sup>1</sup> serves as a useful illustration of the potential for difficulty, particularly with regard to seemingly subjective claims. While manufacturers are required to include certain facts on food labels,<sup>2</sup> they are also permitted to include additional statements related to the healthfulness of the food product,<sup>3</sup> the presence or absence of certain ingredients,<sup>4</sup> and information related to production,<sup>5</sup> among others. Consequently, marketers include information on labels that can be grouped into the following categories - “branding, product images, product claims, and promotions.”<sup>6</sup> Research demonstrates that consumers do, in

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<sup>1</sup> See Food and Drug Administration, *Use of the Term “Healthy” in the Labeling of Human Food Products; Request for Information and Comments*, 81 FR 66562 (Sep. 28, 2016).

<sup>2</sup> See 21 C.F.R. §§ 101.1-101.12 (requirements for information that must be listed on food product packages under the Food and Drug Administration’s jurisdiction, which includes the statement of identity, net quantity, nutrition facts, ingredient list, and manufacturer’s name and address and in what manner that information is to be included on the package.); and 9 C.F.R. § 317.2 (specifying mandatory labeling information for meat and poultry products and the manner in which it must be displayed).

<sup>3</sup> See e.g., 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 E.G., 21 C.F.R. § 101.91 (REQUIREMENTS FOR LABELING FOODS AS GLUTEN-FREE AND DEFINING THE TERM); AND FOOD AND DRUG ADMINISTRATION, *GUIDANCE FOR INDUSTRY: VOLUNTARY LABELING INDICATING WHETHER FOODS HAVE OR HAVE NOT BEEN DERIVED FROM GENETICALLY ENGINEERED PLANTS* (NOV. 2015), [HTTP://WWW.FDA.GOV/FOOD/GUIDANCEREGULATION/GUIDANCEDOCUMENTSREGULATORYINFORMATION/UCM059098.HTM](http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm059098.htm) (NONBINDING GUIDANCE REGARDING USE OF THE TERMS SUCH AS “GE FREE” AND “GMO FREE”).

<sup>5</sup> See e.g. 7 C.F.R. § 205 et seq. (detailing labeling requirements for the national organics program); and Food Safety Inspection Service, *Food Safety and Inspection Service Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submissions* (Sep. 2016), <https://www.fsis.usda.gov/wps/wcm/connect/6fe3cd56-6809-4239-b7a2-bccb82a30588/RaisingClaims.pdf?MOD=AJPERES> (guidance regarding the proper use of claims on meat products including “humanely raised”, “raised without antibiotics” and “grass fed.”).

<sup>6</sup> Institute of Medicine, *Front-of-Package Nutrition Rating Systems and Symbols: Promoting Healthier Choices* 16 (2012), <https://www.nap.edu/read/13221/chapter/4>.

fact, use this information when making purchasing decisions,<sup>7</sup> but may not fully understand or trust the veracity of certain claims.<sup>8</sup> In turn, consumers simultaneously drive industry to develop front of 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 lack of political consensus in “many regulatory policy debates” over the propriety of government intervention in labeling – whether to create a uniform federal requirement for the labeling of genetically engineered foods serves as a good illustration of this issue.<sup>9</sup> Consequently, the resulting regulatory environment consists of a set of inconsistent standards.<sup>10</sup> Because certain claims have specific regulatory definitions whereas others may be influenced by nonbinding agency guidance or subject to agency oversight only

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<sup>7</sup> See Institute of Medicine, *Front-of-Package Nutrition Rating Systems and Symbols: Promoting Healthier Choices* 16 (2012), <https://www.nap.edu/read/13221/chapter/4> (Because consumers are spending less time food shopping, product packaging is designed to influence purchasing decisions.); J. Craig Andrews, Chung-Tung Jordan Lin, Alan S. Levy, and Serena Lo, *Consumer Research Needs from the Food and Drug Administration on Front-of-Package Nutritional Labeling*, 33 *Journal of Public Policy & Marketing* 10 (Spring 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....”).

<sup>8</sup> See e.g. Label Insight, *How Consumer Demand for Transparency is Shaping the Food Industry: The 2016 Label Insight Food Revolution Survey* 4 (2016), [https://cdn2.hubspot.net/hubfs/642447/Label\\_Insight-Food-Revolution-Study.pdf?utm\\_campaign=Food+Revolution+Study&utm\\_source=hs\\_automation&utm\\_medium=email&utm\\_content=30785238&\\_hsenc=p2ANqtz-9D9MkyNgV0-iA9CPflxcbsaoOmBxekoE6Trk-G7DOVklh3UreTPBWCDAlbhaLAj9-6-8OATKSA1oxJDpMVIHDCNaoAxXW3gD5Gt3D6pItYgDfTI&\\_hsmi=30785238](https://cdn2.hubspot.net/hubfs/642447/Label_Insight-Food-Revolution-Study.pdf?utm_campaign=Food+Revolution+Study&utm_source=hs_automation&utm_medium=email&utm_content=30785238&_hsenc=p2ANqtz-9D9MkyNgV0-iA9CPflxcbsaoOmBxekoE6Trk-G7DOVklh3UreTPBWCDAlbhaLAj9-6-8OATKSA1oxJDpMVIHDCNaoAxXW3gD5Gt3D6pItYgDfTI&_hsmi=30785238) (“The study finds that consumers lack access to the complete set of information they’re looking for in order to make informed purchase decisions when shopping for groceries. Even when the information is provided, they don’t fully understand what it means due to inconsistency, information overload and misinformation. As a result, they typically do not know what is in the food they consume on a daily basis and have lost significant trust in brands to provide the right information. More than a third of respondents (35 percent) admit they are sometimes confused by what the labels on food packages are actually saying...”); and Consumer Reports National Research Center, *Food Labels Survey: 2016 Nationally-Representative Phone Survey* (Apr. 2016), [http://greenerchoices.org/wp-content/uploads/2016/08/2016\\_CRFoodLabelsSurvey.pdf](http://greenerchoices.org/wp-content/uploads/2016/08/2016_CRFoodLabelsSurvey.pdf) (“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. Consumers are looking to food labels for information. They have high expectations of those labels.”).

<sup>9</sup> United States Department of Agriculture, Economic Research Service, *Economics of Food Labeling* 18 (Dec 2000), [https://www.ers.usda.gov/webdocs/publications/aer793/18885\\_aer793.pdf](https://www.ers.usda.gov/webdocs/publications/aer793/18885_aer793.pdf) (“However, labeling 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>10</sup> United States Department of Agriculture, Economic Research Service, *Economics of Food Labeling* -- (Dec 2000), [https://www.ers.usda.gov/webdocs/publications/aer793/18885\\_aer793.pdf](https://www.ers.usda.gov/webdocs/publications/aer793/18885_aer793.pdf)

when the statement is allegedly misleading, even the most discerning consumers would likely experience difficulty when attempting to assess the statement.

Recently, consumer demand for greater food product transparency related to a number of factors, has received increasing attention, particularly from industry as it struggles to respond quickly and adapt.<sup>11</sup> Yet, this phenomenon is not necessarily new, as demand for accurate and truthful food labels drove consumer advocacy efforts when Congress enacted Food, Drug, and Cosmetic Act of 1938.<sup>12</sup> Without question, however, modern consumers have a number of means by which to gain product information beyond the food label. Accordingly, consumers are inundated with statements on the food label, as well as countless sources explaining what those claims mean and whether they may be trusted creating an uncertain environment.<sup>13</sup>

Fundamentally, the Food and Drug Administration is a “science-based regulatory agency”<sup>14</sup> with delegated authority to ensure food labels are not misleading.<sup>15</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 regulation<sup>16</sup> due to their inherent inability to be objectively defined through scientific substantiation. The FDA’s

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<sup>11</sup> See generally Deloitte, *Capitalizing on the Shifting Consumer Food Value Equation* (2016), <https://www2.deloitte.com/content/dam/Deloitte/us/Documents/consumer-business/us-fmi-gma-report.pdf>; and Label Insight, *How Consumer Demand for Transparency is Shaping the Food Industry: The 2016 Label Insight Food Revolution Survey 4* (2016), [https://cdn2.hubspot.net/hubfs/642447/Label\\_Insight-Food-Revolution-Study.pdf?utm\\_campaign=Food+Revolution+Study&utm\\_source=hs\\_automation&utm\\_medium=email&utm\\_content=30785238&\\_hsenc=p2ANqtz-9D9MkyNgV0-iA9CPflxcbsaoOmBxekoE6Trk-G7DOVklh3UreTPBWCDAlbhaLAj9-6-8OATKSA1oxJDpMVIHDCNaoAxXW3gD5Gt3D6pItYgDtTI&\\_hsmi=30785238](https://cdn2.hubspot.net/hubfs/642447/Label_Insight-Food-Revolution-Study.pdf?utm_campaign=Food+Revolution+Study&utm_source=hs_automation&utm_medium=email&utm_content=30785238&_hsenc=p2ANqtz-9D9MkyNgV0-iA9CPflxcbsaoOmBxekoE6Trk-G7DOVklh3UreTPBWCDAlbhaLAj9-6-8OATKSA1oxJDpMVIHDCNaoAxXW3gD5Gt3D6pItYgDtTI&_hsmi=30785238).

<sup>12</sup> Louise G. Baldwin and Florence Kirlin, *Consumers Appraise the Food, Drug, and Cosmetic Act*, 6 *Law and Contemp. Probs.* 144, 145 (1939) (“‘Informative labeling’ was a rallying cry for consumers. To the consumer, informative labeling meant much more than the label simply not be false.”).

<sup>13</sup> Deloitte, *Capitalizing on the Shifting Consumer Food Value Equation 7* (2016), <https://www2.deloitte.com/content/dam/Deloitte/us/Documents/consumer-business/us-fmi-gma-report.pdf> (“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>14</sup> Food and Drug Administration, *FDA Facts; Regulatory Science*, <http://www.fda.gov/downloads/NewsEvents/Newsroom/FactSheets/UCM305770.pdf>.

<sup>15</sup> 42 U.S.C. § 343.

<sup>16</sup> While the FDA has developed a regulation to define the term “healthy”, which it is currently in the process of reconsidering, the term “natural” remains undefined. 21 C.F.R. 101.65(d). The agency issued a notice soliciting comment on use of the term “natural”, but has not formalized a regulation. 80 FR 69905 (Nov. 12, 2015).

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>17</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>18</sup>

While many scholars have analyzed First Amendment limits on the FDA's ability to restrict specific types of claims, 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. This Essay proposes the FDA adopt such an approach as a means of effectuating the Food, Drug and Cosmetic Act's purpose of protecting consumers from false or misleading food product labels. As an alternative, if the 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. Consequently, this Essay proceeds in three parts. Part I addresses the FDA's authority to regulate food labels under the Food, Drug, and Cosmetic Act with particular emphasis on the provisions of the statute and accompanying regulations dedicated to misbranding.<sup>19</sup> In Part II, the Essay considers the First Amendment implications of restricting labeling language unsubstantiated by significant scientific agreement, concluding that the courts have not squarely addressed the issue. Finally, Part III concludes by suggesting that all relevant actors - the agency, industry, and consumers - stand to benefit from a consistently applied approach.

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<sup>17</sup> See Nicole Negowetti, *Food Labeling Litigation: Exposing Gaps in the FDA's Resources and Regulatory Authority* 1 (Jun. 2014), [https://www.brookings.edu/wp-content/uploads/2016/06/Negowetti\\_Food-Labeling-Litigation.pdf](https://www.brookings.edu/wp-content/uploads/2016/06/Negowetti_Food-Labeling-Litigation.pdf) (“This ‘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 the Food and Drug Administration (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>18</sup> “Significant scientific agreement” is a term of art applied to health claims, which will be discussed later in the Essay.

<sup>19</sup> See 42 U.S.C. § 343.

## II. FDA’S AUTHORITY TO PROHIBIT MISLEADING LABEL CLAIMS UNDER THE FOOD, DRUG, AND COSMETIC ACT

The history surrounding passage of the Food, Drug, and Cosmetic Act (“Act”) demonstrates that the provisions addressing the prevention of consumer deception through misleading labeling statements are at the core of the statute.<sup>20</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>21</sup>

These debates over how best to protect consumers from unscrupulous manufacturers aided in the creation of a separate definition for “labeling” which includes “label[s]”,<sup>22</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>23</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 containing potentially misleading statements. 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. To that end, the Act specifies that the FDA should consider “the extent to which the labeling or advertising fails to reveal facts material” when assessing whether the labeling is false or misleading.<sup>24</sup>

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<sup>20</sup> Foods are misbranded if the “labeling is false or misleading in any particular.” 21 U.S.C. § 343(a). This includes

<sup>21</sup> Vincent A. Kleinfeld, Legislative History of the Federal Food, Drug, and Cosmetic Act, 50 Food & Drug L.J. 65 (1995) (citing S. 1944, Seventy-Third Congress, First and Second Sessions, Senator Copeland suggesting that this statement reflected the “philosophy” of the Act.).

<sup>22</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>23</sup> 21 U.S.C. § 321(m).

<sup>24</sup> 21 U.S.C. § 321(n).

Labeling claims on food products are also divided into a few major categories for the purposes of regulation. First, health claims describe a relationship between a food substance and a disease or health-related condition.<sup>25</sup> Health claims are further divided into three sub-categories: (1) authorized health claims, which are authorized by regulation once the agency the claim is supported by significant scientific agreement;<sup>26</sup> (2) health claims based on authoritative statements from certain scientific bodies and the National Academy of Sciences;<sup>27</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>28</sup> Second, nutrient-content claims “expressly or implicitly characterize[] the level of a nutrient of the type required to be in nutrition labeling.”<sup>29</sup> The term “healthy” is considered a nutrient-content claim and is defined by federal regulation,<sup>30</sup> yet other common claims include “free”, “low”, “reduced” and “light.”<sup>31</sup> Finally, structure/function claims may “describe the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body” or “characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function.”<sup>32</sup> These claims do not require the FDA’s pre-approval, but must be capable of substantiation.<sup>33</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, the courts traditionally asked “whether the ‘ordinary purchaser’ would be misled by the product in question”, yet there is no commonly accepted

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<sup>25</sup> 21 U.S.C. § 343(r) et seq.; 21 C.F.R. § 101.14(a)(1).

<sup>26</sup> 21 U.S.C. § 343 (r)(3)(B)(i); 21 C.F.R. § 101.14 (c).

<sup>27</sup> 21 U.S.C. § 343 (r)(3)(C)(i).

<sup>28</sup> Food and Drug Administration, *Label Claims for Conventional Foods and Dietary Supplements*, <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm111447.htm>.

<sup>29</sup> 21 C.F.R. § 101.13(b).

<sup>30</sup> 21 C.F.R. § 101.65(d).

<sup>31</sup> 21 C.F.R. §101.13.

<sup>32</sup> 21 U.S.C. § 343(r)(6); 21 C.F.R. 101.93.

<sup>33</sup> Food and Drug Administration, *Label Claims for Conventional Foods and Dietary Supplements*, <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm111447.htm>.

approach to make this determination.<sup>34</sup> The language of the Act itself provides some guidance in the sub-section addressing “the prominence of information” on the food product’s label, as it references including information in a manner that can be “understood by the ordinary individual under customary conditions of purchase and use.”<sup>35</sup> Additionally, one approach proposes asking whether “any appreciable number of prospective purchasers of the product in the country as a whole, or in the region where the product is most heavily marketed, [will] probably be misled by the labeling.”<sup>36</sup> However, such an approach necessarily requires the collection and analysis of survey data, which likely serves as a practical constraint in application.

Moreover, there are many examples of food product claims that do not fall within this regulatory framework and are reviewed within the broader context of the Act’s limits on false or misleading labeling language. Some examples include claims related to the manufacturing or growing process and the inclusion or exclusion of specific ingredients or substances. The “natural” claim serves as an example of a claim that is meant to convey a message to consumers about specific attributes of the manufacturing process that suggests the absence of artificial ingredients. Yet, given a host of factors, including constantly evolving technology, this claim even if defined by federal regulation, remains inherently subjective depending on the understanding of the consumer. The “healthy” claim while falling within the category of nutrient-content claims and benefitting from a regulatory definition that likely included the input of stakeholders, arguably remains subjective due to differing standards and needs for certain populations and constantly evolving opinions about what makes a food product healthful, possibly including concerns that go beyond the pure nutritional aspects of a specific food product. 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.

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<sup>34</sup> Wesley E. Forte, *The Ordinary Purchaser and the Federal Food, Drug, and Cosmetic Act*, 52 Va. L. Rev. 1467, 1468-1471 (1966) (Author notes 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>35</sup> 21 U.S.C. § 343(f); and Forte, *supra* note \_\_\_\_ .

<sup>36</sup> Forte, *supra* note \_\_\_\_ at 1502 (citing Restatement, Torts § 728, comment a (1938)).

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

While there have been cases addresses restrictions on labeling language in other contexts, it is far from clear that a restriction on labeling claims incapable of substantiation by significant scientific agreement is violative of the First Amendment.<sup>37</sup> However, restrictions on labeling statements raise significant concerns, 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>38</sup> On the other hand, Congress delegated authority to the FDA to ensure that food product labels are not misleading.<sup>39</sup> While striking the balance between these competing concerns is difficult, the FDA is a science based, public health agency that needs to ensure food products are safe and accurately labeled.

Many scholars have addressed a variety of First Amendment issues with regard to the FDA's compulsion or restriction of speech in a number of different contexts. This Essay does not seek to provide such an overview, but rather focuses on the caselaw addressing the 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*, which was decided by the Court of Appeals for the D.C. Circuit in 1999.<sup>40</sup>

*Pearson* involved two sets of challenges – one focused on impingement of the appellants First Amendment rights and the other alleging procedural insufficiencies under the Administrative Procedure Act - with regard to the FDA's decision not to allow inclusion of a set of proposed health claims that were not supported by significant scientific agreement on dietary supplement labels.<sup>41</sup> Specifically, the dietary supplement manufacturers argued that the FDA's

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<sup>37</sup> See e.g. Timothy D. Lytton, *Signs of Change or Clash of Symbols? FDA Regulation of Nutrient Profile Labeling*, 20 Health Matrix 90, 114 (2010) (Suggesting that “application of the Frist Amendment commercial speech doctrine to FDA labeling restrictions is a relatively new development, and many important questions have yet to be answered by the courts.”).

<sup>38</sup> Gerald Masoudi and Christopher Pruitt, *The Food and Drug Administration v. The First Amendment: A Survey of Recent FDA Enforcement*, 21 Health Matrix 111 (2011).

<sup>39</sup> 21 U.S.C. § 343(a).

<sup>40</sup> 164 F.3d 650 (D.C. 1999).

<sup>41</sup> *Pearson*, 164 F. 3d at 654.



final regulation setting forth the general requirements for health claims,<sup>42</sup> which included a “definition” of “significant scientific agreement”, 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>43</sup> Rather, the agency “unequivocally rejected the notion of requiring disclaimers to cure ‘misleading’ health claims for dietary supplements.”<sup>44</sup>

The 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>45</sup> Using the framework to assess restrictions on commercial speech laid out in the *Central Hudson Gas & Electric Corp. v. Public Service Comm. Of New York*, the Court rejected the 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>46</sup>

A few years later, the District Court for the D.C. Circuit same court issued the *Whitaker v. Thompson*<sup>47</sup> decision, interpreting *Pearson* to stand for the proposition that the 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>48</sup> However, the court went on to hold that “[e] ven 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

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<sup>42</sup> 21 C.F.R. § 101.14.

<sup>43</sup> *Pearson*, 164 F. 3d at 654.

<sup>44</sup> *Pearson*, 164 F. 3d at 655.

<sup>45</sup> *Pearson*, 164 F. 3d at 655.

<sup>46</sup> *Pearson*, 164 F. 3d at 656-657.

<sup>47</sup> 248 F. Supp. 1 (D.D.C. 2002).

<sup>48</sup> *Whitaker*, 248 F. Supp. at 10 (citing *Pearson*, 164 F.3d at 659 n. 10.).

above [“The evidence in support of this claim is inconclusive” or “The FDA does not approve this claim”] would bewilder consumers and fail to correct for deceptiveness.”<sup>49</sup>

Following the *Pearson* case, the 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 continuum of scientific evidence that extends from very limited to inconclusive evidence, SSA 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) “SSA 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) “SSA 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>50</sup>

Collectively, *Pearson* and *Whitaker* stand for the proposition that the FDA has to consider whether a curative disclaimer can address the misleading nature of health claims on labels and likely would fail to defend an outright ban on a health claim completely, assuming the disclaimer can adequately convey the scientific limitations. However, these types of claims are very different from label claims that are so subjective in nature, it would be virtually impossible to conceive of a situation where a manufacturer could support the claim by significant scientific agreement. Using “natural” as an example, it is difficult to imagine a body of scientific evidence

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<sup>49</sup> *Whitaker*, 248 F. Supp. at 10 (citing *Pearson*, 164 F.3d at 659 n. 10.).

<sup>50</sup> Food and Drug Administration, *Guidance for Industry: Evidence Based Review System for the Scientific Evaluation of Health Claims – Final* (Jan. 2009), <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm073332.htm>.

able to support a claim of this nature making the potential for consumer fraud or confusion very real.

#### IV. CONCLUSION

Presently, there are many advocating both for 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 either 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 changing 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>51</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, possibly 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.

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>52</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,

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<sup>51</sup> Krista Hessler Carver, *A Global View of the First Amendment Constraints on FDA*, 63 Food & Drug L.J. 151, 214 (2008).

<sup>52</sup> Government Accountability Office, *FDA Needs to Reassess Its Approach to Protecting Consumers from False or Misleading Claims* (Jan. 2011), <http://www.gao.gov/new.items/d11102.pdf>.

structure/function, and other health- and nutrient-related claims.”<sup>53</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>54</sup> At the same time, however, information should “focus on concrete facts.”<sup>55</sup> In the context of health, some nutrient-content claims (excluding “healthy”), and structure-function claims, manufacturers use scientific evidence upon which to base 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 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>56</sup> Yet, the FDA’s definition of the term focuses on the product’s fat, cholesterol, and other limited nutrient content.<sup>57</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, are there any food products that could be considered healthy for everyone? If not, can that uncertainty be cured through some sort of disclaimer on the product? If so, does the disclaimer then negate the benefits provided by inclusion of the term? The FDA is currently in the process of considering those questions in addition to a host of others. All of this raises the issue of whether this represents an efficient use of agency resources. Perhaps the agency 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,

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<sup>53</sup> Government Accountability Office, *FDA Needs to Reassess Its Approach to Protecting Consumers from False or Misleading Claims* 16 (Jan. 2011), <http://www.gao.gov/new.items/d11102.pdf>.

<sup>54</sup> United States Department of Agriculture, Economic Research Service, *Economics of Food Labeling* 17 (Dec 2000), [https://www.ers.usda.gov/webdocs/publications/aer793/18885\\_aer793.pdf](https://www.ers.usda.gov/webdocs/publications/aer793/18885_aer793.pdf).

<sup>55</sup> United States Department of Agriculture, Economic Research Service, *Economics of Food Labeling* 18 (Dec 2000), [https://www.ers.usda.gov/webdocs/publications/aer793/18885\\_aer793.pdf](https://www.ers.usda.gov/webdocs/publications/aer793/18885_aer793.pdf)

<sup>56</sup> *Healthy*, Merriam Webster Dictionary (2017).

<sup>57</sup> 21 C.F.R. § 101.65(d)(2)(i).

better effectuate the Food, Drug and Cosmetic Act's purpose of protecting consumers from false or misleading food product labels, and provide consistency for industry.

DRAFT